Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Section 21 Notice Number 20 of 2023

Date of Notice: 12th October 2023

Monopolar and Bipolar Resection

1. The Policy on the Surgical Management of Endoscopic Tissue Resection HSS(MD)14/2015 was introduced in May 2015 (WIT-54032-54055).

   The policy refers to the 'significantly improved safety profile' for bipolar techniques, noting that *'Significantly, the TUR syndrome has not been reported with bipolar equipment. A recent systematic review and meta-analysis comparing traditional monopolar TURP with bipolar TURP established in 22 trials that the TUR syndrome was reported in 35/1375 patients undergoing M-TURP and in none of the 1401 patients undergoing B-TURP. Even taking into account that one study alone was responsible for 17 of the 35 cases, the accompanying editorial states, "the elimination of TUR syndrome alone has been a worthy consequence of adopting bipolar technology."'* [WIT-54041]

   At [WIT54042], it is noted that: *'NICE, in February 2015, also issued guidance for the public on this topic. They indicated that, "the TURis system can be used instead of a surgical system called 'monopolar transurethral resection of the prostate'. Healthcare teams may want to use the TURis system instead of monopolar TURP because there is no risk of a rare complication called transurethral resection syndrome and it is less likely that a blood transfusion after surgery will be needed. Therefore, the case for moving from a monopolar to bipolar technique for resection of the prostate would appear to be well established as safer with regard to the development of the TUR syndrome…'*

   In your statement to the Inquiry (at WIT-53948-53949), you state as follows:

Received from Mark Haynes on 03/11/2023. Annotated by the Urology Services Inquiry.

3.02 Yes, I was concerned at the delay. I have described my concerns in my emails referenced above at 1 (h) (paragraphs 1.25-1.26).

NOTE:

By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers, as well as those sent from official or business accounts or numbers. By virtue of section 21(6) of the Inquiries Act 2005, a thing is under a person's control if it is in his possession or if he has a right to possession of it.

Signed:

Date: 02/11/2023

Received from Mark Haynes on 03/11/2023. Annotated by the Urology Services Inquiry.

Urology Services Inquiry

5. At paragraph 64.15 (WIT-51820), I wish to correct an omission.

    a. I have stated as follows:

    '64.15 The issue in reference to private patients potentially having surgery at an earlier point than expected was first raised, to my knowledge, at the meeting in January 2017 as part of the lookback exercise and I am unaware of further meetings on same.'

    b. I wish to amend this to the following:

    '64.15 *The issue in reference to private patients potentially having surgery at an earlier point than expected was first raised**, I believe, with me in an email from Mr Haynes on 27 May 2015 (WIT-54107) and subsequently in his further email of 26 November 2015 (WIT-54106). I believe that I spoke briefly to Mr Haynes at some point after the first email (I have a recollection it was after a ward round at the nurses' station) and asked him if he was aware of any clinical reason for the patient being seen in the timescales in question. I cannot recall if he responded then or later nor can I recall if I made any attempt to follow up the issue (although, for the avoidance of doubt, I accept that I should have done). I recall that I also spoke to Mr O'Brien at some stage, most likely at a point after receiving the first email, which would be consistent with what I have said in my response to Mr Haynes' second email (at TRU-270116 – 'I had spoken before to the person in question re this issue in general …'). I cannot recall the detail of my conversation with Mr O'Brien but believe that I must have received some reassurance from him that he was not prioritising patients whom he had seen privately. I do not know if I spoke to Mr O'Brien again after the second email from Mr Haynes. On reflection, I believe that it might have been better for me simply to have escalated the second email to more senior managers. It is possible that at the time***

Patients seen privately by Mr O'Brien and added to waiting list and came in for procedure within a short timeframe.

Casenote	Consultant Name	Date on Waiting List	Date Operation	Days between Added to WL to Operation Date	Is there a clinical reason why they should have waited such a short time
Patient 114	O'Brien A Mr	22/02/2016	22/03/2016	29	No
Patient 115	O'Brien A Mr	25/04/2016	04/05/2016	9	Reasonable – Red Flag
Patient 116	O'Brien A Mr	11/04/2016	15/04/2016	4	No
Patient 117	O'Brien A Mr	01/04/2016	27/04/2016	26	No
Patient 118	O'Brien A Mr	08/07/2016	09/08/2016	32	No
Patient 119	O'Brien A Mr	29/07/2016	21/09/2016	54	No
Patient 120	O'Brien A Mr	04/12/2015	24/02/2016	82	Reasonable
Patient 121	O'Brien A Mr	11/07/2016	17/08/2016	37	No
Patient 122	O'Brien A Mr	08/10/16	02/11/16	25	No
Patient 123	O'Brien A Mr	31/10/16	04/11/16	5	No
Patient 124	O'Brien A Mr	16/02/2016	24/02/2016	8	No

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Davis, Anita

From: Carroll, Ronan
Sent: 17 December 2021 15:30
To: Davis, Anita
Subject: FW: Notice of Retirement

Follow Up Flag: Follow up
Flag Status: Completed

Section 21
Ronan Carrroll
Assistant Director Acute Services
Anaesthetics & Surgery
Mob - Personal Information redacted by USI

From: Haynes, Mark Personal Information redacted by USI
Sent: 15 April 2020 10:31
To: Carroll, Ronan; Corrigan, Martina
Cc: Young, Michael
Subject: RE: Notice of Retirement

Needs more discussion than can be had at present.

In short yes, but with strings attached, and these strings need to be clear and accepted before he is offered anything.

Mark

From: Carroll, Ronan
Sent: 15 April 2020 10:29
To: Corrigan, Martina
Cc: Haynes, Mark; Young, Michael
Subject: RE: Notice of Retirement
Importance: High

We are taking Aidan back – yes?

Ronan Carroll
Assistant Director Acute Services
Anaesthetics & Surgery
Mobile Personal Information redacted by USI

From: Clegg, Malcolm
Sent: 15 April 2020 09:32
To: Corrigan, Martina
Cc: Carroll, Ronan; Haynes, Mark; Young, Michael
Subject: RE: Notice of Retirement

Hi Martina,

Mr O'Brien's application for pension benefits is all in hand. He will be processed as a leaver on HRPTS from 30th June 2020.

You will just need to let us know if it has been agreed for him to return to work following 'retirement' and if so, from what date, as we will need to reinstate him to the Payroll.

Thanks

Malcolm

Malcolm Clegg
Medical Staffing Manager
Medical Staffing Department
The Brackens
CRAIGAVON AREA HOSPITAL
BT63 5QQ

Tel No: Personal Information redacted by USI or Personal Information redacted by the USI
Mobile: Personal Information redacted by USI

From: Corrigan, Martina
Sent: 13 April 2020 14:09
To: Clegg, Malcolm; Parks, Zoe

Received from SHSCT on 21/12/2021. Annotated by the Urology Services Inquiry.

MR O'BRIEN: Hello, Mark.

MARK HAYNES: Hey, Aidan. Sorry, I took another call after I texted you so I missed you.

MR O'BRIEN: No bother.

MARK HAYNES: I've got Ronan in the room with me as well. Ronan Carroll.

MR O'BRIEN: Hello, Ronan.

MARK HAYNES: So just following on. Obviously I know you have spoken to myself and you have spoken to Martina about coming back after July, haven't you?

MR O'BRIEN: Yes, I have, and Michael.

MARK HAYNES: Yes. I've taken that forward with a number of conversations within the Trust, with HR and at medical director level. Okay. Unfortunately, the practice of the Trust would be that they don't re-engage people while there's on going HR processes.

MR O'BRIEN: I see.

MARK HAYNES: Which means from my perspective I can't take it any further forwards at present.

MR O'BRIEN: So the reason for -- so who has made that decision?

MARK HAYNES: But that's what I have been advised by both the medical director and by enquiring ~~in enquiry~~ with HR.

MR O'BRIEN: Okay. So it's because of -- because they haven't yet the grievance and all of that thing?

MARK HAYNES: Yes. So as I understand it there's the grievance and there's also -- so the grievance is it from you to the Trust I think, isn't it?

MR O'BRIEN: Yes.

MARK HAYNES: And there was a Trust thing as well ~~(inaudible)~~ was it the maintaining professional standards investigation and everything. That's not closed off as yet.

MR O'BRIEN: Well, the investigation has been closed off. Yes.

MARK HAYNES: Yes. And there's -- from Maria I was advised there's a GMC issue process as well, that's in process.

MR O'BRIEN: Okay. So that's very disappointing. I didn't expect that at all, particularly in view of the amount of need that there is. It is very ironic, and you know that, and somewhat poignant, I returned to Northern Ireland from Bristol 28 years ago today for interview to be appointed on 8 June 1992. So, Mark, can I have that decision made submitted to me in writing?

MARK HAYNES: Yes. I can get that sorted for you.

MR O'BRIEN: And when can this be reviewed?

Received from Tughans OBO Mr Aidan O'Brien on 09/02/22. Annotated by the Urology Services Inquiry.

Note: This "In Confidence" email is referred to in Aidan O'Briens retirement timeline at TRU-01718. Annotated by the Urology Services Inquiry.

Parks, Zoe

From: Parks, Zoe [Personal Information redacted by USI]
Sent: 09 June 2020 17:24
To: Haynes, Mark
Subject: In confidence

As discussed yestersay, I can confirm that when you resign/retire from the Trust, your contract of employment ends at that time. We discussed your request to be reengaged and confirmed that in line our normal practice, your request has been considered. I have discussed this with the Director of Acute Services and we have decided that we are not in a position to reenage given the outstanding MHPS/GMC processes that have still to be concluded.

Received from SHSCT on 08/11/22. Annotated by the Urology Services Inquiry.

