Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: S21 1a of 2022

Date of Notice: 10 March 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 statement, in response to Section 21 Notice No.1A 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
1.	Chris Wamsley, Acute Governance Coordinator Sarah Ward, Head of Urology Clinical Assurance Martina Corrigan, Assistant Director Public Inquiry and Trust Liaison
2.	Chris Wamsley, Acute Governance Coordinator Sarah Ward, Head of Urology Clinical Assurance
3.	Chris Wamsley, Acute Governance Coordinator
4.	Chris Wamsley, Acute Governance Coordinator
5.	Chris Wamsley, Acute Governance Coordinator
6.	Chris Wamsley, Acute Governance Coordinator
7.	Chris Wamsley, Acute Governance Coordinator
8.	Chris Wamsley, Acute Governance Coordinator

9.	Martina Corrigan, Assistant Director Public Inquiry and Trust Liaison
10	Chris Wamsley, Acute Governance Coordinator

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

1. Taking each patient in turn and by name, explain why each of the 10 patients identified on the spreadsheet were initially included within the SCRR process.

In answering this question you are required to provide

a. an account of all of the information and factors that were taken into account,

b. the date each decision was made,

c. and the identity of the person(s) who made the decision to include the patient within the SCRR process and their job title.

4. Originally there were 77 patients identified as meeting the criteria for SAI and they came from the review work that Prof Sethia (March 2020 onwards), Mr Keane (2nd Nov 2020 to 22nd Dec 2020), and Mr Haynes (Nov 2020- March 2021) undertook. The process that led to these 77 patients being identified involved Mr Haynes (Consultant Urologist and Divisional Medical Director in Urology), assisted by Martina Corrigan (Assistant Director for Public Inquiry and Trust Liaison), considering the review forms / letters for each patient mentioned at paragraphs 4.1 to 4.5 below along with other records such as NIECR and asking whether the patient

was at potential risk of having come to harm. If Mr Haynes' opinion was 'yes' then the patient went on to be considered at a formal second stage by the Acute Governance Screening Team (described in more detail at paragraphs 5, 8 and 9 below). These 77 patients were identified from the following cohorts – (please note, as advised in my response to s.21 Notice No.1 of 2022, there were 2113 patients identified as being under the care of Mr O'Brien in the period January 2019 – June 2020 and some of these patients were reviewed on a number of occasions as they sat in a number of the groups below (4.1 - 4.6) and therefore have been counted more than once and this explains why the total sum below is 2446 [1028+215+168+271+466+298] and not 2113).

4.1 1028 Radiology results
4.2 215 Mr Keane urology clinic review
4.3 168 Histopathology results
4.4 271 MDM episodes
4.5 A total of 466 patients were identified from the Western, Northern and Southern Trust areas as having received a prescription for Bicalutamide 50mg. Of these 34 were identified as not meeting the recognised indications
4.6 A total of 298 patients were identified from the Western, Northern and Southern Trust areas as having received a prescription for Bicalutamide 150mg. Of these 26 were identified with concerns.

5. These 77 patients were then subjected to formal SAI screening by the Acute Governance Screening Team (named below at paragraph 9) and were reduced to 53 patients with ~~6~~ 2 under further discussions (which discussions are likely to be completed at a meeting scheduled for 30 May 2022). Therefore, ~~18~~ 22 of the patients who had been screened in at the first stage were screened out through the formal second stage process adopted by the Acute Governance Screening Team. A detailed summary of the decisions made regarding the screening in of the 53 and the screening out of the ~~18~~ 22 can be found in the tables that follow, respectively, paragraphs 12 and 19 of this statement. I understand that this level of detail is available in respect of the second, but not the first, stage of the screening process because, at the second stage, urology screening outcome forms were completed to record the Team's decision-making.

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6. In addition to the above patients, those additional 402 patients (referred to in the table in the answer to Q6 of s.21 Notice 1 of 2022) who were identified by Prof Sethia where there have been clinical queries (missing diagnostics, prolonged antibiotics, lack of communication, or delayed action of scans/results) but who on first discussion with Mr Haynes and Mrs Corrigan did not appear to meet the criteria for SAI, are now also being formally screened by the Acute Governance Screening Team. To date 8 have been identified as meeting the criteria for SAI.

7. As indicated above, the cases which highlighted potential concerns were progressed through the normal SAI screening process following the initial review completed by Mr Haynes and Martina Corrigan.

8. The normal SAI screening process within Acute Services is completed through screening meetings with each division holding their own meeting. The membership of the Screening meetings have a universal core membership of the Assistant Director of the Division, the Divisional Medical Directors of the Division, Clinical Governance Coordinator and Governance Managers. Incidents which reach the threshold are discussed with the group members to collectively decide if a further investigation is necessary to identify system and process learning for the organization using the HSCB SAI investigation criteria. For the Urology cases which reach the threshold for an SAI, these are being reviewed through the SCRR process.

9. The identity of the Urology Screening Team members (the second stage of the process described above) are highlighted below.

   - Ronan Carroll – Assistant Director for SEC and ATICs
   - Mr McNaboe – Divisional Medical Director for SEC
   - Dr McKee – Divisional Medical Director for ATICs

- Mr Haynes – Divisional Medical Director of Urology
- Dr Scullion – Deputy Medical Director Appraisal and Revalidation
- Chris Wamsley – Acute Clinical Governance Coordinator
- Sarah Ward - Head of Clinical Assurance for the Public Inquiry
- Carly Connolly – Governance Manager
- David Cardwell – Governance Manager
- Dawn King – Governance Manager
- Roisin Farrell - Governance Officer

10. The screening of the highlighted Urology cases is an ongoing process in the Southern Trust. An overview of the dates and numbers of cases screened are provided in the table below.

Date	Cases Screened	No. for SCRR	No. excluded for SCRR	No. to return to screening.	Comments
15/11/2021	16	13	0	3	
22/11/2021	22	13	5	4	
29/11/2021	17	7	4	6	
6/12/2021	0– Screening cancelled	N/A	N/A	N/A	Mr Haynes Unavailable

13/12/2021	0– Screening cancelled	N/A	N/A	N/A	Mr Haynes Unavailable
20/12/2021	18	12	5 (1 x not original 77)	1	
10/01/2021	19	8	4 (1 X Duplication)	4	

11. The attendance of Mr Haynes, who is a Consultant Urologist, at the Urology Screening meetings is mandatory as the specialist urological knowledge of NICE guidelines, standards and treatments is essential to inform the screening meeting members to ensure informed decisions surrounding the SCRR process are obtained.

12. A summary of the 53 SCRR Screened IN Patients is set out in the table below and includes their name and a summary of both the relevant patient information and discussions. Those screened out are dealt with in Question 3 from paragraph 19.

15/11/2021

H+C	**Summary of Incident**	
1. Patient 17 [redacted] Personal Information redacted by the USI	Personal Information redacted by the USI gentleman with known history of prostate adenocarcinoma, Gleason score 3+3= 6 March 2011. PMHx of hypertension, AAA, BCC and MI. Patient 17 [redacted] is currently on Bicalutamide 50mg for his prostate cancer. For outpatient review to recommend stopping bicalutamide and management by surveillance with up to date	15.11.21 - MDT surveillance, 2012 PSA rising, hormone and radiotherapy. Not referred for radiotherapy. Were these patients ever brought back to MDT. No mechanism in MDT at present to check or follow up of recommendations. This is a weakness. Has been highlighted at a senior level. **Meets the criteria for review.**

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	MRI staging if his PSA is rising and consideration of management options at that point.	
2. Patient 19 Personal Information redacted by the USI	Personal Information redacted by the USI year old gentleman who had organ confined, Gleason 7, prostatic carcinoma diagnosed in 2011 and managed entirely with androgen blockade alone since then. He has continued to take Bicalutamide 150mg daily in addition to Tamoxifen 10mg daily. Patient 19 is on Bicalutamide 150mg for his non metastatic prostate cancer. Watchful waiting / intermittent ADT are the recommended treatments.	15.11.21 - MDT outcome at aged Personal Information redacted by the USI started on bicalutamide. Looks like hormones alone when treatment options should have been radical treatment or watchful waiting/surveillance. Now onto watchful waiting. Has had fractured neck of femur. ADT increases risk of osteoporosis. **Meets the criteria for review.**
3. Patient 20 Personal Information redacted by the USI	Personal Information redacted by the USI year old gentleman diagnosed with high risk Gleason 4+3 prostate cancer in 2014 and was Started on androgen blockade. His on-going PSA monitoring has showed minimal change in PSA with his most recent PSA in July 2020 being 0.05ng/ml. From medication point of view he currently takes Tamoxifen 10mg once daily and Bicalutamide 150mg once daily	15.11.21 - Looks like hormones alone when treatment options should have been radical treatment or watchful waiting/surveillance. MDT May 2014. Started on 150 mg. Nothing to suggest he was offered radical treatment as MDT suggested. April 2021 consideration of radiotherapy. Has since had same. Due to finish ADT in January 2022. Delay of 7 years - this has resulted in unnecessary ADT. **Meets the criteria for review.**
4. Patient 23 Personal Information redacted by the USI	Patient 23 is currently receiving no treatment for his Prostate cancer. For outpatients review and recommendation of management by active surveillance with an up to date MRI scan and	15.11.21 - This patient is on watchful waiting. Localised prostate cancer 2011. Initially had some discussions about treatment with hormones and radiotherapy. TURP 2013. Stopped ADT himself and switched to surveillance. Prescription of hormones was 50mg initially. Not a

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	consideration of surveillance biopsy on the basis of PSA dynamics and MRI findings. Structured Clinical Judgement Review to be performed	licensed dose. **Meets the criteria for review.**
5. Patient 37 Personal Information redacted by the USI	Patient 37 is currently Bicalutamide 150mg for a high risk non metastatic prostate cancer. For outpatients review to recommend the addition of EBRT and referral to oncology if fit for radiotherapy.	15.11.21 - Diagnosed with high risk locally advanced prostate cancer in Feb 2020. Not referred for radiotherapy. MDT consideration for radial treatment or watch and wait. Commenced on hormones alone. Subsequently referred for radiotherapy. Meets the critera for review. Recurring trend that patients are started on adjuvent treatment and not being followed up. PRO7 study findings have been well known since 2015 - specifically relates to this case (hormones and radiotherapy should have been the management for this patient) **Meets the criteria for review.**
6. Patient 38 Personal Information redacted by the USI	Patient 38 has been managed with Bicalutamide 150mg for prostate cancer. Despite antiandrogens his current PSA is 11.6. For outpatients review to recommend stopping bicalutamide and monitoring of PSA with a view to watchful waiting / intermittent androgen deprivation and to consider staging with CT and bone scan. If hormones are required in the future it should be an LHRH analogue or LHRH antagonist. Following MDM discussion his Bicalutamide has now been discontinued.	15.11.21 - Was started on an unlicensed dose of 50mg. Should have been offered a radical treatment option. PSA was not controlled. Questions around whether he should have been switched to a standard treatment. Should have been offered long term watch and wait rather drug therapy. Three issues which require investigation. **Meets the criteria for review.**
8.	Personal Information redacted year old gentleman diagnosed with Gleason 3+4	15.11.21 - Looks like hormones alone when treatment options should

