Urology Services Inquiry

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Dr Darren Mitchell
Consultant Clinical Oncologist
Belfast Health and Social Care Trust
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

17 April 2023

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.

This Notice is issued to you due to you may have knowledge relevant to the Inquiry's Terms of Reference. 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 detail 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. As you are aware the Trust has already responded to our earlier Section 21 Notice requesting 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 and is not within the custody or power of the Trust and has not been provided to us to date, 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 the Trust's 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

Issued by the Urology Services Inquiry on 17/04/2023. Annotated by the Urology Services Inquiry.

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

Chair's Notice

[No 6 of 2023]

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: Dr Darren Mitchell
Consultant Clinical Oncologist
BHSCT
Headquarters
51 Lisburn Road
Belfast
BT9 7AB

Issued by the Urology Services Inquiry on 17/04/2023. Annotated by the Urology Services Inquiry.

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 15th May 2023.**

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 8th May 2023**.

Issued by the Urology Services Inquiry on 17/04/2023. Annotated by the Urology Services Inquiry.

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 17th April 2023

Signed: Personal Information redacted by the USI

Christine Smith QC

Chair of Urology Services Inquiry

Urology Services Inquiry

SCHEDULE

[No 6 of 2023]

The Inquiry asks that you address the following:

1. You were interviewed by Dr Dermot Hughes on 23 February 2021 in relation to the investigation of a number of SAIs concerning former patients of Mr Aidan O'Brien. The record of that interview states as follows (relevant extracts underlined):

   '*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.*' [**TRU-162276**]

(i) Confirm whether the above is an accurate record of the discussion during interview. To the extent that it is not, please identify any alleged inaccuracies and offer clarification of same.

(ii) Please explicitly state what, to your knowledge or in your view, the '*issues … in relation to*

a. hormone therapy prescribing,
b. prescribing outside guidelines,
c. Bicalutamide'

were.

(iii) How, in your view, did these issues differ from normal medical practice?

(iv) If they differed, what, if any, action was taken by you or others? If none, why not?

(v) How and when did you become first become aware of each of the issues at (ii) above?

(vi) You state that you were aware of issues "*going back a decade*". Please explain what is meant by this, detailing dates (approximate if necessary) and events of which you were aware regarding the issues at (ii) above throughout that period of time.

(vii) Please identify each and every individual with whom you discussed these issues/concerns and provide full details to include dates and means of communication. If it is the case that you did not communicate these issues/concerns to others, please explain why.

(viii) Were you aware of others who had knowledge of these issues or who may have shared similar concerns? Please give full details.

(ix) Please provide further details in respect of the suggestion that the MDM '*challenged*' Mr O'Brien on his use of Bicalutamide in 2015. In particular, please set out:

(a) the nature and form of the said challenge,
(b) who was present or otherwise involved in same, and
(c) Mr O'Brien's response.

Please provide the Inquiry with copies of any relevant contemporaneous documentation (record, note, email, minute or otherwise) relating to this.

2. In his oral evidence to the Inquiry on 29 November 2022 (Day 12) at [**TRA-01074-75**], in exchange with Mr Wolfe KC, Dr Hughes stated as follows:

> ***Dr Hughes:*** *'Dr Mitchell explained it was Regional Hormone Therapy guidelines and it was drafted to address concerns around Bicalutamide prescribing, and it was signed off by Mr O'Brien when Mr O'Brien was the Chair of the Regional Clinical Guidance group.*
>
> ***Mr Wolfe KC:*** *Was the concern about Bicalutamide prescribing that was the trigger for this document?*
>
> ***Dr Hughes:*** *Yes.*
>
> ***Mr Wolfe KC:*** *Were you given to understand that was a general issue, or was he saying it was a Mr O'Brien issue that caused this to be drafted?*
>
> ***Dr Hughes:*** *He was implying it was a Mr O'Brien issue. Professor O'Sullivan had concerns for 17 years. In the document I have shared, Dr Mitchell had concerns for ten years.*
>
> ***Mr Wolfe KC:*** *Yes. Are you clear about that, that Dr Mitchell formulated this document in response to –*
>
> ***Dr Hughes:*** *Yes.*
>
> ***Mr Wolfe KC:*** *-- issues of Bicalutamide prescribing, specifically directed from Mr O'Brien?*
>
> ***Dr Hughes:*** *Yes. That's covered in the minutes of our meeting.*

The relevant extract of the record of your interview, as referred to by Dr Hughes in his evidence, states as follows (relevant extract underlined):

> *'Dr Mitchell wrote the regional guidelines for the use of hormone therapy. <u>This was done in the hope this would address the issues around off-licence</u>*

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.' [**TRU-162276**]

(i) Please confirm whether the Regional Hormone Therapy guidelines referred to were developed in direct response to concerns about Mr O'Brien's prescribing practices in respect of Bicalutamide.

(ii) To the extent that the answer to (i) above is 'yes', please explain why this approach was taken, explaining how, if at all, it was intended that the guidelines should address the issues/concerns around off-licence prescribing of Bicalutamide.

(iii) In your view, ought these guidelines have been subject to audit within individual Trusts? Please explain your answer.

(iv) Please provide any further relevant comments you may have in relation to the development of these guidelines and the process leading to their approval.

3. A further extract from the record of your interview with Dr Hughes of 23 February 2021, states the following (at **TRU-162276**):

'*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 AOB was chair of the southern urology MDM at that stage*.' [TRU-162276]

(i) Please provide this patient's HCN.

(ii) Please explain the significance of this case, giving further details as to the particular concern raised by Mr Hagan and Ms Traub.

(iii) How was this case '*flagged back to SHSCT*"? Please identify the mechanism by which this was raised with the Southern Trust and identify any relevant individual(s).

(iv) Did you seek to discuss this case with Mr O'Brien at any stage? To the extent that the answer is 'yes', please give full details. If no, why not?

4. A further extract of the record of the interview with Dr Hughes of 23 February 2021, further states the following (at **TRU-162277**):

'*Dr Mitchell advised he emailed the consultant in 2016/17 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*.'

(i) Provide the Inquiry with a copy of this email and any response(s) received.

(ii) Did you take any further action in respect of this apparent concern? To the extent that the answer is 'yes', provide full details. If your answer is no, why not?

(iii) The Inquiry notes the statement 'The patients were misled'. Please confirm whether this is your belief and, if so, how and why you consider that patients were misled? If not your belief, why did you say it to Dr Hughes?

5. The record of Dr Hughes' interview with Dr O'Sullivan on 4 January 2021 (at

TRU-162262) states as follows:

'*JOS said he was aware that his colleague DM (as MDT Chair) had raised our concerns about AOB's bicalutamide prescribing with the then CD for oncology SMcA, probably in 2011*.'

(i) Please give details of any discussions you had with Dr O'Sullivan regarding shared concerns.

(ii) How and when did you raise these concerns with the CD Dr McAleer? Please provide full details, together with copies of any relevant contemporaneous documentation.

(iii) Did you discuss or raise these concerns with anyone else? If so, please provide all details, including names, dates and contents of all discussions.

(iv) What was the outcome of your engagement with Dr McAleer?

(v) Was this the only occasion on which you raised concerns with Dr McAleer? To the extent that the answer is 'no', please provide further details of any other occasions on which concerns were raised with the Clinical Director.

6. Please consider the email of 20 November 2014 at AOB-71990.

(i) Please explain the context and purpose of this email.

(ii) Please provide a copy of any response received.

(iii) To the extent that this email may be said to demonstrate concern, please indicate whether, at any stage, these concerns were discussed with others or otherwise escalated.

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7. In his Section 21 Statement to the Inquiry, at [**WIT-84157**] in reference to you and Dr O'Sullivan, Dr Hughes states:

> *'They had also written to him [Mr O'Brien] directly about his practice but did not escalate the issue to the SHSCT – this is something both individuals regretted and reflected upon*.'

(i) To the best of your recollection, please provide all details of every occasion on which you wrote directly to Mr O'Brien about his practice and, where possible, provide copies of this correspondence together with any response received.

(ii) Please explain why the issue was never escalated to SHSCT, providing details of any real or perceived obstacles to such escalation?

(iii) Please provide any further comments/ reflections you may have on the failure to escalate, setting out what might perhaps have been done differently.

8. Please indicate whether, at any stage, you had concerns about or knowledge of issues around the use of Clinical Nurse Specialists. To the extent that your answer is affirmative, please provide further details.

9. The Inquiry is aware of significant issues around the quoracy of SHSCT Urology MDMs, particularly in terms of Oncology attendance. On this issue, the record of the interview of 23 February 2021, at **TRU-162276-77**, indicates that you:

> '*described issues trying to support the MDT in SHSCT it was a busy practice and they had difficult [sic] in recruiting to cover this role*.'

Please further explain the difficulties from your perspective and offer any further

comments or observations which may assist the Inquiry in understanding this issue.

10. To the extent that you have any knowledge of potential governance problems regarding the referral and screening of patients to Regional Urology, Belfast City Hospital, please provide details.

11. Please provide any further details which you consider may be relevant to the Inquiry Terms of Reference.

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.