Stinson, Emma M

From: OKane, Maria
Sent: 11 June 2020 15:02
To: Haynes, Mark; Carroll, Ronan; Corrigan, Martina; McClements, Melanie
Cc: Toal, Vivienne
Subject: FW: Patients to be added to Urgent Bookable List
Attachments:

Mark
this is a really concerning email.
I am very concerned that there are red flag patients with potential cancer diagnoses who have been assessed and not include on waiting lists for months.
How can we assure ourselves that these patients are safe?
How can we know that these are the only patients who might have been delayed?
In the spirit of openness might there have to be conversations with these patients to make them aware potentially?
I am concerned that this appears to be a continuation of the behaviours that led to SAIs and the lack of insight into which precipitated a referral to the GMC. I am very concerned. The first time that this occurred Dr Wright excluded the doctor pending further investigation into patient safety. Can we meet urgently to discuss please?
Regards, Maria

From: Haynes, Mark
Sent: 11 June 2020 12:47
To: OKane, Maria; Carroll, Ronan; Corrigan, Martina; McClements, Melanie
Subject: FW: Patients to be added to Urgent Bookable List

Afternoon

Attached are the green forms as mentioned and highlighted are cases in particular that should have been added to the waiting list at the date indicated. Also attached (in addition to the WL forms) is a copy of the full urology WL as of 11/5/20. As far as I can tell the patients highlighted should have been added to the waiting list on the date shown, but are not on the waiting list and I believe have been added to the waiting list more recently (on the back of the email below).

Received from SHSCT on 21/12/2021. Annotated by the Urology Services Inquiry

	call) I received a telephone call from the Permanent Secretary, Richard Pengelly, asking whether I was aware of 'Craigavon Urology Research and Education – CURE'. I was not aware and advised him of this. He proceeded to explain to me that it was a charity that had been created in 1997 by Mr O'Brien and that he understood Roberta Brownlee had been a director of the charity for 15 years up to 2012. Richard Pengelly asked me if Roberta had been declaring a conflict of interest in our Board meetings with regards to Mr O'Brien and Urology, which she had not. Richard Pengelly then instructed me to telephone the Chair and advise her of our conversation and request that she withdraw herself from any further Trust Board conversations on this topic. I subsequently phoned the Chair and advised her accordingly. It is my understanding that Roberta then telephoned Richard to discuss the issue. From that point forward Roberta excused herself from further Board meeting conversations on the topic. It is important to note that, even though our working relationship was less than optimal, I do not believe that this had any impact on the path that was followed with the Mr O'Brien Case and / or urology. All appropriate regard, to Mrs Brownlee as Trust Chair, was given from me. Our relationship did not alter my behaviours with regards to sharing information with the Chair and Board and I am of the view that the actions Mrs Brownlee chose to take were not affected by our relationship.

Q70	**Please explain how and in what circumstances you first became aware of possible concerns regarding Urology Services in the Trust.**
Response	As referenced in my answer to question 54 on the 6th September 2018 Dr Khan, acting Medical Director, made me aware that in his role as case officer for the Managing High Professional Standards case of Mr A O'Brien he was engaging with the GMC and the Trust HR function to start disciplinary procedures. (Reports included as appendix 18a and 18b) I had been made aware of this case by Vivienne Toal, Director or HR, in the previous months including that she had considerable concerns about the performance Mr O'Brien. At that time I had asked Vivienne for further information and I was advised of the incidents of 2016/17 whereby 783 untriaged letters were discovered in a drawer in Mr O'Brien's office as well as 307 sets of patient notes at his home address. In addition, a further 668 letters had no dictation outcomes and there were queries as to whether the management of private patients was in line with the agreed Trust processes. When the matter was raised to me in September 2018, I asked for an assurance from Esther Gishkori, then Director of Acute Services, and Dr Khan that the issues that had been identified two years previously (i.e., in 2016/17) had been addressed. I was advised that an SAI was being carried out to fully understand the learning, however in the interim control measures had been put in place. This involved monitoring by the service lead, Martina Corrigan, and the Assistant Director for Surgery, Ronan Carroll. This involved weekly monitoring of agreed actions. Following these conversations, I was assured that the existing issues were being dealt with. In the middle of June 2020 (I do not have a note in the diary of the exact date), Maria O'Kane, Medical Director, approached me in my office to raise her serious concerns about an issue that had come to her attention. She had been made aware by Mark Haynes, Associate Medical Director (Surgery), that an e-mail had been sent from Mr O'Brien to request that his patients that had not been added to the waiting list were to be considered for an urgent bookable list. When the Mr Haynes reviewed this further it was clear that there were other patients that required to be investigated. At that point Dr O'Kane had already commenced an administrative review and suggested that the offer for Mr O'Brien to return to work following his retirement should be withdrawn. I supported this proposal. Dr O'Kane and Melanie McClements (Director of Acute Services)

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

	then set about developing system and processes to review the situation and to develop a plan. In addition to the Mr O'Brien challenge I was also aware of waiting list challenges in urology services. Given the consistent under-resourcing of elective care, Urology was one of many elective services with growing waiting lists. The key challenge for Urology was not necessarily a financial challenge but rather there were not the consultant staff available to meet the demand.

Q71	**From your perspective, please set out the circumstances which led to the Trust conducting a Lookback Review of the clinical practice of Mr Aidan O'Brien. This should include a timeline of all key events. Please explain your role in the Lookback Review and describe any discussions on it.**
Response	I do not believe I can do better in this regard than refer to and quote from the paper (appendix 38) that was presented to the Trust Board on the 22nd October 2020 clearly outlined the reasons why I felt we were required had to carry out a lookback exercise. It read On 7th June 2020, the Trust became aware that 2 out of 10 patients listed for surgery under the care of Consultant A were not on the hospital's Patient Administration System at this time. As a result of these potential patient safety concerns a review of Consultant A's work was conducted to ascertain if there could be wider service impacts. As a result of these potential patient safety concerns a review of Consultant A's work was conducted to ascertain if there were wider patient safety concerns and service impacts. The internal reviews, which considered cases over an 18 month period (period 1st January 2019 – 30 June 2020), identified the following: The first internal review concentrated on whether the patients who had been admitted as an emergency had had a stent inserted during procedure and if this had been removed. There were 160 emergency patients listed as being taken to theatre. 3 patients had not had their stent management plans enacted. Clinical Management has been subsequently arranged for these 3 patients. The second internal review was for 343 elective-in patients taken to theatre. Out of the 343 patients reviewed there have been 2 of these patients who have been identified as meeting the threshold of needing a Serious Adverse Incident Review. The following areas have been identified that immediately need to be reviewed and actions taken on these patients to mitigate against potentially preventable harm 1. Jan 2019- June 2020 - Pathology and Cytology results: 168 patients with 50 patients needing reviewed. From this there has been 3 confirmed SAI with a further 5 requiring a review follow-up to determine if they have come to harm. 2. This exercise has also now identified concerns of clinical practice in the prescribing of Bicalutamide drug has revealed examples of poor practice, delay in following up the recommendations from results/MDM's and delay in dictation to other health care professionals in the ongoing care and treatment of the patients. The full extent of this is not yet clear. 3. Jan 2019- June2020 - Radiology results –1536 patients listed on NIECR.These patients may have had the results manually signed off and actioned but as we have identified cases where this hasn't happened we need to review all of these records to reassure ourselves that these have all been actioned. This exercise is ongoing. 4. Jan 2019-July 2020 - MDM discussions – there are 271 patients who were patients of Consultant A and who were discussed at MDM, a review of these patient records is being undertaken. There are currently 2 confirmed SAI's and a further 2 needing a review follow-up to determine if they have come to harm. This exercise is ongoing. 5. Oncology Review Backlog – 236 review oncology outpatients will be seen face to face by a retired Urologist in the independent sector. This consultant will either discharge or make appropriate plans for ongoing management and referral back the Southern Trust Urology Team MDM for further review/management. (Note to date there has been one SAI confirmed from this backlog as the patient presented to Emergency Department and he has been followed up

Received from Shane Devlin on 04/02/22 Annotated by the Urology Services Inquiry.

1 in relation to the SAI in relation to the use of EGRESS
2 to respond to that just to let me know that that had
3 happened. Those, I think, were the different times
4 I spoke to Dr. Hughes.
5 139 Q. At that point then you became aware that there were 11:56
6 actually verifiable or potential clinical concerns
7 around the practice?
8 A. Yes.
9 140 Q. These are new issues, as it were, for you?
10 A. Yes. 11:56
11 141 Q. At that stage did you think it might be best to take
12 some action or to do something around clinical practice
13 of Mr. O'Brien at that point?
14 A. Mr. O'Brien retired from the Trust on 17th July. When
15 we had discovered the difficulties after -- I think 11:56
16 I was informed on 11 June and the Clinical team,
17 principally Mr. Haynes and Mrs Corrigan had been
18 working on an email that they had received that
19 suggested there was a discrepancy in two waiting lists,
20 and that caused them a bit of concern. When they 11:57
21 worked their way through that they realised there
22 wasn't a discrepancy, but what they also discovered on
23 the back of those explorations were the concerns then
24 around the cancer multi-disciplinary team meeting.
25 142 Q. I think Mr. Haynes explained the issue around the 11:57
26 waiting list and the two patients.
27 A. Yes.
28 143 Q. If we go back to 2019, there was a bit more
29 information, if I can put it that way, a bit more

		and conformance to standards for penile cancer management at the time, in order to pass comment specifically regarding Mr O'Brien's case volume, treatment offered (vs guidance) and quality of surgery provided, an audit of penile cancer treatment is required. I regret that I have not been able to initiate such an audit due to the various continuing workload pressure on myself and the team. As recognised within this response, nephron sparing surgery also continued to be provided in CAH and a similar audit is required for this. It is the case that Mr O'Brien would have been trained to perform the procedures undertaken on RC and as acknowledged he would have continued to maintain a practice (albeit limited numbers as it is a rare cancer) until the Western Trust service commenced in December 2019. The audit will inform the annual case load of surgery provided by Mr O'Brien (and colleagues) in CAH and the quality of surgery received by these patients. ***Mr Mark Haynes has responded to both elements b and c in a combined response below.*** ***b. Within the Trust correspondence dated 27 November 2020, reference is made to an audit of a patient's prescribed bicalutamide out with its licensed indications. Is there an official audit document? If so, can you please provide a copy?*** ***and*** ***c. Can you please provide the outcome of the subsequent audit in respect of patient's receiving 150mg Bicalutamide? Please also confirm whether any patients identified were provided with alternative or amended treatment in terms of the prescribing.*** As per comment to answer 2 above there is no official audit document. The 'Bicalutamide audit' was a rapid review of patients receiving

