Urology Services Inquiry

Urology Services Inquiry | 1 Bradford Court | Belfast BT8 6RB
T: 02890 251005 | E: info@usi.org.uk | W: www.urologyservicesinquiry.org.uk

Dermot Hughes
C/O Southern Health and Social Care Trust
Craigavon Area Hospital,
68 Lurgan Road, Portadown,
BT63 5QQ

14 September 2022

Dear Sir,

Re: The Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

Provision of a Section 21 Notice requiring the provision of evidence in the form of a written statement

I am writing to you in my capacity as Solicitor to the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust (the Urology Services Inquiry) which has been set up under the Inquiries Act 2005 ('the Act').

I enclose a copy of the Urology Services Inquiry's Terms of Reference for your information.

You will be aware that the Inquiry has commenced its investigations into the matters set out in its Terms of Reference. The Inquiry is continuing with the process of gathering all of the relevant documentation from relevant departments, organisations and individuals. In addition, the Inquiry has also now begun the process of requiring individuals who have been, or may have been, involved in the range of matters which come within the Inquiry's Terms of Reference to provide written evidence to the Inquiry panel.

The Urology Services Inquiry is now issuing to you a Statutory Notice (known as a Section 21 Notice) pursuant to its powers to compel the provision of evidence in the form of a written statement in relation to the matters falling within its Terms of Reference.

The Inquiry is aware that you have held posts relevant to the Inquiry's Terms of Reference. The Inquiry understands that you will have access to all of the relevant information required to provide the witness statement required now or at any stage throughout the duration of this Inquiry. Should you consider that not to be the case,

please advise us of that as soon as possible.

The Schedule to the enclosed Section 21 Notice provides full details as to the matters which should be covered in the written evidence which is required from you. As the text of the Section 21 Notice explains, you are required by law to comply with it.

Please bear in mind the fact that the witness statement required by the enclosed Notice is likely (in common with many other statements we will request) to be published by the Inquiry in due course. It should therefore ideally be written in a manner which is as accessible as possible in terms of public understanding.

You will note that certain questions raise issues regarding documentation. We have already received a significant amount of documentation from the Trust as an organisation. However if you in your personal capacity hold any additional documentation which you consider is of relevance to our work, then we would ask that this is also provided with this response.

If it would assist you, I am happy to meet with you and/or your legal representative(s) to discuss what documents you have and whether they are covered by the Section 21 Notice.

You will also find attached to the Section 21 Notice a Guidance Note explaining the nature of a Section 21 Notice and the procedures that the Inquiry has adopted in relation to such a notice. In particular, you are asked to provide your evidence in the form of the template witness statement which is also enclosed with this correspondence. In addition, as referred to above, you will also find enclosed a copy of the Inquiry's Terms of Reference to assist you in understanding the scope of the Inquiry's work and therefore the ambit of the Section 21 Notice.

Given the tight time-frame within which the Inquiry must operate, the Chair of the Inquiry would be grateful if you would comply with the requirements of the Section 21 Notice as soon as possible and, in any event, by the date set out for compliance in the Notice itself.

If there is any difficulty in complying with this time limit you must make application to the Chair for an extension of time before the expiry of the time limit, and that

application must provide full reasons in explanation of any difficulty.

Finally, I would be grateful if you could acknowledge receipt of this correspondence and the enclosed Notice by email to Personal Information redacted by the USI.

Please do not hesitate to contact me to discuss any matter arising.

Yours faithfully

Personal Information redacted by the USI

Anne Donnelly
Solicitor to the Urology Services Inquiry

Tel: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI

THE INDEPENDENT PUBLIC INQUIRY INTO
UROLOGY SERVICES IN THE
SOUTHERN HEALTH AND SOCIAL CARE TRUST

Chair's Notice

[No 69 of 2022]

Pursuant to Section 21(2) of the Inquiries Act 2005

WARNING

If, without reasonable excuse, you fail to comply with the requirements of this Notice you will be committing an offence under section 35 of the Inquiries Act 2005 and may be liable on conviction to a term of imprisonment and/or a fine.

Further, if you fail to comply with the requirements of this Notice, the Chair may certify the matter to the High Court of Justice in Northern Ireland under section 36 of the Inquiries Act 2005, where you may be held in contempt of court and may be imprisoned, fined or have your assets seized.

TO:

Mr. Dermot Hughes
C/O Southern Health and Social Care Trust
Headquarters
68 Lurgan Road
Portadown
BT63 5QQ

IMPORTANT INFORMATION FOR THE RECIPIENT

1. This Notice is issued by the Chair of the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust on foot of the powers given to her by the Inquiries Act 2005.

2. The Notice requires you to do the acts set out in the body of the Notice.

3. You should read this Notice carefully and consult a solicitor as soon as possible about it.

4. You are entitled to ask the Chair to revoke or vary the Notice in accordance with the terms of section 21(4) of the Inquiries Act 2005.

5. If you disobey the requirements of the Notice it may have very serious consequences for you, including you being fined or imprisoned. For that reason you should treat this Notice with the utmost seriousness.

WITNESS STATEMENT TO BE PRODUCED

TAKE NOTICE that the Chair of the Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust requires you, pursuant to her powers under section 21(2)(a) of the Inquiries Act 2005 ('the Act'), to produce to the Inquiry a Witness Statement as set out in the Schedule to this Notice by **noon on 26th October 2022.**

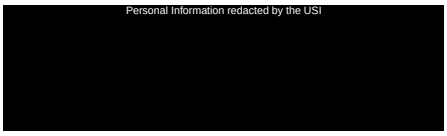
APPLICATION TO VARY OR REVOKE THE NOTICE

AND FURTHER TAKE NOTICE that you are entitled to make a claim to the Chair of the Inquiry, under section 21(4) of the Act, on the grounds that you are unable to comply with the Notice, or that it is not reasonable in all the circumstances to require you to comply with the Notice.

If you wish to make such a claim you should do so in writing to the Chair of the Inquiry at: **Urology Services Inquiry, 1 Bradford Court, Belfast, BT8 6RB** setting out in detail the basis of, and reasons for, your claim by **noon on 19th October 2022.**

Upon receipt of such a claim the Chair will then determine whether the Notice should be revoked or varied, including having regard to her obligations under section 21(5) of the Act, and you will be notified of her determination.

Dated this day 14th September 2022

Signed: 

Christine Smith QC
Chair of Urology Services Inquiry

Urology Services Inquiry

SCHEDULE

[No 69 of 2022]

General

1. Having regard to the Terms of Reference of the Inquiry, please provide a narrative account of your involvement in or knowledge of all matters falling within the scope of those Terms. This should include an explanation of your role, responsibilities and duties, and should provide a detailed description of any issues raised with you, meetings attended by you, and actions or decisions taken by you and others to address any concerns. It would greatly assist the inquiry if you would provide this narrative in numbered paragraphs and in chronological order.

2. Please also provide any and all documents within your custody or under your control relating to the terms of reference of the *Urology Services Inquiry* ("USI"). Please also provide or refer to any documentation you consider relevant to any of your answers, whether in answer to Question 1 or to the questions set out below. Please place any documents referred to in the body of your response as separate appendices set out in chronological order and properly indexed. If you are in any doubt about document provision, please do not hesitate to contact the Inquiry Solicitor.

3. Unless you have specifically addressed the issues in your reply to Question 1 above, please answer the remaining questions in this Notice. If you rely on your answer to Question 1 in answering any of these questions, please specify precisely which paragraphs of your narrative you rely on. Alternatively, you may incorporate the answers to the remaining questions into your narrative and simply refer us to the relevant paragraphs. The key is to address all questions posed. If there are questions that you do not know the answer to, or where someone else is better placed to answer, please explain and provide the name and role of that other person.

Your experience and relationship with the SHSCT

4. Please summarise your qualifications and your occupational history prior to your involvement in conducting a series of Serious Adverse Incident ("SAI") for or on behalf of the SHSCT in 2020-21. Set out all posts you held prior to commencing your involvement with the Trust on the series of SAI reviews in 2020.

5. Set out what, if any, relevant experience you had of SAI processes and of involvement in conducting SAI reviews prior to your involvement with the SHSCT on the series of SAI reviews in 2020. It would be helpful if you detailed the approximate number of SAI review processes you have been involved with, and the capacity in which you were involved.

6. Outline what, if any, prior engagement you may have had with Urology Services within the SHSCT prior to commencing your involvement with the Trust on the series of SAI reviews in 2020. Specifically address the following:

    a. Whether you had any previous experience of conducting SAI reviews within the SHSCT generally and specifically with regard to Urology Services within the Trust.
    b. Whether you had any previous experience or engagement with governance issues with the SHSCT generally and specifically with regard to Urology Services within the Trust.
    c. Whether you were aware of any pre-existing concerns with regard to Urology Services within the Trust.
    d. Whether you had any prior engagement with Mr O'Brien through your membership of the British Association of Urological Surgeons, or in any other capacity.

SAI Reviews

7. Outline what you understood to be the role of and duties associated with the role of Expert External Clinical Advisor to an SAI review and how this role

related to all other individuals involved in the review. Explain how you performed the role of Expert External Clinical Advisor.

8. Specifically with regard to the other members of the review team, and without simply outlining their area of specialty, explain the role of and duties performed by the following individuals in conducting the SAI reviews:

    a. Mr Hugh Gilbert;
    b. Mrs Fiona Reddick;
    c. Ms Patricia Thompson; and
    d. Mrs Patricia Kingsnorth

9. Outline and explain the circumstances in which you were asked to fulfill the role of Expert External Clinical Advisor of SAI reviews into the nine patients by the SHSCT in 2020.

10. Outline what, if any written or oral briefing you received from the SHSCT before commencing the reviews. With regard to any briefing you may have received, address the following:

    a. Who provided the briefing?
    b. What were you told about;
        i. The circumstances giving rise to each individual case.
        ii. The reasons why the nine SAI reviews were necessary.
        iii. The process by which the nine patients were identified and selected for an SAI review.
        iv. The existence of other cases of concern or potentially meeting the threshold for an SAI review.
        v. Previous concerns within Urology Services.
        vi. Previous SAI reports and the findings of same.

11. With regard to each of the nine cases subject to SAI review, generally describe the steps taken and processes adopted by the review team to complete its work. Further, outline, in broad terms,:

a. Your specific role in conducting the reviews and actions taken by yourself.
b. What documentation was made available to the review team?
c. What relevant personnel, including management staff, clinicians and nursing staff;
    i. Did the review team meet with?
    ii. At what stage in the process were those individuals met with?
    iii. What was the purpose of speaking to those individuals?
    iv. What was the outcome of speaking to those individuals?
d. Outline the engagement the review team had with each of the families affected and who took the lead for this aspect of the review team's work, and provide a description of what steps they took.
e. Outline how the review team assessed the performance of the MDT pathway for cancer management and who took the lead for this aspect of the review team's work, and provide a description of what steps they took.
f. Outline how the review team conducted comparative analysis against regional and national guidance and who took the lead for this aspect of the review team's work, along with a description of what steps they took.

12. Outline who was responsible for formulating the findings and/or conclusions in each of the 9 SAI Reviews and the overarching report. Were the findings and/or conclusions reached on the basis of consensus amongst the review team? Do you recall any disagreement arising with regard to any finding and/or conclusion? If so, provide full details relating to the nature of the issue and how, if at all, it was resolved or reconciled. Your answer should include reference to any draft reviews and reports in advance of the final versions and copies of those should be provided.

13. Outline who was responsible for formulating the recommendations and/or action plans in each of the nine SAI reviews and the overarching report. Were the recommendations and/or action plans reached on the basis of a consensus amongst the review team? Do you recall any disagreement arising with regard

to any recommendation and/or action point? If so provide full details relating to the nature of the issue and how, if at all, it was resolved or reconciled.

14. Were any updates provided to the SHSCT during the course of the review(s) conducted by the review team? Who was responsible for providing updates? If updates were provided, disclose the content of same, and explain why updates were provided before the review(s) were completed.

15. Outline, in broad terms, the key themes, trends, findings or conclusions which the review team reached across the nine SAI reviews with regard to both patient safety and governance issues. It may assist you to refer the Inquiry to particular sections of the review reports.

16. Outline what, if any, discussion of the review team's findings, conclusions, recommendations and action plans took place between the review team and the SHSCT.

17. To the best of your knowledge and understanding, were the findings, conclusions, recommendations and action plans for each of the nine SAI reviews accepted by the SHSCT? Outline any disagreement or objection to any finding, conclusion, recommendation or action plan which was raised with you or any member of the review team.

18. What, if any, difficulties or hurdles were you or other members of the review team faced with in the conduct of the nine SAI reviews? For each difficulty or hurdle identified, explain what steps were taken to overcome the issue, and/or whether it was possible to overcome the issue.

19. Having regard to any difficulty identified above, are you of the opinion that it undermined or impacted upon the quality of the SAI review process? If so, elaborate the reasons why you think this is the case.

20. Outline the nature and extent of any interaction you or other members of the review team had with (a) the Trust's Board, (b) the Health and Social Care Board and (c) the Public Health Agency in connection with the reviews, whether before you commenced, during the course of, or after completion of the reviews.

Structured Clinical Record Review Process & Further Actions

21. What, if anything, were you told about the decision of the SHSCT to adopt a Structured Clinical Record Review process ("SCRR") in respect of other cases, apart from the nine you reviewed, which met the threshold for an SAI review? Specifically, address:

    a. When and in what circumstances you became so aware of the intention to adopt a SCRR methodology.
    b. What, if any, view did you express to the SHSCT in writing or orally on the merits of this decision, or generally.

22. Since your participation in the series of SAI reviews in 2020, have you performed any additional work for the SHSCT in connection with Urology Services or governance generally, or have you been asked to do so? If applicable, outline what work you have undertaken or specify what work you have been asked to do.

Learning & Reflections

23. Having had the opportunity to reflect upon the nine SAI reviews you were involved in, is there anything that would wish to say about the cases which you reviewed, the conduct of the review processes and the outcomes of the SAI reviews themselves, which is not already reflected in the respective reports?

24. Given the Inquiry's terms of reference, is there anything else you would like to add to assist the Inquiry in ensuring it has all the information relevant to those Terms?

NOTE:

By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and

minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers, as well as those sent from official or business accounts or numbers. By virtue of section 21(6) of the Inquiries Act 2005, a thing is under a person's control if it is in his possession or if he has a right to possession of it.

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 69 of 2022

Date of Notice: 14th September 2022

Witness Statement of: Dermot F C Hughes MB BCH BAO FRCPath Dip Med

I, Dermot Francis Hughes, will say as follows:-

SCHEDULE [No 69 of 2022]

1. Having regard to the Terms of Reference of the Inquiry, please provide a narrative account of your involvement in or knowledge of all matters falling within the scope of those Terms. This should include an explanation of your role, responsibilities and duties, and should provide a detailed description of any issues raised with you, meetings attended by you, and actions or decisions taken by you and others to address any concerns. It would greatly assist the inquiry if you would provide this narrative in numbered paragraphs and in chronological order.

    - The narrative is provided as answers to the detailed questions below

2. Please also provide any and all documents within your custody or under your control relating to the terms of reference of the *Urology Services Inquiry* ("USI"). Please also provide or refer to any documentation you consider relevant to any of your answers, whether in answer to Question 1 or to the questions set out below. Please place any documents referred to in the body of your response as separate appendices set out in chronological order and properly indexed. If you are in any doubt about document provision, please do not hesitate to contact the Inquiry Solicitor.

    - All documents for the SAI Review were held on a secure system. The SHSCT provided access to "egress" containing all related documents to aid responses to these questions. I have requested the SHSCT to forward same documentation to the USI. I have referenced the documents from this file in my response, as advised.

3. Unless you have specifically addressed the issues in your reply to Question 1 above, please answer the remaining questions in this Notice. If you rely on your answer to Question 1 in answering any of these questions, please specify precisely which paragraphs of your narrative you rely on. Alternatively, you may incorporate the answers to the remaining questions into your narrative and simply refer us to the relevant paragraphs. The key is to address all questions posed. If there are questions

that you do not know the answer to, or where someone else is better placed to answer, please explain and provide the name and role of that other person.

Your experience and relationship with the SHSCT

4. Please summarise your qualifications and your occupational history prior to your involvement in conducting a series of Serious Adverse Incident ("SAI") for or on behalf of the SHSCT in 2020-21. Set out all posts you held prior to commencing your involvement with the Trust on the series of SAI reviews in 2020.

   Qualifications – MB. BCH. BAO. FRCPath. Dip Med Ed

   Fellow of the Royal College of Pathologists

   Diploma in Medical Education (QUB)

- Associate HSC Leadership Centre 2020 –
- Visiting Professor Ulster University 2018 –
- Medical Director WHSCT 2015 – 2019
- Associate Medical Director WHSCT 2014 – 20125
- Clinical Director Diagnostics and Cancer Services WHSCT 2012 – 2015
- Medical Director Northern Ireland Cancer Network 2008 – 2011
- Lead Clinician / Clinical Director Diagnostics and Cancer Services WHSCT 2003 – 2008
- Honorary Senior Lecturer QUB 1998 – 2015
- Clinical Director Pathology Services WHSCT 1993 – 1997
- Consultant Pathologist WHSSB 1990 – 2019
- Pathology Travelling Fellow – George Washington University and National Institute of Health Bethesda USA 1987 -1988
- Northern Ireland Pathology Training Scheme 1983 – 1989
- Junior House Officer Mater Infirmorum Belfast 1982 - 1983

5. Set out what, if any, relevant experience you had of SAI processes and of involvement in conducting SAI reviews prior to your involvement with the SHSCT on the series of SAI reviews in 2020. It would be helpful if you detailed the approximate number of SAI review processes you have been involved with, and the capacity in which you were involved.

- I have formal training SAI processes and training as a Chair of SAI processes.

- As Medical Director of the Western Health and Social Care Trust, I was ultimately responsible for the SAI process and had oversight of all SAI Reports. This was approximately 80 – 90 per year. Each Serious Adverse incident report was reviewed, and quality assured at Director and Medical Director level within the Trust. I chaired this process over a 4-year period amounting approximately 350 cases between 2015 and 2019.

- Since leaving the role of Medical Director WHSCT, I have chaired 22 SAI reviews (including the SHSCT cohort). 20 of the 22 cases related to Cancer Care and 2 related to Hospital acquired Covid 19 outbreaks, involving multiple patients and professionals.

6. Outline what, if any, prior engagement you may have had with Urology Services within the SHSCT prior to commencing your involvement with the Trust on the series of SAI reviews in 2020. Specifically address the following:

1. Whether you had any previous experience of conducting SAI reviews within the SHSCT generally and specifically with regard to Urology Services within the Trust.

- I have not had any previous experience of conducting Serious Adverse Incident Reviews within the SHSCT.

2. Whether you had any previous experience or engagement with governance issues with the SHSCT generally and specifically with regard to Urology Services within the Trust.

- As Medical Director of the Northern Ireland Cancer Network between 2008 and 2011, I set up External Peer Review of Cancer Services. This was performed by the NHS London Peer Review team and related to Breast Cancer Services, Lung Cancer Services and Colorectal Cancer Services. This was a Northern Ireland wide process and provided assurance and quality improvement recommendations. It did not include Urology services at that time, but I would have engaged with the SHSCT Cancer Services Team and the wider Trust Management.

- Other work in the Northern Ireland Cancer Network did include the Urology Cancer Tumour Site Group and the SHSCT Urology Services were constituent members. The work between 2008 and 2011 included drafting Northern Ireland Cancer Pathways for Urological Cancer, patient engagement and service development. Part of pathway development included centralizing specific surgery to meet national best practice guidance. I did meet with the urology services within the SHSCT to discuss this, multidisciplinary teams and the ongoing Peer Review Process which was to be rolled out to all cancer sites in the future.

3. Whether you were aware of any pre-existing concerns with regard to Urology Services within the Trust.

- I was not aware of concerns regarding the Urology services during my time as Medical Director of the Cancer Network between 2008 and 2011. I had not been made aware of issues after this time – this included a period, when I was Medical Director of the Western Health and Social Care Trusts, when following re-organization of Urological services, part of the WHSCT population (Fermanagh area) had Urological services provided by SHSCT.

4. Whether you had any prior engagement with Mr. O'Brien through your membership of the British Association of Urological Surgeons, or in any other capacity.

- This question relates to the External Independent Expert Clinical Advisor to the Serious Adverse Incident Process, Mr. Hugh Gilbert.

SAI Reviews

7. Outline what you understood to be the role of and duties associated with the role of Expert External Clinical Advisor to an SAI review and how this role related to all other individuals involved in the review. Explain how you performed the role of Expert External Clinical Advisor.

- I was the Independent Chair of the Serious Adverse Incident Review Process, and this question relates to Mr. Hugh Gilbert.

8. Specifically with regard to the other members of the review team, and without simply outlining their area of specialty, explain the role of and duties performed by the following individuals in conducting the SAI reviews:

a. Mr. Hugh Gilbert: - Mr. Hugh Gilbert was the Expert External Clinical Advisor to the Serious Adverse Incident Review Process. He is a practicing Urological Surgeon working in an environment similar to the service provided at the Cancer Unit in the SHSCT. He gave independent expert clinical opinion on the care provided to the 9 patients benchmarking this against national best practice and recommendations of the local Multidisciplinary team within Urology Cancer Services SHSCT. Mr. Gilbert also reviewed care considering information and feedback from families.

b. Mrs. Fiona Reddick: - Mrs. Fiona Reddick was the SHSCT Cancer Services Manager who provided local contextual information on how services were operated, supported, and resourced within the SHSCT Cancer Unit.

c. Ms. Patricia Thompson – Ms. Patricia Thompson is a Urology Cancer Nurse Specialist who was recently appointed to the SHSCT and was independent of past care. She brought knowledge and experience of the role and expectations of a Urology Cancer Nurse Specialist from elsewhere in Northern Ireland.

d. Mrs. Patricia Kingsnorth was the nominated SHSCT Governance Lead who supported the Review Process and was a link to governance structures within the SHSCT. She was nominated link person for the 9 families.

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9. Outline and explain the circumstances in which you were asked to fulfill the role of Expert External Clinical Advisor of SAI reviews into the nine patients by the SHSCT in 2020.

- This is a question for Mr. Hugh Gilbert.

10. Outline what, if any written or oral briefing you received from the SHSCT before commencing the reviews. With regard to any briefing, you may have received, address the following:
    a. Who provided the briefing?

- The initial briefing and request to Chair the process, which was initially 5 Serious Adverse Incident Review came from Mr. Stephen Wallace Governance SHSCT and followed up by Dr Maria O'Kane, then Medical Director SHSCT.

    b. What were you told about.

i. The circumstances giving rise to each individual case.

- I was informed that there were ongoing concerns about the care given to certain urological cancer patients by one professional. This initially focused on pharmaceutical prescribing for cancer patients. A local look-back exercise was progressing, and this in-house activity would forward cases that met the threshold for a Serious Adverse Incident as defined by the PHA Document "Procedure for Reporting and Follow up of Serious Adverse Incidents November 2016 version 1.1.". This would reflect relatively normal practice whereby incidents are assessed by service and governance departments before sharing with the PHA as a potential Serious Adverse Incident. The classification of the SAI process would be agreed between Trust and SAI.

ii. The reasons why the nine SAI reviews were necessary.

- It was deemed by the internal SHSCT governance triage process that all 9 cases met the threshold as defined by the PHA Document "Procedure for Reporting and Follow up of Serious Adverse Incidents November 2016 version 1.1." My understanding is that the nine cases also reflected a wider concern involving Prostate, Renal, Testicular, and penile cancer. It was indicated that the in-house governance process would continue but that the nine cases already identified should progress through a Serious Adverse Review process, not least because of responsibilities to patients and families. This I believed to be a pragmatic approach and discussions regarding subsequent cases meeting SAI threshold were not within my remit.

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iii. The process by which the nine patients were identified and selected for an SAI review.

- The process for triage of patients to meet the threshold for inclusion in an SAI process was performed in-house within Governance of the SHSCT. To my knowledge, this was in accordance with the document “Procedure for Reporting and Follow up of Serious Adverse Incidents November 2016 version 1.1.”. Discussing with the PHA on the nature and grade of an SAI would be normal procedure. It would not be unusual in Trusts where a service raising a Serious Adverse Incident, would seek someone uninvolved with the issue to carry out a SAI review. This would be similar when the

  Ref No.1 SAI/PHA

  SHSCT were seeking an Independent Chair of the SAI and an independent external expert to act as clinical advisor to the SAI review.

iv. The existence of other cases of concern or potentially meeting the threshold for an SAI review.

- I was aware of an ongoing process to perform a “look-back exercise” and ongoing triage of cases as potential SAIs. This information became public knowledge as the SAI process was ongoing. It is also knowledge that I shared with families to ensure we were as open and transparent as possible. As Chair of the SAI process, I did not seek nor was I given any further details regarding outcomes of triage to SAI thresholds for subsequent patients, believing this would be inappropriate. The rationale for this was to maintain independence of the SAI process from ingoing triage of the care of other patients.

v. Previous concerns within Urology Services.

- I was initially unaware of the professional involved with the SAI process and was unaware of concerns within the Urology Services SHSCT. This however changed when meeting with professionals who referred to a previous Serious Adverse Incident Review involving the named professional. I believed this could be of importance to the ongoing 9 SAI reviews and to the learning and action plan resulting from that process. This was made available and is referenced in the overarching document. I was informed of the exitance of a past “Maintaining High Professional Standards” Investigation. I did not request this as it lay outside the terms of the SAI review process.

vi. Previous SAI reports and the findings of same.

- SAI HSC unique identifier [redacted] was made available, after it was referred SHSCT professionals during interview. It related to triage of patients referred to Urology Cancer Services within the SHSCT for investigation and diagnosis of “Red Flag” symptoms of cancer. This issue first arose in 2016.

  Ref No.2 20210510

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Ref No3. 2020522

11.With regard to the steps taken and processes adopted by the review team to complete its work. Further, outline, in broad terms,: to each of the nine cases subject to SAI review, generally describe

1. Your specific role in conducting the reviews and actions taken by yourself.

- I was the Independent Chair of the SAI Review process and was responsible for the SAI review, the Root cause analysis, patient timelines and leading on Family Engagement. The External Expert Clinical advisor to the SAI process provided the independent clinical opinion on each case, based on patient records, MDT records and feedback from families. This was benchmarked against regional and national

  standards declared to External Peer Review as the Standard of care by the SHSCT Urology Cancer Services. Variances from expected best practice were identified, formed the learning within each SAI and resulted in an overarching arching plan.

2. What documentation was made available to the review team?

- The review team had full access to the patient record of care. This included radiology scans, laboratory results and multidisciplinary meeting notes and agreed care pathways. Patient and family experience along with patients and family questions were included in this record as care was often delivered by a single professional without recourse to other members of the multidisciplinary team. The review team considered the clinical care and pathways for all 9 patients. The Investigation team wrote to Mr A O'B with specific questions for clarification. These questions were not responded to despite extension of deadlines.

  Ref No4. 20200211

3. What relevant personnel, including management staff, clinicians and nursing staff;

   i. Did the review team meet with?

- Associate Medical Director and Clinical lead for Cancer Services SHSCT
  Ref No5. 20210111
  Ref No6. 20210107

- Assistant Director for Surgical Services SHSCT
  Ref No7. 20210204

- Nursing Director SHSCT

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Ref No8. 20210208

- Urology Cancer MDT including Consultant Urologists
  Ref No9. 20210218
- Clinical Lead NICAN Urology Cancer Tumour Group
  Ref No10. 20210225
- Urology Services Manager
  Ref No11. 20210225
- Urology Cancer Nurse Specialist team
  Ref No12. 210222
- Clinical Director Regional Cancer Centre BHSCT
  Ref No13. 20210106
- Clinical Oncologist BHSCT / Past Chair of NICAN Urology Cancer Tumour Group
  Ref No14. 20210223

ii. At what stage in the process were those individuals met with?

- The meetings took place throughout the SAI process, initially they were with core members of the Multidisciplinary Team providing the service to understand context of care within the SHSCT. Meetings with management and clinicians with managerial roles followed. This was, after identification of initial clinical deficits, in an attempt to understand governance of care and governance of those providing care.

iii. What was the purpose of speaking to those individuals?

- This was to gain a detailed understanding how cancer patient pathways were delivered in Urology Services SHSCT and to reflect how these related to SAI team members experience elsewhere. The meetings also sought assurance regarding how others delivered care within the urology service given the clinical deficits identified. This was critical to provide assurance regarding ongoing care quality. This would be a requirement of any SAI review. Discussions with managers and clinicians with managerial responsibility focused on governance of care and governance of those who provided care. Lastly, the meetings were to discuss how the care experienced by the patients under review varied from best practice and that provided by other members in the Urology Cancer Services Team.

iv. What was the outcome of speaking to those individuals?

- The conversations were at times difficult for staff as there was an undoubted concern that the SAI process was potentially detrimental to public perception of their service and their professional practice. There did appear to be an understanding of the variation in care regarding prescribing in prostate cancer and care delivered without specialist cancer nurse input. There was less knowledge of the other deficits identified by the External Expert Clinical Advisor to the SAI. This included failure to refer to oncologists and failure to further discuss patients at the multidisciplinary team meetings when disease progressed. The Senior Cancer Service management team had no knowledge of the above issues.

  Ref No15. 20210125
  Ref No16. 20210204
  Ref No17. 20210218

- A robust structure to quality assure care given by all within the Urology Services MDT did not exist and inappropriate declarations were made to External Peer Review. When discussing this issue some professionals and managers became defensive and believed that saying “did not know” was appropriate response. Three senior individuals subsequently amended the Overarching SAI report to include their views and concerns – this was raised with the SHSCT as they were not part of the SAI team, did not have editing rights and would have been a major concern for families. I responded to the individual amendments.

  Ref No18. 20210331
  Ref No19. 20210421
  Ref No20. 20210209
  Ref No21. 20210208

- The management team focused on delivery of 31 days to diagnose and 62 days to treat “cancer targets” which are ministerial returns. There was limited understanding how tracking of patients is used to support individuals in complex journeys, provide assurance and act as an evidence base for service improvement. Cancer Structures normally expect business meetings to discuss and improve functioning of the MDTs and service delivery. This should be based on data and evidence but was not in place. The Senior Cancer Management Team should have oversight of all Cancer MDTs learning from best practice and ensuring there is a commonality of approach to all receiving cancer care.

  Ref No22. 20210111
  Ref No23. 20210107
  Ref No24. 20201229

- The regional oncology staff were different and had knowledge of the variation from best practice regarding Prostate Cancer Prescribing. They explained steps taken to address issues. One professional initiated a regional protocol to standardize Androgen Deprivation Therapy for prostate cancer (signed off by Mr. O’Brien as the Regional Urology Cancer Lead for NICAN). They also had written to him directly

about his practice but did not escalate the issue to the SHSCT – this is something both individuals regretted and reflected upon.

Ref No25. 20210106
Ref No26. 20210223
Ref No27. 20210222

4. Outline the engagement the review team had with each of the families affected and who took the lead for this aspect of the review team's work and provide a description of what steps they took.

- The Family Engagement process was led by me supported by the SHSCT Governance team and subsequently by the governance team and a specifically appointed family liaison officer. The families were met on three occasions – at the initiation of the SAI process to explain and contextualize the review. As findings evolved, they were met to get detailed feedback and receive apologies. This was followed by a further meeting to share interim findings and seek detailed family input regarding experience and concerns – by this stage it had become clear that the care received had been given in isolation from the multidisciplinary team, a unique situation in cancer care. Their stories, experiences, concerns, and questions then fed into the clinical questions and SAI process. The families were then met for a third time with their report and a redacted overarching report.

- The families were obviously upset but also angered by the fact the care provided to them was different to that received by others who accessed the SHSCT Urology Cancer Services. Many had believed that the deficits in their care and external support was due to ongoing pandemic and/or resource limitation. They were clearly shocked that their experience was determined by the practice of a single individual and that had been offered differing support and means of accessing services.

- The Family Liaison officer was appointed to provide ongoing support and some redress to ensure patients got immediate access to services that were previously not made available to them.

Ref No28. 20211102
Ref No29. 20210707

5. Outline how the review team assessed the performance of the MDT pathway for cancer management and who took the lead for this aspect of the review team's work and provide a description of what steps they took.

- As with all SAI processes the Review Team formed a patient cancer journey timeline from initial referral or presentation. The assessment of the MDT pathway was led by Mr Hugh Gilbert as external expert clinical advisor to the SAI process. The patient pathways were discussed at weekly / bi-weekly meetings and benchmarked against expected care as defined by NICAN Urology Cancer Guidelines, NICE Guidance, and Cancer Improving Outcomes. This review also included the local SHSCT Urology Cancer MDT recommendations. The findings were compiled into draft reports by myself and Mrs. Patricia Kingsnorth (Governance Lead on the Review). These were

circulated for comment and sign off by the wider team. The assessment for the timeline of each patient was reviewed considering family comments during the family engagement process – this was deemed essential, as the patients were being treated by a single professional, without multiprofessional input.

- The patient pathways and outcomes were also benchmarked against the stated standards of care declared by SHSCT Urology Cancer Services to External Cancer Peer Review.

Ref No30. 20210125
Ref No31. 20210125
Ref No32. 20201230
Ref No33. 20201229
Ref No34. 202010910
Ref No35. 20200910
Ref No36. 20200202
Ref No37. 20200817

6. Outline how the review team conducted comparative analysis against regional and national guidance and who took the lead for this aspect of the review team's work, along with a description of what steps they took.

- The assessment was part of clinical care review and was led by Mr. Hugh Gilbert as external expert clinical advisor to the SAI process. The patient pathways were discussed at weekly meetings and benchmarked against expect care as defined by NICAN Urology Cancer Guidelines, NICE Guidance, and Cancer Improving Outcomes. This review also included the local SHSCT Urology Cancer MDT recommendations. The findings were compiled into draft reports by myself and Mrs. Patricia Kingsnorth (Governance Lead on the Review). These were circulated for comment and sign off by the wider team.

- Team review meetings were held on a weekly / 2 weekly basis and minutes of these are included in the shared evidence pack.

Ref No38. 20210105
Ref No39. 20210204
Ref No40. 20210223
Ref No41. 20201107

12.Outline who was responsible for formulating the findings and/or conclusions in each of the 9 SAI Reviews and the overarching report.

- I, as Independent Chair of the SAI process, was responsible for formulating findings and/or conclusions. These were solely based on the findings of the External Expert Clinical Advisor to the SAI Review and were defined by variance from expected best practice. The best practice standard was that as declared at Urology Cancer Services Peer review.

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Were the findings and/or conclusions reached on the basis of consensus amongst the review team?

- The SAI review team worked on a basis of consensus. The reports were drafted by me, as chair with support from Mrs Patricia Kingsnorth based on the clinical findings from Mr Hugh Gilbert. The reports were circulated as draft for comment, input and sign off. These reports went through several iterations following information and questions from patients and families. I do not recall any difficulty with this process though a member of the team (the SHSCT Cancer Manager) was absent for a period. The process was to review expected care considering Regional and National Urology Cancer care Guidelines and also in light of the recommendations from the SHSCT Urology Multidisciplinary Team meetings.

Do you recall any disagreement arising with regard to any finding and/or conclusion? If so, provide full details relating to the nature of the issue and how, if at all, it was resolved or reconciled. Your answer should include reference to any draft reviews and reports in advance of the final versions and copies of those should be provided.

- The SAI process was relatively straight forward in terms of the identified clinical variation from expected best practice. This aspect of the review was led by the External Expert Clinical Advisor to the SAI Mr. Hugh Gilbert. It identified variation from declared standards of care in the SHSCT, variations from Multidisciplinary Meeting recommendations, variations from normal specialist nurse support and variations in therapy. Discussions with SHSCT Urology MDT provided assurance that they followed expected practice as defined by the regional and national guidelines. This was an essential governance step to assure the SHSCT of ongoing care but did indicate that the care delivered by Mr. O'Brien was unique within the service.

- All nine reports went through multiple draft iterations – the reviews were held as live documents on a secure system. The reports evolved following initial delineation of patient timelines from clinical notes, MDT meeting notes and cancer tracking information. Critically further drafting of reports were required following family information of their experience – as they were not offered normal cancer care support structures (available within SHSCT) – their patient pathways were unusual, complex and at variance from expectations. The detail of this information evolved of a period during family engagement. All families were offered meetings on three occasions with myself and ongoing email / phone calls to address issues were managed by Mrs. Patricia Kingsnorth. This ongoing engagement fed into the weekly / biweekly SAI review meeting. Mr. Gilbert reviewed the patient's timeline of care provided in light of family comments and questions. Details are included within the information submitted on my behalf by SHSCT.

  Ref No42. 20200301 Patient 8
  Ref No43. 20210222
  Ref No44. 20210208
  Ref No45. 20200903
  Ref No46. 20210423

  Ref No47. 20210930 Patient 9
  Ref No48. 20210316

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Ref N049. 20210208 Patient 9
Ref No50. 20210224
Ref No51. 20211215

Ref No52. 20210428 Patient 3
Ref No53. 20210322
Ref No54. 20210226
Ref No55. 20210419

Ref No56. 20210527 Patient 5
Ref No57. 20210419
Ref No58. 20210309
Ref No59. 20210224

Ref No60. 20210427 Patient 1
Ref No61. 20210224
Ref No62. 20210421
Ref No63. 20210205

Ref No64. 20210422 Patient 6
Ref No65. 20210421
Ref No66. 20210301
Ref No67. 20210226
Ref No68. 20210224
Ref No69. 20210222

Ref No70. 20211018 Patient 4
Ref No71. 20210421
Ref No72. 20210018

Ref No73. 20210422 Patient 7
Ref No74. 20210421
Ref No75. 20210413
Ref No76. 20210208
Ref No77. 20210222

Ref No78. 20210316 Patient 2
Ref No79. 20210304
Ref No80. 20210224
Ref No81. 20210218
Ref No82. 20210202
Ref No83. 20210205
Ref No84. 20210204

- There was feedback from the Urology Cancer Nurse Specialists who were concerned about a range of issues not least the use of the term failsafe as part of their role. I would concur with that this should only minor component of their role but when things do wrong an essential component. I believe there was a perception that it was unfair on this group of professionals to suggest that their presence would have been a simple solution to problems. This was not the case as their role is supportive,

educational, therapeutic, and critical good cancer care experience. This is clearly stated in all Regional and National guidance, and I responded to their concerns

Ref No85. 210222
Ref No86. 202101028

- The overarching report was shared with a range of staff to explain the action plan and to ensure delivery of outcomes. The Clinical Lead for Cancer SHSCT, Dr Tariq, his deputy Mr. McCaul and Mr. Barry Conway Cancer Services, did take the opportunity to edit the report with tracked changes. As they were not members of the SAI team and did not have editing rights, I raised this with the SHSCT. There was a lack of understanding of how the SAI process was delivered and why SHSCT had sought external input. I was sensitive to this, as we had shared team member names and roles to families.

  I compiled the tracked changes into a document and provided responses to be shared with cancer team.

  Ref No87. 20210510
  Ref No88. 20210331

Response from Chair SAI Process to the Dr Tariq, Mr. McCaul and Mr. Barry Conway

1. *"There is a regional deficit of Oncology Consultants in NI and this is recognised by HSCB. During the past 2 years, HSCB have produced a stabilisation plan for Oncology / Haematology. Southern Trust has engaged in this process. A costed plan has been prepared and is currently being considered for funding. In the interim period, the Southern Trust has worked closely with Belfast Trust to secure as much Oncology cover for MDMs as possible, whilst recognising the regional pressures in this specialty. More recently Southern Trust has advertised a shared Oncology Consultant post with Belfast and this trawl has been successful with the post to be filed in the summer 2021. This will improve cover for MDMs but significant gaps will remain."*

Response

- *The review team does not accept a differential service for patients based on geography and the report is based on what should be present. It is expected that the out-workings of the SAI will result in better and appropriate resourcing for patients of the SHSCT.*

Ref – The costed Business plan was referred to by SHSCT staff but not submitted with their statement.

2. "Cancer Services Division would welcome the establishment of an MDM administrator role; however it would be helpful if the report clarified that this is not yet a commissioned role in the Trust."

Response

- *This is not the experience of the external members of the review team elsewhere in NI and the UK. The review is based on what is best regional and national practice and that which results in the safest possible service for patients. Commissioning within trust resource or regional resource is not within the remit of a Serious Adverse Incident Review.*

3 "Cancer Services can confirm that these reports would have been produced up to approx. 5 years ago by an experienced Biomedical Scientist in the Lab in CAH. These reports took a long time to produce and feedback from the MDMs was that they were of limited value. Cancer Services have confirmed that some labs in NI still produce these reports but not all do. Cancer Services believe that new Failsafe reports could be included with the scope of an MDM administrator role if this could be established"

Response

- *This is not the experience of the external members of the SAI review team. The fail-safe cancer lists are generated by T site codes and M diagnosis codes for malignancy (xxxx3) weekly, by clerical staff who liaise with MDM trackers. It provides additional assurance and would have been of benefit in cases where patients are lost to follow. Critically it also ensures rapid referral of patients to MDM and better adherence to 31- and 62-day targets.*

4."Cancer Services can confirm that the patient attend clinic on 25/05/2019 and it was noted that the CT was to be requested. The request was not raised until 08/07/2019 as an urgent referral (not Red Flag). The CT was completed 18 days after the CT was requested"

Response

- *The review included the overarching CT timeline, as the critical issue was that the patient had a potentially aggressive tumour and should have been on an appropriately timed pathway that was supported by tracking and assurance mechanisms. The 17week delay should not have happened and ideally systems would have been in place to prevent this.The recommendations in the over-arching SAI review propose patient pathways should be tracked in real time and prevent such delays.*

5."Cancer Trackers will track patients on the 31- and 62-day pathways in line with what has been commissioned. This is confirmed to be the case in other Trusts in NI with the exception of Western Trust. The responsibility for following up other actions sits with the clinician and his / her secretary."

Response

- *This is not the experience of the external members of the SAI review team in NI and UK. Critically the resource in SHSCT Urology MDM was unable to meet patient tacking need in these 9 SAIs and in a previous SAI of 2016. Patients came to harm. The review team believe it essential that enhanced resource is in place to improve MDM tracking, in concert with Key workers (usually Urology Cancer Nurse Specialists) and consultant secretaries. This has been shared with the Urology MDM and welcomed, given that several members had previous experience of this approach from the UK.*

6 and 7 "It would be helpful if the report stated who was aware of this issue."

Response

- *"With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner. It is intended that patients newly diagnosed as inpatients will also be included."*

- *The above statement was made on behalf of the SHSCT to Urology Cancer Peer Review 2017 – it has proven to be inaccurate and not based on an assurance audit process. The review team appreciated the candour of those who admitted to being aware that not all care was supported by Cancer Nurse Specialists. They do expect that governance processes are enhanced to ensure that no patients receive cancer care unsupported and without linkages to other critical services.*

8 "Additional capacity for targeted assurance audits would be useful for MDMs and for Cancer Services."

Response

- *The review team have considered this in the recommendations going forward. They believe prospective assurance audit must be supported by resource and infrastructure. However, between 2017 and 2020 assurance audit was limited in the Urology Service and much led by Urology Nurse Specialists. There was no evidence of targeted audit work in areas of known problems or concerns. Appropriate resourcing of audit should be within the remit of Cancer Service Management and Clinical leadership.*

9."It is important to state that the Cancer Trackers are commissioned to track patients on the 31 and 62 day pathways. It is incorrect to suggest that the scope of tracking was limited due to resources or due to the process being flawed. The Trackers perform this function in line with what has been commissioned and it is in line with other Trusts in NI with the exception of Western Trust. Changes to the scope of tracking should be agreed regionally through NICAN and be consistent across Trusts in NI"

Response

- *The 9 SAI reports detailed wide ranging delays and deficits in care that were not and could not be detected with the current tracking resource within SHSCT Urology Cancer MDT. The external members of the SAI review team have different experiences of cancer tracking, something which is shared by several consultant members of the Urology MDT with UK experience. Patients came to harm which*

could have been prevented by enhanced tracking. The SHSCT is responsible for governance of this service and resource must meet clinical risk and patient need.

10. Cancer Services agree that additional capacity to support compliance audits would be helpful.

Response

- *No comment.*

11. Comments noted above provide evidence of actions taken by Cancer Services to help address deficits in Oncology and Radiology input to MDMS – therefore we would suggest that this paragraph is incorrect.

Response

- *The Chair of the SAI review would dispute this as it is not based on data – attendance at MDM by oncology had become progressively worse in the year 2020 (5%) and radiology is still single handed without appropriate pre- MDM independent review of images. This was a live concern and frustration of the SHSCT Urology MDM 18th February 2021.*

I drafted this initial response to the local SHSCT Cancer leadership, which is factual but possibly perceived as somewhat abrupt. Unfortunately, one of the deficits of an external SAI process is that staff and senior leaders did not actually meet patients and families who suffered because of the deficits within assurance and governance of their cancer services. Their responses were defensive and focused on explaining the past which had failed patients.

Ref No89. 20210421

13. Outline who was responsible for formulating the recommendations and/or action plans in each of the nine SAI reviews and the overarching report. Were the recommendations and/or action plans reached on the basis of a consensus amongst the review team? Do you recall any disagreement arising with regard to any recommendation and/or action point? If so provide full details relating to the nature of the issue and how, if at all, it was resolved or reconciled.

- I was responsible for formulating the recommendations and in discussion with the SHSCT, the action plan. The recommendations were signed off by the SAI team, shared with families and provided to the SHSCT. The SHSCT Cancer Services manager was absent from the SAI process at this stage and could not be involved. The review team had reached consensus on this, but the plan had to be adopted and owned by the local SHSCT Urology Cancer Team for successful implementation.

  Ref No90. 20210419

- The Action Plan (which was included in the overarching report) was intended to provide evidence of a high-quality service going forward, that was externally quality assured and specifically met the expectations of the families who engaged at length with the SAI process (despite personal trauma). The recommendations were routine expectations of a functional high quality cancer service, but the required assurance mechanisms were new to the Urology Services teams and specifically new to the Clinical Cancer Management Team. This process would require additional resource, but I believe the augmented assurance and governance recommendations were perceived to be a criticism of the past. Irrespective of this, I believed that this level of assurance with appropriate external validation, was required to provide evidence to patients, families and the wider public that deficits in service had been addressed.

  Ref No91. 20210419

14.Were any updates provided to the SHSCT during the course of the review(s) conducted by the review team? Who was responsible for providing updates? If updates were provided, disclose the content of same, and explain why updates were provided before the review(s) were completed.

- I provided updates to professionals for separate and appropriate reasons. I had contact with Medical Director – then Dr Maria O'Kane to discuss early findings of importance that had the potential to adversely impact on ongoing patient care within Urology Cancer Services. This was to provide feedback on how ongoing services met expected care standards, while a review was in place.

  Ref No92. 20210419
  Ref No93. 20210121

- I met Mr. Stephen Wallace regarding timelines of work given that this was a high-profile review and that partners in the PHA and Department of Health required feedback on process.

- The SHSCT were given feedback regarding the patient feedback to help inform them of family concerns and allow them to deliver their responsibilities in terms of support and ongoing care for patients and families. As part of redress, the SAI team were able to expedite ongoing care including dates of surgery and access to community support for those with advanced disease.

- I became aware that SHSCT was receiving feedback through the governance lead within the SAI review via the Director Responsible for the Urology Cancer Services.

  Ref No94. 20201216

- The overarching Report and Action Plan was shared with the Cancer Management Team for information and discussion on how recommendations could be achieved. The Report was amended with tracked changes, by the SHSCT Clinical Lead for

Cancer, the assistant clinical lead for cancer and an Assistant director of Surgery. I asked that this was withdrawn by the SHSCT as editing rights had been restricted to the SAI team. I was conscious of the family discussions which focused on independence from those delivering service and those responsible for managing service. I believe this related to a lack of understanding on how Serious Adverse Incident Reviews and how level 3 SAI reviews are carried out. The amendments were edited into a separate document, and these were reviewed by me, shared with the SAI team and forwarded to the Cancer Management Team as a response – please see response to comments in Question 12.

Ref No95. 20210331
Ref No96. 20210421

15.Outline, in broad terms, the key themes, trends, findings or conclusions which the review team reached across the nine SAI reviews with regard to both patient safety and governance issues. It may assist you to refer the Inquiry to particular sections of the review reports.

- International best practice indicates that cancer care is best delivered on an agreed evidenced base by teams of professionals with differing but complementary skill sets. This should ensure patients are partners in care, informed about their care and supported throughout their journey – including the palliative phase of disease. Cancer Care in Norther Ireland has been resourced to a considerable degree to achieve these outcomes. Each cancer type has a regional group which includes patients, to determine best treatment pathways for each aspect of care – this is founded on research and international, national, and regional guidelines. The guidelines explain best care and how it should be delivered. Adherence to such guidelines is delivered at Trust / Hospital levels through patient discussion at the multidisciplinary team meeting.

  Ref No97. 20200817
  Ref No98. 20210125
  Ref No99. 20201230
  Ref No100. 20200910
  Ref No101. 20201229
  Ref No102. 20200202

- The SAI Review indicated that the above standards were not met and raised a range of Patient Safety and Governance issues. This related to a range of cancer types, timely diagnosis, staging, and appropriate treatment. Patients were not informed of treatment varying from national guidelines or varying from the recommendations of the SHSCT Urology MDM. They did not give consent for this. This cohort were unsupported by Clinical Nurse Specialists, could not access services when needed and were not appropriately referred onward to oncology and palliative care as expected.

Urology Services Inquiry

Themes, Trends, Findings and Conclusions

The Overarching SAI report reference exemplifies the themes along the patient journey –

Ref No103. 20210419

All information supporting the identified themes are extracts from the Overarching SAI report.

Professional delivering care without multidisciplinary professional input

- The MDT guidelines indicate "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner". None of the 9 patients had access to a Key Worker or Cancer Nurse Specialist. The use of a CNS is common for all other urologists in the SHSCT urology multidisciplinary team allowing any questions or concerns that patients' have, to be addressed. This did not happen.

Failure of onward referral of patients to Oncology / Palliative care

- Service User A should have been referred to oncology initially and then to palliative care as his disease progressed.
- Service User B should have had an earlier diagnosis and referral to oncology.
- Service User D should have been referred to oncology and palliative care.
- Service User E should have been referred to oncology for time critical care.
- Service User F should have been referred to oncology.
- Service User G should have been referred to the Small Renal Mass Team.
- Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 but a Regional Penile Cancer Pathway was only agreed in January 2020.

Prolonged Treatment Pathways

- 5 of the 9 patients in this review experienced significant delay in diagnosis of their cancer. This was related to patients with prostate cancer and reflected variable adherence to regionally agreed prostate cancer diagnostic pathways, NIACN Urology Cancer Clinical Guidelines (2016).

  Ref No104. 20200817
- Service User B had a delay of over 15 months from presentation.

- The review team could not find evidence of a Digital Rectal Examination in the notes of Service User D - potentially missing an opportunity to detect his high grade cancer earlier in his pathway.

- Service User F had a slow initial diagnostic pathway which was outside expected cancer care timeframes.
- Service User C had a delayed diagnosis of a metastatic prostate cancer following successful treatment of Renal Cancer. This was due to non-action on a follow-up CT scan report.
- Patient I had a delayed diagnosis of Prostate cancer due to non-action on a histopathology report at TURP.
- Patient H with penile cancer had a 5 week wait between referral and first appointment. Subsequent time to diagnosis and MDM were appropriate. He had a 17 week wait for a CT scan for staging.
- Service User G was on a renal mass surveillance programme - a recommendation at MDM to discuss his case with the regional small renal lesion team was not actioned and it is not known if they would have suggested earlier intervention.

Care that varied from Regional and National Best Practice Guidance

- The treatment provided to 8 out of 9 patients was contrary to the NICAN Urology Cancer Clinical Guidelines (2016). This Guidance was adopted by the Southern Health and Social Care Trust Urology Multidisciplinary Team and evidenced by them as their protocols for Cancer Peer review (2017). The Guidance was issued following Dr.1 & Chairmanship of the Northern Ireland Cancer Network Urology Cancer Clinical Reference Group.

  Ref No105. 20200202

  Ref No106. 20200910

  Ref No107. 20201229

Care that varied from SHSCT Urology Services Multidisciplinary Team Recommendations

- The MDM made appropriate recommendations for 8 of the 9 patients but there was no mechanism to check actions were implemented - this included, further investigations, staging, treatment, and appropriate onward referral.
- Dr 1 was present for the discussions and party to the recommendations, 8 of which were compliant with National and Regional Guidelines.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non-implementation of these MDM recommendations was unknown to others in the MDM. One patient D presented as an emergency and his care was changed to the MDM recommendation by another consultant.

Urology Services Inquiry

Patients being unaware of care varying from above recommendations and unable to give informed consent

- Patients were not aware that the care given varied from Regional Standards and MDM recommendations. They could not have given informed consent to this.

Patients receiving care without input from a Cancer Nurse Specialist / Key worker

- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.

Lack of resource within the SHSCT to adequately track cancer patients through their journey

- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31- and 62-day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care.
- Safe cancer patient care and pathway tracking is usually delivered by a three-pronged approach of MDT tracking, Consultants and their Secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that these 9 patients were not referred to Specialist Nurses and contact telephone numbers were not given. Therefore, the CNS were not given the opportunity to provide support and discharge their duties to the 9 patients, who suffered as a consequence. The MDM tracking system was limited. The consultant / secretary led process was variable and resulted in deficits. The weakness of the latter component was known from previous review.

Non-Quorate Multidisciplinary Meetings

- The Urology MDM was under resourced and frequently non quorate due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent Quality Assurance of images by a second radiologist prior to MDM.

Lack of Assurance Audits within the MDT process

- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered.
- Because of resource, the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31- and 62-day targets.

Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were, in essence absent. A collaborative approach did not appear to be actively encouraged within the MDT.

Lack of coherent escalation / governance structures

- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM but did not escalate other issues.
- The Review team found that issues about prescribing, and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.

16.Outline what, if any, discussion of the review team's findings, conclusions, recommendations, and action plans took place between the review team and the SHSCT.

- Discussions with the SHSCT Cancer management Team were limited as the recommendation in the report mirror those outcomes that should be evidenced at External Peer Review of Urology Cancer Services. The underlying difference was the service required a comprehensive assurance mechanism to demonstrate the outcomes and to meet the expectations of the families who contributed to the process. I was keen to ensure the recommendations were externally validated, would meet national standards, and reflect the independent external aspect of the review process. Feedback was received from the Senior Cancer Management team, and I have included this correspondence with my response in Question 12.

  Ref No108. 20210331
  Ref No109. 20210421

Urology Services Inquiry

17.To the best of your knowledge and understanding, were the findings, conclusions, recommendations and action plans for each of the nine SAI reviews accepted by the SHSCT? Outline any disagreement or objection to any finding, conclusion, recommendations or action plan which was raised with you or any member of the review team.

- To the best of my knowledge the recommendations and action plans of the SAI process were accepted by the SHSCT and the SHSCT Urology Cancer Services. I was also contacted to be a “critical friend” to the implementation process and at a later date, contacted by the Urology Services Manager to help with implementation.

- The recommendations relate to expected best practice as defined by National and Regional Guidelines. These were shared and shaped by the Review team and families experience. My understanding of concerns from the Urology Cancer Services was the additional level of assurance placed on the service, the availability of resources to achieve this and the need to address staffing shortages. It represented a change in how patients were supported, managed, and tracked through the system but this was required to ensure patient safety and demonstrate change to service users. Members of the Urology MDT who had worked previously in the UK had requested enhanced MDT resource and appropriate recruitment to all professions contributing to patient care.

- The Senior Clinical and Managerial leadership of Cancer Services had a different view and regarded many of the assurance requirements within the recommendations were questioned based on commissioning and questionable benefit. My response to their concerns is included in question 12.

- The Clinical and Managerial Leadership of Cancer services had no knowledge or insight into the problems identified within the SAI processes. There was lack of understanding of services how were delivered elsewhere and what constituted open and transparent governance in a complex multidisciplinary healthcare setting. Some of their concerns did not reflect views as expressed by the Urology Cancer MDT members and there was a disconnect between senior level clinical management and MDT teams. This was clearly evidenced by Statements made to External Peer Review of Urology Services.

  Ref No110. 20200202

- There seemed to be limited insight from the Senior Cancer management team that the recommendations were routine best practice, expected of all cancer services and reflected the care currently provided by the Urology Team, to a large degree. The assurance mechanisms were in place to address deficits (resource, MDT attendance, variance from expected practice, governance) and were required to provide external assurance. The patients and families were adamant that “words would not be enough”. They wanted evidence and the opportunity to be part of an assurance process. I believed this to an essential part of the process of redress.

Urology Services Inquiry

18.What, if any, difficulties or hurdles were you or other members of the review team faced with in the conduct of the nine SAI reviews? For each difficulty or hurdle identified, explain what steps were taken to overcome the issue, and/or whether it was possible to overcome the issue.

- The major deficit within the review was the inability to engage with the professional who was the named consultant for all the patients. This would have allowed some insight into variations from expected practice, as defined by regional and national guidelines. Despite repeated communications and extended timelines responses to questions regarding patient care were not received.

  Ref No111. 20200211

- I believe the Professionals in the SHSCT found the SAI review process concerning as the process involved review of patient pathways in a multidisciplinary setting. This moved governance questions from the actions of a single professional to the responsibilities of the wider team. I believe some felt this unfair, but the SAI report was based on expected care and on standards of care evidenced by the SHSCT team to Cancer Peer Review of their service.

- The deficits in care covered a range of cancer types, related to diagnosis, timely staging, and appropriate treatment. Patients were not informed of treatment varying from national guidelines or varying from the recommendations of the SHSCT Urology MDM. They did not give consent for this. This cohort were unsupported by Clinical Nurse Specialists, could not access services when needed and were not appropriately referred onward to oncology and palliative care as expected.

- The driver for the SAI team approach was informed by the experience and expectation of patients and families who were adamant that the SAI process should be independent from those providing service. The engagement with families resulted in questions moving from what happened to how it happened,

19.Having regard to any difficulty identified above, are you of the opinion that it undermined or impacted upon the quality of the SAI review process? If so, elaborate the reasons why you think this is the case.

- I do not believe that non-engagement by the named consultant hindered the “finding of fact” aspect of the SAI process – this was a process of benchmarking patient timelines, patient stories and patient outcomes against regional and national guidelines common to all urology cancer care. It is not unusual for SAI processes to caried out independent of the professional delivering care. We were however unable to ascertain why therapeutic choices were made, often at variance with regional guidelines and recommendations of the SHSCT Urology Cancer MDM. We were aware that a Specialist Urology Nurse was included in care of patients with benign

disease but were unable to ascertain why those with malignant disease were not offered the same support.

- I believe that the most the most important aspect of the SAI was the experience of patients and families who experienced care delivered in a uni-professional fashion and different from that experienced by other patients attending SHSCT Urology Cancer Services. The major issue throughout the reviews was the finding of care deficits that were professional specific but happened within a multidisciplinary setting. An SAI is ultimately a learning and improvement tool – the weakness of this process was that those responsible for managing care and service did not have the opportunity to meet the patients and families and contextualize the deficits. The families had offered to be part of the assurance process which considering the trauma suffered was brave and constructive. I ensured this was included within the recommendations but acknowledge that some may have found this challenging.

20.Outline the nature and extent of any interaction you or other members of the review team had with (a) the Trust's Board, (b) the Health and Social Care Board and (c) the Public Health Agency in connection with the reviews, whether before you commenced, during the course of, or after completion of the reviews.

- I had no involvement with the SHSCT Trust Board, the Health and Social Care Board or the Public Health Agency directly. Mrs. Patrricia Kingsnorth managed these interfaces and the sole feedback received related to expected timelines for completion. There was no feedback regarding findings of fact or recommendations from these bodies.

Structured Clinical Record Review Process & Further Actions

21.What, if anything, were you told about the decision of the SHSCT to adopt a Structured Clinical Record Review process ("SCRR") in respect of other cases, apart from the nine you reviewed, which met the threshold for an SAI review? Specifically, address:

a. When and in what circumstances you became so aware of the intention to adopt a SCRR methodology.

- I became aware of this proposal from the Medical Director SHSCT towards the end of the SAI process that I was chairing. I had kept a distance from the SHSCT in-house triage process for patients reaching a threshold for SAI review, as I believed that information on ongoing governance processes could be perceived to inappropriately influence the independent aspect of the SAI process.

b.What, if any, view did you express to the SHSCT in writing or orally on the merits of this decision, or generally.

- I believed that this approach would be constructive, providing patient and family engagement was adequately addressed.

  I have experience of this approach in another setting, and it can deliver high quality review of care – especially when there are expected care pathways to benchmark outcomes. It can be performed external to local service which provides greater public assurance and allows local service to continue for patients. The process of finding fact does not alter how a trust or professionals managing a service should interact with families and patients. My experience is that the Structured Review of notes should be only part of the process and the structure should include additional reviews considering patient and family stories. This can, to some degree, address the concerns that clinical notes, if incomplete, may result in flawed conclusions.

22.Since your participation in the series of SAI reviews in 2020, have you performed any additional work for the SHSCT in connection with Urology Services or governance generally, or have you been asked to do so? If applicable, outline what work you have undertaken or specify what work you have been asked to do.

- I had been asked by the SHSCT Governance Lead to be a critical Friend to the service and the Urology Cancer Service Manager did write to ask me to join the Urology Cancer Services team to help implement Recommendations. I considered this request but believed that if I took up such a role the recommendations might be viewed as “my recommendations” and not owned by the SHSCT. I decided not to undertake this role and explained my rationale to the Medical Director.

Learning & Reflections

23.Having had the opportunity to reflect upon the nine SAI reviews you were involved in, is there anything that would wish to say about the cases which you reviewed, the conduct of the review processes and the outcomes of the SAI reviews themselves, which is not already reflected in the respective reports?

- The SAI Review Team had an essential external component did include professionals from the SHSCT who discharged their duties in an exemplary manner. This was despite a potential perceived conflict of interest by some. I believe the local governance team were able to establish and maintain very positive relationships with patients and families, despite the traumatic nature of some of the findings. Although I met families on three occasions, the local team had ongoing interactions with patients and families ensuring details that would not otherwise have been known were included in the reports.

- Much of the SAI Reviews are framed in terms of what care and support patients did or did not receive. Patients with urological cancers often fall within the older age group and may be more often be passive recipients of decisions and advice. They may not have been able to seek independent information for themselves. They all had faith in the health service but were not given the opportunity to discuss their care or more importantly how their care varied from practice of others. Individual decisions of a single professional took precedence over patient’s rights to best care based on evidence and best supported care. This was not “patients as partners in care” and my

reflections really relate to how this can be prevented going forward. I had been fortunate to be in positions to alter how cancer was structured, delivered, and received. Lack of meaningful governance and assurance has resulted in care and experience of care varying from best practice and varying from what the patients had a right to expect.

- As a result of this and other governance work, I had the opportunity to become the Senior Responsible Owner for the Encompass Project in Northern Ireland. This is the largest implementation of an Electronic Patient Record in Europe covering all of health and social care. It is standardizing all patient and client pathways (benchmarked against international and national best practice) and embedding them digitally within the record. The record is visible to all healthcare staff and managerial staff throughout primary and secondary care. The system will provide real time data on care and will provide near-real time assurance. The system has a portal to allow patients / clients access to their own information. It will address some of the issues identified within the SAI process and hopefully will allow patients can become partners in their own care.

24.Given the Inquiry's terms of reference, is there anything else you would like to add to assist the Inquiry in ensuring it has all the information relevant to those Terms?

The Governance of care delivered by teams, leadership and management by Medical Professionals is covered by GMC Guidance "Leadership and Management for all doctor Published January 2012." – I have used this guidance to benchmark how doctors with additional responsibilities perform in the management of governance of care delivered by teams they manage. The principles set out in this document have informed my clinical and managerial practice and informed the approach to the 10 Serious Adverse Review Reports. I was keen that expected actions of professionals aligned with the expectations of their professional body.

NOTE:

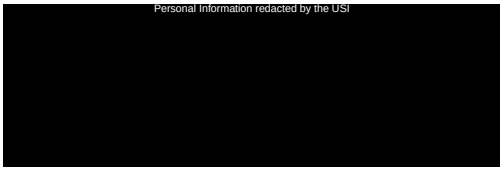
By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and 6

minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers, as well as those sent from official or business accounts or numbers. By virtue of section 21(6) of the Inquiries Act 2005, a thing is under a person's control if it is in his possession or if he has a right to possession of it.

Urology Services Inquiry

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed: __ 

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Date: 17th October 2022

Urology Services Inquiry

APPENDIX

Ref No 1. Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf
Ref No2. 20210510 Overarching Report to HSCB PHA 21.4.2021
Ref No3. 20200522 Final Report
Ref No4. 20200211 letter to Mr O B
Ref No5. 20210111 MEETING WITH DR ST
Ref No6. 20210107 reports 2
Ref No7. 20210204 SAI urology review Patient 3
Ref No8. 20210208 SAI urology Review - HT
Ref No9. 20210218 Notes of Meeting with MDT 18.2.2021
Ref No10. 20210225 SAI Urology review - notes Patient 10
Ref No11. 20210125 SAI Urology Review MC
Ref No12. 210222 Notes of Meeting CNS 22.2.21
Ref No13. 20210106 SAI Urology Review JOS amended
Ref No14. 20210223 Notes of Meeting Dr Darren Mitchell 22.02.2021
Ref No15. 20210125 Meeting patient needs
Ref No16. 20210204 SAI urology review Patient 3
Ref No17. 20210218 Notes of Meeting with MDT 18.2.2021
Ref No18. 20210331 RCA report -overarching report tracked comments from CCS Div
Ref No19. 20210421 urology SAI response
Ref No20. 20210209 LEVEL 3 overarching ereview version 2
Ref No21. 20210208 SAI urology Review - HT
Ref No22. 20210111 MEETIN WITH DR ST
Ref No23. 20210107 reports 2.pdf. 1
Ref No24. 20201229 Urology MDT Peer review External Verification 2017 Action plan
Ref No25. 20210106 SAI Urology Review JOS amended
Ref No26. 20210223 Notes of Meeting Dr Darren Mitchell 22.02.2021
Ref No27. 20210222 ni adt protocol 080615 final
Ref No28. 20211102 Meeting with Families Urology Perso
Ref No29. 20210707 Schedule for meeting with families to follow up on report
Ref No30. 20210125 Meeting patient needs
Ref No31. 20210125 MDT Prostate Cancer Guidance
Ref No32. 20201230 urology review
Ref No33. 20201229 Urology MDT Peer review External Verification 2017 Action pla
Ref No34. 202010910 Urology cancer MDT operational policy final May 2017
Ref No35. 20200910 Urology MDT 2016
Ref No36. 20200202 Self Assessment Peer Review Report 2017 (2)
Ref No37. 20200817 FINAL NICaN Urology Cancer Clinical Guidelines Mar16
Ref No38. 20210105 Notes of meeting 04.01.2021
Ref No39. 20210204 Notes of Meeting 18.1.2021
Ref No40. 20210223 Notes of Meeting 22.2.2021
Ref No41. 20201107 Thematic analysis of considerations
Ref No42. 20200301 Draft Report Personal Information redacted by USI to HSCB 1.3.2021 attachment 5 to email
Ref No43. 20210222 Personal Information redacted by USI Patient 8 Report version 3.3
Ref No44. 20210208 Personal Information redacted by USI Patient 8 Report version 3.2
Ref No45. 20200903 Draft Report to Personal Information redacted by the USI HSCB 1.3.2021 email attachment 1

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Ref No46. 20210423 Cover letter for SAI report issued to solicitor reg post 26.4.2021
Ref No47. 20210930 Final Report issued
Ref No48. 20210316 Draft report issued
Ref No49. 20210208 Report version 3.1 comments
Ref No50. 20210224 Report version 3.4
Ref No51. 20201215 Report version 2
Ref No52. 20210428 Final Report to HSCB 22.4.2021
Ref No53. 20210322 Draft report issued 16.3.2021
Ref No54. 20210226 Report version 3.4. HSCB Copy
Ref No55. 20210419 Report version 3.5 final HSC
Ref No56. 20210527 Final report issued registered post 27.5.2021
Ref No57. 20210419 SAI report version 3.5 Patient copy
Ref No58. 20210309 Amended Draft Report to HSCB 1.3.2021
Ref No59. 20210224 SAI report version 3.3.hg
Ref No60. 20210427 Final Report issued
Ref No61. 20210224 Report version 3.3.hg
Ref No62. 20210421 SAI version 3.5 Family Copy
Ref No63. 20210205 SAI version 3.1
Ref No64. 20210422 Final Report to HSCB 22.4.2021
Ref No65. 20210421 SAI report HSCB 21.4.2021
Ref No66. 20210301 Draft Report to HSCB 1.3.2021
Ref No67. 20210226 Report version 3.4
Ref No68. 20210224 Report version 3.3.hg
Ref No69. 20210222 Report version 3.3
Ref No70. 20211018 Final Report to HSCB 22.4.2021
Ref No71. 20210421 Draft report to HSCB 1.3.2021
Ref No72. 20211018 Final Report to HSCB 22.4.2021
Ref No73. 20210422 Final Report to HSCB
Ref No74. 20210421 SAI version 3.4 Pt copy comments hg
Ref No75. 20210413 SAI version 3.4 Pt copy
Ref No76. 20210208 SAI version 3.2
Ref No77. 20210222 SAI version 3.3
Ref No78. 20210316 Draft report to
Ref No79. 20210304 SAI report version 3.4 Patients copy
Ref No80. 20210224 SAI report version 3.4
Ref No81. 20210218 SAI report version 3.3.1
Ref No82. 20210202 SAI report version 3.1
Ref No83. 20210205 SAI report version 3.2
Ref No84. 20210204 SAI report version 3.1 comments HG
Ref No85. 210222 Notes of Meeting CNS 22.2.21
Ref No86. 202101028 UROLOGY Cancer guidelines
Ref No87. 20210510 Email RE Report Confidential
Ref No88. 20210331 RCA report -overarching report tracked comments from CCS Div
Ref No89. 20210421 urology SAI response
Ref No90. 20210419 Overarching Report to Patient Families
Ref No91. 20210419 Final Report to HSCB 20.4.2021
Ref No92. 20210419 Final Report to HSCB 20.4.2021

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Ref No93. 20210121 Update on early Learning SAI urology
Ref No94. 20201216 SAI Level 3 Summary Position
Ref No95. 20210331feedback from cancer and clinical services
Ref No95.1. 20210331 RCA report -overarching report tracked comments from CCS Div
Ref No96. 20210421 urology SAI response
Ref No97. 20200817 FINAL NICaN Urology Cancer Clinical Guidelines Mar1
Ref No98. 20210125 MDT Prostate Cancer Guidance
Ref No99. 20201230 urology review
Ref No100. 20200910 EMAIL attachment Southern Urology MDT Workplan 2016-17
Ref No101. 20201229 Urology MDT Peer review External Verification 2017 Action plan
Ref No102. 20200202 Self Assessment Peer Review Report 2017 (2)
Ref No103. 20210419 Final Report Personal Information redacted by USI to HSCB 20.4.2021
Ref No104. 20200817 FINAL NICaN Urology Cancer Clinical Guidelines Mar16
Ref No105. 20200202 Self Assessment Peer Review Report 2017 (2)
Ref No106. 20200910 EMAIL attachment Southern Urology MDT Workplan 2016-17 - Copy
Ref No107. 20201229 Urology MDT Peer review External Verification 2017 Action plan
Ref No108. 20210331feedback from cancer and clinical services - Copy
Ref No108.1. 20210331 RCA report -overarching report tracked comments from CCS Div - Copy
Ref No109. 20210421 urology SAI response - Copy
Ref No110. 20200202 Self Assessment Peer Review Report 2017 (2)
Ref No111. 20200211 letter to Mr O B

Health and Social Care Board

Procedure for the Reporting and Follow up of Serious Adverse Incidents

November 2016
Version 1.1

CONTENTS

SECTION TWO - APPENDICES

SECTION THREE - ADDENDUM

FOREWORD

Commissioners and Providers of health and social care want to ensure that when a serious event or incident occurs, there is a systematic process in place for safeguarding services users, staff, and members of the public, as well as property, resources and reputation.

One of the building blocks for doing this is a clear, regionally agreed approach to the reporting, management, follow-up and learning from serious adverse incidents (SAIs). Working in conjunction with other Health and Social Care (HSC) organisations, this procedure was developed to provide a system-wide perspective on serious incidents occurring within the HSC and Special Agencies and also takes account of the independent sector where it provides services on behalf of the HSC.

The procedure seeks to provide a consistent approach to:

- what constitutes a serious adverse incident;
- clarifying the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning;
- fulfilling statutory and regulatory requirements;
- tools and resources that support good practice.

Our aim is to work toward clearer, consistent governance arrangements for reporting and learning from the most serious incidents; supporting preventative measures and reducing the risk of serious harm to service users.

The implementation of this procedure will support governance at a local level within individual organisations and will also improve existing regional governance and risk management arrangements by continuing to facilitate openness, trust, continuous learning and ultimately service improvement.

This procedure will remain under continuous review.

Valerie Watts
Chief Executive

SECTION ONE - PROCEDURE

1.0 BACKGROUND

Circular HSS (PPM) 06/04 introduced interim guidance on the reporting and follow-up on serious adverse incidents (SAIs). Its purpose was to provide guidance for HPSS organisations and special agencies on the reporting and management of SAIs and near misses.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hss(ppm)06-04.pdf

Circular HSS (PPM) 05/05 provided an update on safety issues; to underline the need for HPSS organisations to report SAIs and near misses to the DHSSPS in line with Circular HSS (PPM) 06/04.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hssppm05-05.pdf

Circular HSS (PPM) 02/2006 drew attention to certain aspects of the reporting of SAIs which needed to be managed more effectively. It notified respective organisations of changes in the way SAIs should be reported in the future and provided a revised report pro forma. It also clarified the processes DHSSPS had put in place to consider SAIs notified to it, outlining the feedback that would then be made to the wider HPSS.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/qpi_adverse_incidents_circular.pdf

In March 2006, DHSSPS introduced Safety First: A Framework for Sustainable Improvement in the HPSS. The aim of this document was to draw together key themes to promote service user safety in the HPSS. Its purpose was to build on existing systems and good practice so as to bring about a clear and consistent DHSSPS policy and action plan.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/safety_first_-_a_framework_for_sustainable_improvement_on_the_hpss-2.pdf

The Health and Personal Social Services (Quality Improvement and Regulation) (Northern Ireland) Order 2003 imposed a ‘statutory duty of quality’ on HPSS Boards and Trusts. To support this legal responsibility, the Quality Standards for Health and Social Care were issued by DHSSPS in March 2006.

www.health-ni.gov.uk/publications/quality-standards-health-and-social-care-documents

Circular HSC (SQS) 19/2007 advised of refinements to DHSSPS SAI system and of changes which would be put in place from April 2007, to promote learning from SAIs and reduce any unnecessary duplication of paperwork for organisations. It also clarified arrangements for the reporting of breaches of patients waiting in excess of 12 hours in emergency care departments.

http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/hss__sqsd__19-07.pdf

Under the Provisions of Articles 86(2) of the Mental Health (NI) Order 1986, the Regulation & Quality Improvement Authority (RQIA) has a duty to make inquiry into any

case where it appears to the Authority that there may be amongst other things, ill treatment or deficiency in care or treatment. Guidance in relation to reporting requirements under the above Order previously issued in April 2000 was reviewed, updated and re-issued in August 2007. (Note: Functions of the previous Mental Health Commission transferred to RQIA on 1 April 2009).

http://webarchive.proni.gov.uk/20101215075727/http://www.dhsspsni.gov.uk/print/utec_guidance_august_2007.pdf

Circular HSC (SQSD) 22/2009 provided specific guidance on initial changes to the operation of the system of SAI reporting arrangements during 2009/10. The immediate changes were to lead to a reduction in the number of SAIs that were required to be reported to DHSSPS. It also advised organisations that a further circular would be issued giving details about the next stage in the phased implementation which would be put in place to manage the transition from the DHSSPS SAI reporting system, through its cessation and to the establishment of the RAIL system.

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2022-09.pdf

Circular HSC (SQSC) 08/2010, issued in April 2010, provided guidance on the transfer of SAI reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency. It also provided guidance on the revised incident reporting roles and responsibilities of HSC Trusts, Family Practitioner Services, the Health & Social Care (HSC) Board and Public Health Agency (PHA), the extended remit of the Regulation & Quality Improvement Authority (RQIA), and the Department.

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2008-10.pdf

Circular HSC (SQSD) 10/2010 advises on the operation of an Early Alert System, the arrangements to manage the transfer of Serious Adverse Incident (SAI) reporting arrangements from the Department to the HSC Board, working in partnership with the Public Health Agency and the incident reporting roles and responsibilities of Trusts, family practitioner services, the new regional organisations, the Health & Social Care (HSC) Board and Public Health Agency (PHA), and the extended remit of the Regulation & Quality Improvement Authority (RQIA).

https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2010-10.pdf

In May 2010 the Director of Social Care and Children HSCB issued guidance on 'Untoward Events relating to Children in Need and Looked After Children' to HSC Trusts. This guidance clarified the arrangements for the reporting of events, aligned to delegated statutory functions and Departmental Guidance, which are more appropriately reported to the HSCB Social Care and Children's Directorate.

In 2012 the HSCB issued the 'Protocol for responding to SAIs involving an alleged homicide'. The 2013 revised HSCB 'Protocol for responding to SAIs involving an alleged homicide' is contained in Appendix 14.

Circular HSS (MD) 8/2013 replaces HSS (MD) 06/2006 and advises of a revised Memorandum of Understanding (MOU) when investigating patient or client safety incidents. This revised MOU is designed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required when a serious incident occurs.

www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

DHSSPS Memo dated 17 July 2013 from Chief Medical Officer introduced the HSCB/PHA protocol on the dissemination of guidance/information to the HSC and the assurance arrangements where these are required. The protocol assists the HSCB/PHA in determining what actions would benefit from a regional approach rather than each provider taking action individually.

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/002%20%20HSCB-PHA%20Protocol%20for%20Safety%20Alerts.pdf

Circular HSC (SQSD) 56/16 (21 October 2016) from the Deputy Chief Medical Officer advises of the intention to introduce a Never Events process and that information relating to these events will be captured as part of the Serious Adverse Incident Process. The circular indicates the Never Events process will be based on the adoption of Never Event List with immediate effect.

https://www.health-ni.gov.uk/sites/default/files/publications/health/HSC-SQSD-56-16.pdf

2.0 INTRODUCTION

The purpose of this procedure is to provide guidance to Health and Social Care (HSC) Organisations, and Special Agencies (SA) in relation to the reporting and follow up of Serious Adverse Incidents (SAIs) arising during the course of their business or commissioned service.

The requirement on HSC organisations to routinely report SAIs to the Department of Health (DoH) {formerly known as the DHSSPS} ceased on 1 May 2010. From this date, the revised arrangements for the reporting and follow up of SAIs, transferred to the Health and Social Care Board (HSCB) working both jointly with the Public Health Agency (PHA) and collaboratively with the Regulation and Quality Improvement Authority (RQIA).

This process aims to:

- Provide a mechanism to effectively share learning in a meaningful way; with a focus on safety and quality; ultimately leading to service improvement for service users;

- Provide a coherent approach to what constitutes a SAI; to ensure consistency in reporting across the HSC and Special Agencies;

- Clarify the roles, responsibilities and processes relating to the reporting, reviewing, dissemination and implementation of learning arising from SAIs which occur during the course of the business of a HSC organisation / Special Agency or commissioned/funded service;

- Ensure the process works simultaneously with all other statutory and regulatory organisations that may require to be notified of the incident or be involved the review;

- Keep the process for the reporting and review of SAIs under review to ensure it is fit for purpose and minimises unnecessary duplication;

- Recognise the responsibilities of individual organisations and support them in ensuring compliance; by providing a culture of openness and transparency that encourages the reporting of SAIs;

- Ensure trends, best practice and learning is identified, disseminated and implemented in a timely manner, in order to prevent recurrence;

- Maintain a high quality of information and documentation within a time bound process.

3.0 APPLICATION OF PROCEDURE

3.1 Who does this procedure apply to?

This procedure applies to the reporting and follow up of SAIs arising during the course of the business in Department of Health (DoH) Arm's Length Bodies (ALBs) i.e.

- ***HSC organisations (HSC)***
  - Health and Social Care Board
  - Public Health Agency
  - Business Services Organisation
  - Belfast Health and Social Care Trust
  - Northern Health and Social Care Trust
  - Southern Health and Social Care Trust
  - South Eastern Health and Social Care Trust
  - Western Health and Social Care Trust
  - Northern Ireland Ambulance Service
  - Regulation and Quality Improvement Authority

- ***Special Agencies (SA)***
  - Northern Ireland Blood Transfusion Service
  - Patient Client Council
  - Northern Ireland Medical and Dental Training Agency
  - Northern Ireland Practice and Education Council

The principles for SAI management set out in this procedure are relevant to all the above organisations. Each organisation should therefore ensure that its incident policies are consistent with this guidance while being relevant to its own local arrangements.

3.2 Incidents reported by Family Practitioner Services (FPS)

Adverse incidents occurring within services provided by independent practitioners within: General Medical Services, Pharmacy, Dental or Optometry, are routinely forwarded to the HSCB Integrated Care Directorate in line with the HSCB Adverse Incident Process within the Directorate of Integrated Care (September 2016). On receipt of reported adverse incidents the HSCB Integrated Care Directorate will decide if the incident meets the criteria of a SAI and if so will be the organisation responsible to report the SAI.

3.3 Incidents that occur within the Independent /Community and Voluntary Sectors (ICVS)

SAIs that occur within ICVS, where the service has been commissioned/funded by a HSC organisation must be reported. For example: service users placed/funded by HSC Trusts in independent sector accommodation, including private hospital, nursing or residential care homes, supported housing, day care facilities or availing of HSC funded voluntary/community services. These SAIs must be reported and reviewed by the HSC organisation who has:

- referred the service user (this includes Extra Contractual Referrals) to the ICVS;

or, if this cannot be determined;

- the HSC organisation who holds the contract with the IVCS.

HSC organisations that refer service users to ICVS should ensure all contracts, held with ICVS, include adequate arrangements for the reporting of adverse incidents in order to ensure SAIs are routinely identified.

All relevant events occurring within ICVS which fall within the relevant notification arrangements under legislation should continue to be notified to RQIA.

3.4 Reporting of HSC Interface Incidents

Interface incidents are those incidents which have occurred in one organisation, but where the incident has been identified in another organisation. In such instances, it is possible the organisation where the incident may have occurred is not aware of the incident; however the reporting and follow up review may be their responsibility. It will not be until such times as the organisation, where the incident has occurred, is made aware of the incident; that it can be determined if the incident is a SAI.

In order to ensure these incidents are notified to the correct organisation in a timely manner, the organisation where the incident was identified will report to the HSCB using the HSC Interface Incident Notification Form (see Appendix 3). The HSCB Governance Team will upon receipt contact the organisation where the incident has occurred and advise them of the notification in order to ascertain if the incident will be reported as a SAI.

Some of these incidents will subsequently be reported as SAIs and may require other organisations to jointly input into the review. In these instances refer to Appendix 13 – Guidance on Joint Reviews.

3.5 Incidents reported and Investigated/ reviewed by Organisations external to HSC and Special Agencies

The reporting of SAIs to the HSCB will work in conjunction with and in some circumstances inform the reporting requirements of other statutory agencies and external bodies. In that regard, all existing local or national reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

3.5.1 Memorandum of Understanding (MOU)

In February 2006, the DoH issued circular HSS (MD) 06/2006 − a Memorandum of Understanding − which was developed to improve appropriate information sharing and co-ordination when joint or simultaneous investigations/reviews are required into a serious incident.

Circular HSS (MD) 8/2013 replaces the above circular and advises of a revised MOU Investigating patient or client safety incidents which can be found on the Departmental website:

www.health-ni.gov.uk/sites/default/files/publications/dhssps/hss-md-8-2013.pdf

The MOU has been agreed between the DoH, on behalf of the Health and Social Care Service (HSCS), the Police Service of Northern Ireland (PSNI), the Northern Ireland Courts and Tribunals Service (Coroners Service for NI) and the Health and Safety Executive for Northern Ireland (HSENI). It will apply to people receiving care and treatment from HSC in Northern Ireland. The principles and practices promoted in the document apply to other locations, where health and social care is provided e.g. it could be applied when considering an incident in a family doctor or dental practice, or for a person receiving private health or social care provided by the HSCS.

It sets out the general principles for the HSCS, PSNI, Coroners Service for NI and HSENI to observe when liaising with one another.

The purpose of the MOU is to promote effective communication between the organisations. The MOU will take effect in circumstances of unexpected death or serious untoward harm requiring investigation by the PSNI, Coroners Service for NI or HSENI separately or jointly. This may be the case when an incident has arisen from or involved criminal intent, recklessness and/or gross negligence, or in the context of health and safety, a work-related death.

The MOU is intended to help:

- Identify which organisations should be involved and the lead investigating body.

- Prompt early decisions about the actions and investigations/reviews thought to be necessary by all organisations and a dialogue about the implications of these.

- Provide an understanding of the roles and responsibilities of the other organisations involved in the memorandum before high level decisions are taken.

- Ensure strategic decisions are taken early in the process and prevent unnecessary duplication of effort and resources of all the organisations concerned.

HSC Organisations should note that the MOU does not preclude simultaneous investigations/reviews by the HSC and other organisations e.g. Root Cause Analysis by the HSC when the case is being reviewed by the Coroners Service and/or PSNI/HSENI.

In these situations, the Strategic Communication and Decision Group can be used to clarify any difficulties that may arise; particularly where an external organisation's investigation/review has the potential to impede a SAI review and subsequently delay the dissemination of regional learning.

3.6 Reporting of SAIs to RQIA

RQIA have a statutory obligation to investigate some incidents that are also reported under the SAI procedure. In order to avoid duplication of incident notification and review, RQIA will work in conjunction with the HSCB/PHA with regard to the review of certain categories of SAI. In this regard the following SAIs should be notified to RQIA at the same time of notification to the HSCB:

- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.

- Any SAI that occurs within the regulated sector (whether statutory or independent) for a service that has been commissioned/funded by a HSC organisation.

  *It is acknowledged these incidents should already have been reported to RQIA as a **'notifiable event'** by the statutory or independent organisation where the incident has occurred (in line with relevant reporting regulations). This notification will alert RQIA that the incident is also being reviewed as a SAI by the HSC organisation who commissioned the service.*

- The HSCB/PHA Designated Review Officer (DRO) will lead and co-ordinate the SAI management, and follow up, with the reporting organisation; however for these SAIs this will be carried out in

conjunction with RQIA professionals. A separate administrative protocol between the HSCB and RQIA can be accessed at Appendix 15.

3.7 Reporting of SAIs to the Safeguarding Board for Northern Ireland

There is a statutory duty for the HSC to notify the Safeguarding Board for Northern Ireland of child deaths where:

- a child has died or been significantly harmed (Regulation 17(2)(a)

AND

- abuse/neglect suspected **or** child or sibling on child protection register **or** child or sibling is/has been looked after Regulation (2)(b) (see Appendix 17)

4.0 DEFINITION AND CRITERIA

4.1 Definition of an Adverse Incident

'Any event or circumstances that could have or did lead to harm, loss or damage to people, property, environment or reputation'[1] arising during the course of the business of a HSC organisation / Special Agency or commissioned service.

The following criteria will determine whether or not an adverse incident constitutes a SAI.

4.2 SAI criteria

4.2.1 serious injury to, or the unexpected/unexplained death of:

- a service user, (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit)
- a staff member in the course of their work
- a member of the public whilst visiting a HSC facility;

4.2.2 unexpected serious risk to a service user and/or staff member and/or member of the public;

4.2.3 unexpected or significant threat to provide service and/or maintain business continuity;

[1] Source: DoH - How to classify adverse incidents and risk guidance 2006
http://webarchive.proni.gov.uk/20120830142323/http://www.dhsspsni.gov.uk/ph_how_to_classify_adverse__incidents_and_risk_-_guidance.pdf

4.2.4 serious self-harm or serious assault (*including attempted suicide, homicide and sexual assaults*) by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service;

4.2.5 serious self-harm or serious assault *(including homicide and sexual assaults*)

- on other service users,
- on staff or
- on members of the public

by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

4.2.6 suspected suicide of a service user who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident;

4.2.7 serious incidents of public interest or concern relating to:

- any of the criteria above
- theft, fraud, information breaches or data losses
- a member of HSC staff or independent practitioner.

ANY ADVERSE INCIDENT WHICH MEETS ONE OR MORE OF THE ABOVE CRITERIA SHOULD BE REPORTED AS A SAI.

Note: The HSC Regional Risk Matrix may assist organisations in determining the level of 'seriousness' refer to Appendix 16.

5.0 SAI REVIEWS

SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review. In order to ensure timely learning from all SAIs reported, it is important the level of review focuses on the complexity of the incident and not solely on the significance of the event.

Whilst most SAIs will be subject to a Level 1 review, for some more complex SAIs, reporting organisations may instigate a Level 2 or 3 review immediately following the incident occurring. The level of review should be noted on the SAI notification form.

The HSC Regional Risk Matrix (refer to Appendix 16) may assist organisations in determining the level of 'seriousness' and subsequently the level of review to be

undertaken. SAIs which meet the criteria in 4.2 above will be reviewed by the reporting organisation using one or more of the following:

5.1 Level 1 Review – Significant Event Audit (SEA)

Most SAI notifications will enter the review process at this level and a SEA will immediately be undertaken to:

- assess what has happened;
- assess why did it happened;
  - what went wrong and what went well;
- assess what has been changed or agree what will change;
- identify local and regional learning.

(refer to Appendix 5 – Guidance Notes for Level 1 – SEA & Learning Summary Report; Appendix 9 – Guidance on Incident Debrief); and Appendix 10 – Level 1 Review - Guidance on review team membership)

The possible outcomes from the review may include:

- closed – no new learning;
- closed – with learning;
- requires Level 2 or 3 review.

A SEA report will be completed **which should be retained by the reporting organisation** (see Appendices 4 and 5).

The reporting organisation will then complete a **SEA Learning Summary Report** (see Appendices 4 and 5 – Sections 1, 3-6), which should be signed off by the relevant professional or operational director and submitted to the HSCB within **8 weeks** of the SAI being notified.

The HSCB will not routinely receive SEA reports unless specifically requested by the DRO. This process assigns reporting organisations the responsibility for Quality Assuring Level 1 SEA Reviews. This will entail engaging directly with relevant staff within their organisation to ensure the robustness of the report and identification of learning prior to submission to the HSCB.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, the review will move to either a Level 2 or 3 RCA review. In this instance the SEA Learning Report Summary will be forwarded to the HSCB within the timescales outlined above, with additional sections being completed to outline membership and Terms of Reference of the team completing the Level 2 or 3 RCA review and proposed timescales.

5.2 Level 2 – Root Cause Analysis (RCA)

As stated above, some SAIs will enter at Level 2 review following a SEA.

When a Level 2 or 3 review is instigated immediately following notification of a SAI, the reporting organisation will inform the HSCB within 4 weeks, of the Terms of Reference (TOR) and Membership of the Review Team for

consideration by the HSCB/PHA DRO. This will be achieved by submitting sections two and three of the review report to the HSCB. (Refer to Appendix 6 – template for Level 2 and 3 review reports).

The review must be conducted to a high level of detail (see Appendix 7 – template for Level 2 and 3 review reports). The review should include use of appropriate analytical tools and will normally be conducted by a multidisciplinary team (not directly involved in the incident), and chaired by someone independent to the incident but who can be within the same organisation. (Refer to Appendix 9 – Guidance on Incident Debrief); and Appendix 11 – Level 2 Review - Guidance on review team membership).

Level 2 RCA reviews may involve two or more organisations. In these instances, it is important a lead organisation is identified but also that all organisations contribute to, and approve the final review report (Refer to Appendix 13 Guidance on joint reviews/investigations).

On completion of Level 2 reviews, the final report must be submitted to the HSCB within 12 weeks from the date the incident was notified.

5.3 Level 3 – Independent Reviews

Level 3 reviews will be considered for SAIs that:

- are particularly complex involving multiple organisations;
- have a degree of technical complexity that requires independent expert advice;
- are very high profile and attracting a high level of both public and media attention.

In some instances the whole team may be independent to the organisation/s where the incident/s has occurred.

The timescales for reporting Chair and Membership of the review team will be agreed by the HSCB/PHA Designated Review Officer (DRO) at the outset (see Appendix 9 – Guidance on Incident Debrief); and Appendix 12 – Level 3 Review - Guidance on Review Team Membership).

The format for Level 3 review reports will be the same as for Level 2 reviews (see Appendix 7 – guidance notes on template for Level 2 and 3 reviews).

For any SAI which involves an alleged homicide by a service user who has a mental illness or disorder *(as defined within the Mental Health (NI) Order 1986)* and/or known to/referred to mental health and related services (*including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident, the Protocol for Responding to SAIs in the Event of a Homicide, issued in 2012 and revised in 2013 should be followed (see Appendix 14).

5.4 Involvement of Service Users/Family/Carers in Reviews

- Following a SAI it is important, in the spirit of honesty and openness to ensure a consistent approach is afforded to the level of service user / family engagement across the region. When engaging with Service Users/Family/Carers, organisations should refer to addendum 1 – *A Guide for Health and Social Care Staff Engagement/Communication with Service User/Family/Cares following a SAI.*

- In addition a 'Checklist for Engagement/Communication with the Service User/Family/Carers following a SAI' must be completed for each SAI regardless of the review level, and where relevant, if the SAI was also a Never Event (refer to section 12.2).

- The checklist also includes a section to indicate if the reporting organisation had a statutory requirement to report the death to the Coroners office and that this is also communicated to the Family/Carer.

6.0 TIMESCALES

6.1 Notification

Any adverse incident that meets the criteria indicated in section 4.2 should be reported within **72 hours** of the incident being discovered using the SAI Notification Form (see Appendix 1).

6.2 Review Reports

LEVEL 1 – SEA

SEA reports must be completed using the SEA template which will be retained by the reporting organisation (see Appendices 4 and 5). A SEA Learning Summary Report (see Appendices 4 and 5 – Sections 1, 3-6) must be completed and submitted to the HSCB within **8 weeks** of the SAI being reported for all Level 1 SAIs whether learning has been identified or not. The Checklist for Engagement/Communication with Service User/Family/Carer following a SAI' must also accompany the Learning Summary Report.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review, timescales for completion of the RCA will be indicated by Trusts via the Learning Summary Report to the HSCB.

LEVEL 2 – RCA

For those SAIs where a full RCA is instigated immediately, sections 2 and 3 of the RCA Report, outlining TOR and membership of the review team, must be submitted **no later** than **within 4 weeks** of the SAI being notified to the HSCB.

RCA review reports must be fully completed using the RCA report template and submitted together with comprehensive action plans for each recommendation identified to the HSCB **12 weeks** following the date the incident was notified. (see Appendix 6 – Level 2 & 3 RCA Review Reports and Appendix 8 – Guidance on Minimum Standards for Action Plans).

LEVEL 3 – INDEPENDENT REVIEWS

Timescales for completion of Level 3 reviews and comprehensive action plans for each recommendation identified will be agreed between the reporting organisation and the HSCB/PHA DRO as soon as it is determined that the SAI requires a Level 3 review.

Note: Checklist for Engagement/Communication with Service User/Family/Carer following a SAI must accompany all SAI Review/Learning Summary Reports which are included within the report templates.

6.3 Exceptions to Timescales

In most circumstances, all timescales for submission of reports **must be** adhered to. However, it is acknowledged, by exception, there may be occasions where a review is particularly complex, perhaps involving two or more organisations or where other external organisations such as PSNI, HSENI etc.; are involved in the same review. In these instances the reporting organisation must provide the HSCB with regular updates.

6.4 Responding to additional information requests

Once the review / learning summary report has been received, the DRO, with appropriate clinical or other support, will review the report to ensure that the necessary documentation relevant to the level of review is adequate.

If the DRO is not satisfied with the information provided additional information may be requested and must be provided in a timely manner. Requests for additional information should be provided as follows:

- Level 1 review within **2 week**
- Level 2 or 3 review within **6 weeks**

7.0 OTHER INVESTIGATIVE/REVIEW PROCESSES

The reporting of SAIs to the HSCB will work in conjunction with all other HSC investigation/review processes, statutory agencies and external bodies. In that regard, all existing reporting arrangements, where there are statutory or mandatory reporting obligations, will continue to operate in tandem with this procedure.

In that regard, there may be occasions when a reporting organisation will have reported an incident via another process before or after it has been reported as a SAI.

7.1 Complaints in the HSC

Complaints in HSC Standards and Guidelines for Resolution and Learning (The Guidance) outlines how HSC organisations should deal with complaints raised by persons who use/have used, or are waiting to use HSC services. While it is a separate process to the management and follow-up of SAIs, there will be occasions when an SAI has been reported by a HSC organisation, and subsequently a complaint is received relating to the same incident or issues, or alternatively, a complaint may generate the reporting of an SAI.

In these instances, the relevant HSC organisation must be clear as to how the issues of complaint will be investigated. For example, there may be elements of the complaint that will be solely reliant on the outcome of the SAI review and there may be aspects of the complaint which will not be part of the SAI review and can only be investigated under the Complaints Procedure.

It is therefore important that complaints handling staff and staff who deal with SAIs communicate effectively and regularly when a complaint is linked to a SAI review. This will ensure that all aspects of the complaint are responded to effectively, via the most appropriate means and in a timely manner. Fundamental to this, will obviously be the need for the organisation investigating the complaint to communicate effectively with the complainant in respect of how their complaint will be investigated, and when and how they can expect to receive a response from the HSC organisation.

7.2 HSCB Social Care Untoward Events Procedure

The above procedure provides guidance on the reporting of incidents relating to statutory functions under the Children (NI) Order 1995.

If, during the review of an incident reported under the HSCB Untoward Events procedure, it becomes apparent the incident meets the criteria of a SAI, the incident should immediately be notified to the HSCB as a SAI. Board officers within the HSCB will close the Untoward Events incident and the incident will continue to be managed via the SAI process.

7.3 Child and Adult Safeguarding

Any incident involving the suspicion or allegation that a child or adult is at risk of abuse, exploitation or neglect should be investigated under the procedures set down in relation to a child and adult protection.

If during the review of one of these incidents it becomes apparent that the incident meets the criteria for an SAI, the incident will immediately be notified to the HSCB as an SAI.

It should be noted that, where possible, safeguarding investigations will run in parallel as separate to the SAI process with the relevant findings from these investigations/reviews informing the SAI review (see appendix 17).

On occasion the incident under review may be considered so serious as to meet the criteria for a Case Management Review (CMR) for children, set by the Safeguarding Board for Northern Ireland; a Serious Case Review (SCR) for adults set by the Northern Ireland Adult Safeguarding Partnership; or a Domestic Homicide Review.

In these circumstances, the incident will be notified to the HSCB as an SAI. This notification will indicate that a CMR, SCR or Domestic Homicide Review is underway. This information will be recorded on the Datix system, and the SAI will be closed.

7.4 Reporting of Falls

Reporting organisations will no longer be required to routinely report falls as SAIs which have resulted in harm in all Trust facilities, (as defined in the impact levels 3 – 5 of the regional risk matrix - see appendix 16). Instead a new process has been developed with phased implementation, which requires HSC Trusts to do a timely post fall review debrief to ensure local application of learning. See links below to Shared Learning Form and Minimum Data Set for Post Falls Review:

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/033%20Falls_Shared%20Learning%20Template_%20V2_June%202016.rtf

http://intranet.hscb.hscni.net/documents/Governance/Information%20for%20DROs/032%20Regional%20Falls%20Minimum%20Dataset%202016_V2_June%202016.pdf

Local learning will be shared with the Regional Falls Group where trends and themes will be identified to ensure regional learning.

Reporting organisations will therefore manage falls resulting in moderate to severe harm as adverse incidents, unless there are particular issues or the subsequent internal review identifies contributory issues/concerns in treatment and/or care or service issues, or any identified learning that needs to be reviewed through the serious adverse incident process.

7.5 Transferring SAIs to other Investigatory Processes

Following notification and initial review of a SAI, more information may emerge that determines the need for a specialist investigation.

This type of investigation includes:

- Case Management Reviews
- Serious Case Reviews

Once a DRO has been informed a SAI has transferred to one of the above investigation s/he will close the SAI.

7.6 De-escalating a SAI

It is recognised that organisations report SAIs based on limited information and the situation may change when more information has been gathered; which may result in the incident no longer meeting the SAI criteria.

Where a reporting organisation has determined the incident reported no longer meets the criteria of a SAI, a request to de-escalate the SAI should be submitted immediately to the HSCB by completing section 21 of the SAI notification form (Additional Information following initial Notification).

The DRO will review the request to de-escalate and will inform the reporting organisation and RQIA (where relevant) of the decision as soon as possible and at least within **10 working days** from the request was submitted.

If the DRO agrees, the SAI will be de-escalated and no further SAI review will be required. The reporting organisation may however continue to review as an adverse incident or in line with other HSC investigation/review processes (as highlighted above). If the DRO makes a decision that the SAI should not be de-escalated the review report should be submitted in line with previous timescales.

It is important to protect the integrity of the SAI review process from situations where there is the probability of disciplinary action, or criminal charges. The SAI review team must be aware of the clear distinction between the aims and boundaries of SAI reviews, which are solely for the identification and reporting learning points, compared with disciplinary, regulatory or criminal processes.

HSC organisations have a duty to secure the safety and well-being of patients/service users, the review to determine root causes and learning points should still be progressed **in parallel** with other reviews/investigations, ensuring remedial actions are put in place as necessary and to reduce the likelihood of recurrence.

8.0 LEARNING FROM SAIs

The key aim of this procedure is to improve services and reduce the risk of incident recurrence, both within the reporting organisation and across the HSC as a whole. The dissemination of learning following a SAI is therefore core to achieving this and to ensure shared lessons are embedded in practice and the safety and quality of care provided.

HSCB in conjunction with the PHA will:

- ensure that themes and learning from SAIs are identified and disseminated for implementation in a timely manner; this may be done via:
  - learning letters / reminder of best practice letters;
  - learning newsletter;
  - thematic reviews.

- provide an assurance mechanism that learning from SAIs has been disseminated and appropriate action taken by all relevant organisations;

- review and consider learning from external/independent reports relating to quality/safety.

It is acknowledged HSC organisations will already have in place mechanisms for cascading local learning from adverse incidents and SAIs internally within their own organisations. The management of dissemination and associated assurance of any regional learning is the responsibility of the HSCB/PHA.

9.0 TRAINING AND SUPPORT

9.1 Training

Training will be provided to ensure that those involved in SAI reviews have the correct knowledge and skills to carry out their role, i.e:

- Chair and/or member of an SAI review team
- HSCB/PHA DRO.

This will be achieved through an educational process in collaboration with all organisations involved, and will include training on review processes, policy distribution and communication updates.

9.2 Support

9.2.1 Laypersons

The panel of lay persons, (already involved in the HSC Complaints Procedure), have availed of relevant SAI training including Root Cause Analysis. They are now available to be called upon to be a member of a SAI review team; particularly when a degree of independence to the team is required.

Profiles and relevant contact details for all available laypersons can be obtained by contacting seriousincidents@hscni.net

9.2.2 Clinical/Professional Advice

If a DRO requires a particular clinical view on the SAI review, the HSCB Governance Team will secure that input, under the direction of the DRO.

10.0 INFORMATION GOVERNANCE

The SAI process deals with a considerable amount of sensitive personal information. Appropriate measures must be put in place to ensure the safe and secure transfer of this information. All reporting organisations should adhere to their own Information Governance Policies and Procedures. However, as a minimum the HSCB would recommend the following measures be adopted when

transferring patient/client identifiable information via e-mail or by standard hard copy mail:

- E-Mail - At present there is not a requirement to apply encryption to sensitive information transferred across the HSC network to other HSC organisations within Northern Ireland. Information transferred between the HSCB, Trusts and Northern Ireland Department of Health is not sent across the internet. If you are transferring information to any address that does not end in one of those listed below, it is essential that electronic measures to secure the data in transit, are employed, and it is advised that encryption is therefore applied at all times to transfers of sensitive / personal information.

  List of email addresses **within the Northern Ireland secure network:**
  '.hscni.net',
  'n-i.nhs.uk'
  'ni.gov.uk' or
  '.ni.gov.net'

  No sensitive or patient/service user data must be emailed to an address other than those listed above unless they have been protected by encryption mechanisms that have been approved by the BSO-ITS.

  Further advice on employing encryption software can be sought from the BSO ICT Security Team.

  Note: Although there is a degree of protection afforded to email traffic that contains sensitive information when transmitting within the Northern Ireland HSC network it is important that the information is sent to the correct recipient. With the amalgamation of many email systems, the chances of a name being the same or similar to the intended recipient has increased. It is therefore recommended that the following simple mechanism is employed when transmitting information to a new contact or to an officer you haven't emailed previously.

  Step 1 Contact the recipient and ask for their email address.
  Step 2 Send a test email to the address provided to ensure that you have inserted the correct email address.
  Step 3 Ask the recipient on receiving the test email to reply confirming receipt.
  Step 4 Attach the information to be sent with a subject line 'Private and Confidential, Addressee Only' to the confirmation receipt email and send.

- Standard Mail – It is recommended that any mail which is deemed valuable, confidential or sensitive in nature (such as patient/service user level information) should be sent using 'Special Delivery' Mail.

Further guidance is available from the HSCB Information Governance Team on: Tel [redacted] Irrelevant information redacted by the USI

11.0 ROLE OF DESIGNATED REVIEW OFFICER (DRO)

A DRO is a senior professional/officer within the HSCB / PHA and has a key role in the implementation of the SAI process namely:

- liaising with reporting organisations:
  - on any immediate action to be taken following notification of a SAI
  - where a DRO believes the SAI review is not being undertaken at the appropriate level

- agreeing the Terms of Reference for Level 2 and 3 RCA reviews;

- reviewing completed SEA Learning Summary Reports for Level 1 SEA Reviews and full RCA reports for level 2 and 3 RCA Reviews; liaising with other professionals (where relevant);

- liaising with reporting organisations where there may be concerns regarding the robustness of the level 2 and 3 RCA reviews and providing assurance that an associated action plan has been developed and implemented;

- identification of regional learning, where relevant;

- surveillance of SAIs to identify patterns/clusters/trends.

Whilst the HSCB will not routinely receive Level 1 SEA reports these can be requested, on occasion, by a DRO.

An internal HSCB/PHA protocol provides further guidance for DROs regarding the nomination and role of a DRO.

12.0 PROCESS

12.1 Reporting Serious Adverse Incidents

Any adverse incident that meets the criteria of a SAI as indicated in section 4.2 should be reported within 72 hours of the incident being discovered using the SAI Notification Form (Appendix 1) and forwarded to seriousincidents@hscni.net

HSC Trusts to copy RQIA at seriousincidents@rqia.org.uk in line with notifications relevant to the functions, powers and duties of RQIA as detailed in section 3.6 of this procedure.

Any SAI reported by FPS or ICVS must be reported in line with 3.2 and 3.3 of this procedure.

Reporting managers must comply with the principles of confidentiality when reporting SAIs and must not refer to service users or staff by name or by any other identifiable information. A unique Incident Reference/Number should be utilised on all forms/reports and associated

correspondence submitted to the HSCB and this should NOT be the patients H &C Number or their initials. (See section 10 – Information Governance)

12.2 Never Events

Never Events are SAIs that are wholly preventable, as guidance or safety recommendations that provide strong systemic protective barriers are already available at a national level and should have been implemented by all health care providers.

Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.

It is important, in the spirit of honesty and openness, that when staff are engaging with Service Users, Families, Carers as part of the SAI process, that in addition to advising an individual of the SAI, they should also be told if the SAI is a Never Event. However it will be for HSC organisations to determine when to communicate this information to Service Users, Families, Carers.

All categories included in the current NHS Never Events list (see associated DoH link below) should now be identified to the HSCB when notifying a SAI.

A separate section within the SAI notification form is to be completed to specify if the SAI is listed on the Never Events list. The SAI will continue to be reviewed in line with the current SAI procedure.

https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

12.3 Reporting Interface Incidents

In line with section 3.4 of this procedure, any organisation alerted to an incident which it feels has the potential to be a SAI should report the incident to the HSCB using the Interface Incident Notification form (Appendix 3) to seriousincidents@hscni.net.

An organisation who has been contacted by the HSCB Governance Team re: an interface incident being reported; will consider the incident in line with section 4.2 of the procedure, and if deemed it meets the criteria of a SAI, will report to the HSCB in line with 12.1 of this procedure.

12.4 Acknowledging SAI Notification

On receipt of the SAI notification the HSCB Governance Team will record the SAI on the DATIX risk management system and electronically acknowledge receipt of SAI notification to reporting organisation; advising

of the HSCB/PHA DRO, HSCB unique identification number, and requesting the completion of:

- SEA Learning Summary Report for Level 1 SAIs within 8 weeks from the date the incident is reported;
- RCA Report for Level 2 SAIs within 12 weeks from the date the incident is reported;
- RCA Report for Level 3 SAIs within the timescale as agreed at the outset by the DRO;

Where relevant, RQIA will be copied into this receipt.

12.5 Designated Review Officer (DRO)

Following receipt of a SAI the Governance Team will circulate the SAI Notification Form to the relevant Lead Officers within the HSCB/PHA to assign a DRO.

Once assigned the DRO will consider the SAI notification and if necessary, will contact the reporting organisation to confirm all immediate actions following the incident have been implemented.

12.6 Review/Learning Summary Reports

Note: Appendices 5 and 7 provide guidance notes to assist in the completion of Level 1, 2 & 3 review reports.

Timescales for submission of review/learning summary reports and associated engagement checklists will be in line with section 6.0 of this procedure.

On receipt of a review/learning summary report, the Governance Team will forward to the relevant DRO and where relevant RQIA.

The DRO will consider the adequacy of the review/learning summary report and liaise with relevant professionals/officers including RQIA (*where relevant*) to ensure that the reporting organisation has taken reasonable action to reduce the risk of recurrence and determine if the SAI can be closed. The DRO will also consider the referral of any learning identified for regional dissemination. In some instances the DRO may require further clarification and may also request sight of the full SEA review report.

If the DRO is not satisfied that a report reflects a robust and timely review s/he will continue to liaise with the reporting organisation and/or other professionals /officers, including RQIA (*where relevant*) until a satisfactory response is received. When the DRO has received all relevant and necessary information the timescale for closure of the SAI will be within 12 weeks, unless in exceptional circumstances which will have been agreed between the Reporting Organisation and the DRO.

12.7 Closure of SAI

Following agreement to close a SAI, the Governance Team will submit an email to the reporting organisation to advise the SAI has been closed, copied to RQIA (where relevant). The email will also indicate, if further information is made available to the reporting organisation (for example, Coroners Reports), which impacts on the outcome of the initial review, that it should be communicated to the HSCB/PHA DRO via the serious incidents mailbox.

This will indicate that based on the review / learning summary report received and any other information provided that the DRO is satisfied to close the SAI. It will acknowledge that any recommendations and further actions required will be monitored through the reporting organisation's internal governance arrangements in order to reassure the public that lessons learned, where appropriate have been embedded in practice.

On occasion and in particular when dealing with level 2 and 3 SAIs, a DRO may close a SAI but request the reporting organisation provides an additional assurance mechanism by advising within a stipulated period of time, that action following a SAI has been implemented. In these instances, monitoring will be followed up via the Governance team.

12.8 Regional Learning from SAIs

It is acknowledged HSC organisations will already have in place mechanisms for cascading local learning from adverse incidents and SAIs internally within their own organisations. However, the management of regional learning and associated assurance is the responsibility of the HSCB/PHA.

Therefore, where regional learning is identified following the review of an SAI, the DRO will refer this for consideration via HSCB/PHA Quality and Safety Structures and where relevant, will be disseminated as outlined in section 8.0.

12.9 Communication

All communication between HSCB/PHA and reporting organisation must be conveyed between the HSCB Governance department and Governance departments in respective reporting organisations. This will ensure all communication both written and verbal relating to the SAI, is recorded on the HSCB DATIX risk management system.

13 EQUALITY

This procedure has been screened for equality implications as required by Section 75 and Schedule 9 of the Northern Ireland Act 1998. Equality Commission guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be devoted to these.

Using the Equality Commission's screening criteria, no significant equality implications have been identified. The procedure will therefore not be subject to equality impact assessment.

Similarly, this procedure has been considered under the terms of the Human Rights Act 1998 and was deemed compatible with the European Convention Rights contained in the Act.

SECTION TWO APPENDICES

APPENDIX 1

Revised November 2016 (Version 1.1)

1. ORGANISATION:	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)*	**4.** DATE OF INCIDENT: DD / MM / YYYY
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*	
6. CONTACT PERSON:	**7.** PROGRAMME OF CARE: *(refer to Guidance Notes)*

8. DESCRIPTION OF INCIDENT:

DOB: DD / MM / YYYY *(complete where relevant)* GENDER: M / F AGE: years

9. IS THIS INCIDENT A NEVER EVENT?				If 'YES' *provide further detail on which never event - refer to DoH link below* https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars
YES		NO		

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING

STAGE OF CARE: *(refer to Guidance Notes)*	DETAIL: *(refer to Guidance Notes)*	ADVERSE EVENT: *(refer to Guidance Notes)*

10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:

11. CURRENT CONDITION OF SERVICE USER: *(complete where relevant)*

12. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	YES	NO	N/A
13. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED? *(please specify where relevant)*	YES	NO	N/A

14. WHY IS THIS INCIDENT CONSIDERED SERIOUS?: *(please select relevant criteria below)*

serious injury to, or the unexpected/unexplained death of: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	
unexpected serious risk to a service user and/or staff member and/or member of the public	
unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults)* - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the	

SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

incident	
suspected suicide of a service user who has a mental illness or disorder *(as defined within the Mental Health (NI) Order 1986)* and/or known to/referred to mental health and related services (*including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident	
serious incidents of public interest or concern relating to: - any of the criteria above - theft, fraud, information breaches or data losses - a member of HSC staff or independent practitioner	

15. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED: *(please select)*	YES	NO
if 'YES' (*full details should be submitted*):		

16. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING REVIEWED AS A SAI?	YES	DATE INFORMED: DD/MM/YY
	NO	*specify reason:*

17. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*	YES	NO
if 'YES' (*full details should be submitted including the date notified*):		

18. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DoH EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND (HSENI)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		

19. LEVEL OF REVIEW REQUIRED: *(please select)*	LEVEL 1	LEVEL 2*	LEVEL 3*

* FOR ALL LEVEL 2 OR LEVEL 3 REVIEWS PLEASE COMPLETE AND SUBMIT SECTIONS 2 AND 3 OF THE RCA REPORT TEMPLATE WITHIN 4 WEEKS OF THIS NOTIFICATION REFER APPENDIX 6

20. I confirm that the designated Senior Manager and/or Chief Executive has/have been advised of this SAI and is/are content that it should be reported to the Health and Social Care Board / Public Health Agency and Regulation and Quality Improvement Authority. (*delete as appropriate*)

Report submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION: *(refer to Guidance Notes)*

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

Completed proforma should be sent to: seriousincidents@hscni.net
and (*where relevant*) seriousincidents@rqia.org.uk

APPENDIX 2

Revised November 2016 (Version 1.1)

Guidance Notes
SERIOUS ADVERSE INCIDENT NOTIFICATION FORM

The following guidance designed to help you to complete the Serious Adverse Incident Report Form effectively and to minimise the need for the HSCB to seek additional information about the circumstances surrounding the SAI. This guidance should be considered each time a report is submitted.

1. ORGANISATION: *Insert the details of the reporting organisation (HSC Organisation /Trust or Family Practitioner Service)*	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE *Insert the unique incident number / reference generated by the reporting organisation.*
3. HOSPITAL / FACILTY / COMMUNITY LOCATION *(where incident occurred)* *Insert the details of the hospital/facility/specialty/department/ directorate/place where the incident occurred*	**4.** DATE OF INCIDENT: DD / MM / YYYY *Insert the date incident occurred*
5. DEPARTMENT / WARD / LOCATION EXACT *(where incident occurred)*	
6. CONTACT PERSON: *Insert the name of lead officer to be contacted should the HSCB or PHA need to seek further information about the incident*	**7.** PROGRAMME OF CARE: *Insert the Programme of Care from the following: Acute Services/ Maternity and Child Health / Family and Childcare / Elderly Services / Mental Health / Learning Disability / Physical Disability and Sensory Impairment / Primary Health and Adult Community (includes GP's) / Corporate Business(Other)*

8. DESCRIPTION OF INCIDENT:

*Provide a **brief factual description** of what has happened and a summary of the events leading up to the incident. **PLEASE ENSURE SUFFICIENT INFORMATION IS PROVIDED SO THAT THE HSCB/ PHA ARE ABLE TO COME TO AN OPINION ON THE IMMEDIATE ACTIONS, IF ANY, THAT THEY MUST TAKE.** Where relevant include D.O.B, Gender and Age. **All reports should be anonymised** – the names of any practitioners or staff involved must **not** be included. Staff should only be referred to by job title.*

In addition include the following:

***Secondary Care** – recent service history; contributory factors to the incident; last point of contact (ward / specialty); early analysis of outcome.*

***Children** – when reporting a child death indicate if the Regional Safeguarding Board has been advised.*

***Mental Health** - when reporting a serious injury to, or the unexpected/unexplained death (including suspected suicide, attempted suicide in an in-patient setting or serious self-harm of a service user who has been known to Mental Health, Learning Disability or Child and Adolescent Mental Health within the last year) include the following details: the most recent HSC service context; the last point of contact with HSC services or their discharge into the community arrangements;*
whether there was a history of DNAs, where applicable the details of how the death occurred, if known.

***Infection Control** - when reporting an outbreak which severely impacts on the ability to provide services, include the following: measures to cohort Service Users; IPC arrangements among all staff and visitors in contact with the infection source; Deep cleaning arrangements and restricted visiting/admissions.*

***Information Governance** –when reporting include the following details whether theft, loss, inappropriate disclosure, procedural failure etc.; the number of data subjects (service users/staff)involved, the number of records involved, the media of records (paper/electronic),whether encrypted or not and the type of record or data involved and sensitivity.*

DOB: DD / MM / YYYY GENDER: M / F AGE: years
(complete where relevant)

9. IS THIS INCIDENT A NEVER EVENT? Yes/No *(please select)*	If 'YES' *provide further detail on which never event - refer to DoH link below* https://www.health-ni.gov.uk/topics/safety-and-quality-standards/safety-and-quality-standards-circulars

DATIX COMMON CLASSIFICATION SYSTEM (CCS) CODING		
STAGE OF CARE: *(refer to Guidance Notes)* *Insert CCS Stage of Care Code description*	DETAIL: *(refer to Guidance Notes)* *Insert CCS Detail Code description*	ADVERSE EVENT: *(refer to Guidance Notes)* *Insert CCS Adverse Event Code description*

10. IMMEDIATE ACTION TAKEN TO PREVENT RECURRENCE:
Include a summary of what actions, if any, have been taken to address the immediate repercussions of the incident and the actions taken to prevent a recurrence.

11. CURRENT CONDITION OF SERVICE USER: *(complete where relevant)*
***Where relevant** please provide details on the current condition of the service user the incident relates to.*

12. HAS ANY MEMBER OF STAFF BEEN SUSPENDED FROM DUTIES? *(please select)*	YES	NO	N/A
13. HAVE ALL RECORDS / MEDICAL DEVICES / EQUIPMENT BEEN SECURED *(please select and specify **where relevant**)*	YES	NO	N/A

14. WHY INCIDENT CONSIDERED SERIOUS: *(please select relevant criteria from below)*

serious injury to, or the unexpected/unexplained death of: - a service user (including a Looked After Child or a child whose name is on the Child Protection Register and those events which should be reviewed through a significant event audit) - a staff member in the course of their work - a member of the public whilst visiting a HSC facility.	
unexpected serious risk to a service user and/or staff member and/or member of the public	
unexpected or significant threat to provide service and/or maintain business continuity	
serious self-harm or serious assault *(including attempted suicide, homicide and sexual assaults)* by a service user, a member of staff or a member of the public within any healthcare facility providing a commissioned service	
serious self-harm or serious assault *(including homicide and sexual assaults*) - on other service users, - on staff or - on members of the public by a service user in the community who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident	
suspected suicide of a service user who has a mental illness or disorder *(as defined within the Mental Health (NI) Order 1986)* and/or known to/referred to mental health and related services (*including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident	
serious incidents of public interest or concern relating to: - any of the criteria above - theft, fraud, information breaches or data losses - a member of HSC staff or independent practitioner	

15. IS ANY IMMEDIATE REGIONAL ACTION RECOMMENDED: *(please select)*	YES	NO

if 'YES' *(full details should be submitted):*

16. HAS THE SERVICE USER / FAMILY BEEN ADVISED THE INCIDENT IS BEING REVIEWED AS A SAI? *(please select)*	YES	DATE INFORMED: DD/MM/YY *Insert the date informed*
	NO	*Specify reason:*

17. HAS ANY PROFESSIONAL OR REGULATORY BODY BEEN NOTIFIED? *(refer to guidance notes e.g. GMC, GDC, PSNI, NISCC, LMC, NMC, HCPC etc.) please specify where relevant*	YES	NO

if 'YES' (*full details should be submitted including the date notified*):

GENERAL MEDICAL COUNCIL **(GMC)**
GENERAL DENTAL COUNCIL **(GDC)**
PHARMACEUTICAL SOCIETY NORTHERN IRELAND **(PSNI)**
NORTHERN IRELAND SOCIAL CARE COUNCIL **(NISCC)**
LOCAL MEDICAL COMMITTEE **(LMC)**
NURSING AND MIDWIFERY COUNCIL **(NMC**)
HEALTH CARE PROFESSIONAL COUNCIL **(HCPC)**
REGULATION AND QUALITY IMPROVEMENT AUTHORTIY**(RQIA)**
SAFEGUARDING BOARD FOR NORTHERN IRELAND **(SBNI)**

OTHER – PLEASE SPECIFY BELOW

18. OTHER ORGANISATION/PERSONS INFORMED: *(please select)*	DATE INFORMED:	OTHERS: *(please specify where relevant, including date notified)*
DoH EARLY ALERT		
HM CORONER		
INFORMATION COMMISSIONER OFFICE (ICO)		
NORTHERN IRELAND ADVERSE INCIDENT CENTRE (NIAIC)		
HEALTH AND SAFETY EXECUTIVE NORTHERN IRELAND (HSENI)		
POLICE SERVICE FOR NORTHERN IRELAND (PSNI)		
REGULATION QUALITY IMPROVEMENT AUTHORITY (RQIA)		
SAFEGUARDING BOARD FOR NORTHERN IRELAND (SBNI)		
NORTHERN IRELAND ADULT SAFEGUARDING PARTNERSHIP (NIASP)		

19. LEVEL OF REVIEW REQUIRED: *(please select)*	LEVEL 1	LEVEL 2*	LEVEL 3*

* FOR ALL LEVEL 2 OR LEVEL 3 REVIEWS PLEASE COMPLETE AND SUBMIT SECTIONS 2 AND 3 OF THE RCA REPORT TEMPLATE WITHIN 4 WEEKS OF THIS NOTIFICATION REFER APPENDIX 6

20. I confirm that the designated Senior Manager and/or Chief Executive has/have been advised of this SAI and is/are content that it should be reported to the Health and Social Care Board / Public Health Agency and Regulation and Quality Improvement Authority. (*delete as appropriate*)

Report submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

21. ADDITIONAL INFORMATION FOLLOWING INITIAL NOTIFICATION:

Use this section to provide updated information when the situation changes e.g. the situation deteriorates; the level of media interest changes

The HSCB and PHA recognises that organisations report SAIs based on limited information, which on further review may not meet the criteria of a SAI. Use this section to rrequest that a SAI be de-escalated and send to seriousincidents@hscni.net with the unique incident identification number/reference in the subject line. When a request for de-escalation is made the reporting organisation must include information on why the incident does not warrant further review under the SAI process.

The HSCB/PHA DRO will review the de-escalation request and inform the reporting organisation of its decision within 5 working days. The HSCB / PHA may take the decision to close the SAI without a report rather than de-escalate it. The HSCB / PHA may decide that the SAI should not be de-escalated and a full review report is required.

PLEASE NOTE PROGRESS IN RELATION TO TIMELINESS OF COMPLETED REVIEW REPORTS WILL BE REGULARLY REPORTED TO THE HSCB/PHA REGIONALGROUP. THEY WILL BE MONITORED ACCORDING TO AGREED TIMESCALES. IT IS IMPORTANT TO KEEP THE HSCB INFORMED OF PROGRESS TO ENSURE THAT MONITORING INFORMATION IS ACCURATE AND BREECHES ARE NOT REPORTED WHERE AN EXTENDED TIME SCALE HAS BEEN AGREED.

Additional information submitted by: _____ Designation: _____

Email: Telephone: Date: DD / MM / YYYY

Completed proforma should be sent to: seriousincidents@hscni.net
and (*where relevant*) seriousincidents@rqia.org.uk

APPENDIX 3
Revised November 2016 (Version 1.1)

HSC INTERFACE INCIDENT NOTIFICATION FORM

1. REPORTING ORGANISATION:	**2. DATE OF INCIDENT: DD / MM / YYYY**
3. CONTACT PERSON AND TEL NO:	**4. UNIQUE REFERENCE NUMBER:**

5. DESCRIPTION OF INCIDENT:

DOB: DD / MM / YYYY **GENDER: M / F** **AGE: years**
(complete where relevant)

6. ARE OTHER PROVIDERS INVOLVED? (e.g. *HSC TRUSTS / FPS / OOH / ISP / VOLUNTARY / COMMUNITY ORG'S*)	**YES**	**NO**
	if 'YES' (*full details should be submitted in section 7 below*)	

7. PROVIDE DETAIL ON ISSUES/AREAS OF CONCERN:

8. <u>IMMEDIATE</u> ACTION TAKEN BY REPORTING ORGANISATION:

9. WHICH ORGANISATION/PROVIDER (*FROM THOSE LISTED IN SECTIONS 6 AND 7 ABOVE*) SHOULD TAKE THE LEAD RESPONSIBILITY FOR THE REVIEW AND FOLLOW UP OF THIS INCIDENT?

10. OTHER COMMENTS:

REPORT SUBMITTED BY: _____ **DESIGNATION:** _____

Email: **Telephone:** **Date: DD / MM / YYYY**

Completed proforma should be sent to: seriousincidents@hscni.net

APPENDIX 4

Revised November 2016 (Version 1.1)

LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING LEARNING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1

1. ORGANISATION:	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE:
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE:	4. DATE OF INCIDENT/EVENT: DD / MM / YYYY
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: YES / NO ***Please select as appropriate***	6. IF 'YES' TO 5. PLEASE PROVDE DETAILS:
7. DATE OF SEA MEETING / INCIDENT DEBRIEF: DD / MM / YYYY	
8. SUMMARY OF EVENT:	

SECTION 2	
9. SEA FACILITATOR / LEAD OFFICER:	10. TEAM MEMBERS PRESENT:
11. SERVICE USER DETAILS: ***Complete where applicable***	
12. WHAT HAPPENED?	
13. WHY DID IT HAPPEN?	

SECTION 3 - LEARNING SUMMARY
14. WHAT HAS BEEN LEARNED:
15. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE?
16. RECOMMENDATIONS (please state by whom and timescale)
17. INDICATE ANY PROPOSED TRANSFERRABLE REGIONAL LEARNING POINTS FOR CONSIDERATION BY HSCB/PHA:
18. FURTHER REVIEW REQUIRED? YES / NO Please select as appropriate If 'YES' complete SECTIONS 4, 5 and 6. If 'NO' complete SECTION 5 and 6.

SECTION 4 (COMPLETE THIS SECTION ONLY WHERE A FURTHER REVIEW IS REQUIRED)	
19. PLEASE INDICATE LEVEL OF REVIEW: LEVEL 2 / LEVEL 3 **Please select as appropriate**	20. PROPOSED TIMESCALE FOR COMPLETION: DD / MM / YYYY
21. REVIEW TEAM MEMBERSHIP *(If known or submit asap)*:	
22. TERMS OF REFERENCE *(If known or submit asap)*:	

SECTION 5	
APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR	
23. NAME:	24. DATE APPROVED:
25. DESIGANTION:	

SECTION 6
26. DISTRIBUTION LIST:

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		HSCB Ref Number:	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		
	Comment: ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**		
	If **YES**, insert **date informed**:				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	c) Report not shared but contents discussed **(*if you select this option please also complete 'l' below*)**	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2 **INFORMING THE CORONERS OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**	**NO**	**N/A**	**Not Known**
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 5

Revised November 2016 (Version 1.1)

GUIDANCE NOTES
LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1 (To be submitted to the HSCB)

1. ORGANISATION: *Insert unique identifier number*	2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE: *Self- explanatory*
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE: *Self- explanatory*	4. DATE OF INCIDENT/EVENT: DD / MM / YYYY *Self- explanatory*
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: YES / NO ***Please select as appropriate***	6. IF 'YES' TO 5. PLEASE PROVDE DETAILS: *Self- explanatory*
7. DATE OF SEA MEETING / INCIDENT DEBRIEF: DD / MM / YYYY *Self- explanatory*	
8. SUMMARY OF EVENT: ***As per notification form. (If the notification form does not fully reflect the incident please provide further detail.)***	

SECTION 2	
9. SEA FACILITATOR / LEAD OFFICER: *Refer to guidance on Level 1 review team membership for significant event analysis – Appendix 10*	10. TEAM MEMBERS PRESENT: *NAMES AND DESIGNATIONS*
11. SERVICE USER DETAILS: ***Complete where applicable*** *DOB / GENDER / AGE*	
12. WHAT HAPPENED? *(Describe in detailed chronological order what actually happened. Consider, for instance, how it happened, where it happened, who was involved and what the impact was on the patient/service user[1], the team, organisation and/or others).*	
13. WHY DID IT HAPPEN? *(Describe the main and underlying reasons contributing to why the event happened. Consider for instance, the professionalism of the team, the lack of a system or failing in a system, the lack of knowledge or the complexity and uncertainty associated with the event)*	

[1] *ensure sensitivity to the needs of the patient/ service user/ carer/ family member is in line with Regional Guidance on Engagement with Service Users, Families and Carers issued February 2015 (Revised November 2016)*

All sections below be submitted to the HSCB

SECTION 3 - LEARNING SUMMARY

14. WHAT HAS BEEN LEARNED: *(Based on the reason established as to why the event happened, outline the learning identified. Demonstrate that reflection and learning have taken place on an individual or team basis and that relevant team members have been involved in the analysis of the event. Consider, for instance: a lack of education and training; the need to follow systems or procedures; the vital importance of team working or effective communication)*

15. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE? *Based on the understanding of why the event happened and the identification of learning, outline the action(s) agreed and implemented, where this is relevant or feasible. Consider, for instance: if a protocol has been amended, updated or introduced; how was this done and who was involved; how will this change be monitored. It is also good practice to attach any documentary evidence of change e.g. a new procedure or protocol.*

NOTE: Action plans should also be developed and set out how learning will be implemented, with named leads responsible for each action point (Refer to Appendix 7 Minimum Standards for Action Plans).

Action plans for this level of review will be retained by the reporting organisation.

16. RECOMMENDATIONS (please state by whom and timescale) *It should be noted that it is the responsibility of the HSCB/PHA to consider and review all recommendations, of suggested /proposed learning relevant to other organisations, arising from the review of a SAI. In addition, it is the responsibility if the HSCB/PHA to subsequently identify any related learning to be communicated across the HSC and where relevant with other organisations regionally and/or nationally.*

It is the responsibility of the reporting organisation to communicate to service users, families and carer's that learning identified relevant to other organisations (arising from the review of a SAI) and submitted to the HSCB/PHA, to consider and review, may not on every occasion result in regional learning.

17. INDICATE ANY PROPOSED TRANSFERRABLE REGIONAL LEARNING POINTS FOR CONSIDERATION BY HSCB/PHA:

Self- explanatory

18. FURTHER REVIEW REQUIRED? YES / NO

Please select as appropriate

If 'YES' complete SECTIONS 4, 5 and 6. If 'NO' complete SECTION 5 and 6.

SECTION 4 (COMPLETE THIS SECTION ONLY WHERE A FURTHER REVIEW IS REQUIRED)

19. PLEASE INDICATE LEVEL OF REVIEW:
LEVEL 2 / LEVEL 3
Please select as appropriate

20. PROPOSED TIMESCALE FOR COMPLETION:
DD / MM / YYYY

21. REVIEW TEAM MEMBERSHIP(If known or submit ASAP):

Refer to section 2 of appendix 7.

22. TERMS OF REFERENCE(If known or submit ASAP):

Refer to section 3 of appendix 7.

SECTION 5 - (COMPLETE THIS SECTION FOR ALL LEVELS OF REVIEW)

APPROVAL BY RELEVANT PROFESSIONAL DIRECTOR AND/OR OPERATIONAL DIRECTOR

23. NAME: *Self- explanatory*

24. DATE APPROVED: *Self- explanatory*

25. DESIGANTION: *Self- explanatory*

SECTION 6

26. DISTRIBUTION LIST:

List of the individuals, groups or organisations the final report has been shared with.

APPENDIX 5

To be submitted to the HSCB

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1					
INFORMING THE SERVICE USER[1] / FAMILY / CARER					
1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		
	Comment: ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**		
	If **YES**, insert **date informed**:				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)***				
5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	a) Draft review report has been shared and further engagement planned to share final report	
	b) Plan to share final review report at a later date and further engagement planned	
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
			NO	

SECTION 2							
INFORMING THE CORONERS OFFICE **(under section 7 of the Coroners Act (Northern Ireland) 1959)** ***(complete this section for all death related SAIs)***							
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date report shared**:						
	If **NO**, please provide details:						
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 6

Revised November 2016 (Version 1.1)

Insert organisation Logo

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: (M/F) Age: (yrs)

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

1.0 EXECUTIVE SUMMARY

2.0 THE REVIEW TEAM

3.0 SAI REVIEW TERMS OF REFERENCE

4.0 REVIEW METHODOLOGY

5.0 DESCRIPTION OF INCIDENT/CASE

6.0 FINDINGS

7.0 CONCLUSIONS

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	
	Comment: ***If multiple service users are involved please indicate the number involved***			
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI			
	a) No contact or Next of Kin details or Unable to contact			
	b) Not applicable as this SAI is not 'patient/service user' related			
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user			
	d) Case involved suspected or actual abuse by family			
	e) Case identified as a result of review exercise			
	f) Case is environmental or infrastructure related with no harm to patient/service user			
	g) Other rationale			
	If you selected c), d), e), f) or g) above please provide further details:			
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**	
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY		
	NO	If **NO**, provide details:		
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**		
Content with rationale?	**YES**	**NO**

SECTION 2 **INFORMING THE CORONERS OFFICE** **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*								
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**					
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**					
	If **YES**, insert **date report shared**:							
	If **NO**, please provide details:							
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**	
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 7
Revised November 2016 (Version 1.1)

Health and Social Care Regional Guidance

for

Level 2 and 3 RCA Incident Review Reports

INTRODUCTION

This document is a revision of the template developed by the DoH Safety in Health and Social Care Steering Group in 2007 as part of the action plan contained within "*Safety First: A Framework for Sustainable Improvement in the HPSS.*"

The purpose of this template and guide is to provide practical help and support to those writing review reports and should be used, in as far as possible, for drafting all **HSC Level 2 and Level 3** incident review reports. It is intended as a guide in order to standardise all such reports across the HSC including both internal and external reports.

The review report presents the work of the review team and provides all the necessary information about the incident, the review process and outcome of the review. The purpose of the report is to provide a formal record of the review process and a means of sharing the learning. The report should be clear and logical, and demonstrate that an open and fair approach has taken place.

This guide should assist in ensuring the completeness and readability of such reports. The headings and report content should follow, as far as possible, the order that they appear within the template. Composition of reports to a standardised format will facilitate the collation and dissemination of any regional learning.

This template was designed primarily for incident reviews however it may also be used to examine complaints and claims.

Insert organisation Logo

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier:

Date of Incident/Event:

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: (M/F) Age: (yrs)

Responsible Lead Officer:

Designation:

Report Author:

Date report signed off:

1.0 EXECUTIVE SUMMARY

Summarise the main report: provide a brief overview of the incident and consequences, background information, level of review, concise analysis and main conclusions, lessons learned, recommendations and arrangements for sharing and learning lessons.

2.0 THE REVIEW TEAM

Refer to Guidance on Review Team Membership

The level of review undertaken will determine the degree of leadership, overview and strategic review required.

- *List names, designation and review team role of the members of the Review Team. The Review Team should be multidisciplinary and should have an Independent Chair.*
- *The degree of independence of the membership of the team needs careful consideration and depends on the severity / sensitivity of the incident and the level of review to be undertaken. However, best practice would indicate that review teams should incorporate at least one informed professional from another area of practice, best practice would also indicate that the chair of the team should be appointed from outside the area of practice.*
- *In the case of more high impact incidents (i.e. categorised as catastrophic or major) inclusion of lay / patient / service user or carer representation should be considered.*

3.0 SAI REVIEW TERMS OF REFERENCE

Describe the plan and scope for conducting the review. State the level of review, aims, objectives, outputs and who commissioned the review.

The following is a sample list of statements of purpose that may be included in the terms of reference:

- To undertake a review of the incident to identify specific problems or issues to be addressed;
- To consider any other relevant factors raised by the incident;
- To identify and engage appropriately with all relevant services or other agencies associated with the care of those involved in the incident;
- To determine actual or potential involvement of the Police, Health and Safety Executive, Regulation and Quality Improvement Authority and Coroners Service for Northern Ireland[2] [3]
- To agree the remit of the review - the scope and boundaries beyond which the review should not go (e.g. disciplinary process) – state how far back the review will go (what point does the review start and stop e.g. episode of care) and the level of review;
- To consider the outcome of the review, agreeing recommendations, actions to be taken and lessons learned for the improvement of future services;
- To ensure sensitivity to the needs of the patient/ service user/ carer/ family member, where appropriate. The level of involvement clearly depends on the nature of the incident and the service user's or family's wishes or carer's wishes to be involved and must be in line with Regional Guidance on Engagement with Service Users, Families and Carers issued November 2016;

[2] *Memorandum of understanding: Investigating patient or client safety incidents (Unexpected death or serious untoward harm)- http://www.dhsspsni.gov.uk/ph_mou_investigating_patient_or_client_safety_incidents.pdf*

[3] *Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults 2009*

3.0 SAI REVIEW TERMS OF REFERENCE

- To agree the timescales for completing and submitting the review report, including the SAI engagement checklist, distribution of the report and timescales for reviewing actions on the action plan;

Methodology to be used should be agreed at the outset and kept under regular review throughout the course of the SAI review.

Clear documentation should be made of the time-line for completion of the work.

This list is not exhaustive

4.0 REVIEW METHODOLOGY

This section should provide an outline of the type of review and the methods used to gather information within the review process. The NPSA's "Seven Steps to Patient Safety[4]" and "Root Cause Analysis Review Guidance[5]" provide useful guides for deciding on methodology.

- Review of patient/ service user records and compile a timeline (if relevant)
- Review of staff/witness statements (if available)
- Interviews with relevant staff concerned e.g.
  - Organisation-wide
  - Directorate Team
  - Ward/Team Managers and front line staff
  - Other staff involved
  - Other professionals (including Primary Care)
- Specific reports requested from and provided by staff
- Outline engagement with patients/service users / carers / family members / voluntary organisations/ private providers
- Review of local, regional and national policies and procedures, including professional codes of conduct in operation at the time of the incident
- Review of documentation e.g. consent form(s), risk assessments, care plan(s), photographs, diagrams or drawings, training records, service/maintenance records, including specific reports requested from and provided by staff etc.

