

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

Dr Maria O'Kane Accounting Officer Southern Health and Social Care Trust Headquarters 68 Lurgan Road Portadown BT63 5QQ

18 February 2022

Dear Madam

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 production of documents

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').

You will be aware that the Inquiry is starting its investigations into the matters set out in its Terms of Reference. A key part of that process is gathering all of the relevant documentation from relevant departments, organisations and individuals.

In keeping with the approach we are taking with other departments, organisations and individuals, the Inquiry is now issuing a Statutory Notice (known as a 'Section 21 Notice') pursuant to its powers to compel the production of relevant documentation.

This Notice is issued to you in your capacity as Accounting Officer of the Southern Health and Social Care Trust. It relates to documents within the custody or control of the Trust. It is hoped that this Section 21 Notice will alleviate any concerns that the Trust may have in relation to data protection or confidentiality. As the text of the Section 21 Notice explains, the Trust is required by law to comply with it.

It will be evident from the attached that this Notice is a follow up Notice to No. 4 of 2021 forwarded to Mr Shane Devlin on 5 November 2021.

If it would assist you, I am happy to meet with you, your officials and/or the Trust's

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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 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 your organisation 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. The Inquiry will be pleased to receive your documents in tranches; you do not have to wait until you are in a position to fully comply with the Notice before you begin to send documents. Indeed it will greatly assist the progress of the Inquiry's work if you immediately begin the process of forwarding documents to the Inquiry.

If your organisation does not hold documentation in respect of some of the categories of document specified in the Section 21 Notice, please state this in your response. If it is possible to indicate by whom such information might be held, if it is not held by your organisation, the Inquiry would find that of assistance.

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

Yours faithfully

Personal Information reducted by the USI

Anne Donnelly

Solicitor to the Urology Services Inquiry

Tel: Personal Information redacted by the USI

Mobile: Personal Information redacted by the USI

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

Chair's Notice

[No 1 of 2022]

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

WARNING

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

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

TO: Dr Maria O'Kane

Accounting Officer

Southern Health and Social Care Trust

Headquarters

68 Lurgan Road

Portadown

BT63 500

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.

DOCUMENTS 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)(b) of the Inquiries Act 2005 ('the Act'), to produce to the Inquiry the documents set out in the Schedule to this Notice by 12.00 noon on 18 March 2022.

APPLICATION TO VARY OR REVOKE THE NOTICE

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

If you wish to make such a claim you should do so in writing to the Chair of the Inquiry at: Urology Services Inquiry, 1 Bradford Court, Belfast, BT8 6RB setting out in detail the basis of, and reasons for, your claim by 12.00 noon on 18 March

2022.

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

Dated this day 18 February 2022

Signed:

Christine Smith QC

Chair of Urology Services Inquiry



SCHEDULE [No 1 of 2022]

Preamble

We refer to the Trust's Response to Section 21 No. 4 / 2021 ("the Response"). You are now required to address the following matters arising out of that Response.

Documents

- To the extent not covered in the requests below, please provide any and all documents within your custody or under your control relating to the Lookback Review, except where those documents have previously been provided to the Urology Services Inquiry by the SHSCT.
- 2. Provide the Inquiry with copies of the following documents:
 - Any report containing the conclusions reached by the Trust following completion of the scoping exercise of emergency and elective patients, June 2020.
 - ii. All notes and records arising out of the meetings with the GMC, July 2020.
 - iii. All notes and records arising out of the meeting between Dr Dermot Hughes and Trust Managers, October 2020, which advised Trust managers of the initial findings of the SAI which instigated the Trust to further consider other cohorts of patients from the themes that had arisen for the SAI learning.
 - iv. All correspondence between the Trust and Royal College of Surgeons (RCS), and the Trust and British Association of Urological Surgeons (BAUS), concerning scoping of patient records, November-December 2020.



- v. All notes, records, or emails arising out of the meeting of the Urology Assurance Group on 4th December 2020, at which it was decided that no more than 9 cases would be examined under SAI.
- vi. Terms of reference, job description and terms of engagement for Professor Sethia.
- vii. All patient review forms completed by Professor Sethia.
- viii. Any report, or similar document, arising from the patient scoping exercise.
- ix. Any document setting out changes made to the patient scoping exercise upon receipt and consideration of the Lookback Guidance from the Department of Health.
- x. Any correspondence with RCS concerning their conduct of the Invited Service Review, to include any correspondence from the Trust seeking to expedite the conclusion of that process and the production of a report.
- xi. Copy of the Lookback Review standardised template form (as per answer 10 of No. 4 / 2021) if this is different from the Patient Review Form.
- xii. Provide copies of the five different template letters (per answer 19 of No. 4 / 2021) save to the extent that they are different to the sample letters referred to at answer 11 of the Response.
- xiii. In respect of each of the 67 patients who met the criteria for SAI and whose case has or is now being considered by way of SCRR, provide all of the material which was taken into account when determining that a SCRR was necessary as well as the resultant SCRR forms.
- xiv. Copy of the letter and enclosure sent to patients who have been identified for SCRR (as per answers 21(c) and (d) of No. 4 / 2021).
- xv. Any report or other documentation arising from the Bicalutamide audit as referred to in the minutes of the Urology Assurance Group of 4th December 2020 (per answer 27(c) of No. 4 / 2021).

Answers 3 and 4



3. State precisely the reasons for the delay between the decision to instigate a Lookback Review in October 2020, and the commencement of that Review in March 2021.

Answer 6

4. Has the report of the RCS Invited Review been finalised? If not, what steps have been taken by the Trust to expedite the production of this report, and when is it anticipated that the report will be available to the Trust?

Answer 7

5. In what specific ways has the conduct of the HSCB fortnightly meetings changed as a result of the Lookback Guidance issued by DoH in July 2021?

Answers 8 and 12

6. Provide the Inquiry with all relevant statistics, preferably in tabular form, to reflect the current findings of the Lookback Review. Without being prescriptive it is expected that statistics shall be made available concerning the following: number of cases considered; number of patients found to be on the correct management plan; number of patients found to have been provided with suboptimal care; number of patients moved to a different management plan.

Answer 11

7. What was the process applied for the Lookback Review in Urology? If this is set out in a written document, please provide a copy of the same.

Answer 21(a)

8. What was the criteria applied and process undertaken for the Structured Clinical Record Review in Urology? If this process is set out in a written document, please provide a copy of the same.

Answer 21(b)

9. Explain the factors which were taken into account during the screening process which led to the decision that 8 patients (out of the 75 originally identified) need not be included in the SCRR process, and provide all relevant material in support of the decisions made in each of these 8 cases.



Answer 22

10. Confirm how many of the remaining 503 patients referred to have now been reviewed. If applicable, state the reason for any delays in reviewing this cohort of patients and state the approximate date by which it is anticipated that the work of the Lookback Review will have been completed in respect of all patients originally identified.

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.



USI Ref: S21 1 of 2022

Date of Notice: 18 February 2022

Witness Statement of: ELLEN MARIA O'KANE

I, Ellen Maria O'Kane, will say as follows:-

- I am the Medical Director and Temporary Accounting Officer and Cover for the Chief Executive of the SHSCT ('the Trust'). I make this statement, in response to Section 21 Notice No.1 of 2022 on behalf of the Trust in my capacity as acting Accounting Officer and Covering for the Trust Chief Executive.
- 2. With the permission of the Inquiry, I have relied upon the assistance of other Trust personnel in compiling documents and information in response to this Section 21 Notice. In particular, I have relied upon the following persons:

Question No	Name				
2i.	Martina Corrigan, Assistant Director Public Inquiry and Trust				
	Liaison				
2ii.	Stephen Wallace, Assistant Director, Systems Assurance				
2ii	Melanie McClements, Director of Acute Services				
	Stephen Wallace, Assistant Director, Systems Assurance				
2iv.	Martina Corrigan, Assistant Director Public Inquiry and Trust				
	Liaison				
	Stephen Wallace, Assistant Director, Systems Assurance				
2v.	Martina Corrigan, Assistant Director Public Inquiry and Trust				
	Liaison				
	Stephen Wallace, Assistant Director, Systems Assurance				
	Emma Stinson, Business Support Manager/Document				
	Librarian				

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2 vi.	Stephen Wallace, Assistant Director, Systems Assurance
2 vii.	Sarah Ward, Head of Urology Clinical Assurance
	Mr Mark Haynes, Divisional Medical Director, Urology
	Improvement
	Martina Corrigan, Assistant Director Public Inquiry and Trust
	Liaison
2 viii.	Martina Corrigan, Assistant Director Public Inquiry and Trust
	Liaison
2 ix.	Martina Corrigan, Assistant Director Public Inquiry and Trust
	Liaison
2 x	Martina Corrigan, Assistant Director Public Inquiry and Trust
	Liaison
	Stephen Wallace, Assistant Director, Systems Assurance
2 xi	Sarah Ward, Head of Urology Clinical Assurance
2 xii	Sarah Ward, Head of Urology Clinical Assurance
2 xiii	Sarah Ward, Head of Urology Clinical Assurance
	Chris Wamsley, Acute Governance Coordinator
2 xiv.	Sarah Ward, Head of Urology Clinical Assurance
2 xv.	Mr Mark Haynes, Divisional Medical Director, Urology
	Improvement
3.	Martina Corrigan, Assistant Director Public Inquiry and Trust
	Liaison
	Mr Mark Haynes, Divisional Medical Director, Urology
	Improvement
4.	Martina Corrigan, Assistant Director Public Inquiry and Trust
	Liaison
	Stephen Wallace, Assistant Director, Systems Assurance
5.	Melanie McClements, Director of Acute Services
6.	Sarah Ward, Head of Urology Clinical Assurance
7.	Melanie McClements, Director of Acute Services
	Sarah Ward, Head of Urology Clinical Assurance
8.	Stephen Wallace, Assistant Director, Systems Assurance
	Sarah Ward, Head of Urology Clinical Assurance
	Chris Wamsley, Acute Governance Coordinator

9.	Sarah Ward, Head of Urology Clinical Assurance
10	Sarah Ward, Head of Urology Clinical Assurance

3. Below, I set out in bold text each question asked in Section 21 Notice No.1 of 2022 followed by my answer to it. Any documents being provided are in the form of Appendices to this statement.

Documents

- 1. To the extent not covered in the requests below, please provide any and all documents within your custody or under your control relating to the Lookback Review, except where those documents have previously been provided to the Urology Services Inquiry by the SHSCT.
 - 4. I believe that, through the Trust's response to Section 21 Notice No.2A of 2021 and this response, all such documents have been provided. However, I am aware of the continuing nature of the Trust's disclosure obligation and, if further relevant documents are identified or come into existence, I can confirm that these will be provided.
- 2. Provide the Inquiry with copies of the following documents:
 - i. Any report containing the conclusions reached by the Trust following completion of the scoping exercise of emergency and elective patients, June 2020.

A summary of the patient scoping exercise regarding emergency and elective patients was completed in June 2020. Attachments that were issued to the Director Acute Services, Medical Director, Assistant Director Surgery and Elective Care, Associate Medical Director Surgery and Elective Care and Director of Human Resources include the documented Summary of Exercise Report and an Excel Spreadsheet featuring Emergency Listed patients. These are located in *Relevant to PIT*, reference no 47, 20200618-Summary of exercise done on AOB elective operations 18 June 2020' and 'Relevant to PIT, reference no 47, 20201121 AOB emergencies Jan 2019, June 2020 completed.

The Excel Spreadsheet was created and developed from the point where concerns were identified. It contains the details all of the patients listed as being taken to theatre by Mr O'Brien for elective or emergency procedures in the time period of 18 months between January 2019 and June 2020.

This review of these patients followed on from the email sent to Mr Haynes by Mr O'Brien in June 2020 regarding placing 10 patients on an operative list which alerted Mr Haynes to the awareness that 2 of the patients named had not been contained as should have been expected on the Patient Information systems and that 2 of the patients required stent replacements / removal and were delayed. Initially the patients on the Excel list underwent desktop review to ascertain if there were any others who had delayed replacement of stents, and this initial review alerted the system to the concerns about delays or absence in histopathology, radiology and multidisciplinary reporting which then merited further exploration of these areas.

ii. All notes and records arising out of the meetings with the GMC, July 2020.

Notes and records arising out of discussions with the GMC, July 2020 have been included in GMC submissions regarding Section 21 Notice 2A of 02/2021 Item Reference 76(x). The attachments include email correspondence and email notes of meetings held were sent to the USI on 2nd March 2022 and can be found in folder No 76 GMC Discovery. relevant to GMC called Evidence No 76 - GMC Sensitive Discovery, No 76 GMC Discovery and No 76 GMC Sensitive Discovery

iii. All notes and records arising out of the meeting between Dr Dermot Hughes and Trust Managers, October 2020, which advised Trust managers of the initial findings of the SAI which instigated the Trust to further consider other cohorts of patients from the themes that had arisen for the SAI learning.

Notes of the Trust meeting with Dr Dermot Hughes, which advised of the initial SAI findings, are located in S21 No.1 of 2022 folder as *Q2 iii Meeting Notes 23102020*. No other record of the meeting such as in an email has been identified. However, I also recall that I had a telephone call the same day with Dr Hughes regarding this (of which I do not have specific notes) and I can confirm that the meeting notes attached concur with my recollection of our discussion. In summary, Dr Hughes restated the interim findings of the SAI process to ensure I fully understood the implications. A copy of the Interim SAI Report findings from Dr Dermot Hughes is located in S21 No. 1 of 2022 folder as *Q2 iii Interim SAI Report*.

iv. All correspondence between the Trust and Royal College of Surgeons (RCS), and the Trust and British Association of Urological Surgeons (BAUS), concerning scoping of patient records, November-December 2020.

Notes and records arising out of discussions with the Royal College of Surgeons, November-December 2020 have been included in Royal College of Surgeons submissions regarding Section 21 Notice 2A of 2021 Item Reference 76(vi) are located in Relevant to MDO, Evidence after 4 November MDO, reference number 76 (vi), RCS MOK and Relevant to MDO, Evidence after 4 November MDO, reference number 76 (vi), RCS SW. These include email correspondence and email notes of meetings held. I understand that communications with BAUS were verbal by telephone. In addition to this, a zoom call was held with Professor Krishna Sethia (identified via BAUS as an independent Subject Matter Expert) on 15th December 2020 to discuss prioritisation of review groups. These notes are located in S21 No.1 of 2022 folder as Q2 iv Meeting Notes 15 12 2020.

v. All notes, records, or emails arising out of the meeting of the Urology Assurance
Group on 4th December 2020, at which it was decided that no more than 9
cases would be examined under SAI.

Notes and records of meetings that refer to the discussion regarding no more than 9 cases being examined under SAI are provided below. The discussions note the decision to change from SAI to SCRR processes.

Meeting	Date	Relevance	
Urology HSCB and Trust	05/11/2020	Initial HSCB and Trust discussion	
Group Minutes		regarding SAI continuation	
Urology Assurance Group	04/12/2020	Meeting where decision was made not to progress with SAI process	
Urology HSCB and Trust	17/12/2020	Initial discussions by HSCB / Trust	
Group Minutes		regarding the adoption of Structured Clinical Judgment Review methodology in place of SAI following UAG meeting	
Urology HSCB and Trust	07/01/2021	Further discussions between HSC / Trust	
Group Minutes		regarding the creation of a process outside of existing SAI mechanism	

The minutes of the above meetings are located in *Relevant to PIT, Evidence Added or Renamed 19 01 2022, No 76 minutes and agendas with attachments, HSCB, 20201210 Uro HSCB SHSCT Agenda-mtgs, Relevant to PIT, Evidence Added or Renamed 19 01 2022, No 76 minutes, agendas with attachments, UAG, 20201204 DOH SHSCT Uro MEET, Relevant to PIT, Evidence Added or Renamed 19 01 2022, No 76 minutes and agendas with attachments, HSCB, 20210107 Uro HSCB SHSCT Agenda-mtgs, and in S21 No.1 of 2022 folder, 20201105 HSCB mins.*

vi. Terms of reference, job description and terms of engagement for Professor Sethia.

Professor Sethia is employed on a sessional basis by the Trust. The Trust has indemnified Professor Sethia for his role supporting the lookback review. Documents now being disclosed are: data protection agreement; confidentiality agreement; letter of indemnity, role description and correspondence confirming employment on a sessional basis. They are located in S21 No.1 of 2022 folder as follows: Q2 vi Independent Urology Consultant JD, Q2 vi 20201127 Ltr to Prof Sethia, Q2 vi Data Sharing Agreement, Q2 vi Confidentiality Agreement KKS, Q2 vi 20201215 Re Correspondence and Q2 vi 20210911_Ltr Mr Paul Rajjayabun_indemnity

vii. All patient review forms completed by Professor Sethia.

All 2302 patient letters / patient review forms in pdf format can be located in S21 1 of 2022, Patient Correspondence.

The majority of the 2302 letters/ forms were completed by Professor Sethia (1764). Trust Urology Consultants completed 323 and the remaining number (215) were completed by an Independent Sector Provider (Mr Patrick Keane) and took the form of patient letters and not Patient Review Forms because Mr Keane's work predated the creation of the form.

The Oncology outpatient backlog was given priority, and Mr Patrick Keane was available to commence this work in November 2020. Professor Sethia, who had semi-retired, had more time available to support this work compared to other similar full time NHS employed consultants and was able to provide independence, expertise and time to this process.

Of substantively employed Southern Trust Urologists, initially (November 2020 – December 2021) only Mr Haynes undertook reviews. Since December 2021 both Mr Young and Mr O'Donoghue have also commenced undertaking reviews.

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Clinician	Number of Patient Review Forms	Comment
Professor Krishna Sethia	1764 Patient Review Forms completed	Completed using 9 question form – a portion of these patients were duplicates i.e Prof Sethia completed 1764 forms but this equated to 1232 patients as some patients were reviewed for more than one episode of care.
Mr Mark Haynes (Commenced reviews November 2020 - ongoing)	214 Patient Review Forms Completed	Completed using 9 question form
Mr Michael Young (Commenced reviews December 2021 - ongoing)	63 Forms Completed	Completed using 4 question form (The change to a 4 question form is addressed at 2.xi below)
Mr John O'Donoghue (Commenced reviews December 2021-ongoing)	46 Forms Completed	Completed using 4 question form (the change to a 4 question form is addressed at 2.xi below)
Mr Patrick Keane (Orthoderm, Independent Sector Provider)	215 Letters (see comment)	These are in the form of patient letters as they predate the creation of the Patient Review Form. Mr Keane's work (Nov - Dec 2020) predated the use of the either the 9 question or the 4 question screening questionnaire format in early 2021.

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viii. Any report, or similar document, arising from the patient scoping exercise.

There is no specific report or similar document existing aside from the document already provided at 2.i above. For completeness, I can confirm that reference was made to patient scoping work in the Trust regular updates to the HSCB and Urology Assurance Group papers (previously provided as part of Section 21 Notice No. 2A of 2021 *Item Reference* 48 (HSCB/UAG) Relevant to PIT, Evidence after 4 Nov, Ref No 48, (Attachments 3, 4, 5, 6, 7, 8, 9, 10)

ix. Any document setting out changes made to the patient scoping exercise upon receipt and consideration of the Lookback Guidance from the Department of Health.

Prior to the implementation of the Regional Guidance for Initiating a Lookback Review in September 2021, the Trust was guided on the advice of the Royal College of Surgeons, HSCB and the Department of Health.

The Regional Guidance for Initiating a Lookback Review (guidance and Department of Health Circular attached) did not change the process for clinical review of patients but described more comprehensively governance arrangements surrounding the process.

The Trust completed the Regional Guidance for Initiating a Lookback risk assessment template. This was presented and discussed with the HSCB regarding progressing to further cohorts of patients outside of the original January 2019 – June 2020 grouping (Risk assessment template - including draft versions and minutes of HSCB meetings dates - is located in S21 No.1 of 2022 folder at Q2 ix 20210930-HSCB mins ref risk assessment follow-up discussion, Q2 ix 20210930-HSCB mins risk assessment discussion Q2 ix Regional Guidance for Implementing a Lookback Review Process Draft 5, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v2, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v3, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v4, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v5, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v6 27 oct 21, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v7 29 oct 21, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v7 29 oct 21, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v7 29 oct 21, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v7 29 oct 21, Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v8 Sept 2021 v1.)

x. Any correspondence with RCS concerning their conduct of the Invited Service Review, to include any correspondence from the Trust seeking to expedite the conclusion of that process and the production of a report.

All correspondence with the Royal College of Surgeons relating to the conduct of the invited review prior to 7th October 2021 is included in Section 21 Notice 2A of 2021 Item Reference 76(vi). The report from the Royal College of Surgeons has not yet been finalised. The Trust has contacted the Royal College of Surgeons on several occasions to expedite the production of the report. Copies of email exchanges have been included in discovery relating to Section 21 No.2A of 2021 Item 76(vi) located in *Relevant to MDO*, *Evidence after 4 November MDO*, reference no 76 (vi) folders RCS MOK and RCS SW.

The initial request seeking information on the expected report delivery date was sent on the 8th October 2021. The Royal College of Surgeons has informed the Trust that they estimate that their final report will be ready later in April 2022 following correspondence on the 24th February 2022 and reiterated on 24th March 2022 by email (all located in S21 No.1 of 2022 folder at Q2 x 20200224 Response Ltr from RCS, Q2 x 20210730 - E RCS - Review planning, Q2 x 20210908 - E RCS ENG IRM review planning, Q2 x 20211115 - E Urology invited services review, Q2 x 20211221 - E RCS Eng IRM Review, Q2 x 20220114 - E RCS ENG IRM Review, Q2 x 20220220 Ltr from Dr O'Kane re invited review, Q2 x Email from RCS Eng IRM Review.

xi. Copy of the Lookback Review standardised template form (as per answer 10 of No. 4 / 2021) if this is different from the Patient Review Form.

The Lookback Review form is the same form as the Patient Review Form.

From 25th November 2021, the format of the patient review form was changed to consider each patient's current treatment and care and removed the elements that referred to previous delivered care.

Of the patients screened for SCRR Prof Sethia completed 1764 9-question questionnaires, Mr Haynes completed 214 9-question questionnaires, Mr Young completed 63 4-question questionnaires and Mr O'Donoghue completed 46 4-question questionnaires.

On the basis of progress to date, which has been focussed on ensuring that as many patients as possible are on the correct treatment plan at present, we will now ascertain

whether their care in the past should also be reviewed using the 9-question questionnaire.

9 Question Form (March – November 2021)

- Is the present diagnosis / diagnoses reasonable?
- Are the current medications prescribed appropriate?
- Is a secure clinical management plan currently in place?
- If there is not a secure clinical management plan in place please document immediate actions required to be taken

Regarding The Patients Previous Care

- Were appropriate and complete investigations carried out for all relevant conditions?
- Were the medications prescribed appropriate?
- Were the diagnosis / diagnoses reasonable?
- Was the clinical management approach taken reasonable?
- Were there unreasonable delays within the Consultants control with any aspect of care
- On balance, did the patient suffer any harm or detriment as a result of any of the above questions

4 Question Form (November 2021 – Present)

- Is the present diagnosis / diagnoses reasonable?
- Are the current medications prescribed appropriate?
- Is a secure clinical management plan currently in place?
- If there is not a secure clinical management plan in place please document immediate actions required to be taken

As indicated above, the original form was 9 questions; however following discussions with HSCB the form was revised to feature a reduced number (4) of the original questions. The advice to the Trust in this reduction of questions was discussed at a UAG meeting (as outlined in the table below) and then translated to the Trust through the Southern Urology Coordination Group (also outlined in the table below). The advice was to support the Trust in being able to review more case records more quickly to allow the Trust to assure as many patients as possible that their current management and treatment is appropriate. The reduction in questions concentrated on exploring whether "The patient is safe today" and moved from commenting on whether pervious care had been appropriate or safe.

Regarding the reduction in questions on the Clinical Review Form, the following summary of meetings sets out the decision-making and approvals process for the change.

Date	Action
01.11.2021	UAG Meeting 1 st November 2021 - Extract from Minutes
	Cohort 1 Outcomes Report 13. A paper on the Outcomes Report was provided by Paul Cavanagh and shared with the group prior to the meeting. Paul advised that as this is recognised as a "lookback" that will determine the structure of the report.
	14. Paul advised that nine questions are being asked as part of the lookback and each question will be reported on within the Outcomes Report. The report will focus on the cohort of patients who had been under the care of the Consultant for the period January 2019 to June 2020. Paul advised the intention is that an outcomes report will be completed for the Cohort by May 2022.
	15. The group noted concerns that nine questions was a large number and may not be feasible to report on. The group noted:
	Qualitative questions can become complicated when reporting;
	Learnings from Neurology – use of 3 questions;
	Time it may take for larger number of questions given current pressures; and;
	Recommended consideration be given to streamlining questions.
	It was agreed the Trust and HSCB should reconsider questions. Action: HSCB and SHSCT to reconsider lookback questions and agree final methodology.

25/11/2021

Southern Urology Coordination Group 25th November 2021 - Extract from Minutes

Outcomes Report

Melanie noted there was nothing further to report but once the Trust started to work through the remaining 503 patients, a summary outcomes report will be produced by May 2022.

The issue of the Patient Referral form was discussed and Caroline highlighted if 9 or 4 questions were to be used. Melanie noted the Trust had a series of discussions over the last few weeks regarding the format of the form to try and resolve this.

As a result of this advice from HSCB and Department of Health the decision was taken at this point to move from 9 to 4 questions.

Copies of both forms (9 and 4 question versions) are available and are located in S21 No.1 of 2022 folder at Q2 xi Urology Patient Review Form 4 questions and Q2 xi 20210208-UROLOGY PATIENT REVIEW FORM.

xii. Provide copies of the five different template letters (per answer 19 of No. 4 / 2021) save to the extent that they are different to the sample letters referred to at answer 11 of the Response.

As stated in the Trust's response to Section 21 Notice No.4 of 2021, the Trust had originally planned to develop 5 letter templates. However, subsequently 7 templates have been developed in total. These are:

- i. Record review no issues (patient alive)
- ii. Records still to be reviewed (patient alive)
- iii. Letter for post clinic review updates
- iv. Record reviewed, but requires further review
- v. Letter for patients whose record is going for a SCRR
- vi. Letter to family of deceased patients (no issues identified)
- vii. Letter to family of deceased patients (patient record requires review)

Copies of each of the 7 letter templates above can be found at S21 No.1 of 2022 folder at Q2 xii 20211202 Letter Template A No Issues (Alive), Q2 xii 20211207 Letter Template for SCRR, Q2 xii 20211209 Letter Template A No Issues (RIP), Q2 xii 20211209 Letter Template B Records To Be Reviewed (Alive), Q2 xii 20211209 Letter Template C Requires Further Review, Q2 xii 20211222 Letter Template B Records To Be Reviewed (RIP) and Q2 xii 20211222 Letter Template for Post Clinic Review Updates. Some

contextual information concerning the Public Inquiry contained in these letters was found to have errors within it, for which the Trust has formally apologised to the Inquiry. The relevant correspondence is located in S21 No.1 of 2022 folder at *Q2 xii Letter of Apology to Christine Smith QC*. Letters of apology and correction are currently being prepared for issue to patients.

xiii. In respect of each of the 67 patients who met the criteria for SAI and whose case has or is now being considered by way of SCRR, provide all of the material which was taken into account when determining that a SCRR was necessary as well as the resultant SCRR forms.

An account of the SCRR process is provided at Q8 below and, in respect of screening in/out in particular, also in the response to Section 21 Notice No. 1A of 2022.

Documents considered in respect of the patients who were screened 'in' for SCRR can be located in *S21 1 of 2022 Urology Screening Outcome Sheets*, Confirmed SCRR No SCRR forms have yet been completed. 40 forms are currently in progress by Subject Matter Experts with the delivery of the first of these expected in April 2022. These can be provided to the Inquiry once available.

xiv. Copy of the letter and enclosure sent to patients who have been identified for SCRR (as per answers 21(c) and (d) of No. 4 / 2021).

Copies of the letter and enclosures sent to patients who have been identified for SCRR (as per answers 21(c) and (d) of Section 21 Notice No. 4 of 2021) can be located in S21 1 of 2022, Patient SCRR letters. It has been brought to our attention for the first time on the 24th March 2022 that there is an alleged inaccuracy in one of these letters and we are currently undertaking an investigation and review into this matter. The letter notifying the Trust of the inaccuracy is located in S21 No.1 of 2022 folder at Q2 xiv

and Q2 xiv Item 4592 - re Treatment Southern Trust Urology
Department 21 March 2022

xv. Any report or other documentation arising from the Bicalutamide audit as referred to in the minutes of the Urology Assurance Group of 4th December 2020 (per answer 27(c) of No. 4 / 2021).

A copy of the Bicalutamide audit commencement form and narrative of audit outcome is presented below.

Bicalutamide Audit

Following identification that patients had been prescribed low dose (50mg) Bicalutamide outside of licenced indications or standard practice (as a result of the SAIs conducted by Dr Dermot Hughes) contact was made with the Trust Director of Pharmacy, Dr Tracey Boyce, with a view to identifying patients currently receiving a prescription for Bicalutamide 50mg.

The data was provided on 22nd October 2020. The data provided identified all HSC Trusts' patients who received a prescription for Bicalutamide (any dose) between March and August 2020. For each patient their Health and Care Number, Bicalutamide prescription, number of prescription items and quantity (count of tablets) was provided.

Audit Aims

To ensure that the anti-androgen medicine 'Bicalutamide' has been prescribed as licensed and in line with NICE guideline NG131 Prostate Cancer: Diagnosis and Management located in S21 No. 1 of 2022, Q2 xv Bicalutamide Clinical Audit Form.

Audit Objectives

- To ensure that where Bicalutamide is prescribed only where indicated and as per licensed usage
- To ensure that where Bicalutamide is prescribed this is prescribed in the correct therapeutic dosages
- To ensure that patients prescribed Bicalutamide is appropriately reviewed as part of the patients ongoing care
- To ensure that any deviations from prescribing guidance is based on sound evidence based clinical rationale

Audit Standards

Audit Criteria	Target	Exceptions	Source of Evidence
Bicalutamide prescribed as per indicated conditions in NICE NG131	100%	Clinical rationale f deviation from guidance	NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Therapeutic doses of anti-	100%	Discussions with patient	NICE guideline NG131 Prostate
androgen monotherapy with		/ Clinical rationale	Cancer: Diagnosis and
bicalutamide are prescribed at			Management
recommended dose (150 mg).			