		Bicalutamide in the management of their prostate cancer in order to identify those patients potentially requiring a change to their prostate cancer management. It was conducted as a rapid review of records following identification of a patient safety risk during the SAI process for other patients in whom prostate cancer management concerns had been identified, and which were characterised by the use of low dose Bicalutamide. This patient record review was performed at speed with the NIECR review being conducted by me alone conducting a rapid NIECR review of the prostate cancer management of 764 patients, in my own time (while on leave), with considerable external pressure for haste. This took place in October 2020 when the second wave of the COVID pandemic was also escalating with resultant multi-directional pulls on my time and so my follow-through on formalising the findings was hampered significantly. I have not subsequently re-reviewed these patients' records and not all of these patients' care has been subject to a lookback review as many were under the care of both urology and oncology teams / consultants across multiple trusts while lookback reviews have been done only on patients managed by Mr O'Brien. No prior approval was sought for my review of records for patients managed in other trusts / teams from the other trusts governance teams nor was it registered prospectively with the Southern Trust governance / audit team. Concerns had been identified regarding patients whose prostate cancer management was not to standard and that this was characterised by the prescribing of a low dose (50mg) of Bicalutamide. These cases were subject to an SAI / investigation which was ongoing, but it was felt that there was a significant risk of additional patients also having been managed in the same manner was significant and that any such patients required identification as their treatment may require changing. It was also recognised that patients may have been initially commenced on the low dose of

		Bicalutamide and subsequently escalated to higher doses, but that these patients prostate cancer management may also demonstrate the same deficiencies identified in the initial patients who were subject to an SAI investigation. It was therefore decided that in order to identify patients who were at the time receiving prostate cancer treatment which was not standard practice and potentially required change of management to a standard treatment pathway, a rapid review of patient records was required. The summary below was compiled at a later date to summarise the findings of this review of management. The purpose of the review was simply to identify patients who required clinical review as a matter of urgency in order to consider their ongoing prostate cancer care. As the patients who required a change in management could be identified by their receiving a current prescription of Bicalutamide, a list of patients across all of Northern Ireland who had received a prescription of Bicalutamide at any dose, in the preceding months was obtained from the Health and Social Care Board. Patients from across Northern Ireland were required as the Southern Trust team at the time would see as standard patients from Western, Southern and Northern trust areas. Many patients would also be receiving Bicalutamide as an appropriate part of their standard prostate cancer management. The review of patient records covered patients receiving both Bicalutamide 50mg and 150mg prescriptions during the period between March 2020 and August 2020. This time frame was selected as this would identify patients currently receiving this treatment and therefore those patients who may require changes to their treatment. The data was provided on 22nd October 2020. The data provided identified all patients who received a prescription for Bicalutamide

TRU-280977

Corrigan, Martina

From: Haynes, Mark [Personal Information redacted by USI]
Sent: 26 October 2020 07:30
To: Mitchell, Darren
Subject: Bicalutamide

Morning Darren

This is a list of patients under regular oncology review who I have picked up as on bicalutamide. Some are biochem failure post RT so from text message over WE think this is standard practice and OK. I have highlighted the 3 on low dose bicalutamide.

Could you have a look at these at let me know if you think they need seeing and discussion of treatment changes, and whether I should arrange to see or you will arrange oncology RV.

Thanks

Mark

Patient	Medication	Comment
Personal Information redacted by the USI	Bicalutamide 150mg tablets	IS ON MONOTHERAPY FOR LOCALISED DISEASE SEEN BY ONCOLOGY REG
	Bicalutamide 50mg tablets	CURRENTLY ON BICALUTAMIDE 50MG CONTINUES TO SEE ONCOLOGY, IS
	Bicalutamide 150mg tablets	MONOTHERAPY FOR T3 DISEASE, ONGOING ONCOLOGY FU. ?SHOULD BE
	Bicalutamide 150mg tablets	MONOTHERAPY FOR BIOCHEMICAL FAILURE POST RT
	Bicalutamide 150mg tablets	MONOTHERAPY FOR BIOCHEMICAL FAILURE POST RT. HAS ONGOING ON
Patient 25	Bicalutamide 50mg tablets	INITIAL TREATMENT WAS WITH 50MG THEN HAD RT AFTER 3 YEARS, IS B
Personal Information redacted by the USI	Bicalutamide 150mg tablets	MONOTHERAPY FOR POST RT BIOCHEMICAL FAILURE UNDER ONCOLOGY
	Bicalutamide 150mg tablets	MONOTHERAPY FOR POST RT BIOCHEMICAL FAILURE UNDER ONCOLOGY
	Bicalutamide 150mg tablets	MONOTHERAPY FOR POST RT BIOCHEMICAL FAILURE UNDER ONCOLOGY
	Bicalutamide 50mg tablets	ON 50MG FOR BIOCHEMICAL FAILURE POST RT SINCE 2013
	Bicalutamide 150mg tablets	UNDER ONCOLOGY BELFAST TRUST PATIENT ON MONOTHERAPY FOR LO
	Bicalutamide 150mg tablets	MONOTHERAPY FOR POST RT BIOCHEMICAL FAILURE UNDER ONCOLOGY

Received from SHSCT on 23/12/2021. Annotated by the Urology Services Inquiry

UROLOGY
OUTPATIENTS LETTER

Consultant Urologist: Mr Glackin
Secretary: Elizabeth
Telephone: Personal Information redacted by the USI

Personal Information redacted by the USI

Dear Personal Information redacted by the USI

Re: **Patient Name:** Patient 139
D.O.B.: Personal Information redacted by the USI
Address:
Hospital No: CAH Personal Information redacted by the USI **HCN:** Personal Information redacted by the USI

Date/Time of Clinic: 22/02/16	**Follow Up:** PSA write with results

Diagnosis: Gleason 7 adenocarcinoma of the prostate involving 1 core from the right apex diagnosed January 2010.
Initial PSA 11.3ng/ml.
MRI indicates T2b N0 disease April 2010.
Current Management: Bicalutamide 50mg once daily, Tamoxifen 10mg once daily.

This gentleman was reviewed as a long waiter in my clinic this evening. He does not report any bothersome lower urinary tract symptoms. He is tolerating his Bicalutamide and Tamoxifen very well.

His PSA was 0.74ng/ml in March 2015. This has been repeated this evening. I note that his U+E and alkaline phosphatase were both normal on 2nd February 2016. I will write to Patient 139 with the result in due course. If the result is stable then he remains suitable for continued Bicalutamide monotherapy. Kind regards.

Yours sincerely

Mr AJ Glackin, MD FRCSI (Urol)
Consultant Urologist

Results
PSA 1.02ng/ml

Date Dictated: 22/02/16	**Date Typed:** 24/02/16 - ET

Received from Tughans on behalf of Aidan O'Brien on 19/09/2023. Annotated by the Urology Services Inquiry.

UROLOGY
RESULTS LETTER
Consultant Urologist: Mr Glackin
Secretary: Elizabeth
Telephone: Personal Information redacted by the USI

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

05/05/20

Personal Information redacted by the USI

Dear Personal Information redacted by the USI

Re: Patient Name: Patient 139
D.O.B.: Personal Information redacted by the USI
Address:
Hospital No: CAH Personal Information redacted by the USI **H&C No:** Personal Information redacted by the USI

Diagnosis: Gleason 7 prostate cancer involving 1 core from the right apex diagnosed January 2020.
Initial PSA 11.3ng/ml.
MRI indicates T2b N0 disease April 2010.

Current management: Bicalutamide 50mg once daily, Tamoxifen10mg once daily.

Thank you for checking this gentleman's PSA, LFT and U+E on 1st May. All the results are satisfactory. PSA is 0.1ng/ml. Patient 139 should continue with his current prostate cancer medication. I will copy this letter to him enclosing a form so that he can have his blood test repeated in November 2020. If Patient 139 is having any problematic urinary symptoms and wishes to be seen at clinic I would be grateful if he would contact my secretary at the telephone number above. Kind regards.

Yours sincerely

Dictated but not signed by

Mr AJ Glackin, MD FRCSI (Urol)
Consultant Urologist

Received from Tughans on behalf of Aidan O'Brien on 19/09/2023. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

UROLOGY
OUTPATIENTS LETTER

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

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

Patient 139
Personal Information redacted by the USI

Dear Patient 139

Re: Patient Name: Patient 139
D.O.B.: Personal Information redacted by the USI
Address:
Hospital No: Personal Information redacted by the USI **HCN:** Personal Information redacted by the USI

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

Diagnosis:
Small volume intermediate grade prostate cancer diagnosed on prostate biopsy late 2009/early 2010
Commenced on Bicalutamide 50mg early 2010 and remains on Bicalutamide 50mg and Tamoxifen10mg
Recent PSA May 2020 0.1

Outcome:
Recommend treatment
Discontinue Bicalutamide and Tamoxifen and move to surveillance strategy for managing prostate cancer
Alternative option switch to LH RH analogue as androgen deprivation therapy

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

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

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

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

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

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

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

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

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

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

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

1 concerns about not acting on results, not dictating
2 from clinics, this was me flagging another concern
3 along the same vein. I would contend that, for me, the
4 nature of concerns changed in late June 2020 / early
5 July 2020, when I saw Patient 1 in Daisy Hill and
6 raised concerns there. The nature of the concerns
7 changed, and I'd contend that it's them concerns that
8 actually triggered really where the major change of, if
9 you like, the nature of the concerns regarding
10 Mr. O'Brien. This was a continuation of concerns that
11 he wasn't on top of his administrative work.
12 148 Q. As I say, you raised this issue with Dr. O'Kane on 11th
13 June by e-mail. As I have indicated, the issue which
14 was at the heart of this came to your attention on 7th
15 June when the e-mail came in. You spoke to Mr. O'Brien
16 the next day, 8th June, to tell him what was bad news
17 for him, that he couldn't come back to the Trust
18 following retirement. You didn't speak to him during
19 that meeting about the concern that had arisen the day
20 before, about the waiting list issue, these two
21 patients. Why not?
22 A. I'd raised my concern, as you say, on 11th June. Going
23 back to the urgent bookable list process, at the end of
24 each week there was a deadline for all specialties to
25 let me know the patients that were to be looked at for
26 that, so I tended not to interrogate the e-mails I got
27 until I had everything in and then could look at what
28 Theatre lists we had available and what the demand was
29 across all specialties. I didn't interrogate that

76.2 In addition, I am aware from colleagues in the oncology team that concerns had been raised directly with Mr O'Brien previously with regard to his management of prostate cancer and, in particular, his use of low dose bicalutamide in patients with early prostate cancer but, as has become evident, Mr O'Brien did not change his practice. To the best of my knowledge these concerns did not come to the Southern Trust governance systems / processes.