This list is not exhaustive

5.0 DESCRIPTION OF INCIDENT/CASE

Provide an account of the incident including consequences and detail what makes this incident a SAI. The following can provide a useful focus but please note this section is not solely a chronology of events

- Concise factual description of the serious adverse incident include the incident date and

[4] http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787

[5] http://www.nrls.npsa.nhs.uk/resources/?entryid45=75355

5.0 DESCRIPTION OF INCIDENT/CASE

type, the healthcare specialty involved and the actual effect of the incident on the service user and/or service and others;

- People, equipment and circumstances involved;
- Any intervention / immediate action taken to reduce consequences;
- Chronology of events leading up to the incident;
- Relevant past history – a brief description of the care and/or treatment/service provided;
- Outcome / consequences / action taken;
- Relevance of local, regional or national policy / guidance / alerts including professional codes of conduct in place at the time of the incident

This list is not exhaustive

6.0 FINDINGS

This section should clearly outline how the information has been analysed so that it is clear how conclusions have been arrived at from the raw data, events and treatment/care/service provided. This section needs to clearly identify the care and service delivery problems and analysis to identify the causal factors.

Analysis can include the use of root cause and other analysis techniques such as fault tree analysis, etc. The section below is a useful guide particularly when root cause techniques are used. It is based on the NPSA's "Seven Steps to Patient Safety" and "Root Cause Analysis Toolkit".

(i) Care Delivery Problems (CDP) and/or Service Delivery Problems (SDP) Identified

CDP is a problem related to the direct provision of care, usually actions or omissions by staff (active failures) or absence of guidance to enable action to take place (latent failure) e.g. failure to monitor, observe or act; incorrect (with hindsight) decision, NOT seeking help when necessary.

SDP are acts and omissions identified during the analysis of incident not associated with direct care provision. They are generally associated with decisions, procedures and systems that are part of the whole process of service delivery e.g. failure to undertake risk assessment, equipment failure.

(ii) Contributory Factors

Record the influencing factors that have been identified as root causes or fundamental issues.

- Individual Factors (include employment status i.e. substantive, agency, locum voluntary etc.)
- Team and Social Factors
- Communication Factors
- Task Factors
- Education and Training Factors
- Equipment and Resource Factors
- Working Condition Factors
- Organisational and Management Factors
- Patient / Client Factors

This list is not exhaustive

As a framework for organising the contributory factors reviewed and recorded the table in the NPSA's "Seven Steps to Patient Safety" document (and associated Root Cause Analysis Toolkit) is useful. http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/

Where appropriate and where possible careful consideration should be made to facilitate the involvement of patients/service users / carers / family members within this process.

7.0 CONCLUSIONS

Following analysis identified above, list issues that need to be addressed. Include discussion of good practice identified as well as actions to be taken. Where appropriate include details of any on-going engagement / contact with family members or carers.

This section should summarise the key findings and should answer the questions posed in the terms of reference.

8.0 LESSONS LEARNED

Lessons learned from the incident and the review should be identified and addressed by the recommendations and relate to the findings. Indicate to whom learning should be communicated and this should be copied to the Committee with responsibility for governance.

9.0 RECOMMENDATIONS AND ACTION PLANNING

List the improvement strategies or recommendations for addressing the issues highlighted above (conclusions and lessons learned). Recommendations should be grouped into the following headings and cross-referenced to the relevant conclusions, and should be graded to take account of the strengths and weaknesses of the proposed improvement strategies/actions:

- Recommendations for the reviewing organisation
- Suggested /proposed learning that is relevant to other organisations

Action plans should be developed and should set out how each recommendation will be implemented, with named leads responsible for each action point (Refer to Appendix 8 Guidance on Minimum Standards for Action Plans). This section should clearly demonstrate the arrangements in place to successfully deliver the action plan.

It should be noted that it is the responsibility of the HSCB/PHA to consider and review all recommendations, of suggested /proposed learning relevant to other organisations, arising from the review of a SAI. In addition, it is the responsibility if the HSCB/PHA to subsequently identify any related learning to be communicated across the HSC and where relevant with other organisations regionally and/or nationally.

It is the responsibility of the reporting organisation to communicate to service users/families/carers that regional learning identified and submitted to the HSCB/PHA for consideration may not on every occasion result in regional learning.

10.0 DISTRIBUTION LIST

List the individuals, groups or organisations the final report has been shared with. This should have been agreed within the terms of reference.

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		
	Comment: ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**		
	If **YES**, insert **date informed**:				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**)					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**		
	If **YES**, insert date informed:				
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:				
	a) Draft review report has been shared and further engagement planned to share final report				
	b) Plan to share final review report at a later date and further engagement planned				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	c) Report not shared but contents discussed **(*if you select this option please also complete 'l' below*)**	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2 **INFORMING THE CORONERS OFFICE** **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

APPENDIX 8

GUIDANCE ON MINIMUM STANDARDS FOR ACTION PLANS

The action plan must define:

- Who has agreed the action plan
- Who will monitor the implementation of the action plan
- How often the action plan will be reviewed
- Who will sign off the action plan when all actions have been completed

The action plan **MUST** contain the following

1. Recommendations based on the contributing factors	The recommendations from the report - these should be the analysis and findings of the review
2. Action agreed	This should be the actions the organisation needs to take to resolve the contributory factors.
3. By who	Who in the organisation will ensure the action is completed
4. Action start date	Date particular action is to commence
5. Action end date	Target date for completion of action
6. Evidence of completion	Evidence available to demonstrate that action has been completed. This should include any intended action plan reviews or audits
7. Sign off	Responsible office and date sign off as completed

APPENDIX 9

GUIDANCE ON INCIDENT DEBRIEF

- ## Level 1 - SEA Reviews

For level 1 reviews, the incident debrief can serve the purpose of the SEA review, (these can also be known as 'hot debriefs').

The review should:

- Collect and collate as much factual information on the event as possible, including all relevant records. Also gather the accounts of those directly and indirectly involved, including, where relevant, service user/relatives/carers or other health professionals.

- The incident debrief/significant event meeting should be held with all staff involved to provide an opportunity to:

    - support the staff involved[6]
    - assess what has happened;
    - assess why did it happened;
        - what went wrong and what went well;
    - assess what has been changed or agree what will change;
    - identify local and regional learning.

- The meeting/s should be conducted in an open, fair, honest, non-judgemental and supportive atmosphere and should be undertaken as soon as practical following the incident.

- Write it up – keep a written report of the analysis undertaken using the SEA Report template (see Appendix 4)

- Sharing SEA Report – SEA reports should be shared with all relevant staff, particularly those who have been involved in the incident.

- ## Level 2 and 3 RCA Reviews

An incident debrief can also be undertaken for level 2 and 3 reviews. This would be separate from the RCA review and should occur quickly after the incident to provide support to staff and to identify any immediate service actions.

[6] *Note: link to ongoing work in relation to Quality 2020 - Task 2 - Supporting Staff involved in SAIs and other Incidents*

APPENDIX 10

LEVEL 1 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review of an incident should be proportionate to its significance; this is a judgement to be made by the Review Team.

Membership of the team should include all relevant professionals but should be appropriate and proportionate to the type of incident and professional groups involved. Ultimately, for a Level 1 review, it is for each team to decide who is invited, there has to be a balance between those who can contribute to an honest discussion, and creating such a large group that discussion of sensitive issues is inhibited.

The review team should appoint an experienced facilitator or lead reviewing officer from within the team to co-ordinate the review. The role of the facilitator is as follows:

- Co-ordinate the information gathering process
- Arrange the review meeting
- Explain the aims and process of the review
- Chair the review meeting
- Co-ordinate the production of the Significant Event Audit report
- Ensure learning is shared in line with the Learning Summary Report

APPENDIX 11

LEVEL 2 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review undertaken will determine the degree of leadership, overview and strategic review required. The level of review of an incident should therefore be proportionate to its significance. This is a judgement to be made by the Review Team.

The core review team should comprise a minimum of three people of appropriate seniority and objectivity. Review teams should be multidisciplinary, (or involve experts/expert opinion/independent advice or specialist reviewers). The team shall have no conflicts of interest in the incident concerned and should have an Independent Chair. (*In the event of a suspected homicide HSC Trusts should follow the HSCB Protocol for responding to SAIs in the event of a Homicide – revised 2013*)

The Chair of the team shall be independent of the service area where the incident occurred and should have relevant experience of the service area and/or chairing investigations/reviews. He/she shall not have been involved in the direct care or treatment of the individual, or be responsible for the service area under review. The Chair may be sourced from the HSCB Lay People Panel *(a panel of 'lay people' with clinical or social care professional areas of expertise in health and social care, who could act as the chair of an independent review panel, or a member of a Trust RCA review panel*).

Where multiple (*two or more*) HSC providers of care are involved, an increased level of independence shall be required. In such instances, the Chair shall be completely independent of the main organisations involved.

Where the service area is specialised, the Chair may have to be appointed from another HSC Trust or from outside NI.

Membership of the team should include all relevant professionals, but should be appropriate and proportionate to the type of incident and professional groups involved.

Membership shall include an experienced representative who shall support the review team in the application of the root cause analysis methodologies and techniques, human error and effective solutions based development.

Members of the team shall be separate from those who provide information to the review team.

It may be helpful to appoint a review officer from within the review team to co-ordinate the review.

APPENDIX 12

LEVEL 3 REVIEW - GUIDANCE ON REVIEW TEAM MEMBERSHIP

The level of review shall be proportionate to the significance of the incident. The same principles shall apply, as for Level 2 reviews. The degree of independence of the review team will be dependent on the scale, complexity and type of the incident.

Team membership for Level 3 reviews will be agreed between the reporting organisation and the HSCB/PHA DRO prior to the Level 3 review commencing.

APPENDIX 13

GUIDANCE ON JOINT REVIEWS/INVESTIGATIONS

Where a SAI involves multiple (*two or more*) HSC providers of care (e.g. a patient/service user affected by system failures both in an acute hospital and in primary care), a decision must be taken regarding who will lead the review and reporting. This may not necessarily be the initial reporting organisation.

The general rule is for the provider organisation with greatest contact with the patient/service user to lead the review and action. There may, however, be good reason to vary this arrangement e.g. where a patient/service user has died on another organisation's premises. The decision should be made jointly by the organisations concerned, if necessary referring to the HSCB Designated Review Officer for advice. **The lead organisation must be agreed by all organisations involved.**

It will be the responsibility of the lead organisation to engage all organisations in the review as appropriate. This involves collaboration in terms of identifying the appropriate links with the other organisations concerned and in practice, separate meetings in different organisations may take place, but a single review report and action plan should be produced by the lead organisation and submitted to the HSCB in the agreed format.

Points to consider:

- If more than one service is being provided, then all services are required to provide information / involvement reports to the review team;
- All service areas should be represented in terms of professional makeup / expertise on the review team;
- If more than one Trust/Agency is involved in the care of an individual, that the review is conducted jointly with all Trusts/Agencies involved;
- Relevant service providers, particularly those under contract with HSC to provide some specific services, should also be enjoined;
- There should be a clearly articulated expectation that the service user (where possible) and family carers, perspective should be canvassed, as should the perspective of staff directly providing the service, to be given consideration by the panel;
- The perspective of the GP and other relevant independent practitioners providing service to the individual should be sought;
- Service users and carer representatives should be invited / facilitated to participate in the panel discussions with appropriate safeguards to protect the confidentiality of anyone directly involved in the case.

This guidance should be read in conjunction with:

- Guidance on Incident Debrief (Refer to Appendix 9)
- Guidance on Review Team Membership (Refer to Appendix 11 & 12)
- Guidance on completing HSC Review Report Level 2 and 3 (Refer to Appendix 7)

APPENDIX 14

PROTOCOL FOR RESPONDING TO SERIOUS ADVERSE INCIDENTS IN THE EVENT OF A HOMICIDE – 2013 (updated November 2016 in line with the HSCB Procedure for the Reporting and Follow up of SAIs)

1. INTRODUCTION AND PURPOSE

1.1. INTRODUCTION

The Health and Social Care Board (HSCB) Procedure for the Reporting and Follow up of Serious Adverse Incidents (SAIs) was issued in April 2010 and revised November 2016. This procedure provides guidance to Health and Social Care (HSC) Trusts and HSCB Integrated Care staff in relation to the reporting and follow up of SAIs arising during the course of business of a HSC organisation, Special Agency or commissioned service.

This paper is a revised protocol, developed from the above procedure, for the specific SAIs which involves an alleged homicide perpetrated by a service user who has a mental illness or disorder (*as defined within the Mental Health (NI) Order 1986*) and/or known to/referred to mental health and related services *(including CAMHS, psychiatry of old age or leaving and aftercare services*) and/or learning disability services, in the 12 months prior to the incident.

This paper should be read in conjunction with Promoting Quality Care – Good Practice Guidance on the Assessment and Management of Risk in Mental Health and Learning Disability Services (Sept 2009 & May 2010).

1.2. PURPOSE

The purpose of this protocol is to provide HSC Trusts with a standardised approach in managing and coordinating the response to a SAI involving homicide.

2. THE PROCESS

2.1. REPORTING SERIOUS ADVERSE INCIDENTS

Refer to the HSCB Procedure for the Reporting and Follow up of Serious Adverse Incidents revised in 2016.

2.2. MULTI-DISCIPLINARY REVIEW

As indicated in Promoting Quality Care (5.0) an internal multi-disciplinary review must be held as soon as practicable following an adverse incident. Where the SAI has resulted in homicide a more independent response is required.

An independent review team should be set up within twenty working days, of the notification of the incident, to the Trust.

2.3. ESTABLISHING AN INDEPENDENT REVIEW TEAM

2.3.1 CHAIR

The Chair of the Review Team should be independent from the HSC Trust, not a Trust employee or recently employed by the Trust. They should be at Assistant Director level or above with relevant professional expertise.

It is the role of the Chair to ensure engagement with families, that their views are sought, that support has been offered to them at an early stage and they have the opportunity to comment on the final draft of the report.

2.3.2 MEMBERSHIP

A review team should include all relevant professionals. The balance of the Team should include non-Trust staff and enable the review team to achieve impartiality, openness, independence, and thoroughness in the review of the incident. [ref: Case Management Review Chapter 10 Cooperating to Protect Children].

The individuals who become members of the Team must not have had any line management responsibility for the staff working with the service user under consideration. The review team must include members who are independent of HSC Trusts and other agencies concerned.

Members of the review team should be trained in the Procedure for the Reporting and Follow up of Serious Adverse Incidents 2016.

3. TERMS OF REFERENCE

The terms of reference for the review team should be drafted at the first meeting of the review team and should be agreed by the HSCB before the second meeting.

The Terms of Reference should include, as a minimum, the following:

- establish the facts of the incident;
- analyse the antecedents to the incident;
- consider any other relevant factors raised by the incident;
- establish whether there are failings in the process and systems;
- establish whether there are failings in the performance of individuals;
- identify lessons to be learned from the incident; and

- identify clearly what those lessons are, how they will be acted upon, what is expected to change as a result, and specify timescales and responsibility for implementation.

4. TIMESCALES

The notification to the Trust of a SAI, resulting in homicide, is the starting point of this process.

The Trust should notify the HSCB within 24hours and the Regulation and Quality Improvement Authority (RQIA) as appropriate.

An independent review team should be set up within twenty working days of the notification of the incident to the Trust.

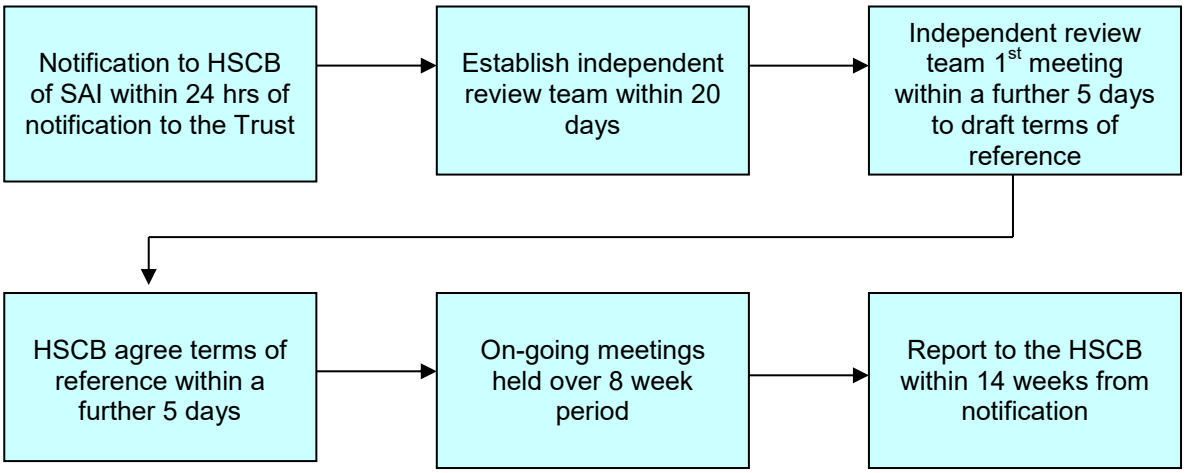
The team should meet to draft the terms of reference within a further five working days (i.e. twenty five days from notification of the incident to the Trust).

The HSCB should agree the terms of reference within a further five working days to enable work to begin at a second meeting.

The review team should complete their work and report to the HSCB within 14 weeks, this may be affected by PSNI investigations.

FLOWCHART OF PROCESS WITH TIMESCALES

NB Days refers to working days from the date of notification of the incident to the Trust



5. THE HEALTH AND SOCIAL CARE BOARD RESPONSIBILITY

On receipt of the completed Trust review report the HSCB will consider the findings and recommendations of the report and must form a view as to whether or not an Independent Inquiry is required.

The HSCB must advise the Department of Health, (DoH) as to whether or not an Independent Inquiry is required in this particular SAI.

APPENDIX 15

ADMINISTRATIVE PROTOCOL

REPORTING AND FOLLOW UP OF SAIs INVOLVING RQIA MENTAL HEALTH/LEARNING DISABILITY AND INDEPENDENT/REGULATED SECTOR

On receipt of a SAI notification and where a HSC Trust has also copied RQIA into the same notification, the following steps will be applied:

1. HSCB acknowledgement email to Trust advising on timescale for review report will also be copied to RQIA.

2. On receipt of the review/learning summary report from Trust, the HSCB Governance Team will forward to the HSCB/PHA Designated Review Officer (DRO).

3. At the same time, the HSCB Governance Team will also forward the review report/learning summary report[1] to RQIA, together with an email advising of a **3 week** timescale from receipt of review report/learning summary report, for RQIA to forward comments for consideration by the DRO.

4. The DRO will continue with his/her review liaising (where s/he feels relevant) with Trust, RQIA and other HSCB/PHA professionals until s/he is satisfied SAI can be closed.

5. If no comments are received from RQIA within the 3 week timescale, the DRO will assume RQIA have no comments.

6. When the SAI is closed by the DRO, an email advising the Trust that the SAI is closed will also be copied to RQIA.

All communications to be sent or copied via:

HSCB Governance Team: ***seriousincidents@hscni.net***
and RQIA: **seriousincidents@rqia.org.uk**

[1] **For Level 1 SAIs the HSCB only routinely receive the Learning Summary Report. If RQIA also wish to consider the full SEA Report this should be requested directly by RQIA from the relevant Reporting Organisation.**

APPENDIX 16

HSC Regional Impact Table – with effect from April 2013 (updated June 2016)

DOMAIN	IMPACT (CONSEQUENCE) LEVELS [can be used for both actual and potential]				
	INSIGNIFICANT (1)	**MINOR (2)**	**MODERATE (3)**	**MAJOR (4)**	**CATASTROPHIC (5)**
PEOPLE *(Impact on the Health/Safety/Welfare of any person affected: e.g. Patient/Service User, Staff, Visitor, Contractor)*	• Near miss, no injury or harm.	• Short-term injury/minor harm requiring first aid/medical treatment. • Any patient safety incident that required extra observation or minor treatment e.g. first aid • Non-permanent harm lasting less than one month • Admission to hospital for observation or extended stay (1-4 days duration) • Emotional distress (recovery expected within days or weeks).	• Semi-permanent harm/disability (physical/emotional injuries/trauma) (Recovery expected within one year). • Admission/readmission to hospital or extended length of hospital stay/care provision (5-14 days). • Any patient safety incident that resulted in a moderate increase in treatment e.g. surgery required	• Long-term permanent harm/disability (physical/emotional injuries/trauma). • Increase in length of hospital stay/care provision by >14 days.	• Permanent harm/disability (physical/ emotional trauma) to more than one person. • Incident leading to death.
QUALITY & PROFESSIONAL STANDARDS/ GUIDELINES *(Meeting quality/ professional standards/ statutory functions/ responsibilities and Audit Inspections)*	• Minor non-compliance with internal standards, professional standards, policy or protocol. • Audit / Inspection – small number of recommendations which focus on minor quality improvements issues.	• Single failure to meet internal professional standard or follow protocol. • Audit/Inspection – recommendations can be addressed by low level management action.	• Repeated failure to meet internal professional standards or follow protocols. • Audit / Inspection – challenging recommendations that can be addressed by action plan.	• Repeated failure to meet regional/ national standards. • Repeated failure to meet professional standards or failure to meet statutory functions/ responsibilities. • Audit / Inspection – Critical Report.	• Gross failure to meet external/national standards. • Gross failure to meet professional standards or statutory functions/ responsibilities. • Audit / Inspection – Severely Critical Report.
REPUTATION *(Adverse publicity, enquiries from public representatives/media Legal/Statutory Requirements)*	• Local public/political concern. • Local press < 1day coverage. • Informal contact / Potential intervention by Enforcing Authority (e.g. HSENI/NIFRS).	• Local public/political concern. • Extended local press < 7 day coverage with minor effect on public confidence. • Advisory letter from enforcing authority/increased inspection by regulatory authority.	• Regional public/political concern. • Regional/National press < 3 days coverage. Significant effect on public confidence. • Improvement notice/failure to comply notice.	• MLA concern (Questions in Assembly). • Regional / National Media interest >3 days < 7days. Public confidence in the organisation undermined. • Criminal Prosecution. • Prohibition Notice. • Executive Officer dismissed. • External Investigation or Independent Review (eg, Ombudsman). • Major Public Enquiry.	• Full Public Enquiry/Critical PAC Hearing. • Regional and National adverse media publicity > 7 days. • Criminal prosecution – Corporate Manslaughter Act. • Executive Officer fined or imprisoned. • Judicial Review/Public Enquiry.
FINANCE, INFORMATION & ASSETS *(Protect assets of the organisation and avoid loss)*	• Commissioning costs (£) <1m. • Loss of assets due to damage to premises/property. • Loss – £1K to £10K. • Minor loss of non-personal information.	• Commissioning costs (£) 1m – 2m. • Loss of assets due to minor damage to premises/ property. • Loss – £10K to £100K. • Loss of information. • Impact to service immediately containable, medium financial loss	• Commissioning costs (£) 2m – 5m. • Loss of assets due to moderate damage to premises/ property. • Loss – £100K to £250K. • Loss of or unauthorised access to sensitive / business critical information • Impact on service contained with assistance, high financial loss	• Commissioning costs (£) 5m – 10m. • Loss of assets due to major damage to premises/property. • Loss – £250K to £2m. • Loss of or corruption of sensitive / business critical information. • Loss of ability to provide services, major financial loss	• Commissioning costs (£) > 10m. • Loss of assets due to severe organisation wide damage to property/premises. • Loss – > £2m. • Permanent loss of or corruption of sensitive/business critical information. • Collapse of service, huge financial loss
RESOURCES *(Service and Business interruption, problems with service provision, including staffing (number and competence), premises and equipment)*	• Loss/ interruption < 8 hour resulting in insignificant damage or loss/impact on service. • No impact on public health social care. • Insignificant unmet need. • Minimal disruption to routine activities of staff and organisation.	• Loss/interruption or access to systems denied 8 – 24 hours resulting in minor damage or loss/ impact on service. • Short term impact on public health social care. • Minor unmet need. • Minor impact on staff, service delivery and organisation, rapidly absorbed.	• Loss/ interruption 1-7 days resulting in moderate damage or loss/impact on service. • Moderate impact on public health and social care. • Moderate unmet need. • Moderate impact on staff, service delivery and organisation absorbed with significant level of intervention. • Access to systems denied and incident expected to last more than 1 day.	• Loss/ interruption 8-31 days resulting in major damage or loss/impact on service. • Major impact on public health and social care. • Major unmet need. • Major impact on staff, service delivery and organisation - absorbed with some formal intervention with other organisations.	• Loss/ interruption >31 days resulting in catastrophic damage or loss/impact on service. • Catastrophic impact on public health and social care. • Catastrophic unmet need. • Catastrophic impact on staff, service delivery and organisation - absorbed with significant formal intervention with other organisations.
ENVIRONMENTAL *(Air, Land, Water, Waste management)*	• Nuisance release.	• On site release contained by organisation.	• Moderate on site release contained by organisation. • Moderate off site release contained by organisation.	• Major release affecting minimal off-site area requiring external assistance (fire brigade, radiation, protection service etc).	• Toxic release affecting off-site with detrimental effect requiring outside assistance.

HSC Regional Risk Matrix – April 2013 (updated June 2016)

HSC REGIONAL RISK MATRIX – WITH EFFECT FROM APRIL 2013 (updated June 2016)

Risk Likelihood Scoring Table			
Likelihood Scoring Descriptors	**Score**	**Frequency (How often might it/does it happen?)**	**Time framed Descriptions of Frequency**
Almost certain	5	Will undoubtedly happen/recur on a frequent basis	Expected to occur at least daily
Likely	4	Will probably happen/recur, but it is not a persisting issue/circumstances	Expected to occur at least weekly
Possible	3	Might happen or recur occasionally	Expected to occur at least monthly
Unlikely	2	Do not expect it to happen/recur but it may do so	Expected to occur at least annually
Rare	1	This will probably never happen/recur	Not expected to occur for years

	Impact (Consequence) Levels				
Likelihood Scoring Descriptors	**Insignificant(1)**	**Minor (2)**	**Moderate (3)**	**Major (4)**	**Catastrophic (5)**
Almost Certain (5)	**Medium**	**Medium**	**High**	**Extreme**	**Extreme**
Likely (4)	**Low**	**Medium**	**Medium**	**High**	**Extreme**
Possible (3)	**Low**	**Low**	**Medium**	**High**	**Extreme**
Unlikely (2)	**Low**	**Low**	**Medium**	**High**	**High**
Rare (1)	**Low**	**Low**	**Medium**	**High**	**High**

APPENDIX 17

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES

The Procedure for the Reporting and Follow up of Serious Adverse Incidents (Revised November 2016) provides guidance to Health and Social Care organisations in relation to the reporting and follow up of Serious Adverse Incidents arising during the course of their business or commissioned service.

The guidance notes that the SAI review should be conducted at a level appropriate and proportionate to the complexity of the incident under review.

The guidance notes that there are three possible levels of review of an SAI and specifies the expected timescale for reporting on a review report as follows:

Level 1 Review – Significant Event Audit (SEA). To be completed and a Learning Summary Report sent to the HSCB within 8 weeks of the SAI being reported.

If the outcome of the SEA determines the SAI is more complex and requires a more detailed review timescales for completion of the RCA will be determined following submission of the Learning Summary Report to the HSCB.

Level 2 Review – Root Cause Analysis (RCA). The final report to be submitted to the HSCB within 12 weeks from the date the incident was notified.

Level 3 Review – Independent Review. Timescales for completion to be agreed by the DRO.

It should be noted that not every referral to child or adult safeguarding processes will proceed to the completion of an SAI report. Within Children's Services, the most complex cases and those that involve death or serious injury to a child, where concerns about how services worked together exist, will be notified to the HSCB as an SAI and may be assessed as meeting the criteria for a Case Management Review (CMR) in which case they will be managed out of the SAI system. The CMR report will highlight the learning from the case.

However, the timescales for the completion of SAI reviews at Level 2 and 3 have proved to be challenging for the cases that do not reach the threshold for a CMR or which result from allegations of abuse of an adult. These are more likely to be some of the more complex cases, and generally involve inter- and multi- agency partnership working.

In responding to allegations of the abuse, neglect or exploitation of a child or vulnerable adult where it is suspected that criminal offence may have been committed, the Health and Social Care Trusts operate under the principles for joint working with the PSNI and other agencies as set out in

- Protocol for Joint Investigation of Alleged and Suspected Cases of Abuse of Vulnerable Adults (2009);

- Sharing to Safeguard (DoH Revised HSCC 3/96 and currently being revised by DoH);
- Co-operating to Safeguard Children (DoH 2003); and
- Protocol for joint Investigation by Social Workers and Police Officers of Alleged and Suspected Cases of Child Abuse – Northern Ireland (2013)

The Memorandum of Understanding: Investigating patient or client safety incidents (2013) states that in cases where more than one organisation may/should have an involvement in investigating any particular incident, then:

"The HSC Organisation should continue to ensure patient or client safety, but not undertake any activity that might compromise any subsequent statutory investigations."

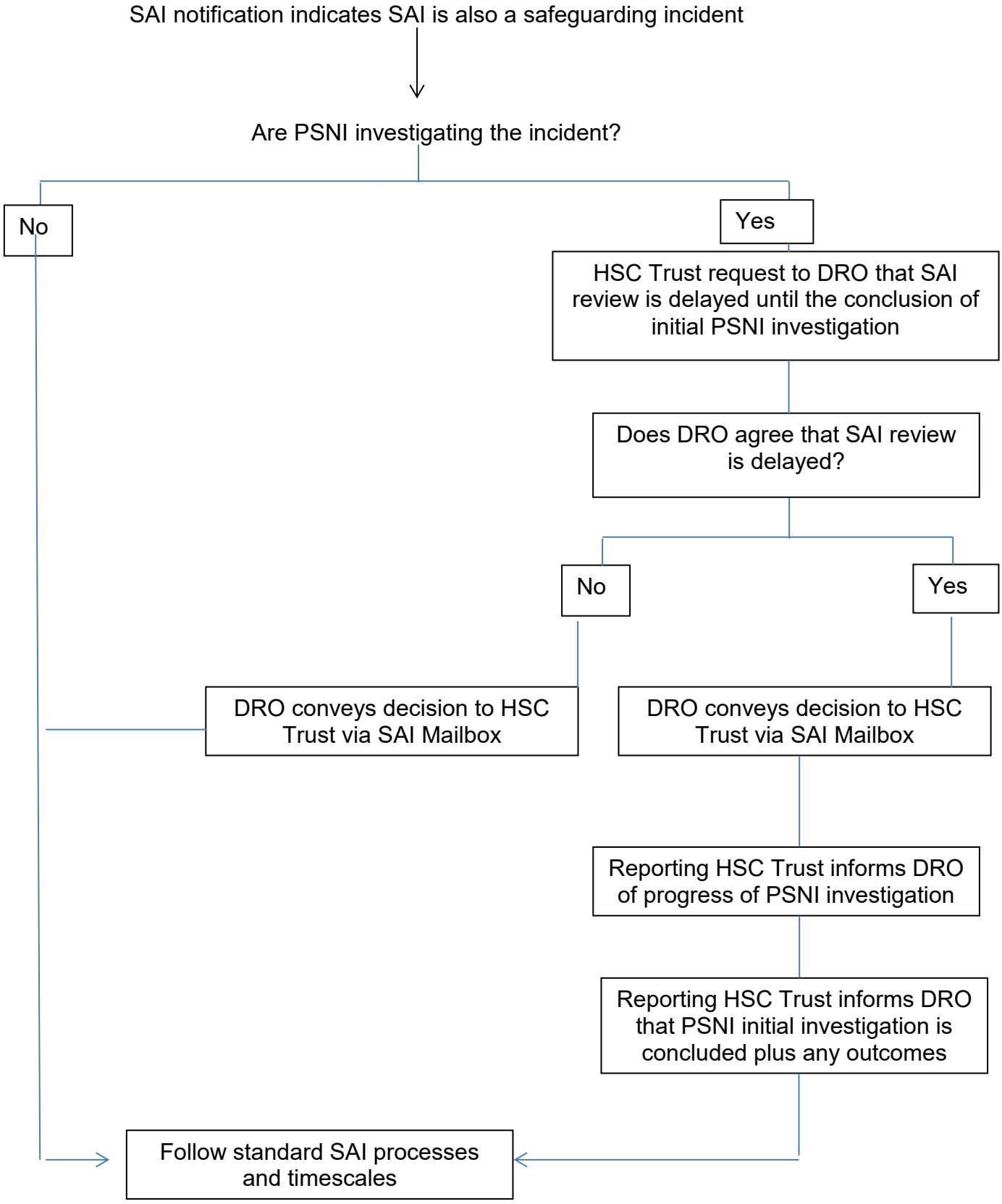
In addition "Achieving Best Evidence: Guidance on interviewing victims and witnesses, the use of special measures and the provision of pre-trial therapy" (revised in 2012), sets out clear protocols for interviewing vulnerable witnesses or victims, whether they are children or adults. This guidance ensures that interviews with vulnerable witnesses and victims are led by specially trained staff, conducted at the victims pace and take place in an environment that is conducive to the needs of the victim.

Clearly, there is an inter-dependency between PSNI and HSC investigations/reviews in complex cases involving multi-agency approaches and protocols. The identification and analysis of learning from these events is likely to be incomplete until both the PSNI and HSC have completed their separate and joint investigations/reviews using the protocols outlined above, and it is unlikely that this can be achieved within the timescales set out for both Level 1 and Level 2 reviews under the SAI procedure.

In such circumstances, the following process should be used:

- Trust report SAI to HSCB using the SAI Notification Form;
- The SAI Notification Form or section 22 of the notification form i.e. 'additional information following initial notification, should indicate the following:
  - The SAI is also a Safeguarding incident
  - PSNI are conducting an investigation of the circumstances surrounding the SAI
  - SAI evaluation will commence at the conclusion of the initial PSNI investigation;
  - Set out the arrangements for keeping the DRO informed of the progress of the PSNI initial investigation;
- If satisfied, the DRO will advise the Trust via the SAI Mailbox that he/she is in agreement with the proposal to delay the SAI review until the conclusion of the initial PSNI investigation;
- The reporting HSC Trust will inform the DRO as soon as the initial PSNI investigation has concluded, along with any outcomes and advise the SAI evaluation has commenced;
- The SAI will continue to be monitored by HSCB Governance team in line with timescales within the Procedure for the Reporting and Follow up of SAIs;
- If the DRO is **not** in agreement with the proposal to delay the SAI review, the reasons for this will be clearly conveyed to the Trust via the SAI Mailbox. Possible reasons for this may include, for example, situations where a criminal incident has occurred on HSC Trust premises but does not involve HSC Trust staff, or an incident involving a service user in their own home and a member of the public is reported to the PSNI by HSC Trust staff.

CHILD AND ADULT SAFEGUARDING AND SAI PROCESSES



Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

SECTION THREE ADDENDUM

ADDENDUM 1

A Guide for Health and Social Care Staff

Engagement/Communication with the Service User/Family/Carers following a Serious Adverse Incident

November 2016
Version 1.1

Contents

Notes on the Development of this Guidance

This guidance has been compiled by the Health and Social Care Board (HSCB) and Public Health Agency (PHA) working in collaboration with the Regulation and Quality Improvement Authority (RQIA), the Patient Client Council (PCC) and Health and Social Care (HSC) Trusts.

This guidance has been informed by:

- National Patient Safety Agency (NPSA) Being Open Framework (2009)
- Health Service Executive (HSE) – Open Disclosure National Guidelines (2013)

Please note the following points:

- *The term 'service user' as used throughout this guidance includes patients and clients availing of Health and Social Care Services from HSC organisations and Family Practitioner Services (FPS) and/or services commissioned from the Independent Sector by HSC organisations.*

- *The phrase 'the service user / family' is used throughout this document in order to take account of all types of engagement scenarios, and also includes a carer(s) or the legal guardian of the service user, where appropriate. However, when the service user has capacity, communication should always (in the first instance) be with them (see appendix 1 for further guidance).*

A review / re-evaluation of this guidance will be undertaken one year following implementation.

1.0 Introduction

When an adverse outcome occurs for a service user it is important that the service user / family (as appropriate) receive timely information and are fully aware of the processes followed to review the incident.

The purpose of a Serious Adverse Incident (SAI) review is to understand what occurred and where possible improve care by learning from incidents. Being open about what happened and discussing the SAI promptly, fully and compassionately can help the service user / family cope better with the after-effects and reduce the likelihood of them pursuing other routes such as the complaints process or litigation to get answers to their questions.

It is therefore essential that there is:

- full disclosure of a SAI to the service user / family,
- an acknowledgement of responsibility,
- an understanding of what happened and a discussion of what is being done to prevent recurrence.

Communicating effectively with the service user / family is a vital part of the SAI process. If done well, it promotes person-centred care and a fair and open culture, ultimately leading to continuous improvement in the delivery of HSC services. It is human to make mistakes, but rather than blame individuals, the aim is for all of us to identify and address the factors that contributed to the incident. The service user / family can add valuable information to help identify the contributing factors, and should be integral to the review process, unless they wish otherwise.

2.0 Purpose

This is a guide for HSC staff to ensure effective communication with the service user / family, following a SAI, is undertaken in an open, transparent, informed, consistent and timely manner.

It is important this guidance is read in conjunction with the regional Procedure for Reporting and Follow up of SAIs (November 2016) and any subsequent revisions relating to the SAI process that have or may be issued in the future. This will ensure the engagement process is closely aligned to the required timescales, documentation, review levels etc. *To view the SAI Procedure please follow the link below* http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-follow-up-of-SAIs-2016.pdf.

The HSCB Process works in conjunction with all other review processes, statutory agencies and external bodies. Consequently, there may be occasions when a reporting organisation will have reported an incident via another process before or after it has been reported as a SAI. It is therefore important that all existing processes continue to operate in tandem with the SAI procedure and should not be an obstacle to the engagement of the service user / family; nor should an interaction through another process replace engagement through the SAI process.

In that regard, whilst this guidance is specific to 'being open' when engaging with the service user / family following a SAI, it is important HSC organisations are also mindful of communicating effectively with the service user / family when investigating adverse incidents. In these circumstances, organisations should refer to the NPSABeingOpenFramework www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726 which will provide assistance for organisations to determine the level of service user / family engagement when investigating those adverse incidents that do not meet SAI criteria.

The Being Open Framework may also assist organisations with other investigative processes e.g. complaints, litigation, lookback exercises, and any other relevant human resource and/or risk management related policies and procedures.

3.0 Principles of Being Open with the Service User / Family

Being open and honest with the service user / family involves:

- Acknowledging, apologising and explaining that the organisation wishes to review the care and treatment of the service user;
- Explaining that the incident has been categorised as a SAI, and describing the review process to them, including timescales;
- Advising them how they can contribute to the review process, seeking their views on how they wish to be involved and providing them with a leaflet explaining the SAI process (see appendix 2);
- Conducting the correct level of SAI review into the incident and reassuring the service user / family that lessons learned should help prevent the incident recurring;
- Providing / facilitating support for those involved, including staff, acknowledging that there may be physical and psychological consequences of what happened;

- Ensuring the service user / family have details for a single point of contact within the organisation.

It is important to remember that saying sorry is not an admission of liability and is the right thing to do.

The following principles underpin being open with the service user / family following a SAI.

3.1 Acknowledgement

All SAIs should be acknowledged and reported as soon as they are identified. In cases where the service user / family inform HSC staff / family practitioner when something untoward has happened, it must be taken seriously from the outset. Any concerns should be treated with compassion and understanding by all professionals.

In certain circumstances e.g. cases of criminality, child protection, or SAIs involving theft, fraud, information breaches or data losses that do not directly affect service users; it may not be appropriate to communicate with the service user / family. When a lead professional / review team make a decision, based on a situation as outlined above, or based on a professional's opinion, not to disclose to the service user / family that a SAI has occurred, the rationale for this decision must be clearly documented in the SAI notification form / SAI review checklist that is submitted to the HSCB.

It is expected, the service user / family will be informed that a SAI has occurred, as soon as possible following the incident, for all levels of SAI reviews. In very exceptional circumstances, where a decision is made not to inform the service user / family, this decision must be reviewed and agreed by the review team, approved by an appropriate Director or relevant committee / group, and the decision kept under review as the review progresses. In these instances the HSCB must also be informed:

- **Level 1 reviews - on submission of Review Report and Checklist Proforma**
- **Level 2 and 3 reviews - on submission of the Terms of Reference and Membership of the review team.**

3.2 Truthfulness, timeliness and clarity of communication

Information about a SAI must be given to the service user / family in a truthful and open manner by an appropriately nominated person (see 4.2.2). The service user / family should be provided with an explanation of what happened in a way that considers their individual circumstances, and is delivered openly. Communication should also be timely, ensuring the service user / family is provided with information about what happened as soon as practicable without causing added distress. Note, where a number of service users are involved in one incident, they should all be informed at the same time where possible.

It is also essential that any information given is based solely on the facts known at the time. Staff should explain that new information may emerge as an incident review is undertaken, and that the service user / family will be kept informed, as the review progresses. The service user / family should receive clear information with a single point of contact for any questions or requests they may have. They should not receive conflicting information from different members of staff, and the use of jargon, should be avoided.

3.3 Apology / Expression of Regret

When it is clear, that the organisation / family practitioner is responsible for the harm / distress to the service user, it is imperative that there is an acknowledgement of the incident and an apology provided as soon as possible. Delays are likely to increase the service user / family sense of anxiety, anger or frustration. Relevant to the context of a SAI, the service user / family should receive a meaningful apology – one that is a sincere expression of sorrow or regret for the harm / distress that has occurred as a result of the SAI.

3.4 Recognising the expectations of the Service User / Family

The service user / family may reasonably expect to be fully informed of the facts, consequences and learning in relation to the SAI and to be treated with empathy and respect.

They should also be provided with support in a manner appropriate to their needs. Specific types of service users / families may require additional support (see appendix 1).

In circumstances where the service user / family request the presence of their legal advisor this request should be facilitated. However, HSC staff

should ensure that the legal advisor is aware that the purpose of the report / meeting is not to apportion liability or blame but to learn from the SAI. Further clarification in relation to this issue should be sought from Legal Services.

3.5 Professional Support

HSC organisations must create an environment in which all staff, whether directly employed or independent contractors, are encouraged to report SAIs. Staff should feel supported throughout the incident review process because they too may have been traumatised by being involved. There should be a culture of support and openness with a focus on learning rather than blame.

HSC organisations should encourage staff to seek support where required form relevant professional bodies such as the General Medical Council (GMC), Royal Colleges, the Medical Defence Union (MDU), the Medical Protection Society (MPS), the Nursing and Midwifery Council, the Northern Ireland Association for Social Work (NIASW) and the Northern Ireland Social Care Council (NISCC).

3.6 Confidentiality

Details of a SAI should at all times be considered confidential. It is good practice to inform the service user / family about those involved in the review and who the review report will be shared with.

3.7 Continuity of Care

In exceptional circumstances, the service user / family may request transfer of their care to another facility; this should be facilitated if possible to do so. A member of staff should be identified to act as a contact person for the service user / family to keep them informed of their on-going treatment and care.

4.0 Process

Being open with the service user / family is a process rather than a one-off event. There are 5 stages in the engagement process:

- Stage 1 – Recognition
- Stage 2 - Communication
- Stage 3 – Initial Meeting
- Stage 4 – Follow up Discussions

- Stage 5 – Process Completion

The duration of this process depends on the level of SAI review being undertaken and the associated timescales as set out in the Procedure for the Reporting and Follow up of SAIs (2013).

4.1 Stage 1 - Recognition

As soon as the SAI is identified, the priority is to prevent further harm / distress. The service user / family should be notified that the incident is being reviewed as a SAI.

4.1.1 Preliminary Discussion with the Service User / Family

On many occasions it will be at this stage when the lead professional / family practitioner responsible for the care of the service user will have a discussion with the service user / family, advising of the need to review the care and treatment. This preliminary discussion (which could be a telephone call) will be in addition to the formal initial meeting with the service user / family (see 4.3).

A Level 1 review may not require the same level of engagement as Levels 2 and 3 therefore the preliminary discussion may be the only engagement with service user / family prior to communicating findings of the review, provided they are content they have been provided with all information.

There may be occasions when the service user / family indicate they do not wish to engage in the process. In these instances the rationale for not engaging further must be clearly documented.

4.2 Stage 2 – Communication

4.2.1 Timing of Initial Communication with the Service User / Family

The initial discussion with the service user / family should occur as soon as possible after recognition of the SAI. Factors to consider when timing this discussion include:

- service user's health and wellbeing;
- service user / family circumstances, preference (in terms of when and where the meeting takes place) and availability of key staff *(appendix 1 provides guidance on how to manage different categories of service user / family circumstances);*

4.2.2 Choosing the individual to communicate

The person[7] nominated to lead any communications should:

- Be a senior member of staff with a comprehensive understanding of the facts relevant to the incident;
- Have the necessary experience and expertise in relation to the type of incident;
- Have excellent interpersonal skills, including being able to effectively engage in an honest, open and transparent manner, avoiding excessive use of jargon;
- Be willing and able to offer a meaningful apology / expression of regret, reassurance and feedback.

If required, the lead person communicating information about the SAI should also be able to nominate a colleague who may assist them with the meeting and should be someone with experience or training in communicating with the service user / family.

The person/s nominated to engage could also be a member/s of the review team (if already set up).

[7] *FPS SAIs involving FPS this will involve senior professionals/staff from the HSCB Integrated Care Directorate.*

4.3 Stage 3 - Initial Meeting with the Service User / Family

The initial discussion is the first part of an on-going communication process. Many of the points raised here should be expanded on in subsequent meetings with the service user / family.

4.3.1 Preparation Prior to the Initial Meeting

- The service user / family should be given the leaflet - What I Need to Know About a SAI (see appendix 2);
- Share with the service user / family what is going to be discussed at the meeting and who will be in attendance.

4.3.2 During the Initial Meeting

The content of the initial meeting with the service user / family should cover the following:

- Welcome and introductions to all present;
- An expression of genuine sympathy or a meaningful apology for the event that has occurred;
- The facts that are known to the multidisciplinary team;
- Where a service user has died, advising the family that the coroner has been informed (where there is a requirement to do so) and any other relevant organisation/body;
- The service user / family are informed that a SAI review is being carried out;
- Listening to the service user's / families understanding of what happened;
- Consideration and formal noting of the service user's / family's views and concerns;
- An explanation about what will happen next in terms of the SAI review, findings, recommendations and learning and timescales;
- An offer of practical and emotional support for the service user / family. This may involve getting help from third parties such as charities and voluntary organisations, providing details of support from other organisations, as well as offering more direct assistance;
- Advising who will be involved in the review before it takes place and who the review report will be shared with;
- Advising that all SAI information will be treated as confidential.

If for any reason it becomes clear during the initial discussion that the service user / family would prefer to speak to a different health / social

care professional, these wishes should be respected, and the appropriate actions taken.

It is important during the initial meeting to try to avoid any of the following:

- Speculation;
- Attribution of blame;
- Denial of responsibility;
- Provision of conflicting information from different health and social care individuals.

It should be recognised that the service user / family may be anxious, angry and frustrated, even when the meeting is conducted appropriately. It may therefore be difficult for organisations to ascertain if the service user / family have understood fully everything that has been discussed at the meeting. It is essential however that, at the very least, organisations are assured that the service user / family leave the meeting fully aware that the incident is being reviewed as a SAI, and knowing the organisation will continue to engage with them as the review progresses, so long as the service user / family wish to engage.

Appendix 3 provides examples of words / language which can be used during the initial discussion with the service user / family.

4.4 Stage 4 – Follow-up Discussions

Follow-up discussions are dependent on the needs and wishes of the service user / family.

The following guidelines will assist in making the communication effective:

- The service user / family should be updated if there are any delays and the reasons for the delays explained;
- Advise the service user / family if the incident has been referred to any other relevant organisation / body;
- Consideration is given to the timing of the meetings, based on both the service users / families health, personal circumstances and preference on the location of the meeting, e.g. the service users / families home;
- Feedback on progress to date, including informing the service user / family of the Terms of Reference of the review and membership of the review panel (for level 2 and 3 SAI reviews);
- There should be no speculation or attribution of blame. Similarly, the health or social care professional / senior manager communicating the SAI must not criticise or comment on matters outside their own experience;
- A written record of the discussion is kept and shared with the service user / family;
- All queries are responded to appropriately and in a timely way.

4.5 Stage 5 – Process Completion

4.5.1 Communicating findings of review / sharing review report

Feedback should take the form most acceptable to the service user / family. Communication should include:

- a repeated apology / expression of regret for the harm / distress suffered;
- the chronology of clinical and other relevant factors that contributed to the incident;
- details of the service users / families concerns;
- information on learning and outcomes from the review
- Service user / family should be assured that lines of communication will be kept open should further questions arise at a later stage and a single point of contact is identified.

It is expected that in most cases there will be a complete discussion of the findings of the review and that the final review report will be shared with

the service user / family. In some cases however, information may be withheld or restricted, for example:

- Where communicating information will adversely affect the health of the service user / family;
- Where specific legal/coroner requirements preclude disclosure for specific purposes;
- If the deceased service users health record includes a note at their request that he/she did not wish access to be given to his/her family.

Clarification on the above issues should be sought form Legal Services.

There may also be instances where the service user / family does not agree with the information provided, in these instances Appendix 1 (section 1.8) will provide additional assistance.

In order to respond to the timescales as set out in the Procedure for the Reporting and Follow up of SAIs (November 2016) organisations may not have completed stage 5 of the engagement process prior to submission of the review report to HSCB. In these instances, organisations must indicate on the SAI review checklist, submitted with the final review report to the HSCB, the scheduled date to meet with the service user / family to communicate findings of review / share review report.

4.5.2 Communicating Changes to Staff

It is important that outcomes / learning is communicated to all staff involved and to the wider organisation as appropriate.

4.6 Documentation

Throughout the above stages it is important that discussions with the service user / family are documented and should be shared with the individuals involved.

Documenting the process is essential to ensure continuity and consistency in relation to the information that has been relayed to the service user / family.

Documentation which has been produced in response to a SAI may have to be disclosed later in legal proceedings or in response to a freedom of information application. It is important that care is taken in all communications and documents stating fact only.

Appendix 4 provides a checklist which organisations may find useful as an aide memoire to ensure a professional and standardised approach.

5.0 Supporting Information and Tools

In addition to this guidance, supporting tools have been developed to assist HSC organisations with implementing the actions of the NPSA's Being Open Patient Safety Alert.

Training on being open is freely available through an e-learning tool for all HSC organisations.

Information on all these supporting tools can be found at: www.**npsa**.nhs.uk/**beingopen** and www.nrls.**npsa**.nhs.uk/**beingopen**/.

Guidance on sudden death and the role of bereavement co-ordinators in Trusts can be found at:
http://webarchive.proni.gov.uk/20120830110704/http://www.dhsspsni.gov.uk/sudden-death-guidance.pdf

List of Acronyms and Abbreviations

FPS	-	Family Practitioner Services
GMC	-	General Medical Council
HSC	-	Health and Social Care
HSCB	-	Health and Social Care Board
HSE	-	Health Service Executive
MDU	-	Medical Defence Union
MPS	-	Medical Protection Society
NIASW	-	Northern Ireland Association for Social Work
NISCC	-	Northern Ireland Social Care Council
NMC	-	Nursing and Midwifery Council
NPSA	-	National Patient Safety Agency
PCC	-	Patient Client Council
PHA	-	Public Health Agency
RC	-	Royal colleges
RCA	-	Root Cause Analysis
RQIA	-	Regulation and Quality Improvement Authority
SAI	-	Serious Adverse Incident
SEA	-	Significant Event Audit

Particular Service user Circumstances

The approach to how an organisation communicates with a service user / family may need to be modified according to the service user's personal circumstances.

The following gives guidance on how to manage different categories of service user circumstances.

1.1 When a service user dies

When a SAI has resulted in a service users death, the communication should be sensitive, empathetic and open. It is important to consider the emotional state of bereaved relatives or carers and to involve them in deciding when it is appropriate to discuss what has happened.

1.2 Children

The legal age of maturity for giving consent to treatment is 16 years old. However, it is still considered good practice to encourage young people of this age to involve their families in decision making.

The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the communication process after a SAI.

The opportunity for parents / guardians to be involved should still be provided unless the child expresses a wish for them not to be present. Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents / guardians alone or in the presence of the child. In these instances the parents' / guardians' views on the issue should be sought.

1.3 Service users with mental health issues

Communication with service users with mental health issues should follow normal procedures unless the service user also has cognitive impairment (see1.4 Service users with cognitive impairments).

The only circumstances in which it is appropriate to withhold SAI information from a service user with mental health issues is when advised to do so by a senior clinician who feels it would cause adverse psychological harm to the service user. However, such circumstances are rare and a second opinion may be required to justify withholding information from the service user.

In most circumstances, it is not appropriate to discuss SAI information with a carer or relative without the permission of the service user, unless in the public interest and / or for the protection of third parties.

1.4 Service users with cognitive impairment

Some individuals have conditions that limit their ability to understand what is happening to them.

In these cases communication would be conducted with the carer / family as appropriate. Where there is no such person, the clinicians may act in the service users best interest in deciding who the appropriate person is to discuss the SAI with.

1.5 Service users with learning disabilities

Where a service user / family has difficulties in expressing their opinion verbally, every effort should be made to ensure they can use or be facilitated to use a communication method of their choice. An advocate / supporter, agreed on in consultation with the service user, should also be identified. Appropriate advocates / supporters may include carer/s, family or friends of the service user or a representative from the Patient Client Council (PCC).

1.6 Service users with different language or cultural considerations

The need for translation and advocacy services and consideration of special cultural needs must be taken into account when planning to discuss SAI information. Avoid using 'unofficial translators' and / or the service users family or friends as they may distort information by editing what is communicated.

1.7 Service users with different communication needs

Service users who have communication needs such as hearing impaired, reduced vision may need additional support.

1.8 Service users who do not agree with the information provided

Sometimes, despite the best efforts the service user/family/carer may remain dissatisfied with the information provided. In these circumstances, the following strategies may assist:

- Facilitate discussion as soon as possible;
- Write a comprehensive list of the points that the service user / family disagree with and where appropriate reassure them you will follow up these issues.
- Ensure the service user / family has access to support services;
- Offer the service user / family another contact person with whom they may feel more comfortable.
- Use an acceptable service user advocate e.g. PCC or HSC layperson to help identify the issues between the HSC organisation and the service user / family and to achieve a mutually agreeable solution;

There may be occasions despite the above efforts the service user/family/carer remain dissatisfied with the HSC organisation's attempts to resolve their concerns. In these exceptional circumstances, the service user/family/carer through the agreed contact person, should be advised of their right to approach the Northern Ireland Public Services Ombudsman (NIPSO). In doing so, the service user/family requires to be advised by the HSC organisation that the internal procedure has concluded (within two weeks of this process having been concluded), and that the service user/family should approach the NIPSO within six months of this notification.

The contact details for the NIPSO are: Freephone 0800 34 34 34 or Progressive House, 33 Wellington Place, Belfast, BT1 6HN.

1.9 Service Users who do not wish to participate in the engagement process

It should be documented if the service user does not wish to participate in the engagement process.

Health and Social Care Board

Public Health Agency

What I need to know about a Serious Adverse Incident

Information for Service Users, Family Members and Carers

Insert Name of Organisation

This leaflet is written for people who use Health and Social Care (HSC) services and their families.

**The phrase service user / family member and carer is used throughout this document in order to take account of all types of engagement scenarios. However, when a service user has capacity, communication should always (in the first instance) be with them.*

Introduction

Events which are reported as Serious Adverse Incidents (SAIs) help identify learning even when it is not clear something went wrong with treatment or care provided.

When things do go wrong in health and social care it is important that we identify this, explain what has happened to those affected and learn lessons to ensure the same thing does not happen again. SAIs are an important means to do this. Areas of good practice may also be highlighted and shared, where appropriate.

What is a Serious Adverse Incident?

A SAI is an incident or event that must be reported to the Health and Social Care Board (HSCB) by the organisation where the SAI has occurred. It may be:

- an incident resulting in serious harm;
- an unexpected or unexplained death;
- a suspected suicide of a service user who has a mental illness or disorder;
- an unexpected serious risk to wellbeing or safety, for example an outbreak of infection in hospital;

A SAI may affect services users, members of the public or staff.

Never events are serious patient safety incidents that should not occur if the appropriate preventative measures have been implemented by healthcare providers. A small number of SAIs may be categorised as never events based on the Department of Health Never Events list.

SAIs, including never events, occurring within the HSC system are reported to the HSCB. You, as a service user / family member / carer, will be informed where a SAI and/or never event has occurred relating to treatment and care provided to you by the HSC.

Can a complaint become a SAI?

Yes, if during the follow up of a complaint the **(insert name of organisation)** identifies that a SAI has occurred it will be reported to the HSCB. You, as a service user / family member and carer will be informed of this and updated on progress regularly.

How is a SAI reviewed?

Depending on the circumstance of the SAI a review will be undertaken. This will take between 8 to 12 weeks depending on the complexity of the case. If more time is required you will be kept informed of the reasons.

The (**insert name of organisation**) will discuss with you how the SAI will be reviewed and who will be involved. The (**insert name of organisation**) will welcome your involvement if you wish to contribute.

Our goal is to find out what happened, why it happened and what can be done to prevent it from happening again and to explain this to those involved.

How is the service user or their family/carer involved in the review?

An individual will be identified to act as your link person throughout the review process. This person will ensure as soon as possible that you:

- Are made aware of the incident, the review process through meetings / telephone calls;
- Have the opportunity to express any concerns;
- Know how you can contribute to the review, for example share your experiences;
- Are updated and advised if there are any delays so that you are always aware of the status of the review;
- Are offered the opportunity to meet and discuss the review findings;
- Are offered a copy of the review report;

- Are offered advice in the event that the media make contact.

What happens once the review is complete?

The findings of the review will be shared with you. This will be done in a way that meets your needs and can include a meeting facilitated by **(insert name of organisation)** staff that is acceptable to you.

How will learning be used to improve safety?

By reviewing a SAI we aim to find out what happened, how and why. By doing this we aim to identify appropriate actions which will prevent similar circumstances occurring again.

We believe that this process will help to restore the confidence of those affected by a SAI.

For each completed review:

- Recommendations may be identified and included within an action plan;
- Any action plan will be reviewed to ensure real improvement and learning.

We will always preserve your confidentiality while also ensuring that opportunities to do things better are shared throughout our organisation and the wider health and social care system. Therefore as part of our process to improve quality and share learning, we may share the anonymised content of the SAI report with other HSC organisations'

Do families get a copy of the report?

Yes, a copy of the review report will be shared with service users and/or families with the service user's consent.

If the service user has died, families/carers will be provided with a copy of the report and invited to meet with senior staff.

Who else gets a copy of the report?

The report is shared with the Health and Social Care Board (HSCB) and Public Health Agency (PHA). Where appropriate it is also shared with the Coroner.

The Regulation and Quality Improvement Authority (RQIA) have a statutory obligation to review some incidents that are also reported under the SAI procedure. In order to avoid duplication of incident notification and review, RQIA work in conjunction with the HSCB / PHA with regard to the review of certain categories of SAI including the following:

- All mental health and learning disability SAIs reportable to RQIA under Article 86.2 of the Mental Health (NI) Order 1986.

- Any SAI that occurs within the regulated sector for example a nursing, residential or children's home (whether statutory or independent) for a service that has been commissioned / funded by a HSC organisation.

In both instances the names and personal details that might identify the individual are removed from the report. The relevant organisations monitor the (**insert name of organisation)** to ensure that the recommendations have been implemented. The family may wish to have follow up / briefing after implementation and if they do this can be arranged by their link person within the (**insert name of organisation**).

All those who attended the review meeting are given a copy of the anonymised report. Any learning from the review will be shared as appropriate with relevant staff/groups within the wider HSC organisations.

Further Information

If you require further information or have comments regarding this process you should contact the nominated link person - name and contact details below:

Your link person is ……..…….

Your link person's job title is……..…..

Contact number …….

Hours of work……..……

Prior to any meetings or telephone call you may wish to consider the following:

Think about what questions and fears/concerns you have in relation to:

(a) What has happened?
(b) Your condition / family member condition
(c) On-going care

You could also:

- Write down any questions or concerns you have;
- Think about who you would like to have present with you at the meeting as a support person;
- Think about what things may assist you going forward;
- Think about which healthcare staff you feel should be in attendance at the meeting.

Patient and Client Council

The Patient Client Council offers independent, confidential advice and support to people who have a concern about a HSC Service. This may include help with writing letters, making telephone calls or supporting you at meetings, or if you are unhappy with recommendations / outcomes of the reviews.

Contact details:
Free phone number: 0800 917 0222

Appendix 3

Examples of communication which enhances the effectiveness of being open	
Stage of Process	**Sample Phrases**
Acknowledgement	"We are here to discuss the harm that you have experienced/the complications with your surgery/treatment" "I realise that this has caused you great pain/distress/anxiety/worry" "I can only imagine how upset you must be" "I appreciate that you are anxious and upset about what happened during your surgery – this must have come as a big shock for you" "I understand that you are angry/disappointed about what has happened" "I think I would feel the same way too"
Sorry	"I am so sorry this has happened to you" "I am very sorry that the procedure was not as straightforward as we expected and that you will have to stay in hospital an extra few days for observation" "I truly regret that you have suffered xxx which is a recognised complication associated with the x procedure/treatment." "I am so sorry about the anxiety this has caused you" "A review of your case has indicated that an error occurred – we are truly sorry about this"
Story	**Their Story** "Tell me about your understanding of your condition" "Can you tell me what has been happening to you" "What is your understanding of what has been happening to you" **Your understanding of their Story: (Summarising)** "I understand from what you said that" xxx "and you are very upset and angry about this"

	Is this correct? (i.e. summarise their story and acknowledge any emotions/concerns demonstrated.) "Am I right in saying that you……..." **Your Story** "Is it ok for me to explain to you the facts known to us at this stage in relation to what has happened and hopefully address some of the concerns you have mentioned? "Do you mind if I tell you what we have been able to establish at this stage?" "We have been able/unable to determine at this stage that……." "We are not sure at this stage about exactly what happened but we have established that ……. We will remain in contact with you as information unfolds" "You may at a later stage experience xx if this happens you should ……."
Inquire	"Do you have any questions about what we just discussed?" "How do you feel about this?" "Is there anything we talked about that is not clear to you?"
Solutions	"What do you think should happen now?" "Do you mind if I tell you what I think we should do?" "I have reviewed your case and this is what I think we need to do next" "What do you think about that?" "These are your options now in relation to managing your condition, do you want to have a think about it and I will come back and see you later?" "I have discussed your condition with my colleague Dr x we both think that you would benefit from xx. What do you think about that?"
Progress	"Our service takes this very seriously and we have already started a review into the incident to see if we can find out what caused it to happen" "We will be taking steps to learn from this event so that we can

	try to prevent it happening again in the future” “I will be with you every step of the way as we get through this and this is what I think we need to do now” “We will keep you up to date in relation to our progress with the review and you will receive a report in relation to the findings and recommendations of the review team” “Would you like us to contact you to set up another meeting to discuss our progress with the review?” “I will be seeing you regularly and will see you next in….days/weeks. “You will see me at each appointment” “Please do not hesitate to contact me at any time if you have any questions or if there are further concerns – you can contact me by……” “If you think of any questions write them down and bring them with you to your next appointment.” “Here are some information leaflets regarding the support services we discussed – we can assist you if you wish to access any of these services”

Appendix 4

Organisations may find this checklist useful an aide memoire to ensure a professional and standardised approach

Before, During and After Communication / Engagement Documentation Checklist

BEFORE	***Note taking***
Service users full name	
Healthcare record number	
Date of birth	
Date of admission	
Diagnosis	
Key HSC professional(s) involved in service user's care	
Date of discharge (if applicable)	
Date of SAI	
Description of SAI	
Outcome of SAI	
Agreed plan for management of SAI	
Agreed professional to act as contact person with the service user / family	

Service user / family informed incident is being reviewed as a SAI: • Date • By Whom • By what means (telephone call / letter / in person)	
Date of first meeting with the service user / family	
Location of first meeting (other details such as room booking, arrangements to ensure confidentiality if shared ward etc)	
Person to be responsible for note taking identified	
Person Nominated to lead communications identified	
Colleague/s to assist nominated lead	
Other staff identified to attend the disclosure meeting	
Anticipated service user / family concerns queries	
Meeting agenda agreed and circulated	
Additional support required by the service user / family, if any?	
The service user / family has been advised to bring a support person to the meeting?	
The service user consented to the sharing of information with others such as designated family members / support person?	

It has been established that the service user / family requires an interpreter? If yes, provide details of language and arrangements that have been or to be made.	

Signature: _____

***Date*:** _____

DURING	***Note taking***
There has been an acknowledgment of the SAI in relation to the service user / family experience.	
An apology / expression of regret provided	
The service user / family was provided with factual information regarding the adverse event	
The service user / family understanding of the SAI was established	
The service user / family was provided with the opportunity to: - Tell their story - Voice their concerns and - Ask questions	
The next steps in relation to the service user's on-going care were agreed and the service user was involved in the decisions made.	
The service user / family was provided with information in relation to the supports available to them.	
Reassurance was provided to the service user / family in relation to the on-going communication of facts when the information has been established and available – continuity provided.	
Next meeting date and location agreed	

Signature: _____

***Date*:** _____

AFTER

Circulate minutes of the meeting to all relevant parties for timely verification.
Follow through on action points agreed.
Continue with the incident review.
Keep the service user included and informed on any progress made – organise further meetings.
Draft report to be provided to the service user in advance of the final report (if agreed within review Terms of Reference that the draft report is to be shared with the service user prior to submission to HSCB/PHA).
Offer a meeting with the service user to discuss the review report and allow for amendments if required.
Follow through on any recommendations made by the incident review team.
Closure of the process is mutually agreed.
When closure / reconciliation was not reached the service user was advised of the alternative courses of action which are open to them i.e the complaints process.

Signature: _____

***Date*:** _____

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier:
[redacted] Personal Information redacted by the USI

Date of Incident/Event: Multiple dates

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: Male Age:

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off: 26 February 2021

Date submitted to HSCB: 1 March 2021

1.0 EXECUTIVE SUMMARY

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 to the patients identified and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided. Nine patients have been identified as potentially suffering harm. This review will examine the timelines of each individual case and analyse if any deficits in treatment or care has occurred. As part of the review the cancer pathways will be used to determine where learning can be extracted.

The SHSCT recognise the life changing and devastating consequences to the 9 families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care they received.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair former Chair of the NICAN. Former Medical Director Western Health and Social Care Trust.
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally from SET / recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high

3.0 SAI REVIEW TERMS OF REFERENCE

quality care.

- Examine any areas of good practice and opportunities for sharing learning from the incidents.
- To share the report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Patients and families involved/ Staff involved.

4.0 REVIEW METHODOLOGY

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

5.0 DESCRIPTION OF INCIDENT/CASE

The review team conducted individual reviews on 9 patients on their treatment and care. A summary of each case is discussed within this report.

Causal deficits in their care and contributory factors were identified.

Service User A

Service User A was diagnosed with prostate cancer and was started on an anti-androgen therapy as opposed to Androgen Deprivation Therapy (ADT). This did not adhere to the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016). These Guidelines had been signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-Disciplinary Meeting (MDM), as their protocols for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. Following discussion with the families, the review team noted that there was no discussion with Service User A that the treatment given was at variance with regionally recommended practice. There was no evidence of informed consent to this alternative care pathway.

The review team have identified that during the MDM that a quorum had not been met. This was due to the absence of an oncologist from these meetings. Even so, the recommendations made by the MDM were not actioned by Dr 1. Members of the MDT may not have been aware of this, but similar practice in prescribing an anti-androgen had been challenged. Any challenges made regarding the appropriateness of treatment options were not minuted nor was the issue escalated.

The Review Team suggested that the initial assessment of Service User A was satisfactory although rather prolonged, the subsequent management with unlicensed anti-androgenic treatment (Bicalutamide) at best delayed definitive treatment. Bicalutamide (50mg) is currently only indicated before (as an anti-flare agent) or in combination with a LHRH analogue (Complete Androgen Blockade) Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer (reference is EAU guidelines), and further it decreases overall survival. Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1.7 nmol/l), which is best accomplished by the use of a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.

Service User A did not have Urology Cancer Nurse Specialist allocated to his care. The review team questioned this and it was established that whilst there were no resources for a Urology Cancer Nurse Specialist to attend any outreach clinics, their contact numbers should have been provided to the patient.

The Review Team conclude that Service User A received unconventional and inadequate treatment. The expected multi-professional involvement in his care was omitted. Service User A's disease progressed whilst being inadequately treated. The opportunity to offer him radical treatment with curative intent was lost.

5.0 DESCRIPTION OF INCIDENT/CASE

Service User B

Service User B was diagnosed clinically and biochemically with prostate cancer, and was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent (or in combination with a LHRH analogue) and is only prescribed before definitive hormonal (LHRH analogue) treatment. The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016), which was signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017). This guidance was issued when Doctor 1 was the chair of this group and had full knowledge of its contents. The review team note that, following discussion with Service User B, he was unaware that his care given was at variance with regionally recommended best practice. There was no evidence of informed consent to this alternative care pathway.

A biopsy result taken at the time of transurethral resection of prostate (TURP) showed benign disease (low volume sample 2g from central area of prostate). There were no further investigations to explore the clinical suspicion of prostate cancer.

The possibility of localised prostate cancer was considered from the time of presentation because the PSA was elevated; however, there was no record in the medical notes of any digital rectal examination (DRE) findings. During the operation further signs might have been elicited and appropriate biopsies could have been performed. TURP is not an adequate way to biopsy the prostate gland for suspected prostate cancer. The Review Team conclude that sufficient evidence of localised prostate cancer was apparent from the time of presentation. A correct course of action would have been to arrange appropriate staging scans and biopsies. Service User B should have undergone investigation with a MRI scan of the prostate and pelvis and a bone scan should have been considered. A transrectal biopsy performed either at the time of the TURP or separately, would have secured the diagnosis.

Arrangement could then have been made to start conventional Androgen Deprivation Therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (EBRT) potentially with radical intent. However, the patient was apparently lost to follow up after his appointment in July 2019.

Service User C

Service User C was referred to urology service following a visit to ED in December 2018. He was reviewed promptly by Dr 1 in January 2019. Investigations were arranged and a diagnosis of a large right-sided renal carcinoma was made. He was counselled regarding the risks and benefits of surgical intervention and chose to proceed with the high-risk surgery.

On 6 March 2019 Service User C was admitted for an elective radical nephrectomy. The procedure was undertaken as planned and he was transferred to the intensive care unit (ICU) to support his blood pressure. He was later transferred to the ward. He developed a bacteraemia (infection) which was successfully managed with the advice of the microbiology team. Follow up CT scans were performed in June with a planned follow up in July 2019. This did not happen. Service User C was admitted to Ward 3 North following an ED admission. He was reviewed again via telephone in November

5.0 DESCRIPTION OF INCIDENT/CASE
2019 by Dr 1 who arranged for a repeat CT scan to be performed on 17 December 2019 with a plan for review in January 2020. This did not happen. The CT scan report was available on 11 January 2020 which showed a possible sclerotic metastasis in a vertebral body which had not been present on the previous CT scans. This report was not actioned until July 2020 when a new consultant reviewed the care. Service User C was subsequently diagnosed with prostate cancer. The Review Team find that the treatment and care in relation to management of the renal tumour was of a high standard. High-risk surgery was performed successfully following informed consent as to the risks and benefits of the surgery. A urology review was planned for July 2019 following the CT scan report in June but this didn't happen. Service User C appeared to be lost to review. The scan performed in December 2019 with a plan to review in January was not actioned and the plan for review did not happen. This resulted in a delay of 6 months in diagnosis of a prostate cancer from the scan result. This would be approximately a delay of 18 months from his first presentation in ED in November 2018. Service User D Service User D attended ED on 24 December 2018 with retention of urine. A urinary catheter was inserted, and a urology consultant review was planned to coincide with a trial removal of catheter with a specialist nurse. Service User D was placed on the waiting list for a TURP. A normal PSA result (2.79 ng/l) was noted. On 19 June 2019 Service User D underwent a TURP. The procedure notes describe the prostate tissue as having "endoscopic appearances of prostatic carcinoma". Histology confirmed adenocarcinoma (Gleason score 5+5) in 90% of the resected tissue. His case was discussed at MDM on 25 July 2019 who noted there was no evidence of metastases on a CT abdomen and pelvis. It recommended a CT scan of chest and a bone scan to check for spread outside the prostate. Further, a LHRH agonist as ADT should be commenced. In August 2019 a bone scan and CT scan were requested together with an ultrasound scan of the urinary tract to assess bladder emptying. Doctor 1 prescribed Bicalutamide (50mgs once daily), in order to 'assess its tolerability in a generally frail man' and in the 'light of the low presenting PSA'. The Review Team could not locate any record in the medical notes of a digital rectal examination being performed at any point during this patient's medical treatment. This may well have provided evidence to support the malignant nature of the prostate gland prompting a swifter biopsy. The patient was discussed at MDM on 25 July 2019 when the recommendation for ADT (a LHRH analogue) was made. He should have been started on this hormonal therapy to achieve "castration testosterone levels" as soon as the diagnosis of poorly differentiated prostate cancer was made. Instead he was started on an inadequate dose of a drug (bicalutamide) which was not licensed for the treatment of prostate cancer and was contrary to the recommendations at MDM. This therapy was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (2016) which were signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Team, as their standard of care for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional

5.0 DESCRIPTION OF INCIDENT/CASE

chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. There was no evidence in the medical notes or from speaking with Service User D's family of informed consent to this alternative care pathway.

Service User D should have been referred to an oncologist to at least allow consideration of other treatment options. His care was not coordinated with the palliative care team. The diagnosis of possible metastasis which would not have changed best practice was nevertheless pursued in a dilatory fashion. The Review Team suggested that when the patient developed anaemia consideration should have been given to the possibility of this being due to malignant involvement of the bone marrow, rather than an effect of severe chronic disease.

The Review Team noted that Service User D's case was not brought back to MDM for rediscussion and multi-disciplinary input despite disease progression.

Service User E

Service User E was diagnosed with testicular cancer. His case was discussed at MDM.He attended for CT chest, abdomen and pelvis on 9 July 2019 which indicated no evidence of metastases (cancer spread). The following day the patient had a left inguinal orchidectomy (removal of left testicle and full spermatic cord) carried out. Pathology of the resection specimen found that the tumour was a classical seminoma measuring 2.6cm across. Although the tumour was confined to the testes, it did involve the rete testis (exit tubules from the testis) and , in addition, intratubular germ cell neoplasia was seen. These findings indicate an increased risk of spread. Service User E's case was discussed at the Urology MDM on 25 July 2019. The plan was for Doctor 1 to review the patient in outpatients and refer him to oncology.

The patient was reviewed on 23 August 2019 and it was noted that Servicer User E had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that he would be reviewed in SWAH again in February 2020 by Doctor 1 to determine if the patient wished to have a testicular prosthesis implanted. The referral to oncology was made on 25 September 2019.

Although, this presentation was unusual, the progress of the patient's investigation and treatment up to the orchidectomy was of a high standard. However, the 2 month delay in his referral to a Medical Oncologist complicated treatment choices. Whether this will compromise the long-term outcome is uncertain as this treatment is recommended to be given within 6 weeks as per the designated protocol.[1,2,3]

The Review Team acknowledge that there is limited oncology presence within the Urology MDT and the date when the patient's case was discussed there was no oncologist present.

The vast majority of the Urology MDMs within the Southern Trust are non-quorate due to the absence of an oncologist and does not meet the existing guidelines. (0% quorate for 2019).

Whilst it was the primary responsibility for the consultant in charge to make the referral to oncology a failsafe mechanism to ensure agreed actions took place, such

5.0 DESCRIPTION OF INCIDENT/CASE

as an MDM administration tracker, was not in place.

Alternatively, the allocation of a Urology Cancer Specialist Nurse as a Key Worker would have supported the patient on his journey as well as having ensured key actions had taken place. Service User E was not referred to a Urology Cancer Nurse Specialist nor was any contact details provided to him. The MDM guidelines indicate "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner"[(4)]. This did not happen. A Key Worker/ Urology Cancer Nurse Specialist would have prompted the oncology referral sooner.

Service User F

Service User F presented with possible prostate cancer and was commenced on bicalutamide 50mgs indefinitely or until biopsy results were available. The diagnosis of prostate cancer was confirmed by biopsy in July 2019. The patient was discussed at the MDM on 8 August 2020. The diagnosis of intermediate-risk organ confined prostate cancer was agreed. The plan was that Doctor 1 should review the patient and discuss management by surveillance or by active treatment with curative intent.

When Service User F was reviewed by a locum consultant in October 2020 the patient did not recall any conversation about the options of external beam radiotherapy (EBRT) as a radical treatment and Active Surveillance. A Urology Cancer Nurse Specialist was appointed as the Key Worker at this review, not having one at time of diagnosis.

Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment. Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer.

The presence of a Urology Cancer Nurse Specialist would support the patient on his journey as well as working collaboratively with the multidisaplinary team to ensure key actions had taken place. Service User F was not referred to a Cancer Nurse Specialist. This is in contrast to declaration for Cancer Peer Review 2017 "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner" [(4)]. This did not happen.

Service User G

Service User G was diagnosed in June 2016 with a renal mass measuring 2.5 cms in diameter on the anteromedial cortex of the lower pole of the left kidney. The case was presented to MDM in July 2016, and the recommendation was for active surveillance with interval CT scans. These were carried out at the scheduled times.

On 23 August 2018 his case was discussed at MDM. The July 2018 scan was reviewed and now showed the lesion to measure 3.0cm. The MDM recommended to review and discuss with the patient the options of continuing active surveillance or

5.0 DESCRIPTION OF INCIDENT/CASE

open partial nephrectomy. The case was to be discussed at the Regional Small Masses MDM.

On 28 March 2019 at MDM the renal mass was noted to be enlarging. A further recommendation for Dr 1 to discuss the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risks was made.

On 29 March 2019 the patient was reviewed by a Locum Consultant Urologist. It was noted that the patient had a 3.1cms left sided kidney mass since July 2018 and this mass was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 13 November 2019 a CT scan was performed which showed a further increase in size of lesion to 3.5 cms. No action was taken.

The overall progress of this patient's management was, on balance, acceptable even though the result of the November 2019 CT scan was not acted on.

The Regional Small Renal Mass MDM was developed to oversee the management of this group of patients. An appropriate referral to this group was omitted, despite the MDM's recommendation on at least two occasions.

The patient was reviewed in 29 March 2019 by locum consultant who appears not to have had an update from the MDM held on 28 March 2019.

The patient underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021 Dr. 5 reviewed Service User G. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

Service User H

Service User H was diagnosed with penile cancer. The pathology confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease, at presentation and subsequently.

The MDM was a virtual meeting conducted by a single urologist. Its plan was that Doctor 2 would review the patient and arrange for a CT scan of the Service User's chest, abdomen and pelvis to complete staging. The CT scan (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no evidence of metastatic disease.

At the MDM of 12 September 2019 it was agreed that the Service User H should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Service User H to a supra-regional penile cancer MDT.

The Review Team found that the MDM recommendations did not follow NICE

5.0 DESCRIPTION OF INCIDENT/CASE

guidance for the management of penile cancer [6,7,8] and that there was an opportunity at each meeting to intervene and question Service User H's management.

The treatment provided to this patient was contrary to the NICAN Urology Cancer Clinical Guidelines (2016) for Penile Cancer where it states that local care is restricted to diagnosis. This Guidance was adopted by the SHSCT Urology MDT and evidenced by them as their protocols for cancer peer review 2017. Dr 1 was chair of the NICAN Urology Tumour Speciality Group when the guidance was issued.

The initial clinical assessment of Service User H would have benefited from staging imaging either before or immediately after the original circumcision. All cases of penile cancer should be discussed by the supra-network MDT as soon as the diagnosis is confirmed by biopsy.

The clinical stage G2 pT1 should have led to a consideration of surgical staging with either a bilateral inguinal lymph node dissection (ILND) or sentinel node biopsy (SNB). This omission reduced the likelihood of Service User H's 5 year survival from 90% to less than 40%. The left ILND yielded only 5 nodes, which might be considered at the lower limit of that expected in experienced hands.

The consent form signed by the surgeon and patient is inadequate as it does not state the rationale for the procedure nor the potential complications. The timings between the steps in treatment and management were unduly long and failed to the show the urgency needed to manage penile cancer.

Service User I

Service User I was seen on 27 October 2014 with lower urinary tract symptoms that continued despite medical treatment. Doctor 1 discussed options with Service User I and he decided to proceed to surgery (TURP).

A letter dated 11 November 2016 Service User I's General Practitioner asked for Service User I TURP to be expedited.

The Patient underwent TURP on 29 January 20 and histology confirmed prostatic adenocarcinoma.

Collation of Multidisciplinary meetings should have a fail-safe whereby lists of all urological cancers by site and SNOMED code are generated weekly. This system was not in place.

Although Doctor 1 planned to review the patient in April 2020, he was not seen until August 2020 at an appointment arranged by another doctor who has continued care. The patient had done well following his TURP. The histology was explained as an incidental finding that required continuing surveillance with an up to date serum PSA level and a prostate MRI scan.

Service User I was informed on 9 September 2020 that the serum PSA level was within the normal range and that the MRI scan did not show any features of prostate cancer. The prostate cancer was considered unlikely to represent a threat during the patient's life expectancy and would not be anticipated to require any treatment other

5.0 DESCRIPTION OF INCIDENT/CASE
than surveillance with PSA monitoring.

6.0 FINDINGS

Diagnosis and Staging

- 5 of the 9 patients in this review experienced significant delay in diagnosis of their cancer. This was related to patients with prostate cancer and reflected variable adherence to regionally agreed prostate cancer diagnostic pathways, NIACN Urology Cancer Clinical Guidelines (2016).
- Service User B had a delay of over 15 months from presentation.
- The review team could not find evidence of a Digital Rectal Examination in the notes of Patient 4 - potentially missing an opportunity to detect his high grade cancer earlier in his pathway.
- Service User F had a slow initial diagnostic pathway which was outside expected cancer care time-frames.
- Service User C had a delayed diagnosis of a metastatic prostate cancer following successful treatment of Renal Cancer. This was due to non-action on a follow-up CT scan report.
- Patient I had a delayed diagnosis of Prostate cancer due to non-action on a histopathology report at TURP.
- Patient H with penile cancer had a 5 week wait between referral and first appointment. Subsequent time to diagnosis and MDM were appropriate. He had a 17 week wait for a CT scan for staging.
- Service User G was on a renal mass surveillance programme - a recommendation at MDM to discuss his case with the regional small renal lesion team was not actioned and it is not known if they would have suggested earlier intervention.

Targets

- Three of the nine patients were said to have met one of their 31 / 62 day targets.
- Service User I was said to have met his diagnostic target for 31 days despite his tissue cancer diagnosis being missed and the patient suffering an 8 month delay.
- Service User H was said to have met his 62 day (1st treatment) target but had been referred down a pathway that did not meet the NICAN Urology Cancer Guidelines 2016. A regional Penile Cancer Pathway was agreed in January 2020.
- Service User B was said to have met his diagnostic target of 31 days despite having a delay from initial presentation of 15 months.

6.0 FINDINGS

Multidisciplinary Meeting

- The MDM made appropriate recommendations for 8 of the 9 patients but there was no mechanism to check actions were implemented - this included, further investigations, staging, treatment and appropriate onward referral.
- Dr 1 was present for the discussions and party to the recommendations, 8 of which were compliant with National and Regional Guidelines.
- In the case of the 5 patients with Prostate cancer, 5 patients were referred to the Multidisciplinary Meeting and had appropriate MDM recommendations.
- Service User A and Service User D to start Androgen Deprivation Therapy with LHRHa while Service User F was advised to have active surveillance or curative intent radiotherapy. None of these recommendations were implemented.
- NICAN Regional Hormone Therapy Guidelines for Prostate cancer 2016 were not followed.
- Service User B had a delayed diagnosis of prostate cancer and was belatedly seen at the Urology MDM 15 months after his first presentation. The recommendations from this MDM were correct but not implemented. Regional NICAN Hormone Therapy Guidelines for Prostate Cancer 2016 were not followed
- Service User I had an unexpected diagnosis of cancer at TURP. His diagnosis on pathology report was not actioned and he was discussed at MDM 8 months after his surgery and pathological diagnosis of cancer. His subsequent MDM recommendations were correct.
- Two patients had renal cancer. Service User C was initially appropriately discussed at MDM with action on recommendations. However a routine CT scan in December 2019 was not actioned, leading to a delayed re-presentation to MDM with a second primary diagnosis of metastatic prostate cancer.
- Service User G was on a surveillance pathway for a small renal lesion he was appropriately discussed at MDM. The meetings were not always quorate but a radiologist was present on 4 out of 5 occasions. An MDM recommendation to seek input from the regional small lesion group was not actioned.
- Service User E had a testicular tumour and was appropriately discussed at MDM with the recommendation onward referral to the regional testicular oncology team. This recommendation was time critical but did not happen.
- Service User H was appropriately discussed at the local MDM at diagnostic stage. Unfortunately his treatments and further discussions were restricted to local level and did not meet the NICAN Urology Cancer Guidelines 2016. Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.
- Collation of MDM lists did not include a fail-safe list from histopathology. This would ensure all tissue diagnoses of cancer were cross checked against clinician declared cases. This would capture unexpected cases of cancer as in case I or as in case B where a delayed diagnosis presented to the GI surgeons

6.0 FINDINGS

for initial biopsy.

- The patient's care was through a Multidisciplinary Team process but unfortunately they did not benefit from it. The Multidisciplinary Meeting failed in its primary purpose to ensure patients received best care as defined by Regional and National Guidelines.
- The Urology MDM was under resourced and frequently non quorate due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent Quality Assurance of images by a second radiologist prior to MDM.
- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31 and 62 day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care.
- Safe cancer patient care and pathway tracking is usually delivered by a three pronged approach of MDT tracking, Consultants and their Secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that these 9 patients were not referred to Specialist Nurses and contact telephone numbers were not given. Therefore the CNS were not given the opportunity to provide support and discharge duties to the 9 patients who suffered as as consequence. The MDM tracking system was limited. The consultant / secretary led process was variable and resulted in deficits. The weakness of the latter component was known from previous review.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non implementation of these MDM recommendations was unknown to others in the MDM. One patient D presented as an emergency and his care was changed to the MDM recommendation by another consultant.

Multidisciplinary working and referral

- The review team noted repeated failure to appropriately refer patients
- Service User A should have been referred to oncology initially and then to palliative care as his disease progressed.
- Service User B should have had an earlier diagnosis and referral to oncology.
- Service User D should have been referred to oncology and palliative care.
- Service User E should have been referred to oncology for time critical care.
- Service User F should have been referred to oncology.
- Service User G should have been referred to the Small Renal Mass Team.
- Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 but a

6.0	FINDINGS

Regnional Penile Cancer Pathway was only agreed in January 2020. Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.

- Patients were not aware that the care given varied from Regional Standards and MDM recommendations. They could not have given informed consent to this.
- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non referral was an unknown to others within the MDM.

Patient Support and Experience

All patients or families reported a positive experience with their treating consultant initially.

All patients and families were unaware of the additional support available to other patients.

Where patients had disease progression, they expressed concern at the disjointed nature of service provision and the inability to access supportive care. As they were unaware of the normal support mechanisms they believed this to be the normal standard of care or a standard that had been compromised by Covid 19 Pandemic.

All patients and their families were shocked by the fact that their care was not supported and that the care did not follow MDM recommendations. This was especially true when appropriate care should have entailed onward referral to oncology or palliative care.

Affects of Covid

- Some patient's planned review appointments did not go ahead but were rescheduled virtually. Some of the patients did not have their planned review in March / April 2020.

- The review team after speaking with the families and hearing their stories learned that for many of these patients they could not access services in their locality due to the covid restrictions. At the time two families described having difficulty accessing district nursing services for intravenous antibiotics in the community as services were stood down. One family expressed dismay at having difficulties visiting their loved one prior to his passing in hospital due to the covid restrictions and the emotional impact this has had on their grieving process. Others described how when catheters blocked they could not access

6.0	FINDINGS

support from their GP and where hence referred to the Emergency Department which the review team agree was not the best place for them. The review team are of the opinion that access to a specialist nurse could have offered support for these families and provide direction to the appropriate services.

Governance / Leadership

- The review team considered the treatment and care of 9 patients who were treated under the care of Dr 1 Consultant Urologist. Individual reviews were conducted on each patient. The review team identified a number of recurrent themes following each review.
- The treatment provided to 8 out of 9 patients was contrary to the NICAN Urology Cancer Clinical Guidelines (2016). This Guidance was adopted by the Southern Health and Social Care Trust Urology Multidisciplinary Team and evidenced by them as their protocols for Cancer Peer review (2017). The Guidance was issued following Dr.1 & Chairmanship of the Northern Ireland Cancer Network Urology Cancer Clinical Reference Group.
- The Urology MDM made recommendations that were deemed appropriate in 8 of 9 cases and were made with contribution and knowledge of Dr.1. Many of the recommendations were not actioned or alternative therapies given. There was no system to track if recommendations were appropriately completed.
- The MDT guidelines indicate “all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner”. None of the 9 patients had access to a Key Worker or Cancer Nurse Specialist. The use of a CNS is common for all other urologists in the SHSCT urology multidisciplinary team allowing any questions or concerns that patients’ have to be addressed. This did not happen.
- The review team considered if this was endemic within the Multidisciplinary Team and concluded that it was not. Patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.
- Statements to Urology Cancer Peer Review (2017) indicated that all patients had access to a Key worker / Urology Cancer Nurse Specialist. This was not the case and was known to be so.
- The Urology Cancer Nurse Specialist play an integral role of the MDT and should be facilitated on all the MDM to advocate on patient’s best interest throughout the patient’s journey. This should include independently referring and discussing patients at MDT.
- The Review Team regard absence of Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and the Professional Leads. The Review team have heard differing reports around escalation of this issue but are clear that patients suffered significant deficit because of non inclusion of nurses in their care. While this is the primary responsibility of the referring consultant, there is a responsibility on the SHSCT

6.0 FINDINGS

to know about the issue and address it.

- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered.
- Because of resource, the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31 and 62 day targets. Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were,in essence absent. A collaborative approach did not appear to be actively encouraged within the MDT.
- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM, but did not escalate other issues.
- The Review team found that issues around prescribing and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.
- The Review team were concerned that the leadership roles focused on service delivery while having a limited process to benchmark quality, identify deficiencies and escalate concerns as appropriate. Senior managers and clinical leaders in medicine and nursing were unaware of the issues detailed in this report.
- There had been a previous SAI signed off in May 2020 regarding adherence to Cancer Red Flag referral Pathways. The SAI process started in July 2016. The review team is concerned that, as part of early learning, assurances regarding other aspects of the cancer pathway were not sought. Clinical Leadership within Cancer Services were unaware of issues leading to the SAI in 2016.
- Patients in this review were not referred back appropriately to MDM as their diseased progressed. This meant there was no access to oncology and palliative care for many patients, when needed. Care needs within the community were unmet and patients left isolated.

7.0 CONCLUSIONS

The Review Team would like to thank the patients and their families for their contribution to the report and their willingness to share their experiences. The process was difficult and at times traumatic for them.The review team acknowledge that this report may cause distress to the patient and their families, however the team has endeavoured to produce a complete and transparent account of each patient's journey.

The Review of nine patients has detailed significant healthcare deficits while under the care of one individual in a system. The learning and recommendations are focused on improving systems of multidisciplinary care and it's governance. It is designed to deliver what was asked of the Review Team by patients and families -" *to ensure that this does not happen again or that another patient suffers".*

The Patients in this review received uni-professional care despite a multidisciplinary resource being available to all others. Best Practice Guidance was not followed and recommendations from MDM were frequently not implemented or alternative treatments chosen. There was knowledge of that prescribing practice varied from regional and national guidelines in the Southern Health and Social care Trust, as well as more widely across the Cancer Network. This was challenged locally and regionally, but not effectively, to provide safe care for all patients. Inappropriate non referral of patients to oncology and palliative care was unknown.

The primary duty of all doctors, nurses and healthcare professionals is for the care and safety of patients. Whatever their role, they must raise and act on concerns about patient safety. This did not happen over a period of years resulting in MDM recommendations not being actioned, off guidance therapy being given and patients not being appropriately referred to specialists for care. Patients were unaware that their care varied form recommendations and guidance. They could not and did not give informed consent to this.

The systems of governance within the Urology SHSCT Cancer Services were ineffective and did not provide assurance regarding the care and experience of the nine patients in the review. Assurance audits were limited, did not represent whole patient journey and did not focus on areas of known concern. Assurances given to Peer review were not based on systematic audit of care given by all.

While it is of little solace to the patients and families in this review, The Review team sought and received assurances that care provided to others adhered to recommendations on MDM and Regional / National Guidance.

Four of the nine patients suffered serious and significant deficits in their care. All patients had sub-optimal care that varied from regional and national guidelines.

As part of the Serious Adverse Incident process, the Review Team had requested input fromDr 1. This related to the timelines of care, for the nine patients involved in the SAI reviews and specifically formed part of the root cause analysis. This fell under professional requirements to contribute to and comply with systems to protect patients and to respond to risks to safety. To date a response has not been received.

8.0 LESSONS LEARNED

The review identified Cancer Care given by Dr 1 that did not follow agreed MDM recommendations nor follow regional or national best practice guidance. It was care given without other input from Cancer Specialist Nurses, Oncology and palliative care. It was inappropriate, did not meet patient need and was the antithesis of quality multidisciplinary cancer care.

Ensure all patients receive appropriately supported high quality cancer care irrespective of the professional delivering care.

Ensure all cancer care is multidisciplinary and centred on patients physical and emotional need.

Have processes in place to provide assurances to patients and public that care meets these requirements.

That the role of the Multidisciplinary Meeting Chair is defined by a Job Description with specific reference to Governance, Safe Care and Quality Care. It should be resourced to provide this needed oversight.

9.0 RECOMMENDATIONS AND ACTION PLANNING

The recommendations represent an enhanced level of assurance. They are in response to findings from nine patients where Dr 1 did not adhere to agreed recommendations, varied from best practice guidance and did not involve other specialist appropriately in care. They are to address what was asked of the Review by families - "that this does not happen again".

Recommendation 1.

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients.

This will be achieved by - Urology Cancer Care delivered through a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis, treatment planning and completion and survivorship.

Timescale – Immediate and ongoing

Assurance - Comprehensive Pathway audit of all patients care and experience. This should be externally benchmarked within a year by Cancer Peer Review / External Service Review by Royal College.

Recommendation 2.

All patients receiving care from the SHSCT Urology Cancer Services should be appropriately supported and informed about their cancer care. This should meet the standards set out in Regional and National Guidance and meet the expectation of Cancer Peer Review.

9.0 RECOMMENDATIONS AND ACTION PLANNING

This will be achieved by - Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent.

Timescale - Immediate and ongoing

Assurance - Comprehensive Cancer Pathway audit and Patient experience.

Recommendation 3.

TheSHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely.

This will be achieved by - Ensuring a culture primarily focused on patient safety and respect for the opinions of all members in a collatorative and equal culture. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical Cancer Services oversight monthly agenda. There must be action on issues escalated.

Timescale – Immediate and ongoing

Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, numbers of issues outstanding.

Recommendation 4.

The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.

This will be achieved by - All MDMs being quorate with professionals having appropriate time in job plans.This is not solely related to first diagnosis and treatment targets. Re-discussion of patients, as disease progresses is essential to facilitate best multidisciplinary decisions and onward referral (e.g. Oncology, Palliative care, Community Services).

Timescale - 3 months and ongoing

Assurance - Quorate meetings, sufficient radiology input to facilitate pre MDM QA of images - Cancer Patient pathway Audit - Audit of Recurrent MDM discussion - Onward referral audit of patients to Oncology / Palliative Care etc.

Recommendation 5.

The Southern Health and Social Care Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations / actions are completed.

This will be achieved by - Appropriate resourcing of the MDM tracking team to encompass a new role comprising whole pathway tracking, pathway audit and pathway assurance. This should be supported by a safety mechanisms from laboratory services and Clinical Nurse Specialists as Key Workers. A report should

9.0 RECOMMENDATIONS AND ACTION PLANNING

be generated weekly and made available to the MDT. The role should reflect the enhanced need for ongoing audit / assurance. It is essential that current limited clinical resource is focused on patient care.

Timescale - 3 months

Assurance - Comprehensive Cancer care Pathway audit - Exception Reporting and escalation

Recommendation 6.

The Southern Health and Social Care Trust must ensure that there is an appropriate Governance Structure supporting cancer care based on patient need, patient experience and patient outcomes.

This will be achieved by - Developing a proactive governance structure based on comprehensive ongoing Quality Assurance Audits of care pathways and patient experience for all. It should be proactive and supported by adequate resources.This should have an exception reporting process with discussion and potential escalation of deficits. It must be multidisciplinary to reflect the nature of cancer and work with other directorates.

Timescale - 3 months

Assurance - Cancer Pathway Audit outcomes with exception discussion and escalation. Data should be declared externally to Cancer Peer Review

Recommendation 7.

The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.

Timescale - 3 months

Recommendation 8.

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

This will be achieved by - Ensuring the multi-disciplinary team meeting is the primary forum in which the relative merits of all appropriate treatment options for the management of their disease can be discussed. As such, a clinician should either defer to the opinion of his / her peers or justify any variation through the patient's documented informed consent.

Timescale – Immediate and ongoing

Assurance - Variance from accepted Care Guidelines and MDM recommendations

should form part of Cancer Pathway audit. Exception reporting and escalation would only apply to cases without appropriate peer discussion.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 9.

The roles of the Clinical Lead Cancer Services and Associate Medical Director Cancer Services should be reviewed. The SHSCT must consider how these roles can redress Governance and Quality Assurance deficits identified within the report.

Timescale - 3 months

Recommendation 10.

The families working as "Experts by Experience" have agreed to support implementation of the recommendations by receiving updates on assurances at 3, 6 and 12 monthly intervals.

Recommendation 11

The Southern Health and Social Care Trust should consider if assurance mechanisms detailed above, should be applied to patients or a subset of patients retrospectively.

References:

1. Hoffmann, R., et al. Innovations in health care and mortality trends from five cancers in seven European countries between 1970 and 2005. Int J Public Health, 2014. 59: 341.

2. Oliver, R.T., et al. Radiotherapy versus single-dose carboplatin in adjuvant treatment of stage I seminoma: a randomised trial. Lancet, 2005. 366: 293.

3. Laguna M.P., et al EAU Guidelines: testicular cancer. https://uroweb.org/guideline/testicular-cancer/note_127-129 (accessed 26/02/2021)

4. Peer review Self-Assessment report for NICaN 2017

5. Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016)

6. EAU guidelines for penile cancer: section 6.2.1 (2019)

7. NICE improving outcomes in urological cancer (2002)

8. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).

9.0	RECOMMENDATIONS AND ACTION PLANNING

10.0	DISTRIBUTION LIST

Mr Shane Devlin – Chief Executive SHSCT

Mrs Melanie McClements – Director of Acute Services SHSCT

Dr Maria O'Kane – Medical Director SHSCT

Mrs Heather Trouton Executive Director of Nursing, Midwifery and AMPs

PHA

HSCB

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information redacted by the USI	**HSCB ref Number:**	Personal Information redacted by the USI

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**	
	Comment: ***If multiple service users involved please indicate the number involved***					
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**			
	If **YES**, insert **date informed**:					
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI					
	a) No contact or Next of Kin details or Unable to contact					
	b) Not applicable as this SAI is not 'patient/service user' related					
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user					
	d) Case involved suspected or actual abuse by family					
	e) Case identified as a result of review exercise					
	f) Case is environmental or infrastructure related with no harm to patient/service user					
	g) Other rationale					
	If you selected c), d), e), f) or g) above please provide further details:					
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**						
Content with rationale?	**YES**		**NO**			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**	x	**NO**	
	If **YES**, insert date informed: **all informed 26 October 2020**			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**d)** No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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APPENDIX 6

Revised November 2016 (Version 1.1)

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal information redacted by USI

Date of Incident/Event: January 2016 – September 2016

HSCB Unique Case Identifier: Personal information redacted by USI

Service User Details: (*complete where relevant*)

Responsible Lead Officer: Dr J R Johnston

Designation: Consultant Medical Advisor

Report Author: The Review Team

Date report signed off: 22 May 2020

Southern Health and Social Care Trust

1.0 EXECUTIVE SUMMARY

During an internal review in 2016, following an Index Case, the Trust identified a number of GP Urology referrals who were not triaged by one particular Consultant Urologist; 30 patients should have been red-flag referrals and of these 4 had cancer. A fifth patient (Patient 15), discovered during an outpatient clinic, was included as he was also not triaged and subsequently had a cancer confirmed.

Patient 15 – a Personal Information redacted by the -old male was referred to Urology Outpatients on 30 August 2015 for assessment and advice for an elevated Prostate specific antigen (PSA) (The blood level of PSA is often elevated in men with prostate cancer). The referral was marked Routine by the GP. The referral was not triaged on receipt. However, a second GP referral was received on 29 January 2016 marked Suspected Cancer Red Flag and had received a red flag appointment. Following this referral, he was seen in clinic on 8 February 2016 (D153). On day 166, Patient 15 was diagnosed with a confirmed cancer; a resultant 6-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 14 – a Personal Information redacted by the -old male was referred to Urology Outpatients on 3 June 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review, the referral was upgraded to Red Flag and was seen in clinic on day 246. On day 304, the patient had a confirmed cancer diagnosis. There has been a resultant 10-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 11 – a Personal Information redacted by the -old male was referred to Urology Outpatients on 28 July 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of an internal review the referral was upgraded to Red Flag and seen in clinic on day 217. On day 258, Patient 11 was diagnosed with a confirmed cancer; a resultant 9-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 13 – a Personal Information redacted by the -old male referred to Urology following an episode of haematuria on 28 July 2016. The referral was marked Routine by the GP. The letter was not triaged and Patient 13 was placed on a routine waiting list on 30 September 2016. As part of an internal review this patient's referral letter was upgraded to a Red Flag referral. Patient 13 was reviewed at OPD on 31January 2017. Subsequent investigations diagnosed with bladder and prostate cancer. Patient 13 has locally advanced bladder cancer. There has been a resultant 6-month significant delay in obtaining a diagnosis and a recommendation of treatment for his bladder cancer.

Patient 12 – a Personal Information redacted by the -old male was referred to Urology Outpatients on 8 Sept 2016 for assessment and advice on lower tract symptoms and elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review the referral was upgraded to Red Flag and was seen in clinic on day 152. On day 215, Patient 12 had a confirmed cancer diagnosis T3a with no nodal metastases. There has been a resultant 8-month delay in

obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Causal Factors

1. Referral letters did not have their clinical priority accurately assigned by the GP. Referral letters were not triaged following receipt by the Hospital.

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely

manner.

Recommendation 8
The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

Recommendation 9
Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10
The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with 'difficult colleagues' and 'difficult issues', ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11
Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12
Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

2.0 THE REVIEW TEAM

Dr J R Johnston - Consultant Medical Adviser - Chair

Mr M Haynes - Consultant Urologist

Mrs K Robinson - Booking & Contact Centre Manager

Mrs T Reid - Acute Clinical & Social Care Governance Coordinator

3.0 SAI REVIEW TERMS OF REFERENCE

1. To undertake an initial investigation/review of the care and treatment of patients "Patient 15", "Patient 13", "Patient 12", "Patient 14" and "Patient 11", in the period after referral to the SHSCT Urology service using

Southern Health and Social Care Trust

3.0 SAI REVIEW TERMS OF REFERENCE

National Patient Safety Agency root cause analysis methodology.

2. To determine whether there were any factors in the health & social care services interventions delivered or omitted to "Patient 15", "Patient 13", "Patient 12", "Patient 14" and "Patient 11" that resulted in an unnecessary delay in treatment and care.
3. The investigation / Review Team will provide a draft report for the Director of Acute Services. This report will include the outcome of the Team's investigation/review, identifying any lessons learned and setting out their agreed recommendations and actions to be considered by the Trust and others.
4. The Trust will share or disseminate the outcomes of the investigation/review with all relevant parties internally and externally including the service user and relevant family member(s) (where appropriate).

4.0 REVIEW METHODOLOGY

The Review Team will undertake an analysis of the information gathered using RCA tools and may make recommendations in order that sustainable solutions can minimise any recurrence of this type of incident. The Review Team will request, collate, analyse and make recommendations on such information as is relevant under its Terms of Reference in respect of the incident outlined above.

Gather and review all relevant information

- Inpatient notes Craigavon Hospital.
- Information from the Northern Ireland Emergency Care Record (NIECR) and Patient Administration System.
- Information from laboratory systems.
- Information obtained from relevant medical, nursing and management staff.
- Review of Relevant Reports, Procedures, Guidelines.

Information mapping

- Timeline analysis
- Change analysis for problem identification and prioritisation of care delivery problems and service delivery problems as well as identifying contributory factors.

5.0 DESCRIPTION OF INCIDENT/CASE

5.1 Triage of GP referrals - background

The general public expect that, when they engage with their GP complaining of symptoms that are potentially due to a cancer, they will be referred to the appropriate secondary care services promptly and that they will respond, also promptly, to confirm or exclude the diagnosis of cancer.

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5.0 DESCRIPTION OF INCIDENT/CASE

The DHSSPSNI **Service Framework for cancer prevention, treatment and care** (Standard 13) of 2011 indicates, "*All people with signs and symptoms that might suggest cancer should be appropriately assessed by their GP and referred promptly on to hospital for further tests if needed*".

Cancer specialists, working in networks, have formulated lists of symptom and sign triggers which can signify the development of a cancer. Using these lists, primary care doctors can refer patients into secondary care; triaging a large number of patients by assigning them to different degrees of urgency (Routine, Urgent and Red-flag). If these are used as designed, this can provide an efficient referral system.

NICE have been instrumental in ensuring uniformity and the validity of these cancer recognition and referral lists of symptoms and signs. They have also formulated guidance regarding how safety nets should be setup to ensure patients are not missed. Local programmes, using this type of guidance, have been established, under the auspices of NICaN and the HSCB, to set up these triage pathways and safety nets.

5.2 Triage of GP referrals – Northern Ireland

NI Referral Guidance for Suspected Cancer (2012)

The Northern Ireland Referral Guidance for Suspected Cancer 2012 is based on the NICE clinical guideline, CG 27 - *Referral guidelines for suspected cancer,* published in June 2005. This has a section on Urological Cancer. It was introduced to GPs by HSCB correspondence (30/12/2012), revealing the new red-flag process and indicating in appendix A that, "*triaging will take place in a timely manner, within 72 hours of receipt of referral or the referral should continue with the GP Prioritisation".*

This is still the only set of referral guidance for suspected urological cancer available online on the NICaN website (last accessed 18/11/2018).

However, the 2005 CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* published in June 2015. This was endorsed by the Department of Health (NI) with HSC (SQSD) (NICE NG12) 29/15 on the 19th August 2015 which instructed the HSCB / PHA to send out the guidance to the appropriate Family Practitioners. This particular kind of guidance requires the HSCB to circulate regionally endorsed NICE guidelines to Trusts and GPs for implementation. Trusts are expected to review guidance against a base line assessment and provide HSCB with an assurance that the guidance has been implemented. If a Trust is unable to fully implement the guidance within the one-year period without regional co-ordination and/or additional resources, they should provide a formal assurance to HSCB, and this is to be managed as part of the risk management process. This assurance process does not however apply to primary care and GP's.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

NICaN Urology Cancer Clinical Guideline (2016)

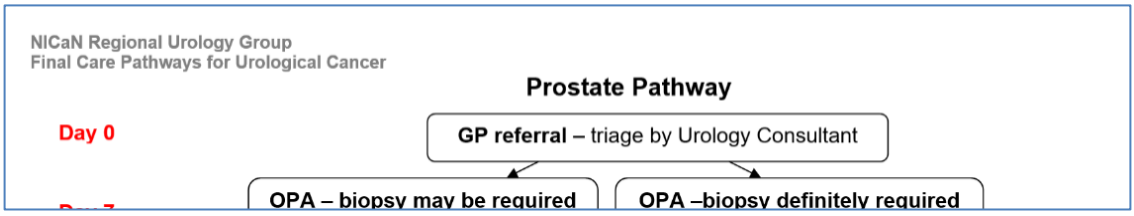
The NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016), was produced regionally to support the diagnosis, treatment and management of urological cancer. This version included amendments, to replace the previous red flag guidelines, with those from NICE NG12; the document was signed off on behalf of the NICaN by Consultant Urologist, Cons1.

The Review Team's evaluation of the advantages of NICE NG12 (2015) over the CG27 (2005) guidelines reveals fewer cases would be red-flagged for Urology, as a result of,

- a reduction in number of non-visible haematuria patients; and
- increases in age criteria of 45 years and over.

However, rollout of NG12 by the HSCB does not appear to have happened. The Review Team understands that the reason NG12 has not been implemented lies with ongoing discussions between the HSCB and GPs.

Appendix 2 of the NICaN Urology Cancer Clinical Guideline guidelines highlights the Urology Care pathways. Cons1 was present at the workshop discussing those on 02/10/2008. It clearly indicates that, for the Prostate pathway, the GP referral would be triaged by the Urology Consultant.



5.3 Triage of GP referrals – SHSCT

The process of Urology triage in CAH is based upon the NI Referral Guidance for Suspected Cancer of 2012 as described above i.e. it is based on the 2005 NICE CG27 guidelines and not the more up to date 2012 NG12. In CAH, triage of referrals is performed by the Consultant Urologist of the week.

The SHSCT Urological Cancer multi-disciplinary team (MDT) was led at the time by Consultant 1 (Cons1), who was also a joint chair.

Over a period of decades, within the SHSCT and Craigavon AH, there were occasions when triage was not performed; and this varied between consultants and specialities. Acute Services had a particular problem with this issue. Preliminary discussions by the Review Team revealed that triaging within Acute Services was a, "*very haphazard process going back for approximately 25 years. There were many Consultants who would not triage but Consultant 1 was the most persistent and there were multiple attempts to tackle this issue*".

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5.0 DESCRIPTION OF INCIDENT/CASE

Interview with Associate Medical Director (AMD1)

AMD1 first became aware of waiting list problems with Cons1 in 1996–8 when AMD1 was the lead clinician in outpatients. Cons1's OPD letters were being kept in a ring binder and were not on any waiting list. Once challenged, Cons1 would stop this practice and improve but would then slip back. There were further non-triage meetings with Cons1 when AMD1 was the Clinical Director of Surgery.

Interview with Director of Acute Services (DAS2)

In 2007, DAS2 (while in previous post in CAH) found a waiting list which was 10 years long. They worked on this with the Consultant, Cons1, and cleaned it up; they found no serious patient related issues.

Interview with Director of Acute Services (DAS1)

DAS1 indicated that the Urology Services were under various kinds of pressure during her time as Director. There was a regional transformation project in place for Regional Urology Services under Mr M. Fordham; this generated an element of pressure to modernise and change. Along with this and other issues, including the triage problem, Consultant 1 struggled to adapt to these changes and to comply with the other issues and triaging. DAS1 paints a picture of many issues with Cons1, triaging being only one of many issues but, in her opinion, not the most important issue.

Nevertheless, in April 2010, Consultant 1 (Cons1) was put under pressure to complete his triage list. The surgical Associate Medical Director (AMD1) brought concerns to DAS1. The other Urologists had been 'covering' triaging for Cons1; the Head of Service Surgery had informed AMD1 of this. They met Cons1 the next day. The European Association of Urology meeting was in Spain the following day and Cons1 wished to attend. DAS1 and AMD1 informed Cons1 he would not be attending the meeting unless he triaged all his referrals immediately. Cons1 duly addressed the triage backlog, completing them that evening. From that time on, AMD1 and the Head of Service (HoS1) monitored that Cons 1 was triaging the GP referral letters. However, DAS1 commented that the HoS1 had a difficult job managing Cons1.

Following interview with Head of Service (HoS1)

The Head of Service for Urology (HoS1) indicated that she inherited the problem upon appointment although she was aware that it was a long running issue, going back perhaps 25 years. She highlighted this was an ongoing issue with Cons1. He had the longest backlog and took longest to triage. There were issues with other Consultants who, on occasion, did not triage but Cons1 was the only one, when asked to triage, didn't do it. This came to head in 2010 (referred to above) and again in 2014.

Informal Default Triage (IDT) process

In May 2014, after escalation to HoS1, an Informal Default Triage (IDT) process was put in place by the Trust's booking centre. This process allowed the booking office to allocate

5.0 DESCRIPTION OF INCIDENT/CASE

patients, who had not been triaged in time, to be allocated to a 'waiting list' using the GP triage category. Therefore, this IDT process of putting patients on the waiting list without triage meant that they did not get missed. However, some patients, who should have been triaged as a red flag, waited on the waiting list with their 'incorrect' GP triage category. After much discussion, this detailed process was formally circulated to all specialties on the 6th November 2015 by the Assistant Director of Support Services (ADSS1).

When questioned about this IDT process, the DAS2 was not aware of it even though it started during her time in post i.e. May '14. When asked about its potential problem of leaving incorrectly triaged (by their GP) patients on a waiting list she stated, "*Completely ridiculous, because would allow a cancer patient who should have been red flagged by their GP to go unchallenged by a Consultant triage process i.e. could have to wait for 11 months*".

5.4 Index case

In 2016, the SHSC Trust investigated (RCA ID [redacted]), in what subsequently became an 'Index case' for the cases in this RCA, the treatment and care of [redacted]. [redacted] was a patient who had had Ca Colon (2010), breast carcinoma (2013) and then developed renal carcinoma. During review for her Breast Ca in June 2014, a CT Scan revealed that, previously noted, renal cysts had increased in size. Further investigation by a MRI scan was reported in a limited and incomplete fashion; resulting in a 'routine' referral GP letter on 29/10/2014.

During the investigation, the Review Team identified that [redacted]'s GP referral letter had not been triaged; the Consultant Urologist with responsibility that week for triage duties was Cons1. This referral therefore waited as a 'new routine' referral till January 2016 to be seen by a Consultant Urologist.

The index case Review Panel agreed 3 main contributing factors led directly to [redacted]'s delay in diagnosis. Firstly, the content of the MRI report; secondly a letter following a CT scan did not mention important information and thirdly, the opportunity to upgrade the referral to red flag was lost by the omission of triage; this resulted in a 64-week delay to diagnosis of a suspicious renal mass.

The index case Review Panel concluded in March 2017 that, ".... *a significant number of letters within Urology are not being triaged by the minority of the Team. It is clear that the default triage management process (*vide infra*) continues to be initiated secondary to the omission of Triage by individual members of the urology team and not the entire Urology Team*".

Of the 2 lessons learnt, one indicated that,

> "*Triage of GP referral letters remains a key element in validating appropriate utilisation of specialist services and ensuring patient safety. Triage also serves as an opportunity for early intervention for patients at risk of malignant disease or clinical deterioration*."

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This led to a recommendation that,

> "*This SAI has demonstrated that patients will be at an increased risk of harm when the opportunity for early intervention at Triage is omitted. The Review Panel recommend that the Trust reviews the process which enables the clinical triaging and escalation of triage non-compliance in accordance with the Integrated Elective Access Protocol (IEAP).*
>
> *In particular the fundamental issue of triaging GP referral letters remains a challenge within Urology. The Urology operational and medical management teams immediately need to address the issue of un-triaged referrals not being processed in accordance with IEAP.*"

The findings of this investigation, chaired by Consultant Urologist 2 (Cons2), were made available in December 2016 and formally signed off on the 15th March 2017. A letter highlighting a number of concerns was sent to the (then) lead for Acute Governance for Acute Services (AGAS1), on the 15th December 2016.

The letter pointed out that the IDT process implied that triage non-compliance was to be expected but that this process did not have a clear escalation plan to include the individual Consultant and, indeed, had not been effective in addressing triage non-compliance. Furthermore, the letter pointed out that, from July 2015 till October 2016, there were 318 non-triaged letters which the Trust could not provide assurance that patients were not being exposed to harm by waiting as a routine or urgent appointment i.e. when they should have been red-flagged.

It is not absolutely clear who wrote this letter as it has no signature, but it appears to have been written by, or on behalf of, Cons2. On the 10th January 2017, Cons2 was requested by the Medical Director (MD3) to share the report with the 2 key Consultants involved in the SAI. One of these was Cons1. Cons2 refused, stating that he was Cons1's colleague and not his manager.

This letter was escalated to the Director of Acute Services (DAS3) and the Assistant Director of Anaesthetics & Surgery. This was further escalated to the Chief Executive of the SHSCT.

Cons1 was written to by AMD1 on the 23rd March 2016, acknowledging his hard work as a Consultant Urologist but pointing out that there were governance and patient safety concerns with regard to untriaged letters dating back over 2 years, and other important issues. Cons1 was asked to respond with a commitment and immediate plan to address these issues.

The Review Panel also determined that there were 7 other patients who were not triaged that week along with Patient 10. They subsequently performed a 'look-back' exercise (number 1) of these referrals. Of the seven referrals, six charts were available and each patient had an appropriate

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management plan. One set of notes were missing and efforts were made to find them.

Cons1 provided his personal review, dated 25/01/2017, of the Index Case to the Chairman of this Review Team. It provides an argued retrospective rationale that a timely triage by himself would not have altered the referral grading. However, it does not provide a sound reason for his actual lack of triage. His report is consistent in arguing his view that he does not have time to perform both Consultant of the Week (CoW) duties and triaging of non-red flag referrals.

5.5 Look back exercise #2

Upon realisation that the 'look-back' exercise #1 had resulted from non-triage over the week beginning the 30/10/2014, further efforts were made to investigate the size of this non-triage issue and to find missing referral letters. Cons1 was contacted and the Head of Service for Urology (HoS1) obtained permission to look for missing GP referral letters in his filing cabinet. Cons1 stated that there were referral letters in a filing cabinet in his office. During interview, he stated that he kept the referrals to ensure they would not be missed or overlooked. The Head of Service for Urology retrieved these referral letters, which numbered over 700 along with the triage lists from the booking centre.

These referrals were then reviewed by the Urology Consultant Team revealing 30 patient referrals should have been red-flagged and four of these patients, following review, were diagnosed with cancer, becoming the subject of this review.

This (RCS Personal information redacted by USI Review Team reviewed the clinical notes from these 4 patients and following discussion, under the Urological guidance of AMD1, detailed the clinical course and made the following conclusions.

Patient 14 03/06/2016 - Personal Information redacted by the -old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
09/08/2016 - added to W/L Urgent.
27/01/2017, as part of the internal review #2, the referral was upgraded to R/F and was seen in clinic on day 246. Therefore, this was an incorrect GP referral.
05/04/2017 (D304), following U/S guided biopsy, the patient obtained a confirmed cancer diagnosis and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 10-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 11 28/07/2016 - Personal Information redacted by the -old male referred to Urology Outpatients by GP for assessment and advice, concerning elevated PSA.
The referral was marked Urgent by the GP.

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The referral was not triaged on receipt.
30/09/2016 - added to W/L Urgent.
18/01/2017 - as part of an internal review #2, upgraded to R/F. Therefore, this was an incorrect GP referral.
20/02/2017 (D207) seen at R/F appointment. Sent for MRI and prostate biopsy.
11/04/2017 (D258) - diagnosed with a confirmed low risk prostate cancer and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 9-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 13 28/07/2016 - Personal Information redacted by the -old male referred to Urology by GP following an episode of haematuria.
The referral was marked Routine by the GP.
The letter was not triaged.
30/09/2016 - Patient 13 was placed on a Routine waiting list.
19/01/2017 - As part of an internal review #2, upgraded to a R/F referral. Therefore, this was an incorrect GP referral.
31/01/2017 (188d) - reviewed at OPD and flexible cystoscopy.
22/02/2017 TURBT/TURP - diagnosed with bladder (locally advanced) and prostate cancer and there was a recommendation of treatment for his bladder cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is clinically significant; time will tell*.

* The Review Team referred to an expert for advice.
Delay in definitive surgical treatment beyond 12 weeks conferred an increased risk of disease-specific and all-cause mortality among subjects with stage II bladder cancer. He remains disease free as of September 2018.

1. John L. Gore, Julie Lai, Claude M. Setodji, Mark S. Litwin, Christopher S. Saigal, and the Urologic Diseases in America Project. Mortality increases when radical cystectomy is delayed more than 12 weeks. Results from a surveillance, epidemiology, and end results–Medicare analysis. Cancer March 1, 2009.
2. Nader M. Fahmy, Salaheddin Mahmud, Armen G. Aprikian. Delay in the surgical treatment of bladder cancer and survival: Systematic Review of the Literature. *European Urology 50 (2006) 1176–1182.*

Patient 12 08/09/2016 - Personal Information redacted by the -old male was referred to Urology Outpatients on for assessment and advice on lower tract symptoms and elevated PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
27/01/2017 – further GP letter – please upgrade to R/F.
30/01/2017 - as part of the internal review #2, upgraded to R/F.

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06/02/2017 - seen in clinic on day 152.
11/04/2017 (D215) - confirmed cancer diagnosis T3a with no nodal metastases – high risk and there was a recommendation of treatment for a locally advanced non-metastatic prostate cancer.

Conclusions

Resultant 8-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is not clinically significant.

At a later date, towards the end of 2018, another patient came to the attention of the Review Team – Patient 15. This patient could also have been one of those found in Cons1 filing cabinet but appeared at an outpatient clinic before the outworking of the look back exercise #2. A Consultant Urologist realised in the clinic that this was also a Cons1 non-triaged patient who was incorrectly referred by their GP.

Patient 15 30/08/2015 - Personal Information redacted by the -old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Routine by the GP.
The referral was not triaged on receipt.
29/01/2016 2nd GP referral marked as Suspected Cancer – Red flag; Patient 15 was added to W/L R/F following this referral.
As part of the internal look back #2, the referral was noted.
Patient 15 had already received an appointment and was seen in clinic on day 153. Therefore, 1st GP referral was incorrect; the 2nd was a correct GP referral.
11/02/2016 (D166), following a prostate biopsy, the patient obtained a confirmed cancer diagnosis T3a and there was a recommendation for treatment of a prostate cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is felt that the delay is unlikely to be clinically significant.

7.0 CONCLUSIONS

The Review Team interviewed a number of Trust staff including Directors (past and present), an Assistant Director, Head of Service and an Associate Medical Director as part of the review process. These interviews, along with clinical documents and health records systems, have helped inform the conclusions by providing the evidence and also corroboration where there appeared to be differences of opinion.

The Review Team and everybody interviewed, including Cons1, provided affirmation that a timely, efficient triage system which checked the initial GP referral was very important to patients. Comments made when interviewees were asked about the importance of triage and where the process of triaging a potential cancer patient ranked alongside other issues such as probity, patient experience and performance, were consistent,

"Very significant". Very high up the list in terms of importance".
"It is fundamental people are seen in the appropriate time".
"Very important" ... "Important for the patient".
"Vital" ... "Very significant .. patients are often anxious and depend on the system to work".

Cons1 replied,

"It is a serious issue, very important"..... "Number one ranking in overall scheme of things"

The Review Team established that there were factors in HSC service delivery to the 5 patients under examination that resulted in an unnecessary delay in treatment and care. In 4 patients the delay was thought not to be clinically significant but in 1 (Patient 13) there probably was a significant delay.

Consideration of the causative factors to the patients' delays reveal,

- Referral letters did not have the clinical priority accurately assigned by the GP; and
- Referral letters were not triaged following receipt by the Hospital.

7.1 Referral letters did not have the clinical priority accurately assigned by the GP.

Contributory factors

Task Factors (policy and guidelines)
The Review Team reviewed the GP referrals regarding the five patients listed above. They concluded, as judged from the Northern Ireland Cancer Network (NICaN) Referral Guidance for Suspected Cancer (December 2012), that all five patients should have been referred to Urology by the GP's as red flag referrals (suspected cancer) i.e. incorrect triage.

Task Factors (decision aids)
The current decision aid for GPs is the NI Referral Guidance for Suspected Cancer 2012 based on NICE CG 27 *Referral guidelines for suspected cancer* published in June 2005. It is clear that Secondary care, in the form of Consultant Urologists, should triage these GP referrals; by doing so, 11% of GP referrals are changed (from Review Team member). It is also clear that Cons1 would have been in no doubt as to his responsibilities; he was intimately

involved in setting this standard and signed off the NICaN clinical guidelines.

However, it is clear this very important and critical triage safety net, work can be considered onerous and other electronic methods which GPs can use might be more efficient and help to reduce that load.

According the HoS1, most patient referrals by GPs to Trusts for outpatient appointments are now made through the electronic Clinical Communication Gateway (CCG). However, some paper referrals are still received. CCG is a digital referral system for Primary care which can contain referral criteria that meet NICE and NICaN guidance. This would enable appropriate clinical triaging of referrals to be performed as part of the selection of referral reasons and/or symptom description.

Using the electronic CCG pathway, some clinical specialties, such as gynaecology, have worked closely with the Public Health Authority to develop a better GP referral tool e.g. using 'banner guidance' (a specialty specific banner, listing symptoms and signs) which complies with NICE/NICaN guidance. This 'banner guidance' helps by directing clinicians to use the NICE/NICaN referral criteria which allow for timely and appropriate triage of patients to clinically appropriate appointment types. It is possible when red flag symptoms are chosen that an immediate alert could go to the Red Flag booking team, to allow the appointment booking process to begin immediately. However, currently, the referral criteria fields are optional i.e. not mandatory, so opening up the possibility that fields are not completed, leading to error and delay.

NICE NG12
The reference CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* but, despite being endorsed by the DHSSPSNI and accepted by the Regional Urologists, it has yet to be implemented. Its use as a triage standard should result in fewer red-flagged cases which should ease some of the pressure on waiting lists. Its adoption would take place in primary care and should form the basis of the electronic CCG referral tool.

There was a consistent medical staff view from the Review Team, the AMD1, and indeed Cons1, that GP's have a crucial and important responsibility in getting the referral criteria/urgency category correct. If the GP does not provide enough, or the correct information, the NI Electronic Care Record (NIECR) needs to be checked and that slows the whole triage process down. It was clear that the triage system works best when the initial GP referral is usually correct and the Secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

7.2 Referral letters were not triaged following receipt by the hospital.

Contributory factor

Task Factors (policy and guidelines)

The Integrated Elective Access Protocol (IEAP) (DHSSPS, April 2008) defines the roles and responsibilities of staff (in both primary and secondary care) when patients enter an elective care pathway. It states,

> '…*an Executive Director will take lead responsibility for ensuring all aspects of this Protocol are adhered to…. Patients will be treated on the basis of their clinical urgency with urgent patients seen and treated first*'.

The Principles for booking Cancer Pathway patients states,

> "Clinical *teams must ensure triage is undertaken daily, irrespective of leave, in order to initiate booking patients*".

and,

> "*Referrals will be received, registered within one working day and forwarded to Consultants for prioritisation*".

However, the IEAP states,

> *"…if clinical priority is not received from Consultants within 72 hours, processes should be in place to initiate booking of urgent patients according to the GP's classification of urgency".*

Following on from the IEAP of 2008, national and regional policies and guidelines, already referred to above, have been introduced which have outlined the detailed role of the Urology Consultant in triaging referrals that have come in from Primary care e.g.,

- Service Framework for cancer prevention, treatment and care (Standard 13) 2011;
- NI Referral Guidance for Suspected Cancer 2012; and
- NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016).

These have provided agreed lists of the critical symptomatology of Urological cancers and the roles and responsibilities of Primary and Secondary care staff in ensuring patients receive prompt recognition and treatment of their cancer.

Review of Adult Urology Services in Northern Ireland

In March 2009, a *Review of Adult Urology Services in Northern Ireland - A modernisation and investment plan* was published. Its External Advisor was Mr Mark Fordham. SHSCT Consultant Urologists were represented on the committee.

Recommendation 4 states, "*Trusts must review the process for internal Consultant to Consultant referrals to Urology to ensure that there are no undue delays in the system".* Consultants indicated that they would routinely upgrade a significant number of routine and urgent referrals (GP) to urgent or red flag. It was noted that the development of agreed referral guidelines/criteria for suspected Urological cancers was a priority piece of work for the recently formed NICaN Group. That work was led by Cons1; see page 6.

Section 3.31 of the report indicates that, "*Consultant Urologists unanimously consider that referral triage should be led by Consultants. With over 40% of referrals being cancer related*

(and with many not red flagged or marked urgent) they believe that they are best placed and skilled to undertake the triage process. They also believe that despite the volume of referrals, this is not a particularly time consuming process."

Contributory factor

Staff factor

It is obvious from reading the documents referred to above that Cons1 has been aware of developments in this field and, indeed has been party to the discussions and signed some of them off. Cons1 was chair of NICaN (Urology) and was involved in drafting the NICaN regional Urology guidance, and therefore was very familiar with the requirement to triage GP referrals.

Despite all of this, and even though Cons1 agreed that this triaging role was, "*very important*", …. it was, "*a very serious matter not to be minimised, very serious"* he stated he would not triage non-red flag referrals.

When asked, *"Does triage still need done?"* Cons1 answered*, "a procedure is needed to highlight when it needs done and who does it".* When further asked, *"Who was involved in SHSCT Urology service in setting up triage"?* Cons1 answered for urological cancer, "*I was the Lead"*.

He felt triage of referral letters was too time consuming and the amount of time spent on triage, in his opinion, rendered inpatient care unsafe. He highlighted that he had previously escalated his concerns about work load to management teams and medical directors.

In relation to triage, Cons1 stated, '*I would love if we had a Trust Urology agreement on the type of triage to be conducted*'. When it was pointed out that, "*Consultant colleagues did triage for you. How did they do it?"* He stated, "*It depends on how you do it"* ..... "*Not all do advanced / enhanced triage, they compromise. It is a spectrum"... "They have not done it in the detail I felt it needed for routine/urgent non-red flag case".*

When questioned further, regarding his way of organising his own work load, Cons1 stated, '*....yes I did it my way – I wasn't cognisant of being unbending, I am very particular*'.

Cons1 highlighted to the Review Team that he currently takes annual leave each Friday and spends the weekend triaging. He stated that it is impossible to be Urologist of the Week and triage referrals appropriately. He stated he still can't do triage and everything else. He stated, '*I do triage entirely in my own time to allow me to do it properly'*.

When asked about using the NIECR - Electronic Referral using the Clinical Communication Gateway (CCG) method, Cons1 stated found the new CCG triage system*, "Very, very good, I wish all information was available on ECR. It is less time consuming. ECR makes it easier to check information".*

The Review Team concluded that there was a serious inconsistency between the guideline

standard that a Consultant should triage GP referrals (which Cons1 helped to construct) along with his stated view of the crucial importance of triage and Cons1's actual practice.

Cons1's chosen method of triage was beyond what is required. His triage is the equivalent of a virtual clinic where he reviews NIECR and books investigations for patients. While the Review Team recognised this was a detailed triage process, they concluded that his prioritisation of work and attention to detail meant that some patients got a higher standard of triage/care, while, crucially, others were not triaged, leading to a potentially critical delay in assessment and treatment for those patients. Cons1 is aware of this.

The Review Team concluded that Cons1's prioritisation of work and attention to detail led to some patients receiving a high standard of care, while others ran the real risk of having a cancer diagnosis delayed till it was dangerously late.

Contributory factor

Work load/scheduling

In 2008, when the IEAP was published, there was a maximum waiting time of 9 weeks for a first Outpatient appointment. On 30th September 2016, there were 2012 patients on the routine Urology outpatient waiting list, with 597 patients showing as waiting 52 weeks and over. The longest waiting time was 554 days (80 weeks). Therefore, if patient referrals are incorrectly referred, or not triaged and continue to use the GP's classification of urgency, there will be a significant wait. Cons1 is aware of this reality.

The Review Team considered the Consultant of the Week (CoW) work load, including ward rounds, clinics, emergency theatre sessions as a contributory factor. Cons1 has consistently argued that he cannot triage non-red flag referrals and carry out the duties of the CoW. He has not indicated who else should carry out the triage duties. However, the Review Team note that the other Consultant Urologists were able to manage this work load and triage referral letters in a timely fashion, with other members of the consultant team also ordering investigations, providing treatment recommendations and adding patients directly to waiting lists, similar to outcomes achieved from Cons1's 'advanced triage'.

Contributory factor

Organisational

The Review Team concluded that the non-triage of Urology referrals by Cons1 has been an ongoing problem in the Trust for many years, possibly decades. While there were pockets of non-compliance by other Consultants, when escalated, compliance improved. However, the Review Team note that Cons1 consistently did not return triage information on referrals thus not allowing the appropriate prioritisation of appointments by clinical need.

Interviews with 2 previous and the current Director of Acute Services, AMD1 and the Head of Surgery Service have highlighted that on many occasions, over a prolonged period, attempts had been made by the Trust's officers to address Cons1's non-compliance with triage. These

attempts encompassed both direct face to face conversations which were often heated, correspondence and, as in 2010, study leave refusal until there was compliance. These interventions all resulted in a familiar pattern of response; temporary improvement in compliance with triage, followed by a return to non-compliance.

In 2014, due to continuing non-compliance, the Trust implemented an 'Informal' Default Triage Process to manage the referrals which were not being triaged and returned to the Booking Centre. The Review Team considered the intention of this process was to prevent any delay in patients being added to the waiting list. However, this meant the 'non-return of triage' was not individually addressed with the non-compliant clinicians. Furthermore, and most importantly, it allowed patients, who should have been red-flagged, to remain on a waiting list until review.

In 2014, the Director of Acute Service 2 (DAS2) discussed non-compliance with Cons1 and agreed that Cons1 would no longer triage referral letters. Cons1 was heavily involved with formulating the NICaN Urology guidelines at the time and was grateful to the extent that he thanked DAS2.This task was delegated to other Urology Consultants for a time. However, Cons1 does not recollect having to formally stop triage. At interview, DAS2 was not aware that he had resumed those duties; she remembered that their Cancer performance figures improved when Cons1 was not triaging.

Escalation within Organisation
At every interview, questions were asked whether Cons1's consistent and prolonged non-compliance with triaging was referred upwards to executive level i.e. the Medical Director and Chief Executive.

Director DAS1 considered that the problem was being managed at Service level, although as it was only one of a series of issues and considered to be a 'minor' one, it did not predominate at higher level meetings with the Medical Director (MD1); to the extent that he may not have been aware of it.

Director DAS2 considered that the problem was dealt with by agreeing with Cons1 to stop triaging. There were other issues that were flagged up to MD2, but she was not able to remember whether MD2 was made aware of the triage problem.

During DAS3's current tenure Executive members certainly knew; at CAH Oversight meeting level and at the time of the look back exercise #2 which ultimately led onto this SAI and RCA process. The Medical Director (MD3) was directly involved in the RCA process and the CEO was aware. At Trust Board level, it is thought that a non-Executive member was asked to examine the situation which would indicate that it had also reached that level.

Overall, the Review Team in considering whether there was a satisfactory escalation of this 'non-triage' issue have concluded that there was no evidence of consistent and proactive escalation of 'non-return of triage' either to the Medical Director or the Chief Executive until the look back exercise #2 basically forced the seriousness of the issue out into the open. Indeed,

they do not appear to have appreciated the importance of triage, certainly from the patient's perspective. The Trust's officers made efforts to address Cons1's non-triage over time but were consistently thwarted by Cons1's refusal to comply. The Trust failed to put systems, processes and fail safes in place to ensure Cons1's consistently triaged patient referrals until 2017.

Systems and processes have now been put in place so that the Head of Service for Urology reviews Cons1's compliance with triage. HoS1 will check all Urology triage on an adhoc basis but, with Cons1, she will check daily when he is the Consultant of the Week. Any non-compliance with returning referrals without triage is addressed immediately. However, this process is heavily dependent on HoS1 who, when she is on leave, often has to recover non-triaged cases upon her return.

8.0 LESSONS LEARNED

1. The clinical urgency category allocated by GPs to 30 patients referred to Urology were incorrect. The referrals using NICaN guidance should have been referred as a Red Flag. Four (plus 1) of these patients were subsequently shown to have cancer.

2. The process of triaging Urology cancer referrals from Primary Care to Secondary Care, under the direction of the HSCB, appears to be less efficient than it could be, bearing in mind that NICE NG12 guidance has not been adopted and electronic referral using CCG is not being used as efficiently as it could.

3. GP's are not mandated to provide HSCB with an assurance that they comply with the most up to date NICE or other guidelines. Therefore, HSCB are unaware of any risks consequent upon the non-compliance with NICE and other guidance within GP practices.

4. GP's are not mandated to refer patients using CCG clinical criteria banners; this can lead to error and delay.

5. There is no Regional or Trust guidance or policy on what is expected of clinicians when triaging referral letters. Triage of patient referrals is obviously viewed as extremely important but does not seem to be at an equivalent level of importance when ranked alongside other clinical governance issues. Despite being an evident problem for decades and requiring considerable time and effort to find a solution, it only really surfaced within the Trust after an Index case forced the situation out into the open.

6. Despite it being absolutely clear to Consultant 1 (based upon his close proximity to the development and signing off of regional guidance) of the consequences of non-triage, he did not routinely triage referral letters. The Review Team consider that Cons1's refusal to triage to a level similar to other clinicians, led to patients not being triaged,

and this resulted in delays in assessment and treatment. This may have harmed one patient.

7. Cons1 confirmed that despite the Trust reminding him of the requirement to triage, he did not consistently triage referrals. He argued that, due to time pressures, he felt he was unable to perform the duties of the Consultant of the Week and his triaging duties. He has highlighted those views to Trust operational and management teams over a number of years.

8. The Trust made efforts to address Cons1's non-triage over time. However, the Trust failed to put systems, processes and fail safes in place to ensure Cons1 consistently triaged patient referrals until 2017. However, this safeguarding process is heavily dependent on the Head of Service checking triage is completed when Cons1 is Consultant of the Week.

9. The Informal Default Triage process allows patients who should be red flagged to remain on a waiting list of routine or urgent cases.

10. From examining the triaging issue over the length of time it has existed, it is obvious that there is an unwillingness or inability within the medical hierarchy to tackle its 'difficult colleague' problem. The reasons behind this probably include not taking ownership of its own problems and poor support from senior medical management perhaps resulting in issues not being referred upwards.

Southern Health and Social Care Trust

9.0 RECOMMENDATIONS AND ACTION PLANNING

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely manner.

Recommendation 8

The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

Southern Health and Social Care Trust

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 9

Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10

The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with 'difficult colleagues' and 'difficult issues', ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11

Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12

Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

10.0 DISTRIBUTION LIST

In addition to the Review Team, the following.

Mr S Devlin, Chief Executive SHSCT.

Dr Maria O'Kane, Medical Director, SHSCT.

Mrs Melanie McClements Interim Director of Acute Services.

Health & Social Care Board (HSCB).

Chairs of Morbidity & Mortality Groups SHSCT.

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Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:	Personal Information redacted by USI	**HSCB Ref Number:**	Personal Information redacted by USI

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	✓	
	Comment: 5 ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**	✓	**NO**		
	If **YES**, insert **date informed**:19.2.18				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	✓
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			✓

Southern Health and Social Care Trust

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**)				
Content with rationale?	**YES**		**NO**	

SECTION 2 **INFORMING THE CORONERS OFFICE** **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**22.5.2020**

[1] *Service User or their nominated representative*

11 December 2020 **Our Ref:**

Private & Confidential

Dear Aidan

As you may be aware, I am the External Chair of the SAI processes into 9 patients who were previously under your care.

As part of the normal SAI process we have been carrying out interviews with all relevant members of staff who have been involved in these patients' care.
The interviews are based on the patient's journey and are aimed at identifying learning and making recommendations for future care. We are seeking to complete the staff interviews before Christmas in order to keep the timeframes of the review.

We would be keen to have your input into this process and would like to agree an appropriate time (in person/ zoom/ telephone).

Yours sincerely

Dermot

Dr Dermot Hughes
Chair of the SAI Panel

Dr Dermot F C Hughes MB BCH BAO FRCPath Dip Med Ed

SAI Urology Review

Meeting with Dr Shahid Tariq
Tuesday 29 December 2020 at 1:45pm

Attendees
Dr Dermot Hughes and Mrs Patricia Kingsnorth

Dermot Hughes (DH)
Shahid Tariq (ST)

Dr Hughes thanked Dr Tariq for facilitating the meeting. He explained the overview of the SAI review in relation to the themes identified during the review. He advised that the NICAN peer review adapted by the Regional group was signed off by the Trust. Mr OB signed off the peer review; however, he did not adhere to the recommendations and standards.

