

From: Emmet Fox [Personal Information redacted by the USI] >
Sent: 18 May 2022 12:46
To: Murphy, Eoin [Personal Information redacted by the USI] >; Donnelly, Anne [Personal Information redacted by the USI]
Cc: Avril Frizell [Personal Information redacted by the USI] >; Keeva Wilson [Personal Information redacted by the USI] >; Casey, Eileen (USI) [Personal Information redacted by the USI] >
Subject: RE: Maria O'Kane Amended S21 Notices

"This email is covered by the disclaimer found at the end of the message."

Dear Mr Murphy

Re: Maria O'Kane Amended S21 Notices

I refer to the matter above and to your email below. Thank you for same.

I can confirm that the amended versions are not intended as replacement documents. The original versions can be kept in case an individual needs to refer back to the original versions or cross reference same.

Ultimately, we defer to the USI in terms of how the documents will be incorporated into the bates referencing system.

Kindest Regards

Emmet Fox
Solicitor

Directorate of Legal Services | Business Services Organisation | 2 Franklin Street | Belfast | BT2 8DQ |

E: [Personal Information redacted by the USI] M: [Personal Information redacted by the USI]

In light of ongoing remote working arrangements and in the interests of reducing environmental impact, please forward correspondence by email only.

From: Murphy, Eoin [Personal Information redacted by the USI]
Sent: 18 May 2022 09:48
To: Avril Frizell [Personal Information redacted by the USI] >; Emmet Fox [Personal Information redacted by the USI] >; Keeva Wilson [Personal Information redacted by the USI] >
Cc: Casey, Eileen (USI) [Personal Information redacted by the USI] >
Subject: Re: Maria O'Kane Amended S21 Notices

Good morning,

Re: Maria O'Kane Amended S21 Notices

Could you confirm whether the amended S21 Notices, received on the 13th May 2022, are intended to replace the previous S21 responses received? BATES numbering of the original statements has already taken place and I we are unable to 'swap out' due to a difference in page numbers.

Kind regards,

Eoin Murphy

Urology Services Inquiry

Contact: [Personal Information redacted by the USI] | Tel: [Personal Information redacted by the USI]





USI Ref: S21 1 of 2022

Date of Notice: 18 February 2022

Amended Witness Statement of: ELLEN MARIA O’KANE

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

1. I am, since 1st May 2022, ~~the Medical Director and Temporary Accounting Officer and Cover for the Chief Executive of the SHSCT (‘the Trust’).~~ I make this amended 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
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

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

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.

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 8 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

at Question 2(vii) above because 215 reviews were in the form of patient letters, rather than patient review forms, completed by Mr Keane)

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)	4 Question Form (November 2021 – Present)
<ul style="list-style-type: none"> • 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 <p>Regarding The Patients Previous Care</p> <ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 previous 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
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01.11.2021	<p>UAG Meeting 1st November 2021 - Extract from Minutes</p> <p>Cohort 1 Outcomes Report</p> <p>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.</p> <p>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.</p> <p>15. The group noted concerns that nine questions was a large number and may not be feasible to report on. The group noted:</p> <ul style="list-style-type: none"> • 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. <p><i>It was agreed the Trust and HSCB should reconsider questions.</i></p> <p>Action: HSCB and SHSCT to reconsider lookback questions and agree final methodology.</p>
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25/11/2021	<p>Southern Urology Coordination Group 25th November 2021 - Extract from Minutes</p> <p>Outcomes Report</p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p>
<p>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.</p>	