77. ~~71.~~ **Do you consider that, overall, mistakes were made by you or others in handling the concerns identified? If yes, please explain what could have been done differently within the existing governance arrangements during your tenure? Do you consider that those arrangements were properly utilised to maximum effect? If yes, please explain how and by whom. If not, what could have been done differently/better within the arrangements which existed during your tenure?**

77.1 I regret not recognizing in late 2017/early 2018 that, in addition to the factors investigated in the MHPS investigation, there was a likelihood of additional issues that had not been identified but which required investigation. The fact that some aspects of good clinical practice were absent in Mr O'Brien's working patterns I feel, in retrospect, ought to have raised the concern that other deficiencies of good practice may also have been present. If this had been recognized, and a comprehensive review of practice been carried out at the time, I feel it is likely that the clinical practice which was identified in 2020 (and which led to the Lookback exercise) would have been identified earlier.

77.2 I am currently developing monitoring processes for data collection / monitoring for the factors monitored for Mr O'Brien in order to roll out across services to provide reassurances that, for the future, similar issues, particularly with regard to clinic outcomes, clinical correspondence, triage, and results management, do not go unidentified in any other clinicians.

78. ~~72.~~ **Do you think, overall, the governance arrangements were fit for purpose? Did you have concerns about the governance arrangements and did you raise those concerns with anyone? If yes, what were those**

Received from Mr Mark Haynes on 20/09/22. Annotated by the Urology Services Inquiry.

Mitchell, Darren

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

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

DMM

Received from Dr Darren Mitchell on 19/05/2023. Annotated by the Urology Services Inquiry.

Not that I can recall.

9. In an email to Mr Haynes on 28 March 2019, Dr Mitchell states:

> ***Mark – this is one of the cases that we chatted about with BC 50 then escalated to BC 150 and we would probably like to have been involved in the decision making process a bit earlier. Suneil's history Feb 2019 on ECR gives the full detail. I don't think this is an isolated occurrence.*** **[WIT-96680]**

Please set out:

(i) The background to the sending of this email, including details of all conversations you had with Dr Mitchell before it was sent, what those conversations were about, and who was present during those conversations.

From memory, Dr Mitchell had been in discussion with Mr Mark Haynes who had indicated there was an investigation ongoing into Mr O'Brien's practice at Craigavon, SHSCT. We therefore agreed that any cases of bicalutamide 50mg monotherapy prescribing would be highlighted, and that Dr Mitchell would send the details to Mr Haynes.

I met this patient for the first time as a new patient, on 1st February 2019 at a waiting list initiative clinic. He had been treated with bicalutamide 50mg monotherapy for a short period of time from January 2013 to May 2013 before this was increased to bicalutamide 150mg. He had required a coronary artery bypass graft (CABG) in 2013 and transurethral resection of prostate (TURP) in April 2014 for lower urinary tract symptoms and his PSA was very low at 0.11 in June 2014. This would have been a good time to refer him for radiotherapy, but this did not happen, and the patient continued on bicalutamide 150mg. His PSA began to climb and eventually reached 3.35 in December 2018. Around that time, an MRI showed his prostate cancer was locally advanced with extra-capsular extension and invasion into the seminal vesicles. He was then referred for consideration of radiotherapy.

I emailed Dr Mitchell to make him aware of this case on 1st February 2019 (See Appendix 1). He indicated, via email (Appendix 1), that he would discuss with me and Jonathan (I believe this was Dr Jonathan McAleese who was the Clinical Director of Oncology at the time). Dr Mitchell then emailed Mr Haynes on 28th March 2019 as above.

(ii) Why did you highlight this case to Dr Mitchell, in particular?

From: Jain, Suneil <Personal Information redacted by the USI>
Sent: 01 February 2019 12:33
To: Mitchell, Darren
Subject: RE: bpr19/0109

Will discuss with you, first one in a while

From: Mitchell, Darren
Sent: 01 February 2019 11:14
To: Jain, Sun ell <Personal Information redacted by the USI>
Subject: Re: bpr19/0109

Will chat to you and Jonathan about this.

Sent from Samsung tvtobilc on 02

-------- Original message --------
From: "Jain, Suneil" <Personal Information redacted by the USI>
Date: 01/.02/2019 11:07 (GMT+00:00)
To: "Mitchell, Darren" <Personal Information redacted by the USI>
Subject: RE: bprl 9/0109

Short AS period then 50mg 1/13 onto 150mg 5/13. Turp 4/14 for luts. Psa 0.116/14 steadily increased to 3.35 12/18. Sv+, significant ece now, I've booked a ibs.

From: Mitchell, Darren
Sent: 01 February 2019 10:53
To: Jain, Suneil <Personal Information redacted by the USI>
Subject: RE: bpr19/0109

BC 50 initially?? I said the next step would be through the CD route at CAH.

DMM

From: Jain, Suneil
Sent: 01 February 2019 10:41
To: Mitchell, Darren <Personal Information redacted by the USI>
Subject: bpr19/0109

NP today from AOB, will get a bone scan but would have been much better to have been seen by us in 2014. MRI and O/E, v. locally advanced now, psa has got to 3.35 on bicalutamide.

Dr Suneil Jain MB BCh MRCP FRCR PhD
Clinical Reader in Clinical Oncology
Centre for Cancer Research and Cell Biology Queen's University Belfast

Honorary Consultant Clinical Oncologist
The Northern Ireland Cancer Centre

Received from Professor Suneil Jain on 24/01/2024. Annotated by the Urology Services Inquiry.

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

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

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

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

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

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

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

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

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

Corrigan, Martina

From: Haynes, Mark <[Personal Information redacted by the USI]>
Sent: 07 February 2019 06:25
To: OKane, Maria
Subject: FW: Patients awaiting results

Morning Maria

See below email regarding results from my colleague and my response FYI.

Mark

From: Haynes, Mark
Sent: 07 February 2019 06:24
To: O'Brien, Aidan; McCaul, Collette; Robinson, Katherine
Cc: Young, Michael; Glackin, Anthony; ODonoghue, JohnP; 'derek.hennessey[Personal Information redacted by the USI]'; Corrigan, Martina
Subject: RE: Patients awaiting results

Morning

The process below is not a urology process but a trust wide process. It is intended, in light of the reality that patients in many specialities do not get a review OP at the time intended (and can in many cases take place years after the intent), to ensure that scans are reviewed and in particular unanticipated findings actioned. Without this process there is a risk that patients may await review without a result being looked at. There have been cases (not urology) of patients imaging not being actioned and resultant delay in management of significant pathologies. As stated this is a trust wide governance process that is intended to ensure there are no unactioned significant findings. There is no risk in the process described.

If the patient described has their scan in May, the report will be available to you and can be signed off and the patient planned for review in June, there is no delay to the patients care. The DARO list is reviewed regularly by the secretarial team and would pick up if the scan has been done but you hadn't received the report, if the scan hasn't been done etc.

It may be ideal that such a patient described would be placed on both the DARO list and a review OP WL but PAS does not allow for this.

I have no issue (as a clinician or as AMD) with the process described as it does not risk a patient not being seen and acts as a safety net for their test results being seen.

Mark

From: O'Brien, Aidan
Sent: 06 February 2019 23:33
To: McCaul, Collette
Cc: Young, Michael; Glackin, Anthony; Haynes, Mark; ODonoghue, JohnP; 'derek.hennessey[Personal Information redacted by the USI]'; Corrigan, Martina
Subject: FW: Patients awaiting results
Importance: High

Dear Ms. McCaul,

I have been greatly concerned, indeed alarmed, to have learned of this directive which has been shared with me, out of similar concern.

Received from Mr Mark Haynes on 16/09/22. Annotated by the Urology Services Inquiry.

TRU-162123

Mr Chris Wamsley

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details

ID & Status

Incident Reference ID	Personal
Submitted time (hh:mm)	07:37

Incident IR1 details

Notification email ID number	W91201
Incident date (dd/MM/yyyy)	17/07/2018
Time (hh:mm)	12:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	
Does this incident involve a Staff Member?	
Description Enter facts, not opinions. Do not enter names of people	Inpatient admission 29/11/17 - 7/12/17. FU CT Renal in 3 months. CT performed 13/3/18 (reported 20/3/18) showed suspected renal cancer. GP referral 17/7/18 as no review / FU had occurred after CT scan. Subsequently underwent surgical treatment of renal cancer.
Action taken Enter action taken at the time of the incident	Upon receipt of referral, OP assessment and further management was arranged.
Learning Initial	Robust mechanisms for clinican review and action of results is required.
Reported (dd/MM/yyyy)	12/03/2019
Reporter's full name	Mark Haynes
Reporter's SHSCT Email Address	mark.haynes Personal Information redacted by USI
Opened date (dd/MM/yyyy)	12/03/2019
Has safeguarding been considered?	
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	Patient 92

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Recipient Name	Recipient E-mail	Date/Time	Contact ID	Telephone Number	Job Title
Carroll, Ronan MR	Personal Information redacted by USI	12/03/2019 07:37:52	56	Personal Information redacted by USI	Assistant Director of Acute Services
Kelly, Brigeen		12/03/2019 07:37:52	8086		Head of Trauma and Orthopaedics
Young, Michael		12/03/2019 07:37:52	29046		Consultant
Haynes, Mark Mr		12/03/2019 07:37:52	88982		Consultant Urologist
McAloran, Paula		12/03/2019 07:37:52	118513		Senior Governance Officer
Kingsnorth, Patricia Mrs		12/03/2019 07:37:52	7553		Risk Midwife
Corrigan, Martina		12/03/2019 07:37:51	9419		Head of ENT and Urology

Management of Incident

Handler Enter the manager who is handling the review of the incident	Martina Corrigan
Additional/dual handler If it is practice within your team for two managers to review incidents together use this field to record the second handler	
Escalate You can use this field to note the incident has been escalated to a more senior manager within your Service/Division-select the manager from this list and send an email via the Communication section to notify the manager the incident has been escalated to them.	
	21/10/2019

Received from SHSCT on 28/09/22. Annotated by the Urology Services Inquiry.