He advised that some of the issues were in relation to the patients not having access to a specialist nurse/ key worker. Therefore when the patient's condition deteriorated there was no referral back to MDT

DH asked did the MDT know that Mr OB was not adhering to guidelines or the recommendations from the MDT. He advised that there was challenge but questioned who was it escalated to?
ST – he was not aware of any concerns mentioned. Any clinical concerns would go through the speciality management structure route.

ST did advise in 2019 he set up a cancer strategic forum which would meet twice a year.
This was to bring together different tumour site specialities under one umbrella, to look at good practice and to identify the need for additional resources for them. They only had one meeting in 2019 and planned to meet in March 2020 but this was cancelled due to covid.

DH advised that some of the patients did not receive the appropriate drug therapy in relation to androgen deprivation therapy. Mr OB chose not to involve other professionals in the patients care. There are now 5 specialist nurses in post.

DH asked if the urology team asked for additional support. The specialist nurses were used by all the clinicians except one. The specialist nurse is a safety net for when things are missed. Do you know if there were any concerns raised by the specialist nurses?
ST – No. was not aware.

DH asked did the chair of the MDM have a pa in their job plan

ST advised that he believe they were given one PA but this would be for the MDT and their leadership to decide. He advised that the cancer service is responsible for cancer performance targets, tracking of patients on cancer pathways and to provide help and operational support to the tumour site teams if it is needed. Governance arrangements lay within the primary team management structure i.e. CD and AMD for the division.

DH acknowledged that people didn't realise the deficits of care as the absence of a key worker impacted on the patient's care.

ST advised that they were removed from that process because the primary team's leadership is responsible for governance arrangements.
DH asked was that appropriate?
ST advised that cancer service would like to strengthen its links with the tumour site specialities to be able to provide better support for them..

Dr Hughes thanked Dr Tariq for his input.

Connolly, Carly

From: Thompson, PatriciaA <Personal Information redacted by the USI>
Sent: 07 January 2021 16:46
To: Kingsnorth, Patricia
Cc: Dermot Hughes (Personal Information redacted by the USI)
Subject: RE: reports

Hello Patricia

Patient 8 had not been reviewed by AOB following his surgery. He was only made aware of his diagnosis when this was picked up and reviewed by another consultant in August in which a CNS was present at that appointment.

Patient 6 had not a CNS at the time of his diagnosis. When reviewed by Consultant 4 on 2nd October a CNS was present at that appointment and contact details were given to him.

Patients are advised to contact the Thorndale unit if they have any concerns or further questions. The CNS do follow up patients by telephone following cancer diagnosis. Patient 8 first contact with key worker/CNS was 14 months following his diagnosis.

Many Thanks

Patricia

From: Kingsnorth, Patricia
Sent: 06 January 2021 16:01
To: Thompson, PatriciaA
Cc: Dermot Hughes (Personal Information redacted by the USI)
Subject: RE: reports

Patricia apologies for the delay in responding. This is very helpful.
Many thanks
So to be clear.
Patient 8 did have a key worker as did Patient 6 and both were given contact details. Would the patient have chosen not to contact the key worker or does she/ he actively follow up the patients?

Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
Personal Information redacted by the USI / Personal Information redacted by the USI

From: Thompson, PatriciaA [Personal Information redacted by the USI]
Sent: 17 December 2020 08:26
To: Kingsnorth, Patricia
Subject: reports

Hi Patricia

I have attached some of the reports and added comments in bold red. Will forward other reports later

Patricia

SAI Urology Review

Discussion with Ronan Carroll (RC) AD for Surgical and Elective Care

Dr Dermot Hughes (DH) and Patricia Kingsnorth (PK)

Monday 18 January 2021 @ 13:45

Dr Hughes provided a summary of where we are regarding the SAI review and summarising the cases involved in the review. He explained that many of the patient's pathway did not follow the recommendations set out by the regional urology pathway. He explained that AOB was the Chair of the regional urology MDM up until 2016. He signed off the guidance for peer review in 2017 but did not adhere to the standards agreed.

DH described the issues regarding the lack of specialised nurse for AOB's patients and the impact this had on the patients and family when trying to access services. He advised that AOB use of ADT was highlighted by the oncologist in Belfast Trust who wrote to AOB to highlight issues. But this wasn't escalated further.

DH- asked how did AOB practice this way?

RC- believed everyone made excuses for AOB the consensus was that he was a very strong personality who could be spiteful and even vindictive. Many of the CNS were afraid of him. But RC was unaware that the CNS were excluded from seeing AOB's patients.

DH explained the SAI process that we are looking at the cancer pathway and benchmarking against the standards regarding diagnosis/ staging/ MDT. He explained that some of the patients were not referred on for palliative care when their disease progressed. AOB was referred to by one of his colleagues as a "holistic physician" who care for the patients in uni-professional manner, but really he was working outside of his scope of practice.

RC speculated about AOB that there was a sense of arrogance/ commanded respect almost "God like" when he walked the corridors.

RC said he wasn't aware of the issues identified by the SAI review and was quite shocked when the issues were identified by PK during the update of early learning from the SAI. He advised that the patients under the care of Mr OB were often elderly and held him in high esteem "the big doctor". He went on to say that staff appeared to be habitualised by AOB's behaviour, that they avoided challenge at MDT.

RC went on to describe a previous concern they had which was escalated to an SAI of a man who had a bladder tumour, his red flag referral was put in a drawer resulting in an extensive delay to review him. There was no remorse and AOB seemed to defer to everyone else's problem not his.

DH advised the language will be neutral describing what the standard of care should be and what it was. He advised that all the families found AOB to be very personable but his care fell below standard.

RC advised that AOB was known to be clinically sound and that any issues raised were regarding system and administration processes. He never thought of him as a poor surgeon. He wasn't aware there were any issues with drug prescription or failure to follow up or non-compliance with MDT recommendations.

DH advised the need for assurances through regular audits for all clinicians.

RC advised that the system is not resourced for re- referral to MDT.

DH said it should be and advised the cancer tracker's remit needs to be wider to include follow up of results and investigations.

DH thanked RC for assisting with the review.

Meeting with Mrs Heather Trouton Executive Director of Nursing SHSCT
Dr Dermot Hughes – Chair of SAI review

Note taker – Patricia Kingsnorth Acute Clinical Governance Coordinator

23 February 2021 at 13:30 via zoom

Patricia welcomed Mrs Trouton and introduced her to Dr Hughes and explained that he was chairing the SAI review and that he had some questions he needed clarification for.

Dr Hughes provided a summary of the urology review to date in relation to meeting 8 of the 9 the families twice and understanding their experiences of their care.

He explained that the main concern was around the patient's access to a cancer nurse specialist. None of the 9 patients received the services of a cancer nurse specialist and therefore they were not supported on their cancer journey which for some caused serious distress.

Dr Hughes explained that as part of the review the quality of care provided was not in question as patients did not receive any care.

He explained that the NICAN guidance recommended that every patient with a cancer diagnosis was provided support from a cancer nurse specialist. This assurance was provided to the peer review in 2017 that additional specialist nurses were resourced to provide this service. This was signed off by the chief executive. But the reality was that Mr OB patients were not given access to a specialist nurse. There were no checks and balances in the system to quality assure that this was happening.

Mrs Trouton advised that she was assistant director of Surgical and Elective Care until March 2016 when she moved to IMWH division. She advised that she was not in post when the NICAN guidance was implemented and could not comment on it. She advised that prior to leaving her post there were only two specialist nurses in post. One who was responsible for cystoscopy and one who was responsible for cancer care.

She went on to advise that as a Director of nursing she would expect any nurse to provide care in their professional role. Dr Hughes advised that he did not have an issue with the standard of care that the specialist nurses provided. His issue was that they did not receive any referrals from Mr O'Brien and therefore did not provide any care. Mrs Trouton asked if Dr Hughes thought that they should have sought referrals He replied that they should not but there should have been a system of checks and balances in place to ensure that Mr'OBrien's patients were being referred.

Dr Hughes advised that this was about the patients not getting access to a nurse and he wanted to understand how that could happen. He advised that this resulted in

severe deficits in the 9 patients' care. He said that all the families have asked how it had happened?

Mrs Trouton said that she had been very recently advised that all the information regarding accessing a specialist nurse and all the leaflets and phone numbers were visible in every consulting room to ensure doctors had the information to give to patients.
She recognised that the checking mechanism to ensure that the consultant was giving the information to the patient was not in place from the investigation findings.

Dr Hughes advised that he has asked the cancer clinical leads and AMDs who were not involved in the urology service but were unaware of any issues regarding specialist nurses not being made available to Mr OB's Patients. But he advised that they should have that oversight/ responsibility.

Mrs Trouton advised that the escalation process is clear for all nursing services. The specialist nurses should escalate to their lead nurse who will seek to address the issue in question. If they cannot resolve the issue, they will escalate to the HOS or AD (one of whom is a nurse) who will in their operational and nursing role seek to address the concern. If there is an issue requiring wider discussion, these issues are brought to the Acute Governance Nursing forum .If necessary the issue will be escalated to Mrs Trouton either directly by the Acute Senior Nurse or via her Assistant Director for nursing safety, quality and Experience. That way there is a clear line of sight between the operational nursing/ midwifery team and the corporate nursing team.

The issue of specialist nurse referrals was never escalated to Mrs Trouton.

Dr Hughes wanted to know if anyone knew about it and how was it not escalated and did anyone consider the consequences to the patients?
He advised that the concerns around the doctor over looked the patients' experience. He advised that the mechanisms in place to provide governance were not fit for purpose.

Dr Hughes advised that he spent two days talking to families and advising that the resources for specialist nurse was in place but they or their loved one didn't get access to one. All the patients/ families wanted to know how this was allowed to happen.

Dr Hughes advised that 8 out of the 9 patients had very appropriate recommendations from the MDM but these were not actioned by the consultant in charge of care. Patients were not forwarded for specialist care, and none of them had access to a specialist nurse or were even provided with a phone number.

Mrs Trouton advised that the governance process has been in place a long time and is a clear process but it needs utilised.

Dr Hughes advised that it not just about nurse to nurse or consultant to consultant escalation. But, he advised that there is an opportunity for the MDT to address the

deficits. He advised the MDT needs to provide safeguards to ensure that guidance is being adhered to. He reiterated that patients have come to harm.

Dr Hughes clarified that Mr OB provided uni-professional care in a multi professional environment. He advised that the right thing wasn't done. He acknowledged that the MDT needs better resourced to ensure that assurance audits are carried out to provide data to show how compliance with guidance was maintained. He advised there will be reputational damage to the trust.

Mrs Trouton advised she will be interested going forward in having a checking mechanism in place for all areas of care.

Dr Hughes advised that there is a cultural problem in that seems to be professional focus and not patient focus. He advised that some people were reluctant to get involved with difficult situations. There was the not environment to raise concerns. He acknowledged that some professionals did escalate concerns.

Dr Hughes asked if Mrs Trouton had any questions. She declined.
He and Patricia thanked Mrs Trouton for taking the time to meet with them.

Southern Health and Social Care Trust

Acute Governance
Urology MDM
Thursday 18 February 2021 @ 12.30pm

PRESENT: **Mr Dr Dermot Hughes (Chair)**
Mrs Patricia Kingsnorth
Mr Michael Young
Mr Anthony Glackin
Jason Young
Jenny McMahon
Martina Corrigan
Kate O'Neill
Mr Mark Haynes
Mr Shawgi Omer
Roisin Farrell, note taker

Dr Hughes introduced himself to the meeting. He provided an update to the meeting. He advised he was asked to chair the Urology review in August. The review team have been working on the review from October 2020 and the draft report is expected to be ready for 28.2.2021. He has met with all 9 families once and is meeting with them between today and tomorrow (18 & 19 February 2021) for the second time and will meet with them for a third time to provide them with the draft report.
Cases in question were: 5 prostate cancers, 1 testicle cancer, 1 penile cancer and 2 renal cancers. He asked if anyone had any questions. – None. He advised in the instance of the prostate cancers there was no adherence to MDM and clinical guidelines of March 2016. Other issues of concern are the timeline for diagnosis, some delays and some were lost in the pathway to diagnosis and follow ups. He confirmed 3 patients have since died. Patient 4, Patient 1 and Patient 3 and other patients are not so well. Dr Hughes advised the group that the external urology reviewer is Mr Hugh Gilbert he was nominated by the professional body that gives professional advice.

Dr Hughes explained that the Cancer Nurse Specialist was excluded from these patients care. 9 patients didn't have the supporting link leading to a greater risk of failsafe measures to ensure pathway is adhere to. Dr Hughes said he was not sure why this happened and he doesn't know if all at MDM were aware. He has been told MrO'B didn't refer patients to Cancer Nurse Specialist. He said these patients needed someone to manage their pathway. He advised he believed MDM was not appropriately resourced leading to a resource deficit in the recommendations referring back to the peer review of 2017. He asked if there were any questions.

Mr Glackin advised he was chair of Urology MDM, he took over from MrO'B. He confirmed nurses were excluded from MrO'B's practice. He doesn't believe there is an issue with other doctors.

Dr Hughes confirmed has been speaking to nurses and will be putting recommendations into the report to reflect this. He is not sure why patients didn't have access to Cancer Nurse Specialist which has caused issues in the community.

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Mr Glackin highlighted there are only 5 Cancer Nurse Specialist covering the services over a number of hospitals.

Dr Hughes advised he thought at the start it was geographical but asked why patients were not given contact details. He advised this is one of the questions he has asked MrO'B. He was concerned there was no multi-disciplinary support for these patients.

Mr Glackin advised the issue surrounding resources of nurses has only improved in the last 2 years.

Dr Hughes highlighted that renal patients needed Cancer Nurse Specialist.

Mr Glackin suggested there was an issue with resources at MDM. He recalled his experience in the West Midlands where MDM was better resourced. The follow up and tracking was more robust, more a priority and had admin support. He advised there were weekly trackers who would liaise with consultants enabling them to meet their timelines. Adding here they are never able to meet timely care.

Dr Hughes agreed with Mr Glackins points. He questioned if the issue was systematic and a problem for more than the 9 cases, if so this would need to be addressed. He added the recommendations will be able to review this through the recommended audits.

Mr Glackin referred to the proposed audits and advised at present they would not have the time or resources.

Dr Hughes advised consultants should have been doing audits and agreed there was a need for more resources. He advised other concerns raised were the appropriate onward referral to other professionals, oncology etc from MDM. He feels MDM focused on first diagnosis.

Mr Glackin suggested this was more or less unique to MrO'B. He added that the MDM chair is rotated among colleagues.

Dr Hughes advised he had raised this with Mr Gilbert and was advised this was a common way of working and feels it is beneficial to rotate the chair, they can review cases in advance and identify where there is care deficit. He said when patients progress they are not being taken back to MDM leading to uni-professional care, causing a problem.
He also said there were issues around flutamide.

Mr Glackin advised this was discussed at MDM. He referred to the specific dose of 150mg and suggested the evidence was weak in the criticism in the use of this treatment and said the scientific evidence was not so robust.

Dr Hughes said he was taking advice from Mr Gilbert. He feels in these cases it was inappropriate and said it would have been more appropriate for onward referral to oncology.

Mr Glackin suggested that generally consultants give other treatments and feels if the review is referring to the use of flutamide this needs to be scientific and not opinion.

Dr Hughes referred to the 5 prostate cancers. 1 being coincidental, 1 was potential prostate that didn't get a diagnosis for 15 months.

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Mr Glackin suggested TURP's was not a good diagnosis for prostate cancer.

Dr Hughes asked if there were any issues of concern raised outside MDM.

Mr Glackin advised management were aware of no nurses.

Dr Hughes advised he had spoken to AD in CCS who was not aware of issues.

Mr Glackin advised they did bring issues of concern a number of years ago. Their reaction was a shrug of shoulders and said "what do you want us to do".

Dr Hughes said he noted staff at MDM was generally locums and that oncology were not attending.

Mr Glackin said he had suggested suspending the Trust MDM due to attendance.

Dr Hughes advised one of the recommendations would be to provide resources for MDM.

Mr Haynes – AMD. He believes there is an enormous disconnection between services and feels consultants are blamed when they fail but at the same time CCS will take credit when they succeed. He referred to occasions where at MDM meetings issues were bounced back to urology. He asked what they can do.

Dr Hughes advised he attended a meeting and was stunned to hear staff was aware of the issues. He feels it's hard for staff if they feel isolated. He added when the report is complete staff need to feel supported.

Mr Glackin said there was no input from outside of MDM, no support from CCS.

Dr Hughes agrees staff do need support and feels supported to raise concerns. He suggested these concerns need minuted and actions taken. He advised he was going through the process of meeting families which has been quite upsetting to patients and their families.
Dr Hughes asked the meeting if they wanted to meet again or if they wanted to raise concerns directly they could contact him.
He advised he has struggled a little regarding the governance, he feels staff were told to sort out themselves which is not appropriate especially when people are paid. He questioned if there was the same issues in breast screening.

Mr Haynes advised breast screening was under the same remit; the same team CCS and they meet their targets.

Dr Hughes advised 8 or 9 recommendations from MDM were appropriate.
One of the safety checks to oncology, if had oncology been attending patient could have got referred.

Mr Glackin advised they use Belfast MDM. He suggested he doesn't feel comfortable making referrals to oncology. He added this has all been minuted at a governance meeting.

Dr Hughes advised them they focusing on the 9 patients.

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Mr Glackin doesn't feel they are addressing any issues.

Dr Hughes suggested the trust needs a forum to address these issues.

Mr Glackin said their workload is another issue which needs to be recognised. He said they are "carrying more than their peers". Pressures causing risk with under resourcing of urologists and Cancer Nurse Specialist.

Dr Hughes agreed and asked to get data, he suggested if workload an issue causing underlying issues.

Mr Haynes advised here there is 1consultant per 90,000 of population, in England it is a lot lower.

Martina Corrigan advised the Western Trust has taken back their referrals from mid-September.

Mr Young advised the change in volume was only recently due to not being able to cope.

Dr Hughes advised he would share the draft report with MDM.

Kate O'Neill CNS advised she was astounded CNS had not been asked or been met with.

Martina Corrigan advised there was a meeting planned for Monday.

Dr Hughes said she had asked Patricia Thompson to speak with staff.

Kate O'Neill has only been made aware of meeting and thought it would have been formal.

Dr Hughes advised the issues were the absence of Cancer Nurse Specialist which was a deficit to the patients.

Kate O'Neill clarified it was not the fault of the nurses.

Dr Hughes agreed and advised when investigating the issues surrounding the Cancer Nurse Specialist he thought it was due to geographical but this was not the issue.

Martina Corrigan advised it was a fast process and the review team had to arrange to meet all the families involved. She advised both her and Patricia Kingsnorth liaised to arrange a meeting with Cancer Nurse Specialists.

Dr Hughes advised he needed to get the background of the cases before meeting with the Cancer Nurse Specialists. He apologised for the confusion and offered to chat more at the meeting arranged for Monday.

Jenny McMahon CNS said their role was central and provides a failsafe process that is benchmarked with other Trusts. She asked if other Trusts have the same issues as the Southern Trust.

Dr Hughes understands nurses meet patients with consultants or contact details are made available. He said one issue highlighted due to COVID was that patients were

going to their GP or ED because they wouldn't know what to do. He advised where he worked Specialist Nurses would refer patients to MDM this would give patients better access to care.

Jenny McMahon didn't think it was unique to one consultant and suggested it was a resource issue.

Dr Hughes said it may be an issue and suggested it needs investigated to see if this is the issue. He said they need to know if there is a deficit, adding if the Trust is saying best care for everybody they need to have the resources available.

Dr Hughes asked if they would like him to come back to update them on the progress. He advised he has no involvement in the independent enquiry.

Patricia Kingsnorth advised there was no criticism of Cancer Nurse Specialists; it highlights how important their role is.

Mr Glackin believes it is criticism of other consultants.

Patricia Kingsnorth said it's not criticism just an acknowledgment of urology being under resourced.

Dr Hughes advised he was writing the report based in evidence and the only criticism of the Clinical Lead and Associate Medical Director was not being aware. He added 8 of the 9 recommendations by MDM were fine, but added these recommendations were not actioned. Another issue was patients not being referred back to MDM. He doesn't know if MDM were aware.

Martina Corrigan asked Dr Hughes to clarify was the AD and AMD for CCS.

Dr Hughes confirmed it was for CCS. He said there was an issue, CCS didn't seem to know.

Mr Young said he recalled MrO'B appearing very keen to have Nurse Specialists and was very vocal.

Dr Hughes said MrO'B was chair of the group and was aware of the rationale behind the need for Nurse Specialist. He said there was a clear role for these nurses. He said he needed to clarify if the Nurse Specialist were available or if it was a decision to leave them out, adding patients should have been given a phone number.

Mr Glackin asked from the discussions has anything become apparent from the 9 cases.

Dr Hughes said he was reluctant to add anything into the report that is hearsay.

Mr Glackin clarified the question, is there any need for immediate action.

Dr Hughes said there was a need for enhanced tracking, more oncology input with assurance audits. These need to be put in place. He said if staff feels there is anything else needs to be put in place to let him know, he said the public need to have confidence. The review team need to be able to go back to families and show them it's not the way it was. He highlighted the need for resources. He said there is a need

to sort team resources. He apologised the Cancer Nurse Specialist and advised he was happy to share the comments about the Nurse Specialists.

Mr Shawgi Omer advised he was new to the team from July. He advised he was glad it was made very clear the central role of the Nurse Specialist and they were not criticised in any way. He hoped it was very clear the quality and quantity of the work was magnificent which relieved any anxiety he had at joining a new team.

Dr Hughes acknowledged it was a good point made and advised he would take it on board in the report.

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Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

Meeting with Mr Mark Haynes AMD SEC and Dr Dermot Hughes Chair of Urology SAI Panel
Note Taker- Mrs Patricia Kingsnorth
Via zoom
18 January 2021 at 11:00

Dr Hughes thanked Mr Haynes for meeting with him a briefly outlined the SAI review and the issues to date.
He advised that Mr OB did not work with specialist nurses and patients did not feel supported in terms of knowledge of their disease. The patients deteriorated in the community with lack of support. In relation to ADT, Dr Hughes advised Mr Haynes that after speaking with the oncologist in Belfast who had known about Mr OB practice for 17 years. . He advised that this practice was off guidance and that patients were treated without informed consent.
Mr OB ignored the recommendations of the MDT and did not bring patients back for discussion.
Dr Hughes asked were there any concerns raised about this practice.
Mr Haynes – advised that he was the person who raised the concerns. He had taken over from AOB as chair of the urology cancer group approx. 3 years ago.
Mr Haynes advised that he works in a different system. He works in a more team based approach with 3 consultants and 5 specialist nurses) Mr AOB worked as more individual. There was non-involvement with any other members of the team which meant that his practice was not scrutinised.
Mr Haynes advised there were a number of concerns about how AOB practiced. But was not acutely aware about his lack of conformities to standard treatments. The benefit from covid is that it encouraged shared working practices.

Dr Hughes advised that cancer care is benchmarked – there is an agreed level of care which is peer reviewed.
Mr Haynes advised that AOB didn't use other people to assist him with his role. He took everything on himself. All queries came to him.
Mr Haynes advised that the MDT did disagree with Mr AOB decision making regarding ADT. He recalled a disagreement with AOB in relation to his use of ADT for a patient he said that Mr AOB became entrenched in his decision making and he never accepted their challenges.

Mr Haynes explained the functions of their MDM. They have a rotating chair who will chair the meeting and represent urology input. They will prepare the week to week cases (40 patients) it's a clinical role. Those patients would have been reviewed. The main Chair has oversight and is responsible for peer review etc – Mr Glackin.

Mr Haynes advised that the challenges were that patients weren't brought back to MDT but there was no correspondence on NIECR, delayed letter writing which were put on NIECR retrospectively.

Dr Hughes advised that patients didn't get staging scans at appropriate times.
Mr Haynes said this was awful and he couldn't understand why that would be.

When asked what is a virtual MDT Mr Haynes advised when they can't run an MDT session either due to bank holiday or clinical audit day – rather than put the case on hold the chair would move patients on through the system to get the treatment and diagnostics to move the patient on to the pathway- MRI / biopsy etc. It would be protocol driven as opposed to discussion with a team. There would be no notes or minutes taken.

Dr Hughes advised about patient Patient 5 - that his haematuria symptoms in ED didn't include PSA. Mr Haynes advised that if the DRE was normal it would not prompt a PSA. There was a normal DRE finding.
Dr Hughes that his CT scan result wasn't actioned and 8 months delay is significant for a man of Personal Infor years.

Dr Hughes queried how patient Patient 2 was referred to oncology- was it Belfast who referred him or Mr OB. Mr Haynes advised that he emailed the oncologists and escalated to the regional MDT.
Dr Hughes wanted to know if Belfast raised a datix about the delay?

Dr Hughes advised that Patient 3 wasn't referred to the regional penile cancer service.

Some patients met their 31/62 day targets.

Dr Hughes said that there should have been oversight from the CD and AMD of cancer services. There needed to be assurance audits / no governance oversight.

Dr Hughes enquired if by raising these concerns Mr Haynes suffered any deficits from his team. He advised that he did not.
But advised that a concern for the team is that they will be criticised.
He advised that AOB was difficult to work with.
His practice would be to involve the CNS in his clinics to support patients and involved in the decision making process.

Mr OB did not involve the CNS- he had a different view of their work -

Dr Hughes thanked Mr Haynes for his time.

SAI Urology Review

Interview with Mrs Martina Corrigan (MC) Head of Service for Urology

18 January 2021 at 12 Midday via zoom

Dr Dermot Hughes (DH)and Patricia Kingsnorth

Dr Hughes provided Martina with an update to date – he advised that there are 9 families involved in the process and that there are similar themes; one being that Mr O' Brien worked in isolation despite MDT involvement and being the Chair of the MDT for a number of years. Martina confirmed that Mr O'Brien never involved a specialist nurse and had always been the case from she had started in the Trust.

Martina advised that she worked in SHSCT for 11 years, and confirmed that during that time Mr O'Brien never recognised the role of the Clinical Nurse Specialists. She confirmed that he never involved them in his oncology clinics. She is aware that some of the Clinical Nurse Specialists would have asked to be at the clinics but Mr O'Brien never included them.

Dr Hughes advised that many of the patients that have been reviewed were given hormone therapy off licence and often without their knowledge and that this treatment was in variance to guidance. He also advised that some of the patients were not referred onwards to oncology when their disease progressed and they had no access to coordinated care. This meant that patient's had difficulty accessing care and the GPs couldn't help which resulted in patients having no option but to go to the Emergency Department during covid which was not appropriate.

Dr Hughes asked if anyone expressed concerns about excluding nurses from the clinics.

Martina advised that two of the Clinical Nurse Specialists did report that they did regularly challenge Mr O'Brien and asked him if he needed them to be in the clinic to assist with the follow-up of the patients but it got to the stage were staff were getting worn down by no action and they gave up asking as they knew that he wouldn't change.

Martina advised that in her opinion that Mr O'Brien could be quite arrogant and that was a big part of the issues with his practice.

Dr Hughes advised that the Clinical Nurse Specialists are so important on the patient's journey.

Martina agreed and said that this support from the CNS was vital both for oncology and for benign conditions, and advised that Mr O'Brien did include the CNS in

Urodynamics as it was the specialist nurse who performed the test, however he didn't include the CNS when he was consulting with the patient after the test.

Martina advised that in her opinion she felt that one of Mr O'Brien's problems was that he took everything on himself and never involved none of the wider team and then because of this never had the time to see everything through.

Dr Hughes reiterated – "at no stage were specialist nurses allowed to share patient care with Mr O'Brien?

Martina confirmed that yes this was correct. She also confirmed that all of the other consultants see the benefits of using a CNS and that they include them in all of their clinics.

Dr Hughes – advised that care was excluded to all professionals and that Mr O'Brien was working outside his scope of practice.

Martina advised that during MDT on occasions there were issues raised about Mr O'Brien and at times these were escalated to the AD and AMD but as with other concerns regarding Mr O'Brien these never got anywhere as he either 'promised' that he would sort or else he gave a reason why he couldn't follow through. Martina advised that there was an ethos among many other staff "well sure that's just Aidan".

Dr Hughes agreed and said that staff appeared to have become habitualised by his bad practice.

He asked Martina if she had any questions.

Martina didn't but did say she questions herself had she done the right thing by escalating the concerns?

Dr Hughes assured her - absolutely!

Martina felt reassured by this and also advised she had been involved in the original admin look back of patients and through this piece of work had identified two of the current SAI during this process.

Dr Hughes advised that the review team will go back to families with a draft report and feedback on the learning. He advised any learning for the MDT would be systematic and constructive.

He thanked Martina for her assistance.

Southern Health and Social Care Trust

Acute Governance
Cancer Nurse Specialists
22 February 2021 @ 11am
Zoom

PRESENT: **Dr Hughes (Chair)**
Patricia Kingsnorth Acute Clinical Governance Co-Ordinator
Roisin Farrell, Governance Officer
Patricia Thompson
Martina Corrigan
Kate O'Neill
Leanne McCourt
Jenny McMahon
Jason

Patricia Kingsnorth thanked all for attending, she explained she tried to arrange the meeting in January but it had to be cancelled due to COVID. She advised the meeting that the CNS care was not brought into question.

Dr Hughes advised he was asked to chair the review. He advised he was previously Medical Director in the NHSCT and Director of NI Cancer Network. He has a pathology background.
He explained there was a huge deficit with not having Nurse Specialist's involvement in the patients care.
He gave a background to patients involved in the SAI review.

Patient 1 – Prostate cancer patient. His disease progressed and was not referred back or provided palliative care. The patient has since died. He did not get best care pathway.

Patient 9 – Personal Information redacted by the USI Biochemical, PSA & potential prostate care. TRP came back negative. Variety of reasons things were missed. He later attended ED with query rectal cancer but was diagnosed with prostate cancer. The disease has progressed.

Patient 5 – Had a large renal cancer, he was treated exemplary. He attended ED no PSA or scan, was missed for 8 months. PSA was over 100 he probable had prostate cancer from start. Never got CNS.
Kate O'Neill believes she had met this man late last summer with Mr Haynes.

Patient 4 – High grade cancer. Should have been referred to oncology, didn't happen. Disease progressed and spread. He wasn't referred back to MDM and no referral to palliative.
Dr Hughes believes issues with lack of onward referrals.

Patient 2 – Very good first time care. He has rheumatoid disease and arthritis. He has been diagnosed with testicular cancer, recommendation referral for treatment, was not referred for treatment and was identified by BHSCT. No CNS assigned.

Patient 6 – elderly with possibility of prostate cancer. MDM suggested active surveillance. No CNS for support. No LRH. Doing reasonably well.

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Patient 7 – Renal mass. Multiple consultants involved. No CNS assigned until tissue diagnosis. Did have surgery and doing well. Question is how to support these patients prior to diagnosis. This family are from a Personal Information redacted by USI and are very angst.

Dr Hughes advised another family has a Personal Information redacted by USI.

Jenny McMahon asked if patient should have got laparoscopy surgery.

Dr Hughes advised he was not sure. He believes a pathway should been drawn up. Then locums would be aware. There was no attendance at MDM.

Patient 3 – Penile cancer. He received local treatment, as a rare cancer should have been on regional and super regional pathway. There was a delay of 17 weeks from CT scan to diagnosis. Cancer very progressive and patient has died.

Patient 8 – Had TURP, small chippings. Wasn't referred back to MDM, missed for 8 months, don't feel he has come to any harm. Have issues with TURP and incontinence.

Dr Hughes feels the issues are
8 of 9 recommendations from MDM were perfect but none were put in place.
1 query of penile cancer.

- Patient 9 – early diagnosis – Referral
- Patient 4 Referral to oncology
- Patient 2 Oncology – missed
- Patient 6 – Oncology
- Patient 7 – Super regional network earlier.

All should have had input from Nurse Specialists.

Dr Hughes invited staff to speak.

Kate O'Neill asked if the review was from Jan 2019 to 2020.

Dr Hughes advised one started in 2016.

Kate O'Neill advised during that time staffing team consisted of 2 staff. January 2017 an additional 2 more staff was allocated. At interview job description was changed. Had to re-advertise for staff. This did add to the staff but was a management role.

Leanne McCourt advised she was one of the original clinical sisters. She started in April 2017 and was successful and joined CNS 2019.

Kate O'Neill advised they had established 1 staff clinic and had new clinics Monday to Thursday. She advised at the clinic you might have 1 consultant and 2 reg's with 15 – 21 patient to process along with other work in 3 ½ - 4 hours. There were issues with staffing levels, she advised she would work longer on a Thursday. Kate said if there were 21 patients Monday – Thursday and 6 reviews their first priority was the 21 patients.

Dr Hughes advised these were first review patients. He advised they weren't given phone numbers. He needs to know if MrO'B had an issue working with Nurse Specialists or was it a deficit.

Leanne McCourt doesn't feel he valued the Nurse Specialists. She recalled him asking her in the kitchen what the role of a Nurse Specialists was. He didn't understand the role if a Nurse Specialists.

Dr Hughes advised the Nurse Specialists was signed off in 2016. He advised the reason for Nurse Specialists are for patients. He advised he needs to know if it was a deficit because of work or this particular doctor.

Jenny McMahon said she had a very different experience. She advised she was not sure why MrO'B didn't invite CNS into the room and feels this is a question MrO'B needs to answer. She advised MrO'B spoke very highly of CNS. She recalls MrO'B having review oncology on Friday but she wasn't asked to attend.

Dr Hughes confirmed he had asked MrO'B this question. He asked if it is reasonable to say resources were made available.

Jenny McMahon said yes they would have been made available if support was need on the day but advised nurse specialists were not invited to attend appointments.

Kate O'Neill advised the period during 2019 MrO'B only seen reviews, she asked Martina Corrigan if this was decided.

Martina Corrigan advised no. MrO'B decided to do this himself.

Kate O'Neill advised reviews changed to Tuesdays. She recalled MrO'B contacting her to help with cath etc.

Leanne McCourt agreed MrO'B would approach her to arrange prostate appointments.

Kate O'Neill advised if there was no nurse available other staff was available to assist.

Dr Hughes advised referrals were not made and no numbers given out even though resources were available.

Jenny McMahon felt MrO'B was very supportive of Nurse Specialists.

Dr Hughes advised there are 9 patients in the review and they were not referred to Nurse Specialists and 3 have died. He advised families were not aware of Nurse Specialists. He feels Nurse Specialist should be imbedded.

Jenny McMahon agreed contact details should have been given. She conceded there may not have anyone available on the day but patients should have been given contact details.

Kate O'Neill advised at MDT Nurse Specialists should have been present or available. She advised there was an audit done from March 2019 to March 2020, 88% was given Nurse Specialist contacts.

Dr Hughes asked Kate if she would send the information to him. He advised he wants to be able to say resources were available but patients were not referred. He feels this is a patient's choice whether or not to avail of the support of Nurse Specialists.

Jason advised he worked with MrO'B and his experience was entirely different. He said he may not have been in the room but would have been introduced after but with MrO'B he would not have had as much input. He said MrO'B may have given contact details in the

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room he doesn't know. He said MrO'B was supportive in other ways, he made him aware of other patients.

Dr Hughes advised families didn't know this service was available. Patients were unsupported and didn't have an understanding of their care.

Patricia Kingsnorth asked Jason if he followed up on patients results.

Jason said no patients were told to contact if needed.

Dr Hughes asked if they all get the opportunity to attend MDM.

Jenny McMahon advised no she hadn't linked for 1 year.

Dr Hughes asked if they can put patients on for discussion.

All said yes.

Kate O'Neill gave an example of contact from a patient. She was never questioned when she added to MDM.

Dr Hughes suggested they didn't have a seamless pathway.

Kate O'Neill asked if the SAI is to be closed at the end of the wee will be inclusive of MrO'B response.

Dr Hughes advised the draft report is to be completed to see if there is any early learning. He advised draft reports would be sent to the families. He advised families are more interested in how this happened. He added the report will include referrals not made and no contact details made available. He said this can't be done if referrals are not made.

Leanne McCourt advised in the year 19/20 they had 2016 patients. 14 from MrO'B. She advised they may have had a call later and took into process.

Dr Hughes asked staff to share their experiences.

Patricia Kingsnorth asked Leanne to clarify. Were those 14 from MrO'B.

Leanne McCourt advised these may not have been from MrO'B. She agreed to check for Patricia.

Dr Hughes asked if staff had any other questions.

Kate O'Neill advised it would be nice to work in an environment doing one job at a time. Reflected work load.

Dr Hughes acknowledged doctors have a work plan. He asked if they have a job plan.

Kate O'Neill advised it's to do what needs done on the day. If theatres need covered their day would change.

Dr Hughes advised there is no criticism of Nurse Specialists. The issues are with the person not refering patients which is best practice. He advised this review has highlighted the importance of Nurse Specialists. These issues are not of Nurse Specialists doing.

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Kate O'Neill asked if this will be reflected in the report.

Both Dr Hughes and Patricia Kingsnorth said yes.

Jenny McMahon said she feels much better supported now, but back years it took all consultants a while to engage. She added in 2019 all resources were there it is indefensible not to provide contact details.

Dr Hughes advised the report will be written without any criticism of Nurse Specialists but will highlight resource issues.

Jenny McMahon asked if the report could be share with CNS.

Patricia Kingsnorth advised not at this stage it is just shared with staff involved.

Dr Hughes agreed to share the part of the report that refers to Nurse Specialists.

Patricia Kingsnorth suggested Patricia Thompson could share that part of the report.

Dr Hughes read the part referring to CNS from the draft report. He advised he wants to say what happened is against regional guidelines and what the Trust signed up to.

Dr Hughes thanked staff for attending the meeting.

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SAI Urology Review

Meeting with Dr Joe O'Sullivan
Monday 4 January 2021 via zoom at 11:15

Attendees
Dr Dermot Hughes and Mrs Patricia Kingsnorth

Dermot Hughes (DH)
Dr Joe O'Sullivan (JOS)

DH thanks JOS for meeting with him and explained the process to date regarding the SAI review involving 9 patients (one with penile cancer, 1 testicular cancer, 5 prostate cancers and 2 renal cancers).

He asked if JOS was aware of any issues regarding the practice of Mr AOB?
JOS advised that when he came into post initially about 17 years ago, he had concerns in relation to the use of bicalutamide and that they had frequently challenged him about the treatment. He made recommendations in clinic letters questioning the use of bicalutamide 50mgs instead of the standard 150mgs or LHRH agonist therapy. In the cases he had seen, the dose of bicalutamide would not have resulted in a major detriment to the patient's therapy/outcome and therefore wasn't escalated further. JOS said he was aware that his colleague D M (as MDT Chair) had raised our concerns about AOB's bicalutamide prescribing with the then CD for Oncology, SMcA, probably in 2011.

JOS said that the MDT improved with the attendance of two of the newer consultants about 7 years ago.

DH advised that there were a number of delays of people being referred for oncology/ palliative care.

DH said that there were issues regarding lack of oncologist attending MDM as it was on the same time as lung MDM and that there was inadequate cover for CAH MDM.

JOS agreed he did want it recognised that there was a lot of good work from urologist in CAH and good involvement in MDT in particular he named two consultants Mr MH and Mr AG.

DH wanted to assure JOS that the SAI review will also recognise the good work the MDT are doing and recognised that the concerns relate to one person's practice. It would seem he worked in isolation despite being involved in a multi-disciplinary team. JOS said that was his impression of Mr AOB

Southern Health and Social Care Trust

Acute Governance
Darren Mitchell
Telephone call
23.02.2021

PRESENT: Dr Darren Mitchell
Dr Dermot Hughes
Mrs P Kingsnorth

Dr Hughes thanked Dr Mitchell for taking time out to talk to him today. Dr Hughes highlighted the reviews concerns identified in the SAI, explaining there was non-adherence to MDT recommendations, non-referral to oncology services for potential curative therapy, prescribing issues.
He asked if there was any knowledge regarding the concerns mentioned.

Dr Mitchell advised aware of issues going back decade in relation to hormone therapy prescribing, prescribing outside guidelines, Bicalutamide. Dr Mitchell advised he took over as chair of the regional urology MDM in 2015. He advised that they had challenged Mr OB on his use of bicalutamide as part of the development of clinical guidelines whilst Mr OB was chair of the NICAN urology group in 2015. Dr Mitchell wrote the regional guidelines for the use of hormone therapy. This was done in the hope this would address the issues around off-licence prescribing of Bicalutamide. This guideline was circulated and presented when Mr OB was chair of the NICAN urology group and he signed off on the guidelines.

Dr Hughes asked Dr Mitchell to share the guidelines mentioned. Dr Hughes advised a number of patients were to be referred to oncology and this was not done.

Dr Mitchell mentioned a radical bladder cancer case in 2016, Chris Hagan and Gillian Traub noted there was a significant delay in treatment whilst waiting for a bone scan, this case was flagged back to SHSCT. Dr Mitchell believes Mr OB was chair of the southern urology MDM at that stage.

Dr Hughes advised the review was looking at 9 cases, there are significant findings, delays in treatment and care, MDT recommendations were not implemented, referrals to oncology were never made for potential curative treatment, and patients were not brought back to MDT for review. Dr Hughes advised there were systematic issues. The recommendations will include structured review process of MDT processes. NICE guidelines were not adhered to regarding prescribing of bicalutamide. There was very poor oncology support at MDT, oncology attendance at MDT was rare. Dr Mitchell described issues

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trying to support the MDT in SHSCT it was a busy practice and they had difficult recruiting to cover this role.

Dr Hughes asked if MDT chair had questioned prescribing methods in accordance with NICE guidelines. Patients did not know, there were no onward referrals. One case of penile cancer was not referred to the super regional MDT for discussion following diagnosis.

Dr Mitchell asked about the testicular cancer case that was brought to his attention.

Dr Hughes advised the consultant did not refer, the oncology centre identified this patient and booked him, there was a delay in treatment.

Dr Hughes advised the consultants prescribing was against NICE/ NICAN guidance and would be grateful if he could forward a copy of the guidance signed off by the consultant.

Dr Mitchell agreed to forward this. Dr Mitchell advised he emailed the consultant in 2016/2017 about his prescribing outside recommended guidelines and highlighting it was his GMC duty to inform patients they were being treated outside the recommended guidelines. The patients were misled.

Dr Hughes advised recommendations of the SAI will reflect this issue. Discussions should be had with patients if treatment is outside the recommended guidelines and reason explained to them in and signed off by peers at MDT. He suspects that the issues around Mr OB were extensive and wide ranging. Dr Hughes advised families are asking the question why no one else knew.

Dr Hughes thanked Dr Mitchell for talking with him today.

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MEETING PATIENTS' NEEDS

IMPROVING THE EFFECTIVENESS OF MULTIDISCIPLINARY TEAM MEETINGS IN CANCER SERVICES

CANCER RESEARCH UK

EXECUTIVE SUMMARY

Around 357,000 people in the UK were diagnosed with cancer in 2014.[1]

This figure is expected to increase: by 2035 the number of diagnoses each year could reach 500,000[2]. Survival has also increased; Cancer Research UK aims to reach 3 in 4 people surviving cancer for 10 years or more by 2034.

To ensure that this ambition is realised, effective cancer services in the UK are key.

Central to the UK's cancer services are multidisciplinary teams – MDTs. An MDT is made up of a variety of health professionals involved in treating and caring for patients, such as surgeons, clinicians, nurses and diagnosticians. Each week, the MDT meets to discuss individual patients' cases and make treatment recommendations.

MDT working is considered the gold standard for cancer patient management[3], bringing continuity of care and reducing variation in access to treatment – and ultimately improving outcomes for patients. However, the health service has changed significantly since their introduction in 1995.

There is now a timely opportunity to review MDTs and consider new ways of working. Although the challenges in each of the four nations are not identical, there is a common theme: a dramatic increase in demand, with only minor increases in capacity. For example, the cancer strategy for England contained recommendations to streamline MDT working.[4]

The number of patients to be discussed in MDT meetings has grown significantly, as has the complexity of patients; due to an ageing population and the growing number of treatment options available.

However, the way that MDT meetings are organised has not adapted to cope with this increased demand. This has meant that MDT meetings are lasting for several hours, with only a few minutes available to discuss each patient. As a result, these discussions often only involve a few people, and often do not include information such as the patient's preferences, comorbidities or whether the patient is suitable for a clinical trial.

TO REFLECT THE CHANGING NATURE OF CANCER CARE AND INCREASED DEMAND FOR SERVICES, THERE IS A NEED TO REFRESH THE FORMAT OF MDT MEETINGS

This strain has also impacted how well the MDT can reflect on their decisions, improve their processes and learn.

To reflect the changing nature of cancer care and the increased demand for services, there is a need to refresh the format of MDT meetings to make them work more effectively. Recognising this, Cancer Research UK commissioned 2020 Delivery to undertake this project.

We do not in any way propose removing or diluting MDT working, or to return to the pre-1990s era of patient care being solely managed by one clinician.

We aimed instead to suggest streamlining MDT meetings and improve the quality of discussions, especially for the more complex patients who would benefit the most from

the input of the full MDT.

Throughout this research we were struck by the willingness of MDT members to be involved, to share their experiences and to improve their meetings so that they worked better for patients – with an unprecedented 2,300 responses to our first survey and over 1,250 in our second. Our fieldwork covered 624 patient discussions, across 24 MDT meetings in 10 clinical sites.

Solutions will not be the same for every MDT, or every specialty. However, in several areas there is a need for updated guidance developed on a national level.

This research should therefore be the start of further, in-depth work to implement these recommendations.

THERE IS NOT ENOUGH TIME TO DISCUSS THE MORE COMPLEX PATIENTS

The mean length of the 624 patient discussions observed in this study was 3.2 minutes, and over half of MDT discussions were less than two minutes long. Meetings could last up to five hours.

It is difficult to imagine that this method of working produces the same quality of discussion for all patients, or that there is always enough time for full discussion of patients with particularly complex cases.

For many tumour sites, certain subgroups of patients now follow very well-established treatment protocols. 74 per cent of MDT members responding to our second survey agreed with the statement that some patients could be streamlined, or reviewed outside of the full MDT meeting. This already happens in some MDTs, but to date there has been no clear national guidance on how this should be managed.

Establishing a 'triage' process to identify patients that should follow these protocolised pathways would reduce the number of discussions happening in the full MDT meeting, allowing more time to discuss the more complex patients.

RECOMMENDATIONS

Recommendation 1: The UKs health services should work with NICE[i] and SIGN[ii] to identify where a protocolised treatment pathway could be applied and develop a set of treatment recommendations for each of these, to be implemented across the UK. Every Cancer Alliance or devolved cancer network should develop their own approach based on these central recommendations. These treatment protocols should be reviewed regularly.

2. MDTs for tumour types for which a protocolised approach has been developed should agree and document their approach to administering protocols. This could include a 'pre-MDT triage meeting'. The implementation and outcomes of these

[i] National Institute for Health and Care Excellence
[ii] Scottish Intercollegiate Guidelines Network

protocols should be audited and reviewed by the full MDT in an operational meeting.

CURRENT MDT MEETING ATTENDANCE IS NOT OPTIMAL

The growing demands placed on MDTs has a significant impact on MDT members' workloads, who must spend increasing amounts of time preparing for or attending MDT meetings. This is particularly true for pathologists and radiologists.

Workforce challenges are wider than MDT working however; the National Audit Office has said that there is a 50,000 shortfall in clinical staff in England alone. [5]

The 24 meetings observed in this study had between 7 and 27 in attendance, with an average of 14. However, the mean number of people contributing to each discussion was only three – with discussions involving just one or two people not uncommon.

In some meetings everyone spoke at some point, whereas in others it was always the same few people.

In contrast to this observation, other MDT meetings were unable to finalise any treatment recommendation because certain individuals were not present. This was mostly a result of a wider staff shortages.

Attendance guidelines are most strict in England, where MDT attendees are required to attend 66 per cent of meetings. This target is often difficult to reach, meaning that many MDTs fall foul of national assessments and there are delays in patient care.

Amending such guidelines to focusing instead on individual specialty cover within a meeting would strike the right balance. This would ensure that the right specialties are represented so as to ensure that discussions can progress, without requiring an unnecessarily large group.

MDT members were very supportive of this, with 80 per cent supporting a move to requiring specialty cover. [iii] When staff are mandated to attend MDTs, adequate time must be allocated in their job plans for preparation and attendance.

RECOMMENDATION

3. National requirements for individual minimum attendance should be reviewed and amended where necessary, with an emphasis on ensuring all required specialties are present at a meeting. NHS England should run a series of pilots to determine optimal percentage attendance requirements. The success of these pilots should be evaluated and national guidance changed as appropriate.

[iii] Responses to our second survey of MDT members.

THE RIGHT INFORMATION IS OFTEN NOT USED TO INFORM DISCUSSIONS

An MDT's treatment recommendation is only as good as the information it takes into account.

MDT discussions must include all relevant information about a patient, so that the patient is given the most appropriate recommendation and can go onto achieve the best outcome possible.

In seven per cent of discussions observed, decisions were deferred due to either missing information (usually diagnostic imaging results) or missing core MDT members.

When information was missing, a treatment recommendation could not be made and so they were deferred for discussion at the following meeting, a week later – introducing an unnecessary seven-day delay, which is distressing for the patient and can lengthen their wait to start vital treatment.

We also found that only 14 per cent of discussions included information that did not relate specifically to their tumour, for example the patient's preference, known comorbidities or psychosocial status.

Although many expected this to be the role of the clinical nurse specialists, in over 75 per cent of meetings there was no verbal contribution from nurses at all in discussions. [iv]

Only 25 per cent of the patients we surveyed were satisfied with the amount of information they were able to contribute to the MDT meeting. [v]

This has a demonstrable impact on patient experience, as well as on clinical care: research has found that between 10 and 15 per cent of MDT recommendations are not implemented, the patient preferring more conservative treatment, since the discussion had not considered information such as their comorbidities or their preferences.[6,7]

Clinical trial recruitment can also be facilitated via MDTs; however we know that there is considerable variation across the UK in how many patients are spoken to about research opportunities.

Disappointingly, only eight of the 624 MDT discussions observed mentioned clinical trials at all.

One way of ensuring that all relevant information is considered by the MDT would be to implement a standardised proforma, which would be completed by the clinician referring the patient to the MDT.

54 per cent of MDT members already use some form of proforma, but this is not consistent and there is no national guidance

[iv] See Appendix 1 for full methodology.
[v] See Appendix 4 for text of patient survey.

on content. 81 per cent of MDT members felt that using a proforma would have a beneficial impact on meeting efficiency.

RECOMMENDATION

4. The UK's health services should lead the development of national proforma templates, to be refined by MDTs. MDTs should require incoming cases and referrals to have a completed proforma with all information ready before discussion at a meeting.

The proforma could include:

- **Patient demographics;**
- **Diagnostic information**
- **Patient fitness and co-morbidities, history of previous malignancies;**
- **Results from a Holistic Needs Assessment (if available);**
- **The patient's preferences (if known);**
- **The rationale for requiring MDT discussion;**
- **Whether there were known treatment protocols for the specific tumour type;**
- **Whether the patient is suitable for any current clinical trials.**

The MDT should have the power to bypass this requirement in exceptional circumstances.

MDTS ARE UNABLE TO FULFIL THEIR SECONDARY ROLES

As well as making treatment recommendations, the MDT plays several other roles: facilitating data validation, ensuring consistency in decision-making, educating team members and managing the pathways of the patients within their care.

Discussion amongst steering group members, and responses to our surveys, indicate concern that current pressures have limited these aspects of MDT working.

Since their introduction, the MDT has played a vital role in ensuring timely and accurate data validation. This has been hugely important for auditing services and facilitating information flows to national cancer registries.

However, we found the extent to which this happened highly variable. The best example seen in our observations was when information was directly added by an oncologist, and was projected on a screen for the whole MDT to view. Real time data entry reduces errors and provides an immediate opportunity to validate and clarify information.

As a central tenet of cancer services, it is important that MDTs review their own performance and that a culture of continuous improvement is fostered. Less than half (48 per cent) of MDT members felt their MDT has a process in place that is sufficient for improving their effectiveness.

The suggestion of holding a regular 'operational' meeting, either quarterly or biannually, was supported by 67 per cent of respondents to our second survey.

RECOMMENDATIONS

5. MDTs should use a database or proforma to enable documentation of recommendations in real time. Ideally this should be projected so that it is visible to team members; if this is not possible there should be a named clinical individual responsible for ensuring the information is accurate. Hospital Trusts and boards should ensure that MDTs are given sufficient resource to do this.

6. Each MDT should ensure that they have a mortality and morbidity process to ensure all adverse outcomes can be discussed by the whole MDT and learned from, rather than discussed in silos. The primary time for this to take place should be a quarterly or biannual operational meeting. Time for quarterly operational meetings should be included in attendees' job plans. There should be oversight from national MDT assessment programmes.

www.cancerresearchuk.org/mdts-research

For more information, or for a copy of the full report, please contact **policydepartment@cancer.org.uk**

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CANCER RESEARCH UK

SAI Urology Review

Discussion with Ronan Carroll (RC) AD for Surgical and Elective Care

Dr Dermot Hughes (DH) and Patricia Kingsnorth (PK)

Monday 18 January 2021 @ 13:45

Dr Hughes provided a summary of where we are regarding the SAI review and summarising the cases involved in the review. He explained that many of the patient's pathway did not follow the recommendations set out by the regional urology pathway. He explained that AOB was the Chair of the regional urology MDM up until 2016. He signed off the guidance for peer review in 2017 but did not adhere to the standards agreed.

DH described the issues regarding the lack of specialised nurse for AOB's patients and the impact this had on the patients and family when trying to access services. He advised that AOB use of ADT was highlighted by the oncologist in Belfast Trust who wrote to AOB to highlight issues. But this wasn't escalated further.

DH- asked how did AOB practice this way?

RC- believed everyone made excuses for AOB the consensus was that he was a very strong personality who could be spiteful and even vindictive. Many of the CNS were afraid of him. But RC was unaware that the CNS were excluded from seeing AOB's patients.

DH explained the SAI process that we are looking at the cancer pathway and benchmarking against the standards regarding diagnosis/ staging/ MDT. He explained that some of the patients were not referred on for palliative care when their disease progressed. AOB was referred to by one of his colleagues as a "holistic physician" who care for the patients in uni-professional manner, but really he was working outside of his scope of practice.

RC speculated about AOB that there was a sense of arrogance/ commanded respect almost "God like" when he walked the corridors.

RC said he wasn't aware of the issues identified by the SAI review and was quite shocked when the issues were identified by PK during the update of early learning from the SAI. He advised that the patients under the care of Mr OB were often elderly and held him in high esteem "the big doctor". He went on to say that staff appeared to be habitualised by AOB's behaviour, that they avoided challenge at MDT.

RC went on to describe a previous concern they had which was escalated to an SAI of a man who had a bladder tumour, his red flag referral was put in a drawer resulting in an extensive delay to review him. There was no remorse and AOB seemed to defer to everyone else's problem not his.

DH advised the language will be neutral describing what the standard of care should be and what it was. He advised that all the families found AOB to be very personable but his care fell below standard.

RC advised that AOB was known to be clinically sound and that any issues raised were regarding system and administration processes. He never thought of him as a poor surgeon. He wasn't aware there were any issues with drug prescription or failure to follow up or non-compliance with MDT recommendations.

DH advised the need for assurances through regular audits for all clinicians.

RC advised that the system is not resourced for re- referral to MDT.

DH said it should be and advised the cancer tracker's remit needs to be wider to include follow up of results and investigations.

DH thanked RC for assisting with the review.

Southern Health and Social Care Trust

Acute Governance
Urology MDM
Thursday 18 February 2021 @ 12.30pm

PRESENT: **Mr Dr Dermot Hughes (Chair)**
Mrs Patricia Kingsnorth
Mr Michael Young
Mr Anthony Glackin
Jason Young
Jenny McMahon
Martina Corrigan
Kate O'Neill
Mr Mark Haynes
Mr Shawgi Omer
Roisin Farrell, note taker

Dr Hughes introduced himself to the meeting. He provided an update to the meeting. He advised he was asked to chair the Urology review in August. The review team have been working on the review from October 2020 and the draft report is expected to be ready for 28.2.2021. He has met with all 9 families once and is meeting with them between today and tomorrow (18 & 19 February 2021) for the second time and will meet with them for a third time to provide them with the draft report.
Cases in question were: 5 prostate cancers, 1 testicle cancer, 1 penile cancer and 2 renal cancers. He asked if anyone had any questions. – None. He advised in the instance of the prostate cancers there was no adherence to MDM and clinical guidelines of March 2016. Other issues of concern are the timeline for diagnosis, some delays and some were lost in the pathway to diagnosis and follow ups. He confirmed 3 patients have since died. Patient 4, Patient 1 and Patient 3 and other patients are not so well. Dr Hughes advised the group that the external urology reviewer is Mr Hugh Gilbert he was nominated by the professional body that gives professional advice.

Dr Hughes explained that the Cancer Nurse Specialist was excluded from these patients care. 9 patients didn't have the supporting link leading to a greater risk of failsafe measures to ensure pathway is adhere to. Dr Hughes said he was not sure why this happened and he doesn't know if all at MDM were aware. He has been told MrO'B didn't refer patients to Cancer Nurse Specialist. He said these patients needed someone to manage their pathway. He advised he believed MDM was not appropriately resourced leading to a resource deficit in the recommendations referring back to the peer review of 2017. He asked if there were any questions.

Mr Glackin advised he was chair of Urology MDM, he took over from MrO'B. He confirmed nurses were excluded from MrO'B's practice. He doesn't believe there is an issue with other doctors.

Dr Hughes confirmed has been speaking to nurses and will be putting recommendations into the report to reflect this. He is not sure why patients didn't have access to Cancer Nurse Specialist which has caused issues in the community.

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Mr Glackin highlighted there are only 5 Cancer Nurse Specialist covering the services over a number of hospitals.

Dr Hughes advised he thought at the start it was geographical but asked why patients were not given contact details. He advised this is one of the questions he has asked MrO'B. He was concerned there was no multi-disciplinary support for these patients.

Mr Glackin advised the issue surrounding resources of nurses has only improved in the last 2 years.

Dr Hughes highlighted that renal patients needed Cancer Nurse Specialist.

Mr Glackin suggested there was an issue with resources at MDM. He recalled his experience in the West Midlands where MDM was better resourced. The follow up and tracking was more robust, more a priority and had admin support. He advised there were weekly trackers who would liaise with consultants enabling them to meet their timelines. Adding here they are never able to meet timely care.

Dr Hughes agreed with Mr Glackins points. He questioned if the issue was systematic and a problem for more than the 9 cases, if so this would need to be addressed. He added the recommendations will be able to review this through the recommended audits.

Mr Glackin referred to the proposed audits and advised at present they would not have the time or resources.

Dr Hughes advised consultants should have been doing audits and agreed there was a need for more resources. He advised other concerns raised were the appropriate onward referral to other professionals, oncology etc from MDM. He feels MDM focused on first diagnosis.

Mr Glackin suggested this was more or less unique to MrO'B. He added that the MDM chair is rotated among colleagues.

Dr Hughes advised he had raised this with Mr Gilbert and was advised this was a common way of working and feels it is beneficial to rotate the chair, they can review cases in advance and identify where there is care deficit. He said when patients progress they are not being taken back to MDM leading to uni-professional care, causing a problem.
He also said there were issues around flutamide.

Mr Glackin advised this was discussed at MDM. He referred to the specific dose of 150mg and suggested the evidence was weak in the criticism in the use of this treatment and said the scientific evidence was not so robust.

Dr Hughes said he was taking advice from Mr Gilbert. He feels in these cases it was inappropriate and said it would have been more appropriate for onward referral to oncology.

Mr Glackin suggested that generally consultants give other treatments and feels if the review is referring to the use of flutamide this needs to be scientific and not opinion.

Dr Hughes referred to the 5 prostate cancers. 1 being coincidental, 1 was potential prostate that didn't get a diagnosis for 15 months.

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Mr Glackin suggested TURP's was not a good diagnosis for prostate cancer.

Dr Hughes asked if there were any issues of concern raised outside MDM.

Mr Glackin advised management were aware of no nurses.

Dr Hughes advised he had spoken to AD in CCS who was not aware of issues.

Mr Glackin advised they did bring issues of concern a number of years ago. Their reaction was a shrug of shoulders and said "what do you want us to do".

Dr Hughes said he noted staff at MDM was generally locums and that oncology were not attending.

Mr Glackin said he had suggested suspending the Trust MDM due to attendance.

Dr Hughes advised one of the recommendations would be to provide resources for MDM.

Mr Haynes – AMD. He believes there is an enormous disconnection between services and feels consultants are blamed when they fail but at the same time CCS will take credit when they succeed. He referred to occasions where at MDM meetings issues were bounced back to urology. He asked what they can do.

Dr Hughes advised he attended a meeting and was stunned to hear staff was aware of the issues. He feels it's hard for staff if they feel isolated. He added when the report is complete staff need to feel supported.

Mr Glackin said there was no input from outside of MDM, no support from CCS.

Dr Hughes agrees staff do need support and feels supported to raise concerns. He suggested these concerns need minuted and actions taken. He advised he was going through the process of meeting families which has been quite upsetting to patients and their families.
Dr Hughes asked the meeting if they wanted to meet again or if they wanted to raise concerns directly they could contact him.
He advised he has struggled a little regarding the governance, he feels staff were told to sort out themselves which is not appropriate especially when people are paid. He questioned if there was the same issues in breast screening.

Mr Haynes advised breast screening was under the same remit; the same team CCS and they meet their targets.

Dr Hughes advised 8 or 9 recommendations from MDM were appropriate.
One of the safety checks to oncology, if had oncology been attending patient could have got referred.

Mr Glackin advised they use Belfast MDM. He suggested he doesn't feel comfortable making referrals to oncology. He added this has all been minuted at a governance meeting.

Dr Hughes advised them they focusing on the 9 patients.

Mr Glackin doesn't feel they are addressing any issues.

Dr Hughes suggested the trust needs a forum to address these issues.

Mr Glackin said their workload is another issue which needs to be recognised. He said they are "carrying more than their peers". Pressures causing risk with under resourcing of urologists and Cancer Nurse Specialist.

Dr Hughes agreed and asked to get data, he suggested if workload an issue causing underlying issues.

Mr Haynes advised here there is 1consultant per 90,000 of population, in England it is a lot lower.

Martina Corrigan advised the Western Trust has taken back their referrals from mid-September.

Mr Young advised the change in volume was only recently due to not being able to cope.

Dr Hughes advised he would share the draft report with MDM.

Kate O'Neill CNS advised she was astounded CNS had not been asked or been met with.

Martina Corrigan advised there was a meeting planned for Monday.

Dr Hughes said she had asked Patricia Thompson to speak with staff.

Kate O'Neill has only been made aware of meeting and thought it would have been formal.

Dr Hughes advised the issues were the absence of Cancer Nurse Specialist which was a deficit to the patients.

Kate O'Neill clarified it was not the fault of the nurses.

Dr Hughes agreed and advised when investigating the issues surrounding the Cancer Nurse Specialist he thought it was due to geographical but this was not the issue.

Martina Corrigan advised it was a fast process and the review team had to arrange to meet all the families involved. She advised both her and Patricia Kingsnorth liaised to arrange a meeting with Cancer Nurse Specialists.

Dr Hughes advised he needed to get the background of the cases before meeting with the Cancer Nurse Specialists. He apologised for the confusion and offered to chat more at the meeting arranged for Monday.

Jenny McMahon CNS said their role was central and provides a failsafe process that is benchmarked with other Trusts. She asked if other Trusts have the same issues as the Southern Trust.

Dr Hughes understands nurses meet patients with consultants or contact details are made available. He said one issue highlighted due to COVID was that patients were

going to their GP or ED because they wouldn't know what to do. He advised where he worked Specialist Nurses would refer patients to MDM this would give patients better access to care.

Jenny McMahon didn't think it was unique to one consultant and suggested it was a resource issue.

Dr Hughes said it may be an issue and suggested it needs investigated to see if this is the issue. He said they need to know if there is a deficit, adding if the Trust is saying best care for everybody they need to have the resources available.

Dr Hughes asked if they would like him to come back to update them on the progress. He advised he has no involvement in the independent enquiry.

Patricia Kingsnorth advised there was no criticism of Cancer Nurse Specialists; it highlights how important their role is.

Mr Glackin believes it is criticism of other consultants.

Patricia Kingsnorth said it's not criticism just an acknowledgment of urology being under resourced.

Dr Hughes advised he was writing the report based in evidence and the only criticism of the Clinical Lead and Associate Medical Director was not being aware. He added 8 of the 9 recommendations by MDM were fine, but added these recommendations were not actioned. Another issue was patients not being referred back to MDM. He doesn't know if MDM were aware.

Martina Corrigan asked Dr Hughes to clarify was the AD and AMD for CCS.

Dr Hughes confirmed it was for CCS. He said there was an issue, CCS didn't seem to know.

Mr Young said he recalled MrO'B appearing very keen to have Nurse Specialists and was very vocal.

Dr Hughes said MrO'B was chair of the group and was aware of the rationale behind the need for Nurse Specialist. He said there was a clear role for these nurses. He said he needed to clarify if the Nurse Specialist were available or if it was a decision to leave them out, adding patients should have been given a phone number.

Mr Glackin asked from the discussions has anything become apparent from the 9 cases.

Dr Hughes said he was reluctant to add anything into the report that is hearsay.

Mr Glackin clarified the question, is there any need for immediate action.

Dr Hughes said there was a need for enhanced tracking, more oncology input with assurance audits. These need to be put in place. He said if staff feels there is anything else needs to be put in place to let him know, he said the public need to have confidence. The review team need to be able to go back to families and show them it's not the way it was. He highlighted the need for resources. He said there is a need

to sort team resources. He apologised the Cancer Nurse Specialist and advised he was happy to share the comments about the Nurse Specialists.

Mr Shawgi Omer advised he was new to the team from July. He advised he was glad it was made very clear the central role of the Nurse Specialist and they were not criticised in any way. He hoped it was very clear the quality and quantity of the work was magnificent which relieved any anxiety he had at joining a new team.

Dr Hughes acknowledged it was a good point made and advised he would take it on board in the report.

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Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by USI

Date of Incident/Event: Multiple dates

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: Male Age:

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB: 1 March 2021

1. EXECUTIVE SUMMARY

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 to the patients identified and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided. Nine patients have been identified as potentially suffering harm. This review will examine the timelines of each individual case and analyse if any deficits in treatment or care has occurred. As part of the review the cancer

pathways will be used to determine where learning can be extracted.

The SHSCT recognise the life changing and devastating consequences to the 9 families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care they received.

1. THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair former Chair of the NICAN. Former Medical Director Western Health and Social Care Trust.
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally from SET / recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical Governance Coordinator (SHSCT)

1. SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing

learning from the incidents.

- To share the report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Patients and families involved/ Staff involved.

1. REVIEW METHODOLOGY

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

1. DESCRIPTION OF INCIDENT/CASE

The review team conducted individual reviews on 9 patients on their treatment and care. A summary of each case is discussed within this report.

Causal deficits in their care and contributory factors were identified.

Service User A

Service User A was diagnosed with prostate cancer and was started on an anti-androgen therapy as opposed to Androgen Deprivation Therapy (ADT). This did not adhere to the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016). These Guidelines had been signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-Disciplinary Meeting (MDM), as their protocols for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. Following discussion with the families, the review team noted that there was no discussion with Service User A that the treatment given was at variance with regionally recommended practice. There was no evidence of informed consent to this alternative care pathway.

The review team have identified that during the MDM that a quorum had not been met. This was due to the absence of an oncologist from these meetings. Even so, the recommendations made by the MDM were not actioned by Dr 1. Members of the MDT may not have been aware of this, but similar practice in prescribing an anti-androgen had been challenged. Any challenges made regarding the appropriateness of treatment options were not minuted nor was the issue escalated.

The Review Team suggested that the initial assessment of Service User A was satisfactory although rather prolonged, the subsequent management with unlicensed anti-androgenic treatment (Bicalutamide) at best delayed definitive treatment. Bicalutamide (50mg) is currently only indicated before (as an anti-flare agent) or in combination with a LHRH analogue (Complete Androgen Blockade) Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer (reference is EAU guidelines), and further it decreases overall survival. Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1.7 nmol/l), which is best accomplished by the use of a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.

Service User A did not have Urology Cancer Nurse Specialist allocated to his care. The review team questioned this and it was established that whilst there were no resources for a Urology Cancer Nurse Specialist to attend any outreach clinics, their contact numbers should have been provided to the patient.

The Review Team conclude that Service User A received unconventional and inadequate treatment. The expected multi-professional involvement in his care was

omitted. Service User A's disease progressed whilst being inadequately treated. The opportunity to offer him radical treatment with curative intent was lost.

Service User B

Service User B was diagnosed clinically and biochemically with prostate cancer, and was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent (or in combination with a LHRH analogue) and is only prescribed before definitive hormonal (LHRH analogue) treatment. The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016), which was signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017). This guidance was issued when Doctor 1 was the chair of this group and had full knowledge of its contents. The review team note that, following discussion with Service User B, he was unaware that his care given was at variance with regionally recommended best practice. There was no evidence of informed consent to this alternative care pathway.

A biopsy result taken at the time of transurethral resection of prostate (TURP) showed benign disease (low volume sample 2g from central area of prostate). There were no further investigations to explore the clinical suspicion of prostate cancer.

The possibility of localised prostate cancer was considered from the time of presentation because the PSA was elevated; however, there was no record in the medical notes of any digital rectal examination (DRE) findings. During the operation further signs might have been elicited and appropriate biopsies could have been performed. TURP is not an adequate way to biopsy the prostate gland for suspected prostate cancer. The Review Team conclude that sufficient evidence of localised prostate cancer was apparent from the time of presentation. A correct course of action would have been to arrange appropriate staging scans and biopsies. Service User B should have undergone investigation with a MRI scan of the prostate and pelvis and a bone scan should have been considered. A transrectal biopsy performed either at the time of the TURP or separately, would have secured the diagnosis.

Arrangement could then have been made to start conventional Androgen Deprivation Therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (EBRT) potentially with radical intent. However, the patient was apparently lost to follow up after his appointment in July 2019.

Service User C

Service User C was referred to urology service following a visit to ED in December 2018. He was reviewed promptly by Dr 1 in January 2019. Investigations were arranged and a diagnosis of a large right-sided renal carcinoma was made. He was counselled regarding the risks and benefits of surgical intervention and chose to proceed with the high-risk surgery.

On 6 March 2019 Service User C was admitted for an elective radical nephrectomy.

The procedure was undertaken as planned and he was transferred to the intensive care unit (ICU) to support his blood pressure. He was later transferred to the ward. He developed a bacteraemia (infection) which was successfully managed with the advice of the microbiology team. Follow up CT scans were performed in June with a planned follow up in July 2019. This did not happen. Service User C was admitted to Ward 3 North following an ED admission. He was reviewed again via telephone in November 2019 by Dr 1 who arranged for a repeat CT scan to be performed on 17 December 2019 with a plan for review in January 2020. This did not happen.

The CT scan report was available on 11 January 2020 which showed a possible sclerotic metastasis in a vertebral body which had not been present on the previous CT scans. This report was not actioned until July 2020 when a new consultant reviewed the care. Service User C was subsequently diagnosed with prostate cancer.

The Review Team find that the treatment and care in relation to management of the renal tumour was of a high standard. High-risk surgery was performed successfully following informed consent as to the risks and benefits of the surgery. A urology review was planned for July 2019 following the CT scan report in June but this didn't happen. Service User C appeared to be lost to review. The scan performed in December 2019 with a plan to review in January was not actioned and the plan for review did not happen. This resulted in a delay in diagnosis of a prostate cancer.

Service User D

Service User D attended ED on 24 December 2018 with retention of urine. A urinary catheter was inserted, and a urology consultant review was planned to coincide with a trial removal of catheter with a specialist nurse. Service User D was placed on the waiting list for a TURP. A normal PSA result (2.79 ng/l) was noted.

On 19 June 2019 Service User D underwent a TURP. The procedure notes describe the prostate tissue as having "endoscopic appearances of prostatic carcinoma". Histology confirmed adenocarcinoma (Gleason score 5+5) in 90% of the resected tissue. His case was discussed at MDM on 25 July 2019 who noted there was no evidence of metastases on a CT abdomen and pelvis. It recommended a CT scan of chest and a bone scan to check for spread outside the prostate. Further, a LHRH agonist as ADT should be commenced. In August 2019 a bone scan and CT scan were requested together with an ultrasound scan of the urinary tract to assess bladder emptying. Doctor 1 prescribed Bicalutamide (50mgs once daily), in order to 'assess its tolerability in a generally frail man' and in the 'light of the low presenting PSA'.

The Review Team could not locate any record in the medical notes of a digital rectal examination being performed at any point during this patient's medical treatment. This may well have provided evidence to support the malignant nature of the prostate gland prompting a swifter biopsy.

The patient was discussed at MDM on 25 July 2019 when the recommendation for ADT (a LHRH analogue) was made. He should have been started on this hormonal therapy to achieve "castration testosterone levels" as soon as the diagnosis of poorly differentiated prostate cancer was made. Instead he was started on an inadequate

dose of a drug (bicalutamide) which was not licensed for the treatment of prostate cancer and was contrary to the recommendations at MDM. This therapy was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (2016) which were signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Team, as their standard of care for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. There was no evidence in the medical notes or from speaking with Service User D's family of informed consent to this alternative care pathway.

Service User D should have been referred to an oncologist to at least allow consideration of other treatment options. His care was not coordinated with the palliative care team. The diagnosis of possible metastasis which would not have changed best practice was nevertheless pursued in a dilatory fashion. The Review Team suggested that when the patient developed anaemia consideration should have been given to the possibility of this being due to malignant involvement of the bone marrow, rather than an effect of severe chronic disease, could have been considered.

The Review Team noted that Service User D's case was not brought back to MDM for rediscussion and multi-disciplinary input despite disease progression.

Service User E

Service User E was diagnosed with testicular cancer. His case was discussed at MDM.He attended for CT chest, abdomen and pelvis on 9 July 2019 which indicated no evidence of metastases (cancer spread). The following day the patient had a left inguinal orchidectomy (removal of left testicle and full spermatic cord) carried out. Pathology of the resection specimen found that the tumour was a classical seminoma measuring 2.6cm across. Although the tumour was confined to the testes, it did involve the rete testis (exit tubules from the testis) and , in addition, intratubular germ cell neoplasia was seen. These findings indicate an increased risk of spread. Service User E's case was discussed at the Urology MDM on 25 July 2019. The plan was for Doctor 1 to review the patient in outpatients and refer him to oncology.

The patient was reviewed on 23 August 2019 and it was noted that Servicer User E had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that he would be reviewed in SWAH again in February 2020 by Doctor 1 to determine if the patient wished to have a testicular prosthesis implanted. The referral to oncology was made on 25 September 2019.

Although, this presentation was unusual, the progress of the patient's investigation and treatment up to the orchidectomy was of a high standard. However, the 2 month delay in his referral to a Medical Oncologist complicated treatment choices. Whether this will compromise the long-term outcome is uncertain as this treatment is recommended to be given within 6 weeks as per the designated protocol.[1,2,3]

The Review Team acknowledge that there is limited oncology presence within the Urology MDT and the date when the patient's case was discussed there was no oncologist present.

The vast majority of the Urology MDMs within the Southern Trust are non-quorate due to the absence of an oncologist and does not meet the existing guidelines. (0% quorate for 2019). (There is a regional deficit of Oncology Consultants in NI and this is recognised by HSCB. During the past 2 years, HSCB have produced a stabilisation plan for Oncology / Haematology. Southern Trust has engaged in this process. A costed plan has been prepared and is currently being considered for funding. In the interim period, the Southern Trust has worked closely with Belfast Trust to secure as much Oncology cover for MDMs as possible, whilst recognising the regional pressures in this specialty. More recently Southern Trust has advertised a shared Oncology Consultant post with Belfast and this trawl has been successful with the post to be filed in the summer 2021. This will improve cover for MDMs but significant~~me~~ gaps will remain.)

Whilst it was the primary responsibility for the consultant in charge to make the referral to oncology a failsafe mechanism to ensure agreed actions took place, such as an MDM administration tracker, was not in place. Cancer Services Division would welcome the establishment of an MDM administrator role; however it would be helpful if the report clarified that this is not yet a commissioned role in the Trust.

Alternatively, the allocation of a Urology Cancer Specialist Nurse as a Key Worker would have supported the patient on his journey as well as having ensured key actions had taken place. Service User E was not referred to a Urology Cancer Nurse Specialist nor was any contact details provided to him. The MDM guidelines indicate "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner"[4]. This did not happen. A Key Worker/ Urology Cancer Nurse Specialist would have prompted the oncology referral sooner.

Service User F

Service User F presented with possible prostate cancer and was commenced on bicalutamide 50mgs indefinitely or until biopsy results were available. The diagnosis of prostate cancer was confirmed by biopsy in July 2019. The patient was discussed at the MDM on 8 August 2020. The diagnosis of intermediate-risk organ confined prostate cancer was agreed. The plan was that Doctor 1 should review the patient and discuss management by surveillance or by active treatment with curative intent.

When Service User F was reviewed by a locum consultant in October 2020 the patient did not recall any conversation about the options of external beam radiotherapy (EBRT) as a radical treatment and Active Surveillance. A Urology Cancer Nurse Specialist was appointed as the Key Worker at this review, not having one at time of diagnosis.

Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment. Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer.

The presence of a Urology Cancer Nurse Specialist would support the patient on his journey as well as ensure key actions had taken place. Service User F was not

referred to a Cancer Nurse Specialist. This is in contrast to declaration for Cancer Peer Review 2017 “all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner” (4). This did not happen.

Service User G

Service User G was diagnosed in June 2016 with a renal mass measuring 2.5 cms in diameter on the anteromedial cortex of the lower pole of the left kidney. The case was presented to MDM in July 2016, and the recommendation was for active surveillance with interval CT scans. These were carried out at the scheduled times.

On 23 August 2018 his case was discussed at MDM. The July 2018 scan was reviewed and now showed the lesion to measure 3.0cm. The MDM recommended to review and discuss with the patient the options of continuing active surveillance or open partial nephrectomy. The case was to be discussed at the Regional Small Masses MDM.

On 28 March 2019 at MDM the renal mass was noted to be enlarging. A further recommendation for Dr 1 to discuss the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risks was made.

On 29 March 2019 the patient was reviewed by a Locum Consultant Urologist. It was noted that the patient had a 3.1cms left sided kidney mass since July 2018 and this mass was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 13 November 2019 a CT scan was performed which showed a further increase in size of lesion to 3.5 cms. No action was taken.

The overall progress of this patient’s management was, on balance, acceptable even though the result of the November 2019 CT scan was not acted on.

The Regional Small Renal Mass MDM was developed to oversee the management of this group of patients. An appropriate referral to this group was omitted, despite the MDM’s recommendation on at least two occasions.

The patient was reviewed in 29 March 2019 by locum consultant who appears not to have had an update from the MDM held on 28 March 2019.

The patient underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021 Dr. 5 reviewed Service User G. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

Service User H

Service User H was diagnosed with penile cancer. The pathology confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease, at presentation and subsequently.

The MDM was a virtual meeting conducted by a single urologist. Its plan was that Doctor 2 would review the patient and arrange for a CT scan of the Service User's chest, abdomen and pelvis to complete staging. The CT scan (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no evidence of metastatic disease.

At the MDM of 12 September 2019 it was agreed that the Service User H should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Service User H to a supra-regional penile cancer MDT.

The Review Team found that the MDM recommendations did not follow NICE guidance for the management of penile cancer [6,7,8] and that there was an opportunity at each meeting to intervene and question Service User H's management.

The treatment provided to this patient was contrary to the NICAN Urology Cancer Clinical Guidelines (2016) for Penile Cancer where it states that local care is restricted to diagnosis. This Guidance was adopted by the SHSCT Urology MDT and evidenced by them as their protocols for cancer peer review 2017. Dr 1 was chair of the NICAN Urology Tumour Speciality Group when the guidance was issued.

The initial clinical assessment of Service User H would have benefited from staging imaging either before or immediately after the original circumcision. All cases of penile cancer should be discussed by the supra-network MDT as soon as the diagnosis is confirmed by biopsy.

The clinical stage G2 pT1 should have led to a consideration of surgical staging with either a bilateral inguinal lymph node dissection (ILND) or sentinel node biopsy (SNB). This omission reduced the likelihood of Service User H's 5 year survival from 90% to less than 40%. The left ILND yielded only 5 nodes, which might be considered at the lower limit of that expected in experienced hands.

The consent form signed by the surgeon and patient is inadequate as it does not state the rationale for the procedure nor the potential complications. The timings between the steps in treatment and management were unduly long and failed to the show the urgency needed to manage penile cancer.

Service User I

Service User I was seen on 27 October 2014 with lower urinary tract symptoms that continued despite medical treatment. Doctor 1 discussed options with Service User I and he decided to proceed to surgery (TURP).

A letter dated 11 November 2016 Service User I's General Practitioner asked for

Service User I TURP to be expedited.

The Patient underwent TURP on 29 January 20 and histology confirmed prostatic adenocarcinoma.

Collation of Multidisciplinary meetings should have a fail-safe whereby lists of all urological cancers by site and SNOMED code are generated weekly. This system was not in place. Cancer Services can confirm that these reports would have been produced up to approx. 5 years ago by an experienced Biomedical Scientist in the Lab in CAH. These reports took a long time to produce and feedback from the MDMs was that they were of limited value. Cancer Services have confirmed that some labs in NI still produce these reports but not all do. Cancer Services believe that new Failsafe reports could be included with the scope of an MDM administrator role if this could be established.

Although Doctor 1 planned to review the patient in April 2020, he was not seen until August 2020 at an appointment arranged by another doctor who has continued care. The patient had done well following his TURP. The histology was explained as an incidental finding that required continuing surveillance with an up to date serum PSA level and a prostate MRI scan.

Service User I was informed on 9 September 2020 that the serum PSA level was within the normal range and that the MRI scan did not show any features of prostate cancer. The prostate cancer was considered unlikely to represent a threat during the patient's life expectancy and would not be anticipated to require any treatment other than surveillance with PSA monitoring.

1. FINDINGS

Diagnosis and Staging

- 5 of the 9 patients in this review experienced significant delay in diagnosis of their cancer. This was related to patients with prostate cancer and reflected variable adherence to regionally agreed prostate cancer diagnostic pathways, NIACN Urology Cancer Clinical Guidelines (2016).
- Service User B had a delay of over 15 months from presentation.
- The review team could not find evidence of a Digital Rectal Examination in the notes of Service User D - potentially missing an opportunity to detect his high grade cancer earlier in his pathway.
- Service User F had a slow initial diagnostic pathway which was outside expected cancer care time-frames.
- Service User C had a delayed diagnosis of a metastatic prostate cancer following successful treatment of Renal Cancer. This was due to non-action on a follow-up CT scan report.

- Patient I had a delayed diagnosis of Prostate cancer due to non-action on a histopathology report at TURP.
- Patient H with penile cancer had a 5 week wait between referral and first appointment. Subsequent time to diagnosis and MDM were appropriate. He had a 17 week wait for a CT scan for staging. Cancer Services can confirm that the patient attend clinic on 25/05/2019 and it was noted that the CT was to be requested. The request was not raised until 08/07/2019 as an urgent referral (not Red Flag). The CT was completed 18 days after the CT was requested.
- Service User G was on a renal mass surveillance programme - a recommendation at MDM to discuss his case with the regional small renal lesion team was not actioned and it is not known if they would have suggested earlier intervention.

Targets

- Three of the nine patients were said to have met one of their 31 / 62 day targets.
- Service User I was said to have met his diagnostic target for 31 days despite his tissue cancer diagnosis being missed and the patient suffering an 8 month delay. The 31 pathway for this patient has been checked against regional guidance and was met. The delays for this patient were outside the 31 day pathway and outside the scope of Cancer Trackers at this time.
- Service User H was said to have met his 62 day (1st treatment) target but had been referred down an incorrect pathway.
- Service User B was said to have met his diagnostic target of 31 days despite having a delay from initial presentation of 15 months. The 31 pathway for this patient has been checked against regional guidance and was met. The delays for this patient were outside the 31 day pathway and outside the scope of Cancer Trackers at this time.

Multidisciplinary Meeting

- The MDM made appropriate recommendations for 8 of the 9 patients but there was no mechanism to check actions were implemented - this included, further investigations, staging, treatment and appropriate onward referral.
- Dr 1 was present for the discussions and party to the recommendations, 8 of which were compliant with National and Regional Guidelines.
- In the case of the 5 patients with Prostate cancer, 5 patients were referred to the Multidisciplinary Meeting and had appropriate MDM recommendations.
- Service User A and Service User D to start Androgen Deprivation Therapy with LHRHa while Service User F was advised to have active surveillance or curative intent radiotherapy. None of these recommendations were implemented.

- NICAN Regional Hormone Therapy Guidelines for Prostate cancer 2016 were not followed.
- Service User B had a delayed diagnosis of prostate cancer and was belatedly seen at the Urology MDM 15 months after his first presentation. The recommendations from this MDM were correct but not implemented. Regional NICAN Hormone Therapy Guidelines for Prostate Cancer 2016 were not followed
- Service User I had an unexpected diagnosis of cancer at TURP. His diagnosis on pathology report was not actioned and he was discussed at MDM 8 months after his surgery and pathological diagnosis of cancer. His subsequent MDM recommendations were correct.
- Two patients had renal cancer. Service User C was initially appropriately discussed at MDM with action on recommendations. However a routine CT scan in December 2019 was not actioned, leading to a delayed re-presentation to MDM with a second primary diagnosis of metastatic prostate cancer.
- Service User G was on a surveillance pathway for a small renal lesion he was appropriately discussed at MDM. The meetings were not always quorate but a radiologist was present on 4 out of 5 occasions. An MDM recommendation to seek input from the regional small lesion group was not actioned.
- Service User E had a testicular tumour and was appropriately discussed at MDM with the recommendation onward referral to the regional testicular oncology team. This recommendation was time critical but did not happen.
- Service User H was appropriately discussed at the local MDM at diagnostic stage. Unfortunately his treatments and further discussions were restricted to local level and did not follow agreed regional and supra-regional pathways for penile cancer.
- Collation of MDM lists did not include a fail-safe list from histopathology. This would ensure all tissue diagnoses of cancer were cross checked against clinician declared cases. This would capture unexpected cases of cancer as in case I or as in case B where a delayed diagnosis presented to the GI surgeons for initial biopsy. Cancer Services can confirm that these reports would have been produced up to approx. 5 years ago by an experienced Biomedical Scientist in the Lab in CAH. These reports took a long time to produce and feedback from the MDMs was that they were of limited value. Cancer Services have confirmed that some labs in NI still produce these reports but not all do. Cancer Services believe that new Failsafe reports could be included with the scope of an MDM administrator role if one was to be established.
- The patient's care was through a Multidisciplinary Team process but unfortunately they did not benefit from it. The Multidisciplinary Meeting failed in its primary purpose to ensure patients received best care as defined by Regional and National Guidelines.
- The Urology MDM was under resourced and frequently non quorate

due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent Quality Assurance of images by a second radiologist prior to MDM. There is a regional deficit of Oncology Consultants in NI and this is recognised by HSCB. During the past 2 years, HSCB have produced a stabilisation plan for Oncology / Haematology. Southern Trust has engaged in this process. A costed plan has been prepared and is currently being considered for funding. In the interim period, the Southern Trust has worked closely with Belfast Trust to secure as much Oncology cover for MDMs as possible, whilst recognising the regional pressures in this specialty. More recently Southern Trust has advertised a shared Oncology Consultant post with Belfast and this trawl has been successful with the post to be filed in the summer 2021. This will improve cover for MDMs but significant~~ome~~ gaps will remain. In relation to Radiology attendance at MDMs, Cancer and Clinical Services have been working as a priority in recent years to fill vacant consultant Radiology posts. In 2016, there were 10 vacant posts and this has now been reduced down to 2 vacancies. Consultant Radiologist with a sub specialty interest in Urology continues to be one of the 'hard to fill' posts, however efforts continue to try and fill this gap. One substantive Radiologist has retrained in Urology to support the other Radiologist who attends the Urology MDM. Cover had improved during 2019, however this has been further impacted during COVID19. Cancer and Clinical Services will continue to work as a priority to improve Radiology cover to the Urology and other MDMs.

- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31 and 62 day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care. The Cancer Trackers continue to track in the same way as other Trackers across NI with the exception of Western Trust. The Cancer Tracker roles are standardised across NI and are in line with what has been commissioned to date. If the scope of the tracking is to change, this should be agreed regionally through NICAN and should be funded by the commissioner.
- Safe cancer patient care and pathway tracking is usually delivered by a three pronged approach of MDT tracking, Consultants and their secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that ~~these~~ these 9 patients were not referred to Specialist Nurses and telephone numbers were not given. The MDM tracking system was limited. The tracking is currently in line with what has been commissioned to date and is in line with tracking in other Trusts in NI with the exception of Western Trust – this has been confirmed with other Cancer Managers in NI and with the Assistant Director for Cancer Commissioning in NI The consultant / secretary led

process was variable and resulted in deficits. The weakness of the latter component was known from previous review.

- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non implementation of these MDM recommendations was unknown to others in the MDM. One patient D presented as an emergency and his care was changed to the MDM recommendation by another consultant.

Multidisciplinary working and referral

- The review team noted repeated failure to appropriately refer patients
- Service User A should have been referred to oncology initially and then to palliative care as his disease progressed.
- Service User B should have had an earlier diagnosis and referral to oncology.
- Service User D should have been referred to oncology and palliative care.
- Service User E should have been referred to oncology for time critical care.
- Service User F should have been referred to oncology.
- Service User G should have been referred to the Small Renal Mass Team.
- Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network.
- Patients were not aware that the care given varied from Regional Standards and MDM recommendations. They could not have given informed consent to this.
- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non referral was an unknown to others within the MDM.

Patient Support and Experience

All patients or families reported a positive experience with their treating consultant initially.

All patients and families were unaware of the additional support available to other patients.

Where patients had disease progression, they expressed concern at the disjointed nature of service provision and the inability to access supportive care. As they were unaware of the normal support mechanisms they believed this to be the normal standard of care or a standard that had been compromised by Covid 19 Pandemic.

All patients and their families were shocked by the fact that their care was not supported and that the care did not follow MDM recommendations. This was especially true when appropriate care should have entailed onward referral to oncology or palliative care.

Affects of Covid

- Some patient's planned review appointments did not go ahead but were rescheduled virtually. Some of the patients did not have their planned review in March / April 2020.

- The review team after speaking with the families and hearing their stories learned that for many of these patients they could not access services in their locality due to the covid restrictions. At the time two families described having difficulty accessing district nursing services for intravenous antibiotics in the community as services were stood down. One family expressed dismay at having difficulties visiting their loved one prior to his passing in hospital due to the covid restrictions and the emotional impact this has had on their grieving process. Others described how when catheters blocked they could not access support from their GP and where hence referred to the Emergency Department which the review team agree was not the best place for them. The review team are of the opinion that access to a specialist nurse could have offered support for these families and provide direction to the appropriate services.

Governance / Leadership

- The review team considered the treatment and care of 9 patients who were treated under the care of Dr 1 Consultant Urologist. Individual reviews were conducted on each patient. The review team identified a number of recurrent themes following each review.
- The treatment provided to 8 out of 9 patients was contrary to the NICAN Urology Cancer Clinical Guidelines (2016). This Guidance was adopted by the Southern Health and Social Care Trust Urology Multidisciplinary Team and evidenced by them as their protocols for Cancer Peer review (2017). The Guidance was issued following Dr.1 & Chairmanship of the Northern Ireland Cancer Network Urology Cancer Clinical Reference Group.
- The Urology MDM made recommendations that were deemed appropriate in 8 of 9 cases and were made with contribution and knowledge of Dr.1. Many of the recommendations were not actioned or alternative therapies given. There was no system to track if recommendations were appropriately completed. Cancer Trackers will track patients on the 31 and 62 day pathways in line with what has been commissioned. This is confirmed to be the case in other Trusts in NI with the exception of Western Trust. The responsibility for following

up other actions sits with the clinician and his / her secretary.

- The MDT guidelines indicate "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner". None of the 9 patients had access to a Key Worker or Cancer Nurse Specialist. The use of a CNS is common for all other urologists in the SHSCT urology multidisciplinary team allowing any questions or concerns that patients' have to be addressed. This did not happen.
- The review team considered if this was endemic within the Multidisciplinary Team and concluded that it was not. Patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.
- Statements to Urology Cancer Peer Review (2017) indicated that all patients had access to a Key worker / Urology Cancer Nurse Specialist. This was not the case and was known to be so. It would be helpful if the report stated who was aware of this issue.
- The Urology Cancer Nurse Specialist play an integral role of the MDT and should be facilitated on all the MDM to advocate on patient's best interest throughout the patient's journey. This should include independently referring and discussing patients at MDT.
- The Review Team regard absence of Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and the Professional Leads. The Review team have heard differing reports around escalation of this issue but are clear that patients suffered significant deficit because of non inclusion of nurses in their care. While this is the primary responsibility of the referring consultant, there is a responsibility on the SHSCT to know about the issue and address it. It would be helpful if the report stated who was aware of this issue.
- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered. Additional capacity for targeted assurance audits would be useful for MDMs and for Cancer Services.
- Because of resource~~,~~ the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31 and 62 day targets. Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were,in essence absent. It is important to state that the Cancer Trackers are commissioned to track patients on the 31 and 62 day pathways. It is incorrect to suggest that the scope of tracking was limited due to resources or due to the process being flawed. The Trackers perform this function in line with what has been commissioned and it is in line with other Trusts in NI with the exception

of Western Trust. Changes to the scope of tracking should be agreed regionally through NICAN and be consistent across Trusts in NI.

- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report. Cancer Services agree that additional capacity to support compliance audits would be helpful.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM, but did not escalate other issues. Comments noted above provide evidence of actions taken by Cancer Services to help address deficits in Oncology and Radiology input to MDMS – therefore we would suggest that this parapraph is incorrect.
- The Review team found that issues around prescribing and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.
- The Review team were concerned that the leadership roles focused on service delivery while having a limited process to benchmark quality, identify deficiencies and escalate concerns as appropriate. Senior managers and clinical leaders in medicine and nursing were unaware of the issues detailed in this report.
- There had been a previous SAI signed off in May 2020 regarding adherence to Cancer Red Flag referral Pathways. The SAI process started in July 2016. The review team is concerned that, as part of early learning, assurances regarding other aspects of the cancer pathway were not sought. Clinical Leadership within Cancer Services were unaware of issues leading to the SAI in 2016.
- Patients in this review were not referred back appropriately to MDM as their diseased progressed. This meant there was no access to oncology and palliative care for many patients, when needed. Care needs within the community were unmet and patients left isolated.

1. CONCLUSIONS

The Review Team would like to thank the patients and their families for their contribution to the report and their willingness to share their experiences. The process was difficult and at times traumatic for them.The review team acknowledge that this report may cause distress to the patient and their families, however the team has endeavoured to produce a complete and transparent account of each patient's journey.

The Review of nine patients has detailed significant healthcare deficits while under the care of one individual in a system. The learning and recommendations are focused on improving systems of multidisciplinary care and it's governance. It is designed to deliver what was asked of the Review Team by patients and families -" *to ensure that this does not happen again or that another patient suffers".*

The Patients in this review received uni-professional care despite a multidisciplinary resource being available to all others. Best Practice Guidance was not followed and recommendations from MDM were frequently not implemented or alternative treatments chosen. There was knowledge of that prescribing practice varied from regional and national guidelines in the Southern Health and Social care Trust, as well as more widely across the Cancer Network. This was challenged locally and regionally, but not effectively, to provide safe care for all patients. Inappropriate non referral of patients to oncology and palliative care was unknown.

The primary duty of all doctors, nurses and healthcare professionals is for the care and safety of patients. Whatever their role, they must raise and act on concerns about patient safety. This did not happen over a period of years resulting in MDM recommendations not being actioned, off guidance therapy being given and patients not being appropriately referred to specialists for care. Patients were unaware that their care varied form recommendations and guidance. They could not and did not give informed consent to this.

The systems of governance within the Urology SHSCT Cancer Services were ineffective and did not provide assurance regarding the care and experience of the nine patients in the review. Assurance audits were limited, did not represent whole patient journey and did not focus on areas of known concern. Assurances given to Peer review were not based on systematic audit of care given by all.

While it is of little solace to the patients and families in this review, The Review team

sought and received assurances that care provided to others adhered to recommendations on MDM and Regional / National Guidance.

Four of the nine patients suffered serious and significant deficits in their care. All patients had sub-optimal care that varied from regional and national guidelines.

1. LESSONS LEARNED

The review identified Cancer Care given by Dr 1 that did not follow agreed MDM recommendations nor follow regional or national best practice guidance. It was care given without other input from Cancer Specialist Nurses, Oncology and palliative care. It was inappropriate, did not meet patient need and was the antithesis of quality multidisciplinary cancer care.

Ensure all patients receive appropriately supported high quality cancer care irrespective of the professional delivering care.

Ensure all cancer care is multidisciplinary and centred on patients physical and emotional need.

Have processes in place to provide assurances to patients and public that care meets these requirements.

That the role of the Multidisciplinary Meeting Chair is defined by a Job Description with specific reference to Governance, Safe Care and Quality Care. It should be resourced to provide this needed oversight.

1. RECOMMENDATIONS AND ACTION PLANNING

The recommendations represent an enhanced level of assurance. They are in response to findings from nine patients where Dr 1 did not adhere to agreed recommendations, varied from best practice guidance and did not involve other specialist appropriately in care. They are to address what was asked of the Review by families - "that this does not happen again".

Recommendation 1.

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients.

This will be achieved by - Urology Cancer Care delivered through a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis, treatment planning and completion and survivorship.

Timescale – Immediate (suggest the timescale reflects the time to plan and implement the peer review process– possibly 3 months)

Assurance - Comprehensive Pathway audit of all patients care and experience. This should be externally benchmarked within a year by Cancer Peer Review / External Service Review by Royal College.

Recommendation 2.

All patients receiving care from the SHSCT Urology Cancer Services should be appropriately supported and informed about their cancer care. This should meet the standards set out in Regional and National Guidance and meet the expectation of Cancer Peer Review.

This will be achieved by - Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent.

Timescale - Immediate

Assurance - Comprehensive Cancer Pathway audit and Patient experience.

Recommendation 3.

The SHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely.

This will be achieved by - Ensuring a culture primarily focused on patient safety and respect for the opinions of all members. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical Cancer Services oversight fortnightly agenda. There must be action on issues escalated.

Cancer Services suggest that the MDM chair is the main point of escalation in the first instance where it is suggested that patient safety is compromised. The MDM chair should then address the issue and involve the CD/AMD for the specialty and also the CD/AMD for Cancer. The recommendation refers to a fortnightly cancer services meeting. The Cancer Service meeting is actually a monthly meeting with the AMD, CD, AD and HOS present. We believe the fortnightly meeting may be a reference to a COVID rebuild Friday PM meeting which is not the correct forum for raising issues of this nature.

Furthermore, Cancer Services recommend that a quarterly Cancer Services Oversight Group be established to oversee delivery of cancer care. This was proposed pre-COVID 19 as a forum to raise the profile of Cancer Services with a focus on service improvement. With the learning from these SAIs, we believe the TOF for this group should be revisited and a governance role included.

Cancer Services believe governance around delivery of cancer care could be improved by:

- Reviewing the role of chair of MDMs
- Reviewing the role of all AMDs, CDs, ADs and HOS involved in delivery cancer care
- Closer working between the chair of MDMs, other Divisions and Cancer Services
- Additional capacity for clinical audit to support assurance audits
- Establishment of MDM administrator and a new failsafe function for histopathology
- Additional support for tracking

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Timescale – Immediate (suggest this work may take 3-6 months to complete)

Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, numbers of issues outstanding.

Recommendation 4.

The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.

This will be achieved by - All MDMs being quorate with professionals having appropriate time in job plans.This is not solely related to first diagnosis and treatment targets. Re-discussion of patients, as disease progresses is essential to facilitate best multidisciplinary decisions and onward referral (e.g. Oncology, Palliative care, Community Services).

Cancer Service agrees that we should be aiming to have all MDMs quorate as soon as possible. We do need to acknowledge that some of the gaps are due to regional deficits in workforce – Oncology and Radiology being two examples of this. Cancer and Clinical Services are working to address the Radiology gap as noted above in this report. The Oncology gap is more difficult to address as this support is mainly provided to the Trust by Belfast Trust.

Timescale - 3 months (given that this is a regional gap, it may take much longer than 3 months to address this – possible up to 1 year)

Assurance - Quorate meetings, sufficient radiology input to facilitate pre MDM QA of images - Cancer Patient pathway Audit - Audit of Recurrent MDM discussion - Onward referral audit of patients to Oncology / Palliative Care etc.

Recommendation 5.

The Southern Health and Social Care Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed

recommendations / actions are completed.

This will be achieved by - Appropriate resourcing of the MDM tracking team to encompass a new role comprising whole pathway tracking, pathway audit and pathway assurance. This should be supported by fail-safe mechanisms from laboratory services and Clinical Nurse Specialists as Key Workers A report should be generated weekly and made available to the MDT. The role should reflect the enhanced need for ongoing audit / assurance. It is essential that current limited clinical resource is focused on patient care.

As stated in the feedback above, the Cancer Trackers currently track patients on the 31 and 62 day pathways. This is in line with what has been commissioned to date. If the tracking role is to change, we suggest that this will need to be considered regionally and endorsed through NICAN. If full pathway tracking was to be introduced for all tumour sites, this would require a major investment - possibly seeing the current tracking team double and possibly triple in size from 8wte to between 16 and 24 Band 4 staff. Given the workforce / financial implications of this, we may need to consider putting this in place for Urology in the first instance and then looking to expand further in due course

Timescale - 3 months (given the lead in time for securing funding, recruitment and training, it would be more realistic to state 6 months for this recommendation and that would be for Urology MDM only)

Assurance - Comprehensive Cancer care Pathway audit - Exception Reporting and escalation

Recommendation 6.

The Southern Health and Social Care Trust must ensure that there is an appropriate Governance Structure supporting cancer care based on patient need, patient experience and patient outcomes.

This will be achieved by - Developing a proactive governance structure based on comprehensive ongoing Quality Assurance Audits of care pathways and patient experience for all. It should be proactive and supported by adequate resources.This should have an exception reporting process with discussion and potential escalation of deficits. It must be multidisciplinary to reflect the nature of cancer and work with other directorates.

Comments for recommendation 3 above also apply to this recommendation.

Timescale - 3 months

Assurance - Cancer Pathway Audit outcomes with exception discussion and escalation. Data should be declared externally to Cancer Peer Review

Recommendation 7.

The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.

See comments for recommendation 3 above. Cancer Services believe it would be prudent to review the Job Descriptions for the chair of the MDMs alongside those for the AMDs, CDs, ADs and HOS involved in delivery cancer care. This is necessary to have complete clarity around the clinical governance function for Cancer Care and also the escalation arrangements where there are concerns in relation to patient safety.

Timescale - 3 months

Recommendation 8.

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

This will be achieved by - Ensuring the multi-disciplinary team meeting is the primary forum in which the relative merits of all appropriate treatment options for the management of their disease can be discussed. As such, a clinician should either defer to the opinion of his / her peers or justify any variation through the patient's documented informed consent.

Timescale - Immediate

Assurance - Variance from accepted Care Guidelines and MDM recommendations should form part of Cancer Pathway audit. Exception reporting and escalation would only apply to cases without appropriate peer discussion.

Recommendation 9.

The roles of the Clinical Lead Cancer Services and Associate Medical Director Cancer Services should be reviewed. The SHSCT must consider how these roles can redress Governance and Quality Assurance deficits identified within the report.

See comments against recommendation 7 above. Same comments apply to recommendation 9.

Timescale - 3 months

Recommendation 10.

--This recommendation will be agreed following discussion with families.

Recommendation 11

The Southern Health and Social Care Trust should consider if assurance mechanisms detailed above, should be applied to patients or a subset of patients retrospectively.

References:

1. Hoffmann, R., et al. Innovations in health care and mortality trends from

five cancers in seven European countries between 1970 and 2005. Int J Public Health, 2014. 59: 341.

2. Oliver, R.T., et al. Radiotherapy versus single-dose carboplatin in adjuvant treatment of stage I seminoma: a randomised trial. Lancet, 2005. 366: 293.

3. Laguna M.P., et al EAU Guidelines: testicular cancer. https://uroweb.org/guideline/testicular-cancer/note_127-129 (accessed 26/02/2021)

4. Peer review Self-Assessment report for NICaN 2017

5. Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016)

6. EAU guidelines for penile cancer: section 6.2.1 (2019)

1. NICE improving outcomes in urological cancer (2002)

1. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).

1. DISTRIBUTION LIST

Mr Shane Devlin – Chief Executive SHSCT

Mrs Melanie McClements – Director of Acute Services SHSCT

Dr Maria O'Kane – Medical Director SHSCT

Mrs Heather Trouton Executive Director of Nursing, Midwifery and AMPs

PHA

HSCB

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report <u>for all levels of SAI reviews)</u>

Reporting Organisation SAI Ref Number:	Personal Information redacted by USI	**HSC B ref Number:**	Personal Information redacted by USI

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER						
1. Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**	
	Comment: ***If multiple service users involved please indicate the number involved**					
1. Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**			
	If **YES**, insert **date informed**:					
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI					
	a. No contact or Next of Kin details or Unable to contact					
	a. Not applicable as this SAI is not 'patient/service user' related					
	a. Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user					
	a. Case involved suspected or actual abuse by family					
	a. Case identified as a result of review exercise					
	a. Case is environmental or infrastructure related					

	with no harm to patient/service user	
	a. Other rationale	
	If you selected c), d), e), f) or g) above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

1. Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**	**x**	**NO**	
	If **YES**, insert date informed: **all informed 26 October 2020**			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a. Draft review report has been shared and further engagement planned to share final report			
	a. Plan to share final review report at a later date and further engagement planned			
	a. Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	a. No contact or Next of Kin or Unable to contact			
	a. No response to correspondence			
	a. Withdrew fully from the SAI process			
Continued overleaf	a. Participated in SAI process but declined review report			
	(if you select any of the options below please also complete 'I' below)			
	a. concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer			
	a. case involved suspected or actual abuse by family			
	a. identified as a result of review exercise			
	a. other rationale			

	a. If you have selected **c), h), i), j), or k)** above please provide further details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER S OFFICE **(under section 7 of the Coroners Act (Northern Ireland) 1959)** ***(complete this section for all death related SAIs)***				
1. Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
1. Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
1. If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

1.“There is a regional deficit of Oncology Consultants in NI and this is recognised by HSCB. During the past 2 years, HSCB have produced a stabilisation plan for Oncology / Haematology. Southern Trust has engaged in this process. A costed plan has been prepared and is currently being considered for funding. In the interim period, the Southern Trust has worked closely with Belfast Trust to secure as much Oncology cover for MDMs as possible, whilst recognising the regional pressures in this specialty. More recently Southern Trust has advertised a shared Oncology Consultant post with Belfast and this trawl has been successful with the post to be filed in the summer 2021. This will improve cover for MDMs but significant gaps will remain.”

The review team does not accept a differential service for patients based on geography and the report is based on what should be present. It is expected that the out-workings of the SAI will result in better and appropriate resourcing for patients of the SHSCT.

2. “Cancer Services Division would welcome the establishment of an MDM administrator role; however it would be helpful if the report clarified that this is not yet a commissioned role in the Trust.”

This is not the experience of the external members of the review team elsewhere in NI and the UK. The review is based on what is best regional and national practice and that which results in the safest possible service for patients. Commissioning within trust resource or regional resource is not within the remit of a Serious Adverse Incident Review.

3 “Cancer Services can confirm that these reports would have been produced up to approx. 5 years ago by an experienced Biomedical Scientist in the Lab in CAH. These reports took a long time to produce and feedback from the MDMs was that they were of limited value. Cancer Services have confirmed that some labs in NI still produce these reports but not all do. Cancer Services believe that new Failsafe reports could be included with the scope of an MDM administrator role if this could be established”

This is not the experience of the external members of the SAI review team. The fail-safe cancer lists are generated by T site codes and M diagnosis codes for malignancy (xxxx3) weekly, by clerical staff who liaise with MDM trackers. It provides additional assurance and would have been of benefit in cases where patients are lost to follow. Critically it also ensures rapid referral of patients to MDM and better adherence to 31 and 62 day targets.

4. “Cancer Services can confirm that the patient attend clinic on 25/05/2019 and it was noted that the CT was to be requested. The request was not raised until 08/07/2019 as an urgent referral (not Red Flag). The CT was completed 18 days after the CT was requested”

The review included the overarching CT timeline, as the critical issue was that the patient had a potentially aggressive tumour and should have been on an appropriately timed pathway that was supported by tracking and assurance mechanisms. The 17week delay should not have happened and ideally systems would have been in place to prevent this.

The recommendations in the over-arching SAI review propose patient pathways should be tracked in real time and prevent such delays.

5. “Cancer Trackers will track patients on the 31 and 62 day pathways in line with what has been commissioned. This is confirmed to be the case in other Trusts in NI with the exception of Western Trust. The responsibility for following up other actions sits with the clinician and his / her secretary.”

This is not the experience of the external members of the SAI review team in NI and UK. Critically the resource in SHSCT Urology MDM was unable to meet patient tacking need in these 9 SAIs and in a previous SAI of 2016. Patients came to harm. The review team believe it essential that enhanced resource is in place to improve MDM tracking, in concert with Key workers (usually Urology Cancer Nurse Specialists) and consultant secretaries. This has been shared with the Urology MDM and welcomed, given that several members had previous experience of this approach from the UK.

6 and 7 “It would be helpful if the report stated who was aware of this issue.”

“With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner. It is intended that patients newly diagnosed as inpatients will also be included.”

The above statement was made on behalf of the SHSCT to Urology Cancer Peer Review 2017 – it has proven to be inaccurate and not based on an assurance audit process. The review team appreciated the candour of those who admitted to being aware that not all care was supported by Cancer Nurse Specialists. They do expect that governance processes are enhanced to ensure that no patients receive cancer care unsupported and without linkages to other critical services.

8 ”Additional capacity for targeted assurance audits would be useful for MDMs and for Cancer Services.”

The review team have considered this in the recommendations going forward. They believe prospect assurance audit must be supported by resource and infrastructure. However between 2017 and 2020 assurance audit was limited in the Urology Service and much led by Urology Nurse Specialists. There was no evidence of targeted audit work in areas of known problems or concerns. Appropriate resourcing of audit should be within the remit of Cancer Service Management and Clinical leadership.

9.”It is important to state that the Cancer Trackers are commissioned to track patients on the 31 and 62 day pathways. It is incorrect to suggest that the scope of tracking was limited due to resources or due to the process being flawed. The Trackers perform this function in line with what has been commissioned and it is in line with other Trusts in NI with the exception of Western Trust. Changes to the scope of tracking should be agreed regionally through NICAN and be consistent across Trusts in NI”

The 9 SAI reports detailed wide ranging delays and deficits in care that were not and could not be detected with the current tracking resource within SHSCT Urology Cancer MDT. The external members of the SAI review team have different experiences of cancer tracking, something which is shared by several consultant members of the Urology MDT with UK experience. Patients came to harm which could have been prevented by enhanced tracking. The SHSCT is responsible for governance of this service and resource must meet clinical risk and patient need.

10.Cancer Services agree that additional capacity to support compliance audits would be helpful.

No comment.

11. Comments noted above provide evidence of actions taken by Cancer Services to help address deficits in Oncology and Radiology input to MDMS – therefore we would suggest that this paragraph is incorrect.

The Chair of the SAI review would dispute this as it is not based on data – attendance at MDM by oncology had become progressively worse in the year 2020 (5%) and radiology is still single handed without appropriate pre- MDM independent review of images. This was a live concern and frustration of the SHSCT Urology MDM 18th February 2021.

SAI Urology Review

Meeting with Barry Conway
Tuesday 29 December 2020 at 1pm

Attendees
Dr Dermot Hughes and Mrs Patricia Kingsnorth

Dermot Hughes (DH)
Barry Conway (BC)

Dr Hughes thanked Mr Conway for facilitating the meeting. He explained the overview of the SAI review in relation to the themes identified during the review. He advised that the NICAN peer review adapted by the Regional group was signed off by the Trust. Mr OB signed off the peer review; however, he did not adhere to the recommendations and standards.
He advised that some of the issues were in relation to the patients not having access to a specialist nurse/ key worker. Therefore when the patient's condition deteriorated there was no referral back to MDT

He advised the MDT was set up to keep patients safe and to provide challenge from the multidisciplinary teams. If there was challenge why did it not effect change and who knew about it.

BC advised that it would be down to the individual clinicians to bring patients back for discussion at MDT
BC advised that the structure of the cancer services would consist of him, HOS (Fiona Reddick) AMD (Dr Shahid Tariq) and CD (Mr David McCaul).
They would meet monthly to discuss operational issues regarding service delivery, workforce issues/ Pathways/ Incidents and Risk Registers and consider any pressures in the system.
They don't have a feed from the chairs of the MDM and would not be made aware of any individual's practices.
DH – what would happen when things go wrong?
BC – this would be managed by the specialist route.

BC advised that he has been employed by the Trust since 2005 and he was aware of some issues regarding Mr O'B in relation to back logs and dictation but not clinical concerns. BC said he was aware of a previous SAI on a higher level. He has been in this role as AD for clinical cancer services for 2.5 years and was not aware of any formal escalation relating to Mr O'B.

BC stated he wasn't aware that specialist nurses were not involved in the patients identified in the SAI review.

DH stated that there needs to be a corporate understanding of the MDM process with clear lines of accountability and governance processes. He advised that we need to understand were there any opportunities to identify concerns earlier?
DH give an example of the experiences of one of the patient's involved.

BC welcomed the opportunity to review the next years plans and how to manage next year's processes.
DH suggested that routine audits are carried out annually to ensure that patients are getting the treatment recommended.

DH asked for the feedback documents from the chief executive following the annual reports. BC advised that Fiona Reddick will be able to provide them.

BC advised that his services look mainly at service improvement and capacity and demand
DH advised that the peer review provided assurance to the Chief Executive that were not being followed by a clinician.

BC advised that you would expect staff within the speciality to ask the questions
DH advised that in urology the chair of MDM is rotational.
BC advised that this was unique to urology.

BC advised that the CCS provides direct responsibility for the service. It is an oversight role. The governance aspect would sit within the specialities.

BC highlighted some of the good work that is being done by the MDT particularly in relation to the patient / client experience data. (Fiona or Mary Haughey will be able to provide).

DH asked for examples of the good work being done would be welcome to ensure a balanced view of the MDM.

BC welcomed a review of the current processes and would welcome more clarity around the governance role with evidence of audit. He advised that he wouldn't have the assurances when the audit process is undertaken by Quality Improvement team.

DH thanked BC for assisting the review.

Meeting with Mrs Heather Trouton Executive Director of Nursing SHSCT
Dr Dermot Hughes – Chair of SAI review

Note taker – Patricia Kingsnorth Acute Clinical Governance Coordinator

23 February 2021 at 13:30 via zoom

Patricia welcomed Mrs Trouton and introduced her to Dr Hughes and explained that he was chairing the SAI review and that he had some questions he needed clarification for.

Dr Hughes provided a summary of the urology review to date in relation to meeting 8 of the 9 the families twice and understanding their experiences of their care.

He explained that the main concern was around the patient's access to a cancer nurse specialist. None of the 9 patients received the services of a cancer nurse specialist and therefore they were not supported on their cancer journey which for some caused serious distress.

Dr Hughes explained that as part of the review the quality of care provided was not in question as patients did not receive any care.

He explained that the NICAN guidance recommended that every patient with a cancer diagnosis was provided support from a cancer nurse specialist. This assurance was provided to the peer review in 2017 that additional specialist nurses were resourced to provide this service. This was signed off by the chief executive. But the reality was that Mr OB patients were not given access to a specialist nurse. There were no checks and balances in the system to quality assure that this was happening.

Mrs Trouton advised that she was assistant director of Surgical and Elective Care until March 2016 when she moved to IMWH division. She advised that she was not in post when the NICAN guidance was implemented and could not comment on it. She advised that prior to leaving her post there were only two specialist nurses in post. One who was responsible for cystoscopy and one who was responsible for cancer care.

She went on to advise that as a Director of nursing she would expect any nurse to provide care in their professional role. Dr Hughes advised that he did not have an issue with the standard of care that the specialist nurses provided. His issue was that they did not receive any referrals from Mr O'Brien and therefore did not provide any care. Mrs Trouton asked if Dr Hughes thought that they should have sought referrals He replied that they should not but there should have been a system of checks and balances in place to ensure that Mr'OBrien's patients were being referred.

Dr Hughes advised that this was about the patients not getting access to a nurse and he wanted to understand how that could happen. He advised that this resulted in

severe deficits in the 9 patients' care. He said that all the families have asked how it had happened?

Mrs Trouton said that she had been very recently advised that all the information regarding accessing a specialist nurse and all the leaflets and phone numbers were visible in every consulting room to ensure doctors had the information to give to patients.
She recognised that the checking mechanism to ensure that the consultant was giving the information to the patient was not in place from the investigation findings.

Dr Hughes advised that he has asked the cancer clinical leads and AMDs who were not involved in the urology service but were unaware of any issues regarding specialist nurses not being made available to Mr OB's Patients. But he advised that they should have that oversight/ responsibility.

Mrs Trouton advised that the escalation process is clear for all nursing services. The specialist nurses should escalate to their lead nurse who will seek to address the issue in question. If they cannot resolve the issue, they will escalate to the HOS or AD (one of whom is a nurse) who will in their operational and nursing role seek to address the concern. If there is an issue requiring wider discussion, these issues are brought to the Acute Governance Nursing forum .If necessary the issue will be escalated to Mrs Trouton either directly by the Acute Senior Nurse or via her Assistant Director for nursing safety, quality and Experience. That way there is a clear line of sight between the operational nursing/ midwifery team and the corporate nursing team.

The issue of specialist nurse referrals was never escalated to Mrs Trouton.

Dr Hughes wanted to know if anyone knew about it and how was it not escalated and did anyone consider the consequences to the patients?
He advised that the concerns around the doctor over looked the patients' experience. He advised that the mechanisms in place to provide governance were not fit for purpose.

Dr Hughes advised that he spent two days talking to families and advising that the resources for specialist nurse was in place but they or their loved one didn't get access to one. All the patients/ families wanted to know how this was allowed to happen.

Dr Hughes advised that 8 out of the 9 patients had very appropriate recommendations from the MDM but these were not actioned by the consultant in charge of care. Patients were not forwarded for specialist care, and none of them had access to a specialist nurse or were even provided with a phone number.

Mrs Trouton advised that the governance process has been in place a long time and is a clear process but it needs utilised.

Dr Hughes advised that it not just about nurse to nurse or consultant to consultant escalation. But, he advised that there is an opportunity for the MDT to address the

deficits. He advised the MDT needs to provide safeguards to ensure that guidance is being adhered to. He reiterated that patients have come to harm.

Dr Hughes clarified that Mr OB provided uni-professional care in a multi professional environment. He advised that the right thing wasn't done. He acknowledged that the MDT needs better resourced to ensure that assurance audits are carried out to provide data to show how compliance with guidance was maintained. He advised there will be reputational damage to the trust.

Mrs Trouton advised she will be interested going forward in having a checking mechanism in place for all areas of care.

Dr Hughes advised that there is a cultural problem in that seems to be professional focus and not patient focus. He advised that some people were reluctant to get involved with difficult situations. There was the not environment to raise concerns. He acknowledged that some professionals did escalate concerns.

Dr Hughes asked if Mrs Trouton had any questions. She declined.
He and Patricia thanked Mrs Trouton for taking the time to meet with them.

SAI Urology Review

Meeting with Dr Shahid Tariq
Tuesday 29 December 2020 at 1:45pm

Attendees
Dr Dermot Hughes and Mrs Patricia Kingsnorth

Dermot Hughes (DH)
Shahid Tariq (ST)

Dr Hughes thanked Dr Tariq for facilitating the meeting. He explained the overview of the SAI review in relation to the themes identified during the review. He advised that the NICAN peer review adapted by the Regional group was signed off by the Trust. Mr OB signed off the peer review; however, he did not adhere to the recommendations and standards.

He advised that some of the issues were in relation to the patients not having access to a specialist nurse/ key worker. Therefore when the patient's condition deteriorated there was no referral back to MDT

DH asked did the MDT know that Mr OB was not adhering to guidelines or the recommendations from the MDT. He advised that there was challenge but questioned who was it escalated to?
ST – he was not aware of any concerns mentioned. Any clinical concerns would go through the speciality management structure route.

ST did advise in 2019 he set up a cancer strategic forum which would meet twice a year.
This was to bring together different tumour site specialities under one umbrella, to look at good practice and to identify the need for additional resources for them. They only had one meeting in 2019 and planned to meet in March 2020 but this was cancelled due to covid.

DH advised that some of the patients did not receive the appropriate drug therapy in relation to androgen deprivation therapy. Mr OB chose not to involve other professionals in the patients care. There are now 5 specialist nurses in post.

DH asked if the urology team asked for additional support. The specialist nurses were used by all the clinicians except one. The specialist nurse is a safety net for when things are missed. Do you know if there were any concerns raised by the specialist nurses?
ST – No. was not aware.

DH asked did the chair of the MDM have a pa in their job plan

ST advised that he believe they were given one PA but this would be for the MDT and their leadership to decide. He advised that the cancer service is responsible for cancer performance targets, tracking of patients on cancer pathways and to provide help and operational support to the tumour site teams if it is needed. Governance arrangements lay within the primary team management structure i.e. CD and AMD for the division.

DH acknowledged that people didn't realise the deficits of care as the absence of a key worker impacted on the patient's care.

ST advised that they were removed from that process because the primary team's leadership is responsible for governance arrangements.
DH asked was that appropriate?
ST advised that cancer service would like to strengthen its links with the tumour site specialities to be able to provide better support for them..

Dr Hughes thanked Dr Tariq for his input.

SAI Urology Review

Meeting with Mr David McCaul
Monday 4 January 2021

Attendees
Dr Dermot Hughes and Mrs Patricia Kingsnorth

Dermot Hughes (DH)
David McCaul (DM)

DH thanks DM for meeting with him and explained the process to date regarding the SAI review involving 9 patients (one with penile cancer, 1 testicular cancer, 5 prostate cancers and 2 renal cancers). He explained that in all cases the recommendations from the MDM were not actioned and that there was a delay in referring patients to oncology / specialist services. None of the patients had access to a key worker/ specialist nurse. This was unique to this consultant. Other concerns raised were inappropriate diagnostics, issues around hormone therapy, using treatments outside of licence and not according to guidance. When the patients deteriorated they were not referred back to MDT.
He advised that two patients had died and 2 are currently palliative.

DH – asked if DM was made aware of any concerns about Mr OB?
DM advised he was not made aware of any concerns, the first he became aware of any issues was from the Irish News. DM went on to advise that his role as clinical director of clinical cancer services was limited to Peer Review and outcomes of business meetings. His role had no power to control or influence pathways or change. He advised that he has control over acute oncology and he had an under preforming doctor which he sorted.

DM advised that firstly he had no idea Mr OB had issues because it was not communicated to him and secondly as there is no role in job-planning/day to day running of urology it would not have been his role anyway, unlike acute oncology/palliative care whose doctors I do job plans etc..

DH advised that the peer review document in 2017 provided assurances to the board that all patients had access to a key worker/ specialist nurse. This didn't happen. There was no one to support these patients on their journey and who would have been able to follow up results.

DH advised that there was a previous SAI which showed issues regarding delays in triage and asked if DM was aware of it.
DM was not aware of any SAI relating to the consultant.
DH advised that he had spoken with the Chair of the urology MDM and advised that practices were challenged but not minuted. Were these concerns escalated?

DM advised that any issues with the consultant must have been addressed within the speciality and not escalated to him.

DM noted the only urology issues escalated to him was in relation to lack of radiographer for attending MDM. Also issues about centralization of nephrectomy services and these issues were not escalated to me formally, but I was aware of them through conversations with other urology consultants, these issues where being dealt with through NICAN regional urology group.

DH thanked him for meeting with him.

Update on the concerns identified from the Urology MDT Peer review External Verification - October 2017

EV RAG rating – RED; % compliance 2017: 65%

Serious concerns	**Update May 2018**
1. No cover in place for the clinical oncologist and the consultant radiologist	Clinical Oncology representation (core & cover) – provided through the regional Oncology Centre when possible but is not the same person each time and is still not consistent Consultant radiology representation – no cover for the radiologist though an expression of interest is being developed to recruit an additional radiologist with urology interest/expertise
2. 11% quoracy due to low clinical oncology and radiology attendance	Quoracy has decreased from previous year (25% down to 11%). Only 5 meetings were quorate throughout 2016 and it is perceived that this has decreased even further. Therefore more patients are not benefitting from the knowledge and expertise of a full multidisciplinary team when decisions are being made about diagnosis and care. This could lead to delays in the decision making processes and treatment.
3. Long waits for routine referrals	Due to increasing number of referrals, the service is concentrating resource on meeting red flags and urgent demand. Routine referrals waiting times have increased from 52 weeks to 128 weeks (present day). Referrals are triaged by consultants so there is the opportunity for routine referrals to be upgraded.
4. Nephron sparing surgery undertaken locally	This issue was resolved at the time of the external validation as Mr Haynes was providing support to undertake nephron sparing surgery at Belfast City Hospital. The situation has

	now changed as the BT surgeon has left and there is no capacity to provide a centralised service. Currently this is being provided by both the Southern trust and the Western trust.

Other Concerns identified	Update
Out-sourced cancer diagnostics	There has been inaccurate reporting of MRI Prostates. This could place patients at risk as clinicians rely on these reports to inform decision making and counsel patients.
Job plan - MDT Clinical Lead	Dedicated time and support is required for the MDT Clinical Lead to fully undertake the role, including administration support.
Audits	There is a lack of resource to support the implementation of audits to inform quality improvement and service development.

SAI Urology Review

Meeting with Dr Joe O'Sullivan
Monday 4 January 2021 via zoom at 11:15

Attendees
Dr Dermot Hughes and Mrs Patricia Kingsnorth

Dermot Hughes (DH)
Dr Joe O'Sullivan (JOS)

DH thanks JOS for meeting with him and explained the process to date regarding the SAI review involving 9 patients (one with penile cancer, 1 testicular cancer, 5 prostate cancers and 2 renal cancers).

He asked if JOS was aware of any issues regarding the practice of Mr AOB?
JOS advised that when he came into post initially about 17 years ago, he had concerns in relation to the use of bicalutamide and that they had frequently challenged him about the treatment. He made recommendations in clinic letters questioning the use of bicalutamide 50mgs instead of the standard 150mgs or LHRH agonist therapy. In the cases he had seen, the dose of bicalutamide would not have resulted in a major detriment to the patient's therapy/outcome and therefore wasn't escalated further. JOS said he was aware that his colleague D M (as MDT Chair) had raised our concerns about AOB's bicalutamide prescribing with the then CD for Oncology, SMcA, probably in 2011.

JOS said that the MDT improved with the attendance of two of the newer consultants about 7 years ago.

DH advised that there were a number of delays of people being referred for oncology/ palliative care.

DH said that there were issues regarding lack of oncologist attending MDM as it was on the same time as lung MDM and that there was inadequate cover for CAH MDM.

JOS agreed he did want it recognised that there was a lot of good work from urologist in CAH and good involvement in MDT in particular he named two consultants Mr MH and Mr AG.

DH wanted to assure JOS that the SAI review will also recognise the good work the MDT are doing and recognised that the concerns relate to one person's practice. It would seem he worked in isolation despite being involved in a multi-disciplinary team. JOS said that was his impression of Mr AOB

Southern Health and Social Care Trust

Acute Governance
Darren Mitchell
Telephone call
23.02.2021

PRESENT: Dr Darren Mitchell
Dr Dermot Hughes
Mrs P Kingsnorth

Dr Hughes thanked Dr Mitchell for taking time out to talk to him today. Dr Hughes highlighted the reviews concerns identified in the SAI, explaining there was non-adherence to MDT recommendations, non-referral to oncology services for potential curative therapy, prescribing issues.
He asked if there was any knowledge regarding the concerns mentioned.

Dr Mitchell advised aware of issues going back decade in relation to hormone therapy prescribing, prescribing outside guidelines, Bicalutamide. Dr Mitchell advised he took over as chair of the regional urology MDM in 2015. He advised that they had challenged Mr OB on his use of bicalutamide as part of the development of clinical guidelines whilst Mr OB was chair of the NICAN urology group in 2015. Dr Mitchell wrote the regional guidelines for the use of hormone therapy. This was done in the hope this would address the issues around off-licence prescribing of Bicalutamide. This guideline was circulated and presented when Mr OB was chair of the NICAN urology group and he signed off on the guidelines.

Dr Hughes asked Dr Mitchell to share the guidelines mentioned. Dr Hughes advised a number of patients were to be referred to oncology and this was not done.

Dr Mitchell mentioned a radical bladder cancer case in 2016, Chris Hagan and Gillian Traub noted there was a significant delay in treatment whilst waiting for a bone scan, this case was flagged back to SHSCT. Dr Mitchell believes Mr OB was chair of the southern urology MDM at that stage.

Dr Hughes advised the review was looking at 9 cases, there are significant findings, delays in treatment and care, MDT recommendations were not implemented, referrals to oncology were never made for potential curative treatment, and patients were not brought back to MDT for review. Dr Hughes advised there were systematic issues. The recommendations will include structured review process of MDT processes. NICE guidelines were not adhered to regarding prescribing of bicalutamide. There was very poor oncology support at MDT, oncology attendance at MDT was rare. Dr Mitchell described issues

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trying to support the MDT in SHSCT it was a busy practice and they had difficult recruiting to cover this role.

Dr Hughes asked if MDT chair had questioned prescribing methods in accordance with NICE guidelines. Patients did not know, there were no onward referrals. One case of penile cancer was not referred to the super regional MDT for discussion following diagnosis.

Dr Mitchell asked about the testicular cancer case that was brought to his attention.

Dr Hughes advised the consultant did not refer, the oncology centre identified this patient and booked him, there was a delay in treatment.

Dr Hughes advised the consultants prescribing was against NICE/ NICAN guidance and would be grateful if he could forward a copy of the guidance signed off by the consultant.

Dr Mitchell agreed to forward this. Dr Mitchell advised he emailed the consultant in 2016/2017 about his prescribing outside recommended guidelines and highlighting it was his GMC duty to inform patients they were being treated outside the recommended guidelines. The patients were misled.

Dr Hughes advised recommendations of the SAI will reflect this issue. Discussions should be had with patients if treatment is outside the recommended guidelines and reason explained to them in and signed off by peers at MDT. He suspects that the issues around Mr OB were extensive and wide ranging. Dr Hughes advised families are asking the question why no one else knew.

Dr Hughes thanked Dr Mitchell for talking with him today.

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Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

REGIONAL HORMONE THERAPY GUIDELINE

The regional guidelines on hormonal therapy for prostate cancer are drawn from the extensive research in this region and broadly adhere to the EAU guidelines (1) and NICE guidelines (2) on this topic.

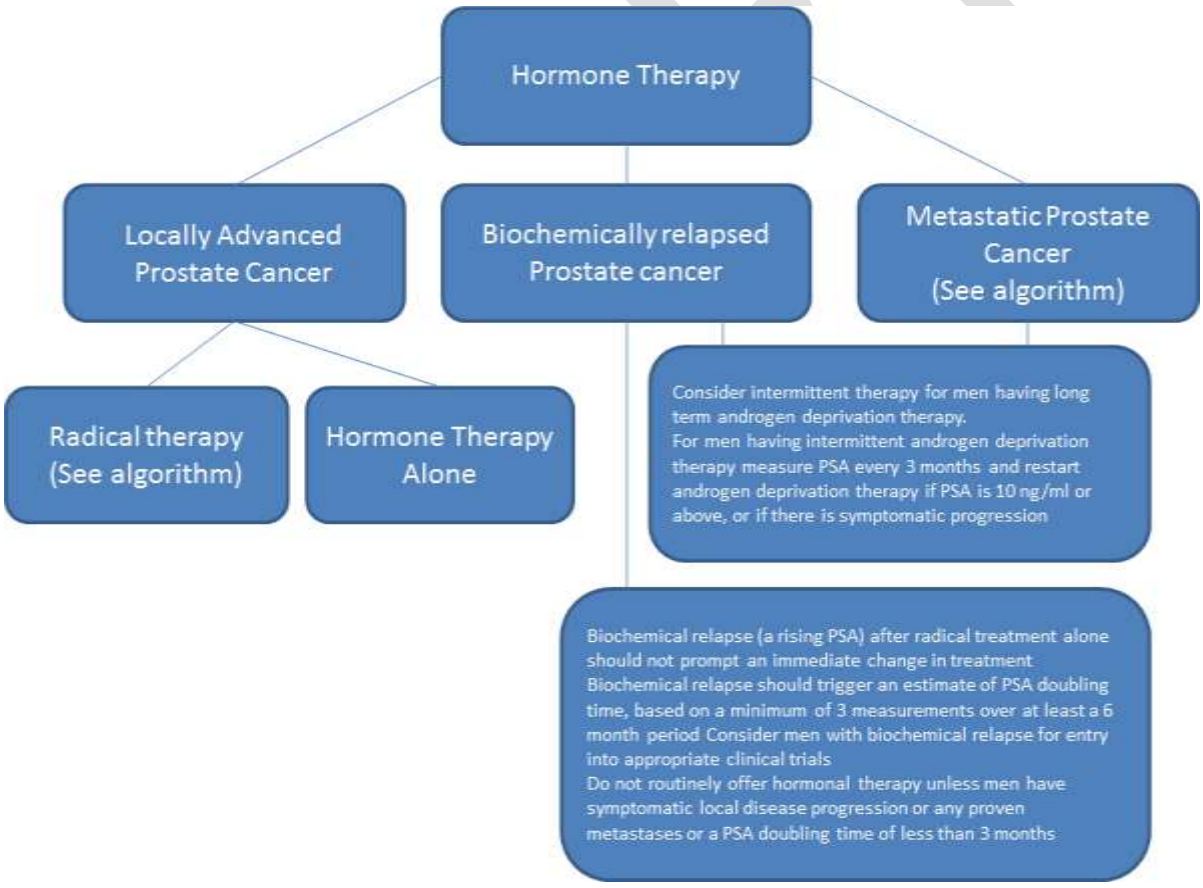
The role of hormonal manipulation in men with prostate cancer is well established and fits within 3 broad groups.

1) Neo-adjuvant, concurrent and adjuvant hormone therapy with radical treatment.

2) Treatment of biochemical failure after radical treatment.

3) Treatment of metastatic disease.

Men within each group should be advised of the role of hormonal therapy in the management of their cancer and where appropriate PSA trigger points should be given.
Men should be advised of alert signs and symptoms of cancer progression which should be reported to the supervising clinical team and rapid access arrangements explained.



NEO-ADJUVANT, CONCURRENT AND ADJUVANT HORMONE THERAPY WITH RADICAL TREATMENT.

There is clear randomised evidence supporting the addition of hormone therapy to radical radiotherapy in men with non-metastatic prostate cancer. The majority of this evidence is for hormone therapy in men with an increased risk of systemic disease and is based on pre-treatment clinical and pathological features.

Men with intermediate or high risk prostate cancer should be offered neo-adjuvant hormone therapy for at least 3 months before the commencement of radical radiotherapy.
For very large prostate glands or patients with high risk prostate cancer or pelvic node positive prostate cancer a longer period of neo-adjuvant hormone therapy may be required (3, 4).
Cyto-reductive hormone therapy is also considered for men with large prostate's prior to their prostate brachytherapy volume study.

Men with intermediate or high risk prostate cancer should continue their hormone therapy through the course of radiotherapy.

Men with Intermediate risk prostate cancer should receive a total of 6 months of hormone therapy before, during and after their radiotherapy is complete (6-9)

Up to 3 years of adjuvant hormone therapy after radical radiotherapy should be considered for men with high risk prostate cancer. The benefits and risks of long term androgen deprivation therapy should be discussed. [NICE 2014] (5)

Hormone therapies options with radical radiotherapy include

LHRH agonists:-
Zoladex (goserelin) 3.6mg subcut every 4 weeks or
Prostap (leuproreline) 3.75 mg IM every 4 weeks or
Decapeptyl (triptorelin) 3mg IM every 4 weeks

Consider transferring to the 12weekly preparation of androgen deprivation therapy if the 4weekly preparation is tolerated and the intention is to proceed with longer term therapy.

In order to prevent testosterone flare, anti-androgen cover with Bicalutamide 50mg is given for 3 weeks in total with the first LHRHa given 1week after the start of the Bicalutamide.

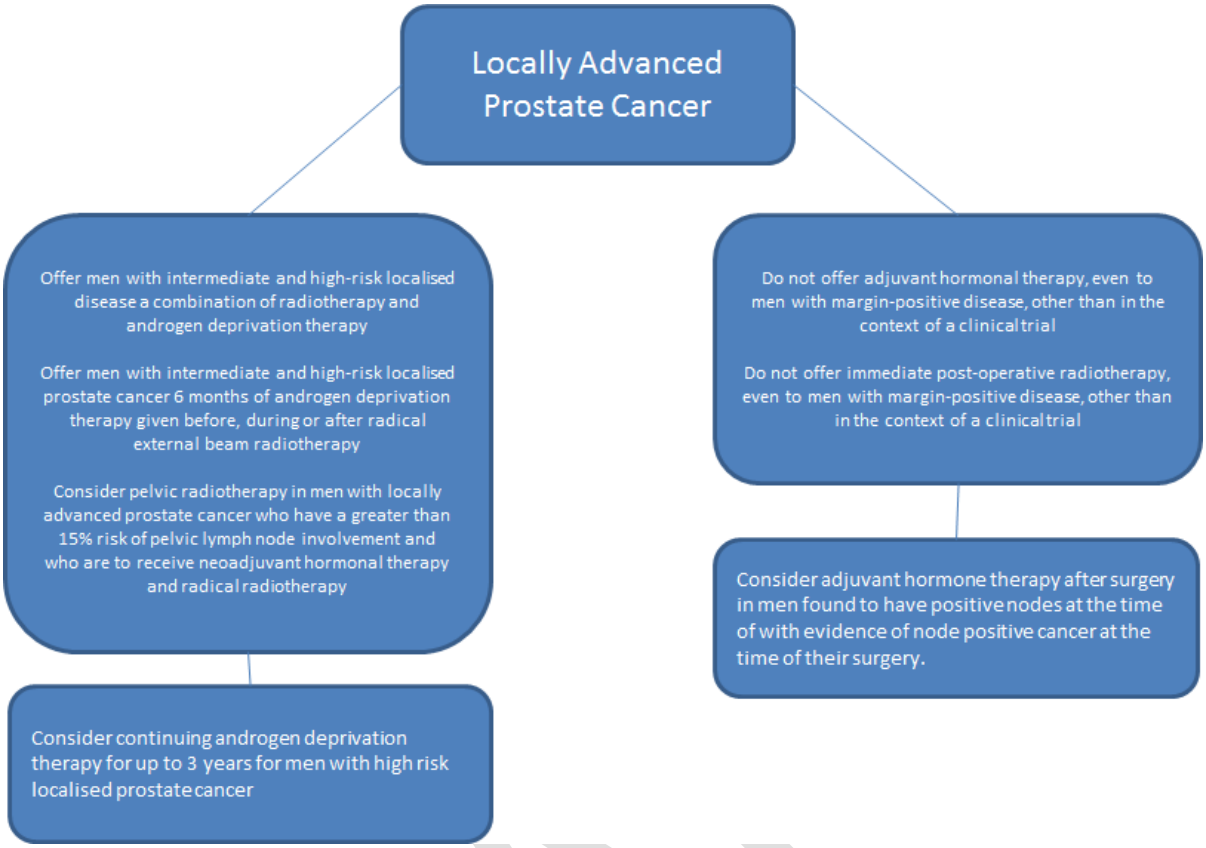
The anti-androgen - Bicalutamide 150mg OD mono-therapy can be used as neo-adjuvant hormone therapy especially in men where preservation of physical capacity or sexual function is important or in those who may not tolerate hot flushes.

The cardiovascular and metabolic toxicities of LHRHa should be discussed and the patient advised to address cardiovascular risk factors with their GP.