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UROLOGY SERVICES INQUIRY

USI Ref: Notice …6… of 2023

Date of Notice: 17 April 2023

Witness Statement of: Dr Darren Mitchell

I, Darren Mitchell, will say as follows:-

1. You were interviewed by Dr Dermot Hughes on 23 February 2021 in relation to the investigation of a number of SAIs concerning former patients of Mr Aidan O'Brien. The record of that interview states as follows (relevant extracts underlined):

'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.' [TRU-162276]

(i) Confirm whether the above is an accurate record of the discussion during interview. To the extent that it is not, please identify any alleged inaccuracies and offer clarification of same.

1(i) I accept that this is an accurate record of the discussion during the interview. I would note that I was appointed to regional MDM chair in August 2014.

(ii) Please explicitly state what, to your knowledge or in your view, the 'issues … in relation to

a. hormone therapy prescribing,

b. prescribing outside guidelines,

c. Bicalutamide were.

1(ii) a *hormone therapy prescribing*

I had been referred a few prostate cancer patients by Mr O'Brien who had been commenced on an unlicensed dose of Bicalutamide hormone therapy prior to referral to oncology.

1(ii) b *prescribing outside guidelines*

The licenced doses for Bicalutamide are either 150mg once daily as a monotherapy, or 50mg once daily when used in combination with hormone therapy injections known as luteinizing hormone releasing hormone agonists. There are no licenced indications that I am aware of for Bicalutamide 50mg once daily as a monotherapy. As such I viewed the used of the Bicalutamide 50mg once daily as a monotherapy as being outside the licenced indications.

Mr O'Brien in his position as chair of the NICAN Urology group in 2015 had asked for guidelines to be written for each urology disease sub-site. I wrote the androgen deprivation therapy guidelines in 2015 to accurately define our regional use of hormone therapy at that stage in line with the licenced indications. I hoped that this would standardise practise with the appropriate of dose Bicalutamide being used within our regional guidance document. Following discussion at the NICAN urology group meeting on a number of occasions in 2015 a final version was sent to Mr O'Brien on 10/10/2016 (***AOB3***)

1(ii) c *Bicalutamide*

As outlined above

(iii) How, in your view, did these issues differ from normal medical practice?

1(iii) Normal practise would have been to prescribe a dose of Bicalutamide that was within the licenced indications or to refer to oncology for discussion and allow the oncology team to discuss treatment options including the use of hormone therapies such as Bicalutamide.

(iv) If they differed, what, if any, action was taken by you or others? If none, why not?

1(iv) Firstly - I emailed Mr O'Brien in November 2014 (***AOB1***) highlighting a case that had been passed to me as the new chair of the regional urology MDM. The patient had been commenced on Bicalutamide 50mg once daily as a monotherapy. In that email I outlined the standard of care that we as oncologists would have offered in terms of hormone therapy. I advised that I was writing the regional guidelines to standardise the approach to hormone therapy prescription across the region, and pasted a link to guidance on off label prescription, good practise recommendations and our responsibilities within that. I offered further discussion on this.

Secondly I wrote the regional guidelines on androgen deprivation therapy and passed these through to Mr O'Brien as the NICAN urology chair and the NICAN urology group for sign off. These guidelines reflected the licenced indications and doses of hormone therapy.

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Thirdly I spoke informally to Mr Haynes when he attended the regional urology multidisciplinary meeting in early 2019 and passed a health and care number through for a case that had been referred to oncology and reviewed by Professor Suneil Jain in February 2019 (***AOB4***). This case had been diagnosed in 2011 and had been on Bicalutamide 50mg once daily monotherapy as part of his management prior to referral. I advised that I didn't think this was an isolated case. The HCN of a second case identified in August 2020 following a new patient appointment with Professor Jain was also passed through to Mr Haynes. (***AOB12***)

I contributed to a look back exercise of subsequent cases identified by Mr Haynes.

(v) How and when did you become first become aware of each of the issues at (ii) above?

1 (v) The email sent to Mr O'Brien in 2014 (***AOB1***) is the first document that I am aware of which documents the concern over Bicalutamide prescription off licence. I believe I may have been referred a few cases in the years prior to this date who had been prescribed Bicalutamide 50mg once daily monotherapy regimen, but I would not be able to recall patient names or full details at this stage.

(vi) You state that you were aware of issues "going back a decade". Please explain what is meant by this, detailing dates (approximate if necessary) and events of which you were aware regarding the issues at (ii) above throughout that period of time.

1 (vi) As stated above in 1(v) the email sent in November 2014 was the first document that I can identify regarding the off-license prescription of Bicalutamide 50mg monotherapy. I have been a Consultant Oncologist since June 2008 and believe there may have been a few cases referred to me who had also been on the Bicalutamide 50mg monotherapy regimen between 2008 and 2014.

(vii) Please identify each and every individual with whom you discussed these issues/concerns and provide full details to include dates and means of communication. If it is the case that you did not communicate these issues/concerns to others, please explain why.

1(vii) I discussed the case identified in 2014 with Professor Suneil Jain and emailed Mr O'Brien directly. A copy of this email was sent to Prof. O'Sullivan, Prof. Jain and Dr Lucy Jellet (***AOB2***) who may have been in a non-substantive role in Oncology supporting the southern trust.

I spoke to Mr Haynes informally as he attended the regional urology MDM in 2019 and subsequently emailed him about the off licence prescribing of Bicalutamide 50mg monotherapy in 2019 (***AOB4***) and 2020 (***AOB12***). I also contributed to the look back exercise with Mr Haynes and I believe the senior management team from the southern trust were involved at that stage. Listed on the Terms of reference/Agenda for look back exercise 1/10/20 were Dr Maria O'Kane, Dr Damian Gormley, Mr Mark Haynes, Mr Ronan Carroll, Mrs Martina Corrigan and Mrs Patricia Kingsnorth. (***AOB5, AOB6***)

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I spoke to Mr McAleer I believe in 2019 at the point of initial discussion with Mr Haynes and then again in 2020 at the point of being asked to contribute to the look back exercise.

(viii) Were you aware of others who had knowledge of these issues or who may have shared similar concerns? Please give full details.

1(viii) I believe the oncologists providing support as part of their job plan to the Craigavon urology service would have routinely been referred cases from Mr O'Brien and may have come across this off license prescribing. This would include Dr Jonathan McAleese, Professor David Stewart and Dr Fionnuala Houghton. I am not aware of any discussions they had if they had concerns.

(ix) Please provide further details in respect of the suggestion that the MDM 'challenged' Mr O'Brien on his use of Bicalutamide in 2015. In particular, please set out:

(a) the nature and form of the said challenge,

(b) who was present or otherwise involved in same, and

(c) Mr O'Brien's response.

Please provide the Inquiry with copies of any relevant contemporaneous documentation (record, note, email, minute or otherwise) relating to this.

1(ix) I believe this to relate to the discussions at the NICAN urology group meeting on the androgen deprivation guidelines that had been circulated to the group. I was chair of the regional urology MDM at that stage and attended the NICAN meeting in that role. I believe I raised the point at the NICAN urology meeting on 3/1/2015 that the androgen deprivation guidelines were to standardise the prescription of hormone therapy and stop the use of off licence Bicalutamide 50mg monotherapy, however the minutes of the NICAN meetings have not recorded this. (***AOB7, AOB8, AOB9***)

I remember there being a prolonged pause following my point, before Mr O'Brien "extended thanks to Dr Darren Mitchell and Dr Suneil Jain for their work in taking this forward"

2 (i) Please confirm whether the Regional Hormone Therapy guidelines referred to were developed in direct response to concerns about Mr O'Brien's prescribing practices in respect of Bicalutamide.

2 (i) The guidelines were in large part written to address concerns over off licence prescription of Bicalutamide 50mg monotherapy by Mr O'Brien.

(ii) To the extent that the answer to (i) above is 'yes', please explain why this approach was taken, explaining how, if at all, it was intended that the guidelines should address the issues/concerns around off-licence prescribing of Bicalutamide.

2 (ii) This approach was taken in the knowledge that Mr O'Brien would be required to formally review and accept the guidelines in his role as NICAN Chair. I was aware that the guidelines would be discussed at a subsequent NICAN Urology meeting and that would both allow me to formally raise the point as outlined 1(ix) and give Mr O'Brien an opportunity to discuss this off licence practise. I hope that the guidelines and the verbal point as 1 (xi) above would be a prompt for Mr O'Brien to address the off-licence prescription of Bicalutamide 50mg monotherapy.

2 (iii) In your view, ought these guidelines have been subject to audit within individual Trusts? Please explain your answer.

2 (iii) These guidelines could have been audited within each trust. If my belief that Mr O'Brien was the only person in the region using Bicalutamide 50mg monotherapy is correct then it would in essence have been an audit of his hormone therapy prescriptions in the southern trust. The guidelines were written to encourage good practice and provide a point of reference if there were future cases identified with this off-licence prescribing.

2 (iv) Please provide any further relevant comments you may have in relation to the development of these guidelines and the process leading to their approval.

2 (iv) I am not aware that the guidelines were ever formally approved by Mr O'Brien.

3 (i) Please provide this patient's HCN.

3. (i) Patient 127

3 (ii) Please explain the significance of this case, giving further details as to the particular concern raised by Mr Hagan and Ms Traub.