TRU-162168

Mr Chris Wamsley

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details

ID & Status

Incident Reference ID	Personal Informatio
Submitted time (hh:mm)	06:25

Incident IR1 details

Notification email ID number	W123551
Incident date (dd/MM/yyyy)	20/08/2019
Time (hh:mm)	12:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	No
Does this incident involve a Staff Member?	Yes
Description Enter facts, not opinions. Do not enter names of people	Diagnosed with high grade prostate cancer July 2019. MDM outcome '...commence an LHRHa, arrange a CT Chest and bone scan and for subsequent MDM review.' Seen in OP 20/08/19, commenced on 50mg bicalutamide, Radiological investigations requested on 4/10/19 (6.5 weeks after OP attendance), no subsequent MDM review. Admitted with local progression January 2020 requiring transurethral resection and ureteric stent / nephrostomy. During inpatient admission it was not recognized that he had not been started on an LHRHa and he subsequently started standard treatment for his locally advanced prostate cancer (Degeralex) February 2020.
Action taken Enter action taken at the time of the incident	Patient 4 had been started on appropriate treatment at the time this was identified.
Learning Initial	Non standard treatment started for prostate cancer, at variance with MDM recommendation
Reported (dd/MM/yyyy)	12/11/2020
Reporter's full name	Mark Haynes
Reporter's SHSCT Email Address	mark.haynes Personal Information redacted by USI
Opened date (dd/MM/yyyy)	12/11/2020
Has safeguarding been considered?	
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	Patient 4

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Recipient Name	Recipient E-mail	Date/Time	Contact ID	Telephone Number	Job Title
Connolly, Carly	Personal Information redacted by USI	12/11/2020 06:26:42	159980	Personal Information redacted by USI	Clinical Governance Manager
Bell, Joanne MRS		12/11/2020 06:26:42	198896		Quality and Safety Lead SEC
Carroll, Ronan MR		12/11/2020 06:26:41	56		Assistant Director of Acute Services
Young, Michael		12/11/2020 06:26:41	29046		Consultant
Haynes, Mark Mr		12/11/2020 06:26:41	88982		Consultant Urologist
Connolly, Connie		12/11/2020 06:26:41	9424		Acting Acute Governance Co-Ordinator
Cardwell, David		12/11/2020 06:26:41	12		Clinical Governance Manager
Kingsnorth, Patricia Mrs		12/11/2020 06:26:41	7553		Risk Midwife
Clayton, Wendy		12/11/2020 06:26:40	8243		OSL
Corrigan, Martina		12/11/2020 06:26:40	9419		Head of ENT and Urology

Management of Incident

Handler Enter the manager who is handling the review of the incident	Martina Corrigan
Additional/dual handler If it is practice within your team for two managers to review incidents together use this field to record the second handler	

Received from SHSCT on 28/09/22. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

Quality Care - for you, with you

JOB DESCRIPTION

POST: Divisional Medical Director – Urology Improvement (Temporary post – 2 years initially)

DIRECTORATE: Acute Services

RESPONSIBLE TO: Director of Acute Care

ACCOUNTABLE TO: Medical Director

COMMITMENT: 3 PAs

LOCATION: Trustwide

Context:

The Divisional Medical Director (DivMD) will be a leader of the Urology Divisional Management Team, member of the Directorate Senior Management Team and Medical Directors divisional representative. The DivMD will have a lead role in ensuring the division maintains high quality, safe and effective services and will also contribute to the division's strategic direction.

The DivMD will embody HSC values of Openness & Honesty, Excellence, Compassion and Working Together. The Trust is firmly committed to embedding the "right culture" where everyone's "internal culture" or values are realized through the provision of caring, compassionate, safe and continuously improving high quality health and social care.

For the Southern Trust, the "right" culture is underpinned by a collective and compassionate leadership approach, model and behaviours. This Collective Leadership approach will be supported with the implementation of a more collective leadership (CLT) model within the Service Directorates.

Job Purpose:

The DivMD has a lead responsibility within the Division for the delivery and assurance surrounding all aspects of Professional and Clinical and Social Care Governance.

In partnership with the Assistant Director and Professional Leads the DivMD will also be responsible for setting divisional direction; service delivery; development; research and innovation; collaborative working; communication; financial and resource management; people management and development; information management and governance and performance management.

Main Duties / Responsibilities

- To develop a culture of collective and compassionate leadership.

Received from Mr Mark Haynes on 16/09/22. Annotated by the Urology Services Inquiry.

- To medically lead on all aspects of patient safety.
- To lead on all aspects of medical professional and clinical and social care governance including:

• Professional Medical Governance –Staffing and Staff Management –Professional Performance Management –Appraisal and Revalidation • Adverse and Serious Adverse Incident Management • Litigation and Claims Management • Coronial Matters • Complaints • Morbidity and Mortality • Patient Safety (Including Infection Prevention and Control) • Medications management	• Research and Development • Risk Management / Mitigation and Reduction • Learning from Experience • Medical Education in conjunction with DMD/ Dir Med Ed • Medical Workforce development • Quality Improvement • Clinical Audit • Education, Training and Continuing Professional Development • Ensuring Delivery of Effective Evidence-Based Care • Patient and Carer Experience and Involvement • Medical leadership in delivery of MCA and Safeguarding

Specific Divisional Responsibilities

- Provide medical leadership and direction regarding strategic development of Urology Services within the Southern Trust.

- In conjunction with the AD Surgery and Elective Care lead on the Urology review lookback and coordinate clinical resources as appropriate.

- In conjunction with the AD Surgery and Elective Care provide clinical leadership on the development of business cases to involve independent sector support for lookback reviews as required.

- Be the Trust key clinical contact for liaising with external bodies such as the Royal College of Surgeons and BAUS to gain independent expert advice on urology lookback and quality improvement proposals.

- Review and provide input into the modification of the department to improve and expand Urology services and have an active involvement in the implementation of quality improvement initiatives. This includes specifically:

  - Chairing the urology quality improvement group designated with responsibility for ensuring effective, high quality care is provided.

  - Co-Chairing the Urology SAI task and finish group responsible for ensuring compliance with SAI recommendations made in the 2016 and 2021 urology SAI reviews regarding urology and cancer services.

- Ensure all clinical staff are aware of Trust policies and procedures in relation to good medical practice, and compliant with relevant standards and guidelines.

Terms of Reference- Agreed by Group 11 October 2021

Trust's Task and Finish Group into Urology SAI Recommendations

Terms of Reference of Task and Finish Group

The Task and Finish group is charged with implementing all the recommendations and providing assurance/evidence to the Urology Oversight Group

Membership of Task and Finish Group

Consultant	Nurse	Manager/Admin
Philip Murphy, Deputy Med Director	Clair, Quin, Cancer Lead	Ronan Carroll Assistant Director
Shahid Tariq, Deputy Med Director	Tracey McGuigan, Lead Nurse	Martina Corrigan, Assistant Director
Mark Haynes – Deputy Med Director	Kate O'Neil, Clinical Nurse Specialist	Anne McVey, Assistant Director
David McCaul Clinical Director	Leanne McCourt Clinical Nurse Specialist	Barry Conway Assistant Director
Ted McNaboe Clinical Director	Patricia Thompson, Clinical Nurse Specialist	Helen Walker, Assistant Director
Manos Epanomeritakis, Gen Surgery	Sarah Walker, Clinical Nurse Specialist	Stephen Wallace, Assistant Director
Kevin McElvanna General Surgery	Catherine English, Clinical Nurse Specialist	Mary Haughey, Service Improvement Lead
Art OHagan Dermatology	Fiona Keegan, Clinical Nurse Specialist	Sharon Glenny, performance manager
Geoff McCracken, Gynae	Matthew Kelly, Clinical Nurse Specialist	Jane Scott performance manager
Helen Mathers Breast	Nicola Shannon, Clinical Nurse Specialist	Wendy Clarke, Head of Service
Rory Convery Lung	Stephanie Reid, Clinical Nurse Specialist	Amie Nelson Head of Service
Christina Bradford;, Hematology	Janet Johnstone, Family Liaison Officer	Wendy Clayton, Head of Service
Anthony Glackin,; Urology	Lisa Polland-O'Hare, Service User Officer	Patricia Loughan, Head of Service
Marian Korda, ENT		Chris Wamsley, Head of Service
		Kay Carroll, Head of Service
		Sarah Ward, Head of Service Clinical Assurance

Role of Task and Finish Group

The Task and Finish Group will bring together a breadth of experience, expertise and perspective from across all cancer Multi-disciplinary teams to enable the recommendations to be achieved within the given time frames through

1. overseeing the delivery of all the recommendations
2. ensuring sustainable delivery of all the recommendations;
3. oversee and action quality, safety and governance risks as a result of implementing all, the recommendations

Life span of Task and Finish Group

The group is a task and finish group and the anticipated timescales for completion and this work will be 12 months

Reporting and Communications

1. Task and Finish Group meeting minutes (decisions & actions) from each meeting will be prepared and circulated to members and once agreed the notes can be shared with other parties as directed by the Chairs.

Received from Dr Maria O'Kane on 01/04/22. Annotated by the Urology Services Inquiry.