The use of concurrent and adjuvant androgen deprivation with adjuvant and salvage radiotherapy post prostatectomy remains undefined. It is currently being assessed as part of the RADICALs study. Use is therefore at the discretion of the treating clinician.

Limited evidence suggested that the patients who may gain most benefit from the addition of hormone therapy to adjuvant post-prostatectomy radiotherapy have Gleason scores of ≥8 (13) or positive nodes at the

time of the prostatectomy. (15) This supports the randomised evidence of benefit for adjuvant LHRHa following prostatectomy with positive nodes (pN1) (14).



BIOCHEMICAL RELAPSE AFTER RADICAL THERAPY

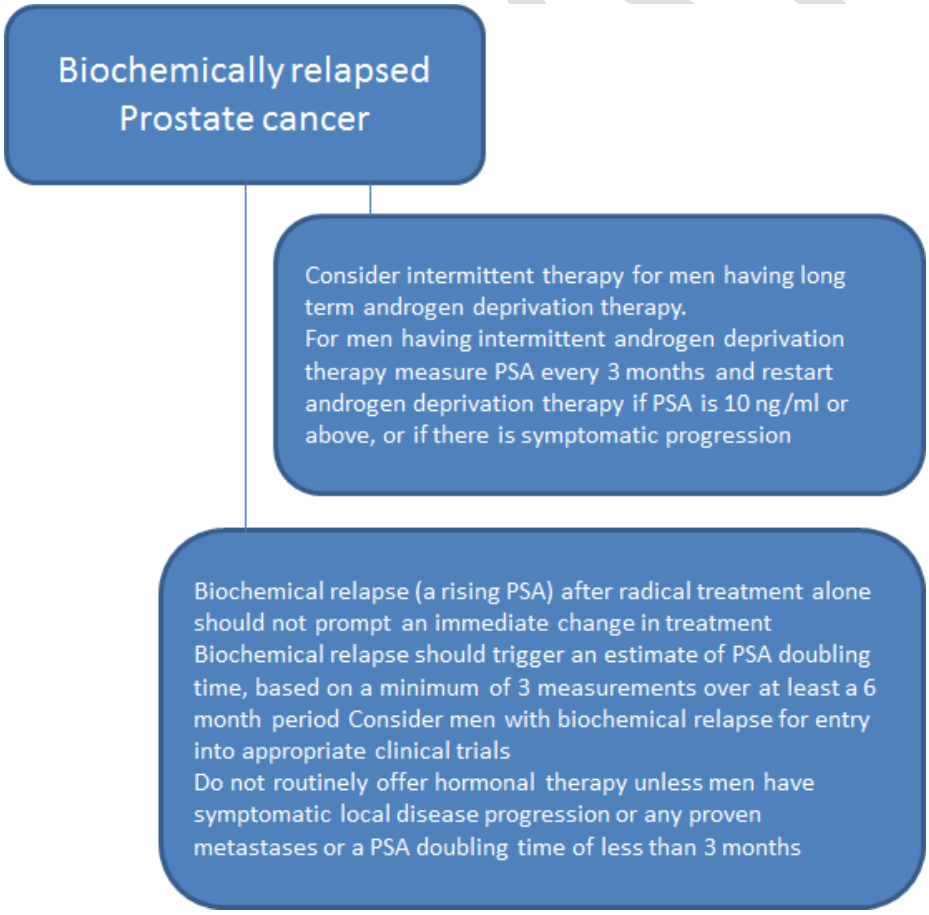
It is not known whether initiating hormone treatment at the time of biochemical relapse, rather than waiting until there are clinical signs of disease, will influence survival. Biochemical relapse after radical treatment, in many cases, does not lead to metastases or death from prostate cancer. Whether men with biochemical relapse should be treated depends in part on the timing and rate of rise of PSA as a predictor of clinical progression. Management options for men at the time of biochemical relapse can be divided into local salvage therapies and systemic therapy with hormones.

Local salvage options may be appropriate in highly selected cases, where the balance of achieving biochemical control and potential toxicity of the salvage therapy should be explained

For men who are considering systemic therapy the exact timing of intervention remains undefined.

NICE recommends that hormonal therapy should not routinely be offered to men with prostate cancer who have a biochemical relapse unless they have:

symptomatic local disease progression, or
any proven metastases, or
a PSA doubling time of < 3 months.



TREATMENT OF METASTATIC DISEASE

Hormone therapy is a crucial component of the management of metastatic prostate cancer and may successfully control the disease for several years. LHRHa's provide equivalent benefit when compared with orchiectomy and have the advantage of allowing the consideration of using them intermittently.

LHRHa's may be used alone (after a short course of anti-androgens such as Bicalutamide 50mg OD for 3weeks to cover testosterone flare on initiation of LHRHa's, with the first LHRHa given 1 week after the start of the Bicalutamide) or in combination with anti-androgens (Known as combined androgen blockade – typically with Bicalutamide 50mg OD).

If LHRHa mono-therapy fails to control the disease then anti-androgen's may be added as second-line hormonal therapy. PSA triggers for initiation of anti-androgens should be identified and recorded for each patient.

PSA monitoring is recommended every 3 months and men should be advised of the signs and symptoms of progression in their cancer which should be reported to the supervising clinical team and rapid access arrangements explained.

Anti-androgen mono-therapy

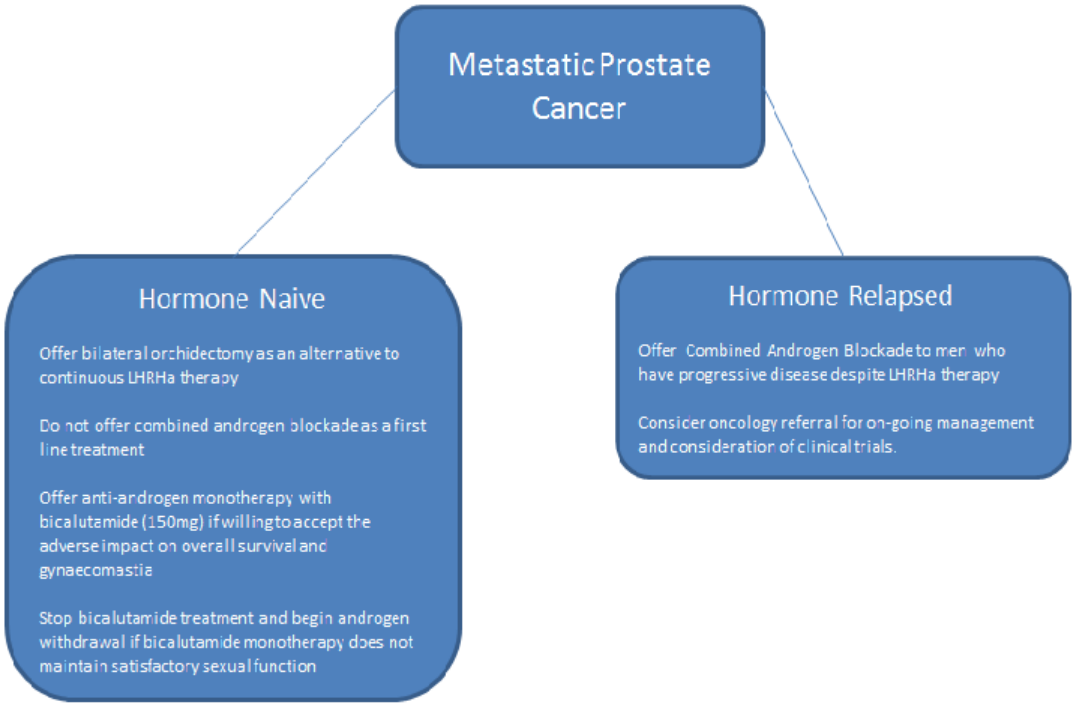
Research demonstrates inferior outcomes with Anti-androgen mono-therapy in the metastatic setting when compared to LHRHa therapy (12). For well-informed men with metastatic prostate cancer who are willing to accept the adverse impact on overall survival and potential of gynaecomastia in the hope of maintaining sexual function then anti-androgen therapy with Bicalutamide 150mg OD can be offered (Off-licence prescribing). If sexual function is not maintained then androgen deprivation should be used instead.(2)

LHRH antagonists.

Immediate androgen suppression without risk of testosterone flare may be required in selected cases. Noting the limitation of the monthly administration formulation and risk of injection site reaction LHRH antagonist provide rapid testosterone suppression and should be considered in such cases.
Degarelix (Firmagon) is used in the treatment of adult male patients with advanced hormone-dependent prostate cancer.

It's use is currently being under review by NICE, the current 'final appraisal decision' recommends that:

'Degarelix is recommended as an option for treating advanced hormone-dependent prostate cancer, only in adults with spinal metastases who present with signs or symptoms of spinal cord compression'.



INTERMITTENT HORMONE THERAPY

Intermittent therapy for men having long-term androgen deprivation therapy in the metastatic or biochemical relapse after radical treatment setting can be considered as a potential method of reducing the side-effects of hormone therapy (10,11). There is limited evidence of an improvement in quality of life with intermittent hormone therapy when compared to continuous therapy.

NICE CG175 recommends that when it is offered there should be discussion with the man, and his partner, family or carers if he wishes, about:

the rationale for intermittent therapy and
the limited evidence for reduction in side effects from intermittent therapy and
the effect of intermittent therapy on progression of prostate cancer.

For men who are having intermittent androgen deprivation therapy:

Measure PSA every 3 months and
Restart androgen deprivation therapy if PSA is 10 ng/ml or above, or if there is symptomatic progression.

EAU guidelines on intermittent blockade recommend:

The induction cycle must last between 6 to 9 months, otherwise testosterone recovery is unlikely.

The treatment is stopped only if patients have fulfilled all the following criteria:

- well-informed and compliant patient
- no clinical progression
- clear PSA response, empirically defined as a PSA < 4 ng/mL in metastatic disease and <0.5ng/ml in non-metastatic patients (<4ng/ml may be used at the clinicians discretion in this subgroup)

• Strict follow-up with clinical examination every 3-6 months. The more advanced the disease, the closer the follow-up.

• Treatment is resumed when the patient reaches either on clinical progression, or if PSA rises above a predetermined, empirically fixed, threshold: typically 10-20 ng/mL in metastatic cases (NICE recommends 10ng/ml) or if greater than 4ng/ml in non-metastatic patients ((up to 10ng/ml may be used at the clinicians discretion in this sub group)

• The same treatment is used for at least 3-6 months.

• Subsequent cycles of treatment are based on the same rules until the there is evidence of castration resistant disease – i.e. a rising PSA despite testosterone suppression/rising PSA while on LHRHa.

The PSA response to the first cycle of hormone therapy appears to be the best indicator of a patient's suitability for intermittent hormone therapy.

TOXICITIES

Managing the complications of hormone therapy -

Nice guidelines provide recommendations on the management of hot flushes, sexual function and osteoporosis.

Hot flushes
Offer medroxyprogesterone (20mg per day), initially for 10 weeks, to manage troublesome hot flushes caused by long-term androgen suppression and evaluate the effect at the end of the treatment period.
Consider cyproterone acetate or megestrol acetateh (20 mg twice a day for 4 weeks) to treat troublesome hot flushes if medroxyprogesterone is not effective or not tolerated. [new 2014]

It should be noted that there is no good-quality evidence for the use of complementary therapies to treat troublesome hot flushes.

Sexual function

Before starting hormone therapy, men and their partners should be made aware of the effect of androgen deprivation therapy on sexual function. The reduction in libido, loss of erectile function and loss of ejaculation should be explained and men concerned about infertility should be counselled about sperm storage.

Where required and available men should be reviewed by specialised erectile dysfunction clinic and if not contra-indicated they should be offered PDE5 inhibitors.

If PDE5 inhibitors fail to restore erectile function or are contraindicated, offer a choice of vacuum device, intraurethral inserts, penile injections, penile prostheses.

Osteoporosis

The increased risk of osteoporosis with long term androgen deprivation is well documented.

Consider assessing fracture risk in men with prostate cancer who are having androgen deprivation therapy, in line with Osteoporosis fragility fracture (NICE clinical guideline 146).
The FRAX or Qfracture online tools may be used to identify men who would benefit from having a formal bone mineral density assessment.
Bisphosphonates should be offered to men who are having androgen deprivation therapy and have osteoporosis. Denosumab (Prolia™ 60mg every 6 months) should be considered in men on ADT who have osteoporosis and are unable to tolerate bisphosphonates.
Denosumab (Xgeva™ 120mg every 4 weeks) is **not** recommended by NICE for the reduction in skeletal related events.

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Meeting with Families Urology SAI

Monday 9th November 2020
Gordon Thompson Suite South Tyrone Hospital

Medical Library 9-12	Committee Room 12-6
9:30 Patient 1's Daughter	
	12:00 Patient 2
	14:00 Patient 9

Daisy Hill Hospital
Meeting Room Clanrye House
11 November 2020

2pm - Patient 3 via zoom
3pm – phone call to Patient 6
3:30 - Patient 8

Schedule for meeting with families.

Thursday 8th April	Time	Zoom
Patient 5's Daughters	14:15	Zoom
Patient 2	15:30	zoom
Patient 3's Wife	16:30 to confirm	zoom
Patient 8 - response via his solicitor Patient 6 – doesn't want any response. Patient 1 – sent her comments doesn't want a meeting [redacted] – recently deceased. Patient 4 - family don't want a meeting. Patient 7 will forward responses to some queries her father has.		
Friday 9th April 2021		

MEETING PATIENTS' NEEDS

IMPROVING THE EFFECTIVENESS OF MULTIDISCIPLINARY TEAM MEETINGS IN CANCER SERVICES

CANCER RESEARCH UK

EXECUTIVE SUMMARY

Around 357,000 people in the UK were diagnosed with cancer in 2014.[1]

This figure is expected to increase: by 2035 the number of diagnoses each year could reach 500,000[2]. Survival has also increased; Cancer Research UK aims to reach 3 in 4 people surviving cancer for 10 years or more by 2034.

To ensure that this ambition is realised, effective cancer services in the UK are key.

Central to the UK's cancer services are multidisciplinary teams – MDTs. An MDT is made up of a variety of health professionals involved in treating and caring for patients, such as surgeons, clinicians, nurses and diagnosticians. Each week, the MDT meets to discuss individual patients' cases and make treatment recommendations.

MDT working is considered the gold standard for cancer patient management[3], bringing continuity of care and reducing variation in access to treatment – and ultimately improving outcomes for patients. However, the health service has changed significantly since their introduction in 1995.

There is now a timely opportunity to review MDTs and consider new ways of working. Although the challenges in each of the four nations are not identical, there is a common theme: a dramatic increase in demand, with only minor increases in capacity. For example, the cancer strategy for England contained recommendations to streamline MDT working.[4]

The number of patients to be discussed in MDT meetings has grown significantly, as has the complexity of patients; due to an ageing population and the growing number of treatment options available.

However, the way that MDT meetings are organised has not adapted to cope with this increased demand. This has meant that MDT meetings are lasting for several hours, with only a few minutes available to discuss each patient. As a result, these discussions often only involve a few people, and often do not include information such as the patient's preferences, comorbidities or whether the patient is suitable for a clinical trial.

TO REFLECT THE CHANGING NATURE OF CANCER CARE AND INCREASED DEMAND FOR SERVICES, THERE IS A NEED TO REFRESH THE FORMAT OF MDT MEETINGS

This strain has also impacted how well the MDT can reflect on their decisions, improve their processes and learn.

To reflect the changing nature of cancer care and the increased demand for services, there is a need to refresh the format of MDT meetings to make them work more effectively. Recognising this, Cancer Research UK commissioned 2020 Delivery to undertake this project.

We do not in any way propose removing or diluting MDT working, or to return to the pre-1990s era of patient care being solely managed by one clinician.

We aimed instead to suggest streamlining MDT meetings and improve the quality of discussions, especially for the more complex patients who would benefit the most from

the input of the full MDT.

Throughout this research we were struck by the willingness of MDT members to be involved, to share their experiences and to improve their meetings so that they worked better for patients – with an unprecedented 2,300 responses to our first survey and over 1,250 in our second. Our fieldwork covered 624 patient discussions, across 24 MDT meetings in 10 clinical sites.

Solutions will not be the same for every MDT, or every specialty. However, in several areas there is a need for updated guidance developed on a national level.

This research should therefore be the start of further, in-depth work to implement these recommendations.

THERE IS NOT ENOUGH TIME TO DISCUSS THE MORE COMPLEX PATIENTS

The mean length of the 624 patient discussions observed in this study was 3.2 minutes, and over half of MDT discussions were less than two minutes long. Meetings could last up to five hours.

It is difficult to imagine that this method of working produces the same quality of discussion for all patients, or that there is always enough time for full discussion of patients with particularly complex cases.

For many tumour sites, certain subgroups of patients now follow very well-established treatment protocols. 74 per cent of MDT members responding to our second survey agreed with the statement that some patients could be streamlined, or reviewed outside of the full MDT meeting. This already happens in some MDTs, but to date there has been no clear national guidance on how this should be managed.

Establishing a 'triage' process to identify patients that should follow these protocolised pathways would reduce the number of discussions happening in the full MDT meeting, allowing more time to discuss the more complex patients.

RECOMMENDATIONS

Recommendation 1: The UKs health services should work with NICE[i] and SIGN[ii] to identify where a protocolised treatment pathway could be applied and develop a set of treatment recommendations for each of these, to be implemented across the UK. Every Cancer Alliance or devolved cancer network should develop their own approach based on these central recommendations. These treatment protocols should be reviewed regularly.

2. MDTs for tumour types for which a protocolised approach has been developed should agree and document their approach to administering protocols. This could include a 'pre-MDT triage meeting'. The implementation and outcomes of these

[i] National Institute for Health and Care Excellence
[ii] Scottish Intercollegiate Guidelines Network

protocols should be audited and reviewed by the full MDT in an operational meeting.

CURRENT MDT MEETING ATTENDANCE IS NOT OPTIMAL

The growing demands placed on MDTs has a significant impact on MDT members' workloads, who must spend increasing amounts of time preparing for or attending MDT meetings. This is particularly true for pathologists and radiologists.

Workforce challenges are wider than MDT working however; the National Audit Office has said that there is a 50,000 shortfall in clinical staff in England alone. [5]

The 24 meetings observed in this study had between 7 and 27 in attendance, with an average of 14. However, the mean number of people contributing to each discussion was only three – with discussions involving just one or two people not uncommon.

In some meetings everyone spoke at some point, whereas in others it was always the same few people.

In contrast to this observation, other MDT meetings were unable to finalise any treatment recommendation because certain individuals were not present. This was mostly a result of a wider staff shortages.

Attendance guidelines are most strict in England, where MDT attendees are required to attend 66 per cent of meetings. This target is often difficult to reach, meaning that many MDTs fall foul of national assessments and there are delays in patient care.

Amending such guidelines to focusing instead on individual specialty cover within a meeting would strike the right balance. This would ensure that the right specialties are represented so as to ensure that discussions can progress, without requiring an unnecessarily large group.

MDT members were very supportive of this, with 80 per cent supporting a move to requiring specialty cover. [iii] When staff are mandated to attend MDTs, adequate time must be allocated in their job plans for preparation and attendance.

RECOMMENDATION

3. National requirements for individual minimum attendance should be reviewed and amended where necessary, with an emphasis on ensuring all required specialties are present at a meeting. NHS England should run a series of pilots to determine optimal percentage attendance requirements. The success of these pilots should be evaluated and national guidance changed as appropriate.

[iii] Responses to our second survey of MDT members.

THE RIGHT INFORMATION IS OFTEN NOT USED TO INFORM DISCUSSIONS

An MDT's treatment recommendation is only as good as the information it takes into account.

MDT discussions must include all relevant information about a patient, so that the patient is given the most appropriate recommendation and can go onto achieve the best outcome possible.

In seven per cent of discussions observed, decisions were deferred due to either missing information (usually diagnostic imaging results) or missing core MDT members.

When information was missing, a treatment recommendation could not be made and so they were deferred for discussion at the following meeting, a week later – introducing an unnecessary seven-day delay, which is distressing for the patient and can lengthen their wait to start vital treatment.

We also found that only 14 per cent of discussions included information that did not relate specifically to their tumour, for example the patient's preference, known comorbidities or psychosocial status.

Although many expected this to be the role of the clinical nurse specialists, in over 75 per cent of meetings there was no verbal contribution from nurses at all in discussions. [iv]

Only 25 per cent of the patients we surveyed were satisfied with the amount of information they were able to contribute to the MDT meeting. [v]

This has a demonstrable impact on patient experience, as well as on clinical care: research has found that between 10 and 15 per cent of MDT recommendations are not implemented, the patient preferring more conservative treatment, since the discussion had not considered information such as their comorbidities or their preferences.[6,7]

Clinical trial recruitment can also be facilitated via MDTs; however we know that there is considerable variation across the UK in how many patients are spoken to about research opportunities.

Disappointingly, only eight of the 624 MDT discussions observed mentioned clinical trials at all.

One way of ensuring that all relevant information is considered by the MDT would be to implement a standardised proforma, which would be completed by the clinician referring the patient to the MDT.

54 per cent of MDT members already use some form of proforma, but this is not consistent and there is no national guidance

[iv] See Appendix 1 for full methodology.
[v] See Appendix 4 for text of patient survey.

on content. 81 per cent of MDT members felt that using a proforma would have a beneficial impact on meeting efficiency.

RECOMMENDATION

4. The UK's health services should lead the development of national proforma templates, to be refined by MDTs. MDTs should require incoming cases and referrals to have a completed proforma with all information ready before discussion at a meeting.

The proforma could include:

- **Patient demographics;**
- **Diagnostic information**
- **Patient fitness and co-morbidities, history of previous malignancies;**
- **Results from a Holistic Needs Assessment (if available);**
- **The patient's preferences (if known);**
- **The rationale for requiring MDT discussion;**
- **Whether there were known treatment protocols for the specific tumour type;**
- **Whether the patient is suitable for any current clinical trials.**

The MDT should have the power to bypass this requirement in exceptional circumstances.

MDTS ARE UNABLE TO FULFIL THEIR SECONDARY ROLES

As well as making treatment recommendations, the MDT plays several other roles: facilitating data validation, ensuring consistency in decision-making, educating team members and managing the pathways of the patients within their care.

Discussion amongst steering group members, and responses to our surveys, indicate concern that current pressures have limited these aspects of MDT working.

Since their introduction, the MDT has played a vital role in ensuring timely and accurate data validation. This has been hugely important for auditing services and facilitating information flows to national cancer registries.

However, we found the extent to which this happened highly variable. The best example seen in our observations was when information was directly added by an oncologist, and was projected on a screen for the whole MDT to view. Real time data entry reduces errors and provides an immediate opportunity to validate and clarify information.

As a central tenet of cancer services, it is important that MDTs review their own performance and that a culture of continuous improvement is fostered. Less than half (48 per cent) of MDT members felt their MDT has a process in place that is sufficient for improving their effectiveness.

The suggestion of holding a regular 'operational' meeting, either quarterly or biannually, was supported by 67 per cent of respondents to our second survey.

RECOMMENDATIONS

5. MDTs should use a database or proforma to enable documentation of recommendations in real time. Ideally this should be projected so that it is visible to team members; if this is not possible there should be a named clinical individual responsible for ensuring the information is accurate. Hospital Trusts and boards should ensure that MDTs are given sufficient resource to do this.

6. Each MDT should ensure that they have a mortality and morbidity process to ensure all adverse outcomes can be discussed by the whole MDT and learned from, rather than discussed in silos. The primary time for this to take place should be a quarterly or biannual operational meeting. Time for quarterly operational meetings should be included in attendees' job plans. There should be oversight from national MDT assessment programmes.

www.cancerresearchuk.org/mdts-research

For more information, or for a copy of the full report, please contact **policydepartment@cancer.org.uk**

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CANCER RESEARCH UK

Multi-disciplinary Team (MDT) Guidance for Managing Prostate Cancer

September 2013

Produced by:

- **British Uro-oncology Group (BUG)**
- **British Association of Urological Surgeons (BAUS) Section of Oncology**

PLEASE NOTE: THIS GUIDANCE IS AN INTERIM PUBLICATION AND IS SCHEDULED FOR IMMEDIATE REVIEW IN 2014 WHEN IT WILL ADDRESS THE UPDATED NICE GUIDELINE AND THE OUTCOME OF OTHER RELEVANT TECHNOLOGY APPRAISALS

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Abbreviations

3D-CRT: three-dimensional conformal radiotherapy

ADT: androgen deprivation therapy

ASAP: atypical small acinar proliferation

BF: biochemical failure

BPFS: Biochemical progression free survival

BPH: benign prostatic hyperplasia

CAB: combined androgen blockade

CHHiP: Conventional or Hypofractionated High Dose IMRT for Prostate Cancer

CI: confidence interval

CPA: cyproterone acetate

CPFS: clinical progression free survival

CT: computed tomography

DES: diethylstilbestrol

DFS: disease-free survival

DRE: digital rectal examination

EBRT: external beam radiation therapy

EPC: Early Prostate Cancer

ERSPC: European Randomised Study of Screening for Prostate Cancer

FFF: freedom from failure

FSH: follicle stimulating hormonE

GnRH: gonadotrophin-releasing hormone

HDR: high dose rate

HIFU: high-intensity focused ultrasound

HR: hazard ratio

HRPC: hormone-refractory prostate cancer

HT: Hormone therapy

IAD: intermittent androgen blockade

IGRT: image guided radiotherapy

IMRT: intensity modulated radiotherapy

ISUP: International Society of Urologic Pathology

IPSS: International Prostate Symptom Score

LDR: low dose rate

LH: luteinising hormone

LHRH: luteinising hormone releasing hormone

LTAD: long-term androgen deprivation

MDT: multi-disciplinary team

MRC: Medical Research Council

MRI: magnetic resonance imaging

MRS: magnetic resonance spectroscopy

NCCN: National Comprehensive Cancer Network

NICE: National Institute for Health and Clinical Excellence

ONJ: osteonecrosis of the jaw

OS: overall survival

OR: Odds ratio

PET: positron emission tomography

PFS: progression-free survival

PLCO: Prostate, Lung, Colorectal and Ovarian

ProtecT: Prostate Testing for Cancer and Treatment

PSA: prostate-specific antigen

PSADT: prostate-specific antigen doubling time

RANK: Receptor activator of nuclear factor kappa-B

RCT: randomised controlled trial

RECIST: Response Evaluation Criteria in Solid Tumors

SRE: skeletal-related events

STAD: short-term androgen deprivation

TRUS: transrectal ultrasound

TURP: transurethral resection of the prostate

CRPC: castration resistant prostate cancer

mCRPC : metastatic castration resistant prostate cancer

Integrated Care and the Multi-disciplinary Team (MDT)

- The concept of integrated care is becoming increasingly accepted as a way to overcome fragmentation of patient management and to provide a consistent treatment strategy across the MDT. It also creates an optimal structure that facilitates audit and peer review.
- Integration within the MDT is essential for patients with prostate cancer because the collaboration between MDT members (Table 1) is central to the treatment strategy, with ongoing support from the wider team to manage pain and the adverse effects of therapy. By being familiar with the complete spectrum of management strategies, the MDT can assist patients in making treatment decisions that are specific for their individual disease state, co-morbid conditions, age and lifestyle.

Table 1: The make-up of the MDT in the prostate cancer setting

• Urological surgeons	• Oncology and urology nurse specialists
• Clinical and medical oncologists	• Palliative care specialist
• MDT co-ordinator and secretarial support	• Histopathologists
• Radiologists	

- Moves to true integrated practice can add value in the following ways: [Integrated Care Network 2004]
  - Changing the identity or branding of a service to create more positive user responses and staff allegiances, enabling a clear break with the past.
  - Securing organisational efficiencies, for example, in the shape of shared support services, integrated management, innovative administrative processes and emerging hybrid roles.
  - Defining a focus for action that includes clearer processes of accountability and is less prone to distraction by wider organisational concerns.
  - Introducing more robust arrangements for team-working and leadership-working in challenging times.
  - Creating new opportunities for investment, for example, in IT systems, and opening access to new sources of funding.
- The algorithms presented in this guidance provide a single framework that is adapted for each major category of prostate cancer: localised, locally advanced and advanced (Figure 1).
- The treatment algorithms presented in this document (Figures 2–4) represent a management structure that goes beyond a simple co-ordinated system and will work most efficiently when the MDT is functioning as a single integrated unit.

Integrated care and clinical governance

- The effective functioning of the MDT and tailored care pathways for patients will support the (now routine) clinical governance procedures implemented throughout the NHS. Traditionally, clinical governance relates to a single organisation or service and this can raise challenges, with the recognition that patients require management across different organisations and services. Therefore, it is appropriate to apply the principles of clinical governance to individual patients or groups of patients.
- The focus should be on optimum patient satisfaction and care, rather than on performance of the NHS institution. The MDT and development of organised pathways ensures that the patient's journey is monitored and assessed as a single entity.

Approach within the MDT

Key questions for the MDT – Localised Prostate Cancer

- TNM stage?
- Gleason grade?
- Prostate-specific antigen (PSA)/PSA kinetics?
- Performance Status?
- Co-morbidity/life expectancy?
- Symptoms:
  - bowel
  - urine (IPSS score)
  - bone
- Sexual Function?
- Social Situation?
- Family History?
- Clinical Trials?

Diagnostic Tests

- Digital rectal exam (DRE)
- PSA
- Transrectal ultrasound
- (TRUS)/biopsy
- MRI/CT pelvic scan*
- Bone scan*

(*Not mandatory for low-risk patients)

Key points for discussion with the patient

- Prognosis with and without radical treatment?
- Treatment options?
- Treatment side-effects?
- Impact on quality of life?
- Importance of:
  - Sexual function?
  - Urinary function?
  - Bowel function?
  - Physical strength, energy?
  - Level of activity?
  - Accessibility to prescribed drugs?
  - Psychosocial impact on them and their family?
- Family history?
- Clinical trials?

Approach within the MDT

Key questions for the MDT – Locally Advanced Prostate Cancer

- TNM stage?
- Gleason grade?
- Prostate-specific antigen (PSA)/PSA kinetics?
- Performance Status?
- Co-morbidity/life expectancy?
- Symptoms:
  - bowel
  - urine (IPSS score)
  - bone
- Sexual Function?
- Social Situation?
- Family History?
- Clinical Trials?

Diagnostic Tests

- DRE
- PSA
- TRUS
- TRUS biopsy/Transperineal biopsy
- MRI/CT pelvic scan
- Bone scan
- Specialist imaging where indicated e.g. choline PET
- Consider lymph node sampling (if this will determine changes in management approach)

Key points for discussion with the patient

- Survival prognosis?
- Treatment options?
- Treatment side-effects?
- Impact on quality of life?
- Importance of:
  - Sexual function?
  - Urinary function?
  - Bowel function?
  - Physical strength, energy?
  - Level of activity?
  - Accessibility to prescribed drugs?
  - Psychosocial impact on them and their family?
- Family history?
- Clinical trials?

Approach within the MDT

Key questions for the MDT – Advanced Prostate Cancer

- TNM stage?
- Gleason grade?
- Prostate-specific antigen (PSA)/PSA kinetics?
- Performance Status?
- Co-morbidity/life expectancy?
- Symptoms:
  - bowel
  - urine (IPSS score)
  - bone
- Sexual Function?
- Social Situation?
- Family History?
- Clinical Trials?
- Palliative Care Referral?

Diagnostic Tests

- DRE
- PSA
- Limited? TRUS biopsy (to confirm histological diagnosis for future therapies – e.g. entry into clinical studies)
- Biochemistry screen
- Full blood count
- Bone scan
- Consider CT Chest / Abdomen; CT/MRI pelvis if it may influence management decisions and entry into future clinical trials

Key points for discussion with the patient

- Survival prognosis?
- Treatment options?
- Treatment side-effects?
- Impact on quality of life?
- Importance of:
  - Sexual function?
  - Urinary function?
  - Bowel function?
  - Physical strength, energy?
  - Level of activity?
  - Accessibility to prescribed drugs?
  - Psychosocial impact on them and their family?
- Family history?
- Clinical trials?

The MDT ***Meeting*** is an essential part of cancer management. However, there are often difficulties in identifying which patients to discuss and whether time allows for presentation of relapsed patients as well as new diagnoses, ensuring that their details and diagnoses are available, and keeping a record of decisions made at the meetings.

- MDTs have repeatedly been endorsed as the principal mechanism for ensuring that all relevant disciplines and professional groups contribute to, and participate in, decisions regarding the clinical management of patients [NICE 2002].
- MDT-working is positively related to a range of measures of effectiveness, including the quality of clinical care.
- It is important to emphasise the distinction between management and administration.
- A central concept of integrated care is to reinforce the role of the MDT (working as a single unit), but with enough clinical freedom to tailor management strategies to the needs of individual patients.
- Treatment strategies are influenced by the stage of disease and by an interaction between the risk of disease progression, survival and key patient characteristics, such as age, lifestyle and general health. The discussion of these factors is of crucial importance in determining the most appropriate way forward. For example, age and the presence of co-morbidities may be a restrictive factor when considering surgery.
- The case notes, pathology reports, test results and radiology for each patient must be available to be discussed at the meeting. The MDT must also ensure that the patient has the fullest possible role in determining treatment – the importance of this cannot be overstated. Patient preference should be discussed within the MDT. Although the majority of men with prostate cancer want to be involved in treatment decisions, an estimated one in five of all patients does not raise, or really understand, the potential issues and associated side-effects of treatments and alternatives that may be available to them [House of Commons Committee of Public Accounts 2006].
- The possibility of including a patient in a relevant clinical trial should be highlighted.

Approach to the Patient

The patient's expectations

The patient should have the right to discuss their treatment with appropriately trained members of the MDT

- After a diagnosis of prostate cancer, most men will want to have some involvement in the decisions concerning their care. The following aspects have been found to be important [Davison BJ, *et al* 2004]:
  - Honesty about the severity of the cancer and their prognosis
  - Discussion of the best treatment options
  - The clinician being up-to-date on ongoing and recent research
  - Disclosing all treatment options
  - How cancer may affect their daily functioning
- It is essential that the patient and healthcare professionals discuss the likelihood of adverse events associated with each treatment option and implications for their future lifestyle when determining management strategies.
- The patient and his partner, family and/or other carers should be fully informed about care and treatment options and therefore able to make appropriate decisions based upon the choices offered by their healthcare professionals. For example, the choice between radical treatment and active surveillance may be influenced by a patient's desire to retain sexual activity, physical energy and quality of life.
- Patients should be informed and advised regarding the available treatment options and the potential effects of these on their lifestyle and quality of life.

Discussing evidence with patients

There is a lack of evidence to guide how healthcare professionals can most effectively share clinical data with those patients facing treatment decisions. However, basing recommendations largely on relevant clinical studies and expert opinion, it is possible to achieve five communication objectives when framing and communicating clinical evidence.

1. Understand the patient's experience, expectations and preferences
2. Build partnerships with the patient and carer
3. Provide evidence and discuss uncertainties and side-effects
4. Present recommendations
5. Check for understanding and agreement

Assessment and Diagnosis

Screening

PSA screening remains a relatively contentious subject in the field of prostate cancer. Assessment of the value of a test, which is so widely disseminated in clinical practice, is a particular challenge. There is conflicting evidence regarding whether screening results in a reduction in mortality from the disease. As a consequence available evidence must be used to minimize the risk of harms and maximize the benefits for an individual man.

- Three ongoing large, randomised, controlled clinical trials are evaluating the value of PSA screening for prostate cancer: the European Randomised Study of Screening for Prostate Cancer (ERSPC) [Schroder FH, *et al* 2012], the Prostate, Lung, Colorectal and Ovarian (PLCO) cancer screening trial in the US [Andriole GL, *et al* 2012] and the UK-based Prostate Testing for Cancer and Treatment (ProtecT) study [Rosario DJ, *et al* 2008]. The first reports from these trials have been published and have added further information to the PSA screening debate:
    - The PLCO study reported no mortality benefit with the combination of PSA screening and digital rectal examination (DRE) during a median follow-up of 13 years [Andriole GL, *et al* 2012]. However, this was not a trial of screening versus no screening, but rather of "systematic" versus "opportunistic" screening, and there were high rates of screening in the control group.
    - In contrast, the ERSPC trial found that PSA screening was associated with a 21% relative reduction in prostate cancer mortality at a median follow-up of 11 years, equivalent to the prevention of approximately 7 prostate cancer deaths per 10,000 men screened. This mortality benefit was associated with a high risk of overdiagnosis, with nearly 76% of men who underwent a biopsy following an elevated PSA value having no cancer detected on biopsy [Schroder FH, *et al* 2012].
    - ProtecT has demonstrated a benefit of repeat PSA testing in reducing the risk of high-grade prostate cancer in men with an initial PSA concentration of 3–20 ng/ml [Rosario DJ, *et al* 2008].
- Based on the results of these two large, randomised trials, the general consensus is that at present there is insufficient evidence for widespread mass screening for prostate cancer. However early detection (opportunistic screening) should be offered to the well-informed man Quality of life and cost-effectiveness analyses from the ERSPC and PLCO trials, along with mortality results from ProtecT are needed to help resolve the ongoing PSA screening debate.

Risk factors for prostate cancer

The risk factors for prostate cancer are generally well-documented, but are highlighted here for completeness of the Guidance.

- Age
    - Relatively rare in men under the age of 50 years.
    - Incidence increases in those over 60 years.
- Race
    - A higher incidence of the disease is seen in African-Caribbean, African-American and West African races. The UK PROCESS study demonstrated that black men in the UK have substantially greater risk of developing prostate cancer compared with white men [Ben-Shlomo Y, *et al* 2008]
    - Men of Chinese and Japanese origin have a lower incidence of disease [Delongchamps NB, *et al* 2006].

- Geography
  - The highest incidence of prostate cancer is currently seen in North America and Northern Europe.
- Family history
  - Men with a first-degree relative affected by prostate cancer have a relative risk of developing the disease themselves 2-fold greater than men with no relatives affected [Steinberg GD, *et al* 1990].
  - Those men with an affected second-degree relative have an increased relative risk of 1.7 of developing the disease.
  - Men with both a first- and second-degree relative affected have an increased relative risk of 8.8 of developing the disease.
  - A small subpopulation of individuals with prostate cancer (about 9%) has true hereditary prostate cancer. This is defined as three or more affected relatives or at least two relatives who have developed early onset disease, i.e. before age 55 [Hemminki K 2012].
  - There is also some evidence to show a link between an increased risk of prostate cancer where there is a family history of breast, ovarian, bladder or kidney cancer [Negri E, *et al* 2005].
  - The UK Familial Prostate Cancer Study is currently looking at the genetics of the disease with possible sites of interest lying on chromosomes 2, 5, Y and loss of heterozygosity at 10q and 16q.

Diagnostic tests

The main diagnostic tools for prostate cancer include digital rectal examination (DRE), serum prostate specific antigen (PSA), and transrectal ultrasound (TRUS). The definitive diagnosis depends on the histological verification of adenocarcinoma in prostate biopsy cores or operative specimens.

DRE

- The DRE remains valid as an initial method for assessing the prostate; however, DRE findings should not be regarded as a fail-safe test.

PSA

- PSA is a kallikrein-like serine protease produced almost exclusively by the epithelial cells of the prostate.
- As an independent variable, PSA concentrations are a better predictor of cancer than suspicious findings on DRE or TRUS [Catalona WJ, *et al* 1994;Elgamal A-AA, *et al* 1996].
- PSA is organ specific but not cancer-specific. Therefore, serum concentrations of PSA can be elevated in the presence of benign prostatic hyperplasia (BPH), prostatitis and other non-malignant conditions. Furthermore, there is, as yet, no recommendation for the optimal PSA threshold value that most effectively avoids the detection of insignificant cancers that are unlikely to be life-threatening [Aus G, *et al* 2003; Aus G, *et al* 2004].
- While PSA concentrations generally increase with advancing disease stage, the ability of PSA levels to accurately predict pathological stage in any one individual is low [Hudson MA, *et al* 1989; Brawer MK & Lange PH 1989; Partic AW, *et al* 1990].

- Asymptomatic patients who request a PSA test should be counselled before the procedure for the following reasons [Dearnaley DP, *et al* 1999]:
    - Although the test may detect a cancer at a stage where curative treatment can be offered, PSA will fail to detect some early tumours.
    - A PSA test may detect early prostate cancer in an estimated 5% of men aged 50–65 years.
    - Treatment of early prostate cancer can put the patient at some risk of toxicity and may not necessarily improve life expectancy

Factors affecting PSA concentrations are summarised below.

Age and race

Table 2: Age-specific PSA (ng/ml) reference ranges, by race [DeAntoni EP, *et al* 1996]

Age (years)	White	Black	Latino	Asian
40–49	0–2.3	0–2.7	0–2.1	0–2.0
50–59	0–3.8	0–4.4	0–4.3	0–4.5
60–69	0–5.6	0–6.7	0–6.0	0–5.5
70–79	0–6.9	0–7.7	0–6.6	0–6.8

Biopsy/Transurethral Resection of the Prostate (TURP) can cause an increase in PSA for a variable time period (4–12 weeks) [Xu ZQ, *et al* 2002].

Prostatitis can cause an increase in PSA concentration, which can be reduced to within a normal range with antibiotic treatment [Tchetgen MB, *et al* 1997; Gamé X, *et al* 2003].

Prostate size – a benignly enlarged gland can influence PSA concentrations.

Infection – elevated PSA levels can be sometimes be seen with febrile urinary tract infections.

Free and complexed PSA should be understood. Catalona *et al*. conclude that percentage free PSA is most useful in men with a PSA concentration in the range 2–15 ng/ml (Table 3); the higher the percentage of free PSA the lower the probability of cancer [Catalona WJ, *et al* 1998].

Table 3: Probability of prostate cancer based on total and percentage free PSA [Catalona WJ, *et al* 1998].

	Probability of cancer (%)
Total PSA (ng/ml)	
0–2	~1
2–4	15
4–10	25
>10	>50
Free PSA (%)	
0–10	56
10–15	28
15–20	20
20–25	16
>25	8

PSA density i.e. $\frac{\text{PSA level (ng/ml)}}{\text{TRUS-determined prostate volume (ml)}}$

May be helpful in differentiating BPH from prostate cancer in patients who have a normal DRE with a PSA 4–10ng/ml. A PSA density >0.15 may suggest prostate cancer.

PSA velocity can be valuable in the follow-up of men with a normal PSA but prior negative biopsies. Velocity is measured by a change in PSA concentration in three consecutive measurements taken at 6-monthly intervals. A change in PSA concentration of >0.75 ng/ml per year is more likely to indicate prostate cancer than BPH. The usefulness of PSA velocity in those with a PSA concentration >10 ng/ml is unknown [Smith DS & Catalona WJ 1994].

Transrectal Ultrasound (TRUS)

- TRUS detects 50% more patients with prostate cancer than physical examination alone [Gustafsson O *et al* 1992; Mettlin C, *et al* 1996], but the ultrasonic appearance of prostate cancer is variable and only a very small number of cancers are detected if a DRE and PSA test are normal [Mettlin C, *et al* 1996; Jones WT & Resnick MI 1990; Ellis WJ, *et al* 1994]. Therefore, TRUS is mainly used to aid biopsy.

Biopsy and tumour grading

- The first elevated PSA level should not prompt an immediate biopsy. The PSA level should be verified after a few weeks by the same assay under standardised conditions (i.e. no ejaculation and no manipulations).
- Prostate biopsies are traditionally guided by TRUS. The alternative is to use a transperineal approach with template biopsies.
- The National Institute for Health and Clinical Excellence (NICE) Prostate Cancer Guideline recommends that the serum PSA level alone should not automatically lead to a prostate biopsy [NICE 2008]. It states that to help men decide whether to have a prostate biopsy, healthcare professionals should discuss with them their PSA level, DRE findings (including an estimate of prostate size) and co-morbidities, together with their risk factors (including increasing age and black African and black Caribbean ethnicity) and any history of a previous negative prostate biopsy.
- NICE further highlights that men and their partners or carers should be given information, support and adequate time to decide whether or not they wish to undergo prostate biopsy [NICE 2008]. Men will need to comprehend the potential risks (such as potentially living with a diagnosis of prostate cancer that is deemed clinically insignificant) and the benefits of prostate biopsy.
- Where TRUS-guided biopsy is indicated, a minimum of 10 biopsies (as recommended by The British Prostate Testing for Cancer and Treatment Study) [Donovan J, *et al* 2003] should be obtained, according to the volume of the prostate. Biopsies should be performed under local anaesthetic and antibiotic cover [Eskicorapci SY, *et al* 2004].
- For each biopsy site, the number of biopsies positive for carcinoma and the International Society of Urologic Pathology (ISUP) 2005 Gleason score should be reported [Epstein JI, *et al* 2005]. The amount of cancer in each core should also be recorded either in terms of cancer core length (mm) or proportion of core involvement (%) as this correlates with tumour volume, extraprostatic extension, and prognosis after prostatectomy [Grossklaus DJ, *et al* 2002].
- The indications for a repeat biopsy if the first biopsy is negative include: rising and/or persistently elevated PSA; suspicious DRE; atypical small acinar proliferation (ASAP); extensive (multiple biopsy sites) prostatic intraepithelial neoplasia
- Magnetic Resonance Imaging (MRI) may be used to identify the possibility of an anterior located tumour and also allow targeted biopsies of any suspicious or abnormal area [Lemaitre L, *et al* 2009].
- A European study has reported that a prostate cancer detection rate for the first set of biopsies is 24% and for the second set of biopsies after a negative initial set as 13% [Djavan B, *et al* 2005].31
- Complications of transrectal biopsy include macrohaematuria and haematospermia. Severe infections were initially reported in <1% of cases, but this rate has increased in the last few years as a consequence of the evolution of antibiotic resistance strains with more post-biopsy hospitalisations for infectious complications while the rate of non-infectious complications has remained stable [Loeb S, *et al*. 2011].
- In some patients, prostate biopsy may be performed using a transperineal, template guided technique as the preferred approach. Possible reasons for this include: previous repeated negative TRUS biopsies; clinical or radiological suspicion of a large anterior tumour; more accurate characterization of tumour location and extent in order to guide management and assess eligibility for inclusion into focal therapy trials.
- In these patients, the prostate is divided into 20 anatomical zones and each zone is biopsied at 5mm intervals in a systematic manner using a template grid to guide the biopsy needle placement. Typically this results in between 40-70 biopsies depending on the size of the prostate gland.

- The biopsies are reported in a similar manner to TRUS-guided biopsies, with Gleason score, cancer core length (mm) and proportion of core involvement (%) recorded for each zone.
- This information can also be conveyed in a visual format by creating a 'map' of the prostate that illustrates the Gleason score and extent of tumour in each individual zone.

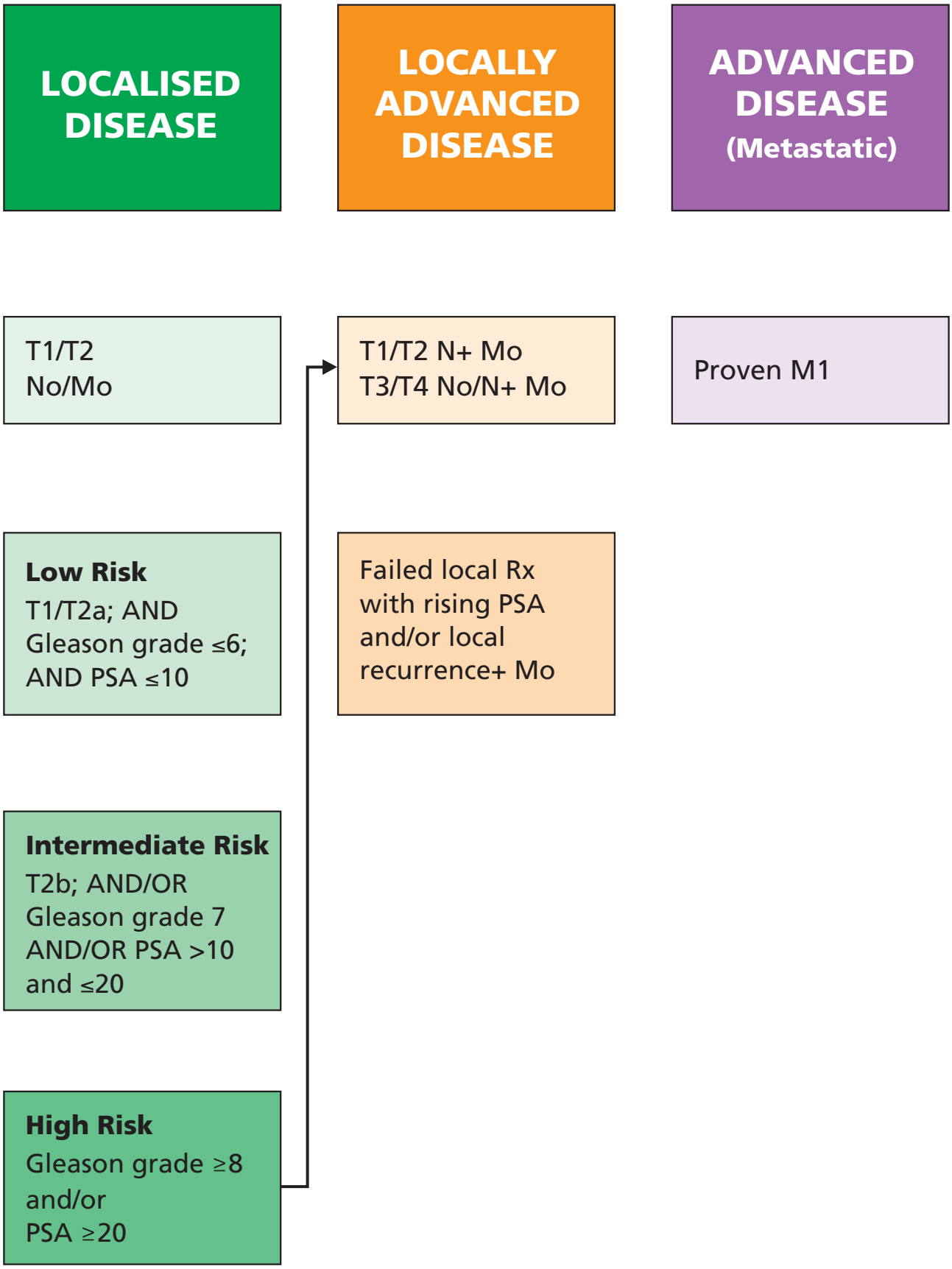
Magnetic Resonance Imaging (MRI)

- TNM staging, Gleason score, and PSA concentration facilitate estimation of the risk of extracapsular disease and lymph node metastases. Pelvic staging is required for those of high or intermediate risk (according to NCCN classification). MRI is the preferred option to stage pelvic lesions and where MRI is contraindicated, computed tomography (CT) should be used [NICE 2008].
- MRI is sensitive and specific in identifying extracapsular extension of prostate cancer in patients with high - or intermediate-risk disease [Allen DJ, *et al* 2004].
- NICE concludes [NICE 2008]:
    - MRI is now the most accurate and commonly-used imaging technique for tumour-staging men with prostate cancer. Many of the original publications on MRI technology are now considered to be outdated, and the accuracy reported for MRI is improving, typically with multiparametric, diffusion weighted scans
    - After transrectal prostate biopsy, intra-prostatic haematoma can affect image interpretation for at least 4-6 weeks.

Bone scans

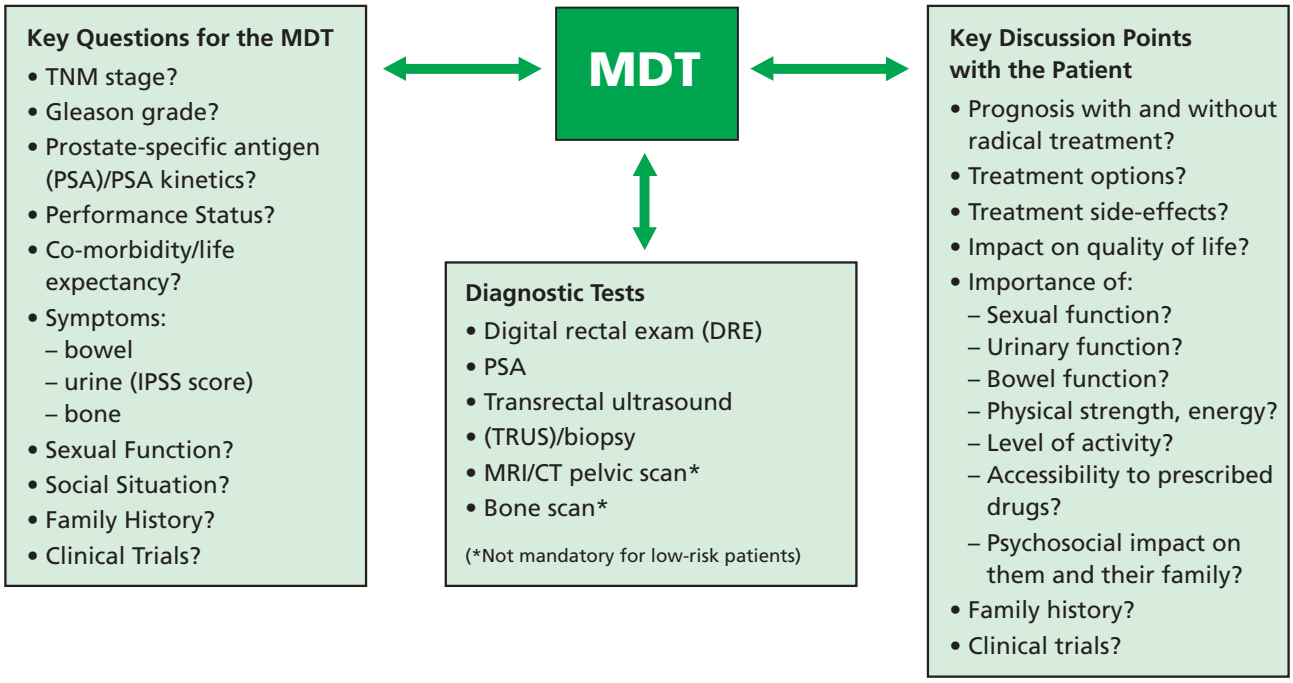
- Bone scans (particularly in patients with PSA concentration >20 ng/ml) are also important in the assessment process. A PSA concentration of <10 ng/ml is unlikely to indicate bone metastases at presentation. A PSA cut-off value of 10 ng/ml for men with Gleason grade ≤7 indicates a negative predictive value range of 91.5–100% [Gerber G & Chodak GW 1991].
- MRI can be an additional approach for distinguishing borderline metastases.

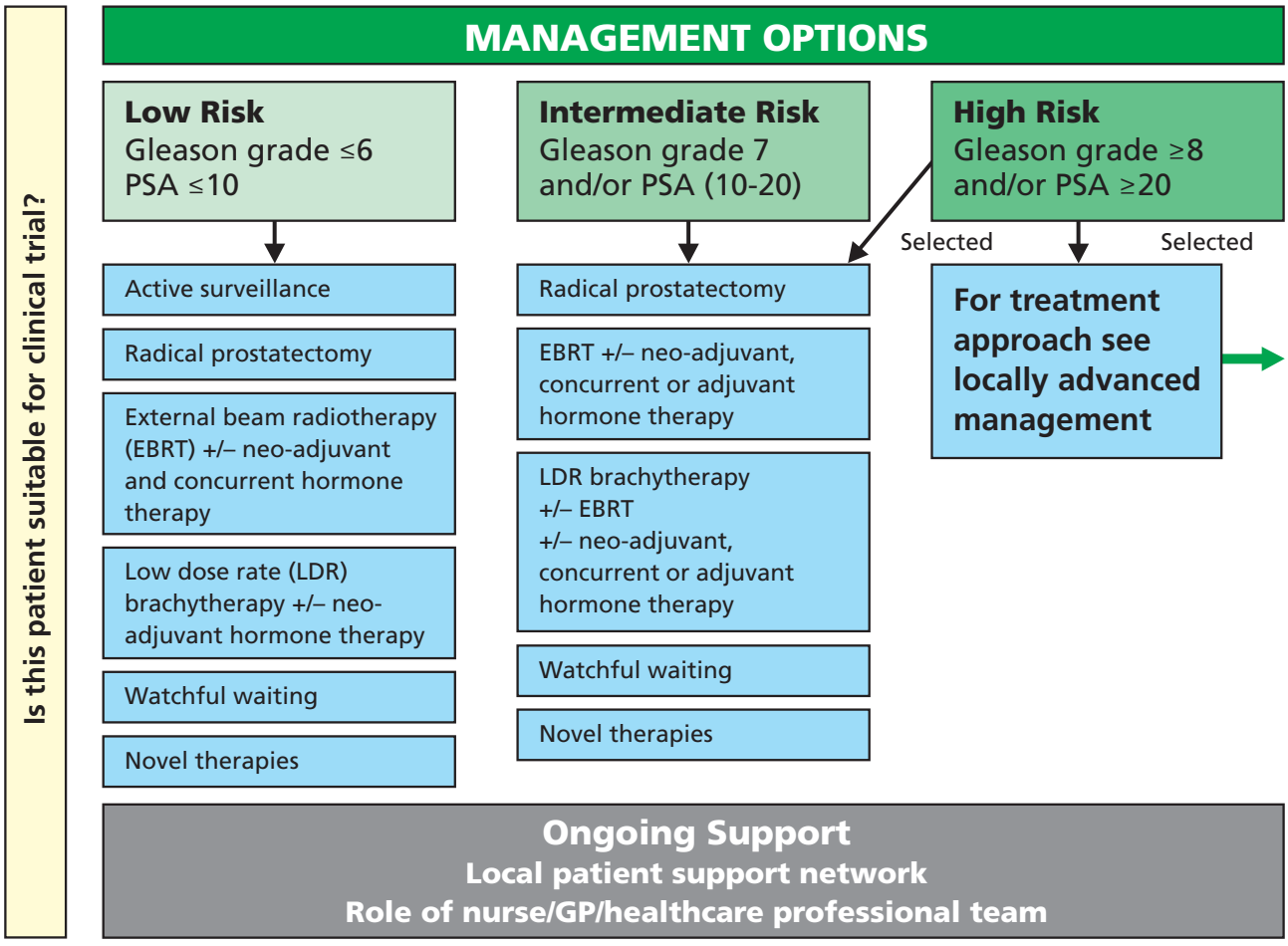
Figure 1: Summary of the definition of prostate cancer stages



Localised Disease: Management Options

Figure 2: Treatment algorithm for localised disease





The following guidance for managing localised prostate cancer focuses on low- and intermediate-risk categories, defined here as [D'Amico AV, *et al* 1998]:

- Low risk (T1/T2a; AND Gleason grade ≤6; AND PSA concentration ≤10 ng/ml)
- Intermediate risk (T2b; AND/OR Gleason grade 7 AND/OR PSA concentration: >10 and ≤20 ng/ml)

In the proposed management algorithms, high-risk localised disease falls more naturally into management of locally advanced disease.

Patient choice and the presence or absence of co-morbidities should be an essential component of management decisions in men with localised disease. Decisions concerning the choice of radical treatments need to be carefully balanced with the different options available and the impact of such treatments on a patient's co-morbidities.

In this section available evidence for the following management approaches is outlined:

- Active surveillance
- Watchful waiting
- Radical prostatectomy
- External Beam Radiation Therapy (EBRT)
- Low dose rate (LDR) brachytherapy
- Neoadjuvant/adjuvant hormone therapy
- Novel therapies

Active surveillance

Overview

- Active surveillance is an approach to the management of early prostate cancer in which the choice between curative treatment and observation is based on evidence of disease progression (PSA kinetics, repeat biopsy or MRI findings) during a period of close monitoring. The aim is to reduce the burden of treatment side-effects without compromising survival.
- Patients suitable for active surveillance are those with low-risk localised disease who are fit for radical treatment. Ongoing prospective studies of active surveillance have shown that 60–80% of such men will avoid the need for treatment, and that 99-100% prostate cancer-specific survival at 10 years is achievable [Selvadurai ED, *et al* 2013; van den Bergh RC, *et al* 2008].
- Active surveillance should be clearly distinguished from watchful waiting. Traditional watchful waiting involves relatively unstructured observation with late, palliative treatment for those who develop symptoms of progressive disease. In contrast, active surveillance involves close monitoring with early radical treatment in those with signs of disease progression.

Patient selection

- Low (or intermediate) risk, clinically localised prostate cancer
  - Clinical stage T1c/2a
  - Gleason grade ≤3+4
  - PSA concentration <15 ng/ml
  - Positive biopsies ≤50%
  - Age 50–80 years
  - Fit for radical treatment
- Active surveillance is particularly suitable for a subgroup of men with low-risk localised prostate cancer who have clinical stage T1c, a Gleason score of 3+3, a PSA density of <0.15 ng/ml per ml with <10 mm of any core involved [NICE 2008].

Side-effects

- Psychological uncertainty

Clinical evidence

- The case for active surveillance is based on the knowledge that PSA testing leads to significant overdiagnosis of prostate cancer. That is, approximately 50% of all cases detected as a result of PSA testing would never have been diagnosed in the absence of testing [Draisma G *et al* 2003]. It follows that treatment is 'unnecessary' in approximately half of all cases of PSA-detected prostate cancer.
- van den Bergh has reported the outcome of expectant management in 616 men who were diagnosed with prostate cancer between 1994 and 2007 at a mean age of 66.3 years in the ERSPC [van den Bergh RC, *et al* 2008]. All patients had low-risk disease with PSA <10 ng/ml, PSA density <0.2 ng/ml per ml, stage T1c/T2, Gleason score ≤3+3=6, and ≤2 positive biopsy cores. Median follow-up was 3.9 years. The 10-year prostate cancer-specific survival (21 patients at risk) was 100%, which sharply contrasted with 77% overall survival (OS), due to deaths from other causes.
- Selveduarai *et al*. reported the outcome of 471 men recruited to the Royal Marsden active surveillance study since 2002, at a median follow-up of 5.7 years [Selvadurai ED, *et al* 2013]. Median age was 66 years, and median initial PSA concentration 6.4 ng/ml. The 5-yr treatment-free probability was 70% (95% CI, 65–75%). There were two deaths from prostate cancer. Predictors of time to adverse histology were GS 7, PSAV >1 ng/ml per year, low ratio of free PSA to total PSA, and PPC >25%. There were two deaths from prostate cancer [Selvadurai ED, *et al* 2013].

Watchful waiting

Overview

- Watchful waiting is an approach to the management of localised prostate cancer that aims to avoid treatment, or delay it for as long as possible.
- Watchful waiting is particularly suitable for patients aged over 75 years or younger men with significant co-morbidities.
- Watchful waiting should be clearly distinguished from active surveillance. Conventional watchful waiting involves relatively unstructured observation with late, palliative treatment (usually hormone therapy) for those who develop symptoms of progressive disease. In contrast, active surveillance involves close monitoring with early, radical treatment in those with signs of progression.

Patient selection

- Asymptomatic clinically localised prostate cancer
  - Clinical stage T1–3 N0 M0
  - Gleason score ≤7
  - Any PSA concentration
  - Not suitable for radical treatment (usually by virtue of older age or co-morbidities)

Side-effects

- Uncertainty

Clinical evidence

- The NICE clinical guideline confirms a lack of evidence for watchful waiting and the Guideline Development Group reached a consensus that the recommendation from NICE would avoid unnecessary investigations [NICE 2008]:
  - Men with localised prostate cancer who have chosen a watchful waiting regimen and who have evidence of significant disease progression (rapidly rising PSA level or bone pain) should be reviewed by a member of the urological cancer MDT.

Radical Treatments

Radical Prostatectomy (RP)

Overview

- The procedure involves removal of the entire prostate gland between the urethra and bladder, and resection of both seminal vesicles, along with sufficient surrounding tissue to obtain a negative margin. This can be accompanied by bilateral pelvic lymph node dissection. There are now four approaches to performing a radical prostatectomy: retropubic, perineal, laparoscopic and robotic. Laparoscopic and robotic approaches have the potential advantage of reduced blood loss and shorter inpatient stays.
- Selley *et al*. reviewed a total of 17 studies (two randomised controlled trials [RCTs] and 15 observational studies involving a total of 5410 patients) to investigate the efficacy of radical prostatectomy for men with localised prostate cancer. Cancer-specific survival after 10 years of follow-up ranged from 86% to 91%, with clinical disease-free survival (DFS) ranging from 57% to 83% [Selley S, *et al* 1997].

Patient selection

- Anaesthetic fitness
- At least 10 years' life expectancy

Side-effects

- Based on the systematic review by Selley *et al*., the following side-effects should be considered [Selley S, *et al* 1997]:
  - Operative and post-operative mortality: 0.2–1.2%
  - Sexual dysfunction: 51–61%
  - Incontinence (mild stress): 4–21%
  - Incontinence (total): 0–7%

Clinical evidence

- Two randomised trials have compared radical prostatectomy with watchful waiting in localised prostate cancer [Bill-Axelson A, *et al* 2011].
    - After a follow-up of 15 years, the SPCG-4 trial showed that RP was associated with a reduction of all-cause mortality: RR=0.75 (0.61 to 0.92). According to a post hoc statistical sub-group analysis, the number to treat (NNT) to avert one death was 15 overall and 7 for men younger than 65 years of age. Radical prostatectomy was also associated with a reduction in prostate cancer-specific mortality: RR=0.62 (0.44 to 0.87).
- This OS and CSS benefit could not be reproduced in another prospective randomised study [Wilt TJ, *et al* 2012]. After a median follow-up of 10 years, the PIVOT trial showed that RP did not significantly reduce all cause mortality: HR=0.88 (0.71 to 1.08); p=0.22, nor did RP significantly reduce prostate cancer mortality: HR=0.63 (0.36 to 1.09); p=0.09. According to a preplanned sub-group analysis among men with low-risk prostate cancer (n=296), RP non-significantly increased all-cause mortality: HR=1.15 (0.80 to 1.66). For men with intermediate-risk tumours (n=249), RP significantly reduced all-cause mortality: HR=0.69 (0.49 to 0.98). Among men with high-risk tumours (n=157), RP non-significantly reduced all-cause mortality: HR=0.40 (0.16 to 1.00).Among men with PSA > 10, RP significantly reduced all cause mortality: HR=0.67 (0.48 to 0.94).
    - Faced with these figures, some patients would choose surgery, but should also be given the option of conservative management with active surveillance [Singer PA, *et al* 1991].

Neoadjuvant and adjuvant hormone therapy with radical prostatectomy

- A review and meta-analysis of the role of Neoadjuvant Hormone Therapy (NHT) and RP has shown that this approach did not improve OS or DFS, but did significantly reduce positive margin rates [relative risk (RR): 0.49; 95% confidence interval (CI): 0.42-0.56, P < 0.00001), organ confinement (RR: 1.63; 95% CI: 1.37-1.95, P < 0.0001) and lymph node invasion (RR: 0.49; 95% CI: 0.42-0.56, P < 0.02) [Shelley MD, *et al* 2009]. Therefore, evidence suggests that the down-staging achieved with neoadjuvant hormone therapy does not translate into improved DFS, and therefore cannot be recommended outside of clinical trials [Bonney WW, *et al* 1999; Paul R, *et al* 2004; Selli C & Milesi C. 2004; Witjes WPJ, *et al* 1997].
- Similarly, there is currently no evidence that adjuvant hormone therapy provides a survival advantage for patients with pathologically proven localised disease [Hachiya T, *et al* 2002; Prayer-Galetti T, *et al* 2000]. A recent Cochrane review and meta-analysis studied the role of adjuvant HT following RP: the pooled data for 5-year OS demonstrated an odds ratio (OR) of 1.50 and 95% CI: 0.79-2.84 [Shelley MD, *et al* 2009]. Although this finding was not statistically significant, there was a trend favouring adjuvant HT. There was no survival advantage at 10 years.

Adjuvant radiotherapy after radical prostatectomy

- Extracapsular invasion (pT3), Gleason score > 7, and positive surgical margins (R1) can be associated with a risk of local recurrence and the role of adjuvant treatments for this high risk group is considered in the section of locally advanced prostate cancer and radical prostatectomy.

External Beam Radiotherapy (EBRT)

Overview

- Selley *et al*. reviewed 21 observational studies and one RCT involving radiotherapy and found that survival and recurrence rates are associated with grade and stage of the disease. The 5-year DFS for those with T1–T2 stage disease averaged 70–80%. Local progression was observed in 10–20% of these patients, while distant metastases were observed in 20–40% [Selley S, *et al* 1997].
- Nilsson *et al*. performed a systematic overview of radiotherapy in prostate cancer. Data from 26 non-randomised trials of conventional EBRT showed a 10-year DFS of 100%, 69% and 57% for T1a, T1b and T2 stage disease, respectively [Nilsson S, *et al* 2004].
- Long-term follow-up after EBRT continues to demonstrate an improvement in cause-specific survival. Improved selection and technical developments in radiotherapy leading to increased doses have shown better results.

Three-dimensional conformal radiotherapy (3D-CRT)

- There is evidence that increased radiation dose is associated with increased cancer cell kill for men with localised prostate cancer. However, the traditional two-dimensional technique of treatment planning and delivery is limited by the normal tissue toxicity of the surrounding structures (bladder, rectum and bowel), such that the dose that can be safely delivered to the prostate by EBRT is of the order of 64Gy in 2Gy per day fractions. Several technological advances over the last 20 years have enhanced the precision of EBRT, and have resulted in improved outcomes.
- The three-dimensional conformal radiotherapy (3D-CRT) approach reduces the dose-limiting late side-effect of proctitis [Dearnaley DP, *et al* 1999] and has allowed for dose escalation to the whole prostate to up to78 Gy.

Intensity Modulated Radiotherapy (IMRT)

- IMRT is an advanced technique which has superseded 3D-CRT. IMRT can modify the shape and intensity of the multiple radiotherapy beams. It is very precise in targeting the treatment area, sparing surrounding tissue and allowing dose escalation above 80Gy. IMRT is currently recommended, particularly for the irradiation of pelvic lymph nodes.

Dose escalation

- Several randomised studies have shown that dose escalation with 3D conformal radiotherapy and more recently with IMRT has a significant impact on the 5-year biochemical relapse free survival. However, no trials to date have shown an improvement in long term overall survival
- Evidence of the benefits of dose escalation has been demonstrated for T1–T3 prostate cancer by Pollack *et al*. in a phase III randomised study undertaken at the MD Anderson Hospital [Pollack A, *et al* 2002].
    - A total of 305 men were randomised between 1993 and 1998 to compare the efficacy of 70 Gy versus 78 Gy with a median follow-up of 60 months. The primary endpoint was freedom from failure (FFF), including biochemical failure, which was defined as three rises in PSA level.
    - The FFF rates for the 70 Gy and 78 Gy arms at 6 years were 64% and 70%, respectively (p=0.03). Dose escalation to 78 Gy preferentially benefited those with a pre-treatment PSA concentration >10 ng/ml; the FFF rate was 62% for the 78 Gy arm versus 43% for those who received 70 Gy (p=0.01). For patients with a pre-treatment PSA concentration ≤10 ng/ml, no significant dose-response relationship was found, with an average 6-year FFF rate of about 75%.
    - Although no difference in OS occurred, the freedom from distant metastasis rate was higher for those with PSA levels >10 ng/ml who were treated to 78 Gy (98% versus 88% at 6 years, p=0.056).
- Dearnaley and colleagues have reported their findings from the MRC RT01 study [Dearnaley DP, *et al* 2007].
    - In this 3D-CRT trial, 843 men were randomised to a standard dose of 64 Gy compared with an escalated dose of 74 Gy, with all men also receiving neoadjuvant hormone therapy.
    - Patients receiving the conventional dose had 5-year biochemical PFS rates of 60% compared to 71% in the dose-escalated arm. Advantages were also seen in terms of clinical PFS and the decreased use of androgen suppression.
    - An update of this study with 10 years of follow up has not shown any further benefit in biochemical PFS of 54% (172 events) versus 42% (224 events), HR 0.688 (0.56-0.84) p<0.0001 in favour of the dose escalated group [Dearnaley DP, *et al* 2011]. However, no overall survival benefit was demonstrated, with both the 64Gy and 74Gy arms having an overall survival of 70% HR 0.99 (0.77-1.28) p=0.337. The number of men requiring long term hormone therapy was reduced in the dose escalated arm HR 0.77 (0.59-1.00) p=0.05.
- Recently the long-term follow-up of the pilot study, which provided the initial safety and feasibility information for the national MRC RT01 trial have been published [Creak A, *et al* 2013].
    - In this study, 126 patients were randomised to a standard dose of 64 Gy compared with an escalated dose of 74 Gy after neoadjuvant androgen suppression.
    - After a follow up of 13.7 years, 49 of 126 patients restarted AS, 34 developed metastases and 28 developed CRPC. Median OS was 14.4 years.
    - Although escalated dose results were favourable, no statistically significant differences were seen between the randomised groups; PSA control (hazard ratio (HR): 0.77 (95% confidence interval (CI): 0.47–1.26)), development of CRPC (HR: 0.81 (95% CI: 0.40–1.65)), PC-specific survival (HR: 0.59 (95% CI:0.23–1.49)) and OS (HR: 0.81 (95% CI: 0.47–1.40)).
- The Dutch randomised phase III trial comparing 68 Gy with 78 Gy also demonstrated a significant increase in the 5-year rate of freedom from clinical or biochemical failure in patients treated with a higher dose of radiotherapy [Peeters ST, *et al* 2006]

- The phase III trial of the French Federation of Cancer Centres compared 70 Gy with 80 Gy in men with localised prostate cancer, in 306 patients with a low risk of pelvic lymph node involvement [Beckendorf V, *et al* 2011]. At a median follow up of 61 months, they demonstrated improved 5-year biological outcomes in favour of dose-escalated radiotherapy group. Using the Phoenix definition, the 5-year biochemical relapse rate was 32% and 23.5%, respectively (p = .09).
- Although these and other studies have shown benefits from dose escalation this has been offset to a degree by a reported increase in late rectal toxicity.
- Prospective non-randomised studies conducted at the Memorial Sloan Kettering cancer centre have compared the outcomes of 1100 men who received doses in the range of 64–70 Gy and 76–86 Gy using IMRT [Zelefsky MJ, *et al* 2001].
    - The results were evaluated within prognostic risk groups (using clinical stage, Gleason grade and presenting PSA concentration). They demonstrated that increasing the dose delivered beyond 70.2 Gy in men with intermediate- and high-risk disease improved the 5-year actuarial PSA relapse-free survival rate from 50% to 70% and 21% to 47%, respectively, in these two risk categories.
- IMRT has the potential to reduce late rectal toxicity as shown in a further study that reports 3-year actuarial ≥grade 2 gastrointestinal toxicity at 4% [Zelefsky MJ, *et al* 2002].
- A further development under investigation involves a change in the traditional fractionation schedules. Hypofractionation may improve cancer control for the same level of radiation-related toxicity and be a more effective treatment for prostate cancer with a predicted low alpha/beta ratio. Phase II dose escalation studies using shortened schedules of hypofractionated IMRT regimens have indicated acceptable early toxicity [Amer AM, *et al* 2003].
- The CHHiP (Conventional or Hypofractionated High Dose IMRT for Prostate Cancer) study is currently recruiting patients in the UK to compare standard fractionation IMRT (74 Gy in 37 fractions) to two hypofractionated IMRT regimens (60 Gy in 20 fractions or 57 Gy in 19 fractions) in combination with neoadjuvant hormone therapy [South CP, *et al* 2008]. There is no overall survival data available from this trial as yet but preliminary safety results have shown that hypofractionated high-dose radiotherapy seems equally well tolerated as conventionally fractionated treatment at 2 years

Image Guided Radiotherapy (IGRT)

- The advantages of dose escalation using IMRT means that organ movement becomes a critical issue, in terms of both tumour control and treatment toxicity to the bladder, rectum and bowel. Techniques should therefore combine IMRT with some form of IGRT (fiducial markers, imaging), in which organ movement can be visualised and corrected for in real time, although the optimum means of achieving this is still under investigation.

Patient selection

- EBRT can be unsuitable for patients with bilateral hip replacement, previous radiotherapy, severe proctitis or bowel morbidity (such as ulcerative colitis or Crohns' disease).

Side-effects

- Acute complications include cystitis, faecal frequency and urgency, proctitis and rectal bleeding.
- Late complications occurring 3 months or later after treatment include impotence, bleeding, proctitis and diarrhoea.

EBRT plus neoadjuvant hormone therapy

- Neoadjuvant hormone therapy with an LHRH agonist can reduce the prostate volume by up to 30–40% [Shearer RJ, *et al* 1992;Forman JD, *et al* 1995] This can allow smaller treatment fields and as a result the level of toxicity experienced.
- There are also reports of an additive or synergistic effect on tumour cell kill with combined therapy. Theories as to the mechanism of this include improved oxygenation by reducing tumour bulk and movement of hormone-responsive cells into a resting phase, which could reduce repopulation rate and enhance tumour cell death (increased apoptosis) [Hara I, *et al* 2002].
- The RTOG 86-10 trial randomised 471 men with T2–T4 prostate cancer to radiotherapy +/– 4 months of androgen deprivation therapy (ADT) before and during EBRT or to radiotherapy alone [Pilepich MV, *et al* 2001].
    - At median follow-up of 8.7 years, there was a trend to improved survival (8-year survival 53% versus 44%, p=0.1) for those treated by hormone therapy with radiotherapy, which was significant for the subgroup with Gleason grade 2–6 disease (70% versus 52%, p=0.015) [Pilepich MV, *et al* 2001]..
    - Ten-year OS estimates (43% versus 34%) and median survival times (8.7 versus 7.3 years) favoured combined therapy with hormones and radiation compared to radiation treatment alone; however, these differences did not reach statistical significance (p=0.12).
    - There was a statistically significant improvement in 10-year disease-specific mortality (23% versus 36%; p=0.01), distant metastases (35% versus 47%; p=0.006), DFS (11% versus 3%; p<0.0001) and biochemical failure (65% versus 80%; p<0.0001) with the addition of neoadjuvant hormone therapy, but no differences were observed in the risk of fatal cardiac events [Roach M 3rd, *et al* 2008].
- The TROG 96.01 trial has shown that in the intermediate-risk patient group a 6-month course of ADT has shown some benefit when compared with a 3-month course [Denham JW, *et al* 2008].
    - Relative to radiation alone, the HR of prostate cancer-specific mortality from randomisation was 0.95 (95%CI: 0.63–1.41; p=0.79) in the 3-month ADT treatment arm and 0.56 (95%CI: 0.36–0.88; p=0.01) in the 6-month arm.
- A separate 6-month study compared 3D-CRT plus ADT and 3D-CRT alone [D'Amico AV, *et al* 2004].
    - After a median follow-up of 4.52 years, patients receiving 3D-CRT + ADT demonstrated a significantly lower prostate cancer–specific mortality rate (p=0.02).
    - 5-year OS rates were estimated at 88% (95%CI: 80–95) in the 3D-CRT + ADT group versus 78% (95%CI: 68–88) in the 3D-CRT group (p=0.04).

EBRT plus adjuvant hormone therapy

- Refer to section "EBRT plus adjuvant hormonal therapy" on pp 40.

Low dose rate (LDR) brachytherapy

Overview

- In 2005, NICE reviewed the medical literature on LDR brachytherapy and concluded that, in the absence of randomised trials, the results of LDR brachytherapy are comparable to those achieved with surgery or EBRT in well-selected patients [NICE 2005].
- Suitable patients include those with localised disease (up to T2a) with a Gleason grade ≤6, and a PSA concentration ≤10 ng/ml. Patients with significant urinary symptoms or post-TURP may not be suitable.
- Brachytherapy is as effective as radical prostatectomy in patients with low-risk localised disease [Crook J, *et al* 2001; Grimm P, *et al* 2012].
- In intermediate-risk localised disease, the comparison is less clear, because many studies have added EBRT in combination [Merrick GS, *et al* 2001].
- Brachytherapy is a single-step day case procedure following a spinal or general anaesthetic.

Brachytherapy plus EBRT

- In a matched-pair analysis, the 5-year biochemical failure-free survival rate was 86% for patients treated with EBRT and LDR brachytherapy, and 72% for patients treated with EBRT alone (p=0.03). Both treatments were associated with comparable incidences of late genitourinary side-effects (18-19%). Late rectal toxicity decreased by 15% in patients treated with EBRT and brachytherapy (p=0.0003). [Singh AM, *et al* 2005].

Brachytherapy plus neoadjuvant hormone therapy

- The role of neoadjuvant hormone therapy with brachytherapy is controversial. It is used to reduce the prostate volume when it exceeds 50 ml, in order to facilitate brachytherapy. Volume reduction decreases the total isotope activity required, potentially improves implant dosimetry and decreases pubic arch interference. [Potters L, *et al* 2005].

Patient selection (exclusions)

- Prostate size >50 ml
- Recent TURP
- Significant urinary outflow obstruction
- Previous AP resection
- Previous high dose pelvic radiotherapy

Side-effects

- A review of 16 studies by Crook *et al*. showed acute adverse events as [Crook J, *et al* 2001]:
  - Irritant urinary symptoms: 46–54%
  - Acute urinary retention: 1–14%
  - Acute proctitis: 1–2%
  - Chronic adverse events (reinforced by Wills & Hailey, 1999 [Wills F & Hailey D. 1991]:
    - Incontinence: 5–6%
    - Haematuria: 1–2%
    - Strictures: 1–2%
    - Proctitis: 1–3%
    - Erectile dysfunction: 4–14% (or up to 38% in Wills & Hailey, 1999 [Wills F & Hailey D. 1991] and up to 50% at 5 years in Merrick *et al*., 2001 [Merrick GS, B, *et al* 2001]).

Clinical evidence

- Very few comparative studies to date have evaluated the results of treatment options for prostate cancer using the most sensitive measurement tools. PSA has been identified as the most sensitive tool for measuring treatment effectiveness. To date, comprehensive unbiased reviews of all the current literature are limited for prostate cancer. A large scale comprehensive review of the literature comparing risk stratified patients by treatment option and with long-term follow-up was carried out by Grimm *et al* 2012 [Grimm P, *et al* 2012]. The results of the studies were weighted, respecting the impact of larger studies on overall results. The review identified a lack of uniformity in reporting results amongst institutions and centres. A large number of studies had been conducted on the primary therapy of prostate cancer but very few randomised controlled trials had been conducted. The comparison of outcomes from individual studies involving surgery (radical prostatectomy or robotic radical prostatectomy), external beam radiation (EBRT) (conformal, intensity modulated radiotherapy, protons), brachytherapy, cryotherapy or high intensity focused ultrasound remains problematic due to the non-uniformity of reporting results and the use of varied disease outcome endpoints. Technical advances in these treatments have also made long-term comparisons difficult. This international group conducted a comprehensive literature review to identify all studies involving treatment of localised prostate cancer published during 2000-2010. Over 18,000 papers were identified and a further selection was made based on the following key criteria: minimum/median follow-up of 5 years; stratification into low-, intermediate- and high-risk groups; clinical and pathological staging; accepted standard definitions for prostate-specific antigen failure; minimum patient number of 100 in each risk group (50 for high-risk group). A statistical analysis of the study outcomes suggested that, in terms of biochemical-free progression, brachytherapy provided superior outcome in patients with low-risk disease. For intermediate-risk disease, the combination of EBRT and brachytherapy appears equivalent to brachytherapy alone. For high-risk patients, combination therapies involving EBRT and brachytherapy plus or minus androgen deprivation therapy appear superior to more localized treatments such as seed implant alone, surgery alone or EBRT.
- A significant correlation has been demonstrated between recurrence rates and the implanted dose [Stock RG, *et al* 1998]. It has been shown that men receiving a D90 of > 140 Gy had a significantly higher biochemical control rate (PSA < 1.0 ng/mL) at 4 years than those who received less than 140 Gy (92% vs. 68%).

- Kupelian *et al*. studied 2991 consecutive patients with T1/T2 tumours treated with radical prostatectomy, LDR brachytherapy, EBRT or a combination of EBRT and brachytherapy. Biochemical relapse-free survival was similar in all groups when EBRT <72 Gy was excluded [Kupelian PA, *et al* 2004].
- Potters *et al* studied 1,449 consecutive patients treated with permanent prostate brachytherapy between 1992 and 2000. The mean pre-treatment PSA of 10.1ng/ml and 55% presented with Gleason 6 prostate cancer and 28% Gleason 7 disease. 400 patients (27%) were treated with neoadjuvant hormones and 301 (20%) were treated with combination EBRT. At a median follow up of 82 months, the overall and disease specific survival at 12 years was 81% and 93%, respectively. The 12-year biochemical free recurrence rates varied between 77% and 81% depending on the method of reporting recurrence. They concluded from multivariate analyses that implant dosimetry remains an important predictor for biochemical recurrence and that the addition of adjuvant hormone therapy or external radiation had an insignificant effect. [Potters L, *et al* 2005].

Novel therapies

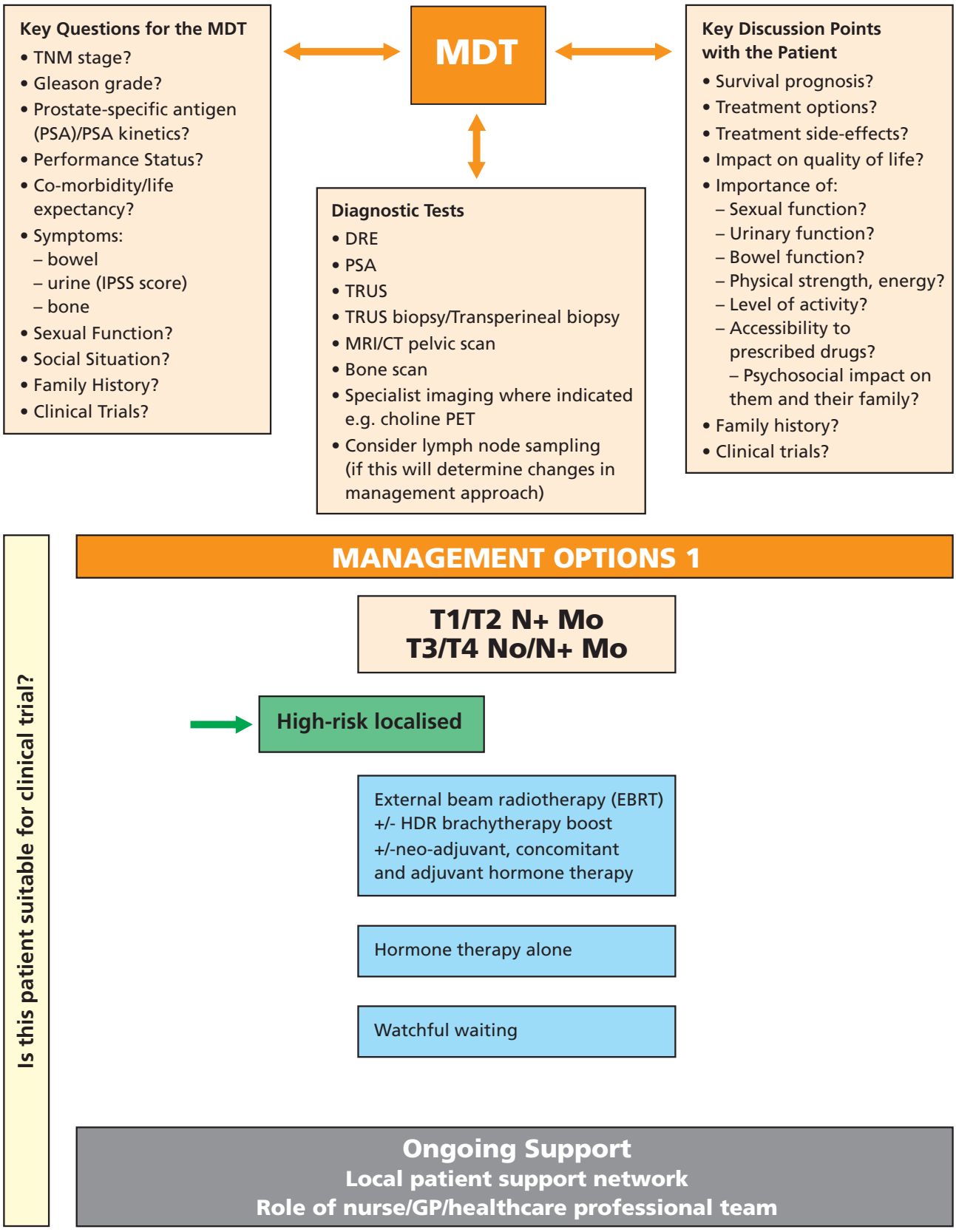
Cryotherapy/High-Intensity Focused Ultrasonography (HIFU)

The development of third-generation prostate cryotherapy has allowed the introduction of ultra-thin needles to deliver a minimally-invasive treatment for prostate cancer patients in the primary and salvage setting.

- Long *et al*. have performed a retrospective analysis of the multicentre, pooled, results of 975 patients treated with cryotherapy [Long JP, *et al* 2001]. The patients were stratified into three risk groups. Using PSA thresholds of 1.0 ng/mL and < 0.5 ng/mL and had a mean follow-up of 24 months. The 5-year actuarial biochemical disease free survival rates were:
  - 76% and 60%, respectively, for the low-risk group
  - 71% and 45%, respectively, for the intermediate-risk group
  - 61% and 36%, respectively, for the high-risk group
- Bahn *et al*. [Bahn DK, *et al* 2002], have reported the results of 7 year follow up on 590 patients treated with cryotherapy for clinically localised and locally advanced PCa. Using a PSA cut-off response level of < 0.5 ng/mL, the 7-year biochemical disease free survival for low-, medium- and high-risk groups was 61%, 68% and 61%, respectively.
- Longer-term follow-up series show biochemical DFS at 10 years of 80.56% for low-risk, 74.16% for moderate-risk and 45.54% for high-risk prostate cancer patients
- The toxicity from cryotherapy has reported erectile dysfunction in approximately 80% of patients and remains a consistent complication of the procedure, regardless of the generation of the system used. The complication rates described in third generation cryosurgery include tissue sloughing in about 3%, incontinence in 4.4%, pelvic pain in 1.4% and urinary retention in about 2% [De La Taille A, *et al* 2000]. Around 5% of all patients require transurethral resection of the prostate (TURP) for subvesical obstruction.
- This treatment has been approved by the American Urological Association and the European Association of Urology for treatment of patients with primary and radiation-failed prostate cancer
- In the NICE guidelines, the minimally-invasive treatments of cryosurgery and HIFU were considered to be experimental and for use only within the clinical trial setting [NICE 2008].
- Poissonnier reported on 227 patients with localised prostate cancer who were treated with HIFU at a single institution. The projected 5-year biochemical disease free survival rate was 66%, or 57% for patients with a pre-treatment PSA value of 4-10 ng/mL after a mean follow up of 27 months (range: 12-121) [Poissonnier L, *et al* 2007]
- Blana *et al*. have reported the results of 163 patients treated with HIFU for clinically organ confined prostate cancer. The actuarial disease free survival rate at 5 years was 66%, with salvage treatment initiated in 12% of patients [Blana A, *et al* 2008].
- In another study, 517 men with organ-confined or locally advanced PCa were treated with HIFU .Biochemical failure was defined as the PSA nadir + 2 ng/mL, After a median follow-up of 24 months, the biochemical disease free survival was 72% for the entire cohort. The biochemical disease free survival rates for low-, intermediate- and high-risk groups at 5 years was 84%, 64% and 45%, respectively (P < 0.0001) [Uchida T, *et al* 2009].
- Urinary retention appears to be one of the most common side effects of HIFU, with stress incontinence occurring in about 12% of patients. Subsequent TURP or bladder neck incision to treat subvesical obstruction can be used to treat these symptoms and is sometimes performed at the time of HIFU. Postoperative impotence has been reported in 55-70% of patients.

Locally Advanced Disease: Management Options

Figure 3: Treatment algorithm for locally advanced disease



The term 'locally advanced prostate' cancer can be used to encompass a spectrum of disease profiles that may include any of the following:

- Clinical stage T3, T4 or N1 cancers without evidence of distant metastases (M0)
- Clinical stages T1 and T2 ('localised') at diagnosis, where 'high-risk' features (PSA concentration ≥20 ng/ml or Gleason grade ≥8) indicate the likelihood of extraprostatic invasion or clinically undetectable metastatic disease.
- Pathological stage pT2 or pT3 disease with 'high-risk' features due to upstaging from additional pathological information after radical prostatectomy.

Men with locally advanced or high-risk prostate cancer generally have a significant risk of disease progression and cancer-related death if left untreated. These patients present two specific challenges. There is a need for local control and also a need to treat any microscopic metastases likely to be present but undetectable until disease progression. The optimal treatment approach will often therefore utilise multiple modalities. The exact combinations, timing and intensity of treatment continue to be strongly debated. Management decisions should be made after all treatments have been discussed by the MDT and the balance of benefits and side effects of each therapy modality have been considered by the patient with regard to their own individual circumstances.

Watchful waiting (deferred or immediate hormone therapy)

The waiting ('deferred treatment' or 'symptom-guided treatment') should be distinguished from active surveillance which involves close monitoring with early, radical treatment in those with signs of disease progression. Watchful waiting by contrast involves relatively unstructured observation with late, palliative treatment for those who develop symptoms of progressive disease.

Overview

- A pooled analysis of data from 2 RCTs involving 1036 men with locally advanced disease not suitable for curative treatment (T2–T4) suggested no survival benefit for immediate versus delayed hormone therapy at 1, 5 or 10 years [Wilt T, *et al* 2001].

Clinical evidence

- Adolfsson *et al*. prospectively followed 50 patients with locally advanced prostate cancer who were only treated upon patient request or when they became symptomatic. All patients were followed-up for more than 144 months, or had died before that point. OS and DFS at 5, 10 and 12 years was 68% and 90%, 34% and 74%, and 26% and 70%, respectively [Adolfsson J, *et al* 1999].
- Immediate versus deferred treatment for advanced prostate cancer was investigated by the MRC Prostate Working Party Investigators Group. An RCT of 943 men with asymptomatic metastases or locally advanced disease, not suitable for curative treatment, was undertaken, with randomisation to immediate or deferred hormone therapy [MRC Prostate Working Party Investigators Group 1997].
    - There was a significant advantage in the immediate treatment group in terms of distant progression. Mortality was only significantly changed by treating immediately in those with M0 disease (Table 5).
    - A modest but statistically significant increase in OS was seen in the immediate treatment group, but no significant difference in prostate cancer mortality or symptom-free survival was demonstrated.

- Due consideration must therefore be given to potential effects of long-term ADT versus the potential avoidance of such effects in patients if hormone therapy is deferred [Studer UE, *et al* 2008].

Table 5: Effect of immediate versus deferred hormonal treatment [MRC Prostate Working Party Investigators Group 1997]

		Immediate	Deferred
Distant progression		26%	45%
Mortality due to prostate cancer	M0 disease M1 disease	31.6% No significant difference	48.8% No significant difference

- A prospective randomised clinical phase III trial (EORTC 30981) by Studer UE *et al*, randomised 985 patients with T0-4 N0-2 M0 prostate cancer to immediate hormone or hormone treatment on the development of symptomatic disease progression [Studer UE, *et al* 2008]. After a median follow-up of 7.8 years, the overall survival hazard ratio was 1.25 (95% confidence interval [CI]: 1.05-1.48; non-inferiority $p > 0.1$) favouring immediate treatment. This appeared to be due to fewer deaths of non-prostatic cancer causes ($p = 0.06$). There was no difference in the time from randomisation to progression of hormone-refractory disease or prostate cancer-specific survival. The median time to the start of deferred treatment after study entry was 7 years. The conclusion suggested that immediate hormone therapy resulted in a modest but statistically significant increase in overall survival, but that there was no significant difference in prostate cancer mortality or symptom-free survival.
- The multicentre, International Early Prostate Cancer (EPC) study evaluated the efficacy and tolerability of adding the non-steroidal anti-androgen bicalutamide 150 mg once-daily to standard care (prostatectomy, radiotherapy or watchful waiting). 8,113 patients with localised or locally advanced non-metastatic prostate cancer were included [Iversen P, *et al* 2010].
  - Objective PFS and OS were defined as the primary endpoints. At a fourth analysis, the median follow-up was 9.7 years. Exploratory analyses were also conducted to determine the efficacy of bicalutamide in clinically relevant subgroups.
- A significant improvement in objective PFS in favour of bicalutamide 150 mg for all locally advanced disease patients was demonstrated. For those men with locally advanced disease who were managed by watchful waiting, there was a significant difference in PFS. The median time to progression was 6.6 years for those randomised to bicalutamide 150 mg compared to 3.7 years for those randomised to placebo. Patients in the watchful waiting subgroup showed a trend towards improved overall survival, this was statistically significant in sub-study 025 (carried out in Scandinavian in 1218 patients) HR=0.76 (0.59, 0.98) p=0.031 but did not reach significance in sub-study 24 (carried out in Europe, South Africa, Australia, Israel, and Mexico in 3603 patients) HR=1.03 (0.77, 1.37) p=0.844 [Iversen P, *et al* 2010].

Hormone therapy versus radiotherapy and hormone therapy

- A study by Widmark *et al* has shown that the addition of radiotherapy to hormone therapy for men with locally advanced or high-risk prostate cancer halves the 10-year prostate cancer-specific mortality and substantially decreases overall mortality [Widmark A, *et al* 2009].
    - This phase III study comparing endocrine therapy with and without local radiotherapy randomised 875 patients with locally advanced prostate cancer (T3; 78%; PSA concentration <70 ng/ml; N0; M0) to hormone therapy alone (3 months of total androgen blockade followed by continuous endocrine therapy using flutamide), or to the same hormone treatment combined with radiotherapy.
    - After a median follow-up of 7.6 years, 79 men in the hormone therapy group and 37 men in the hormone therapy plus radiotherapy group had died of prostate cancer. The cumulative incidence at 10 years for prostate cancer-specific mortality was 23.9% in the hormone alone group and 11.9% in the hormone therapy plus radiotherapy group (difference 12.0%; 95%CI: 4.9–19.1).
    - The 10-year cumulative incidence for overall mortality was 39.4% in the hormone therapy group and 29.6% in the hormone therapy plus radiotherapy group (difference 9.8%; 95%CI: 0.8–18.8).
    - The 10-year cumulative incidence for PSA recurrence was substantially higher in men in the hormone therapy group (74.7% versus 25.9%; HR 0.16; 95%CI: 0.12–0.20; p<0.0001).
    - After 5 years, urinary, rectal, and sexual problems were slightly more frequent in the hormone plus radiotherapy group.
- The National Cancer Institute of Canada (NCIC)/UK Medical Research Council (MRC)/Southwest Oncology Group (SWOG) intergroup PR3/PR07 study included 1,205 patients with stage T3-4 (n = 1057) or stage T2 with additional high risk features i.e. PSA > 40 ng/mL, or PSA > 20 ng in addition to Gleason Score > 8 and N0-X M0 prostate cancer [Warde, P, *et al* 2011]. These patients were randomly assigned to lifelong hormone therapy (bilateral orchidectomy or LHRH agonist), with or without radiotherapy (65-70 Gy to the prostate, with or without 45 Gy to the pelvic lymph nodes). The addition of radiotherapy to lifelong hormone treatment at a median follow up of 6 years demonstrated a reduced the risk of death from any cause by 23% (P = 0.03) and the risk of death due to prostate cancer by 46% (P = 0.0001) [Warde, P, *et al* 2011].

Side-effects of Hormone Therapy

- LHRH agonists: side-effects include erectile dysfunction and loss of libido, reduction in bone mineral density, hot flushes and sweating, and weight gain and metabolic effects.
- Bicalutamide (anti-androgens): side-effects include gynaecomastia and breast tenderness.
    - Mild to moderate gynaecomastia and breast pain are the most common adverse events described [McLeod DG, *et al* 2006].

External beam radiotherapy (EBRT) +/– neoadjuvant, concomitant and adjuvant hormone therapy

Radiotherapy Alone

- In locally advanced disease, EBRT alone has been shown to have a poorer outcome than in localised prostate cancer. Consequently, combination therapy with radiotherapy and hormone therapy is accepted as standard practice.
- Although it has been widely used, there are still many uncertainties associated with radical radiotherapy with regard to the optimum dose and field size (particularly to what extent the treatment volume should try to include pelvic lymph nodes). The advent of 3D Conformal radiotherapy (3D-CRT) and Intensity Modulated Radiotherapy (IMRT) in combination with Image Guided Radiotherapy (IGRT) has allowed the radiation field to be more precisely targeted to the tumour volume, thereby potentially reducing the side-effects of treatment and possibly allowing dose escalation that enhances its local efficacy.

Three-dimensional conformal radiotherapy (3D-CRT)

- There is evidence that increased radiation dose is associated with increased cancer cell kill for men with localised prostate cancer. However, the traditional two-dimensional technique of treatment planning and delivery is limited by the normal tissue toxicity of the surrounding structures (bladder, rectum and bowel), such that the dose that can be safely delivered to the prostate by EBRT is of the order of 64 Gy in 2 Gy per day fractions. Several technological advances over the last 20 years have enhanced the precision of EBRT, and have resulted in improved outcomes.
- The 3D-CRT approach reduces the dose-limiting late side-effect of proctitis [Dearnaley DP, *et al* 1999] and has allowed for dose escalation to the whole prostate to up to78 Gy.

Intensity Modulated Radiotherapy (IMRT)

- IMRT is an advanced technique which has superseded 3D-CRT. IMRT can modify the shape and intensity of the multiple radiotherapy beams. It is very precise in targeting the treatment area, sparing surrounding tissue and allowing dose escalation above 80 Gy. IMRT is currently recommended, particularly for the irradiation of pelvic lymph nodes.

Dose escalation

- Evidence suggests that patients treated with radiotherapy to the prostate have a significantly better outcome, because the dose to the gland is increased. The benefit is greatest in those patients with high-risk features.
- Debate remains over the best way of increasing the dose without significantly increasing normal tissue toxicity. 3D-CRT, IMRT and High Dose Rate (HDR) brachytherapy boost are methods currently under evaluation.
- Several randomised studies have shown that dose escalation with 3D-CRT and more recently with IMRT has a significant impact on the 5-year biochemical relapse free survival. However no trials to date have shown an improvement in long term overall survival.

- Evidence of the benefits of dose escalation has been demonstrated for T1–T3 prostate cancer by Pollack *et al*. in a phase III randomised study undertaken at the MD Anderson Hospital [Pollack A, *et al* 2002].
    - A total of 305 men were randomised between 1993 and 1998 to compare the efficacy of 70 Gy versus 78 Gy with a median follow-up of 60 months. The primary endpoint was freedom from failure (FFF), including biochemical failure, which was defined as three rises in PSA level.
    - The FFF rates for the 70 Gy and 78 Gy arms at 6 years were 64% and 70%, respectively (p=0.03). Dose escalation to 78 Gy preferentially benefited those with a pre-treatment PSA concentration >10 ng/ml; the FFF rate was 62% for the 78 Gy arm versus 43% for those who received 70 Gy (p=0.01). For patients with a pre-treatment PSA concentration ≤10 ng/ml, no significant dose-response relationship was found, with an average 6-year FFF rate of about 75%.
    - Although no difference in OS occurred, the freedom from distant metastasis rate was higher for those with PSA levels >10 ng/ml who were treated to 78 Gy (98% versus 88% at 6 years, p=0.056).
- Dearnaley and colleagues have reported their findings from the MRC RT01 study [Dearnaley DP, *et al* 2007].
    - In this 3D-CRT trial, 843 men were randomised to a standard dose of 64 Gy compared with an escalated dose of 74 Gy, with all men also receiving neoadjuvant hormone therapy.
    - Patients receiving the conventional dose had 5-year biochemical PFS rates of 60% compared to 71% in the dose-escalated arm. Advantages were also seen in terms of clinical PFS and the decreased use of androgen suppression.
    - An update of this study with 10 years of follow up has not shown an a further benefit in biochemical PFS of 54% (172 events) versus 42% (224 events) , HR 0.688 (0.56-0.84) p<0.0001 in favour of the dose escalated group. However, no overall survival benefit was demonstrated, with both the 64 Gy and 74 Gy arms having an overall survival of 70% HR 0.99 (0.77-1.28) p=0.337. The number of men requiring long term hormone therapy was reduced in the dose escalated arm HR 0.77 (0.59-1.00) p=0.05 [Dearnaley DP, *et al* 2011].
- Recently the long-term follow-up of the pilot study, which provided the initial safety and feasibility information for the national MRC RT01 trial have been published [Creak A, *et al* 2013].
    - In this study, 126 patients were randomised to a standard dose of 64 Gy compared with an escalated dose of 74 Gy after neoadjuvant androgen suppression.
    - After a follow up of 13.7 years, 49 of 126 patients restarted AS, 34 developed metastases and 28 developed CRPC. Median OS was 14.4 years.
- Although escalated dose results were favourable, no statistically significant differences were seen between the randomised groups; PSA control (hazard ratio (HR): 0.77 (95% confidence interval (CI): 0.47–1.26)), development of CRPC (HR: 0.81 (95% CI: 0.40–1.65)), PC-specific survival (HR: 0.59 (95% CI:0.23–1.49)) and OS (HR: 0.81 (95% CI: 0.47–1.40))
- The Dutch randomised phase III trial comparing 68 Gy with 78 Gy also demonstrated a significant increase in the 5-year rate of freedom from clinical or biochemical failure in patients treated with a higher dose of radiotherapy [Peeters ST, *et al* 2006].

- The phase III trial of the French Federation of Cancer Centres compared 70 Gy with 80 Gy in men with localised prostate cancer, in 306 patients with a low risk of pelvic lymph node involvement [Beckendorf V, *et al* 2011]. At a median follow up of 61 months, they demonstrated improved 5-year biological outcomes in favour of dose-escalated radiotherapy group. Using the Phoenix definition, the 5-year biochemical relapse rate was 32% and 23.5%, respectively (p = .09).
- Although these and other studies have shown benefits from dose escalation this has been offset to a degree by a reported increase in late rectal toxicity.
- Prospective non-randomised studies conducted at the Memorial Sloan Kettering cancer centre have compared the outcomes of 1100 men who received doses in the range of 64–70 Gy and 76–86 Gy using IMRT [Zelefsky MJ, *et al* 2001].
    - The results were evaluated within prognostic risk groups (using clinical stage, Gleason grade and presenting PSA concentration). They demonstrated that increasing the dose delivered beyond 70.2 Gy in men with intermediate- and high-risk disease improved the 5-year actuarial PSA relapse-free survival rate from 50% to 70% and 21% to 47%, respectively, in these two risk categories.
- IMRT has the potential to reduce late rectal toxicity as shown in a further study that reports 3-year actuarial ≥grade 2 gastrointestinal toxicity at 4% [Zelefsky MJ, *et al* 2002].
- A further development under investigation involves a change in the traditional fractionation schedules. Hypofractionation may improve cancer control for the same level of radiation-related toxicity and be a more effective treatment for prostate cancer with a predicted low alpha/beta ratio. Phase II dose escalation studies using shortened schedules of hypofractionated IMRT regimens have indicated acceptable early toxicity [Zelefsky MJ, *et al* 2001].
- The CHHiP (Conventional or Hypofractionated High Dose IMRT for Prostate Cancer) study is currently recruiting patients in the UK to compare standard fractionation IMRT (74 Gy in 37 fractions) to two hypofractionated IMRT regimens (60 Gy in 20 fractions or 57 Gy in 19 fractions) in combination with neoadjuvant hormone therapy [Zelefsky MJ, *et al* 2002]. There is no overall survival data available from this trial as yet but preliminary safety results have shown that hypofractionated high-dose radiotherapy seems equally well tolerated as conventionally fractionated treatment at 2 years
- Debate remains over the best way of increasing the dose without significantly increasing normal tissue toxicity. 3D-CRT, IMRT and HDR brachytherapy boost are methods currently under evaluation.

Image Guided Radiotherapy (IGRT)

The advantages of dose escalation using IMRT means that organ movement becomes a critical issue, in terms of both tumour control and treatment toxicity to the bladder, rectum and bowel. Techniques should therefore combine IMRT with some form of IGRT (fiducial markers, imaging), in which organ movement can be visualised and corrected for in real time, although the optimum means of achieving this is still under investigation.

Radiotherapy target volume/lymph nodes

- In high-risk patients the consensus is that the seminal vesicles should be included. There remains some debate for the benefit for prophylactic whole-pelvic irradiation, since randomised trials have failed to show conclusive advantages.
- The RTOG 9413 trial was designed to determine whether there was an advantage in terms of PFS with androgen deprivation therapy, whole pelvic radiotherapy followed by a prostate boost compared with androgen deprivation therapy and prostate-only radiotherapy. The trial also investigated the timing of hormone therapy with a further randomisation. One group received neoadjuvant hormone therapy followed by concurrent total androgen suppression and radiotherapy while the other group was treated with radiotherapy followed by adjuvant hormone therapy. Patients with non-metastatic disease but an estimated risk of lymph node involvement of >15% were randomised between the 4 arms [Lawton CA, *et al* 2007].
    - The difference in OS for the 4 arms was statistically significant (p=0.027).
    - However, no statistically significant differences were found in PFS or OS between neoadjuvant versus adjuvant hormone therapy and whole pelvis radiotherapy compared with prostate-only radiotherapy. A trend towards a difference was found in PFS (p=0.065) in favour of the whole pelvic radiotherapy + neoadjuvant hormone arm compared with the prostate-only radiotherapy + neoadjuvant hormones and whole pelvic radiotherapy + adjuvant hormone treatment arms.
    - These results have demonstrated that when neoadjuvant hormone therapy is used in conjunction with radiotherapy, whole pelvic treatment yields a better PFS than prostate-only radiotherapy. It also showed an improved OS when whole pelvic radiotherapy was combined with neoadjuvant rather than short-term adjuvant hormone therapy.

Patient selection

- EBRT can be unsuitable for patients with bilateral hip replacement, previous radiotherapy, severe proctitis or bowel morbidity.

Side-effects

- Acute complications include cystitis, faecal frequency and urgency, proctitis and rectal bleeding.
- Late complications occurring 3 months or later after treatment include impotence, bleeding, proctitis and diarrhoea.

HDR brachytherapy boost

- HDR brachytherapy using an iridium-92 temporary implant is a safe, reproducible and effective way of boosting conventional EBRT. There is published evidence for this approach demonstrating improved biochemical control and cause-specific survival without a significant increase in toxicity.
- Currently, HDR brachytherapy is mainly used as a boost treatment in combination with EBRT
- In a single randomised trial of EBRT vs. EBRT plus HDR brachytherapy boost, 220 patients with organ confined prostate cancer were randomised to EBRT alone with a dose of 55 Gy in 20 fractions, or EBRT with a dose of 35.75 Gy in 13 fractions, followed by HDR brachytherapy with a dose of 17 Gy in two fractions over 24 hours. In comparison with EBRT alone, the combination of EBRT and HDR brachytherapy showed a significant improvement in the biochemical relapse free survival (P = 0.03). There were no differences in the rates of late toxicity. Patients randomly assigned to EBRT plus brachytherapy had a significantly better QoL as measured by their Functional Assessment of Cancer Therapy-Prostate (FACT-P) score at 12 weeks. However, a very high, uncommon rate of early recurrences was observed in the EBRT arm alone, even after 2 years, possibly due to the uncommon fractionation used [Hoskin PJ, *et al* 2007].

- A further single centre study evaluated the 10-year outcomes for 472 intermediate- and high-risk prostate cancer patients treated with pelvic EBRT to a dose of 46 Gy in 23 fractions and a HDR brachytherapy boost. The HDR dose fractionation was divided into two dose levels. The prostate biologically equivalent dose (BED) low-dose-level group received <268 Gy, and the high-dose group received >268 Gy. Phoenix biochemical failure (BF) definition was used.At a median follow up of 8.2 years , the 10-year biochemical failure rate 43.1% vs. 18.9%, ($p < 0.001$), the clinical failure rate of 23.4% vs. 7.7%, ($p < 0.001$), and the distant metastasis of 12.4% vs. 5.7%, ($p = 0.028$) were all significantly better for the high-dose level group. Grade 3 genitourinary complications were 2% and 3%, respectively, and grade 3 gastrointestinal complication was <0.5%.This prospective trial using P-EBRT with HDR boost and hypofractionated dose escalation demonstrates a strong dose-response relationship for intermediate- and high-risk prostate cancer patients [Martinez AA, *et al* 2011].

EBRT plus neoadjuvant hormone therapy

- Neoadjuvant hormone therapy reduces prostate volume by 30–40% [Shearer RJ, *et al* 1992; Forman JD, *et al* 1995]. This can reduce the size of the treatment field and as a result the potential level of toxicity experienced.
- There are also reports of an additive or synergistic effect on tumour cell kill with combined therapy. Theories as to the mechanism of this include improved oxygenation by reducing tumour bulk and movement of hormone-responsive cells into a resting phase, which could reduce repopulation rate and enhance tumour cell death (increased apoptosis) [Hara I, *et al* 2002].
- The RTOG 86-10 trial randomised 471 men with T2–T4 prostate cancer to radiotherapy +/– 4 months of ADT (goserelin 3.6 mg depot once-monthly plus flutamide 250 mg tid) before and during EBRT or to radiotherapy alone. The median follow-up was 6.7 years for all patients and 8.6 years for surviving patients [Pilepich MV, *et al* 2001].
    - At median follow-up of 8.7 years for surviving patients, there was a trend to improved survival (8-year survival 53% versus 44%, p=0.1) for those treated by hormone therapy with radiotherapy, which was significant for the subgroup with Gleason grade 2–6 disease (70% versus 52%, p=0.015) [Pilepich MV, *et al* 2001].
    - Ten-year OS estimates (43% versus 34%) and median survival times (8.7 versus 7.3 years) favoured combined therapy with hormones and radiation compared to radiation treatment alone; however, these differences did not reach statistical significance (p=0.12) [Roach M, *et al* 2008].
    - There was a statistically significant improvement in 10-year disease-specific mortality (23% versus 36%; p=0.01), distant metastases (35% versus 47%; p=0.006), DFS (11% versus 3%; p<0.0001) and biochemical failure (65% versus 80%; p<0.0001) with the addition of neoadjuvant hormone therapy, but no differences were observed in the risk of fatal cardiac events [Roach M, *et al* 2008].

EBRT plus adjuvant hormonal therapy

- Long-term application of adjuvant androgen suppression should be seriously considered in prostate cancer patients with an unfavourable prognosis.
- A combination of radiotherapy and hormone therapy is superior to radiotherapy alone in patients with locally advanced disease. The combination is associated with better survival and increased time to progression.
- Optimal duration of adjuvant therapy is uncertain (6 months to indefinite) and the results of further studies are awaited.

Clinical evidence

- Adjuvant androgen suppression immediately after radical radiotherapy has been shown to significantly increase OS, PFS, and significantly reduce local progression, distant metastases and biochemical progression in several large randomised studies.
- Bolla *et al*. (EORTC 22863) randomised 415 patients with locally advanced prostate cancer (T1–4, Nx, M0) to receive either radiotherapy with immediate goserelin 3.6 mg therapy (every 4 weeks for 3 years) plus cyproterone acetate (CPA) during the first month of treatment for disease flare (n=207) or radiotherapy alone (n=208) [Bolla M, *et al* 2010].
    - After a mean follow-up of 9.1 years the 10-year clinical DFS was 22·7% (95% CI 16·3-29·7) in the radiotherapy-alone group and 47·7% (39·0-56·0) in the combined modality therapy group (HR= 0·42, 95% CI 0·33-0·55, p<0·0001). The 10-year OS was 39·8% (95% CI 31·9-47·5) in patients receiving radiotherapy alone and 58·1% (49·2-66·0) in those allocated combined treatment (HR 0·60, 95% CI 0·45-0·80, p=0·0004), and 10-year prostate-cancer mortality was 30·4% (95% CI 23·2-37·5) and 10·3% (5·1-15·4), respectively (HR 0·38, 95% CI 0·24-0·60, p<0·0001). No significant difference in cardiovascular mortality was noted between treatment groups.
- In the EORTC 22961 study, men with locally advanced prostate cancer who had all previously completed EBRT and 6 months of adjuvant ADT were randomised to receive either no further treatment (short-term ADT), or 2.5 years of further treatment with a LHRH agonist (long-term ADT) [Bolla M, *et al* 2009].
    - The 5-year overall mortality rates were 19.0% for short-term ADT versus 15.2% for long-term ADT (HR 1.42; p=0.65 for non-inferiority).
    - The 5-year prostate cancer-specific mortality rates were 4.7% for short-term ADT versus 3.2% for long-term ADT (HR 1.71; 95%CI: 1.14–2.57; p=0.002).
    - This study showed inferior survival for men treated with RT and 6 months of ADT compared with RT plus 3 years of ADT in the treatment of locally advanced prostate cancer.
- Pilepich *et al*. (RTOG 85-31) randomised 977 patients with locally advanced non-metastatic prostate cancer to receive either pelvic radiation plus goserelin 3.6 mg depot (started during the last week of radiotherapy, to be continued indefinitely every month or until relapse; n=488) or radiotherapy alone (n=489) [Pilepich MV, *et al* 2005].
    - A total of 945 patients remained appropriate for analysis: 477 in the adjuvant arm and 468 in the control arm. Thirty-two patients were retrospectively classified as ineligible. the most common reason was a T2 primary tumour with negative lymph nodes
    - Median follow-up was 7.6 years for all patients and 11 years for surviving patients.
    - The data clearly identified that the use of goserelin in combination with radiotherapy in this group of high-risk patients resulted in significant improvements in all endpoints.
    - Goserelin adjuvant therapy significantly (p<0.002) reduced the risk of dying by approximately 25%. The absolute 10-year survival rate compared with radiotherapy alone was 49% versus 39%. The improvement in survival appeared preferentially in patients with a Gleason grade of 7–10.
    - Goserelin treatment also resulted in a significant improvement in local control, freedom from distant metastasis, DFS and biochemical DFS.

- Horwitz *et al*. (RTOG 92-02) investigated the use of long-term androgen suppression following neoadjuvant hormonal cytoreduction and radiotherapy in locally advanced prostate cancer (T2c to T4 with no extra pelvic lymph node involvement and PSA <150 ng/ml) [Horwitz EM, *et al* 2008].
    - A total of 1554 patients were treated with goserelin and flutamide for 2 months prior to and 2 months during radiotherapy, and then randomised to 24 months of goserelin long-term (LTAD) or no further treatment short-term hormone therapy (STAD).
    - At 10 years, the LTAD and radiotherapy group showed significant improvement over the STAD + radiotherapy group for all endpoints except OS: DFS (13.2% versus 22.5%; p<0.0001), disease-specific survival (83.9% versus 88.7%; p=0.0042), local progression (22.2% versus 12.3%; p<0.0001), distant metastasis (22.8% versus 14.8%; p<0.0001), biochemical failure (68.1% versus 51.9%; p≤0.0001) and OS (51.6% versus 53.9%, p=0.36).
    - One subgroup analysed consisted of all cancers with a Gleason score of 8–10 cancers. An OS difference was observed (31.9% versus 45.1%; p= 0.0061), as well as in all other endpoints.
- As previously described, in the EPC study, exploratory analyses were conducted to determine the efficacy of bicalutamide in clinically relevant subgroups with a median follow-up of 9.7 years at the third analysis. The primary endpoints were objective PFS and OS [McLeod DG, *et al* 2006].
- Patients who derived benefit from bicalutamide in terms of PFS were those with locally advanced disease, with OS significantly favouring bicalutamide in patients with locally advanced disease undergoing radiotherapy (HR = 0.70 (CI 0.51 to 0.97), p=0.03). The overall tolerability of bicalutamide was consistent with previous analyses, with breast pain (73.7%) and gynaecomastia (68.8%) the most frequently reported adverse events in patients randomized to bicalutamide.

Radical Prostatectomy

There is debate about the role of radical prostatectomy for men with locally advanced or high risk prostate cancer. Surgical treatment of this stage has traditionally been discouraged because patients have an increased risk of positive surgical margins and lymph node metastases and/or distant relapse

Radical prostatectomy may be considered for selected cases with low volume tumour provided that the tumour is not fixed to the pelvic side wall, or that there is no invasion of the urethral sphincter. Management decisions should be made after all treatments have been discussed by the multidisciplinary team and after the balance of benefits and side effects of each therapy modality have been considered by the patients with regard to their own individual circumstances. It is essential that patients are counselled regarding the high risks of needing additional adjuvant and salvage therapies and understand that the surgery may be part of a multimodality approach.

It is recommended that lymph node dissection should be performed in all high-risk cases.

Clinical evidence

- The Mayo clinic have reported 15-year outcomes for 5662 men with locally advanced prostate cancer treated with radical prostatectomy [Ward JF, *et al* 2005].
    - Freedom from local or systemic disease at 5, 10, and 15 years after radical prostatectomy were reported as 85%, 73% and 67%; the respective cancer-specific survival rates were 95%, 90% and 79%. Significantly many men who did not receive neoadjuvant therapy (27%) were clinically over-staged (pT2) and most men with pT3 disease (78%) received adjuvant therapy. The mean time to adjuvant therapy after radical prostatectomy was 4.0 years. Pathological grade (> or =7), positive surgical margins, and nondiploid chromatin were all independently associated with a significant risk for clinical disease recurrence, while preoperative PSA level had little effect on outcome.
    - The authors also noted that many patients with clinically T3 prostate cancer are overstaged (pT2) (27% in this series who did not have neoadjuvant hormone therapy)
- In a further single institution series the 10-year outcomes of radical prostatectomy in 200 men with unilateral clinical T3a disease who had not received neoadjuvant hormone therapy, have been reported by Hsu [Hsu CY, *et al* 2007]. Clinical over-staging was again noted in 23.5% of cases who had a pathological stage of pT2. 56% of patients received adjuvant or salvage therapy. The overall survival at 5 and 10 years was 95.9% and 77.0%, respectively, and cancer specific survival was 98.7% and 91.6%. Biochemical progression free survival (BPFS) at 5 and 10 years was 59.5% and 51.1%, respectively, and clinical progression free survival (CPFS) was 95.9% and 85.4%. Margin status was a significant independent predictor in BPFS; cancer volume was a significant independent predictor in CPFS.

Radical Prostatectomy and Neoadjuvant/Adjuvant Hormone Therapy

- A review and meta-analysis of the role of NHT and prostatectomy has shown that NHT before prostatectomy did not improve OS or disease-free survival (DFS), but did significantly reduce positive margin rates [relative risk (RR): 0.49; 95% confidence interval (CI): 0.42-0.56, P < 0.00001), organ confinement (RR: 1.63; 95% CI: 1.37-1.95, P < 0.0001) and lymph node invasion (RR: 0.49; 95% CI: 0.42-0.56, P < 0.02) [Shelley MD, *et al* 2009]. Therefore, evidence suggests that the down-staging achieved with neoadjuvant hormone therapy does not translate into improved DFS, and therefore cannot be recommended outside of clinical trials [Bonney WW, *et al* 1999; Paul R, *et al* 2004; Selli C & Milesi C. 2004; Witjes WPJ, *et al* 1997].

- Similarly, there is currently no evidence that adjuvant hormone therapy provides a survival advantage for patients with pathologically proven localised disease [Hachiya T, *et al* 2002; Prayer-Galetti T, *et al* 2000]. A recent Cochrane review and metaanalysis studied the role of adjuvant HT following RP: the pooled data for 5-year OS demonstrated an odds ratio (OR) of 1.50 and 95% CI: 0.79-2.84 [Shelley MD, *et al* 2009]. Although this finding was not statistically significant, there was a trend favouring adjuvant HT. There was no survival advantage at 10 years. The pooled data for DFS gave an overall OR of 3.73 and 95% CI: 2.3-6.03. The overall effect estimate was highly significant (P < 0.00001) in favour of the HT arm.
- The ECOG 7887 trial compared adjuvant ADT after radical prostatectomy and deferred hormonal therapy in patients with nodal metastases [Messing EM, *et al* 2006]. A total of 98 patients with locally advanced prostate cancer (T1–T2, N+ disease) who had undergone pelvic lymphadenectomy were included in the study. These patients were randomised to receive adjuvant hormone ablation or followed until disease progression and then given hormone therapy [Messing EM, *et al* 2006].
    - At 11.9 years' median follow-up, adjuvant ADT increased survival by 2.6 years compared with surgery alone, in node-positive patients. Median survival in the adjuvant ADT and deferred treatment groups was 13.9 and 11.3 years, respectively. 64% of patients treated with adjuvant ADT were still alive at this time, compared with 45% of patients who received radical prostatectomy alone.
    - In this setting, adjuvant ADT reduced the risk of dying by approximately 46% compared with RP alone (HR 0.54; 95%CI: 0.99–0.30; p=0.04).

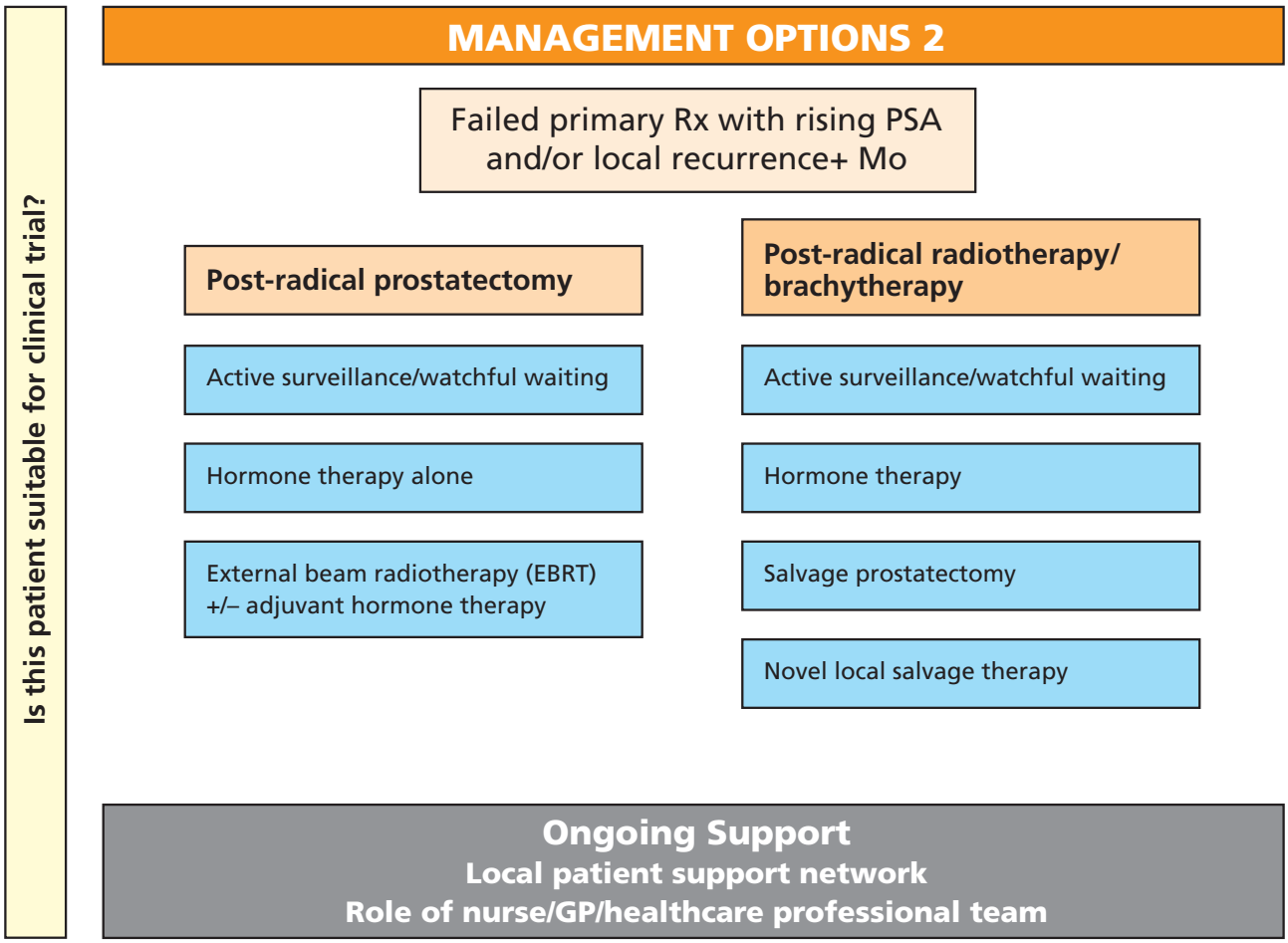
Radical Prostatectomy and Adjuvant Radiotherapy

- Extracapsular invasion (pT3), Gleason score > 7, and positive surgical margins (R1) can be associated with a risk of local recurrence [Hanks GE. E 1988]. Adjuvant radiotherapy has been assessed in three prospective randomised studies
- The EORTC 22911 study was designed to investigate benefit for immediate postoperative radiotherapy (60 Gy) in a target sample size of 1005 patients with pT3 disease or positive surgical margins as opposed to salvage radiotherapy offered for biochemical or clinical relapse [Bolla M, *et al* 2012].
    - After a median follow up of 10 years, overall survival did not differ significantly between the treatment arms. For patients younger than 70, the study concluded that adjuvant RT significantly improved the 10-year biological PFS: 60.6% vs. 41.1%. A previous reported difference in the clinical progression rates for the entire cohort that favoured adjuvant RT after 5 years of follow up was not sustained at 10 years, although locoregional control was improved after immediate irradiation (hazard ratio, HR = 0.45, P < 0.0001).
    - In terms of toxicity, adjuvant RT was well tolerated with no reported Grade 4 toxicity. The grade 3 genitourinary toxicity rate was 5.3%, in comparison with 2.5% in the observation group after 10 years.
- SWOG 8794 reported the results of 425 men with pT3 disease who were randomised to adjuvant radiotherapy to the prostate bed (60–64 Gy) or observation and subsequent salvage therapy [Swanson GP, *et al* 2008]. At a median follow up of more than 12 years, this study demonstrated a significant improvement in metastasis-free survival, with a 10-year metastasis-free survival of 71% vs. 61% (median prolongation of 1.8 years, P = 0.016) and a 10-year OS of 74% vs. 66% (median: 1.9 years prolongation; P = 0.023)

- The ARO trial 96-02 randomly assigned men with pT3 N0 tumours and an undetectable post operative PSA to immediate post operative radiotherapy (114 men) or a 'wait and see' policy (154 men). After a median follow-up period of 54 months, the radiotherapy group demonstrated a significant improvement in biochemical PFS of 72% vs. 54%, respectively (P = 0.0015). Further follow up is needed to assess metastases-free survival and overall survival. The rate of grade 3 to 4 late adverse effects was 0.3% [Wiegel T, *et al* 2009].
- The Medical Research Council (MRC) Radiotherapy and Androgen Deprivation In Combination After Local Surgery (RADICALS) study is investigating the timing of radiotherapy (immediate versus early salvage) and hormone duration and will be important in guiding future decision making.

Locally Advanced Disease: Recurrence after Primary Treatment

Figure 3a: Treatment algorithm for locally advanced disease (cont.)



Rising PSA levels

- The PSA concentration at which to define treatment failure after prostatectomy varies in the literature. An international consensus states that recurrent cancer may be defined by two consecutive PSA values of > 0.2 ng/mL [Heidenreich A, *et al*. EAU guidelines 2013].

Definitions of recurrence

- The Phoenix definition of relapse after radiotherapy is PSA nadir plus 2 ng/ml [Roach M, *et al* 2006].
- Patients whose PSA never falls to an undetectable level in the post-operative period are generally considered to have systemic disease. However, some may have local disease amenable to salvage radiotherapy, and so need to be carefully assessed to determine the best management plan.
- A PSA concentration that rises rapidly in the post-operative setting may be indicative of metastatic disease, while a PSA that remains undetectable over a long period then gradually rises may be more likely to indicate local recurrence.

- Pound *et al*. carried out a retrospective review of 1997 men undergoing radical prostatectomy by a single surgeon for clinically localised disease with no neoadjuvant or adjuvant treatment [Pound CR, *et al* 1999]. A PSA ≥0.2 ng/ml was deemed evidence of recurrence.
    - At 15 years, 15% had PSA elevation and 34% of these had developed metastases.
    - The median time from PSA elevation to metastatic disease was 8 years.
    - After development of metastases, the median actuarial time to death was 5 years. In the survival analysis, time to biochemical progression, Gleason grade and PSA doubling time were predictive of the probability and time to the development of metastatic disease.
- After completion of radiotherapy and hormonal treatment, testosterone recovery usually occurs. This may cause some PSA elevation that is related to normal prostate tissue recovery and not disease recurrence.
- The definition of disease recurrence in the setting of combined therapy remains a matter of debate and consensus is awaited.
- Benign PSA rises (PSA bounce) occur in approximately 12% of patients following EBRT and 30% following LDR brachytherapy in the absence of neoadjuvant hormonal treatment (starting between 18 months and 2 years after treatment).

Local recurrence after radical prostatectomy

Overview

- Overall, approximately 40% of patients who have a radical prostatectomy have biochemical evidence of recurrence at some point.
- Determining whether relapse is local or distant is important in determining optimal treatment. However, post-prostatectomy imaging is often unhelpful. Other factors that may aid this distinction include:
  - Timing and pattern of PSA relapse (rapid rise post-operatively favours distant spread)
  - Involvement of seminal vesicles or lymph nodes
  - Margin status at surgery
  - Gleason grade
- Radical salvage treatment is usually via radiotherapy to the prostate bed +/– hormone therapy. The optimal time of treatment, i.e. immediate adjuvant or early salvage EBRT, is currently uncertain. The timing and duration of hormone therapy is also unclear.
- The RADICALS study is investigating the timing of radiotherapy (immediate versus early salvage) and hormone duration [Parker C, *et al* 2007].

Clinical evidence

- Extracapsular invasion (pT3), Gleason score > 7, and positive surgical margins (R1) can be associated with a risk of local recurrence [Hanks GE. 1988]. Adjuvant radiotherapy has been assessed in three prospective randomised studies.

Adjuvant radiotherapy

- The EORTC 22911 study was designed to investigate benefit for immediate postoperative radiotherapy (60Gy) in a target sample size of 1005 patients with pT3 disease or positive surgical margins as opposed to salvage radiotherapy offered for biochemical or clinical relapse [Bolla M, *et al* 2012].

  After a median follow up of 10 years, overall survival did not differ significantly between the treatment arms. For patients younger than 70, the study concluded that adjuvant RT significantly improved the 10-year biological PFS: 60.6% vs. 41.1%. A previous reported difference in the clinical progression rates for the entire cohort that favoured adjuvant RT after 5 years of follow up was not sustained at 10 years, although locoregional control was improved after immediate irradiation (hazard ratio, HR = 0.45, P < 0.0001).

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- The ARO trial 96-02 randomly assigned men with pT3 N0 tumours and an undetectable post-operative PSA to immediate post operative radiotherapy (114 men) or a 'wait and see' policy (154 men). After a median follow-up period of 54 months, the radiotherapy group demonstrated a significant improvement in biochemical PFS of 72% vs. 54%, respectively (P = 0.0015). Further follow up is needed to assess metastases-free survival and overall survival. The rate of grade 3 to 4 late adverse effects was 0.3% [Wiegel T, *et al* 2009].

- Further results are awaited from a recently completed randomised controlled phase III study from the RTOG-96-01 in 771 men comparing salvage radiotherapy and placebo vs. a combination of salvage radiotherapy and bicalutamide 150 mg daily in the postoperative setting [Heney N *et al*, 2010]. At a median follow-up of 7.1 years, actuarial OS at 7 years was 91% for the RT and bicalutamide group and 86% for RT alone. Too few primary end-point events have occurred to allow a statistical comparison between groups. Freedom from PSA progression at 7 years was 57% for the combined modality group and 40% for RT alone (P < 0.0001) and for the 134 men with Gleason Score 8-10 was 56% and 26% (P < 0.0008). The 7-yr cumulative incidence of metastatic prostate cancer was less in the RT and bicalutamide arm, 7% vs. 13% in the RT alone arm (p<0.041). Late grade 3-4 toxicities were similar in both arms.

- The Medical Research Council (MRC) Radiotherapy and Androgen Deprivation In Combination After Local Surgery (RADICALS) study is investigating the timing of radiotherapy to a dose of 66Gy in 33 fractions (immediate versus early salvage) and hormone duration and will be important in guiding future decision making.

Salvage hormone therapy

- Systemic failure following radical prostatectomy is predicted with > 80% accuracy by a PSA relapse < 1 year, a PSADT of 4-6 months, Gleason score 8-10, and stage pT3b, pTx pN1. In this situation early hormone therapy may help delay progression in selected patients.
- A retrospective study including 1,352 patients with postoperative PSA recurrence showed no significant difference overall in the time to clinical metastases with early hormone therapy (after PSA recurrence, but before clinical metastases) vs. delayed hormone therapy (at the time of clinical metastases). However, for high risk patients (Gleason score > 7 and/or a PSA doubling time < 12 months) it was found that early hormone therapy delayed the time to clinical metastases although had no overall impact on prostate cancer specific mortality [Moul JW, *et al* 2004].

Recurrence after radical radiotherapy

Overview

- After radiotherapy, local failure is documented by a positive prostatic biopsy and negative imaging studies for systemic disease such as CT or MRI and bone scan.
- It must however be noted that most imaging studies are not sensitive enough to identify the anatomic location of relapsing PCa at PSA levels < 0.5-1.0 ng/mL. Prostatic biopsy after RT is only considered necessary if local procedures with curative intent, such as a salvage radical prostatectomy, are indicated in an individual patient.
- The therapeutic options for recurrence following radiotherapy include:
    - Salvage radical prostatectomy: associated with 5-year biochemical DFS rates of 55–69%, but the technique is associated with a significant incidence of complications, such as rectal injury, anastamotic stricture and urinary incontinence. In general, salvage radical prostatectomy should be considered only after multidisciplinary team and patient discussion with regards to potential benefits and toxicities. It should be limited to men with low comorbidity, a life expectancy of at least 10 years, an organ-confined prostate cancer with a Gleason score < 7, and preoperative PSA < 10 ng/mL.
    - Salvage cryotherapy: 5-year biochemical PFS ranges from 40% to 73%. The complications of salvage cryotherapy are erectile dysfunction, pelvic, rectal or perineal pain, recto-urethral fistula, bladder outlet obstruction and urethral stricture.
    - Salvage HIFU is currently under investigation.
    - Hormone therapy can be given in combination with local treatments or as monotherapy.