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Patient 51 Personal Information redacted by the USI	prostate cancer which is currently managed with androgen deprivation therapy. Patient 51 is currently receiving Bicalutamide for his prostate cancer. For outpatients review to arrange up to date staging with an MRI and to discuss options of EBRT vs surveillance/watchful waiting.	have been radical treatment or watchful waiting/surveillance. **Meets the criteria for review.**
10. Patient 61 Personal Information redacted by the USI	Personal Information redacted year old gentleman diagnosed with Gleason score 4+4=8 organ confined adenocarcinoma of his prostate gland, June 2012. Patient 61 is on an LHRHa for his prostate cancer. For outpatient review to discuss re-staging and referral to oncology if fit for radiotherapy and to refer for assessment of bone density	15.11.21 - Was not offered radial treatment at time of diagnosis - options were surveillance or watchful waiting. Has received a prolonged period of ADT which was not indicated. Diagnosis in 2012, MDT decided radiotherapy but this was not followed up. Was discussed at MDT on 8 April 2021 and opinion of group was that restaging and discuss. Not offered radical treatment at the time of diagnosis in 2012 as he should have been. Patient has not got the service that they should have got - **meets the criteria for an SJR** as he was not offered the primary treatment.
11. Patient 77 Personal Information redacted by the USI	Personal Information redacted year old gentleman was diagnosed with clinical and biochemical diagnosis of prostatic carcinoma in May 2018 when he was reported to have a prostatic volume was reported to be 88ml and his residual urine volume was reported to be 201ml. Patient commenced him on Bicalutamide and Tamoxifen 2018. Patient 77 is on Bicalutamide 150mg for a clinical diagnosis of prostate cancer. For outpatient review, to recommend stopping bicalutamide and management with surveillance with	15.11.21 - Reluctance to manage patients without treatment. Breast growth with bicalutamide. Tamoxifen to reduce this. Was started on medication without evidence of metastatic disease. Now being managed with watchful waiting and PSA monitoring. No diagnosis of cancer. Suspect reduced dose was to reduce complications of treatment. **Meets the criteria for review.**

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	consideration of staging / investigation dependent upon PSA dynamics.	
13. Patient 74 [redacted] Personal Information redacted by the USI	Patient 74 has a low risk non muscle invasive bladder cancer treated by TURBT. For review by Mr O'Brien to recommend flexible cystoscopy in 3 months. Complaint about his treatment under Mr O'Brien. Comment MDH - ?indications for why a TURP was performed in 2013	15.11.21 - Patient who contacted the Trust re concerns about management. Helpline. Was seen in clinic by Mr Haynes. Prostate cancer treated with radiotherapy. Now incontinent managed with pads. Issues are incontinence. Mr Haynes could not satisfy the decision to proceed to TURP - this is incontinence stems from. Continuous stress incontinence. Bladder cancer first and then TURP when he attended for bladder procedure. Prostate cancer diagnosed at this point. 2013 given botox, went into retention, subsequent TURP (10% risk of retention) not an indication for bladder outflow surgery. In absence of obstruction TURP can worsen obstruction. Stress incontinence relates to closure pressures. Concerns re bladder outflow surgery. **Meets the criteria for review**.
14. Patient 6 [redacted] Personal Information redacted by the USI	[redacted] Patient 6 has an intermediate risk organ confined prostate cancer. Initially treated with Bicalutamide 50mg, switched to 150mg in November 2019 and then [redacted] Patient 6 has discontinued Bicalutamide since his last prescription in February 2020 - Recent PSA 15	15.11.21 - Initially started on 50mg for stage of disease which options were radical treatment or surveillance. Neither has he been treated or monitored. **Meets the criteria for review**
15. Patient 66 [redacted] Personal Information redacted by the USI	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	15.11.21 - 2019 Raised PSA. No evidence of metastsis. Commenced on 50mg and planned for a TURP. No diagnosis of prostate cancer. PSA 28.8. Standard investigation of a raised PSA would include consideration of MRI and prostate biopsy. Started on unlicensed dose and investigation plan was not

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	regards to prostate cancer likely diagnosis	standard for diagnosis. Received hormone treatment to December 2020. Still no tissue diagnosis. Now on watchful waiting. Personal Information redacted year old. PSA dynamics do not trigger any indication for treatment. The only standard use for 50mg is for testestrone flair for patients being started on LHRHa. Difficult to understand why this drug was used. **Meets the criteria for review**
16. Patient 60 [redacted] Personal Information redacted by the USI	High risk locally advanced prostate cancer diagnosed 2017 and treated with oral Bicalutamide to date	15.11.21 - 2017 MDT high risk locally advanced disease. Treatment with curative intent. Started on 150 mg in March 2017. For patients having ADT with radiotherapy will receive this drug from oncologist. **Meets the criteria for review.**

22/11/2021

No. Name **H+C**	**Summary of Incident**	**Summary of Discussions**
7. Patient 40 [redacted] Personal Information redacted by the USI	Personal Information redacted year old gentleman diagnosed in 2012 with an PSA of 9, Gleason 7 (4+3) T2 adenocarcinoma Of prostate gland. Treatment history: Completed radical radiotherapy January 2013. Various doses of hormone treatment over the years stopping in January. PMHx of Prostate Ca and Renal Stone disease. Patient 40 has been treated with radiotherapy for his prostate cancer. He had some concerns regarding the delay	15.11.21 - Patient advised during consultation with Mr Haynes. Was not referred for radiotherapy on diagnosis. Diagnosis in 2008 (prostate cancer). Started on Bicalutamide 50mg. Also had Tamoxifen started. In 2012 started on LHRHa in addition to Bicalutamide - referred to oncology. In documentation regarding radiotherapy, it is noted patient found it difficult to travel but later raised concerns about a delay in radiotherapy from 2008 to 2012. Need to obtain MDT outcomes. Standard pathway MDT at point of diagnosis would not come back when switching treatments. 19/11/2021 There was no MDT at this time. 22.11.2021 there is

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	from diagnosis to having radiotherapy.	documentation in letters about radiotherapy, but patient advised he had difficulty travelling for radiotherapy. 2008 no MDM on CaPPs system. The patient has raised the concern in consultation, reviewing this one comment. Not keen for surgery, would not travel to Belfast on daily basis for 7/52. Adequate evidence, offered radio and patient choice not to get radiotherapy. Low dose Bicalutamide unlicensed treatment. **For SJR.**
18. Patient 31 [redacted] Personal Information redacted by the USI	Bicalutamide 2011 and then Radiotherapy 2014 for CaP had assessment of LUTS prior to RT but dose of bicalutamide 50mg and 3 years from diagnosis to RT incorrect dose of bicalutamide referral to oncology delayed	22.11.2021 Discussed at screening- 01.05.2021 tel consultant with Mr Haynes. Patient was on an unlicensed dose of Bicalutamide, Now on correct treatment, **For SJR.**
22. Patient 67 [redacted] Personal Information redacted by the USI	Colovesical fistula, Haematuria / ?TCC bladder and raised PSA initial pathological interpretation 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. Subsequently PSA has been found to remain elevated and is undergoing further investigations currently - Repeat PSA not checked despite MDM recommendation	22.11.2021 Discussed at screening. MDM Jan 2019 advised to repeat serum PSA- this was not done. Has had PSA repeated since and was elevated. Has since gone through prostate cancer diagnostic pathway and treated for prostate cancer. Patient aware. Would have had an earlier diagnosis had PSA done earlier. Patient has not come to harm. Earlier treatment small/ slight increase in cure. Patient inadvertently went onto watchful waiting. There is the potential of harm. MDM outcome not followed. **For SJR review.**
24.	Admitted and catheterised for high pressure retention 2x	22.11.2021 Discussed at screening- unlicensed use of Bicalutamide-

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Patient 43 [redacted] Personal Information redacted by the USI	TURPs CVA after 2nd TURP commenced on off license bicalutamide dizziness (SE of both tamsulosin and bicalutamide). Concerns; 1)no evidence of discussion of off license use or risks of bicalutamide 2)no offer of alternatives to TURP for large glands (NICE CG97 2010/15 recommendation 1.5.4) Bicalutamide off license use with no evidence discussion of this or risks prostate volume not assessed formally on initial admission and no discussion of alternatives to TURP as per NICE CG97 maybe had CVA after second GA. If he had been offered and opted for holmium enucleation (would have been ECR to England) would have only required 1 GA	bladder outflow surgery reasonable, TURP failed to establish voiding, 2nd TURP failed to establish voiding and pt had a stroke. Prostate volume 148cm3 at the time, NICE guidelines recommend Prostate volume >80 alternative treatment should be used, should have been offered alternative treatment and avoided 2nd anaesthetic, which resulted in a stroke. Cardiovascular complications risk doubles after 1st anaesthetic- patient was Personal Information redacted by at the time. Issues: 2 operation could have been avoided if offered alternative treatment; Bicalutamide off licensed dose. ADT given afterwards. NICE guidance offer alternative treatment, and maybe would have had a better outcome (no CVA). Unlicensed dose of medication, with side effects. **FOR SJR**
27. Patient 26 Personal Information redacted by the USI	Diagnosis: Intermediate risk localised prostate cancer diagnosed 2009 – on Bicalutamide 50mg since July 2010	22.11.2021 Discussed at screening- on a prolonged period of unlicensed dose of Bicalutamide. Mr Haynes reviewed patient 02.11.2020, patient aware. **FOR SJR**
28. Patient 33 Personal Information redacted by the USI	Diagnosis: T2 intermediate risk localised prostate cancer diagnosed in 2014 treated with low dose Bicalutamide since 2014	22.11.21 Mr Haynes reviewed patient on 3.11.2020. Perso nal Infor at diagnosis. 2014 commenced on low dose Bicalutamide. Patient had a prolonged period of unlicensed dose of low Bicalutamide. Patient aware. Now switched to watchful waiting, **FOR SJR**