Audit Methodology

The following audit methodology will be followed:

- HSCB to provide information on primary care prescriptions of the medication Bicalutamide
- Southern Health and Social Care Trust patients to be identified and a consultant led review of prescribing to take place to identify prescribing of Bicalutamide that is outside of that prescribed in NICE guideline NG131 Prostate Cancer: Diagnosis and Management

A review of each patient's electronic care record, for patients from the Southern, Western and Northern Trust areas (as patients from these areas urological care was provided by the Southern Trust urology service at this time) was conducted by Mr Haynes in order to determine if the prescription of Bicalutamide 50mg was in line with the licenced indications / standard practice / guidelines. 'Standard practice' being defined as;

- Short course Bicalutamide 50mg OD to cover testosterone flare immediately before and after first LHRH analogue (hormone) injection
- Bicalutamide 50mg in addition to LHRHa (hormone) as combined androgen blockade (which may be as primary Androgen Deprivation Therapy for metastatic disease or as addition to LHRHa monotherapy upon development of a rising Prostatic Cancer Marker, Prostate Specific Antigen).
- In line with British Association of Urological Surgeons (BAUS) COVID-19 pandemic response guidelines during initial wave of COVID-19.
- Where clinical justification of low dose use given in correspondence.

Low Dose Bicalutamide Prescribing (50mg)

A total of 466 patients was identified from the Western, Northern and Southern Local Commissioning Group areas as having received a prescription for Bicalutamide 50mg.

34 of these patients were identified as being on the correct treatment as determined by the clinical indications above. 2 patients had been commenced on the medication by services outside of NI Urology (1 by GP, 1 in in 2005 and continued following move to NI).

Of the remaining 32 patients 31 had been commenced on the low dose Bicalutamide by Mr O'Brien. 1 patient had been on combined androgen blockade (LHRHa and 50mg bicalutamide) and had been switched to intermittent treatment by another Southern Trust Consultant Urologist. However only the LHRHa had been stopped at the time of this switch.

This patient has since been reviewed by the oncology team and the Bicalutamide discontinued. From the remaining 31 patients, 2 were subjects of 2020 SAIs (conducted by Dr Dermot Hughes) and had already been reviewed and management changed.

High Dose Bicalutamide Prescribing (150mg)

A review of patients' medication regarding the prescribing of Bicalutamide 150mg was undertaken. This was to determine if additional patients currently receiving the 150mg dose had previously been treated with low dose Bicalutamide as this practice had been identified in some patients and to ensure this use was in line with recognised indications. In addition for those patients receiving monotherapy alone records were assessed to see if Multi-disciplinary Meeting (MDM) recommendations / curative treatment options had been discussed / offered to the patient.

Recognised indications for Bicalutamide 150mg were defined as;

- · As adjunctive treatment for patients receiving radical radiotherapy.
- As monotherapy for patients with PSA recurrence following previous radical treatment (External Beam Radiation Therapy (EBRT) or radical prostatectomy)
- As monotherapy for patients having failed watchful waiting or electing primary ADT alone for non-metastatic disease and wishing to preserve erectile function.
- In patients receiving ADT alone for metastatic prostate cancer or having failed watchful waiting, who wish to maintain erectile function (in line with NICE guidance / comment re reduced efficacy in metastatic disease).

A total of 298 patients were identified from Northern, Western and Southern Trust areas as having received Bicalutamide 150mg during the time period.

- 26 patients, all of whom had their prostate cancer treatment initiated by Mr O'Brien were identified with concerns.
- 1 patient had already been identified and his care subject to an SAI.
- 1 patient was prescribed Bicalutamide monotherapy for metastatic disease with no evidence of discussion of reduced efficacy of treatment.
- 9 had initially been treated with low dose Bicalutamide which had then been increased to 150mg by Mr O'Brien.
- 21 patients there was no evidence of discussion of MDM recommendations of radical treatment or evidence of discussion of watchful waiting as an alternative to hormone manipulation.

Where patients (from both groups) were identified as requiring management changes they were offered a review as an outpatient by a Consultant Urologist where a discussion of clinical management to date was held and recommendations regarding ongoing management were made, along with MDM discussions and referral to other teams as required.

As far as possible these consultations were supported by members of the urology Clinical Nurse Specialist team and a clinical pharmacist. Ongoing follow-up has continued under the care of the reviewing Consultant Urologist.

While in the process of conducting this audit many patients' care was assessed. A detailed review of their entire urological care was not performed and it is possible as work continues additional concerns regarding historic care delivery may be identified.

Documentation supporting this is located in S21 1 of 2022, Bicalutamide Database			

Answers 3 and 4

3. State precisely the reasons for the delay between the decision to instigate a Lookback Review in October 2020, and the commencement of that Review in March 2021.

Although Lookback review formally commenced in March 2021 there was no delay in the review of patients' treatment and care in the period between October 2020 – March 2021. The Lookback Review commenced formally in March 2021 following the agreement of the Patient Review Form with both the HSCB and Department of Health (email correspondence located in S21 No.1 of 2022 folder at Q3 Patient Review Forms 27 01 2021, Q3 Patient Review Forms 27 01 2021 Email, Q3 Patient Review Forms 27 01 2021 Email v2, Q3 Patient Review Forms 27 01 2021 Email v3, Q3 Patient Review Forms 27 01 2021 Email, Q3 Patient Review Forms 09 02 2021, Q3 Patient Review Forms 11 02 2021 Email, Q3 Patient Review Forms 11 02 2021, Q3 Patient Review Forms 01 03 2021 Email, Q3 Patient Review Forms 11 02 2021, Q3 Patient Review Forms 01 03 2021 Email, Q3 Patient Review Forms 01 03 2021, Q3 Patient Review Forms Email 03 03 2021, Q3 Patient Review Forms 03 03 2021). In the interim period immediate actions were prioritised and patients were reviewed from October 2020. These included the following:

Patients reviewed who received Bicalutamide therapy

The Bicalutamide audit undertaken in November 2020 resulted in 38 patients requiring a face to face appointment to adjust their prescribed medications. These patients were subsequently reviewed during November and December 2020. Further detail of this audit is contained in 2.xv above.

Information Line Patients

The Trust established a dedicated urology patient information line in October 2020. 12 patients who contacted this service required a face to face review.

Review Backlog Relating to Mr O'Brien

25 patients who were previously under the care of Mr O'Brien and were on an outpatient review waiting list were reviewed via telephone.

Oncology backlog patients reviewed by an independent sector provider

Mr Patrick Keane (employed Orthoderm) was contracted to support the review of oncology patients. Between the 3rd November 2020 and 22 December 2020 the following took place:

- 215 management plans were been received back from Independent Sector
 - 139 of these have been referred back to the care of their GP
 - **34** were sent back to Trust for further care/follow-up.
 - **39** were reviewed at Trust's Urology MDT
 - 3 referral to Oncologist in Belfast Trust for Urgent reassessment of treatment

Answer 6

4. Has the report of the RCS Invited Review been finalised? If not, what steps have been taken by the Trust to expedite the production of this report, and when is it anticipated that the report will be available to the Trust?

All correspondence with the Royal College of Surgeons relating to the conduct of the invited review prior to 7th October 2021 is included in Section 21 Notice 2A of 2021 Item Reference 76(vi). The report from the Royal College of Surgeons has not yet been finalised. The Trust has contacted the Royal College of Surgeons on several occasions to expedite the production of the report. Copies of email exchanges have been included in discovery relating to Section 21 Notice 2A of 2021 Item 76(vi) as noted above.

The initial request seeking information on the expected report delivery date was sent on the 8th October 2021. The Royal College of Surgeons has informed the Trust that they estimate that their final report will be ready later in April 2022 following correspondence on the 24th February 2022 and reiterated on 24th March 2022 by email these are located in S21 No.1 of 2022 folder at Q4 Ltr from Dr O'Kane re invited review and Q4 Ltr to Dr O'Kane re invited review and copies of email exchanges have been included in discovery relating to Section 21 Notice No.2a of 2021, Item 76(vi) located in Relevant to MDO, Evidence after 4 November MDO, reference no 76 (vi) folders RCS MOK and RCS SW.

Answer 7

5. In what specific ways has the conduct of the HSCB fortnightly meetings changed as a result of the Lookback Guidance issued by DoH in July 2021?

The HSCB fortnightly meetings are led by the HSCB. Trust staff participate in these meetings along with PHA. At the point of introduction of the 2021 Lookback Guidance being introduced in draft and then agreed, the terms of reference for the HSCB Oversight group were reviewed and updated. The original terms of reference are attached at Relevant to PIT, Evidence after 4 November, reference 48, attachments 28, 29 and 30. The decision making process and agreement to change the terms of reference is set out below.

Relevant to PIT – Evidence Added or Renamed 19 01 2022 – No 76 – minutes and agendas with attachments – HSCB - 20211028 Uro HSCB SHSCT Agenda-mtgs

Relevant to PIT – Evidence Added or Renamed 19 01 2022 – No 76 – minutes and agendas with attachments – HSCB - **20211125 Uro HSCB SHSCT Agenda-mtgs**

Relevant to PIT – Evidence Added or Renamed 19 01 2022 – No 76 – minutes and agendas with attachments – HSCB - 20220106 Uro HSCB SHSCT Agenda-mtgs

At the time of submission of the Trust's response to Section 21 Notice No.4 of 2021, it was envisaged that the Trust would chair this meeting. However, in the interim it has been recognised that the Chair should remain with the HSCB and the originally agreed format was continued. The format of these meetings therefore has not in fact changed. The minutes below outline the discussion about whether the revised Lookback Guidance would change the format of these meetings and the final consensus was that, in essence, these meetings would remain the same.

Date	Action
28.10.2021	HSCB Meeting Minutes - Terms of Reference and Name for Rebranded Co-ordination Group going forward. HSCB advised the draft Terms of the renamed HSCB chaired Co-ordination Group. Reference for the rebranded group going forward had been circulated for comments called the Southern Urology Co-ordination Group.
25.11.2021	HSCB Meeting minutes - Melanie McClements, Director of Acute Services noted that in discussions at earlier meetings it had been suggested that the Lookback Guidance recommended this meeting would be chaired by her as Director of Acute Services. However, she noted that having read the guidance in great detail, she was unable to find this reference to responsibility for chair of these meetings as Director of Acute Services. Melanie also noted the governance aspect of the meeting being chaired by Trust staff. HSCB agreed to follow this up and respond.
06.01.2022	UAG Meeting minutes - Melanie McClements, Director of Acute Services advised that the initial Lookback group had been chaired by Internal Directors but this was no longer relevant to this wider group remit and therefore not applicable. HSCB confirmed that they would continue to Chair the group if everyone was in agreement. Dr O'Kane noted the difference in executive directors and management team and noted that it was important to have the meetings chaired by someone separate from the Trust and therefore more accountable. It was therefore agreed that HSCB would continue to chair meetings going forward.

Answers 8 and 12

6. Provide the Inquiry with all relevant statistics, preferably in tabular form, to reflect the current findings of the Lookback Review. Without being prescriptive it is expected that statistics shall be made available concerning the following: number of cases considered; number of patients found to be on the correct management plan; number of patients found to have been provided with sub-optimal care; number of patients moved to a different management plan.

Please see below table providing details regarding the number of patients considered, number of patients found to be on the correct management plan; number of patients found to have been provided with sub-optimal care; and number of patients moved to a different management plan. This data is taken from the master spreadsheet which is updated and forwarded to the USI monthly, next version due to be disclosed to the Inquiry by the 31st March 2022.

Туре	Number of Patients	Details of Patient Cohort	Comments
Correct Management	1040	Patients that had Virtual Record Review, including any category of Oncology, Emergency, Review Backlog, Elective Waiting List, Discharged to GP or seen at Outpatient Appointment under AOB	Includes Alive and Deceased Patients
Sub Optimal Care	483	Suboptimal deemed as missing diagnostics, on prolonged antibiotics, lack of communication, delayed action of scans/ results but all resulted in no harm to patient. Also includes patients screened OUT of SCRR	This number will continue to change as reviews at clinics are still ongoing and interna screening continues
Required New Plan	48 (part of 483 Sub- Optimal Care Group above)	New plan deemed as patients being removed from waiting list for surgical procedure, different pathway of treatment or referral to another service/team/ speciality or gaps in the diagnostic/ treatment pathway	This number will continue to change as reviews at clinics are still ongoing and interna screening continues
Patients Still To Be Seen at Clinics	47	These are the remaining patients on Review Backlog/ Elective Waiting List & Information Line Contact who will be seen by the 3 In House Consultants completing additional review clinics	This equates to approx 6 sessions. Does not include the patients that cancelled, DNA
Records Still to Be Screened	402	These are records screened initially by Prof Sethia but were screened out. For purpose of robust process all these records are being screened through the internal screening process	These are patients that were seen by another Consultant between 2019 and 2020 bu won't have had a review form completed. Internal screening process ongoing a per Governance direction to ensure all patients through the same process.
SCRR & SAI Patients	53 SCRR & 9 SAI (not part of the 483 suboptimal care group above as have previously been identified)	Identified SCRR patients and SAI Patients	·

Answer 11

7. What was the process applied for the Lookback Review in Urology? If this is set out in a written document, please provide a copy of the same.

The Trust does not have a separate formal written process document regarding the Lookback Review in Urology. The Trust is guided by the Regional Guidance for Implementing a Lookback Review (2021). The Trust is in the process of developing a Standard Operating Procedure which is not yet available. However the process of the review can be described as follows.

The purpose of the Lookback Review is to ensure that all patients who had been under the care of Mr O'Brien have a review to ensure that they are on the correct management plan and to identify any patients who may not have received optimal care and address this and advise the patient of the issues.

All patients under Mr O'Brien's care from January 2019-June 2021 were included except for those new outpatient referrals that GP's sent into the Urology Service that were directly named to Mr O'Brien but were never seen by him.

During the initial patient scoping exercise a number of patients were identified as meeting the threshold for a serious adverse incident. At a meeting attended by:

Dr Maria O'Kane - Medical Director

Dr Damian Gormley – Deputy Medical Director

Mr Mark Haynes – Consultant Urologist/Associate Medical Director for Surgery

Mrs Martina Corrigan – Head of Urology

Mr Stephen Wallace – Assistant Director for Systems and Quality Assurance

The clinical priority was agreed for the cohorts listed below and the Lookback oversight group was advised to prioritise these patient groups :

Type of Review	Method of Review	Personnel Involved
Patients on Oncology Review Backlog waiting	Face to Face consultations	Mr Patrick Keane
list – to identify if they were on the correct	In Independent Sector	
management plan		
Complete		
Patients who had been discussed at Oncology	Meeting via Zoom	Prof Krishna Sethia (Chair)
MDM to make sure they had had follow-up	_	Mr Mark Haynes
Complete		Mr Darren Mitchell
		Kate O'Neill – CNS
		Leanne McCourt – CNS

		Sinead Lee – Cancer Tracker
Histopathology results of patients who had had	Virtual review by electronic record	Mr Mark Haynes/ Dr
a biopsy done to ensure their result had been		Darren Mitchell/ Kate
actioned – Complete		O'Neill and Leanne
	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	McCourt
Review of patients on Bicalutamide - Complete	Virtual/Telephone and face to face consultations	Mr Mark Haynes
Patients who had had a radiology test and where the result had not been signed off electronically to ensure they were on the correct management plan and that their result had been actioned. – Complete	Remote electronic record review	Prof Krishna Sethia
Patients that were on the Review Outpatient Backlog list to review the current management plan and if required to make changes in line with best practice with a new consultant. Ongoing	Virtual/Telephone and face to face consultations	Mr Mark Haynes/ Mr Michael Young/ Mr John O'Donoghue
Patients that are currently waiting on Mr O'Brien's elective waiting list to ensure that they still need surgery and to put a management plan in place with a new consultant Complete	Virtual/Telephone and face to face consultations	Core Urology Team of Consultants
Patients who had contacted the information line with questions/issues/concerns – an acknowledgement letter was sent to these patients/families and follow-up is being currently put in place. Complete	Virtual/Telephone and face to face consultations	Core Urology Team of Consultants

Answer 21(a)

8. What was the criteria applied and process undertaken for the Structured Clinical Record Review in Urology? If this process is set out in a written document, please provide a copy of the same.

1. IDENTIFICATION AND SCREENING OF PATIENTS FOR SCRR

How were patients initially identified

The identification of the original 77 patients for SCRR screening came from the following sources

- 25 patients from clinic or telephone reviews,
- 12 patients from desktop virtual reviews
- 40 patients from review backlog reviews and the Bicalutimide exercise that Mr Haynes completed (please refer to xv for further information).

How Screening was Undertaken

The initial clinical record review was undertaken by a range of staff. Once the patient was identified as potentially reaching the threshold for SCRR, they were brought to the SCRR internal screening meeting which was attended by the following persons:

- Ronan Carroll (Assistant Director, Surgery and Elective Care),
- Mr Mark Haynes (Divisional Medical Director Urology Improvement, Consultant Urologist)
- Dr Raymond McKee (Divisional Medical Director, Anaesthetics, Theatres and ICU Consultant Intensivist)
- Dr Damian Scullion (Deputy Medical Director, Appraisal and Revalidation, Consultant Anaesthetist),
- Mr Ted McNaboe (Divisional Medical Director, Surgery and Elective Care, Consultant ENT Surgeon)
- Chris Wamsley (Head of Acute Clinical Governance)
- Sarah Ward (Head of Clinical Assurance),
- Carly Connolly (Acute Clinical Governance Manager)
- David Cardwell (Acute Clinical Governance Manager)
- Dawn King (Acute Clinical Governance Manager)
- Roisin Farrell (Acute Clinical Governance Officer)

Collectively the detail recorded on the patient review form was considered and discussed along with the patients NIECR record to establish a timeline of the patients treatment pathway, treatment(s) delivered, Multidisciplinary Meeting discussions and recommendations and results of relevant associated blood / tissue samples and radiology reports. Discussions took place to decide if the patient came to harm or their outcome was negatively affected by the care delivered and if threshold for SCRR reached.

The screening in or out process is addressed in more detail in my response to Section 21 Notice No.1a of 2022.

2. PROCESS FOR CONDUCTING SCRRS

In terms of the process undertaken for the Structured Clinical Record Review as agreed by the UAG following identification this is set out below. Proposal documents including those that have

been superseded are also attached. Internal communications regarding the decision to progress with the SCRR process including legacy documents are also provided as attachments

Relevant Attachments

- Email dated 20220128 Confirmation from Trust Chief Executive Mr Shane Devlin to commence SCRR process
- Proposal for Structured Clinical Record Review V1
- Proposal for Structured Clinical Record Review V2
- Proposal for Structured Clinical Record Review March 2022
- Draft Timeline for Delivery of SCRR October 2021 (This document is currently being revised in light of the change in timescales)
 Located in S21 No.1 of 2022 folder at Q8 220128 Email RQIA Review of SCRR Process, Q8 20220217 Proposal for SCRR, Q8 20220217 Proposal for SCRR 1, Q8 20220217 Proposal for SCRR 2, Q8 20220217 Proposal for SCRR Timeline, Q8 20220217 Proposal for SCRR Timeline 1, Q8 20220217 Proposal for SCRR Timeline 2, Q8 20220217 Proposal for SCRR Timeline 3

Patients Identified as Requiring an SCRR

When a patient has identified as requiring an SCRR the Acute Governance Team conduct two actions.

- Contact the patient (initially by telephone call from a member of the family liaison service and then in writing) to explain what has happened and what the next steps are (correspondences have been provided as part of No.1a of 2022 response)
- The Acute Governance Team collate the hard copy patient notes and electronically scan these to the Trust 'Egress' secure electronic storage system.

Identification of Consultant Urologist Subject Matter Experts (SMEs) to conduct SCRRs

The Trust has via the British Association of Urological Surgeons (BAUS) sought to identify Subject Matter Experts who have the training, knowledge and experience in applying Structured Judgement Review methodology to support the conduct of the SCRR process. The identification of SMEs via BAUS was initially proposed to ensure that Trust clinicians remained available to undertake lookback work. Once an SME has been identified a period of due diligence that takes place, this comprises of the following:

- Introductory Email (sample attached)
- SME to complete Data Protection and Confidentiality Agreements (sample attached)

- Trust review of GMC record to ensure the SME is of Good Standing (sample attached)
- A letter of indemnity provided by the Trust to underwrite the SMEs participation in this work (sample attached)
- A role description of the work required (attached)
- Copy of the Structured Clinical Record Review Document (attached)
- A telephone conversation with the Trust Deputy Medical Director Governance, Safety and Quality Improvement
- Permissions granted for SME to access Trust electronic systems including Egress and NIECR electronic patient records.

Relevant Attachments

- 20221216 Sample Introductory Email
- 20210911 Sample Letter of Indemnity
- Sample Confidentiality Agreement
- Sample Data Sharing Agreement
- Sample GMC Good Standing Record
- Sample Role Description
- Structured Clinical Record Review Engagement Document August 2021
- Structured Clinical Record Review Engagement Document March 2022

Located in S21 No.1 of 2022 folder at *Q8 20211216 Southern Trust Structured Clinical Record Reviews*, *Q8 20210911_Ltr* Personal Information redacted by the USI __indemnity, *Q8 Confidentiality Agreement PHR*, *Q8* Personal Information redacted by the USI SHSCT Data Sharing, *Q8* Personal Information redacted by the USI 4103419, *Q8 Independent Consultant Urology*, *Q8 Structured Clinical Record Review Engagement*, *Q8 SCRR Form*, *Q8 Structured Clinical Record Review Engagement* 1, *Q8 SCRR Form* 1.

Conducting of SCRRs

The SCRR process utilises the underpinning principles and methodology found in the Structured Judgement Review (SJR) Process as created by the Royal College of Physicians (attachments provided). Each SME has / will be provided with 10 patients with which to conduct a SCRR and the following documentation:

 National Mortality Case Record Review Programme - Frequently Asked Questions Document (Structured Judgement Review Methodology, Royal College of Physicians 2019) (attached)

- National Mortality Case Record Review Programme Guide for Reviewers (Structured Judgement Review Methodology, Royal College of Physicians 2019) (attached)
- A Description of the SCRR process (attached)
- A copy of the SCRR form (attached)
- A summary of the exact issue identified via screening

Each SME is required to complete the SCRR form for each of the 10 charts issued and return each completed form to the Trust.

Relevant Attachments

- National Mortality Case Record Review Programme Frequently Asked Questions
 Document (Structured Judgement Review Methodology, Royal College of Physicians
 2019)
- National Mortality Case Record Review Programme Guide for Reviewers (Structured Judgement Review Methodology, Royal College of Physicians 2019)
- Copy of a Role Description for the SME's work
- A copy of the SCRR form
 Located in S21 No.1 of 2022 folder at Q8 NMCRR FAQs 2019, Q8 NMCRR Guide for Reviewers 2019, Q8 Structured Clinical Record Review Engagement, Q8 SCRR Form, Q8 20210930 Appendix 6a Summary of Patients (Sept 21) AOB

Communication with Patients of SCRR Outcomes

The Trust will write formally to patients with details of the outcome of their individual SCRR when available.

Quality Assurance of the SCRR Process

Although Structured Judgement Review methodology has been validated by the RCP the SCRR process itself has not been. The Trust approached the Department of Health to request RQIA provide a quality assurance review of the process. Correspondence regarding this request and RQIA and Department of Health responses are attached. RQIA are currently (as of 21st March 2022) developing a methodology to progress this work.

The Trust also formally approached the Royal College of Surgeons to undertake a quality assurance review of the SCRR process however the College formally replied to say this is not work that they would consider under their Invited Review Service.

Relevant Attachments

- Email Correspondence dated 20220209 Email correspondence with Department of Health to request RQIA review of SCRR process
- Letter dated 20220220 Letter to RQIA requesting Quality Assurance Review of SCRR Process
- Letter dated 20220302 Response to Trust re Quality Assurance Request
- Email dated 20211126 Re Southern Health and Social Care Trust Northern Ireland

Located in S21 No.1 of 2022 folder at Q8 Reply to Ltr RQIA SCRR Review 020322, Q8 20220220_Ltr RQIA SCRR Review, Q8 20211126 Re SHSCT and Q8 20200209 FW RQIA Review of SCRR Process

Thematic Analysis of SCRR

A thematic analysis of SCRR outcomes will be undertaken by Mr Hugh Gilbert, Consultant Urologist and member of BAUS upon completion of the initial cohort of SCRRs (those referred to in No.1a of 2022 response). Mr Gilbert will be conducting the thematic review in a personal capacity.

Current Status of the SCRR Process

The Trust has contacted 12 SMEs as identified by BAUS. Of these SMEs 4 currently have progressed to a stage to undertake reviews.

Currently Undertaking Reviews	4
Formally Withdrawn	2
No Follow-up Responses to	5
Communication	
Due Diligence In-Progress	1

Relevant Attachments

Email Correspondence dated 20220315 – Email to BAUS SME Coordinator regarding SME Status, located in S21 No.1 of 2022 folder at Q8 2020315 Re SHSCT-Subject Matter Expert

To date (21st March 2022) 40 SCRRs (10 per SME) have been issued for completion. The Trust has not yet received returned forms from SMEs. The first of these are expected in April 2022.

Independent Sector Providers

In an attempt to increase capacity for processing SCRRs the Trust has commenced engagements with Independent Sector Providers to explore if additional capacity (SMEs) can be gained to support the SCRR process if required.

Answer 21(b)

9. Explain the factors which were taken into account during the screening process which led to the decision that 8 patients (out of the 75 originally identified) need not be included in the SCRR process, and provide all relevant material in support of the decisions made in each of these 8 cases.

This matter is addressed in my response to Section 21 Notice No.1A of 2022

Answer 22

10. Confirm how many of the remaining 503 patients referred to have now been reviewed. If applicable, state the reason for any delays in reviewing this cohort of patients and state the approximate date by which it is anticipated that the work of the Lookback Review will have been completed in respect of all patients originally identified.

In December 2021 there were 503 patients who required their care reviewed, as until then, their care had not been included in the previous reviews of 2095 patients. In the course of validation we identified 20 further patients to join these lists bringing this total to 523 patients requiring review. As of the 24th March 2022, there are 47 patients of these 523 still to be reviewed and it is anticipated all of these remaining patients will have an appointment by the end of April 2022.

Statemer	t of Truth			
	nat the facts stated in thi	is witness stateme	ent are true.	
Signed:	Personal Information redacted by the	usi		
Date: 28 th	March 2022			

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.

Section 21 Number 1 of 2022

Table of Attachments

Attachment Number	Document Name
1	Q2 iii Meeting Notes 23102020
2	Q2 iii Interim SAI Report
3	Q2 iv Meeting Notes 15 12 2020
4	20201105 HSCB mins
5	Q2 vi Independent Urology Consultant JD
6	Q2 vi 20201127 Ltr to Prof Sethia
7	Q2 vi Data Sharing Agreement
8	Q2 vi Confidentiality Agreement KKS
9	Q2 vi 20201215 Re Correspondence
10	Patient Correspondence
10a	Q2 vi 20210911_Ltr Mr Personal Information redacted by the uslindemnity
11	Q2 ix 20210930-HSCB mins ref risk assessment follow-up discussion
12	Q2 ix 20210930-HSCB mins risk assessment discussion
13	Q2 ix Regional Guidance for Implementing a Lookback Review Process Draft 5
14	Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v2
15	Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v3
16	Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v4
17	Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v5
18	Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v6 27 oct 21
19	Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST v7 29 oct 21
20	Q2 ix Regional Guidance for Implementing a Lookback Review risk template ST 8 Sept 2021 v1
21	Q2 x 20200224 Response Ltr from RCS
22	Q2 x 20210730 - E RCS - Review planning
23	Q2 x 20210908 - E RCS ENG IRM review planning
24	Q2 x 20211115 - E Urology invited services review
25	Q2 x 20211221 - E RCS Eng IRM Review
26	Q2 x 20220114 - E RCS ENG IRM Review
27	Q2 x 20220220 Ltr from Dr O'Kane re invited review
28	Q2 x Email from RCS Eng IRM Review
29	Q2 xi Urology Patient Review Form 4 questions
30	Q2 xi 20210208-UROLOGY PATIENT REVIEW FORM
31	Q2 xii 20211202 Letter Template A No Issues (Alive)
32	Q2 xii 20211207 Letter Template for SCRR
33	Q2 xii 20211209 Letter Template A No Issues (RIP)
34	Q2 xii 20211209 Letter Template B Records To Be Reviewed (Alive)
35	Q2 xii 20211209 Letter Template C Requires Further Review
36	Q2 xii 20211222 Letter Template B Records To Be Reviewed (RIP)
37	Q2 xii 20211222 Letter Template for Post Clinic Review Updates
38	Q2 xii Letter of Apology to Christine Smith QC
39	Urology Screening Outcome Sheets
40	Patient SCRR letters
41	Q2 xiv

	Patient 38
42	Q2 xiv Item 4592 - re Treatment Southern Trust Urology
	Department 21 March 2022
43	Q2 xv Bicalutamide Clinical Audit Form
44	Bicalutamide Database
45	Q3 Patient Review Forms 27 01 2021
46	Q3 Patient Review Forms 27 01 2021 Email
47	Q3 Patient Review Forms 27 01 2021 Email v2
48	Q3 Patient Review Forms 27 01 2021 Email v3
49	Q3 Patient Review Forms 27 01 2021 v3
50	Q3 Patient Review Forms 09 02 2021 Email
51	Q3 Patient Review Forms 09 02 2021
52	Q3 Patient Review Forms 11 02 2021 Email
53	Q3 Patient Review Forms 11 02 2021
54	Q3 Patient Review Forms 01 03 2021 Email
55	Q3 Patient Review Forms 01 03 2021
56	Q3 Patient Review Forms Email 03 03 2021
57	Q3 Patient Review Forms 03 03 2021
58	Q4 Ltr from Dr O'Kane re invited review
59	Q4 Ltr to Dr O'Kane re invited review
60	Q8 220128 Email RQIA Review of SCRR Process
61	Q8 20220217 Proposal for SCRR
62	Q8 20220217 Proposal for SCRR 1
63	Q8 20220217 Proposal for SCRR 2
64	Q8 20220217 Proposal for SCRR Timeline
65	Q8 20220217 Proposal for SCRR Timeline 1
66	Q8 20220217 Proposal for SCRR Timeline 2
67	Q8 20220217 Proposal for SCRR Timeline 3
68	Q8 20211216 Southern Trust Structured Clinical Record Reviews
69	Q8 20210911_Ltr Mr Personal Information redacted by the uslindemnity
70	Q8 Confidentialy Agreement PHR
71	Q8 Personal Information redacted by the USS SHSCT Data Sharing
72	Q8 Personal Information redacted by the USI 4103419
73	Q8 Independent Consultant Urology
74	Q8 Structured Clinical Record Review Engagement
75	Q8 SCRR Form
76	Q8 Structured Clinical Record Review Engagement 1
77	Q8 SCRR Form 1
78	Q8 NMCRR FAQs 2019
79	Q8 NMCRR Guide for Reviewers 2019
80	Q8 Structured Clinical Record Review Engagement
81	Q8 SCRR Form
82	Q8 20210930 Appendix 6a Summary of Patients (Sept 21) AOB
83	Q8 Reply to Ltr RQIA SCRR Review 020322
84	Q8 20220220_Ltr RQIA SCRR Review
85	Q8 20211126 Re SHSCT
86	Q8 20200209 FW RQIA Review of SCRR Process
87	Q8 2020315 Re SHSCT-Subject Matter Expert

Wallace, Stephen

From: Wallace, Stephen
Sent: 23 October 2020 14:58
To: Wallace, Stephen

Subject: MNOTES - 23.10.2020 11:30am SAI Dermot Hughes

9 cases to date.