Clinical evidence

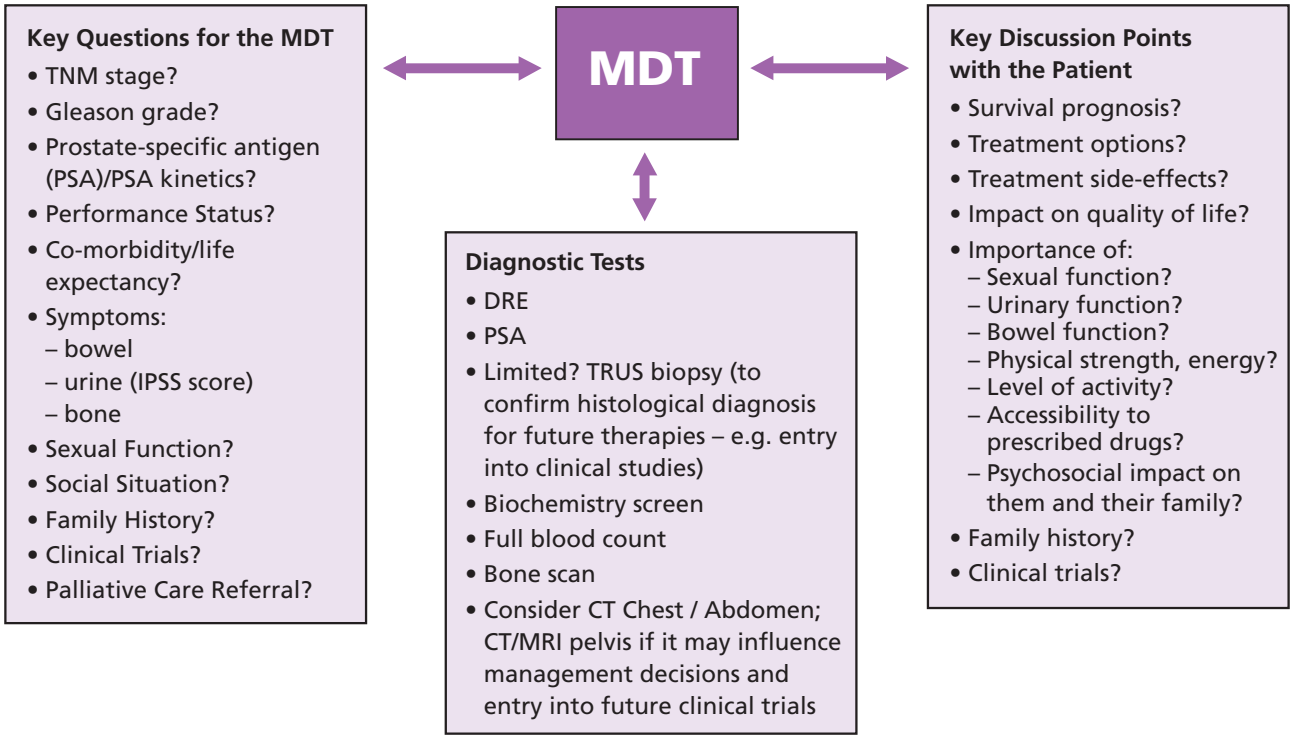
- In a recent systematic review of the literature, Chade *et al*. showed that salvage radical prostatectomy allowed 5-year and 10-year biochemical recurrence-free survival estimates ranging from 47% to 82% and from 28% to 53%, respectively. The 10-year cancer-specific and OS rates ranged from 70% to 83% and from 54 to 89%, respectively. The PSA value before salvage radical prostatectomy and prostate biopsy Gleason score were the strongest predictors of the presence of organ-confined disease, progression, and cancer specific survival [Chade DC, *et al* 2011]
- The four studies of salvage cryotherapy reviewed used varying definitions of recurrence. The 5-year biochemical PFS ranged from 40% when failure was defined as PSA 2 above nadir, to 62% and 73% when failure was defined as PSA greater than 2 and greater than 4, respectively.
    - The complications of salvage cryotherapy are erectile dysfunction, pelvic, rectal or perineal pain, rectourethral fistula, bladder outlet obstruction and urethral stricture.
- In a multicentre study reporting the current outcome of salvage cryotherapy in 279 patients, the 5-year biochemical -free survival estimate according to the Phoenix criteria was 54.5 ± 4.9%. Positive biopsies were observed in 15 of the 46 patients (32.6%) who underwent prostate biopsy following the procedure. The urinary incontinence rate was 4.4%. The rectal fistulae rate was 1.2%, and 3.2% of patients had to undergo transurethral resection of the prostate (TURP) for removal of sloughed tissue [Pisters LL, *et al* 2008].
- In 71 patients with localised disease following EBRT who were treated with salvage HIFU, 80% demonstrated negative biopsies and 61% had a nadir PSA concentration <0.5 ng/ml [Gelet A, *et al* 2004].
    - At a mean follow-up of 14.8 months, 44% of the patients had no evidence of disease progression.
    - Adverse events included recto-urethral fistula in 6%, grade 3 incontinence in 7%, and bladder neck stenosis in 17% of patients.

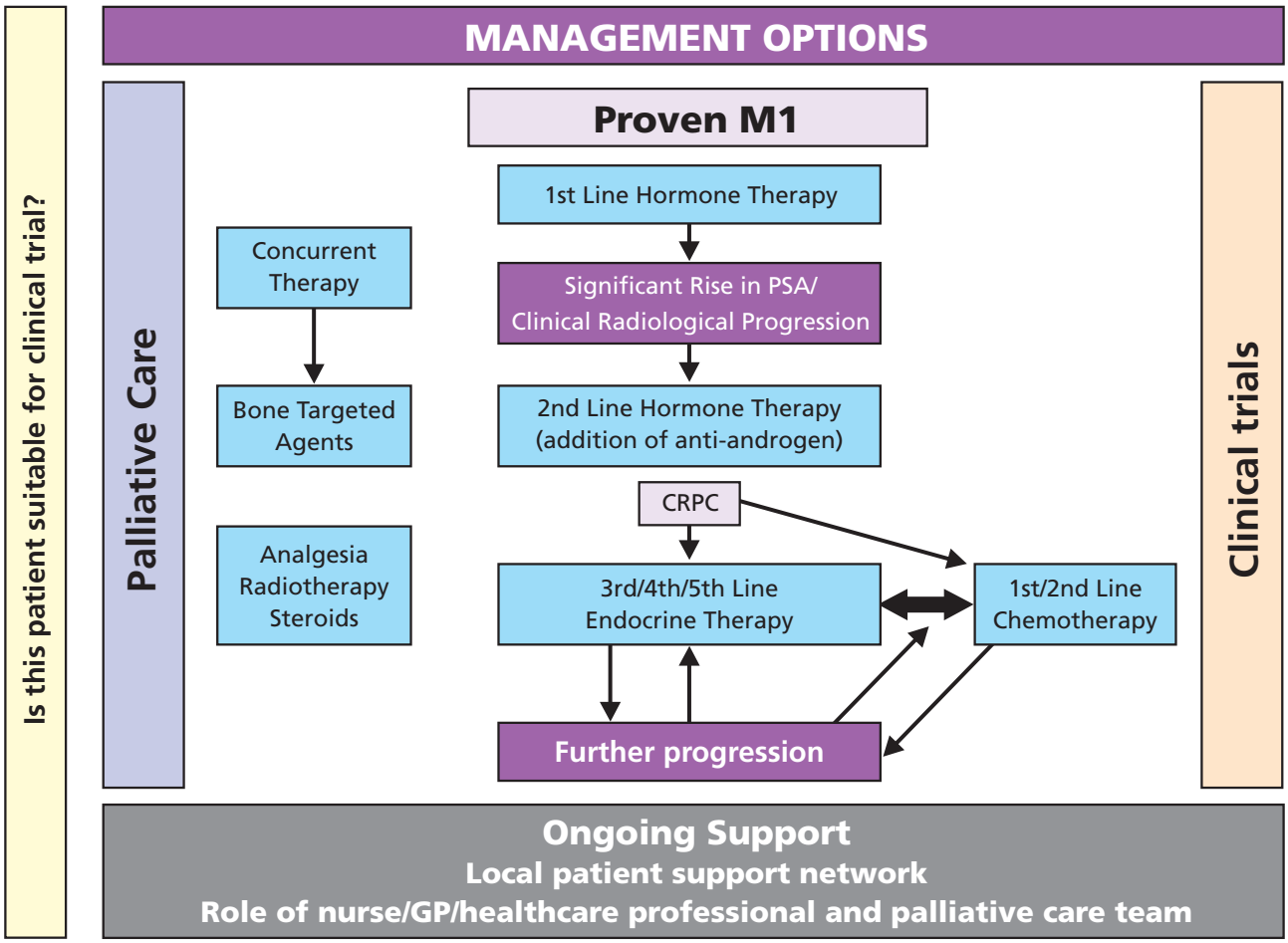
Salvage hormone therapy

- Patients with a PSA relapse who are not eligible for salvage therapy or who have high risk of systemic disease may be treated with immediate or delayed hormone therapy. Intermittent androgen deprivation for PSA elevation after radiotherapy may improve quality of life and theoretically delay hormone resistance. Overall survival rates of intermittent versus continuous androgen deprivation have been assessed in a noninferiority randomised trial.1386 patients with a PSA level greater than 3 ng/ml more than 1 year after primary or salvage radiotherapy for localised prostate cancer were randomised. Intermittent treatment was provided in 8-month cycles, with non-treatment periods determined according to the PSA level [Crook JM, *et al* 2012].
- At a median follow-up of 6.9 years, OS was 8.8 years in the intermittent-therapy group versus 9.1 years in the continuous-therapy group (hazard ratio for death, 1.02; 95% confidence interval, 0.86 to 1.21). The estimated 7-year cumulative rates of disease-related death were 18% and 15% in the two groups, respectively (P=0.24). Intermittent androgen deprivation was shown to be noninferior to continuous therapy in this setting with respect to OS. In the intermittent-therapy group, testosterone recovery to the trial-entry threshold occurred in 79%. Intermittent therapy provided potential benefits with respect to physical function, fatigue, urinary problems, hot flashes, libido, and erectile function.

Advanced (Metastatic) Prostate Cancer Management Options

Figure 4: Treatment algorithm for advanced (metastatic) disease





Based on MRC evidence, the majority of patients with advanced (metastatic) disease should be treated. Deferred treatment is acceptable only in highly selected, informed patients.

First line hormone therapy

Overview

- Androgen deprivation therapy (ADT) is standard first-line treatment for the management of patients with advanced disease. ADT can involve orchidectomy, LHRH agonists, and gonadotrophin-releasing hormone (GnRH) antagonists and anti-androgens
- Orchidectomy remains the gold-standard ADT against which all other treatments are compared because of its rapid effects on total testosterone concentrations [Tombal B.2007].
- The standard castrate level is <50 ng/dL. It was defined more than 40 years ago and current, more accurate methods of testosterone measurement have shown the mean value after surgical castration is 15 ng/dL(1.7 nmol/L) [Oefelein MG, *et al* 2000]. This has led to a revisiting of the current definition of castration, with many authors suggesting a more appropriate level is < 20 ng/dL
- Long-acting luteinising hormone-releasing hormone (LHRH) agonists have been used in advanced prostate cancer for more than 15 years. They are synthetic analogues of LHRH, generally delivered as depot injections on a 1-, 2-, 3-, 6-monthly, or yearly basis. After the first injection, they stimulate pituitary LHRH receptors, inducing a transient rise in LH and FSH release leading to a testosterone and potential clinic flare phenomenon, which begins 2-3 days after administration and lasts for about 1 week. The effects of the testosterone flare can be blocked by the co administration of an antiandrogen before and up to 2 weeks after the initial injection. Survival is generally considered equivalent with LHRH agonists and orchidectomy [Vogelzang NJ, *et al* 1995; Kaisary AV, *et al* 1995]. Although a meta-analysis has indicated that 2-year survival may be worse with medical treatment than with orchidectomy [Seidenfeld J, *et al* 2000].
- Patients, however, generally prefer medical treatment and in terms of usage, drug treatment represents the standard of care for advanced prostate cancer [Shahinian VB, *et al* 2005; Shahinian VB, *et al* 2006; Cassileth BR, *et al* 1992].
- In contrast to LHRH agonists, GnRH antagonists bind immediately and competitively to LHRH receptors in the pituitary gland. The effect is a rapid decrease in LH, FSH and testosterone levels without any testosterone flare. Now licensed on the evidence of phase III clinical trial data, degarelix demonstrates reduced testosterone concentrations to below castrate levels in 3 days (90% decrease in median testosterone compared with leuprolide group experiencing a 65% increase in median testosterone levels; p<0.001) [Klotz L, *et al* 2010].
    - Degarelix shows long term suppression of testosterone for up to 364 days. 97.2% of patients on degarelix maintained medical castrate levels (<50 ng/dl from day 28 to Day 364 (95% /CIS) compared to 96.4% with leuprolide.
    - PSA levels were lowered by 64% after 2 weeks, 85% after 1 month and 95% after 3 months and remained suppressed throughout the 1-year treatment.
    - An extended follow-up has been recently published (median 27.5 months), suggesting that degarelix might result in better progression-free survival compared to monthly leuprorelin [Crawford ED, *et al* 2011].
    - Ongoing research suggests that degarelix may reduce the risk of further cardiovascular events in men who have suffered an event prior to commencing hormone therapy [Smith MR, *et al* 2011].
    - Degarelix can cause local skin reactions after delivery of the initial injection but this isles common with subsequent treatments.

Immediate versus deferred hormonal treatment

- All symptomatic advanced prostate cancer patients should have immediate treatment with ADT.
- Immediate versus deferred treatment for advanced prostate cancer was investigated by the MRC Prostate Working Party Investigators Group. An RCT of 943 men with asymptomatic metastases or locally advanced disease, not suitable for curative treatment, was undertaken, with randomisation to immediate or deferred hormone therapy [MRC Prostate Working Party Investigators Group 1997].
    - There was a significant advantage in the immediate treatment group in terms of distant progression. Mortality was only significantly changed by treating immediately in those with M0 disease (Table 6).
    - A modest but statistically significant increase in OS was seen in the immediate treatment group, but not significant difference in prostate cancer mortality or symptom-free survival was demonstrated.
    - Due consideration must therefore be given to potential effects of long-term ADT versus the potential avoidance of such effects in patients if hormone therapy is deferred [Studer UE, *et al* 2008].

Table 6: Effect of immediate versus deferred hormonal treatment [MRC Prostate Working Party Investigators Group 1997].

		Immediate	Deferred
Distant progression		26%	45%
Mortality due to prostate cancer	M0 disease M1 disease	31.6% No significant difference	48.8% No significant difference

Combined androgen blockade (CAB)

- There is debate over the use of combined androgen blockade (CAB). In 2000, the Prostate Cancer Trialists' Collaborative Group published a meta-analysis of the available trials of CAB versus monotherapy. The analysis included 27 trials, which incorporated 8275 men, representing 98% of men ever randomised in trials of CAB versus monotherapy [Prostate Cancer Trialists' Collaborative Group 2000; Klotz L 2001].
    - The 5-year survival for all patients receiving CAB was 25.4%, compared with 23.6% for patients receiving monotherapy.
    - In subgroup analyses, patients treated with cypretone acetate (CPA) seemed to fare slightly worse than those treated with flutamide or nilutamide, mostly secondary to non-prostate cancer-related deaths.

- If the CPA studies were excluded, the results were as follows [Prostate Cancer Trialists' Collaborative Group 2000]:
    - CAB with flutamide alone was associated with an 8% reduction in the risk of death (95%CI: 0.86–0.98; p=0.02), which translates to a small but significant improvement in 5-year survival over castration alone.
    - CAB with flutamide plus nilutamide was associated with an 8% reduction in the risk of death (95%CI: 1.00–1.27; p=0.005), which translates to a small but significant improvement in 5-year survival of 2.9% over castration alone.
    - Conversely, CAB with CPA is associated with an increased risk of death of 13% (95%CI: 1.00–1.27; p=0.04), which translates to a small but significant reduction in 5-year survival of 2.8% over castration alone.
- It can be concluded that the choice of anti-androgen used for CAB has an impact on outcome, and that CAB with a non-steroidal anti-androgen may offer a small but significant survival benefit.

Intermittent versus Continuous Androgen Blockade

- The use of intermittent androgen blockade (IAD) has the advantage of potentially reducing the toxicities of therapy and improving quality of life in the periods of no treatment and also a potential theoretical advantage of delaying the emergence of the androgen-independent clone.
- A systematic review has concluded that intermittent IAD was feasible and accepted by patients [Abrahamsson PA 2010]. Results from ongoing randomised controlled trials are awaited although many studies had mixed advanced and locally advanced patients and used different criteria for starting and stopping ADT and the duration of therapy time.
- A study of 766 patients conducted by the South European Uroncological (SEUG) Group included 30% with advanced disease. After a median follow-up of 51 months, there was no difference in either time to progression (HR: 0.81; p = 0.11) or overall survival (HR: 0.99). No overall quality of life benefit was demonstrated but there was a clear benefit for improved sexual function in the IAD group, with 28% sexually active vs. 10% in the continuous group at 15 months after randomization, respectively [Calais da Silva FE, *et al* 2009].
- The FinnProstate Study VII, randomized 554 patients (50% with advanced disease) to intermittent versus continuous ADT. After a median follow-up of 65 months, no significant difference was observed in the median PFS (34.5 months in the IAD group vs. 30.2 months in the continuous group, p = 0.29) in either the total study population or in the N+ or M1 subgroup populations. The median OS was 45 months in both groups.
- Results are awaited from the SWOG trial 9346, which is the largest study to randomize patients with advanced prostate cancer (1134 men out of 3040) to intermittent and continuous ADT [Hussain M, *et al* 2012]. The presented abstract indicated that IAD was not 'non inferior' compared to continuous ADT (median OS 5.1 years for IAD compared to 5.8 years for the continuous treatment arm).
- Published results of this and other ongoing studies are awaited to determine the further benefits and safety of IAD in men with advanced disease.

Second line hormone therapy

- Some patients will respond to second-line hormone therapy with the addition of an anti-androgen, to achieve combined androgen blockade (CAB) With further progression anti-androgen withdrawal responses are seen in approximately 25% of cases who have been treated with first-line CAB or have had substantial (>1 year response) to second-line CAB.
- A common second-line treatment is the addition of an anti-androgen. A retrospective analysis of 122 patients who received the addition of bicalutamide 50 mg to goserelin for PSA and clinical progression showed a >50% decrease in PSA concentration in 30% of patients (responders) and a reduction in PSA concentration in 75% of all patients. The median duration of response from start of bicalutamide 50 mg was 291 days for responders and 193 days for the population as a whole. Those patients with a short duration of response to goserelin monotherapy (<1 year) appeared less likely to respond to CAB with the addition of bicalutamide 50 mg than those who had a longer response (1–2 years).
    - There are reports of PSA responses as a result of anti-androgen withdrawal in men whose disease is progressing on CAB. A recently reported multi-institutional, prospective study demonstrated PSA decreases of ≥50% in 21% (16% to 27%) of 210 men with progressive prostate cancer who discontinued the anti-androgen component of their CAB therapy [Sartor AO, *et al* 2008].
    - Median PFS was 3 months; however, 19% of responders had 12-month or greater progression-free intervals. Longer duration of initial anti-androgen use was shown to be a significant predictor of PSA response.

Side-effects of hormone therapy

- LHRH agonists and GnRH antagonists have a similar tolerability profile: side-effects include erectile dysfunction and loss of libido, reduction in bone mineral density, hot flushes and sweating, and weight gain and injection-site reactions (GnRH antagonists) and metabolic syndrome.
- Anti-androgen side-effects include gynaecomastia and breast tenderness. Mild to moderate gynaecomastia (68.8%) and breast pain (73.6%) are the most common adverse events described.

Castration Resistant Prostate Cancer: Management Options

Prostate cancers that progress despite castrate levels of testosterone are considered castration resistant and not hormone refractory. This is based on findings that the cancer is not uniformly refractory to further hormonal manipulation. Castration-resistant prostate cancer (CRPC), which is still hormone sensitive, has been clearly characterized, with new drugs targeting the androgen receptor, such as enzalutamide, or androgen biosynthesis, via CYP 17 inhibition, such as abiraterone acetate

There are a number of options for therapy for CRPC but the exact sequencing remains undetermined and will depend on both tumour characteristics (e.g. Gleason Score, PSA velocity) patient comorbidities and fitness for therapy and patient choice. The results of sequencing studies are awaited.

Further hormone therapies for CRPC

- Corticosteroids alone have definite activity against prostate cancer (approximately 20% response rate) and provide significant palliation in terms of anorexia, pain and depression. The optimal drug and dose have not been determined, but even prednisone at a dose of 5 mg bid resulted in subjective and PSA responses in one randomised trial [Tannock IF, *et al* 1996].
- Dexamethasone has been shown to be effective for men with progressive metastatic CRPC [Venkitaraman R, *et al* 2008]. In a study of 102 patients treated with oral dexamethasone (0.5 mg daily), 49% had a confirmed PSA response. The median time to PSA progression for the entire cohort was 7.4 (1-28) months and in responders, the median duration of the PSA response was 11.6 (1-24) months.
- Abiraterone acetate is a non-steroidal ester that selectively and irreversibly inhibits both 17α-hydroxylase and the C17, 20-lyase function of CYP17A1, a cytochrome involved in the production of dehydroepiandrosterone (DHEA) and androstenedione (precursors of testosterone). Abiraterone inhibits androgen biosynthesis at all three key sources in prostate cancer: the testes, adrenal glands and prostate tumour cells. It is administered in combination with glucocorticoids to prevent elevated levels of other steroid hormones and associated fluid balance abnormalities.
- Abiraterone in combination with prednisolone (5 mg twice daily) has been investigated in the pre-docetaxel setting in the COU 302 study in asymptomatic or minimally symptomatic men with a performance status of 0 to 1 and progressive castration resistant prostate cancer [Ryan CJ, *et al* 2013]. This multi-centre, double blind study randomised 1088 patients to abiraterone acetate 1000 mg daily and prednisolone versus placebo plus prednisolone. The study was unblinded after a planned interim analysis that was performed after 43% of the expected deaths had occurred. Results showed a significant improvement in radiographic progression-free survival with a median of 16.5 months with abiraterone-prednisone and 8.3 months with prednisone alone, HR 0.53; 95% CI 0.45 to 0.62; P<0.001). Over a median follow-up period of 22.2 months, overall survival was improved with abiraterone-prednisone (median not reached, vs. 27.2 months for prednisone alone; HR, 0.75; 95% CI, 0.61 to 0.93; P=0.01) but did not cross the efficacy boundary. Abiraterone-prednisone showed superiority over prednisone alone with respect to time to initiation of cytotoxic chemotherapy, opiate use for cancer-related pain, prostate-specific antigen progression, and decline in performance status. Toxicity included mineralocorticoid-related adverse events and abnormalities on liver-function testing were more common with abiraterone-prednisone, but mainly grade 1 or 2.
- Oestrogen therapy with DES demonstrated a comparable efficacy to castration in 1977 and was one of the first initial promising hormone manipulations. However the first Veterans studies showed that early treatment of advanced prostate cancer with DES 5 mg did not increase OS when compared to placebo, as the drug was associated with an increased incidence of cardiovascular deaths [Byar DP 1972].
- A second study compared the DES 5 mg dose to 1 mg and the results showed that this lower dose was equally effective but was associated with a much lower incidence of cardiovascular deaths. The risk of cardiovascular events may require the concomitant use of aspirin/anticoagulants [Robinson MR (a), *et al* 1995].
- Other new agents such as enzalutamide and orteronel are currently under evaluation in the prechemotherapy setting.
- There is now evidence for further use of hormone therapies after docetaxel (see below) The choice between these drugs or the use of second line chemotherapy remains unclear and sequencing studies are urgently awaited.

- Abiraterone has also been investigated in the COU 301 study [Fizazi K, *et al* 2012]. This was multicentre, prospective double blind randomised trial of 1195 patients with metastatic CRPC who were randomly assigned (ratio2:1) abiraterone acetate 1000 mg daily plus prednisolone (5 mg twice daily) or placebo and prednisolone (5 mg twice daily). All patients had progressive disease after docetaxel therapy (with a maximum of two previous chemotherapeutic regimens). After a median follow-up of 20.2 months, the median survival in the abiraterone group was 15.8 months compared to 11.2 months in the placebo arm (HR: 0.74, P < 0.001). The median time to PSA progression was 8·5 months, CI 8·3-11·1, in the abiraterone group vs. 6·6 months, 5·6-8·3, in the placebo group; HR 0·63, 0·52-0·78; p<0·0001), median radiologic progression-free survival (5·6 months, 5·6-6·5, vs. 3·6 months, 2·9-5·5; HR 0·66, 0·58-0·76; p<0·0001), and proportion of patients who had a PSA response (235 [29·5%] of 797 patients vs. 22 [5·5%] of 398; p<0·0001) were all improved in the abiraterone group compared with the placebo group. The most common grade 3-4 adverse events were fatigue (72 [9%] of 791 patients in the abiraterone group vs. 41 [10%] of 394 in the placebo group), anaemia (62 [8%] vs. 32 [8%]), back pain (56 [7%] vs. 40 [10%]), and bone pain (51 [6%] vs. 31 [8%]).The benefit was observed irrespective of age, baseline pain intensity, and type of progression.
- Enzalutamide is a novel oral antiandrogen that targets multiple steps in the androgen-receptor-signalling pathway and has shown a significant survival benefit for men with CRPC following docetaxel chemotherapy
- In the AFFFIRM study 1199 men with castration resistant prostate cancer after docetaxel chemotherapy were randomly assigned them, in a 2:1 ratio, to receive oral enzalutamide at a dose of 160 mg per day or placebo (399 patients) [Scher HI, *et al* 2012]. The study was stopped after a planned interim analysis at the time of 520 deaths. The median overall survival was 18.4 months (95% CI, 17.3 to not yet reached) in the enzalutamide group versus 13.6 months (95% CI, 11.3 to 15.8) in the placebo group (hazard ratio for death in the enzalutamide group, 0.63; 95% CI, 0.53 to 0.75; P<0.001). All the secondary objectives were in favour of enzalutamide. the proportion of patients with a reduction in the PSA level by 50% or more (54% vs. 2%, P<0.001), the soft-tissue response rate (29% vs. 4%, P<0.001), the quality-of-life response rate (43% vs. 18%, P<0.001), the time to PSA progression (8.3 vs. 3.0 months; hazard ratio, 0.25; P<0.001), radiographic progression-free survival (8.3 vs. 2.9 months; hazard ratio, 0.40; P<0.001), and the time to the first skeletal-related event (16.7 vs. 13.3 months; hazard ratio, 0.69; P<0.001). Rates of fatigue, diarrhoea, and hot flashes were higher in the enzalutamide group with a lower incidence of grade 3-4 side effects in the enzalutamide arm. Seizures were reported in five patients (0.6%) receiving enzalutamide.

Chemotherapy

An alternative treatment for advanced CRPC is chemotherapy. Docetaxel is now recommended as first line chemotherapy.

Side-effects of chemotherapy depend on the exact treatment regime, but usually include fatigue, nausea and vomiting, diarrhoea, hair loss and bone marrow suppression with increased susceptibility to infection. Specific therapies to handle these side-effects may be necessary to improve the patient's quality of life.

- A prospective study by Tannock in 1996 compared the benefits of mitoxantrone 12 mg/m² every 3 weeks plus prednisone 5 mg twice-daily with prednisone alone in 161 men with symptomatic HRPC [Tannock IF, *et al* 1996].
    - The primary endpoint was palliative response defined as a 2-point decrease in pain as assessed by a 6-point pain scale.
    - There was a significant advantage to the chemotherapy combination with a 29% pain response compared to 12% with steroids alone.
    - The duration of palliation was 43 weeks versus 18 weeks ($p<0.0001$) in favour of mitoxantrone and prednisone.
    - There was no difference in PSA or survival. It was therefore concluded that chemotherapy with mitoxantrone and prednisone provides palliation for some patients with symptomatic HRPC.
- The TAX 327 study randomised 1006 men with advanced prostate cancer to three treatment regimens [Tannock IF, *et al* 2004].
    - These were docetaxel 75 mg/m² administered every 3 weeks, docetaxel 30 mg/m² every week and mitoxantrone 12 mg/m² every 3 weeks, each with prednisone 5 mg twice-daily.
    - Initial results were published in 2004 and showed a significant improvement in median survival with 3-weekly docetaxel plus prednisolone (18.9 months), compared with the comparator arm of mitoxantrone plus prednisolone (16.5 months) ($p<0.001$).
    - A total of 45% of those in the docetaxel arm had a PSA reduction ≥50% compared to 32% of those having mitoxantrone ($p=0.0005$).
    - Increased benefits in pain response (35% versus 22%, $p=0.01$) were demonstrated in favour of docetaxel.
    - Quality of life was improved in 13% of patients receiving mitoxantrone, 22% of patients receiving 3-weekly docetaxel ($p=0.009$) and 23% of patients receiving weekly docetaxel ($p=0.005$).
- Further results have recently been reported and the survival benefit with 3-weekly docetaxel has persisted with extended follow-up [Berthold DR, *et al* 2008].
    - Median survival was 19.3 months for 3-weekly docetaxel versus 16.3 months in the mitoxantrone arm ($p=0.006$) with respective 3-year survival figures of 17.9% versus 13.7% in favour of docetaxel.
    - This study has confirmed the benefits of docetaxel chemotherapy.
    - The extended analysis of the TAX 327 study included subgroup analyses and demonstrated survival benefits for men both <65 years and >75 years of age.

- Cabazitaxel is a novel tubulin-binding taxane drug with antitumour activity in docetaxel-resistant prostate cancers. Positive results were seen for cabazitaxel from a large prospective randomised, phase III trial (TROPIC study) [de Bono JS, *et al* 2010]. In this study, 755 men with metastatic castration-resistant prostate cancer whose disease had progressed during or after treatment with a docetaxel-containing regimen were treated with 10 mg oral prednisone daily, and were randomly assigned to receive either 12 mg/m2 mitoxantrone intravenously or 25 mg/m2 cabazitaxel intravenously every 3 weeks. An overall survival benefit (15.1 vs. 12.7 months, P < 0.0001) was observed in the cabazitaxel arm. There was also a significant improvement in PFS (2.8 vs. 1.4 months, P < 0.0001), objective response rate according to RECIST criteria (14.4% vs. 4.4%, P <0.005), and PSA response rate (39.2% vs. 17.8%, P < 0.0002). The most common clinically significant grade 3 or higher adverse events were neutropenia (cabazitaxel, 303 [82%] patients vs mitoxantrone, 215 [58%]) and diarrhoea (23 [6%] vs. one [<1%]). 28 (8%) patients in the cabazitaxel group and five (1%) in the mitoxantrone group had febrile neutropenia.

Bone targeted agents

Bisphosphonates

- The benefits of zoledronic acid, in combination with hormone therapy have been investigated in a study by Saad in men with HRPC and bone metastases [Saad F, *et al* 2002]. This was a multicentre, randomised, placebo-controlled trial evaluating the efficacy of zoledronic acid 4 mg administered every 3 weeks in 422 patients with HRPC for 15 months, with an option to continue for an additional 9 months.
    - At the 2-year analysis, treatment with zoledronic acid was found to significantly reduce the percentage of patients with at least one skeletal-related event (SRE; defined as radiation for bone pain or to prevent pathological fracture/spinal cord compression; pathological fracture; spinal cord compression; surgery to bone; change in antineoplastic therapy) compared with placebo (38% versus 49%; p=0.028). All SREs were delayed.
    - Zoledronic acid also significantly delayed the time to first SRE by around 6 months (median 488 versus 321 days; p=0.009). Furthermore, patients in the zoledronic acid group had consistently lower incidences of all types of SRE than the placebo group. Pain scores were consistently lower in patients taking zoledronic acid 4 mg than placebo, and significantly at 3, 9, 18, 21 and 24 months (p<0.05).
- In the MRC PR05 and PR04 trials, men with advanced prostate cancer were randomised to sodium clodronate 2080 mg/day or placebo for up to 3 years (metastatic disease) or up to 5 years (non-metastatic disease) [Dearnaley DP, *et al* 2009].
    - A benefit of sodium clodronate versus placebo in men with metastatic disease was demonstrated for OS (HR: 0.77; 95%CI: 0.60–0.98; p=0.032).
    - However, no benefit of sodium clodronate versus placebo for OS in men with non-metastatic disease was demonstrated (HR: 1.12; 95%CI: 0.89–1.42; p=0.94).

Side-effects

- Bisphosphonates are generally well tolerated.
- Side-effects include: hypophosphataemia, anaemia, influenza-like symptoms, gastrointestinal effects, headache, conjunctivitis, very rarely osteonecrosis of jaw and renal impairment.
- To avoid this, patients on bisphosphonates should avoid dental surgery and extractions. If required this should be performed before starting treatment.
- In the study by Saad *et al*., zoledronic acid was generally well-tolerated [Saad F, *et al* 2002]:
    - Bone pain, nausea and constipation were reported most frequently both by patients receiving zoledronic acid and by those in the placebo group
    - In the zoledronic acid group, fatigue, anaemia, myalgia, fever and lower limb oedema occurred in at least 5% more patients than that observed in the placebo group
- In uncommon cases, patients treated with intravenous zoledronic acid have reported osteonecrosis of the jaw (ONJ) [Marx RE, *et al* 2005].
    - Risk factors associated with the development of ONJ include concomitant chemotherapy and corticosteroids, the patient's underlying disease, and other co-morbid risk factors (e.g. anaemia, local infection, pre-existing oral disease) [Zometa SPC].

RANK ligand inhibitors

- Denosumab is a fully human monoclonal antibody directed against RANKL and a key mediator of osteoclast formation, function, and survival.
- The efficacy and safety of denosumab (n = 950) compared with zoledronic acid (n=951) in patients with metastatic CRPC was assessed in a large randomised phase III trial [Fizazi K, *et al* 2011]. In this multicentre phase 3 study, 1904 men with CRPC and no previous exposure to intravenous bisphosphonate were randomised to receive 120 mg subcutaneous denosumab plus intravenous placebo, or 4 mg intravenous zoledronic acid plus subcutaneous placebo, every 4 weeks until the primary analysis cutoff date. Supplemental calcium and vitamin D were strongly recommended. Median duration on study at primary analysis cutoff date was 12·2 months (IQR 5·9-18·5) for patients on denosumab and 11·2 months (IQR 5·6-17·4) for those on zoledronic acid.
- Results showed that denosumab was superior to zoledronic acid in delaying or preventing SREs, as shown by time to first on-study SRE (pathological fracture, radiation or surgery to bone, or spinal cord compression) of 20.7 vs. 17.1 months, respectively (HR 0.82; P = 0.008). Denosumab also extended time to first and subsequent on-study SRE (HR 0.82; P = 0.008). Both urinary NTX and BAP were significantly suppressed in the denosumab arm compared with the zoledronic acid arm (P < 0.0001 for both). There was no overall survival benefit seen. Adverse events were recorded in 916 patients (97%) on denosumab and 918 patients (97%) on zoledronic acid, and serious adverse events were recorded in 594 patients (63%) on denosumab and 568 patients (60%) on zoledronic acid. More events of hypocalcaemia occurred in the denosumab group (121 [13%]) than in the zoledronic acid group (55 [6%]; p<0·0001). Osteonecrosis of the jaw occurred infrequently (22 [2%] vs. 12 [1%]; p = 0·09).

Systemic radionuclide therapy

Strontium

- Metastatic pain can be palliated effectively with systemic radionuclide therapy with strontium chloride.
- Relief of bone pain starts within 2 weeks. Possible initial bone pain flare may occur within 2 days, lasting 2–4 days.
    - Pain relief lasts 4–15 months.
    - 75–80% of patients experience significant palliation of pain.
- A Canadian collaborative study showed significant improvement in quality of life, increased time to further metastases, significant reduction in the amount of additional radiotherapy needed, and significant falls in PSA and alkaline phosphatise [Porter AT, *et al* 1993].
- Strontium is not associated with improvements in OS [Brundage MD, *et al* 1998].
- Four randomised clinical trials have reviewed the use of strontium [Robinson RG (b), *et al* 1995].
    - One trial reported significant improvement in pain control, two trials reported fewer new sites of pain.
    - One trial showed no significant difference in pain control compared to a placebo but an improved 2-year survival rate.
- A randomised clinical trial examining strontium versus placebo found a significant increase in median time to progression, but no significant effects on median OS or clinical response [Tu SM, *et al* 2001].

Side-effects

- The most notable side-effect of strontium is mild haematological suppression with a fall in circulating platelet and leukocyte counts recognised in most patients.
    - With usual therapeutic doses, platelets typically fall by 30% and leucocytes by 20%.
    - Clinically significant toxicity is rare, but its use is not recommended in patients with severely compromised bone marrow, platelet count <100, superscan prior to therapy, or impending spinal cord progression.

Radium 223

- Radium-223 dichloride (radium-223) is an alpha emitter which selectively targets bone metastases with alpha particles.
- The efficacy and safety of radium-223 was assessed in the ALSYMPCA study [Parker C, *et al* 2013]. In this multicentre, phase 3, randomized, double-blind, placebo-controlled study, 902 men , who had received, were not eligible to receive, or declined docetaxel, were randomly assigned in a 2:1 ratio, to receive six injections of radium-223 (at a dose of 50 kBq per kilogram of body weight intravenously) or matching placebo; one injection was administered every 4 weeks. In addition, all patients received the best standard of care. At the interim analysis, which involved 809 patients, radium-223, as compared with placebo, significantly improved overall survival (median, 14.0 months vs. 11.2 months; hazard ratio, 0.70; 95%CI, 0.55 to 0.88; two-sided P=0.002). The updated analysis involving 921 patients confirmed the radium-223 survival benefit (median, 14.9 months vs. 11.3 months; hazard ratio, 0.70; 95% CI, 0.58 to 0.83; P<0.001). Assessments of all main secondary efficacy end points also showed a benefit of radium-233 as compared with placebo. Radium-223 was associated with low myelosuppression rates and fewer adverse events.

Palliative Care

Overview

- Radiotherapy has been a mainstay in the palliation of painful metastatic bone lesions. Palliative radiotherapy can also aid other complications of metastatic disease, such as compression of the spinal cord or a nerve root, haematuria, ureteric obstruction, perineal discomfort caused by the local progression of prostate cancer, and symptomatic metastatic lymphadenopathy.

Clinical evidence

- Good evidence for the role of radiotherapy in palliation comes from McQuay *et al*. This systematic review covered 20 trials, which reported on 43 different radiotherapy fractionation schedules, and eight studies of radioisotopes [McQuay HJ, *et al* 1997].
    - Radiotherapy produced complete pain relief at 1 month in 395 out of 1580 (25%) patients, and at least 50% relief in 788 out of 1933 (41%) patients at some time during the trials.
    - In the largest trial, which included 759 patients, 52% achieved complete pain relief within 4 weeks and the median duration of complete relief was 12 weeks.
    - The study found no difference between the use of radioisotopes (such as strontium) and EBRT for generalised disease, a finding supported by the work of Quilty *et al* [Quilty PM, *et al* 1994].
    - In this latter study, 284 patients with prostate cancer and painful bone metastases were treated with local or hemi-body radiotherapy or strontium. Median survival was non-significantly different between groups (33 weeks with strontium versus 28 weeks with radiotherapy; p=0.1) [Quilty PM, *et al* 1994].
    - Both radiotherapy and strontium provided effective pain relief that was sustained for 3 months in 63.6% of patients after hemi-body radiotherapy compared with 66.1% of patients after strontium, and in 61% of patients after local radiotherapy compared with 65.9% of patients in the comparable strontium group.
    - Fewer patients reported new pain sites after strontium than after local or hemi-body radiotherapy ($p<0.05$) and radiotherapy to a new site was required by 12 patients in the local radiotherapy group compared with two receiving strontium ($p<0.01$).

Ongoing Support

The MDT team should ensure regular communication with the primary care team.

This may mean:

- Timely provision of detailed discharge or outpatient summaries
- Explanation of why a treatment route has been decided upon
- The patient's response to the chosen treatment
- Sharing of protocols
- Online educational resources
- Agreement on prescribing policies
- Provision of contact numbers for requests for information

The local patient support network, e.g. partner/family, must be included in the information/education process through the use of:

- Patient information materials
- Audio visual materials such as videos, DVDs and Web-based information

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Connolly, Carly

From: Dermot Hughes <[redacted]>
Sent: 30 December 2020 18:32
To: Kingsnorth, Patricia
Subject: Re: Urgent - SAI review - Urology

This is the 2020 SOP which has some wriggle room but would be regarded as non - confirmatory to NICAN guidance

Penile Cancer

Direct referral to the regional penile cancer service is the preferred option. In cases of clinical uncertainty initial assessment may be required by the designated local penile cancer lead (Mr Glackin, SHSCT) followed by referral to the regional penile cancer service in accordance with the NW Penile Cancer operational policy 2019- 2020.

NICAN guidance 2016

TREATMENT

Patients with penile cancer should be managed by specialist penile cancer teams working at the supra-network level. Such teams should serve up to four networks, with a combined population base of at least four million for penile cancer and expect to manage a minimum of 25 new patients each year. The team should include members of the specialist urological cancer team who work in the cancer centre within which it is based, and it should also have access to expertise in plastic surgery.

All penile cancer cases should be discussed with the supranetwork team prior to proposed treatment if not referred directly to that team.

Local care is classed as:
(i) The diagnostic process only.
Local care should be carried out by local teams for their catchment.

We are only looking at the care given by AOB - but there may be wider issues outwith our remit.

Penile cancer may well be a confused pathway but Hugh is very clear and his view the Regional guidance..

Hope this helps

Dermot

Dr Dermot F C Hughes MB BCH BAO FRCPath Dip Med Ed

[redacted]

On Dec 30, 2020, at 5:23 PM, Kingsnorth, Patricia <[redacted]> wrote:

Thank you Dermot.
I will bring this to the table on Monday.

Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
[redacted]


From: Dermot Hughes [redacted]
Sent: 30 December 2020 17:10
To: Kingsnorth, Patricia
Subject: Re: Urgent - SAI review - Urology

Dear Patricia

This is the detailed reason for an MDT from the 2020 document

This should be the benchmark by which we measure the pathways of our 9 patients

Helpful not to have opinions but simple measure what people experienced against the publicly stated service.

I realize there is no 2019 but this information should have been produced much sooner

1.0 Purpose of the MDT

MDTs bring together staff with the necessary knowledge, skills and experience to ensure high quality diagnosis, treatment and care for patients with cancer. MDT working has been advocated in each of the NICE Improving Outcomes Guidance and is strongly supported by clinicians.

The primary aim of the SHSCT Urology Cancer MDT is to ensure equal access to diagnosis and treatment for all patients in the agreed catchment area with Urology cancer. In order to achieve this aim we provide a high standard of care for all patients including: efficient and accurate diagnosis, treatment and ensuring continuity of care.

The MDT ensures a formal mechanism for multidisciplinary input into treatment planning and ongoing management and care of patients with Urology cancer with the aim of improving outcomes and to:

- • Provide an opportunity for multidisciplinary discussion of all new cases of Urology cancer presenting to the team
- • To assess newly diagnosed cancers and determine, in the light of all available information and evidence, the most appropriate treatment and care plan for each individual patient
- • Ensure care is delivered according to recognised guidelines
- • Ensure that the MDT work effectively together as a team regarding all aspects

  of diagnosis, treatment and care

- • Facilitate communication with other professional groups within the hospital

  and between the MDT and other agencies e.g. primary care, palliative care

- • Facilitate collection and analysis of high quality data to inform clinical decision

  making and to support clinical governance/audit

- • Promote multidisciplinary decision making regarding the team's operational

  policies

- • Support implementation of service improvement initiatives
- • Ensure incorporation of new research and best practice into patient care
- • Ensure mechanisms are in place to support entry of eligible patients into

  clinical trials, subject to patients fully informed consent

- • Provide education to senior and junior medical, nursing and allied health staff.

Dr Dermot F C Hughes MB BCH BAO FRCPath Dip Med Ed

Personal Information redacted by the USI

On Dec 29, 2020, at 4:39 PM, Kingsnorth, Patricia <[redacted]> wrote:

<Urology Cancer MDT Operational Policy 2020.pdf>

Southern Health & Social Care Trust IT Department [redacted]

Update on the concerns identified from the Urology MDT Peer review External Verification - October 2017

EV RAG rating – RED; % compliance 2017: 65%

Serious concerns	**Update May 2018**
1. No cover in place for the clinical oncologist and the consultant radiologist	Clinical Oncology representation (core & cover) – provided through the regional Oncology Centre when possible but is not the same person each time and is still not consistent Consultant radiology representation – no cover for the radiologist though an expression of interest is being developed to recruit an additional radiologist with urology interest/expertise
2. 11% quoracy due to low clinical oncology and radiology attendance	Quoracy has decreased from previous year (25% down to 11%). Only 5 meetings were quorate throughout 2016 and it is perceived that this has decreased even further. Therefore more patients are not benefitting from the knowledge and expertise of a full multidisciplinary team when decisions are being made about diagnosis and care. This could lead to delays in the decision making processes and treatment.
3. Long waits for routine referrals	Due to increasing number of referrals, the service is concentrating resource on meeting red flags and urgent demand. Routine referrals waiting times have increased from 52 weeks to 128 weeks (present day). Referrals are triaged by consultants so there is the opportunity for routine referrals to be upgraded.
4. Nephron sparing surgery undertaken locally	This issue was resolved at the time of the external validation as Mr Haynes was providing support to undertake nephron sparing surgery at Belfast City Hospital. The situation has

	now changed as the BT surgeon has left and there is no capacity to provide a centralised service. Currently this is being provided by both the Southern trust and the Western trust.

Other Concerns identified	Update
Out-sourced cancer diagnostics	There has been inaccurate reporting of MRI Prostates. This could place patients at risk as clinicians rely on these reports to inform decision making and counsel patients.
Job plan - MDT Clinical Lead	Dedicated time and support is required for the MDT Clinical Lead to fully undertake the role, including administration support.
Audits	There is a lack of resource to support the implementation of audits to inform quality improvement and service development.

Southern Health and Social Care Trust

Quality Care - for you, with you

Urology Cancer MDT Operational Policy - Agreement Cover Sheet

This MDT Operational Policy has been agreed by:

Position	Director of Acute Services
Name	Mrs Esther Gishkori
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by the USI

Position	Clinical Director Cancer Services
Name	Dr Rory Convery
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by the USI

Position	MDT Lead Clinician (on behalf of MDT members)
Name	Mr Anthony Glackin
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by the USI

The MDT members agreed this Operational Policy on:

Date Agreed	**1st September 2017**
Operational Policy Review Date	**1st September 2018**

Southern Health and Social Care Trust

Quality Care - for you, with you

Table of Contents

Introduction

This document outlines the Operational Policy for the Urology MDT and will be reviewed on an annual basis at the Annual General Meeting. It has been developed to ensure all relevant members of staff are aware of the purpose and organisation of the MDT meeting.

Background

The Southern Health and Social Care Trust (SHSCT) was formed on 1 April 2007. The Southern Trust (ST) is an integrated Trust, providing acute and community hospital services together with a range of community health and social services to a population of approximately 324,000 people.

Southern Trust Urological Cancer Services

The Southern Trust has provided a Urology service for patients living in the southern part of Northern Ireland since 1992. Outpatient services are located at a dedicated unit, the Thorndale Unit, based in Craigavon Area Hospital. The Unit is staffed by Consultant Urologists, Clinical Nurse Specialists, Staff Nurses and Health Care workers, in addition to visiting Radiographers and Radiologists.

Following a review of urological service provision in Northern Ireland in 2008/09, the trust took on responsibility for the provision of services to the population of County Fermanagh, with effect from 1st January 2013. County Fermanagh has a population of 61,175. More recently, the trust has agreed on a temporary basis to provide urological services to the population of and surrounding Cookstown, County Tyrone, bringing the entire catchment population to 427,000.

Within the SHSCT, urological cancer services include surgery to treat kidney, urothelial, penile and testicular cancers. The service does not provide radical pelvic surgery for prostate and bladder cancer.

In addition to all of the urological services provided at Craigavon Area Hospital, other services provided include endoscopic and day case surgery at South Tyrone Hospital in Dungannon, outpatient clinics at Banbridge Polyclinic, Armagh Community Hospital and South West Acute Hospital in Enniskillen, County Fermanagh.

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SECTION 1: STRUCTURE AND FUNCTION OF THE MDT

1.0 Purpose of the MDT

MDTs bring together staff with the necessary knowledge, skills and experience to ensure high quality diagnosis, treatment and care for patients with cancer. MDT working has been advocated in each of the NICE Improving Outcomes Guidance and is strongly supported by clinicians.

The primary aim of the SHSCT Urology Cancer MDT is to ensure equal access to diagnosis and treatment for all patients in the agreed catchment area with Urological cancer. In order to achieve this aim we provide a high standard of care for all patients including: efficient and accurate diagnosis, treatment and ensuring continuity of care.

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- Provide an opportunity for multidisciplinary discussion of all new cases of Urological cancer presenting to the team
- To assess newly diagnosed cancers and determine, in the light of all available information and evidence, the most appropriate treatment and care plan for each individual patient
- Ensure care is delivered according to recognised guidelines
- Ensure that the MDT work effectively together as a team regarding all aspects of diagnosis, treatment and care
- Facilitate communication with other professional groups within the hospital and between the MDT and other agencies e.g. primary care, palliative care
- Facilitate collection and analysis of high quality data to inform clinical decision making and to support clinical governance/audit
- Promote multidisciplinary decision making regarding the team's operational policies
- Support implementation of service improvement initiatives
- Ensure incorporation of new research and best practice into patient care
- Ensure mechanisms are in place to support entry of eligible patients into clinical trials, subject to patients fully informed consent
- Provide education to senior and junior medical, nursing and allied health staff.

1.1 Membership Arrangements

Core and extended membership of the Urology cancer MDT is detailed below:

Core Membership **(14-2G-101)**

Position	Name	Cover
Consultant Urological Surgeon*/**	Anthony Glackin	Aidan O'Brien Mark Haynes

Consultant Urological Surgeon	Aidan O'Brien	Anthony Glackin Mark Haynes
Consultant Urological Surgeon	Mark Haynes	Anthony Glackin John O'Donoghue
Consultant Urological Surgeon	John O'Donoghue	Mark Haynes Aidan O'Brien
MDT Co-coordinator	Shauna McVeigh	Member of Cancer Tracker Team
Consultant Clinical Oncologist**	Ciara Lyons (locum)	vacant
Consultant Radiologist	Dr Marc Williams	vacant
Consultant Histopathologist (EQA certified)	Dr Gareth McClean	Dr R.Shah Dr K.Dedic
Clinical Nurse Specialist***	Kate O'Neill	Dolores Campbell
Palliative Care Nurse	Stephanie Reid	Member of Palliative Care Nursing Team

** Lead Clinician*
*** Lead for clinical trial recruitment*
****Lead for patient involvement, information & service improvement*

Extended Membership **(14-2G-105)**

Position	Name	Cover
Consultant Urological Surgeon	Michael Young	Anthony Glackin Aidan O'Brien Mark Haynes
Consultant Psychologist	Dr Mary Daly	Mrs M.Duggan
Consultant in Palliative Care Medicine	Dr Tracy Anderson	Clinical Nurse Specialist
Stoma / Coloproctology Nurse Specialist	Claire Young	Clinical Nurse Specialist

1.2 Leadership Arrangements and Responsibilities **(14-2G-101)**

The Lead Clinician for the Urology Cancer MDT is Mr Anthony Glackin. The Trust and the Clinical Director for Cancer Services, Mr Rory Convery, have agreed the position and the responsibilities (See Appendix 1).

Key Responsibilities of the Lead Clinician:

- Chair the alternate week MDT meeting or delegate to a named deputy
- Ensure that patient management is planned and with input and consensus from the full panel of core members (or their nominated cover)
- Provide leadership for staff within the MDT and facilitate regular business meetings

- Lead the clinical activity of the MDT, working to agreed guidelines, ensuring a high quality integrated service which meets, local, regional and national standards.
- Provision of clear communication to all staff within the MDT and facilitation of effective team working
- Actively participate in the NICaN Urology network meeting and contribute to its work
- Ensure that regional clinical management guidelines are produced and revised regularly
- To be responsible for MDT performance monitoring against activity for National, Network and Trust targets
- To ensure that there are mechanisms in place to assess all patients with cancer for eligibility into clinical trials or research projects
- To ensure the collection of the appropriate cancer minimum dataset, working with the teams and MDT Coordinator
- To establish an audit programme and review of outcomes (this will include audits carried out across the Network)
- To ensure that local policies and guidelines are written, agreed and followed by the MDT and that these complement the Network guidelines
- Working in partnership with key stakeholders to lead on and promote a programme of service improvement and development for the MDT
- Ensuring the integration of patients/users and carers in assessment of service and service improvement

  The Clinical Lead may wish to delegate some of these duties but will remain responsible for their completion.

1.4 MDT Quorum and Attendance (14-2G-102) (14-2G-104)

It is intended that all core members of the MDT attend at least two thirds of all meetings. However, in the event that a core member cannot attend they will agree an individual who will be expected to cover the MDT meeting in their absence. In addition the core members needed for a quorum or their cover should aim to attend all meetings so the MDT will be quorate for at least 95% of meetings.

The quorum for the urology cancer MDT is made up of the following core members or their cover: urology surgeon, clinical oncologist (with responsibility for chemotherapy), imaging specialist, histopathologist, clinical nurse specialist and MDT Co-coordinator.

It is the responsibility of the individual to sign in on arrival. A record of attendance of meetings will be kept by the MDT coordinator. Attendance records of the MDT will be calculated on a quarterly basis and fed back to the individual core member.

1.5 Chairing of meetings

The chairing of MDMs has been shared by Mr Glackin, Mr O'Brien and Mr Haynes on a rotational basis. Mr O'Donoghue joined in chairing on a rotational basis during 2016. The person appointed to chair each MDM is decided at least one month previously, when a period of time equivalent to one session is allocated to the appointed Chair to preview all cases one day prior to the MDM. Adequate preparation time is included in Job Plans and in a pro rata, annualised, quantitative manner.

1.6 MDT Review **(14-2G-103)**

The MDM takes place every Thursday, unless otherwise notified, and begins promptly at 14:15 in the tutorial room, Medical Education Centre in Craigavon Area Hospital. The meeting takes place in a room with video conferencing facilities, enabling communication by video to Daisy Hill Hospital, Newry, and with the Specialist MDM in Belfast.

Video conferencing with the Specialist MDT is scheduled to take place at 3.30 pm, or as soon as is mutually convenient thereafter.
It is the policy of the Southern MDT that all MDMs should finish by 5 pm at the latest. It has been the experience of the MDT that the number of cases to be discussed has had to be limited to 40 in order to enable the MDM to finish by 5 pm.

All new cases of Urological cancer and those following Urological biopsy will be discussed. Patients with disease progression or treatment related complications will also be discussed and a treatment plan agreed. Patient's holistic needs will be taken into account as part of the multidisciplinary discussion. The Clinician who has dealt with the patient will represent the patient and family concerns and ensure the discussion is patient-centred.

All meetings are supported and organised by the MDT Coordinator. The MDT Coordinator is responsible for collating the information on all patients being discussed and ensuring that all the necessary information is available to enable clinical decisions to be made.

Responsibilities of the MDT Coordinator:

- Ensuring all cancer patients are discussed at the MDT meeting
- Inserting notes onto the pro forma and ensuring it has been signed-off as being a correct record of the meeting's discussion (this forms the main body of the MDT letter to GP)
- Insertion of clinical summaries and updates onto CaPPs
- Filing the pro forma into the relevant notes and forwarding a copy to the oncology department of those patients who need to be referred to the oncologists
- Posting a summary sheet or the pro forma to the referring General Practitioner within 24 hours of the MDT discussion taking place
- Recording the MDT attendance for every meeting
- Adding any patient on the MDT list not discussed (notes, films or results missing, lack of time), to the following week's list

- Prospectively track all patients with cancer or suspected cancer in achieving the regional cancer access targets
- Ensuring that all patients with cancer or suspected cancer have pre booked appointments and treatment in line with cancer access targets and to raise delays with the MDT
- Ensuring that direct referrals or inter trust transfers are implemented
- Liaising with the Specialist MDT Co-ordinator prior to any MDM when it is intended to discuss patients with that MDM
- Maintaining timely and accurate data collection, within the databases

Referrals to the MDT meeting

All referrals to the MDT meeting should be through any core member of the team to the MDT Coordinator who will then add the patient to the MDT list for discussion.

Clinicians will place cases for presentation onto the meeting agenda by informing the MDT Coordinator of the relevant case details by the day before the MDM at 12.00 hrs. In all instances it is the responsibility of the presenting clinician to ensure all appropriate clinical results are available for the meeting.

MDM Documentation

It is the responsibility of the MDM Co-ordinator to make a documentary record of the MDM, including a record of attendance, and it is the responsibility of the Chair to approve that record.

It is the responsibility of both the MDM Chair and the MDT Co-ordinator to ensure the accuracy of the completed textual record of Clinical Summaries, Updates and MDM Plans of all patients discussed at the MDM, and so that the documentation, in correspondence format, may be sent without delay to Family Doctors and to other clinicians to whom it had been agreed patients would be referred (see Appendix 2).

1.7 Protocol for taking action between meetings (14-2l-203)

When clinical circumstance dictates it may be necessary to give patients results and decide treatment plans prior to the next MDT meeting. The clinician responsible for the patient's care may contact the relevant member by telephone to arrange the management. These decisions will be recorded in the patient notes. Additionally this decision will be subsequently discussed and endorsed at the next MDT meeting. The MDT Coordinator will ensure that results from any investigations (including those initiated as part of the agreed emergency plan) are available.

1.8 Virtual MDM

As the numbers of patients discussed at each MDM has increased, it has been necessary to limit the number discussed at each meeting to 40 in order to ensure and maintain the quality of discussion of each patient. On occasion, when it has not been possible to have a MDM this has resulted in a backlog that may take a number of weeks to clear, resulting in delays in progressing the investigation, diagnosis and management of patients in a timely manner. In 2015, the MDT decided to experiment with the concept of a Virtual MDM where an appointed Chair would preview all cases who would have been discussed on the date on which it was not

possible to hold a MDM, arriving at considered MDM Outcomes, which are circulated by email, as soon as is possible thereafter, to all core members, seeking their comments and proposed amendments, before being recorded on CaPPS, the Northern Ireland Electronic Care Record and sent to Family Doctors. It was also the experience of the MDT that the availability of histopathological reports enabled the further assessment and management of many patients to be advanced without controversy or further delay. Dr McClean has ensured that histopathological reports have been agreed and issued to the Chair of Virtual MDM. The MDT has found this practice to be successful and it has been adopted as its routine practice on such occasions.

SECTION 2: CO-ORDINATION OF CARE/PATIENT PATHWAYS

2.1 Clinical Guidelines and Pathways (14-2G-106) (14-2G-110)

The MDT has participated through the Northern Ireland Cancer Network in the development of Clinical Guidelines and Pathways for Urology cancer. This includes referral to the regional Teenager & Young Adult service as appropriate for patients aged between 14-25 years.

2.2 Regular Prostate Clinic & Regular Haematuria Clinic(14-2G-107) (14-2G-108)

There are four New Clinics held each week in the Thorndale Unit. The maximum configuration of a New Clinic is that it will be staffed by two Consultant Urologists and by one Specialist Registrar, and at which a maximum of 24 patients will attend, 9 for each Consultant and 6 for the Registrar. The numbers of patients appointed are reduced pro rata depending upon attending doctors. Red Flag referrals are given priority of appointment. Each Consultant Urologist has one New Clinic each week.

The New Clinics are also staffed by Clinical Nurse Specialists and Practitioners, Health Care Assistants and Radiographers, in order to facilitate patients having further assessment during their visit to the New Clinic. Further investigations include ultrasound scanning of the urinary tract, mictiometry, flexible cystoscopy and transrectal, ultrasound guided, prostatic biopsies. It is also usual to have scrotal ultrasound scanning performed if there is a suspicion of testicular tumour. The purpose of advanced triage and of attendance at the New Clinic is that the New Clinic appointment has an enhanced prospect of having the patient reassured and discharged, requiring more complex assessment, listed for MDM discussion or placed on a waiting list for surgery.

2.3 Agreed Policy for Patient Access to MDT to Discuss Treatment Options (14-2G-109)

Patients with early (organ-confined) prostate cancer, high risk superficial bladder cancer and muscle invasive bladder cancer are referred to the Specialist Urology MDT in Belfast Trust whereby patients will be offered a meeting to discuss treatment options prior to deciding which modality of treatment to use. Patients with early (stage 1) penile cancer are discussed at the local MDT and will be offered a meeting with relevant specialities to discuss treatment options

Patient Review following MDM discussion

If it has been agreed at MDM that the patient is to be reviewed to be advised of the further assessment or management as recommended by the MDT and stipulated in the MDM Plan, a Review Appointment will be made at the Oncology Review Clinic of the responsible Consultant Urologist. Each is provided with six oncology review slots per week. It is the policy of the MDT that all patients are reviewed by the end of the first week following their MDM discussion. If that is not possible, the Chair of MDM

may exercise the right to allocate the review of any patient to that of another consultant, if possible, and if it is considered pertinent to do so.

When it has been concluded by the MDT that a patient's further management may have options, as may be the case in organ confined, prostatic carcinoma, then the patient will be advised of all of those options at review, and will be provided with written information regarding each option. Importantly, it is the policy of MDT that such patients are offered the opportunity of referral to consultant specialists relating to each management modality, such as oncologists, for their further advice, so that the patient may arrive at an optimally informed choice.

2.4 Treatment Planning (14-2G-111)

All applicable patient information should be available for the case discussion to proceed.

Case discussion incorporates the patient's age, clinical condition and any psychosocial aspects impacting on clinical management. All patients are discussed at diagnosis or prior to this where confirmation of malignancy is complex.

The MDT should agree and record the multidisciplinary treatment planning decision (i.e. to which modality of treatment - surgery, oncology, best supportive care).
The CaPPS system is used for collecting data on patients and documenting MDT decisions.
The MDT outcome report (Appendix 2) acts as the patient's individual treatment plan and includes:

- The patient's identity
- The diagnosis at the time of making the referral decision: benign, malignant (with histological confirmation), malignant (without histological confirmation)
- The multidisciplinary treatment planning decision (i.e. to which modality(s) of treatment – surgery, radiotherapy, chemotherapy, hormone therapy or supportive care or combinations of the same, that are to be referred for consideration)
- Confirmation that the holistic needs of the patient have been taken into account

Investigation plans and treatment recommendations are formulated during the meeting and recorded in narrative format by the MDT Co-coordinator.
The chairperson should articulate a summary of the recommendations arising from the discussion before proceeding to the next case.

2.5 Attendance at the Network (14-2G-110)

A representative from the team will attend the Network Meetings as follows:

- The MDT will provide representation from either the Lead Clinician or a deputy to all the meetings with minimum attendance of two thirds of meetings.
- The MDT will engage with the Network to develop and implement network-wide clinical, referral, imaging and pathology guidelines.

Mr Aidan O'Brien was Clinical Lead of the network's Urology Clinical Reference Group from January 2013 – January 2016. Mr Mark Haynes has taken up the Clinical Lead post from September 2016.

2.6 Supportive Care and Rehabilitation Services

A comprehensive range of supportive care and rehabilitation services are available for Urology cancer patients. Referral to these services can be made by members of MDT, directly or by way of MDM, by Key Workers, while some can be accessed by patients directly.

2.6.1 Physiotherapy Services

A wide range of physiotherapy is available at Craigavon Area Hospital and to varying degrees at all the other hospitals within the catchment area of the Urology Service.

2.6.2 Stoma Care Services

A readily accessible, stoma care service is available at Craigavon Area Hospital.

2.6.3 Clinical Psychology & Counselling Services

Dr. Mary Daly, Consultant Clinical Psychologist, is an extended member of the Urology MDT, and is based in the Bluestone Unit at Craigavon Area Hospital.
Two nurse counsellors, Mrs Mavis Dougan and Ms Terri Deehan, have been funded by Cancer Focus NI, are based at Craigavon Area Hospital.

2.6.4 Community Continence Services

There is a Community Continence Service serving the entire catchment area and its population. Referrals are made by email and by any member of the MDT, Key Workers and other nursing staff, at any time. The response to referrals is impressively prompt. The service is highly regarded by MDT.

2.6.5 Pre-chemotherapy Education Sessions & Helpline

All patients requiring chemotherapy are invited to attend a pre-chemotherapy education session in the Mandeville Unit at Craigavon Area Hospital. A 24 hour Helpline service is available for advice and support for patients who are receiving chemotherapy.

2.6.6 Complimentary Therapies

A reflexologist provides complimentary therapies on Mondays and Tuesdays in the Mandeville unit at Craigavon Area Hospital. Cancer Focus NI also provides Art therapy at Craigavon Area Hospital.

2.6.7 Welfare Services

Citizens Advice Bureau (CAB) representative offers financial and benefits advice. Referrals are e-mailed to a central Macmillan/CAB address and allocated from there. The CAB representative contacts the patient to arrange a suitable appointment.

2.6.8 Macmillan Cancer Support

Macmillan Cancer has an information centre located in the reception foyer of Craigavon Area Hospital. In association with the Southern Trust, Macmillan also conduct a six-week course called **H.O.P.E** (Helping to Overcome Problems Effectively) aimed at helping patients with cancer manage the day-to-day impact of living with the disease.

2.6.9 Other Support Services

The Southern Trust has developed strong partnerships with local charities and support centres which offer a range of services such as complementary therapies, counselling, family support, welfare rights advice and short courses etc.
Information about these groups and services are available in the Macmillan Information Centre.

SECTION 3: PATIENT EXPERIENCE

3.1 Key Worker (14-2G-113)

The identification of the Key Worker(s) will be the responsibility of the designated MDT Core Nurse member.

It is the joint responsibility of the MDT Clinical Lead and of the MDT Core Nurse Member to ensure that each Urology cancer patient has an identified Key Worker and that this is documented in the agreed Record of Patient Management. In the majority of cases, the Key Worker will be a Urology Clinical Nurse Specialist (Band 7) or Practitioner (Band 6). It is the intent that all Key Workers will have attended the Advanced Communications Skills Course.

Patients and families should be informed of the role of the Key Worker. Contact details are given with written information, and in the Record of Patient Management.

As patients progress along the care pathway, the Key Worker may change. Where possible, these changes should be kept to a minimum. It is the responsibility of the Key Worker to identify the most appropriate healthcare professional to be the patient's next Key Worker. Any changes should be negotiated with the patient and carer prior to implementation, and a clear handover provided to the next Key Worker.

Urology Clinical Nurse Specialists and Practitioners should be present or available at all patient consultations where the patient is informed of a diagnosis of cancer, and should be available for the patient to have a further period of discussion and support following consultation with the clinician, if required or requested. They may also be present, and should be available, when patients attend for further consultations along their pathway.

Key responsibilities of the Key Worker:

- Act as the main contact person for the patient and carer at a specific point in the pathway
- Should be present when the cancer diagnosis is discussed and any other key points in the patients journey
- Offer support, advice and provide information for the patient and their carers, referring to Macmillan Information and Support Service as appropriate to enable access to services
- Ensure continuity of care along the patients pathway and that all relevant plans are communicated to all members of the MDT involved in the patients care
- Ensure that the patient and carer have their contact details, that these contact details are documented and available to all professionals involved in that patients care

- Support the patient in identifying their needs, review these as required and co-ordinate care accordingly
- Liaise and facilitate communication between the patient, carer and appropriate health professionals and vice versa
- Offer verbal and written information with regard to diagnosis, investigations, treatment options and support groups
- Assist to empower patients as appropriate

3.2 Patient Information (14-2G-114)

The key worker will offer the patient and their carers a core information pack and a variety of information at various stages of their pathway, pertaining to their condition as well as any diagnostic procedures or treatments.

This information includes information specific to the MDT's cancer site and its treatment options (including names and functions / roles of the team treating them), information specific to that MDT about local provision of services, information about patient involvement groups / self-help groups, information about services offering psychological, social/cultural, financial information and effects of living with cancer and dealing with its emotional effects.

For patients with sensory, cognitive or language difficulties bespoke information can be arranged via the Macmillan Health & Wellbeing Manager.
Additionally a regional interpreting service is offered with trained health related interpreters. The Trust also has a contract with the 24 hour telephone interpreting service to ensure that patients have support in the planned or emergency situation.

Patients are offered information by appropriate staff in a phased manner relevant to the stage of their journey. For teenager and young adults, additional support is provided through the Regional Teenager and Young Adult (TYA) service, and appropriate information leaflets are available (see TYA regional pathway Appendix 5).

3.3 Permanent Record of Consultation (14-2G-115)

At a results clinic an identified member of the multidisciplinary team will effectively convey the patient diagnosis and recommendations of the meeting to the patient, to assist them in participating in decision making about ongoing treatment and care. This should be undertaken in line with the Trust Breaking Bad News policy. The patient should be given the opportunity to have a family member or friend with them.

During 2016, the MDT discussed the developmental priority of ensuring that all newly diagnosed patients had a key worker, had core and tumour specific information provided, had a holistic needs assessment conducted and any needs addressed. The MDT also discussed the format of a Record which would include details of the patients' diagnoses and management, and would include a check list of key worker, information, holistic needs assessment and actual needs or concerns (Appendix 3). The MDT agreed to initially pilot the implementation of the patient record for three

months (from 1st October – 31st December 2016) and to seek feedback from all clinicians before fully implementing.

3.4 Patient Feedback (14-2G-116)

Feedback from service users is obtained on a regular basis both formally and informally. Feedback on patient's experience will be sought using a range of mechanisms including patient surveys, focus groups, complaints, compliments, and participation in the patient and public involvement processes within the Trust.

The Trust has participated in a regional Cancer Patient Experience Survey exploring the patient experience throughout their cancer journey, and completed a local patient feedback survey. Findings have been presented and discussed at an operational meeting and an action plan agreed.

Complaints and compliments will be monitored by the Head of Service and lessons learned will be discussed in the Operational Meetings.
There is the opportunity via the Cancer Services User Forum to present new service developments or information leaflets to capture patients' views.

SECTION 4: CLINICAL OUTCOMES/INDICATORS

4.1 Clinical Indicators Review/Audit (14-2G-217)

The MDT will annually review its data and discuss progress of audits or discuss the completed results, as relevant, of audits. These should be presented at one of the regular network group meetings.
Data on compliance with the Cancer Access Standards in relation to the 31 and 62 day targets will also be reviewed.

4.2 Clinical Trials (14-2G-218)

Clinical trials in Urological Cancers are conducted in Northern Ireland, either as participants in UK and International studies, or designed by the Cancer Centre in Belfast. Recruitment of Urological Cancer patients to clinical trials now accounts for over 20% of all cancer patients recruited to cancer clinical trials in Northern Ireland.

The MDT will promote recruitment to clinical trials both locally and regionally with support from the Clinical Trials Research Nurse. The MDT should produce a report at least annually on clinical trials, for discussion with the network group.

4.3 Attendance at Advanced Communication Skills Training (14-2G-219)

All core members of the team who have direct clinical contact with patients will have attended the national advanced communications skills training.

4.4 Communication with Primary Care (14-2G-220)

The importance of timely communication with primary care is essential.
Where a patient is given a diagnosis of Urology cancer it will be the responsibility of the relevant MDT member to ensure that the patients GP is informed in writing by the end of the next working day of the diagnosis being given (Appendix 4).
An audit of timeliness of GP notification will take place annually.

APPENDIX 1: Clinical Lead appointment letter

Southern Health and Social Care Trust

……..
Consultant Urology Surgeon,
Craigavon Hospital.

October 2016

Dear Mr Glackin

Re: Clinical Lead for the Urology Cancer Team

Further to our recent discussion, I understand that the Urology cancer team members have nominated you as the clinical lead for the service.

I would like to confirm your position as Clinical Lead for the Urology Cancer Service from the XXXXX. This term of office will be for an initial 3 years, after which time it will be reviewed.

The role and responsibilities for the lead are detailed in the operational policy for the service.

I would like to welcome you to the wider Cancer team and thank you for your agreement to act as the Clinical Lead.

Yours sincerely

Rory Convery (Dr)
Clinical Director
Cancer Services

APPENDIX 2: MDT Outcomes Proforma

MDM Report from Urology MDM @ The Southern Trust

RE: xxxxxxxxxxxxxx
Address:xxxxxxxxxxxxx
DOB, Hospital Number: xxxxxxx , HCN: xxxxxxx
Contact Tel: xxxxxxxxxx

MDM Report from the Urology MDM @ The Southern Trust on 13/10/2016
Diagnosis Renal clear cell carcinoma
Histology Clear cell adenocarcinoma, NOS,
Laterality: left

MDM Update
CONSULTANT MR GLACKIN: This 50 year old man was found to have a solid, left renal lesion on ultrasound scanning in April 2016. His previous medical history included recurrent bouts of vertigo.

Renal CT scanning on 11 May 2016 confirmed the presence of an enhancing mass lesion in the upper pole of the left kidney, highly suspicious for renal cell carcinoma.

Discussed @ Urology MDM 26.05.16. This gentleman has been found to have a lesion of the upper pole of his left kidney, characteristic of a renal cell carcinoma, and considered suitable for partial nephrectomy. For review by Mr Glackin to arrange a CT chest, a DMSA renogram and to arrange surgery.

There was no evidence of thoracic metastatic disease on CT scanning of his chest in July 2016. Renography in August 2016 indicated that his left renal differential function was 45%. Mr XXXXXXXXX was admitted on the 30th September 2016 for a Left Open Partial Nephrectomy.

Histology showed a clear cell adenocarcinoma. Fuhrman nuclear grade III. Tumour necrosis - no. Local invasion - pT1a. Lymphovascular invasion - no. Lymph nodes - none submitted. Margins – on macroscopic examination, tumour was present at the base margin. This was confirmed microscopically. pT1a.

MDM Action
Discussed at Urology MDM 13.10.16. This gentleman has had a renal cell carcinoma of his left kidney resected by partial nephrectomy. The patient has been advised of the pathological findings.

For review by Mr Glackin in 6 weeks to request a renal CT scan in January 2017. To be rediscussed at MDM with CT report.

Radiology
CT Findings
Latest Findings from CT performed on 25/07/2016

CT chest without contrast.
Findings
No lung mass seen. There is no hilar or mediastinal lymphadenopathy.
No bony lesion visualised.

Conclusion
No thoracic metastasis seen.

Comorbidity Summary
Vertigo

APPENDIX 3: MDT Letter to GP

Urology/Head & Neck MDM @ the Southern Trust

<GP Name>
<GP Address>
<GP Address>
<GP Address>
<GP postcode>

RE: <Patient Name>
<Patient Address>
<DOB>, <Hospital Number>, <HCN>

Dear <GP Name>

This patient was discussed at the Urology MDM @ The Southern Trust
On 13/10/2016.

Diagnosis: Renal clear cell carcinoma

MDM Update:
CONSULTANT MR GLACKIN: This 50 year old man was found to have a solid, left renal lesion on ultrasound scanning in April 2016. His previous medical history included recurrent bouts of vertigo. Renal CT scanning on 11 May 2016 confirmed the presence of an enhancing mass lesion in the upper pole of the left kidney, highly suspicious for renal cell carcinoma.

Discussed @ Urology MDM 26.05.16. This gentleman has been found to have a lesion of the upper pole of his left kidney, characteristic of a renal cell carcinoma, and considered suitable for partial nephrectomy. For review by Mr Glackin to arrange a CT chest, a DMSA renogram and to arrange surgery.

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MDM Plan:
Discussed at Urology MDM 13.10.16. This gentleman has had a renal cell carcinoma of his left kidney resected by partial nephrectomy. The patient has been advised of the pathological findings. For review by Mr Glackin in 6 weeks to request a renal CT scan in January 2017. To be rediscussed at MDM with CT report.

Appendix 4

Department of Urology

Addressograph label or patient details
Patient Name
DOB
H&C Number

Patient Record Of Management

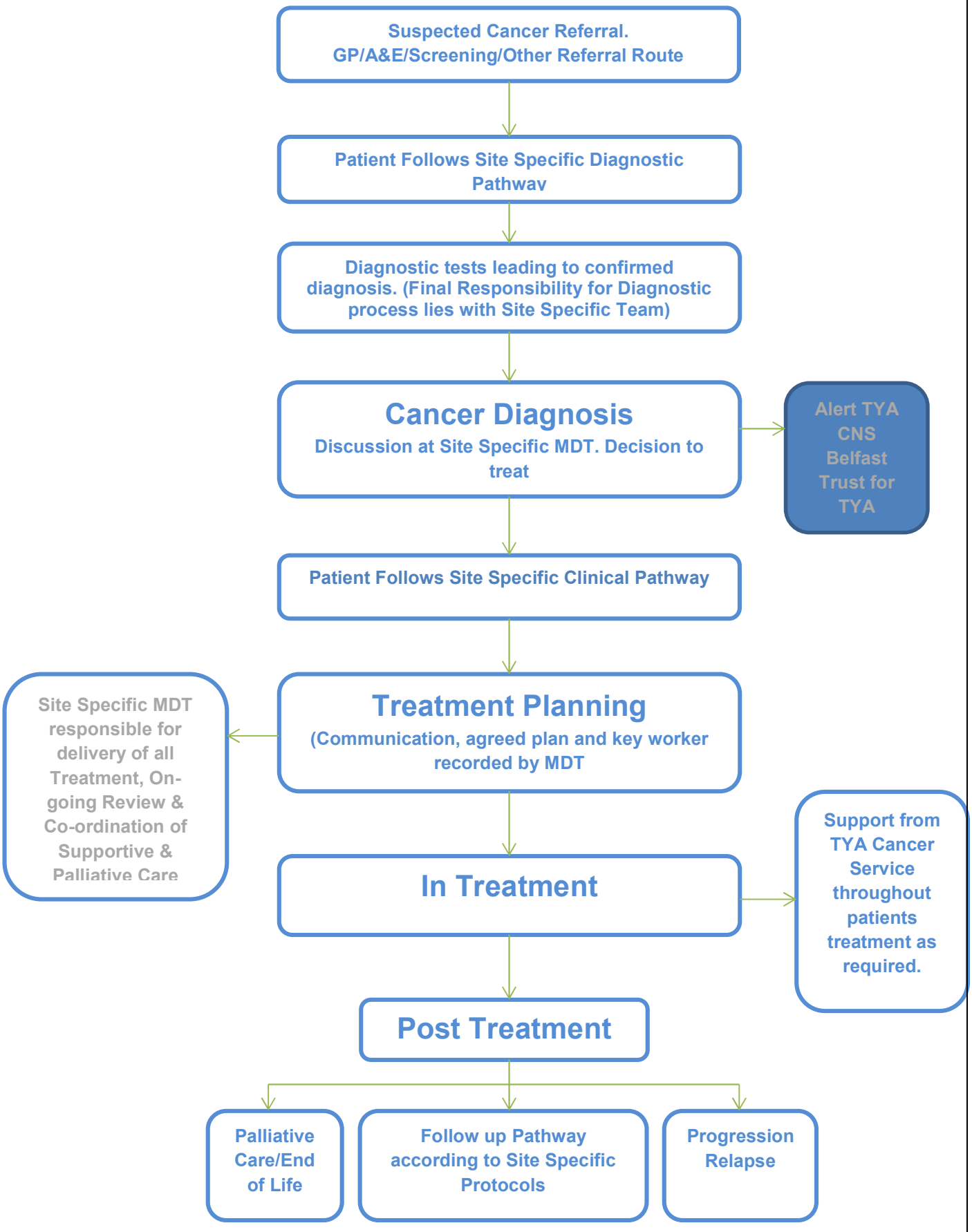
Consultant Name:	
Diagnosis:	
Management Plan:	
Key worker contact details given?	**Yes ☐ No ☐**
Key worker name:_____	
Cancer Specific Information given: **Comments:**	**Yes ☐ No ☐**
Core/general Information Pack given: **Comments:**	**Yes ☐ No ☐**
Plan for Holistic needs assessment: **Comments:**	**Yes ☐ No ☐**

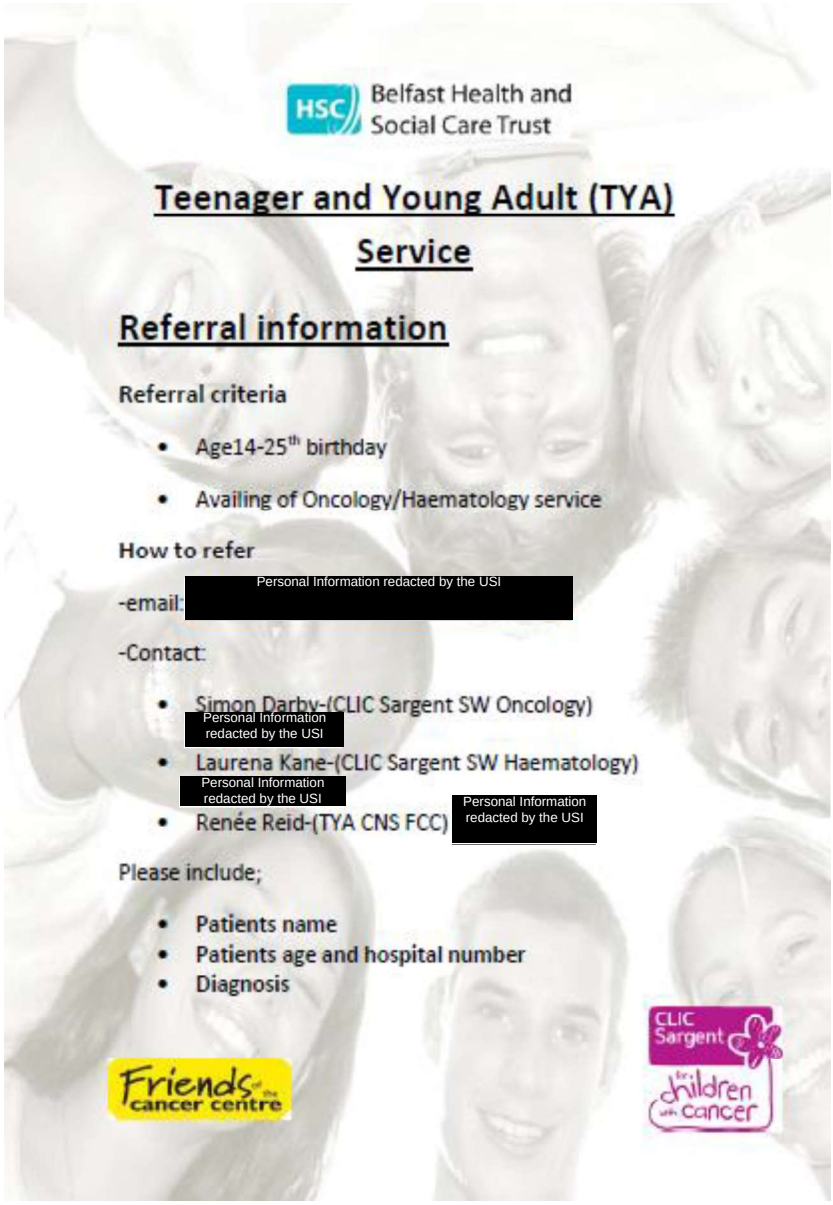
Areas of concern identified:	**Actions:**

Signed by: **Date:**

To contact your specialist or clinical team during working hours please phone Craigavon Area Hospital Urology Nurse Specialist on (028) Personal Information redacte

Appendix 5: Regional referral pathway for Teenagers & Young Adults





Southern Health and Social Care Trust

Quality Care - for you, with you

Urology MDT

Annual Report for January – December 2016

Presented to the MDT on: 1st September 2017

Agreed by the Urology MDT and signed on their behalf by Mr Anthony Glackin, MDT Lead Clinician on 1st September 2017

CONTENTS

1.0 INTRODUCTION

This annual report relates to the operational period 01/01/2016 – 31/12/2016 for the Southern Trust Urology Multi-disciplinary Team (MDT) and the clinical data presented relates to patients diagnosed in this period.

2.0 KEY ACHIEVEMENTS

Whilst 2016 had begun with 6 Consultant Urologists in post, one consultant, Mr Suresh, subsequently left in October 2016. This post was filled by Locums.

Perhaps our achievements during this past year or more have been crowned by the award of the Trust Excellence Award to the Thorndale Unit in June 2016.

3.0 KEY CHALLENGES

Oncology and Radiology

The greatest challenge for the MDT during the past year has been the inadequacy of the availability of a clinical oncologist and or a radiologist at all MDMs. The inadequacy in both cases has essentially been due to the inability to recruit adequate numbers of clinical oncologists and radiologists to the post where they are required. The inadequacy has been addressed with the appointment authorities.

Red Flag Referrals

There had been a 40% increase in the number of Red Flag referrals throughout Northern Ireland during the past few years, up from 2902 in 2013 to 4761 in 2015/16. The greatest increase was to the Southern Trust, with an increase of 84% from 410 in 2013 to 753 in 2014. The increase has continued throughout 2015/16 – there were 1878 red flag referrals in 2016.

Performance

Even though there has been an increase in Red Flag referrals over the past few years, the increased compliment of Consultant Urologists has enabled the MDT to absorb the increased demand and complete the assessment of patients and enact their definite management within the agreed time period of 62 days.

This has been reflected in the Cancer Performance data. The monthly average waits for an appointment between September-December 2016 were as follows:

Prostate: 22 day wait
Haematuria: 23 day wait
Others: 15 day wait

The diagnostic and operative activity has been reflected in an increase in the numbers of specimens received by the Cellular Pathology Laboratory at Craigavon Area Hospital, Tissue specimens increased from 874 in 2014 to 903 in 2016.

Even though not all tissue specimens were known, suspected or found to be cancerous, the analysis of the tissue type below demonstrates the varied spread of organ biopsies and resections. Biopsies and resections of prostate and bladder comprise the bulk of urological pathological diagnostic activity.

SPECIMENS	2012	2013	2014	2015	2016
Prostate Biopsies	**345**	**225**	**248**	**340**	**318**
TURP	**158**	**141**	**163**	**176**	**147**
Bladder Biopsies	**182**	**253**	**224**	**205**	**180**
TURBT	**78**	**70**	**115**	**120**	**123**
Testis Biopsies	**-**	**-**	**4**	**8**	**5**
Testis	**28**	**37**	**36**	**38**	**32**
Renal Biopsies	**-**	**-**	**24**	**14**	**12**
Kidney	**28**	**33**	**46**	**76**	**77**
Penile Biopsies	**6**	**9**	**13**	**13**	**7**
Penis	**4**	**3**	**1**	**3**	**2**

It is notable that there has been an increase in the numbers of Prostate biopsies which reflects the use of MRI to avoid unnecessary TRUS biopsy. The increase in kidney biopsies is in part due to cases being referred from outside the Southern Trust.

New Clinics

The introduction of the New Patient Clinics in October 2014 has contributed significantly to the ability of MDT to absorb the increased Red Flag referrals and meet the target times in all cases by early 2015. For 2016, the 31 day performance for the SHSCT was 100% and the 62 day performance was 81% - this reflects the marked increase in GP red flag referrals for the trust.

Operative Capacity

The main limiting factor in providing a complete cancer service is operating theatre capacity and operator time. Though the MDT has provided for the increased demand on Red Flag pathways, it has been at the expense of patients having, or suspected of having, recurrent bladder tumours, and those awaiting prostatic resection to facilitate their progress to radical radiotherapy for prostatic carcinoma having to wait increasingly longer periods of time for surgery, in addition to all those with non-cancerous pathology. This is a common and concerning experience across Northern Ireland, and will remain an increasing challenge until operative capacity is increased.

Conduct of MDM

The quality of the conduct of MDM has been a singular achievement these past six years. The quality of participation has been enhanced by increasing the number of persons chairing, and by having time allocated for preview.

Development Priorities

In addressing the concerns raised at Peer Review and the findings of Patient Satisfaction Surveys, it has been agreed that we could and should endeavour to make substantial progress in the implementation of Key Worker, Holistic Needs Assessment, Communication and having a Permanent Record of Patient Management. With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner. It is intended that patients newly diagnosed as inpatients will be included.

Conclusion

While a firm MDM foundation has now been established, and while much success has been achieved during the past year, there remain inadequacies and challenges which are to be addressed in the coming year.

4.0 MDT ATTENDANCE 2016

The Urology MDM takes place every Thursday from 2.15 pm to 5 pm (at the latest) in Tutorial Room 1, Craigavon Area Hospital, with videoconferencing available to Daisy Hill Hospital. The attendance is monitored by the MDT Coordinator. There were 47 meetings held in 2017. The dates of the MDT meetings can be seen in **Appendix 1** along with an attendance spread-sheet for core members and extended members.

Table: Urology MDT Attendance record January 2016 – December 2016

Name	**Role**	**Attended**	**DNA**	**% Attended**	**% Attendance by core /cover**
	Surgeon				**100%**
Mr A Glackin*	Surgeon	41	6	87	
Mr M Haynes	Surgeon	33	14	70	
Mr A O'Brien	Surgeon	32	15	68	
Mr R Suresh (left Trust in Oct 2016)	Surgeon	28	19	60	
Mr J O'Donoghue	Surgeon	36	11	77	
	Radiologist				**51%**
Dr M Williams	Radiologist	24	23	51	
Vacant	Radiologist				
	Pathologist				**91%**
Dr G McClean	Pathologist	37	10	79	
Dr R Shah	Pathologist	3	46	6	
A Pathologist	Pathologist	3	7	6	
	Clinical Oncologist				**28%**
Dr Ciara Lyons	Clinical Oncologist	1	46	2	
Dr Jolyne O'Hare	Clinical Oncologist	7	40	15	
Dr Keith Rooney	Clinical Oncologist	3	44	6	
	Urology Specialist Nurse				**98%**
Kate O'Neill**	Urology Specialist Nurse	39	8	83	

Dolores Campbell	Urology Clinical Sister	6	41	13	
	Palliative Nurse Specialist				**100%**
Stephanie Reid	Palliative Nurse Specialist	36	11	77	
A Palliative Nurse Specialist	Palliative Nurse Specialist	10	37	21	
	MDT Co-ordinator				**100%**
Shauna McVeigh	MDT Co-ordinator	38		81	
A MDT Co-Ordinator	MDT Co-ordinator	9		19	

- *Responsible for clinical trials & research
- **Responsible for users issues and patient information

The MDT quorum for 2016 was 11% with Radiology and Clinical Oncology presence being the key issues.

4.1 Attendance at Network Clinical Reference Group Meetings 2016

There was only one meeting of the Urology Clinical Reference Group (CRG) held on 29th January 2016. Details of the attendees are listed below.

Mr O'Brien has since stepped down as Clinical Lead of the Urology CRG. Following an expression of interest process in autumn of 2016, Mr Mark Haynes has been appointed as the new Clinical Lead.

29th January 2016
Aidan O'Brien
Gareth McClean
Kate O'Neill
Gerry Millar

5.0 MDT Workload January to December 2016

Workload	Number
Meetings	47
Number of discussions	1565
Number of patients	910
Number of new patients	746

5.1 Number of New Diagnoses 2016

Final MDM Diagnosis	Number
Prostate	277
Bladder	68
Kidney	64
Testicular	14
Penile	1
Total	**424**

5.2 Cancers by referral source 2016

Referral type	No. of referrals
GP Red Flag	**1878**
Consultant Upgrade	**424**
Other consultant referrals	**868**
Total	**3170**

5.3 Breakdown of first definitive treatments in 2016

The table below provides a breakdown of first definitive treatments of Urology patients on 31 and 62 day pathways during 2016.

Breakdown of first definitive treatments between 1st Jan 201-31 Dec 2016

Pathway	Surgery	Pall	Chemo	Radio	Brachy	Other treatment	No treatment	Active monitoring	Watchful waiting	Total
31 day	67	1	48	3	2	18	1	33	12	185
62 day	84	0	60	2	8	33	0	29	10	227
										412

5.4 Breakdown of cancer waiting times performance

The table below summarizes the performance of Urology patients on 31 and 62 day pathways. Cancer Access Standards mandate that 98% of patients have their definitive treatment within 31 days of decision to treat (when the treating consultant agrees the

treatment with the patient) and 95% of patients on a 62 day pathway are given their first definitive treatment within 62 days of suspect GP referral or consultant upgrade. The 31 day performance for the SHSCT was 100% in 2016 and the 62 day performance was 81%. Pathway breaches are considered at Trust Performance meetings and reasons detailed and escalated as appropriate. The majority of breach reasons are due to the complexity of the pathway, with multiple investigations and discussions often required to obtain a diagnosis and agree a treatment plan.

	31 Day Performance				62 Day Performance			
	Over Target	Within Target	Total	% Within Target	Over Target	Within Target	Total	% Within Target
Jan 16	0	26	26	**100%**	1	14	14	**93%**
Feb 16	0	36	36	**100%**	2	14	14	**88%**
Mar 16	0	26	26	**100%**	4	15	15	**79%**
Apr 16	0	34	34	**100%**	1	21.5	21.5	**96%**
May 16	0	29	29	**100%**	1.5	11.5	11.5	**88%**
Jun 16	0	31	31	**100%**	4	15	15	**79%**
Jul 16	0	33	33	**100%**	5.5	15	15	**73%**
Aug 16	0	22	22	**100%**	2	11.5	11.5	**85%**
Sep 16	0	28	28	**100%**	1.5	14.5	14.5	**91%**
Oct 16	0	33	33	**100%**	4	16	16	**80%**
Nov 16	0	24	24	**100%**	3.5	11	11	**76%**
Dec 16	0	24	24	**100%**	3	10.5	10.5	**78%**
Totals	**0**	**346**	**346**	**100%**	**33**	**169.5**	**169.5**	**81%**

Trends for breaches

- Delay in 1st out-patient appointment
- Delay in reporting of MRI scans / delay in discussion at MDT due to no radiologist being present
- Accessing TRUSB appointments due to capacity issues
- Complex cases requiring multiple MDT discussion

6.0 Advanced communication skills training

This has been identified as an area for development. The following members of the MDT have participated in Advanced Communication Skills training and the remaining core members will be offered a position when courses are available in 2017/18:

NAME	ROLE
Aidan O'Brien	Consultant Urologist
Kate O'Neill	Clinical Nurse Specialist
Stephanie Reid	Palliative Nurse Specialist
Joanne Frazer	Palliative Nurse Specialist
Tony Glackin	Consultant Urologist
John O'Donoghue	Consultant Urologist
Mark Haynes	Consultant Urologist
Leanne McCourt	Clinical Sister

7.0 Patient Experience

The Public Health Agency with support from Macmillan Cancer Support commissioned a regional Cancer Patient Experience Survey (CPES) in 2015. This was the first time the survey was undertaken in Northern Ireland and was based on similar surveys used in England and Wales. The survey was issued to over five thousand patients in active treatment for cancer during December 2013 – May 2014, including Urology patients and there was a 62% response rate i.e. 3,217 respondents across the 5 trusts. The results from the survey can be benchmarked against England and Wales and reports are available at a regional and trust level.

It showed overall 91% of patients in Southern Trust rated their care as excellent or very good which was similar to the NI score (92%) and higher than the NHS England score (89%).
Access to a clinical nurse specialist came out as a key issue although those who were given the CNS contact details found it much easier to contact the CNS compared to England.

Areas where SHSCT scored high or higher than the NI score included:

- Possible side effects explained in an understandable way: NI-78%; SHSCT-82% (highest**)
- Patient given written information about side effects: NI – 78%; SHSCT – 80% (highest**)
- Got understandable answers to important questions: NI – 93%; SHSCT – 95% (highest**)
- Hospital staff explained what would be done during operation: NI – 89%; SHSCT – 91% (2/5)
- Given clear written information about what to do / not do post discharge: NI – 85%; SHSCT – 89% (2/5)

- GP given enough info about patient's condition & treatment: NI – 96%; SHSCT – 95%

Access to a clinical nurse specialist came out as a key issue and this is reflective of the disparity of clinical nurse specialists across some of the tumour sites. Cancer research was an area for improvement which reflects the paucity of trials open for some of the tumour sites. Other areas where scores were lower included:

- Patient told about side effects that could affect them in future: NI – 58%; SHSCT – 59%
- Hospital staff gave information on getting financial help: NI – 66%; SHSCT – 67%
- Patient's family had opportunity to talk to doctor: NI – 69%; SHSCT: 63% (**lowest trust)
- Patient offered written assessment and care plan: NI – 21%; SHSCT – 27%

451 patients responded to the survey from the SHSCT and 17% of these were patients with urological cancer.

Further details regarding feedback from the SHSCT CPES report is available in **Appendix 2.**
A local survey was also carried out with Urology patients in August 2016, a report is available in **Appendix 3.** Following these surveys, a service development action plan has been developed, see **Appendix 4.**

8.0 Communication of diagnosis to GPs

When a patient is given a diagnosis of Urological Cancer, the aim of the MDT is that the patient's GP is informed by the end of the next working day of the consultation via a typed letter from the responsible consultant. An audit of GP timeliness of communication was carried out. Please refer to **Appendix 5** for results of the audit.

9.0 Audit

The MDT reviews its data and discusses the progress of its audits annually as part of the MDT annual report at one of the MDT business meetings.

Please refer to **Appendix 7** for results of the following audits:

- Audit on Bladder Cancer Access Standards for non-superficial disease, Mr David Curry, 2016
- Audit of Nurse Provided TRUS Biopsy Service in 2016, Sr Kate O'Neill
- Nephrectomy dashboard - data submitted to the British Association of Urological Surgeons (BAUS) Data and Audit database in 2016

10.0 Clinical Trials

The Urological clinical research activity in Craigavon during 2016 is detailed below:

Urology open studies:

HaBio: Haematuria Biomarker Study

12 patients

UKGPCS: The UK Genetic Prostate Cancer Study
4 patients

See **Appendix 6** for further details of open trials from the NI Cancer Trials Network

Appendix 1: MDT Attendance spreadsheet 2016

MDM Date	MDM Location	Suspect	Gladkin	Haynes	O'Brien	Suresh	Young	John O'Donoghue	Consultant Urologist X 2	Dr Marc Williams	Con. Radiologist x1	Dr Gareth McOlean	Dr Rajeev Shah	A Pathologist	Pathologist x1	Dr Ciara Lyons	Dr Jolyne O'Hare	Dr Keith Rooney	Clinical/Medical Oncologist x1	Kate O'Neill	Dolores Campbel	Urology Nurse Specialist	Stephanie Reid	palliative nurse cover	Palliative Nurse x 1	Shauna McVeigh	A MDT Co-Ordinator	MDT Co-ordinator x1	Quorate
7/01/2016	CAH	Urological Cancer	1	1	1	1	0	0	2	1	1	1			1			0	0	1		1	1		1	1	0	1	NO
14/01/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	0	0	1			1			1	1	1		1	1		1	1	0	1	NO
21/01/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
28/01/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	0	0	1			1			1	1	1		1	1		1	1	0	1	NO
4/02/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1			1			0	0	0		0	0	1	1	0	1	1	NO
11/02/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	0	0	1			1			1	1	1		1	1		1	1	0	1	NO
18/02/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	1	1	1			1			0	0	1		1	0	1	1	1	0	1	NO
25/02/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	0		1	1			0	0	1		1	1		1	1	0	1	NO
3/03/2016	CAH	Urological Cancer	1	1	0	1	0	1	2	1	1	1			1			0	0	1		1	1		1	1	0	1	NO
10/03/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	1	1	1			1		1	0	1	0	1	1	1		1	1	0	1	YES
17/03/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
24/03/2016	CAH	Urological Cancer	0	1	1	1	0	1	2	1	1	1			1			0	0	1	0	1	1		1	1	0	1	NO
31/03/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	1	1	0	1		1		1	0	1	1	0	1	1		1	1	0	1	YES
7/04/2016	CAH	Urological Cancer	0	1	1	1	0	1	2	0	0	1			1		1	0	1	1	0	1	1		1	1	0	1	NO
14/04/2016	CAH	Urological Cancer	1	1	1	1	0	0	2	1	1	1			1			0	0	1	0	1	1		1	1	0	1	NO
21/04/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	0	0	1			1		1	0	1	1	0	1	1		1	1	0	1	NO
28/04/2016	CAH	Urological Cancer	1	1	0	1	0	0	2	1	1	0	1		1			0	0	1	0	1	0	1	1	1	0	1	NO
5/05/2016	CAH	Urological Cancer	1	0	0	1	0	1	2	1	1	0	1		1			0	0	1	0	1	1		1	1	0	1	NO
12/05/2016	CAH	Urological Cancer	1	0	0	1	0	1	2	0	0	1	0		1			0	0	1	0	1	1		1	1	0	1	NO
19/05/2016	CAH	Urological Cancer	1	0	1	1	0	0	2	0	0	1	0		1			0	0	1	0	1	1		1	0	1	1	NO
26/05/2017	CAH	Urological Cancer	1	0	1	1	0	0	2	1	1	1	0		1			0	0	1	1	1	1		1	1	0	1	NO
2/06/2016	CAH	Urological Cancer	1	0	1	1	0	1	2	1	1	1	0		1			0	0	1	0	1	1		1	1	0	1	NO
9/06/2016	CAH	Urological Cancer	0	1	1	0	0	1	2	0	0	1	0		1		1	0	1	1	0	1	1		1	1	0	1	NO
16/06/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
23/06/2016	CAH	Urological Cancer	1	0	0	0	0	1	2	1	1	1	0		1		1	0	1	1	0	1	1		1	1	0	1	YES
30/06/2016	CAH	Urological Cancer	0	1	1	0	0	0	2	1	1	1	0		1		1	0	1	1	0	1	0	1	1	1	0	1	YES
7/07/2016	CAH	Urological Cancer	0	0	1	1	1	0	2	1	1	1	0		1		0	0	0	1	0	1	1		1	0	1	1	NO
14/07/2016	CAH	Urological Cancer	1	0	0	0	1	0	2	0	0	0	0	1	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
21/07/2016	CAH	Urological Cancer	1	0	1	1	1	1	2	0	0	0	0	0	0		0	0	0	1	1	1	1		1	1	0	1	NO
28/07/2016	CAH	Urological Cancer	1	1	1	0	1	0	2	1	1	0	0	1	1		0	0	0	1	0	1	1		1	1	0	1	NO
4/08/2016	CAH	Urological Cancer	1	0	1	0	0	1	2	1	1	1	0	0	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
11/08/2016	CAH	Urological Cancer	1	1	0	1	0	1	2	0	0	1	0	0	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
18/08/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1	0	0	1		0	0	0	0	1	1	0	1	1	1	0	1	NO
25/08/2016	CAH	Urological Cancer	0	1	1	1	0	0	2	0	0	1	0	0	1		0	0	0	1	0	1	0	1	1	1	0	1	NO
01/09/2016	CAH	Urological Cancer	1	1	1	1	0	0	2	1	1	1	0	0	1		0	0	0	1	0	1	1		1	1	0	1	NO
08/09/2016	CAH	Urological Cancer	1	1	1	1	1	1	2	1	1	1	0	0	1		0	0	0	1	0	1	1		1	1	0	1	NO
15/09/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
22/09/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1	0		1		0	0	0	1	0	1	1		1	1	0	1	NO
29/09/2016	CAH	Urological Cancer	1	1	1	1	0	1	2	0	0	1	0		1		0	0	0	1	0	1	1		1	1	0	1	NO
06/10/2016	CAH	Urological Cancer	1	1	1	0	0	1	2	1	1	1	0		1		0	0	0	1	0	1	1		1	1	0	1	NO
13/10/2016	CAH	Urological Cancer	1	1	1	0	1	1	2	1	1	0		0	0		0	0	0	1	0	1	1		1	0	1	1	NO
20/10/2016	CAH	Urological Cancer	1	1	1	0	0	1	2	0	0	1	0		1	1	0	0	1	1	0	1	1		1	1	1	1	NO
27/10/2016	CAH	Urological Cancer	1	1	0	0	0	1	2	1	1	1	0		1	0	0	0	1	0	1	1	1		1	1	1	1	YES
03/11/2016	CAH	Urological Cancer	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM	NO MDM
10/11/2016	CAH	Urological Cancer	1	1	0	0	0	1	2	1	1	1	0		1	0	0	0	0	1	0	1	1		1	1	0	1	NO
17/11/2016	CAH	Urological Cancer	1	1	0		0	1	2	1	1	0	0	0	0	0	0	0	0	1	0	1	1		1	0	1	1	NO
24/11/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	1	0	0	1	0	0	0	0	1	0	1	1		1	0	1	1	NO
01/12/2016	CAH	Urological Cancer	1	1	0		0	1	2	1	1	1	0	0	1	0	0	0	0	0	1	1	0	1	1	0	1	1	NO
08/12/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	1	0	0	1	0	0	0	0	1	0	1	1		1	0	1	1	NO
15/12/2016	CAH	Urological Cancer	1	1	0		0	1	2	0	0	1	0	0	1	0	0	0	0	1	0	1	1	1	1	0	1	1	NO
22/12/2016	CAH	Urological Cancer	1	1	1		0	0	2	0	0	1	0	0	1	0	0	0	0	1	0	1	1		1	1	0	1	NO
29/12/2016	CAH	Urological Cancer	1	1	1		0	1	2	0	0	0	0	0	0	0	0	0	0	1	0	1	1		1	0	1	0	NO
Weeks Attended			41	33	32	28	9	36	47	24	24	37	3	3	43	1	7	3	13	39	6	46	36	10	47	38	9	47	5
47 Week Year			87%	70%	68%	60%	19%	77%	100%	51%	51%	79%	6%	6%	91%	2%	15%	6%	28%	83%	13%	98%	77%	21%	100%	81%	19%	100%	11%

Appendix 2: Feedback from the NI Cancer Patient Experience Survey 2015

Southern Health and Social Care Trust

Quality Care - for you, with you

NI Cancer Patient Experience Survey – SHSCT results from Urology patients (17% of ST respondents i.e.77)

Questions highlighted in yellow - % difference is +5% less than NI average (-)
Questions highlighted in red - % difference is +5% more than NI average (+)

Question number	Detail	Southern %	NI Average %	Difference %
Q1	Saw GP once/twice	82	74	+8
Q2	Pt thought seen as soon as necessary	87	86	+1
Q4	Pt's health got better or remained about same while waiting	82	84	-2
Q6	Staff gave complete explanation of purpose of test	86	84	+2
Q7	Staff explained what would be done during test	89	88	+1
Q8	Given easy to understand written info about test	83	88	-5
Q9	Given complete explanation of test results in understandable way	80	80	-
Q11	Pt told could bring friend when first told they had cancer	71	76	-5
Q12	Pt felt they were told sensitively that they had cancer	83	86	-3
Q13	Pt completely understood explanation of what was wrong	76	77	-1
Q14	Pt given written info about type of cancer they had	54	48	+6
Q15	Pt given a choice of different type of treatment	67	81	-14
Q16	Pt's views taken into account when discussing treatment	63	69	-6
Q17	Side effects explained in an understandable way	77	75	+2
Q18	Pt given written information about side effects	61	64	-3
Q19	Pt told about side effects that could affect them in future	53	51	+2
Q20	Pt definitely involved in decisions about care and	71	75	-4

	treatment			
Q21	Pt given the name of the CNS in charge of their care	48	53	-5
Q22	Pt finds it easy to contact their CNS	88	82	+6
Q23	CNS listened carefully last time spoken to	90	95	-5
Q24	Get understandable answers to important questions all/most of the time (CNS)	90	89	+1
Q25	Hospital staff gave info about support groups	47	67	-20
Q26	Hospital staff gave info about impact cancer could have on work/education	55	60	-5
Q27	Hospital staff gave info on getting financial help	33	41	-7
Q28	Pt saw cancer research info in hospital	84	79	+5
Q29*	Taking part in cancer research discussed with patient	1	9	-8
Q36	Got understandable answers to important questions all/most of time(doctors)	72	74	-2
Q37	Pt had confidence and trust in all doctors treating them	90	86	+4
Q38	Doctors did not talk in front of pt as if they were not there	86	80	+6
Q39	Pt's family had opportunity to talk to doctor	56	58	-2
Q40	Got understandable answers to important questions all/most of time from (ward nurses)	71	75	-4
Q41	Patient had confidence and trust in all ward nurses	81	79	+2
Q42	Nurses did not talk in form of pt as if they were not there	84	86	-2
Q43	Always/nearly always enough nurses on duty	47	60	-13
Q44	Pt did not think hospital staff deliberately misinformed them	81	86	-5
Q45	Pt never thought they were given conflicting info	83	84	-1
Q46	All staff asked pt what name they preferred to be called by	71	67	+4
Q47	Always given enough privacy when discussing condition or treatment	79	81	-2
Q48	Always given enough privacy when being examined or treated	93	94	-1
Q49	Pt was able to discuss worries or fears with staff during visit	67	69	-2
Q50	Hosp staff did everything to help control pain all of the time	83	84	-1

Q51	Always treated with respect and dignity by staff	86	88	-2
Q52	Given clear written info about what should/should not do post discharge	84	78	+6
Q53	Staff told pt who to contact if worried post discharge	78	81	-3
Q54	Family definitely given all info needed to help care at home	68	59	-9
Q55	Pt definitely given enough care from health or social services	59	51	+8
Q57	Staff definitely did everything to control side effects of chemo	82	82	-
Q58	Staff definitely did everything they could to help control pain	78	80	-2
Q59	Hospital staff definitely gave patient enough emotional support	71	75	-4
Q61	Doctor had the right notes and other documentation with them	98	97	+1
Q62	GP given enough info about pt's condition and treatment	91	94	-3
Q63	Practice staff definitely did everything they could to support patient	81	79	+2
Q64	Hospital and community staff always worked well together	78	73	+5
Q66	Given the right amount of info about condition and treatment	83	85	-2
Q67	Pt offered written assessment and care plan	9	11	-2
Q68	Pt did not feel that they were treated as 'a set of cancer symptoms'	78	84	-6
Q69	Pt's rating of care excellent/very good	90	90	-

Appendix 3: Feedback from local patient experience survey August 2016

Urology Cancer Patient Experience Survey

August 2016

The Urology cancer team, as part of their service improvement plan to seek feedback from patients on the service, issued a patient feedback survey to 20 patients who were diagnosed with a urological cancer in 2015.

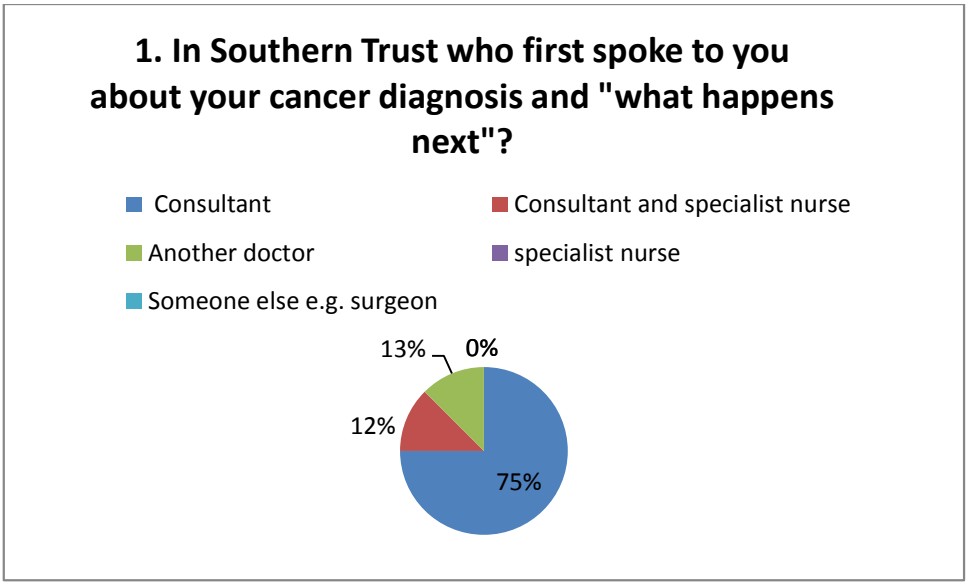
The survey asked questions in relation to their hospital visit and the results from the survey along with the feedback from the NI Cancer Patient Experience Survey will help the team to look at the service currently provided and to plan for the future to make sure they are meeting the on-going needs of patients and families.

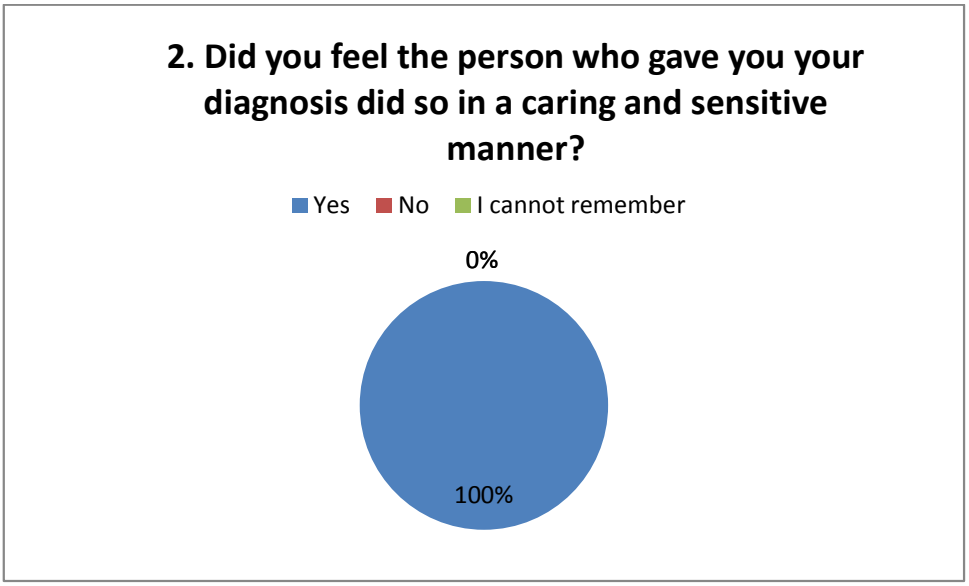
Summary of responses:

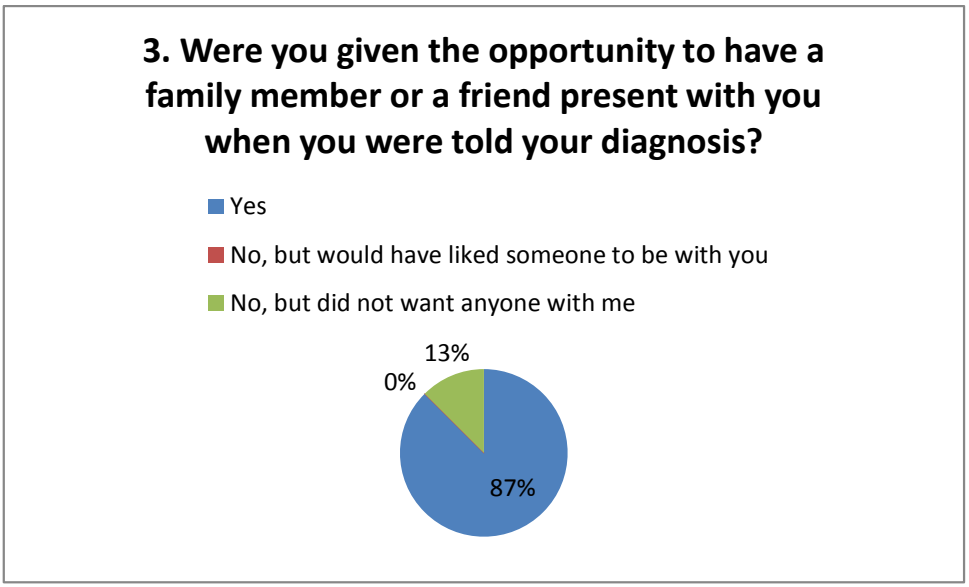
- 8 people completed and returned the questionnaires n = 8 (40%). The age range of the respondents was from 55-75 years & 75% were male. Three respondents were diagnosed with prostate cancer, 2 with bladder cancer and 2 with kidney cancer. All were treated in Craigavon Hospital.
- All patients (100%) were told their diagnosis in person, in a private environment, and felt that the person who gave the diagnosis did so in a caring and sensitive manner.
- All respondents (100%) that they had the opportunity to ask questions.
- 50% of respondents got answers to questions that they could completely understand and 50 % got answers that they understood to some extent
- 87% had the opportunity to have a family member or a friend present
- 75% had the opportunity to meet or speak to a clinical nurse specialist and 12% required further information and support from the CNS in addition to their clinic appointment
- 50% were provided with contact details of a clinical nurse specialist / key worker
- 75% were given a written record of their consultation
- 62% were offered information about their cancer, 12% were offered but did not want it
- 12% were offered printed information about the team looking after them, 37% were not and 38% can’t remember
- Other sources of printed information provided to patients were: Local support centre (17%), other hospital services (16%), Local/regional support groups (50%), Psychological/emotional support (17%).
- 43% felt their holistic needs were addresses, 29% felt they were addressed to some extent

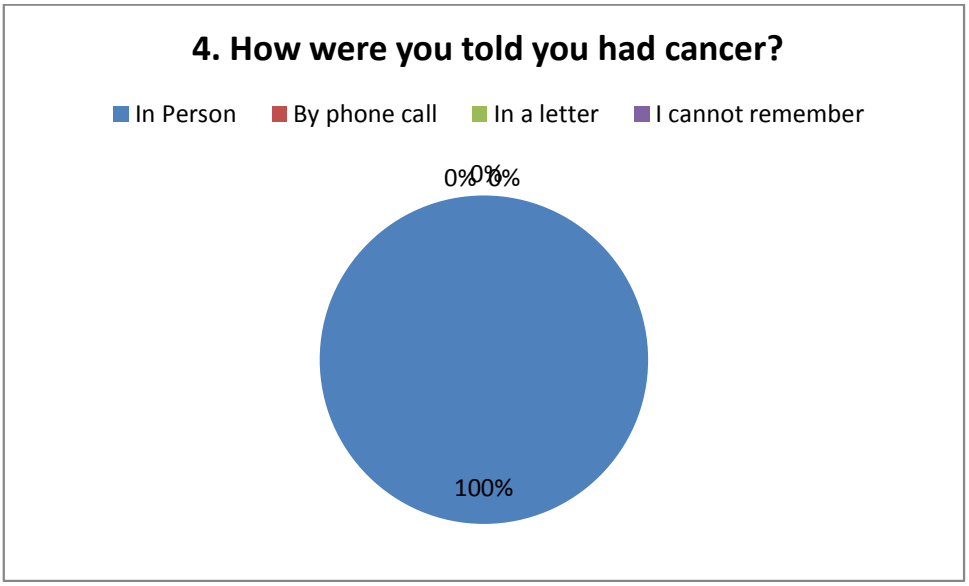
- The respondents rated the quality of information as excellent (37%), or very good / good (37%) and 62% thought the quantity was about right

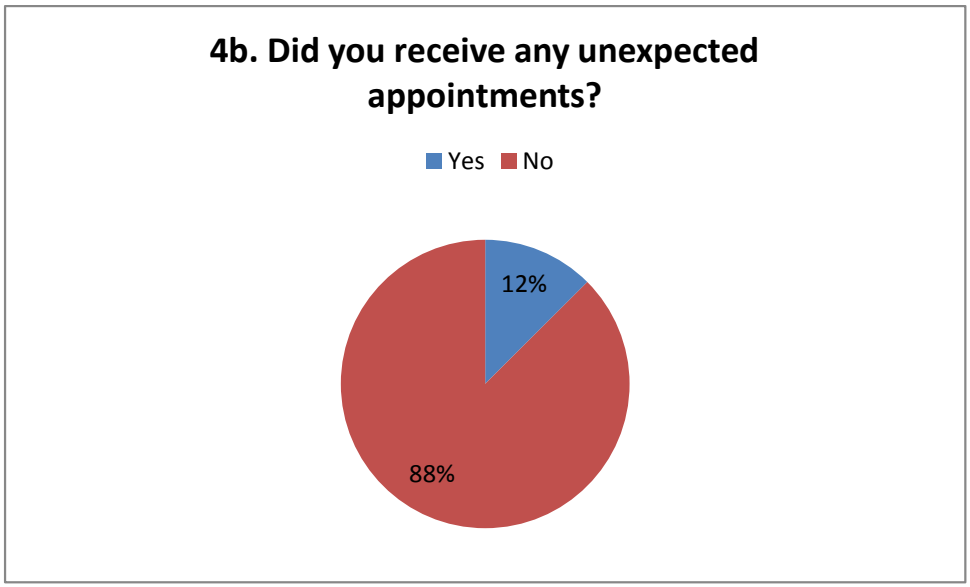
8/20 responses (40%)

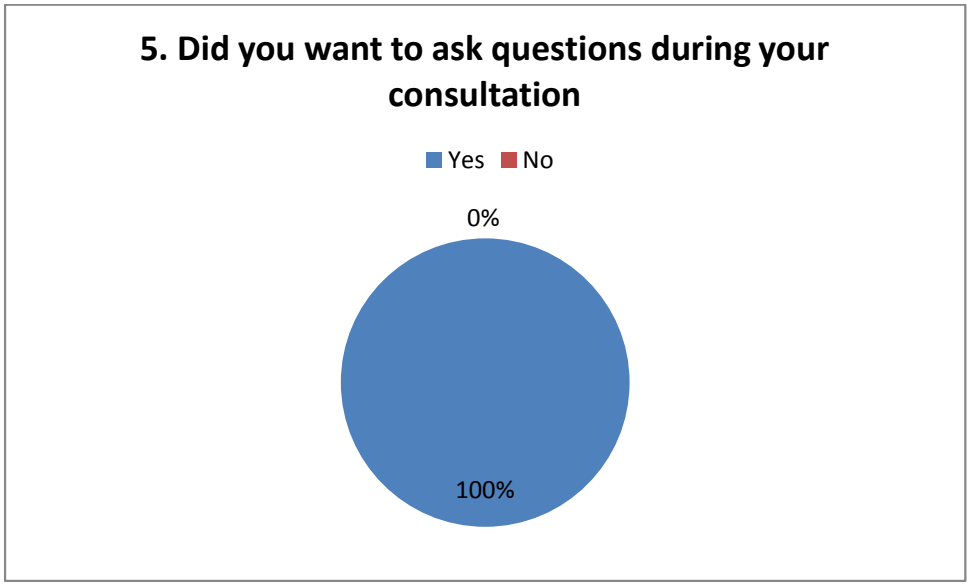


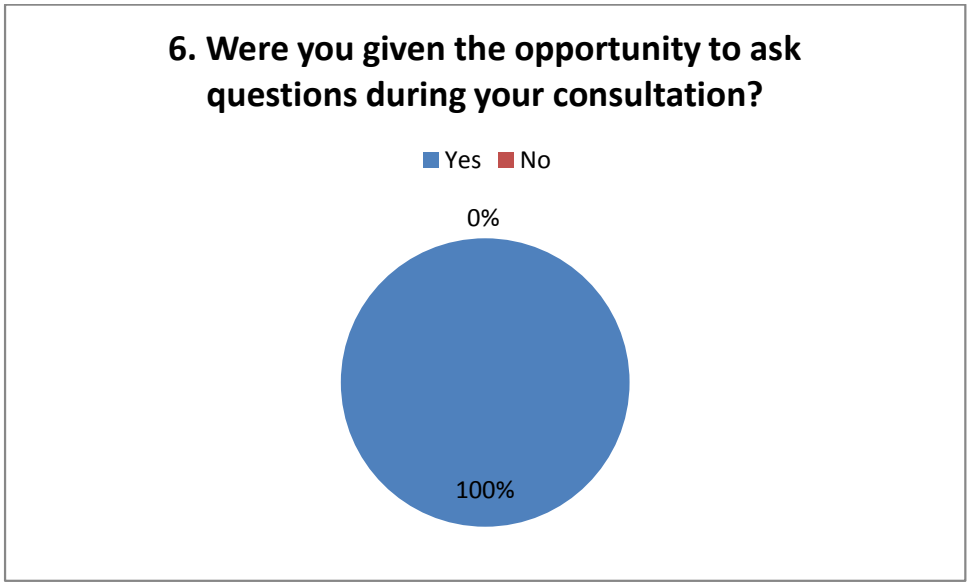


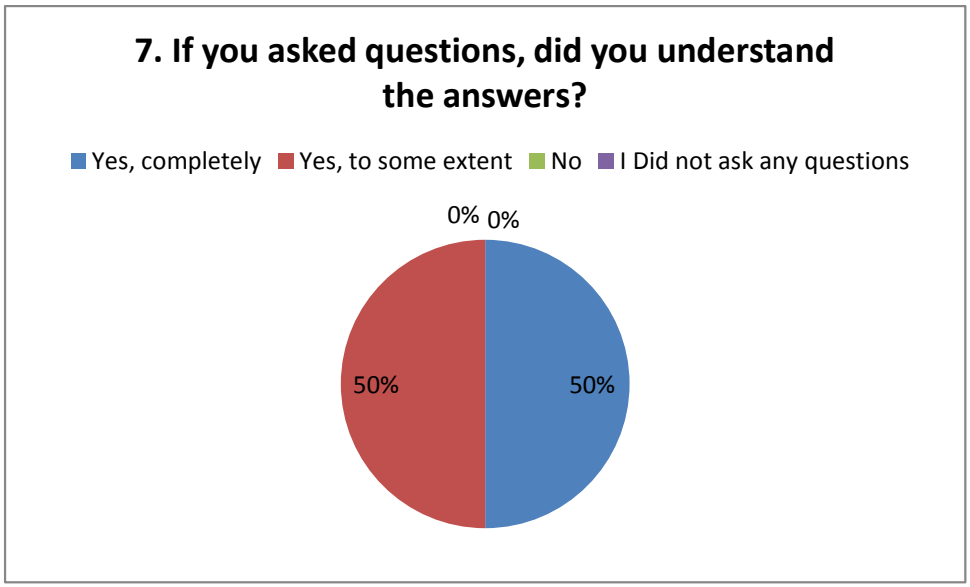


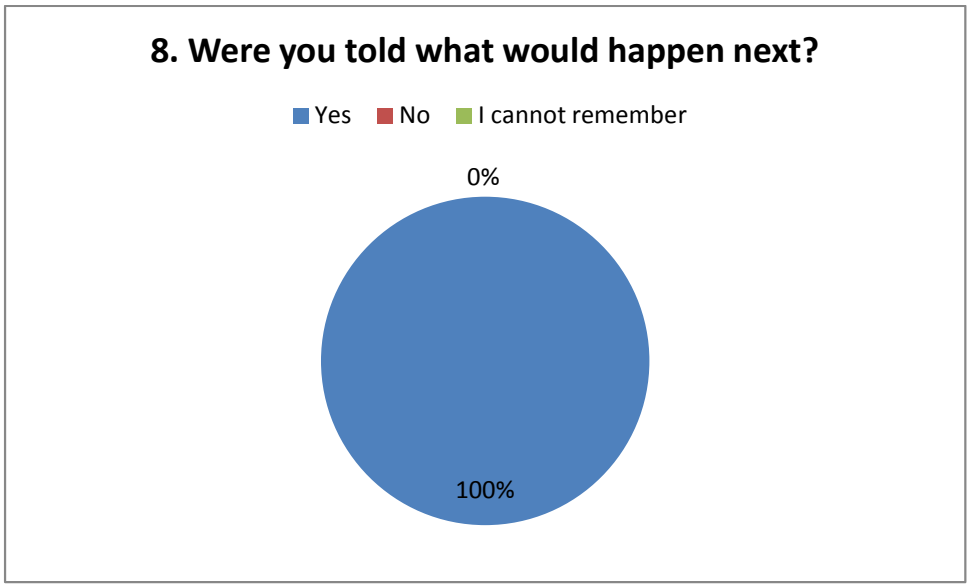


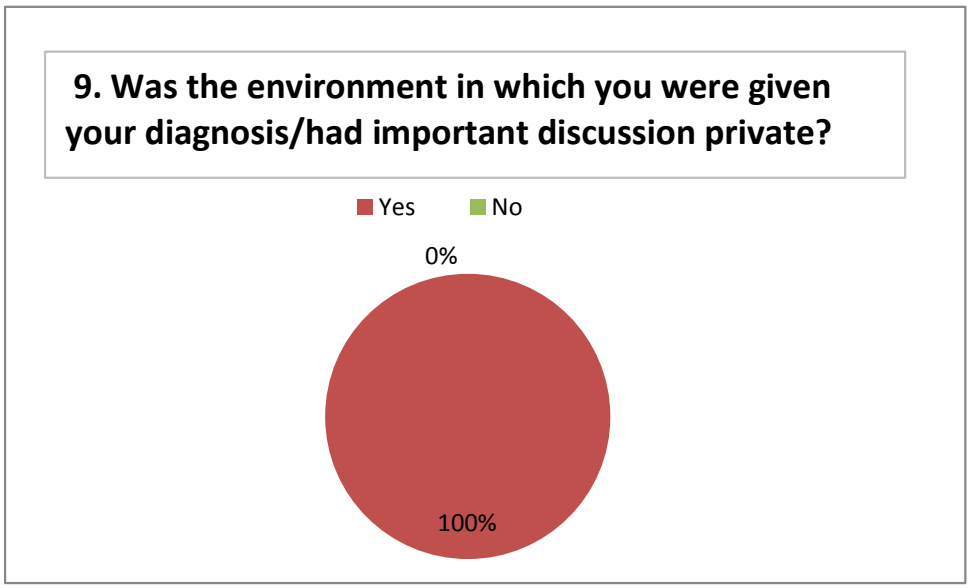


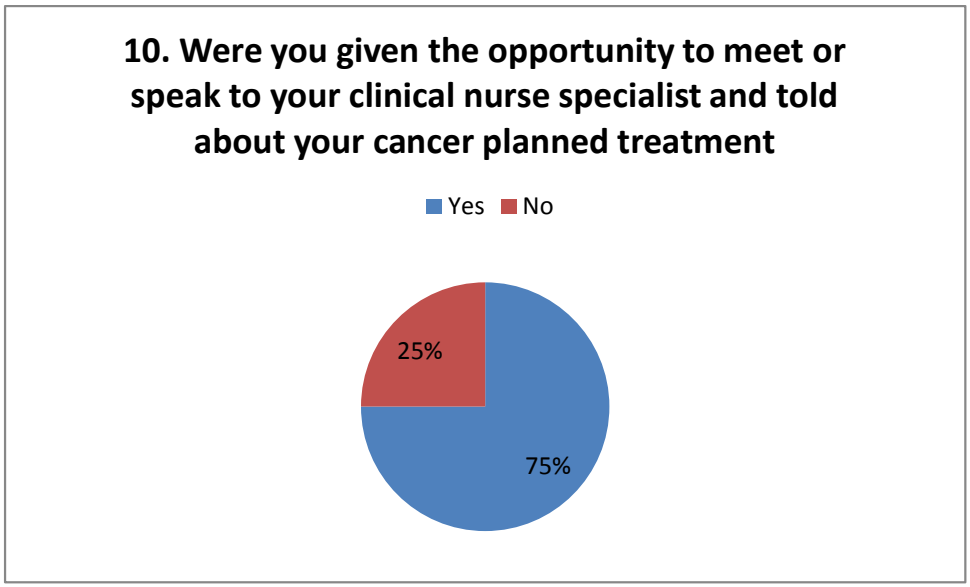


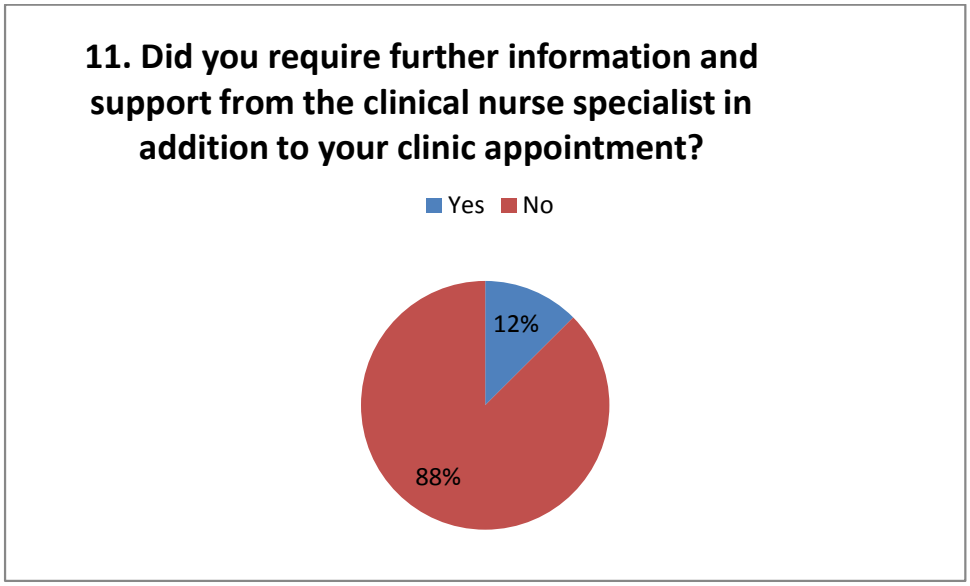




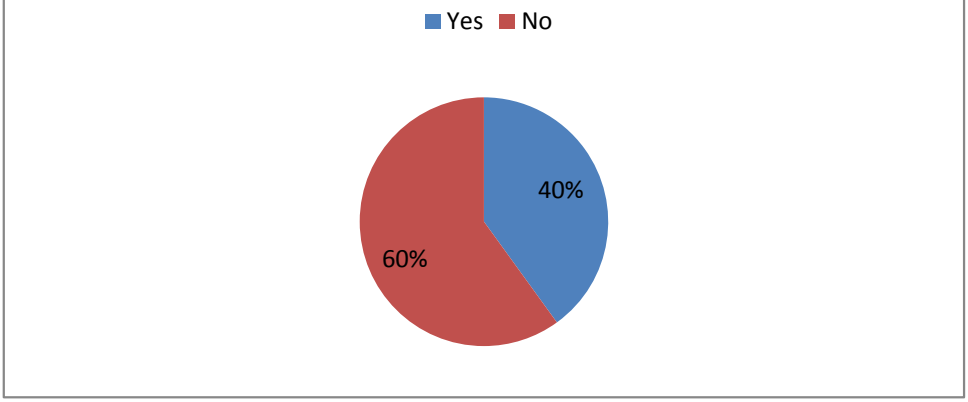




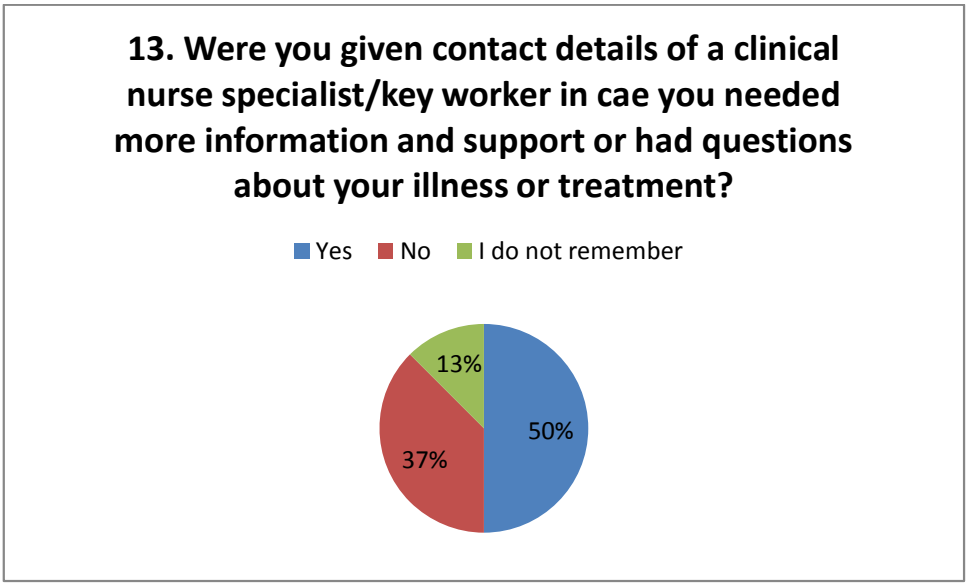


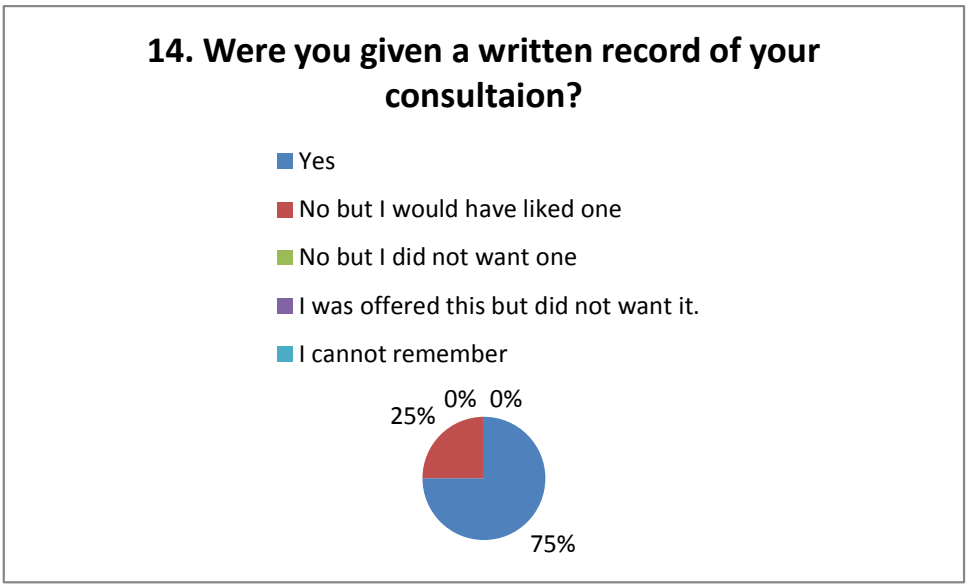


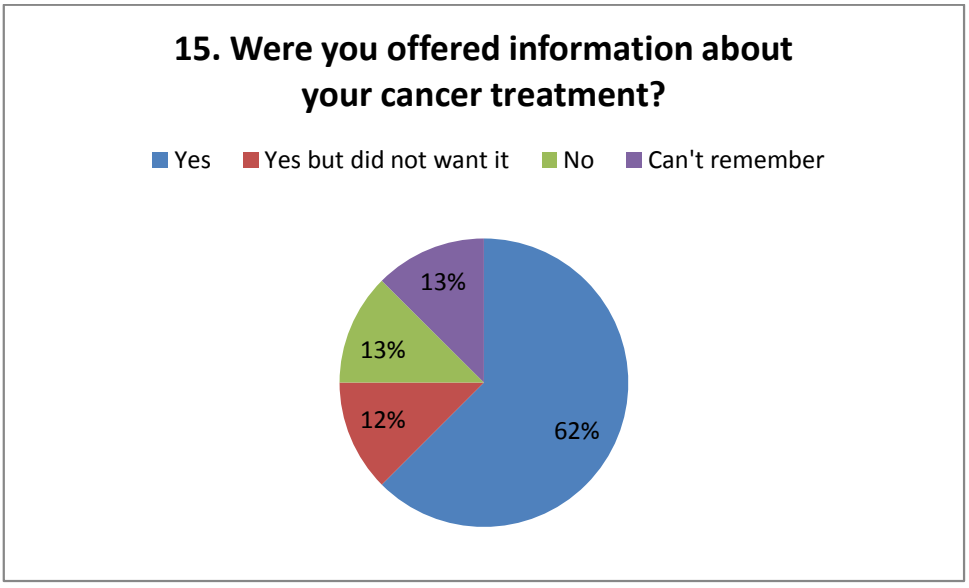
12. If you did require further information and support from the clinical nurse specialist, did you find this beneficial?

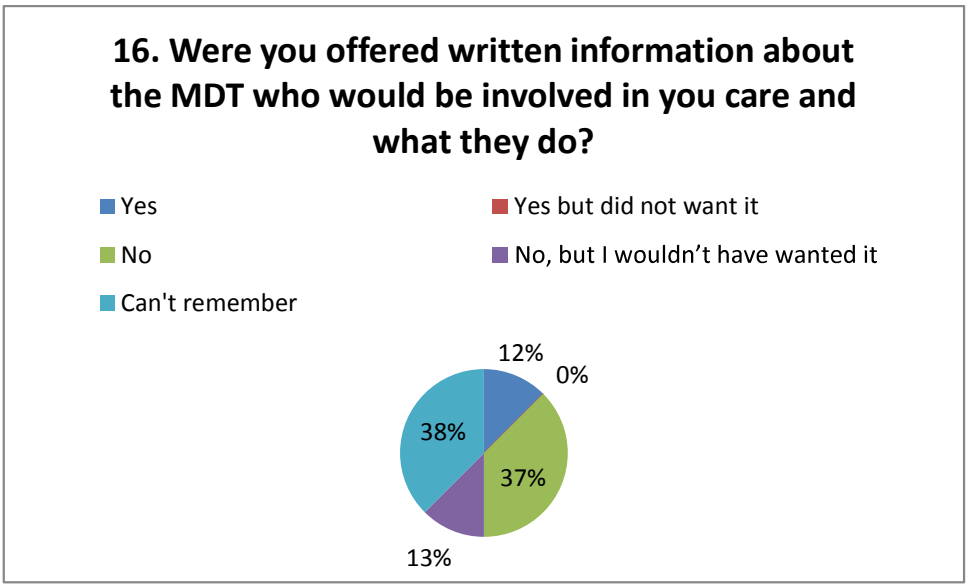


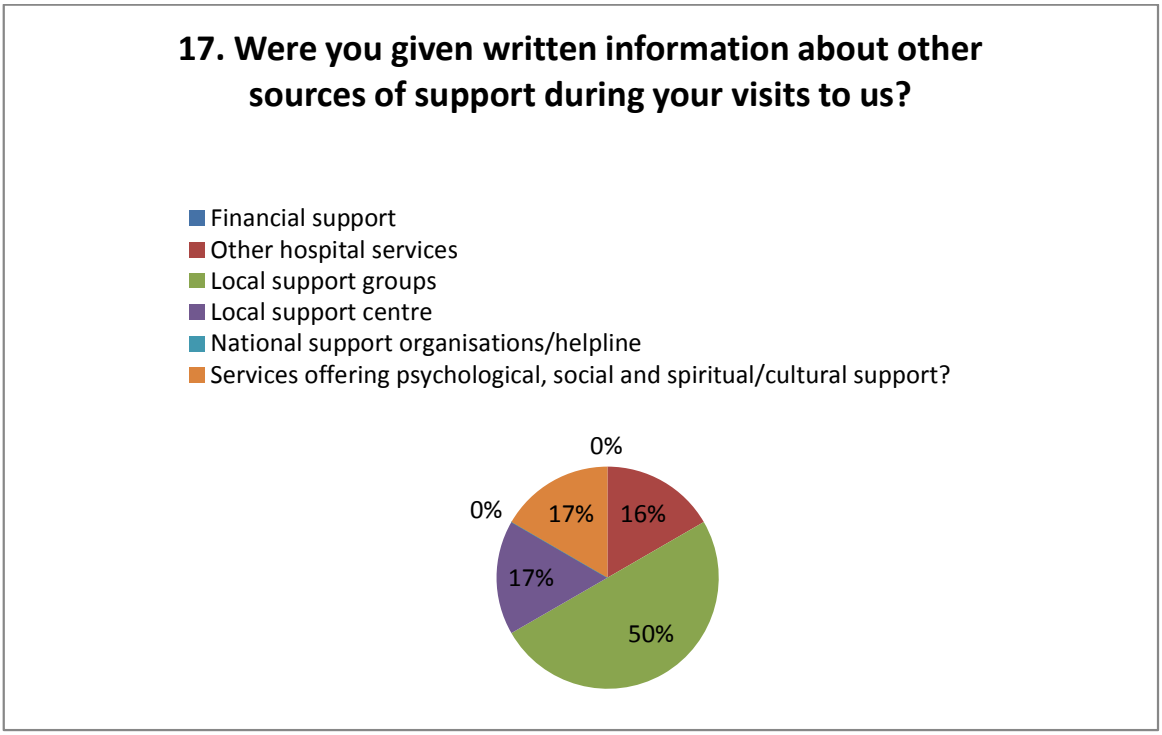
13. Were you given contact details of a clinical nurse specialist/key worker in cae you needed more information and support or had questions about your illness or treatment?