3 (ii) Mr Hagan raised concern to Ms Davinia Lee who I believe was the cancer services manager at the time about avoidable delays in the management of a muscle invasive bladder case referred to him from Craigavon. His concern was around multiple discussions at the southern trust MDM prior to the patient being referred for discussion at the regional meeting and he was concerned that the delays would adversely affect the outcome in this case. Mr Hagans email also identified the use of isotope bone scans as being outside the guidance for staging in muscle invasive bladder cancer. (***AOB11***)

3 (iii) How was this case 'flagged back to SHSCT'? Please identify the mechanism by which this was raised with the Southern Trust and identify any relevant individual(s).

3 (iii) This case was flagged back to Mr O'Brien by email on 26th of August 2016 (***AOB10***) suggesting case note review and consideration of shared learning either locally or regionally. The urology MDM co-ordinator Shauna McVeigh at the southern trust was copied to that email.

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3 (iv) Did you seek to discuss this case with Mr O'Brien at any stage? To the extent that the answer is 'yes', please give full details. If no, why not?

3 (iv) Yes – as noted above Mr O'Brien was emailed about the case.

4. A further extract of the record of the interview with Dr Hughes of 23 February 2021, further states the following (at TRU-162277):

'Dr Mitchell advised he emailed the consultant in 2016/17 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.'

4 (i) Provide the Inquiry with a copy of this email and any response(s) received.

4 (i) The email referenced in the interview with Dr Hughes was actually sent in 2014 and has been discussed in section 1. I did not receive any response. (***AOB1***)

4 (ii) Did you take any further action in respect of this apparent concern? To the extent that the answer is 'yes', provide full details. If your answer is no, why not?

4(ii) As per my response in section 1, I wrote the androgen deprivation guidelines and presented these to the NICAN urology group in 2015. When I was made aware of the cases seen by Prof Jain in 2019 and 2020 I spoke to and emailed Mr Haynes. (***AOB4, AOB12***)

4 (iii) The Inquiry notes the statement 'The patients were misled'. Please confirm whether this is your belief and, if so, how and why you consider that patients were misled? If not your belief, why did you say it to Dr Hughes?

4 (iii) I do believe patients were being misled. The hyperlink included in my 2014 email to Mr O'Brien leads to guidance on off-licence prescribing. This outlines our responsibilities as prescribers to use medication within licence and if a decision is made to use a medication outside its licenced indication or dose then good practice would be to make the patient aware of the reason for this decision in their case. In the cases identified in my statement I could see no evidence that the patients had been advised about the off-licence use of Bicalutamide 50mg monotherapy.

The delayed referral to oncology in the cases in my statement meant that these men waited longer than other men in a similar situation to have an oncology opinion.

5 (i) Please give details of any discussions you had with Dr O'Sullivan regarding shared concerns.

5 (i) The discussions with Prof O'Sullivan would have been as part of the joint Thursday morning outpatient case note review. I believe there would have been a number of cases discussed at that meeting with off licence prescription or perceived delayed referral.

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5 (ii) How and when did you raise these concerns with the CD Dr McAleer? Please provide full details, together with copies of any relevant contemporaneous documentation.

5 (ii) I believe my first discussion with Dr McAleer occurred at the time of the informal discussions with Mr Haynes in 2019 outlined above. I advised Dr McAleer that I was contributing to a process of investigation of Mr O'Brien's practice and that I anticipated that as it evolved that it was likely I would have to provide evidence to any subsequent investigation within the southern trust. When I was invited to a case review meeting with the southern trust on 1/10/2020 I also advised Dr McAleer of my role in this at that time. I have no documentation from these discussions.

5 (iii) Did you discuss or raise these concerns with anyone else? If so, please provide all details, including names, dates and contents of all discussions.

5 (iii) At the time of my discussions in 2020 with Dr McAleer there were a number of people aware, including those from the southern trust listed on the meeting for 1/10/2020 and I had also advised Prof O'Sullivan and Prof Jain that I was taking part in a formal investigation process.

5 (iv) What was the outcome of your engagement with Dr McAleer?

5 (iv) I have no documentation from these discussions but remember Dr McAleer agreeing that it was appropriate for me to contribute to this process.

5 (v) Was this the only occasion on which you raised concerns with Dr McAleer? To the extent that the answer is 'no', please provide further details of any other occasions on which concerns were raised with the Clinical Director.

5 (v) I believe I spoke to Dr McAleer twice as outlined in 5 (ii) above

6. Please consider the email of 20 November 2014 at AOB-71990.

(i) Please explain the context and purpose of this email.

6 (i) The email referenced (***AOB-71990***) is the same email discussed in section 1

The purpose was to outline standard of care for this case and to make him aware of his responsibilities as a prescriber when using off licence medication.

6 (ii) Please provide a copy of any response received.

6 (ii) I did not receive a response.

6 (iii) To the extent that this email may be said to demonstrate concern, please indicate whether, at any stage, these concerns were discussed with others or otherwise escalated.

Urology Services Inquiry

6 (iii) A copy of the email sent to Mr O'Brien in 2014 (***AOB2***) was copied to Prof O'Sullivan, Prof Jain as well as Dr Lucy Jellet, who may have been covering the Craigavon urology oncology clinic in a temporary capacity.

7 (i) To the best of your recollection, please provide all details of every occasion on which you wrote directly to Mr O'Brien about his practice and, where possible, provide copies of this correspondence together with any response received.

7 (i) The email sent in November 2014 (***AOB1***) regarding off licence prescription and the email sent in August 2016 about the muscle invasive bladder cancer case (***AOB10***) are I believe the only 2 times that I wrote to Mr O'Brien about his practice. I do not believe I received a response from either email.

7 (ii) Please explain why the issue was never escalated to SHSCT, providing details of any real or perceived obstacles to such escalation?

7 (ii) This was escalated to Mr Haynes in 2020.

7 (iii) Please provide any further comments/ reflections you may have on the failure to escalate, setting out what might perhaps have been done differently.

7(iii) On reflection my hope that Mr O'Brien had taken note of the email sent in 2014 and ADT guideline discussion at the NICAN was misplaced. If the ADT guidelines had been signed off then some form of audit may have identified ongoing off licence prescription.

8. Please indicate whether, at any stage, you had concerns about or knowledge of issues around the use of Clinical Nurse Specialists. To the extent that your answer is affirmative, please provide further details.

8 I had no knowledge of any issues around the use of clinical nurse specialists.

9 The Inquiry is aware of significant issues around the quoracy of SHSCT Urology MDMs, particularly in terms of Oncology attendance. On this issue, the record of the interview of 23 February 2021, at TRU-162276-77, indicates that you:

'described issues trying to support the MDT in SHSCT it was a busy practice and they had difficult [sic] in recruiting to cover this role.'

Please further explain the difficulties from your perspective and offer any further comments or observations which may assist the Inquiry in understanding this issue.

9 The oncology post formally supporting the urology service in the southern trust had been occupied by non-substantive consultants for a period of time. As part of the job plan for those posts it was not always possible for an oncologist to be present at the southern trust MDM. I believe the substantive post was advertised on a number of occasions. I believe this would have been raised by SHSCT with the clinical director in clinical oncology.

Urology Services Inquiry

10 To the extent that you have any knowledge of potential governance problems regarding the referral and screening of patients to Regional Urology, Belfast City Hospital, please provide details.

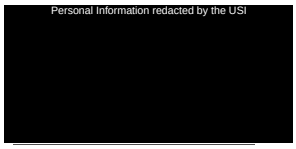
10 As an Oncologist I am not aware of any potential governance problems regarding the referral and screening of patients to regional urology, Belfast.

11. Please provide any further details which you consider may be relevant to the Inquiry Terms of Reference.

11 I have no further details

Statement of Truth

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

Signed: 

Date: 18/05/2023

S21 102 of 2022

Witness statement of: Dr Darren Mitchell

Table of Attachments

Attachment	Document Name
1	AOB1 20 Nov 2014 Email from Dr Mitchell to Dr Aidan O'Brien
2	AOB2 20 Nov 2014 Email from Dr Mitchell to Lucy Jellet, Joe O'Sullivan and Suniel Jain
3	AOB3 10 Oct 2016 Email from Dr Mitchell to Dr Aidan O'Brien re NI ADT Protocol
4	AOB4 28 Mar 2019 Email from Dr Mitchell to Mark Haynes
5	AOB5 30 Sep 2020 Email from Mark Haynes to Dr Mitchell
6	AOB6 01 Oct 2020 Minute of Meeting
7	AOB7 18 Sep 2015 Urology Network Site Specific Group Meeting record of Discussion & Agreed Actions
8	AOB8 30 Jan 2015 Urology Network Site Specific Group Meeting Record of Discussion & Agreed Actions
9	AOB9 17 Apr 2015 Urology Network Site Specific group Meeting Record of Discussion & Agreed Actions

10	AOB10 28 Aug 2016 Email from Dr Mitchell to Dr Aidan O'Brien
11	AOB11 18 Aug 2016 Email from Chris Hagan to Dr Mitchell, Gillian Traub, Davinia Lee, Jena Crawford re Query
12	AOB12 07 Aug 2020 email from Mark Haynes to Dr Mitchel & Suneil Jain

WIT-96677

AOB1

MailMeter

Message ID - 6f3e4e1b99884902bd4a2018085386f9 - 146322497

Archived on 20/11/2014 13:52:47. Printed on 18/05/2023 05:19:43.