TRU-303588

Southern Health and Social Care Trust

Quality Care - for you, with you

CANCER MULTIDISCIPLINARY TEAM MEETINGS (MDM'S)

SUMMARY OF IMPROVEMENTS

DECEMBER 2022

Key issues regarding Urology Cancer Multidisciplinary Team (arising from Urology SAI Report):

- Not all patients with a cancer diagnosis brought for discussion at the Urology Cancer Multidisciplinary Team (MDT) meeting
- Not all patients with a cancer diagnosis to the Urology Cancer MDT meeting were allocated a Cancer Nurse Specialist (CNS) as the key worker
- Deviation from the specific plan of cancer care that was agreed at the Urology Cancer MDT meeting
- Management unaware of weaknesses in the Urology Cancer MDT meeting

Contextual Issues in relation to all the Trust MDTs:

- MDT meetings have broadly remained unchanged since they commenced in 2008
- There was no commissioned post to oversee the effectiveness of each of the MDTs (Cancer MDT Administrator)
- The Trust had no monthly reports in place to show how each MDT was working – including information on quoracy. This information was contained within an Annual Report for each MDT. This was high level and retrospective.
- There was no audit activity support in place to check that actions agreed at MDT where implemented
- There was no way of recording that the key worker had been allocated (or not) for each patient at MDT
- There was no way of checking if a Cancer Nurse Specialist was involved (or not) with each patient and that information was shared with each patient in terms of their cancer diagnosis, their treatment plan and support available
- Information from the pathology department, including cancers confirmed through laboratory tests, was not being cross referenced back to cases presented to each cancer MDT to ensure all cancer patients were discussed at MDT meetings

Received from SHSCT on 24th November 2023. Annotated by the Urology Services Inquiry.

Actions taken / or ongoing:

- New resources are being put in place at financial risk to support the Cancer MDTs and to provide monthly monitoring by way of assurance.

- A Cancer MDT Administrator & Project Officer commenced in January 2022. This is the first post of this kind in NI.

- A Cancer Information and Audit Officer was appointed at financial risk. This is a Band 5 post and the postholder took up post on 28th November 2022. He will have a key role in running reports to provide assurance on MDT effectiveness and these audit details are listed below.

- An Interim Lead Nurse for Cancer Services has been appointed. This post is not commissioned. This needs to be progressed as soon as possible to appoint a permanent lead Nurse for Cancer Services. This Lead nurse will have responsibility for nursing staff in the Mandeville Unit, all the Cancer Nurse Specialists (under the Cancer Services Division) and the Haematology ward.

New monthly reports are being established as follows:

- MDT Attendance / quoracy reports on a weekly / monthly basis
- Audits to confirm that actions agreed by the MDT were implemented (this is currently being done for Urology and will be rolled out for all 8 Cancer MDTs)
- Longest patients waiting for diagnostic tests (over 100 days)
- Confirmation that a key worker had been identified and documented – will be audited for assurance
- The list of confirmed cancers per tumour site will be shared with all CNS's on a weekly basis as an additional assurance that a key worker has been identified and contact has been made with the patient
- Confirmation that the Cancer Nurse Specialist (CNS) was involved with patients with a confirmed cancer – will be audited for assurance
- Establishing a cross check mechanism with the Cellular Pathology Laboratory in Craigavon Area Hospital to ensure that, patients with a laboratory confirmed cancer, were brought to the MDT by their consultant for discussion. This is completed on a weekly basis and any issues are shared with the relevant MDT Lead.

Received from SHSCT on 24th November 2023. Annotated by the Urology Services Inquiry.

ADMINISTRATIVE & CLERICAL Standard Operating Procedure

DRAFT

Title	Management of Results		
S.O.P. Number	29		
Version Number	v1.0	Supersedes:	
Drafted by	Orla Poland		
Page Count			
Date of Implementation			
Date of Review	April 2023	Reviewed by: April 2025	
Approved by			

Introduction

The scope of this SOP is to detail out the process of how results are to be managed and the escalation process for non-completion.

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

New patients referred for tests prior to having their first appointment with a consultant

In some cases, following triage, a consultant will make the decision to send a patients for tests before having them be booked for an outpatient appointment. In these circumstances the following process is to be followed:

- For Urgent/Routine patients where the consultant decides to send to test this will come through to the secretary on E triage. The secretary then must update PAS to change the cons code to the triaging consultant and discharge to DTR. The DTR report will be run monthly and sent to secretaries to check the status of the non-suspect Cancer patient's referrals/results.

- For Red Flag patients where the consultant decides to send to test this will come through to the secretary on E triage. The secretary then must update PAS to change the cons code to the triaging consultant and discharge to DTR. The Red Flag team with monitor the DTR report for Suspect Cancer patients and contact us with any queries.

- The result should ideally be electronically signed off by the consultant on ECR when received with instructions on the next steps for the patient relayed in a dictation for the secretary to complete on PAS.

- Paper results will be received by the secretary who is then to check ECR to see if these have been electronically signed off. If signed off then no action required and paper result can go to shredding. If result has not been electronically signed off then paper copy is to be scanned to shared results folder for consultant's attention. **No results are to be passed in paper form, Secretaries should set up folders showing results forwarded, completed etc.**

DRAFT

Clayton, Wendy

From: Haynes, Mark
Sent: 20 July 2022 07:45
To: ODonoghue, JohnP; Clayton, Wendy
Subject: Results

Morning John

As you are aware Wendy and I have started to receive weekly reports regarding radiology results sign-off (based upon NIECR signoff data). How we use this data is currently in development.

Below is the data for you for the past few weeks. The information presented only relates to radiology results only, up to 42 days after reporting (and so older results do not appear). I appreciate you have been off on annual leave and therefore results have built up a bit as a result and anticipate that you already plan to catch up with these (in particular those in the orange and red column as these are the longest since reporting) and so would anticipate seeing an improvement in next weeks report.

Mark

20/07/2022	Unsigned - Days since reported			total signed	total unsigned
	0-13	14-27	28+		
JOD	25	16	9	77	50

13/07/2022	Days since reported			total signed	total unsigned
	0-13	14-27	28+		
JOD	18	19	4	89	41

06/07/2022	0-14	14-28	28+	Total not signed off	Total signed off
JOD	20	8	0	28	105

Received from SHSCT on 21 April 2023. Annotated by the Urology Services Inquiry.

- The SA should spot check the DARO report to ensure proper action is being taken by secretarial staff
- All Results outstanding need to be clearly identified in monthly backlog reports

All staff to be aware of the importance of this report. There are 3 failsafe's for dealing with results, the first is electronic sign off, the 2nd paper copies, the 3rd the DARO report.

If results are not signed off electronically but arrive in paper form the secretary must scan to the consultant. Handing a folder over has been proven to be ineffective and increases the risk of a patient being missed for follow up. By scanning there is proof that results have been sent. Failure by medics to act on paper copies should be followed up by secretaries but even if this fails the DARO is the final step which should pick up if a patients results have not been actioned. Failure to action results can have serious consequences for a patients care and lead to Datix's.

DRAFT

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

anaesthetist that [Patient 90] did not attend his appointment.

The review team concluded that even if [Patient 90] had been able to attend this appointment, it was not a timely referral to pre-operative assessment. The referral did not give sufficient time to appropriately pre-operatively assess and optimise [Patient 90] for surgery considering his significant comorbidities.

14. WHAT HAS BEEN CHANGED or WHAT WILL CHANGE?

15. RECOMMENDATIONS (please state by whom and timescale)

Recommendation 1

The Trust should develop and implement guidance for clinical result sign off
Monthly audit of sign off will be presented to the Governance Forums

Recommendation 2

All patients undergoing elective surgery must have a formal pre-operative assessment completed prior to surgery, including liaison with other specialties to ensure maximal optimization of patients prior to procedure. The Trust will update the pre-operative guidance to recommend appropriately timely referral times and escalation of non-attendance.
Audit of surgical patient pre-operative assessment should be undertaken and be presented to the Governance Forums

Recommendation 3

Discussions regarding the risks and benefits of surgery must be clearly documented in the patient record and reflected on the patient consent form, to ensure patients are able to make informed consent.
Audit of surgical patient consent should be undertaken and be presented to the Governance Forums

Recommendation 4

Blood loss during procedure should be escalated during and at the end of the procedure, the blood loss must be recorded on the operation note.
Blood loss post operatively must be escalated to the surgical and anaesthetic teams.
Monthly audits will be conducted and result presented to the Governance Forums

Recommendation 5

VTE risk assessment must be completed for all patients prior to surgical intervention.
Monthly audit of VTE risk assessment in the patient record/medicine prescription and administration record and WHO surgical safety check list blood loss section will be presented to the Governance Forum

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

17. FURTHER REVIEW REQUIRED? YES / NO
Please select as appropriate

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

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

The review team considered the discussion between Doctor 1, Doctor 2 and Doctor 3 who agreed that given the patient's precarious state and lack of compelling evidence of haemorrhage (Robinson drains in situ, Hb static, abdomen not distended), not to perform an emergency laparotomy. The review team noted the total output of 1220mls on the fluid balance chart of which 400mls was from surgical drains at approximately 21:00 plus the 1098mls at time of procedure (the review team note the blood volume lost in theatre was 1098 not 1298 on the measurement of blood loss in theatre). The review team note the World Health Organisation (WHO) surgical safety check list has questions on blood loss on the sign in and time out sections of the form but did not have this form available to them during the review. The review team have been informed it is custom to notify the surgical and anaesthetic team of blood loss of 500mls and 1000mls during the procedure and total blood loss at the end of the procedure. The escalation is not documented in the medical notes available to the review team, with the exception of the Measurement of Blood Loss in Theatre form. However, the review team noted there was equivalent fluid replacement.

The review team note that Hb appeared to be sustained at 82, however, haemodilution may not have occurred at that time. The review team note the Hb of 68 which was collected at 22:25. This result may not have been available to the clinical team before Patient 90's death.
The review team concluded that Patient 90 was at high risk of bleeding due to myelodysplastic syndromes, and the nature of the surgery. The intra operative blood loss, post-operative tachycardia and loss from operative drains indicated bleeding, which with Patient 90's history of heart failure would have been a contributory factor for hypovolemic shock. The review team note the post mortem findings '*death was due to bleeding, or haemorrhage, into the abdominal cavity itself and into the fatty tissues at the back of the abdomen*,.