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29. Patient 41 Personal Information redacted by the USI	Diagnosis: Prostate cancer diagnosed September 2014, gleason 3+5=8 in 2 of 6 cores with initial PSA of 8.02 initially commenced on Bicalutamide and Tamoxifen at a dose of 150/10. Discontinued due to hot flushes. He was then more recently started on Bicalutamide to 50mg	22.11.21 Discussed at screening 02.11.20 reviewed by Mr Haynes, Patient had high-risk disease, no MRI was completed but had CT scan, commenced Bicalutamide and discontinued, then was restarted on Bicalutamide 50mg, treatment options should have been watchful waiting or hormone/ radiotherapy. Discussed at 2014 MDT histology review, no evidence of subsequent MDM discussion. Patient informed. Patient is currently on watchful waiting pathway. **For SJR.**
30. Patient 45 Personal Information redacted by the USI	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. on combined androgen blockade	22.11.21 Discussed at screening. Mr Haynes has reviewed patient - non-metastatic cancer standard treatment would be surveillance/ watchful waiting or radical treatment. Not offered referral to Radiotherapy. Patient was on unlicensed treatment. Patient now aware. **FOR SJR**
31. Patient 48 Personal Information redacted by the USI	Diagnosis: Locally prostate cancer diagnosed in 2010, on anti-androgen since diagnosis	22.11.2021 Clinical relevant index, diagnosed in 2010, PSA 15 prostate cancer, non-metastases prostate cancer 2010, pt was Personal Infor, commenced on hormone treatment, AOB thought no need for radiotherapy, no evidence of benefits to treat with hormone treatment. Not offered opportunity for radiotherapy. Mr Haynes has reviewed patient and now on watchful waiting as this is the appropriate pathway. Patient could have had 10 yrs without hormone treatment on watchful waiting pathway. **For SJR**
32. Patient 49 Personal Information redacted by the USI	Diagnosis: Clinical/radiological suspicion of prostate cancer diagnosed in 2015 with PSA of 6.24 (on finasteride) and radiological suspicion of T2 (localised)	Mr Haynes met and reviewed patient- Radiological suspicion of localised disease, Personal Inform at time, not biopsied, started low dose Bicalutamide and continued on same. Personal Information yrs old showed evidence

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	prostate cancer - No prostate biopsy performed	PSA of 12 and evidence with localised disease, watchful waiting without biopsy, now on surveillance pathway as appropriate treatment. Unlicensed treatment dose of Bicalutamide, no sign of consent process, risks and benefits explained. **For SJR.**
33. Patient 56 Personal Information redacted by the USI	Diagnosis: Low risk prostate cancer diagnosed 2003 treated with initially LH RH analogue for short period followed by low dose Bicalutamide treatment which he has remained on since diagnosis	22.11.2021- Personal Information redacted by the diagnosed in 2003 with low risk prostate cancer, placed on LHRH then Bicalutamide 50mg, treatment now discontinued current treatment on surveillance pathway. Can't find all details, should have been offered surveillance/ watchful waiting as most appropriate, patient had an unlicensed dose for 16 years before stopped Dec 2019. Patient is aware, NH patient won't actively follow up. **For SJR.**
34. Patient 68 Personal Information redacted by the USI	Diagnosed 2017 with an iPSA of 43, Gleason 7 (4+3), T2, N0, M0, adenocarcinoma of the prostate Gland – seen in Independent Sector and recommended that his case management is reviewed	22/11/2021 Discussed at screening diagnosed in 2011 prostate cancer, then treated with Bicalutamide at 150mg then sub LHRH, had non metastases disease at presentation, no discussion about radiotherapy until 3-4 years later, subs referral made to radiotherapy 2016/17. HIGH RISK localised cancer, MDMT outcome not followed, could have been off treatment if referred to radiotherapy earlier. Radiotherapy was recommended, no mechanism for tracking MDM outcomes. Responsibility lies with clinician to carryout MDT outcomes. Has been treated and currently on appropriate treatment. **For SJR review.**
36. Patient 80 Personal Information redacted by the USI	Perso nal Infor year old gentleman diagnosed with Intermediate risk small volume localised prostate cancer in May 2012 with initial PSA of 7.36 and gleason 3+4=7 prostate cancer in 3 of 12 cores	22/11/2021 screening recurrent theme, unlicensed dose of bicalutamide, follow on from morning decision, seen by Mark Haynes on unlicensed treatment for prolonged period, without indication, should have been surveillance or radical

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	radiological stage T2 N0 M0. Treatment with low dose (50mg) Bicalutamide and tamoxifen since diagnosis.	treatment, now on surveillance. **For SJR**

29/11/2021

No. Name **H+C**	**Summary of Incident**	**Summary of Discussions**
37. Patient 82 Personal Information redacted by the USI Personal Information redacted by the USI	Perso nal Infor year old gentleman Personal Information redacted by the USI Personal Information redacted by the USI diagnosed with Localised intermediate risk prostate cancer initially in 2010 and commenced on low dose Bicalutamide 50mg and Tamoxifen 10mg February 2011.	29/11/2021 - Seen Mr Hayes recently -standard localised prostate cancer age Perso nal Infor - low dose Bicalutamide maintained, patient was never offered radical treatment, Mr Haynes took of treatment Nov 2020. **For SJR.**
38. Patient 42 Personal Information redacted by the USI	Prostate cancer treated with radical radiotherapy – phoned Urology Inquiry Information line – wants his care under Mr O'Brien looked into (transferred to Mr Young on his wishes)	29/11/2021- Query timescales- seen in 2017 urinary symptoms raised PSA, clinical obs USS done March 2018; pt went on holiday bloods done Aug 2018. Letter March 2018 stated for blood test in June, if PSA was up to arrange MRI, pt tried to contact AOB with results and no action was taken. Despite contact with sec, no action taken, pt escalated to HOS and had an app with Mr Young. Patient was then diagnosed and had radiotherapy. Pt describes interaction he had with Mr AOB led to AOB not to take action for review. Patient contacted secretary and received no response. We do not know if sec shared info with AOB. Patient was investigated and assessed as intermediate risk prostate cancer. The

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		patient's interaction was unsatisfactory and led to him not being followed up. Escalated following multiple contacts with secretary. Sec should add to doaro list and remain on list until PSA done, In August this should have been identified and flagged up. There was delay in diagnosis, no evidence harm done.. There is potential harm, doaro list is a failsafe and should be used. **FOR SJR**.
40. Patient 36 Personal Information redacted by the USI	This Personal Information redacted by the USI man attended Urology in 2017 and had Adenocarcinoma Prostate Gleason 3+4 diagnosed in April 2017. He was commenced on Bicalutamide and Tamoxifen on 05.05.17 and subsequently commenced on Fesoterodine 4mg daily in September 17.	29/11/2019 MDM outcome watchful waiting was started on hormone treatment, never referred for radiotherapy. Patient not aware DNA appointment. Not offered radio or watchful waiting, Quality impact on life on hormonal treatment. Evidence should have had hormone and radiotherapy, or watchful waiting. **FOR SJR**
42. Patient 55 Personal Information redacted by the USI	Diagnosis: Gleason 3+4=7 prostate adenocarcinoma diagnosed 2015 Radical radiotherapy completed July 2015 – IPSS =17 Subsequent treatment with Bicalutamide, Tamoxifen and medroxyprogesterone under Mr O'Brien	29/11/2021 Discussed at screening. Noted some clinicians rely on outpatient review to trigger a follow up, even with recognition they cannot provide review within recommended time scales due to backlog. Outpatient reviews. 3/12 No PSA, there was a delay in referral, then pt DNA appointment. There are complex letters query excuse for 8/12 delay in dictation. Definitely, there was a delay in action from clinic outcome, delayed referral to oncology. Patient DNA himself, although pt might have miss-understood urgency due to the delay in appointment. DNA are common for a variety of reasons. Delay in referral was too long. Reason provided in letter does not justify reason for delay and non-action from MDT recommendation. **FOR SJR**.

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48. Patient 35 Personal Information redacted by the USI Personal Information redacted by the USI	Highlighted by professor Sethia Initial diagnosis in 2009 with a Gleason 7 T2 adenocarcinoma of the prostate gland. US guided biopsy in 2012 Gleason 7 was noted and a PSA of 3.9.	29/11/2021 Discussed at screening. Same as previous cases. Feb 2013 Bicalutamide 50mg, Off licence dose, later increased 150mg, no evidence offered surgery instead of hormone treatment, completed radiotherapy December 2014. FOR SJR Surgery should be a treatment option, no evidence choice offered, low dose of Bicalutamide . Treatment discussion in outpatient department should be in notes. See attached notes.07/02/2022 Discussed at screening, Bicalutamide dose. **FOR SJR**
72. Patient 57 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector SJR - Bicalutamide - medication unlicensed dose	28/11/2021 Discussed at screening. Off licence dose of Bicalutamide, prolonged period of ADT, subsequently referred to Oncology in 2014, completed radiotherapy 2015. Has had good outcome and done well. **FOR SJR**
74. Patient 18 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector 'you may wish to review the hormone initial management of Patient 18'	29/11/2021 Discussed at screening. Initial hormone treatment with Bicalutamide 50mg. Discontinued himself because of side effects, then referred later for radiotherapy. Initial diagnosis was Sept 2011. Seen for discussion re surgery Nov 12, then referred to Radiotherapy. There was a delay in referral for radical treatment. Has now had treatment and has had a good outcome, patient unaware. **FOR SJR.**

20/12/2021

No. Name **H+C**	**Summary of Incident**	**Summary of Discussions**
59.	Highlighted by Professor Sethia	Discussed at screening 20/12/2021 - Patient had CT scan Dec 2017- new lung nodule- follow up not done. CT