Time Sent	20/11/2014 13:34:43
Time Received	20/11/2014 13:34:43
Time Archived	20/11/2014 13:52:47
From:	mitchell, darren < Personal Information redacted by the USI >
To	aidan o'brien Personal Information redacted by the USI
Subject:	Patient 126

Aidan –could I ask you to have a look at this case which was passed to me as the regional MDT chair.

Looks like young man with high grade organ confined disease from 2012. From my prospective he w

I'm not aware of any of his co-morbidities or performance status.

As hormonal therapy in this case we would use LHRHa or occasionally Bicalutamide 150mg OD monc

I'm told he has only just been referred for radiotherapy at 2 years after initial MDT presentation.

I'm not aware of supportive research for 24months of neo-adjuvant hormones prior to EBRT but the 6 months of LHRHa prior to EBRT is also recommended in the STAMPEDE protocol for men with high

I'm also told that he was on Bicalutamide 50mg OD for the first year of his management.

The NICAN hormone protocol (in process) would be useful in standardising our therapy across the re

The MRHA site provides information on 'off-label' prescribing and our responsibilities within that.

http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990

Happy to discuss this further.

DMM

WIT-96678
AOB2

MailMeter
Message ID - 292349e8743d4571b4a2c28b2d725874 - 146321847
Archived on 20/11/2014 13:47:53. Printed on 18/05/2023 05:20:41.

Time Sent	20/11/2014 13:38:19
Time Received	20/11/2014 13:38:19
Time Archived	20/11/2014 13:47:53
From:	mitchell, darren < Personal Information redacted by the USI >
To	jellett, lucy Personal Information redacted by the USI >
CC	'joe.osullivan@ Personal Information redacted by the USI suneil jain Personal Information redacted by the USI
Subject:	FW: Patient 126

Lucy (Joe & Suneil) – I've emailed Aidan to open discussion on this case.

Copy below for your information only.

DMM

Dr DM Mitchell FRCR
Consultant in Clinical Oncology
Northern Ireland Cancer Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB

☎ - Personal Information redacted by the USI
✉ - Personal Information redacted by the USI
Secretary - Personal Information redacted by the USI

From: Mitchell, Darren
Sent: 20 November 2014 13:35
To: 'O'Brien, Aidan'
Subject: Patient 126

Aidan –could I ask you to have a look at this case which was passed to me as the regional MDT chair.

Looks like young man with high grade organ confined disease from 2012. From my prospective he w

I'm not aware of any of his co-morbidities or performance status.

As hormonal therapy in this case we would use LHRHa or occasionally Bicalutamide 150mg OD monc

I'm told he has only just been referred for radiotherapy at 2 years after initial MDT presentation.

Mitchell, Darren

From: Mitchell, Darren
Sent: 10 October 2016 07:11
To: O'Brien, Aidan [redacted]
Subject: NI ADT protocol final LHRHantagonist edit
Attachments: ni adt protocol final lhrhantagonist edit.doc.htm

Enc – should be complete – the page following the Antagonists is a flow chart.

DMM

Mitchell, Darren

From: Mitchell, Darren
Sent: 28 March 2019 13:28
To: Haynes, Mark
Subject: Personal Information redacted by the USI

Mark – this is one the cases that we chatted about with BC 50 then escalated to BC 150 and we would probably like to have been involved in the decision making process a bit earlier.
Suneil's history Feb 2019 on ECR gives the full detail. I don't think this is an isolated occurrence.

DMM

Mitchell, Darren

From: Haynes, Mark [redacted]
Sent: 30 September 2020 15:08
To: Mitchell, Darren
Subject: Meeting tomorrow
Attachments: Meeting 011020.docx

Hi Darren

Am trying to get others to confirm for 9am tomorrow, and will get meeting link to you when they have. I have attached the agenda / TOR. Are you OK with it?

Mark

Southern Health & Social Care Trust IT Department [redacted]

Meeting 1/10/20

Purpose;

To review summary of patient history where initial review of electronic care records has raised possible concerns regarding patient pathway in order to agree next step for each case.

Membership;

Maria O'Kane (Medical Director)

Damian Gormley (Deputy Medical Director)

Darren Mitchell (Consultant Clinical Oncologist and Urology Regional MDM Chair)

Mark Haynes (Consultant Urologist / Associate Medical Director)

Ronan Carroll (Assistant Director Surgery and Elective Care)

Martina Corrigan (Head of Service, Urology and ENT)

Patricia Kingsnorth (Acting Acute Clinical Governance Coordinator)

Agenda;

11 case records to review with Dr Mitchell present.

23 additional cases to be reviewed (Dr Mitchell not required).

Summary of each case to be screen shared at time of meeting.

For each case agree;

Has there been an avoidable delay in their cancer pathway?

Has this delay impacted or risked impact on outcome of treatment?

Is further independent review of the case required either by SAI or external opinion?

Urology Network Site Specific Group Meeting
Friday 18th September 2015
2.30pm-4.30pm, Conference room 4, Linenhall Street, Belfast

Record of Discussion & Agreed Actions

In Attendance **Videoconference**	Aidan O'Brien (SHSCT), Darren Mitchell (BHSCT), Edel Aughey (NICaN), Ali Thwaini (BHSCT), Hugh O'Kane (BHSCT), Ruth Johnston (BHSCT), Colin Mulholland (WHSCT), Wilma Boyd Carson (SET), Robin Gray (PPI Rep), Mark Haines (SHSCT), Gareth McClean (SHSCT), Kate O'Neill (SHSCT)
Apologies	Fiona Reddick (SHSCT), Davinia Lee(BHSCT), Elizabeth England (WHSCT), Teresa Majury (PPI Rep), Harry Lockhart (PPI Rep), Samantha Thompson (BHSCT), Mary Haughey (NICaN), Mary Jo Thompson (PHA/NICaN), Chris Hagan (BHSCT), Kerry Chambers (WHSCT), Declan O'Rourke (BHSCT), Thamra Ayton (BHSCT), Suneil Jain (BHSCT), Pat Sheils (BHSCT), Jacque Warwick (BHSCT)

	Item	Responsibility / Date
	Welcome & Introductions Aidan O'Brien welcomed everyone to the meeting and apologies were recorded as above.	
1.	**Minutes of last meeting** **The minutes of the last meeting were agreed.** **Matters arising:** **i)** Meeting with DLA Advisory Board: Mr O'Brien advised that the meeting with ATOS Director regard the lasting impacts of cancer with a particular focus on fatigue has not yet taken place but will be arranged and he will update the group at the next meeting. **Action point 1:** Mr O'Brien to arrange a meeting with ATOS and to invite key people to attend. ii) Regional Urology meeting: Mr O'Brien provided update. There have been a number of regional meetings but the local meetings have not taken place as yet. Mr O'Brien would be keen that the NICaN network group would take on one of the sub group roles particularly with regard reviewing and updating clinical management guidelines for suitability of	

	these being implemented in Northern Ireland. Mr O'Brien is keen that the network group agrees local guidelines which can be reported back to the HSCB and the regional Urology group by the end of the year. Mr Ali Thwaini advised that local guidelines need to be manageable for NI but should also be in line with UK / National guidelines. Mr Mark Haines queried whether the role of the group is to offer advice to HSCB regard what is clinically appropriate or if HSCB advise the network group what should be done clinically?	
5.	**Audits:** It was agreed to move agenda item 5 up and Mr O'Brien invited Dr Anna Gavin, NI Cancer Registry, to present an update on the UK wide patient reported outcomes programme for prostate cancer patients. Dr Gavin advised that the programme aims to find out what effect prostate cancer has had on men's physical, emotional and social wellbeing, as well as exploring the impact on their families and will consist of a number of work-streams including dissemination of a UK wide survey, organisational performance and benchmarking, health economics & patient and public involvement. In Northern Ireland, approximately 4,000 men will be surveyed who have been diagnosed with prostate cancer between 18-24 months previously and registered by NI Cancer Registry between 1st July 2012 and 30th June 2014. The survey will cover urinary and bowel functioning, sexual functioning, psychological and social well-being, physical, social and financial concerns. To date, the survey has been developed and ethical approval will be sought after the methodology has been finalised for NI. The expected outcomes include population based patient reported outcomes from UK which will help to identify gaps, organisational performance measured with feedback, toolkit for comparators and to identify factors associated with poor outcomes. Information about the programme was circulated to all members. Mr O'Brien thanked Dr Gavin and queried if the local Research & Development offices should be contacted regarding the research as well as senior personnel within the trusts. There was also some discussion regard how best to correspond with patients living in the different trust areas and there was a suggestion that a cover letter could be issued through NICaN with HSC / Trust logos and the MDT Lead signatures. There was also discussion on the need to ensure death checks are completed through BSO before any correspondence is issued to patients. **Action point 1**: Ms Edel Aughey to liaise with Lisa McWilliams and Mary Jo Thompson regard using a headed cover letter from NICaN for dissemination of the patient surveys.	**Ms Edel Aughey**
2.	**Peer review: feedback** There was discussion around the issues outlined from peer review. The general consensus was that members should work on taking recommendations forward within each of the trust teams including response to immediate / serious concerns raised. In relation to peer review feedback there was a query if a meeting is required to discuss and decide what is feasible in NI and it was agreed that this may require further discussion with the commissioners.	