Communication
Consent
Patient 90 was consented by Doctor 1for cystoscopy, replacement of ureteric stent, laparotomy and bilateral ureterolysis.
The review team was unable to find documentation of detailed discussion of Patient 90's individual risks based on his comorbidities in the medical notes.
Ureterolysis a high risk surgical procedure which is rarely performed in the SHSCT urology department, with only a few per year. There is no documentation of alternatives e.g. nephrostomies or referral to other centers being discussed with Patient 90.

Patient 90 did not have a full preoperative outpatient assessment which would have identified all his individual anaesthetic risks to be assessed and discussed with Patient 90 to ensure informed consent.

Liaison with other teams
The review team was unable to evidence communication between Doctor 1 and the haematology team regarding optimisation of Patient 90 preoperatively; however, the review team note that Patient 90 did receive a blood transfusion pre-operatively. Patient 90's Hb was 86 and there would have been an anticipated blood loss of approximately 500mls with the proposed procedure. During the procedure the actual blood loss was 1098mls.

Patient 90 was added to a urology waiting list on 9 June 2017 and was pre-admitted for surgery at 15:50 on Thursday 3 May 2018 by Doctor 1's secretary and referred to the preoperative team the same day. The preoperative team booked Patient 90 for an assessment at 13:45 on 4 May 2018. Patient 90 was in the emergency department of Craigavon Area Hospital on 4 May 2018 and called with the preoperative team at 09:00, as his preoperative assessment appointment was booked for 13:45 they were unable to assess him. He was advised to contact the preoperative team later that day if he was unable to attend his 13:45 appointment. Patient 90 did not attend his preoperative assessment later that day. The review team was informed that the pre-operative team informed the consultant

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Consenting In TURBTs & URS for stones, How good are we?

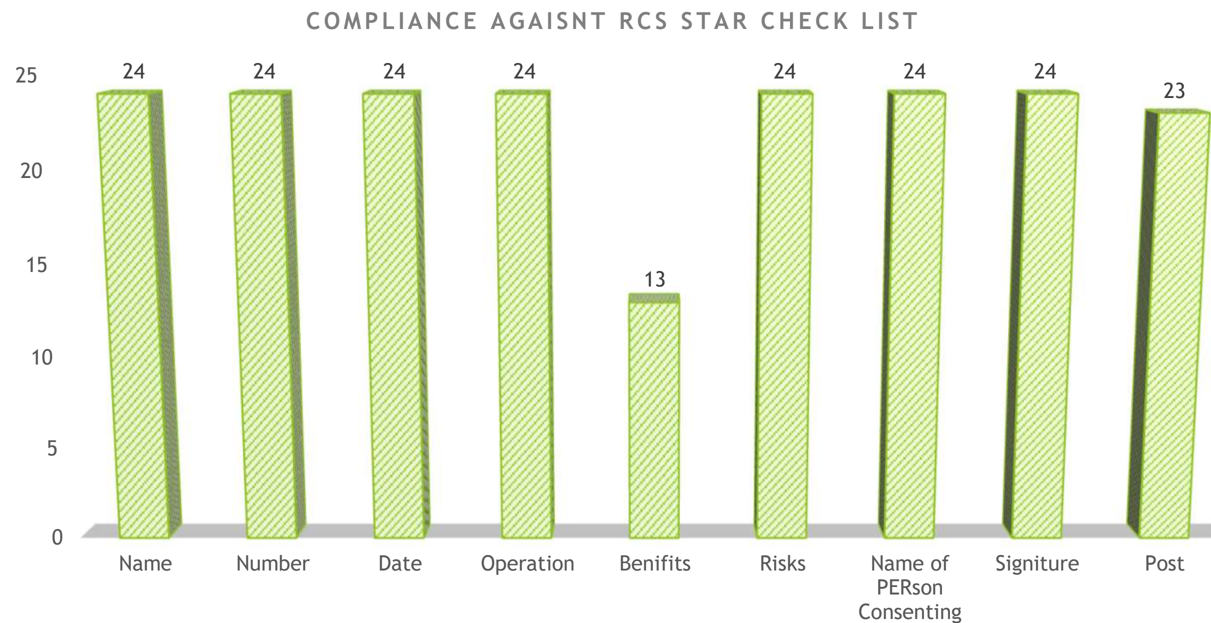
Zuhdi Al-Nabulsi - ST3

Craigavon Area Hospital

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

TRU-320295

Other Domains: RCS, STAR Check list



- Total patients number in both arms is 24, hence most parameters are excellent, significant room of improvement can be achieved in writing down the intended benefits on the consent forms!

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

Urology Division Annual Clinical Audit Programme 2023/2024 - Mid Year Update October 2023

Priority Level	Descriptor		Host Organisation or Standard	Audit Title	Clinical Lead	Audit Supervisor	Local Audits - Update / Comments
1	NEW External 'Must Do'	National HQIP	British Association Of Urological Surgeons (BAUS)	**Nephrostomy Audit**	Dr Omar Ababneh	Mr Mark Haynes, Consultant Urologist	
1	ON-GOING External 'Must Do'	National HQIP	British Urology Researchers in Surgical Training (BURST)	**Transurethral REsection and Single instillation intra-vesical chemotherapy Evaluation in bladder Cancer Treatment (RESECT) Improving quality in TURBT surgery.**	Mr Conor McCann Specialty Doctor	Mr A Glackin, Consultant Urologist	
1	On-Going External 'Must Do'	National HQIP	National Confidential Enquiry into Patient Outcome and Death (NCEPOD)	**Testicular Torsion - Child Health Clinical Outcome Review Programme - Clinician Questionnaire**	Participation in National Enquiry Director approval 14/10/2022 Multiple Clinicians	Participation in National Enquiry Director approval 14/10/2022 Not Assigned	
1	On-Going External 'Must Do'	National HQIP	National Confidential Enquiry into Patient Outcome and Death (NCEPOD)	**Testicular Torsion - Child Health Clinical Outcome Review Programme - Organisational Questionnaire - CAH**	Participation in National Enquiry Director approval 14/10/2022 Mr A Glackin	Not Applicable	
2	ON-GOING Internal 'Must Do'	Public Inquiry	NICE NG2 Bladder cancer: diagnosis and management (2015)	**Retrospective audit all cases from all consultants in the two financial year periods of 2012/2013 and FY 2013/2014 (working title)**	CNS - Leanne McCourt & Patricia Thompson	Mr M Haynes & Mr J O'Donoghue	
2	Internal 'Must Do'	Regional	Urology Regional Audit Meeting for Northern Ireland Topics	**To be advised by Clinical Team**	No current regional audit programme	No current regional audit programme	
On-going Internal Divisional Priority Audits from 2022/2023 to be rolled forward for completion by July / August 2023							
3	Divisional Priorities	Local SHSCT based on Morecambe Bay Report	STAR Methodology / BAUS Leaflet compliance on consenting practice	**Consenting in TURBTs (transurethral resection of bladder tumour) + URS (Ureteroscopy) for Stone, How good we are?**	Dr Zuhdi Al-Nabulsi, ST3 Urology	Mr J O'Donoghue, Consultant Urologist	Due for presentation 18/10/2023 PSM
3	Divisional Priorities	Local SHSCT based on Morecambe Bay Report	Getting It Right First Time Programme (GIRFT)	**Comparing GIRFT recommendation that definitive treatment following ureteric stent insertion for ureteric stone should be provided no longer than 4weeks from the acute septic episode to our secondary URS waiting list times for these cases.**	Ms Laura McAuley, Urology Specialty Doctor	Mr Matt Tyson, Consultant Urologist	
3	Divisional Priorities	Local SHSCT based on Morecambe Bay Report	Compliance with NICE Guidance / EAU guidelines	**Review of Serum Calcium Assessment in New Stone Patients**	Dr Sadaf Imitaz	Mr Matt Tyson, Consultant Urologist	Presented 20/04/2023 PSM
3	Divisional Priorities	Local SHSCT based on Morecambe Bay Report	International Continence Society (ICS) Guidelines	**Comparative Audit of Urodynamics Practice in the Southern Trust 2018 & 2023**	Ms Abigail Nelson / Jenny McMahon	Mr J O'Donoghue, Consultant Urologist	Due for presentation 18/10/2023 PSM
On-going Internal Divisional Priority Audits from 2023/2024 for completion by March 2024							
3	Divisional Priorities	Local SHSCT based on Morecambe Bay Report	NICE Guidelines – 2015 update, EAU Guidelines – 2022 update, ICS Guidelines	**Male LUTS Service Re-Audit**	Dr Andrew McAdam (Urology Registrar)	Mr A Glackin, Consultant Urologist	? For presentation Nov 2023 PSM
3	Divisional Priorities	Local SHSCT topic important to division	UK & European LUTS Guidelines for selection of patients for Rezum Procedure	**Patient outcomes following REZUM surgery within Southern Trust**	Jason Young, Urology Specialist Nurse	Mr A Glackin, Consultant Urologist	? For presentation Nov 2023 PSM
3	Divisional Priorities	Local SHSCT rolling audits	None Advised	**CNS Audits on TP Biopsies**	TBC	TBC	
3	Divisional Priorities	Local SHSCT	None Advised	**Female Lower Urinary Tract Service Audit (registered but on hold)**	Ms Laura McAuley and Clare Crothers	Mr J O'Donoghue, Consultant Urologist	Agreed to proceed 07/09/2023 departmental meeting
3	Divisional Priorities	Local SHSCT	https://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/ESWL.pdf	**Audit of Complication rates for ESWL against national averages- mainly haematoma formation, infection and steinstrasse**	Ms Laura McAuley	Mr Matt Tyson, Consultant Urologist	Agreed to proceed 07/09/2023 departmental meeting
4	Individual Priority	Clinician / Educational Interest	Comparison with National Complication Rates - Clavien Dindo	**Local Anaesthetic urology procedures (Complex Procedures Audit)**	Dr Sabahat Hasnain, Specialty Doctor Urology	Mr M Haynes (Div Medical Director)	? To be agreed for re-audit allocation

Noted at departmental meeting on 07/09/2023 - awaiting confirmation of NiCAN CRG Regional Audit Topics, ? Access to emergenct theatre / ureteric stones and ? 1 - 2 Guideline adherence audits / CNS audits - for consideration / discussion and then to update the CA plan at Oct PSM - 18/10/2023

Please Note: **Cancer MDT / MDM pathway audit sit within Cancer and Clinical Services Division**
National Cancer Audits - NI HSCTS do not participate and are part of NiCAN / Cancer Registry

Not Applicable to NI HSCTs	National HQIP	e.g National Prostate Cancer Audit (NPCA) - All men newly diagnosed with C61 prostate cancer. Such patients are identified for inclusion from the country-specific cancer registries (NCRAS in England and Canisc in Wales)

Hyponatraemia Inquiry - Recommendation 29 that all Medical Notes be subject to rigourous and routine audit
Independent Neurology Inquiry - Recommendation 51 - Healthcare organisations should ensure that newly introduced therapies are the subject of early clinical audit processes.