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Patient 63 Personal Information redacted by the USI	Delayed diagnosis of Ca lung	2018 Nodule bigger. There was a 9-month delay in lung cancer, CT report was not actioned. Patient attended as an emergency and only then was action taken, referred to oncology. **FOR SJR**, Patient not aware but may have some insight.
62. Patient 34 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector SJR no letters pt was on bicalutamide for a number of years before being offered radiotherapy	Discussed at screening 20/12/2021 - Patient commenced bicalutamide 2013. Off license dose, delay in referral to radiology, pt seen privately. **FOR SJR.**
64. Patient 72 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector SJR - on bicalutamide for years before he had alternative treatment (2012-2014) and only started his LH/RHa in May 2014	Discussed at screening 20/12/2021- off license dose of bicalutamide. **FOR SJR**. Patient not aware. Sarah to follow up**.**
66. Patient 25 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector Current management plan in place with MDH but needs an SJR for previous episodes	Discussed at screening 20/12/21. Off license dose of Bic 50mg, delay in referral for radiotherapy**. FOR SJR**. Sarah to inform patient.
67. Patient 32 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector SJR as appears to have been on hormones for longer than should be and has FU planned	Discussed at screening 20/12/21- Intermediate risk -MDT- started Bicalultamide 50mg Feb 2014, switched to LHRHa May 2015, Radiotherapy Dec 2015. Issues off license dose of Nic and delay in referral for radiotherapy. Sarah to inform patient, PSA due March 2022. **For SJR**

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68. Patient 24 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector SJR for appropriateness of radical prostatectomy	Discussed at screening 20.12.21. Limited information 1998 PSA 26, High-grade prostate cancer, placed on hormone treatment before radiotherapy. PSA of 26 would not normally perform surgery, however query evidence base at the time, pt was not offered radical treatment, what was the standard practice in 1998. Mr Haynes is unable to advise. 2 issues identified: pt should have had prosectomy for high-grade disease; should have had hormone treatment then radiotherapy; 29 years on hormone therapy. **FOR SJR**. Sarah to advise patient, nest PSA due March 2022, Sarah to arrange appointment with Mr Haynes before March 2022.
69. Patient 75 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector This chap was diagnosed with Gleason 4+5 adenocarcinoma in 2011. He was then put on minimal androgen blockade using 50mg of bicalutamide and tamoxifen. There was no MDM discussion and he eventually ended up in the BCH system as he was referred on for radiotherapy on which he has done very well. obviously treating somebody with Gleason 9 adenocarcinoma of the prostate with 50mg of bicalutamide would need to be looked into	Discussed at screening 20.12.21. Personal Information redacted by old at the time, PSA 10.9, Gleason 9 on biopsy, locally advanced on MRI. 2011 Commenced bicalutamide 50mg, 2014 referred for radiotherapy, Unsure if missed at MDM in 2010/2011. Patient has since deceased Personal Information redacted by the USI, unsure of cause of death, Sarah to follow up. **FOR SJR**
70.	Highlighted by Mr Keane at OPD clinic in Independent Sector	Discussed at screening 10.01.2022. Mr Haynes unable to see MDT notes. Personal Information old male, appears started hormone alone, intermediate risk for prostate cancer, and should have

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Patient 78 Personal Information redacted by the USI	He was last seen in 2017 and hasn't been seen since nor his PSA checked. He is still fit and well and the issue of radiation therapy might still arise or intermittent androgen therapy with delayed radiation treatment but this still needs discussed with the oncology and the surgeons	been offered radical treatment. Commenced off license dose of bicalutamide 50mg increasing to 150mg. Did not refer for radiotherapy. **FOR SJR**. Pt is awaiting clinic appt with Mr Haynes.
71. Patient 70 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector SJR (bicalutamide - medication unlicenced dose)	2013 Bicalultamide 50mg, switch LHRh 2016, discussion had about radiotherapy, felt best to proceed with drug therapy, who made decision? Letter 2019 documented declined radical radiotherapy. Off license dose of androgen dep therapy. **For SJR**. Sarah to follow up with patient letter to advise of SJR, patient is on Mr Haynes waiting list to be reviewed.
73. Patient 39 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector SJR started on Bicalutamide 50mg and never offered radiotherapy	SCREENED 20.12.21. 2008 Patient prescribed off license dose of Bicalutamide 50mg, no referral made to oncology at the until January2021, pt developed metastic disease. Patient was not offered appropriate treatment **FOR SJR**. Sarah to book into Mr Haynes clinic.
75. Patient 81 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector He is entering a hormone refractory period and his management and follow up will need to be reviewed at MDT at Craigavon	2012 intermediate risk prostate cancer. Patient was commenced on Bicalutamide 50mg, not referred to Radiology at the time. Patient had rectal bleeding and was referred to surgery. Unlicensed dose of Bicalutamide, failure to referral to oncology. **FOR SJR**. Patient not aware, Sarah to book into clinic, due PSA check January 2021.
77. Patient 76 Personal Information redacted by the USI	Highlighted by Professor Sethia This Personal Information redacted by the USI man was placed on a waiting list in August 2014 for elective	Urodynamic study – 2012 no evidence of bladder issues. 2014 added to waiting list for TURP. Question was consent acquired, where risks and benefits explained- complication incontinence. Decision

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	admission for prostatic resection to relieve bladder outlet obstruction. His prostate gland was resected on 19 December 2019. Histopathological examination of resected tissue found Gleason 3+3 adenocarcinoma involving approximately 7% of tissue. There was no perineural or lymphovascular infiltration. He has had severe urinary incontinence since surgery.	making odd. There is no record for indication/justification for procedure in notes, investigations showed no obstruction. Cancer was an incidental finding.. Sarah to book patient an apt with Mr Haynes clinic. **FOR SJR review**

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No. Name **H+C**	**Summary of Incident**	**Summary of Discussions**
41. Patient 46 Personal Information redacted by the USI	SJR on bicalutamide for years before going on an LA analogue and started on non-recommended treatment	Discussed at screening 10/01/2022: off license dose of bicalutamide **FOR SJR**
43. Patient 28 Personal Information redacted by the USI	Diagnosis: T3b N1 prostate cancer at diagnosis 2017 treated with oral Bicalutamide	Discussed at screening 10/01/2022. Metastases prostate cancer, Personal Information redacted by the commenced Bicalutamide , MDT recommended LHRHa, carried on Bicalutamide, no documentation of consultation about inferior outcomes of treatment, no referral to oncology **for SJR**
44.	Diagnosis: 4.5cm left renal mass Prostate cancer on androgen deprivation	Discussed at screening 10/01/2022 - Kidney cancer was incidental finding, pt was restaged and this was

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Patient 27 Personal Information redacted by the USI	therapy On Bicalutamide and Tamoxifen for gleason 3+4 prostate cancer since 2014, stage T2 N0 M0	identified, 2014 Initially commenced on low dose Bicalutamide then increased to 150mg, pt should have been offered radical treatment in 2014. Mr Haynes has referred pt for radiotherapy. 2 issues off license dose Bicalutamide and surveillance or radical treatment. **FOR SJR,** recent clinical letter documents pt informed of options
45. Patient 62 Personal Information redacted by the USI	Patient request and highlighted by professor Sethia: I would like to have my care reviewed I was operated on by Mr Hagan in the City Hospital but the diagnosis and original procedure were carried out by Mr OBrien. As a result I had bladder cancer and prostate cancer I also had a kidney removed and as a result I had a stent inserted and now wear a colostomy bag.	Discussed at screening 10/01/2022 - 2017 pt had stroke, renal impairment right hydronephrosis, 2018 CT urogram 2018, which showed thick bladder wall, TURP July 2018. There was some delay in diagnosis management, flexible cystoscopy should have been considered based on urogram result. CT showed hydronephrosis, no stone evident, pt had a thick bladder wall. Flexible cystoscopy would not have required GI anaesthetic therefore low risk post stroke **FOR SJR** patient need to be informed.
51. Patient 64 Personal Information redacted by the USI	Highlighted by professor Sethia Diagnosis: T2, N0, M0 Gleason 4+3 iPSA 27NGS/ML (on 5ARI) prostate cancer. 9 out of 14 cores recent TURP.	Discussed at screening . Patient was on bicalutamide 150mg. Pt seen with raised PSA in Jan 2017, no correspondence from consultant, planned PSA + USS, both were completed. There is no evidence the results were actioned until patient attended clinic appt August 2018. There is no evidence patient was reviewed. Concerns raised in relation to initial management Jan 2017, high risk prostate cancer, was diagnostic investigation TURP standard practice at the time, patient now has pelvic node. Had patient had earlier management for same in 2017 would be in a different position. PSA raised significantly and no documentation action was taken. **FOR SJR.** Unsure if patient is aware.

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53. Patient 58 Personal Information redacted by the USI	Highlighted by professor Sethia DIAGNOSIS: Adenocarcinoma of prostate - He has been diagnosed with prostate cancer in 2008 and has been kept on active surveillance since then.	Discussed at screening 10/01/2021. Localised prostate cancer 2008, commenced low dose Bicalutamide then therapeutic dose 159mg, patient should have been referred for radiotherapy, **FOR SJR** patient aware Mr Haynes informed, pt does not recall offer of radiotherapy.
55. Patient 47 Personal Information redacted by the USI	Highlighted by Professor Sethia incorrect management of Ca prostate in 2010 - possible harm	Discussed at screening 10/01/2021. Patient seen privately, no letters on NIECR, patient had non-metastases disease in 2010, should have been offered radical treatment, did patient decline? Patient was seen privately but getting scans done on NHS. Patient commenced primary hormone treatment as stated on Radiology request forms. Sarah to inform patient **FOR SJR**, need to acquire private consultation notes from the GP if not already obtained.
57. Patient 59 Personal Information redacted by the USI	Diagnosis: Low risk prostate cancer diagnosed 2006 - Upgrade to intermediate risk prostate cancer on surveillance biopsies 2012 commenced Bicalutamide 50mg daily September 2019	Discussed at screening 10/01/2021. Commenced off license dose of Bicalutamide, should have had radical treatment or watchful wait. Mr Haynes has spoken with pt, telephone consultation and discussed treatments. Discussed at MDT. On appropriate treatment now, surveillance. **FOR SJR**

The above information contained within these tables can be located in S21 No 1a of 2022, Outcome Screening Sheets Excluded from SCRR and Screening Outcome Sheets for Confirmed SCRR Patients.

2. Explain whether the initial decisions in respect of these 10 patients, to include them within the SCRR process, were the subject of oversight and/or an approval mechanism? If so, describe how this mechanism worked in respect of each

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patient, its outcome in respect of each patient and identify who was responsible for its operation and their job title.