3.	**Urology guidelines & pathways** **Regional hormone therapy guideline & pathway:** Following the last network meeting, the guideline and pathway were circulated to all network members for final comment. Dr Darren Mitchell advised that he had received no further comments. Members agreed to ratify the regional guideline and pathway. **Clinical Management Guidelines:** Reference was made to the updated NICE referral guidance which was issued in June 2015 and the need to ensure that the NICaN regional guidance is in line with the updated NICE guidance. There was discussion on: • the need to look at the pathway for muscle invasive bladder cancer in order to reduce delays for e.g. if patient is offered neo-adjuvant chemotherapy • delivering a partial nephrectomy surgery service **Action point 2**: Mr Darren Mitchell agreed to provide appropriate wording on the early use of Docetaxel concomitant with androgen deprivation for patients with prostate cancer. **Action point 3**: All members to review the issues highlighted by Mr O'Brien in relation to the clinical management guidelines and feedback any comments in relation to these.	**Mr Darren Mitchell** **All members**
4.	**Clinical Trials** Information on open urological trials from the NI Clinical Centre was circulated to all members for information.	
6.	**TCFU Prostate sub group** To be deferred to the next meeting.	
7.	**Updates** **Cancer Service Framework:** The urology site specific section for the new Cancer Services Framework was circulated to all members for review and comment back by 4th September 2015.	

	Restructuring to Clinical Reference Groups: Dr Martin Eatock will be writing formally to all the Clinical Leads regard restructuring the existing network groups to Clinical Reference groups. It is proposed that the groups will have a stronger link to HSCB as they will take on the role as expert advisory groups to commissioners. Formal correspondence will be issued shortly. **Cancer Patient Experience Survey:** The findings from the regional report will be formally launched on Friday 9th October. **PCUK BHSCT Physiotherapy programme (written update from Ms Thamra Ayton)** There have been 75 referrals to date; the majority of those are pre/post-op surgical patients. 30 men have completed their physiotherapy intervention. Evaluations on whole are good with most men stating they felt it had been beneficial to them to have someone seeing them regularly and guide them in their recovery. Particular emphasis on being examined pre-op in order to be reassured or retaught how to do their pelvic floor muscles correctly. The outcomes are currently being collated. 6 - 8 of these men have signed up for the new Pilates exercise programme in October (pilot being run in conjunction with MacMillan by Will Moore-exercise therapist) to work on combatting fatigue and improving core strength and exercise tolerance. Staff will also be presenting at the Prostate Cancer HWBE in November regard issue of continence. A reminder to all network members that we are happy to accept referrals for any men currently living with Prostate Cancer and having problems with bladder/bowel/pelvic pain.	
8.	**Emerging Issues** Mr Darren Mitchell raised the issue of oncology radiology cover at Belfast City Hospital which is under significant pressure. There is a real risk that oncology imaging will be out sourced and this would have a real impact on the MDT, overall service quality and would be a significant risk to the service. Davinia Lee has advised that the issue has been escalated to Jennifer Welsh. **Date of next meeting** Thursday 26th November 2015, 2.30pm-4.30pm, venue to be confirmed.	

Urology Network Site Specific Group Meeting
Friday 30th January 2015
2.30pm-4.30pm, Conference room 2, Linenhall Street

Record of Discussion & Agreed Actions

In Attendance	Aidan O'Brien, Mary Haughey, Mary Jo Thompson, Edel Aughey, Robin Gray, Suneil Jain, Darren Mitchell, Teresa Majury, Pat Sheils, Alison Downey, Rae Browne, Patricia Thompson, Lin Shum, Rae Browne, Karen Parsons, Kate White,
Teleconference	Fiona Reddick, Kate O'Neill, Gareth McClean, Gerry Millar
Apologies	Elizabeth England, Moyra Mills, Kerry Chambers, Jackie Harney, Thamra Ayton, Harry Lockhart, Hugh O'Kane, Ali Thwaini, Karen Johnston, Wilma Boyd Carson, Davinia Lee

	Item	Responsibility / Date
1.	**Welcome, Introductions & Apologies** Mr Aidan O'Brien welcomed everyone to the meeting and invited members to introduce themselves. Edel Aughey advised of her role as Macmillan Service Improvement Lead for Patient information and the Recovery Package. Alison Downey, SHO, was there to present the outcomes of cystectomy for bladder cancer 2012-2014.	
2.	**Minutes of Last Meeting** Minutes of the last meeting were read and agreed. **Matters Arising:** **AP1 Letter to DLA Advisory Board:** Mr O'Brien advised that he has written a letter to the DLA Advisory Board highlighting the significance of fatigue for people with cancer and referenced the statistics from the information presented by Anna Gavin at the last network meeting. Mr O'Brien offered to meet with the DLA Advisory Board along with Dr Gerry Millar. To date, there has been no response.	

	A task and finish group has been established to assess the current pathway for patients with gastro-intestinal consequences following pelvic radiotherapy treatment. Ms Edel Aughey will support the group in her new role. It was also noted that Dr Suneil Jain will be invited to be involved in the group from an oncology perspective. Further updates will be provided at future network meetings. All other matters will be covered on the agenda.	
3.	**Urology guidelines & pathways** **Regional hormone therapy guideline & pathway:** Mr O'Brien extended thanks to Dr Darren Mitchell and Dr Suneil Jain for their work in taking this forward. Dr Mitchell advised that the draft guideline has been circulated to oncology colleagues for comment and to pharmacy to advise regard licensing restrictions. It was proposed that the guideline and pathway would also be circulated to the Urology Network Group for consultation. A deadline date of end of February 2015 was agreed. Mr O'Brien queried if bone densitometry testing should be considered within the guidance. Dr Mitchell advised that he would review guidance regard this. **AP1: All members to forward comments on the draft guideline and pathway by end of February 2015** **Patient Care pathways**: Mr O'Brien advised that he is currently reviewing and updating all pathways. **Clinical management guidelines:** <u>Surgical</u>: Mr Ali Thwaini is currently developing new surgical guidelines and will have them completed for the next Urology network meeting. <u>Imaging</u>: Ms Haughey advised that Dr Arthur Grey has proposed that the updated Yorkshire network imaging guidelines are adopted by the network group – this has been agreed by Dr Stephen Vallely and Dr Eoin Napier. It was agreed that the imaging guidelines would be circulated to all members for information. **AP2: Ms Haughey to circulated Yorkshire imaging guidelines to all members.** <u>Pathology</u>: Dr Gareth Mc Clean advised that he had reviewed the EAU guidelines which detailed some sections on pathology. He highlighted that the Royal College of Pathologists has produced datasets across all sites and it may be appropriate to reference these as opposed to providing a large amount of detail within the guidelines. Mr O'Brien concurred as long as there is assurance of compliance here to the datasets. Ms Haughey advised that reference to datasets was provided for some of the other tumour sites and agreed to forward an example to Dr McClean. **AP3: Ms Haughey to forward an example of a pathology guideline from another tumour site to Dr McClean** <u>Radiotherapy protocol:</u> Need to check about including this protocol within the guidelines	**All members by end of Feb'15** **Ms Haughey** **Ms Haughey**

	Nursing section: Ms Kate O'Neill, Ms Patricia Thompson and Ms Kerry Chambers to work together on developing a nursing section within the guideline to include reference to the inclusion of the recovery package. **AP4: Ms O'Neill, Ms Thompson and Ms Chambers to develop nursing section for inclusion in the guidelines before next network meeting.** Follow up section: All TCFU pathways to be included. Mr O'Brien updated members on the outpatient model which is being followed in SHSCT. CT scans / tests are arranged for patients prior to attending their outpatient appointment. This ensures that the outpatient visit is definitive; the patient will either be discharged or placed on a waiting list for a therapeutic procedure. The key worker is also introduced to the patient at the first visit. The patient is usually seen within 2-3 weeks with most tests already completed. Dr Gerry Millar advised there is a need to improve information flow to patients and GPs as there is still uncertainty regard what is going to happen and when and this would help to manage patient's fears. Communicating with patients in a timely manner can be an issue as patients are reluctant to answer phone if it is a withheld number. It was suggested that it would be useful to do an audit of the new system against the previous system to see if it works. It was noted that the model only works if there is good tracking as this will help to identify dates for surgery within the 62 day timeline. NICE consultations: there are currently two consultations out regard bladder cancer and the draft prostate quality standards. Mr O'Brien noted the increasing reference of MRI scanning prior to first biopsy in the draft prostate guidance. It was observed that more MRI capacity is required to make this change and that this issue has been flagged with commissioners.	**Ms O'Neill, Ms Thompson & Ms Chambers**
4.	**Targeted Service Improvement Activity** Ms Mary Jo Thompson advised that Ms Lynne Charlton is currently leading the review of the regional urology service and has been linking with individual teams regard taking this forward. Ms Charlton had indicated there was an indicative 40% increase in red flag referrals and would be keen to understand what this is reflective off and queried if there were any changes to the microscopic haematuria pathway or any other reasons. Ms Thompson suggested that the Be Clear on Cancer ''Blood in Pee'' campaign may have impacted on an increase in referrals. Dr Millar highlighted the difficulty by GPs in accessing investigations e.g. ultrasounds, and there could be a reduction of referrals to secondary care if there was better and timely access to diagnostic testing.	
5.	**Audit** **i) Audit of patient outcomes following radical cystectomy** Mr O'Brien invited Alison Downey to present the audit of patient outcomes following radical cystectomy. Hard copies of the audit were circulated to all members for information. Data included source of referral, timing from TURBT to radical surgery, indications, peri-	