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

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*  3519302640

and Q2 xiv Item 4592 - Mr [Patient 38] 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 SAls 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 for deviation from guidance	NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Therapeutic doses of anti-androgen monotherapy with bicalutamide are prescribed at recommended dose (150 mg).	100%	Discussions with patient / Clinical rationale	NICE guideline NG131 Prostate Cancer: Diagnosis and Management
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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 whose responsibility was 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 incorrect 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 South Africa 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 correctly commenced by Mr O'Brien on combined androgen blockade (LHRHa and 50mg bicalutamide) and had been switched to intermittent treatment by another Southern Trust Locum Consultant Urologist (Personal Information redacted by the USI) on review. However only the LHRHa (rather than both treatments) 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 (Patient 6 DOB (Personal Information redacted by the USI) and Patient 4 DOB (Personal Information redacted by the USI)) were subjects of 2020 SAIs (conducted by Dr Dermot

Hughes) and had already been reviewed and management changed. Of the 53 patients screened in for SCRR by 15 April 2022, 32 were on low dose Bicalutamide (i.e., the same 32 patients mentioned above).

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. No concerns were identified with the remaining 272.
- 1 patient (Patient 1, DOB [redacted] Personal Information redacted by the USI) 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.

Of the 53 patients screened in for SCRR by 15 April 2022, 15 were on high dose Bicalutamide (i.e., 15 of the 26 patients mentioned above).

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 v3*, Q3 *Patient Review Forms 09 02 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 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.

As indicated above, the Lookback focused on all patients listed as under the care of Mr O'Brien between January 2019 and June 2020 based on data obtained from the Trust Electronic Patient Administration System ('PAS'). This resulted initially in 2346 patients being identified.

During the validation of these patients there were 233 who, while on a named 'New Outpatient Waiting List' of Mr O'Brien's, were still waiting to be given an appointment at a new outpatient clinic and, therefore, as they had never been under the care of Mr O'Brien, they were discounted.

The remaining 2113 (being 2346 less 233) were identified as being under Mr O'Brien's care in the January 2019 to June 2020 period. This figure of 2113 includes:

- Patients seen at an outpatient clinic (new and review);
- Patients who were admitted under his care, as emergency or elective patients;
- Patients who had been seen by him either whilst on the ward or at an outpatient clinic and had been added to his inpatient and daycase lists;
- Patients who were on a review outpatient waiting list and were past their planned appointment date.

Please see below table providing details as at 09 May 2022 regarding the number of 2113 patients considered, including: 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 May 2022.

Type	Number of Patients	Details of Patient Cohort	Comments
Correct Management	1040 <u>1533</u>	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 <u>475</u> <u>(please note these include those patients still needing screened for SCRR – 300 records – see below)</u>	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 internal screening continues

Required New Plan	48 (part of 483 <u>475</u> 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 internal screening continues
Patients Still To Be Seen at Clinics	47 <u>34</u>	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 <u>300</u> <u>(please note these are part of the 475 Sub-Optimal Care Group above and, as they are screened, may move from that Group to the SCRR cohort below)</u>	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 but won't have had a review form completed. Internal screening process ongoing as per Governance direction to ensure all patients through the same process.
SCRR & SAI Patients	53 SCRR & 9 SAI & <u>a further 8 identified to likely progress through the SCRR process</u> (not part of the 483 <u>475</u> 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 list – to identify if they were on the correct management plan Complete	Face to Face consultations In Independent Sector	Mr Patrick Keane
Patients who had been discussed at Oncology MDM to make sure they had had follow-up Complete	Meeting via Zoom	Prof Krishna Sethia (Chair) Mr Mark Haynes Mr Darren Mitchell Kate O'Neill – CNS Leanne McCourt – CNS

		Sinead Lee – Cancer Tracker
Histopathology results of patients who had had a biopsy done to ensure their result had been actioned – Complete	Virtual review by electronic record	Mr Mark Haynes/ Dr Darren Mitchell/ Kate 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

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 Mr Paul Rajjayabun_indemnity, Q8 Confidentiality Agreement PHR, Q8 Paul Rajjayabun SHSCT Data Sharing, Q8 Paul Rajjayabun 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 Communication	5
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 34 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

Statement of Truth

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

Signed:

Personal information redacted by the USI

Date: 13th May 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.