13. The process outlined at Question 1 above describes how the index 77 patients were identified initially by Mr Haynes and Mrs Corrigan and how the Acute Governance Screening Team acts as an oversight mechanism for their initial decisions.
14. As at 3rd December 2021, there were 10 patients screened 'out' of the SAI process by the Acute Governance SAI Screening Team leaving 67 still to be screened.
15. In the period since then more work has been done and we now have all of the initial 77 screened by the Team, resulting in 53 who will now be subjected to the SCRR process, and ~~6~~ 2 others that remain undecided but who are likely to be determined at a meeting scheduled for 30 May 2022.

16. As the Urology cases identified by Prof Sethia progress through the normal screening process the total number of SCRRs will change. . There are a further ~~247~~ 300 cases highlighted by Prof Sethia (8 identified as SAI) ~~which~~ who will likely progress through the screening meetings and therefore the potential total number of SCRRs will likely increase following completion of this process. I say 'likely' because the further progress of the SCRR process is to be the subject of discussion with, among others, the Deputy Chief Medical Officer, Dr Geoghegan, on or before 23 May 2022 (the next scheduled meeting of the UAG) – I refer in this regard to paras 5 and 6 of the draft minutes of the UAG meeting of 23 February 2022 (These are located in UPI Folder Access - Ongoing Discovery May 2022 Document Number - 20220223-UAG Draft Minutes of Meeting).

17. As highlighted in the table below, the screening process has confirmed and excluded SCRRs from the initial review following assessment within the standardised screening processes within Acute Services.

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18. In respect of the limb of the question that asks for identification of the responsible individual and their job title, the screening meetings are designed so that the final decisions are collective, the sum of all its members, and therefore the membership highlighted within question one identifies the collective group undertaking the decision making process.

3. Without merely repeating the generic explanation contained on the spreadsheet (i.e. "*no longer felt the patient met the threshold criteria for an SCRR*"), and taking each patient in turn and by name, explain why each of the 10 patients was removed from the SCRR process.

In answering this question you are required to provide an account of all of the information and factors that were taken into account when reaching the decision to remove the patient from SCRR, and to fully explain the process of clinical screening which led to these decisions. You should also provide the date each decision was made, and the identity of the person(s) who made the decision to remove the patient from the SCRR process and their job title.

19. I have attempted to answer this question by presenting in the table below a summary of each patient screened out at each relevant meeting (taken in sequence, between 15 November 2021 and 7 February 2022). After the table I have included a glossary of some of the acronyms and terms used.

15/11/2021 - No cases were screened out at this session.

22/11/2021 – detail of cases screened out

No. Initials	**Summary of Incident**	**Summary of Discussions**

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H+C		
35. Personal Information redacted by the USI Personal Information redacted by the USI	Seen in Independent Sector – has 2 urological issues – he was seen with a complex cyst in 2016 and the kidney was asymptomatic. There had been various / many investigations done but this needs to be formally reviewed as there has yet to be an MDM discussion and if there is a raise he may be better advised to have either cryotherapy or microwave ablation of the lesion. His other urological issue is that his PSA has remained between 4 and under 5 for last 4 years. His case needs reviewed.	22.11.2021 Patrick Keane letter – As outlined in the query opposite, the patient had complex conditions and the SJR review was requested because he had not been reviewed to establish a definitive diagnosis and prognosis. Mr Keane reviewed him and deemed that clinically his tumour was non cancerous and his psa not raised and that he did not have clinical concerns. (minimum complex benign cyst marginalised, elevated PSA, patient ok) - **Not SJR.**
25. Personal Information redacted by the USI Personal Information redacted by the USI	Haematuria - Antibiotics recommended for finding of pyuria on MSU with no positive culture, and no documented symptoms of infection	22.11.2021 Discussed at screening Telephone cons 17.4.2021 with Mr Haynes. Not sure if patient aware, referred for investigation of haematuria and was commenced on long-term low dose antibiotic for pyuria without infection, question raised re long term dose of antibiotic. Not clinically UTI, abx prescribed for Pyuria. Prescribing antibiotic without indication would not normally be a

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		SAI, therefore would not amount to SJR. **NOT SJR.**
19. Personal Information redacted by the USI Personal Information redacted by the USI	Initially seen privately so no letter for initial assessment. OP review June 2016 and then OP and UDS July 2016 - OP review / UDS / cystoscopy in July 2016 happened in an expedited timescale compared with NHS patients - Topical vaginal oestrogens are an alternative option to low dose antibiotics for managing recurrent UTIs in post-menopausal patients. Managed with low dose antibiotics (no longer taking).	22.11.2021 Discussed at screening - re-occurring theme treatment expedited following private appt. Topical oestrogen should have used as first line treatment. Antibiotic treatment now discontinued. Patient came to no harm- **NOT SJR**
21 Personal Information redacted by the USI Personal Information redacted by the USI	Storage LUTS initially assessed by gynaecology and referred to urology for cystoscopy and had urodynamic 2018 prior to trial of medical treatment - could have had a trial of anticholinergics before urodynamic as these have improved symptoms and would have avoided the investigation.	22.11.2021- discussed at screening- part of review Dr Sythia completed, series of questions asked, concerns highlighted in this case. 1.5.2021 Mr Haynes has reviewed patient, initially should be offered lifestyle changes, and instead went straight to invasive investigation. NICE guidelines pathway advised first line of treatment lifestyle changes, bladder retraining; then offer anti-cholergenic medication; then offer invasive investigations. Has patient come to

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		harm? No. Treatment pathway could have been different patient has not come to harm, could have avoided invasive investigation Potential harm from urodynamic studies UTI. **Does not meet criteria for SAI/ SJR.**
12. Personal Information redacted by the USI Personal Information redacted by the USI	With regards to his large post void residual patient and I discussed at length his treatment options and explained more fully his anatomy and what has been happening to him as he has described dissatisfaction with his care in these last couple of years feeling that he has been "neglected.	15.11.21 - Has a patient review form been filled in by Professor Sethia. Will need to come back to him. Wendy Clarke asked for information, patient review form. Martina Corrigan advised patient came through Laura McCauley, who asked for patients care to be reviewed. Did not come from Prof Sethia, Laura McCauley raised concerns, patient not happy with care. Relates to waiting times. Seen in 2017 added to waiting list for surgery, referred in retention, was catheterised, had trial removal. Which failed, listed for TURP 2017, since then come off meds and has had catheter removal. Feels he has being neglected. Agreed is the Trusts waiting times due to demand and capacity issues. Appropriately managed at the time, trail removal, highlighted TURP, WAITING TIMES rather than clinician. **NOT SJR.**

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29/11/2021– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
49. Personal Information redacted by the USI Personal Information redacted by the USI Personal Information redacted by the USI	Highlighted by professor Sethia Prostatic adenocarcinoma of Gleason score 3+4 = 7 is present in 6 out of 6 cores with a maximum length of 13 mm. Tumour occupies approximately 70% of the total tissue volume. Personal Information redacted by the USI Has not been seen since AOB Aug 19	29.11.2021 Discussed at screening. Management : Was seen when pandemic hit, consultants did not know what was happening, MDM results were awaited, report not available, died very soon after he was seen, cause of death not related to urology, Personal Information redacted by the USI. AOB tried to make contact and realised patient had died. No harm had come. MDT 27/02, seen on 09/03 then died Personal Information redacted by. There was a delay in correspondence. This is a theme; delay in actions from outpatient clinic 09/03/2020 correspondence. 27/04/2020. In this patient did not make a difference. Discussed at MDT commenced on treatment, reviewed in appropriate timescale. Pandemic hit, Came to no harm. General letter to be sent to family. **NOT FOR SJR.**
54.	Highlighted by professor Sethia	29/11/2021 Discussed at screening. Patient was seen 2011 UDS

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Personal Information redacted by the USI Personal Information redacted by the USI	Post prostatectomy incontinence - why wait until 2019 to treat?	treatment, outpatient review back log, not offered another apt. In Feb 2015 patient was discharged without been seen, asked for re-referral if required. GP re referred and patient seen AOB in 2019. There was no delay by Mr AOB, there was system review back log and patient was discharged by someone else without a review, this was a Board driven process at the time, review on waiting list was beyond 3 years, **NOT SJR**
50. Patient 69 Personal Information redacted by the USI	Recurrent intermediate risk TCC bladder. Last resection 13th February 2021. pTa grade 2 (high) urothelial cancer of right ureter treated by right laparoscopic nephron-urethrectomy 31st July 2020.	29/11/2021 Discussed at screening. Mr Haynes has reviewed care and unsure of concerns raised from NIECR notes. Sarah forwarded review by Dr Sethia. Initial presentation haematuria, first resection grade 2 Ta , renogram 2020 result right kidney non-functioning , there was delay in surgery, however that year there was industrial strikes. Patient had check of bladder, further re-occurrence was resected, Covid Pandemic 2020 , all surgery was moved to DHH. Delays due to industrial action and Covid. Sarah Ward to review wording on form 'right Nephron-ureterostomy' MDM outcomes, makes no sense, typo error. Brought back to MDT 3/52 and outcome essential corrected for

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		ureterostomy 6/52. No concerns raised. Low risk, if kidney is well-functioning then potentially look at distal ureterostomy to confirm disease. Renogram was not performed until Jan 2020, plan was reasonable , Post op Feb 2020 rechecked bladder, **External issues affected provision of service, MDT was reasonable. NOT SJR** Sarah Ward to arrange comment from MDT and feedback to group.
47. Personal Information redacted by the USI Personal Information redacted by the USI Personal Information redacted by the USI	Highlighted by professor Sethia 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 Personal Information redacted by the USI – comment from Prof Sethia - Enzalutamide might have improved survival for 4-6 months?	Discussed at screening 10/01/2021. Personal Information redacted by the USI gentleman, performance status poor, care package, had multiple emergency admission pneumonia, would not have been suitable for other treatments due to poor performance status, palliative care. **NOT SJR**

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20/12/2021– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
76. Patient 53 Personal Information redacted by the USI	Came via phone inquiry to Urology CNS – passed to Mr Haynes who advises. He needs an SCRR. He was referred as RF, downgraded (unclear if downgrade letter went) but met RF criteria at time	GP appropriately red flagged urology referral. Patient met criteria for red flag, non-visible haematuria, Personal Information redacted by. AOB inappropriately downgraded this referral to urgent. Investigations fortunately were all normal, patient came to no harm in this case. Discussed: agree this can happen in all departments, human error, other department would not generally produce a letter to the GP to advise as this would be a massive workload. Booking centre would send letter? Ultrasound was not reviewed until patient attended appointment. **Not for SJR as patient came to no harm.**
65. Patient 22 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector under on-going oncology FU SJR into previous care	Discussed at screening 20/12/21- no issues identified patient care managed appropriately. **NOT SJR.**