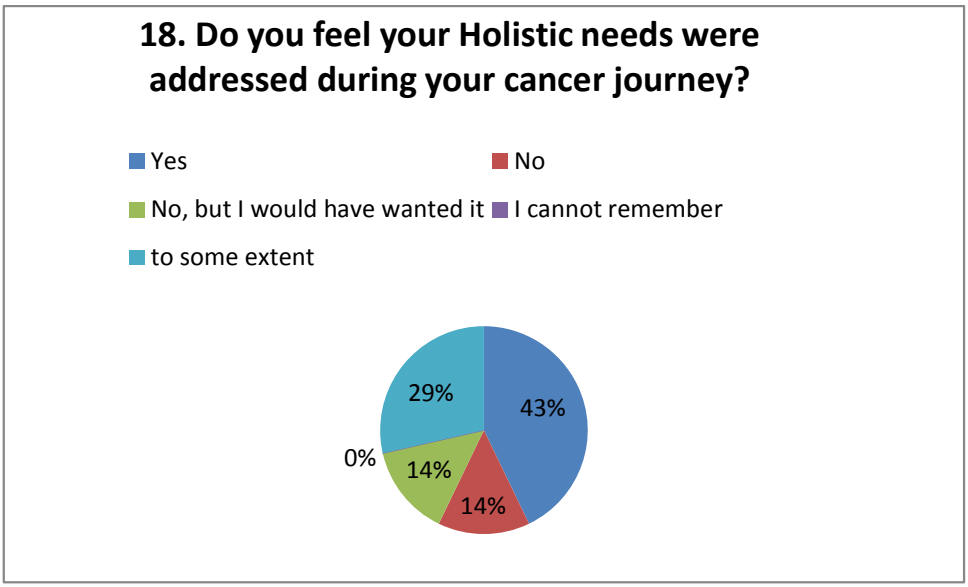


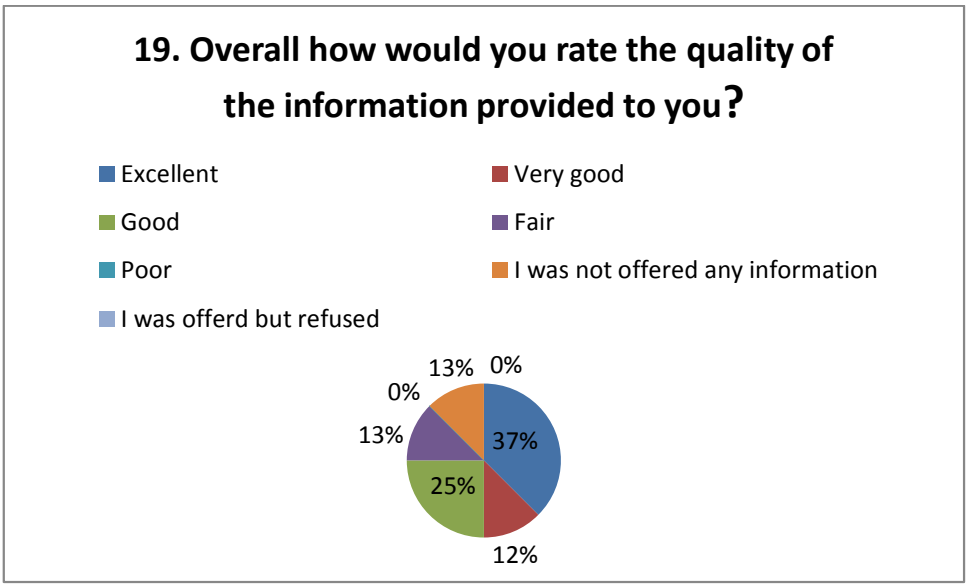


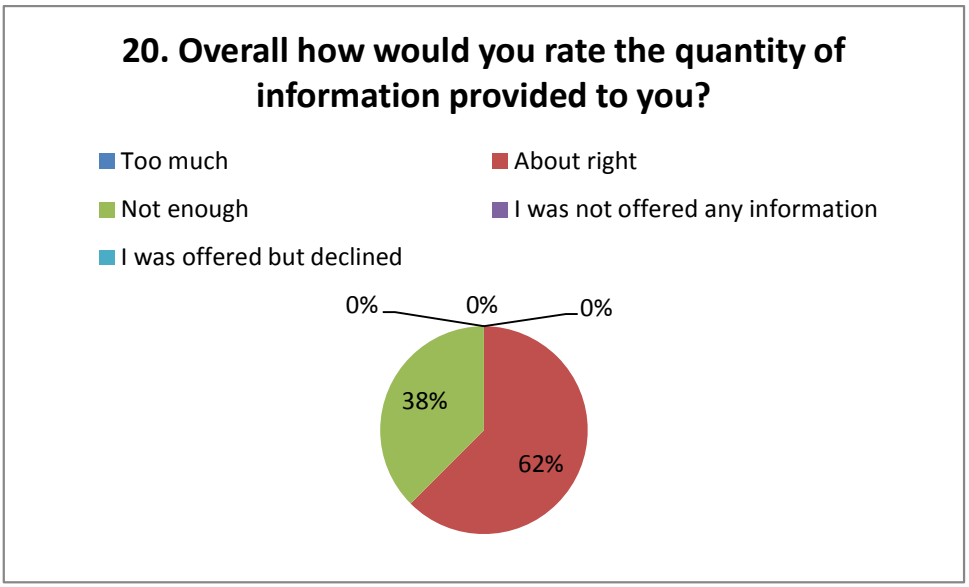


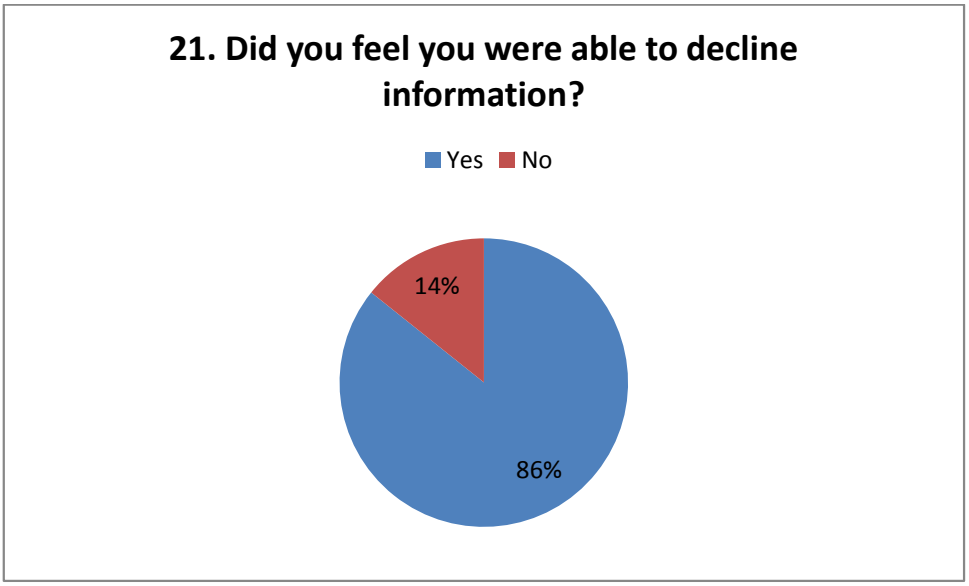












Qualitative Feedback

Was there anything particularly good about the care you received?

- Mr Glackin and his team were excellent throughout the journey, thank you and well done.
- I feel I received good care and when I was diagnosed by the consultant I was treated very quickly and the staffs were very helpful.
- The staff was brilliant in looking after me.
- The treatment from I was red flagged in A&E was quick efficient and positive. Consultants and staff excellent and outcome positive
- Getting all care needed at moment.

Was there anything that could be improved?

- When the machine he was assigned to broke down, sometimes they forgot to put up on board you were left sitting wondering why you weren't called.
- It would have been nice to talk to someone about financial help.
- A&E experience horrendous. 7 hour wait following ambulance admission after collapsing at home with major haematuria; was told again at 4 hours I was next. That took another 3 hours even though my wife explained I was deteriorating. I was left in the minors with a repetitive message on the TV for 7 hours and no seat only a wheelchair if we managed to get.

Any other comments?

- Once seen by a doctor in A&E after 7 hours, care was excellent. Referral and follow up second to none. Only problem was following theatre procedure to diagnosis cancer. I was handed a leaflet in word to read about chemo I just received in theatre; and I didn't even know I had cancer until they give me the leaflet and walked away. I was traumatised as on my own.
- Staff and consultants at Craigavon are very caring and professional.

Appendix 4: Service Improvement Action plan based on patient feedback 2016/17

Area	Lead responsibility	Date	Update
Appointment of two extra nurses to the Thorndale Unit	Martina Corrigan /Kate O'Neill	Dec 2016	Two new clinical sisters have been appointed and will take up post early 2017
Allocation of Clerical staff to the Thorndale Unit	Martina Corrigan	Dec 2016	New clerical staff member appointed to the unit
Allocation of named Key Worker to all newly diagnosed patients	Urology consultants / CNS's	Dec 2016	All newly diagnosed patients are allocated a key worker and contact details provided to the patient along with the core information pack and site specific information
Ensure a Holistic Needs Assessment is completed for all newly diagnosed patients	Kate O'Neill / CNS's	Ongoing	Due to appointment of new staff, work is ongoing to ensure that an assessment is being completed for all newly diagnosed patients
Pilot a Permanent Record of Management for all newly diagnosed patients.	Urology consultants / nurses	Oct-December 2016	Permanent record of management form developed and implemented for 3 months. Patient evaluation to be completed and results shared with Urology team for further consideration.
Pilot a community prostate review clinic	Martina Corrigan / urology team / Mary Haughey	June 2017	Steering group established to take forward community based review clinics for stable prostate cancer patients

Appendix 5: Audit of Communication of Diagnosis to GPs

Standard

One of the local peer review measures outlined by NICaN relates to communication with the patient's GP following the diagnosis of a cancer; the standard states:

"The MDT should have an agreed policy whereby after a patient is given a diagnosis of cancer the patient's general practitioner (GP) is informed of the diagnosis by the end of the follow working day"

Methodology

To test if the MDT is meeting this standard and if GPs are receiving timely information on all patients diagnosed with cancer an audit was carried out. 10 patients from the Southern Trust who were discussed at the MDT held between January and December 2016 were selected at random. The audit was carried out by using the Northern Ireland Electronic Care Record (NIECR) to establish when the patient was given their diagnosis, when the letter was typed and then by phoning the GP practices to establish when the letter was received.

Results

Four GP practices out of 10 received notification of the patient's diagnosis within 1 day. The letters of four of the patients were received by GP Practices within 4-7 days, the letter of one patient was received within 13 days and one patient letter was received within 16 days. Six of the letters were typed on the same day as the patient was given their diagnosis and therefore these would have been available on the NIECR for the GP to view. Two letters were typed within 1 day and two were typed within 4 days.

Time between patient being informed of diagnosis and GP receiving Clinic letter:

	Southern Trust
Shortest time	1 days
Longest time	16 days
Median	6 days

Time between diagnosis given to patient and letter typed:

	Southern Trust
Shortest time	0 days
Longest time	5 days
Median	1 day

Appendix 6: Clinical Trial Activity 2016

UROLOGY CANCER TRIAL ACTIVITY 2016

During the past year urological cancer clinical trial activity in NI has contributed significantly to the overall NICTN portfolio with 20 trials being open to recruitment during this time. In total 1266 participants were recruited into urology cancer studies, with 79 participants being recruited into interventional trials. No Teenage and Young Adult patients were recruited to urology trials in 2016.

Prostate cancer trials continue to dominate urology clinical trial activity with 17 trials recruiting 1160 participants (1055 non-interventional, 75 interventional). Activity in testicular cancer was limited to one open trial; **UKGTC**, a genetic epidemiology study in testicular cancer open at all Cancer Units. This study closed in June 2016, recruiting no patients in the current reporting period. Only one randomised controlled trial was available for patients with renal cell cancer (**STAR**). A further 4 patients were recruited in 2016. One Belfast Trust sponsored study in bladder haematuria (**HaBio**) continued to recruit steadily in Belfast but was extended to recruit patients within the South Eastern and Southern Health and Social Care Trusts due to the exceedingly challenging recruitment target and timeframe set for this study. The study has now closed to recruitment.

Appendix 1 gives recruitment details on a per trial per site basis.

Urological cancer clinical trial activity is still predominantly conducted within the Belfast Cancer Centre, although activity at the Cancer Units is increasing, not only in their role as Patient Identification Centres, but also in supporting full trial activity for studies such as **UKGPC**, **HaBio** and **Life After Prostate Cancer Diagnosis**. At the Cancer Centre, Professor Joe O'Sullivan and Dr Suneil Jain have driven the establishment of an extensive portfolio of prostate cancer clinical trials and following the success of being awarded Movember Centre of Excellence in 2014, activity in this area is set to grow. The portfolio already includes randomised controlled trials of investigational medicinal products, radionuclide and radiotherapy studies, translational biomarker studies and delivers a good balance of commercial, non-commercial and investigator-led studies; however there is now a very real increase in investigator led activity and a number of 'Born in Belfast, Led by Belfast' studies have been developed. These include **ADRRAD**, a trial looking at neo-adjuvant androgen deprivation therapy, pelvic radiotherapy and radium-223 in prostate cancer patients. This study developed by Professor O'Sullivan opened to recruitment in January 2016, and has recruited 21 patients to date (14 in 2016). Recruitment to Dr Jain's **SPORT** feasibility study evaluating stereotactic body radiotherapy in men with high-risk prostate cancer commenced in August 2016 and has recruited 7 patients to date, 5 within this reporting period. A further Belfast led study, **CASPIR** opened in November 2015. This prospective feasibility study assesses calcifications as an alternative to surgically implanted fiducial markers for Prostate Image Guided Radiotherapy and has currently recruited 55 patients. To facilitate the fiducial insertion associated with CASPIR, PACE and SPORT, a dedicated research clinic (the **FAST Clinic)** has been developed using a multidisciplinary approach. Trial patients are now routinely seen at this bimonthly clinic.

The Phase II PARP inhibitor trial **TOPARP** recruited a further two patients in 2016 and remains open to recruitment. The screen failure rate is high with 15 patients screened and found to be ineligible in 2016. The **PROSPER** trial remains open in Belfast and recruited a further 4 patients in 2016, a total of 9 to date. The **PACE** study also continued to recruit patients in the current reporting year, 11 patients entered the trial, bringing the total recruitment to 15. Seven patients were recruited in total to the **BAYER 15396** study before enrolment closed in August 2016. The **Janssen Prostate Study** opened to recruitment in March 2016 and recruited 4 patients before closing in February 2017. The **Life After Prostate Cancer Diagnosis** study, a UK wide questionnaire study opened in April 2016 and recruited 1028 patients regionally. The radiographer led study **TRUFU** opened to recruitment in August and completed enrolment of its target of 30 patients in November.

Several further prostate studies have been presented to the Northern Ireland Cancer Trials Coordinating Committee in 2016 and are currently in set up or are now open. These include:

RE-AKT: A randomised phase II study of Enzalutamide (MDV3100) in combination with AZD5363 in patients with metastatic castration – resistant prostate cancer (PI: Dr S Jain). This study was presented in January 2016 and was initiated in August 2016. The study did not open to recruitment within the reporting period (opened in March 2017) and has not yet recruited to date.

Core: **A randomised trial of conventional care versus radioablation (stereotactic body radiotherapy) for extracranial metastases** (PI: Dr S Jain). This study will recruit patients with breast, prostate and NSCLC primaries. The study was presented in January 2016. Set up has been delayed due to requirements for pulmonary function tests and finalising IRMER requirements, as well as delays in receiving all relevant documents from the coordinating centre.

Add-Aspirin:

A phase III, double blind, placebo controlled, randomised trial assessing the effects of aspirin on disease recurrence and survival after primary therapy in common non-metastatic solid tumours (PI: Professor R Wilson). The Add Aspirin trial was adopted to the portfolio is January 2016 and will recruit across the disease sites of colorectal, prostate, breast and gastro-

oesophageal cancers. R&D approval was granted in September 2016 and study should open to recruitment in June 2017.

TRUFU: **Therapeutic radiographer undertaking follow-up for prostate cancer patients** (PI: Ms Stacey Hetherington). This study was presented in February 2016 and opened to recruitment in August 2016. The target recruitment was met in November and the study closed to recruitment.

GAP 4: **Intense exercise for survival among men with metastatic castrate-resistant prostate cancer (INTERVAL – MCRPC): A multicentre, randomized, controlled phase III study** (PI: Dr S Jain). The study was adopted into the portfolio in April 2016. Submission to R&D has been delayed as the lead site has not yet obtained ethics approval.

Enzalutamide Extension Study:

A phase 2 open-label extension study for subjects with prostate cancer who previously participated in an Enzalutamide clinical study (PI: Professor J O'Sullivan). This study is the extension of two Enzalutamide studies (TERRAIN and AFFIRM) which have now closed. Opening this study will allow patients continue Enzalutamide treatment. The study was presented in November 2016. R&D approval is awaited.

CTC Stop: **Utilising Circulating Tumour Cell (CTC) Counts to optimize systemic therapy of metastatic prostate cancer** (PI: Dr S Jain). This study was presented by Dr Jain in November. The study has been submitted to Research Governance and approval is awaited.

ARASENS Bayer 17777:

A randomized, double-blind, placebo-controlled Phase III study of ODM-201 versus placebo in addition to standard androgen deprivation therapy and docetaxel in patients with metastatic hormone-sensitive prostate cancer (PI:

Professor Joe O'Sullivan). This study was presented in November 2016 and is currently with Research Governance for approval.

MADCAP: **A phase I/randomised phase II trial of abiraterone acetate with or without RO5503781 in patients with metastatic castrate resistant prostate cancer (mCRPC) who have not previously received docetaxel** (PI: Dr V Coyle). Although presented in 2013 significant delays encountered with the sponsor has resulted in the local decision to only open the phase II component of this study in late 2016, however phase II of this study is no longer proceeding.

Appendix 1: PROSTATE STUDIES OPEN TO RECRUITMENT 2016

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/05/17)	% of Target	Recruit. 2016	Project status
RADIATION BIOMARKER STUDY	**A Study Examining Serum Biomarkers Of DNA And Tissue Damage In Patients Undergoing Radical Radiotherapy For Prostate Cancer**								
	O'Sullivan, Prof Joe	BHSCT	01/11/2011	01/11/2016	50	39	78%	1	Suspended
RADICALS (MRC PR10)	**Radiotherapy and Androgen Deprivation In Combination After Local Surgery - A RCT in prostate Cancer**								
	O'Sullivan, Prof Joe	BHSCT	26/11/2009	30/06/2016	5 per year	27	84%	0	Open
RAPPER	**Radiogenomics: assessment of polymorphisms for predicting the effects of radiotherapy**								
	O'Sullivan, Prof Joe	BHSCT	03/06/2011	31/08/2018	15-20 per annum	141	101%	3	Open
	Mitchell, Dr Darren	WHSCT - patient identification and consent only				13	N/A	0	Open
STAMPEDE	**Systemic Therapy in Advancing or Metastatic Prostate Cancer: Evaluation of Drug Efficacy**								
	O'Sullivan, Prof Joe	BHSCT	16/12/2005	01/01/2017	Original Target 50 (now 200)	191	95%	5	Open
UKGPC	**UK Genetic Prostate Cancer Study (formerly Familial Prostate Cancer Study)**								
	O'Sullivan, Prof Joe	BHSCT	27/10/2006	31/12/2017	240	211	88%	5	Open
	Harney, Dr Jackie	SEHSCT	02/03/2009		NK	17	NK	9	Open
	Carser, Dr Judith	SHSCT	21/01/2009		NK	50	NK	4	Open
	McAleese, Dr Jonathan	NHSCT	25/11/2013		NK	25	NK	1	Open
	Mitchell, Dr Darren	WHSCT	22/03/2008		NK	50	NK	4	Open
PROMPTS	**Prospective randomised phase III study of observation versus screening MRI and pre-emptive treatment in castrate resistant prostate cancer patients with spinal metastasis**								
	Jain, Dr Suneil	BHSCT	30/05/2014	02/05/2017	21	7	33%	1	Closed
	Mitchell, Dr Darren	WHSCT - patient identification and consent only				0	0	0	

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/05/17)	% of Target	Recruit. 2016	Project status
TOPARP	**Phase II Trial of Olaparib in Patients with Advanced Castration Resistant Prostate Cancer**								
	Jain, Dr Suneil	BHSCT	09/04/14	28/2/2017	15	4	20%	2	Open
PROSPER	**A multinational, phase 3, randomized, double-blind, placebo-controlled, efficacy and safety study of Enzalutamide in patients with non-metastatic castration-resistant prostate cancer**								
	Jain, Dr Suneil	BHSCT	27/08/2014	31/12/2018	10	9	90%	4	Open
BUSTIN	**A randomised trial comparing 2 bladder filling instruction sheets in achieving bladder volume consistency using an ultrasonic bladder scan device and biomarker analysis during intensity modulated prostate radiotherapy**								
	Hynds, Mrs Sharon	BHSCT	05/11/2012	24/12/2018	100	45	45%	0	Open
BAYER 15396	**A phase III randomized, double-blind, placebo-controlled trial of radium-223 dichloride in combination with abiraterone acetate and prednisone/prednisolone in the treatment of asymptomatic or mildly symptomatic chemotherapy-naïve subjects with bone predominant metastatic castration-resistant prostate cancer (CRPC)**								
	O'Sullivan, Prof Joe	BHSCT	14/07/2015	22/08/2016	10	7	10%	3	Closed - in FU
PACE	**PACE - International Randomized Study of Laparoscopic Prostatectomy vs Robotic Radiosurgery and Conventionally Fractionated Radiotherapy vs Radiosurgery for Early Stage Organ-Confined Prostate Cancer**								
	Jain, Dr Suneil	BHSCT	22/10/2015	01/09/2016	20	15	75%	11	Open
CASPIR	**Calcifications as an alternative to surgically implanted fiducial markers for Prostate Image guided Radiotherapy: A prospective feasibility study**								
	O'Sullivan, Prof Joe	BHSCT	20/11/2015	30/10/17	90	55	61%	26	Open
ADRRAD	**Neo-adjuvant Androgen Deprivation Therapy, Pelvic Radiation and RADium-23 for new presentation of T1-4 N0/1 M1B adenocarcinoma of prostate (ADRRAD Trial)**								
	O'Sullivan, Prof Joe	BHSCT	21/01/2016	31/07/2017	30	21	70%	14	Open
SPORT	**A Randomised Feasibility Study Evaluating Stereotactic PrOstate RadioTherapy in High-Risk Localised Prostate Cancer with or without Elective Nodal Irradiation (SPORT High-Risk Trial)**								
	Jain, Dr Suneil	BHSCT	18/01/2016	18/01/2018	30	7	23%	5	Open

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
Janssen Prostate Study	**A Phase 3 Randomized, Placebo-controlled Double-blind Study of JNJ-56021927 in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone in Subjects with Chemotherapy-naive Metastatic Castration-resistant Prostate Cancer (mCRPC)**								
	Jain, Dr Suneil	BHSCT	08/03/2016	11/02/2017	10	4	40%	4	Closed – in FU
LAPCD	**Life After Prostate Cancer Diagnosis**								
	Mitchell, Dr Darren	BHSCT	22/04/2016	31/12/2018	4000	1028	171%	1028	Closed
	McAleese, Dr Jonathan	NHSCT							
	Harney, Dr Jacqui	SEHSCT							
	Glackin, Dr Anthony	SHSCT							
TRUFU	**Therapeutic Radiographer undertaking Follow-Up for Prostate Cancer Patients**								
	Hetherington, Stacey	BHSCT	22/06/2016	03/11/2016	30	30	100%	30	Closed

TESTICULAR

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
UKGTC	**Identification of testicular germ cell tumour susceptibility genes**								
	Dr Olabode Oladipo	BHSCT	19/01/2010	01/06/2016	500	334	67%	0	Closed

RENAL

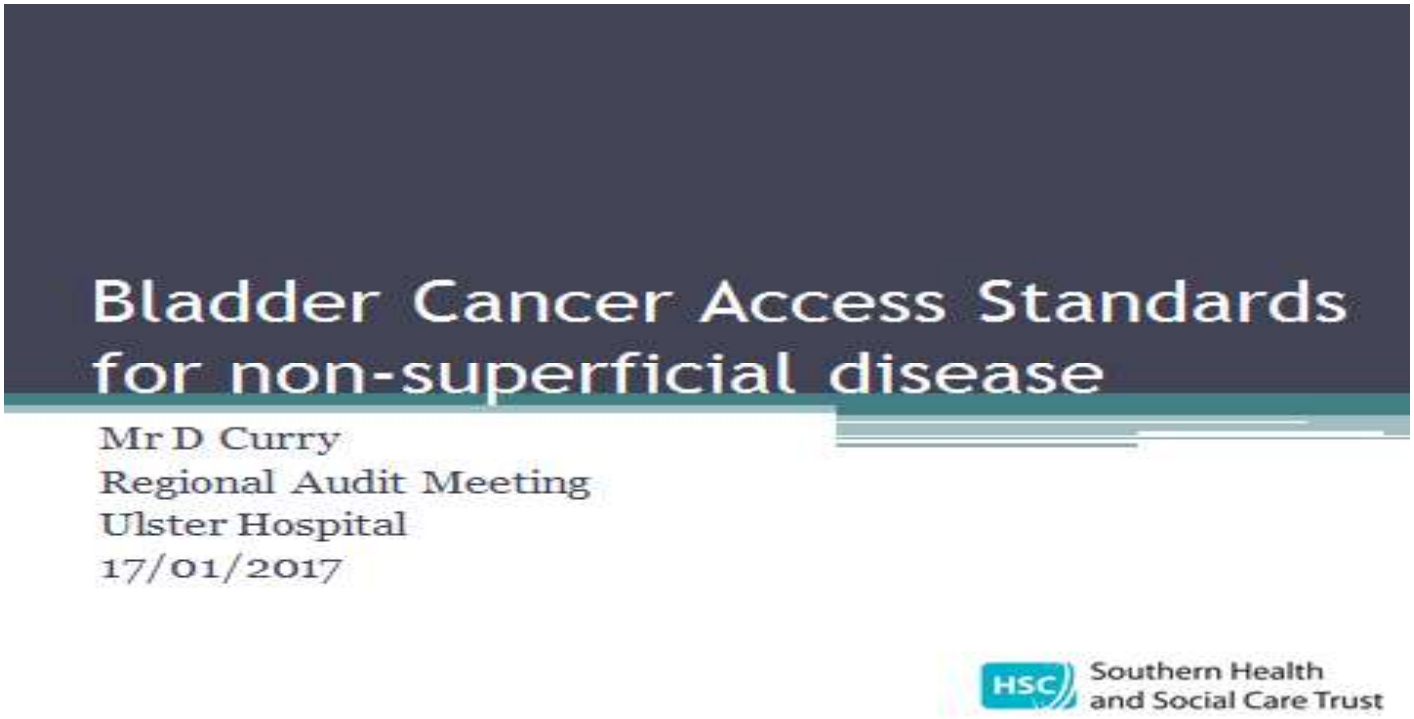
Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
STAR	**A randomised multi-stage phase II/III trial of Sunitinib comparing temporary cessation with allowing continuation, at the time of maximal radiological response, in the first-line treatment of locally advanced and/or metastatic renal cancer**								
	Clayton, Dr Alison	BHSCT	30/08/2013	03/04/2018	72	13	18%	4	Open

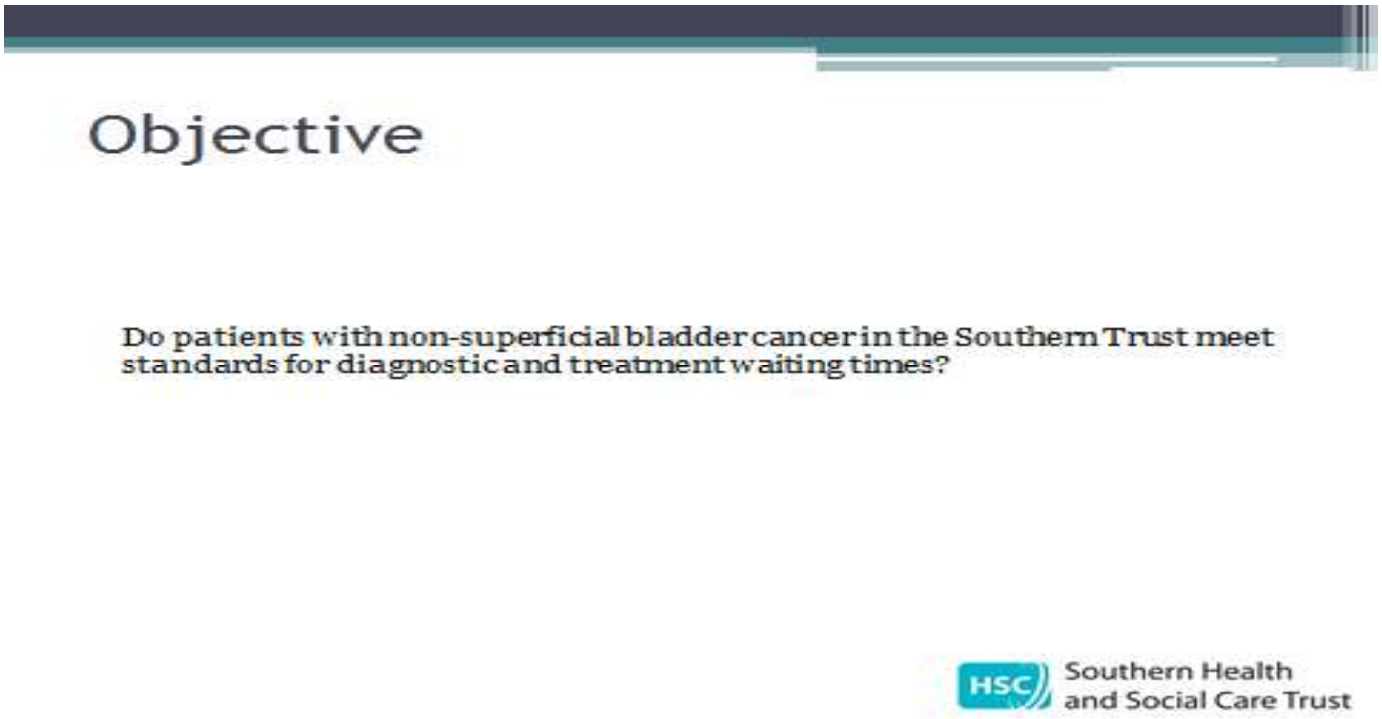
BLADDER

Trial	Principal Investigator	Site	Open to recruit.	Close to recruit.	Target	Total recruited (31/5/17)	% of Target	Recruit. 2016	Project status
HaBio	**Haematuria Biomarker Study**								
	O'Kane, Dr Huge	BHSCT	10/10/2012	30/06/2016	333 pts 666 cont.	585	66%	78	Closed – in FU
	Duggan, Dr Brian	SEHSCT	02/06/2014			75		12	
	Glackin, Mr Anthony	SHSCT	NK			17		12	

Appendix 7 AUDITS

7.1 Audit on Bladder Cancer Access Standards for non-superficial disease





Standards - NICE

Bladder cancer

1.6.4 Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- aged 45 and over and have:
  - unexplained visible haematuria without urinary tract infection **or**
  - visible haematuria that persists or recurs after successful treatment of urinary tract infection, **or**
- aged 60 and over and have unexplained non-visible haematuria **and** either dysuria or a raised white cell count on a blood test. **[new 2015]**

1.6.5 Consider non-urgent referral for bladder cancer in people aged 60 and over with recurrent or persistent unexplained urinary tract infection. **[new 2015]**

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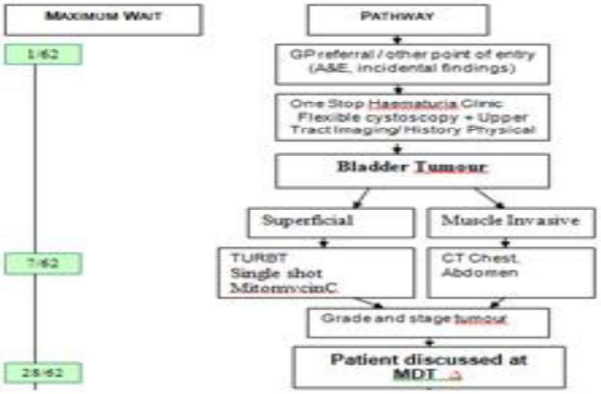
Standards -NICaN - CAH



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Standards - NICaN - CAH/BCH

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Standard 1-Red Flag Referral n=18

1.6.4 Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- 18/25 Patients triaged red flag
- Median Time from ref to 1st review – 16 days (IQR 14-17)
- 7/18 (38.9%) seen within 14 days
- 14/18 (77.8%) seen within 21 days
- Longest 42 days – however appointment at 25 days cancelled by patient

- NHS England target is 93%

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Materials and Methods

- Review of all bladder cancer patients through MDT Aug 2015 –Aug 2016
- Retrospective review of electronic records.
- 82 bladder cancer patients through MDT
- 25 (30.5%) had MIBC or required tertiary referral

- Mean age 76 (Range 56-90)
- 10 Female/ 15 Male

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Results - Demographics

- 25 (30.5%) had MIBC or required tertiary referral
  - Small cell carcinoma - 2 (8%)
  - Lymphoma - 1 (4%)
  - Squamous Cell Carcinoma - 3 (12%)
  - Transitional Cell Carcinoma – 19 (76%)
    - 2 BCG Refractory/ 17MIBC
- Referral Pathways
  - Emergency - 4 (16%)
  - Red Flag – 18 (72%)
  - Routine – 1 (4%)
  - Upstaged – 2 (85)

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Standard 1-Red Flag Referral n=18

1.6.4 Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- 18/25 Patients triaged red flag
- Median Time from ref to 1st review – 16 days (IQR 14-17)
- 7/18 (38.9%) seen within 14 days
- 14/18 (77.8%) seen within 21 days
- Longest 42 days – however appointment at 25 days cancelled by patient
- NHS England target is 93%

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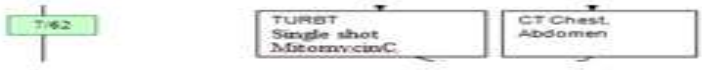
Standard 2 n=18



- Cystoscopy to TURBT
  - Median Time 23 days (IQR 13-32)
  - 2/18 (11%) within 7days
  - 10/18 (55.6%) >21 days

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Standard 3 n=22

- **Referral to MDT**
  - Median time 37days (IQR 31-56)
  - 5/22 (22.7%) within 28 days
  - 6/22 (27.3%) >56 days
- **TURBT to MDT**
  - Median Time -10 days (IQR 8-13)

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Standard 4 -

- **MDT to Results (n=21)**
  - Median Time 12 days (IQR 5-25)
  - 6/21 (28.6%) seen within 3 (working) days
  - 9/21 (42.9%) seen with 7 days
- **Referral to Results (n=22)**
  - Median Time 54 days (IQR 37-63days)
  - 5/22 (22.7%) within 31 days

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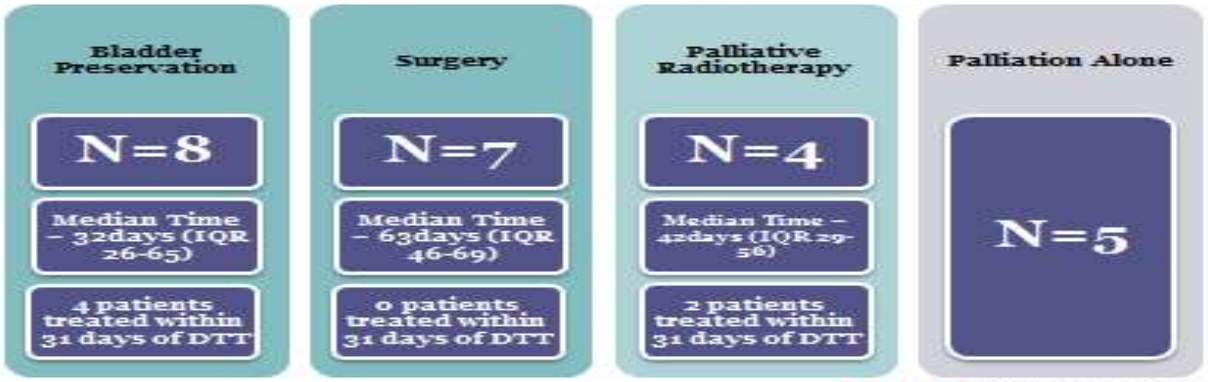
Standard 5 -

Decision to Treat (DTT) to Intervention – 31days



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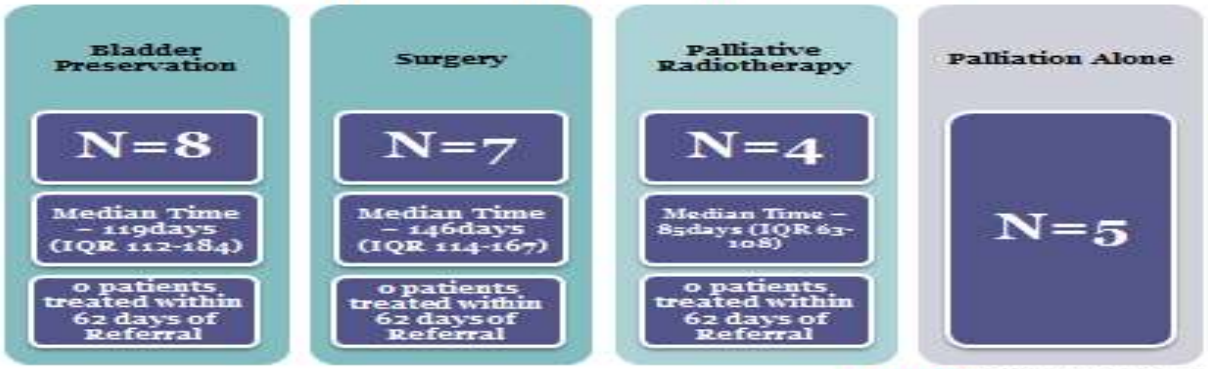
Standard 6 -

Referral to Definitive Treatment – 62days



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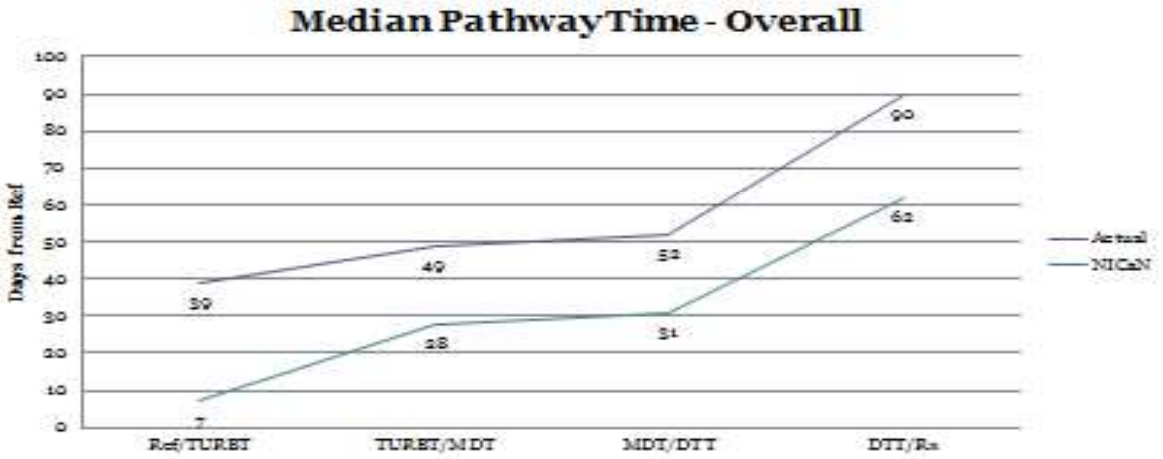
Overall Pathway



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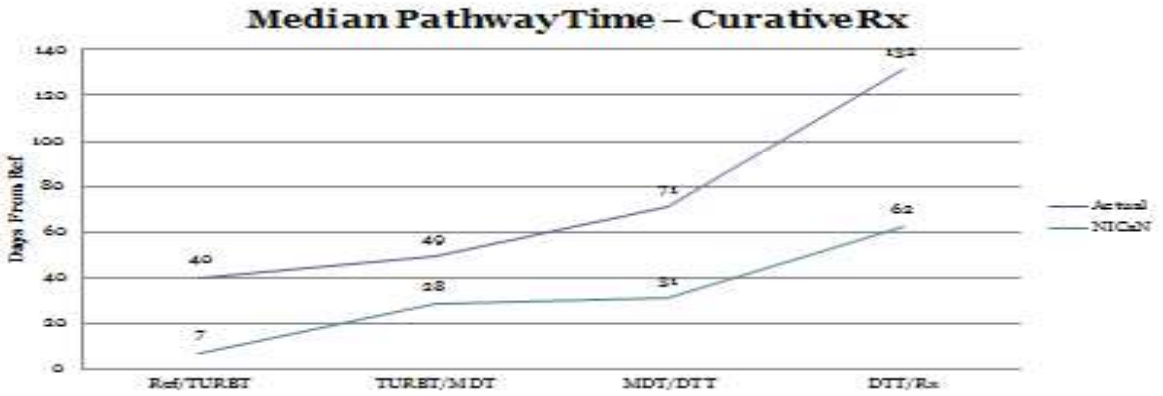
Pathway for Curative Rx



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TURBT to Radical Therapy

J Urol. 2003 Jan;169(1):110-5; discussion 115.

An interval longer than 12 weeks between the diagnosis of muscle invasion and cystectomy is associated with worse outcome in bladder carcinoma.

Sánchez-Ortiz RF*, Huang WC, Mick R, Van Arsdalen KN, Wein AJ, Malkowicz SB.

J Urol. 2003 Oct;170(4 Pt 1):1085-7.

Delaying radical cystectomy for muscle invasive bladder cancer results in worse pathological stage.

Chang SS*, Hassan JM, Cookson MS, Wells N, Smith JA Jr.

- Radiotherapy (n=6)
  - Median 107 days (IQR 87-131)
  - 67% >90days
- Surgery (n=7)
  - Median 89 days (IQR 79-110)
  - 42.8% >90days

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Summary

- Failure to meet NICE/NICaN access standards
  - Red flag Cystoscopy
  - Initial TURBT
  - MDT to DTT
  - DTT to Treatment
- Improvements?
  - Fast cystoscopy access
  - Dedicated pooled red flag GA lists/slots
  - Results - clinic timing and ref pathway
  - Regional discussion

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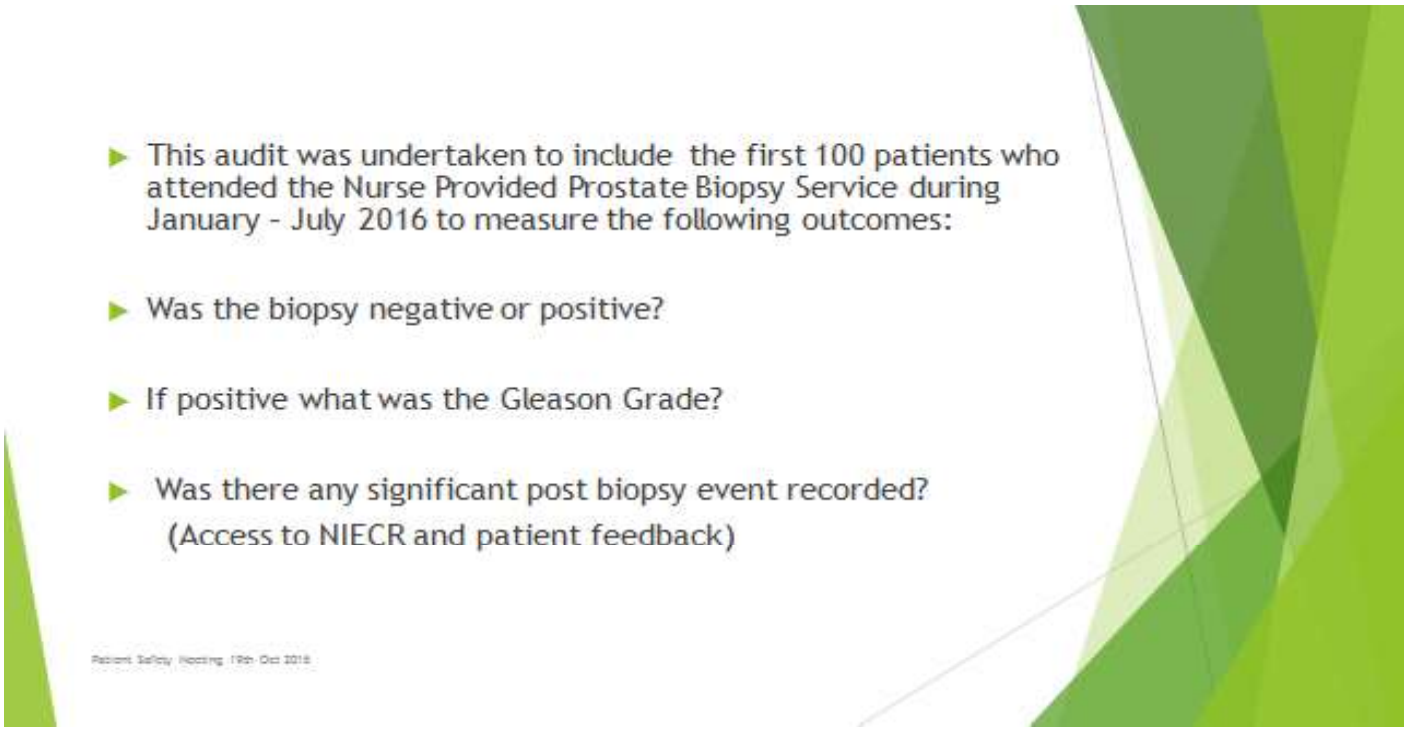
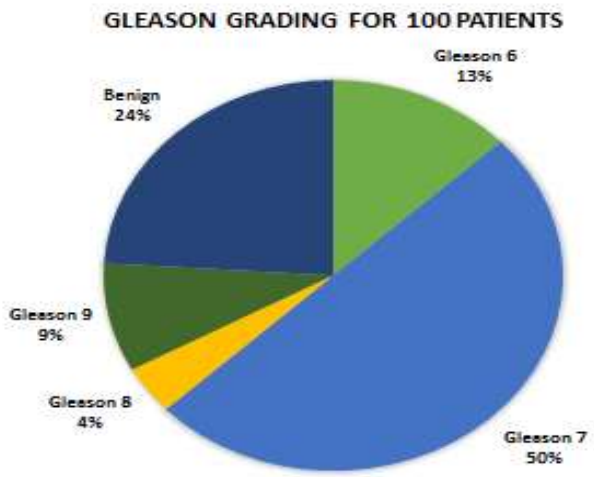
7.2 Audit of Nurse Provided TRUS Biopsy Service 2016





Patient Safety Meeting 19th Oct 2016

Significant Post Biopsy Events

- Attendance at Out Of Hours services
  - 1 x Day 1 attendance with Retention of Urine (successful TROC followed)
  - 1 x Day 6 attendance with Dysuria (antibiotic prescribed)
- Attendance at Emergency Department
  - 1 x Day 8 attendance with UTI (antibiotic prescribed)
- Admission to Hospital
  - 1 x admission on the day with Bradycardia (Pacemaker inserted that PM)
  - 1 x admission Day 1 post biopsy with Pyrexia (Treated with IV antibiotics for 4 days. Negative Blood Cultures, no evidence of MSSU collected)

Patient Safety Meeting 19th Oct 2016

Biopsies Performed By Colleagues

(During same period Jan - July 2016)

Name	TRUS	GA- Biopsy	Total
Mr Glackin	10	7	17
Mr Haynes	11	2	13
Mr O' Donoghue	11	2	13
Mr Suresh	18	2	20
Radiology	31	0	31
Overall Total			94

Patient Safety Meeting 19th Oct 2016

7.3 BAUS Data and Audit System

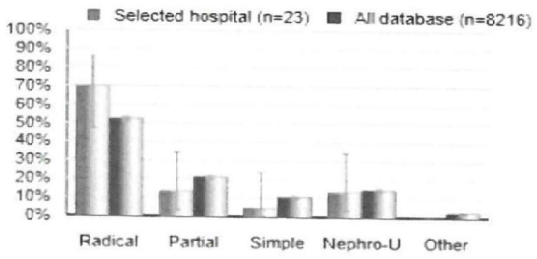
BAUS Data and Audit System

Nephrectomy dashboard

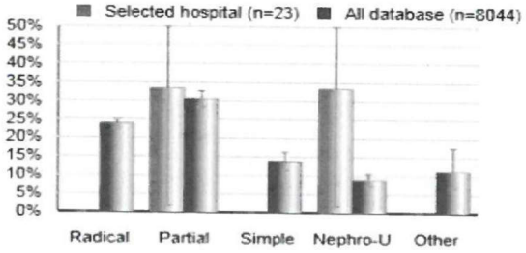
All the data for Craigavon Area Hospital, Portadown

Period between 01 January 2016 and 31 December 2016

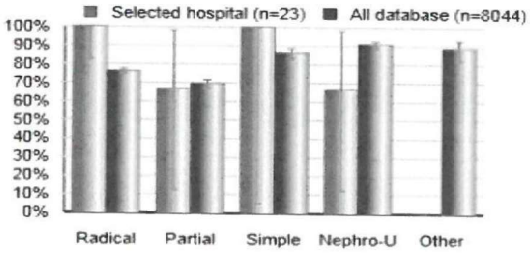
Kind of nephrectomy



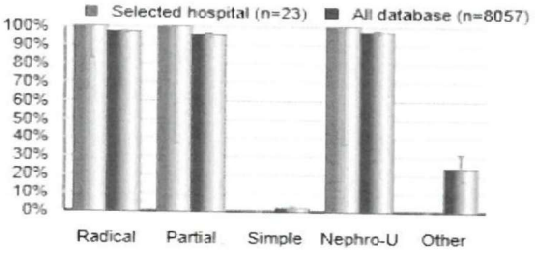
Open approach used



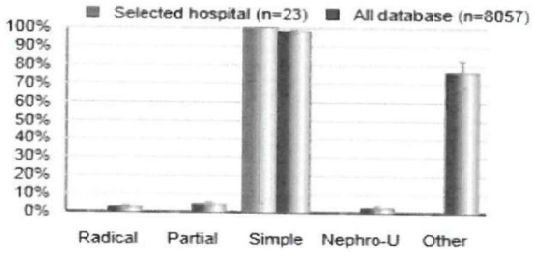
Use of minimally invasive surgery



Malignant diagnosis



Non-malignant diagnosis



Network	NICaN
Trust	Southern Health and Social Care Trust
MDT	Urology
MDT Lead Clinician	Anthony Glackin
Date	21st September 2017

Key Themes
Please provide comments including details of strengths, areas for development and overall effectiveness of the team. Any specific issues of concern or good practice should also be noted in the following sections. It is important to demonstrate any measurable change in performance compared to previous assessments.

Structure and function of the service
Comment in relation to leadership, membership, attendance and meeting arrangements, operational policies and workload.

The Urology MDT is held every Thursday from 2.15pm, with the exception of public holidays. There are video-conferencing facilities to Belfast Cancer Centre. Mr Anthony Glackin, Consultant Urologist, is the Lead Clinician of the MDT.
The Urology MDT is a well-structured MDT. Overall weekly attendance is good, however on some occasions this can be difficult due to competing demands.

The greatest challenge for the MDT during the past year has been the inadequacy of the availability of a clinical oncologist and or a radiologist at all MDMs. The inadequacy in both cases has essentially been due to the inability to recruit adequate numbers of clinical oncologists and radiologists to the post where they are required. The inadequacies have been escalated to trust senior management team and are being addressed with the appointment authorities.

With increasing numbers of consultant urologists, the functions of Lead Clinician and of Chair of MDM have been separated to enhance active participation in and responsibility for MDM. The Chair of each MDM will have been decided when scheduling takes place at least one month previously. Scheduling has also ensured that time is allocated to the appointed Chair to preview in detail each Wednesday all of the cases to be discussed at MDM the following day. All of the required clinical summaries, results and reports of investigations will have been provided to the appointed Chair for preview. It also enables all multidisciplinary participants to preview cases and to prepare their contributions to the discussion of cases. This provision has greatly enhanced the quality of scrutiny and preparation for discussion of each case.

The quality of the conduct of MDM has been a singular achievement these past six years. The quality of participation has been enhanced by increasing the number of persons chairing, and by having time allocated for preview.

There had been a 40% increase in the number of Red Flag referrals throughout Northern Ireland during the past few years, up from 2902 in 2013 to 4761 in 2015/16. The greatest increase was to the Southern Trust, with an increase of 84% from 410

in 2013 to 753 in 2014. The increase has continued and in 2016 there were 1878 red flag referrals.

For 2016, the 31 day performance for the SHSCT was 100% and the 62 day performance was 81% - this reflects the marked increase in GP red flag referrals for the trust.

The diagnostic and operative activity has been reflected in an increase in the numbers of specimens received by the Cellular Pathology Laboratory at Craigavon Area Hospital. Tissue specimens increased from 874 in 2014 to 903 in 2016.

It is notable that there has been an increase in the numbers of Prostate biopsies which reflects the use of MRI to avoid unnecessary TRUS biopsy.

Progress is ongoing in relation to the full implementation of the Key Worker, Holistic Needs Assessments, Communication and ensuring all patients are offered a Permanent Record of Patient Management. With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner. It is intended that patients newly diagnosed as inpatients will also be included.

Coordination of care/patient pathways
Comment on coordination and patient centred pathways of care, network guidelines and communication.

The MDT adheres to the regional Urology Clinical Reference Group guidelines & patient pathways and these have been agreed at an MDT meeting. There are clear pathways in place for the management of Urology cancers. The network has agreed a pathway for the management of Teenage and Young Adult (TYA) cancer patients. When TYA's are discussed at MDM, the cancer tracker will inform the Trust TYA nurse who will ensure appropriate onward support / referral to the TYA regional service.

Patient experience
Comment on patient experience and gaining feedback on patients' experience, communication with and information for patients and other patient support initiatives.

Patient feedback and experience is very important in planning service development. Patients' views are taken on board through compliments, complaints and feedback through patient surveys. These are considered by the MDT to identify areas for improvement.

A regional cancer patient experience survey (NICPES) was carried out during 2015. 17% of the Southern Trust respondents were from Urology cancer patients. The majority of patients (90%) rated their care as excellent/very good.

A local patient survey was also undertaken in 2016. Response rates were overall complimentary of the service provided. Staff were said to be caring towards patients, giving sensitive but clear explanations of diagnosis and treatment. Verbal information was reinforced by written materials and patients were given adequate time and opportunity to ask questions. Results of the survey have been reviewed and discussed at an operational meeting and an action plan developed to address areas of weakness.

Patients are offered information by appropriate staff in a phased manner relevant to the stage of their journey. An MDT patient information leaflet has been developed and is provided to all patients along with core and site specific information.

For patients with sensory, cognitive or language difficulties bespoke information can be arranged via the Macmillan Health & Wellbeing Manager.
Additionally a regional interpreting service is offered with trained health related interpreters. The Trust also has a contract with the 24 hour telephone interpreting service to ensure that patients have support in the planned or emergency situation. For teenager and young adults, additional support is provided through the Regional Teenager and Young Adult (TYA) service, and appropriate information leaflets are available.

Clinical outcomes/indicators
Where available the data from the clinical indicators should be used. You should comment on the top five clinical priority issues for your team.

The urology MDT holds an annual business meeting to discuss the MDT workload over the previous 12 months. The figures are presented.

At this meeting audit activity is reviewed and suggestions made for future audit activity. There were two audits presented in the past year and data was also submitted to the British Association of Urological Surgeons (BAUS) Data and Audit database:

-Audit on Bladder Cancer Access Standards for non-superficial disease, Mr David Curry, 2016
-Audit of Nurse Provided TRUS Biopsy Service in 2016, Sr Kate O'Neill
-Nephrectomy dashboard - data submitted to the British Association of Urological Surgeons (BAUS) Data and Audit database in 2016

Good Practice/Significant Achievements
Identify any areas of good practice.

Trust Excellence Award to the Thorndale unit

Increased consultant capacity to meet 31 and 62 day targets

Four new clinics per week to provide equitable access to all Red flag referrals.

Appointment of two additional nurses and clerical staff to the unit

Allocation of named key worker to all newly diagnosed patients

Implementation of holistic needs assessment for all newly diagnosed patients

Development of permanent record of patient management

New MDT patient leaflet developed and provided to all patients

Specify Immediate Risks

Refer to the guidance on identifying concerns.

An "Immediate Risk" is an issue that is likely to result in significant harm to patients or staff or have a direct serious adverse impact on clinical outcomes and therefore requires immediate action.

Specify Serious Concerns

A "Serious Concern" is an issue that, whilst not presenting an immediate risk to patient or staff safety, is likely to seriously compromise the quality of patient care, and therefore requires urgent action to resolve.

Update on serious concerns highlighted from peer review assessment 2016:

Single handed radiologist with no cover arrangements in place – **Update**: this is still ongoing - radiology cover is a regional issue.

Only 11% of MDT meetings quorate due to low clinical oncology representation and lack of radiology cover – **Update:** arrangements have been made with Belfast Trust to ensure clinical oncology representation at MDT meetings.

Wait for routine referrals: **Update**: all referrals are triaged by consultants and may be upgraded to red flag or urgent which will reduce risk to patients

Nephron sparing surgery being undertaken locally – **Update:** this is no longer happening as Mr Mark Haynes is providing support to undertake nephron sparing surgery in Belfast City Hospital

Concerns

A concern is an issue that is affecting the delivery or quality of the service that does not require immediate action, but can be addressed through the work programmes of the services.

Highest percentage increase in red flag referrals across the region

Operating theatre capacity and operator time

Summary of the validation process
Describe how the process was undertaken..

A working group was established to examine documentation. The group consisted of Urology Clinical Lead, Urology Clinical Nurse Specialist, Head of Service & Service Improvement Lead. At regular intervals the documentation was circulated to MDT members for review and comments. Feedback was received and documents were adjusted accordingly. The Self-assessment was carried out by the Clinical Lead for the Upper GI MDT, the UGI Nurse Specialist, the Head of Service and a Lay reviewer, who also reviewed the patient information evidence.

Organisational Statement		
	Name & Role	Date
MDT lead agrees this is an honest and accurate assessment	Anthony Glackin MDT Lead Clinician	21st September 2017
Agreed by CEO representative		

NICaN Urology Cancer Clinical Guidelines

March 2016

Document Title	Guidelines for the Referral, Diagnosis, Treatment and Management of Urological Cancer
Document Date	March 2015 – version 1.1 January 2016 – version 1.2 March 2016 – version 1.3
Document Purpose	This guidance has been produced to support the diagnosis, treatment and management of urological cancer. Treatment decisions for individual patients require the weighing of a multiplicity of factors, which cannot all be accounted for in a CMG. The CMG provides a description of the range of treatment options available for a clinical scenario. To maximise the benefit of multi-professional working management strategies for the individual are best discussed with a multidisciplinary meeting (MDM).
Authors	Surgical: New NI guidelines have been developed by Ali Thwaini, Consultant Urologist, BHSCT, for Bladder, Prostate, Penile, Renal Cell, Testicular & Upper Urinary Tract Urothelial Cell Carcinomas Imaging: Yorkshire Cancer Network Imaging Guidelines (These guidelines have been adopted by the Network group as they reflect NI Practice) Pathology: Royal College of Pathologists Standards and Minimum Datasets for reporting Cancers (These guidelines have been adopted by the Network group as they reflect NI Practice) Systemic Anti-cancer Therapy Protocols: Reference to separate guidance developed on behalf of the NI Cancer Network and the HSCB Radiotherapy Protocols: These guidelines have been adopted by the Network group as they reflect NI Practice) Urological Nursing Sections: Kate O'Neill (SHSCT), Kerry Chambers (WHSCT), Patricia Thompson (SEHSCT), Hazel Kerr (SEHSCT) Follow up section: Transforming Cancer Follow Up Project team

Version 1	Original Draft
Version 1.1	Reformatted with inclusion of new Surgical guidelines, Imaging, Pathology, Clinical Nurse Specialist, Follow Up and Specialist Radiographer Sections
Version 1.2	Discussed at the Regional Urology Network Group Meeting on 29th January 2016
Version 1.3	Amendments following circulation January2016 Population base adjusted to reflect updated NISRA figures and NW urology population base NG12 Urology referral guidelines replace red flag guidelines Reference to guidance regarding 150 robotic prostatectomies requirement removed

Regional Agreements	Electronically agreed and issued 18th March 2016 (of note any change in commissioning arrangements will require inclusion)
Agreed:	
Review:	April 2017

Contents

1.0 INTRODUCTION

Urological cancers include a range of tumours with different presentations including:

- Prostate cancer
- Bladder cancer
- Kidney cancer
- Testicular cancer
- Penile cancer

Prostate cancer is a form of cancer that develops in the prostate. Advanced prostate cancer can spread to other parts of the body. It accounts for 24% of all new cancers in UK males, and in 20-30% of cases, prostate cancer spreads to other locations in the body. In Northern Ireland, the average number of cases per year between 2009-2013 was 1,039 per year (figures provided by NI Cancer Registry).

Bladder cancer is any of several types of malignant growths of the urinary bladder and isthe 4th most common male tumour. The most common type of bladder cancer begins in cells lining the inside of the bladder and is called transitional cell carcinoma. Incidence of bladder cancer is higher in males than in females, with over 6,400 cases in 2009 in males compared to under 2,400 in females. In Northern Ireland, the average number of cases per year between 2009-2013 was 211 per year, with a breakdown of 150 males and 61 females (figures provided by NI Cancer Registry).

Kidney cancer is a form of cancer that develops in the kidneys. Kidney cancer is often asymptomatic until an advanced stage. In approximately one third of cases, the tumour is detected incidentally during imaging carried out for other reasons. The two most common types of kidney cancer, reflecting their location within the kidney, are renal cell carcinoma (RCC) and urothelial cell carcinoma (UCC) of the renal pelvis.

In Northern Ireland, the average number of cases per year between 2009-2013 was 288 per year, with a breakdown of 173 males and 115 females (figures provided by NI Cancer Registry).

Testicular cancer or cancer of the testicles is one of the less common cancers. It usually affects younger men between the ages of 15 and 49. Testicular cancer is relatively uncommon, accounting for just 1% of all cancers that occur in men. The most common type of testicular cancer is known as ‘germ cell testicular cancer’, which accounts for around 95% of all cases. In Northern Ireland, the average number of cases per year between 2009-2013 was 65 per year (figures provided by NI Cancer Registry).

Penile cancer is a rare type of cancer that occurs on the skin of the penis or within the penis. In the UK, around 550 men are diagnosed with cancer of the penis each year. It

most commonly affects men over 60 years of age. Over the last 30 years, the number of penile cancer cases has increased by more than 20%, possibly due to changes in sexual practices.

2.0 NETWORK CONFIGURATION OF THE UROLOGY CANCER SERVICES

Northern Ireland Cancer Network has three cancer MDTs which diagnose and treat patients with urological cancers. These are held at the following locations:

- Craigavon Area Hospital – Southern HSC Trust
- Belfast City Hospital – combined team for Belfast HSC Trust and South Eastern HSC Trust
- Altnagelvin Hospital – combined team for Western HSC Trust & Northern HSC Trust

The catchment populations of these MDTs are shown below:

Urology MDT	**Catchment**[1]
SHSCT	366,000
Combined for: BHSCT and SEHSCT	 366,000 341,085
Combined for: WHSCT and NHSCT	 297,000 467,000 *Of note the population base for urology is 480,000 representing the upper two thirds of both the NHSCT & WHSCT*
Total	**1,830,000**

Each MDT meets on a weekly basis. All MDTs have named surgeons who deal with urological cancers.

[1] *Source: NISRA, 2013 MYEs*

3.0 REFERRAL GUIDELINES FOR UROLOGY CANCER

Patients can be referred to their local hospital as 'red flags' (i.e. suspect cancer) by their GPs under the following NICE guidance:

This section is a direct lift from the NICE NG12 Suspect Cancer: Recognition and Referral (June 2015).

Prostate cancer

Refer men using a suspected cancer pathway referral (for an appointment within 2 weeks) for prostate cancer if their prostate feels malignant on digital rectal examination. **[new 2015]**

Consider a prostate-specific antigen (PSA) test and digital rectal examination to assess for prostate cancer in men with:

- any lower urinary tract symptoms, such as nocturia, urinary frequency, hesitancy, urgency or retention **or**
- erectile dysfunction **or**
- visible haematuria. **[new 2015]**

Refer men using a suspected cancer pathway referral (for an appointment within 2 weeks) for prostate cancer if their PSA levels are above the age-specific reference range. **[new 2015]**

Bladder cancer

Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- aged 45 and over and have:
    - unexplained visible haematuria without urinary tract infection **or**
    - visible haematuria that persists or recurs after successful treatment of urinary tract infection, **or**
- aged 60 and over and have unexplained non-visible haematuria **and** either dysuria or a raised white cell count on a blood test. **[new 2015]**

Consider non-urgent referral for bladder cancer in people aged 60 and over with recurrent or persistent unexplained urinary tract infection. **[new 2015]**

Renal cancer

Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for renal cancer if they are aged 45 and over and have:

- unexplained visible haematuria without urinary tract infection **or**
- visible haematuria that persists or recurs after successful treatment of urinary tract infection. **[new 2015]**

Testicular cancer

Consider a suspected cancer pathway referral (for an appointment within 2 weeks) for testicular cancer in men if they have a non-painful enlargement or change in shape or texture of the testis. **[new 2015]**

Consider a direct access ultrasound scan for testicular cancer in men with unexplained or persistent testicular symptoms. **[new 2015]**

Penile cancer

Consider a suspected cancer pathway referral (for an appointment within 2 weeks) for penile cancer in men if they have either:

- a penile mass **or** ulcerated lesion, where a sexually transmitted infection has been excluded as a cause, **or**
- a persistent penile lesion after treatment for a sexually transmitted infection has been completed. **[new 2015]**

Consider a suspected cancer pathway referral (for an appointment within 2 weeks) for penile cancer in men with unexplained or persistent symptoms affecting the foreskin or glans. **[new 2015]**

3.1 Haematuria Referral Guideline – please see Appendix 1

4.0 UROLOGY CARE PATHWAYS

Cancer Care Pathways outline the steps and stages in the patient journey from referral to diagnostics, staging, treatment, follow up, rehabilitation and if applicable onto palliative care.

Timed effective care pathways are central to delivering quality and timely care to patients throughout their cancer journey and to the delivery of an equitable service.

Please see **appendix 2** for the care pathways for:

- Prostate
- Renal Tumour
- Testicular Cancer Pathway
- Transitional Cell Carcinoma
- Castration Resistant Prostate Cancer
- Penile Cancer Pathway

5.0 REGIONAL GUIDELINES FOR THE IMAGING OF UROLOGICAL CANCERS

Document Title	**Guidelines for the Imaging of Urological Cancers**
Document Date	**March 2015 – Version 2**
Document Purpose	**This guidance has been produced to support the diagnosis, treatment and management of urological cancer** **Treatment decisions for individual patients require the weighing of a multiplicity of factors, which cannot all be accounted for in a CMG. The CMG provides a description of the range of treatment options available for a clinical scenario. To maximise the benefit of multi-professional working management strategies for the individual are best discussed with a multidisciplinary meeting (MDM).**
Authors	**Dr Arthur Grey – Consultant Radiologist** **Dr Stephen Vallelly – Consultant Radiologist** **Dr Eoin Napier – Consultant Radiologist**
Version Changes	**Version 1 – issued to Regional Group 7/4/11** **Version 1.1 – the updated Yorkshire Cancer Network Imaging Guidelines for the Investigation and Treatment of Urological Cancers were reviewed by the authors in September 2014 and they agreed to adopt the updated guidelines as they reflected NI Practice. The guidelines were circulated to the Urology Network Group for sign off on 17 April 2015. Copies of the Yorkshire Cancer Network Imaging Guidelines are available at http://www.ycn.nhs.uk/**

6.0 REGIONAL PATHOLOGY GUIDELINES FOR UROLOGICAL CANCERS

Document Title	**Regional Pathology Guidelines for Urological Cancers**
Document Date	**Version 2 29th January 2016**
Document Purpose	**The guidance has been produced to support the pathological diagnosis and staging of Urological Malignancies**
Author	**Dr G McClean**
Evidence	**Royal College of Pathologists Standards and Minimum Datasets for reporting Cancers;** **Dataset Adult Renal Parenchymal Cancer Histopathology Reports Nov 2006** https://www.rcpath.org/resourceLibrary/dataset-adult-renal-parenchymal-cancer-histopathology-reports.html **Dataset for penile and distal urethral cancer histopathology reports July 2015** https://www.rcpath.org/resourceLibrary/dataset-for-penile-and-distal-urethral-cancer-histopathology-reports.html **Dataset for histopathology reports for prostatic carcinoma (2nd edition) October 2009** https://www.rcpath.org/resourceLibrary/dataset-for-histopathology-reports-for-prostatic-carcinoma.html **Dataset for the histological reporting of testicular neoplasms May 2014** https://www.rcpath.org/resourceLibrary/dataset-for-the-histological-reporting-of-testicular-

	neoplasms.html **Dataset for tumours of the urinary collecting system** **(renal pelvis, ureter, urinary bladder and urethra) (2nd edition) April 2013** https://www.rcpath.org/resourceLibrary/dataset-for-tumours-of-the-urinary-collecting-system--renal-pelvis--ureter--urinary-bladder-and-urethra.html

Version changes

Version 1 – 23rd March 2015

Version 2 – 29th January 2016. Replacement of dataset for penile histopathology with dataset released July 2015. Update of website addresses for all datasets.

Statement:

Via Consultation with Pathologists at all Trusts it has been confirmed that all Pathologists in Northern Ireland are reporting to the standards laid down by the Royal College of Pathologists in the following College Publications and that there is no additionality of practice.

Dr Gareth McClean

7.0 REGIONAL SYSTEMIC ANTI-CANCER THERAPY PROTOCOLS FOR UROLOGICAL CANCERS

Document Title	**Systemic Anti-cancer Therapy Protocols**
Document Date	**2015**
Document Purpose	Please refer to separate NICaN guidance documents for the Systemic Anti-cancer Therapy Protocols for Bladder, Penile, Testicular Germ Cell tumours, Prostate and Renal Cell. These documents are available on the NICaN website **www.cancerni.net.**

8.0 REGIONAL RADIOTHERAPY PROTOCOLS FOR UROLOGICAL CANCER

Document Title	**Radiotherapy Protocols**
Document Date	**2015**
Document Purpose	Radiotherapy is delivered in the Northern Ireland Cancer Centre at the Belfast City Hospital with a second department due to open in Altnagelvin in 2016. The Cancer Centre is equipped with 10 Linear Accelerators and a full range of conventional and CT simulation equipment. The Radiotherapy Department employs approximately 90 radiographers. The department is accredited by ISO9000 and Charter mark standards. There is a modern treatment planning system with 10 planning terminals. A comprehensive radiology service is available within the Cancer Centre and in the main City Hospital. IMRT is routinely delivered for radically treating prostate cancer, radiotherapy may also be used palliatively for all urological cancers. Further details of treatment regimens and fractionations are contained within treatment protocols are located in the radiotherapy department. For further information please contact Joanne McCarthy Clinic Coordinator joanne.mccarthy@belfasttrust.hscni.net or cristiona.mccavana@belfasttrust.hscni.net

9.0 REGIONAL GUIDELILNES FOR THE SURGICAL TREATMENT AND MANAGEMENT OF UROLOGY CANCER

Document Title	**Guidelines for the Surgical Treatment and Management of Urological Cancer**
Document Date	March 2011 – Final Version January 2016 – Version updated and finalised
Document Purpose	This guidance has been produced to support the diagnosis, treatment and management of urological cancer Treatment decisions for individual patients require the weighing of a multiplicity of factors, which cannot all be accounted for in a CMG. The CMG provides a description of the range of treatment options available for a clinical scenario. To maximise the benefit of multi-professional working management strategies for the individual are best discussed with a multidisciplinary meeting (MDM)
Authors	Ali Thwaini, BHSCT
Version Changes	It was agreed at the Urology Network Meeting on 11th June 2014 to review the Surgical components of the EAU guidelines for urological cancers. Mr Ali Thwaini has developed new Urological surgical guidelines to reflect practice within NI. It was agreed at the Urology Network Meeting on 17th April 2015 that the EAU guidelines for Kidney would continue to be adopted by the Network group until the guideline has been reviewed by the relevant core members to highlight exceptions in practice in NI.

9.1 Bladder Cancer Surgical Guidelines (2014)

Bladder Cancer

Epidemiology:
Bladder cancer is the ninth most commonly diagnosed cancer worldwide, with more than 380,000 new cases each year and more than 150,000 deaths per year, and an estimated male-female ratio of 3.8:1. At any one time, 2.7 million people have a history of urinary bladder cancer. Recently, overall and stage-specific age-adjusted incidence rates of bladder cancer have been analysed in the U.S. (5 year survival and mortality rates between 1973 and 2009). Although the analysis of the Surveillance, Epidemiology and End Results (SEER) database implies some limitations it is worrying to note that in the last 30 years the mortality rate associated with bladder cancer has not changed substantially, highlighting gaps in diagnosis, monitoring and management of these patients (3). At the initial diagnosis of bladder cancer, 70% of cases are diagnosed as non-muscle-invasive bladder cancer (NMIBC) and approximately 30% as muscle-invasive bladder cancer (MIBC). Among patients treated with radical cystectomy because of MIBC, 57% had muscle invasion at presentation, while 43% were initially 8 MUSCLE-INVASIVE AND METASTATIC BLADDER CANCER - LIMITED UPDATE APRIL 2014 diagnosed with NMIBC that progressed despite organ-preserving treatment (4). Approximately one-third of patients diagnosed with MIBC have undetected metastases at the time of treatment for the primary tumour (5), while 25% of patients who undergo radical cystectomy present with lymph node involvement at the time of surgery.

Risk factors:
Tobacco smoking:

- is the most well-established risk factor for bladder cancer, causing 50-65% of male cases and 20-30% of female cases
- the incidence of bladder cancer is directly related to the duration of smoking and the number of cigarettes smoked per day
- the risk of bladder cancer is also higher in those who start smoking at a young age or who are exposed to environmental tobacco smoke during childhood
- the reduction of bladder cancer was about 40% within 1-4 years of quitting smoking and 60% after 25 years of cessation.

Occupational exposure:

- is the second most important risk factor for bladder cancer. Work-related cases have accounted for 20-25% of all bladder cancer cases in several series.
- substances involved in chemical exposure include benzene derivatives and aryl amines (2-naphthylamine, 4-ABP, 4,4’-methylenedianiline, and o-toluidine), and it is likely to occur in occupations in which dyes, rubbers, textiles, paints, leathers, and chemicals are used .

- risk of bladder cancer due to occupational exposure to carcinogenic aromatic amines is significantly greater after 10 years or more of exposure; the mean latency period usually exceeds 30 years.
- carcinogens can be inactivated by a metabolic acetylation pathway. The presence of an NAT2 slowacetylation genotype has been associated with a higher risk of bladder cancer (16), suggesting that patients who are slow acetylators may be more susceptible to bladder cancer than rapid acetylators. Other risk factors include phenacetin, which the International Agency for Research on Cancer (IARC) included in 1987 among proven human carcinogens. Some studies have suggested that the risk of bladder cancer due to phenacetin is dose-dependent; however, the data concerning its metabolite acetaminophen are controversial.

Radiotherapy: Increased rates of secondary bladder malignancies have been reported after external-beam radiotherapy (EBRT) for gynaecological malignancies, with relative risks of 2-4.

Dietary factors have been considered to be related to bladder cancer; however, the links remain controversial. Currently, there is limited evidence of a causal relationship between bladder cancer and dietary factors.

Bladder schistosomiasis (bilharzia) is the second most common parasitic infection after malaria, with about 600 million people exposed to infection in Africa, Asia, South America, and the Caribbean.

Chronic urinary tract infection: bladder cancer, particularly invasive squamous cell carcinoma, has been linked to the presence of chronic urinary tract infection (UTI) distinct from schistosomiasis. A direct association between bladder cancer and UTIs has been observed in several case-control studies, which have reported a two-fold increased risk of bladder cancer in patients with recurrent UTIs in some series.

Chemotherapy: The use of cyclophosphamide, an alkylating agent used to treat lymphoproliferative diseases and other nonneoplastic diseases, has been correlated with subsequent development of MIBC, with a latency period of 6-13 years. Acrolein is a metabolite of cyclophosphamide and is responsible for the increase in the incidence of bladder cancer. This effect occurs independently of the association of haemorrhagic cystitis with the same treatment and was counteracted with concomitant application of mercapto-ethanesulfonate (MESNA).

Synchronous and metachronous upper urinary tract tumours: In some cases, there is an association between upper tract urothelial carcinoma (UTUC) and bladder cancer.

- The incidence of UTUC after a diagnosis of NMIBC has been reported to be between 1.7% and 26%. Although synchronous UTUC and NMIBC are uncommon, 46% of UTUCs are invasive. In a retrospective review of 1,529 patients with primary non-muscle-invasive bladder carcinoma who underwent initial examination of the upper urinary tract with excretory urography, those with a tumour in the bladder trigone were almost six times more likely to develop a synchronous tumour in the upper urinary tract. Examination of the upper urinary tract alone in patients with a tumour in the trigone or with multiple bladder tumours was capable of diagnosing 41% or 69% of UTUCs, respectively.
- In multiple and high-risk tumours, there is an increased risk of tumour recurrence in the upper urinary tract.
- Carcinoma in situ (CIS) in the bladder is an important risk factor for subsequent upper urinary tract recurrence . It has been shown in various studies that tumour involvement of the distal ureter at RC is an independent risk factor for metachronous upper urinary tract (mUUT) recurrence, with an approximate 2.6-fold increase in the relative risk.
- The overall incidence of bladder cancer developing after treatment for UTUC has been reported in the literature as 15-50%.

Gender:

- women were more likely to be diagnosed with primary muscle-invasive disease than men (85% vs. 51%).
- women are more likely to be older than men when diagnosed, with a direct effect on their survival. In addition, delayed diagnosis is more likely in women after haematuria is observed, as the differential diagnosis in women includes diseases that are more prevalent than bladder cancer.
- Differences in the gender prevalence of bladder cancer may be due to other factors besides tobacco and chemical exposure. In a large prospective cohort study, postmenopausal status was associated with an increase in bladder cancer risk, even after adjustment for smoking status.

Ethnic and socioeconomic status: There are limited data on this topic, but a study based on 13,234 cases diagnosed in the SEER database in the period 1979-2003 showed that the survival time from diagnosis was significantly lower among cancer cases in patients with low socioeconomic status (SES) compared with those with higher SES. Hazard ratios for all causes and cancer-specific mortality among blacks in comparison with whites for eight of the most common types of cancer combined lost statistical significance after adjustment for SES factors and treatments. However, blacks still had unfavourable prognoses in comparison with whites even after adjustment for SES and treatment for tumours such as breast, colorectal, and urinary bladder cancer (44).

Genetic factors: There is growing evidence that genetic susceptibility factors and family associations may influence the incidence of bladder cancer. The relationship between family history of cancer and risk of bladder cancer was examined in the Spanish Bladder Cancer Study. It was found that family history of cancer in first-degree relatives was associated with an increased risk of bladder cancer; the association being stronger among younger patients. Shared environmental exposure was recognised as a potentially confounding factor.

TNM classification of urinary bladder cancer (2009)

T - Primary Tumour
Tx Primary tumour cannot be assessed
T0 No evidence of primary tumour
Ta Non-invasive papillary carcinoma
Tis Carcinoma in situ: “flat tumour”
T1 Tumour invades subepithelial connective tissue
T2 Tumour invades muscle
T2a Tumour invades superficial muscle (inner half)
T2b Tumour invades deep muscle (outer half)
T3 Tumour invades perivesical tissue:
T3a Microscopically
T3b Macroscopically (extravesical mass)
T4 Tumour invades any of the following: prostate stroma, seminal vesicles, uterus, vagina, pelvic wall, abdominal wall
T4a Tumour invades prostate stroma, seminal vesicles, uterus, or vagina
T4b Tumour invades pelvic wall or abdominal wall
N - Regional Lymph Nodes
Nx Regional lymph nodes cannot be assessed
N0 No regional lymph-node metastasis
N1 Metastasis in a single lymph node in the true pelvis (hypogastric, obturator, external iliac, or presacral)
N2 Metastasis in multiple lymph nodes in the true pelvis (hypogastric, obturator, external iliac, or presacral)
N3 Metastasis in common iliac lymph node(s)
M - Distant Metastasis
M0 No distant metastasis
M1 Distant metastasis

World Health Organization grading for bladder cancer

1973 WHO grading
Urothelial papilloma
Grade 1: well differentiated
Grade 2: moderately differentiated
Grade 3: poorly differentiated

2004 WHO grading
Flat lesions Hyperplasia (flat lesion without atypia or papillary aspects)
Reactive atypia (flat lesion with atypia)
Atypia of unknown significance
Urothelial dysplasia
Urothelial CIS is always high-grade
Papillary lesions
Urothelial papilloma (completely benign lesion)
Papillary urothelial neoplasm of low malignant potential (PUNLMP)
Low-grade papillary urothelial carcinoma
High-grade papillary urothelial carcinoma

Non-muscle-invasive (Ta, T1 and CIS) Bladder Cancer

Diagnosis and Initial Treatment Steps

The following guidelines for urgent referral (within two weeks) have been published by the Department of Health:

- Macroscopic haematuria in adults.
- Microscopic haematuria in adults over 50 years.
- Swellings in the body of the testis.
- Palpable renal masses.
- Solid renal masses found on imaging.
- Elevated age-specific prostate specific antigen (PSA) in men with a 10 year life expectancy.
- A high PSA (>20ng/ml) in men with a clinically malignant prostate or bone pain.
- Any suspected penile cancer.

Papillary (Ta, T1) Tumours

The diagnosis of papillary BC ultimately depends on cystoscopic examination of the bladder and histological evaluation of the resected tissue.

The standard initial therapy for Ta and T1 papillary bladder tumours is complete macroscopic transurethral resection (TURB), including a part of the underlying muscle. TURB should be performed systematically in individual steps, which Non-muscle invasive (Ta, T1, CIS) Bladder Cancer 11 are described in the full version of the guidelines. Small tumours (< 1 cm) can be resected en bloc, including a part of the underlying muscle. Larger tumours should be resected separately in fractions, which include the exophytic part of the tumour, the underlying bladder wall with the detrusor muscle and the edges of the resection area. The specimens from different fractions must be referred to the pathologist in separate containers.

A second TURB 2-6 weeks after initial resection is recommended in the following situations:

- After incomplete initial TURB, if there was no muscle in the specimen after initial resection (with exception of Ta low grade (G1) tumours);
- In all T1 tumours and in all high grade (G3) tumours (except primary CIS).

CIS

CIS is diagnosed by a combination of cystoscopy, urine cytology, and histological evaluation of multiple bladder biopsies.

Biopsies are taken from suspect areas. In patients with positive urine cytology and no papillary tumour, multiple biopsies from normal looking mucosa including prostatic urethra (random

biopsies) are recommended. If equipment is available, photodynamic diagnosis (PDD) is a useful tool to target the biopsy in these patients. Urine cytology is useful in the diagnosis and follow-up of CIS. CIS cannot be eradicated by TURB and further treatment is mandatory.

Guidelines for primary assessment of NMIBC	GR
Patient history should be taken and recorded regarding all important information with a possible association with bladder cancer, including risk factors and suspicious symptoms.	A
Renal and bladder US may be used during the initial work-up in patients with haematuria.	C
At the time of the initial diagnosis of bladder cancer, CT urography (or IVU) should be performed only in selected cases (e.g., tumours located in the trigone).	B
Cystoscopy is recommended in all patients with symptoms suggestive of bladder cancer. It cannot be replaced by cytology or by any other non-invasive test.	A

Guidelines for primary assessment of NMIBC	GR
Cystoscopy should describe all macroscopic features of the tumour (site, size, number and appearance) and mucosal abnormalities. A bladder diagram is recommended.	C
Voided urine cytology is advocated to predict high grade tumour before TURB.	C
Cytology should be performed on fresh urine with adequate fixation. Morning urine is not suitable because of the frequent presence of cytolysis.	C

TURB	GR
TURB should be performed systematically in individual steps: • bimanual palpation under anaesthesia; • insertion of the resectoscope, under visual control with inspection of the whole urethra; • inspection of the whole urothelial lining of the bladder; • biopsy from prostatic urethra (if indicated); • cold-cup bladder biopsies (if indicated); • resection of the tumour; • bimanual palpation after resection; • protocol formulation; • formulation of order form for pathological evaluation.	C
Perform resection in one piece for small papillary tumours (< 1 cm), including part from the underlying bladder wall.	B
Perform resection in fractions (including muscle tissue) for tumours > 1 cm in diameter.	B
Biopsies should be taken from abnormal-looking urothelium. Biopsies from normal-looking mucosa (trigone, bladder dome, and right, left, anterior and posterior bladder walls) are recommended only when cytology is positive or when exophytic tumour has a non-papillary appearance.	C
Biopsy of the prostatic urethra is recommended for cases of bladder neck tumour, when bladder CIS is present or suspected, when there is positive cytology without evidence of tumour in the bladder, or when abnormalities of the prostatic urethra are visible. If biopsy is not performed during the initial procedure, it should be completed at the time of the second resection.	C
Biopsy of the prostatic urethra should be taken from abnormal areas and from the precollicular area (between 5 and 7 o'clock position) using a resection loop. In primary non-muscle-invasive tumours when stromal invasion is not suspected, the cold-cup biopsy with forceps can be used.	C
If equipment is available, fluorescence-guided (PDD) biopsy should be performed instead of random biopsies when bladder CIS or high-grade tumour is suspected (e.g., positive cytology, recurrent tumour with previous history of a high-grade lesion)	B
The specimens from different biopsies and resection fractions must be referred	C

TURB	GR
to the pathologist in separate containers and labelled separately.	
TURB protocol must describe all steps of the procedure, as well as the extent and completeness of resection.	C
A second TURB is recommended in the following situations: • after incomplete initial TURB; • if there is no muscle in the specimen after initial resection, with exception of Ta G1 tumours and primary CIS; • in all T1 tumours; • in all G3 tumours, except primary CIS.	A
When done, a second TURB should be performed within 2-6 weeks after initial resection.	C

Classification and pathological report	**GR**
Depth of tumour invasion is classified according to the TNM system.	A
For histological classification, 1973 and 2004 WHO grading systems are used. Until the WHO 2004 is validated by more prospective trials and incorporated into prognostic models, both classifications should be used.	A
Whenever the terminology NMIBC is used in individual cases, the tumour stage and grade should be mentioned.	A
The pathological report should specify tumour location, tumour grade, depth of tumour invasion, presence of CIS, and whether the detrusor muscle is present in the specimen.	A
The pathological report should specify the presence of LVI or unusual histology	C

CIS = carcinoma in situ;
CT = computed tomography;
IVU = intravenous urography;
LVI = lymphovascular invasion;
PDD = photodynamic diagnosis;
US = ultrasound;
TURB = transurethral resection of the bladder

Prognostic Factors and Adjuvant Treatment

It is recommended to stratify patients according to prognostic factors into three risk groups that will facilitate treatment recommendations. Their definition, which takes into account the EORTC risk tables probabilities of recurrence and especially progression, can be found in Table 3. For individual prediction of the risk of tumour recurrence and progression at different intervals after TURB, application of EORTC risk tables and calculator (http://www.eortc.be/tools/bladdercalculator/) is strongly recommended.

Table 3: Treatment recommendations in Ta, T1 tumours and CIS according to risk stratification

Risk Category	**Definition**	**Treatment recommendation**
Low-risk Tumours	Primary, solitary, Ta, LG/ G1, < 3 cm, no CIS	One immediate instillation of Chemotherapy
Intermediate risk tumours	All cases between categories of low and high risk	One immediate instillation of Chemotherapy followed by further instillations, either chemotherapy for a maximum of 1 year or 1-year full dose BCG
High-risk Tumours	Any of the following: • T1 tumours; • HG/G3 tumours; • CIS; • Multiple and recurrent and large (> 3 cm) Ta G1G2 tumours (all these conditions must be presented)	Intravesical full dose BCG instillations for 1-3 years or cystectomy (in highest-risk tumours)
Subgroup of highest-risk tumours	T1G3 associated with concurrent bladder CIS, multiple and/or large T1G3 and/or recurrent T1G3, T1G3 with CIS in prostatic urethra, micropapillary variant of urothelial carcinoma, LVI	Radical cystectomy should be considered
	BCG failures	Radical cystectomy is recommended

CIS = carcinoma in situ; HG = high-grade; LG = low-grade; LVI = lymphovascular invasion

Since there is considerable risk for recurrence and/or progression of tumours after TURB, adjuvant intravesical therapy is recommended for all stages (Ta, T1, and CIS). Immediate postoperative

instillation of chemotherapy within 6 hours after TURB is recommended in tumours presumed to be at low or intermediate risk, except in cases of bladder perforation or severe bleeding. The choice of drug (mitomycin C, epirubicin, or doxorubicine) is optional. Intravesical chemotherapy reduces the risk of recurrence but not progression and is associated with minor side-effects. Intravesical immunotherapy with Bacillus Calmette-Guérin (BCG) (induction and maintenance) is superior to intravesical chemotherapy in reducing recurrences and in preventing or delaying progression to muscle-invasive bladder cancer. However, intravesical BCG is more toxic. The individual choice

of further intravesical adjuvant therapy depends on the patient's risk (Table 3). In patients at highest risk of progression (Table 3), radical cystectomy should be considered in patients with BCG failure since they are unlikely to respond to further BCG therapy; radical cystectomy is therefore the preferred option.

Recommendations for adjuvant therapy in Ta, T1 tumours and for therapy of CIS	GR
Smokers with confirmed NMIBC should be counselled to stop smoking.	B
The type of intravesical therapy should be based on risk groups.	A
One immediate chemotherapy instillation is recommended in tumours presumed to be at low or intermediate risk.	A
In patients with low-risk tumours, one immediate instillation of chemotherapy is recommended as the complete adjuvant treatment.	A
In patients with intermediate-risk Ta tumours, one immediate instillation of chemotherapy should be followed by 1-year full-dose BCG treatment, or by further instillation of chemotherapy for a maximum of 1 year.	A
In patients with high-risk tumours, full-dose intravesical BCG for 1-3 years is indicated.	A
In patients with CIS in the epithelial lining of the prostatic urethra, TUR of the prostate followed by intravesical instillation of BCG can be offered.	C
In patients at highest risk of tumour progression (Table 3), immediate radical cystectomy should be considered.	C
In patients with BCG failure, radical cystectomy is indicated.	B
In patients with BCG failure ineligible for radical cystectomy, gemcitabine or MMC in combination with hyperthermia are options.	C

Intravesical chemotherapy	GR
One immediate instillation should be administered within 24 hours after TURB.	C

One immediate instillation of chemotherapy should be omitted in any case of overt or suspected intra- or extra-peritoneal perforation (after extensive TURB, or bleeding requiring bladder irrigation).	C
The optimal schedule of further intravesical chemotherapy instillation and its duration is not defined and should not exceed 1 year.	C
If intravesical chemotherapy is given, it is advised to use the drug at its optimal pH and to maintain the concentration of the drug during instillation by reducing fluid intake.	B
The length of individual instillation should be 1-2 hours.	C

BCG intravesical immunotherapy	GR
Absolute contraindications of BCG intravesical instillation are: • during the first 2 weeks after TURB; • in patients with macroscopic haematuria; • after traumatic catheterization; • in patients with symptomatic urinary tract infection.	C
The management of side effects after BCG intravesical instillation should reflect their type and grade	C

BCG = bacillus Calmette-Guérin;
CIS = carcinoma in situ;
MMC = mitomycin C;
TUR = transurethral resection;
TURB =transurethral resection of the bladder

Follow-up for Non-Muscle Invasive Bladder Tumours

As a result of the risk of recurrence and progression, patients with Ta, T1 bladder tumours and with CIS need to be followed up. However, the frequency and duration of cystoscopy and imaging should reflect the individual patient's degree of risk.

When planning the follow-up schedule and methods, the following aspects should be considered:

- The prompt detection of muscle-invasive and HG/G3 nonmuscle-invasive recurrence is crucial because a delay in diagnosis and therapy can be life-threatening.

- Tumour recurrence in the low-risk group is nearly always low stage and LG/G1.

Small, non-invasive (Ta), LG/G1 papillary recurrence does not present an immediate danger to the patient, and early detection is not essential for successful therapy (LE: 2b).

Fulguration of small papillary recurrences on an outpatient basis could be a safe option that reduces the therapeutic burden.

- The first cystoscopy after TURB at 3 months is a very important prognostic indicator for recurrence and progression. The first cystoscopy should thus always be performed.

3 months after TURB in all patients with Ta, T1 tumours and CIS.

- In tumours at low risk, the risk of recurrence after 5 recurrence-free years is low.
- Discontinuation of cystoscopy or its replacement with less invasive methods can be considered.
- In tumours originally intermediate- or high-risk, recurrences after 10 years tumour-free are not unusual. Therefore, lifelong follow-up is recommended.
- The risk of upper urinary tract recurrence increases in patients with multiple and high-risk tumours.
- Positive urine test results have a positive impact on the quality of performed follow-up cystoscopy). It supports the adjunctive role of urine tests during follow-up.

The following recommendations are only based on retrospective experience.

Recommendations for follow-up	GR
The follow-up of Ta, T1 tumours and CIS is based on regular cystoscopy.	A
Patients with low-risk tumours should undergo cystoscopy at 3 months. If negative, subsequent cystoscopy is advised 9 months later, and then yearly for 5 years.	C
Patients with high-risk tumours should undergo cystoscopy and urinary cytology at 3 months. If negative, subsequent cystoscopy and cytology should be repeated every 3 months for a period of 2 years, and every 6 months thereafter until 5 years, and then yearly	C
Patients with intermediate-risk Ta tumours should have an in-between follow-up scheme using cystoscopy and cytology, which is adapted according to personal and subjective factors.	C
Regular (yearly) upper tract imaging (CT-IVU or IVU) is recommended for high-risk tumours.	C
Endoscopy under anaesthesia and bladder biopsies should be performed when office cystoscopy shows suspicious findings or if urinary cytology is	B

Recommendations for follow-up	GR
positive	
During follow-up in patients with positive cytology and no visible tumour in the bladder, R-biopsies or biopsies with PDD (if equipment is available) and investigation of extravesical locations (CT urography, prostatic urethra biopsy) are recommended.	B

CIS = carcinoma in situ;
CT-IVU = computed tomography intravenous urography;
IVU = intravenous urography;
PDD = photodynamic diagnosis;
R-biopsies = random biopsies.

Bladder Cancer – Muscle invasive and metastatic

DIAGNOSIS AND STAGING

Primary diagnosis

Symptoms: Painless haematuria is the most common presenting complaint. Others include urgency, dysuria, increased frequency, and in more advanced tumours, pelvic pain and symptoms related to urinary tract obstruction.

Physical examination: including rectal and vaginal bimanual palpation. A palpable pelvic mass can be found in patients with locally advanced tumours. In addition, bimanual examination under anaesthesia should be carried out before and after TURB, to assess whether there is a palpable mass or if the tumour is fixed to the pelvic wall. However, considering the discrepancy between bimanual examination and pT stage after cystectomy (11% clinical overstaging and 31% clinical understaging), some caution is suggested with the interpretation of bimanual examination.

Endoscopic bladder imaging: Ultimately, the diagnosis of bladder cancer is made by cystoscopy and histological evaluation of resected tissue. In general, cystoscopy is initially performed in the office using flexible instruments. If a bladder tumour has been visualised unequivocally in earlier imaging studies, such as computed tomography (CT), magnetic resonance imaging (MRI), or ultrasound (US), diagnostic cystoscopy may be omitted and the patient can proceed directly to TURB for histological diagnosis. A careful description of the cystoscopic findings is necessary. This should include documentation of the site, size, number, and appearance (papillary or solid) of the tumours, as well as a description of mucosal abnormalities. Use of a bladder diagram is recommended. The use of photodynamic diagnosis could be considered, especially if a T1 high-grade tumour is present, to find associated CIS. The additional presence of CIS may lead to a modified treatment

plan. Photodynamic diagnosis is highly sensitive for the detection of CIS; with experience, the rate of false-positive results may be similar to that with regular white-light cystoscopy.

Urinary cytology and urinary markers: Examination of voided urine or bladder washings for exfoliated cancer cells has high sensitivity in high-grade tumours (LE: 3) and is a useful indicator in cases of high-grade malignancy or CIS. Positive urinary cytology may originate from a urothelial tumour located anywhere in the urinary tract. Evaluation of cytology specimens can be hampered by low cellular yield, UTIs, stones or intravesical instillations, but for experienced readers, specificity exceeds 90% (LE: 2b). However, negative cytology does not exclude tumour. Cytology should be performed on fresh urine with adequate fixation. Early morning urine is not suitable as cytolysis may often be present. There is no known urinary marker specific for the diagnosis of invasive bladder cancer.

Random bladder and prostatic urethral biopsy: Bladder tumours are often multifocal and can be accompanied by CIS or dysplasia. These lesions may present themselves as velvet-like, reddish areas, indistinguishable from inflammation, or may not be visible at all. The biopsies from normal-looking mucosa in patients with invasive bladder tumours, so-called random biopsies (R-biopsies) show a low yield. Fluorescence cystoscopy is performed using filtered blue light after intravesical instillation of a photosensitiser, such as 5-aminolevulinic acid (5-ALA), and more recently, hexaminolaevulinate (HAL), following approval by the European Medicines Agency. It has been confirmed that fluorescence-guided biopsy and resection are more sensitive than conventional procedures in detecting malignant tumours, particularly CIS (9-12) (LE: 2a). However, false-positive results may be induced by inflammation, or recent TURB or intravesical instillation therapy. A recent multicentre, prospective, international trial showed that, in experienced hands, the rate of false-positive results is no higher than that seen for regular, white-light cystoscopy (7). Material obtained by random or directed biopsies must be sent for pathological assessment in separate containers. The involvement of the prostatic urethra and ducts in men with bladder tumours has been reported. The exact risk is not known, but it seems to be higher if the tumour is located on the trigone or bladder neck, in the presence of bladder CIS, and in multiple tumours (LE: 3). Involvement of the prostatic urethra can be determined either at the time of primary TURB or by frozen section during the cystoprostatectomy procedure. A frozen section has a higher negative predictive value and is more accurate.

Second resection: In the case of high-grade non-muscle-infiltrative tumour, residual disease is observed in 33-53% of patients (18-24). In order to reduce the risk of understaging, a second TURB resection is often required to determine the future treatment strategy. In consultation with the patient, orthotopic neobladder should be considered in case reconstructive surgery does not expose the patient to excessive risk (as determined by comorbidity and age). Age greater than 80 years is often

considered to be the threshold after which neobladder reconstruction is not recommended, however, there is no exact age for strict contraindication. In most large series coming from experienced centres, the rate of orthotopic bladder substitution after cystectomy for bladder tumour is up to 80% for men and 50% for women. Nevertheless, no randomized controlled studies comparing conduit diversion with neobladder or continent cutaneous diversion have been performed. Diagnosis of urethral tumour before cystectomy or positive urethral frozen section leads to uretrectomy and therefore excludes neobladder reconstruction. If indicated, in males urethral frozen section has to be performed on the cysto-prostatectomy specimen just under the verumontanum and on the inferior limits of the bladder neck for females. When there are positive lymph nodes, orthotopic neobladder can nevertheless be considered in case of N1 involvement (metastasis in a single node in the true pelvis) but not for N2 or N3 tumours. Oncological results after orthotopic neobladder substitution or conduit diversion are similar in terms of local or distant metastasis recurrence, but secondary urethral tumours seem less common in patients with neobladder compared with those with conduits or continent cutaneous diversions.

Imaging for staging MIBC: The treatment and prognosis for MIBC is determined by tumour stage and grade. In clinical practice, CT and MRI are the imaging techniques used. The purpose of using imaging for staging MIBC is to determine prognosis and provide information to assist treatment selection. Tumour staging must be accurate to ensure the correct choice of treatment is made. Imaging parameters required for staging MIBC are:

- extent of local tumour invasion;
- tumour spread to lymph nodes;
- tumour spread to the upper urinary tract and other distant organs (e.g., liver, lungs, bones, peritoneum, pleura, and adrenal glands).

CT imaging for local staging of MIBC: The advantages of CT include high spatial resolution, shorter acquisition time, wider coverage in a single breath hold, and lower susceptibility to variable patient factors. Computed tomography is unable to differentiate between stages Ta and T3a tumours, but it is useful for detecting invasion into the perivesical fat (T3b) and adjacent organs. The accuracy of CT in determining extravesical tumour extension varies from 55% to 92% and increases with more advanced disease.

MRI for local staging of invasive bladder cancer: Magnetic resonance imaging has superior soft tissue contrast resolution compared with CT, but poorer spatial

resolution. In studies performed before the availability of multidetector CT, MRI was reported as more accurate in local assessment. The accuracy of MRI for primary tumour staging varies from 73% to 96% (mean 85%). These values were 10-33% (mean 19%) higher than those obtained with CT. Dynamic contrast-enhanced (DCE) MRI may help to differentiate bladder tumour from surrounding tissues or post-biopsy reaction, because enhancement of the tumour occurs earlier than that of the normal bladder wall, due to neovascularisation. In 2006, a link was established between the use of gadolinium-based contrast agents and nephrogenic systemic fibrosis (NSF), which may result in fatal or severely debilitating systemic fibrosis. Patients with impaired renal function are at risk of developing NSF and the non-ionic linear gadolinium-based contrast agents should be avoided (gadodiamide, gadopentetate dimeglumine and gadoversetamide). A stable macrocyclic contrast agent should be used (gadobutrol, gadoterate meglumine or gadoteridol). Alternatively, contrast-enhanced CT could be performed using iodinated contrast media (LE: 4).

TREATMENT

Recommendations for treatment failure of non-muscle-invasive bladder cancer

Recommendations	GR
In all T1 tumours at high risk of progression (i.e., high grade, multifocality, CIS, and tumour size, as outlined in the EAU guidelines for non-muscle-invasive bladder cancer [7]), immediate radical treatment is an option	**C**
In all T1 patients failing intravesical therapy, radical treatment should be offered.	**B**

CIS = carcinoma in situ

NEOADJUVANT CHEMOTHERAPY

Advantages and disadvantages:

- Chemotherapy is delivered at the earliest time-point, when the burden of micrometastatic disease is expected to be low.

- Potential reflection of in vivo chemosensitivity.

- Tolerability of chemotherapy and patient compliance are expected to be better before rather than after cystectomy.
- Patients might respond to neoadjuvant therapy and reveal a favourable pathological status, determined mainly by achieving pT0, a negative lymph node status, and negative surgical margins.

- Delayed cystectomy might compromise the outcome in patients not sensitive to chemotherapy (8,9), although published studies on the negative effect of delayed cystectomy only entail series of chemonaive patients. There are no trials or large patient series indicating that delayed surgery, due to neoadjuvant chemotherapy, has a negative impact on survival.

Conclusions	**LE**
Neoadjuvant cisplatin-containing combination chemotherapy improves overall survival (5-8% at 5 years).	1a
Neoadjuvant treatment of responders and especially patients who show complete response (pT0 N0) has a major impact on OS.	2
Currently, no tools are available to select patients who have a higher probability to benefit from neoadjuvant chemotherapy. In the future, genetic markers, in a personalised medicine setting, might facilitate the selection of patients for neoadjuvant chemotherapy and to differentiate responders from non-responders.	

Recommendations	**GR**
Neoadjuvant chemotherapy is recommended for T2-T4a, cN0M0 bladder cancer and should always be cisplatin-based combination therapy.	A
Neoadjuvant chemotherapy is not recommended in patients who are ineligible for cisplatin-based combination chemotherapy.	A

RADICAL SURGERY AND URINARY DIVERSION

Radical cystectomy is the standard treatment for localised MIBC in most western countries. Recent interest in patients' quality of life (QoL) has increased the trend toward bladder preservation treatment modalities, such as radio- and/or chemotherapy. Performance status (PS) and age influence the choice of primary therapy, as well as the type of urinary diversion, with cystectomy being reserved for younger patients without concomitant disease and with a better PS. The value of assessing overall health before recommending and proceeding with surgery was emphasised in a multivariate analysis. The analysis found an association between comorbidity and adverse pathological and survival outcome following radical cystectomy. PS and comorbidity have a different impact on treatment outcome and must be evaluated independently. Controversy remains about age, radical cystectomy and the type of urinary diversion. Cystectomy is associated with the greatest risk reduction in disease-related and non-disease-related death in patients aged > 80 years. The largest, retrospective, single-institution study on cystectomy to date found that patients aged > 80 years had increased postoperative morbidity but

not increased mortality. Although some patients successfully underwent a neobladder procedure, most patients were treated with an ileal conduit diversion. It is particularly important to evaluate the function and QoL of elderly patients using a standardised geriatric assessment, as well as carrying out a standard medical evaluation.

Each network should agree clear guidelines on treatment and follow up of bladder cancer which ensure that cystectomy is considered for patients with muscle-invasive or high-risk recurrent disease. Cystectomy is a complex operation which should be undertaken only by specialist surgeons working in cancer centres. Ideally, all radical cystectomies undertaken in each network should be carried out by a single team. Teams providing this form of surgery should carry out a cumulative total of at least 50 radical operations (cystectomies or radical prostatectomies) for bladder or prostate cancer per year.

Timing and delay of cystectomy:

Patients treated > 90 days after the primary diagnosis showed a significant increase in extravesical disease (81 vs 52%). Delay in cystectomy affects treatment outcome and the type of urinary diversion. In organ-confined urothelial cancer of the bladder, the average time from primary diagnosis to cystectomy was 12.2 months in patients who received a neobladder and 19.1 months in those who received an ileal conduit. This was even more noticeable with organ-confined invasive cancer; the average time to surgery was 3.1 months with a neobladder and 15.1 months with an ileal conduit (8). Similar results have been observed in a series of 247 patients: recurrence-free survival and OS were significantly better in patients treated before 90 days compared to others treated after 90 days.

LN removal at the time of cystectomy:

The extent of LND has not been established to date. Standard lymphadenectomy in bladder cancer patients involves removal of nodal tissue cranially up to the common iliac bifurcation, with the ureter being the medial border, and including the internal iliac, presacral, obturator fossa and external iliac nodes (10). Extended lymphadenectomy includes all lymph nodes in the region of the aortic bifurcation, and presacral and common iliac vessels medial to the crossing ureters. The lateral borders are the genitofemoral nerves, caudally the circumflex iliac vein, the lacunar ligament and the lymph node of Cloquet, as well as the area described for standard lymphadenectomy. A super-extended lymphadenectomy extends cranially to the level of the inferior mesenteric artery.

Morbidity and mortality from cystectomy:

The perioperative mortality was reported as 1.2-3% at 30 days and 2.3-5.7% at 90 days. In a large single-centre series, early complications (within 3 months of surgery) were seen in 58% of patients. Late morbidity is usually due to the type of urinary diversion. Early morbidity associated with radical cystectomy for NMIBC (at high risk for disease progression) is similar and no less than that associated with muscle-invasive tumours. In general, lower morbidity and (perioperative) mortality have been observed by surgeons and in hospitals with a higher caseload and therefore more experience.

Survival:

According to a multi-institutional database of 888 consecutive patients undergoing radical cystectomy for bladder cancer, the 5-year recurrence-free survival was 58% and the cancer-specific survival was 66%. Recent external validation of postoperative nomograms for bladder-cancer-specific mortality showed similar results, with 5-year OS of 45% and cancer-specific survival of 62%. Recurrence-free survival and OS in a large single-centre study of 1,054 patients was 68% and 66% at 5 years and 60% and 43%, at 10 years, respectively. The 5-year recurrence-free survival in node-positive patients who underwent cystectomy was considerably less at 34-43%. However, in patients with a low level of lymph node metastasis, the survival is better. In a surgery only study, the 5-year recurrence-free survival was 76% in patients with pT1 tumours, 74% for pT2, 52% for pT3, and 36% for pT4. Another study reported 10-year disease-specific survival and OS rates of 72.9% versus 49.1% for organ-confined disease (defined as pT < 3a), and 33.3% versus 22.8% for non-organconfined disease. A trend analysis according to the 5-year survival and mortality rates of bladder cancer in the United States, between 1973 and 2009 with a total of 148,315 bladder cancer patients, revealed an increased stage-specific 5-year survival rate for all stages, except for metastatic disease. However, no changes in mortality were recorded among localized and regional stage. In patients with visceral metastases an increase in mortality rates was observed, but differences were minor, and hardly of any clinical importance.

Recommendations:

Recommendations	**GR**
Radical cystectomy is recommended in T2-T4a, N0 M0, and high-risk non-MIBC (as outlined above).	A
Do not delay cystectomy for > 3 months because it increases the risk of progression and cancerspecific mortality.	B
Preoperative radiotherapy is not recommended in subsequent cystectomy with urinary diversion.	A
Lymph node dissection should be an integral part of cystectomy. Extended	B

Recommendations	GR
LND is recommended.	
The urethra can be preserved if margins are negative. If no bladder substitution is attached, the urethra must be checked regularly.	B
Laparoscopic cystectomy and robot-assisted laparoscopic cystectomy are both management options. However, current data have not sufficiently proven the advantages or disadvantages for oncological and functional outcomes.	C
Before cystectomy, the patient should be fully informed about the benefits and potential risks of all possible alternatives, and the final decision should be based on a balanced discussion between patient and surgeon.	B
Pre-operative bowel preparation is not mandatory. “Fast track” measurements may reduce the time of bowel recovery.	C
An orthotopic bladder substitute should be offered to male and female patients lacking any contraindications and who have no tumour in the urethra or at the level of urethral dissection.	B

NON-RESECTABLE TUMOURS

Recommendations	LE	GR
In patients with inoperable locally advanced tumours (T4b), primary radical cystectomy is a palliative option and cannot be offered as curative treatment.		B
In patients with symptoms palliative cystectomy may be offered. Prior to any further interventions, surgery-related morbidity and quality of life should be fully discussed with the patient.	3	B

BLADDER-SPARING TREATMENTS FOR LOCALIZED DISEASE

Transurethral resection of bladder tumour (TURBT)

Recommendation	LE	GR
Transurethral resection of bladder tumour (TURB) alone is not a curative treatment option in most patients.	2a	B

External beam radiotherapy (EBRT)

Based on available trials, a Cochrane analysis has demonstrated that radical cystectomy has an overall survival benefit compared to radiotherapy. However, external radiotherapy is an alternative treatment in patients unfit for radical surgery. The target dose for curative radiotherapy for bladder cancer is 60-66 Gy, with a

subsequent boost using external radiotherapy or interstitial brachytherapy. The daily dose is usually 1.8-2 Gy and the course of radiotherapy should not extend beyond 6-7 weeks to minimize the repopulation of cancer cells. The use of modern standard radiotherapy techniques results in major, related, late morbidity of the urinary bladder or bowel in less than 5% of tumour-free patients. Overall, 5-year survival rates in patients with MIBC range between 30% and 60%, depending on whether they show a complete response (CR) following radiotherapy. Cancer-specific survival rates are between 20% and 50%.

Conclusions:

Conclusions	**LE**
External beam radiotherapy alone should only be considered as a therapeutic option when the patient is unfit for cystectomy or a multimodality bladder-preserving approach.	3
Radiotherapy can also be used to stop bleeding from the tumour when local control cannot be achieved by transurethral manipulation because of extensive local tumour growth.	3

Recommendation:

Recommendation	**GR**
Surgical intervention or multimodality treatment are the preferred curative therapeutic approaches because they are more effective than radiotherapy alone.	B

Chemotherapy

Chemotherapy alone rarely produces durable CRs. In general, a clinical CR rate of up to 56%, as reported in some series, must be weighed against a staging error of > 60%. Response to chemotherapy is a prognostic factor for treatment outcome and eventual survival, though it may be confounded by patient selection. For very selected patients, a bladder-conserving strategy with TURB and systemic cisplatin-based chemotherapy, preferably with MVAC, may allow long-term survival with intact bladder. However, this approach cannot be recommended for routine use.

Conclusion:

Conclusion	**LE**
With cisplatin-based chemotherapy as primary therapy for locally advanced	2b

tumours in highly selected patients, complete and partial local responses have been reported.	
Recommendation	**GR**
Chemotherapy alone is not recommended as primary therapy for localized bladder cancer.	A

Multimodality bladder-preserving treatment

Recent organ-preservation strategies combine TURB, chemotherapy and radiation (1,2). The rationale for performing TURB and radiation is to achieve local tumour control. Application of systemic chemotherapy, most commonly as methotrexate, cisplatin and vinblastine (MCV), aims at the eradication of micrometastasis. Many protocols use cisplatin and/or 5-FU and, recently, gemcitabine with radiation, because of their established role as radiosensitizers. Cisplatin-based chemotherapy in combination with radiotherapy, following TURB, results in a CR of 60-80%.

Conclusions:

Conclusions	**LE**
In a highly selected patient population, long-term survival rates of multimodality treatment are comparable to those of early cystectomy.	3
Delay in surgical therapy can compromise survival rates.	2b

Recommendations	**GR**
Transurethral resection of bladder tumour alone cannot be offered as a standard curative treatment option in most patients.	B
Radiotherapy alone is less effective than surgery and is only recommended as a therapeutic option when the patient is unfit for cystectomy or a multimodality bladder-preserving approach.	B
Chemotherapy alone is not recommended as primary therapy for MIBC.	A
Surgical intervention or multimodality treatments are the preferred curative therapeutic approaches as they are more effective than radiotherapy alone.	B
Multimodality treatment could be offered as an alternative in selected, well-informed, well-selected and compliant patients, especially for whom cystectomy is not an option.	B

ADJUVANT CHEMOTHERAPY

Adjuvant chemotherapy after radical cystectomy for patients with pT3/4 and/or lymph node positive (N+) disease without clinically detectable metastases (M0) is under debate and still infrequently used.

The general benefits of adjuvant chemotherapy include:

- Chemotherapy is administered after accurate pathological staging, therefore treatment in patients at low risk for micrometastases is avoided.
- No delay in definitive surgical treatment.

The drawbacks of adjuvant chemotherapy are:

- Assessment of in vivo chemosensitivity of the tumour is not possible and overtreatment is an unavoidable problem.
- Delay or intolerability of chemotherapy, due to postoperative morbidity.

Conclusions:

Conclusion	**LE**
Neither randomised trials nor two meta-analyses have provided sufficient data to support the routine use of adjuvant chemotherapy.	1a
Recommendations	GR
Adjuvant chemotherapy should only be given within clinical trials, whenever possible.	A
Adjuvant cisplatin based combination chemotherapy may be offered to patients with pN+ disease if no neoadjuvant chemotherapy has been given.	C

METASTATIC DISEASE

Conclusions	LE
In a first-line setting, PS and the presence or absence of visceral metastases are independent prognostic factors for survival.	1b
In a second-line setting, negative prognostic factors are: liver metastasis, PS > 1 and low haemoglobin (< 10 g/dL) 1b Cisplatin-containing combination chemotherapy can achieve median survival of up to 14 months, with long-term disease-free survival reported in ~15% of patients with nodal disease and good PS.	1b
Single-agent chemotherapy provides low response rates of usually short duration.	2a
Carboplatin combination chemotherapy is less effective than cisplatin-based	2a

Conclusions	LE
chemotherapy in terms of complete response and survival.	
Non-platinum combination chemotherapy produces substantial responses in first- and second-line settings, but has not been tested against standard chemotherapy in patients who are fit or unfit for cisplatin combination chemotherapy.	2a
There is no defined standard chemotherapy for unfit patients with advanced or metastatic urothelial cancer.	2b
Vinflunine reaches the highest level of evidence ever reported for second-line use.	1b
Post-chemotherapy surgery after partial or complete response may contribute to long-term diseasefree survival.	3
Zoledronic acid and denosumab have been approved for all cancer types including urothelial cancer, because they reduce and delay skeletal related events in metastatic bone disease.	1b

Recommendations	GR
First-line treatment for fit patients: Use cisplatin-containing combination chemotherapy with GC, PCG, MVAC, preferably with G-CSF, or HD-MVAC with G-CSF.	A
Carboplatin and non-platinum combination chemotherapy is not recommended.	B
First-line treatment in patients ineligible (unfit) for cisplatin: Use carboplatin combination chemotherapy or single agents.	C
For cisplatin-ineligible (unfit) patients, with PS2 or impaired renal function, as well as those with 0 or 1 poor Bajorin prognostic factors and impaired renal function, treatment with carboplatin-containing combination chemotherapy, preferably with gemcitabine/carboplatin is indicated.	A
Second-line treatment: In patients progressing after platinum-based combination chemotherapy for metastatic disease, vinflunine should be offered. Alternatively, treatment within a clinical trial setting may be offered.	A
Zoledronic acid or denosumab is recommended for treatment of bone metastases.	B

9.2 Prostate cancer

Epidemiology

Prostate cancer is the most common cancer in elderly males in Europe. It is a major health concern, especially in developed countries with their greater proportion of elderly men in the general population. The incidence is highest in Northern and Western Europe (> 200 per 100,000), while rates in Eastern and Southern Europe have showed a continuous increase. There is still a survival difference between men diagnosed in Eastern Europe and those in the rest of Europe. Overall, during the last decade, the 5-year relative survival percentages for prostate cancer steadily increased from 73.4% in 1999-2001 to 83.4% in 2005-2007.

There are three well-established risk factors for PCa:

- increasing age;
- ethnic origin;
- heredity

Genetics:

- If one first-line relative has PCa, the risk is at least doubled. If two or more first-line relatives are affected, the risk increases by 5-11-fold.
- A small subpopulation of individuals with PCa (about 9%) have true hereditary PCa. This is defined as three or more affected relatives, or at least two relatives who have developed early onset disease, i.e. before age 55.
- Patients with hereditary PCa usually have an onset six to seven years earlier than spontaneous cases, but do not differ in other ways.

Geography:

- The frequency of autopsy-detected cancers is roughly the same in different parts of the world.
- This finding is in sharp contrast to the incidence of clinical PCa, which differs widely between different geographical areas, being high in the USA and northern Europe and low in South-East Asia.
- However, if Japanese men move from Japan to Hawaii, their risk of PCa increases. If they move to California their risk increases even more, approaching that of American men.

Metabolic syndrome and prostate cancer:

- Metabolic syndrome is weakly and non-significantly associated with the risk of PCa, but associations vary with geography.
- Among single components of the syndrome (body mass index, dysglycaemia or dyslipidaemia, high triglycerides, low HDL cholesterol) only hypertension and waist circumference >102 cm were associated with a significantly greater risk of PCa, increasing it by 15% (p = 0.035) and 56% (p = 0.007), respectively.

Chemoprevention in prostate cancer:

- Currently, there are no data to suggest that medical intervention would effectively reduce progression of PCa.
- Several 5-alpha-reductase inhibitors (5-ARIs) have been studied to assess their effect on reducing risk of developing PCa. Although it seems that 5-ARIs have a potential benefit in preventing or delaying the development of PCa (~25%, only of Gleason 6 cancer), this must be weighed against treatment-related sideeffects as well as the potential increased risk of high-grade PCa. None of the available 5-ARIs have been approved for this indication.

SCREENING FOR PROSTATE CANCER:

Prostate cancer screening is one of the most controversial topics in urological literature. The main summary of findings from literature published on PCa screening is the Cochrane review published in 2013. Its findings are as follows:

- Screening was associated with an increased diagnosis of PCa (RR: 1.3; 95% CI: 1.02-1.65).

- Screening was associated with more localized disease (RR: 1.79; 95% CI: 1.19-2.70) and less advanced PCa (T3-4, N1, M1) (RR: 0.80; 95% CI: 0.73-0.87).

- From the results of five RCTs, representing more than 341,000 randomized men, no PCa-specific survival benefit was observed (RR: 1.00; 95% CI: 0.86-1.17). This was the main objective of all the large trials.

- From the results of four available RCTs, no overall survival benefit was observed (RR: 1.00; 95% CI: 0.96-1.03).

ERSPC: at 11 years of median follow-up, there was a 21% reduction in PCa-specific mortality and a 29% reduction after adjustment for non-compliance. However, there is still no overall survival benefit.

Thus, an individualized risk-adapted strategy for early detection might be offered to a well-informed man with a least 10-15 years of individual life expectancy. Men who have less than a 15-year life expectancy are unlikely to benefit based on the PIVOT and the ERSPC trials. Screening is associated with minor and major harms such as overdiagnosis and overtreatment.

Recommendations:

Recommendations	**LE**	**GR**
An individualized risk-adapted strategy for early detection might be offered to a well-informed man with a good performance status and at least 10-15 years of life expectancy.	3	B
Early PSA testing in men at elevated risk of having PCa: • men over 50 years of age • men over 45 years of age and a family history of PCa • African-Americans • men with a PSA level of > 1 ng/mL at 40 years of age • men with a PSA level of > 2 ng/mL at 60 years of age	2b	A
A risk-adapted strategy might be considered (based on initial PSA level), which may be every 2 years for those initially at risk, or postponed up to 8 years in those not at risk. 3 C The age at which early diagnosis of PCa should be stopped is influenced by life expectancy and performance status; men who have < 15-year life expectancy are unlikely to benefit based on the PIVOT and the ERSPC trials.	3	A

DIAGNOSIS:

The following guidelines for urgent referral (within two weeks) have been published by the Department of Health:

- Macroscopic haematuria in adults.
- Microscopic haematuria in adults over 50 years.
- Swellings in the body of the testis.
- Palpable renal masses.
- Solid renal masses found on imaging.
- Elevated age-specific prostate specific antigen (PSA) in men with a 10 year life expectancy.
- A high PSA (>20ng/ml) in men with a clinically malignant prostate or bone pain.
- Any suspected penile cancer.

Digital rectal examination:

- Most prostate cancers are located in the peripheral zone of the prostate and may be detected by DRE when the volume is about 0.2 mL or larger.
- In about 18% of all patients, PCa is detected by a suspect DRE alone, irrespective of the PSA level.
- A suspect DRE in patients with a PSA level up to 2 ng/mL has a positive predictive value of 5-30%.
- An abnormal DRE is associated with an increased risk of a higher Gleason score and should therefore be considered an indication for prostate biopsy.

Prostate-specific antigen (PSA):

PSA is a kallikrein-like serine protease produced almost exclusively by the epithelial cells of the prostate, which is organ- but not cancer specific. Thus, serum levels may be elevated in the presence of benign prostatic hypertrophy (BPH), prostatitis and other non-malignant conditions. The level of PSA as an independent variable is a better predictor of cancer than suspicious findings on DRE or transrectal ultrasound (TRUS).

PSA and the risk of prostate cancer:

PSA level (ng/mL)	Risk of PCa (%)	Risk of Gleason > 7 PCa (%)
0.0-0.5	6.6	0.8
0.6-1.0	10.1	1.0
1.1-2.0	17.0	2.0
2.1-3.0	23.9	4.6
3.1-4.0	26.9	6.7

Practical modifications of serum PSA value that may improve the specificity of PSA in the early detection of PCa have been described. They include:

- PSA density;
- PSA velocity; defined as the absolute annual increase in serum PSA (ng/mL/year).
- PSA doubling time: the exponential increase in serum PSA over time, reflecting a relative change.
- age-specific reference ranges;
- The free/total PSA ratio: between 4 ng/mL and 10 ng/mL and a negative DRE, PCa was found on biopsy in 56% of men with f/t PSA < 0.10, but in only 8% of men with f/t PSA > 0.25.

PCA3: is an increasingly studied new biomarker that is detectable in urine sediments obtained after three strokes of prostatic massage during DRE. The costly Progensa urine test for PCA3 is now commercially available. The amount of the prostate-specific non-coding mRNA marker PCA3 normalized against PSA mRNA (urine sediment) gives a PCA3 score. This is superior to total PSA and percent-free PSA in the detection of PCa in men with elevated PSA levels as it shows slight but significant increases in the area under the receiveroperator characteristics curve (AUC) for positive biopsies. The main current indication for the PCA3 urine test may be to determine whether a man needs a repeat biopsy after an initially negative biopsy outcome, but its cost-effectiveness remains to be shown.

Prostate biopsy:

- Indications: PSA level and/or a suspicious DRE.

- The first elevated PSA level should not prompt an immediate biopsy.

- The PSA level should be verified after a few weeks by the same assay under standardized conditions (i.e. no ejaculation, no manipulations such as catheterisation, cystoscopy or transurethral resection, and no urinary tract infections) in the same diagnostic laboratory, using the same methods.

- It is now considered the standard of care to perform prostate biopsies guided by ultrasound.

Types of prostatic biopsy:

- Transrectal approach is used for most prostate biopsies, with ultrasound-guided periprostatic block as state-of-the-art. The British Prostate Testing for Cancer and Treatment (PROTECT) Study recommended 10 core biopsies, with > 12 cores being not significantly more conclusive.

- Transperineal approach is another alternative used by some urologists, with less incidence of biopsy related sepsis, but requires sedation or general anaesthetic (GA). There are two types:
    - Template biopsy requiring 24-30 cores using the brachytherapy grid and is performed under GA, with higher tumour detection rate (38%), but with a higher incidence of acute urinary retention (AUR) (up to 10%).
    - Targeted biopsy, which requires less cores and is more tolerated and less incidence of AUR.

- Diagnostic transurethral resection of the prostate: is a poor tool for cancer detection.

- Transition zone sampling during baseline biopsies gives a very low detection rate and should therefore be confined to repeat biopsies.

- Indications for a repeat biopsy are:
  - rising and/or persistently elevated PSA;
  - suspicious DRE, 5-30% risk of cancer;
  - atypical small acinar proliferation (ASAP), 40% risk of cancer;
  - extensive (multiple biopsy sites) prostatic intra-epithelial neoplasia (PIN), 20-30% risk of cancer.
  - **Consider multiparametric MRI (using T2- and diffusion-weighted imaging) for men with a negative transrectal ultrasound 10–12 core biopsy to determine whether another biopsy is needed.**
  - **Do not offer another biopsy if the multiparametric MRI (using T2- and diffusion-weighted imaging) is negative, unless any of the risk factors above is present.**

- An isolated high-grade PIN as finding is no longer considered an indication for repeat biopsy.

- Antibiotics prior to biopsy: Oral or intravenous antibiotics are state-of-the-art treatment. Optimal dosing and treatment time vary. Quinolones are the drugs of choice, with ciprofloxacin being superior to ofloxacin, but increased resistance to quinolones associated with a rise in severe infectious complications after biopsy has been reported in the past few years.

- Percentage of complications per biopsy session, irrespective of the number of cores:

Complications	**Percentage of biopsies affected**
Haematospermia	37.4
Haematuria > 1 day	14.5
Rectal bleeding< 2 days	2.2
Prostatitis	1.0
Fever > 38.5°C (101.3°F)	0.8
Epididymitis	0.7
Rectal bleeding > 2 days ± requiring surgical intervention	0.7
Urinary retention	0.2
Other complications requiring hospitalisation	0.3

The role of imaging

- **TRUS:** Grey-scale TRUS is not adequately reliable at detecting areas of PCa. It is therefore used as a guide to direct systematic biopsies of the prostate gland.

- **Multiparametric MRI:**
  - has excellent sensitivity for detecting aggressive Gleason > 7 cancers
  - mMRI is particularly good at accurately detecting anterior tumours that are usually missed by systematic biopsy and therefore trigger a (targeted) repeat biopsy.
  - cost-effectiveness of mMRI as a triage test before the first biopsy has not been assessed.
  - Inter-reader variability is also a current concern, especially outside reference centres.

Recommendations for the diagnosis of prostate cancer:

Recommendations	LE	GR
Prostate cancer should be graded according to the ISUP 2005 modified Gleason grading system. 2a A The decision to biopsy should be based on PSA testing and DRE.	2b	A
For initial diagnosis, a core biopsy of 10-12 systematic transrectal or transperineal peripheral zone biopsies should be performed under ultrasound imaging guidance.	2a	B
Transrectal prostate needle biopsies should be taken under antibiotic protection.	1b	A
Local anaesthetic by periprostatic infiltration is recommended for prostate needle biopsies.	1a	A
Prostate core biopsies from different prostatic sites should be submitted separately for processing and pathology reporting.	3	A
Processing and reporting of prostatectomy specimens by pathology should follow the guidelines provided by the 2010 ISUP consensus meeting.	3	A

STAGING FOR PROSTATE CANCER

T - Primary tumour	
TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
T1	Clinically inapparent tumour not palpable or visible by imaging
T1a	Tumour incidental histological finding in 5% or less of tissue resected
T1b	Tumour incidental histological finding in more than 5% of tissue resected

T1c Tumour identified by needle biopsy (e.g. because of elevated PSA level) T2 Tumour confined within the prostate T2a Tumour involves one half of one lobe or less T2b Tumour involves more than half of one lobe, but not both lobes T2c Tumour involves both lobes T3 Tumour extends through the prostatic capsule T3a Extracapsular extension (unilateral or bilateral) including microscopic bladder neck involvement T3b Tumour invades seminal vesicle(s) T4 Tumour is fixed or invades adjacent structures other than seminal vesicles: external sphincter, rectum, levator muscles, and/or pelvic wall
N - Regional lymph nodes
NX Regional lymph nodes cannot be assessed N0 No regional lymph node metastasis N1 Regional lymph node metastasis
M - Distant metastasis
MX Distant metastasis cannot be assessed M0 No distant metastasis M1 Distant metastasis M1a Non-regional lymph node(s) M1b Bone(s) M1c Other site(s)

- Provisional treatment intent should be determined (radical or non-radical) before decisions on imaging are made.

- Imaging should not be routinely offered to men who are not candidates for curative intent.

- Isotope bone scans should be offered when hormonal therapy is being deferred through watchful waiting to asymptomatic men who are at high risk of developing bone complications.

- Multiparametric MRI (or CT if MRI is contraindicated) should be offered for men with histologically proven prostate cancer if knowledge of the T or N stage could affect management.

- Urological cancer MDTs should assign a risk category (below) to all newly diagnosed men with localised prostate cancer.

Risk stratification for men with localised prostate cancer

Level of risk	PSA		Gleason score		Clinical stage
Low risk	<10 ng/ml	and	≤6	and	T1–T2a
Intermediate risk	10–20 ng/ml	or	7	or	T2b
High risk[1]	>20 ng/ml	or	8–10	or	≥T2c
[1] High-risk localised prostate cancer is also included in the definition of locally advanced prostate cancer.					

- CT of the pelvis should not be offered to men with low- or intermediate-risk localised prostate cancer (see table 1).
- Isotope bone scans should not be routinely offered to men with low-risk localised prostate cancer.
- Positron emission tomography imaging should not be offered for prostate cancer in routine clinical practice.

TREATMENT:

LOCALIZED PROSTATE CANCER (stage T1-T2c, Nx-N0, M0):

DEFERRED TREATMENT (ACTIVE SURVEILLANCE/ WATCHFUL WAITING):

Definitions:

Active surveillance is active monitoring, aiming at the proper timing of curative treatment; an active decision not to treat the patient immediately.

- The patient remains under close surveillance, and treatment is prompted by predefined thresholds indicative of the presence of a potentially life-threatening disease, while taking the patient's life-expectancy into consideration.

- The treatment options are intended to be *curative*.
- Aim is to reduce overtreatment in patients with clinically confined very low-risk PCa, without giving up the option of curative treatment.

Patients selected for active surveillance:

The various series have applied several eligibility criteria for enrolment in active surveillance programmes (D'Amico, Epstein, PRIAS, etc.):

- clinically confined PCa (T1-T2);
- Gleason score < 7 for most studies;
- PSA < 10-15 ng/mL;
- prostate cancer volume criteria on biopsies, e.g. number of positive biopsies, maximum cancer involvement of biopsy.

Protocol for active surveillance

There are several studies with variable protocols for the active surveillance patients. However, NICE recommends the following:

Timing	**Tests** [1]
At enrolment in active surveillance	Multiparametric MRI if not previously performed
Year 1 of active surveillance	Every 3–4 months: measure PSA[2] Throughout active surveillance: monitor PSA kinetics[3] Every 6–12 months: DRE[4] At 12 months: prostate rebiopsy
Years 2–4 of active surveillance	Every 3–6 months: measure PSA[2] Throughout active surveillance: monitor PSA kinetics[3]

	Every 6–12 months: DRE[4]
Year 5 and every year thereafter until active surveillance ends	Every 6 months: measure PSA[2] Throughout active surveillance: monitor PSA kinetics[3] Every 12 months: DRE[4]
[1] If there is concern about clinical or PSA changes at any time during active surveillance, reassess with multiparametric MRI and/or rebiopsy. [2] May be carried out in primary care if there are agreed shared-care protocols and recall systems. [3] May include PSA doubling time and velocity. [4] Should be performed by a healthcare professional with expertise and confidence in performing DRE.	

Triggers for active treatment:

- A PSA doubling time (PSADT) with a cut-off value ranging between < 2 and < 4 years.
- Gleason score progression to > 7 during systematic follow-up biopsies, at intervals ranging from one to four years.
- Patients' requests for treatment are based mainly on anxiety.
- Radiological progression, supported with an updated biopsy.

Recommendations:

Recommendations - active surveillance	LE	GR
Active surveillance is an option in patients with the lowest risk of cancer progression: over 10 years of life-expectancy, cT1-2, PSA < 10 ng/mL, biopsy Gleason score < 6 (at least 10 scores), < 2 positive biopsies, minimal biopsy core involvement (< 50% cancer per biopsy).	2a	A
Follow-up should be based on DRE, PSA and repeated biopsies. The optimal timing for follow-up is still unclear.	2a	A
Patients with biopsy progressions should be recommended to undergo active treatment.	2a	A

Watchful waiting is the delayed application of palliative treatment options. The rationale behind watchful waiting is the observation that PCa often progresses slowly, and is predominantly diagnosed in older men in whom there is a high incidence of co-morbidity and related high competitive mortality. Watchful waiting can be considered as an option for treating patients with localized PCa and a limited life-expectancy, or for older patients with less aggressive cancers.

Recommendations:

Recommendations - watchful waiting	LE	GR
Watchful waiting may be offered to all patients not willing to accept the side-effects of active treatment, particularly patients with a short life-expectancy.	1b	A
When on watchful waiting, the decision to start any non-curative treatment should be based on symptoms and disease progression.	1a	B

RADICAL PROSTATECTOMY

- Radical prostatectomy can be offered to men with intermediate-risk localised prostate cancer.
- Radical prostatectomy can be offered to men with high-risk localised prostate cancer when there is a realistic prospect of long-term disease control.
- Patients for radical prostatectomy should be referred to urological cancer team that has a specialist interest in urological cancer and all team members must attend a majority of meetings. The team should carry out a cumulative total of at least 50 radical operations for prostate or bladder cancer per year.
- Commissioners of urology services should consider providing robotic surgery to treat localised prostate cancer.
- Commissioners should ensure that robotic systems for the surgical treatment of localised prostate cancer are cost effective by basing them in centres that are expected to perform at least 150 robot-assisted laparoscopic radical prostatectomies per year.

Low risk prostate cancer (cT1-T2a, Gleason score < 6 and PSA < 10 ng/mL):

- Patients should be informed about the results of two randomized trials comparing retropubic RP versus watchful waiting (WW) in localized PCa.
- In the SPCG-4 study, the survival benefit associated with RP was similar before and after 9 years of follow-up and was also observed in men with low-risk PCa, and was confined to men < 65 years of age.

- In the PIVOT trial, a preplanned subgroup analysis of men with low-risk tumours showed that RP did not significantly reduce all-cause mortality.
- The decision to offer RP in cases of incidental cancer should be based upon the estimated probability of clinical progression compared to the relative risk of therapy and potential benefit to survival.
- In stage T2a patients with a 10-year life expectancy, RP is one of the recommended standard treatments, as 35-55% of these patients will show disease progression after 5 years if not treated.
- Extended pelvic lymph node dissection (eLND) is not necessary in low-risk PCa because the risk for positive lymph nodes does not exceed 5%.

Intermediate-risk, localized prostate cancer (cT2b-T2c or Gleason score = 7 and/or PSA 10-20 ng/mL):

- Radical prostatectomy is one of the recommended standard treatments for patients with intermediate risk PCa and a life expectancy of > 10 years.
- The prognosis is excellent when the tumour is confined to the prostate, based on pathological examination
- Although active monitoring could be proposed for some selected patients with intermediate-risk localized tumours, however, when the tumour is palpable or visible on imaging and clinically confined to the prostate, disease progression can be expected in most long term survivors.
- An eLND should be performed in intermediate-risk PCa if the estimated risk for positive lymph nodes exceeds 5%.
- Limited LND should no longer be performed because this misses at least half of the nodes involved

High-risk localized and locally advanced prostate cancer (Gleason score 8-10 and/or PSA > 20 ng/mL):

- RP is a reasonable treatment option in selected patients.
- RP is offered after all treatments have been discussed at the multidisciplinary team, with the pros and cons of each therapy has been considered by the patients with regard to their own individual circumstances.
- If RP is performed, pelvic eLND must be performed, because the estimated risk for positive lymph nodes is 15-40%.
- The patient must be informed about the likelihood of a multimodal approach.
- Neoadjuvant androgen depriviation therapy before RP does not provide a significant DSF or OS advantage over prostatectomy alone.

Complications and functional outcome in RP and RALP:

Complication, mean %	Retropubic RP	RALP
Continence*	80-97	89-100
Potency *	51-81	26-63
Peri-operative death	0.1	0.04
Readmission	3.0	3.5
Reoperation	2.3	0.9
Vessel injury	0.04	0.08
Nerve injury	0.4	0.4
Ureteral injury	1.5	0.1
Bladder injury	0.05	0.07
Rectal injury	0.5	0.3
Bowel injury	0	0.09
Ileus	0.8	0.8
Deep vein thrombosis	1.0	0.3
Pulmonary embolism	0.5	0.3
Pneumonia	0.5	0.05
Myocardial infarction	0.2	0.2
Haematoma	1.6	0.7
Lymphocele	3.2	0.8
Anastomotic leakage	10.0	3.5
Fistula	0.07	0.03
Bladder neck/anastomotic stricture	2.2	0.9
Sepsis	0.2	0.1
Wound infection	2.8	0.7

RALP = robot-assisted laparoscopic prostatectomy
RP = radical prostatectomy
***** The major limitations of the included studies were the frequent retrospective study design and the use of different assessment tools preventing a proper comparison between techniques and series.