	operative outcomes, incidental prostate cancer, complications, re-admissions and survival. 110 patients were identified in the timeframe from 04/01/2012 to 22/07/2014, gender breakdown of 95 male patients, 15 female patients and median age of 66 years. Following the presentation, Mr O'Brien thanked Ms Downey and asked for questions / comments from members: ➢ It was noted that there was no chart review of patients, data was retrieved from PAS,ECR, Link Labs, BAUS database and CaPPS ➢ Oldest patient was aged early 80's ➢ Average length of stay was 2.5 months and it was noted that there is more disease progression if stay is delayed beyond 3 months ➢ Mortality rates are consistent with national figures: 34% death rate, 66% survivor rate ➢ Greater number of lymph nodes retrieved – 20-30 lymph nodes, survival marginal benefit is equivalent to neo-adjuvant chemotherapy ➢ Dr Suneil Jain suggested looking at some standards in relation to the audit e.g. reported rates of neo-adjuvant chemotherapy ➢ There were a significant number unrecorded for pre-op neo-adjuvant chemotherapy and form of urinary diversion - though it was noted that there was no access to COHIS. This highlights the need for clinical teams to document information. ➢ Approximately one third of patients undergoing lymph node resection were node positive – members queried if this was higher than should be? ➢ Pre-op staging provides 5-10% increase of survival benefit ➢ A pathological based audit is required to look at the management of all patients with muscle invasive disease ➢ Radical radiotherapy for bladder – survival comparable for 50% of patients, should be re-run for neo-adjuvant patients ➢ CT scanning is difficult to use for staging bladder cancer, MRI should be considered ➢ For the data which was not on ECR, Mr O'Brien suggested contacting Mr Ali Thwaini to gain access to Lablinks which has a repository of histologies in BHSCT **AP5: Ms Downey to send the database, without patient names, to Dr Darren Mitchell, and he will re-run audit for neo-adjuvant patients** ii) **Erectile & lower urinary tract dysfunction following radical prostactectomy audit** **AP6: Mr Hugh O'Kane will present audit findings at the next network meeting.**	
6.	**Peer review** Ms Haughey advised that upload of documentation is the 18th May and the peer review visits are scheduled for the weeks of 15th and 22nd June across different trusts. Ms Haughey outlined the structure of the visit and timescale for resulting reports. Peer review training is taking place on Thursday 16th April 2015 and members should book a place through their Trust Cancer Manager.	

7.	**TCFU Prostate Sub group** Ms Thompson referenced the progress report on prostate follow-up implementation which was circulated prior to the meeting. This provided an update on prostate cancer patients moving onto shared care / nurse led pathways across all of the Trusts. It was noted that the follow-up pathways are being implemented at varying degrees and Prostate cancer follow-up has come a long way to moving patients to nurse led follow up. Ms Thompson also provided an update on the PSA IT Tracking feature within RISOH. The triggers are set at disease level though further work is required with the developers to ensure functionality. The tracking feature is allocated an identifier reflective of the PSA tracking category, including a prefix to indicate what trust. A search can also be initiated via the patient health and care number. Customised reports can be written to facilitate reporting requirements and letters can be set up for correspondence. It is envisaged that the RISOH system will go live from 20th April in BHSCT for oncology moving on to other trust sites over a five week period with a final go live on 15th June for haematology. Staff can start to utilise once go live. PAS virtual clinics to be developed within trusts to facilitate timely monitoring and training for staff will be rolled out. **Stage 3 TCFU evaluation: –** PWC has completed the evaluation. The draft report is currently out for comment and when finalised, it will be issued to stakeholders.	
8.	**Updates** **Clinical Trials:** Dr Suneil Jain advised that 8 trials are due to open in next year for local and metastatic prostate cancer and these will help to improve access to new therapies. Members highlighted the importance of dedicated staff within trusts to support recruitment of suitable patients for trials. **Cancer Patient Experience Survey:** Ms Haughey advised that the survey will be issued within the next week or two and will be sent to over 5,000 patients who received treatment for cancer over a defined six month period. It is hoped that interim trust reports will be available prior to peer review upload. It was also acknowledged that trusts are carrying out their own surveys to capture patient experience and feedback for peer review. **Prostate Cancer UK research:** Ms Haughey advised that PCUK carried out a nursing survey and a report will be published in March. Ms Haughey advised that PCUK researcher, Morven Masterson, has offered to present the finding of the study at a future network group meeting. **PCUK BHSCT Physiotherapy pilot:** Ms Thamra Ayton was unable to attend the meeting but has advised that her-self and Alison Robinson started the 18 month pilot on 19th January 2015. The next few months will involve background work: setting up the service, pathways, patient recruitment, assessment forms, outcome measures and meeting with nursing and medical colleagues. A further update will be provided at the next meeting.	

9.	**Emerging Issues** **Presentation of completed audits:** It was agreed that it would be useful to present findings / recommendations from completed Trust audits at the next network meeting. Completed audits include the Brachytherapy audit, Patient history audit, the Docetaxel neutropenic sepsis audit, and possibly a Bladder chemo audit. **AP7: Dr Darren Mitchell and Dr Lin Shum to contact relevant audit personnel regard summaries of completed audits for presentation at the next network meeting**	**Drs' Darren Mitchell & Lin Shum**
10.	**Date of Next Meeting** **Friday 17 April 2015 at 2.30pm – 4.30pm in Conference room 4, Linenhall Street, Belfast.**	

Urology Network Site Specific Group Meeting
Friday 17th April 2015
2.30pm-4.30pm, Conference room 4, Linenhall Street, Belfast

Record of Discussion & Agreed Actions

In Attendance **Teleconference** **Videoconference**	Aidan O'Brien (SHSCT), Mary Haughey (NICaN), Suneil Jain (BHSCT), Darren Mitchell (BHSCT), Mary Jo Thompson (PHA/NICaN), Edel Aughey (NICaN), Chris Hagan (BHSCT), Ali Thwaini (BHSCT), Thamra Ayton (BHSCT), Hugh O'Kane (BHSCT), Pat Sheils (BHSCT),Jacque Warwick (BHSCT), Karen Parsons (BHSCT), Melanie Blackwood (BHSCT), Ruth Johnston (BHSCT) Moyra Mills (NHSCT) Gareth McClean (SHSCT), Kate O'Neill (SHSCT)
Apologies	Fiona Reddick (SHSCT), Davinia Lee(BHSCT), Patricia Thompson, Elizabeth England(WHSCT), Robin Gray(PPI rep), Teresa Majury(PPI Rep), Harry Lockhart (PPI Rep), Samantha Thompson (BHSCT)

	Item	Responsibility / Date
1.	**Welcome & Introductions** Aidan O'Brien welcomed everyone to the meeting and apologies were recorded as above.	
2.	**Minutes of last meeting** **The minutes of the last meeting were** **Matters arising:** i) <u>Letter to DLA Advisory Board:</u> Mr O'Brien advised that he had spoken to the ATOS Director and she welcomed an opportunity for the network group to make representation regard the lasting impacts of cancer with a particular focus on fatigue. The Director proposed a meeting is set up with herself and the medical assessor before the end of June to discuss further. Mr O'Brien suggested that an oncologist and a GP should also attend the meeting. Ms Edel Aughey highlighted the fatigue management programme and the need for further promotion to clinicians. Ms Thamra Ayton advised that she would speak to Jane Rankin regard AHP representation and to Janet Morrison, Macmillan Information Manager.	