Inappropriate androgen deprivation therapy – clear international regional guidance. Should be used with an anti RH drug. Not a lot of logic of prescribing, doesn't benchmark against local or national guidance. How was this not picked up. These are patients with metastatic prostate cancer. Only data is from 2016 – oncology attendance at the MDM is very poor – three different oncologists. May not be able to pick up a trend. One of the safety nets wasn't there. Primary care and pharmacists role in this. These were patients who weren't being given correct treatment. There may be good reason for consultants to act off guidance. MDM focused on initial appointments, less on review on going forward.

Inaction on results, one x-ray. Safety net via trackers required.

Young patient testicular cancer – first 6 weeks. MDM suggested a referral immediately, waited for 2 months. However did that happen. Have to forensically examine the MDM function. SME thinks one directly related to death and another linked wider. Link every patient with Prostate cancer with that consultants name. SME – letters are very full – patients don't seem to have a full understanding of their conditions. If this isn't reflected then this is not an informed decision, if deviation from the pathway informed decision making is crucial.

If full testosterone suppression your prognosis could be worse, this was related to death in one case. Wouldn't be sure it is only one drug, this may be wider for androgen deprivation drugs.

Kidney cancer, SME would have suggested earlier review, patient came to no harm. One case of cancer wasn't added to MDM, need a link with labs as a safety check to the tracker. How we are assured when referrals are to be made they are done esp in time critical cases. Lab attendance at MDM was excellent, though this should happen automatically, list goes to the tracker. There are always cases that will be forgotten about. Some patients didn't have appropriate diagnostic issues were completed. Diagnostic, pathway and prescribing issues. Alert letters have been issued re consultant.

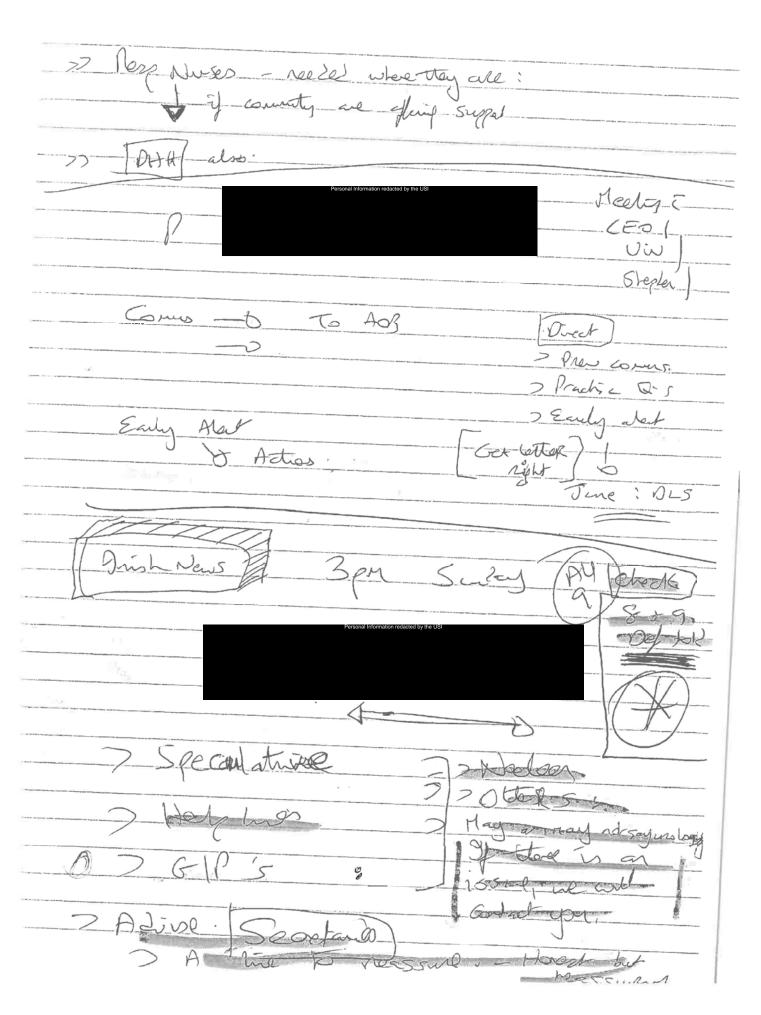
MMcC in confidence – Dermot informed that weekly meetings with the HSCB. DoH and HSCB – may want to release information very soon. We have asked the DoH to consider holding the information release. Not sure if we will be given more time. MMcC aim to is synchronise releases with DoH timelines. MOK – other potential professionals who may be implicated in this – DH potentially 300 prostate cancer in SHSCT, not all metastatic, how many consultant saw. Some staff further downstream must have noted the therapy was bizarre. DH – delay to definitive treatments leading to poor outcomes. Wasn't a culture of bringing patients back to MDM following initial decision making. MMcC – is this different to what happens elsewhere, DH this is different. Usually the treatments are more complex for metastatic cancers, there wasn't ability to provide this in the SHSCT.

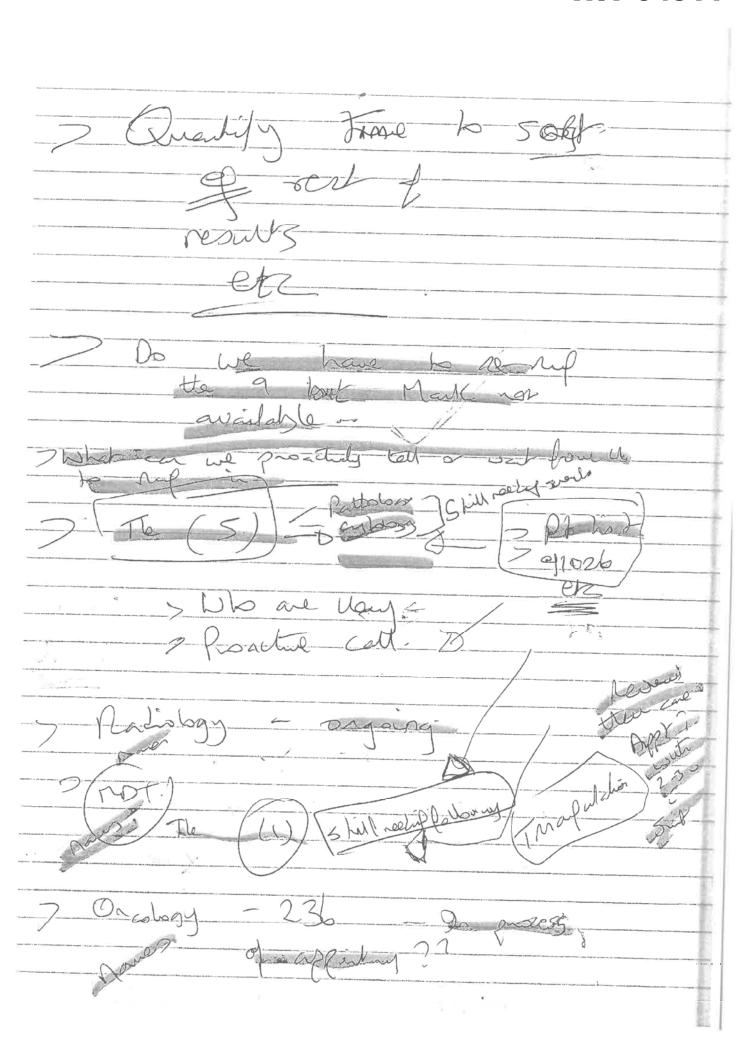
Each MDM timeline will have decisions, will detail who was present. MDM discussions for part of your journey, not for others. Everyone would assume that this would be along pre-agreed pathways. DH – initial thoughts that it should have been the oncologists who pick up on this. SHSCT has been poorly served with oncologists for a number of reasons and is a key part of the safety net not there. DH – need to have a discussion with the team to say where we are. MOK – potential of discussing with the urology team, the potential of stating there is a range of alerts among certain groups of patients.

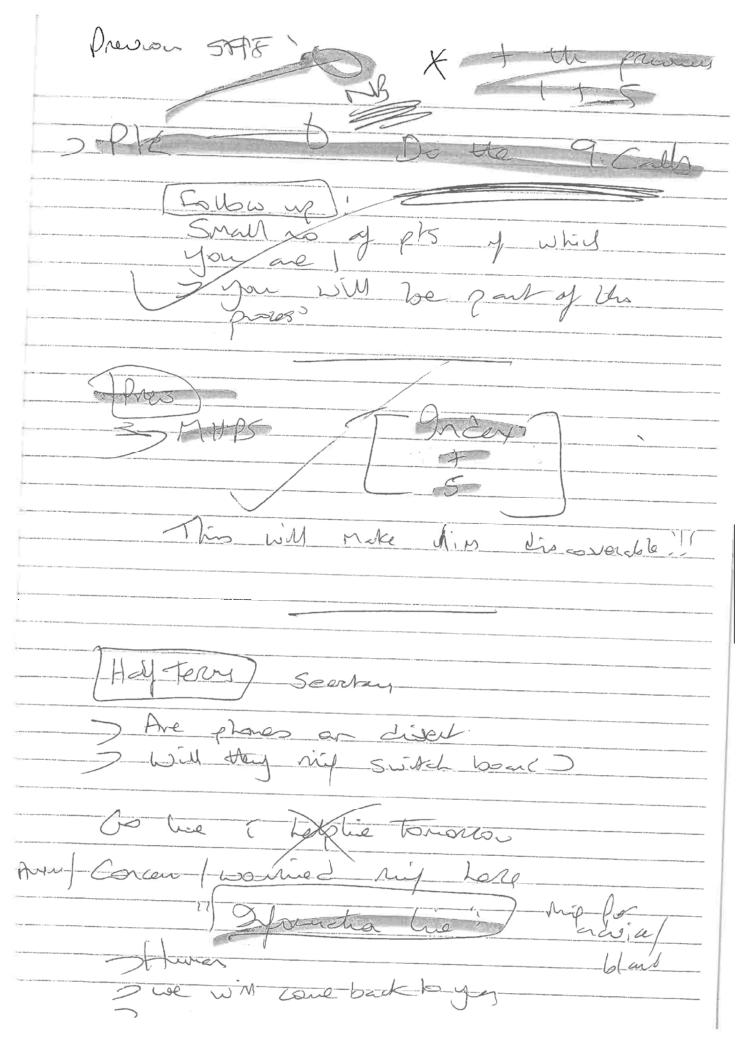
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Progress Report on Level 3 Urology Services Serious Adverse Incidents



Introduction

This paper provides an update on the Level 3 Serious Adverse Incident (SAI) reviews that are being carried out regarding the treatment and care provided by Trust Consultant Urologist who is no longer employed by Health and Social Care Services in Northern Ireland.

SAI Process

In total the quality of care for nine patients who were under the care of Doctor 1 have been identified as meeting the threshold as requiring a SAI review. To ensure a robust and expedient process is conducted to identify learning themes and areas for improvement for all cases is carried out, the Health and Social Care Board (HSCB) and Public Health Agency (PHA) agreed that nine separate SAI's should be conducted supplemented by an overarching SAI report complete with themed recommendations.

The HSCB and PHA agreed that given the similarities between the cases identified and to ensure consistency of approach a single SAI chairperson and nominated panel should conduct each of the SAI's concurrently.

Case Summaries

The table below provides an overview of each of the nine patients identified as part of the SAI review cohort, the table includes details of their clinical summary and current status.

Patient	Clinical summary	Current
details		status
Patient 9	In May 2019 had an assessment which indicated	Alive -
	he had a malignant prostate. was commenced on	Palliative
	androgen deprivation therapy (ADT). Reviewed in July	
	2019 in outpatients and planned for repeat PSA and	
	further review. Patient lost to review and attended	
	Emergency Department in May 2020. Rectal mass	



	investigated and diagnosed as locally advanced	
	prostate cancer.	
Patient 1	was diagnosed with locally advanced prostate	Deceased
	cancer in August 2019. An MDT discussion on 31	
	October 2019 recommended androgen deprivation	
	therapy (ADT) and external beam radiation therapy	
	(EBRT). was not referred for ERBT and his	
	hormone treatment was not as per guidance. Patient	
	commenced bicalutamide. In March 2020 PSA	
	was rising and when restaged in June 2020 had	
	developed metastatic disease.	
Patient 4	Diagnosed with high grade prostate cancer July 2019.	Deceased
	MDM outcome 'commence androgen deprivation	
	therapy (LHRHa), arrange a CT Chest and bone scan	
	and for subsequent MDM review.' MDM	
	recommendations not followed. Patient commenced on	
	bicalutamide. Patient now deceased.	
Patient 3	Diagnosed with penile cancer, recommended by	Palliative
	cancer MDM for CT scan of Chest, Pelvis and	
	Abdomen to complete staging. Patient managed locally	
	by MDT and delay to refer to tertiary centre in Western	
	Trust. Penile Cancers should be managed by specialist	
	team as per NICE guidelines.	
Patient 5	had a right radical nephrectomy March 2019.He	Alive
	had a follow up CT scan of chest abdomen and pelvis	
	performed on 17 December 2019. The indication for	
	this was restaging of current renal cell carcinoma.	
	The CT scan report noted possible sclerotic metastasis	
	in L1 vertebral body. Result was not actioned. Patient	
	contacted with result on 28 July 2020 and further	
	assessment required diagnosed with prostate cancer.	



	Delay in diagnosis due to delay in actioning the CT	
	scan result.	
Patient 2	Patient diagnosed with a slow growing testicular	Alive
	cancer (Seminoma) had delayed referral to oncology	
	and therefore delay in commencing chemotherapy.	
Patient 7	Patient has had a small renal mass since 2017 which	Alive
	was under surveillance by Urology. On the 13	
	November 2019 the patient had a follow up CT renal	
	scan. The report identified an enhancing lesion which	
	had increased slightly in size. There was a delay in the	
	follow up process for cancer care management.	
Patient 8	Patient underwent transurethral resection of prostate	Alive
	(TURP) on 29 January 2020. Pathology reported	
	incidental prostate cancer. There was a delay in the	
	follow up process for cancer care management.	
Patient 6	Patient diagnosed with prostate cancer Gleason 7.	Alive
	MDM 08/08/19- Significant Lower urinary tract	
	symptoms but declined investigations. On maximum	
	androgen blockade - No onward oncology referral was	
	made.	

Identification of Panel Chair

As per Level 3 SAI requirements the Trust has commissioned an external review panel to ensure independence and a robust investigation. HSCB, PHA and patients / families have been informed of the panel membership and have communicated their agreement. The below table provides details of each member.

Panel Member	Role
Dr Dermot Hughes	External independent Chair: Former Medical Director
	Western Health and Social Care Trust. Former Chair of
	the Northern Ireland Cancer Network (NICAN)



Mr Hugh Gilbert	Expert External Consultant Clinical Urologist - Clinical
	Advisor from the British Association of Urological
	Surgeons BAUS
Mrs Fiona Reddick	Head of Clinical Cancer Services (SHSCT)
Ms Patricia Thompson	Clinical Nurse Specialist (SHSCT)
Mrs Patricia Kingsnorth	Acting Acute Clinical Governance Coordinator
	To provide facilitation

Terms of Reference

A full term of reference for the reviews can be found in Appendix 1. The terms of reference have been shared and discussed with each of the patients / families and agreed by the HSCB/PHA.

Family Engagement

Trust engagement with families has commenced and is ongoing, key points are below:

- All families have received an initial phone call to advise of the SAI process.
 Some of the families were made aware of the SAI process previously directly by the clinical team.
- The Chair of the SAI team and the Clinical Governance Coordinator and personally met with all families (with the exception of one who didn't want to meet with the team or be involved in family engagement, however discussions have taken place with his family and the patient wants to wait the outcome of the review).
- The families have been advised about the process, shared terms of reference and told their stories.
- Support in the form of counselling has been provided to those families who wished to avail of the support.



• For those who didn't want to avail of support, they have contact numbers to the clinical governance coordinator who will update them.

Support for Families (Family Liaison)

The Trust is in the process of recruitment of a Family Liaison Officer. The role of this staff member will be to support families through the SAI process including after the report is completed. An appointment is expected to be made at the beginning of January 2021, a full role description is provided in Appendix 2.

Documentation

All requested documentation that has been requested by the panel has been provided:

- Patient Medical Notes have been reviewed and timelines generated for each of the nine patients and shared with the review team.
- The review team have been provided with the appropriate clinical guidelines and protocols.
- NICAN Urology cancer clinical guidelines (2016)
- The Urology MDT Operational Policy
- SHSCT Urology MDT annual report
- NICE: Suspected cancer recognition and referral: site or type of cancer
- Self-Assessment Peer Review document 2017/ 2019
- Leadership and management for all doctors (GMC)

Staff Interviews

The review team are in the process of interviewing relevant staff members and aim for completion in early January. To date interviews have been carried out with the following staff:

- Trust MDM chairperson

Further interviews are scheduled for January 2021 including:

Lead for Cancer Services



- AMD for Urology Services
- Doctor 1

Doctor 1 has been sent a letter from the panel chairperson offering for him to contribute to the process, a response is awaited. The panel have agreed that if a response is not received by 24th December 2020 written questions will be provided to Doctor 1 via his legal team for consideration and response.

Any Early Findings

- To date early learning has identified potential concerns regarding the
 prescribing of anti-androgen therapy (Bicalutamide) at low dose, sub
 therapeutic levels. A review of Bicalutamide prescribing has been undertaken
 and where required patients whose medication has required review has
 commenced.
- Concerns regarding non adherence to regionally agreed pathways
- Concerns regarding non adherence to MDM decisions
- Concerns regarding isolated working with non-use of specialist nurses uniquely resulting in unsupported patient experience
- Concerns regarding non re-referral to MDM when patients deteriorated resulting in non-access of appropriate services

Timescales

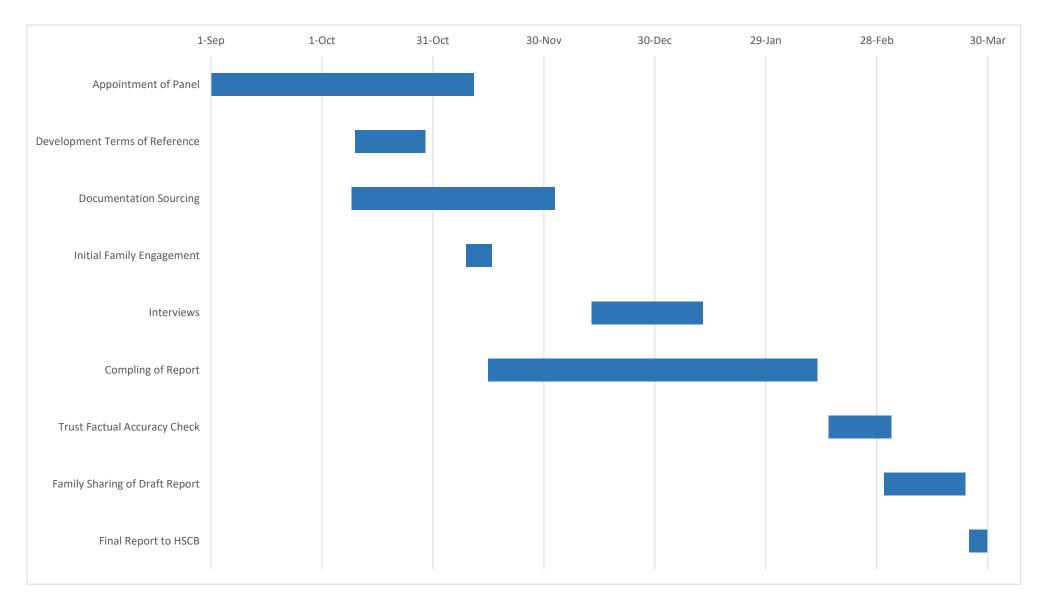
The SAI is currently on target for completion end of January.

- A draft copy of the report will be sent to relevant staff for factual accuracy check a response period is normally two weeks for staff to comment.
- Families will be provided with a draft copy of the reports for comments. A
 period of 3 weeks will be given to families to respond to the report and meet
 with the chair of the panel to discuss the findings and ask for amendments.
- A draft copy of the report will be shared with the HSCB at the same time as the families pending family engagement. Once comments are received and report finalised the completed report will be submitted to the HSCB.



A Gantt chart featuring key milestones is provided below.







Appendix 1 - Terms of Reference

Introduction

The core values of the Southern Health and Social Care Services (Northern Ireland) are of openness, honesty, respect and compassion. In keeping with these values, the Director of Acute Service has commissioned a level 3 SAI review to address the issues referenced above. The draft terms of reference may be amended pending engagement with all affected patients and families.

Purpose of Review

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided.

Scope of Review

As part of an internal review of patients under the care of Doctor 1, a number of patients have been identified as possibly been exposed to increased or unnecessary risk.

Review Team

The proposed review team is as follows:

Chairperson / Lead Reviewer	Dr Dermot Hughes
Independent Consultant	Mr Hugh Gilbert
Urologist	
Cancer Services Lead	Mrs Fiona Reddick
Clinical Nurse Specialist	Ms Patricia Thompson
Clinical Governance Facilitator	Mrs Patricia Kingsnorth



Review Aims and Objectives

The aims and objectives of this review are to:

- To carry out a systematic multidisciplinary review of the process used in the diagnosis, multidisciplinary team decision making and subsequent follow up and treatment provided for each patient identified, using a Root Cause Analysis (RCA) Methodology.
- To review individually the quality of treatment and care provided to each patient identified and consider any factors that may have adversely influenced or contributed to subsequent clinical outcomes.
- To engage with patients / families to ensure where possible questions presented to the review team or concerns are addressed within the review.
- To develop recommendations to establish what lessons are to be learned and how our systems can be strengthened regarding the delivery of safe, high quality care.
- Examine any areas of good practice and opportunities for sharing learning from the incidents.

Review Team Access Arrangements

Through the Review Commissioner, the Review Team will:

- Be afforded the assistance of all relevant staff and other relevant personnel.
- Have access to all relevant files and records (subject to any necessary consent/data protection requirements, where necessary).

Should immediate safety concerns arise, the Lead Reviewer will convey the details of these concerns to the Director of Acute Services / Trust Board (known as Review Commissioner) as soon as possible.

Review Methodology

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to



privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

Recommendations and Implementation

The report, when finalised, will be presented to the Review Commissioner. The Review Commissioner is responsible for ensuring that the local managers responsible for the service where the incident occurred will implement the recommendations of the review report. The Review Commissioner is responsible for communicating regionally applicable recommendations to the relevant services for wider implementation.



Appendix 2 – Service User Liaison Officer

JOB TITLE Acute Service User Liaison Officer

BAND 7

DIRECTORATE Medical Directorate

INITIAL LOCATION Trustwide

JOB SUMMARY

The post holder will have responsibility for management of the proactive liaison service for service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. The post holder will be the key central point of contact between the affected service users, relatives¹ and carers and will ensure they remain fully supported, including pastoral and tangible supports where required, throughout and following any Trust review processes.

The post holder will ensure the Trust maintains a responsive liaison service for patients, relatives, carers at all times. This will include liaising with internal Trust services and external agencies to ensure that appropriate supports are provided to service users and families who may require access.

KEY RESULT AREAS

Provide a central point of contact for service users, relatives and carers who
have had contact with a serious adverse incident or submitted a complaint to the
Trust regarding service user safety. The contact may be in person, by
telephone, e-mail or written correspondence.

¹ The definition of family includes any person(s) who may be affected as a result of a healthcare related incident regardless of their personal connection to the services provided



- 2. Facilitate meetings with service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. This will include dealing with situations which are highly emotive and challenging where information may be of a sensitive and complex clinical nature.
- 3. Where necessary, advise and support service users to access alternative sources of information, including advocacy services, other healthcare organisations, or voluntary sector services suited to their needs.
- 4. Keep service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety continuously informed of Trust review processes and expected timescales for completion.
- 5. In cases where service users, families or carers require on-going help and support to regarding their contact with a serious adverse incident of complaint, chair liaison meetings between Trust staff and service users, families or carers to discuss any concerns they have.
- 6. With the consent of service users, families or carers, provide links to Trust services, General Practitioner services or external counselling agencies.
- 7. Lead on communication with service users, families or carers when sharing sensitive and complex information and with input from clinical subject matter experts the factors that led to adverse events affected them.
- 8. With operational directorate teams, make objective analysis and assessment of concerns that may be complex and/or sensitive, make judgements and through liaison with chair / reviewer to ensure the appropriate level of reviews are carried out and if required, facilitate negotiations with all concerned to find solutions.



- With operational directorate teams, communicate the outcome of any review to individuals in response to concerns or feedback raised, either verbally and/or in writing.
- 10. Keep accurate and contemporaneous records of all communications with service users, relatives and carers including outcomes and actions and input data onto the Datix system.
- 11. Work collaboratively with directorates to monitor the progress of action plans as a result of concerns and patient feedback and ensure that lessons are learned and share with affected service users, relatives and carers.
- 12. Work closely with directorates to embed a culture which views adverse events, complaints, concerns and patient feedback as opportunities for learning and support services to ensure adequately supported and empowered to deal with complaints quickly, effectively and objectively at local level
- 13. Represent the Trust at regional meetings and forums including the patient and client council regional working group
- 14. Lead and manage multidisciplinary service improvement projects designed to create improved systems and processes for the identification and dissemination of learning from adverse events and complaints
- 15. Provide guidance to the Chief Executive, operational directors, senior managers and clinicians on the management of communications with patients, relatives and carers.
- 16. Using evidence based approaches, design and deliver specialist training for clinical staff to support them when communicating with patients, families and carers.



- 17. Lead on the local development of guidance in respect of service user, relative and carer engagement processes by leading on the assessment, interpretation and implementation of national and regional guidance and policies.
- 18. Lead and oversee an ongoing review of organisational engagement processes with regard to patients, relatives and carers and lead on the development of appropriate levels of staff, public and service user consultations.
- 19. Lead on the development of quality metrics and targets based on national and regional policies and provide action plan and monitoring information to the Medical Director.
- 20. Have input in the governance agenda by highlighting patient safety issues raised through concerns, complaints and patient feedback to the AD Clinical and Social Care Governance
- 21. Assist the AD Clinical and Social Care Governance and Head of Patient Safety
 Data and improvement analysing trends and themes arising from
 concerns/complaints or feedback and assist in the production of reports to Care
 Groups and departments
- 22. Work to undertake surveys, audits and other projects relevant to the department
- 23. Ensure that members of the public know how to raise concerns and complaints and that any barriers preventing this are addressed
- 24. Provide assistance to the AD Clinical and Social Care Governance collating and presenting data in preparation for external audits
- 25. To contribute to Trust-wide training on customer services including; staff supporting service users; relatives and carers; frontline resolution of concerns and complaints, in order to ensure that staff are supported and enabled to meet patients' needs in practice



26. Responsible for maintaining own professional development and to be aware of current practices and developments within the Trust and the Health and Social Care in order to fulfil the role effectively

Notes of meeting with Professor K Sethia, Mr M Haynes and M Corrigan 15 December 2020 via Zoom

Martina explained that the purpose of the meeting was to agree the work that would be undertaken by Professor Sethia for the ST in relation to the Public Inquiry in relation to the patients that had been under Mr O'Brien's care.

Points discussed and actions from meeting:

- 1. Follow-up with IT regarding remote access for Prof Sethia into the NIECR system. (Martina to action)
- 2. Prof Sethia to Chair the extra MDM meetings and agreement on who should be at these meetings:
 - i. At least one other ST urologist Mark and or Tony
 - ii. Oncologist (Mark to speak to D Mitchell, Belfast Trust)
 - Clinical Nurse Specialist (Martina to discuss with the CNS on identifying who should attend)
 - iv. Cancer Tracker (Martina to speak with Barry on support for these MDM meetings
 - v. It was agreed that there was no requirement for radiology to attend these meetings unless the need arose and then Mark would approach Radiology for input.
- 3. It was agreed that the best time to hold these meetings was a Thursday AM and to start with fortnightly and then agree the frequency once these were established.
- 4. Discussion then took place around the remote work that Prof would do for the Trust and it was agreed as per clinical priority the following cohorts of patients:
 - i. Patients who had been discussed at Oncology MDM to ensure that they had had a follow-up
 - ii. Histopathology results of patient who had a biopsy done to ensure their result was actioned.
 - iii. Patient who had a radiology test and where the result had not been signed off electronically to ensure they were on the correct management plan and that their result had been actioned.
 - iv. Patients who had contacted the information line with questions/issues/concerns and now needed a follow-up conversation/consultation.
 - v. Patients who were on a review backlog (outside of the oncology one)
 - vi. Patient that were currently waiting for a procedure on Mr O'Brien's elective waiting lists to check that they still needed their procedure.

It was recognised that the Prof would not have the capacity to do all of this but it was agreed that he would make a start and as a cohort was completed the next cohort of patients would be shared with him.

- 5. It was discussed and agreed that any patients of significant concern would be shared immediately with Martina who would share with Mark to ensure that if not on the correct management plan that they would be seen and sorted.
- 6. It was agreed that Martina would be the main point of contact with Professor Sethia.