RADIOTHERAPY

Radical Radiotherapy:

- There have been no randomized studies comparing radical prostatectomy (RP) with either external-beam radiotherapy (EBRT) or brachytherapy for localized prostate cancer (PCa).

- The National Institutes of Health (NIH) consensus statement in 1988 stated that external irradiation offers the same long-term survival results as surgery.
- EBRT provides a QoL at least as good as that following surgery. A recent systematic review has provided a more sophisticated overview of outcomes from trials that meet the criteria for stratifying patients by risk group, standard outcome measures, numbers of patients, and minimum median follow-up period.
- Radiotherapy continues to be an important and valid alternative to surgery alone for curative therapy.
- Intensity-modulated radiotherapy (IMRT), with or without image-guided radiotherapy (IGRT), is the gold standard for EBRT.
- All centres that do not yet offer IMRT should plan to introduce it as a routine method for the definitive treatment of PCa.
- Radiotherapy can be offered to men with intermediate-risk localised prostate cancer.
- Radiotherapy can be offered to men with high-risk localised prostate cancer when there is a realistic prospect of long-term disease control.
- Radiotherapy should be offered for localised prostate cancer a minimum dose of 74 Gy to the prostate at no more than 2 Gy per fraction.
- Men with intermediate- and high-risk localised prostate cancer should be offered a combination of radical radiotherapy and androgen deprivation therapy, rather than radical radiotherapy or androgen deprivation therapy alone.
- Men with intermediate- and high-risk localised prostate cancer should be offered 6 months of androgen deprivation therapy before, during or after radical external beam radiotherapy.
- Androgen deprivation therapy can be continued for up to 3 years for men with high-risk localised prostate cancer and the benefits and risks of this option should be discussed with them.
- Incidence of late toxicity and outcome by Radiation Therapy Oncology Group (RTOG) grade (from EORTC trial 22863):

Toxicity	Grade 2 %	Grade 3 %	Grade 4 %	Any significant toxicity (> grade 2)%
Cystitis	4.7	0.5	0	5.3
Haematuria	4.7	0	0	4.7
Urinary stricture	4.7	1.3	1	7.1
Urinary incontinence	4.7	0.5	0	5.3
Overall GU toxicity	12.4	2.3	1†	15.9

Toxicity	Grade 2 %	Grade 3 %	Grade 4 %	Any significant toxicity (> grade 2)%
Proctitis	8.2	0	0	8.2
Chronic diarrhoea	3.7	0	0	3.7
Small bowel obstruction	0.2	0.2	0	0.5
Overall GI toxicity	9.5	0.2	0	9.8
Leg oedema	1.5	0	0	1.5
Overall toxicity*	19.0	2.7	1	22.8
Potency after 1 year	--	--	--	55
Secondary malignancy	--	--	--	0.16

- Men with signs or symptoms of radiation-induced enteropathy should be offered care from a team of professionals with expertise in radiation-induced enteropathy.
- The nature and treatment of radiation-induced enteropathy should be included in the training programmes for oncologists and gastroenterologists.
- Full investigations should be carried out, including flexible sigmoidoscopy, in men who have symptoms of radiation-induced enteropathy to exclude inflammatory bowel disease or malignancy of the large bowel and to ascertain the nature of the radiation injury.
- Caution should be used when performing anterior wall rectal biopsy after brachytherapy because of the risk of fistulation.

Immediate (adjuvant) post-operative external irradiation after RP:

There's currently conflicting evidence with biochemical free and overall survival advantages of adjuvant versus salvage radiotherapy in the following post RP patients:

- Patients classified as pT3 pN0.
- Positive margins (highest impact)
- Capsule rupture, and/or invasion of the seminal vesicles

- with a PSA level of < 0.1 ng/mL.

RADICALS trial outcome is awaited. However, currently two options can be offered in the framework of informed consent. These are:

- Immediate adjuvant radiotherapy to the surgical bed (79,81-83,86) after recovery of urinary function; or
- Clinical and biological monitoring followed by salvage radiotherapy (SRT) before the PSA exceeds 0.5 ng/mL.
- Immediate post-operative radiotherapy after radical prostatectomy, even to men with margin-positive disease, other than in the context of a clinical trial.

Post radiotherapy biochemical failure:

- After primary RT, with or without short-term hormonal manipulation, the RTOG-ASTRO Phoenix Consensus Conference definition of PSA failure (with an accuracy of > 80%) is any PSA increase > 2 ng/mL higher than the PSA nadir value, regardless of the serum concentration of the nadir.
- In patients with BCF who are candidates for local salvage therapy, prostate multiparametric MRI can guide biopsy.
- Selected patients with localized PCa at primary treatment and histologically proven recurrence without evidence of metastatic disease should be treated with salvage RP (SRP).
- Due to the increased rate of treatment-related complications and side effects, SRP and salvage brachytherapy should only be performed in experienced centres.
- Permanent seed implantation, high-intensity focused ultrasound (HIFU) and cryosurgical ablation are treatment options in carefully selected patients without evidence of metastasis and with histologically proven local recurrence.

Experimental therapeutic options to treat clinically localized PCa:

- High frequency focused ultrasound (HIFU) has been shown to have a therapeutic effect in low-stage PCa, but prospective randomized comparison studies are not available to support its routine use.
- Cryotherapy for PCa compares unfavourably with external-beam radiation for the preservation of sexual function. Similarly this modality should be used in the context of clinical trials.
- Focal therapy of any sort is investigational, and the follow-up and retreatment criteria are unclear.

- In patients who are unfit for surgery or radiotherapy, cryotherapy can be an alternative treatment for PCa but cannot be recommended as a therapeutic alternative outside clinical trials.
- If HIFU is offered, the lack of long-term comparative outcome data (> 10 y) should be discussed with the patient.

LOCALLY ADVANCED PROSTATE CANCER (stage T3-T4, Nx-N0, M0):

DEFERRED TREATMENT

- Only indicated in selected patients with non-poorly differentiated T3 tumours and a life expectancy of less than 10 years.
- Significant risk factors associated with a worse outcome hence indications of active treatment are:
  - patients with a baseline PSA > 50 ng/mL.
  - in patients with a baseline PSA < 50 ng/mL, a PSADT of < 12 months carries the risk of PCa related death (approximately 7.5-fold).

RADICAL RADIOTHERAPY

- In patients with locally advanced PCa T3-4 N0 M0, concomitant and adjuvant hormonal therapy for a total duration of 3 years, with external-beam irradiation for patients with WHO 0-2 performance status, is recommended, as it improves the overall survival.
- In a subset of patients with T2c-T3 N0-X and a Gleason score of 2-6, short-term androgen deprivation therapy ADT before and during radiotherapy can be recommended, as it may favourably influence the overall survival.

ADT monotherapy:

- ADT monotherapy can be offered to patients with locally advanced disease who are unwilling or unable to receive any form of associated local treatment.
- Immediate castration should be considered in the most aggressive situations (PSA > 50 ng/mL, PSADT < 12 months).
- Otherwise a wait-and-see policy with deferred treatment at clinical progression is a reasonable option.

RADICAL PROSTATECTOMY

- RP is optional in highly selected patients with cT3b-4 N0 or any cT N1 PCa in the context of a multimodality approach.
- When nodal involvement is detected after surgery:
  - Adjuvant ADT is recommended when > 2 nodes are involved;
  - Expectant management is optional when the patient has undergone eLND and < 2 nodes show microscopic involvement.

Focal therapeutic options:

High-intensity focused ultrasound and cryotherapy should not be offered to men with locally advanced prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions.

METASTATIC PCa (stage M1):

ANDROGEN DEPREVATION THERAPY (ADT):

- In patients with symptomatic metastatic prostate cancer, ADT is recommended to palliate symptoms and to reduce the risk for potentially catastrophic sequelae of advanced disease (spinal cord compression, pathological fractures, ureteral obstruction, extraskeletal metastasis).

- In patients who are asymptomatic from their metastatic disease:
  - Immediate ADT can be used to defer progression to a symptomatic stage and prevent serious disease progression-related complications.
  - An active clinical surveillance protocol is an acceptable option in clearly informed patients if survival is the main objective.

- Anti-androgens are initially used to reduce the risk of the ‘flare-up’ phenomenon in patients with advanced metastatic disease who are to receive an LHRH agonist.

- It may be sufficient to give an anti-androgen for some weeks of concomitant use, starting treatment on the same day as an LHRH analogue is started, or for up to 7 days before the first LHRH analogue injection.

- Anti-androgens as monotherapy can be considered as an option in highly selected and motivated patients with a low PSA.

- Intermittent ADT:
  - When this method is used, it should reproduce what has been used in clinical trials; treatment is usually stopped when the PSA level is < 4 ng/mL (M1) and < 0.5-4 ng/mL (relapsing). Treatment is usually re-started when the PSA is > 4-10 (relapsing) and > 10-20 ng/mL (M1).
  - This can be used in patients with asymptomatic metastatic disease and are very motivated, with a major PSA response after the induction period.
  - Other cohort includes patients relapsing after radiotherapy; patients with a clear response after the induction period.

Contraindications of ADT

Therapy	**Contraindications**	**LE**	**GR**
Bilateral orchiectomy	Psychological reluctance to undergo surgical castration.	3	A
Oestrogens	Known cardiovascular disease.	2b	B
LHRH agonists monotherapy	Patients with metastatic disease at high risk for clinical 'flare-up' phenomenon.	2b	A
ADT, anti-androgen	Localized PCa as primary monotherapy (except in some high-risk localized situations in patients unwilling or unable to receive any form of local treatment).	1b	A

DEFERRED TREATMENT:

- Only indicated in asymptomatic patients with a strong wish to avoid treatment-related side-effects
- If a deferred treatment policy is chosen for a patient with advanced PCa, close follow-up must be possible.

RADICAL RADIOTHERAPY

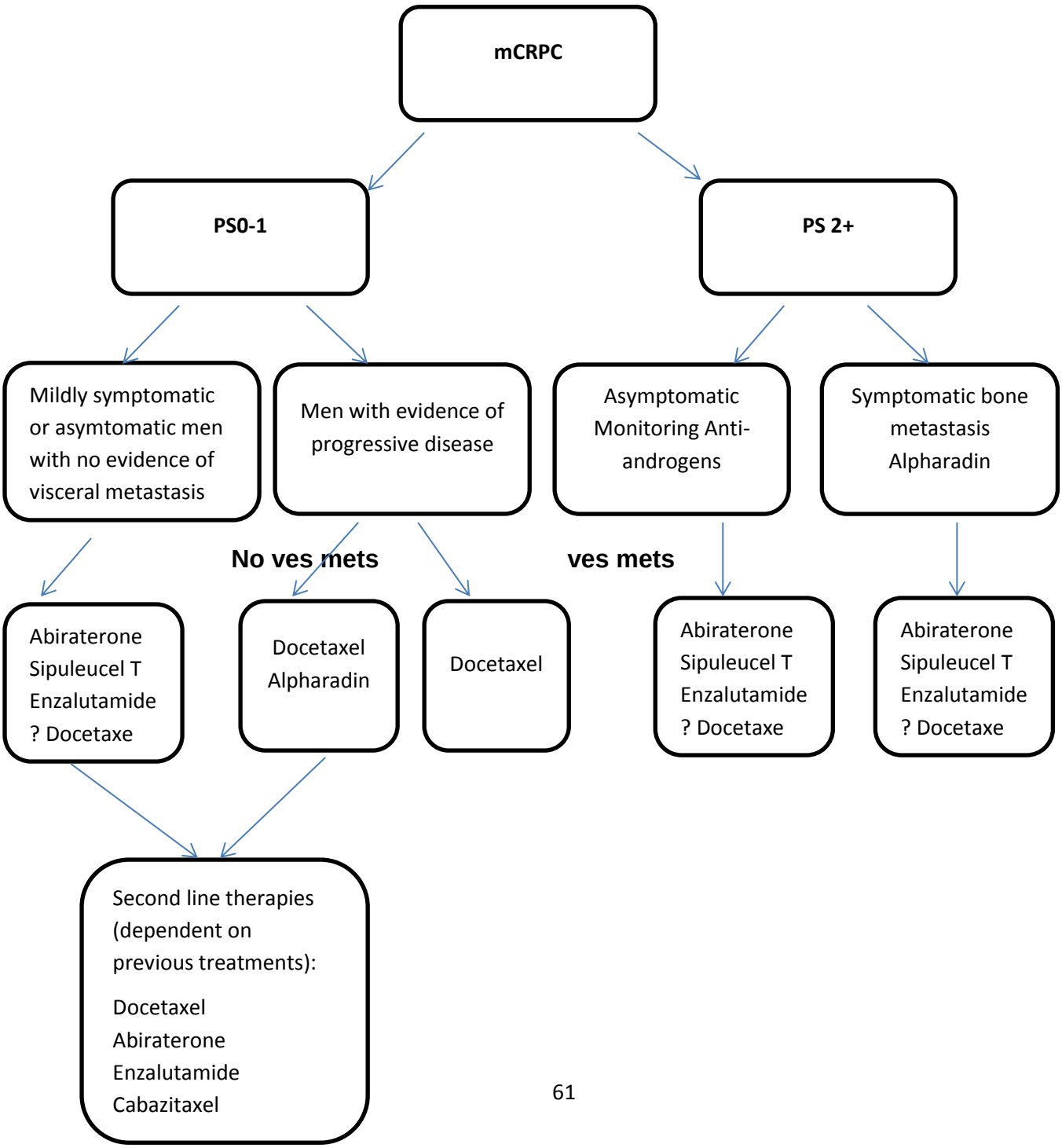
- In patients with very high-risk PCa c-pN1 M0, with no severe comorbidity, pelvic external irradiation and immediate long-term adjuvant hormonal treatment is recommended, as it may improve the overall survival, disease-specific failure rate, metastatic failure rate, and biochemical control.

CASTRATION-RESISTANT PCa (CRPC)

Defined as:

- Castrate serum testosterone < 50 ng/dL or 1.7 nmol/L plus either:
  - Biochemical progression: Three consecutive rises of PSA, 1 week apart, resulting in two 50% increases over the nadir, with PSA > 2 ng/mL. or
  - Radiological progression: The appearance of two or more bone lesions on bone scan or enlargement of a soft tissue lesion using RECIST (Response Evaluation Criteria in solid tumours).

Flowchart of the potential therapeutic options after PSA progression following initial hormonal therapy:



- Patients with mCRPC should be counselled, managed and treated by a multidisciplinary team.

FOLLOW UP

Guidelines for follow-up of prostate cancer patients with curative intent/watchful waiting:

- Men should be clearly advised with prostate cancer about potential longer-term adverse effects of treatment and when and how to report them.
- Men with prostate cancer who have chosen a watchful waiting regimen with no curative intent should normally be followed up in primary care in accordance with protocols agreed by the local urological cancer MDT and the relevant primary care organisation(s). Their PSA should be measured at least once a year.
- PSA levels for all men with prostate cancer who are having radical treatment should be checked at the earliest 6 weeks following treatment, at least every 6 months for the first 2 years and then at least once a year thereafter.
- DRE is not routinely offered to men with localised prostate cancer while the PSA remains at baseline levels [NICE].
- After radical prostatectomy, a serum PSA level of more than 0.2 ng/mL can be associated with residual or recurrent disease.
- After radiation therapy, a rising PSA level over 2 ng/mL above the nadir PSA, rather than a specific threshold value, is the most reliable sign of recurrent disease.
- Both a palpable nodule and a rising serum PSA level can be signs of local disease recurrence.
- Detection of local recurrence by imaging studies is only recommended if it will affect the treatment plan. In most cases, a biopsy is not necessary before second-line therapy.
- Routine bone scans and other imaging studies are not recommended in asymptomatic patients with no signs of biochemical relapse. If a patient has bone pain or other symptoms of disease progression, re-staging should be considered irrespective of the serum PSA level.
- In asymptomatic patients, a disease-specific history and a serum PSA measurement supplemented by DRE are the recommended tests for routine

follow-up. These should be performed at 3, 6 and 12 months after treatment, then every 6 months until 3 years, and then annually [EAU].

- After at least 2 years, follow-up can be performed outside hospital (for example, in primary care) by telephone or secure electronic communications to men with a stable PSA who have had no significant treatment complications, unless they are taking part in a clinical trial that requires formal clinic-based follow-up. Direct access to the urological cancer MDT should be offered and explained.

Guidelines for follow-up of prostate cancer patients on ADT:

- Patients should be evaluated at 3 and 6 months after the initiation of treatment.
- As a minimum, tests should include serum PSA measurement, DRE, serum testosterone, and careful evaluation of symptoms in order to assess the treatment response and side effects.
- In patients undergoing intermittent androgen deprivation, PSA and testosterone should be monitored at set intervals during the treatment pause (one or three months).
- Follow-up should be tailored for the individual patient, according to symptoms, prognostic factors and the treatment given.
- In patients with stage M0 disease with a good treatment response, follow-up is scheduled every 6 months, and as a minimum should include a disease-specific history, DRE and serum PSA determination.
- In patients with stage M1 disease with a good treatment response, follow-up is scheduled for every 3 to 6 months. As a minimum, this should include a disease-specific history, DRE and serum PSA determination, and is frequently supplemented with haemoglobin, serum creatinine and alkaline phosphatase measurements. The testosterone level should be checked, especially during the first year.
- Patients (especially with M1b status) should be advised about the clinical signs that could suggest spinal cord compression.
- When disease progression occurs, or if the patient does not respond to the treatment given, follow-up needs to be individualized.
- In patients with suspected progression, the testosterone level must be checked. By definition, CRPC is based on the assumption that the patient has a testosterone level of at least < 50 ng/mL.
- Routine imaging of stable patients is not recommended.

9.3 PENILE CANCER

Penile carcinoma is mostly a squamous cell carcinoma (SCC) but other types of carcinoma exist as well. It usually originates from the epithelium of the inner prepuce or the glans. Also, penile SCC occurs in several histological subtypes. Penile SCC shares similar pathology with SCC of the oropharynx, the female genitalia (cervix, vagina and vulva) and the anus and it is therefore assumed that it also shares to some extent the natural history.

EPIDEMIOLOGY

- In Western countries, primary penile cancer is uncommon, with an incidence of less than 1.00 per 100,000 males in Europe and the United States.

- Incidence is also affected by race and ethnicity in North America, with the highest incidence of penile cancer found in white Hispanics (1.01 per 100,000), followed by a lower incidence in Alaskan, Native American Indians (0.77 per 100,000), blacks (0.62 per 100,000) and white non-Hispanics (0.51 per 100,000), respectively.

- In contrast, in some other parts of the world such as South America, South East Asia and parts of Africa the incidence of penile cancer is much higher and can represent 1-2% of malignant diseases in men.

- Penile cancer is common in regions with a high prevalence of human papilloma virus (HPV). The annual age-adjusted incidence is 0.7-3.0 per 100,000 men in India, 8.3 per 100,000 men in Brazil and even higher in Uganda, where it is the most commonly diagnosed cancer in men.

- There are no data linking penile cancer to HIV or AIDS.

- In European countries, the overall incidence has been stable from the 1980s until today. Recently, an increased incidence has been reported from Denmark and the UK.

- A longitudinal study from the UK has confirmed a 21% increase in incidence over the period 1979-2009.

- The incidence of penile cancer increases with age, with an age peak during the sixth decade of life. However, the disease does occur in younger men.

RISK FACTORS AND PREVENTION

Risk factors	Relevance
• Phimosis	OR 11-16 versus no phimosis
• chronic penile inflammation (balanoposthitis related to phimosis) • balanitis xerotica obliterans (lichen sclerosus)	Risk
• sporalene and UV-A phototherapy for various dermatologic conditions such as psoriasis	Incidence rate ratio 9.51 with > 250 treatments
• smoking	5-fold increased risk (95% CI: 2.0-10.1) versus nonsmokers
• HPV infection condylomata acuminata	22.4% in verrucous SCC and 36-66.3% in basaloid-warty
• Rural areas, low socio-economic status, unmarried	Risk
• multiple sexual partners early age of first intercourse	3-5-fold increased risk of penile cancer

- Neonatal circumcision reduces the incidence of penile cancer in countries and cultures where this is routinely practiced.
- The lowest incidence of penile cancer is reported from Israel amongst Jews (0.3/100,000/ year).
- Medical circumcision in adult life does not influence the incidence of penile cancer.
- The controversial discussion about any preventive value of neonatal circumcision must take into consideration that circumcision removes about 50% of the tissue that can develop penile cancer.
- The protective effect of neonatal circumcision against invasive penile cancer (OR 0.41) - which does apparently not apply to CIS (OR 1.0) - is much weaker when the analysis is restricted to men without a history of phimosis (OR 0.79, 95% CI 0.29-2).

TNM clinical and pathological classification of penile cancer (2009)

T - Primary Tumour
Tx Primary tumour cannot be assessed T0 No evidence of primary tumour Ta Non-invasive carcinoma Tis Carcinoma in situ T1 Tumour invades subepithelial connective tissue T1a Tumour invades subepithelial connective tissue without lymphovascular invasion and is not poorly differentiated or undifferentiated (T1G1-2) T1b Tumour invades subepithelial connective tissue with lymphovascular invasion or is poorly differentiated or undifferentiated (T1G3-4) T2 Tumour invades corpus spongiosum and/or corpora cavernosa T3 Tumour invades urethra T4 Tumour invades adjacent structures
N - Regional Lymph Nodes
Nx Regional lymph nodes cannot be assessed N0 No palpable or clinically visible inguinal lymph-node N1 Palpable mobile unilateral inguinal lymph node N2 Palpable mobile multiple unilateral or bilateral inguinal lymph nodes N3 Fixed inguinal nodal mass or pelvic lymphadenopathy, unilateral or bilateral
M - Distant Metastasis M0 No distant metastasis M1 Distant metastasis
Pathological classification The pT categories correspond to the clinical T categories. The pN categories are based upon biopsy or surgical excision.
pN - Regional Lymph Nodes
pNX Regional lymph nodes cannot be assessed pN0 No regional lymph node metastasis pN1 Intranodal metastasis in a single inguinal lymph node pN2 Metastasis in multiple or bilateral inguinal lymph nodes pN3 Metastasis in pelvic lymph node(s), unilateral or bilateral or extranodal extension of any regional lymph node metastasis
pM - Distant Metastasis
pM0 No distant metastasis pM1 Distant metastasis
G - Histopathological Grading
GX Grade of differentiation cannot be assessed G1 Well differentiated G2 Moderately differentiated G3-4 Poorly differentiated/undifferentiated

Premalignant penile lesions (precursor lesions)

Lesions sporadically associated with SCC of the penis • Cutaneous horn of the penis • Bowenoid papulosis of the penis • Lichen sclerosus (balanitis xerotica obliterans)
Premalignant lesions (up to one-third transform to invasive SCC) • Intraepithelial neoplasia grade III • Giant condylomata (Buschke-Löwenstein) • Erythroplasia of Queyrat or Bowen's disease • Paget's disease (intradermal ADK)

Histological subtypes of penile carcinomas, their frequency and outcome

Subtype	**Frequency (% of cases)**	**Prognosis**
common SCC	48-65	depends on location, stage and grade
basaloid carcinoma	4-10	poor prognosis, frequently early inguinal nodal metastasis
warty carcinoma	7-10	good prognosis, metastasis rare
verrucous carcinoma	3-8	good prognosis, no metastasis
papillary carcinoma	5-15	good prognosis, metastasis rare
sarcomatoid carcinoma	1-3	very poor prognosis, early vascular metastasis
mixed carcinoma	9-10	heterogeneous group
pseudohyperplastic carcinoma	< 1	foreskin, related to lichen sclerosus, good prognosis, metastasis not reported
carcinoma cuniculatum	< 1	variant of verrucous carcinoma, good prognosis, metastasis not reported
pseudoglandular carcinoma	< 1	high grade carcinoma, early metastasis, poor prognosis
warty-basaloid carcinoma	9-14	poor prognosis, high metastatic potential (12) (higher than in warty, lower than in basaloid SCC)
adenosquamous carcinoma	< 1	central and peri-meatal glans, high grade carcinoma, high metastatic potential but low mortality
mucoepidermoid carcinoma	< 1	highly aggressive, poor prognosis
clear cell variant of penile carcinoma	1-2	exceedingly rare, associated with HPV, aggressive, early metastasis, poor prognosis, outcome lesion dependent, frequent lymphatic metastasis

DIAGNOSIS AND STAGING

The following guidelines for urgent referral (within two weeks) have been published by the Department of Health:

- Macroscopic haematuria in adults.
- Microscopic haematuria in adults over 50 years.
- Swellings in the body of the testis.
- Palpable renal masses.
- Solid renal masses found on imaging.
- Elevated age-specific prostate specific antigen (PSA) in men with a 10 year life expectancy.
- A high PSA (>20ng/ml) in men with a clinically malignant prostate or bone pain.
- Any suspected penile cancer:
  GPs should refer men with suspicious penile lesions such as growths, swelling at or near the glans, painless ulcers which do not appear to be due to infection, or other unexplained abnormalities such as plaques on the skin or foreskin of the penis, to a local urological cancer team.

Recommendations for the diagnosis and staging of penile cancer

Recommendations	**GR**
Primary tumour: • Physical examination, recording morphology, extent and invasion of penile structures. • MRI with artificial erection in selected cases with intended organ preserving surgery.	**C**
Inguinal lymph nodes: • Physical examination of groins, recording number, laterality and characteristics of inguinal nodes. • If nodes are not palpable, invasive lymph node staging in high-risk patients. • If nodes are palpable, a pelvic CT may be indicated, PET/CT is an option.	**C**
Distant metastases: • In N+ patients, abdomino-pelvic CT scan and chest X-ray are required for systemic staging. • PET/CT scan is an option. • In patients with systemic disease or with relevant symptoms, a bone scan may be indicated.	**C**

TREATMENT

Patients with penile cancer should be managed by specialist penile cancer teams working at the supra-network level. Such teams should serve up to four networks, with a combined population base of at least four million for penile cancer and expect to manage a minimum of 25 new patients each year. The team should include members of the specialist urological cancer team who work in the cancer centre within which it is based, and it should also have access to expertise in plastic surgery.

All penile cancer cases should be discussed with the supranetwork team prior to proposed treatment if not referred directly to that team.

Local care is classed as:
(i) The diagnostic process only.
Local care should be carried out by local teams for their catchment.

It should also be carried out by specialist teams and supranetwork teams for the local catchment of their host locality.

Specialist care is classed as:
(i) Resection (except in cases needing penile reconstruction or lymph node resection).

All resections should be carried out in the host hospital of the team.

(ii) Radiotherapy and chemotherapy. The site(s) where this is carried out should be agreed in the
network guidelines.

Specialist care may be delivered by:

- A specialist urological team without a supranetwork interest in penile cancer provided this is agreed in the network guidelines and with the relevant supranetwork team. It should not be delivered by local urological teams.

- A supranetwork team for referring specialist teams provided this is agreed in the network guidelines.

- The supranetwork team for the local catchment of their host locality.

Supranetwork care is classed as:
Resection in cases needing penile reconstruction or lymph node resection.

All resections should be carried out in one of the hospitals named as part of the facilities of the host locality. All such operations should be carried out in the same hospital.

Supranetwork care should be delivered by the *supranetwork team only.* This is not subject to alteration by the network guidelines.

- The aims of the treatment of the primary penile cancer lesion are complete tumour removal with as much organ preservation as possible while radicality of the treatment should not be compromised.
- A local recurrence in itself has little influence on long-term survival so that organ preservation strategies are justified.
- There are no randomised controlled trials for any of the surgical management options of localised penile cancer, neither are there any observational studies comparing different surgical approaches or studies comparing surgical and non-surgical treatment modalities.
- The available studies all have one or more form of bias such as bias of selection, performance, detection, attrition, selective reporting or publication. Thus, the overall quality of the existing evidence must be regarded as low.
- Penile preservation appears to be superior in functional and cosmetic outcomes and should be offered as the primary treatment modality to men with localised penile cancer.
- Histological diagnosis with local staging must be obtained in all cases, especially if non-surgical treatment modalities are considered
- The treatment of the primary tumour and that of the regional nodes can be done as staged procedures.
- In both cases, it is essential to remove all malignant tissue with negative surgical margins.
- Patients must be counselled about all relevant treatment modalities.
- There are a variety of local treatment modalities for small and localized penile cancer including
    - excisional surgery,
    - external beam radiotherapy,
    - brachytherapy and laser ablation which are used to treat localized invasive disease.

Treatment of superficial non-invasive disease (CIS)

- For penile CIS, topical chemotherapy with imiquimod or 5-FU is an effective first-line treatment.
- Toxicity and adverse events of these topical treatments are relatively low but the efficacy is limited.
- Complete responses have been reported in up to 57% of cases of CIS.
- For the reason of a high rate of persistence and/or recurrence, close and long-term surveillance of such patients is required.
- If topical treatment fails it should not be repeated. Laser treatment can be used for CIS.
- Photodynamic control may be used in conjunction with CO2 laser treatment.
- Alternatively, total or partial glans resurfacing can be offered as a primary treatment modality for CIS and as a secondary treatment in case of treatment failure with topical chemotherapy or laser therapy.
- Glans resurfacing is a surgical technique which consists of complete abrasion of the glandular epithelium with covering by a split skin graft.
- With glans resurfacing for presumed non-invasive disease, up to 20% of patients are found to have superficial invasive disease.

Treatment of invasive disease confined to the glans (category Ta/T1a)

- Penis-preserving strategy is recommended.
- Prior to conservative treatment modalities, it is mandatory to obtain histopathological diagnosis by biopsy.
- All patients must be circumcised before considering conservative non-surgical treatment modalities.
- For tumours confined to the prepuce, radical circumcision alone may be curative, if negative surgical margins are confirmed by definitive histology.
- For all surgical treatment options, the intra-operative assessment of surgical margins by frozen section is recommended as tumour-positive margins lead to local recurrence.
- Total removal of the glans (glansectomy) and prepuce does have the lowest recurrence rate among the treatment modalities for small penile lesions (2%).
- Negative surgical margins are imperative when using penile-conserving treatments and a margin of 5 mm is considered oncologically safe.
- Treatment choice should depend on tumour size, histology including stage and grade, localization especially relative to the meatus, as well as patient preference as there are no documented differences in the long term local recurrence rates between surgery, laser and radiation therapy.

Summary of reported complications and oncological outcomes of local treatments

treatment	complications	local recurrence	nodal recurrence	cancer-specific deaths
Nd:YAG laser	none reported	10-48%	21%	2-9%
CO2-laser	bleeding, meatal stenosis(both < 1%)	14-23%	2-4%	none reported
Lasers (unspecified)	bleeding (8%), local infection 2%	11-26%	2%	2-3%
Moh's micrographic surgery	local infection 3%, meatal stenosis 6%	32%	8%	3-4%
Glans resurfacing	none reported	4-6%	not reported	not reported
Glansectomy	none reported	8%	9%	none reported
Partial penectomy	not reported	4-13%	14-19%	11-27%
Brachytherapy	meastal stenosis> 40%	10-30%	not reported	not reported
Radiotherapy	urethral stenosis 20-35%, glans necrosis10-20%	not reported	not reported	not reported

Recommendations for stage-dependent local treatment of penile carcinoma

Recommendations			
Primary tumour	Organ-preserving treatment is to be considered whenever possible	LE	GR
Tis	• Topical treatment with 5-fluorouracil or imiquimod for superficial lesions with or without photodynamic control. • Laser ablation with CO2 or Nd:YAG laser. • Glans resurfacing.	3	C
Ta, T1a (G1, G2)	• Wide local excision with circumcision CO2 or Nd:YAG laser surgery with circumcision.	3	C

Recommendations			
	• Laser ablation with CO2 or Nd:YAG laser. • Glans resurfacing. Glansectomy with reconstructive surgery, with or without skin grafting. • Radiotherapy by external beam or as brachytherapy for lesions < 4 cm.		
T1b (G3) and T2 confined to the glans	• Wide local excision plus reconstructive surgery, with or without skin grafting. • Laser ablation with circumcision. • Glansectomy with circumcision, with reconstruction. • Radiotherapy by external beam or brachytherapy for lesions < 4 cm in diameter.	3	C
T2 with invasion of the corpora cavernosa	• Partial amputation and reconstruction. • Radiotherapy by external beam or brachytherapy for lesions < 4 cm in diameter.	3	C
T3 with invasion of the urethra	• Partial penectomy or total penectomy with perineal urethrostomy.	3	C
T4 with invasion of other adjacent structures	• Neoadjuvant chemotherapy followed by surgery in responders. Alternative: palliative external beam radiation. • Local recurrence after conservative treatment Salvage surgery with penis-sparing treatment in small recurrences or partial amputation. • Large or high stage recurrence: partial or total amputation	3	C

Management of regional lymph nodes

- The development of lymphatic metastases in penile cancer follows some anatomic rules.
- The inguinal and the pelvic lymph nodes are the regional drainage system of the penis.
- The superficial and deep inguinal lymph nodes are thereby the first regional nodal group reached by lymphatic metastatic spread.
- Spread to the inguinal lymph nodes can be uni- or bilateral from any primary penile cancer.
- The second regional lymph node groups are the ipsilateral pelvic lymph nodes.

- Pelvic nodal disease does not seem to occur without ipsilateral inguinal lymph node metastasis and cross-over metastatic spread from one inguinal side to the other pelvic side has never been reported in penile cancer.
- Further metastatic lymph node spread from the pelvic nodes to paraaortic and paracaval nodes is outside the regional lymph node drainage system of the penis and is therefore classified as systemic metastatic disease.
- The management of regional lymph nodes is decisive for long-term patient survival.
- Cure can be achieved in metastatic disease confined to the regional lymph nodes.
- Lymphadenectomy is the treatment of choice for patients with inguinal lymph node metastases but multimodal treatment combining surgery and polychemotherapy is often indicated.
- Management of the regional lymph nodes should be stage-dependent. In clinically node-negative patients (cN0), there is a definite risk of micro-metastatic lymph node involvement in about 25% of cases which is related to local tumour stage and grade.
- In clinically positive lymph nodes (cN1/cN2), metastatic disease is highly likely and no time should be wasted on antibiotic treatment before surgical treatment.
- With enlarged fixed inguinal lymph nodes (cN3), multimodal treatment by chemotherapy and surgery is indicated. Capsular penetration and extranodal extension in lymph node metastasis even if present in only one node carries a high risk of progression and is classified as pN3 which also requires multimodal treatment.

Recommendations for treatment strategies for nodal metastases

Regional lymph nodes	**Management of regional lymph nodes is fundamental in the treatment of penile cancer**	**LE**	**GR**
No palpable inguinal nodes (cN0)	• Tis, Ta G1, T1G1: surveillance. • > T1G2: invasive lymph node staging by bilateral modified inguinal lymphadenectomy or DSNB.	2a	B
Palpable inguinal nodes (cN1/cN2)	Radical inguinal lymphadenectomy.		
Fixed inguinal lymph nodes (cN3)	• Neoadjuvant chemotherapy followed by radical inguinal lymphadenectomy in responders. • Pelvic lymphadenectomy Ipsilateral pelvic lymphadenectomy is indicated if two or more inguinal nodes are involved on one side (pN2) and in extracapsular nodal metastasis (pN3).	2a	B

Regional lymph nodes	Management of regional lymph nodes is fundamental in the treatment of penile cancer	LE	GR
Adjuvant chemotherapy	• Indicated in pN2/pN3 patients after radical lymphadenectomy • Radiotherapy Radiotherapy is not indicated for the treatment of nodal disease in penile cancer.	2b	B

Chemotherapy

- Multimodal treatment can improve patient outcome in many tumour entities.
- The value of adjuvant chemotherapy after radical inguinal lymphadenectomy in node-positive penile cancer has a long-term disease-free survival (DFS) as opposed those without chemotherapy of (84% vs 39% respectively).
- There is limited evidence to support the use of neoadjuvant chemotherapy for patients with fixed, unresectable nodal disease, particularly with a triple combination including cisplatin and a taxane, whenever feasible.

Recommendations for chemotherapy in penile cancer patients

	LE	GR
Adjuvant chemotherapy (3-4 cycles of TPF) is an option for patients with pN2-3 tumours.	2b	C
Neoadjuvant chemotherapy (4 cycles of a cisplatin and taxane-based regimen) followed by radical surgery is recommended in patients with non-resectable or recurrent lymph node metastases.	2a	B
Chemotherapy for systemic disease is an option in patients with limited metastatic load.	3	C

FOLLOW UP

Recommendations for follow-up in penile cancer

	Interval of follow-up Years 1-2	**Interval follow-up Years 3-5**	**Examinations examination and investigations**	**Minimum duration of follow-up**	**GR**
Primary tumour: penile preserving treatment	3 months	6 months	Regular physician or self examination Repeat biopsy after topical or laser treatment for CIS.	5 years	C
Amputation	3 months	1 year	Regular physician or self examination	5 years	C
Recommendations for follow-up of the inguinal lymph nodes: Surveillance	3 months	6 months	Regular physician or selfexamination	5 years	C
pN0 at initial treatment	3 months	1 year	• Regular physician or self examination. • Ultrasound with FNAB optional.	5 years	C
pN+ at initial treatment	3 months	6 months	• Regular physician or selfexamination • Ultrasound with FNAC optional, • CT/MRI optional.	5 years	C

9.4 Renal Cell Carcinoma

Epidemiology:

- Renal cell carcinoma (RCC) represents 2-3% of all cancers.
- In 2012, there were approximately 84,400 new cases of RCC and 34,700 kidney cancer-related deaths in the European Union.
- In Europe, overall mortality rates for RCC increased up to the early 1990s, and stabilised or declined thereafter. Mortality has decreased since the 1980s in Scandinavian countries and since the early 1990s in France, Germany, Austria, the Netherlands, and Italy. However, in some European countries (Croatia, Estonia, Greece, Ireland, Slovakia), mortality rates still show an upward trend.
- Different RCC types have specific histopathological and genetic characteristics.
- There is a 1.5:1 male predominance, with peak incidence between 60 and 70 years.
- Having a first-degree relative with kidney cancer also increases the risk of RCC.
- Literature results are inconclusive regarding the association of specific dietary habits and occupational exposure to RCC.
- Moderate alcohol consumption appears to have a protective effect for unknown reasons.
- Effective prophylaxis includes avoidance of cigarette smoking and obesity.

Aetiology:

- Smoking:
  - The RR of RCC for ever-smokers is 1.38 times higher than that for non-smokers
  - A strong dose-response relationship between number of cigarettes smoked and increased risk of RCC has been established; Smokers with a history of ≥20 pack-years have an increased risk of RCC 1.35 times that of never-smokers

- Obesity:
  - Increasing body weight and body mass index (BMI) incrementally increases the risk of developing RCC
  - Being overweight (BMI 25–29.9 kg/m2) increases the risk of RCC by 1.35 times versus BMI

- Hypertension and antihypertensive therapy:
  - The presence of hypertension is estimated to increase the RR of RCC by 1.4–1.9 times compared with normotensive individuals
  - Systolic blood pressure ≥160 mmHg increases the RR of RCC by 2.5 times versus <120 mmHg.

- Diastolic blood pressure ≥100 mmHg increases the RR of RCC by 2.3 times versus <80 mmHg.
- Treatment with diuretics also increases the risk of RCC (OR 1.43), but this is only significant in women

- End-stage renal disease:
  - Patients undergoing dialysis for end-stage renal disease are estimated to have a 3.6 times higher RR of developing renal cancer than healthy individuals.

- Renal cancer syndromes:

Disease	**Renal and other tumours**	**Gene mutation**
Von Hippel–Lindau disease	Clear cell RCC: Clear cell renal cysts Retinal and central nervous system haemangioblastomas, phaeochromocytoma, pancreatic cyst and endocrine tumour, endolymphatic sac tumour, epididymal and broad ligament cystadenomas	VHL
Birt-Hogg-Dubé syndrome	Hybrid oncocytic RCC, chromophobe RCC, oncocytoma, clear cell RCC multiple and bilateral Cutaneous lesions (fibrofolliculoma +++, trichodiscoma, acrochordon), lung cysts, spontaneous pneumothorax, colonic polyps or cancer	Folliculin (FLCN)
Hereditary papillary RCC	Type 1 papillary RCC: multiple and bilateral	MET
Hereditary leiomyomatosis and RCC	Type 2 papillary RCC: solitary and aggressive Uterine leiomyoma and leiomyosarcoma, cutaneous leiomyoma and leiomyosarcoma	Fumarate hydratase
Tuberous sclerosis complex	Angiomyolipoma, clear cell RCC, cyst, oncocytoma: bilateral and multiple Facial angiofibroma, subungual fibroma, hypopigmentation and café au lait spots, cardiac rhabdomyoma, seizure, mental retardation, CNS tubers, lymphangioleiomyomatosis	TSC-1 TSC-2
Familial clear cell RCC	Clear cell RCC	Unknown

Diagnosis:

The following guidelines for urgent referral (within two weeks) have been published by the Department of Health:

- Macroscopic haematuria in adults.
- Microscopic haematuria in adults over 50 years.
- Swellings in the body of the testis.
- Palpable renal masses.
- Solid renal masses found on imaging.
- Elevated age-specific prostate specific antigen (PSA) in men with a 10 year life expectancy.
- A high PSA (>20ng/ml) in men with a clinically malignant prostate or bone pain.
- Any suspected penile cancer.
- Many renal masses remain asymptomatic until the late stages of the disease.
- More than 50% of renal cell carcinomas (RCCs) are detected incidentally when noninvasive imaging is used to investigate a variety of nonspecific symptoms and other abdominal diseases.
- The classic triad of flank pain, gross haematuria and palpable abdominal mass is now rare (<10%).
- Other clinical symptoms include new onset varicocele or bilateral lower extremity oedema; these symptoms should initiate radiological examinations.
- Renal Cell Carcinoma Paraneoplastic syndromes are found in approximately 30% of patients with symptomatic RCCs.
- A few symptomatic patients present with symptoms caused by metastatic disease, such as bone pain or persistent cough.

Investigations:

- Radiological and other investigations of RCC Radiological investigations of RCC include CT imaging, before and after intravenous contrast to verify the diagnosis and provide information on:
    - function and morphology of the contralateral kidney
    - assess tumour extension
    - extrarenal spread
    - venous involvement
    - enlargement of lymph nodes and adrenals.
- Abdominal US and magnetic resonance (MR) imaging are supplements to CT.
- Contrast enhanced US can be helpful in specific cases (e.g., chronic renal failure with a relative contraindication for iodinated or gadolinium contrast media, complex cystic masses, and differential diagnosis of peripheral vascular disorders such as infarction and cortical necrosis).

- Magnetic resonance imaging can be used in patients with possible venous involvement, or allergy to intravenous contrast.
- Chest CT is the most accurate chest staging; a routine chest X-ray should be done as a minimum only.
- Indications of renal biopsy:
  - for histological diagnosis of radiologically indeterminate renal masses
  - to select patients with small renal masses for surveillance approaches
  - to obtain histology before ablative treatments
  - to select the most suitable form of targeted pharmacologic therapy in the setting of metastatic disease.
- Total renal function should always be evaluated.
- In patients with any sign of impaired renal function, a renal scan and total renal function evaluation should be undertaken to optimise the treatment decision.

Staging system:

The current UICC 2009 TNM (Tumour Node Metastasis) classification is recommended for the staging of RCC.

T - Primary tumour	
TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
T1	Tumour ≤ 7 cm in greatest dimension, limited to the kidney
T1a	Tumour ≤ 4 cm in greatest dimension, limited to the kidney
T1b	Tumour > 4 cm but ≤ 7 cm in greatest dimension
T2	Tumour > 7 cm in greatest dimension, limited to the kidney
T2a	Tumour > 7 cm in greatest dimension but ≤ 10 cm
T2b	Tumour > 10 cm limited to the kidney
T3	Tumour extends into major veins or perinephric tissues, but not into the ipsilateral adrenal gland and not beyond Gerota's fascia
T3a	Tumour grossly extends into the renal vein or its segmental (muscle-containing) branches, or tumour invades perirenal and/or renal sinus (peripelvic) fat but not beyond Gerota's fascia
T3b	Tumour grossly extends into the vena cava below diaphragm
T3c	Tumour grossly extends into vena cava or its wall above the diaphragm or invades the wall of the vena cava
T4	Tumour invades beyond Gerota's fascia (including contiguous extension into the ipsilateral adrenal gland)
N - Regional lymph nodes	
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis

N1	Metastasis in a single regional lymph node
N2	Metastasis in more than one regional lymph node
M - Distant metastasis	
M0	No distant metastasis
M1	Distant metastasis

Histopathological classification:

Fuhrman nuclear grade is the most commonly used grading system. The most aggressive pattern observed defines the Fuhrman grade. The most common histological subtypes of rCC are below:

Histological subtype	**Frequency (%)**
clear cell RCC	80-90%),
papillary RCC	10-15%),
chromophobe RCC	4-5%
collecting duct carcinoma	1%

- Generally, the RCC types have different clinical courses and responses to therapy.

Recommendations for diagnosis and staging of RCC:

Recommendations for the diagnosis and staging of RCC	GR
The Fuhrman grading system and classification of RCC subtype should be used	B
In a patient with one or more suspicious laboratory or physical findings, the possible presence of RCC should be suspected	B
Contrast-enhanced abdominal CT and MRI are recommended for the work-up of patients with RCC. These are the most appropriate imaging modalities for renal tumour staging prior to surgery	A
A chest CT is most sensitive for assessment of the lung, but at least a plain chest radiograph should be taken for clinical staging	A
In patients at risk for bone metastases (raised alkaline phosphatase level or bone pain), further evaluation with a bone scan is needed	A
Evaluation of renal function is recommended before treatment decision in any patient in whom renal impairment is suspected	B
Percutaneous biopsy is recommended in active surveillance strategies in order to stratify the follow-up according to tumour histology	B

Recommendations for the diagnosis and staging of RCC	GR
Percutaneous biopsy is always required before ablative therapy and systemic therapy without previous pathology	A
When biopsy is indicated, good-quality needle cores should be obtained with a coaxial technique in order to increase the safety of the procedure and maximize its diagnostic yield	B

Recommendations for “other renal tumours”:

Recommendations for “Other renal tumours”	LE	GR
Except for angiomyolipomas, most of these less common renal tumours cannot be differentiated from RCC on the basis of radiology and should therefore be treated in the same way as RCC.	3	C
Bosniak cysts ≥ type III should be treated surgically. When possible, a nephron-sparing procedure should be performed in Bosniak type III.	3	C
In oncocytomas verified on biopsy, follow-up is an option.	3	C
In angiomyolipomas, treatment (surgery, thermal ablation, and selective arterial embolisation) can be considered in only very well selected cases. A nephron-sparing procedure is preferred	3	C
In advanced uncommon types of renal tumours, a standardised oncological treatment approach does not exist.	4	C

Bosniak classification of renal cysts:

Bosniak category	**Features**	**Work-up**
I	Simple benign cyst with a hairline-thin wall without septa, calcification, or solid components. Same density as water and does not enhance with contrast medium.	Benign
II	Benign cyst that may contain a few hairline-thin septa. Fine calcification may be present in the wall or septa. Uniformly high-attenuation lesions < 3 cm in size, with sharp margins without enhancement.	Benign
IIF	These may contain more hairline-thin septa. Minimal enhancement of a hairline-thin septum or wall. Minimal thickening of the septa or wall. The	Follow-up. Some are malignant.

Bosniak category	Features	Work-up
	cyst may contain calcification, which may be nodular and thick, with no contrast enhancement. No enhancing soft-tissue elements. This category also includes totally intrarenal, non-enhancing, high attenuation renal lesions > 3 cm. Generally well-marginated.	
III	These are indeterminate cystic masses with thickened irregular walls or septa with enhancement.	Surgery or active surveillance Over 50% are malignant
IV	Clearly malignant containing enhancing soft-tissue components.	Surgery. Most are malignant

Guidelines for primary treatment for RCC:

- Based on the available oncological and QoL outcomes, the current evidence suggests that localised renal cancers are best managed by nephron-sparing surgery (partial nephrectomy) rather than by radical nephrectomy, irrespective of the surgical approach.
- Radical nephrectomy with complete removal of the tumour-bearing kidney with perirenal fat and Gerota's fascia is currently recommended only for patients with localised RCC, who are not suitable for nephron-sparing surgery due to locally advanced tumour growth, when partial resection is technically not feasible due to an unfavourable localisation of the tumour or local growth.
- Complete resection of the primary RCC either by open or laparoscopic surgery offers a reasonable chance for cure.
- If pre-operative imaging is normal, routine adrenalectomy is not indicated.
- Lymphadenectomy should be restricted to staging because extended lymphadenectomy does not improve survival.
- In patients who have RCCs with tumour thrombus and no metastatic spread, prognosis is improved after nephrectomy and complete thrombectomy.
- Embolisation of the primary tumour is indicated in patients with gross haematuria or local symptoms (e.g. pain), in patients unfit for surgical intervention, and before surgical resection of large skeletal metastases. No benefit is associated with tumour embolisation before routine radical nephrectomy.

Nephron sparing surgery (NSS):

- Absolute indications for partial nephrectomy are
  - anatomical or functional solitary kidney or
  - bilateral RCC.
- Relative indications are
  - a functioning opposite kidney affected by a condition that might impair renal function and
  - hereditary forms of RCC with a high risk of developing a tumour in the contralateral kidney.
- Elective indications also localised unilateral RCC with a healthy contralateral kidney, which is the recommended approach, when technically feasible, since recurrence-free and long-term survival rates are similar to those for radical nephrectomy.
- Even in selected patients with a tumour diameter of up to 7 cm, nephron-sparing surgery has achieved results equivalent to those of a radical approach.
- If the tumour is completely resected, the thickness of the surgical margin (> 1 mm) does not correlate with the likelihood of local recurrence.
- If RCCs of larger size are treated with nephron-sparing surgery, follow-up should be intensified, as there is an increased risk of intrarenal recurrences.
- These procedures should only be delivered under the care of members of the specialist urology team and this is not subject to change by the network's own guidelines (National Cancer Action Team- Manual of Cancer Services 2011).

Laparoscopic radical and partial nephrectomy:

- Laparoscopic radical and partial nephrectomy Laparoscopic radical nephrectomy has a lower morbidity compared with open surgery.
- It has become an established surgical procedure for RCC.
- Whether done retro- or transperitoneally, the laparoscopic approach must duplicate established, open surgical, oncological principles.
- Long-term outcome data indicate equivalent cancer-free survival rates versus open radical nephrectomy.
- Thus, laparoscopic radical nephrectomy is now considered the standard of care for patients with T1 and T2 RCCs, who are not treatable by nephron-sparing surgery.
- Laparoscopic radical nephrectomy should not be performed in patients with T1 tumours for whom partial resection is indicated. Laparoscopic and robot assisted nephron-sparing surgery has become available treatment options in experienced hands.
- Laparoscopic partial resection has a risk for longer intraoperative ischaemia time than open partial nephrectomy and therefore carries a higher risk for reduced long-term renal function.
- The oncological outcome seems comparable in available series.

- Robotic-assisted partial nephrectomy requires further evaluation and more mature data before any conclusive technical recommendations can be made.
- Conclusion: Radical nephrectomy, preferably laparoscopic, is recommended for patients with localised RCC, who are not suitable for nephron-sparing surgery. Nephron-sparing surgery is the standard of care despite the surgical approach.

Minimally invasive alternative treatment:

- Minimally invasive techniques, such as ablation with percutaneous radio-frequency, crytherapy, microwave, and high-intensity focused US (HIFU), are suggested alternatives to surgery.
- Microwave therapy should only be used within the context of research.
- Potential advantages of these techniques include reduced morbidity, outpatient therapy, and the ability to treat high-risk patients not fit for conventional surgery.
- These experimental treatments might be recommended for selected patients with small, incidentally found, renal cortical lesions, elderly patients, patients with a genetic predisposition to multiple tumours, patients with a solitary kidney, or patients with bilateral tumours.
- The oncological efficacy remains to be determined for both cryotherapy and RFA, which are the most often used minimally invasive techniques.
- Current data suggest that cryoablation, when performed laparoscopically, results in fewer re-treatments and improved local tumour control compared with RFA.
- Current evidence on the safety and efficacy of percutaneous radiofrequency ablation (RFA) for renal cancer in the short and medium term appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit, and provided that patients are followed up in the long term.
- For both treatments, tumour recurrence rates are higher compared with nephron-sparing surgery.
- Further research is needed to determine the oncological success rate and complications associated with these procedures.
- NICE encourages collection and publication of data on the long-term outcomes of these procedures.

Adjuvant therapy:

- Adjuvant tumour vaccination may improve the duration of the progression-free survival (PFS), which is especially important in patients at high risk of metastases, e.g. T3 RCC. Cytokine therapy does not improve survival after nephrectomy.
- Although there is no current data supporting adjuvant therapy with targeting agents, three worldwide phase III randomised trials are ongoing.

- Outside controlled clinical trials, there is no indication for adjuvant therapy following surgery.

Surgical treatment for metastatic RCC (mRCC):

- Nephrectomy of the primary tumour is curative only if surgery can excise all tumour deposits.
- For most patients with mRCC, nephrectomy is palliative.
- In a meta-analysis of two randomised studies, comparing nephrectomy + immunotherapy versus immunotherapy alone, increased long term survival was found in patients who underwent prior nephrectomy.
- For targeting agents, there is no current knowledge whether cytoreductive surgery is advocated before or after successful medical therapy. The CARMENA and SURTIME trials comparing cytoreductive nephrectomy with neoadjuvent/adjuvant (respectively) targeted therapy versus control arms of nephrectomy alone are awaited.
- However, in the absence of available evidence data, cytoreductive nephrectomy is recommended when possible.
- Complete removal of metastases contributes to improved clinical prognosis.
- Metastasectomy should be carried out in patients with resectable disease and a good PS.
- It should also be considered in patients with residual and respectable metastatic lesions, who have previously responded to systemic therapy.

Radiotherapy for metastasis:
For selected patients with non-resectable brain or osseous lesions, radiotherapy can induce significant symptom relief.

Systemic chemotherapy for mRCC:
Chemotherapy as monotherapy should not be considered effective in patients with mRCC.

Immunotherapy for mRCC:

- Interferon-alpha monotherapy is no longer recommended as first-line therapy for mRCC.
- Interferon alpha monotherapy still has a role only in selected cases (good performance status, clear cell type, lung metastases only).
- Interleukin-2 has more side effects than INF-α.
- High-dose IL-2 is associated with durable complete responses in a limited number of patients.

- Interleukin-2 can be considered as monotherapy in selected patients with a good prognosis profile.
- A combination of bevacizumab and IFN-α is more effective than IFNα in treatment-naïve, low-risk and intermediate-risk tumours.
- Vaccination therapy with tumour antigen 5T4 showed no survival benefit over the first-line standard of care.

Recommendations:

Recommendations for immunotherapy	**GR**
Monotherapy with IFN-α or high-dose bolus IL-2 can only be recommended as a first-line treatment for mRCC in selected patients with clear cell histology and good prognostic factors.	A
Bevacizumab + IFN-α is recommended as first-line therapy in low-risk and intermediate-risk patients.	B
Cytokine combinations, with or without additional chemotherapy, do not improve the overall survival in comparison with monotherapy.	A

Drugs targeting VEGF or mammalian target of rapamycin (mTOR):

- Recent advances in molecular biology have led to the development of several novel agents for the treatment of mRCC.
- In sporadic clear cell RCC, HIF accumulation due to von Hippel-Lindau (VHL) inactivation results in overexpression of VEGF and PDGF, both of which promote neoangiogenesis and contributes to the development and progression of RCC.
- At present, several targeting drugs have been approved both in the USA and in Europe for the treatment of mRCC:
- Their general inability to produce durable CRs necessitates chronic treatment in most patients
- The benefits must therefore be weighed against the overall burden of treatment, including acute and chronic toxicity, time and cost.

Recommendations:

Recommendations	**GR**
Sunitinib is recommended as first-line therapy in favorable-risk and intermediate-risk patients.	A
Bevacizumab + IFN-α is recommended as first-line therapy in favourable-risk and intermediate-risk patients.	A
Sorafenib is recommended as a second-line treatment for mRCC after	A

Recommendations	GR
cytokine failure.	
Pazopanib is recommended as first-line or after cytokine failure in favourable-risk and intermediaterisk patients.	A
Temsirolimus is recommended as first-line treatment in poor-risk patients.	A
Everolimus is recommended as second-line treatment after failure of tyrosine kinase inhibitors.	A
Axitinib is recommended as second-line treatment after failure of cytokines or tyrosine kinase inhibitors.	A

EAU recommendations for first and second line systemic therapy in mRCC:

Treatment	Risk or prior treatment	Recommended agent
First-line	Low- or intermediate-risk mRCC	Sunitinib Bevacizumab + IFN-a Pazopanib
	High-risk mRCC	Temsirolimus
Second-line	Prior cytokine therapy	Sorafenib Pazopanib
	Prior VEGFR therapy Prior mTOR inhibitor therapy	Everolimus Clinical trials

Surveillance following surgery for RCC:

- The aim of surveillance is to detect either local recurrence or metastatic disease while the patient is still surgically curable.
- There is no evidence for whether early versus later diagnosis of recurrence improves survival.
- Depending on the availability of new effective treatments, more strict follow-up schedules may be required, particularly as there is a higher local recurrence rate after cryotherapy and RFA.
- At present there is no evidence-based standard for the follow-up of patients with RCC as well as the optimal duration of follow-up.
- It is therefore a need for a surveillance algorithm that monitors patients after treatment for RCC that recognises not only the patient's risk profile but also treatment efficacy.

Algorithm for surveillance following treatment for RCC taking into account patient risk profile and treatment efficacy

Risk profile	**Treatment**	**Surveillance**						
		6 months	1 year	2 years	3 years	4 years	5 years	After 5 years
Low	RN/PN only	US	CT	US	CT	US	CT	Discharge
Inter-mediate	RN/PN/cryo/ RFA	CT	US	CT	US	CT	CT	CT alternate 2 years
High	RN/PN/cryo/ RFA	CT	CT	CT	CT	CT	CT	CT alternate years

Recommendations:

Recommendations	LE	GR
Surveillance after treatment for RCC should be based on a patient's risk factors and the type of treatment delivered.		C
For low-risk disease, CT/MRI can be used infrequently.	4	C
In the intermediate-risk group, intensified follow-up should be performed, including CT/MRI scans at regular intervals in accordance with a risk-stratified nomogram.	4	C
In high-risk patients, the follow-up examinations should include routine CT/MRI scans.	4	C
There is an increased risk of intrarenal recurrences in larger-size (> 7 cm) tumours treated with nephron-sparing surgery, or when there is a positive margin. Follow-up should be intensified in these patients		C

9.5 Testicular Cancer

Background:

- Testicular cancer represents between 1% and 1.5% of male neoplasms and 5% of urological tumours in general, with 3-10 new cases occurring per 100,000 males/per year.
- Data from the Surveillance Epidemiology and End Results (SEER) Program during the years 1973 to 1998 show a continuing increased risk among Caucasian men in the USA only for seminoma.
- Only 1-2% of cases are bilateral at diagnosis.
- There is a clear predominance (90-95%) of germ cell tumours
- Peak incidence is in the third decade of life for non-seminoma, and in the fourth decade for pure seminoma.
- Familial clustering has been observed, particularly among siblings
- Epidemiological risk factors for the development of testicular tumours are:
    - history of cryptorchidism or undescended testis (testicular dysgenesis syndrome)
    - Klinefelter's syndrome
    - familial history of testicular tumours among first-grade relatives (father/brothers)
    - the presence of a contralateral tumour or TIN
    - infertility.

PATHOLOGICAL CLASSIFICATION

The recommended pathological classification (modified from the 2004 version of the World Health Organization [WHO] guidance) is shown below:

- **Germ cell tumours**
    - Intratubular germ cell neoplasia, unclassified type (IGCNU)
    - Seminoma (including cases with syncytiotrophoblastic cells)
    - Spermatocytic seminoma (mention if there is sarcomatous component)
    - Embryonal carcinoma
    - Yolk sac tumour
    - Choriocarcinoma
    - Teratoma (mature, immature, with malignant component)
    - Tumours with more than one histological type (specify percentage of individual components)
- S**ex cord/gonadal stromal tumours**
    - Leydig cell tumour
    - Malignant Leydig cell tumour

  - Sertoli cell tumour - lipid-rich variant - sclerosing - large cell calcifying
  - Malignant Sertoli cell tumour
  - Granulosa cell tumour - adult type - juvenile type
  - Thecoma/fibroma group of tumours
  - Other sex cord/gonadal stromal tumours
    - incompletely differentiated
    - mixed
  - Tumours containing germ cell and sex cord/gonadal stromal (gonadoblastoma)
- **Miscellaneous non-specific stromal tumours**
  - Ovarian epithelial tumours
  - Tumours of the collecting ducts and rete testis
  - Tumours (benign and malignant) of non-specific stroma.

DIAGNOSIS:

The following guidelines for urgent referral (within two weeks) have been published by the Department of Health:

- Macroscopic haematuria in adults.
- Microscopic haematuria in adults over 50 years.
- Swellings in the body of the testis.
- Palpable renal masses.
- Solid renal masses found on imaging.
- Elevated age-specific prostate specific antigen (PSA) in men with a 10 year life expectancy.
- A high PSA (>20ng/ml) in men with a clinically malignant prostate or bone pain.
- Any suspected penile cancer.

- **Clinical examination.**
- **Testicular imaging:**
  - US serves to confirm the presence of a testicular mass and to explore the contralateral testis.
  - Its sensitivity in detecting a testicular tumour is almost 100%, and it has an important role in determining whether a mass is intra- or extratesticular
  - Ultrasound of the testis has to be performed in young men without a palpable testicular mass who have retroperitoneal or visceral masses or elevated serum human chorionic gonadotrophin (hCG) or AFP or in men consulting for fertility problems
  - Ultrasound may be recommended in the follow-up of patients at risk, when other risk factors than microlithiasis are present (e.g. size < 12 ml or

atrophy, inhomogeneous parenchyma). Solely, the presence of microlithiasis is not an indication for a regular scrotal US
    - MRI of the scrotum offers a sensitivity of 100% and a specificity of 95-100%, but its high cost does not justify its use for diagnosis.
- **Serum tumour markers at diagnosis**
    - AFP (produced by yolk sac cells)
    - hCG (expression of trophoblasts)
    - LDH (lactate dehydrogenase).
- **Inguinal exploration and orchidectomy**
- **Organ-sparing surgery:** indicated in:
    - In synchronous bilateral testicular tumours
    - metachronous contralateral tumours
    - in a tumour in a solitary testis with normal pre-operative testosterone levels
    - organ preserving surgery can be performed when the tumour volume is less than 30% of the testicular volume and surgical rules are respected
    - the rate of associated TIN is high (at least up to 82%)
    - all patients must be treated with adjuvant radiotherapy (16-20 Gy) at some point.

STAGING

Serum tumour markers:

- The mean serum half-life of AFP and hCG is 5-7 days and 2-3 days, respectively.
- Tumour markers have to be re-evaluated after orchidectomy to determine half-life kinetics.
- Marker decline in patients with clinical stage I disease should be assessed until normalisation has occurred.
- Markers before start of chemotherapy are important to classify the patient according to the International Germ Cell Cancer Collaborative Group (IGCCCG) risk classification.
- The persistence of elevated serum tumour markers after orchidectomy might indicate the presence of metastatic disease (macro- or microscopically), while the normalisation of marker levels after orchidectomy does not rule out the presence of tumour metastases.
- During chemotherapy, the markers should decline; persistence has an adverse prognostic value

Radiological staging:

- Abdominopelvic CT offers a sensitivity of 70-80% in determining the state of the retroperitoneal nodes.
- Magnetic resonance imaging (MRI) produces similar results to CT in the detection of retroperitoneal nodal enlargement.
- MRI can be helpful when abdominopelvic CT or US are inconclusive, when CT is contraindicated because of allergy to contrast media, or when the physician or the patient are concerned about radiation dose.
- There is no evidence to support the use of the fluorodeoxyglucose (FDG)-PET in the staging of testis cancer.
- It is recommended in the follow-up of patients with seminoma with any residual mass at least 6 weeks after chemotherapy in order to decide on watchful waiting or active treatment.
- The use of FDGPET is not recommended in the re-staging of patients with non-seminomatous tumours after chemotherapy.

Recommended tests for staging at diagnosis

Test	**Recommendation**	**GR**
Serum tumour markers	AFP hCG LDH	A
Abdominopelvic CT	All patients	A
Chest CT	All patients	A
Testis US (bilateral)	All patients	A
Bone scan	In case of symptoms	
Brain scan (CT/MRI)	In case of symptoms and patients with metastatic disease with multiple lung metastases and high beta-hCG values	

Further investigations

Fertility investigations: Total testosterone LH FSH Semen analysis	B
Sperm banking should be offered	A

TNM classification for testicular cancer (UICC, 2009):

pT Primary tumour

pTX Primary tumour cannot be assessed

pT0 No evidence of primary tumour (e.g. histological scar in testis)

pTis Intratubular germ cell neoplasia (testicular intraepithelial neoplasia)

pT1 Tumour limited to testis and epididymis without vascular/lymphatic invasion: tumour may invade tunica albuginea but not tunica vaginalis

pT2 Tumour limited to testis and epididymis with vascular/lymphatic invasion, or tumour extending through tunica albuginea with involvement of tunica vaginalis

pT3 Tumour invades spermatic cord with or without vascular/lymphatic invasion

pT4 Tumour invades scrotum with or without vascular/lymphatic invasion

N Regional lymph nodes clinical

NX Regional lymph nodes cannot be assessed

N0 No regional lymph node metastasis

N1 Metastasis with a lymph node mass 2 cm or less in greatest dimension or multiple lymph nodes, none more than 2 cm in greatest dimension

N2 Metastasis with a lymph node mass more than 2 cm but not more than 5 cm in greatest dimension, or multiple lymph nodes, any one mass more than 2 cm but not more than 5 cm in greatest dimension

N3 Metastasis with a lymph node mass more than 5 cm in greatest dimension

pN Pathological

pNX Regional lymph nodes cannot be assessed

pN0 No regional lymph node metastasis

pN1 Metastasis with a lymph node mass 2 cm or less in greatest dimension and 5 or fewer positive nodes, none more than 2 cm in greatest dimension

pN2 Metastasis with a lymph node mass more than 2 cm but not more than 5 cm in greatest dimension; or more than 5 nodes positive, none more than 5 cm; or evidence or extranodal extension of tumour

pN3 Metastasis with a lymph node mass more than 5 cm in greatest dimension

M Distant metastasis

MX Distant metastasis cannot be assessed

M0 No distant metastasis

M1 Distant metastasis

M1a Non-regional lymph node(s) or lung

M1b Other sites

S Serum tumour markers

Sx Serum marker studies not available or not performed

S0 Serum marker study levels within normal limits

	LDH (U/l)		hCG (mIU/mL)		AFP (ng/mL)
S1	< 1.5 x N	and	< 5,000	and	< 1,000
S2	1.5-10 x N	or	5,000-50,000	or	1,000-10,000
S3	> 10 x N	or	> 50,000	or	> 10,000

Prognostic-based staging system for metastatic germ cell cancer (International Germ Cell Cancer Collaborative Group (IGCCCG):

Good-prognosis group	
Non-seminoma (56% of cases) 5-year PFS 89% 5-year survival 92%	All of the following criteria: • Testis/retroperitoneal primary • No non-pulmonary visceral metastases • AFP < 1,000 ng/mL • hCG < 5,000 IU/L (1,000 ng/mL) • LDH < 1.5 x ULN
Seminoma (90% of cases) 5-year PFS 82% 5-year survival 86%	All of the following criteria: • Any primary site • No non-pulmonary visceral metastases • Normal AFP • Any hCG • Any LDH
Intermediate prognosis group	
Non-seminoma (28% of cases) 5-year PFS 67% 5-year survival 72%	• Testis/retroperitoneal primary • AFP 1,000 - 10,000 ng/mL or • No non-pulmonary visceral metastases • hCG 5,000 - 50,000 IU/L or • LDH 1.5 - 10 x ULN
Seminoma (10% of cases) 5 years PFS 75% 5-year survival 80%	All of the following criteria: • Any primary site • Non-pulmonary visceral metastases • Normal AFP • Any hCG • Any LDH
Poor prognosis group	
Non-seminoma (16% of cases) 5-year PFS 41% 5-year survival 48%	Any of the following criteria: • Mediastinal primary • Non-pulmonary visceral metastases • AFP > 10,000 ng/mL or • hCG > 50,000 IU/L (10,000 ng/mL) or • LDH > 10 x ULN
Seminoma	No patients classified as poor prognosis

Prognostic factors for occult metastatic disease in testicular cancer

	For seminoma	For non-seminoma
Pathological (for stage I)		
Histopathological type invasion of the primary tumour	• Tumour size (> 4 cm) • Invasion of the rete testis	• vascular/lymphatic • Proliferation rate > 70% • Percentage of embryonal carcinoma > 50%
Clinical (for metastatic disease)		
• Primary location • Elevation of tumour marker levels • Presence of non-pulmonary visceral metastasis		

TREATMENT: STAGE I GERM CELL TUMOURS

Supranetwork Testicular Team

- The minimum catchment population for the specialist treatment of testicular cancer is two million.
- Supranetwork teams for testicular cancer deliver supranetwork care for their referring catchment.
- The minimum catchment population of two million means that currently no cancer network in England should host more than one such team on the basis of their own network population and some networks will not be able to host a team, needing to refer such patients to a team in a neighbouring network.
- In order that supranetwork teams for testicular cancer experience the full range of practice for the disease, they are required to deliver all of the care including local care to at least part of their network, usually the local catchment of their host locality. For testicular teams to add their full potential value to patient care, some surgical procedures and their immediate post-op care are required to be restricted to certain named hospitals.

Stage I seminoma

- After modern staging procedures, about 15-20% of stage I seminoma patients have subclinical metastatic disease, usually in the retroperitoneum, and will relapse after orchidectomy alone.

Surveillance

- The actuarial relapse rate is in the order of 15-20% at 5 years, and most of the relapses are first detected in infra-diaphragmatic lymph nodes.
- In patients with low risk the recurrence under surveillance is as low as 6%.
- Chemotherapy, according to the IGCCCG classification, is a possible treatment for seminoma relapse under surveillance.
- The overall cancer-specific survival rate reported under surveillance performed by experienced centres is 97-100% for seminoma stage I.
- The main drawback of surveillance is the need for more intensive follow-up, especially with repeated imaging examinations of the retroperitoneal lymph nodes, for at least 5 years after orchidectomy.
- There is a small but clinically significant risk of relapse more than 5 years after orchidectomy for stage I seminoma, which supports the need for long term surveillance.

Adjuvant chemotherapy

- Compared with adjuvant radiotherapy, studies did not show a significant difference with regard to recurrence rate, time to recurrence and survival after a median follow-up of 4 years.
- Adjuvant carboplatin therapy using a dosage of one course AUC 7 is an alternative to radiotherapy or surveillance in stage I seminoma.

Adjuvant radiotherapy

- Seminoma cells are extremely radiosensitive.
- Adjuvant radiotherapy to a para-aortic (PA) field or to a hockeystick field (para-aortic and ipsilateral iliac nodes), with moderate doses (total 20-24 Gy), will reduce the relapse rate to 1-3%.
- After modern radiotherapy, nearly all relapses will first occur outside the irradiated field (supradiaphragmatic lymph nodes or in the lungs).
- Adjuvant irradiation of supradiaphragmatic lymph nodes is not indicated in seminoma stage I. With regard to the irradiation dose, the MRC recently finished a large randomised trial of 20 Gy versus 30 Gy PA radiation in stage I seminoma that showed equivalence for both doses in terms of recurrence rates.
- The rate of severe radiation-induced long-term toxicity is < 2%. Moderate chronic gastrointestinal (GI) side-effects are seen in ~5% of patients, and moderate acute GI toxicity in ~60%.

Retroperitoneal lymph node dissection (RPLND)

- Post RPLND incidence of retroperitoneal relapses is high (9.5%).
- This policy should not be recommended in stage I seminoma.

Risk-adapted treatment

- Using tumour size > 4 cm and rete testis invasion, patients with seminoma stage I may be subdivided into a low-and high-risk group of occult metastatic disease.
- Patients with and without both risk factors have a risk of occult disease of 32% and 12%, respectively.
- These risk factors were introduced by an analysis of retrospective trials (29). A prospective trial based on these risk factors (no risk factors: surveillance; both risk factors: two courses of carboplatin AUC 7) showed the feasibility of a risk-adapted approach.
- Early data with limited follow-up indicate that patients without either risk factor have a 6.0% risk of relapse at 5 years.
- Patients in the high risk group treated with carboplatin experienced a 1.4% relapse rate at mean follow-up of 34 months.
- However, given the fact that cure is achieved in ~100% in patients with stage I seminoma whatever therapy used (adjuvant radiotherapy, adjuvant chemotherapy, or surveillance) and that the relapse rate in large surveillance series not using risk factors is ~15-20%, indicates a risk of over-treatment. Therefore, the therapeutic decision should be shared with an informed patient.

Guidelines for the treatment of seminoma stage I

Guidelines	GR
Surveillance is the recommended management option (if facilities available and patient compliant).	A
Carboplatin-based chemotherapy (one course at AUC 7) is recommended.	B
Adjuvant treatment is not recommended for patients at very low risk.	A
Radiotherapy is not recommended as adjuvant treatment.	A

NSGCT stage I

- Up to 30% of NSGCT patients with clinical stage I (CS1) disease have subclinical metastases and will relapse if surveillance alone is applied after orchidectomy

Surveillance

- The largest reports of the surveillance strategy indicate a cumulative relapse rate of ~30%, with 80% of relapses occurring during the first 12 months of follow-up, 12% during the second year and 6% during the third year, decreasing to 1% during the fourth and fifth years, and occasionally even later.

- About 35% of relapsing patients have normal levels of serum tumour markers at relapse.
- About 60% of relapses are in the retroperitoneum. Despite very close follow-up, 11% of relapsing patients presented with large-volume recurrent disease.
- Based on the overall cancer-specific survival data, surveillance within an experienced surveillance programme may be offered to patients with non-risk stratified clinical stage I non-seminoma as long as they are compliant and informed about the expected recurrence rate as well as the salvage treatment.

Primary chemotherapy

- Two courses of chemotherapy with cisplatin, etoposide and bleomycin (PEB) as primary treatment for high-risk patients (having ~50% risk of relapse) are recommended , with a relapse rate of only 2.7% was reported, with very little long-term toxicity.
- Adjuvant chemotherapy do not seem to adversely affect fertility or sexual activity.
- Long term (> 20 years) side effects of adjuvant chemotherapy in this setting are currently unknown.
- It is important to be aware of slow-growing retroperitoneal teratomas after primary chemotherapy.

Risk-adapted treatment

- It is based on the risk factor vascular invasion.
- Risk-adapted treatment is an equally effective alternative treatment of choice in CS1 NSGCT.
- If applied, patients with vascular invasion are recommended to undergo adjuvant chemotherapy with two cycles of PEB, and patients without vascular invasion are recommended to undergo surveillance.
- The Swedish-Norwegian Testicular Cancer Project (SWENOTECA) recently showed that in a large population-based study with a risk-adapted approach within a management programme and a median follow-up of 4.7 years, the relapse rate was 3.2% for patients with vascular invasion treated with only one adjuvant PEB.
- Taken together, ~300 patients with high-risk CS I have been adjuvantly treated with 1 x PEB with a follow-up of > 5 yrs. As long as 1 x PEB has not been proven superior or at least equivalent to 2 courses PEB, this adjuvant treatment cannot be recommended outside of a clinical trial or a prospective registry.

Retroperitoneal lymph node dissection

- If performed, ~30% of patients are found to have retroperitoneal lymph node metastases, which corresponds to pathological stage II (PS2).
- 10% of the PS1 patients relapse at distant sites.
- The main predictor of relapse in CS1 NSGCT is histopathological evidence of vascular invasion by tumour cells in, or near, the primary tumour in the testis.
- For CS1, patients without vascular invasion have only a 15-20% risk of relapse on surveillance, compared with a 50% relapse rate in patients with vascular invasion.
- The risk of relapse for PS1 patients is < 10% for those without vascular invasion and ~30% for those with vascular invasion.
- If two (or more) courses of cisplatin-based chemotherapy are given adjuvant to RPLND in PS2 cases, the relapse rate is reduced to < 2%, including teratoma relapse).
- The risk of retroperitoneal relapse after a properly performed nerve-sparing RPLND is very low (< 2%), as is the risk of ejaculatory disturbance or other significant side-effects.
- If there is a rare indication to perform a staging RPLND, a laparoscopic or robot-assisted RPLND is feasible in expert hands. This minimal-invasive approach cannot be recommended as a standard approach outside of a specialised laparoscopic centre.
- In a randomised comparison of RPLND with one course of PEB chemotherapy, adjuvant chemotherapy significantly increased the 2-year recurrence-free survival to 99.41% (confidence interval [CI] 95.87%, 99.92%) as opposed to surgery, which had a 2-year recurrence-free survival of 92.37% (CI 87.21%, 95.50%).
- Therefore, one course of adjuvant PEB is superior to RPLND with regard to recurrence rates in patients unstratified for risk factors . In the SWENOTECA data mentioned in section 7.3.3 it was also found that one adjuvant PEB reduced the number of recurrences to 3.2% in the high-risk and to 1.4% in the low-risk patients.

CS1S with (persistently) elevated serum tumour markers

- If the marker level increases after orchidectomy, the patient has residual disease. If RPLND is erformed, up to 87% of these patients have pathologically documented nodes in the retroperitoneum (165). An
- US examination of the contralateral testicle must be performed, if this was not done initially.
- The treatment of true CS1S patients is still controversial. They may be treated with three courses of primary PEB chemotherapy and with follow-up as for CS1B patients after primary chemotherapy, or by RPLND. The presence of vascular invasion may strengthen the indication for primary chemotherapy as most CS1S with vascular invasion will need chemotherapy sooner or later anyway.

Guidelines for the treatment of NSGCT stage I

NSGCT stage 1	**GR**
CS1 risk-adapted treatments based on vascular invasion or surveillance without using risk factors are recommended treatment options.	A
Risk-adapted treatments for CS1 based on vascular invasion	
CS1A (pT1, no vascular invasion): low risk	
If the patient is willing and able to comply with a surveillance policy, long-term (at least 5 years) close follow-up should be recommended.	A
In low-risk patients not willing (or suitable) to undergo surveillance, adjuvant chemotherapy or nerve-sparing RPLND are treatment options. If RPLND reveals PN+ (nodal involvement) disease, chemotherapy with two courses of PEB should be considered.	A
CS1B (pT2-pT4): high risk	
Primary chemotherapy with two courses of PEB should be recommended (one course of PEB within a clinical trial or registry).	A
Surveillance or nerve-sparing RPLND in high-risk patients remains an option for those not willing to undergo adjuvant chemotherapy. If pathological stage II is revealed at RPLND, further chemotherapy should be considered.	A

TREATMENT: METASTATIC GERM CELL TUMOURS

The treatment of metastatic germ cell tumours depends on:

- the histology of the primary tumour;
- prognostic groups as defined by the IGCCCG.

Low-volume metastatic disease (stage IIA/B)

Seminoma:

- The standard treatment for stage IIA/B seminoma has been radiotherapy.
- The radiation dose delivered in stage IIA and IIB is approximately 30 Gy and 36 Gy, respectively.
- The standard radiation field compared with stage I will be extended from the PA region to the ipsilateral iliac field (the hockey-stick field).
- Overall survival is almost 100%. Conversely, dose reduction to 27 Gy has been associated with 11% of relapses.

Non-seminoma

- Initial chemotherapy is recommended in all advanced cases of NSGCT (except for stage II NSGCT disease without elevated tumour markers, which alternatively can be managed by primary RPLND or surveillance to clarify stage).
- If surveillance is chosen, one follow-up after 6 weeks is indicated to document whether the lesion is growing, remaining stable or shrinking.
    - A shrinking lesion is likely to be of non-malignant origin and should be observed further.
    - A stable or growing lesion indicates either teratoma or an undifferentiated malignant tumour.
    - If the lesion is growing without a corresponding increase in the tumour markers AFP or beta-hCG, RPLND should be performed by an experienced surgeon because of suspected teratoma.
    - Patients with a growing lesion and a concomitant increase in the tumour markers AFP or beta-hCG should not undergo surgery; they require chemotherapy with PEB according to the treatment algorithm for patients with metastatic disease and IGCCCG recommendations.
- An alternative to the surveillance strategy in marker-negative II A/B non-seminoma with suspicion of an undifferentiated malignant tumour is a (CT-guided) biopsy, if technically possible.
- There is insufficient published data on PET scans in this situation.
- Patients not willing to undergo primary chemotherapy have the option of primary nerve-sparing RPLND with adjuvant chemotherapy (two cycles of PEB) in case of metastatic disease.
- Primary chemotherapy and primary RPLND are comparable options in terms of outcome but side-effects and toxicity are different, allowing for involvement of the patient in selecting the treatment of choice. The cure rate with either approach will be close to 98%.

Advanced metastatic disease

- The primary treatment of choice for advanced disease is three or four cycles of PEB combination chemotherapy, depending on the IGCCCG risk classification. This regimen has proven superiority to cisplatin, vinblastine and bleomycin (PVB) in patients with advanced disease.
- Good prognosis group (IGCCCG Classification):
    - standard treatment consists of three cycles of PEB
    - in very selected cases where bleomycin is contraindicated, four cycles of EP.
- Intermediate prognosis group (5-year survival rate of ~80%):
    - four cycles of PEB as standard treatment.
- Poor prognosis group (5-year progression-free survival is 45-50%):
    - standard treatment consists of four cycles of PEB, or etoposide and ifosfamide (PEI) with similar effect but more toxicity.

- poor-prognosis patients should be transferred to a reference centre because a better outcome was reported for intermediate and poor prognosis patients who had been treated within a clinical trial in a high volume centre.
- There are no general recommendations for treatment modifications for patients with a poor general condition (Karnofsky < 50%) or extended liver infiltration (> 50%).
- Patients with extended pulmonary infiltration are at risk for acute respiratory distress syndrome: adapting the doses of the PEB regimen in the first cycle of chemotherapy (only 3 days of EP without bleomycin) was suggested to reduce the risk of early death in this setting.

Residual tumour resection

- A residual mass of seminoma should not be primarily resected, irrespective of the size, but controlled by imaging investigations and tumour markers.
- FDG-PET has a high negative predictive value in patients with residual masses after treatment of seminoma but false positive results can be a problem and scans should not be performed < 2 months after chemotherapy.
- In patients with residuals of > 3 cm, FDG-PET should be performed in order to gain more information on the viability of these residuals.
- In patients with residuals of < 3 cm, the use of FDG-PET is optional.
- On progression, salvage therapy is indicated (chemotherapy, salvage surgery, radiotherapy) .
- In patients with concurrent hCG elevation, progressing seminoma after first-line chemotherapy should be treated by salvage chemotherapy (or radiotherapy if only small volume recurrence is present).
- Progressing patients without hCG progression should undergo histological verification (e. g. by biopsy or open surgery) before salvage chemotherapy is given. In the case of non-seminoma and complete remission after chemotherapy (no tumour visible), residual tumour resection is not indicated.
- The long-term relapse rate in this patient group is 6-9%, however, one third of the late relapsing patients will not survive.
- In the case of any visible residual mass and marker normalisation, surgical resection is indicated. In patients with lesions < 1 cm, there still is an increased risk of residual cancer or teratoma although the role of surgery in this setting is debated.
- In persistent larger volume retroperitoneal disease, all areas of primary metastatic sites must be completely resected within 4-6 weeks of completion of chemotherapy.
- If technically feasible, a nerve-sparing procedure should be performed.

- Overall, following PEB induction chemotherapy, only 10% of residual masses contain viable cancer, 50% contain mature teratoma, and 40% contain necrotic-fibrotic tissue.
- As yet, no imaging investigations, including PET or a prognosis model, are able to predict histological differentiation of the non-seminomatous residual tumour. Thus, residual tumour resection is mandatory in all patients with residual disease > 1 cm.
- The extent of surgery should be based on the risk of relapse of an individual patient and quality of life issues. If possible, all the masses should be resected, because a complete resection, in the setting of viable malignant cells, is more critical than recourse to post-operative chemotherapy.
- There is growing evidence that “template” resections in selected patients yield equivalent long-term results compared to bilateral systematic resections in all patients.
- Mere resection of the residual tumour (so called “lumpectomy”) should not be performed.
- The histology may diverge in different organ sites. Resection of contralateral pulmonary lesions is not mandatory in case pathologic examination of the lesions from the first lung shows complete necrosis.

Consolidation chemotherapy after secondary surgery

- After resection of necrosis or mature/immature teratoma, no further treatment is required.
- In the case of incomplete resection of other germ cell tumour pathologies, two adjuvant cycles of conventionally dosed cisplatin-based chemotherapy may be given in certain subgroups (e.g. ‘poor prognosis’ patients).
- After complete resection of ‘vital’ tumour < 10% of the total volume, especially in patients with an initially good prognosis group according to IGCCCG, the relapse rate is very low and adjuvant chemotherapy is not beneficial for preventing further relapse.
- The prognosis will definitely deteriorate if vital malignant neoplasm is found in resection specimens after second- and third-line chemotherapy. In this latter situation, post-operative chemotherapy is not indicated and is unable to improve the prognosis.

Systemic salvage treatment for relapse or refractory disease

- Cisplatin-based combination salvage chemotherapy will result in long-term remissions for about 50% of the patients who relapse after first-line chemotherapy (255). The.

- Regimens of choice are four cycles of PEI/VIP (etoposide, ifosfamide, cisplatin), four cycles of TIP (paclitaxel, ifosfamide, cisplatin) or four cycles of VeIP (vinblastine, ifosfamide, cisplatin)
- Due to the lack of evidence, it is therefore of the utmost importance that these rare patients are treated within clinical trials and at experienced centres.

Treatment of brain metastases

- Brain metastases occur in the frame of a systemic relapse and rarely as an isolated relapse.
- The longterm survival of patients presenting with brain metastases at initial diagnosis is poor (30-40%)
- 5-year survival-rate for brain metastasis as a recurrent disease is even poorer (2-5%)
- Chemotherapy is the initial treatment in this case, and some data support the use of consolidation radiotherapy, even in the case of a total response after chemotherapy.
- Surgery can be considered in the case of a persistent solitary metastasis, depending on the systemic state, the histology of the primary tumour and the location of the metastasis.

FOLLOW-UP AFTER CURATIVE THERAPY

Recommended follow-up schedule in a surveillance policy: stage I non-seminoma

Procedure	**Year**	**Year**	**Year**	**Year**
	1	**2**	**3-5**	**6-10**
Physical examination	4 times	4 times	Once/year	Once/year
Tumour markers	4 times	4 times	Once/year	Once/year
Plain radiography chest	Twice	Twice		
Abdominopelvic CT	Twice (at 3 and 12 months)			

Recommended follow-up schedule after retroperitoneal lymphadenectomy or adjuvant chemotherapy: stage I non-seminoma

Procedure	**Year**	**Year**	**Year**	**Year**

	1	2	3-5	6-10
Physical examination	4 times	4 times	Once/year	Once/year
Tumour markers	4 times	4 times	Once/year	Once/year
Plain radiography chest	Twice	Twice		
Abdominopelvic CT	Once	Once		

Recommended follow-up schedule for post-orchidectomy surveillance, radiotherapy or chemotherapy: stage I seminoma

Procedure	**Year**	**Year**	**Year**	**Year**
	1	**2**	**3-5**	**6-10**
Physical examination	4 times	4 times	Once/year	Once/year
Tumour markers	4 times	4 times	Once/year	Once/year
Plain radiography chest	Twice	Twice		
Abdominopelvic CT	Once	Once		

Recommended minimum follow-up schedule in advanced NSGCT and seminoma

Procedure	**Year**	**Year**	**Year**	**Year**
	1	**2**	**3-5**	**Thereafter**
Physical examination	4 times	4 times	Twice/year	Once/year
Tumour markers	4 times	4 times	Twice/year	Once/year
Plain radiography chest	Twice	Twice	Twice/year	Once/year
Abdominopelvic CT	Twice	Twice	As indicated	As indicated
Chest CT	As indicated	As indicated	As indicated	As indicated
Brain CT	As indicated	As indicated	As indicated	As indicated

9.6 Upper Urinary Tract Urothelial Cell Carcinomas

Epidemiology:

- Upper urinary tract urothelial cell carcinomas (UUT-UCCs) are uncommon and account for only 5-10% of urothelial carcinomas
- The estimated annual incidence of UUT-UCCs in Western countries is about one or two new cases per 100,000 inhabitants.
- Pyelocaliceal tumours are about twice as common as ureteral tumours.
- In 8-13% of cases, concurrent bladder cancer is present.
- Recurrence of disease in the bladder occurs in 30-51% of UUT-UCC patients
- Recurrences in the contralateral upper tract are observed in 2-6%.
- 60% of UUT-UCCs are invasive at diagnosis.
- Upper urinary tract urothelial cell carcinomas have a peak incidence in people in their 70s and 80s, and UUT-UCC is three times more prevalent in men than in women.
- There are familial/hereditary cases of UUT-UCCs linked to hereditary nonpolyposis colorectal carcinoma (HNPCC)

Risk factors:

- Tobacco and occupational exposure remain the principal exogenous risk factors for developing these tumours. Exposure to tobacco increases the relative risk of developing a UUT-UCC from 2.5 to 7
- UUT-UCC “amino tumours” are related to occupational exposure to certain aromatic amines. These aromatic hydrocarbons are used in many industries (e.g., dyes, textiles, rubber, chemicals, petrochemicals, and coal). They are responsible for the carcinogenicity of certain chemicals, including benzidine and β-naphthalene. The estimated risk (odds ratio) of developing UCC after exposure to aromatic amines is 8.3.
- Upper urinary tract tumours resulting from phenacetin consumption almost disappeared after the product was banned in the 1970s.
- Although the incidence of Balkan endemic nephropathy is also on the decline, roles have been proposed for aristolochic acid and the consumption of Chinese herbs in the physiopathology and induction, respectively, of this nephropathy.
- One polymorphism specific to UUT-UCC has been reported so far. A variant allele, SULT1A1*2, which reduces sulfotransferase activity, enhances the risk of developing UUT-UCC.
- Epidermoid carcinoma of the UUT is associated with chronic inflammatory and infectious disease arising from stones in the UUT.

TNM classification of UUT-UCC (2009)

T - Primary Tumour
Tx Primary tumour cannot be assessed

T0 No evidence of primary tumour Ta Non-invasive papillary carcinoma Tis Carcinoma in situ T1 Tumour invades subepithelial connective tissue T2 Tumour invades muscle T3 (Renal pelvis) Tumour invades beyond muscularis into peripelvic fat or renal parenchyma (Ureter) Tumour invades beyond muscularis into periureteric fat T4 Tumour invades adjacent organs or through the kidney into perinephric fat
N - Regional Lymph Nodes
Nx Regional lymph nodes cannot be assessed N0 No regional lymph-node metastasis N1 Metastasis in a single lymph node 2 cm or less in the greatest dimension N2 Metastasis in a single lymph node more than 2 cm but not more than 5 cm in the greatest dimension or multiple lymph nodes, none more than 5 cm in greatest dimension N3 Metastasis in a lymph node more than 5 cm in greatest dimension
M - Distant Metastasis M0 No distant metastasis M1 Distant metastasis

World Health Organization grading for bladder cancer

1973 WHO grading
Urothelial papilloma
Grade 1: well differentiated
Grade 2: moderately differentiated
Grade 3: poorly differentiated

Diagnosis:

The following guidelines for urgent referral (within two weeks) have been published by the Department of Health:

- Macroscopic haematuria in adults.
- Microscopic haematuria in adults over 50 years.
- Swellings in the body of the testis.
- Palpable renal masses.
- Solid renal masses found on imaging.
- Elevated age-specific prostate specific antigen (PSA) in men with a 10 year life expectancy.
- A high PSA (>20ng/ml) in men with a clinically malignant prostate or bone pain.
- Any suspected penile cancer.

Imaging:

CT Urogram (CTU)

- CTU is the gold standard for exploration of the upper urinary tract and has replaced intravenous excretory urography.
- It must be conducted under optimal conditions, particularly with acquisition of an excretory phase.
- The detection rate of UUT-UCC is satisfactory for this type of imaging: 96% sensitivity and 99% specificity for polypoid lesions between 5 and 10 mm.
- Sensitivity drops to 89% for polypoid lesions < 5 mm and 40% for polypoid lesions < 3 mm.

Magnetic resonance imaging (MRI):

- MRI urography is indicated in patients who cannot be subjected to a CTU.
- The detection rate of MRI is 75% after contrast injection for tumours < 2 cm.
- MRI urography with contrast injection, however, remains contraindicated in selected patients with severe renal impairment (< 30 ml/min creatinine clearance) due to the risk of nephrogenic systemic fibrosis.
- Magnetic resonance urography without contrast is less helpful compared with CTU in diagnosing UUT-UCCs.

Cystoscopy and urinary cytology

- Positive urine cytology is highly suggestive of UUT-UCC when bladder cystoscopy is normal and if CIS of the bladder or prostatic urethra has been excluded.
- Cytology is less sensitive for UUT-UCC than for bladder tumours, even for high-grade lesions, and it should ideally be performed in situ (i.e. in the renal cavities).
- A positive cytology may be valuable in staging because it has been associated with muscle-invasive and nonorgan-confined disease.

Diagnostic ureteroscopy

- Ureteroscopy is a better approach to diagnose UUT-UCCs.
- Flexible ureteroscopy is especially useful when there is diagnostic uncertainty, when conservative treatment is being considered, or in patients with a solitary kidney.
- The possible advantages of ureteroscopy should be discussed in the preoperative assessment of any UUT-UCC patient. Combining ureteroscopic biopsy grade, ipsilateral hydronephrosis, and urinary cytology may help decision making on radical nephroureterectomy (RNU) versus endoscopic treatment.

Guidelines for the diagnosis of UUT-UCC

Recommendations	GR
Urinary cytology	A
Cystoscopy to rule out a concomitant bladder tumour	A
CTU	A

Prognostic factors:

- Upper urinary tract urothelial cell carcinomas that invade the muscle wall usually have a very poor prognosis.
- The 5-yr specific survival is < 50% for pT2/pT3 and < 10% for pT4.
- Tumour stage and grade: the primary recognised prognostic factors.
- Age: poor prognosis with advanced age at diagnosis.
- Gender: no relation.
- Tumour location: no relation.
- Lymphovascular invasion: is present in approximately 20% of UUT-UCCs and an independent predictor of survival.
- Extensive tumour necrosis: is an independent predictor of clinical outcomes in patients who undergo RNU.
- The tumour architecture (e.g., papillary vs. sessile) of UUT-UCCs appears to be associated with prognosis after RNU. A sessile growth pattern is associated with worse outcomes (LE: 3) (8,63,69).
- The presence of concomitant CIS in patients with organ-confined UUT-UCC is associated with a higher risk of recurrent disease and cancer-specific .

Treatment

Localised disease:

- Radical nephroureterectomy (RNU)with excision of the bladder cuff is the gold standard treatment for UUT-UCCs, regardless of the location of the tumour in the upper urinary tract
- The RNU procedure must comply with oncologic principles, which consist of preventing tumour seeding by avoiding entry into the urinary tract during tumour resection.
- Resection of the distal ureter and its orifice is performed because it is a part of the urinary tract with considerable risk of recurrence.
- After removal of the proximal part, it is almost impossible to image or approach it by endoscopy during follow-up.
- Plucking/endoscopic resection of the distal ureter (apart from ureteral stripping) are non-inferior to excision of the bladder cuff.

- A delay > 45 d between diagnosis and resection of the tumour constitutes a risk for disease progression.
- Lymph node dissection associated with RNU is of therapeutic interest and allows for optimal staging of the disease.
- Lymphadenectomy in pN+ allows for reduction of the tumour mass to guide patients towards adjuvant treatments.
- Anatomic sites of lymphadenectomy have not yet been clearly defined.
- The number of lymph nodes to be removed depends on the tumour location.
- Lymphadenectomy appears to be unnecessary in cases of TaT1 UUT-UCCs.
- The safety of laparoscopic RNU has not yet achieved final proof. In early experience, there were reports of retroperitoneal metastatic dissemination and dissemination along the trocar pathway when large tumours were manipulated in a pneumoperitoneal environment.
- Recent data, however, show a tendency towards equivalent oncologic results between laparoscopic RNU and open surgery.
- In addition, the laparoscopic approach appears to be superior to open surgery only with regard to functional outcomes.
- When considering laparoscopic RNU the following precautions must be considered:
    - Entering the urinary tract should be avoided.
    - Direct contact of the instruments with the tumour should be avoided.
    - Laparoscopic RNU must take place in a closed system.
    - Morcellation of the tumour should be avoided, and an endobag is necessary to extract the tumour.
    - The kidney and ureter must be removed en bloc with the bladder cuff.
    - Invasive, large (T3/T4 and/or N+/M+), or multifocal tumours are contraindications for laparoscopic RNU, until proven otherwise.

Guidelines for radical management of UUT-UCC: radical nephroureterectomy

Indications for RNU for UUT-UCC	GR
Suspicion of infiltrating UUT-UCC on imaging	B
High-grade tumour (urinary cytology)	B
Multifocality (with two functional kidneys)	B
Techniques for RNU in UUT-UCC Open and laparoscopic access are equivalent in terms of efficacy	B
Bladder cuff removal is imperative	A
Several techniques for bladder cuff excision are acceptable except stripping	C
Lymphadenectomy is recommended in case of invasive UUT-UCC	C

Conservative surgery

- Conservative surgery for low-risk UUT-UCCs allows for preservation of the upper urinary renal unit while sparing the patient the morbidity associated with open radical surgery
- Conservative management of UUT-UCCs can be considered in imperative cases (renal insufficiency, solitary functional kidney) or in elective cases (i.e. when the contralateral kidney is functional) for low-grade, low-stage tumours.
- The choice of technique depends on technical constraints, the anatomic location of the tumour, and the experience of the surgeon.
    - Ureteroscopy: Endoscopic ablation can be considered in highly selected cases (96,97,98) and in these situations:
        - A flexible rather than a rigid ureteroscope, laser generator, and pliers (pluck) for biopsies are available.
        - The patient is informed of the need for closer, more stringent surveillance.
        - A complete resection is advocated.
    - Segmental resection:
        - It provides adequate pathologic specimens for definitive staging and grade analysis while also preserving the ipsilateral kidney.
        - Segmental resection is possible for the treatment of low- and high-risk tumours of the distal ureter .
        - It is necessary, however, to ensure that the area of tissue around the tumour is not invaded.
        - Segmental resection of the iliac and lumbar ureter is associated with a failure rate greater than that for the distal pelvic ureter.
        - Open resection of tumours of the renal pelvis or calices has almost disappeared.
        - Resection of pyelocaliceal tumours is technically difficult, and the recurrence rate is higher than for tumours of the ureter.
    - Percutaneous access:
        - It is considered for low-grade or non-invasive UUT-UCCs in the renal cavities.
        - This treatment option may be offered to patients with low-grade tumours in the lower caliceal system that are inaccessible or difficult to manage by ureteroscopy.
        - A theoretical risk of seeding exists in the puncture tract and in perforations that may occur during the procedure.
        - This approach, however, is being progressively abandoned due to enhanced materials and advances in distal-tip deflection of recent ureteroscopes.
    - Adjuvant topical agents:
        - BCG or mitomycin C in the urinary tract by percutaneous nephrostomy via a three-valve system open at 20 cm (after

complete eradication of the tumour), or even through a ureteric stent is technically feasible after conservative treatment of UUT-UCCs or for the treatment of CIS.

- The medium-term results are similar to those observed for the treatment of bladder tumours but have not been confirmed in long-term studies.

Guidelines for conservative management of UUT-UCC

Indications for conservative management of UUT-UCC	**GR**
Unifocal tumour	B
Small tumour	B
Low-grade tumour (cytology or biopsies)	B
No evidence of an infiltrative lesion on MDCTU	B
Understanding of close follow-up	B
Techniques used in conservative management of UUT-UCC	
Laser should be used in case of endoscopic treatment	C
Flexible ureteroscopy is preferable over rigid ureteroscopy	C
Open partial resection is an option for pelvic ureteral tumours	C
A percutaneous approach remains an option in small low-grade caliceal tumours unsuitable for ureteroscopic treatment	C

Advanced disease:

- There are no benefits of RNU in metastatic (M+) disease, although it can be considered a palliative option.
- Because UUT-UCCs are urothelial tumours, platinum-based chemotherapy is expected to produce similar results to those seen in bladder cancer.
- Limited evidence to support the used of neoadjuvant chemotherapy in RNU.
- Adjuvant chemotherapy (depending on patient fitness and renal function) achieves a recurrence-free rate of up to 50% but has minimal impact on survival.
- Adjuvant radiotherapy may improve local control of the disease.
- When given in combination with cisplatinum, it may result in a longer disease-free survival and longer overall survival.
- Radiation therapy appears to be scarcely relevant nowadays both as a unique therapy and associated with chemotherapy as a tumour adjuvant.

Follow-up

- Strict follow-up of UUT-UCC patients after surgical treatment is mandatory to detect metachronous bladder tumours.
- Bladder recurrence after treatment of a primary UUT-UCC varies considerably from 15% to 50%. Thus the bladder should be observed in all cases.
- A prior history of bladder cancer and upper tract tumour multifocality are the risk factors most often reported for bladder tumours following UUT-UCCs.
- The surveillance regimen is based on cystoscopy and urinary cytology for at least 5 yr.
- When conservative treatment is performed, the ipsilateral upper urinary tract requires careful follow-up due to the high risk of recurrence.

Guidelines for follow-up of UUT-UCC patients after initial treatment

After RNU, over at least 5 yr	**GR**
Noninvasive tumour Cystoscopy/urinary cytology at 3 mo and then yearly	C
MDCTU every year	C
Invasive tumour Cystoscopy/urinary cytology at 3 mo and then yearly	C
MDCTU every 6 mo over 2 yr and then yearly	C
After conservative management, over at least 5 yr	
Urinary cytology and MDCTU at 3 mo, 6 mo, and then yearly	C
Cystoscopy, ureteroscopy and cytology in situ at 3 mo, 6 mo, and then every 6 mo over 2 yr, and then yearly	C

10.0 UROLOGICAL NURSING

It is well-documented that the CNS plays an essential role within the cancer multidisciplinary team (MDT) in providing high-quality care from diagnosis throughout the patient journey (National Peer Review Programme, 2014). The National Institute for Clinical Excellence (NICE) (2002) called for major changes in improving outcomes for patients with Urological Cancers. In particular they recommended that the CNS should have specific knowledge and expertise and should be trained in advanced communication skills. More recently, NICE (2014) emphasised that the CNS can ensure that patients have information that is tailored to their individual needs, therefore enhancing shared decision making. The CNS is also in an excellent position to provide individualised care following treatment which promotes cancer survivorship (National Cancer Survivorship Initiative, 2011). A recent Macmillan census on specialist nurses workforce in Northern Ireland (2014) has highlighted that cancer care teams of the future will need to have more flexibility working with people who are living with cancer. This census emphasised that the role of the CNS must be optimised to support those living in the community with a diagnosis of cancer.

The combination of improved life expectancy, advancements in diagnostics and treatment, and increased use of PSA testing in primary Care have all contributed to a significant rise in Urological cancer diagnosis. In Northern Ireland the number of new cases of Urological cancers diagnosed annually has increased and the associated workload creating significant challenges for Urological cancer teams and further demands on Uro-Oncology Clinical Nurse Specialists (CNS).

10.1 Responsibilities of the Uro-oncology Specialist Nurses

All patients should be assigned a key worker (usually a CNS) at the time of diagnosis, and appropriate arrangements should be in place to facilitate easy access to the key worker during working hours and an appropriate source of advice in his/her absence, as per National Cancer Peer Review standards. All patients should be offered a holistic needs assessment (HNA) at diagnosis and subsequently if their disease status changes. Patients should be offered advice and support to address any immediate concerns – physical, mental, spiritual or financial – on completion of the HNA with onward referrals made as necessary.

The responsibilities of the uro-oncology CNS include, ensuring patients undergoing investigations for suspected cancers have adequate information and support. On diagnosis, the CNS has a supportive role and will help ensure that the patient and significant others are equipped to make informed decisions regarding their ongoing treatment and care. The CNS may have a role in the review of patients following treatment for urological cancer. The CNS also has a key role in equipping the patient to live with and beyond the urological cancer, as advocated by the National Cancer Survivorship Initiative (2011). National Cancer Survivorship Initiative (2011) has also recommended the use of Holistic Needs Assessment (HNA) by the CNS to assess patient's needs for physical, psychological, social, spiritual and financial support at key points of their journey. A structured pack has been provided for use by professionals to assist with this process (NCAT, 2010). This HNA approach and subsequent care planning is a process which would ensure that people's needs are met in a timely and appropriate way and that resources are targeted to those who need them most. As a result of the HNA patients should be appropriately referred or signposted to any required support services.

Where cystectomy is considered, the involvement of the Stoma Therapist and/or Urology Clinical Nurse Specialist soon after diagnosis is essential. Patients should be offered the opportunity to meet a patient who has had a cystectomy and urinary diversion to help the decision making process. Patients who may have problems with urinary incontinence should be given information about local continence services.

11.0 SUPPORTIVE AND PALLIATIVE CARE

Supportive care is available to people with cancer and their carers throughout the patient pathway, from pre-diagnosis onwards and is a term used to describe all services that may be required to support people with cancer and their carers(NICE,2004). It is identified by NICE (2004) that patients and carers may have a series of problems preceding diagnosis (when cancer is suspected) which may include physical and anxiety related symptoms which require appropriate management, and information should be available for patients at this stage if they require it. As recognised by NICE (2004) supportive care is the responsibility of all health and social care professionals involved in delivering care and effective communication within teams will enable a seamless transition from one service to another if and when required.

Patients with advanced urological cancer may benefit from supportive and palliative care. Palliative care is defined by the World Health Organization (WHO, 2014) as an approach that improves the quality of life of patients and their families, facing the problems associated with life threatening illness. Uncontrolled symptoms can adversely affect quality of life and a patient's ability to cope with their illness, therefore, early identification, thorough assessment and treatment of pain and other problems, physical, psychological and spiritual, is essential (WHO 2014). The overall goal of palliative care is to help manage the symptoms and difficulties that may arise with disease progression, through appropriate support and intervention.

Palliative Care is an integral part of the multidisciplinary team and patients may require palliative care at different stages of the patient pathway (NICE, 2004). Generalist palliative care is the level of care required by most people and is provided by non-palliative/ end of life care specialist's i.e. primary and secondary health care teams (Living Matters, Dying Matters, 2010). Specialist palliative care may be required for those patients with more demanding care needs, i.e. unresolved symptoms and complex psychosocial, end of life and bereavement issues (Living Matters, Dying Matters, 2010).Referral to Specialist Palliative Care may be made at any time in the course of the disease when the patient wishes and would benefit from it.

References:

Living Matters, Dying Matters (2010) A Palliative and End of Life Care Strategy for Adults in Northern Ireland www.dhsspsni.gov.uk

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National Institute for Clinical Excellence (2004) Guidance on Cancer Services. Improving Supportive and Palliative Care for Adults with Cancer. London: NICE.

National Institute for Clinical Excellence (2014) Prostate Cancer: diagnosis and treatment. NICE: London.

National Peer Review Programme (2014) Manual for Cancer Services- Urology Measures.

World Health Organisation (2014) http://www.who.int./cancer/palliative/definition/en/

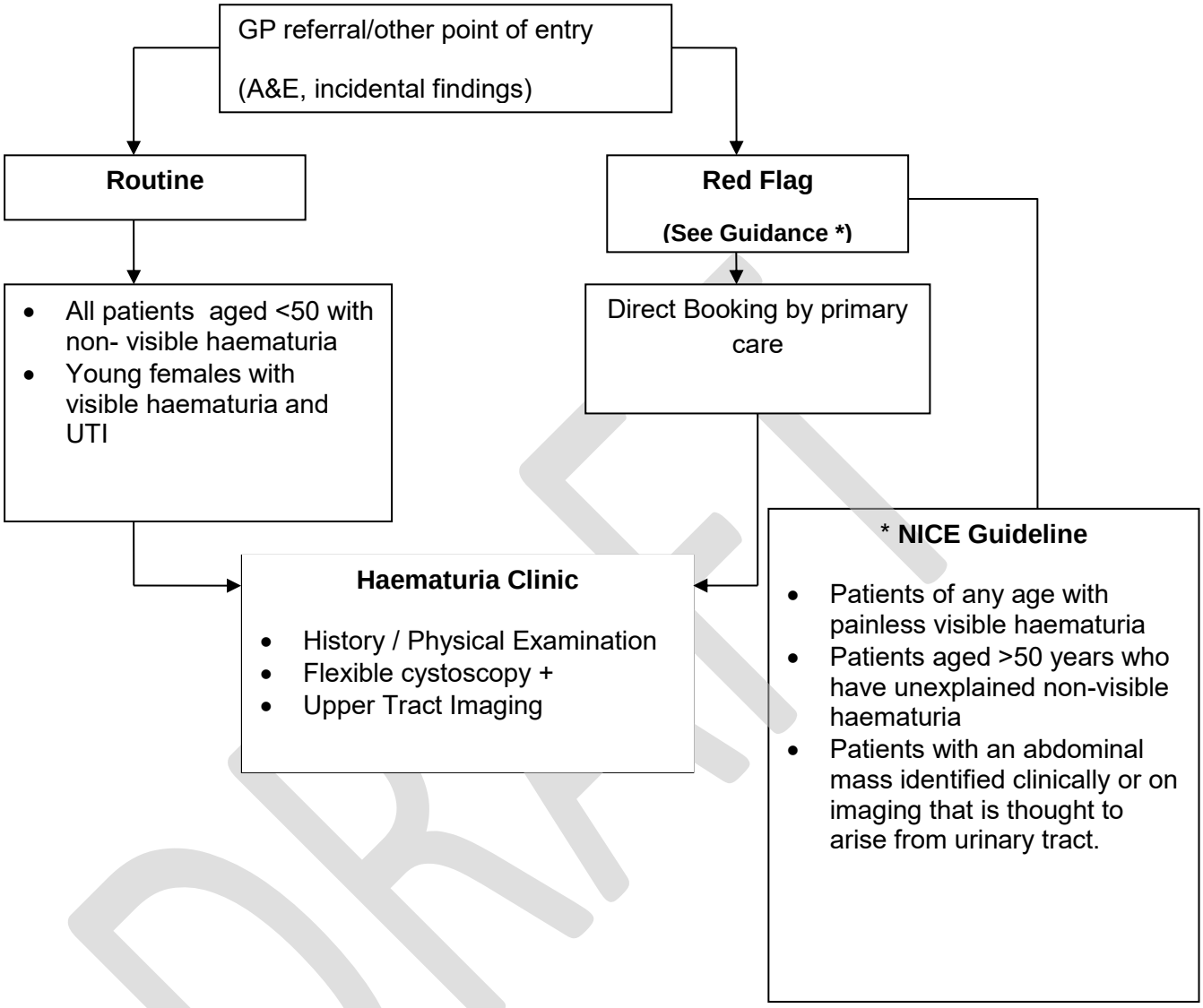
APPENDICES

1. **Haematuria Referral Guideline**

2. **Urology Care Pathways:**
   Prostate Pathway,
   Renal Tumour
   Testicular Cancer Pathway
   Transitional Cell Carcinoma
   Castration Resistant Prostate Cancer
   Penile Cancer Pathway

3. **Guidelines for nurse led follow up prostate cancer pathways**

Haematuria Referral Guideline



NOTE: Please Consider Nephrology referral as well as referral to haematuria clinic if the patient has any of the following:

- Diabetes
- Proteinuria
- Hypertension

Appendix 2; Urology Care Pathways

Cancer Care Pathways outline the steps and stages in the patient journey from referral through to diagnostics, staging, treatment, follow up, rehabilitation and if applicable onto palliative care.

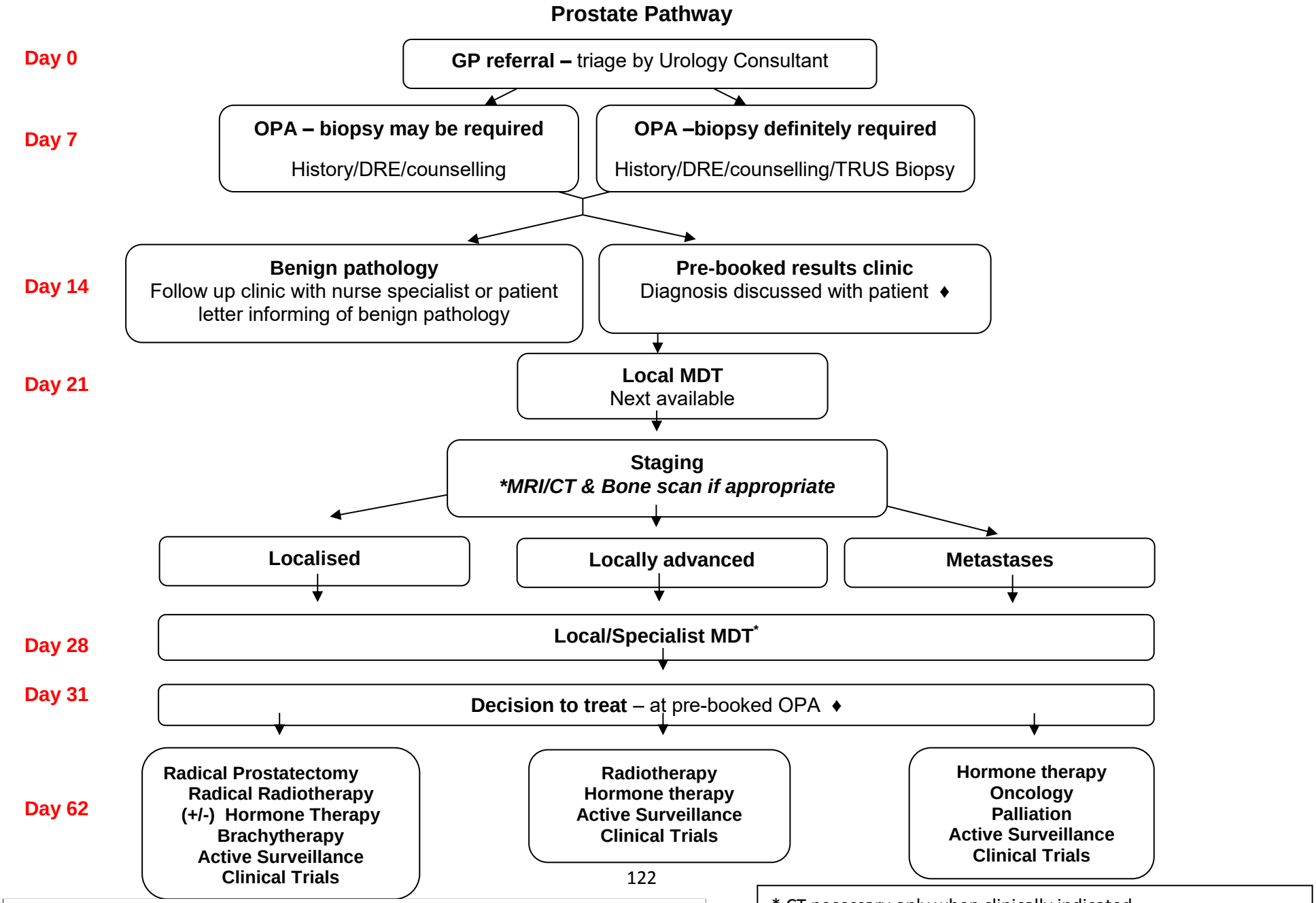
Timed effective care pathways are central to delivering quality and timely care to patients throughout their cancer journey and to the delivery of an equitable service. These pathways have been developed following with reference to available best practice guidance. They represent an 'ideal' pathway that can be adapted for local use. The timelines on the pathway are intended to facilitate the proactive management of patients within the access standards and it is to be noted that for some urological tumours, the patient will move much quicker through the pathway (e.g. testicular cancer).

The pathways are in draft form and amendments have been made following discussion at the workshop of the NICaN Regional Urology group held on Thursday 2nd October, 2008

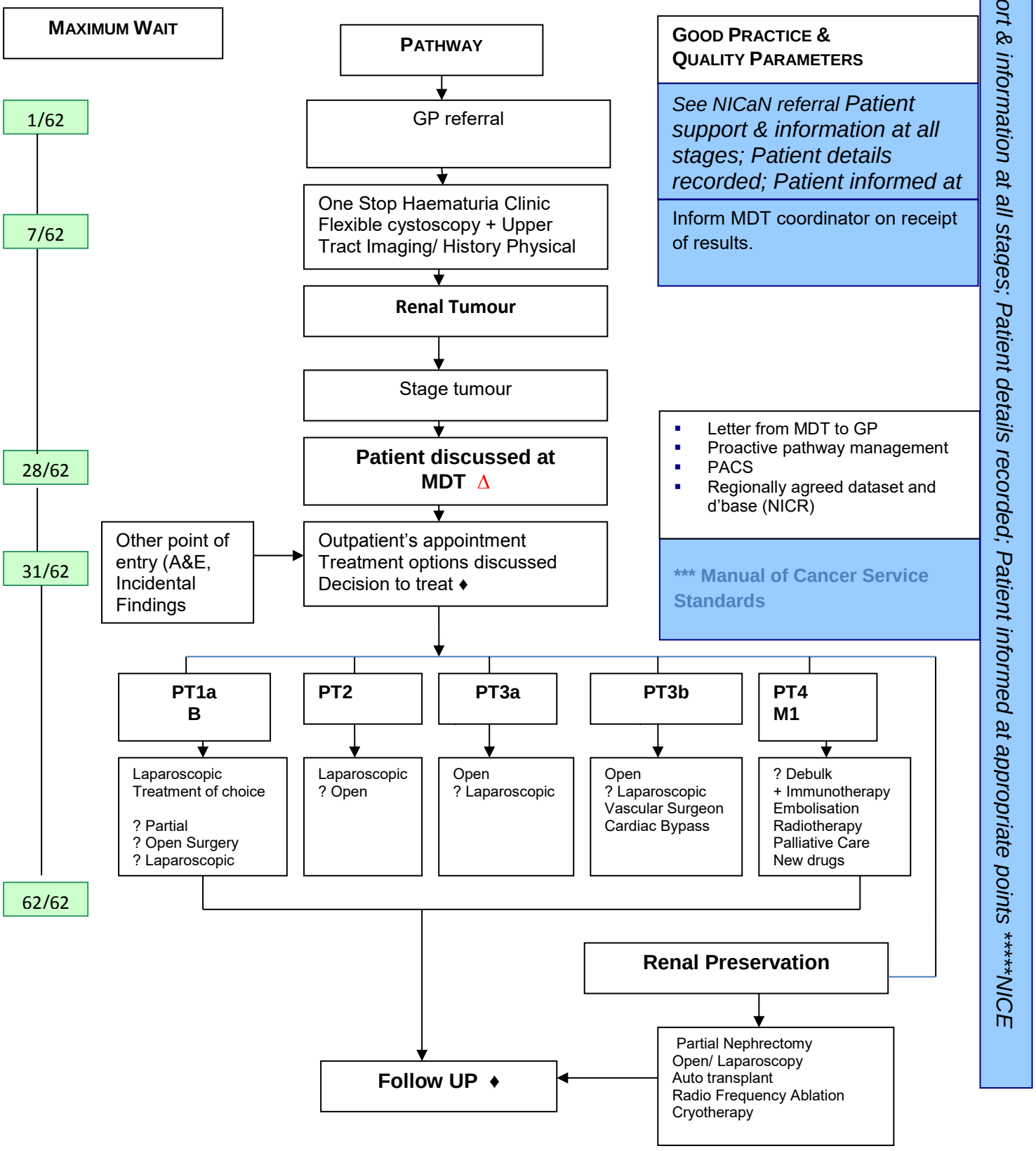
Document History

V1 Draft discussed at workshop 2/10/08
V2 Draft discussed 29/1/09 and amendments noted
Version 3 circulated for final comments 26/02/09
Pathways agreed at regional meeting 23/4/09

Appendix 2 of NICaN Urology Cancer Clinical Guidelines

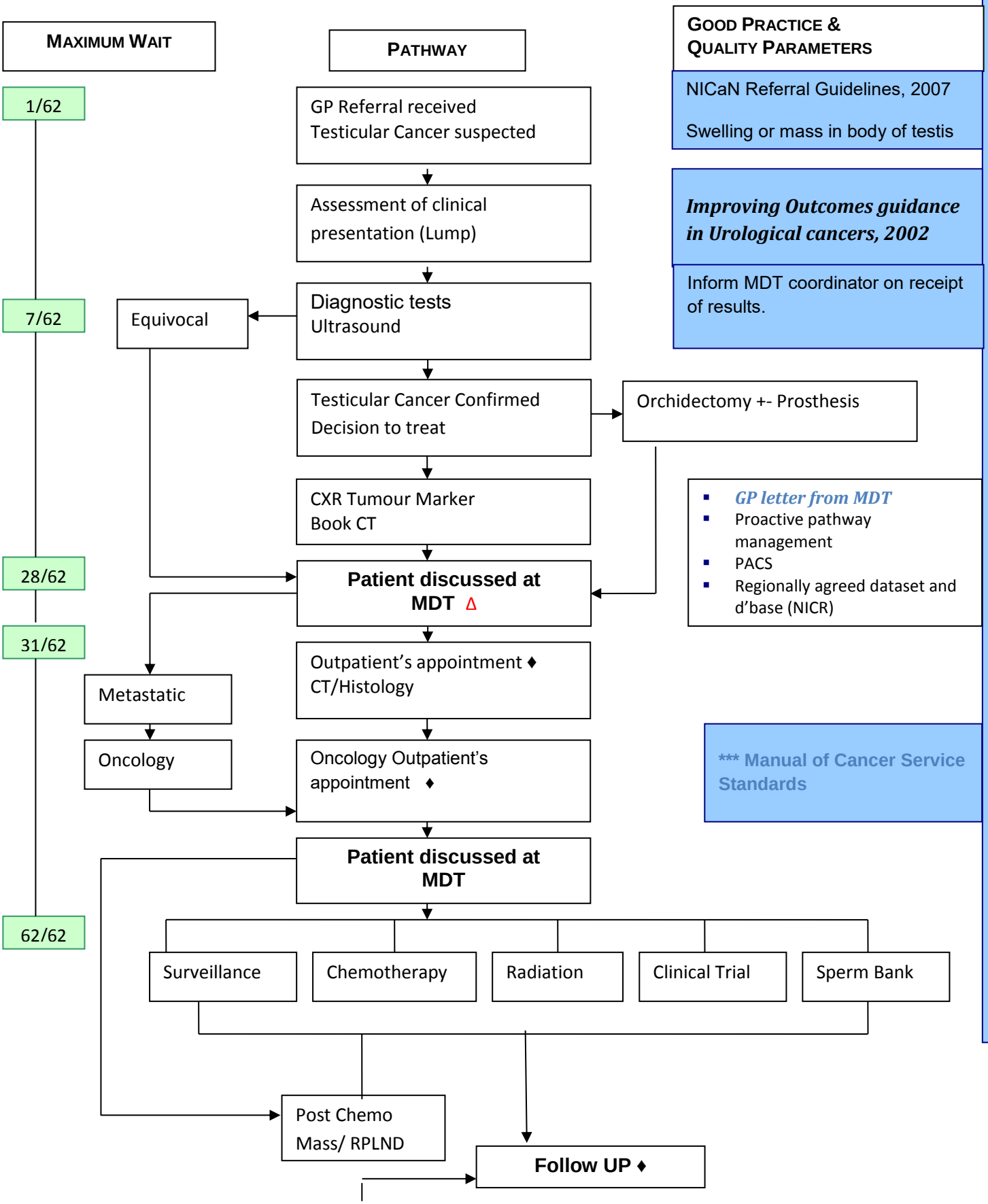


Renal Tumour



Appendix 2 of NICaN Urology Cancer Clinical Guidelines

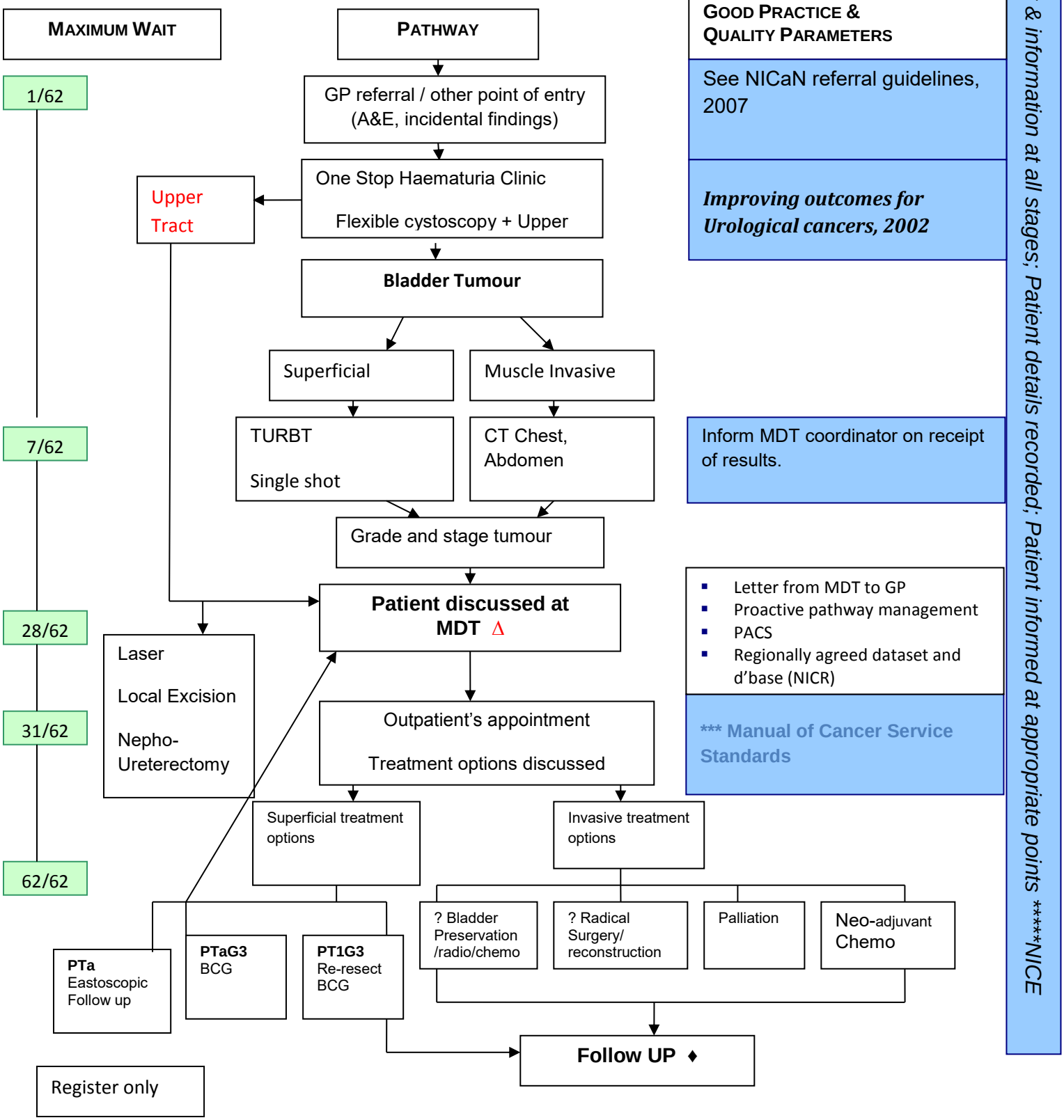
Testicular Cancer Pathway



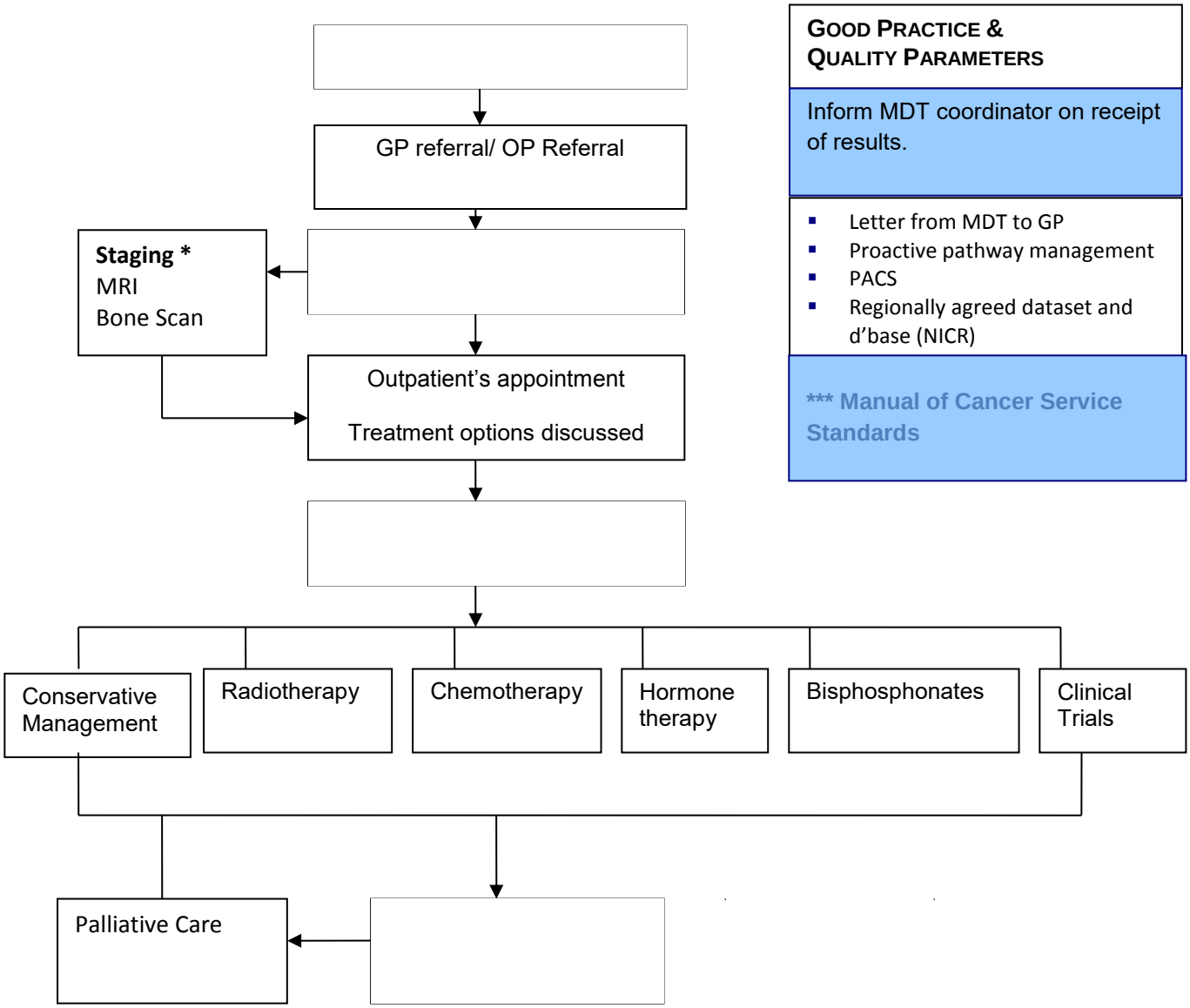
♦ Indicates point of holistic assessment Δ Inter-Trust transfer by Day 28

Appendix 2 of NICaN Urology Cancer Clinical Guidelines

♦ Indicates point of holistic assessment Δ Inter-Trust transfer by Day 28



Castration Resistant Prostate Cancer



GOOD PRACTICE & QUALITY PARAMETERS

Inform MDT coordinator on receipt of results.

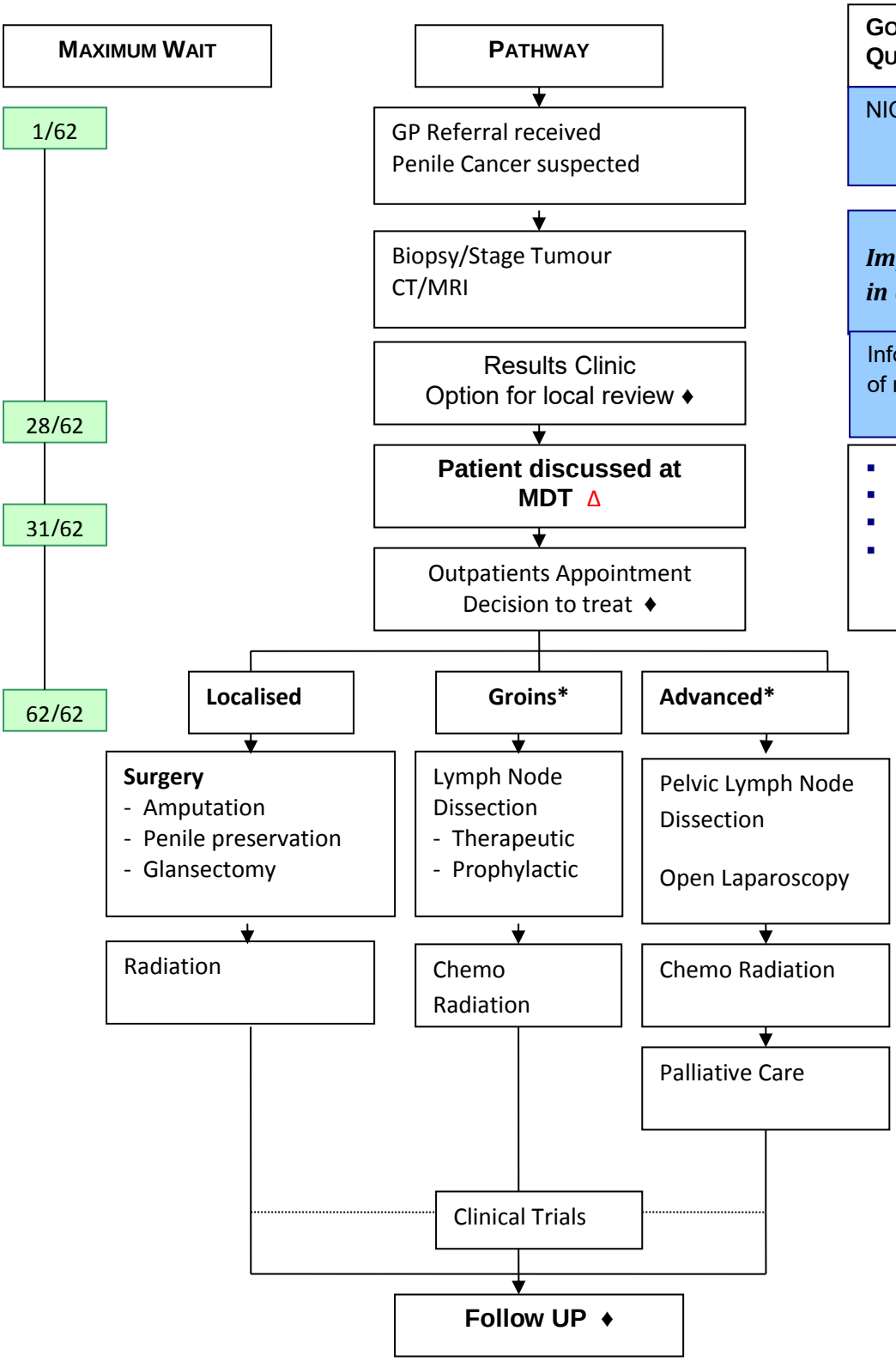
- Letter from MDT to GP
- Proactive pathway management
- PACS
- Regionally agreed dataset and d'base (NICR)

*** Manual of Cancer Service Standards

*Patient support & information at all stages; Patient details recorded; Patient informed at appropriate points ****NICE

* MRI/Bone Scan as clinically indicated

Penile Cancer Pathway



GOOD PRACTICE & QUALITY PARAMETERS

NICaN Referral Guidelines, 2007

Improving Outcomes guidance in Urological cancers, 2002

Inform MDT coordinator on receipt of results.

- *GP letter from MDT*
- Proactive pathway management
- PACS
- Regionally agreed dataset and d'base (NICR)

*Patient support & information at all stages; Patient details recorded; Patient informed at appropriate points *****NICE*

V1.3 ♦ Indicates point of holistic assessment Δ Inter-Trust transfer by Day 28

References

- NICE (2002) Improving Outcomes in Urological Cancer
  http://www.nice.org.uk/guidance/index.jsp?action=byID&o=10889
- NICE (2008) Prostate Cancer: Diagnosis and Treatment
  http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11924
- British Association Of Urological Surgeons Guidelines
  http://www.baus.org.uk/
- European Association Of Urology
  http://www.europeanurology.com/

Policy Code / Reference No:

Trust Logo

Add Trust Name

Title:	**Guidelines for Nurse Led Assessment and Follow up of patients with stable Prostate Cancer**			
Author(s)	*Adapted from SET*			
Ownership:				
Approval by:	**NICaN Urology NSSG Group**		**Approval date:**	**29th November 2013**
Operational Date:			**Next Review:**	
Version No.	**3**	**Supercedes**	**N/A**	
Links to other policies	**Policy for consent to examination, Treatment and Care, European Association of Urologists (Feb, 2012) Guidelines on Prostate Cancer**			

1.0 INTRODUCTION / PURPOSE OF GUIDELINE

This document outlines the guiding principles for nurse led prostate cancer follow-up and should be closely followed. However these guidelines are only a foundation and it is recommended that nurses maintain their continuing education in this specialist area of care.

The aim of this guideline is to set a minimum standard for nurse led assessment and follow up of patients with prostate cancer which will:

- Enable the follow up of patients with prostate cancer who are on the watchful wait or hormone treatment pathway
- Promote the education of patients about their disease management and potential for self directed aftercare
- Monitor patient progress and enable detection of progression and refer to the appropriate Consultant Urologist
- Enable holistic assessment
- Identify late effects of treatment quickly, provide support and signpost to the appropriate service if necessary
- Inform patients about and refer them to specialists services that can help with their medical, practical, emotional and rehabilitation needs
- Support patients living with and beyond cancer
- Offer patients a choice of follow-up

1.1 Objectives

The objectives of this guideline are to improve and maintain standards of clinical practice and quality of care patients receive by:

- Providing evidence based guidance for establishing and maintaining a nurse led clinic for the assessment of patients with prostate cancer, promoting excellence in the care that is delivered
- Reducing variation in clinical practice and encouraging uniformity of practice
- Providing a framework from which individual practitioners can apply their own level of clinical expertise and competency
- To ensure that all patients entering the prostate cancer follow up service are on the appropriate risk stratified pathway (Appendix 5 & 6)
- Helping nurses and health care providers to make informed decisions, aiding the education process and reducing the risk of clinical negligence
- Identifying competencies for nursing care
- Aiding development of locally agreed guidelines
- Promoting audit

1.2 Background

The NHS is undergoing radical changes particularly in its approach to cancer. Traditional nursing roles are being challenged in a bid to meet the demands of the changing NHS climate. Prostate cancer follow up forms a substantial part of the urology outpatient workload. Nurse led clinics are becoming increasingly common, offering patients an alternative method of follow up either via more convenient clinics or the telephone. By developing these new roles and services, nurse are playing a key role in increasing patient choice, reducing waiting times, increasing accessibility to services and improving the quality of care

New standards have been developed within the Cancer Services Framework that are intended to ensure that patients experience the best possible quality of life after treatment by:

- providing new models of follow-up which focus on health and wellbeing
- improving access to psychological support

2.0 DEFINITIONS/SCOPE OF THE GUIDELINE

These guidelines should be used by suitably trained health care professionals who are providing nurse led follow up to patients with prostate cancer. Patients will enter nurse led follow up services on a clearly defined follow up pathway following discussion at MDM.