Figure 3: Current medical workforce

Trust	Funded Consultant Urologists	Consultant Urologists WTE	Trainees WTE	Trust doctors WTE	Physician Associate	Comments
Belfast HSC	8.8	8	5 StR (Funded = 5.0wte; 4.4wte in post) and 1 CT Doctor (Funded = 1.0wte)	1 (Funded = 3.0wte; 2 in post inc. 1 agency)	0	2x Trust (Specialty Grade) Doctors recruited Sept 2023 to take up positions before December 2023. In addition, there are, 2x temporary Clinical Fellows and 1x temporary LAS Doctors in post.
Northern HSC	0	0	0	0	0	
South Eastern HSC	7	6(1 on mat leave)	1	3	2	1 consultant post vacancy 1 locum consultant currently covering maternity leave
Southern HSC	6	4.41	3 (4.5 funded)	0.87 (1.1 funded)	0.5 (0.5 funded)	Current advertisement for 3 urologists Includes 1 long term agency locum 1 works half time at Belfast City
Western HSC	9	7.6	3 (0 funded)			2 vacant posts consultant posts

Each unit remains understaffed with respect to Urology Clinical Nurse Specialist (CNS) support, detailed in **Figure 4**, and this has a major impact on the functioning of the unit. There is a paucity of CNS provision in diagnostics, with CNS provision of prostate biopsy, flexible cystoscopy, flexible cystoscopy and Botox limited to Craigavon Area Hospital.

Figure 4: Current Whole Time Equivalent (WTE) clinical nurse specialist (CNS) and physician associate (PA) provision in Urology in NI

Role	Belfast HSC	Northern HSC	South Eastern HSC	Southern HSC	Western HSC
Band> 8c and above	-	-	-	-	-
Band 8b	-	-	-	-	-
Band 8a	1.00	-	1.00	2.42	-
Band 7	2.00	-	1.00	4	6.27
Band 6	3.00	-	2.00	0	3.52
Band 5	0	-	-	0	0
Physician Associate	-	-	2	0.5	-

Received from Department of Health on 30/11/2023. Annotated by the Urology Services Inquiry.

Financial costs of cancer for patients and families

- Many people describe financial hardship related to having cancer. There are costs associated with travelling to appointments. People of working age may need time off work during their treatment, and many of these people will have reduced earnings because of this.

- Families also have increased costs from visiting relatives in hospital or taking time off work to support the cancer patient.

- MacMillan Cancer charity carried out a study in 2006 which estimated each cancer patient spent £325 per year on additional costs related to their cancer

- Cancer patients or their families are already entitled to a range of financial help. This includes statutory sick pay, employment and support allowance, disability living allowance, attendance allowance, income support, carer’s allowance and hospital travel scheme. Most of these are benefits run by DSD.

- Macmillan have recently been provided additional funding from DSD to increase information for cancer patients about their benefit entitlements

- Patients attending for chemotherapy and radiotherapy are exempt from car parking fees in hospitals here.

- There are no prescription charges for anyone in NI. Re-introduction of prescription charges may increase the financial burden on cancer patients.

Impact of cold on patients with cancer and other conditions

Received from Department of Health on 03/07/2023. Annotated by the Urology Services Inquiry.

staff I was responsible for did not have any in date job plans and, during my tenure as CD and subsequently as AMD, we have moved this to a position of most consultants having agreed job plans, with Mr O'Brien being an outlier in this regard. Having now got into a position of the job planning process being embedded in the urology team, along with the HoS and AD we are now working to incorporate some quantitative performance management reports into the job planning process in my role as Divisional Medical Director for Urology Improvement. However, there has been a little delay in this for a number of reasons including work for the Public Inquiry taking up the time of several members of the team, including myself, coupled with the clinical pressures which result from vacant posts within the team.

31.4 Qualitative performance management is more challenging as this relies on data. Surgical quality assurance was commenced across the NHS within urology and coordinated by BAUS. This focussed on some key surgical procedures and involved significant data collection regarding treatments given. I have attached an example of such an output relating to my nephrectomy practice. This data highlighted outliers in key outcome measures and facilitated further assessment of practice where outliers were identified.

31.5 Unfortunately, following the Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016, clinicians in Northern Ireland have been unable to continue to contribute to this initiative. It is my understanding that this is a policy issue sitting with the Northern Ireland Executive. I am also aware that this impacts on a number of other similar surgical 'quality control' initiatives. Unfortunately, the format for this outcomes monitoring has changed and it is now collated from Trust data in England (the pervious format was clinician collated which clearly is open to critique) and so, even if this barrier to participation was removed, urologists in NI would not be able to take part in this.

31.6 I am not confident that the data collected from Trust information in Northern Ireland is of sufficient depth or sufficiently robust to provide reliable consultant-

Received from Mr Mark Haynes on 20/09/22. Annotated by the Urology Services Inquiry.

Southern HSC Trust

Getting it Right First Time

Urology

Southern Trust Recommendations November 2023

RAG rating	No. of actions
	6 (33%)
	10 (56%)
	2 (11%)

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

WORKFORCE					
RECOMMENDATION 1					
The Trust should continue to address barriers to recruitment, where these are within their control. A middle grade rota can comprise an extended workforce that can include advanced nurse practitioners and physician's associates in addition to more usual medical roles. Developing areas of sub-specialist practice can also aid recruitment and retention of staff.					
Original Findings	**Responsible Person**	**Action(s) Required to Deliver Recommendation(s)**	**Timescale**	**Status RAG**	**Evidence of Completion**
The medical workforce remains reliant on locum appointments and has difficulty recruiting to substantive posts. This is a recognised problem nationally across the UK due to unfilled consultant posts and a lack of National Training Number's (NTN's) accredited each year.	Cathrine Reid / Mark Haynes	Since the GIRFT Visit in March 2023 the Urology Team have advertised for the following medical staff: • Specialty Doctor – Commenced Aug 2024 Temp initially until recurrent funding is secured • International recruitment – successfully appointed 3 Urology Consultants. Commencing 1 x Dec 23 and 2 x Feb 24 • Physician Associate – advertised, offered and declined. Back out to advertise. Temp initially until recurrent funding is secured We will continue with one Locum Consultant until all Substantive Consultant posts are filled.	Complete		

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

Urology PIG Meeting

Wednesday 8 November 2023

Via Teams

Attendees

David McCormick – Chair

Alex MacLeod, WHSCT

Anthony Glackin, SHSCT

Chris Thomas, BHSCT

David Connolly, BHSCT

Ajay Pahuja, BHSCT

Joanne Elliott, DOH

Colleen McDonnell, DOH

Brian Duggan, SEHSCT

Mark Haynes, SHSCT

Samantha Sloan, BHSCT

Matthew Tyson, SHSCT

Hugh O'Kane, BHSCT

Rachel Hutton, SEHSCT

Tracey Hawthorne, DOH

Matthew Stewart, DOH

Apologies: Christine Allam, SEHSCT, Katherine Dane, SEHSCT

David McCormick welcomed members to the meeting and noted the apologies.

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Getting it Right First Time (GIRFT) Urology Update and Recommendations

David McCormick stated that the final draft was ready and was going to Permanent Secretary before issuing and publishing. Joanne advised the group that the GIRFT report had been finalised, with factual inaccuracies and wording being agreed. The recommendations were shared among the group and discussed. There are forty recommendations cover maximising surgical assessment, diagnostic pathways, efficiency, skills mix and regionalisation of services. Some actions are strategic, and many are operational, and several are already underway. Some actions will require

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.

recurrent funding to function. Joanne advised that the Programme Implementation Group (PIG) for Urology would help implement some of these and would need its Terms of Reference (ToR) revised and membership re-assessed.

ACTION – *Revised Terms of Reference to be drafted and circulated.*

David McCormick noted the GIRFT recommendations and told members that the next step would be to work through the recommendations and agree their priority. No formal timescales had been identified on the report but it is expected that the priorities will have to be grouped as short, medium and long term. Task and Finish Groups will be set up by each Trust Urology team, but the focus will also need to be regional.

Discussion moved to regional pathways and protocols for NHSCT. It was agreed that input would be sought from NHSCT on what Urology service the Trust had prior to 2015, compared to service now and desired service in the future. Additionally, guidance to Emergency Departments on Urological procedures will be re-issued. David Connolly and Brian Duggan agreed to share the previous guidance with the group for consideration and update by PIG in the first instance.

ACTION – *David Connolly and Brian Duggan to circulate Regional Urology guidance to PIG members for update.*

ACTION – *Meeting with NHSCT Emergency Clinical Leads, Senior Management, General Surgery Leads and Urology Leads regarding Urology provision to be arranged.*

ESWL service Update

Mark Haynes updated on progress in the Extracorporeal ShockWave Lithotripsy (ESWL) service in Craigavon Area Hospital (CAH). Progress was significant and a further update would be provided at the next meeting.

PCNL service Update

Received from SHSCT 16/02/2024. Annotated by the Urology Services Inquiry.