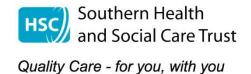


Urology HSCB and Trust Group Minutes

Thursday 5 November 2020, 15:30 Via Zoom

	Itam	Actions
1	In Attendance	Actions
_	Paul Cavanagh Mark Haynes	
	Brid Farrell Damian Gormley	
	Helen Rogers Jane McKimm	
	Melanie McClements Stephen Wallace	
	Ronan Carroll Martina Corrigan	
2	Apologies	
	Maria O'Kane	
	Margaret O'Brien	
3	Purpose of this Group	HSCB will chair
	Chair of this group	weekly
	Terms of Reference	Thursday
	Frequency of Meetings	meetings
	The Trust's Tuesday Urology Oversight meeting will be used to update this group and	Notes and actions to be
	then this group will update the Friday Urology Assurance Group	recorded
	Serious Adverse Incident (SAI) Reviews	recorded
4	Process for Managing SAI's going forward	Paul and
-	Update by the Trust that there are now 9 confirmed SAI's and that there are 10	Melanie to raise
	notifications (9 SAI and one overarching one) Melanie asked what process should	at the Urology
	govern new SAI's, for example did each incident still need to be screened and a SAI if	Assurance
	appropriate, completed, or going forward should this process become a clinical review?	Group on what
		was the best
		way to review
		future incidents
	Management of Patient Reviews	
5	IPT for Review Process	Martina
	Trust are currently working on the IPT for submission to Board which will detail the	Corrigan is
	impact, financial or otherwise that is expected with respect to the SAI's /Clinical	working with
	Reviews and this will include	Trust's Planning
	- Patient impact to date, for example stood down clinics, theatre lists etc.;	
	Fig. 1. Let a transfer a section by the letter of the contract	and Finance
	- Future look at impact as patients who would have been appointed next are	Teams in
	likely to be displaced for reprioritised cases from this current review;	
	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for	Teams in
	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin,	Teams in
	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc	Teams in
	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc Continued use of the Independent Sector	Teams in
	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc - Continued use of the Independent Sector - Urology Experts	Teams in
	 likely to be displaced for reprioritised cases from this current review; Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc Continued use of the Independent Sector Urology Experts Resources for SAI 	Teams in
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	 likely to be displaced for reprioritised cases from this current review; Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc Continued use of the Independent Sector Urology Experts Resources for SAI 	Teams in
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6	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc - Continued use of the Independent Sector - Urology Experts - Resources for SAI - Family liaison; - Psychology input; - 3 rd sector support from charities etc. Bicalutamide Patient Review	Teams in finalising this Mark Haynes to
6	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc - Continued use of the Independent Sector - Urology Experts - Resources for SAI - Family liaison; - Psychology input; - 3 rd sector support from charities etc. Bicalutamide Patient Review 26 patients identified from the first look into the patients:	Teams in finalising this Mark Haynes to continue audit
6	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc - Continued use of the Independent Sector - Urology Experts - Resources for SAI - Family liaison; - Psychology input; - 3 rd sector support from charities etc. Bicalutamide Patient Review 26 patients identified from the first look into the patients: Two all-day clinics (Monday 2 nd & Tuesday 3 rd November) were held in Craigavon	Teams in finalising this Mark Haynes to continue audit and arrange
6	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc - Continued use of the Independent Sector - Urology Experts - Resources for SAI - Family liaison; - Psychology input; - 3 rd sector support from charities etc. Bicalutamide Patient Review 26 patients identified from the first look into the patients: Two all-day clinics (Monday 2 nd & Tuesday 3 rd November) were held in Craigavon Hospital clinical team (1 x Consultant, 2 x Specialist Nurses and 1 x Pharmacist in	Teams in finalising this Mark Haynes to continue audit and arrange with Martina
6	likely to be displaced for reprioritised cases from this current review; - Clinical and operational resource required to date and going forward, for example, Urologist time, Clinical Nurse Specialists, Head of Service, admin, information line, booking, staffing clinics etc - Continued use of the Independent Sector - Urology Experts - Resources for SAI - Family liaison; - Psychology input; - 3 rd sector support from charities etc. Bicalutamide Patient Review 26 patients identified from the first look into the patients: Two all-day clinics (Monday 2 nd & Tuesday 3 rd November) were held in Craigavon	Teams in finalising this Mark Haynes to continue audit and arrange

	2 patients cancelled on the day 1 patient DNA	04555 as
	14 patients (or their main carer) declined face to face appointment and these patients will be followed up by a telephone consultation	identified
7	Engagement of ISP to undertake waiting list work 191 oncology review patients transferred to the Independent Sector: 131 patients have been offered and accepted an appointment over the next four weeks. 39 patients still to be contacted (not answering phone) so a letter has been sent asking them to ring to arrange an appointment 21 patients do not want to attend ISP so have been returned to Trust for a follow-up appointment by end November 2020	
8	Telephone Support Service / Patient Triage Update Total calls – 151 (up to and including Thursday 5 November) 2 patients are being seen as part of the oncology review backlog in Independent Sector 1 patient was on Bicalutamide and was seen at clinic on Monday 2 November 1 patient was picked up as not having been added to any system for a Red Flag Flexible Cystoscopy and has an appointment for this on Monday 9 November 2020 1 GP has called the GP Information line - communication has been sent by HSCB	
9	Private Patients Helen asked about Private Patients and how the Trust was dealing with these. It was stated that this is an unknown quantity and no way of finding out what number of patients may be affected. It was discussed that this may need to come via Primary Care as they may have a record if their patient had been seen privately by Consultant A. but if not named in the release then no way of picking up this information	Paul and Melanie to discuss this at the Urology Assurance Group
	Any Other Business	
10	None raised	
	Date of Next Meeting	
11	Via Zoom – 12 th November 2020 15:30	Martina to send out link



ROLE DESCRIPTION

JOB TITLE Independent Consultant Urology Subject Matter

Expert

REPORTS TO Melanie McClements, Acute Director

OPERATIONALLY

REPORTS TO Dr Maria O'Kane, Medical Director

PROFESSIONALLY

TIME COMMITMENT Sessional Work on an ongoing basis

ROLE SUMMARY

To support the ongoing review of urology patients the Southern Health and Social Care Trust requires an independent Consultant Urologist to undertake a range of clinical review and quality assurance processes. The Subject Matter Expert will report operationally to the Director of Acute Services and Professionally to the Medical Director.

ROLE DUTIES

- 1. To review and quality assure the Trust audit of patients prescribed the medication Bicalutamide taking into account the audit methodology employed, audit findings and where appropriate the proposed changes in medication.
- To chair a weekly extraordinary Multidisciplinary Team Meeting (MDT) to discuss and review patients which have been identified by independent Consultant Urologist as requiring MDT discussion. MDT will be supported by one additional Consultant Urologist, Consultant Oncologist and where required Consultant Radiologist / Pathologist.

- To review radiology results (1028 patients) held on Electronically (NIECR System) to ascertain if appropriate action has been taken in response to the radiology results.
- To review MDT meeting outcomes (271 patients) held on Electronically (NIECR System) to ascertain if appropriate action has been taken in response to the MDT discussions.
- 5. To quality assure the outcomes and conclusions for all patients that have been reviewed at clinic as part of the urology review to date from all identified workstreams.
- 6. To assist in the development on parameters for use when triaging patients who contact the patient information line including identification of what constitutes a potential delay in actioning treatments, reviews, referrals and reviews.



V4 – Released 16.08.2019_______Page 1 of 2



Quality Care - for you, with you

27th November 2020 Ref: MOK/lw

Dear Professor Sethia

Consultant Urologist

via email only

RE: SUPPORT FOR SOUTHERN HEALTH AND SOCIAL CARE TRUST UROLOGY REVIEW

Thank you for agreeing to undertake this urological work with the Southern Health and Social Care Trust. I am writing to confirm that the Southern Health and Social Care Trust will indemnify you for civil claims arising out of your clinical review of this matter, subject to this being conducted within the normal limits of reasonable clinical competence.

Yours sincerely
Personal Information redacted by the USI

Dr Maria O'Kane Medical Director

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Tel: Personal Information redacted by the USI

Email:

Data Sharing Agreement

This Agreement is made on the day of 20

BETWEEN

THE Southern Health & Social Care Trust, (hereinafter referred to as "the SHSCT")

Of 68 LURGAN ROAD, PORTADOWN, COUNTY ARMAGH, BT63 5QQ

of the one part

AND

Professor K K Sethia

Of [Norfolk & Norwich University Foundation Trust

of the other part

The SHSCT is the provider of Health and Social Care services for the population of Northern Ireland in the Southern Trust Area. In the course of providing those services, the SHSCT may on occasion require to engage services from third party Associates/Consultants at times when additional specialist support would be of benefit to the SHSCT in conducting its functions.

The purpose of this Agreement ("the Agreement") is to ensure the lawful processing of Personal Data passing between the SHSCT and the Associate during the course of providing such support. This Agreement sets out the framework for the sharing of Personal Data between the parties as Controllers. It defines the principles and procedures that the parties shall adhere to and the responsibilities the parties owe to each other. This Agreement will benefit the SHSCT and the patients and service users it represents by allowing timely sharing of Personal Data and by providing the SHSCT and Data Subjects with clarity about how Personal Data will be processed and securely transferred between the SHSCT and Associate/Consultant. The parties recognise that the SHSCT will regularly disclose Personal Data to the Associate/Consultant and that, on occasion, the Associate/Consultant will disclose Personal Data to the SHSCT.

For the purpose of this Agreement, the Southern Health and Social Care Trust is described as 'the SHSCT' and associate instructed is described as 'Associate' and collectively they are referred to as 'the parties'.

The terms of this Agreement shall apply as appropriate to all occasions in which the SHSCT has provided Instructions to an Associate for the provision of services including Instructions provided prior to the date stated at the start of this Agreement.

- A. The SHSCT agrees to share Personal Data with the Associate on the terms set out in this Agreement. If the Associate shares Personal Data with the SHSCT, it will also be shared on the terms set out in this Agreement.
- B. The Associate agrees to use the Personal Data within the European Economic Area "the EEA" (which comprises the countries in the European Union and Iceland, Liechtenstein and Norway) and on the terms set out in this Agreement.

C. This is a free standing Agreement and does not incorporate any commercial business terms established by the parties under separate commercial Agreements.

AGREED TERMS

1. INTERPRETATION

1.1 The following definitions and rules of interpretation apply in this Agreement:

Agreed Purposes: In connection with Services sought by the SHSCT: (i) the provision of specialist support and services; (ii) engagement with other HSC bodies and third parties on behalf of the SHSCT.

Controller, Data Subject, Personal Data, processing (and related expressions including process, processed or processes shall be construed accordingly) and Appropriate technical and organisational measures: have the meanings given to them in the Data Protection Legislation in force at the time.

Data Protection Legislation: means all applicable data protection and privacy legislation in force from time to time in Northern Ireland including the UK General Data Protection Regulation ("UK GDPR") ((EU) 2016/679), the Data Protection Act 2018 or any successor legislation and any other European Union legislation relating to personal data.

Health and Social Care Bodies means as defined in the Health and Social Care (Reform) Act (Northern Ireland) 2009, as amended.

Instructions means the instructions, requests for work to be done (and all accompanying materials), this Agreement and any other applicable terms and conditions, whether written or oral, given by the SHSCT to the Associate for the purposes of the supply of services by the Associate.

Personal Data Breach: a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to the Shared Personal Data.

Permitted Recipients: (i) The parties to this Agreement; (ii) the employees, servants or agents of each party; (iii) any third parties engaged to perform obligations in connection with this Agreement; and (iv) any third party to whom it is necessary to allow access to the Shared Personal Data (as defined in clause 3 of this Agreement) for one or more of the Agreed Purposes as set out in this Agreement.

Sensitive Personal Data: has the meaning given in the Data Protection Legislation in force at the time and in particular has the same meaning as "special categories of personal data" in Article 9 of the UK GDPR and for the purposes of this Agreement Criminal Offence Data (as defined in the Data Protection Act 2018) is to be treated in the same way as special categories of personal data.

Services/Support means the particular service or support required, whether contentious or non-contentious, in respect of which the Associate is instructed to supply services to the SHSCT.

Shared Personal Data: means the Personal Data and Sensitive Personal Data to be shared between the parties under this Agreement.

Data Subject Request: meaning a request made by or on behalf of a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data.

Term: This Agreement shall commence on the date stated at the start of this Agreement and shall continue indefinitely thereafter.

- 1.2 The schedule forms part of this Agreement and shall have effect as if set out in full in the body of this Agreement. Any reference to this Agreement includes the schedule.
- 1.3 Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.
- 1.4 References in this Agreement to statutory provisions shall (where the context so admits and unless otherwise expressly provided) be construed as references to those provisions as respectively amended, consolidated, extended or re-enacted (as the context requires) and to any orders, regulations, instruments or other subordinate legislation made under the relevant statutes.
- 1.5 Any words following the terms "including", "include" "in particular" or "for example" or any similar phrase shall be construed as illustrative and shall not limit the generality of the related general words.
- 1.6 In the case of any ambiguity between any provision contained in the body of this Agreement and any provision contained in the schedule, the provision in the body of this Agreement shall take precedence.
- 1.7 Any reference to writing or written includes email.
- 1.8 Unless otherwise required the reference to one gender shall include a reference to the other gender.
- 1.9 In the event of any inconsistency between this Agreement and any other terms and conditions between the parties, the terms of the Agreement shall prevail.

2. COMPLIANCE WITH NATIONAL DATA PROTECTION LAWS

2.1 The Associate must ensure compliance with Data Protection Legislation at all times during the Term of this Agreement. Any material breach of the Data Protection Legislation by the Associate shall, if not remedied with 30 days of written notice from the SHSCT, allow the SHSCT to terminate the Associates Instruction for the provision of services to the SHSCT.

3. SHARED PERSONAL DATA

- 3.1 The following types of Personal Data may be shared between the parties during the Term of this Agreement for any of the Agreed Purposes:
- 3.1.1 personal details (including contact and location details);
- 3.1.2 family details;
- 3.1.3 lifestyle and social circumstances;
- 3.1.4 financial details:
- 3.1.5 education, training and employment details;
- 3.1.6 information relating to the matter in which the SHSCT is seeking support, services or representation;
- 3.1.7 Any other Personal Data which is relevant and necessary to be shared for the Agreed Purposes.
- 3.2 The following types of Sensitive Personal Data may be shared between the parties during the Term of this Agreement for any of the Agreed Purposes:
- 3.2.1 racial or ethnic origin;
- 3.2.2 political opinions;
- 3.2.3 religious or philosophical beliefs;
- 3.2.4 trade union membership;
- 3.2.5 data concerning a natural person's physical or mental health or condition;
- 3.2.6 data concerning a natural person's sex life or sexual orientation;
- 3.2.7 genetic or biometric data used to uniquely identify a natural person;
- 3.2.8 the commission or alleged commission of any offence; and
- 3.2.9 any proceedings for any offence committed or alleged to have been committed, the disposal of such proceedings or the sentence of any court in such proceedings.
- 3.3 Requirements for Third Party (Individual)

The Trust expects all individual third parties, to agree and ensure the following:

- 3.3.1 Have previously completed data protection/information governance training and/or participate in data protection training provided by the Trust (if required).
- 3.3.2 Confidentiality will endure after the individual has completed their interaction with the Trust and will remain in place, indefinitely.
- 3.3.3 All information generated by the individual (via the Trust's manual/electronic systems), remains the property of the Trust and may be disclosed or used by the Trust, where the disclosure is deemed legitimate.
- 3.3.4 The individual must not take copies, remove or retain any electronic/manual information, unless specifically agreed by the Trust.
- 3.3.5 The individual will notify the Trust immediately if there is a data breach or they witness any incident or concern, during their time in the Trust.
- 3.3.6 Any transfer of information (manually or electronically) and the method of

- transfer must be approved by senior staff within the Trust (section 2).
- 3.3.7 Where there is agreement to transfer or retain information, it must be kept secure and in line with Trust policies.
- 3.3.8 All ICT equipment and devices belonging to the Trust must be returned directly to the appropriate Trust manager and it is the third party's responsibility to arrange and ensure the equipment/devices are safely returned.
- 3.3.9 All ICT equipment and devices belonging to the Trust must be returned directly to the appropriate Trust manager and it is the third party's responsibility to arrange and ensure the equipment/devices are safely returned.
- 3.3.10 The organisation must be registered with the Information Commissioner's Office and provide assurance that there is no legal issue, potential concern or obstruction, to undertaking the proposed work within the Trust.
- 3.3.11 Third party organisations must ensure their staff have an understanding of data protection responsibilities (either through training or policies) and these can be evidenced, if required.

4. PARTICULAR OBLIGATIONS RELATING TO DATA SHARING

The Associate agrees to:

- 4.1 ensure that all necessary notices and consents are in place to enable the lawful transfer of the Shared Personal Data to any of the Permitted Recipients for any of the Agreed Purposes;
- 4.2 give full information to the SHSCT regarding any Data Subject whose Personal Data may be processed under this Agreement of the nature of such processing. This includes giving notice that, where processing of the Shared Personal Data is no longer necessary for the Agreed Purposes, on the termination of their Instruction for a particular Service to the SHSCT, Personal Data relating to them may be retained by, or as the case might be may be transferred to, one or more of the Permitted Recipients;
- 4.3 process the Shared Personal Data only for the Agreed Purposes;
- 4.4 not disclose or allow access to the Shared Personal Data to anyone other than the Permitted Recipients or otherwise as required by law;
- 4.5 ensure that any disclosure of the Shared Personal Data to any Permitted Recipients is in compliance with Data Protection Legislation;
- 4.6 ensure that Appropriate technical and organisational measures are adopted by them to ensure safekeeping against unauthorised or unlawful processing of the Shared Personal Data and against accidental loss, or destruction of, or damage to, the Shared Personal Data, including taking all such measures as may be required to comply with Article 32 of the GDPR and without prejudice to any other obligation in this clause 4.6 comply with the reasonable instructions of the SHSCT in that regard;
- 4.7 not transfer any Shared Personal Data outside the EEA unless the Associate:

- 4.7.1 complies with the provisions of Article 26 of the UK GDPR (in the event the third party is a joint controller); and
- 4.7.2 ensures that:
 - (i) the transfer is to a country approved by the European Commission as providing adequate protection pursuant to Article 45 of the UK GDPR; or
 - (ii) there are appropriate safeguards in place pursuant to Article 46 of the UK GDPR; or
 - (iii) one of the derogations for specific situations in Article 49 of the UK GDPR applies to the transfer.
 - 4.8 The following policies must be complied with, before the third party commences with the Trust or accesses Trust information / systems:
 - (i) Data Protection and Confidentiality policy
 - (ii) ICT Server, desktop and portable security policy
 - (iii) Mobile Telephone and Devices Policy
 - (iv) Social Media Policy

For access to particular service areas/premises or Trust information systems, the following additional policies or procedures must be reviewed:

Policy/Procedure name	Applicable area	

5. ASSISTANCE TO THE SHSCT

The Associate shall assist the SHSCT in complying with all applicable requirements of the Data Protection Legislation. In particular the Associate shall:

- 5.1 consult with the SHSCT about any notices given to Data Subjects in relation to the Shared Personal Data;
- 5.2 promptly inform the SHSCT about the receipt of any Data Subject Request;
- 5.3 provide the SHSCT with reasonable assistance in complying with any Data Subject Request;
- 5.4 not disclose or release any Shared Personal Data in response to a Data Subject Request without first consulting the SHSCT wherever possible;
- 5.5 assist the SHSCT, at the costs of the Associate, in responding to any request from a Data Subject and in ensuring compliance with its obligations under the Data Protection Legislation with respect to security breach notifications, data privacy impact assessments and consultations with supervisory authorities or regulators;

- 5.6 notify the SHSCT without undue delay upon becoming aware of any breach of the Data Protection Legislation;
- 5.7 shall either securely and permanently delete or securely return Shared Personal Data and copies thereof to the SHSCT who provided the copies of the Shared Personal Data, where processing of the Shared Personal Data is no longer necessary for the Agreed Purposes, or on termination of Instruction in a provision of Service to the SHSCT, unless otherwise agreed between the parties or unless required by law or professional obligation to retain the Shared Personal Data, in which case it shall be retained no longer than is necessary for such purpose(s) and only that Shared Personal Data which is necessary shall be processed for such purpose(s).
- 5.8 use compatible technology for the processing of Shared Personal Data to ensure that there is no lack of accuracy resulting from Personal Data transfers;
- 5.9 maintain complete and accurate records and information to demonstrate its compliance with this clause;
- 5.10notify the SHSCT of any Personal Data Breach without undue delay (but in any event no later than 24 hours after becoming aware of the Personal Data Breach) and thereafter provide the SHSCT with such details as they reasonably require.

6. Freedom of Information Act 2000

The Freedom of Information Act (FOIA) applies to all of the Trust's activities/functions and will include the information generated or collected from the activities and functions. The third party shall accept and support the Trust's obligations under the FOIA by ensuring all relevant records are retained. The Trust may have to disclose information about an organisation or individual, in response to a request under the FOIA, but will (where appropriate) inform the third party ahead of the disclosure.

The FOIA does permit some exemptions to the release of information and if the Trust decides that an exemption is applicable, it will withhold the information but will not inform the third party.

7. INDEMNITY

The Associate will carry their own professional indemnity insurance. The Associate shall indemnify the SHSCT against all liabilities, costs, expenses, damages and losses (including but not limited to any direct, indirect or consequential losses, loss of funding, loss of reputation and all interest, penalties and legal costs (calculated on a full indemnity basis) and all other reasonable professional costs and expenses) suffered or incurred by the SHSCT arising out of or in connection with breach of the Data Protection Legislation by the Associate, provided that the SHSCT gives to the Associate prompt notice of such claim, full information about the circumstances giving rise to it, reasonable assistance in dealing with the claim and sole authority to manage defend and/or settle it.

SIGNED



Associate (INSERT NAME OF ASSOCIATE / CONSULTANT)



SHSCT Chief Executive/SHSCT Director

For and on behalf of the Southern Health & Social Care Trust

SCHEDULE

1 Subject-matter of processing:

Personal Data related to the provision of services/support to the SHSCT

2 Duration of the processing:

For as long as is necessary for the Agreed Purposes or until termination of Instruction for Services by the SHSCT unless otherwise as may be agreed between the parties or unless required by law or professional obligation to retain the Shared Personal Data, in which case it shall be retained no longer than is necessary for such purpose(s) and only that Shared Personal Data which is necessary shall be processed for such purpose(s).

3 Nature and purpose of the processing:

The nature of the processing means any operation such as collection, recording, Type text here organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of data (whether or not by automated means) etc.

The purpose is as defined in the Agreed Purposes.

4 Type of Data:

Personal Data may include:

Personal details (including contact and location details)

Family details

Lifestyle and social circumstances

Financial details

Education training and employment details

Information relating to the matter in which the SHSCT is seeking services or representation

Any other Personal Data which is relevant and necessary to be shared for the Agreed Purposes.

Sensitive Personal Data may include:

Racial or ethnic origin;

Political opinions;

Religious or philosophical beliefs;

Trade union membership;

Data concerning a natural person's physical or mental health or condition;

Data concerning a natural person's sex life or sexual orientation;

Genetic or biometric data used to uniquely identify a natural person;

The commission or alleged commission of any offence; and

Any proceedings for any offence committed or alleged to have been committed, the disposal of such proceedings or the sentence of any court in such proceedings.

5 Categories of Data Subjects:

SHSCT or other Health and Social Care Body former or current staff; actual or prospective patients/service users; family, carers, and next of kin of Data Subject; members of the public; plaintiff; claimant; defendant; respondent; debtor; solicitors; counsel; pupils; witnesses; experts; professional advisers; staff of Northern Ireland Courts and Tribunals Service, PSNI, Ombudsman, regulatory or investigatory bodies, legal aid, CRU, costs drawer, public registers such as land registry or registrar of deeds, external auditors, Embassies, Consulates, Schools, Northern Ireland Prison Service, Labour Relations Agency, Tracing and Service Agents, UKBA, insurance companies; anyone related to or ancillary to actual or potential proceedings and/or legal advices or services sought or given or to the Agreed Purposes.

6 Processing Instructions

All Personal Data will be dealt with confidentially and with appropriate security measures in place to prevent unauthorised or unlawful processing, accidental loss, destruction or damage.



SECTION C: USER ACCEPTANCE FORM

I understand it is my responsibility to work within the Trust's guidelines and procedures.

I understand a breach of Trust Policies may result in the termination of access by the Southern Health and Social Care Trust and may lead to disciplinary procedures by my employer.

I agree to only use Trust information and data for the purpose of the agreed business which includes but is not limited to information, knowledge or data however disclosed including copies which are of intellectual, technical, scientific, financial or commercial which are not in the public domain.

I understand that my use of Trust facilities and systems will be logged and may be monitored and that any information I create may be subject to disclosure under Freedom of Information legislation.

Upon completion of the appointment, I shall make no further use of the Trust's information /data. I will return all information /data in my procession, which will include all originals and any subsequent copies of the information /data held.

This agreement will come into effect on (date)

Non-Trust Staff member to complete	SHSCT Staff to complete	
Signature	Signature	
Print Name K K Sethia	Print Name	
Job title	Job title	
Date 04.11.20	Date	

NB. Signed forms should be retained by the Trust Signatory or appropriate SHSCT Manager and a copy given to the non-Trust staff member.

Any queries should be directed to the Information Governance Team, Bannvale Site, Ferndale House, Gilford.

Tel — Personal Information redacted by the USI	Personal Information (educated by the USI —
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20180723_Confidentiality_Agreement_PMCM



Confidentiality

During the course of your time with the SHSCT, non-Trust staff may have access to confidential information. Confidential information includes all information relating to the business of the Trust and its patients/clients and employees.

This information must not be disclosed to any other person unless in pursuit of your duties as detailed within a data access agreement or contract between SHSCT and your employer. Under the DPA, it is an offence to obtain or disclose personal data belonging to SHSCT, without its prior consent. This includes the unauthorised accessing of personal data from SHSCT electronic systems or manual files and/or the supply of personal data to a third party, outside of the agreed contractual terms.

You may also have access to and be entrusted with information in respect of the services, business and financing of the SHSCT and its dealings, transactions and affairs, all of which is confidential.

All notes and memoranda or any intellectual property or confidential information concerning the business of the SHSCT which shall be acquired, received or made during the course of your appointment with the SHSCT shall be the property of the SHSCT and shall be surrendered by you to someone duly authorized by the Trust, at the termination of your appointment or at the request of the SHSCT at any time during the course of your appointment. This information will be retained (as per the Trust's Retention and Disposal schedule) for the appropriate period thereafter.



Confidentiality Agreement for Non-Trust Staff

ECTION A: GENERAL DETAILS	
Name of Non-Trust Staff Member:	
Company Name, Address & Phone number:	
SHSCT Contact	
Contact Number	
Service/Department:	
Duration of Appointment	
- 10-2	



SECTION B: Agreement Details

Data Protection

The Data Protection Act 2018 ('DPA') and the General Data Protection Regulation (GDPR) regulates the use of all personal information held within electronic and paper records, relating to living individuals (patients, service users, staff and the wider public). Within this agreement the term 'personal data' includes sensitive personal data and the term 'processing' refers to the accessing, handling, storing, transfer or disposal of personal data belonging to the Southern Health and Social Care Trust ('SHSCT').

The SHSCT adheres to the six data protection principles within the GDPR which provide a framework for the processing of personal and sensitive personal data. In general terms, the principles state personal information must be:

- · Fairly and lawfully processed
- Processed for one or more specified purposes
- Adequate, relevant and not excessive
- Kept accurate and up to date (when necessary)
- Kept only for as long as is necessary
- Processed in a manner that ensures appropriate security

Policy, procedures and legislation

The SHSCT processes large volumes of personal data and requires non-Trust Staff to adhere to Trust policies and procedures when processing any personal data belonging to the SHSCT.

The SHSCT requires all non-Trust staff to use the information technology and communications facilities sensibly, professionally and lawfully; and abide by corporate policy and procedures in respect of the use of IT and communications equipment. The Trust monitors the use of ICT systems for this purpose.

Non-Trust staff should be aware that contravention of polices and/or the legislation from which the polices are derived (DPA/GDPR and the Computer Misuse Act 1990) may lead to disciplinary action by your employer and possible prosecution.

Wallace, Stephen

From: Wallace, Stephen
Sent: 15 December 2020 10:40

To: krishna sethia

Subject: RE: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Apologies Professor Sethia, the rate will be represent per hour – grateful if you can confirm you are happy with this

Thanks Stephen

From: krishna sethia

Sent: 14 December 2020 16:07

To: Wallace, Stephen

Subject: Re: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Dear Stephen

I note from previous correspondence that you propose to reimburse my time for this on "a sessional basis". Could you let know what that sessional rate will be?

Thank you

Krishna

From: Wallace, Stephen

Sent: 14 December 2020 14:40

To: krishna sethia

Subject: RE: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Thanks I have included a link below for 2pm

Much appreciated

Stephen

Join Zoom Meeting

Irrelevant Information Redacted by the US

Meeting ID: Irrelevant Information Redacted by the USI
Passcode: Redacted by the USI

One tap mobile

Irrelevant Information Redacted by the US

From: krishna sethia

Sent: 14 December 2020 13:53

To: Wallace, Stephen

Subject: Re: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Fine

What time? I should be free between 1400 and 1630

From: Wallace, Stephen

Sent: 14 December 2020 13:45

To: krishna sethia

Subject: RE: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Thanks Professor Sethia, would zoom be ok?

Stephen

From: krishna sethia

Sent: 14 December 2020 13:14

To: Wallace, Stephen

Subject: Re: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Tomorrow afternoon would be good?

From: Wallace, Stephen

Sent: 14 December 2020 11:52

To: krishna sethia

Subject: RE: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Dear Professor Sethia, would you be free for call this week anytime re below?

Thanks Stephen

From: Wallace, Stephen

Sent: 08 December 2020 18:17

To: 'krishna sethia'

Subject: RE: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Dear Professor Sethia,

Please find attached a role description as promised re our engagement. Would it be possible to catch up to discuss further this week?

Best regards Stephen

From: krishna sethia

Sent: 27 November 2020 14:05

To: Wallace, Stephen

Subject: Re: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Thank you

I will await your further instructions

Regards

Krishna

From: Wallace, Stephen

Sent: 27 November 2020 13:58

To: krishna sethia

Subject: Corresepondence from Dr Maria O'Kane, Medical Director SHSCT

Dear Professor Sethia,

Please find attached correspondence from Dr Maria O'Kane, Medical Director, Southern Health and Social Care Trust for your attention.

Regards Stephen

Stephen Wallace

Assistant Director of Clinical and Social Care Governance

Mob:

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Southern Health & Social Care Trust IT Department

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Southern Health & Social Care Trust IT Department Personal Information reduced by the USI



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR J. MCCLUNG

Personal Information redacted by the USI

Dear DR MCCLUNG

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Personal Information redacted by

HCN:

.

Diagnosis:

Intermediate risk small volume localised prostate cancer diagnosed May 2012 with initial PSA of 7.36 and gleason 3+4=7 prostate cancer in 3 of 12 cores radiological stage T2 N0 M0

Treatment with low dose (50mg) Bicalutamide and tamoxifen since diagnosis

Outcome:

Stop Bicalutamide and tamoxifen
Check PSA and write with result
Please check PSA February 2021 and I will write with the result Patient 80 has a request form for this)

I reviewed having reviewed his notes. He was diagnosed with a small volume intermediate risk localised prostate cancer in May 2012 with a PSA of 7.36 and was commenced on low dose Bicalutamide at this point. I have explained that standard treatment options that would be recommended for a localised prostate cancer are either radical curative treatments or surveillance and given his history of motor neurone disease and the small volume of localised prostate cancer he had at diagnosis with a PSA of less than 10, surveillance would have been an entirely sensible option.