Recommended exclusion criteria

- Patients who do not wish to be followed up by a nurse
- Patients who require adjuvant treatment in the form of radiotherapy or chemotherapy
- Patients with dementia/short term memory loss (unless meeting patients with carer present)
- Patients who develop resistance to Hormone Therapy during follow up and require referral to oncologist
- Patients deemed unsuitable for review at a nurse led clinic by the consultant in charge

3.0 ROLES/RESPONSIBILITIES

Implementation of these guidelines is the responsibility of those involved in nurse led follow-up of prostate cancer patients.

Accountability is a key concern for all registered nurses today. Professional accountability is defined as being responsible for your actions and for the outcomes of these actions as part of the framework of clinical Governance, which aims to provide good quality, cost-effective evidence based care (Tilley & Watson 2004)

Nurses need to be aware of their limitations as well as their clinical competence. If there are any areas in which they do not feel clinically competent to undertake an activity they should decline the activity until the appropriate learning and practice activities have been achieved to demonstrate competency (NMC 2008)

Nurses are responsible for ensuring their own educational preparation and experience to safely perform the role. They should maintain documented evidence of completion of continuing education and of demonstrating clinical competence

Competencies required for assessing patients with prostate cancer can be found in (Appendix 2)

4.0 KEY GUIDELINE PRINCIPLES

4.1 Key Policy Statement

The purpose of the nurse led clinic is to enhance the quality of care and to promote the health and well being of patients who have been treated for prostate cancer. The clinic will also facilitate the provision of emotional support for patients and their families/carers requiring the opportunity to discuss treatment or care options
Nurse led clinics have been shown to improve the quality of care in the following ways:

- Provide continuity of care for patients and their family
- Provide information, education and support
- Be accessible to patients and their family
- Release consultant time to see more complex patients
- Apply the principles of transforming cancer follow up

A risk stratified model of aftercare in line with the National Cancer Survivorship Initiative will be utilised and patients will be stratified into different arms of the follow up pathway according to their staging and personal characteristics by the Consultant.

Risk stratified means that the clinical team and the person living with cancer make a decision about the best form of aftercare based on their knowledge of the disease, (what type of cancer and what is likely to happen next), the treatment (what the effects or consequences may be both in the short term and long term) and the person (whether they have other illnesses or conditions, and how much support that they feel they need).

This will include the ongoing follow up of patients who are clinically stable and are stratified into the relevant pathway

Watchful waiting	(Pathway 1)
Active surveillance	(Pathway 2)
Raised PSA – negative biopsy	(Pathway 3)
Post radical surgery	(Pathway 4)
Post brachytherapy	(Pathway 5)
Post radical radiotherapy	(Pathway 6)

4.2 Policy Principles

Patients with prostate cancer who are on the pathways outlined above will be risk stratified into a pathway as discussed below

- Self-Care with Support and Open Access
    - No routine outpatient attendances
    - Stable disease pattern
    - After treatment with curative intent
    - Holistic assessment completed and care plan agreed
    - Information and/or some form of educational intervention
    - Surveillance tests with results by post or phone co-ordinated by a provider
    - Ability to re access system with/without reference to GP
- Shared Care – where patients continue to have face to face or telephone contact with professionals as part of continuing follow up.
    - Planned follow up either as an outpatient or planned phone follow up
    - Clinical examination required
    - High clinical or individual risks identified (disease, treatment, person)
    - Multi professional input required
    - Patients with co-morbidities
    - Those who decline or are considered to be unable to self manage

4.3 Long-term follow-up

Definitive guidance on the long term follow-up for patients with prostate cancer is included within the pathways which are concordant with NICE and European Association of Urologists Clinical Management Guidelines on Prostate Cancer.

4.4 Telephone Review Protocol

A telephone review service enables the Clinical Nurse Specialist to follow up patients through an alternative route and thereby reduce unnecessary hospital appointments for patients who have stable disease and are not fit to travel.

This service will be offered to those patients referred to the nurse led clinic and a telephone assessment protocol will be utilised. See appendix 7

4.5 Holistic Needs Assessment (HNA)

The HNA is used to identify and address patient's needs and concerns. The HNA may build on action plans developed from previous assessments. The HNA should

be conducted during the follow-up appointment. The patient or carer is encouraged to complete the form and the assessor uses this as a guide to explore their needs and collaboratively develop an appropriate action or care plan

An agreed Holistic Needs Assessment (HNA) tool will be utilised within the aftercare pathways

4.6 Support Information and Education

The consultant or clinical nurse specialist should offer patients support information tailored to the individual. This should cover as a minimum:

- Disease Progression
- Fatigue
- Pain
- Urinary Symptoms
- Finances/benefits
- Nutrition/exercise
- Signposting
- Health and well being

4.7 Rapid Access Protocol

Prostate cancer follow-up is the responsibility of the MDT. All patients should be able to access the Consultant responsible for their care through the Urology CNS. Any patient that contacts the Urology CNS with worrying symptoms will be seen by a Consultant promptly. If necessary, their case should be discussed by the MDT.

4.8 Triage Protocol

Each patient will be able to contact the Urology CNS outside of scheduled follow up appointments The Urology CNS will triage the patient on their concerns/issues to the most appropriate member of the Urology team or refer on to other agencies accordingly. Outcomes may include:

- Face to face consultant appointment promptly
- Face to face Nurse led clinic (where appropriate)
- Advised to contact GP
- Advised to attend the emergency department
- Signpost to other support agencies e.g. Citizens Advice Bureau (CAB), AHP, Counselling

Only clinical issues will result in a clinical appointment.

5.0 IMPLEMENTATION OF POLICY

5.1 Dissemination

Urology Clinical Nurse Specialists

Urology Consultants

Oncologists

6.0 MONITORING

Monitoring of these guidelines is the responsibility of the Urology Nurse under the direction of the line manager.

7.0 EVIDENCE BASE / REFERENCES

Evidence:

BAUN (2008) Guidelines for nurse-led assessment and follow up of men with stable prostate cancer British Association for Urological Nurses
Cox A, Jenkins V, Catt S, Langridge C, Fallowfield LJ Information needs and experiences: an audit of UK cancer patients. European Journal of Oncology Nursing 2006; 10(4):263-72, doi:10.1016/j.ejon.2005.10.007
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Nursing and Midwifery Council (NMC): The Code: Standards of conduct, performance and ethics for nurses and midwives (2008)

Service Framework for Cancer Prevention, Treatment and Care (2011)

Tilley, S. Watson, R. (2004) Accountability in Nursing and Midwifery. 2nd Edition. London: Blackwell Publishing.

8.0 CONSULTATION PROCESS

Cancer Services User Forum

NICaN Regional Urology Group

9.0 APPENDICES / ATTACHMENTS

See attached

10.0 EQUALITY STATEMENT

In line with duties under the equality legislation (Section 75 of the Northern Ireland Act 1998), Targeting Social Need Initiative, Disability discrimination and the Human Rights Act 1998, an initial screening exercise to ascertain if this policy should be subject to a full impact assessment has been carried out.
The outcome of the Equality screening for this policy is:

Major impact ☐

Minor impact ☐

No impact ☐

SIGNATORIES

(Policy – Guidance should be signed off by the author of the policy and the identified responsible director).

_____ **Date:**
Name
Title:

_____ **Date:**
Name
Title:

_____ **Date:**
Name
Title:

_____ **Date:**
Name
Title:

Appendix 1

Prostate Cancer Review Assessment Form

Name…….

Unit No……..

DOB……

Consultant…… GP……

Date:……. Time…….

Type of review: Telephone □ Clinic Contact □

Treatment Pathway: Hormone Treatment □Watchful Waiting □

Histology Gleason's Score …….. TNM ……

PSA

PSA Trigger.....

Date of PSA……..... Current PSA..... Previous PSA.....

PSA obtained from ECR……

Record what was discussed with patient

Changes in Urinary Symptoms

Storage	Yes / No
Voiding	Yes / No
Pain	Yes / No
Haematuria	Yes / No

If yes to any of the above, please comment and record advice given

General Symptoms

Hot Flushes	Yes/No
Tiredness	Yes/No
Weight gain	Yes/No
Breast Pain	Yes/No
Bone pain	Yes/No
Sexual Problems	Yes/No
Change in bowel pattern	Yes/No

Additional comments

Problems and concerns

Has patient had a Holistic Needs Assessment Yes/No

If yes, Date of HNA ……..

Discuss resolution of any problems identified in previous HNA □

Are there any new concerns Yes/No

- Financial
- Psychological
- Information and Support

Please record any issues

Follow up

Nurse Led follow up 3 months yes/no 6months Yes/No

Referral to:

Urologist Yes/No
Oncologist Yes/No

Letter to GP □
Letter to Consultant □

Signature of CNS……

Appendix 2
Competencies for Nurse-led Follow-up

Competencies required assessing patients with stable prostate cancer include:

- Advanced nurse practitioner/clinical nurse specialist having been employed for a minimum of twelve months working with a urologist/oncologist in the follow up setting

- Demonstrate a full understanding of the network site specific group pathways for prostate cancer. As agreed by the local tumour network

- To be enrolled in or be undertaking, a programme of study in their specialist area of nursing practice which has been accredited for at least 20 CAT points at level 3 (DH2004) e.g. Health Assessment module

- Have advanced communication skills – to have enrolled in, or be undertaking a recognised course/module in communication skills (DH 2004)

- In order to run a clinic the individual must be a core member or extended member of the urology multidisciplinary team

- To be able to demonstrate knowledge of the disease trajectory in Prostate Cancer

- To be able to demonstrate knowledge of risk stratified pathways

- To have competent consultation and symptom analysis skills. To have worked under supervision for a minimum of six months and have been deemed competent by the consultant urologist/oncologist

- To be able to demonstrate knowledge of the tests and investigation required during follow up of prostate cancer patients

- To be competent at performing DRE (if appropriate)

- To be competent in the assessment of lower urinary tract symptoms (LUTS) and facilitate onward referral to LUTS clinic is required

- To be competent in bladder palpation

- To be competent in the assessment of bladder empting

- To demonstrate ability to advise on erectile dysfunction and know where and how to refer to appropriate service

- To be able to demonstrate knowledge of survivorship issues

- To be able to demonstrate knowledge of rehabilitation services

- Demonstrate knowledge of drugs and treatments used in prostate cancer including side effect

Appendix 3

Guideline for Nurse Led Assessment Protocol

Actions
Discuss • Nurse led clinic • History/treatment to date • Timeline for routine follow up such as PSA, DRE and Admission Profile
Physical Examination
Carry out physical assessment including: • Digital Rectal Examination (DRE) • International Prostate Symptom Score (IPSS) if required
Symptoms
Is the patient experiencing any symptoms . • Hot Flushes • Ask about pain – any new pain lasting more than a week (use locally agreed pain scale) • Weight loss/gain • Fatigue • Sexual dysfunction • Neurological symptoms – Numbness, tingling or odd sensations in limbs • Lower Urinary tract symptoms • Haematuria • Gynaecomastia • Change in bowel habit • Deterioration in renal function Is the patient experiencing any symptoms suggestive of local or metastatic disease • Abdominal /Pelvic /Skeletal pain • Weight loss • Anorexia • Nausea or vomiting

Ask about any other symptoms/concerns

- PSA at each visit if rising discuss with consultant
- Admission Profile at each visit
- FBP at first visit
- Ultrasound renal tracts following discussion with Consultant

Perform holistic assessment suggested tools:

- Macmillan Concerns Checklist & Care-plan

Nurse to check information has been provided and tailored to the individual patient. This will include information about:

- Timeline for tests and investigations
- Survivorship programme
- Rapid Access to service
- Contact numbers
- What symptoms need to be reported
- Consequences and side effects of the treatment
- Holistic Assessment
- Rehabilitation services

Discuss and offer referral to:

- Community Health and Well-being Clinics
- Signposting to other services

Care plan
Letter to patient
Letter to GP & referring consultant with copy of assessment form,

To include:

- Date and time of nurse consultation
- Patients identifiable details
- Diagnosis
- Treatment,
- Assessment summary,
- Most recent PSA reading
- Date of next nurse appointment
- Potential or actual problems identified during the consultation.

Adapted from BAUN (British Association for Urological Nurses) - Guidelines for nurse-led assessment and follow up of men with stable prostate cancer (2008)

Appendix 4

Problem Management Plan

This plan will help to identify the appropriate actions when there is a change in the patients condition/needs during nurse led assessment and follow-up of patients with prostate cancer.

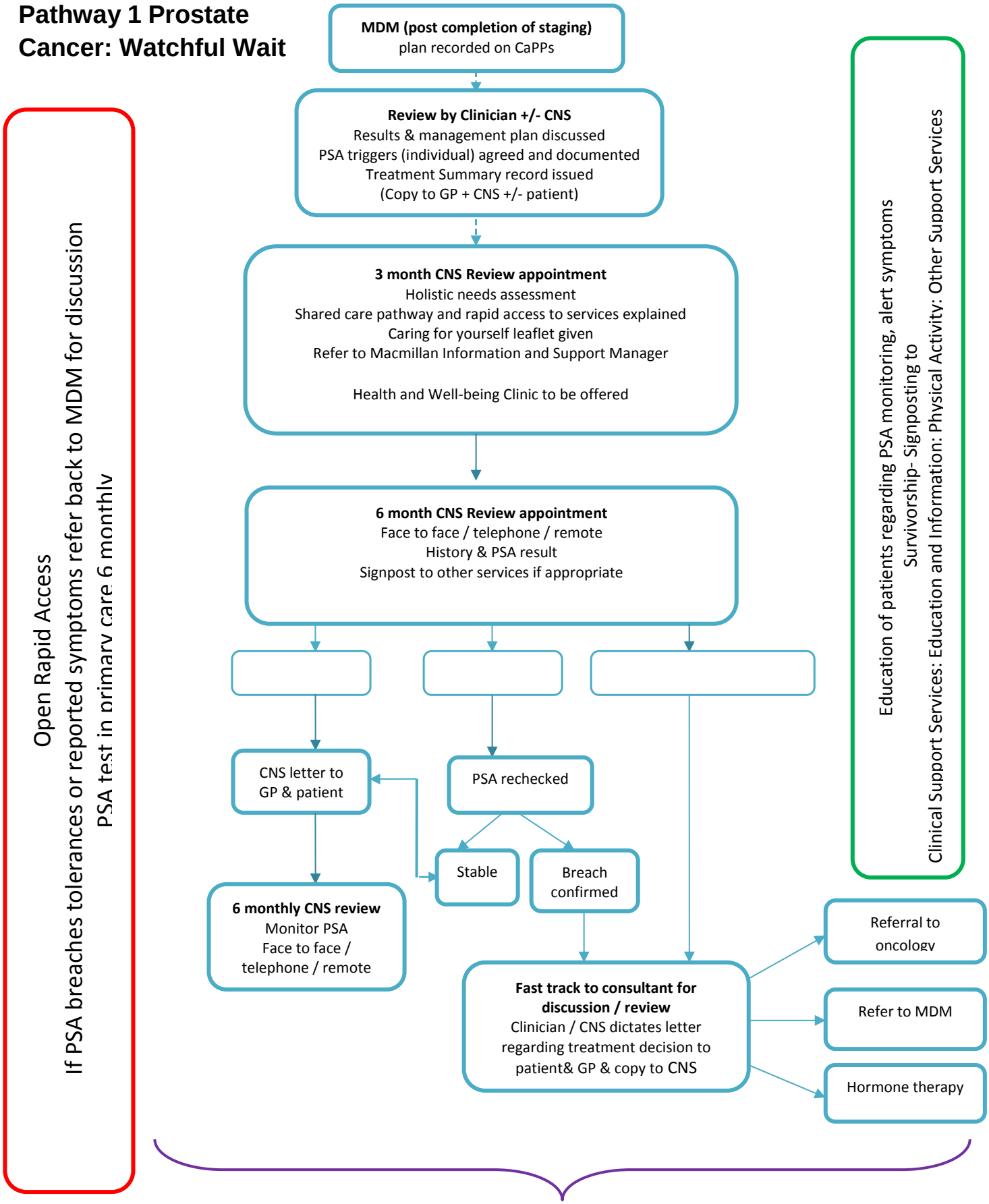
Problem	Management plan
Sudden Rise in PSA	Repeat PSA as determined by consultant
Lower urinary tract symptoms that are more bothersome to the patient	Refer to LUTS clinic Urinalysis to exclude UTI Refer or discuss with appropriate consultant
Haematuria	Exclude UTI Assess lower urinary tract symptoms Refer for investigations
Hot flushes	Give support and advice and discuss with consultant
Pain - new onset bone pain	Request investigations – bone profile, pain and neurological assessment(use locally agreed pain scale) Consider MSCC Appropriate referral to urologist/ oncologist for further management
Change in bowel habit	Assess asking about change in consistency regularity. Give advice or refer to specialist as appropriate
Weight loss	If unexplained weight loss refer to consultant. Refer to dietician if appropriate
Gynaecomastia	Discuss with consultant and if required refer to oncologist
Deterioration in renal function	Discuss and if appropriate refer back to urologist Assess for poor bladder emptying by post void residual scan Order USS of renal tracts if appropriate

Problem	Management plan
Weight gain, fatigue general malaise and anaemia	Give advice Consider referral for physical activity programme Check haemoglobin and if below normal levels discuss with consultant
Sexual Dysfunction	Assess for erectile dysfunction Give advice and consider referral to ED clinic if appropriate
Psychological needs	At time of the assessment any psychological concerns identified through use of NICaN Concerns Checklist will be discussed with the patient. Refer as appropriate to: Health and well being clinics Support groups Counselling Service Clinical psychologist
Financial concerns	Refer to CAB
Information needs	Discuss information needs Give written information if appropriate Consider onward referral if required Refer to Macmillan Information and Support Centre

Adapted from BAUN (British Association for Urological Nurses) - Guidelines for nurse-led assessment and follow up of men with stable prostate cancer (2008)

Appendix 3 of NICaN Urology Cancer Clinical Guidelines

Pathway 1 Prostate Cancer: Watchful Wait

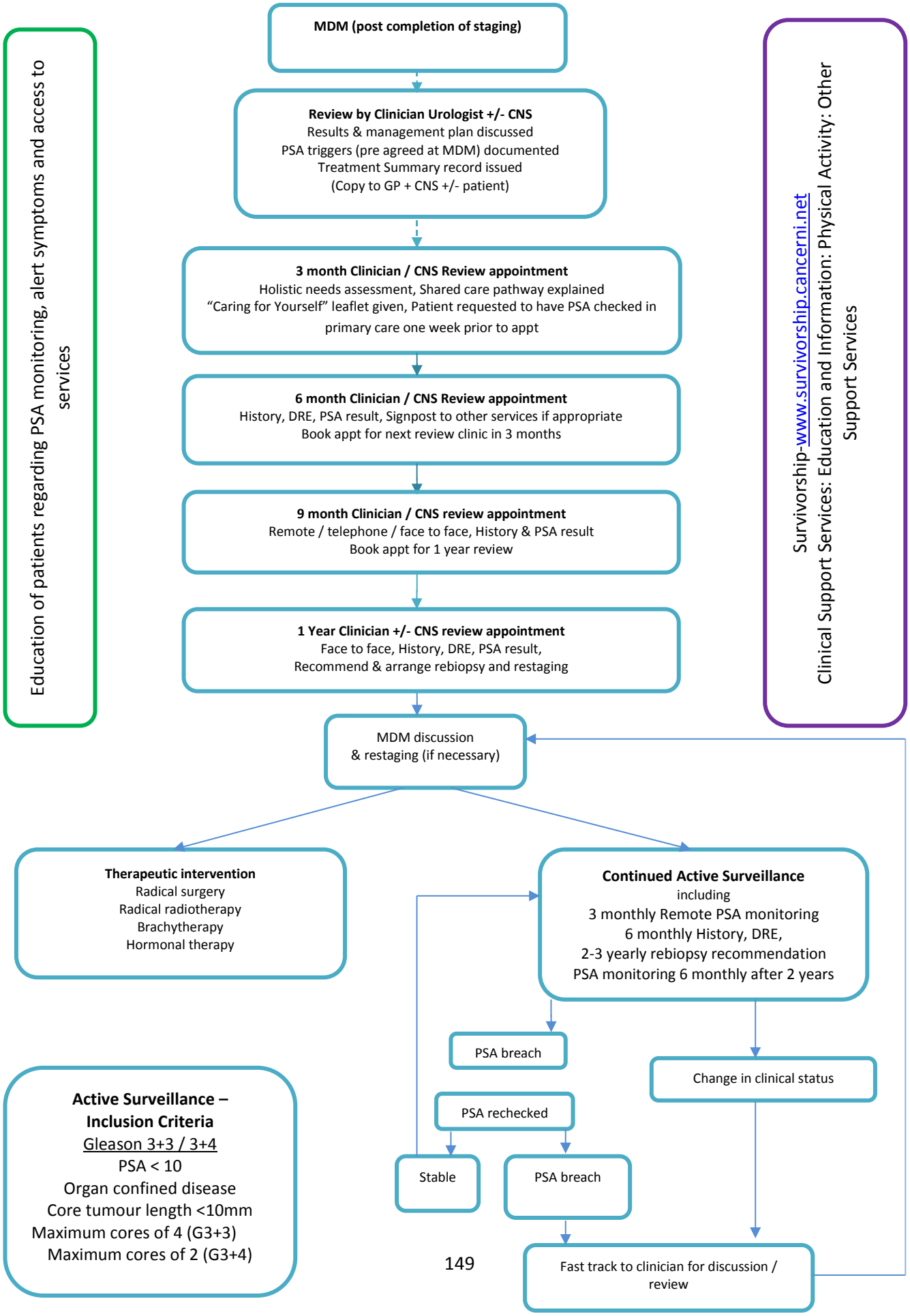


Watchful waiting – Adapted from NICE Guidance 2008

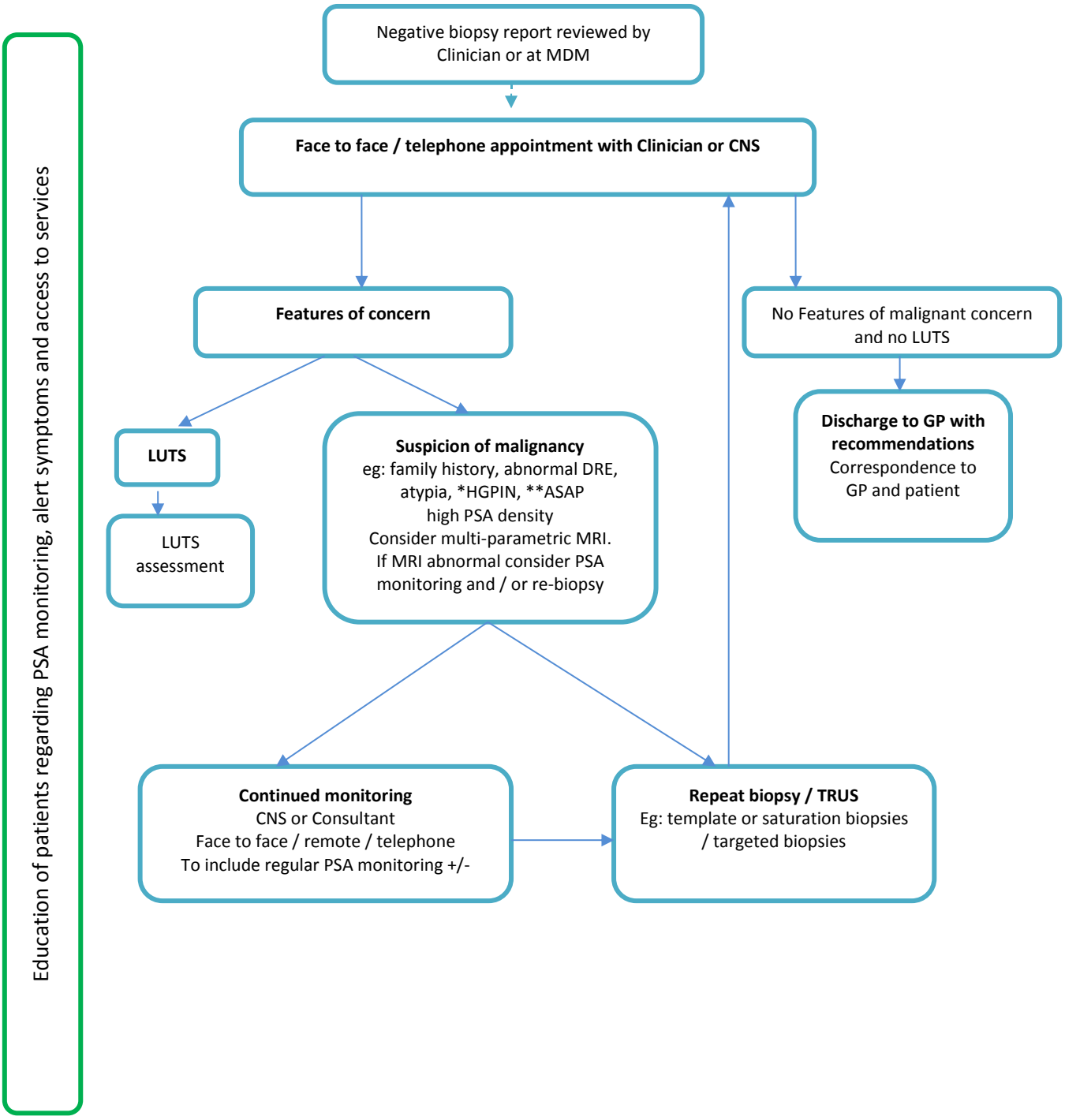
'Watchful Waiting is the form of continued review of Prostate Cancer patients for whom future therapeutic intervention with curative intent has been considered to be inappropriate'.

Appendix 3 of NICaN Urology Cancer Clinical Guidelines

Pathway 2 Prostate Cancer: Active Surveillance



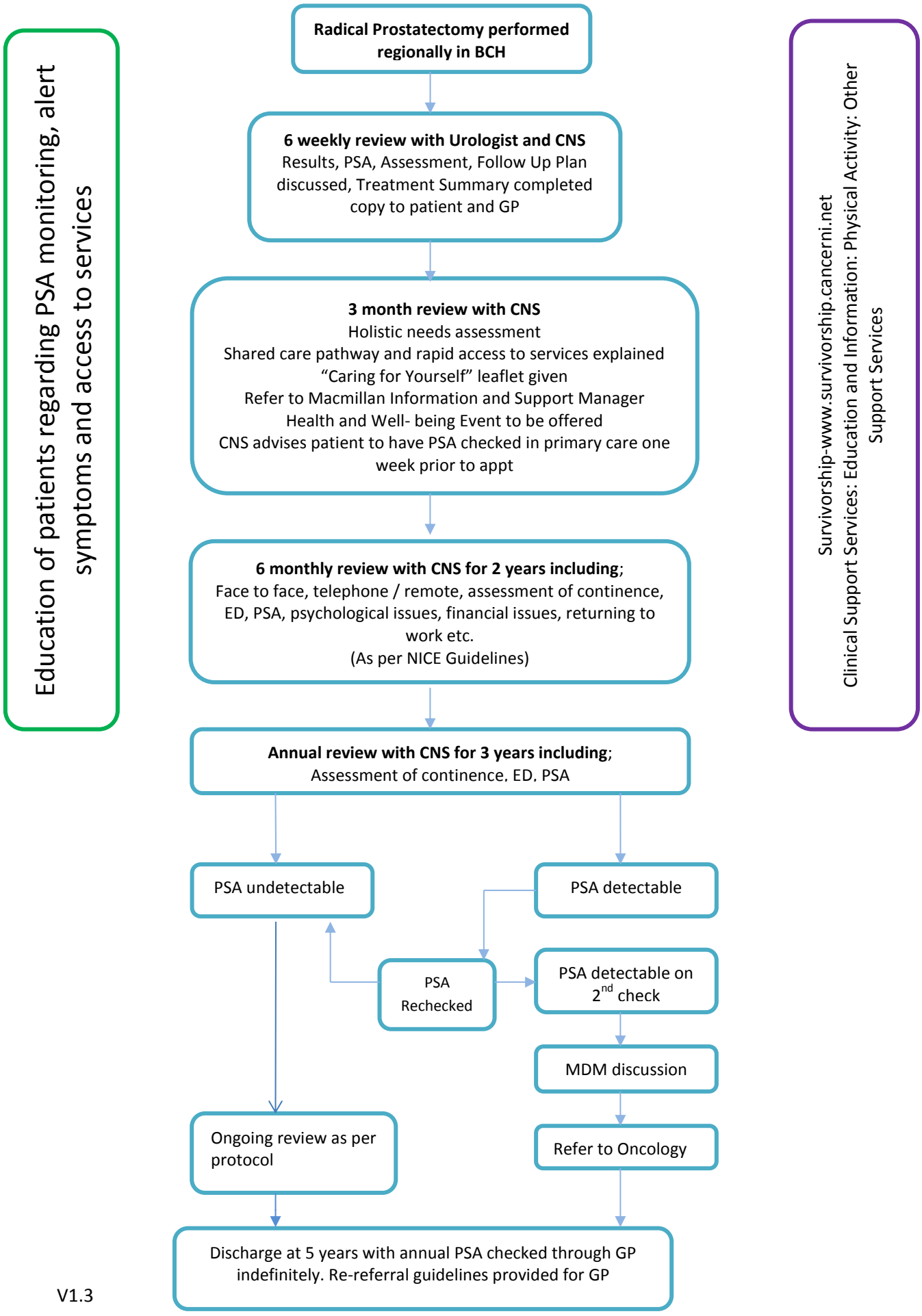
Pathway 3 Raised PSA & Negative Biopsy



*HGPIN – High grade prostatic intra-epithelial neoplasia
**ASAP – Atypical small acinar proliferation

Appendix 3 of NICaN Urology Cancer Clinical Guidelines

Pathway 4 **Prostate Cancer: Radical Surgery – Negative margins**



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Appendix 3 of NICaN Urology Cancer Clinical Guidelines

Pathway 5 Prostate Cancer: Permanent Prostate Brachytherapy (LDR)

Permanent Prostate Brachytherapy Implant performed (Pt discharged)

Post implant AUR management if required

4week Post implant CT scan and QA/peer review (PSA, IPSS, Dosimetry to database)

3month - Radiographer telephone review (PSA to database)

6month - Consultant led clinical review (PSA, IPSS,IIEF,EPIC to database)

6monthly Consultant led clinical review.
GP check PSA every 3-6months
(PSA, IPSS,IIEF,EPIC to database)
Transfer to annual review at 3years if PSA <1ng/ml & falling

12monthly clinical review
GP check PSA every 6 months
(PSA, IPSS,IIEF, EPIC to database)
Discharge to GP care at 5 years if PSA <1ng/ml & falling

GP information letter re biochemical and clinical triggers and re-referral pathway

Sigmoidoscopy by experienced practitioner at year 5, 10, 15 If deemed fit for procedure

Education of patients regarding PSA monitoring, alert symptoms and access to services

Rising PSA Year 0 – 3 could be benign PSA bounce.
PSA 3monthly with clinical review.
MRI/CT/IBS if:
1 PSA level>10ng/ml
2 Clinically indicated

Survivorship-www.survivorship.cancerni.net
Clinical Support Services: Education and Information: Physical Activity: Other Support Services

Selection criteria for Permanent Prostate Brachytherapy

Clinical inclusion criteria:
Organ confined prostate cancer T1 or T2
Estimated life expectancy >10yrs
Gleason 6 and PSA <15ng/ml
Gleason 7 and PSA <15ng/ml

Clinical exclusion criteria for brachytherapy:
Prostate volume >50ml (> 65ml prior to hormonal cytoreduction)
IPSS >9. (Would consider for implant is <15 & Qmax >12ml/sec)
Life expectancy <5years
Large or poorly healed TURP defect
Unacceptable operative risk
Relative contraindications for brachytherapy:
Large median lobe

Selection criteria for combined Permanent Prostate Brachytherapy + EBRT

Selected men with:
High volume Gleason 7 or
Low volume Gleason >7 or
Early T3a disease
May be suitable for dose escalation with combination therapy and should be referred for discussion to central

Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

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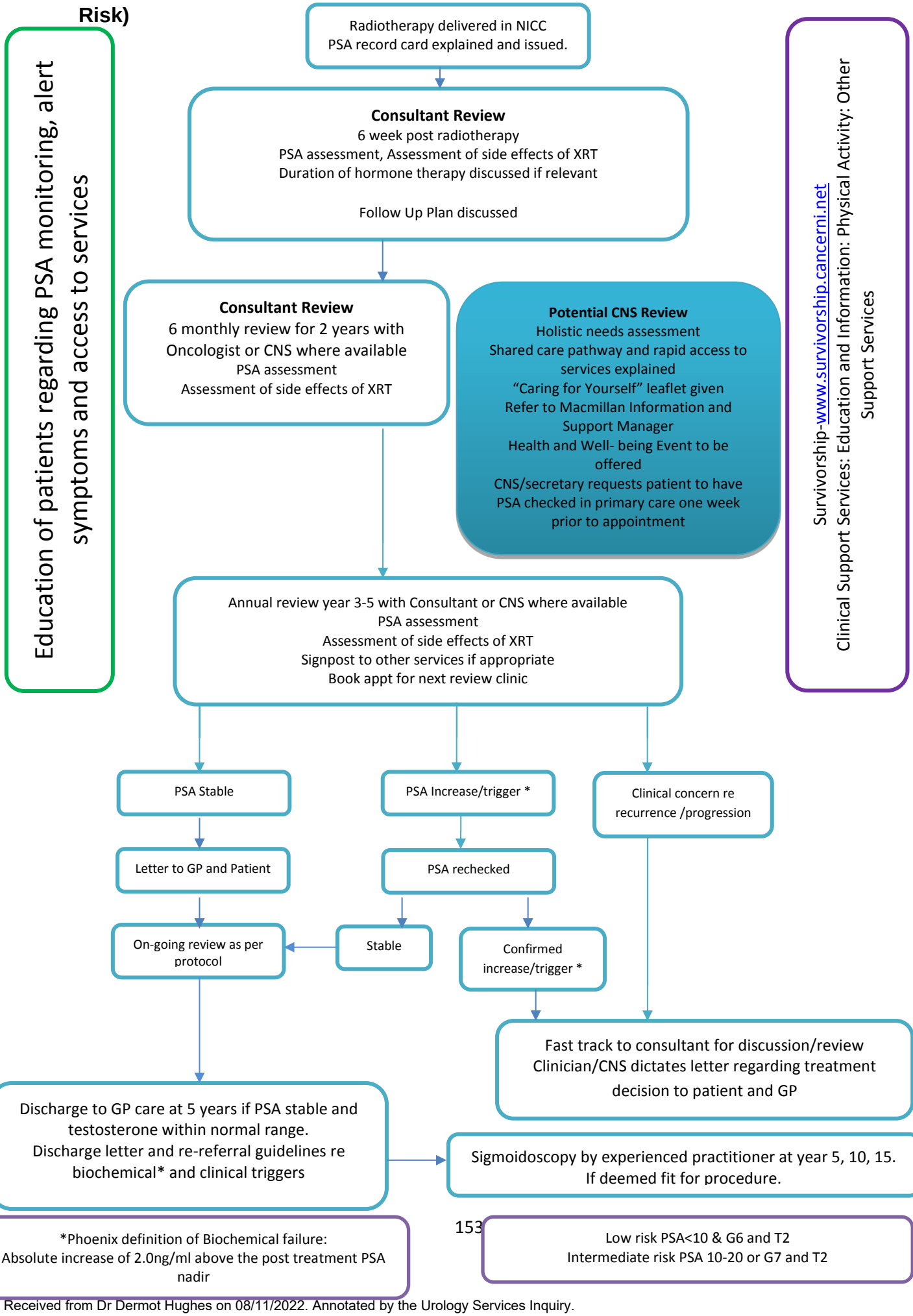
Pathway 6: Prostate Cancer: Radiotherapy+/-Hormones (Low Intermediate Risk)



Directorate of Acute Services

Notes of a meeting held on Monday 4th of January 2021 to discuss the Complaint regarding Mr O'Brien

Present: Patricia Kingsnorth
Fiona Reddick
Patricia Thompson
Hugh Gilbert
Dermot Hughes

In Attendance: Peter Rodgers

Meeting Began with Introductions as usual,

Mr Hugh Gilbert Clarifies he has most recent reports done and he shall forward them onto Mrs Patricia Kingsnorth. PK agrees that once she receives most recent data she shall collate data and then return them to HG for a final draft of applicable data.

PK acknowledges that Mr O'Brein's solicitor has requested the specific questions that will be asked during their meeting.

Mr Dermot Hughes Advises that questions should be specific and to the point, to ensure clarity of answer requested.

Patient 2

Team Begin to Discuss Mr Patient 2 Case,

Questions Raised:- why was Patient 2 not referred on as per the MDM 25/07/2019 and recommended he was referred onto oncology and seen on 23rd of august

MDM said Patient 2 should have been referred a month prior however the referral did not happen until 25 September and discussed on the 26th

Review team question, why was there an absence of a key worker/ specialist nurse, was Mr O'Brien intentionally excluding key workers in his practice and why this happened.

Review team then acknowledge that throughout all nine cases there are no mention of key workers.

HG curious as to why each stage/ progression for investigation or treatment took up to a month when in reality it should have taken 2 weeks and review team questioned whether this was due to the absence of a key worker that this was overlooked.

HG also expressed concern that Mr O'Brien was intentionally excluding other health professionals from his patients care

Also curious as to what policy is as per MDM for testicular cases, Does the MDM allow for sufficient patient tracking.

Questions posed to ask Mr O'Brien:-

Why did it take so long and why was there no key worker?

Why didn't Mr O'Brien follow NI diagnostic pathway?

Patient 7

Team Continue on discussion of Mr Patient 7 's case

Comes to light that Mr Patient 7 may have been told by a different clinician that his tumour should have been excised sooner

HG acknowledges that the lesion was in a difficult position to proceed without invasive procedures if it had of been in a different position Dr's may have recommended a different procedure

HG raises question why wasn't guidance followed which would suggest this patient was discussed at small kidney mass MDM

Mr Obrien Missed a scan was this due to lack of a key worker/ specialist nurse, considering the difficulty of the case why wasn't a specialist's opinion involved from the outset.

Team acknowledge this case was brought back again and again to MDM and question why the MDM did not question the decision to not seek advice. Also questioned why regional policy was not followed.

PK also raises that Mr Patient 7 had 3 locum consultants however Mr O'Brien was primary consultant, with this he had primary responsibility who had the likes of MDM support and why wasn't it consulted.

Team Acknowledges Mr O'Brien had ample oppurtunities to refer Mr Patient 7 , and question why he decided to vary from established guideline practice.

Patient 1

Team Begin to discuss Mr Patient 1 case

HG raises that Patient should have been referred to clinical Oncologist

Also acknowledges that the patient was given an unconventional hormone therapy where dosage differed.

Question again raised, why Mr O'Brien deviated from guidelines and still no key worker present.

HG voices how as the patient was on inadequate hormone therapy it may have supressed hormone related cancer however this would not have affected non hormone related cancer this was surmised as prostate cancer having the ability to be made up of a multitude of cancers. HG perceived the treatment provided could have accelerated the cancers progression.

Team curious again, converse as to why no key worker/ nurse was utilised when this was this support was available. Taking into consideration how Mr O'Brien worked in isolation reiterating was there a reason for excluding members of the MDT.

Patricia Thompson does acknowledge this fact and the reluctance of key worker use. Brought to Review team's attention that Mr Patient 1 had phoned unit to enquire about medication, this led to the key worker discovering a number of scans not organised.

The team questioned again the lack of utilisation on Mr O'Brien's part of a key worker could have been detrimental to patient care.

Patient 5

Team Begins Discussion Of Mr Patient 5 's Case

HG Vocalises how he perceives management was correct with patient being given clear instructions etc, until a post-operative CT scan shown another lesion that was missed.

Once Patient had seen another consultant along with daughter metastasis was noted team questioned why finding of scan was not acted upon. Which in turn raised the question the lack of utilisation of key workers/ specialist nurses and exclusion of others from Mr O'Brien's work was detrimental to patient care.

HG Iterates how a delay in Hormone intervention would also be detrimental to patient health/care. Patient's age was discussed and how hormone intervention could be influential on life expectancy.

Team quickly revisit how a key worker would have been imperative to adequate patient care.

Patient 4

Team Begin Discussion of Mr Patient 4 's Case

Team understand how Mr Patient 4 was discussed at the MDM who suggested standard treatment

Team looking over notes discover that Mr O'Brien had decided on 50mg per day of medication which is not licensed.

Continued discussion of Mr Patient 4 s timeline, showing bone scan wasn't abnormal with excess uptake in one area. Radiologist suggested MRI however this was not requested. Team discuss the ramifications that a lack of a key worker played in the inadequacies of patient care.

A Non Re-Referral to MDT as disease progress and MDM recommendations not followed discussed with disregard for use of drug dosage.

PK questions whether redeployment of key workers may have proven a factor in patient care. PT iterates that CNS were kept in Thorndale unit were as Fiona Reddick believes they may have been. PT acknowledges she herself was given time during Covid redeployments to get in touch with patients from her own experience.

PK Suggested that this be clarified

HG says that patients may have been unaware they had access to key workers due to previous experience with Mr O'Brien.

Patient 6

Team begin discussion of Mr Patient 6 's timeline and case, it is discussed how Mr O'Brien did not adhere to androgen therapy, and that Mr Patient 6 did not have a clear understanding of what was happening throughout his care.

Brought up again amongst team how lack of key workers severely impacted patient care and how this could have drastically changed patient's experience.

HG voiced that there was no critic on starting tamoxifen, DH however acknowledged that Mr Patient 6 still was not treated to guidelines and again how no key workers were involved.

Patient 3

Team Begin discussion of Mr Patient 3 and his case.

The team note that although Mr Patient 3 was diagnosed with penile cancer he was not referred on.

HG disbelief towards treatment. Does not understand why MDM would condone treatment provided after diagnoses.

Believes Excision biopsy should have been referred to MDM, HG iterated how there are rarely experts in penile cancer due to the rarity as such Mr O'Brien should have consulted more with MDM. Also noted is that Mr Obrien should have taken more appropriate measures for early intervention after biopsy.

Team discuss how this patient should have been referred and discuss how Mr O'Brien was at fault for not referring further.

Patient 9

Team begin discussion of Mr Patient 9 timeline and case.

Noted how the delays in investigations was subpar for patient care and how Mr O'Brien again did not follow regional guidelines.

HG voiced concern about how Mr Patient 9 was on inappropriate hormone therapy considering he initially presented in retention.

Team discuss how Mr Patient 9 was not brought to MDM as he was not being treated for cancer. Iterating how a lack of investigation led to an incorrect treatment. An MRI was not provided for Mr Patient 9 until much later that the team said could again be due to lack of key worker.

Team discussed that if Mr O'Brien was positive that he was treating Mr Patient 9 for prostate cancer why was he not referred to the MDM. Discussed that appropriate diagnostic and staging not used also correct cancer guidelines were not followed. This resulted in a lost opportunity for treatment with curative intent for the patient.

Patient 8

Team Discuss Mr Patient 8 's Case and timeline

Understand that Mr Patient 8 s Cancer was a coincidental find, however no follow up investigation provided. Regarding Mr O'Briens knowledge of the patients result he failed to inform the patient, Team curious again whether this was due to lack of a key worker.

Team discussed was this possibly due to Covid, as well as a lack of safety net for pathology to go on to MDT.

PK & DH iterate that guidelines that Mr O'Brien was to follow are not current guidelines and to consult those during further investigation.

HG raised question regarding all cases as to why Mr O'Brien did not use the opportunity to consult those who may have had more exposure or expertise in the cases he was dealing with

FR Voices how it is imperative to have good communication amongst MDT which Mr O'Brien neglected.

Team voice their concerns as to the standard that had been stated and standard that SHSCT had signed up for as opposed to the standard of care Mr O'Brien provided to his patients.

DH, PK curious as to why no key worker had not been noted in previous SAI this was thought to be because it was not a solely cancer SAI.

HG voiced concern regarding how a MDT may feel compromised in "raising their hand" if something is out of guidelines due to a senior member of staff as well as the MDM condoning treatment.

HG also clarifies he is in the midst of chasing more information regarding hormone therapy with a man who has more expertise in the field this data will then be shared with PK.

Another meeting arranged for 18/01/2021 at 0930

Southern Health and Social Care Trust

Acute Governance
UROLOGY
18 January 2021 @ 9.30am

PRESENT: Dr D Hughes
Patricia Kingsnorth
Fiona Reddick

Dr Hughes advised he had now met all the families. He met with the family of Patient 5 (Patient 5) who was very concerned with his care. Dr Hughes advised Patient 5 had a large tumour but had reasonable care. Follow up scan was missed. Patient 5 has prostate cancer and the missed follow up scan was an issue. He advised Patient 5 attended ED and there was no PSA done and he believes if a PSA was done by either ED or GP this may have changed the course of treatment. Need to check why a PSA wasn't done as there was opportunities to do one. Dr Hughes advised the family have sent in a 5 page timeline. He believes the family feels all is bad but Dr Hughes feels this is not the case. He advised where there are issues this will be acknowledged but where there is none this will be said. The family have asked staff to follow up scan results.
Patricia checked and they were followed up and were reported by radiologists. Imran agreed to recheck.
Fiona agreed to provide timeline for radiology on Patient 5.

Dr Hughes advised oncology was surgical and if radiologists were at the review this will confirm the follow up. He added he has reviewed most of the patient's information. He is looking at: Presenting complaint, diagnosis, MDT, Nursing support, Referrals, Compliance to guidelines, Referral back to MDT and onward referrals. This will be the bench mark for all 9 cases. He advised the medical director has concerns not taking patients back to MDT when patients are clearly dying.
Dr Hughes advised it's not done through SAI review but through the royal college review. It is generally done on each individual. He advised it is not generally done by a specialist in that field.
Patricia said when it comes to MDT they need an insight. She asked Fiona if she could provide a clearer insight.
Dr Hughes wants to complete individual review first. He has spoken to Tony Glackin and Joe Sullivan. Joe advised he had sent referrals to the prescribing clinician.
Dr Hughes has also spoken to AMD, the Lead and Barry in Cancer services; he advised none of them were aware. Dr Hughes believes if they were to be giving assurances through the CX they need to be doing audits in 25% of the cases.
Fiona suggested audits need to come down through the specialities. Dr Hughes suggested these are usually done by junior doctors or specialist nurses for their own learning.
He suggested patients don't get a 62 day review.
Fiona to check if any of the 9 patients were on their pathway and if they were on the breach report. She advised there are several breaches within urology.
Dr Hughes is aware of this, he advised best practice was 31/62 day agreed target as this was part of the pathway. The issue is if system is working. Dr Hughes feels AO'B didn't work within the process and sometimes worked on his own which is hard.

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GP referral 1st month, treatment 2nd month (31/62), he doesn't think this was the thinking of AO'B.
He said after talking to families they are left not knowing.
Dr Hughes is to meet with Martina, Ronan and Mark.
Dr Hughes said AO'B care was very personable. He would like to know if staff were in the position to know or didn't know, if not - why.
He said as part of the learning he will ask staff how they can work together. He feels there is an inappropriate hierarchy within consultants which is wrong. Fiona advised that's what MDT is about.
Dr Hughes feels no nursing care involvement is a huge deficit. He said its bad not treating patients under the guidelines but not to tell the patient they are being treated off the guidelines. He added you can't expect patients to know as this is generally their first cancer. He also added they need to be aware language is not inflammatory.
Patricia advised she had sent out questions along with redacted notes for all patients to AO'B solicitor with a timeframe of 29 January 2021 for response.
Dr Hughes advised they had asked 2-3 questions per case. He said he had already got an external opinion. He said he would be meeting with families again in February and feels this may be tough for some families who found AO'B very personable.
Dr Hughes said AO'B had excluded key workers and had issues picking up scans.

Patient 9 (Patient 9) Patricia asked Fiona to liaise with palliative of care nurse for an update on Patient 9.
Fiona to contact community nursing team caring for status of Patient 9. She advised it has been a difficult time for community nursing team as they have to be mindful of conversations.
Patricia contacted the family a couple of weeks ago and at that stage Patient 9 was very low and family didn't want to engage. She advised she is trying to keep in contact with families especially if something is going to press she would like to tell the families first to prevent more stress.

Dr Hughes advised he was made aware of a AO'B support group. It was the Patient 5 family that took it to his attention at the meeting. He is considering whether to put it in the report. He advised families have been dignified at dealing with the trauma.
Patricia believes it is particularly stressing for families and this is why they come forward as they saw GP names in the group.

Further meeting Monday 25 January at 9.30am

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Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

Acute Governance
UROLOGY
22 February 2021 @ 9.30am

PRESENT: **Dr D Hughes**
Mr Hugh Gilbert
Patricia Kingsnorth
Patricia Thompson
Fiona Sloan
Roisin Farrell – Note Taker

Dr Hughes provided feedback about the meetings with the families involved with the exception of Patient 6, he has declined further communication and has requested a copy of the report. He described the meetings as quite difficult.

Patient 7 – the family have reflected from the previous meeting and are happy with the care Patient 7 received. Their concerns are around governance and want assurance around the care of other patients.

Patient 5 – family reflected from previous meeting. They thought the care for their father's tumour was good. They queried the PSA and the role of the urologist. The advised their father is doing better. Dr Hughes advised the family he had got the scan reviewed retrospectively and there were no issues. They were seeking assurance on the scan. They asked if his cancer had been detected earlier would it have made a difference.

Mr Gilbert was certain with hindsight his outcome was not affected.

Dr Hughes said they asked would he have had the same degree of metastasis if seen earlier.

Mr Gilbert advised this was an unanswerable question, still feels he would have the same longevity. He does feel it may have progressed and Patient 5 may have more metastasis.

Patient 2 – Dr Hughes advised Patient 2 has considerable arthritis. He had concerns around governance. Dr Hughes referred to the MDT follow up of 31 & 62 day. He described the tracking as a 3 leg stool when you take on away it all falls.
He told Patient 2 about the SAI review in 2016. He advised it had gone on for 4 years which caused a delay in recommendations. The main concern is the pathway. If the patient or family knows what is going to happen they would follow up.

Patient 8 – Dr Hughes advised from cancer point of view Patient 8 is doing well. He does have consequences of TURP's.

Patricia Kingsnorth asked if the 5 year delay would symptoms been less troublesome.

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Mr Gilbert said if symptoms bad enough to warrant surgery he feels yes. In his own opinion the 5 year delayed surgery would have made symptoms worse.

Patient 1 – Dr Hughes advise family not in a good place.
Their concerns were they were unaware Patient 1 was given in appropriate treatment and hadn't been on the proper pathway. Patient 1's Daughter recalled MrO'B contacting them after Patient 1's death and advised the biopsy didn't reflect the cancer.
Dr Hughes feels it was one of those self-serving statement he has heard before.

Mr Gilbert feels it was a good biopsy and should have been referred on.
Dr Hughes said he would reflect all the patient/families concerns in the reports. He advised of a local politician coming out in support of MrO'B and that families feel hurt.

Mr Gilbert believes politicians are putting themselves in the firing line and should wait for the results of the enquiry.

Patient 9 – Dr Hughes spoke to the family at length. Patient 9 has 5 children who asked to attend the meeting. Dr Hughes felt Patient 9 had told the family but believed the family were quite shocked at what they were being told. It was a difficult meeting. He was asked if this was not 1 person but a lot how did this happen. Dr Hughes believes one of the issues us how did this happen.

Patient 4 – Dr Hughes advised the family were unaware there was no input from oncology or palliative care. Family also concerned how did it happen, how did no one know it was going on.

Mr Gilbert has concerns regarding consent.

Dr Hughes advised patients were not aware they were not being treated normally.

Dr Hughes advised he had met with MDT. He described it as "quite silent conversation". He advised some urologists trained in UK mainland and they questioned the Southern Trust processes. One consultant suggested the team go back to the guidelines. He advised the patient had flutamide treatment. Dr Hughes feels urologists are concerned about themselves. He explained he had gone back to the Medical Director to give an update. Dr Hughes queried why recommendations not been taken forward. He also discussed resources.

Mr Gilbert believes there are issues around MDT, not properly structured. Issues with members attending but there is a separate issues with the inappropriate treatment. He suggested asking MDT if this is the treatment MDT agreed.

Dr Hughes advised there are issues they are aware of. He spoke to the AD & AMD of CCS, they were not aware.

Mr Gilbert suggested people did raise concerns.

Dr Hughes said they were aware if the absence of oncology and radiology but not aware of the internal issues.

Dr Hughes advised he would draft the findings and learning. He believes there are issues they are not aware of, onward referrals to palliative care. The recommendations need to be a retrospective review. It's concerning especially when patients are not being brought back to MDT.

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He said the review team need assurance it is not systemic.

Mr Gilbert advised he is the part time urology lead for IRM and believes that is the reason he is doing this review as the Southern Trust approached IRM. He advised there are 2 processes going on. The Trust is going back to review and has asked for guidelines. Asked to do structure guidelines review. He asked if anyone was aware.

Dr Hughes is aware and asked not to be told about this, and he believes families will welcome this especially as it is an issue in Northern Ireland with urology.

Patricia Kingsnorth advised she had received some correspondence from MrO'B in respect of Patient 1 & Patient 9, the review team should have response by the end of this week or start of next week; she advised she would share correspondence with MR Gilbert.

Mr Gilbert happy to look at responses being provided by MrO'B.

Dr Hughes feels issues are black and white but raise significant concerns.

Mr Gilbert feels it concerning the chair of MDT asked the review team to read guidelines. He added the chair referred to MrO'B 13 times and never once mentioned the patients.

Dr Hughes advised he had added lessons learnt into the report, but advised some may be recommendations. Dr Hughes read from the lessons learnt in report. He feels there are mechanisms in place. He also advised the chair of MDT has no job description and should be. Dr Hughes does think MDT has an understanding.

Dr Hughes advised there are themes for recommendations - Need robust governance structure, he feels there is an issue in culture.

Mr Gilbert feels staff knew about issues.

Dr Hughes feels they need to capture this in the report.

Patricia Kingsnorth feels the feedback from staff was "oh that's just Aidan".

Dr Hughes feels it was professional centred care and not patient centred care. staff have more concerns regarding professional.

Mr Gilbert questioned professional. He advised working in an unprofessional way, MrO'B will feel the consequences. He doesn't understand anyone in a professional way can harm patients. He appreciates MrO'B is a caring person.

Patricia Kingsnorth said it is hard to understand as she would have the knowledge, but to provide treatment so far off base and make patients feel protective, which is concerning.

Mr Gilbert said you need good clinical practice and quoted "you don't need to be a nice doctor to be a good doctor".

Dr Hughes feels MrO'B is very personable. He said when trying to understand "why" he can't. He feels non-referrals verging into cruelty.

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Mr Gilbert advised the duty of a clinician is to ensure patients get best treatment. He added the penile patient should have been referred. He is not sure how MDT works in Northern Ireland but knows patients are entitled to best treatment and if not being done this needs to be highlighted.
He referred to Patient 7 – feels if an initial plan had been in place there would have been less confusion.

Dr Hughes expectations of MDT should have been driven by doctors.

Patricia Kingsnorth asked Patricia Thompson if any feedback from MDT regarding specialist nurses.

Patricia Thompson advised the specialist nurses were concerned it would be a question answer. She advised specialist nurses felt concerned at MDT but by the end felt more reassured. She advised they were happy to meet today.

Dr Hughes advised he was happy to meet with specialist nurses.

Patricia Kingsnorth advised they had tried to set up 2 meetings in January and advised the specialist nurses were not being ignored.

Dr Hughes asked if staff had any other thoughts.

Fiona Sloan asked about the review back in 2017, she asked did this not raise alarm bells with MrO'B, was there no protection plan.

Dr Hughes advised the review was around red flag referrals. The review team had made multiple recommendations.

Patricia Kingsnorth advised there were concerns raised as far as SMT. Notes left at home, referrals kept in drawers. Did review 5 patients may have suffered. Significant defect of care, learning focused on triage letters. The issues were with admin. There was no concerns regarding practice or nobody raised any concerns.

Dr Hughes confirmed issues were referrals and advised nobody asked at an early stage regarding pathway, this was a missed opportunity.

Fiona Sloan suggested it was a risk management – admin.

Dr Hughes is concerned with what is on Facebook, referring to admin. He explained it is about patient care. The trust didn't take the opportunity to ask about patient pathway.

Fiona Sloan said it is alarming it was missed.

Mr Gilbert believes the issue is with governance it is not robust enough.

Patricia Kingsnorth advised she sent the reports to Mr Gilbert and asked him to review and add ant recommendations in red for the individual cases.

Mr Gilbert advised each family should have the precise learning for their loved ones.

Patricia Kingsnorth asked Patricia Thompson to review the cases. Patricia Kingsnorth will provide Mr Gilbert the kardex.

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Mr Gilbert feels there may be an issue with regards to what is documented and word of mouth.

Patricia Kingsnorth advised reports needed completed by Friday. Need response fairly quickly. Fiona Reddick is on annual leave.

Mr Gilbert will work on reports tomorrow 23/02/2021.

Dr Hughes relayed to Mr Gilbert that the families are immeasurably grateful for his input.

Patricia Kingsnorth said the families appreciated his honesty.

Next Meeting Friday 26 February @ 2.30pm.

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Thematic analysis of concerns

A:	The relationships between individual clinicians, the MDM and regional MDMs	
	Communication: mechanisms and responsibilities	1,6
	Independent key workers	2
	Policies: guidelines and exceptions	3,4,5
	Interventions and Colleagues' reticence	5, 19
	Audit	3, 16
B:	Inappropriate management pathways	
	Outside normal practice ****	7-10, 12&17*
	Delays: individual or systemic	13, 14
	Independent monitoring of waiting times	
C:	Administration	
	How are clinical decisions put into effect?	11, 15
	How are investigation results flagged?	18, 20
	How are delays identified?	21

Items

1. There is no record of the Testis MDM having received any communication. What is the usual means of informing it of a new case?
2. Cases, such as this, benefit from having a Key Worker (usually a Cancer Nurse Specialist) who can follow the patient across specialities. Is there any provision for this?
3. Should the MDM monitor its recommendation and request explanations for any deviations from conventional and timely treatment?
4. What were the circumstances that AO considered, which meant the management should not follow published guidelines?
    a. EAU guidelines for penile cancer: section 6.2.1 (2019)
    b. NICE improving outcomes in urological cancer (2002)

5. Why did the MDM feel that the management was acceptable?

6. Why was the Reference Centre not involved from the outset?
7. Why did AO consider bicalutamide (50 mg) a reasonable alternative to the options outlined by the MDM?

8. Given that bicalutamide (150mg) is not approved for use as therapy for patients with localised prostate cancer who are otherwise candidates for watchful waiting, why was it used?
9. Why did **AO** consider it inappropriate to pursue radical therapy in this case?
10. Why were key investigations missed and inadequate treatment started?
11. What mechanisms were in place to ensure appropriate follow up arrangements?
12. The treatment offered is likely to have accelerated the tumours de-differentiation development of metastases (REF)
13. Was the waiting time for admission for elective surgery, as indicated in AO's letter of 23/01/20, 5 years?
14. How did this wait compare to other local providers and what measures where considered by AO, the urology department and the Southern Trust to ameliorate this?
15. What mechanism was in place to convert the indicated follow up on the operation note into an appointment?
16. What role was played by the MDM in ensuring compliance with its recommendations.
17. The treatment offered is likely to have accelerated the tumours de-differentiation development of metastases (REF)
18. AO failed to act on the result of the November 2019 CT scan.
19. Why was this man's case not reviewed by the MDM when it was clear at the time of his emergency admissions that he was not in adequate treatment.
20. What are the administrative mechanisms in place to alert clinicians to abnormal results?
21. At which points may they break down?

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 10 August 2020

HSCB Unique Case Identifier: Personal Information redacted by USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB: 1 March 2021

1.0 EXECUTIVE SUMMARY

Patient 8, a Personal Information old gentleman presented with urinary tract symptoms and was placed on the waiting list for a transurethral resection of the prostate (TURP) in October 2014. At that time his serum prostate specific antigen level was 1.2ng/ml, which indicated a low risk of prostate cancer. Patient 8 was to come in (TCI) for his TURP on 18 December 2019 however this was cancelled due to industrial action. His admission was rearranged for 29 January 2020. The histology reported on the resected specimen confirmed incidental prostate cancer. A plan was documented to review Patient 8 in April 2020 but this did not happen until August 2020.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents.
- To share the report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Patient/ Staff involved in his care.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement – discussion with patient

MDT pathway for Cancer Management and appropriate guidelines

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 8, a Personal Information redacted by the USI old gentleman was seen in March 2013 complaining of lower urinary tract symptoms and was commenced on Finasteride and Alfuzosin with a plan to review in 3 months. On 27 October 2014 he was reviewed by a specialist urology doctor (Dr.2). Patient 8 explained that his lower urinary tract symptoms continued despite medical treatment with Finasteride and Alfuzosin. His International Prostate Symptom Score (IPSS) had been 26/35 indicating a significant impact on his quality of life. An ultrasound scan of the urinary tract showed no immediate concern and the prostate was noted to be relatively small at 29 cc. Dr.2 discussed treatment options with Patient 8 who decided to proceed to surgery (TURP). Dr.2 explained the procedure and risks to Patient 8 and asked for him to be added to Dr.1's waiting list.

A letter, dated 11 November 2016, was received by the Southern Trust Booking Centre on 15 November 2016 from Patient 8 s General Practitioner (GP), which asked if Patient 8 's TURP could be expedited. As a result of this letter Patient 8 had a repeat ultrasound scan carried out on 8 February 2017 which did not give rise for concern.

Dr.1 arranged for Patient 8 to come in for his TURP on 18 December 2019, however, this was cancelled due to industrial action. His admission was rearranged for 29 January 2020.The histology of the resected specimen confirmed low volume well-differentiated prostatic adenocarcinoma. On the operation note, Dr. 1 planned to review Patient 8 in April 2020.This did not happen until Patient 8 's case was brought to the attention of Dr.3 who arranged to review Patient 8 on 11 August 2020. At that appointment it was noted that Patient 8 had done well following his TURP with an improvement in his urinary symptoms and good continence. Dr.3 explained the pathology and findings as an incidental prostate cancer. He also explained that further assessment with an up to date serum PSA level and an MRI scan of the prostate was required.

Dr.3 wrote to Patient 8 on 9 September 2020 to confirm that the serum PSA level (9 September 2020) was within the normal range (1.75ng/ml) and that the MRI scan (1 September 2020) showed a normal prostate appearance aside from the channel created during the TURP; it specifically did not show any features of prostate cancer.

Dr.3 advised that the prostate cancer was incidental (unlikely to represent a threat

5.0 DESCRIPTION OF INCIDENT/CASE

during Patient 8's life expectancy and, therefore, would not be anticipated to require any treatment) and surveillance with PSA monitoring was recommended. Dr.3 asked for the next PSA level to be done in December 2020 and said that he would review the result.

6.0 FINDINGS

- The management of Patient 8's lower urinary tract symptoms followed a standard pathway.
- Patient 8 was appropriately listed for TURP but appears to have remained on the waiting list for over 5 years, despite requests for an expedited admission.
- Patient 8 was not followed up following his TURP in January 2020. He was not advised of his diagnosis until a review in August 2020. The operation notes specify a planned review in April 2020. This did not happen.
- The TURP histology showed well-differentiated adenocarcinoma in just under 5% of the tissue resected. This in the light of the stable PSA must be regarded as a co-incidental diagnosis with a low probability of any impact on Patient 8's life expectancy or quality of life.
- The review team considered the MDM plan for surveillance appropriate.
- The review team considered whether the Covid pandemic played any part in this delay. At that time telephone virtual clinics were in place which allowed reviews to continue.
- The review questioned why the histology had not automatically entered Patient 8 onto the MDT database to allow prompt discussion.
- This usually falls to the laboratory to search all urology patients on a weekly basis by SNOMED code for cancer and site.
- The review team questioned whether the mechanisms for post-operative follow up were robust.
- The delays and omissions are matters of the operational policies of the department and/or Trust rather than any individual.
- The review team met with Patient 8 on two occasions and have established that the delay in being reviewed did cause him considerable anxiety.
- When he was advised of his malignancy diagnosis 8 months after his surgery Patient 8 described being very shocked by it. However, he was reassured about the

6.0 FINDINGS

long-term outcome and is now on a surveillance programme.

- The delay in performing surgery may have led to a less satisfactory outcome, with a greater chance of the development of secondary instability.

7.0 CONCLUSIONS

Patient 8 was appropriately listed for TURP, but appears to have remained on the waiting list for over 5 years despite requests for an expedited admission.
The TURP histology showed well-differentiated adenocarcinoma in just under 5% of the tissue resected. This in the light of the stable PSA must be regarded as a co-incidental diagnosis with no impact on Patient 8's health. No material harm was caused to Patient 8's health, other than that of an unacceptably long wait to resolve his significant symptoms

8.0 LESSONS LEARNED

- The processes by which outpatient appointments and operation waiting lists are administered require review and modernising.

9.0 RECOMMENDATIONS AND ACTION PLANNING

- There should be a routine failsafe mechanism within laboratories to identify all pathological diagnoses of cancer. This should be correlated with MDT lists to ensure all unexpected or missed cases of cancer are appropriately discussed

10.0 DISTRIBUTION LIST

Mr Shane Devlin – Chief Executive SHSCT

Mrs Melanie McClements – Director of Acute Services SHSCT

Dr Maria O'Kane – Medical Director SHSCT

Mrs Heather Trouton Executive Director of Nursing, Midwifery and AHP

HSCB

PHA

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **26 OCTOBER 2020**						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**,			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			x
	c) Report not shared but contents discussed (***if you select this option please also complete 'l' below***)			
	d) No contact or Next of Kin or Unable to contact			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 10 August 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 8, a Personal Information old gentleman presented with urinary tract symptoms and was placed on the waiting list for a transurethral resection of the prostate (TURP) in October 2014. At that time his serum prostate specific antigen level was 1.2ng/ml, which indicated a low risk of prostate cancer. Patient 8 was to come in (TCI) for his TURP on 18 December 2019 however this was cancelled due to industrial action. His admission was rearranged for 29 January 2020. The histology reported on the resected specimen confirmed incidental prostate cancer. A plan was documented to review Patient 8 in April 2020 but this did not happen until August 2020.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of Northern Ireland Electronic Care Record

MDT pathway for Cancer Management and appropriate guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 8, a Personal Information old gentleman was seen in March 2013 for a flexible cystoscopy for lower urinary tract symptoms he was commenced on Finasteride and Alfuzosin and a plan to review in 3 months. On 27 October 2014 he was reviewed by a specialist urology doctor (Dr.2). Patient 8 explained that his lower urinary tract symptoms continued despite medical treatment with Finasteride and Alfuzosin. His International Prostate Symptom Score (IPSS) had been 26/35 indicating a significant impact on his quality of life. An ultrasound scan of the urinary tract showed no immediate concern and the prostate was noted to be relatively small at 29 cc. Dr.2 discussed treatment options with Patient 8 who decided to proceed to surgery (TURP). Dr.2 explained the procedure and risks to Patient 8 and asked for him to be added to Dr.1's waiting list.

A letter, dated 11 November 2016, was received by the Southern Trust Booking Centre on 15 November 2016 from Patient 8's General Practitioner (GP), which asked if Patient 8's TURP could be expedited. As a result of this letter Patient 8 had a repeat ultrasound scan carried out on 8 February 2017 which did not give rise for concern.

Dr.1 arranged for Patient 8 to come in for his TURP on 18 December 2019, however, this was cancelled due to industrial action. His admission was rearranged for 29 January 2020. The histology of the resected specimen confirmed low volume well-differentiated prostatic adenocarcinoma. On the operation note, Dr. 1 planned to review Patient 8 in April 2020.This did not happen when Patient 8's case was brought to the attention of Dr.3 who arranged to review Patient 8 on 11 August 2020. At that appointment it was noted that Patient 8 had done well following his TURP with an improvement in his urinary symptoms and good continence. Dr.3 explained the pathology and findings as an incidental prostate cancer. He also explained that further assessment with an up to date serum PSA level and an MRI scan of the prostate was required.

Dr.3 wrote to Patient 8 on 9 September 2020 to confirm that the serum PSA level (9 September 2020) was within the normal range (1.75ng/ml) and that the MRI scan (1 September 2020) showed a normal prostate appearance aside from the channel created during the TURP; it specifically did not show any features of prostate cancer.

Dr.3 advised that the prostate cancer was incidental (unlikely to represent a threat during Patient 8's life expectancy and, therefore, would not be anticipated to require any treatment) and surveillance with PSA monitoring was recommended. Dr.3 asked for the next PSA level to be done in December 2020 and said that he would review the

5.0 DESCRIPTION OF INCIDENT/CASE

result.

6.0 FINDINGS

- The management of Patient 8's lower urinary tract symptoms followed a standard pathway.

- Patient 8 was appropriately listed for TURP but appears to have remained on the waiting list for over 5 years, despite requests for an expedited admission.
- Patient 8 was not followed up following his TURP in January 2020. He was not advised of his diagnosis until a review in August 2020. The operation notes specify a planned review in April 2020. This did not happen.

- The TURP histology showed well-differentiated adenocarcinoma in just under 5% of the tissue resected. This in the light of the stable PSA must be regarded as a co-incidental diagnosis with a low probability of any impact on Patient 8's life expectancy or quality of life.

- The review team considered the MDM plan for surveillance appropriate.

<u>Contributory factors</u>

- The review team considered whether the Covid pandemic played any part in this delay. At that time telephone virtual clinics were in place which allowed reviews to continue.
- The review questioned why the histology had not automatically entered Patient 8 onto the MDT database to allow prompt discussion.

- This usually falls to the laboratory to search all urology patients on a weekly basis by SNOMED code for cancer and site.

- The review team questioned whether the mechanisms for post-operative follow up were robust.

- The delays and omissions are matters of the operational policies of the department and/or Trust rather than any individual.

Commentary

- The review team met with Patient 8 and have established that the delay in being reviewed did cause him considerable anxiety.

- Patient 8 was on the waiting list for TURP for 5 years despite requests for an expedited admission.

- When he was advised of his malignancy diagnosis 8 months after his surgery Patient 8 described being very shocked by it. However, he was

6.0 FINDINGS
reassured about the long-term outcome and is now on a surveillance programme. • The review team conclude that the delay to review did not affect his long term outcome but recognised the anxiety caused.

7.0 CONCLUSIONS
Patient 8 was appropriately listed for TUR (P) appears to have remained on the waiting list for over 5 years despite requests for an expedited admission. The TUR (P) histology showed well-differentiated adenocarcinoma in just under 5% of the tissue resected. This in the light of the stable PSA must be regarded as a co-incidental diagnosis with no impact on Patient 8's health. No material harm was caused to Patient 8's health, other than that of an unacceptably long wait to resolve his significant symptoms Considerations 1. Was the waiting time for admission for elective surgery, as indicated in AO's letter of 23/01/20, 5 years? 2. How did this wait compare to other local providers and what measures where considered by AO, the urology department and the Southern Trust to ameliorate this? 3. What mechanism was in place to convert the indicated follow up on the operation note into an appointment?

8.0 LESSONS LEARNED
Question for Hugh- would a delay of 5 years worsen the his symptoms

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed (***if you select this option please also complete 'I' below***)			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: [redacted]

Date of Incident/Event: 10 August 2020

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted]

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 8, a Personal Information old gentleman presented with urinary tract symptoms and was placed on the waiting list for a transurethral resection of the prostate (TURP) in October 2014. At that time his serum prostate specific antigen level was 1.2ng/ml, which indicated a low risk of prostate cancer. Patient 8 was to come in (TCI) for his TURP on 18 December 2019 however this was cancelled due to industrial action. His admission was rearranged for 29 January 2020. The histology reported on the resected specimen confirmed incidental prostate cancer. It was planned to review Patient 8 in April 2020 but this did not happen until August 2020.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Clinical Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 8, a Personal Information old gentleman was seen by Dr.1 (a specialist urology doctor in training, ST4) on 27 October 2014. Patient 8 explained that his lower urinary tract symptoms continued despite medical treatment with Finasteride and Alfuzosin. His International Prostate Symptom Score (IPSS) had been 26/35 indicating a significant impact on his quality of life. An ultrasound scan of the urinary tract showed no immediate concern and the prostate was noted to be relatively small at 29 cc. Dr.1 discussed treatment options with Patient 8 who decided to proceed to surgery (TURP). Dr.1 explained the procedure and risks to Patient 8 and asked for him to be added to Dr.2's waiting list.

A letter, dated 11 November 2016, was received by the Southern Trust Booking Centre on 15 November 2016 from Patient 8's General Practitioner (GP), which asked if Patient 8's TURP could be expedited. As a result of this letter Patient 8 had a repeat ultrasound scan carried out on 8 February 2017 which did not give rise for concern.

Dr.2 arranged for Patient 8 to come in for his TURP on 18 December 2019, however, this was cancelled due to industrial action. His admission was rearranged for 29 January 2020. The histology of the resected specimen confirmed low volume well-differentiated prostatic adenocarcinoma. On the operation note, Doctor 2 planned to review Patient 8 in April 2020.This did not happen when Patient 8's case was brought to the attention of Dr.3 who arranged to review Patient 8 on 11 August 2020. At that appointment it was noted that Patient 8 had done well following his TURP with an improvement in his urinary symptoms and good continence. Dr.3 explained the pathology and findings as an incidental prostate cancer. He also explained that further assessment with an up to date serum PSA level and an MRI scan of the prostate was required.

Dr.3 wrote to Patient 8 on 9 September 2020 to confirm that the serum PSA level (9 September 2020) was within the normal range (1.75ng/ml) and that the MRI scan (1 September 2020) showed a normal prostate appearance aside from the channel created during the TURP; it specifically did not show any features of prostate cancer.

Dr.3 advised that the prostate cancer was incidental (unlikely to represent a threat during Patient 8's life expectancy and, therefore, would not be anticipated to require any treatment) and surveillance with PSA monitoring was recommended. Dr.3 asked for the next PSA level to be done in December 2020 and said that he would review the result.

6.0 FINDINGS

The management of this man's lower urinary tract symptoms followed a standard pathway.

- A patient appropriately listed for TURP appears to have remained on the waiting list for over 5 years despite requests for an expedited admission.
- Patient 8 was not followed up following his TURP in January 2020. He was not advised of his diagnosis until a review in August 2020. The operation notes specify a planned review in April 2020. This did not happen.
- The TURP histology showed well-differentiated adenocarcinoma in just under 5% of the tissue resected. This in the light of the stable PSA must be regarded as a co-incidental diagnosis with a low probability of any impact on Patient 8's life expectancy or quality of life.

Contributory factors

- The review team considered whether the Covid pandemic played any part in this delay. At that time telephone virtual clinics were in place which allowed reviews to continue.
- The review questioned why the histology had not automatically entered Patient 8 onto the MDT database to allow prompt discussion.
- The review team questioned whether the mechanisms for post-operative follow up were robust.
- The delays and omissions are matters of the operational policies of the department and/or Trust rather than any individual.

Commentary

- The review team met with Patient 8 and have established that the delay in being reviewed did cause him considerable anxiety.
- Patient 8 was on the waiting list for TURP for 5 years despite requests for an expedited admission. Was the waiting time for admission for elective surgery, as indicated in AO's letter of 23/01/20, 5 years?
- When he was advised of his malignancy diagnosis 8 months after his surgery Patient 8 described being very shocked by it. However, he was reassured about the long-term outcome and is now on a surveillance programme.
- The review team conclude that the delay to review did not affect his long term outcome but recognised the anxiety caused.

Conclusion

No material harm was caused to Patient 8's health, other than that of an unacceptably long wait to resolve his significantly bothersome symptoms

7.0 CONCLUSIONS
A patient appropriately listed for TUR (P) appears to have remained on the waiting list for over 5 years despite requests for an expedited admission. The TUR (P) histology showed well-differentiated adenocarcinoma in just under 5% of the tissue resected. This in the light of the stable PSA must be regarded as a co-incidental diagnosis with no impact on Patient 8's health. No material harm was caused to Patient 8's health, other than that of an extremely long wait to resolve his significant symptoms Considerations 1. Was the waiting time for admission for elective surgery, as indicated in AO's letter of 23/01/20, 5 years? 2. How did this wait compare to other local providers and what measures where considered by AO, the urology department and the Southern Trust to ameliorate this? 3. What mechanism was in place to convert the indicated follow up on the operation note into an appointment?

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed (***if you select this option please also complete 'I' below***)			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
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	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
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	If **NO**, please provide details:			
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	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 03/09/2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB: 1March 2021

1.0 EXECUTIVE SUMMARY

Patient 7 had a small renal mass since 2017 which was under surveillance by Urology. At an outpatient's review clinic on 29 March 2019 Patient 7 was advised that his renal mass was stable and he was for surveillance. This is despite the urology multi-disciplinary team meeting outcome of the previous day advising that Patient 7 should have the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risk discussed.

On 13 November 2019 Patient 7 had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a subsequent delay in the follow up process for cancer care management.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally SET recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents.
- To share the report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Patient/ Staff involved.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of Northern Ireland Electronic Care Record

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 28 June 2016, Patient 7 was urgently referred as a 'red flag 'to the urology services at Craigavon Area Hospital (CAH), because an abdominal ultrasound scan, requested to investigate raised liver enzymes, had shown a renal lesion. A subsequent CT scan (16 June 2016) confirmed a mildly enhancing renal lesion. The CT scan also showed mesenteric lymphadenopathy suspicious of lymphoma and a simultaneous 'red flag' referral was made to haematology.

On 19 July 2016, Patient 7 was seen by Dr.1 (Consultant Urologist) at an outpatient clinic at which the CT images were explained and discussed. Dr.1 advised of the presence of a solid lesion, measuring 2.5cms in diameter, which was partly protruding out of the anteromedial cortex of the lower pole of the left kidney's outer surface. The lesion was described as mildly enhancing and being rather homogeneous in appearance. Dr.1 explained that the lesion could very well be a papillary renal cell carcinoma and advised that its location did not allow biopsy without significant risk.

Patient 7 was discussed at the urology multidisciplinary meeting (MDM) on 28 July 2016. The MDM recommended active surveillance and that Dr.1 should review Patient 7 in a further 4 months with the results of a CT scan to assess both the mesenteric nodes and the renal mass.

On 12 August 2016, Patient 7 was reviewed by Dr.1 at an outpatient clinic and found him to remain "entirely well" and that he was happy with the plan, and to have the left renal lesion and the mesenteric lymphadenopathy reassessed by CT scan in November 2016. Dr.1 also advised an outpatient appointment for December 2016 to review the CT images and report. Patient 7 was also to be followed up by the haematology team.

Patient 7 had a repeat CT scan on 7 December 2016 and on 6 January 2017 was reviewed in outpatients by Dr.2 (Locum Consultant Urologist) who noted that the CT scan had shown a slight increase in the size of the kidney mass, but the mesenteric lymph nodes were unchanged. Of note, there was no new retroperitoneal or pelvic lymph node enlargement, nor any bony lesions. Dr.2 noted that Patient 7 had been doing well since his last outpatient review and had no lower urinary tract symptoms or haematuria. Dr.2's planned to re-discuss Patient 7 at the urology MDM in January, but

5.0 DESCRIPTION OF INCIDENT/CASE

provisionally requested a repeat CT scan and outpatient review in a further 4 months.

On 19 January 2017, Patient 7's case was discussed at the MDM, which noted that the first repeat CT scan showed minimal changes to the renal mass. There were no changes in the mesenteric appearances, which were now felt to be not significant. A follow up MRI scan of the kidney was recommended.

A second repeat CT was carried out on 23 March 2017.

On 11 April 2017, Dr.2 (Locum Consultant Urologist) wrote to Patient 7's GP to advise on the findings on the latest CT scan. Some mild bilateral apical pleural thickening and a 4mm right basal pulmonary nodule, which had been described on the previous CT had now resolved. All else was reportedly normal and Dr.2 noted that Patient 7 awaited an MRI of his kidney which had been booked for 8 May 2017.

The MRI of the kidney was said to show no change in size of the left kidney mass when compared with the CT of December 2016. It was noted that the MRI radiologist's report described the lesion as non-specific and may have represented a papillary renal cell carcinoma. As Patient 7 remained on active surveillance, Dr.2 listed the case for discussion at MDM to agree which modality (CT/MRI) and what intervals for further reimaging were appropriate in this case.

On 25 May 2017, Patient 7's case was presented to the MDM by Dr.1 and after discussion the plan was for Dr.1 to review Patient 7 in outpatients and organise a further CT scan in a further 12 months.

On 9 June 2017, Patient 7 was reviewed by Dr.1 who noted that a further renal CT scan was to be performed during November 2017.

On 5 January 2018, Dr.1 reviewed Patient 7 at an outpatient clinic. Dr.1 noted, in relation to latest CT scan (November 2017) that "I consider it to have increased by 2mm in maximum diameter up to 2.8cm".

Dr.1 recommended proceeding to partial nephrectomy if the left renal lesion became closer to 3cms in diameter than it had been on first assessment in June 2016. A CT scan was requested for August 2018 with the intention of discussion at the Regional Small Renal Masses MDM.

On 25 July 2018, a CT scan was performed which showed a slight increase in the size of the left kidney mass. Further, it was commented that it did not appear suitable for ablative therapy.

23 August 2018 Patient 7's case was again discussed at MDM. The July scan was reviewed which now showed the lesion to measure 3.0cm and it was recommended that, at an imminent review, both continuing active surveillance and open partial nephrectomy should be discussed. Furthermore, Patient 7 case should be discussed at the Regional Small Masses MDM.

On 14 September 2018, Dr.1 reviewed Patient 7 at outpatients when Patient 7 remained undecided, and it was concluded that a further CT scan should be performed in March

5.0 DESCRIPTION OF INCIDENT/CASE

2019 and that Patient 7 would proceed to partial nephrectomy if a further increase in the size of the left kidney mass was confirmed.

On 28 March 2019, on discussion at MDM the left kidney mass was noted to be enlarging and it was recommended that Dr.1 discussed laparoscopic radical nephrectomy in relation to continued surveillance with its attendant risks.

On 29 March 2019 Patient 7 was reviewed by Dr.3 (Locum Consultant Urologist). It was noted that Patient 7 had had a 3.1cms left sided kidney mass since July 2018, which was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 6 July 2019, a routine referral to the surgical team was made for Patient 7 after he complained of some months of intermittent right lower abdominal swelling.

13 November 2019, a CT scan was performed which showed an increase in size (3.5 cm) of lesion. No urology review was noted.

On 19 November 2019, Patient 7 was reviewed at the cardiology clinic and it was noted his condition was stable from a cardiac perspective. There was no plan for any further investigation other than an echocardiogram as Patient 7 was under review with urology and, according to his wife, was due an operation. On 14 January 2020 a letter to Patient 7's GP indicated that the result of the echocardiogram was normal.

Patient 7 was seen at the surgical clinic on 21 January 2020 when it was confirmed he had a right inguinal hernia and agreed to treat on an expectant basis.

On 14 August 2020 Patient 7 was reviewed by Dr.4 (Locum Consultant Urologist). The CT scans were reviewed and it was noted that the kidney mass was 3.1 cms in March 2019 and had increased to 3.5 cms in November 2019. A plan was made for MDM discussion.

On 3 September 2020, Patient 7 case was discussed at MDM. It was noted that he had a 3.5cm lesion at the centre of his left kidney which had been slowly increasing in size since 2017. The MDT recommended that Patient 7 needed an up-to-date staging CT chest scan and renal function scans. Bloods to be taken for urea and electrolytes. To be reviewed by Dr.5 (Consultant Urologist) to discuss his suitability for radical nephrectomy.

On 26 October 2020, Patient 7 was reviewed by Dr.5 when there were further discussions about a laparoscopic radical nephrectomy and an agreement to discuss the way forward with Patient 7's daughter.

Patient 7 underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021Dr. 5 reviewed Patient 7. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

6.0 FINDINGS

- The review team acknowledge that Patient 7 was on a surveillance pathway for a renal mass below 4cm.
- The plan in 2017 was to proceed to partial nephrectomy if the tumour size increased to 3.0cm.
- The review team note that following discussions, Patient 7 remained undecided regarding surgery.
- The review team found that the planning of the intervals and imaging modalities was reactive, with no obvious proactive scheduling.
- In cases such as these, a referral to the Small Renal Mass MDM would be expected according to the NICAN Urology Cancer Clinical Guidelines (2016). This was recommended on two separate occasions by the MDM. Dr.1 advised that he would make the referral, but this was not actioned.
- Patient 7 case was brought repeatedly back to MDM at the request of locum surgeons to clarify the follow up surveillance protocol. The review team found that the MDM did not question why regional policy was not followed and why an appropriate opinion was not sought from the small renal mass MDM.
- Patient 7 was reviewed at MDMs 28/7/2016, 19/01/2017/ 28/08/2018, 28/3/2019/ 3/09/2020. All these meetings were non quorate due to the absence of an oncologist. Patient 7 case comprised of complex decisions based on tumour size and interpretation of radiological images. The review team note that a radiologist was present to provide additional interpretation of radiological images on all occasions except 23/8/2018.
- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% 2020
- Patient 7 was seen by Dr.1 and by 3 different locum consultants over this surveillance period, which led to somewhat fragmented care, inconsistency in investigations and a poor experience. Locum staff did not attend MDM and so did not feedback on the patient reviewed at outpatients.
- The review team believe a key worker or cancer specialist nurse would have improved the coordination of care, allowed a better understanding of the options available, and provided more consistent support to Patient 7 who was living with a potential and presumed diagnosis of cancer.
- The review team questions why it is not current practice for the SHSCT urology team to provide specialist nurses/ key worker to patients in a renal mass surveillance programme: whilst a histological diagnosis has not been made, the patient is fully aware of the high likelihood of cancer.
- The review team believes that Dr.1 had ample opportunities to refer Patient 7 for a specialist opinion and questioned why he decided to vary from established

6.0 FINDINGS

guidelines practice and MDM recommendations.

- The MDM is only funded to track 31 and 62 day targets - Patient 7 had not received a tissue diagnosis of cancer he would not fall within the remit. Similarly appointment of a CNS would occur at time of cancer diagnosis. This resource was not allocated prior to this. Complex tracking of this case was in essence outside the MDM structures.

7.0 CONCLUSIONS

The ideal pathway for Patient 7 would have been to present the full details of his presentation, medical history, investigations and proposed management to the specialist MDT responsible advising on the management of small renal masses. The patient should have been fully informed of the presumed diagnosis of renal cell carcinoma (a 90% likelihood) and so should have been allocated a Key Worker. Active surveillance was a reasonable management, option but should have been proactively planned so that even if there was a lack of continuity in overall responsibility for care, the timing and type imaging modality was clear. Even so, further prompt MDT discussions, informed by the patient's expectations and health status, should have been arranged whenever there was any change in the surveillance findings.

8.0 LESSONS LEARNED

- The management of small renal masses should all be referred to a specialist MDM to guide management.
- The surgical management of small renal masses should be the responsibility of clinicians with the appropriate experience, normally at the specialist centre.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

The MDM should appoint a Chair responsible for the regular review and auditing of patient pathways to ensure a common and collaborative approach.

Recommendation 2

Individualised protocols for surveillance – especially the frequency and modality of imaging - should be clarified with the specialist MDT, which should be informed of any variation.

Recommendation 3

9.0 RECOMMENDATIONS AND ACTION PLANNING

Any patient with a potential cancer diagnosis to be managed by surveillance should be independently allocated a Key Worker, usually a cancer nurse specialist, responsible for supporting and co-ordinating their care.

Recommendation 4

The MDM must have an open supportive culture allowing members to raise clinical concerns.

Recommendation 5

The Southern Health and Social Care Trust must develop cancer service governance processes to identify deficits in care and to escalate these appropriately

10.0 DISTRIBUTION LIST

Mr Shane Devlin – Chief Executive SHSCT

Mrs Melanie McClements Director of Acute Services SHSCT

Dr Maria O'Kane – Medical Director SHSCT

Mrs Heather Trouton – Executive Director of Nursing Midwifery and AHPs

HSCB

PHA

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**	
	Comment: **This part of an overarching report involving multiple service users.** ***If multiple service users involved please indicate the number involved***					
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**	x		
	If **YES**, insert **date informed**:					
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI					
	a) No contact or Next of Kin details or Unable to contact					
	b) Not applicable as this SAI is not 'patient/service user' related	x				
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	d) Case involved suspected or actual abuse by family					
	e) Case identified as a result of review exercise					
	f) Case is environmental or infrastructure related with no harm to patient/service user					
	g) Other rationale					
	If you selected c), d), e), f) or g) above please provide further details:					

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed (***if you select this option please also complete 'I' below***)			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

23 April 2021 **Our Ref:** Personal Information redacted by the USI **Your Ref:** Personal Information redacted by the USI

Private & Confidential

Personal Information redacted by the USI

Dear Sirs

RE: Mr Patient 8

Please see attached SAI Report in regards to your client Mr Patient 8

Yours sincerely

Personal Information redacted by the USI

MELANIE McCLEMENTS
Director of Acute Services

Working together Excellence Openness & Honesty Compassion

Clinical and Social Care Governance Team
Directorate of Acute Services
Ground Floor, The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by the USI
Email: Personal Information redacted by the USI

Southern Health and Social Care Trust

30 September 2021 **Our Ref:** Personal Information redacted by the USI **Your Ref:**

Private & Confidential

Patient's Wife

Dear Mrs Patient 9's Wife

As you are aware from my letter to you on 16 March 2021, the Trust has carried out a review of the treatment and care provided to your late husband Patient 9 As part of this process, the Trust has shared with both you and the regional Health and Social Care Board a draft copy of the review team's findings.

I attach for your attention the final report. This final report will also be shared with the Health and Social Care Board.

Our review of this Serious Adverse Incident (SAI) has now concluded. Should you remain dissatisfied you may refer to the Northern Ireland Public Services Ombudsman (NIPSO) within 6 months of the date of this letter. The Ombudsman's contact details are Progressive House, 33 Wellington Place, Belfast, BT1 6HN or Freepost NIPSO; Email: nipso@nipso.org.uk or Freephone number 0800 343 424. Further information on the role of the NI Public Services Ombudsman can be found at www.nipso.org.uk.

Yours sincerely

Personal Information redacted by the USI

Mrs Melanie McClements
Director of Acute Services

enc

Clinical and Social Care Governance Team
Directorate of Acute Services
The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by the USI
E-Mail: Personal Information redacted by the USI

16 March 2021 **Our Ref:** Personal Information redacted by the **Your Ref:**

Private & Confidential

Patient 9

Dear Mr Patient 9

I have previously been in contact with you about a review that the Southern Trust has been carrying out into the care you received.

As advised at the meeting with you on 19 February 2021 the team has concluded their review.

Please find enclosed a draft copy of the SAI report for you to consider. Mr O'Brien has asked that a copy of correspondence he has issued to the Trust be enclosed with the draft report. This is also attached.

I also enclose a feedback form which we would be grateful if you would return to the Acute Governance Team within 2 weeks of receipt of this letter. This form details the two options now available.

1. If after reviewing the report you have no further comment and indicate this to us, we will forward a final draft to both you and the Health and Social Care Board.

2. Alternatively if you would like to discuss the findings and outcome of this review further, please state this on the attached form and a member of the Governance Team will be in contact with you.

If after 2 weeks the Acute Governance Team has not received a response from you the report will be finalised and issued to both the family and Health and Social Care Board in its final format.

I look forward to hearing from you in due course.

Yours sincerely

Personal Information redacted by the USI

_____

Mrs Melanie McClements
Director of Acute Services

encs

Clinical and Social Care Governance Team
Directorate of Acute Services
The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by the USI
E-Mail: Personal Information redacted by the USI

Sharing of Draft SAI Report

Patient/Family Feedback Form

Please complete the form below and return to the Acute Clinical Governance Team in the enclosed return envelope or email to acute.governance@southerntrust.hscni.net within 2 weeks of receipt of the report.

I _____ (name) confirm I have read the draft SAI report Personal Information redacted by the .

Please tick one of the two boxes below.

I confirm I have read and approve the draft report to be issued as the final report. ☐

or

I confirm I have read the draft SAI report and I would like to discuss it further. ☐

Signed: _____

Date: _____ Telephone: _____

Working together Excellence Openness & Honesty Compassion

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 2 July 2020

HSCB Unique Case Identifier: Personal Information redacted by USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information redacted

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

Patient 9 , Personal Information redacted by the USI -year-old man, ~~who~~ was referred to urology services in Craigavon Area Hospital (CAH) via the Emergency Department (ED) ~~in May 2019~~ following an episode of retention of urine in May 2019. He was reviewed by ~~Dr 1~~Dr.1 who noted a raised PSA. ~~Dr 1 was s~~Suspicious of prostate cancer, Dr.1 ~~and~~ commenced Patient 9 on B~~b~~icalutamide (50mgs od) whilst awaiting transurethral resection of the prostate ~~prostatic resection~~(TURP).

A TURP ~~transurethral resection of the prostate~~ was performed. The findings were thought to be in keeping with bladder outlet obstruction due to bladder neck hypertrophy (enlargement). The bladder neck and prostate gland were partially resected and ~~biopsies taken at the time~~histology showed benign disease only. Patient 9 was able to pass urine prior to discharge home. ~~a~~ A routine review for September 2019 did not happen~~ed~~. ~~and~~ Patient 9 presented in ED in May 2020 complaining of abdominal pain and urinary retention. Following digital rectal examination an initial diagnosis of bowel cancer was made, histological examination later concluded Patient 9 had advanced prostate cancer. Patient 9 is now terminally ill.

Dr Dermot Hughes – External independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Clinical Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The terms of reference for the review of the care and treatment provided to Patient 9 were:

- To carry out a systematic review in the process used in the diagnosis, MDT decision making and subsequent follow up provided, using a Root Cause Analysis (RCA) Methodology.
- To use a multidisciplinary team approach to the review.
- To identify those factors which may have had an influence, or may have contributed to the process.
- To engage with Patient 9 ensuring where possible, questions presented to the review team are addressed.
- To agree the outcome of the review and subsequent recommendations.
- To action any recommendations and disseminate any lessons to be learnt.

- To report the findings and the recommendations of the review through the Director of Acute Services SHSCT, Medical Director of SHSCT and disseminate to the staff involved and Patient 9.

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

At presentation, Patient 9 was a Personal Information redacted by the -old gentleman who attended the Emergency Department (ED) in Craigavon Area Hospital (CAH) on 1 May 2019 complaining of ~~urinary retention and~~ severe abdominal pain and urinary retention. He was catheterised and referred to urology.

He was seen on 24 May 2019 by ~~Dr 1~~Dr.1 (Consultant Urologist) who noted ~~his~~ a history of lower urinary tract symptoms and a failed ~~trail~~ trial removal of catheter (TROC). A serum prostate specific antigen (PSA), which is a blood test that indicates the risk of the presence of prostate cancer, was elevated. Following examination ~~Doctor 1~~Dr.1 was suspicious of the presence of significant prostate cancer. He initiated partial androgen blockade by prescribing bicalutamide (50mgs, once daily) whilst awaiting a prostatic resection which was arranged for 12 June 2019.

On 12 June 2019, Patient 9 attended for ~~transurethral resection of prostate~~TURP. The procedure was performed by ~~Doctor 1~~Dr.1 who noted that the prostate gland did not look "particularly enlarged or obstructive". Severe bladder neck hypertrophy and a trabeculated bladder were seen, (trabeculation represents bladder muscle that has thickened over time, possibly, but not exclusively as a result of obstruction to outflow of urine). The findings were thought to be in keeping with bladder outlet obstruction due to bladder neck hypertrophy (enlargement). The bladder neck and prostate gland were partially resected and Patient 9 was able to pass urine prior to discharge home.

Patient 9 was reviewed on 2 July 2019 when he was noted to have suffered an increase in urinary symptoms since discharge. It was noted there was no evidence of malignancy on histopathological examination, however, ~~Doctor 1~~Dr.1 documented in the patient's GP letter that he suspected there may be a cancer in the unresected prostate gland and therefore arranged a repeat PSA level, ~~and~~ an ultrasound scan of the urinary tract and a MRI scan of the prostate. Depending on the PSA result, ~~Doctor 1~~Dr.1 stated in the GP letter that he was considering performing a prostatic biopsy of the gland

5.0 DESCRIPTION OF INCIDENT/CASE

~~remnant, but~~remnant but deferred this until a planned review Patient 9 ~~-~~in September 2019.

No appointment is recorded ~~on the system~~ until Patient 9 attended the Emergency Department (ED) at ~~Craigavon Area Hospital~~CAH on 8 May 2020. He complained of severe urinary symptoms and was found to be in retention of urine. He was also noted to have some diarrhoea with associated rectal bleeding and tenesmus (~~feeling~~ an uncomfortable feeling or pain~~ful~~ indicating a need to open the bowels). He was reviewed by ~~Doctor 2~~Dr.2 (a specialist surgical trainee, ST4) who documented that Patient 9 was known to urology services and queried if he had been lost to follow up. On digital rectal examination ~~Doctor 2~~Dr.2 felt a rectal mass and suspected prostate cancer. Bloods for a PSA level was taken. Patient 9 was catheterised and allowed home with a referral to both urology and colo-rectal surgery.

According to a letter, dated 12 May 2020, from ~~Doctor 1~~Dr.1 to Patient 9 following a virtual clinic review, Doctor 1 prescribed bicalutamide (50mg) for the suspected prostate cancer, in addition to tamsulosin (0.4mg) for the urinary symptoms. He had asked for Patient 9's GP to arrange for the district nurse/ practice nurse to ~~be~~ review Patient 9 on 18 May 2020 for a TROC. ~~removal of the indwelling urethral catheter.~~

On 18 May 2020 Patient 9 attended for the TROC ~~trial removal of catheter~~ as arranged. He was unable to void urine and as a bladder scan showed 500mls of residual urine a catheter was reinserted. He was reviewed by ~~Doctor 3~~DR.3 (specialist urology trainee, ST3) who noted that the serum PSA level (9.5ng/ml) was elevated. ~~Doctor 3~~DR.3 also noted that during Patient 9's attendance at ED ~~and that Doctor 2~~Dr.2 had ~~felt~~ recorded ~~that during rectal examination~~ that the prostate felt malignant. ~~Doctor 3~~Dr.3 requested a MRI scan of the prostate and pelvis and wrote a referral letter ~~to Doctor 1~~ to request an outpatient review by ~~Doctor 1~~Dr.1. In addition, ~~,~~ a red flag referral ~~for~~ to general surgery was made and a letter for information was sent to Patient 9's GP.

On 27 May 2020, Patient 9 attended for the MRI ~~prostate~~ scan, which demonstrated a pelvic mass that was highly suspicious of prostate cancer ~~demonstrating pelvic mass and~~causing a ~~urethro-rectal fistulae~~urethro-rectal fistula.

On 12 June 2020, Patient 9 attended for ~~the~~ a CT scan which showed a large rectal mass with small volume groin nodes but no distant metastasis.

Patient 9 was reviewed by ~~general surgeon Doctor 4~~Dr.4 ~~-~~(General Surgery Consultant) on 30 June 2020 who performed a biopsy of the ~~rectal~~ mass *per rectum*. Histology confirmed poorly~~-~~-differentiated (aggressive) prostate adenocarcinoma (Gleason 9/10).

Patient 9's case was discussed at the urology MDM (2 July 2020) ~~who~~ which noted a locally advanced prostate cancer. The MDM recommended prompt urology review, to commence androgen deprivation therapy (ADT), and ~~for~~ that a bone scan ~~to be~~was ~~re~~arranged.

~~Doctor 5~~Dr.5 (Consultant Urologist) saw Patient 9 (6 July 2020) and found that he continued with rectal bleeding and tenesmus ~~(feeling of incomplete emptying of bowel).~~ . ~~-~~ Patient 9 had stopped his bicalutamide (May 2020) and, so, was ~~taking~~ on no ~~medication~~ treatment for his prostate cancer. ~~A bone scan was requested and~~ Patient 9

5.0 DESCRIPTION OF INCIDENT/CASE

~~was to commence androgen deprivation therapy as an LHRH analogue.~~The MDM recommendations were followed. Further discussion at MDM was planned for when the bone scan results were available. It was intended that if there was no metastatic disease, he would be referred to oncology.

Patient 9 attended the ED (27 July 2020) with ongoing problems with his urinary catheter which was changed earlier in the day but was still ~~unable to pass urine~~not draining. His catheter was changed again and he was commenced on oral antibiotics. He was discharged home.

Two days later (29 July 2020) Patient 9 returned to the ED with urinary retention after again having his catheter changed in the community. He was noted to have a very low urine output through the catheter despite good hydration. Patient 9 reported passing urine per rectum. Faeces were seen in the catheter bag. ~~and tube.~~

Patient 9 was admitted under the care of ~~Doctor 6~~Dr.6 (Consultant Urologist) as he was in painful urinary ~~retention~~retention, but the urology team were unable to pass a urethral catheter. He was taken to theatre for the open insertion of a suprapubic catheter under general anaesthetic.

A bone scan did not show metastases.

Patient 9 was reviewed by the acute oncology service during this admission; ~~who recommended~~ palliative treatment was recommended. It was decided that Patient 9 would need a defunctioning faecal stoma and possibly an ileal conduit (stoma bag for the bladder). Patient 9 was reviewed by the ~~Stoma~~ stoma nurse regarding future stoma.

The surgeons planned surgery for the defunctioning colostomy when Patient 9 felt able: Patient 9 he wanted to return home to recuperate before undergoing any further ~~surgeries~~intervention. He was discharged home on 1 August 2020.

Patient 9's case was discussed at MDM on 6 August 2020. The ~~recommended~~ recommendation for de-functioning colostomy was confirmed, but the supra pubic catheter was to be maintained for urinary drainage. Palliative radiotherapy could be considered after Patient 9's surgery and he was to remain on hormone therapy.

On 13 August 2020 Patient 9 attended the ED complaining of severe abdominal pain and was noted to have a recto-vesical fistula. He was admitted under the general surgical team and underwent an emergency laparotomy and defunctioning sigmoid loop colostomy ~~()~~ on 14 August 2020. He was discharged home with a planned review by the urology team.

On 19 October 2020 Patient 9 was reviewed by ~~Doctor 5~~Dr.5 (Consultant Urologist), it was noted that Patient 9 was having intermittent episodes of diarrhoea and penile discomfort. His PSA was noted to have risen to 17.30ng/ml and a referral was made to Clinical Oncology in Belfast City Hospital for further assessment.

6.0 FINDINGS

This man presented in urinary retention and demonstrated features of possible prostate cancer. This possibility should have been pursued by the request of a MRI of the prostate and pelvis and ultrasound guided needle biopsy of the gland. Alternatively, an urgent TURP and the needle biopsies could have been performed simultaneously after the MRI scan. This would have established the diagnosis and, following staging with a bone scan, the patient could have been referred for a specialist opinion on radical therapy.

~~Causal Factors~~

- The review team believe that ~~Doctor 1~~Dr.1 suspected prostate cancer based on clinical examination and raised PSA. Following ~~Trans urethral Resection of Prostate (~~TURP~~)~~ , which showed benign disease, ~~(low volume sample 2g from central area of prostate)~~ there was no intention to consider this further ~~investigation to explore this suspicion.~~ until 3 months after presentation.
- Patient 9 was not referred for ~~multidisciplinary meeting (~~MDM~~)~~ discussion even on clinical and biochemical grounds. ~~for multidisciplinary input.~~
- Although the~~The~~ possibility of ~~localised~~ prostate cancer ~~could have been~~was considered from the time of presentation~~;~~ - the PSA was elevated - there ~~is~~ was no record in the medical notes of a digital rectal examination~~-~~ (DRE). ~~but the PSA was elevated.~~
- During the operation further signs might have been elicited and ~~.~~ ~~A~~appropriate (ultrasound guided needle) biopsies could have been performed. A transrectal biopsy, performed at the time of the TURP, would have secured the diagnosis.
- TURP is not an adequate way to biopsy the prostate gland. NICAN Urology Clinical Guidelines 2016 indicate that TURP is a poor clinical tool for cancer diagnosis and recommend prostate biopsy by the ~~Trans~~trans-rectal or trans-perineal approach.
- ~~-~~ The Review Team conclude that the signs of localised prostate cancer were apparent from the time of presentation and that~~.~~
- ~~A~~ the correct course of action would have been to arrange appropriate staging scans and biopsies ~~and staging scans~~. Patient 9 should have undergone investigation with a MRI scan of the prostate and pelvis together with a bone scan.
- ~~A transrectal biopsy, performed at the time of the TURP, would have secured the diagnosis.~~
- ~~-~~ Arrangement ~~should~~ could then have been made to start ~~conventional~~ androgen deprivation therapy (a LHRH analogue) before ~~.~~
- ~~R~~referral on to ~~an~~ a clinical oncologist for consideration of external beam radiotherapy (ERBT) with a realistic prospect of effective disease control.
- ~~Dr 1~~Dr.1 still suspected cancer within the prostate gland in a GP letter (dated 24 May 2019) but deferred definitive investigation~~intervention~~ until a review ~~in~~ planned for September 2019.
- ~~Sadly~~ Patient 9 Patient 9's appointment in September was not made and he was lost to

6.0 FINDINGS

follow up.~~up. His appointment in September was not made.~~

- Patient 9 presented to Emergency Department (ED) on 8 May 2020 with urinary tract symptoms and signs of locally progressive prostate disease.~~retention of urine.~~
- After interactions with Urology and Lower Gastro-intestinal surgical colleagues, Patient 9 was diagnosed with high grade carcinoma of prostate origin Gleason score 9. The patient had locally advanced disease and a colo-vesical fistula.
- When Patient 9 was reviewed at a virtual clinic in May 2020 by Dr 1, he was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment.
- The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) guidance (2016) which was signed off by the Southern health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017).
- This guidance was issued when ~~Doctor 1~~Dr.1 was the regional chair of this group and had full knowledge of its contents.
- The review team note that following discussion with Patient 9, he was unaware that his care given was at variance with regionally recommended best practice.
- The review team believe that Patient 9 could not and did not give informed consent to this alternative pathway.
- A urology Cancer Nurse Specialist was not appointed to support Patient 9 and his family.

~~Contributory Factors~~

~~Urology Cancer Nurse Specialist~~

- The review team met with Patient 9 and his wife as part of the family engagement for the SAI. He described feeling isolated with no guidance on how to seek support or further care when he needed it. This resulted in numerous attendances to the Emergency Department with blocked catheters and urinary retention which Patient 9 found to be quite distressing. He was advised that the ED was the wrong place for him and that he should seek help from his GP. His experience in ED was further compounded by the ~~covid~~ Covid-19 restrictions.
- The review team acknowledge that the ED was not the most appropriate route for him to access. However, Patient 9 did not have access ~~from~~ to a ~~Urology Cancer Nurse Specialist~~urology CNS to support him and his family with his diagnosis and despite having complex healthcare needs ~~to support him with his diagnosis~~.
- The Southern Health and Social Care Trust Urology Cancer Peer Review submission 2017 states *"all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner".(*ref)
- ~~This did not happen even after belated diagnosis. Patricia T can you confirm please~~

6.0 FINDINGS

Multidisciplinary Team Meetings

- Patient 9 was not referred to MDM in a timely fashion because of no adherence to diagnostic pathways (NICAN) Urology Cancer clinical Guidelines 2016) and a delayed diagnosis of cancer.
-

~~For clarification~~

~~1. Why did AO consider it inappropriate to pursue radical therapy in this case?~~

~~2. Why were key investigations missed and inadequate treatment started?~~

~~3. What mechanisms were in place to ensure appropriate follow up arrangements?~~

~~4. The treatment offered is likely to have accelerated the tumours de-differentiation development of metastases (REF)~~

~~MDM~~

~~- Post tissue diagnosis of Prostate Cancer at GI MDM~~

~~2/07/2020. - Quorate~~

~~6/08/2020 - non quorate due to absence of oncology~~

7.0 CONCLUSIONS

The possibility of localised prostate cancer should have been considered from the time of presentation; although there is no record of a digital rectal examination the PSA was elevated. Further, signs should have been elicited during the TURP and appropriate biopsies could have been performed. TURP does not provide an adequate biopsy the prostate gland.

A MRI scan prompted by a digital rectal examination together with the elevated PSA might have revealed the need for biopsy. A transrectal biopsy performed either before or at the time of the TURP would have secured the diagnosis. Arrangements could have been made to start appropriate hormone therapy (a LHRH analogue) prior to referral to a clinical oncologist for an opinion on external beam radiotherapy with a realistic prospect of effective disease control.

To compound this, the patient was apparently lost to follow up after his appointment in

July 2019.

Patient 9 is likely to have suffered an unnecessary outcome owing to delays in the investigation of his symptoms and signs, the unconventional treatment of prostate cancer, and failures in follow up procedures.

Had the appropriate investigations and treatment been instituted in a timely fashion, there is likelihood that Patient 9 would have enjoyed a good quality of life for an extended period.

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 2 July 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information redacted

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 9, a Personal Information redacted by the -old man, was referred to urology services in Craigavon Area Hospital (CAH) via the Emergency Department (ED) following an episode of retention of urine in May 2019. He was reviewed by Dr.1 who noted a raised PSA. Suspicious of prostate cancer, Dr.1 commenced Patient 9 on Bicalutamide (50mgs od) whilst awaiting transurethral resection of the prostate (TURP).

A TURP was performed. The findings were thought to be in keeping with bladder outlet obstruction due to bladder neck hypertrophy (enlargement). The bladder neck and prostate gland were partially resected and histology showed benign disease only. Patient 9 was able to pass urine prior to discharge home. A routine review for September 2019 did not happen. Patient 9 presented in ED in May 2020 complaining of abdominal pain and urinary retention. Following digital rectal examination an initial diagnosis of bowel cancer was made; histological examination later concluded Patient 9 had advanced prostate cancer. Patient 9 is now terminally ill.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally SET recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents.
- To share the review to the Director of Acute Services/ Medical Director/ staff involved/ patient/ staff involved.
- To share with the HSCB.

3.0 SAI REVIEW TERMS OF REFERENCE

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of the Northern Ireland Health Care Record

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

At presentation, Patient 9 was a Personal Information redacted by the -old gentleman who attended the Emergency Department (ED) in Craigavon Area Hospital (CAH) on 1 May 2019 complaining of severe abdominal pain and urinary retention. He was catheterised and referred to urology.

He was seen on 24 May 2019 by Dr.1 (Consultant Urologist) who noted a history of lower urinary tract symptoms and a failed trial removal of catheter (TROC). A serum prostate specific antigen (PSA), (which is a blood test that indicates the risk of the presence of prostate cancer), was elevated. Following examination, Dr.1 was suspicious of the presence of significant prostate cancer. He initiated partial androgen blockade by prescribing bicalutamide (50mgs, once daily) whilst awaiting a prostatic resection which was arranged for 12 June 2019.

On 12 June 2019, Patient 9 attended for TURP. The procedure was performed by Dr.1 who noted that the prostate gland did not look “particularly enlarged or obstructive”. Severe bladder neck hypertrophy and a trabeculated bladder were seen, (trabeculation represents bladder muscle that has thickened over time, possibly, but not exclusively as a result of obstruction to outflow of urine). The findings were thought to be in keeping with bladder outlet obstruction due to bladder neck hypertrophy (enlargement). The bladder neck and prostate gland were partially resected and Patient 9 was able to pass urine prior to discharge home.

Patient 9 was reviewed on 2 July 2019 when he was noted to have suffered an increase in urinary symptoms since discharge. It was noted there was no evidence of malignancy on histopathological examination, however, Dr.1 documented in the patient’s GP letter that he suspected there may be a cancer in the unresected prostate gland and therefore arranged a repeat PSA level, an ultrasound scan of the urinary tract and a

5.0 DESCRIPTION OF INCIDENT/CASE

MRI scan of the prostate. Depending on the PSA result, Dr.1 stated in the GP letter that he was considering performing a prostatic biopsy of the gland remnant but deferred this until a planned review in September 2019.

No appointment is recorded until Patient 9 attended the Emergency Department (ED) at CAH on 8 May 2020. He complained of severe urinary symptoms and was found to be in retention of urine. He was also noted to have some diarrhoea with associated rectal bleeding and tenesmus (an uncomfortable feeling or pain indicating a need to open the bowels). He was reviewed by Dr.2 (a specialist surgical trainee, ST4) who documented that Patient 9 was known to urology services and queried if he had been lost to follow up. On digital rectal examination Dr.2 felt a rectal mass and suspected prostate cancer. Bloods for a PSA level was taken. Patient 9 was catheterised and allowed home with a referral to both urology and colo-rectal surgery.

According to a letter, dated 12 May 2020, from Dr.1 to Patient 9 following a virtual clinic review, Doctor 1 prescribed bicalutamide (50mg) for the suspected prostate cancer, in addition to tamsulosin (0.4mg) for the urinary symptoms. He had asked for Patient 9's GP to arrange for the district nurse/ practice nurse to review Patient 9 on 18 May 2020 for a TROC.

On 18 May 2020 Patient 9 attended for the TROC as arranged. He was unable to void urine and as a bladder scan showed 500mls of residual urine a catheter was reinserted. He was reviewed by Dr.3 (specialist urology trainee, ST3) who noted that the serum PSA level (9.5ng/ml) was elevated. Dr.3 also noted that during Patient 9's attendance at ED that Dr.2 had recorded that the prostate felt malignant. Dr.3 requested a MRI scan of the prostate and pelvis and wrote a referral letter to request an outpatient review by Dr.1. In addition, a red flag referral to general surgery was made and a letter for information was sent to Patient 9's GP.

On 27 May 2020, Patient 9 attended for the MRI scan, which demonstrated a pelvic mass that was highly suspicious of prostate cancer causing a urethro-rectal fistula.

On 12 June 2020, Patient 9 attended for a CT scan which showed a large rectal mass with small volume groin nodes but no distant metastasis.

Patient 9 was reviewed by Dr.4 (General Surgery Consultant) on 30 June 2020 who performed a biopsy of the mass *per rectum*. Histology confirmed poorly-differentiated (aggressive) prostate adenocarcinoma (Gleason 9/10).

Patient 9's case was discussed at the urology MDM (2 July 2020) which noted a locally advanced prostate cancer. The MDM recommended prompt urology review, to commence androgen deprivation therapy (ADT), and that a bone scan was arranged.

Dr.5 (Consultant Urologist) saw Patient 9 (6 July 2020) and found that he continued with rectal bleeding and tenesmus. Patient 9 had stopped his bicalutamide (May 2020) and, so, was on no treatment for his prostate cancer. The MDM recommendations were followed. Further discussion at MDM was planned for when the bone scan results were available. It was intended that if there was no metastatic disease, he would be referred to oncology.

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 9 attended the ED (27 July 2020) with ongoing problems with his urinary catheter which was changed earlier in the day but was still not draining. His catheter was changed again and he was commenced on oral antibiotics. He was discharged home.

Two days later (29 July 2020) Patient 9 returned to the ED with urinary retention after again having his catheter changed in the community. He was noted to have a very low urine output through the catheter despite good hydration. Patient 9 reported passing urine per rectum. Faeces were seen in the catheter bag.

Patient 9 was admitted under the care of Dr.6 (Consultant Urologist) as he was in painful urinary retention, but the urology team were unable to pass a urethral catheter. He was taken to theatre for the open insertion of a suprapubic catheter under general anaesthetic.

A bone scan did not show metastases.

Patient 9 was reviewed by the acute oncology service during this admission; palliative treatment was recommended. It was decided that Patient 9 would need a defunctioning faecal stoma and possibly an ileal conduit (stoma bag for the bladder). Patient 9 was reviewed by the stoma nurse regarding future stoma.

The surgeons planned surgery for the defunctioning colostomy when Patient 9 felt able: he wanted to return home to recuperate before undergoing any further intervention. He was discharged home on 1 August 2020.

Patient 9's case was discussed at MDM on 6 August 2020. The recommendation for de-functioning colostomy was confirmed, but the supra pubic catheter was to be maintained for urinary drainage. Palliative radiotherapy could be considered after Patient 9's surgery and he was to remain on hormone therapy.

On 13 August 2020 Patient 9 attended the ED complaining of severe abdominal pain and was noted to have a recto-vesical fistula. He was admitted under the general surgical team and underwent an emergency laparotomy and defunctioning sigmoid loop colostomy on 14 August 2020. He was discharged home with a planned review by the urology team.

On 19 October 2020 Patient 9 was reviewed by Dr.5 (Consultant Urologist), it was noted that Patient 9 was having intermittent episodes of diarrhoea and penile discomfort. His PSA was noted to have risen to 17.30ng/ml and a referral was made to Clinical Oncology in Belfast City Hospital for further assessment.

6.0 FINDINGS

Patient 9 presented in urinary retention and demonstrated features of possible prostate cancer. This possibility should have been pursued by the request of a MRI of the prostate and pelvis and ultrasound guided needle biopsy of the gland. Alternatively, an urgent TURP and the needle biopsies could have been performed simultaneously after the MRI scan. This would have established the diagnosis and, following staging

6.0 FINDINGS

with a bone scan, the patient could have been referred for a specialist opinion on radical therapy.

- The review team believe that Dr.1 suspected prostate cancer based on clinical examination and raised PSA. Following TURP, which showed benign disease, there was no intention to consider this further until 3 months after presentation.

- Although the possibility of prostate cancer was considered from the time of presentation - the PSA was elevated - there was no record in the medical notes of a digital rectal examination (DRE).

- During the operation further signs might have been elicited and appropriate (ultrasound guided needle) biopsies could have been performed. A transrectal biopsy, performed at the time of the TURP, would have secured the diagnosis.

- TURP is not an adequate way to biopsy the prostate gland. NICAN Urology Clinical Guidelines 2016 indicate that TURP is a poor clinical tool for cancer diagnosis and recommend prostate biopsy by the trans-rectal or trans-perineal approach.

- The Review Team conclude that the signs of localised prostate cancer were apparent from the time of presentation and that the correct course of action would have been to arrange appropriate staging scans and biopsies . Patient 9 should have undergone investigation with a MRI scan of the prostate and pelvis together with a bone scan.

- Arrangement could then have been made to start androgen deprivation therapy (a LHRH analogue) before referral on to a clinical oncologist for consideration of external beam radiotherapy (ERBT) with a realistic prospect of effective disease control.

- Dr.1 still suspected cancer within the prostate gland in a GP letter (dated 24 May 2019) but deferred definitive investigation until a review planned for September 2019.

- Patient 9's appointment in September was not made and he was lost to follow up.

- Patient 9 presented to Emergency Department (ED) on 8 May 2020 with urinary tract symptoms and signs of locally progressive prostate disease.

- After interactions with Urology and Lower Gastro-intestinal surgical colleagues, Patient 9 was diagnosed with high grade carcinoma of prostatic origin, Gleason score 9. The patient had locally advanced disease and a colo-vesical fistula.

- When Patient 9 was reviewed at a virtual clinic in May 2020 by Dr 1, he was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment.

- The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines

6.0 FINDINGS

(2016) which was signed off by the Southern health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017).

- This guidance was issued when Dr.1 was the regional chair of this group and had full knowledge of its contents.

- The review team note that following discussion with Patient 9, he was unaware that his care given was at variance with regionally recommended best practice.

- The review team believe that Patient 9 could not and did not give informed consent to this alternative pathway.

- Patient 9 was not Urology Cancer Nurse Specialist no phone numbers were provided, despite Patient 9's delayed diagnosis immediate complex needs.

- The review team met with Patient 9 and his wife as part of the family engagement for the SAI. He described feeling isolated with no guidance on how to seek support or further care when he needed it. This resulted in numerous attendances to the Emergency Department with blocked catheters and urinary retention which Patient 9 found to be quite distressing. He was advised that the ED was the wrong place for him and that he should seek help from his GP. His experience in ED was further compounded by the Covid-19 restrictions.

- The review team acknowledge that the ED was not the most appropriate route for him to access. However, Patient 9 did not have access to a urology CNS to support him and his family with his diagnosis and despite having complex healthcare needs.

- The Southern Health and Social Care Trust Urology Cancer Peer Review submission 2017 states "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner." (1)

<u>Multidisciplinary Team Meetings</u>

- Patient 9 was not referred to MDM in a timely fashion because of non-adherence to diagnostic pathways Northern Ireland Cancer Network (NICAN) Urology Cancer clinical Guidelines 2016) and a delayed diagnosis of cancer.

- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% in 2020.

6.0 FINDINGS

7.0 CONCLUSIONS

The possibility of localised prostate cancer should have been considered from the time of presentation; although there is no record of a digital rectal examination the PSA was elevated. Further, signs should have been elicited during the TURP and appropriate biopsies could have been performed. TURP does not provide an adequate biopsy the prostate gland.

A MRI scan prompted by a digital rectal examination together with the elevated PSA might have revealed the need for biopsy. A transrectal biopsy performed either before or at the time of the TURP would have secured the diagnosis. Arrangements could have been made to start appropriate hormone therapy (a LHRH analogue) prior to referral to a clinical oncologist for an opinion on external beam radiotherapy with a realistic prospect of effective disease control.

To compound this, the patient was apparently lost to follow up after his appointment in July 2019.

Patient 9 is likely to have suffered an unnecessary outcome owing to delays in the investigation of his symptoms and signs, the unconventional treatment of prostate cancer, and failures in follow up procedures.

Had the appropriate investigations and treatment been instituted in a timely fashion, there is likelihood that Patient 9 would have enjoyed a good quality of life for an extended period.

8.0 LESSONS LEARNED

The effective management of urological cancers requires a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis, treatment planning and the completion and survivorship.

A single member of the team should not choose to, or be expected to, manage all the clinical, supportive, and administrative steps of a patient's care.

A key worker, usually a cancer nurse specialist, should be independently assigned to every

patient learning of a new cancer diagnosis.

Any divergence from a MDT recommendation should be justified by further MDT discussion and the informed consent of the patient.

The clinical record should include the reason for any deferments in management decisions.

After any patient interaction, best practice includes the prompt communication, with the patient and their General Practitioner, of the rationale for any decisions made.

References

1. Peer review Self-Assessment report for NICaN 2017).

9.0 RECOMMENDATIONS AND ACTION PLANNING

- The MDT should audit all aspects of its primary function.
- The multi-disciplinary team meeting is primarily a forum in which the relative merits of all appropriate treatment options for the management of their disease can be discussed. Any other function is secondary to, and if necessary be sacrificed to, this aim.
- The multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.
- An operational system that allows the future scheduling of any investigations or appointments should be available during all clinical interactions

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

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Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 2 July 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information redacted

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Dr Dermot Hughes – External independent Chair: Former Medical Director Western Health and Social Care Trust. Former Chair of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BASU
Mrs Fiona Reddick – Head of Clinical Cancer Services
Ms Patricia Thompson – Clinical Nurse Specialist
Mrs Patricia Kingsnorth – Acting Acute Clinical Governance Coordinator

3.0 SAI REVIEW TERMS OF REFERENCE

The terms of reference for the review of the care and treatment provided to Patient 9 were:

- To carry out a systematic review in the process used in the diagnosis, MDT decision making and subsequent follow up provided, using a Root Cause Analysis (RCA) Methodology.
- To use a multidisciplinary team approach to the review.
- To identify those factors which may have had an influence, or may have contributed to the process.
- To engage with Patient 9 ensuring where possible, questions presented to the review team are addressed.
- To agree the outcome of the review and subsequent recommendations.
- To action any recommendations and disseminate any lessons to be learnt.
- To report the findings and the recommendations of the review through the Director of Acute Services SHSCT, Medical Director of SHSCT and disseminate to the staff involved and Patient 9.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

At presentation, Patient 9 was a Personal Information redacted by the -old gentleman who attended Emergency Department (ED) in Craigavon Area Hospital (CAH) on 1 May 2019 complaining of urinary retention and severe abdominal pain. He was catheterised and referred to urology.

He was seen on 24 May 2019 by Dr 1 (Consultant Urologist) who noted his history of lower urinary tract symptoms and a failed trail removal of catheter. A serum prostate specific antigen (PSA), which is a blood test that indicates the risk of the presence of prostate cancer, was elevated. Following examination Doctor 1 was suspicious of the presence of significant prostate cancer. He initiated androgen blockade by prescribing bicalutamide (50mgs, once daily) whilst awaiting a prostatic resection which was arranged for 12 June 2019.

On 12 June 2019 Patient 9 attended for transurethral resection of prostate. The procedure was performed by Doctor 1 who noted that the prostate gland did not look "particularly enlarged or obstructive Severe bladder neck hypertrophy and a trabeculated bladder were seen; trabeculation represents bladder muscle that has thickened over time, possibly, but not exclusively as a result of obstruction to outflow of urine. The findings were thought to be in keeping with bladder outlet obstruction due to bladder neck hypertrophy (enlargement). The bladder neck and prostate gland were partially resected and Patient 9 was able to pass urine prior to discharge home.

Patient 9 was reviewed on 2 July 2019 when he was noted to have suffered an increase in urinary symptoms since discharge. It was noted there was no evidence of malignancy on histopathological examination, however, Doctor 1 did suspect there may be a cancer in the unresected prostate gland and therefore arranged a repeat PSA level, and an ultrasound scan of the urinary tract and a MRI scan of the prostate. Depending on the PSA result Doctor 1 was considering performing a prostatic biopsy of the gland remnant, but deferred this until a review Patient 9 in September 2019.

No appointment is recorded until Patient 9 attended Emergency Department (ED) at Craigavon Area Hospital on 8th May 2020. He complained of severe urinary symptoms and was found to be in retention of urine. He was also noted to have some diarrhoea with associated rectal bleeding and tenesmus (feeling an uncomfortable or painful need to open the bowels). He was reviewed by Doctor 2 (a specialist surgical trainee, ST4) who documented that Patient 9 was known to urology services and queried if he had been lost to follow up. On digital rectal examination Doctor 2 felt a rectal mass and suspected prostate cancer. Bloods for a PSA level was taken. Patient 9 was catheterised and allowed home with a referral to urology and colo-rectal surgery.

On 12 May 2020 Doctor 1 telephoned Patient 9 for virtual clinic review. Doctor 1 prescribed bicalutamide (50mg) for the suspected prostate cancer, in addition to tamsulosin (0.4mg) for the urinary symptoms. Patient 9 was to be reviewed on 18 May 2020 for removal of the indwelling urethral catheter.

18 May 2020 Patient 9 attended for the trial removal of catheter as arranged. He was unable to pass urine and as a bladder scan showed 500mls of residual urine a

5.0 DESCRIPTION OF INCIDENT/CASE

catheter was reinserted. He was reviewed by Doctor 3 (specialist urology trainee, ST3) who noted that the serum PSA level (9.5ng/ml) was elevated. Doctor 3 noted Patient 9's attendance at ED and that Doctor 2 had felt that during rectal examination that the prostate felt malignant. Doctor 3 requested a MRI scan and wrote a referral letter to Doctor 1 to request an outpatient review by Doctor 1, a red flag referral for general surgery was made and a letter for information was sent to Patient 9's GP.

On 27 May 2020 Patient 9 attended for the MRI prostate which was highly suspicious of prostate cancer demonstrating pelvic mass and a urethro-rectal fistulae.

On 12 June 2020 Patient 9 attended for the CT scan which showed a large rectal mass with small volume groin nodes but no distant metastasis.

Patient 9 was reviewed by general surgeon Doctor 4 (General Surgery Consultant) on 30 June 2020 who performed a biopsy of rectal mass Histology confirmed poorly differentiated (aggressive) prostate adenocarcinoma (Gleason 9/10).

Patient 9's case was discussed at the urology MDM (2 July 2020) who noted a locally advanced prostate cancer. The MDM recommended prompt review to allow to commencement of androgen deprivation therapy (ADT) and for a bone scan to be rearranged.

Doctor 5 (Consultant Urologist) saw Patient 9 (6 July 2020) and found that he continued with rectal bleeding and tenesmus (feeling of incomplete emptying of bowel). Patient 9 had stopped his bicalutamide (May 2020) and was taking no medication for his prostate cancer. A bone scan was requested and Patient 9 was to commence androgen deprivation therapy as an LHRH analogue. Further discussion at MDM was planned for when the bone scan results were available. It was intended that if there was no metastatic disease, he would be referred to oncology.

Patient 9 attended the ED (27 July 2020) with ongoing problems with his urinary catheter which was changed earlier in the day but was still unable to pass urine. His catheter was changed and he was commenced on oral antibiotics. He was discharged home.

Two days later (29 July 2020) Patient 9 returned to the ED with urinary retention after again having his catheter changed in the community. He was noted to have a very low urine output through the catheter despite good hydration. Patient 9 reported passing urine per rectum. Faeces were seen in the catheter bag and tube.

Patient 9 was admitted under the care of Doctor 6 (Consultant Urologist as he was in painful urinary retention but the urology team were unable to pass a urethral catheter. He was taken to theatre for the open insertion of a suprapubic catheter.

A bone scan did not show metastases.

Patient 9 was reviewed by acute oncology during admission who recommended palliative treatment. It was decided that Patient 9 would need a defunctioning faecal stoma and possibly an ileal conduit (stoma bag for the bladder). Patient 9 was reviewed by the Stoma nurse regarding future stoma.

5.0 DESCRIPTION OF INCIDENT/CASE

The surgeons planned surgery for the defunctioning colostomy when Patient 9 felt able: Patient 9 wanted to return home to recuperate before undergoing any further surgeries. He was discharged home on 1 August 2020.

Patient 9's case was discussed at MDM on 6 August 2020. The recommended defunctioning colostomy was confirmed, but the supra pubic catheter was to be maintained. Palliative radiotherapy could be considered after Patient 9's surgery and he was to remain on hormone therapy.

On 13 August 2020 Patient 9 attended the ED complaining of severe abdominal pain and was noted to have a recto-vesical fistula. He was admitted under the general surgical team and underwent an emergency laparotomy and defunctioning sigmoid loop colostomy () on 14 August 2020. He was discharged home with a plan review by the urology team.

On 19 October 2020 Patient 9 was reviewed by Doctor 5 (Consultant Urologist), it was noted that Patient 9 was having intermittent episodes of diarrhoea and penile discomfort. His PSA was noted to have risen to 17.30ng/ml and a referral was made to Clinical Oncology in Belfast City Hospital for further assessment.

6.0 FINDINGS

Causal Factors

The review team deliberated that Doctor 1 suspected prostate cancer but following TURP which showed benign disease (low volume sample 2g from central area of prostate) there was no further investigations to explore this suspicion. Patient 9 was not referred for multidisciplinary meeting (MDM) even on clinical and biochemical grounds for multidisciplinary input.

The possibility of localised prostate cancer could have been considered from the time of presentation; there is no record in the medical notes of a digital rectal examination (DRE) but the PSA was elevated. During the operation further signs might have been elicited. Appropriate biopsies could have been performed. TURP is not an adequate way to biopsy the prostate gland.

The Review Team conclude that the signs of localised prostate cancer were apparent from the time of presentation. A correct course of action would have been to arrange appropriate biopsies and staging scans. Patient 9 should have undergone investigation with a MRI scan of the prostate and pelvis together with a bone scan. A transrectal biopsy, performed at the time of the TURP, would have secured the diagnosis. Arrangement should then have been made to start conventional androgen deprivation therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (ERBT).

Arrangement could then have been made to start conventional hormone therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (ERBT) with a realistic prospect of effective disease control. However,

6.0 FINDINGS

the patient was apparently lost to follow up after his appointment in July 2019.

However, the review team are mindful that when Patient 9 was reviewed at a virtual clinic in May 2020 by Doctor 1, he was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment. The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) guidance (2016) which was signed off by the Southern health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017). This guidance was issued when Doctor 1 was the regional chair of this group and had full knowledge of its contents. The review team note that following discussion with Patient 9, he was unaware that his care given was at variance with regionally recommended best practice. There was no evidence of informed consent to this alternative care pathway.

Only following Patient 9 ED attendance was it recognised that the disease had progressed.

Contributory Factors

Key worker/ Urology Nurse Specialist

The review team met with Patient 9 and his wife as part of the family engagement for the SAI. He described feeling isolated with no guidance on how to seek support or further care when he needed it.

This resulted in numerous attendances to the Emergency Department with blocked catheters and urinary retention which Patient 9 found to be quite distressing. He was advised that the ED was the wrong place for him and that he should seek help from his GP. His experience in ED was further compounded by the covid restrictions.

The review team acknowledge that the ED was not the most appropriate route for him to access. However, Patient 9 did not have access from a Clinical Nurse Specialist or Keyworker despite having complex healthcare needs to support him with his diagnosis. The recommendations from MDT indicate *"all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner".*(ref) This did not happen

6.0 FINDINGS

For clarification

1. Why did AO consider it inappropriate to pursue radical therapy in this case?

2. Why were key investigations missed and inadequate treatment started?

3. What mechanisms were in place to ensure appropriate follow up arrangements?

4. The treatment offered is likely to have accelerated the tumours de-differentiation development of metastases (REF)

MDM

- Post tissue diagnosis of Prostate Cancer at GI MDM

2/07/2020. - Quorate

6/08/2020 - non quorate due to absence of oncology

7.0 CONCLUSIONS

This patient is very likely to have suffered an unnecessary outcome owing to: delays in the investigation of symptoms and signs of locally advanced prostate cancer; the unconventional treatment of prostate cancer; and a failure in appropriate follow up procedures.

Had the appropriate investigations and treatment been instituted in a timely fashion, there is a likelihood that Patient 9 would have enjoyed a good quality of life for an extended period.

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: 18 April 2019

HSCB Unique Case Identifier: Personal Information redacted by the USI

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information redacted

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off: 26 February 2021

Date submitted to HSCB: 1 March 2021

Personal Information

1.0 EXECUTIVE SUMMARY

Patient 3 was referred to urology services on 20 February 2019 in view of a growth on his foreskin. He was referred for urgent circumcision which was performed on 10 April 2019. Histology confirmed squamous cell carcinoma. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease at presentation or subsequently. The MDM – which was a virtual meeting conducted by a single urologist recommendation was that Dr 1 would review Patient 3 and arrange for a CT scan of Patient 3's chest, abdomen, and pelvis to complete staging.

He was referred to the regional penile cancer service in February 2020.

On Personal Information redacted by the USI Patient 3 passed away. The review team wish to extend their sincere sympathies to his wife and family.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally SET recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents.
- To share the report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Family/ Staff involved in the care.

Personal Information

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

The Review of the Northern Ireland Electronic Care Records

Family Engagement

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 3 was referred by his General Practitioner (GP) to the urology service on 20 February 2019. The GP documented that a firm mass was arising from under the left side of the foreskin and that there was pain on attempted retraction. It was noted that although the symptoms had been present for three months or more, Patient 3 had been reluctant to attend the GP. He had seen a locum GP two weeks previously and was prescribed a trial of miconazole and clarithromycin. Patient 3 re-attended as advised as the problem had not resolved.

On 2 April 2019, Patient 3 attended the urology outpatient clinic and was seen by Dr 2 (a specialist urology trainee) who noted the abnormal penile growth under the foreskin which was unable to be retracted. Dr.2 recorded that there were no palpable lesions in the penile shaft or either inguinal (groin) area. Patient 3's case was discussed with Dr.1 (Consultant Urologist) who examined Patient 3 and confirmed these findings. It was noted that Patient 3 needed a red flag (urgent) circumcision and he was asked to come in for operation on 10 April 2019.

The circumcision was carried out as planned by Dr 1 who subsequently advised the GP that in the course of the procedure it was evident that the lesion was confined to the glans (inner) aspect of the foreskin. Dr 1 noted that there was no suspicion of any glans penis involvement and that he anticipated that the circumcision had been curative. The specimen had been submitted for histology and the findings would be discussed at the Multi-Disciplinary Meeting (MDM) of 18 April 2019 with a review appointment to be subsequently arranged.

At the meeting on 18 April 2019, Patient 3's case was discussed. Histology had confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease at presentation or subsequently. The MDM – which was a virtual meeting conducted by a single urologist - recommendation was that Dr 1 would review Patient 3 and arrange for a CT scan of Patient 3's chest, abdomen, and pelvis to complete staging.

Patient 3 was reviewed by Dr 1 on 24 May 2019 and was advised of the histology. Dr 1 found Patient 3 to be keeping very well and to be satisfied with the cosmetic appearance of

Personal Information

5.0 DESCRIPTION OF INCIDENT/CASE

the circumcision. He advised Patient 3 that he had requested the CT appointment and that he would arrange an outpatient review when the report was available.

The CT (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no suspicion or evidence of any metastatic disease.

Dr 1 reviewed Patient 3 with this result on 23 August 2019. On clinical examination, Dr 1 was unable to palpate any left inguinal lymphadenopathy, but he arranged for an ultrasound guided, needle biopsy of the abnormal node to be performed on 6 September 2019 and for further management to be discussed at the urology MDM.

Cytology confirmed metastatic squamous cell carcinoma. At a MDM (12 September 2019) it was agreed that Patient 3 should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Patient 3 to a supra-regional penile cancer multi-disciplinary team. On 20 September 2019, when Dr 1 reviewed Patient 3, he was informed of the plan for him to return on 9 October 2019 for left inguinal lymphadenectomy. This was duly performed by Dr 1. Patient 3 was fit for discharge, four days later on 13 October 2019, but left hospital with an indwelling drain remaining on continuous drainage to prevent the development of a lymphocele.

Patient 3's case was discussed again on 17 October 2019 at the MDM and it was noted that the inguinal node dissection showed 2 of 5 nodes involved with metastatic disease. The MDM plan was that Dr 1 would review Patient 3 in outpatients and arrange a follow-up CT abdomen and pelvis.

Dr 1 reviewed Patient 3 twice weekly after discharge and found that significant volumes of lymphatic fluid drained daily from the left groin. Dr 1 incrementally withdrew the drain until it was removed altogether on 5 November 2019. He arranged to review Patient 3 on 8 November 2019 when he was able to aspirate 250mls of lymphatic fluid from Patient 3's groin; a volume that had accumulated over a period of three days.

Dr 1 arranged for Patient 3 to return to outpatients on Wednesday 13 November 2019 for further review and in the interim asked the GP to issue a prescription for antibiotics to be taken until the review, even though there was no suspicion of any infective complication. Dr 1 also requested a further staging CT scan for January 2020 and listed him for discussion at the Urology MDM with the result.

Patient 3 had a CT chest, abdomen and pelvis carried out on 22 January 2020 which showed a fluid collection and possible lymph node enlargement in the left groin. Furthermore, abnormal lymph node enlargement was seen within the pelvis and in front of the hip joint.

Patient 3 was discussed at the Urology MDM on 6 February 2020 when the new lymph node abnormalities were noted. The MDM recommended that Dr 1 would review Patient 3 in outpatients and refer him to the supra-regional penile cancer group for further management.

Patient 3 was seen by Dr 1 on 14 February 2020. He was referred to the penile cancer MDT

Personal Information

5.0 DESCRIPTION OF INCIDENT/CASE

at the Western Health and Social Care Trust on 17 February 2020.

Patient 3 was admitted to hospital in December 2020 following a fall at home which resulted in a fractured femur. His disease had progressed and he passed away on Personal Information redacted by the USI Personal Information redacted by .

6.0 FINDINGS

- The review team state that the MDM recommendations did not follow NICE guidance for the management of penile cancer [1,2] and there were opportunities at each meeting to intervene and question Patient 3's management.
- The treatment provided to Patient 3 was contrary to the NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 [3]. This Guidance was adopted by the SHSCT Urology MDT and evidenced by them as their protocols for Cancer Peer Review (2017).
- This Guidance was issued following Dr 1's chairmanship of the NICAN Urology Clinical Cancer Reference Group.
- The initial clinical assessment of Patient 3 would have benefited from staging imaging either before or immediately after the original circumcision. The 17 week wait between the MDM recommending a staging CT and informing Patient 3 of the result was unacceptable.
- All cases of penile cancer should be discussed by the supra-network multidisciplinary team (MDT) as soon as the diagnosis is confirmed by biopsy.
- Patient 3 should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.
- The clinical stage G2 pT1 should have led to a consideration of surgical staging with either a bilateral Inguinal Lymph Node Dissection or sentinel node biopsy. This omission reduced the likelihood of Patient 3's 5-year survival from 90% to less than 40%.
- The left Inguinal Lymph Node Dissection yielded only 5 nodes, which might be considered at the lower limit of that expected in experienced hands (raising the risk of under - staging).
- The consent form signed by the surgeon and patient is inadequate as it does not state the rationale for the procedure nor the potential complications.
- The timings between the steps in treatment and management were unduly long and failed to the show the urgency needed to manage penile cancer successfully.

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