	Action point 1: Mr O'Brien to arrange a meeting with ATOS before end of June and to invite key people to attend as highlighted above. ii) Regional Urology meeting: Ms Mary Jo Thompson advised that Ms Lynne Charlton & Ms Sara Long are facilitating a Regional urology meeting on 30th April 2015 in Linenhall Street, chaired by Mr Dean Sullivan. Mr O'Brien advised that he would be attending in his capacity as SHSCT MDM Chair but it was agreed that it would be useful to have further representation on behalf of the Network Group. **Action point 2:** Ms Mary Jo Thompson to contact Lynne Charlton to seek Urology network group representation at the meeting iii) Audit of patient outomes following radical cystectomy: This audit was presented by Ms Alison Downey at the last meeting. Mr Darren Mitchell advised that he had not received the database to re-run the audit for neo-adjuvant patients. **Action point 3:** Mr Hugh O'Kane agreed to follow this up. iv) Audit on erectile & lower urinary tract dysfunction following radical prostactectomy: Mr Hugh O'Kane advised that this audit is on-going and will be presented at the regional Urology audit meeting next month. He advised that a registrar could present at a future network meeting. **Action point 4**: Mr Hugh O'Kane to arrange for presentation of audit at next network meeting.	**Aidan O'Brien** **Mary Jo Thompson** **Hugh O'Kane** **Hugh O'Kane**
3.	**Urology guidelines & pathways** **Regional hormone therapy guideline & pathway:** Following the last network meeting, the guideline and pathway were circulated to all network members for comment. Dr Darren Mitchell advised that he had received no comments to date. Mr O'Brien queried the term 'shared care' used in the pathway and thought that this may require clarification as it implies shared care with GPs. **Action point 5**: Ms Mary Jo Thompson agreed to review and define the term. **Action point 6:** Dr Mitchell advised that he will send the guideline to pharmacy colleagues to clarify licensing restrictions and following this, the document will be ready for final sign off. **Clinical Management Guidelines:** A draft version of the guidelines was circulated to members prior to the meeting. It was noted that Mr Ali Thwaini has done extensive work in reviewing and developing guidelines for Bladder, Prostate, Penile, Renal Cell, Testicular & Upper Urinary Tract Urothelial Cell Carcinomas, using the EAU guidelines as a template and including others from BAUS, NICE, NHS England and the Improvement of Outcomes Guidelines (IOG).	**Mary Jo Thompson** **Darren Mitchell**

	Mr Thwaini advised that he would need to circulate the draft document to other colleagues for review and to ensure it is in accordance with other appropriate guidelines. Ms Mary Haughey advised that the updated Yorkshire Imaging guideline were adopted following review by the lead authors. Dr Gareth McClean advised that he had consulted with colleagues to adopt the Royal College of Pathologists datasets. Ms Haughey advised that the existing SACT and Radiotherapy guidelines / protocols have been referenced in the document. Ms Kate O'Neill in partnership with nursing colleagues has developed the nursing section and it was also noted that the TCFU Prostate follow up documents have been included in the document. It was noted that the network should consider follow up pathways for other groups of patients besides prostate patients. There was discussion on whether Mr Thwaini should remove the chemotherapy and radiotherapy sections from his sections as they are already referenced under the relevant sections. Ms Haughey advised that the network group needs to agree guidelines and pathways which are circulated to trust MDTs – this needs to happen before the peer review documentation upload on 18th May. As there will not be a network meeting before this, it was agreed that the most up to date version would be sent to trusts with a rider that the document was still under review. **Action point 7:** Mr Ali Thwaini to circulate guidelines to relevant colleagues for review and comment. **Pathways:** Mr O'Brien advised that there are referral pathways, patient pathways and follow-up pathways. He has reviewed all the Urology care pathways and is content that they do not require any further update at this time. **Follow up:** It was highlighted that follow up pathways should be considered for other groups of patients besides prostate patients. There was discussion on the need to review all national guidance in relation to a number of procedures that are not currently available in Northern Ireland. Mr Chris Hagan suggested that the Urology CMGs should consider the inclusion of unique solutions to problems of managing cancer in NI when there are smaller volumes. Reference was made to the fact that patients currently travel to England for robotic prostatectomy under current commissioning arrangements and that a proposal for robotic surgery is being developed by BHSCT.	**Mr Ali Thwaini**
4.	**Clinical Trials** Dr Suneil Jain referred to the annual report on urology cancer trial activity 2014 which was developed by Melanie Morris from the NI Cancer Trials Network and was circulated to members prior to the meeting. Dr Jain highlighted that during 2014, 1415 participants, (16.6%) of incidental cancers, were recruited into regional cancer clinical trials, 2.7% of participants (235) received interventional, systemic or radiotherapy treatment. There were 14 urological cancer trials open to recruitment during this time and a total of 495 participants were recruited into urology cancer studies, with 59 participants into interventional trials. There were ten prostate trials which recruited 144	

	participants, there were two open testicular trials and only one randomised controlled trial (STAR) available for renal cell cancer, which was halted due to limited staff and will re-open for recruitment in April 2015. Urological cancer clinical trial activity is increasing at the Cancer Units, not only in identifying patients but also supporting full trial activity for studies such as UKGPC and HaBio. Dr Jain advised that further information on all open urological trials in 2014 was detailed in the report.	
5.	**Peer review update** All trusts are preparing documentation for upload on the 18th May. Visits are scheduled for weeks of 15th and 22nd June 2015. Some members attended the peer review training on 16th April 2015 and feedback was that it was very informative. It was noted that that there may be network actions after the peer review visits which may need discussion / action at the next network group meeting.	
6.	**TCFU Prostate sub group** **Implementation of pathways:** Ms Mary Jo Thompson advised that the TCFU project team finished in December 2014 and work is on-going within trusts to implement the prostate pathways though it was noted that the focus has been on surgical rather than oncology. Ms Thompson advised that Macmillan Service Improvement Leads posts for trusts are being recruited to support the transformation of cancer services. Ms Thompson also advised that the HSCB and PHA have been requested to develop a risk-based, prioritised, incremental development plan to address the gaps in the specialist cancer nursing workforce. This plan will be supported through charitable organisations using a pump prime model. A recent workshop in March has begun the discussion with key stakeholders on how this programme will be managed and prioritised across the region and across tumour sites. It was noted that there needs to be flexibility of how these nurse roles are utilised to ensure best use of time and cost effectiveness and consideration of skill mix. Chemotherapy prescribing nurses will be looked at through the chemotherapy review work stream. It was also highlighted that Friends of the Cancer Centre in partnership with Belfast trust have a CNS development programme currently underway. The TCFU evaluation report has been signed off and will be circulated to key stakeholders. Ms Edel Aughey advised that a Gastro-Intestinal (GI) Consequences of Pelvic Radiotherapy task and finish group has been set up following a workshop held last year, to assess the current pathway for patients with gastro-intestinal consequences following pelvic radiotherapy treatment and to bring forward recommendations to improve the pathway and patients' experience. The first meeting took place in February 2015, and the group is establishing a baseline of patients affected, identifying clinical champions in each trust, implementing a redesigned pathway to include patient information, raising awareness with GPs and introducing a treatment summary record. They are also going to explore the way forward for patients with complex cases. It was noted that a PSA tracking functionality has been developed for the RISOH system and currently this functionality is being tested.	

7.	**Updates** **Cancer Patient Experience Survey:** There has been a 62% response rate to the survey which was issued in February 2015 and is closing today. Interim data reports will be available for those MDTs that are being reviewed this year by late April and the full CPES reports will be available by late May 2015. **Prostate Cancer UK funded programmes:** Dr Jain advised that Charis Integrated Cancer Care had delivered two successful pilot programmes of education and support to individuals affected by prostate cancer and their families from diagnosis onwards. Dr Maura O'Neill advised that the second session took place in Causeway Hospital and was well attended **Physiotherapy programme** Ms Thamra Ayton advised that the 18 month pilot started on 19th January 2015. Work has been on-going to set up the service, including developing pathways and assessment forms, recruiting patients and agreeing outcome measures. To date 30 patients were identified from the pre-op surgery clinic, 50% were post-op patients, 17% were historical patients. The aim of the programme is to ensure that patients are doing their pelvic floor exercises correctly. From the 10 patients from the pre-op clinic, 4 were doing it correctly, 5 were doing it wrong. Of the 14 post-op patients assessed, 7 could do reasonably well, 7 were doing the exercises wrong and 1 patient was over active, so in this case it is best that they don't do. Ms Ayton advised that referral rates have been good to date and patients are assessed by DRE.	
8.	**Emerging Issues** There were no emerging issues. **Date of next meeting** Friday 18th September 2015, 2.30pm-4.30pm, Conference room 4, Linenhall Street, Belfast.	

WIT-96698
AOB10

MailMeter

Message ID - [redacted]
Archived on 26/08/2016 12:19:54. Printed on 18/05/2023 05:51:20.

Time Sent	26/08/2016 12:19:39
Time Received	26/08/2016 12:19:39
Time Archived	26/08/2016 12:19:54
From:	mitchell, darren [redacted] >
To	aidan o'brien [redacted]
CC	mcveigh, shauna [redacted]
Subject:	Case for review
Attachment	[redacted]pathway.xls 33.0 KB

Aidan – this was one of the bladder cases flagged up from the review of timelines for muscle invasive bladder cancer – I think she has been seen by Chris Hagan and was deemed unfit for surgery.

We' ll review it here and I suspect you' ll want to do a case note review there and see if there is any shared learning from it either regionally or locally?

Thanks

DMM

Dr DM Mitchell FRCR
Consultant in Clinical Oncology
Northern Ireland Cancer Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB

☎ - [redacted]
✉ - [redacted]
Secretary - [redacted]

Mitchell, Darren

From: Hagan, Chris
Sent: 18 August 2016 09:29
To: Mitchell, Darren; Traub, Gillian; Lee, Davinia; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Follow Up Flag: Follow up
Flag Status: Completed

The issue for me is the regional shared learning, and clinician to clinician may not capture this. Raising it as an IR1 and hoping ST then escalate to SAI may not happen and therefore no regional learning will follow. I think we should ensure that this is shared regionally.
I agree it would be useful to look back at referrals for MIBC and their timelines
The NICAN urology chair is part of the ST MDT and NICAN should also be involved in this
chris

From: Mitchell, Darren
Sent: 17 August 2016 18:42
To: Traub, Gillian; Lee, Davinia; Hagan, Chris; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Route 1 seems best. I think I would add weight to the discussion if we saw this as a trend and had evidence to that effect.