I have also discussed evidence of side effects of longterm androgen deprivation therapy and I have recommended that we stop his Bicalutamide and Tamoxifen. I will monitor his PSA initially. He is aware that if his PSA rises in particular if it rises above 20 I will look to reassess his prostate cancer stage and discuss treatment options available at this point.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 2

Page 1 of 2



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR D. CLEARY
Irrelevant Information Reducted by the USI

Dear DR CLEARY

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

Information redacted by the USI

Personal Information redacted by the

Date/Time of Clinic: 02/11/20 **Follow Up:** PSA now & PSA February 2021

Diagnosis:

Prostate cancer initially diagnosed with low risk localised prostate cancer 2008 progressed to intermediate risk prostate cancer 2012

Has been treated with Bicalutamide 50mg and Tamoxifen 10mg

Outcome:

Stop Bicalutamide and Tamoxifen Check PSA and write with result (I have given him a blood request form) PSA February 2021 and write with result

was reviewed following review of his records and treatment for prostate cancer. I believe he is currently on 50mg dose of Bicalutamide. He had initially been diagnosed with a low risk localised prostate cancer in 2008. Surveillance assessment in 2012 then progressed to an intermediate risk localised prostate cancer. He had been commenced on Bicalutamide monotherapy. I believe there was some discussion of radical treatment with radiotherapy but he had not been referred for this.

I have explained to Mr and his wife that standard treatment recommendations for intermediate risk localised prostate cancer would be curative treatments with either radiotherapy or surgery or continued surveillance. We have also discussed that low dose Bicalutamide monotherapy is not a standard recommended treatment and indeed there is evidence of it being an inferior treatment.

I have discussed with Mr his options for moving forward being either progressing directly to radical treatment with radiotherapy at this point or

discontinuing his anti-androgen treatment with a view to reassessing his current PSA levels/disease status and reconsideration of treatment options at this point.

Mr does not feel he particularly wishes to proceed directly to radiotherapy and I think it is reasonable to stop his Bicalutamide with a view to reassessing his PSA baseline/restaging disease if required and reconsidering his treatment options at this point.

I have advised him to stop his Bicalutamide and Tamoxifen. I have checked his PSA today. I shall write with the result. He is aware that if his PSA has compared to previous readings then it is likely that I will look to recommend androgen deprivation therapy with an LH RH analogue and arrange restaging. If his PSA is satisfactory from today then I would look to repeat PSA in February 2021.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page **2** of **2**



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR R. FLOOD



Dear DR FLOOD

Re: Patient Name:

D.O.B.:

Address:

Hospital No: Personal Information reducted by the USI HCN: Personal Information reducted by the USI

Diagnosis:

Intermediate risk localised prostate cancer diagnosed 2009

Outcome:

Stop Bicalutamide

Check PSA and write with result

Please check PSA February 2021 and I shall write with the result Patient 26 has a request form for this)

I reviewed following review of his records. He was diagnosed with a localised intermediate risk small volume prostate cancer in 2009 and has been on Bicalutamide 50mg since July 2010. I have discussed with him and his daughter that the standard treatment options that would be discussed for localised prostate cancer would be either surveillance or treatment with curative intent and given the small volume disease he had diagnosis surveillance would have been a reasonable option. He has been treated with Bicalutamide 50mg since 2010 and I discussed with him and his daughter the evidence regarding this treatment in that early androgen deprivation therapy does not increase survival from localised prostate cancer and exposes men to risks of side effects to the androgen deprivation therapy. In addition he has bene on a low dose of the treatment and there is evidence this is an inferior treatment.

I have recommended we should switch to surveillance and therefore he should stop his Bicalutamide. I have checked his PSA and will write with the result. In addition I have given him a blood test to have a PSA checked in February 2021 and will write with this result. He is aware that if his PSA baseline is found to rise above 20 I will reassess his prostate cancer and re-discuss options at this point.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 2



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

DR J. GUETTE

2015/2014 Information reserved by the USI

Dear DR GUETTE

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

mation redacted by the USI

HCN: Personal Information redacted by the I

Diagnosis:

Previous left inguinal orchidectomy for T1 seminoma treated with subsequent chemotherapy

Burning sensation/pain related to scar

Outcome:

Refer Pain Team

I reviewed who was treated surgically for a seminoma in July 2019. He was reviewed in clinic on 23rd August 2019 but a referral to Oncology was not dictated until 25th September. He was subsequently seen very quickly by the Oncology Team and underwent a single cycle of Carboplatin chemotherapy. He has done very well from the cancer perspective. I have outlined to and his wife that there was a delay in dictation of referral to Oncology following his outpatients review on 23rd August until the letter was dictated on 25th September. They were already suspicious that this may be the case and I have advised them that an IR1 has been completed and investigation will look into how this occurred.

With regards his testicular cancer treatment he has done very well and has been delighted to have recently been advised that his tumour markers and his CT scan in the Summer was also entirely reassuring.

He has ongoing pain/burning sensation related to his inguinal orchidectomy wound and is not able to wear a belt as a result of this. He is on a number of analgesics for his sero-negative arthritis. I have suggested referral to the Pain Team to see if any local anaesthetic injection/ablation treatments may help with this and he is happy to pursue this.

Patient 2

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 2



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear DR MCCANDLESS

Re: Patient Name:

D.O.B.:

Address: Hospital No:

Date/Time of Clinic: 02/11/20

Personal Information redacted by the USI

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The USI

Personal Information redacted by the USI

Follow Up: PSA February 2021

Diagnosis:

Localised intermediate risk prostate cancer initially diagnosed 2010 and commenced on low dose Bicalutamide 50mg and Tamoxifen 10mg February 2011

Outcome:

Stop Bicalutamide/Tamoxifen

Check PSA and write with result. (At request I have also checked a number of other bloods as he says he has not had his diabetes blood test checked for a while)

Check PSA February 2021 and write with result

came to see me in the outpatient department following review of his notes. He has been treated with a low dose of Bicalutamide since diagnosis with a localised intermediate risk prostate cancer back 2010. From memory or his daughter could not recall having any discussion regarding alternative radical treatment options such as radiotherapy nor any discussions of active surveillance/watchful waiting.

I have explained the rationale behind reviewing his prostate cancer treatment and have explained the concerns associated with longterm anti-androgen treatment, in addition I have explained the dose of Bicalutamide he was on is below the recommended treatment dose and studies have shown a worse outcome for men treated with this dose of Bicalutamide as monotherapy.

Assessing his prostate cancer it may well be that he does not need any treatment for his prostate cancer and I have recommended in the first instance we stop his Bicalutamide and Tamoxifen and monitor his PSA. I have advised that if his PSA

Page **1** of **2**

is found to rise about 20 then we should look to restage the diseases and consider his treatment options at this point.

In addition he has also been treated some lower urinary tract symptoms with nocturia being the primary issue of up to 2-3 times a night. Discussing with his daughter he sleeps on a ground floor level, the same level as the bathroom and she does not feel the nocturia is proposing a particular falls risk. Understandably she is keen for him to avoid the potential side effects of any anti-cholinergics. We have checked his residual volume today and assuming this is satisfactory I have advised that we should leave him managing his urinary symptoms at present. I note he had Botox injections in 2013 and he needed to commence intermittent self catheterisation after this. All being well they do not need to continue this.

I have checked his PSA today and will write with the result. I shall also forward on to you a number of other blood tests that I performed at request. I have given him a blood form to have a further PSA in February 2021 and shall write with the result.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page **2** of **2**



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 500



Dear DR GLENDINNING

Re: Patient Name:

D.O.B.:

Address: Personal Information redacted by the USI H H H H Personal Information redacted by the USI HCN: Personal Information redacted by the USI HCN:

Diagnosis:

Prostate cancer diagnosed September 2014, gleason 3+5=8 in 2 of 6 cores with initial PSA of 8.02

No radiological stage as could not have MRI scan due to stents Has had CT scans with no evidence of nodal or bony metastatic disease

Outcome:

Stop Bicalutamide and switch to surveillance

Check PSA and write with results

Check PSA February 2021 and write with result (Patient 41 has a request form for this)

I reviewed following review of his notes. He was diagnosed with a high grade (gleason 8) prostate cancer in September 2014 with a low PSA at 8.02. He was initially commenced on Bicalutamide and Tamoxifen at a dose of 150/10. This was subsequently discontinued and I believe this was due to hot flushes. He was then more recently started on Bicalutamide and his daughter advises me the dose was reduced to 50mg as he found the hot flushes intolerable.

I have discussed the treatment options for a localised prostate cancer with and his daughter and in the first instance have advised that we discontinue the Bicalutamide 50mg treatment. Depending upon his subsequent PSA levels/kinetics they are aware that we will reassess regarding the most appropriate treatment options.

I have checked his PSA today and will write with the result and plan his next PSA in February 2021 and will write with the result.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 2



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500



Dear DR SHANNON

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Personal Information reducted by the USI

HCN:

Personal Information reducted by the

Date/Time of Clinic: 02/11/20 | **Follow Up:** PSA now & PSA February 2021

Diagnosis:

Intermediate risk prostate cancer diagnosed 2015 with initial PSA 13.25, gleason 4+3=7 prostate cancer in 5 of 10 cores and radiological evidence of no metastases and possible early T3a disease. Currently on combined androgen blockade Currently on Nocdurna 50mg at night for nocturia

Outcome:

Stop Leuprorelin and Bicalutamide Check PSA

Check PSA February 2021 and write with result

To complete bladder diary on and off Nocdurna and for CNS LUTS review Refer General Surgery for hernia management

I reviewed following review of his records regarding his prostate cancer treatment. He was diagnosed with a non metastatic intermediate risk prostate cancer in 2015. I have explained that standard treatment options would be those of surveillance with watchful waiting or radical treatment most likely at an age of of diagnosis with radical radiotherapy. He has been treated with combined androgen blockage. I have explained that there is no evidence of early treatment with hormones for localised disease confers any survival benefit and it does expose patients to risks of side effects from the androgen deprivation therapy including hot flushes and a slight increased risk of cardiovascular disease.

We have discussed the options for manging his prostate cancer now. On balance we have agreed to stop his combined androgen blockade with a view to determining his new PSA baseline and PSA kinetics and subsequent assessment of appropriate treatment options at that point.

With regards his urinary symptom he is on Nocdurna at present. He has not had any up to date U&E's to check that he has not developed any hyponatraemia on this and I have checked this today. He is uncertain as to whether this has improved his nocturia and he tells me even on it he is still up three times a night. His daughter feels that the volume of urine produced is however less than when he was not on it.

We have agreed that he will complete a bladder diary for three nights on Nocdurna and then for three nights off Nocdurna in order to assess whether there is a benefit in taking the Nocdurna. I will arrange subsequent CNS LUTS review with regards this.

From a prostate cancer perspective I have checked his PSA today and will write with the results. I have also made plans for his PSA to be checked in February 2021 and will write with the result. I have given him a request form for this PSA in February.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 3



Consultant Urologist: Mr Mark Haynes
Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

JENNY MCMAHON Urology Nurse Specialist CAH

Dear Jenny

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

sonal Information redacted by the U

Personal Information redacted by the

HCN: Personal Information redacted by the USI

Date/Time of Clinic: 02/11/20

I would be grateful if you could make arrangements for a telephone review for in 1-2 weeks. He has been on Nocdurna for nocturia and was uncertain as to whether this has improved things. I have asked him to complete a three day bladder diary on the Nocdurna and three days off the Nocdurna to assess whether it has been beneficial. He will aim to do this over the next 7 days. I would be grateful if he could have a subsequent telephone review to assess whether the Nocdurna has been beneficial and therefore whether it should be continued. Many thanks.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 3



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR A. TROUGHTON

Personal Information redacted by the USI

Dear DR TROUGHTON

Re: Patient Name:

D.O.B.:

Address:

Hospital No: Personal Information redacted by the USI HCN: Personal Information redacted by the USI

Date/Time of Clinic: 02/11/20 | **Follow Up:** PSA now & PSA February 2021

Diagnosis:

Clinical/radiological suspicion of prostate cancer diagnosed in 2015 with PSA of 6.24 (on finasteride) and radiological suspicion of T2 (localised) prostate cancer No prostate biopsy performed

Outcome:

Stop Bicalutamide and Tamoxifen
Check PSA and write with result
Please check PSA February 2021 and I will write with the result
has a request form for this)

I reviewed following review of his treatment. He had seen Mr O'Brien in 2015 and on the basis of a rising PSA which had gone from just over 2 to 6.2 over a three year period and MRI scan showing areas of possible abnormality amounting to a small localised (T2) prostate cancer was commenced on low dose Bicalutamide treatment.

I have discussed the rationale behind investigation, treatment and management of localised prostate cancer and discussed proven treatments for localised prostate cancer. I have also discussed the risks associated with longterm androgen deprivation therapy and that the low dose Bicalutamide is at a subtherapeutic dose.

I have recommended that we stop the Bicalutamide and is in agreement with this. I have advised him that further management will depend on his PSA level and kinetics. If he has a rapidly rising PSA or a PSA above 20 then it may be worth considering restaging, biopsy and consideration of suitability for treatment

WIT-04573

eg LHRH analogue and radical radiotherapy, or alternatively he may continue on watchful waiting.

I have checked PSA today and will write with the result. I have advised him to stop his Bicalutamide and Tamoxifen. I have given him a blood request form for a PSA in February 2021.

Yours sincerely

dictated but not signed by

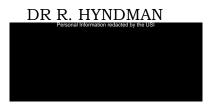
Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 2



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear DR HYNDMAN

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

ersonal mornagon reduced by the Cor

ation redacted by the USI HCN: Personal Information redacted by the

Diagnosis:

T2 intermediate risk localised prostate cancer diagnosed in 2014 treated with low dose Bicalutamide

Outcome:

Stop Bicalutamide and tamoxifen
Please check PSA February 2021 and I shall write with the result (***
has a request form for this)
CNS LUTS review 6-8 weeks

was reviewed by me following review of his records and prostate cancer treatment. He has been treated with low dose Bicalutamide for his clinically localised prostate cancer since his diagnosis in 2014. His recent PSA is 1.08.

He does have some urinary symptoms and had a TURP over 40 years ago. His predominant urinary symptoms are storage related and they have deteriorated over recent months with significant urgency and on occasion urge incontinence. He has never had any haematuria. He has emptied his bladder well on post void residual scanning and clinically his prostate feels small and firm.

He had complained of a palpable lump on his penis and on examination his residual foreskin (he had been previously circumcised as a child) is adherent to the glans with a mobile piece of smegma palpable. I have reassured him regarding this.

With regards his prostate cancer treatment I have outlined standard treatment options for an early localised prostate cancer would be surveillance or consideration of radical treatment. I have outlined that longterm androgen

deprivation therapy does not provide survival advantage for localised disease and is not recommended. In addition I have outlined the dosage of Bicalutamide he is on is below the recommended dose for treatment and studies comparing the low dose with a full dose of treatment suggest an inferior outcome.

In terms of manging his prostate cancer from now I have recommended we stop his Bicalutamide and monitor his PSA in the first instance. If his PSA is found to be rising rapidly once a baseline is established or is found to rise above 20 then I will organise restaging of his prostate cancer with a view to considering treatment options which may include medical treatment if his disease remains non metastatic. However, radiotherapy may be problematic given his storage symptoms and it may be that we elect for a watchful waiting strategy. I will be in contact with

I have arranged LUTS assessment in 6-8 weeks to ensure his urinary symptoms do not rapidly deteriorate following cessation of his Bicalutamide.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 3



Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

Consultant Urologist: Mr Mark Haynes Telephone:

JENNY MCMAHON Urology Nurse Specialist CAH

Dear Jenny

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

Personal Information redacted by the USI

HCN:

Personal Information redacted by the US

Date/Time of Clinic: 03/11/2020

I would be grateful if you could arrange a CNS LUTS appointments for in 6-8 weeks. He has significant urgency symptoms and describes episodes of urge incontinence if he does not obey the urge.

He would not be a candidate for an anti-cholinergic due to his cognitive impairment and has history of hypotension and has had an admission with postural hypotension so would not be an alpha blocker candidate.

If his symptoms have deteriorated significantly it would probably be worth a flexible cystoscopy in the first instance to ensure he has not developed a stricture or bladder neck stenosis having had previous TURP 40 years ago. Many thanks.

Yours sincerely

dictated but not signed by

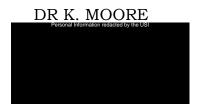
Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 3



Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear DR MOORE

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Date/Time of Clinic: 25/11/2020

Personal Information redacted by the USI ation redacted by the USI

HCN: Personal Information redacted

Follow Up: CT urinary tract, Flexible

Cystoscopy & Urodynamics

Diagnosis:

Ongoing urinary symptoms

Previous TURP (2013)

Prior to TURP treated with intradetrusor Botox injections

Urodynamics 2014 showing reduced detrusor function and intermittent self catheterisation used since this point

Previous inpatient admission with urosepsis November 2017

Background history of spinal stenosis

Outcome:

CT urinary tract Flexible cystoscopy

Urodynamics after CT and flexible cystoscopy

I reviewed along with his wife after they had contacted the Trust Information line regarding his treatment. He has a long complex history having attended and been treated within the Urology Department on a number of occasions over a number of years and has previously seen both Mr O'Brien and Mr Glackin.

Unfortunately I do not have any written documentation from his assessments and treatments prior to 2013 available in clinic. From his histology and the information available on ECR from other Specialities initially presented with a spinal stenosis and some neurological symptoms. From discussion with him the symptoms sound consistent with a diagnosis of neurogenic detrusor overactivity and as would be a recognised standard management option for this he underwent intradetrusor Botox injections. In male patients there is a

significant risk that intradetrusor Botox injections result in a subsequent failure to void and unfortunately did run into voiding difficulties following the Botox injections. We have discussed that in men in age group when he received the Botox injections with neurogenic bladder symptoms it is recognised that there may be co-existing bladder outflow obstruction and from discussion this would appear to have been the clinical diagnosis made at the time and he therefore underwent a TURP in 2013. He was discharged on Day 1 post surgery with a catheter insitu with a plan for subsequent removal of catheter. and his wife raised some concerns that at the time of discharge he was provided with limited information/education on catheter management and they themselves are concerned that the discharge on Day 1 was early. He was subsequently readmitted with clot retention on 17th November 2013 and discharged on 19th November 2013.

Since his surgery has had ongoing urinary symptoms and has had further urological procedures in the form of cystodistensions for a diagnosis of bladder hypersensitivity. He was also taught intermittent self catheterisation which he was performing on a twice daily basis. Now he performs the intermittent self catheterisation far less frequently and only does it when he has worsening of his symptoms. When he self catheterises he has minimal volume of urine drained from his bladder.

He had an admission under the Medical Team in November 2017 with urosepsis. Following this admission he had been reviewed and assessed by Mr Glackin and at last review in January 2019 although he had ongoing urinary symptoms these were unchanged and had been refractory to medical treatment. Given that the symptoms were refractory to medical treatment and previous surgical treatment Mr Glackin had not planned any ongoing follow up.

continuing to impact on his quality of life. Proceedings also raised concerns following his episode of sepsis that his general health has deteriorated since then and that she herself wonders whether he has ongoing infection. She has also noted that he feels the cold increasingly since the admission in 2017.

I had a long discussion with running through their treatment in the Urology Department from the start of his urinary symptoms. I have reassured him that the investigation and treatment for his symptoms at the time of his initial presentation would be consistent with the investigation and treatment of suspected neurogenic detrusor overactivity. The management with intradetrusor Botox injections is a standard treatment for this. It is well recognised that men may have co-existent bladder outflow obstruction and it would appear that this was the case for

With regards their concerns of being discharged on Day 1 post TURP I have reassured that this would be a practice in a number of instances and for Day 1 discharge following bladder outflow surgery it would be relatively common for patients to be discharged with a catheter as patients experience significant discomfort when voiding when catheters are removed on Day 1 post surgery. His subsequent readmission with clot retention is unfortunately a recognised risk following any transurethral prostate resection and unfortunately it happened to readmission. With regards their concerns of the level of catheter education they had on discharge I do not have any documentation regarding this

but I have apologised that this would not be the standard accepted practice on discharge with catheters insitu.

Since the TURP and due to his ongoing symptoms underwent further investigation including urodynamics and additional urological procedures and medical treatments attempting to improve his symptoms. Again I have reassured and his wife that all of the treatments and investigations that they have undergone are accepted standard practice and I have no concerns with regards the treatment he has received.

Unfortunately may well be the case and very limited options we have available to further manage his urinary symptoms.

An additional concern that raised related to an outpatient consultation which I do not have any documentation around. This happened prior to his TURP and describes having attended with concerns regarding ongoing urinary symptoms and management and specifically concerns regarding waiting times. She had been advised of the existence of the Patients Charter and raised this during the consultation. She describes the doctor as having got visibly distressed/angry at her raising this and advises that he had sworn during his response to her raising this. During the consultation had been given a date for his admission. She raised concern that as a result of this unsatisfactory consultation was discharged too early following his TURP and was not seen by the Consultant on the morning following surgery.

With regards this concern I have apologised to for this consultation although they are aware that I have no records of the consultation so cannot pass specific comment regarding their experience that they described. We did discuss the difficulties that Government produced documents such as the Patients Charter have created particularly within Urology services in Northern Ireland where our capacity to meet patient demand is significantly limited and result in waiting times are extremely long. They recognise that documents assuring treatment with specific time-frames that cannot be met within the capacity do result in significant specific challenges for the Teams working within the service. I have assured them that all Urologists working in Northern Ireland would like to see a service whereby we can offer both assessment and treatments within significantly shorter time-frames than we are currently able to do so.

With regards ongoing treatment I have reassured that there are no signs of any ongoing infection related to his bladder. He remains on a low dose antibiotic. Given that when he intermittently catheterises there is no significant residual volume I think it is unlikely that he has a significant degree of chronic urinary retention which had been an underlying cause for his admission in 2017 with urosepsis. He is aware that intermittent self catheterisation itself carries a very small risk of infection and he only uses this sparingly when he has symptoms. It is unclear to me whether this is necessary given that he does not get any significant volume on catheterising. His predominant storage symptoms may well be related to ongoing detrusor overactivity.

With regards further assessment I have recommended a CT urinary tract in the first instance to reassure us that there are no urinary tract stones giving an increased risk of urinary infections. Following his CT urinary tract I plan a

flexible cystoscopy to ensure he does not have any significant urethral stricture or intravesical cause of his symptoms. If these two investigations are satisfactory then I will be looking to organise a urodynamic assessment to assess whether further treatment options are available to manage his symptoms. I have explained that if as I suspect the underlying issue is ongoing detrusor overactivity we will be left with a choice between a further intradetrusor Botox injections which runs the risk of incomplete voiding and a need to become reliant on intermittent self catheterisation for bladder emptying or persisting with his symptoms as at present. A third option may be to explore neuromodulation if the urodynamics to prove detrusor overactivity.

Yours sincerely

dictated but not signed by

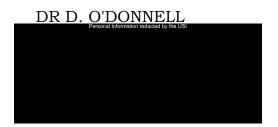
Mr M Haynes, MD FRCS (Urol) Consultant Urologist





Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear DR O'DONNELL

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Personal Information redacted by the USI
USI

HCN:

Personal Information redacted by the USI

Diagnosis:

Previous treatment for muscle invasive bladder cancer

As you are aware you initially referred with haematuria on 28th July 2016. The urgency category requested on this referral was routine. Unfortunately the referral was not triaged and his haematuria referral was not immediately upgraded to red flag. He was subsequently first seen in the Urology Outpatients Department in January 2017. He was subsequently found to have invasive bladder cancer and underwent a nephroureterectomy and cystoprostatectomy with ileal conduit urinary diversion in May 2017.

I discussed the delay in red flag assessment with I law assessment with I law assessment with I law as routine and within the Trust unfortunately the safety net process of triage did not occur and therefore his referral was not upgraded to red flag and consequently he was seen in the Urology Department approximately six months after referral. He is aware that at the time of his assessment he had an invasive bladder cancer and that subsequent radical surgical treatment was required. He has had a good oncological outcome from this treatment.

was asking whether if he had been seen earlier following referral whether the radical surgery he has undergone would have been necessary.

He also has some questions regarding previous cyclophosphamide use and the risk this poses regarding the development of bladder cancer.

Patent 13 Page 1 of 3

While I cannot provide absolute certainty with regards the stage of bladder cancer at the time of referral, I have advised that given his bladder cancer pathology which showed lymphoepithelial like pattern in some areas and was high grade it is likely that he either already had muscle invasive bladder cancer at the time of presentation or had high risk non muscle invasive disease at the time of presentation. If he had high risk non muscle invasive disease at the time of presentation given the adverse pathological feature of lymphoepithelial like pattern the recommendation would have been to proceed to radical surgery.

He was also asking with regards whether earlier diagnosis would have prevented the need for a nephroureterectomy. I cannot be certain as to when his ureteric obstruction occurred. Reviewing his blood results and specifically his U&Es it is notable that he had a normal GFR (greater than 60) in June 2015 however his GFR had fallen to 52 in February 2016. His GFR has remained in the 50's since February 2016 and therefore it is unlikely that the obstruction occurred after February 2016 as the loss of a functioning kidney with pre-existing renal impairment would have expected to be apparent in his blood test with a fall in his EGFR. I have therefore advised that although there was a delay in him being seen as noted above, the ultimate treatment which he required with a cystoprostatectomy and nephroureterectomy would recommended a the point of initial referral.

We have also discussed the risk of delay in diagnosis in bladder cancer with regards subsequent outcome from cancer treatment. I have advised that the evidence base for invasive bladder cancer treatment suggests that early treatment following onset of haematuria is associated with a better oncological outcome (an increase in survival rate). However, fortunately in case he is now $2\frac{1}{2}$ years following treatment with no evidence of metastatic disease. If he were to develop metastatic disease invasive bladder cancer is aggressive and he would most likely have developed metastatic disease at this point and therefore it is unlikely that the delay in diagnosis and subsequent treatment has impacted on his cancer survival.

We have also discussed the risk of Cyclophosphamide in relation to bladder cancer. was questioning whether he should have been on a bladder surveillance programme having received Cyclophosphamide in the past. He was also asking questions as to whether Cyclophosphamide was an appropriate treatment when he received it.

With regards his questions regarding the Cyclophosphamide treatment I have advised that I am not able to answer this as it is outside of my expertise.

I discussed with risk factors for bladder cancer. In addition to his previous Cyclophosphamide treatment it is notable that is also a smoker. I have discussed with that smoking itself is the biggest cause of bladder cancer accounting for more than a third of all cases. Smokers are up to four times more likely to develop bladder cancer than non smokers. With regards Cyclophosphamide treatment the risk of bladder cancer varies according to the dose of Cyclophosphamide received with the risk being highest in patients receiving longterm Cyclophosphamide treatment. This risk varies from 2 times for patients who receive low doses of Cyclophosphamide to as high as 6

times for patient who received very high doses. I do not know the total dose of Cyclophosphamide which received and therefore cannot give a specific estimate of risk that this posed.

With regards bladder surveillance following Cyclophosphamide treatment the recommendation is monitoring for haematuria with investigation of haematuria with cystoscopy in patients who develop haematuria. had been investigated for haematuria prior his referral in 2016 in the late 1990's and investigations at this time were satisfactory.

I have discussed bladder surveillance strategies with and advised him that there is not an existing recommendation that all patients who have received Cyclophosphamide in the past are placed on a surveillance cystoscopy programme.

With regards his questions as to whether his Cyclophosphamide treatment was required I have written to the Neurology Team in Belfast Trust requesting they review to discuss these concerns.

Hospital following his bladder cancer surgery. We do not have any ongoing plans for review under the Urology Team in Southern Trust but I would be happy to see upon request or if he has any further questions.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist





Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR S. LENNON



Dear DR LENNON

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

rsonal Information redacted by the USI

Personal Information redacted by the U

Date/Time of Clinic: 25/11/2020

Follow Up: PSA & write, USS & CNS LUTS

review 2-3 months

Diagnosis:

Lower urinary tract symptoms

Concern regarding prostate cancer with history of prostate cancer in his father

Outcome:

Recommend prescription Solifenacin 5mg daily, dose can be increased to 10mg daily depending upon affect/side effect. Please arrange for resolution to arrange prescription and ongoing repeat prescription

Check PSA and write with result

CNS LUTS review and if no improvement in urinary symptoms for urodynamics

contacted the Trust Information line with some questions regarding his assessment. He was referred to the Department with some urinary symptoms in December 2019 and had been assessed by Mr O'Brien privately.

He has two concerns. The first is a concern regarding a risk of prostate cancer and the second are his urinary symptoms.

With regards his concerns around prostate cancer his father was diagnosed with an aggressive prostate cancer aged 85 and had a low PSA at presentation. There is no additional family history of prostate cancer and there is no family history of breast cancer to arrange suspicion of him being a BRCA 2 gene carrier.

His PSA's previously are satisfactory being 1.09 in April 2014 and 0.61 in December 2019. Clinically he has a benign feeling prostate. He is on finasteride at present but was not on Finasteride for his previous PSA's.

I have discussed with that on the basis of the information I have namely his low PSA and his benign feeling prostate on DRE the risk of him harbouring a significant prostate cancer at present is low. We discussed options for further investigation including those of repeat PSA/PSA monitoring and MRI scan and we discussed the potential risks of additional investigation for prostate cancer specifically including risks of over diagnosis and over treatment. On balance would be satisfied to proceed down a PSA monitoring route and I have checked his PSA today and will write with the result.

With regards his urinary symptoms his primary complaint is that of storage symptoms namely urgency and rare episodes of urge incontinence. He has not had any history of previous urological interventions. He was tried with Combodart initially but the alpha blocker element made him light headed and this has been discontinued. He is now on Finasteride. We have discussed lifestyle modification as management of his urinary symptoms and I have recommended the addition of an anti-cholinergic as above. I would be grateful if you could arrange for him to receive a prescription and ongoing repeat prescription for this. I have also requested an ultrasound of his urinary tract as part of the assessment of his lower urinary tract symptoms and he will receive an appointment from the X-ray Department for this in due course. I have requested follow up in our Clinical Nurse Specialist clinic with regards his urinary symptoms and if his symptoms have not improved with the addition of Solifenacin I would have thought it reasonable to proceed to urodynamics before considering any bladder outflow surgery.

I have reassured reasonable that there are no issues with his management to date and I will be in contact next with the result of his PSA from today.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Page 2 of 3



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

JENNY MCMAHON Urology Nurse Specialist LUTS Clinic CAH

Dear Jenny

Re: Patient Name:

D.O.B.:
Address:

Hospital No: Personal Information reducted by USI

Personal Information redacted by the USI

Personal Information redacted by the USI

HCN: Personal Information redacted by the US

Date/Time of Clinic: 25/11/2020

I would be grateful if you could arrange a Nurse Specialist LUTS follow up for in 2-3 months to assess the response of his urinary symptoms to Solifenacin. Many thanks.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 5QQ



Dear DR SCOTT

Re: **Patient Name:**

D.O.B.:

Address:

Hospital No: Date/Time of Clinic: 25/11/2020

Follow Up: Already on waiting list for

Flexible cystoscopy December 2020

Diagnosis:

High risk non muscle invasive urothelial cancer of bladder treatment with transurethral resection and subsequent intravesical BCG (was not able to tolerate full BCG maintenance)

Outcome:

Already on planned flexible cystoscopy December 2020

I reviewed recommendation recognised by following recent contact with the Department. As you aware his TURBT in June 2019 was complicated by an extra-peritoneal bladder perforation which resulted in readmission and a lower midline laparotomy and repair of bladder. Personal information reduced by and his wife have raised concerns with me previously regarding whether his initial discharge on 28th June 2019 was sound particularly in light of his subsequent readmission due to his bladder perforation and laparotomy. In addition to their concerns regarding decision to discharge they also had concerns with regards communication by Medical Staff at assessment while an inpatient during this admission.