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63. Patient 44 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector currently on combined Androgen Blockade - SJR for bicalutamide 50mg	Discussed at screening 20/12/2021- treatment was reasonable, on both treatments maximum blockade and LHRHa- no issues -treatment was appropriate- **NOT SJR**
60. Patient 21 Personal Information redacted by the USI	Diagnosis: Circumcision June 2019 for lichens sclerosus (balanitis xerotica obliterans) Lower urinary tract symptoms	Discussed at screening information line contact. No clinical issue .Mr Haynes has wrote detailed letter, **NOT SJR**

10/01/2022– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
54. Personal Information redacted by the USI Personal Information redacted by the USI **(not removed from screening**	Highlighted by professor Sethia Post prostatectomy incontinence - why wait until 2019 to treat?	29/11/2021 Discussed at screening. Patient was seen 2011 UDS treatment, outpatient review back log, not offered another apt. In Feb 2015 patient was discharged without been seen, asked for re- referral if required. GP re referred and patient seen AOB in 2019. There was no delay by Mr AOB, there was system review back log and patient was discharged by

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list, on two review lists)		someone else without a review, this was a Board driven process at the time, review on waiting list was beyond 3 years, **NOT SJR**
39. Patient 73 Personal Information redacted by the USI	Telephone clinic on 15 May 2021: comment on PRF Although would likely have been recommended to proceed to orchidectomy, the US was not reviewed at urology MDM prior to surgery, and subsequent pathology was benign. The US report had raised a number of differentials so I feel best practice would have been review at MDM	Discussed at screening 10/01/2021- USS reported abnormal right testes, orchiectomy completed- result - benign disease, Given the report would have completed orchiectomy, however best practice would be to present at MDT for peer review. USS reported definite abnormalities and raised concerns, probably would have had orchiectomy. **NOT SJR**
23. Patient 29 Personal Information redacted by the USI	LUTS - assessed with UDS >> BNI and botox No improvement >> UDS >> TURP >>improved but ongoing symptoms and ED. Advised in consultation was not made aware that ED / retrograde ejaculation were risks of TURP although he would have gone ahead with the surgery even if he had known this risk Seen privately 30/4/16>>UDS 27/5/16>>TURP 27/7/16	22.11.2021 Discussed at screening- at consultation patient brought up concerns - not consented for risk of erectile dysfunction, retrograde ejaculation. Mr Haynes to review and bring back next week. 20/01/2022 Discussed at screening , notes reviewed, AOB did not perform procedure, question about consent, were all risks explained, difficult to read consent form and what risks were identified. No concerns raised in relation to treatment and care. Patient advised he still would have

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	likely shorter waits than other patents seen in NHS	gone ahead had he known the risks. **NOT SJR.**
58. Patient 65 [redacted] Personal Information redacted by the USI	Was TURP necessary? Now incontinent	29/11/2021 Discussed at screening. Decision for TURP not always taken to MDT. Mr Haynes unable to provide information from NIECR. Require full notes to review. Post op retention following hernia repair, TURP and now incontinent. 80-90% retention after hernia repair resolves after 3-4 months. Should offer trial removal of catheter in 3 months, anaesthesia can also cause bladder voiding problems. 10% risk in hernia repair in men over 65 yrs. Mr Haynes advised need notes to review. Notes attached 10.01.2022 discussed at screening, patient already had a catheter in place 2005, did not relate to hernia repair. Generally urodynamic studies would be completed initially, is there sufficient documented evidence for bladder obstructions and decision to proceed to TURP. Patient had catheter inserted in 2015 due to urinary retention, blocked catheter in Nov 2015, AOB seen patient privately in February 2016, noted in NIECR, had TURP completed in March 2016. It was agreed the plan was reasonable, patient was not suitable for urodynamic studies due to Personal Information redacted by the

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		Personal Information redacted by the USI , patient probably not able to complete investigation. Sarah to follow up in relation to treatment times, seen privately and then procedure expedited on NHS waiting list. **NOT SJR**

7/2/2022– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
52. Patient 52 Personal Information redacted by the USI	1. Previous transitional cell carcinoma of bladder 2. Bladder outlet obstruction 3. Urinary infection Potentially incorrect management	29/11/2019 Discussed at screening. June 2018 TURPT, resection Aug 2018 - standard management, pt was Personal Information redacted by at the time recommended for BCG treatment, completed this treatment, he had a check of bladder. Had a TURP, appears to have continued on surveillance pathway, had a MRI, patient had PE. Right hydronephrosis nephrostomy was completed. Unsure of the concerns raised in this case. Sarah Ward to contact Mr Sethia for more information in relation to concerns he had raised and feedback. 07/02/2022 Discussed at screening Questions raised why urethra not stented

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		earlier. Mr Haynes advised there is good documentation in relation to decision-making, AOB justified decision in his letters, patients has had multiple reviews since, justification for not stenting. Had USS in Feb which identified hydronephrosis, march -April there was a shift in service due to pandemic out of AOB hands. Decision for stenting documented and reasonable. **NOT SAI.**
17. Patient 50 Personal Information redacted by the USI	Report from Mr Haynes review letter - Varicocele currently asymptomatic: I reviewed Patient 50 following his contact with the Trust Information line. He had seen Mr O'Brien in 2014 and 2015 having been referred initially with azoospermia and a varicocele. The reason behind this referral was whether management of the varicocele would impact on fertility issues him and his wife were experiencing. His semen analysis as stated at the time had shown azoospermia however subsequent analysis did	For screening, clinical notes and MDM attached. Mr Haynes has reviewed case, patient not happy with care not offered surgery. Mr Haynes advised patient had a low sperm count and low quality sperm, embolization surgery unfortunately would not have improved fertility chances. No urological treatments would improve fertility. AOB decision therefore reasonable. However, service was of a poor standard, pt unable to make contact with AOB, received no response to his letter. communication was poor. No harm to patient, communication could have been better. Treatment in this case was appropriate, **NOT SJR**

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	improve with lifestyle change. At the time that [redacted] Patient 50 saw Mr O'Brien he also had some testicular pain which would fit with pain being related to the varicocele however this has since resolved. Ultimately Patient 50 did not have his varicocele treated and him Personal Information redacted by the USI	

22/11/2021 – detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
35. Personal Information redacted by the USI Personal Information redacted by the USI	Seen in Independent Sector – has 2 urological issues – he was seen with a complex cyst in 2016 and the kidney was asymptomatic. There had been various many investigations done but this	22.11.2021 Patrick Kean letter - minimum complex benign cyst marginalised elevated PSA, patient ok - **Not SJR.**

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	needs to be formally reviewed as there has yet to be an MDM discussion and if there is a reis he may be better advised to have either cryotherapy or microwave ablation of the lesion. His other urological issue is that his PSA has remained between 4 and under 5 for last 4 years. His case needs reviewed.	
25. Personal Information redacted by the USI Personal Information redacted by the USI	Haematuria - Antibiotics recommended for finding of pyuria on MSU with no positive culture, and no documented symptoms of infection	22.11.2021 Discussed at screening Telephone cons 17.4.2021 with Mr Haynes. Not sure if patient aware, referred for investigation of haematuria and was commenced on long-term low dose antibiotic for pyuria without infection, question raised re long term dose of antibiotic. Not clinically UTI, abx prescribed for Pyuria. Prescribing antibiotic without indication would not normally be a SAI, therefore would not amount to SJR. **NOT SJR.**
19. Personal Information redacted by the USI Personal Information redacted by the USI	Initially seen privately so no letter for initial assessment. OP review June 2016 and then OP and UDS July 2016 - OP review / UDS / cystoscopy in July 2016	22.11.2021 Discussed at screening - re-occurring theme treatment expedited following private appt. Topical oestrogen should have used as first line treatment. Antibiotic

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	happened in an expedited timescale compared with NHS patients - Topical vaginal oestrogens are an alternative option to low dose antibiotics for managing recurrent UTIs in post-menopausal patients. Managed with low dose antibiotics (no longer taking).	treatment now discontinued. Patient came to no harm- **NOT SJR**
21. Personal Information redacted by the USI Personal Information redacted by the USI	Storage LUTS initially assessed by gynaecology and referred to urology for cystoscopy and had urodynamic 2018 prior to trial of medical treatment - could have had a trial of anticholinergics before urodynamic as these have improved symptoms and would have avoided the investigation.	22.11.2021- discussed at screening- part of review Dr Sethia completed, series of questions asked, concerns highlighted in this case. 1.5.2021 Mr Haynes has reviewed patient, initially should be offered lifestyle changes, and instead went straight to invasive investigation. NICE guidelines pathway advised first line of treatment lifestyle changes, bladder retraining; then offer anti-cholergenic medication; then offer invasive investigations. Has patient come to harm? No. Treatment pathway could have been different patient has not come to harm, could have avoided invasive investigation Potential harm from urodynamic studies UTI. **Does not meet criteria for SAI/ SJR.**

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12. Personal Information redacted by the USI Personal Information redacted by the USI	With regards to his large post void residual patient and I discussed at length his treatment options and explained more fully his anatomy and what has been happening to him as he has described dissatisfaction with his care in these last couple of years feeling that he has been “neglected.	15.11.21 - Has a patient review form been filled in by Professor Sethia. Will need to come back to him. Wendy Clarke asked for information, patient review form. Martina Corrigan advised patient came through Laura McCauley, who asked for patients care to be reviewed. Did not come from Prof Sethia, Laura McCauley raised concerns, patient not happy with care. Relates to waiting times. Seen in 2017 added to waiting list for surgery, referred in retention, was catheterised, had trial removal. Which failed, listed for TURP 2017, since then come off meds and has had catheter removal. Feels he has being neglected. Agreed is the Trusts waiting times due to demand and capacity issues. Appropriately managed at the time, trail removal, highlighted TURP, WAITING TIMES rather than clinician. **NOT SJR.**