I suspect we'd see a longer lag than would be expected.

DMM

Sent from my Windows Phone

From: Traub, Gillian
Sent: 17/08/2016 18:28
To: Lee, Davinia; Mitchell, Darren; Hagan, Chris; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Hi Davinia, thanks for following this up.

I would add 2 points:

a) There should be a Consultant to Consultant discussion as Carol Anne says but should this discussion be with the MDT chair in SHSCT rather than with the individual Consultant Urologist, if the plan for this patient was agreed at MDT, rather than being the patient's urologist own treatment plan?
b) In past experience with interface incidents (which must meet criteria for an SAI) they are not the most palatable route. We could do a 3rd way – completion of a BHSCT incident report, with discussion with SHSCT clinician, and then incident report shared with them and they are asked to investigate. It also gets shared between corporate governance teams so it is formally logged. If the SHSCT then investigate it and find that it meets SAI criteria, it would then be incumbent on them to declare an SAI.

Gillian

From: Lee, Davinia
Sent: 17 August 2016 17:39
To: Mitchell, Darren; Hagan, Chris; Traub, Gillian; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Thanks Darren. I have chatted to Carol Anne and she says there are two options to raise this with Southern Trust

1) Speak directly to the colleague in the SHSCT who referred the patient (she advised discussion should be consultant to consultant) and advise of the concerns below and ask them to take forward an investigation locally
2) Report this as an interface incident with HSCB. In this scenario we complete a one page summary and submit to HSCB and they then contact the SHSCT for investigation. In either option we will need to have a discussion with the Southern Trust referrer.

Chris/Darren – would be keen to see if you have a preference?

I will ask Tracey to pull the MDT data for Jan-June 16 and pull out the muscle invasive bladder cancers – do you want to look at all Trusts or just Southern?

Thanks
Davinia

From: Mitchell, Darren
Sent: 17 August 2016 15:47
To: Lee, Davinia; Hagan, Chris; Traub, Gillian; Crawford, Jena
Subject: RE: query

Chris – I agree there is no recommendation for isotope bone scan in the regional guidelines or NICE guidelines.

1.2.8 Consider further TURBT within 6 weeks if the first specimen does not include detrusor muscle.

1.2.9 Offer CT or MRI staging to people diagnosed with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer that is being assessed for radical treatment.

1.2.10 Consider CT urography, carried out with other planned CT imaging if possible, to detect upper tract involvement in people with new or recurrent high-risk non-muscle-invasive or muscle-invasive bladder cancer.

1.2.11 Consider CT of the thorax, carried out with other planned CT imaging if possible, to detect thoracic malignancy in people with muscle-invasive bladder cancer.

1.2.12 Consider fluorodeoxyglucose positron emission tomography (FDG PET)-CT for people with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer before radical treatment if there are indeterminate findings on CT or MRI, or a high risk of metastatic disease (for example, T3b disease).

I think this should be flagged back to the southern trust and I would suggest to all non-regional MDTs that any muscle invasive bladder cancer on pathology should be discussed at the regional meeting at the earliest opportunity to allow early surgical assessment and guidance on role of neo-adjuvant chemo or suitability for XRT/ ChemoXRT. Scans as per guidance can occur in tandem.

The outcomes from muscle invasive bladder cancer are poor and as you have demonstrated early intervention is crucial.

Perhaps the southern team would wish to do a case note review – either as part of an MDT process review or SAI.

SAI might be more appropriate if we see this as a consistent trend – So I also agree that a review of timelines for the last 30-50 muscle invasive cases coming to central-MDT could be reviewed to identify trends.??

Happy to discuss further.

DMM

Dr DM Mitchell FRCR
Consultant in Clinical Oncology
Northern Ireland Cancer Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB

☎ - Personal Information redacted by the USI
✉ - Darren Mitchell's email address
Secretary - Elizabeth Burgess' email address

From: Hagan, Chris
Sent: 16 August 2016 11:01
To: Lee, Davinia; Crawford, Jena
Cc: Traub, Gillian
Subject: RE: query

Davinia – it may be more appropriate for the MDM lead to comment.

However, from the guidance:

1. I can see no role for bone scan and we do not routinely do this in Belfast. I would ask them to justify this – from the guidance:

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 32 V1.3

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).

2. **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.

Happy to discuss further. It may well be worth looking at other ITTs for cystectomy
chris

From: Lee, Davinia
Sent: 15 August 2016 16:08
To: Hagan, Chris; Crawford, Jena
Cc: Traub, Gillian
Subject: FW: query

Hi Chris,

Can I check if you have had an opportunity to review this patients pathway, and whether you still have concerns we need to follow up on?

Thanks
Davinia

From: Lee, Davinia
Sent: 22 June 2016 17:19
To: Hagan, Chris
Cc: Crawford, Jena; Traub, Gillian
Subject: RE: query

Hi Chris

I have had a look at the patients pathway from CaPPS, see attached.

I have compared it against the NICaN pathway (page 125 of the clinical guidelines) and the guidance is for muscle invasive bladder cancer to send to CT chest abdomen before MDT discussion, however in this case it was discussed at MDT first. There was then a delay to the bone scan and it took over a month for the CT after the first MDM and nearly 2 months from the original report of the pathology. They then discussed at local MDT again on 28/4/16 and decided on a plain film of left shoulder and central MDM discussion. The first discussion at the regional MDT was following this on 12/5 at which a CT was recommended of the shoulder. An MRI was carried out as recommended by the radiologist on 26/5 and then was discussed centrally again and transferred on 9/6/16.

Would you have a look at the pathway prior to the first central MDM discussion on 12/5 for me? It looks like a CT should have been requested following the original path on 29/2 in line with the pathway attached which would have

saved at least a month, but would welcome your clinical view as to what should have happened post original resection and pre specialist MDT discussion before we decide on how to proceed.

Thanks
Davinia

From: Hagan, Chris
Sent: 22 June 2016 10:01
To: Lee, Davinia
Subject: RE: query

Sorry its: Patient 127
chris

From: Lee, Davinia
Sent: 22 June 2016 09:13
To: Hagan, Chris
Subject: RE: query

Hi Chris

We can't find anything for patient Personal Information redacted by the USI on CaPPS or ECR – is the HCN definitely correct? What is the patients name?

Thanks
Davinia

From: Hagan, Chris
Sent: 21 June 2016 16:24
To: Lee, Davinia
Cc: Crawford, Jena
Subject: query

Davinia
I'm very concerned about delays in ITT from Craigavon and how we raise this – is it possibly an interface SAI?

patient Personal Information redacted by the USI muscle invasive bladder cancer.
Original resection16.02.206 with multiple local MDT discussions before a regional discussion 09.06.2016 and I see her today 21.06.2016. In my view there are multiple avoidable delays which will potentially lead to an adverse outcome – she is not fit for cystectomy today.

Contrast this with an exemplar. Patient Personal Information redacted by the USI TURBT 25/05/2016 in Derry. Muscle invasive bladder cancer; discussed regional MDT 09/06/2016 and seen today with radical surgery next week.

What do you think?

happy to discuss

Chris

Mitchell, Darren

From: Haynes, Mark [redacted]
Sent: 07 August 2020 20:02
To: Mitchell, Darren; Jain, Suneil
Subject: RE: 20/2537 HCN [redacted]

Thanks.

This is not the only case with a similar issue that I have become aware of.

We have some processes happening currently looking into a number of patients through our governance processes. Are you OK for me to submit and IR1 to commence an investigation into this case, and Suneil will be named within the IR1 as you are now seeing the patient (only to provided input re care and impacts)?

What does the evidence say about the impact of such a delay in EBRT?

Re the choice of ADT I see no evidence in the letters that the pros and cons of antiandrogens vs LHRH in high risk disease were discussed with the patient.

Mark

From: Mitchell, Darren [redacted]
Sent: 07 August 2020 11:38
To: Jain, Suneil; Haynes, Mark
Subject: RE: 20/2537 HCN [redacted]

Thanks. I'll pass to mark just noting the time frames and extent of disease.

DMM

Sent from Samsung Mobile on O2

-------- Original message --------
From: "Jain, Suneil" <[redacted]
Date: 07/08/2020 11:26 (GMT+00:00)
To: "Mitchell, Darren" [redacted]
Subject: 20/2537 HCN [redacted]

Hi Darren,

Could I highlight this 65y old man's case. Diagnosed in 11/19 t3an0m0, iPSA 85, G4+3 12/12 cores. Commenced on bical 150mg 12/19 with psa dropping to 17 in April, then 20 in July when AOB converted him to MAB and referred for radical radiotherapy. I met him as NP today. My preference would have been for LHRH agonist at the outset given his PSA level and immediate onward referral for EBRT. I think the choice was made for antiandrogen to try and avoid LHRH agonist side-effects (including impotence) and referral was delayed with the intention of achieving a satisfactory PSA response prior to radiotherapy.

Thanks,

Suneil

Professor Suneil Jain MB BCh MRCP FRCR PhD

Friends of the Cancer Centre's Professor in Clinical Oncology
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P: Personal Information redacted by the USI
W: https://pure.qub.ac.uk/portal/en/persons/suneil-jain(711b974e-8330-4eb0-93c3-ed886de9eeb3).html