We have discussed the mechanism of the developments of a bladder perforation and Personal Information reduced by the USI and his wife recognise that this is a recognised small risk for any patients undergoing a TURBT. As Personal Information redacted by and his wife are aware the history that Personal information reducted by gives as to the progressive development of his pain and symptoms following catheter removal are clearly in keeping with the development of a bladder perforation. Unfortunately this was not recognised at the point of discharge. He was subsequently readmitted on 30th June and had his bladder perforation repaired.

I have apologised to and his wife with regards this misdiagnosis at the time of discharge and have again assured them that the Junior Doctor who had reviewed him on the Ward and unfortunately had not recognised that his symptoms were consistent with bladder perforation has engaged in both education and reflection regarding his care and I am satisfied that the doctor in question fully understands both the clinical and emotional impact this episode has had on and his wife. Unfortunately the failure to recognise these symptoms was a factor of experience/training.

As I have explained to responsibility for supervision of Junior Doctors lies with the Consultant Team and therefore ultimately as the Consultant who was on-call on the day of his discharge (Friday 28th June 2019) the responsibility for the decision lies with me. I have also explained that due to the nature of our practices and the fact that a number of our clinical sessions occur on sites away from Craigavon our on-call Consultant is the Consultant who provides input to both elective and emergency inpatients irrespective of the operating consultant as the operating consultant on the day after a procedure may not be based in Craigavon. Therefore Mr O'Brien who had performed Personal Information reducted by line operation would not be expected to have been present on the day of Poisonal Information redacted by the discharge on 28th June. Unfortunately as can be the case as the Consultant covering emergencies I believe I was not available at the time of the ward round on 28th June due to competing emergency commitments eg emergency theatre operating and so I myself was not present on the ward round on Friday 28th to identify that his symptoms were consistent with a perforation. I have apologised to resonal information reduced by and his wife in this regard. As stated I am satisfied that the Junior Doctor involved in decision making has undergone additional education, supervision and reflection and has a full understanding of the misdiagnosis. As the Junior Doctors have rotated I am also going to present to Personal Information redacted by the case at our next patient safety meeting as a learning prompt for our current Junior Doctor Team.

With regards his ongoing management surveillance for his previous high risk non muscle invasive bladder cancer. His recent CT urogram was satisfactory and bladder washings were in keeping with instrumentation with no malignant cells seen. This is reassuring.

He understands the nature of bladder cancer surveillance that for the first two years he will be on three monthly flexible cystoscopy surveillance. If he remains cancer free after two years of surveillance he will move to six monthly surveillance for two years and if at this point he remains free of recurrence then he will move to annual surveillance and his surveillance will continue for ten years.

did raise questions as to whether the perforation itself will have impacted on his cancer treatment and or outcome. I have reassured him that I would not anticipate this to be the case and indeed his recent CT scan was entirely satisfactory.

has specifically requested that we ensure that the Junior Doctor who was involved in his discharge does not contribute to his ongoing care and I have assured that we will make every arrangement to ensure that this is the case. I have suggested that when they get their appointment for each check cystoscopy that they contact the number on the admission letter just to confirm that the Junior Doctor will not be performing or present at the time of the procedure.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Page **3** of **3**



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 5QQ

DR E. MILLAR

Dear DR MILLAR

Re: **Patient Name:**

D.O.B.:

Address:

Hospital No:

HCN:

Date/Time of Clinic: 25/11/2020 Follow Up: Discharge

Diagnosis:

Lower urinary tract symptoms secondary to bladder outflow obstruction Concerns with regards outcome following circumcision

Outcome:

Agreed remove from waiting list for TURP Please consider request for commode chair for toileting at night Reassured regarding outcome from circumcision

Personal Information was reviewed by me in the Outpatients Department for 25th November following contact with the Trust Information line. He had raised concerns with regards the outcome following his circumcision. In addition we took the opportunity to review current management plans regarding his bladder outflow obstruction symptoms.

With regards the outcome following his circumcision the concern noted is that there is a feeling that he has lost some penile length and as a result has to sit to void. On clinical examination the cosmetic outcome from his circumcision is satisfactory. He has a left sided hydrocele and a reasonable pre-pubic fat pad and the result of these features is some burying of his penis giving the appearance of penile length shortening. The circumcision had removed the foreskin as planned but no penile length has been removed in the surgery. I was able to reassure Personal and his family of this.

With regards his bladder outflow obstruction symptoms he is currently on the urology waiting list for a TURP but his family have concerns with regards proceeding down a surgical route. We had a discussion of the management options for his urinary symptoms namely those of clean intermittent self

catheterisation, a longterm urethral catheter or a suprapubic catheter in addition to the option of bladder outflow surgery with a TURP.

On balance and his family feel they would prefer to continue managing things as at present. They do not wish to proceed with TURP and he has been removed from the waiting list.

With regards his urinary symptoms night-time voiding causes a degree of concern with mobilising to and from the toilet and I would be grateful if you could consider referral for a commode chair to have closer to the bed.

If his urinary symptoms do deteriorate to a point where further intervention is considered [PROSONELLI PROSONELLI PROSONE

For the time being no ongoing urology review is required and I have discharged him back to your care.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Personal Information redacted by the U



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 5QQ

DR D. CLEARY

Dear DR CLEARY

Re: **Patient Name:**

> **D.O.B.:** Address:

Hospital No:

Date/Time of Clinic: 25/11/2020Follow Up: Refer Ms Randhawa

Altnagelvin Area Hospital

Diagnosis:

Previous Nesbitt's procedure for Peyronies disease (May 2016) Circumcisions performed at time of Nesbitt's procedure Ongoing erectile dysfunction

Reduced penile sensation following Nesbitt's procedure

Outcome:

Refer Ms Randhawa Altnagelvin Hospital for discussion of further treatment options in particular potential of penile prosthesis

Further to previous correspondence I reviewed on 25th November after he had contacted the Trust with concerns regarding his treatment.

was initially seen in the Urology Department in 2013 presenting with complaints of erectile dysfunction and a penile bend. History and examination at the time were felt consistent with Peyronies disease. Medical treatment of his erectile dysfunction was continued with PDE5 inhibitors. At further review in 2014 by Mr O'Brien further assessment of the penile bend was made as the Peyronies disease would have been expected to have stabilised at this point and it was noted that the angulation was approximately 80° in dorsal direction. He remained on a PDE5 inhibitor at this point and was placed on the waiting list for surgical correction of the bend. There is documented within correspondence discussion of the risks of the Nesbitt's procedure with specific discussion of the expectation of penile shortening as a result of the penile plication. underwent his surgery on 18th May. As is the case with uncircumcised men

Received from Dr Maria O'Kane on 29/03/22. Annotated by the Urology Services Inquiry.

undergoing Nesbitt's procedure a circumcision was performed as part of the procedure.

Following recovery from his surgery underwent further review. At the time of outpatients review in August 2016 reported that the bend had improved. As a result of this improvement it was no longer causing a problem with penetration. He did report at this time that there was worsening of persistent erectile dysfunction. Adjustments to his prescriptions of PDE5 inhibitors were made and he was next review in June 2017. Unfortunately at this time his erectile dysfunction had not improved with the adjustments in his PDE5 inhibitor medication and following discussion he was commenced on intracavernosal injections of Alprostadil. His current prescriptions for his erectile dysfunction remain Tadalafil 10mg daily with Sildenafil 50mg taken on a prn basis one hour before sexual activity and Viridal duo intracavernosal injections at a dose of 40mcg injected on a prn basis at the time of sexual activity.

presents with a number of concerns/questions regarding his treatment and ongoing difficulties with sexual function. His concerns he raised with regards his treatment are that his surgery has resulted in a significant degree of penile shortening, his erectile dysfunction is worse post surgery than pre surgery, he has developed reduced sensation within his penis and a circumcision was performed at the time of his surgery.

I have discussed these outcomes with him and we discussed the process of decision making and consent for his surgery. I have also shared with him standard patient information sheets from the British Association of Urological Surgeons for the Nesbitt's procedure. Procedure acknowledges that the risks of the surgery had been discussed with him but that perhaps it had not been as clear to him how likely those risks were to happen. With regards the penile shortening it is recognised that there is an approximately 1cm loss in penile length for each 15° of penile bend which is corrected at surgery. With a severe bend such as [Procedure accessed by 100 US] had prior to surgery of 80° therefore it would be anticipated that a 4cm loss of penile length would occur.

With regards his erectile dysfunction reson had pre-existing erectile dysfunction prior to surgery and unfortunately the surgery itself runs a risk of worsening erectile function. Unfortunately this was the case with redaded by the USI

I discussed the surgical technique and have explained to rescal information redacted why a circumcision is performed as part of the procedure in particular where in order to reach the site of the deformity in order to perform the plication a full degloving of the penis is required and redacted by the USI understands why this was done.

With regards the loss of sensation again we have discussed how a loss of sensation may occur following this surgery and this risk is recognised as a risk of the procedure he has undergone.

With regards the ongoing management I had a discussion with regarding the three aspects namely his ongoing erectile dysfunction, his penile shortening and loss of sensation. He is aware that there is no specific treatment that I can offer that will rectify the altered sensation. With regards the erectile dysfunction he is on maximum medical therapy and therefore there are no additional options on this front. I suspect the best treatment for

would be insertion of a penile prosthesis and I have discussed this with him and provided him with BAUS information sheet regarding this procedure. He is aware that this procedure is not commissioned to be performed in Northern Ireland at present. Patients who do meet criteria for this treatment are referred at present to London through the Extra-Contractual referrals process. A colleague, Ms Randhawa who works in Altnagelvin Hospital is trained in surgical andrology and spent time in her training with the Team in London and I have written to her to request an outpatient review with processed for her assessment as to whether she feels that a penile prosthesis would be the most appropriate treatment for him.

The only other erectile dysfunction treatment he has not yet tried is that of a vacuum device. He is aware of these but I would hold a very low expectation of these being successful in treating [Particular Information regulators Lay Industrial Institute of the contract of the contract

With regards the loss of penile length again we have discussed this. remainded is aware that the Team in London do on occasion perform some penile lengthening procedures but I do not know whether this would be possible as part of the procedure of insertion of a penile prosthesis.

With regards contact with our information line and concerns regarding his treatment I have reassured that the treatment he has undergone would be in line with treatment offered by other Urologists and the post operative effects he has experienced are expected in patients undergoing the surgery he has undergone. I have referred to Ms Randhawa and hopefully he will receive an appointment in due course.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Ms Rhandawa, Consultant Urologist, Altnagelvin



Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

DR N. MCELVANNA

Personal Information redacted by the USI

Dear DR MCELVANNA

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

sonal Information redacted by the USI

Personal Information redacted by the USI

HCN: Personal Information redacted by the USI

Date/Time of Clinic: 25/11/2020 | Follow Up: Review LUTS 3/12

Diagnosis:

Recurrent urinary tract infections currently on longterm low dose antibiotics Storage urinary symptoms with urgency and urge incontinence as predominant symptoms

Outcome:

Recommend prescription topical vaginal oestrogens, please arrange prescription and ongoing repeat prescription

Once established on topical vaginal oestrogens for 1-2 months recommend trial off longterm low dose antibiotics

If during trial off longterm low dose antibiotics experiences a recurrence of her recurrent urinary tract infections then it would be recommended to recommence longterm low dose antibiotics with a view to these continuing as ongoing longterm treatment

Clinical Nurse Specialist telephone review three months to assess response of urinary symptoms to topical vaginal oestrogens with a view to potential urodynamic assessment if ongoing significant urgency and urge incontinence to assess for evidence of detrusor overactivity with a view to consider of intradetrusor Botox injections

Further to your recent advice request and contact with the Department I arranged to see in clinic on 25th November. She has a history of recurrent urinary tract infections and storage lower urinary tract symptoms. She is on anti-cholinergics (Oxybutynin and is also on Amitriptyline which has anti-cholinergic effects) and continues to experience significant urgency and episodes of urge incontinence such that she ensures she has spare clothing in the car in case she experiences episodes while out of the house. She does not describe any vaginal symptoms. She is peri-menopausal.

Personal information redacted by the USI

Page 2 of 3

With regards her recurrent urinary infections these have been well controlled on longterm low dose antibiotics and I note your query whether it is reasonable to consider a trial off the low dose antibiotics.

I have discussed management of both recurrent urinary infections and storage symptoms with In first instance I recommend commencing topical vaginal oestrogen as these can be effective in treating both storage related urinary symptoms and recurrent urinary tract infections. Once she has been established on these for a period of 1-2 months it would be reasonable for her to have a trial off the longterm low dose antibiotics. If her recurrent urinary tract infections recur while off the longterm low dose antibiotics despite topical vaginal oestrogens and lifestyle advice for which she has also been provided with today then it would be reasonable for her to recommence longterm low dose antibiotics and remain on these longterm. She understands the concerns however with regards longterm low dose antibiotics and the developed of antibiotic resistance.

Specifically with regards her storage urinary symptoms the urge incontinence in particular has a significant impact on her quality of life. The topical vaginal oestrogens may improve things and I have requested a Clinical Nurse Specialist review in around three months to assess how things have been impacted by the commencement of topical vaginal oestrogen. It can take up to 12 months for topical vaginal oestrogens to have maximum effect so if there is some improvement at initial review it may be that we give more time before considering urodynamics. Ultimately if her urge incontinence does not improve she would be keen to seek additional treatment. However I briefly highlighted that in patients who have significantly symptomatic detrusor overactivity Botox injections into the bladder can successfully treat this. If we are looking to proceed down this route I would look to arrange up to date urodynamics to prove detrusor overactivity prior to instigating treatment.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Jenny, Urology Nurse Specialist, CAH



JENNY MCMAHON Urology Nurse Specialist LUTS OPC CAH

Dear Jenny

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

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Personal Information redacted by the USI

HCN: Personal Information redacted by the US

Date/Time of Clinic: 25/11/2020

I would be grateful if could have a CNS LUTS telephone review in around three months to assess her response to topical vaginal oestrogens with a view to considering urodynamics/Botox injections if her urge incontinence does not response to this treatment. Many thanks.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Personal Information redacted by the US



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR J. MCCONVILLE



Dear DR MCCONVILLE

Re: Patient Name:

D.O.B.:

Address: Hospital No:

ospital No:

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Personal Information redacted by the USI

HCN: Personal Information redacted by the USI

Date/Time of Clinic: 25/11/2020 | **Follow Up:** USS, CNS Telephone review 3/12

Diagnosis:

Lower urinary tract symptoms

Outcome:

Ultrasound urinary tract

Flow rate assessment (at South West Acute Hospital) CNS LUTS telephone clinic follow up three months

I reviewed on 25th November following his contact with the Trust Information line. He was seen by Mr O'Brien privately in 2017 and has been added to the waiting list a TURP. He is currently on Tamsulosin and Finasteride for his lower urinary tract symptoms. I have reviewed his previous investigations which include an ultrasound of his urinary tract in 2013 and his last PSA in 2017 which was satisfactory at 3.4.

With regards his lower urinary tract symptoms describes variable symptoms with good and bad days. His primary symptoms are storage related with nocturia 5-6 times a night, daytime frequency of up to 8 times and urgency and on occasion urge incontinence. He describes his flow as poor with some post micturition dribble but no significant hesitancy and he has not experienced any haematuria.

With regards his fluid intake he describes drinking 3 pints of tea or coffee all caffeinated with his last caffeinated drink being in the evening.

On clinical examination he has a large benign feeling prostate and no other finding of note on examination of his abdomen or external genitalia.

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I have discussed management of urinary symptoms with record of the waiting list for TURP at present I do not have documented evidence of bladder outflow obstruction with either urodynamics or a flow rate and this information is required in order to confirm that a TURP will benefit him in terms of symptomatic improvement. I have discussed this with

In addition I have recommended ultrasound assessment of his urinary tract primarily to assess his prostate size as prostate size also has an impact on the type of bladder outflow surgery that would be recommended. I have also checked his PSA and this remains normal at 1.09.

I have requested the ultrasound and will write to with the result. I have also written to our Nurse Specialist colleague in South West Acute Hospital, Kathy Travers, requesting a flow rate be performed. has also been given fluid advice specifically to reduce the volume of caffeinated fluid intake as this may have an impact of improving his storage related urinary symptoms. I have requested that he is followed up by telephone by our Clinical Nurse Specialist in three months.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Personal information reduced by the USI Page ${f 2}$ of ${f 4}$



UROLOGY REFERRAL LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

Kathy Travers
Urology Nurse Specialist
South West Acute Hospital,
124 Irvinestown Road
Enniskillen
BT74 6DN

Dear Kathy

Re: Patient Name:

D.O.B.:

Address: Hospital No:

Personal Information redacted by the USI

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HCN: Personal Information redacted by the USI

Date/Time of Clinic: 25/11/2020

I would be grateful if you could arrange for to have a flow rate at your earliest convenience. He has a significant mix of urinary symptoms with storage related symptoms being his primary concerns. We have also given him lifestyle/fluid advice as he has a significant caffeinated fluid intake and this may improve his symptoms. Many thanks.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

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Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

UROLOGY NURSE SPECIALIST LUTS clinic CAH

Dear Jenny/Patricia

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

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HCN: Personal Information redacted by the

Date/Time of Clinic: 25/11/2020

is currently on the waiting list for a TURP however upon review he required some lifestyle advice which may improve his storage urinary symptoms. I have requested Kathy Travers arrange a flow rate. I would be grateful if you could perform a telephone review in three months. If despite reducing his caffeinated fluid intake his symptoms remain predominantly storage related I would be grateful if urodynamics could be arranged. Similarly if his flow rate does not show obstructed flow pattern again I would be grateful if urodynamics could be arranged. Many thanks.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 500

DR H. BEATTY

Personal Information reclacted by the USI

Dear DR BEATTY

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Personal Information

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February 2021

Diagnosis:

Clinical impression of malignant prostate

Small bladder stones

Outcome:

Please stop Bicalutamide

Please add PSA to planned blood tests next week

Check PSA February 2021 and write with result (has been sent a request form for this)

In light of PSA and situation regarding coronavirus pandemic in February 2021 consider CT chest, abdomen and pelvis and flow rate assessment

I reviewed by telephone on 1st December 2020 having confirmed his identity. was initially seen with a PSA which was elevated at 33.37 and clinical examination was felt consistent with a prostate cancer. A bone scan was performed at the time and showed no evidence of metastatic disease. He also had significant urinary symptoms.

On review with Mr O'Brien he was commenced on a low dose of Bicalutamide and placed on the waiting list for a TURP with the intent that the TURP would improve his urinary symptoms and obtain tissue for pathology with regards to prostate cancer likely diagnosis. The TURP did not happen as blood sugars were very poorly controlled at this time and it is notable that his urinary symptoms have significantly improved following control of his blood sugars to a point where himself does not feel any surgery to improve his urinary symptoms is necessary. With regards the bladder stones he has been noticed to

have bladder stones on flexible cystoscopy but tells me he has passed bladder stones intermittently for more than 20 years and these cause him little problems.

With regards the Bicalutamide treatment I have advised that the dose he has been started is below the dose that would be used as a treatment for prostate cancer and continuing on this is not required at present. We have not made a definite diagnosis of prostate cancer and we have not got any evidence to suggest that he requires treatment for this and cannot be managed by watchful waiting. It is notable that he has also experienced painful gynaecomastia which is likely as result of taking the Bicalutamide.

I would be grateful if you could discontinue this treatment.

With regards further monitoring he tells me he is due a blood test next week with yourselves and I would be grateful if you could add a PSA to this request. In addition I have sent a request form to have a prostate blood test in February 2021 and I shall write with the result. I will review his PSA and also the situation with regards the coronavirus pandemic at this time with a view to considering a CT scan and flow rate assessment.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Date Dictated: 01/12/20 **Date Typed:** 02/12/2020-LH



Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

DR M. O'NEILL
Personal Information redacted by the USI

Dear DR O'NEILL

Re: Patient Name:

D.O.B.:

Address:

Hospital No: Personal Information redacted by the USI HCN: Personal Information redacted by the USI

Diagnosis:

Previous TURP for bladder outflow obstruction

Recurrent pseudomonas urinary infections prior to TURP and following TURP Ongoing bladder/penile pain with significant storage urinary symptoms

Outcome:

CT urinary tract

MRI scan pelvis and prostate

If CT and MRI scan show no surgically treatable cause for recurrent infections liaise with Microbiology regarding prolonged treatment dose antibiotics for recurrent pseudomonas infections

Outpatient review following CT and MRI scan

Trust Advice line with regards his ongoing management. He initially presented with recurrent significant infections which had included severe urosepsis with pseudomonas being a noted organism. He subsequently underwent a TURP. Since the TURP his symptoms have deteriorated and he has ongoing daily pain. The pain itself preceded his TURP but prior to the TURP was managed adequately with analgesic. Since TURP his analgesics requirement has increased.

He describes continuing penile pain which is present all the time but increases on voiding. It radiates into his rectum. It is associated with significant severe storage urinary symptoms with a daytime frequency of up to every 20 minutes and a night-time frequency of 7-8 times. He describes a very small functional capacity.

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His mobility is reduced by neuropathic pain he experiences in his legs from his diabetes. I note his most recent HBA1c shows good control of his sugars at 48. I also note previous CT scan had shown a small lower pole stone measuring 4mm. The absence of any loin pain or upper urinary infections makes me of the opinion that this stone is not related to his current symptoms.

I have explained to that his ongoing symptoms are largely down to bladder symptoms and these may be the result of underlying prostate pathology such as obstruction. As his symptoms predate his TURP I suspect however that the major component here is of some overactivity or cystitis. It is notable that his MSUs have grown pseudomonas on a number of occasions but even when cultures are negative there is a pyuria.

I have reassured that the TURP would have been recommended given the evidence at the time of upper tract obstruction and the suspicion that his bladder outflow obstruction was an underlying factor in his recurrent infections. Indeed although he has had further infections since his TURP these have not been as severe prior to his TURP.

I have recommended a CT urinary tract in the first instance to ensure that his kidney stone has not increased significantly. I also plan an MRI scan of the pelvis and prostate to ensure there is no prostate abscess.

If these investigations are satisfactory I shall liaise with Microbiology as I wonder whether given that he has had recurrent proven pseudomonas infections it would be appropriate for to receive a prolonged treatment course of antibiotics. Once I have discussed with Microbiology I will make arrangements to review review in outpatients to discuss the advice from Microbiology and make a plan for further management. I have advised recommending that I feel it is likely that I will be recommending both a flexible cystoscopy and urodynamic assessment at some point in the future. He is extremely reluctant to undergo these investigations but understands the reasoning behind them.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 2



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear DR MCSHANE

Re: Patient Name:

D.O.B.:

Date/Time of Clinic: 01/12/2020 **Follow Up:** Urodynamics

Diagnosis:

Previous radiotherapy for prostate cancer

Pre-existing significant lower urinary tract symptoms which have deteriorated following radiotherapy

Outcome:

Await urodynamics with a view to potential treatment which may include intradetrusor Botox injections

was seen by me in clinic on 1st December following contact with our Trust Information line. was previously treated by Mr O'Brien having been diagnosed with prostate cancer in November 2017. At this time he had significant lower urinary tract symptoms and indeed these were such as he underwent TURP in January 2016. He had continuing lower urinary tract symptoms and although he had been started on treatment for his androgen deprivation therapy further radical treatment was deferred while attempts were made to control his symptoms. He subsequently underwent radiotherapy in 2018.

Unfortunately his urinary symptoms have worsened with urgency and urge incontinence being primary features with a significant daytime frequency and nocturia up to 5-6 times a night. He describes his functional bladder capacity as small. A recent flexile cystoscopy was satisfactory.

On fluid intake he drinks approximately 4 cups of caffeinated tea a day with the remainder of his intake being water or diluted orange. I note he is currently on Solifenacin and advises me that alternative medications have not been able to be started due to concerns of interaction with his cardiac drugs or issues with regards their side effect profile and his heart history.

Mr O'Brien had made plans for further management of gradual urinary symptoms with urodynamics in the first instance and I have reiterated this recommendation to I have advised him that the urodynamics will look to ascertain the underlying function issues with his bladder and enable us to consider appropriate treatment and also discuss the side effect profile of such treatment.

I suspect that given him symptoms we are most likely looking at Botox injections to the bladder and I have discussed this briefly with him today and I also made him aware that there is a risk of urinary retention and the need to intermittently self catheterise after intradetrusor Botox injections.

I have reassured that he remains on the waiting list for urodynamics. At present we have not been able to perform any urodynamics since the onset of the coronavirus pandemic. Hopefully we will be in a position to start performing these procedures in the near future.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

on redacted by the USI Page **2** of **2**



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear DR DOLAN

Re: Patient Name:

D.O.B.:

Address:

Hospital No: Personal Information redacted by the USI HCN: Personal Information redacted by the USI

Diagnosis:

High risk radiologically T3a prostate cancer treated with combination androgen deprivation therapy and radical radiotherapy Peyronies disease

Outcome:

Refer Mr Young for surgery for Peyronies

contacted the Trust Information line and was reviewed by me in clinic today 1st December 2020. I had previously seen him in 2018 when I performed his transperineal prostate biopsies and subsequently reviewed him with the results and referred him to the Oncology Team.

Reviewing his history he was initially referred with Peyronies disease and I shall come to this later in this letter.

He was found to have a raised PSA and underwent prostate biopsy in late 2015. This had shown two cores containing some prostatic intraepithelial neoplasia but no evidence of cancer. His pathology was reviewed at Multi-Disciplinary Team meeting and the recommendation of PSA monitoring and MRI scan a minimum three months after the biopsies was given. He subsequently underwent an MRI scan in February 2016 and this had shown a small area of anterior right sided abnormality. There is outpatient consultation letter from the attendance on 30th November 2015 when was advised of his prostate biopsy pathology. The next recorded letter was dictated in November 2016. This letter discusses the finding of the MRI scan and subsequent surveillance PSA levels which had stayed steady at around 9.4 in November 2016. The letter documents a discussion

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regarding further biopsies stating that was not keen on having further biopsies at this time. The next consultation took place again by telephone with the letter dated 4th July 2018 when Mr O'Brien arranged to see following a further MRI scan as his PSA levels had increased to 15.3 in May 2018. Was subsequently reviewed in outpatients on 6th August 2018. His PSA had been found to have risen to 21 and subsequently transperineal biopsies of the prostate were performed which I undertook on 29th August 2018. These demonstrated a diagnosis of prostate cancer with the tumour being located in the anterior portion of the prostate. was subsequently commenced on androgen deprivation therapy and has undergone radical radiotherapy. While there had been a plan for him to receive a longer course of neoadjuvant androgen deprivation therapy due to side effects this was discontinued. His PSA remains under control at present.

delay in him having his second set of prostate biopsies and whether this would have impacted on his subsequent management.

I have discussed this with provided that the option of further biopsies was discussed with but the letter states he was not keen to pursue this route. Certainly his PSA was stable in late 2016 and therefore PSA monitoring in light of a previous set of negative biopsies and accepting of the findings of the MRI scan would be a reasonable option, as would proceeding to biopsies have been. It is difficult to be certain as to whether proceeding biopsies at this time would have definitely made the diagnosis of prostate cancer given the anterior location of the tumour. In 2016 we were not performing our biopsies transperineally and anterior tumours are recognised as easily missed on transrectal ultrasound guided biopsies of the prostate. In 2018 appropriately when his PSA had started to rise Mr O'Brien arranged a further MRI scan and subsequently underwent biopsies and treatment for his prostate cancer.

understands the uncertainty as to whether earlier biopsies would have definitely made a diagnosis of prostate cancer and he also understands that the letters we have state that the option of earlier biopsy was discussed with him. He also understands that had he had a biopsy earlier radical radiotherapy would have remained an option with the main change in treatment being that he would have been offered a different duration of androgen deprivation therapy in combination with radiotherapy. As noted he has discontinued his androgen deprivation therapy due to side effects.

With regards the Peyronies disease waiting list in 2014 having been seen by Mr O'Brien regarding this. When he was contacted in July 2018 resolutions had undertaken to explore the option of private treatment. Mr O'Briens advice at this time was not to proceed with his plan for private treatment and given that his PSA had risen and he subsequently has been diagnosed with prostate cancer this advice is very sensible advice as had developed any post prostate cancer treatment erectile dysfunction any treatment for his Peyronies disease may have not been appropriate.

Fortunately has not been impacted by any loss of erectile function and continues to get early morning erections. He has a bend which he describes as slightly dorsal and to the left of approximately 45° and precludes intercourse. He

is keen for treatment and has researched this himself online. I have reiterated to him that the recommended treatment and with a bend of 45° a Nesbitt's procedure would be recommended. He understands that there would be a loss of penile length approximately 3cm (1cm of 15°). He also understands a risk of worsening of his erectile function, altered sensation/numbness and that a circumcision would typically be performed as part of the procedure. He is keen to peruse this treatment. I note he had been added to the waiting list in November 2014 and was subsequently removed at the time Mr O'Brien advised suspending treatment. I have suggested to that it would have been appropriate to suspend him in 2018 while he underwent prostate treatment and I will look to have him reinstated on the waiting list for surgery as of his original listing date.

understands that I do not perform Nesbitt's procedure and I have referred him to my colleague Mr Young who does perform this surgery. He also understands that Mr Young may wish to review him.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Cc Mr Young, Consultant Urologist, CAH



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

DR J. MERCER



Dear DR MERCER

Re: Patient Name:

D.O.B.:

Address:

Hospital No: Personal Information redacted by the USI HCN: Personal Information redacted by the USI

Diagnosis:

Bladder neck incision approximately 2009. Intermittent self catheterisation since Recent onset of new symptoms with nocturia, nocturnal enuresis and increasing frequency of needing to self catheterise

Outcome:

Ultrasound urinary tract and write with result Check PSA and write with result

I reviewed following his contact with the Trust Information line. He underwent a bladder neck incision in 2009. Following this he failed to void. He describes a period of a number of failed trial removal of catheters and found the experience difficult. Since then he has been taught intermittent self catheterisation and he is happy managing his bladder as he is at present. Three years ago he started with some new symptoms of nocturia up to three times a night and has also experienced some daytime and nocturnal incontinence. He had a trial of Oxybutynin which he had to discontinue due to side effects.

On balance with regards his urinary symptoms he would not wish any additional invasive treatment and is happy to continue manage things as he is. His specific concern is with regards whether there is any concern regarding his prostate gland.