29/11/2021– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**

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49. Personal Information redacted by the USI Personal Information redacted by the USI Personal Information redacted by the USI	Highlighted by professor Sethia Prostatic adenocarcinoma of Gleason score 3+4 = 7 is present in 6 out of 6 cores with a maximum length of 13 mm. Tumour occupies approximately 70% of the total tissue volume. Personal Information redacted by the USI Has not been seen since AOB Aug 19	29.11.2021 Discussed at screening. Management : Was seen when pandemic hit, consultants did not know what was happening, MDM results were awaited, report not available, died very soon after he was seen, cause of death not related to urology, Personal Information redacted by the USI. AOB tried to make contact and realised patient had died. No harm had come. MDT 27/02, seen on 09/03 then died Personal Information redacted by. There was a delay in correspondence. This is a theme; delay in actions from outpatient clinic 09/03/2020 correspondence. 27/04/2020. In this patient did not make a difference. Discussed at MDT commenced on treatment, reviewed in appropriate timescale. Pandemic hit, Came to no harm. General letter to be sent to family. **NOT FOR SJR.**
54. Personal Information redacted by the USI Personal Information redacted by the USI	Highlighted by professor Sethia Post prostatectomy incontinence - why wait until 2019 to treat?	29/11/2021 Discussed at screening. Patient was seen 2011 UDS treatment, outpatient review back log, not offered another apt. In Feb 2015 patient was discharged without been seen, asked for re-referral if required. GP re referred and patient seen AOB in 2019. There was no delay by Mr AOB, there was system review back log and patient was discharged by

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		someone else without a review, this was a Board driven process at the time, review on waiting list was beyond 3 years, **NOT SJR**
50. Patient 69 [redacted] Personal Information redacted by the USI	Recurrent intermediate risk TCC bladder. Last resection 13th February 2021. pTa grade 2 (high) urothelial cancer of right ureter treated by right laparoscopic nephron-urethrectomy 31st July 2020.	29/11/2021 Discussed at screening. Mr Haynes has reviewed care and unsure of concerns raised from NIECR notes. Sarah forwarded review by Dr Sethia. Initial presentation haematuria, first resection grade 2 Ta , renogram 2020 result right kidney non-functioning , there was delay in surgery, however that year there was industrial strikes. Patient had check of bladder, further re-occurrence was resected, Covid Pandemic 2020 , all surgery was moved to DHH. Delays due to industrial action and Covid. Sarah Ward to review wording on form 'right Nephron-ureterostomy' MDM outcomes, makes no sense, typo error. Brought back to MDT 3/52 and outcome essential corrected for ureterostomy 6/52. No concerns raised. Low risk, if kidney is well-functioning then potentially look at distal ureterostomy to confirm disease. Renogram was not performed until Jan 2020, plan was reasonable , Post op Feb 2020 rechecked bladder, **External issues**

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		affected provision of service, MDT was reasonable. NOT SJR Sarah to arrange comment from MDT and feedback to group.
47. Personal Information redacted by the USI Personal Information redacted by the USI Personal Information redacted by the USI	Highlighted by professor Sethia 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 Personal Information redacted by the USI – comment from Prof Sethia - Enzalutamide might have improved survival for 4-6 months?	Discussed at screening 10/01/2021. Personal Information redacted by the USI gentleman, performance status poor, care package, had multiple emergency admission pneumonia, would not have been suitable for other treatments due to poor performance status, palliative care. **NOT SJR**

20/12/2021– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**

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76. Patient 53 Personal Information redacted by the USI	Came via phone inquiry to Urology CNS – passed to Mr Haynes who advises. He needs an SCRR. He was referred as RF, downgraded (unclear if downgrade letter went) but met RF criteria at time	GP appropriately red flagged urology referral. Patient met criteria for red flag, non-visbale haematuria, Personal Information redacted by. AOB inappropriately downgraded this referral to urgent. Investigations fortunately were all normal, patient came to no harm in this case. Discussed: agree this can happen in all departments, human error, other department would not generally produce a letter to the GP to advise as this would be a massive workload. Booking centre would send letter? Ultrasound was not reviewed until patient attended appointment. **Not for SJR as patient came to no harm.**
65. Patient 22 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector under on-going oncology FU SJR into previous care	Discussed at screening 20/12/21- no issues identified patient care managed appropriately. **NOT SJR.**
63. Patient 44 Personal Information redacted by the USI	Highlighted by Mr Keane at OPD clinic in Independent Sector currently on combined Androgen Blockade - SJR for bicalutamide 50mg	Discussed at screening 20/12/2021- treatment was reasonable, on both treatments maximum blockade and LHRHa- no issues -treatment was appropriate- **NOT SJR**

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60. Patient 21 Personal Information redacted by the USI	Diagnosis: Circumcision June 2019 for lichens sclerosus (balanitis xerotica obliterans) Lower urinary tract symptoms	Discussed at screening information line contact. No clinical issue .Mr Haynes has wrote detailed letter, **NOT SJR**

10/01/2022– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
54. Personal Information redacted by the USI Personal Information redacted by the USI **(not removed from screening list, on two review lists)**	Highlighted by professor Sethia Post prostatectomy incontinence - why wait until 2019 to treat?	29/11/2021 Discussed at screening. Patient was seen 2011 UDS treatment, outpatient review back log, not offered another apt. In Feb 2015 patient was discharged without been seen, asked for re- referral if required. GP re referred and patient seen AOB in 2019. There was no delay by Mr AOB, there was system review back log and patient was discharged by someone else without a review, this was a Board driven process at the time, review on waiting list was beyond 3 years, **NOT SJR**
39.	Telephone clinic on 15 May 2021: comment on PRF	Discussed at screening 10/01/2021- USS reported abnormal right testes,

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Patient 73 Personal Information redacted by the USI	Although would likely have been recommended to proceed to orchidectomy, the US was not reviewed at urology MDM prior to surgery, and subsequent pathology was benign. The US report had raised a number of differentials so I feel best practice would have been review at MDM	orchiectomy completed- result - benign disease, Given the report would have completed orchiectomy, however best practice would be to present at MDT for peer review. USS reported definite abnormalities and raised concerns, probably would have had orchiectomy. **NOT SJR**
23. Patient 29 Personal Information redacted by the USI	LUTS - assessed with UDS >> BNI and botox No improvement >> UDS >> TURP >>improved but ongoing symptoms and ED. Advised in consultation was not made aware that ED / retrograde ejaculation were risks of TURP although he would have gone ahead with the surgery even if he had known this risk Seen privately 30/4/16>>UDS 27/5/16>>TURP 27/7/16 likely shorter waits than other patents seen in NHS	22.11.2021 Discussed at screening- at consultation patient brought up concerns - not consented for risk of erectile dysfunction, retrograde ejaculation. Mr Haynes to review and bring back next week. 20/01/2022 Discussed at screening , notes reviewed, AOB did not perform procedure, question about consent, were all risks explained, difficult to read consent form and what risks were identified. No concerns raised in relation to treatment and care. Patient advised he still would have gone ahead had he known the risks. **NOT SJR.**
58. Patient 65	Was TURP necessary? Now incontinent	29/11/2021 Discussed at screening. Decision for TURP not always taken to MDT. Mr Haynes unable to provide information from NIECR. Require full

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Personal Information redacted by the USI		notes to review. Post op retention following hernia repair, TURP and now incontinent. 80-90% retention after hernia repair resolves after 3-4 months. Should offer trial removal of catheter in 3 months, anaesthesia can also cause bladder voiding problems. 10% risk in hernia repair in men over 65 yrs. Mr Haynes advised need notes to review. Notes attached 10.01.2022 discussed at screening, patient already had a catheter in place 2005, did not relate to hernia repair. Generally urodynamic studies would be completed initially, is there sufficient documented evidence for bladder obstructions and decision to proceed to TURP. Patient had catheter inserted in 2015 due to urinary retention, blocked catheter in Nov 2015, AOB seen patient privately in February 2016, noted in NIECR, had TURP completed in March 2016. It was agreed the plan was reasonable, patient was not suitable for urodynamic studies due to Personal Information redacted by the Personal Information redacted by the USI, patient probably not able to complete investigation. Sarah to follow up in relation to treatment times, seen privately and then procedure

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		expedited on NHS waiting list. **NOT SJR**

7/2/2022– detail of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
52. Patient 52 Personal Information redacted by the USI	1. Previous transitional cell carcinoma of bladder 2. Bladder outlet obstruction 3. Urinary infection Potentially incorrect management	29/11/2019 Discussed at screening. June 2018 TURPT, resection Aug 2018 - standard management, pt was Personal Information redacted by at the time recommended for BCG treatment, completed this treatment, he had a check of bladder. Had a TURP, appears to have continued on surveillance pathway, had a MRI, patient had PE. Right hydronephrosis nephrostomy was completed. Unsure of the concerns raised in this case. Sarah Ward to contact Mr Sethia for more information in relation to concerns he had raised and feedback. 07/02/2022 Discussed at screening Questions raised why urethra not stented earlier. Mr Haynes advised there is good documentation in relation to decision-making, AOB justified decision in his letters, patients has had multiple reviews since,

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		justification for not stenting. Had USS in Feb which identified hydronephrosis, march -April there was a shift in service due to pandemic out of AOB hands. Decision for stenting documented and reasonable. **NOT SAI.**
17. Patient 50 Personal Information redacted by the USI	Report from Mr Haynes review letter - Varicocele currently asymptomatic: I reviewed Mr Irvine following his contact with the Trust Information line. He had seen Mr O'Brien in 2014 and 2015 having been referred initially with azoospermia and a varicocele. The reason behind this referral was whether management of the varicocele would impact on fertility issues him and his wife were experiencing. His semen analysis as stated at the time had shown azoospermia however subsequent analysis did improve with lifestyle change. At the time that [redacted] Patient 50 saw Mr O'Brien he also had some testicular pain which would fit with	For screening, clinical notes and MDM attached. Mr Haynes has reviewed case, patient not happy with care not offered surgery. Mr Haynes advised patient had a low sperm count and low quality sperm, embolization surgery unfortunately would not have improved fertility chances. No urological treatments would improve fertility. AOB decision therefore reasonable. However, service was of a poor standard, pt unable to make contact with AOB, received no response to his letter. communication was poor. No harm to patient, communication could have been better. Treatment in this case was appropriate, **NOT SJR**