I note a PSA from September 2019 was normal at 1.59. On clinical examination he has a small benign feeling prostate. Examination was slightly difficult as clinically he had a palpable bladder despite having self catheterised prior to examination.

I have discussed further assessment with provided to obtain post void residual and a flexible cystoscopy to ensure that he has not got any urethral or bladder neck contractures provided to an ultrasound of his urinary tract and this will provide us with useful information as to how successful bladder emptying is. It will also assess his prostate size. In addition I have checked his PSA today and shall write with the result.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



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Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR B. ALLEN



Dear DR ALLEN

Re: Patient Name:

D.O.B.:

Address:

Hospital No:

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Personal Information redacted by the USI

Personal Information redacted by the USI

Personal Information redacted by the USI

Date/Time of Clinic: 01/12/2020 | **Follow Up:** CNS Telephone review 3/12

Diagnosis:

Previous left ureteroscopy for PUJ stone

Ongoing storage urinary symptoms

Recent Hospital admission with acute sigmoid diverticular perforation managed conservatively

Outcome:

Stop longterm low dose antibiotic

ersonal information restacted by the USI plans to have a trial off her Oxybutynin

Please arrange prescription of topical vaginal oestrogen to be continued as an ongoing repeat prescription

CNS telephone review 3 months

contacted the Trust Information line. She had undergone previous treatment under the care of Mr O'Brien for a left PUJ stone. She had an acute ureteroscopy and successful treatment of this stone and did not require a stent insertion. A follow up CT scan performed recently has confirmed she has no residual stones. She had been experiencing recurrent left sided pain but this has been explained more recently following her recent acute admission under the Surgeons in Daisy Hill Hospital with localised diverticular perforation which has been managed conservatively.

I note she had proven urinary infections prior to her admission with her stone but she has not had any proven urinary infections since then. She currently remains on a low dose antibiotic and she wishes to stop this. I have advised that this would be recommended and I have therefore advised her to discontinue this. In addition she was asking regarding the Oxybutynin. As this would be given primarily for symptoms I have suggested that she can make a decision on this. She is aware that one of its side effects is that of constipation and is keen to try and see how her urinary symptoms are off the Oxybutynin.

I note she was seen by the Gynaecology Team in the Summer with regards a prolapse and a ring pessary was tried. She was not able to keep this in and is planned for a gynaecology review.

On examination she does not have any significant cystocele but a moderate rectocele.

I have discussed her ongoing urinary symptoms and have explained that the urinary symptoms she describes can often be seen in post menopausal ladies and may well respond to topical vaginal oestrogen. I have suggested these as a first line treatment. I would be grateful if you could arrange a prescription for these and an ongoing repeat prescription.

I will be making arrangements for her to be reviewed by our Clinical Nurse Specialist Team via telephone in three months time and depending upon her response to treatment will plan further investigations from there. If urgency symptoms remain significant then we can consider urodynamics at this point.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



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Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

UROLOGY NURSE SPECIALIST CAH

Dear Jenny/Patricia

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

ersonal Information redacted by the USI

Personal information redacted by the OSI

HCN: Personal Information redacted by the US

Date/Time of Clinic: 01/12/2020

I would be grateful of could have a telephone review in approximately three months time regarding her urinary symptoms. Many thanks.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Personal Information redacted by the U



Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

DR G. NICHOLSON



Dear DR NICHOLSON

Re: Patient Name:

D.O.B.: Address:

Hospital No:

Patient 21
onal Information redacted by the USI

al Information redacted by the USI

HCN: Personal Information redacted by the USI

Diagnosis:

Circumcision June 2019 for lichens sclerosus (balanitis xerotica obliterans) Lower urinary tract symptoms

Outcome:

Recommend Canasten HC (1% hydrocortisone) to be applied topically to penis twice a day for one week

Recommend prescription Tamsulosin MR 400mcg once at night and Solifenacin 5mg once a day to be continued as ongoing repeat prescriptions, Solifenacin dose can be increased to 10mg daily depending on affect/side effect

Outpatient review 2-3 weeks

contacted the Trust Information line with some queries regarding his previous treatment. I have reviewed this with him in consultation. He was referred initially in April 2017 with problems with his foreskin and he tells me that these problems had gradually worsened over a significant number of years. Having been on the waiting list for around two years he sought a private consultation which he had with Mr O'Brien. At the time he was quoted a cost for a circumcision but could not afford this. Having increasing problems he searched again online for alternative private providers and was seen in Hillsborough Clinic by Mr O'Donoghue. He was quoted a price for a circumcision which he could afford and he subsequently underwent surgery at Hillsborough. He had some issues with Hillsborough with regards the quote and subsequent billing which he has involved his solicitor with.

Page 1 of 2

WIT-04617

From a circumcision perspective the foreskin was adequately removed. Pathology was sent which has confirmed lichens sclerosus with specifically no evidence of malignancy or carcinoma insitu.

has ongoing symptoms. With regards his previous circumcision he still noted some redness and itching/soreness.

He also has urinary symptoms which are predominantly storage in nature with urgency and urge incontinence. I note his history of type 2 diabetes and sleep apnoea. On reviewing his fluid intake he drinks 6-8 cups of caffeinated coffee per day.

Clinical examination of his abdomen is unremarkable. Rectally he has a benign feeling prostate.

On examination of his external genitalia he has a pre-pubic fat pad which results in the apparent appearance of some residual foreskin however when putting his penis to full length the remaining penile shaft skin is adequate when in an erect state. There is a small approximately 2cm patch of red skin at the corona on the left side of the glans penis which likely represents benign balanitis.

With regards the patch of balanitis I have recommended topical steroid cream as above and I would be grateful if you could arrange for to receive a prescription for this. I also plan a review in 2-3 weeks to assess response to this treatment and I have advised that if the red area remains it may be prudent to arrange a biopsy.

With regards his urinary symptoms we have discussed the impact of type 2 diabetes and I note his most recent HBA1c indicates that his sugar controls could improve. We also discussed sleep apnoea and its impact on particularly night-time symptoms. I have discussed the impact of caffeinated fluids on urinary symptoms and have advised him to reduce this. has been given an information sheet regarding male urinary symptoms and we will post out a fluid advice sheet. In order to also hopefully improve his symptoms I have recommended a prescription of alpha blocker and anti-cholinergic and I would be grateful if you could arrange for him to receive a prescription and ongoing repeat prescription.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

DR P. CARSON

Personal Information redacted by the USI

Dear DR CARSON

Re: Patient Name:

D.O.B.: Personal Information redacted by the

Address:

Personal Information redacted by the USI

Hospital No: Personal Information reducted by the USI HCN: Personal Information reducted by the USI

Date/Time of Clinic: 01/12/2020 **Follow Up:** Urine cytology & urodynamics

Diagnosis

G2 Ta urothelial cancer of bladder diagnosed 2015. Single recurrence 2016, no recurrence since. On annual flexible cystoscopy surveillance Storage lower urinary tract symptoms

Outcome:

Voided urine for cytology and write with results Urodynamics

Further to previous correspondence contacted the Trust Information line requesting review assessment whether he should have any concerns. I have reassured him that having reviewed his records and following consultation today I have not concerns with regards his previous treatment.

He initially presented to the Department with a non muscle invasive urothelial cancer of the bladder which has been treated in standard fashion with TURBT and subsequent endoscopic surveillance. Standard Practice would be that he would have received a single dose of intravesical Mitomycin C while on the ward, this is not detailed on his e-discharge and I was not able to double check his notes to confirm this for him. Following his TURBT he has subsequently developed storage urinary symptoms and this is something we see for a small number of patients who have had bladder cancer surgery. Reassuringly surveillance cystoscopy since 2016 has shown no recurrence of his bladder cancer and also confirmed no evidence of any urethral stricture disease. His primary symptom is that of urgency and urge incontinence and he does wear a pad both at night and for long journeys incase he is caught short. He does not drink any significant caffeinated fluid intake.

Personal Information redacted by the USI

Clinical examination is unremarkable and rectally he has a benign prostate.

In order assess his current symptoms further I have sent a voided urine for cytology and shall write with the result. I have also recommended urodynamics as I note he is already on combination of alpha blocker and anti-muscarinic.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Personal Information redacted by the USI Page **2** of **2**



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

DR K. WEBSTER
Personal Information reducted by the USI

Dear DR WEBSTER

Re: Patient Name:

D.O.B.:

Address:

Hospital No: Personal Information redacted by the USI HCN: Personal Information redacted by the USI

Date/Time of Clinic: 01/12/2020 **Follow Up:** Flexible cystoscopy

Diagnosis:

Previous cystectomy/orthotopic bladder substitution Mitrofanoff urinary catheterisable urinary diversion which was unsuccessful Currently managing bladder with clean intermittent self catheterisation Recurrent urinary infections and neo-bladder pain

Outcome:

Frequency volume chart Flexible cystoscopy (MDH to do)

I reviewed following your referral from 28th October. She has a long history in the Urology Department having had a previous cystectomy, orthotopic neo-bladder substitution. She subsequently manages her bladder by urethral intermittent self catheterisation but previously had a Mitrofanoff which she tells me was unsuccessful. She gets recurrent urinary infections and has been seen and assessed through the Immunology Team. She currently continues on low dose Nitrofurantoin 100mg daily. She self catheterises 7-8 times a day when she feels that her bladder is full. She is unsure of the volume of urine obtained when she self catheterises but tells me that her impression is that it is relatively low. Drainage can be positional and on occasion she also sees mucus. In managing her symptoms has also had a number of cystodistension/urethral dilatations.

self catheterises when she gets a cramping pain which she associates with her neo-bladder being full. Passage of the catheter is painless and satisfactory. Following drainage of urine the cramping pain dissipates immediately. Subsequently when she gets up and walks experiencing pain which

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radiates up from her urethra into both sides of her pelvis. She finds that if she sits for approximately 5 minutes this pain will subsequently settle.

On clinical examination of her abdomen there is a slight suprapubic pain but otherwise unremarkable. On vaginal examination she has a very slight grade 1 rectocele but no demonstrable cystocele and her urethra externally appears normal.

I discussed ongoing management with and ultimately we may not be able to find a solution to her recurrent urinary infections. In the first instance we need to know what her functional bladder capacity is and I have requested that she completes a frequency volume chart for me noting both her intake and the timing of her intermittent catheterisation along with volume drained from her bladder. In addition I have advised that we recommend continued endoscopic surveillance of bowel within the urinary tract due to a slight increased risk of developing malignancy within the bowel segments. In addition it would be helpful to perform a cystoscopy to check for the presence of any mucosa or stones. She is aware that I will perform this under local anaesthetic as a flexible cystoscopy and I will make arrangements for this to be performed by me.

I will review her frequency volume chart at the time of this attendance and have a further discussion as to how we can take things forward.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Personal information redacted by the USI Page ${f 2}$ of ${f 2}$



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear DR BEATTY

Re: Patient Name:

D.O.B.: Address:

Hospital No:

sonal Information redacted by the USI

onal information redacted by the USI HCN:

Diagnosis:

Locally prostate cancer diagnosed in 2010, on anti-androgen since Most recent PSA less than 0.01

Outcome:

Stop Bicalutamide and Tamoxifen

Please check PSA March 2021 (has request form for this)

was diagnosed with a prostate cancer in 2010. I do not have the pathology report however his letter states it was gleason 4+4=8. Staging at the time showed this to be localised disease. He had been subsequently started an anti-androgens. This has maintained a low PSA and his last recording earlier this year was less than 0.01. I note he is also anaemic which can be a longterm side effect of androgen deprivation therapy.

I discussed with his options for ongoing management of his prostate cancer. Given that the in the ten years since diagnosis his PSA remains well controlled I have suggested it would be reasonable to manage further with either watchful waiting or intermittent deprivation therapy. This will hopefully enable him to minimise any risk of side effects from the treatment. If necessary after a period of time off his treatment we could also look to restage his prostate cancer and consider whether alternative treatment options are available.

He is therefore in agreement with stopping his Bicalutamide and Tamoxifen and I would be grateful if you could cancel these repeat prescriptions. I have given him a blood form for a check PSA in March 2021 and I shall write with the result.

Yours sincerely

dictated but not signed by

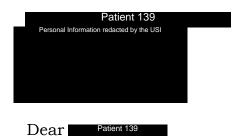
Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page 2 of 2



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Patient 139

Personal Information redacted by the USI

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Date/Time of Clinic: 02/12/2020 | **Follow Up:** CNS telephone review 2 weeks

Diagnosis:

Small volume intermediate grade prostate cancer diagnosed on prostate biopsy late 2009/early 2010

Commenced on Bicalutamide 50mg early 2010 and remains on Bicalutamide 50mg and Tamoxifen10mg

Recent PSA May 2020 0.1

Outcome:

Recommend treatment

Discontinue Bicalutamide and Tamoxifen and move to surveillance strategy for managing prostate cancer

Alternative option switch to LH RH analogue as androgen deprivation therapy

I write following our telephone consultation on 2nd December 2020 during which I spoke with your wife. We discussed your diagnosis of prostate cancer which was made on prostate biopsy performed in late 2009/early 2010. The prostate biopsy you had at the time had shown a single small focus of intermediate grade prostate cancer in a single core taken from your prostate. An MRI scan performed as part of your staging investigations was satisfactory and showed features consistent with a small organ confined (cancer which has not spread outside of the prostate or spread elsewhere prostate cancer). You were commenced on treatment with Bicalutamide 50mg and Tamoxifen 10mg at this time and have remained on this treatment since. Your prostate blood test is low at 0.1.

We discussed on the phone that the treatment you are currently taking is a dose of Bicalutamide which is not licensed for use and evidence shows it is an inferior

Patient 139 DOB: Personal Information redacted by the USI H+C: Personal Information redship the USI

treatment to the licensed and recognised treatments. This is the case now and was the case in 2010. There is also concern that patients treated with this low dose of Bicalutamide are at risk of having a less favourable outcome from their prostate cancer than those treated on the licensed dose.

For men who present with small volume intermediate grade prostate cancers such as yours the standard recognised treatment options are those of active surveillance or consideration of curative treatment with either surgical or radiotherapy. Hormone treatment alone is not a recommended treatment for small volume early prostate cancer as studies show that hormone treatment does not prolong life expectancy and there are risks associated with longterm hormone treatment.

Active surveillance is a treatment where men do not have any active treatment for their prostate cancer but remain under follow up with regular blood tests and more recently regular MRI scans have become part of active surveillance protocols. The purpose of active surveillance is to identify those men whose prostate cancers do need treatment as a significant number of men with prostate cancer such as yours will never need treating for their prostate cancer during their lifetime. This is very likely the case with your prostate cancer.

Curative treatments such as surgery or radiotherapy are also offered at diagnosis and may also be offered to patients who have been treated previously with active surveillance where there are signs of the prostate cancer growing.

Hormone treatment alone does not rid a man of prostate cancer and only works for a temporary period. It reduces the growth of prostate cancer but does not stop it growing and over time prostate cancers develop the ability to grow despite the hormone treatment.

As discussed on the phone given that you had a small volume prostate cancer at diagnosis which would have been entirely suitable for active surveillance this would remain my recommended treatment options for your going forward. Therefore my recommendation is that you should stop the current Bicalutamide 50mg and Tamoxifen 10mg treatment. The advantage of this to you is that any side effects that you experience from the Bicalutamide will cease and in addition the risk of longterm effects of hormone treatment will not be a continued concern. If on surveillance we find that your prostate cancer were to be growing then we would be able to reassess the prostate cancer and consider a curative treatment if the cancer remains suitable for curative treatments.

If you do not wish to stop hormone treatment and wish to continue hormone treatment as a longterm treatment recognising that evidence shows that this treatment will not increase your life expectancy and that continued hormone treatment does continue to give side effects then the recommended hormone treatment would be an injection treatment which is given every three months. If you were to elect to proceed with this treatment there would need to be a two week overlap with your current Bicalutamide treatment after your first injection treatment (the injection treatment is Decapeptyl 11.25mg intramuscularly). An alternative hormone treatment would be to increase your Bicalutamide dose to 150mg daily. The recommended hormone treatment however is the injection treatment.

As discussed on the phone I hope this letter clearly outlines the options and recommendations for treating your prostate cancer going forward.

My recommendation is to discontinue the hormone treatment and move on to surveillance. I have requested one of the Urology Clinical Nurse Specialists to contact you in two weeks again by telephone to discuss your thoughts regarding your treatment options and hopefully make a decision as to how you wish to take things forward.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



CNS Urology Nurse, CAH



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 500



Dear Patient 83

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

rsonal Information redacted by the USI

HCN: Personal Information redacted by the US

Diagnosis:

Chronic pelvic pain syndrome symptoms

Storage lower urinary tract symptoms

Urethral strictures

Currently intermittent self catheterisation/dilatation 16 gauge catheter daily

Outcome:

Urodynamics to assess lower urinary tract symptoms

Referral to Pain Service with regards chronic pelvic pain symptoms

Continue intermittent self dilatation daily at present for strictures, if passage of catheters becomes progressively more difficult suggesting further stricturing then for urethrogram

Consider trial of anti-cholinergic eg Fesoterodine 4mg daily with dose increased to 8mg depending on affect/side effect or Solifenacin 5mg daily with dose increased to 10mg daily depending on affect/side effect if there is no concern of interaction with other medications/comorbidities

I write following our consultation on 2^{nd} December in Armagh Community Hospital. We discussed your treatment to date which you have undergone in the Urology Department and your ongoing symptoms.

You described urinary symptoms which had been a factor in your life for a significant number of years and in part predated your first prostate surgery. You underwent TURP in 2004 which was performed in Craigavon Area Hospital and a further TURP in 2007 again in Craigavon Area Hospital. From your notes there is a comment that you experienced bladder neck contractures requiring incision after both of these procedures. Following the surgery you developed prostatitis

and now describe symptoms of ongoing chronic pelvic pain syndrome. You have also experienced urethral strictures which have been treated with optical urethrotomy (a surgical procedure where the scarred area is incised) or dilatation (stretching of the scarred area of urethra). To manage your urethral strictures you are currently self catheterisation/dilating using a 16 gauge catheter on a daily basis. As management of your symptoms you have also undergone a number of bladder stretch procedures over the years.

With regards the pelvic pain symptoms you experience daily ongoing testicular pain and suprapubic (lower abdominal) which is worse after voiding and this increased level can last for up to around five minutes. In addition you experience pain after sexual intercourse both in the testes, suprapubic area and in the perineal area.

With regards your lower urinary tract symptoms the predominant features are those of storage symptoms relating to when urine is in your bladder. You experience daytime frequency and urgency. The urgency is a significant issue. You are also waking at night needing to void and the current average number of times a night is 2-3 times but things have been at a much higher level previously. as such an impact on your quality of life previously due to the sleep deprivation had impacted on your psychological well being. I note your fluid intake is predominantly water with decaffeinated coffee only and no tea.

With regards the urethral strictures things are satisfactory at the moment with the passage of 16 gauge catheter for intermittent self catheterisation./dilatation. You are concerned that things may be tightening up a little.

As we discussed from the information available to me the treatments you have undergone and management to date does not raise any cause for concern. Unfortunately it is recognised that the symptoms have vou experienced/complications of your previous surgery are recognised risks associated with undergoing transurethral surgery. For instance strictures can occur following a transurethral resection of prostate and affect between 1 in 10 and 1 in 20 patients. Similarly post operative infection is well recognised and unfortunately in a small number of patients this infection can result in a prostate infection which can leave patients experiencing chronic pelvic pain symptoms as experienced by yourself.

Taking things forward clearly your quality of life remains significantly impacted by your symptoms. We discussed referral to the Pain Service for the chronic pelvic pain symptoms and you are keen to pursue this. I have referred you to my colleagues and you will receive an appointment in due course. I note you had seen Dr McConaghy previously about some back pain issues.

With regards your urinary symptoms I recommend a functional assessment of your bladder with urodynamics. As we discussed you had undergone this investigation previously prior to one of your prostate operations. This investigation will allow us to assess both the functional capacity of your bladder and how your bladder muscle is behaving in relation to bladder filling and voiding. This will enable us to discuss options for managing your urinary symptoms going forward.

Page **2** of **3**

As we also discussed it may be worth a trial of some medications for your urinary symptoms. I have recommended some options above and if you wish to trial these medications I would be grateful if you could arrange to obtain a prescription for these from your GP. These would need to be continued as ongoing repeat prescriptions.

With regards your urethral strictures we discussed the recurrence rates of urethral strictures after treatment which affects around 50% of patients. The purpose of the self catheterisation/dilatation is to minimise the risk of recurrence of your strictures. Hopefully things will remain static and satisfactory with the self catheterisation however if you find that self catheterisation becomes progressively more difficult or you are unable to insert the catheter suggesting recurrence of your stricture then I would recommend an x-ray test to delineate your stricture and a further discussion with me regarding the options for management as in patients with recurrent strictures there is an alternative surgical management call a urethroplasty which is a bigger procedure but in the longterm may have a more successful outcome with regards risk of recurrence of the stricture.

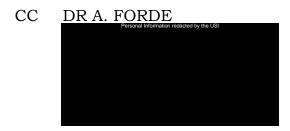
I will review you following your urodynamics. As we discussed there is a waiting time for urodynamics and we have not been able to provide this service during the pandemic. We are hopeful that this service will restart in the near future.

You asked regarding having the urodynamics performed privately. As we discussed I do not provide any private healthcare however I have colleagues who do private work and would be able to do the urodynamics privately. I do not know the cost of this infection but if you wish to explore this option I would be happy to refer you to a colleague in the private sector for a discussion regarding this.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Page **3** of **3**



Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear Personal Information redacted

Re: Patient Name:

D.O.B.: Address:

Hospital No:

onal Information redacted by the USI

HCN: Personal Information redacted by the USI

HOSPITAL NO: He US HCN:

Date/Time of Clinic: 02/12/2020 **Follow Up:** STC follow up & CNS telephone

review 3 months

Diagnoses:

Renal stones currently undergoing shockwave lithotripsy treatment

Previous ureteric stone treated with ureteroscopy and laser fragmentation with ureteric stent insertion

Subsequent encrustation of stent and laser fragmentation of encrusted stone, removal of stent and rigid/flexible ureteroscopy and laser fragmentation of renal stone

Lower urinary tract symptoms

Outcome:

Blood test for uric acid, please arrange with your GP using the enclosed blood test request form and I will write with the result

Dietary advice information sheet for recurrent stone formers

Patient information sheet regarding recurrent urinary symptoms

Recommend prescription Solifenacin 5mg daily, dose can be increased to 10mg daily depending on affect/side effect, please organise to obtain a prescription and repeat prescription from your GP

Telephone review Nurse Led clinic 3 months

If continuing to get sensation of passing bubbles when you attend for your next Stone Treatment Centre appointment please advise the Nursing Team and I would recommend a telescope examination of the bladder (flexible cystoscopy to further assess this)

I write following our telephone consultation which was performed on $2^{\rm nd}$ December. Apologies for the initial misunderstanding. As we discussed the purpose of this telephone consultation was to discuss both your concerns regarding your previous care and to discuss current symptoms and make plans

for ongoing management of your current symptoms. In addition the purpose was to discuss how we will look to take your concerns regarding previous treatment forward for further assessment/investigation. If you require a meeting between Trust Representatives and your Solicitor then this would usually be done through the Trust Complaints/Legal Services Department.

As discussed you were first admitted under the care of Urology in 2017. Prior to this admission you had undergone investigation for blood in your urine in 2016. You had been further referred for investigation of blood in your urine in 2017 and as part of the investigation prior to being seen in outpatients a CT scan had been arranged which was performed in May 2017. The CT in May 2017 had shown a stone in your right kidney and on the left side there was a stone both in the left kidney and a number of stones in the pipe draining the kidney (ureter). The lead stone (the stone at the front of a line of stones) measured 4mm. At this time you were on the waiting list to be seen in our Outpatients Department however you had not received an appointment at the time that you experienced worsening symptoms and attended the Emergency Department in July 2017.

ou were admitted as an emergency under the care of the Urology Team with the on-call consultant being Mr O'Brien and during this admission you underwent surgery to treat the stones in the pipe draining your left kidney. This was achieved by insertion of a camera into the pipe draining the kidney and a laser was used to fragment the stones to dust. As we discussed unfortunately when we completely fragment stones using a laser the fragments can be so small that it is not possible to retrieve them for analysis and this was the case for you and so no stones were sent for analysis.

After the procedure a stent was inserted. This stent was inserted to serve two purposes, firstly after surgery for a number of stones we often see a reaction in the ureter where it becomes inflamed and swollen and this results in blockage of urine drainage from the kidney, this situation can cause significant symptoms. The stent is therefore inserted as a temporary measure to prevent blockage of urine drainage from the kidney. Additionally you were known to have a further stone within the left kidney itself and the stent also served a purpose of facilitating some passive ureteric dilation (with a stent in place the ureter pipe widens) to facilitate/enable a further telescope procedure where a telescope is passed into the kidney and the laser used to break the stone up that is in the kidney.

Following discharge you were given the impression that you would be reviewed with a short timeframe (4 weeks was your impression) with a view to this surgery. The discharge note states that you were to return for repeat surgery where the stent would be removed and the telescope passed into the kidney to treat the stone.

Over the following weeks and months you described experiencing a number of significant stent related symptoms. You also described making contact with Mr O'Briens secretary on a number of occasions attempting to obtain information as to when you would get treated. You describe having been spoken to by Mr O'Briens secretary and told that it was down to the Booking Office that you had not been seen. You also describe being advised on a number of occasions that Mr O'Briens secretary would pass your messages on to Mr O'Brien but you did not hear back. In addition you also describe on one occasion attending the Hospital

itself and locating Mr O'Briens office to attempt to speak to him with regards when your treatment was going to occur.

Subsequently with ongoing worsening symptoms you attended the Emergency Department in March 2018 and were again admitted as an Emergency. At the time of your attendance a plain x-ray was taken which demonstrated that a stone had grown on the lower end of the stent. You underwent surgery where a laser was again used to break the stone up which had grown on the stent and in addition the stent was removed and a telescope passed into the left kidney to treat the stone that remained in the kidney. Subsequent CT scan performed in April 2018 confirmed that the left urinary tract was now stone free. There remained a stone in the right kidney. You were referred to the Stone Treatment Centre for further management of this right sided stone and have undergone two treatments with shockwave lithotripsy on an outpatient basis. You are due a further attendance for this in the near future.

With regards ongoing symptoms you describe ongoing intermittent episodes of pain which can be on both the right and left side. The stent related symptoms and specifically the pain in your lower abdomen and vagina have improved now the stent has been removed.

From a urinary symptom perspective you describe significant impact on your quality of life with urinary urgency, frequency, urge incontinence and night-time incontinence. You also describe a sensation of needing to void when your bladder is empty (strangury).

With regards your ongoing stone management we had a discussion regarding why people develop stones and the lifestyle measures that you can adopt to reduce your risk of future stone formation. These essentially come down to increasing fluid intake, reducing salt and limiting meat intake particularly red meat. I enclose a patient information leaflet which contains this dietary advice for you.

In addition when we see patients with stones we perform some tests to ensure there is not an underlying reason to develop kidney stones. Your blood calcium levels have been normal and this is reassuring. You have not had a uric acid blood test checked and I enclose a blood test request form and would be grateful if you could arrange this to have your blood test with your GP at your earliest convenience. I will write with this result.

With regards your urinary symptoms I recommend a prescription of medication which may improve things, this medication is taken daily and should be continued as an ongoing repeat prescription. I would be grateful if you could arrange to obtain a prescription and ongoing repeat prescription with your GP. We also discussed the sensation of passing bubbles. This may be related to your recent urinary infection and if this sensation settles it would not require any additional investigation. If however this sensation has not settled when you next attend the Stone Treatment Centre please advise the Nursing Team on your arrival as I would recommend further investigation with a telescope examination of the bladder in the first instance (flexible cystoscopy).

With regards ongoing management of your kidney stones as you are aware your most recent CT scan had again confirmed a 5mm stone on the right and since your scan from April 2018 a small 2mm stone has grown on the left side. At 2mm

this stone would not be of a size where treatment is advised and I anticipate that the Stone Treatment Team will be planning ongoing follow up of this stone to ensure it is not increasing in size. I note the Stone Team have made plans for an up to date CT scan before your next attendance in the Stone Treatment Centre. As we discussed if you have not received an appointment of this CT scan one week before the planned attendance date please contact the Stone Treatment Centre to advise them of this as they may wish to defer your attendance to await the CT scan.

With regards your concerns regarding your previous treatment your primary concern is the duration of time between your stent insertion in July 2017 and subsequent removal in March 2018 which indeed occurred as an emergency. As discussed the duration of time that your stent remained in is far longer than a Urologist would have intended. We discussed manufacturers recommended stent change times but this time period relates to patients who have ureteric problems which are managed with longterm stents. In this situation stents are recommended to be changed on six monthly intervals due to risk of encrustation. With regards patients who have stents inserted as part of ongoing stone treatment Urologists would aim for a shorter period as possible for stents to be in place before subsequent treatment and removal. As discussed one of the reasons stents are inserted is to allow passive ureteric dilatation and studies suggest that the time required for this is around two weeks. Studies also show that the risk of complications related to stents increases the longer the stent is in place with risk of stones growing on stents (encrustation) and risk of infection increasing the longer a stent is in place.

Once again I acknowledge your stent was in longer than would be intended and the encrustation that was found on your stent on your attendance in March 2018 will have been related to the duration of time the stent was in place. At present I am not able to answer your query as to why you waited such a period of time. We did discuss that there are two potential factors which need investigation. Firstly it is possible that this duration of wait was a factor of waiting lists and we discussed the difficulties with significant waiting lists in many specialities but in particular Urology at present. The second reason for such a wait could be a factor aside from waiting list. As discussed during our telephone consultation I can assure you that I have instigated a further look into your waiting times to ascertain whether it was a factor of the waiting list or there is another explanation. Additionally you raised concerns regarding the outcomes of your multiple contacts with Mr O'Brien secretary and whether any action was taken to look into your waiting time at the time of these contacts. Again I have instigated a look into these questions.

As we discussed if you have additional concerns that I have not documented within this letter I would be grateful if you contact the Trust Complaints Team either in writing or by phone:

Complaints Team
Southern Health and Social Care Trust
Beechfield House
Craigavon Area Hospital
Portadown
BT63 5QQ
Telephone:

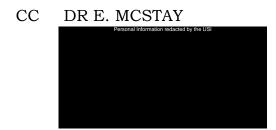
With regards ongoing follow up as we discussed your stone treatment remains under the care of the Stone Treatment Team who have ongoing plans for further review.

With regards your urinary symptoms I have requested a telephone consultation with one of our Clinical Nurse Specialists in around three months time to assess if your symptoms have improved with the Solifenacin treatment.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Personal Information redakted by the USI Page **5** of **5**



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500



Dear Personal Information redacted by the USI

Re: Patient Name:

D.O.B.: Address:

Hospital No:

Date/Time of Clinic: 02/12/2020

HCN:

Follow Up: Review face to face

Diagnosis:

Bilateral complete duplex

Right lower pole hemi-nephrectomy as child

Left lower pole hemi-nephrectomy July 2017

Recurrent urinary tract infections currently well controlled following most recent surgery

Ongoing problems with pain and concerns regarding left sided surgical wound

Outcome:

Face to face outpatient review South Tyrone Hospital

Further to today's telephone consultation we discussed your previous treatment in the Urology Department. It is reassuring to note that your recurrent urinary infections have significant improved following your most recent surgery.

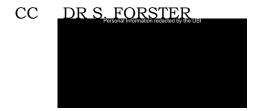
Your concerns relate to your wound site you feel has not been right since the surgery with sensation of it popping, ongoing pain, swelling and cramping sensations related to the scar. I note as you state from the operation note that the incision used was a loin incision and as part of the incision the tip of the 10th rib was excised. One of your questions you raised was whether there was a true hernia at the site of your wound given the bulge. As discussed on the phone I reviewed a CT scan from 2018 which was after your surgery and this has confirmed that the muscle layer in the area of your wound appears intact but a bulge is visible. As discussed on the phone this bulge is due to denervation of the muscle in the area of the wound and the effect this has is that this muscle cannot tense in the way that the muscle of the rest of your abdominal wall does. The result is a bulge that you experience.

With regards the other concerns you have regarding your wound as we discussed I need to see you face to face in order to examine the wound and discuss options as to how we can manage the difficulties are you experiencing. We will be making arrangements for me to see you in person as an outpatient in South Tyrone Hospital and will discuss things further at this point.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Information redacted by the USI



Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 5QQ



Dear Personal Information by the USI

Re: **Patient Name:**

> D.O.B.: Address:

Hospital No:

Date/Time of Clinic: 02/12/2020

Follow Up: Discharge

Diagnosis:

Previous bladder outflow surgery 2005 (Patrick Keane) and 2019 (Mr O'Brien)

HCN:

Outcome:

Discharge

As you are aware we met in the Outpatients Department in Armagh on 2nd December after you had contacted the Trust Information line following recent press coverage.

You have been under the care of Urology Teams at various points over a number of years starting with urinary symptoms commencing in your 40's. You underwent a prostate operation (TURP) in 2005 under the care of Mr Keane and underwent further surgery in 2019 under the care of Mr O'Brien. At the time of the surgery one of the presenting features was that of recurrent e-coli urinary infections. Following your prostate surgery you are satisfied with the outcome from a functional urinary symptom perspective and reassuringly your urinary infections have all settled.

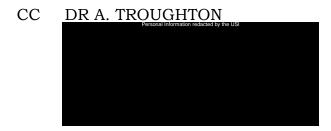
I have reassured you that your treatment to date has been entirely satisfactory with no concerns.

At present as your symptoms are satisfactory no ongoing urology follow up is required and I have discharged you back to your doctor.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist





Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ

DR J. DILLON
Personal Information reducted by the USI

Dear DR DILLON

Re: Patient Name:

D.O.B.:

Address: Hospital No:

Date/Time of Clinic: 09/12/2020

HCN:

Follow Up: TCI 22/12/20

Diagnosis:

Low risk non muscle invasive urothelial cancer of bladder treated by TURBT April 2019

Recovery complicated by ureteric obstruction requiring emergency stenting Planned for further TURBT due to recurrence in near future Previous circumcision

Outcome:

Proceed with planned TURBT

Examination of white plaque on penis at time of attendance for TURBT with consideration of biopsy if required

I reviewed by telephone following his contact with the Trust Information line with some questions he had regarding previous treatment. He was initially diagnosed with a bladder cancer in early 2019 and underwent a transurethral resection on 3rd April. This procedure was performed by Mr O'Brien. The tumour itself was on the lateral wall of the bladder just above the ureteric orifice. At the completion of surgery the ureteric orifice was clear of the resection site and so no issue was anticipated.

recovery however was not as expected and he underwent assessment with a CT scan. The CT did not report any concern regarding ureteric obstruction/injury to the ureteric orifice however given his symptoms and upon inspection of the images the weekend On-call Team felt it highly likely that there may be ureteric obstruction and therefore he proceeded to theatre. A ureteric stent was inserted and this immediately resolved his symptoms. The stent itself was subsequently removed at flexible cystoscopy. He has continued on

surveillance for his bladder cancer and most recently underwent a flexible cystoscopy and has a small recurrence and is planned for resection.

In addition he has previously undergone a circumcision. This was performed with the intent of helping resolve an abnormality on his glans penis. Unfortunately this abnormality has not resolved.

O'Brien did the operation himself and whether he should have any concerns with regards his surgery. I have reassured that the complication he experienced unfortunately is recognised as a potential complication of TURBT in particular where the tumour is around or just above the ureteric orifice. Unusually in his case the CT scan did not make the diagnosis and this was picked up by a high degree of clinical suspicion of the Clinical Team upon review of the images. Treatment with the ureteric stenting was standard treatment. I have assured him there are no concerns with regards this treatment.

Secondly he was wondering whether his recurrent bladder tumour was due to any incompleteness of his previous treatment and again I have reassured him that this is not the case. Unfortunately with bladder cancer patients are at high risk of developing recurrent tumours and this has been the case with risk of developing recurrent tumours and this has been the case with risk to be high we will consider intravesical treatments to reduce this risk of recurrence. He is planned for a repeat TURT in December 2020. From review of the records the tumour itself appears to be well away from the ureteric orifices and I have reassured reduced by the US that his risk of having a repeat complication like last time is extremely low.

With regards his circumcision while this has achieved the intent of removing the foreskin unfortunately the white plaque on his penis has recurred. It had been biopsied previously and was benign and he had previously been followed up by the Dermatology Team. I have reassured him that this can be the case with circumcision that it does not result in the skin condition affecting the glans being resolved. Reassuringly previous biopsies of this have been benign. I have assured him again that there would be no concerns with regards the treatment he has received. I have advised him to mention the plaque of his glans penis to the treating Team when he attends for his procedure in the near future.

In summary I have reassured that I have no concerns regarding his previous treatment and his ongoing plans for further management.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist





UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear Mr Weir

Re: Patient Name:

D.O.B.:

Address: Hospital No:

Tiospital No.

HCN:

Diagnosis:

Previous treatment for bilateral renal/ureteric stones

Concerns stent inserted February 2016 was insitu for six months during which significant stent symptoms were experienced and stent subsequently encrusted requiring more complex surgery for removal

Outcome:

Raise concerns through Complaints Process CT urinary tract and write with result DMSA renogram and write with result

Further to today's telephone consultation I am pleased to hear you are doing well at present and have no symptoms relating to your previous kidney stones. With regards ongoing current review from a urological perspective I have recommended a follow up CT scan to ensure you have not developed any new stones within your kidneys. I also discussed that on scans your left kidney appears smaller than your right kidney and I have requested a renogram to assess how well this kidney functions. I shall be in contact with the result of the scans.

You had contacted the Trust Information line with some concerns regarding your treatment previously. As we briefly discussed with regards your history you initially presented as an Emergency in February 2016 with stones blocking the pipe draining your left kidney. You had had previous treatment for kidney stones back in 2012. Due to the stones blocking the pipe draining your kidney a stent was inserted in February 2016 with a view to subsequent return for repeat surgery to treat the stones with a laser. Following this admission and while you had the stent in you experienced symptoms from the stent with pain and urinary incontinence. You had to wear a pad during this time due to incontinence. You

advised me you contacted Mr O'Briens secretary on multiple occasions to enquire as to how long you were likely to wait for your subsequent surgery but did not hear back. I note you had a further admission as an Emergency in April 2016. On this occasion you had pain on the right side and a CT scan showed no stones on the right side but as you are aware your stent removed insitu. The expectation on discharge was that plans were in place for this subsequent to remove the stent.

You were subsequently admitted in October 0216 and at the time of this surgery the stent had grown stones on requiring laser treatment to remove the stones from the stent in order for the stent to be removed. This was performed and after the surgery was no stent was left in place. You were again readmitted in November 2016 with worsening of your kidney function and stones within the pipes draining both kidneys. You subsequently underwent a number of operations under my care to treat the stones and also during this treatment some of your stents also grew stones. Your final procedure was in November 2017 when you were rendered stent free with no stones visible within your urinary tract at this time.

As we discussed all Urologists would like to be able to remove stents that have been inserted for stones within a much shorter time window than you experienced and our reason for this is that there is a risk of stone encrustation and a high risk of infection. I am not in a position to advise you as to why it was from February to October that you waited with the stent despite your multiple contacts with the Trust. As we discussed the explanation may be that waiting lists were this length of time at that time or there may be another explanation. As we have discussed I have forwarded this letter to the Trust Complains Team to raise this concern through the complaints process so that your concerns can be looked into.

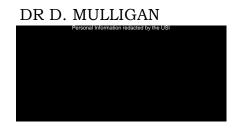
As per my comments earlier I have requested the scans detailed and will be in contact with the results.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

CC Complaints Department, CAH





UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital 68 Lurgan Road Portadown Co Armagh BT63 500

DR F. O'HAGAN

Dear DR O'HAGAN

Re: **Patient Name:**

> D.O.B.: Address:

Hospital No:

HCN:

Date/Time of Clinic: 09/12/2020 Follow Up: USS & flexible cystoscopy

Diagnosis:

Previous surgery for renal cancer Visible haematuria Query hyperdense cyst on last CT

Outcome:

Ultrasound and write with result Flexible cystoscopy with oral Diazepam at South Tyrone Hospital Flow rate prior to flexile cystoscopy and discussion regarding glower urinary tract symptom management

Further to Mr Keane's letter I saw Personal Information redacted in outpatients to discuss further investigation of his haematuria. He had a bad experience with flexible cystoscopy previously and has previously declined flexible cystoscopy to investigate his visible haematuria. It has been ongoing and intermittent over the last 5 years. Upper tract imaging has been satisfactory. He has had a TURP before so I suspect the most likely cause of that is bleeding from some prostate regrowth and indeed he does have some recurrence of his urinary symptoms. I have recommended a flexible cystoscopy and have discussed how this could be performed. He is willing to try it with some oral sedation and we will look to arrange this in South Tyrone Hospital. He is aware he will need to arrange a lift both to and from the Hospital in order to receive this. With regards his urinary symptoms we will also arrange for him to have a flow rate assessment when he attends. From a renal perspective I plan an ultrasound scan to assess the abnormality on his CT from March as to whether this is a cyst and I shall write with the result.

Yours sincerely

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Date Dictated: 09/	/12/20	Date Typed:	11/12/2020-LH
Date Dictated: 05/	12/20	Date Lypeu.	11/12/2020 111

ersonal Information redacted by the USI Page **2** of **2**



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500



Dear Patient 42

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Date/Time of Clinic: 09/12/2020

Patient 42

HCN:

Follow Up: Oncology follow up

Diagnosis:

Prostate cancer treated with radical radiotherapy

Outcome:

Continue Oncology follow up as planned

Just to confirm today's telephone consultation. I phoned following your recent contact with Trust Information line. As you are aware you were initially seen in late 2017 by Mr O'Brien with regards some urinary symptoms and raised prostate blood tests. Assessment was performed at that time with clinical examination and an ultrasound scan was arranged which was performed in December 2017. You subsequently attended follow up in March 2018. At this time a plan for further follow up with a repeated prostate blood test was planned for June 2018. You had contacted Mr O'Briens secretary to advise that you were not able to arrange the follow up prostate blood test for June but had arranged it in August 2018. Despite a number of contacts with Mr O'Briens secretary you did not hear back with regards the result of the blood test or any ongoing follow up and eventually you escalated this speaking of Head of Service for Urology Martina Corrigan and a subsequent outpatient consultation with Mr Young was arranged. Following your consultation with Mr Young you went on to have further investigation with an MRI scan and subsequent prostate biopsy. Following this a diagnosis of an intermediate risk prostate cancer was made and you have subsequently undergone radiotherapy. As you stated you have been happy with the care received following your first consultation with Mr Young.

With regards your concerns your first concern was the delay in regards the blood test result from August 2018 and your subsequent attendance with Mr Young in

2019. As we discussed the factor in this may well have been capacity issues for the Urology Service with more patients requiring outpatient consultations than space is available. However as you state you contacted the Department on a number of occasions and did not hear back. As discussed I apologised for this delay and indeed had you been seen earlier the diagnosis of prostate cancer may have likely been made at an earlier point. However fortunately your prostate cancer at the time it was diagnosed remained an early stage and has been treated with radical treatment that we would anticipate a good outcome from. Given this and evidence regarding prostate cancer treatment this delay would not have impacted on either your treatment option or the expected outcome from your treatment.

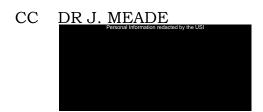
In addition to your concerns regarding the delay you raised some concerns with regards your interaction with Mr O'Brien and whether this interaction had impacted on the delay occurring. As we discussed I have offered further contact from the Trust to look into your concerns regarding this further and at present you stated you did not wish to take this further. However, I will raise the concerns you have raised with our Team and it is possible you may receive further contact to discuss them further. With regards the delay I will raise your case as part of our investigation to ascertain the reason behind the delay.

As you aware are plans are in place for ongoing follow up with the Oncology Team.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Complaints Team/Martina Corrigan, Head of Service

Page **2** of **2**



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes Telephone:

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500



Dear Personal Information redacted by the USI

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

Date/Time of Clinic: 09/12/2020

HCN:

Follow Up: CTU, DMSA renogram & write

Diagnosis:

Incidental finding asymptomatic right hydronephrosis on MR renal angiogram Appearances most likely to represent benign PUJ obstruction

Mag 3 repogram showing essentially equal split function and delayed time

Mag 3 renogram showing essentially equal split function and delayed time to peak on right but satisfactory drainage indicating no obstruction

Outcome:

CT urogram and write with results

DMSA renogram and write with the results

Up to date kidney function blood test in preparation for scans

Just to confirm our telephone consultation we discussed the findings of your previous scans. You had an MRI of your kidneys arranged by the Cardiologists which had found an incidental hydronephrosis on the right kidney. The appearances of this are in keeping with a benign incidental pelvic ureteric junction obstruction. Following the MRI scan the Cardiology Team referred you to the Urology Team. As you are aware you were called by Mr O'Brien late one night following receipt of this referral and he advised you that he had arranged a renogram and you would subsequently be seen in clinic. There is no documentation of this contact.

You underwent the renogram in January 2020 and to date have not received the results.

I am pleased to report the renogram is satisfactory. Although there is a delayed time to peak on the study there is adequate drainage of urine from the kidney.

Personal Information redacted by the U

As we discussed the appearances are those of a benign PUJ obstruction and in the presence of no symptoms and maintained kidney function no intervention is required.

We would always recommend complete assessment of the ureter to ensure there is no other cause for the appearance of hydronephrosis and to this end I have requested a CT urogram. You will receive an appointment for this from the X-ray Department. In order to have the scan you require an up to date kidney function blood test and I would be grateful if you could arrange this at your earliest convenience with your GP using the enclosed blood test request form.

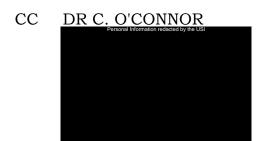
As follow up I also plan to monitor the relative function of your kidneys and have requested a DMSA renogram which is a slightly different renogram and gives a more accurate representative of split function. You will also receive an appointment for this from the X-ray Department. I shall write with each result as they become available.

If imaging confirms the appearances of a benign PUJ obstruction with maintained function I would propose a further follow up DMSA renogram one year after you have the study that I have requested today.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist



Page ${f 2}$ of ${f 2}$



UROLOGY OUTPATIENTS LETTER

Consultant Urologist: Mr Mark Haynes
Telephone: Personal Information restacted by the USI

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 5QQ



Dear Miss Headley

Re: Patient Name:

D.O.B.:
Address:

Hospital No:

HCN:

Date/Time of Clinic: 09/12/2020

Follow Up: Follow up Mr Glackin & Refer

Pain Team

Diagnosis:

Previous right nephrectomy for poorly functioning kidney with PUJ obstruction Previous left pyeloplasty for benign left PUJ obstruction

Previous balloon dilatation of left PUJ for recurrent obstruction following previous pyeloplasty

Ongoing left sided pain with normal drainage of urine on renograms

Significant storage lower urinary tract symptoms previously treated with intradetrusor Botox injections, urodynamics attempts previously had not been successful in proving detrusor overactivity

Outcome:

Ongoing follow up with Mr Glackin regarding urinary symptoms Referral to Pain Team

Just to confirm today's consultation we discussed your treatment over many years in the Urology Department. As discussed and to reassure you following your contact with the Trust Information line the treatment you have undergone is entirely sensible and indeed would have been the treatment recommended had you presented for the first time today.

You had initially presented with pain on both sides and were found to have blockage to urine drainage from both kidneys caused by a benign pelvi-ureteric junction obstruction. Your right kidney was poorly functioning with your left providing almost all of your overall kidney function and you went on to have treatment with removal of the right kidney and an operation to improve the drainage of urine from the left kidney (pyeloplasty). This improved your right sided pain. On the left side however you developed recurrent symptoms and

underwent balloon dilatation to again improve drainage of urine from this kidney. While follow up renograms have been very good in that they have shown no signs of blockage to urine drainage you have continued to experience left sided pain.

We discussed phenomenon and as we discussed we do not have any test which has demonstrated a cause for this pain that we are able to offer surgical treatment for. Your renograms show good drainage of urine from the kidney and therefore in the absence of any tests showing obstruction of urine drainage from the kidney we would not look to offer any further surgery to the collecting system of your left kidney. Whilst this is good news from a kidney functional perspective it does not provide an explanation for your pain. I have seen patients who get recurrent intermittent pain which is due to intermittent worsening of drainage of urine from the kidneys however we do not have any evidence for this being the case with you. As we discussed the reason we would not recommend any redo surgery to your kidney is that this would have a very significant risk of making things worse from a kidney function drainage and urine drainage perspective.

You experience the pain on a daily basis and we did discuss further management and I have referred you to our Pain Team to see if they can offer any treatments. You will receive an appointment to be seen in the Pain Clinic in due course.

With regards your urinary symptoms your urodynamics test in the past have unfortunately not been successful in demonstrating the reason for your symptoms however your symptoms and response to Botox treatment suggest that this is due to detrusor overactivity (overactivity of your bladder muscle). As stated you have had Botox injections in the past and while these improved your storage symptoms you needed to self catheterise for a period of time and also felt unwell immediately after the treatment. You are aware that Botox treatment is temporary and generally where it is successful in managing patients symptoms, ongoing repeat treatment is recommended. Typically this would be repeated every 6-9 months. On balance although the Botox did improve your urinary symptoms and indeed self catheterisation you described as being better than your pre-existing urinary symptoms/incontinence your whole experience with Botox was such that you currently would not wish to have repeat Botox injections.

As we discussed Mr Glackin has mentioned previously to you sacral nerve stimulation as a potential alternative option. This is now being offered on a limited basis by a colleague of ours in Altnagelvin and this is a potential option you could explore. However, as discussed generally we would not look to proceed to sacral nerve stimulation without urodynamics demonstrating detrusor overactivity and therefore repeat urodynamics would be required.

For your ongoing follow up you remain under the care of Mr Glackin and I have written to him requesting he make arrangements for further review with regards management of your urinary symptoms. As discussed you would be happy to have this as a telephone consultation.

I have also referred you to the Pain Team.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

CC Mr Glackin, Consultant Urologist, CAH

Pain Team, CAH



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UROLOGY OUTPATIENTS LETTER

Craigavon Area Hospital
68 Lurgan Road
Portadown
Co Armagh
BT63 500

Consultant Urologist: Mr Mark Haynes Telephone:

MR GLACKIN Consultant Urologist CAH

Address:

Dear Tony

Re: Patient Name: Personal Information redacted by the USI

D.O.B.:

Hospital No: HCN:

Date/Time of Clinic: 09/12/2020

Please find enclosed a copy of my letter on previous treatment. Hopefully my enclosed letter is self explanatory. I have given previous treatment. Hopefully my enclosed letter is an information sheet regarding sacral nerve stimulation as she does not feel she would want further Botox injections. I would be grateful if you could arrange further review to discuss management of her urinary symptoms. She would be happy for a telephone review.

Yours sincerely

dictated but not signed by

Mr M Haynes, MD FRCS (Urol) Consultant Urologist

Page **2** of **4**



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Personal Information reducted by the USI
H&C Number	
Date of Birth	

Patient Details

Presenting Condition(s)	LUTS secondary to prostatic enlargement
Patient Summary	Assessed regarding LUTS 2018 and commenced on medical treatment (Tamsulosin)

i x	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	÷



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	No	
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9) ?	0	
		2	

Name Mark Haynes		
Title	Consultant	Submit
Date of Appointment	27/03/2021	



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Personal Information redacted by the USI
H&C Number	
Date of Birth	

Patient Details

Presenting Condition(s)	Undescended testes	
Patient Summary	Seen October 2013 and listed for Orchidopexy, performed March 2015 Mum involved ombundsman regarding waiting time for surgery Testes ascended and repeat procedure Dec 2018 (recognised risk 2%)	

112	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	No	
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?		
		ž	

Clinical Professional Reviewing Care			
Name Personal Information redacted by the USI	Mark Haynes		
Title Consultant Submit		Submit	
Date of Appointment 27/03/2021			



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Personal Information reducted by the USI	
H&C Number		
Date of Birth		
,		

Patient Details

Presenting	Circumcision for BXO January 2016
Condition(s)	Non-visible haematuria and Atypia on urinary cytology March 2018
Patient Summary	Circumcision for BXO January 2016 (Mr Young) >> Discharged Re-referred with non visible haematuria and atypia on cytology 2018, seen March 2018. CT requested at attendance.

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Yes	CT performed 27/6/2018. Patient planned for OP review with result but patient not informed of result while awaiting review.
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?	No	

Name	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	27/03/2021	



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Personal Information redacted by the USI	
H&C Number		
Date of Birth		

Patient Details

Presenting	Overactive bladder
Condition(s)	Recurrent UTIs
Patient Summary	Initial assessment 2012 with DOA symptoms and recurrent UTIs managed medically. Urodynamics 2017 as ongoing symptoms despite medical management Botox to bladder 2018

	Question		Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Yes	No dictation from OP attendance 4/9/2012
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?		
		2	

Name	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	27/03/2021	



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Personal Information redacted by the USI
H&C Number	
Date of Birth	

Patient Details

Presenting Condition(s)	LUTS
Patient Summary	Urodynamics 2018 and Alpha blocker recommended

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	No	
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?		
		2	

Name	Personal Information redacted by the USI	Mark Haynes	
Title		Consultant	Submit
Date o	T Appointment	27/03/2021	



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Personal Information redacted by the USI	
H&C Number		
Date of Birth		

Patient Details

Presenting Condition(s)	1) LUTS 2) Erectile dysfunction
Patient Summary	Initial assessment of LUTS and ED 2012 LUTS managed with medication ED has tried all medical treatments, ECR for prosthesis sent but turned down (see below)

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken	

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Yes	No letters at time of OP consultations 13/3/2012 and 12/2/2013 Letter 15/10/2013 states will seek ECR for penile prosthesis but next letter is dated as 17/8/2015, but was dictated on 17/12/16. states ECR was submitted 'earlier this year' not clear if this was earlier in 2015 or earlier in 2016. Appears to have been a delay in submitting ECR after attendance October 2013.
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?		
		Š	

Name Personal Information redacted by the USI	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	27/03/2021	



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Personal Information redacted by the USI	
11001		
H&C Number		
Date of Birth		
Date of Birth		
		+

Patient Details

Presenting Condition(s)	LUTS / poor detruser function
Patient Summary	LUTS / straining to void, patient content with symptoms so no treatment desired

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	No	
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?	No	

Name	ame Mark Haynes	
Title	itle Consultant	
Date of Appointment	27/03/2021	



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Patient Details

Name	Personal Information redacted by the USI	
H&C Number		
Date of Birth		

Patient Details

Presenting Condition(s)	incidental renal lesion on CT - likely AML
Patient Summary	Incidental renal lesion on CT FU US done June 2018

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Yes	US performed on 7/6/2018. Planned for OP review with result. No evidence of patient being informed of result while awaiting FU US.
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?		
	. , ,	o N	

Personal Information redacted by the USI	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	27/03/2021	



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Patient Details

Name	Personal Information redacted by the USI	\Box
H&C Number		
Date of Birth		

Patient Details

Presenting Condition(s)	LUTS
Patient Summary	Managed with cystodistension with good result Symptoms now recurred

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	No	
9	On balance, did the patient suffer any harm or detriment as a result of any of the		
	above questions (4-9) ?	0	
	1.59	ž	



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Patient Details

Name	
	Personal Information redacted by the USI
H&C Number	
Date of Birth	

Patient Details

Presenting Condition(s)	Voiding dysfunction
Patient Summary	Long history of voiding dysfunction (since childhood) managed with ISC

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Unable to Determine	Some attendances 2011-2015 no letters on ECR but appears to have had treatment during this time, and the episodes are attributed as other consultants so unclear if had attendances and if did who she saw. No concerns regarding treatment given.
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?		
		ž	

Name Personal Information redacted by the USI	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	27/03/2021	



This form is to be completed for each patient previously under the care of Mr O'Brien reviewed by the Southern Trust Urology team since Mr O'Brien's departure on 17th July 2020. This form is to be retained in the patient notes and copied to Martina Corrigan, Head of Service.

Patient Details

Name	Patient 30	
H&C Number	Personal Information redacted by the USI	
Date of Birth		

Patient Details

Presenting Condition(s)	Raised PSA
Patient Summary	January 2018 PSA 4.9, 5.6 May 2018 MRI showed left apical lesion September 2018 PSA 6.4 (7.5 in April), December PSA 8 Biopsies January 2019 Gleason 6 tumour. Active surveillance August 2020 PSA 10.2
	MDM recommended MRI ? further biopsy • No further investigation found *

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)		No May have higher grade disease as yet undiagnosed
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with	212	

4	If there is not a secure clinical management plan in place please document immediate actions required to be taken	Needs MRI +/- further biopsies
3	current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?) Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	No

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)		Yes
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)		3
6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if		Yes

9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?	No but should be restaged urgently
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Biopsies should have been performed after MRI in May 2018 i.e.8 month delay
7	consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?) Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes

Name	Krishna Sethia	
Title	Professor	
Date of Appointment		





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Patient Details

Name	Personal Information redacted by the USI
H&C Number	Personal Information redacted by the USI
Date of Birth	

Patient Details

Presenting Condition(s)	Malaise/ weight loss
Patient Summary	August 2018 diagnosed metastatic prostate cancer PSA>400
	Started on degarelix
	MDM 16.08.18 -to continue ADT
	PSA rise to 9.2 in February 2019. Started on
	bicalutamide 50mg.
	March 2019 PSA 15 Started on dexamethasone
	MDM recommended referral to oncology if
	performance status permits
	Died

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)		Yes
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and		N/A



	rationale fully noted?)	
3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	N/A
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken	

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)		Yes
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)		Yes Not clear what his performance status was in March 2019 but possibly should have been considered for enzalutamide
6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is		Yes



	consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	No
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?	Enzalutamide might have improved survival for 4-6 months but need oncology opinion as to whether he would have been suitable for it

Name	Krishna Sethia
Title	Professor
Date of Appointment	





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Patient Details

Name		
	Patient 67	
H&C Number		
Date of Birth		

Patient Details

Presenting Condition(s)	Colovesical fistula, Haematuria / ?TCC bladder and raised PSA
Patient Summary	Initial pathological intermpretation of bladder lesion as G2Ta bladder cancer but review at MDM in keeping with inflammatory process. Raised PSA at time. MDM review January 2019 ' For review by Mr O'Brien to reassure and to repeat serum PSA.' Letter 16/1/19 discharged. No repeat PSA checked

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	No	The recommended repeat PSA was not checked. Subsequently PSA has been found to remain elevated and is undergoing further investigations currently
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	12
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Unable to Determine	See above re PSA
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Yes	Repeat PSA no checked despite MDM recommendation
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?	Unable to De	Awaiting further investigation

Name	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	03/04/2021	



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Patient Details

Name	Personal Information redacted by the USI	
H&C Number		
Date of Birth		

Patient Details

Presenting Condition(s)	Storage LUTS
Patient Summary	Storage LUTS On currently on maximal medical therapy Urodynamic evidence DOA Previous nephrectomy for non functioning kidney

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	Yes	There appear to be a number of OP consultations without correspondance to GP from 2012/2013
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?		
c		2	

Name	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	10/04/2021	



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Patient Details

Name	Personal Information reducted by the USI	
H&C Number		
Date of Birth		

Patient Details

Presenting Condition(s)	Nocturnal enuresis
Patient Summary	Managed with medical treatment and now resolved Also phimosis managed conservatively

	Question	Y / N / Unable to Determine	Details
1	Is the present diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried out to date, is there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
2	Are the current medications prescribed appropriate? ('Appropriate' to consider if prescribing is consistent with current best evidence based practice, are any deviations from guidance recorded and rationale fully noted?)	Yes	



3	Is a secure clinical management plan currently in place? ('Secure Clinical Management Plan' to consider if the current patient treatment pathway is optimal and in line with current best evidence based practice and guidance)	Yes	11
4	If there is not a secure clinical management plan in place please document immediate actions required to be taken		

No.	Question	Y / N / Unable to Determine	Details
4	Were appropriate and complete investigations carried out for all relevant conditions? ('Appropriate' to consider if investigations consistent with current best evidence based practice at the time of review, are deviations from guidance recorded and rationale fully noted?)	Yes	
5	Were the medications prescribed appropriate? ('Appropriate' to consider if prescribing was consistent with current best evidence based practice at the time of previous review, are deviations from guidance recorded and rationale fully noted?)	Yes	



6	Were the diagnosis / diagnoses reasonable? ('Reasonable' to consider if diagnosis / diagnoses is consistent with investigations and examinations carried at the time of review, was there a requirement for further investigations / examinations to confirm diagnosis / diagnoses?)	Yes	
7	Was the clinical management approach taken reasonable? ('Reasonable' to consider if clinical management plan if the patient treatment pathway at the time was optimal and in line with best evidence based practice and guidance available at that time.)	Yes	
8	Were there unreasonable delays within the Consultants control with any aspect of care (reviews, prescribing, diagnostics, dictation etc) ('Unreasonable Delays' to consider if diagnosis required more urgent treatment / intervention that was received based on best evidence based practice and guidance available at that time. The Southern Health and Social Care Trust will consider any delays in treatment highlighted to assess if these were within the Consultants control or due to systematic issues e.g. length of waiting lists)	No	
9	On balance, did the patient suffer any harm or detriment as a result of any of the above questions (4-9)?	No	

Name	Mark Haynes	
Title	Consultant	Submit
Date of Appointment	10/04/2021	