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	pain being related to the varicocele however this has since resolved. Ultimately [redacted] Patient 50 did not have his varicocele treated and him [redacted] Personal Information redacted by the USI	
26. [redacted] Patient 79 [redacted] Personal Information redacted by the USI	See progress notes on NIECR - Long history of urology attendances / interventions states 19 procedures in total although limited documentation on NIECR	22.11.2021 Discussed at screening- Mr Haynes has reviewed patient – Patient had a significant number of treatments due to chronic pelvic pain syndrome without evidence. 19 Procedures, timing for waiting lists and getting treatment were expedited, seen privately and added to list. Currently on appropriate management pathway. [redacted] Patient 79 contacted Trust, Mr Haynes reviewed care and would appreciate an external review of his management and care. Need external reviewer to review case. 10/01/2022 await feedback from Sarah07/02/2022 Discussed at screening, had 19 procedures, were these procedures justified. Mr Haynes he would not personally have done all but other clinicians may. Issue with waiting times, pt seen privately and had appt

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		/surgery expediated on NHS. NOT SJR

11 April 2022 details of cases screened out

No. Initials **H+C**	**Summary of Incident**	**Summary of Discussions**
20. Personal Information redacted by the USI Personal Information redacted by the USI	Ureteric / renal stones - ureterostomy June and October 2018 - FU CT April 2019 - no action - CT April 2019 showed residual / recurrent stones, patient not informed of result / no evidence of action of result	22.11.2021 discussed at screening. Highlighted in SAI 2020- Imaging not actioned- had investigation June/ Oct 2018. No evidence of action taken, up to date scan has now been completed. Patient did not come to harm, stone size did not change, gone to have treatment. However could have come to harm if stone got bigger and not actioned and treatment could become complicated. Could have been offered treatment at an earlier stage. Potential harm, For SJR review. Patient now aware and has had treatment.Email from SW 21/01/22 advising not for SJR 11.03.22 Email from Sarah to advise there are discrepancies in outcomes on the SCRR list see email attached -added to screening again for further discussion/clarification 11/04/2022 Discussed at screening , patient had scan 2019, stable renal stone, still stable after two years. Has not come

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		to harm. Not able to determine if scan report was reviewed. Patient had no admissions during this period. Possibly could have been offered ESWR earlier although this still may not have happened due to waiting lists. Not SCRR
56. Personal Information redacted by the USI Personal Information redacted by the USI	Incorrect management of Ca prostate - complicated case- may have suffered harm	29/11/2021 Discussed at screening.- Sarah Ward to ask Chris for update on concerns, Mr Haynes reviewed notes, unable to identify concerns raised. 07/02/2022 Sarah has received no response from Chris, will follow up. UPDATE 08/03/22 via email from Sarah. Sarah has spoken with Chris and Sarah has advised tht he has nothing to add and was unsure why being asked to comment. Sarah has reviewed her notes and had previously coded as not for SCRR with note that patient was not suitable for surgery and extra radiotherapy and the lung was a likely new primary diagnosis. For further discussion at next meeting. 11/04/2022 Discussed at screening: Given unlicensed dose Bicalutamide 50mg for short term - 3months treatment risk of harm minimal. Radical treatment options were considered however patient was not considerd suitable due to other

		diagnoses and received hormone treatment. Not felt to have been put at risk from low dose Biacalutamide and did not experience delays in treatment. Not SCRR

Glossary of Terms used in SCRR process

Term	Definition
AAA	Abdominal aortic aneurysm
abx	antibiotics
ADT	Androgen deprivation therapy
AOB	Mr Aiden O'Brien
appt/ apt	Appointment
BCC	Basal Cell Carcinoma
BCG	Bacillus Calmette-Guerin
BCH	Belfast City Hospital
Bic	Bicalutamide
Ca	Cancer
CAH	Craigavon Area Hospital
CaPPs	Cancer Patient Pathway System
CaP	prostate cancer

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cons	Consultant
CT	computerised tomography
DHH	Daisy Hill Hospital
DNA	Did not attend
EBRT	External Beam Radiation Therapy
ED	Emergency Department
FU	Follow up
G*Ta	Grade (*) non-invasive papillary carcinoma
GI	Gastrointestinal
GP	General Practitioner
HOS	Head of Service
LA analogue	Luteinizing hormone-releasing hormone agonists
LHRH / LHRHa	Luteinizing hormone-releasing hormone agonists
LUTS	Lower Urinary Tract Symptons
MDM	Multidisciplinary Meeting
MDT	Multidisciplinary Team
MI	Mycardial Infarction
MRI	Magnetic resonance imaging
MSU / MSSU	Mid Stream Sample of Urine
NICE	The National Institute for Health and Care Excellence

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NIECR	Northern Ireland Electronic Care Record
obs	observation
op	Out Patients
op	operative
OPD	Out Patients Department
PMH/ PMHx	Past Medical History
PSA	Prostate-Specific Antigen Test
pt	Patient
pTa (grade X	pTa tumours are those neoplasms that are confined to the epithelial layer of the bladder ('noninvasive papillary carcinoma')
RF	Red Flag
RIP	Rest in Peace / Death
RT	radiotherapy
SAI	Serious Adverse Advent
SCRR	Structure Care Record Review
sec	secretary
SJR	Structured Judgement Review
TCC	Transitional cell cancer
TURP	Transurethral resection of the prostate
UDS	Urodynamic studies
US	Ultrasound

UTI	Urinary Tract Infection

4. Explain whether the decisions to remove the 10 patients from the SCRR process, were the subject of oversight and/or an approval mechanism? If so, describe how this mechanism worked in respect of each patient, and identify who was responsible for its operation and their job title.

20. The process and rationale for each case is provided in the table at Question 3 above. The decision was that of the group identified at Question 1, reviewing the initial screening decisions of Mr Haynes and Mrs Corrigan.
21. The composite data emanating from the SCRR meetings is reported to the internal (the Southern Co-ordination Group) and external oversight groups (the HSCB Group and the Urology Assurance Group).

22. An audit of the SCRR process is being undertaken by RQIA at the request of the Trust

5. Is the screening panel and/or an oversight panel (if applicable) with responsibility for decisions in respect of the SCRR process required to declare any conflicts of interest prior to deciding on whether to include or exclude a particular case from the SCRR process?

23. The panel was not directly asked surrounding conflicts of interest. However, members are expected to declare any conflict. In this regard, one member of the panel declared that one of the 77 cases was a relative and excluded themselves for the discussion surrounding their relative's case.

6. Were each of the 66 patients contacted by the Trust to confirm their initial inclusion within the SCRR process?

24. In keeping with the usual SAI process within the NHS, it is usual custom and practice not to inform patients of inclusion until their cases have been screened in as in this situation.
25. The patients included in the screening process were not made aware that their case was being screened until a clear decision was made as to whether or not their care merited inclusion or exclusion using the regional SAI criteria for further SCRR. This decision was made in discussion with the HSCB and the DOH and was based on the premise of not causing unnecessary alarm or suffering to patients following the usual SAI process and in the absence of definitive decision making which in the context of the complexity of the review we realised would take a considerable time to work through. These patients have been made aware by the Trust of their inclusion of the SCRR process.

7. Were the 10, now excluded patients, informed of the Trusts decision to remove them from the SCRR process?

26. In keeping with the usual SAI process within the NHS, it is usual custom and practice not to inform patients if they have been screened for SAI and if they have been excluded.
27. The patients included screened out of the screening process were not made aware that their case was being screened or that it had been screened out using the regional SAI criteria for further SCRR. This decision was made in discussion with the HSCB and the DOH and was based on the premise of not causing unnecessary alarm or suffering to patients in the absence of definitive decision making which in the context of the complexity of the review we realised would take a considerable time to work through. These patients have been made aware by the Trust of their exclusion of the SCRR process.

8. What opportunity, if any, were the patients given to make comments on the Trust's decision to exclude them?

28. In keeping with the usual SAI process within the NHS, it is usual custom and practice not to inform patients of inclusion until their cases have been screened in as in this situation.
29. The patients included in the screening process were not made aware that their case was being screened until a clear decision was made as to whether or not their care merited inclusion or exclusion using the regional SAI criteria for further SCRR. This decision was made in discussion with the HSCB and the DOH and was based on the premise of not causing unnecessary alarm or suffering to patients in the absence of definitive decision making which in the context of the complexity of the review we realised would take a considerable time to work through. Patients were advised by letter of the information line should they have any concerns or queries. These letters can be located in S21 1 of 2022, SCRR Letters.

9. Confirm that the precise number of patients captured within the SAI reviews which were triggered in 2020 concerning the practices of Mr O'Brien is 9.

30. There were 9.

10. Confirm that the precise number of patients captured within the initial SCRR process (prior to the latest reduction of 10) is 66, meaning collectively there are 75 patients within these combined categories.

31. The process of identifying patients for SCRR is ongoing. Other than the case of [redacted] Patient 6 (at Question 11 below), the remaining 76 cases of the original 77 identified as SCRR have not been part of the previous 9 person SAI process,

32. The process of reviewing patients using the SCRR is also ongoing. Given that this is a highly specialised and intricate speciality relying on a variety of information from

various sources, this is by definition a complex process for each patient and takes time.

33. As indicated above, the initial screening undertaken by Mr Haynes and Mrs Corrigan yielded 77 patients from the last 18 months of Mr O'Brien's NHS work. These have subsequently been subjected to second screening by the Acute Governance Screening Team (membership included above) which in turn has identified these now as 53 patients with ~~6~~ 2 patients yet to be decided. ~~18~~ 22 patients have been identified as not requiring SCRR out of the original 77.

34. In addition to this, as part of the Quality Assurance measures on the screening being undertaken, screening using the same SAI criteria to identify patients for the SCRR process is being undertaken on 402 patients who were identified by Professor Sethia and the other consultant urologists involved as having queries in relation to their care but not reaching caseness previously in relation to SAI criteria. The initial SAI screening of these patients for SCRR has yielded 8 further patients to date. This is an ongoing process and may yield further patients.

11. Confirm whether Patient 6 is within the SAI 2020 category or the SCRR category.

35. Patient 6 was on both lists. Patient 6 was identified as part of the original cohort of 9 patients contained in the 2020 SAI process, as result of delays in responding adequately to histopathology results with adequate radiological screening. What was also noted in the SAI was the need for the review of Bicalutamide.

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36. Patient 6 was also placed on Prof Sethia's list for review and he identified similar difficulties and was screened in for SAI screening by the Acute Governance Screening Team.

37. Patient 6 then was identified by 2 independent consultants working separately as requiring an SAI process.

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