Urology Services Inquiry

Urology Services Inquiry Questionnaire

Points to assist with completion of the USI Questionnaire

- A helpful **Guide to Completing the USI Questionnaire** is available (see attached) and you are advised to read these guidance notes before attempting to complete this questionnaire.
- This questionnaire will assist the Inquiry to gain information from you regarding your experience of Urology services provided within the Southern Health and Social Care Trust (SHSCT).
- We appreciate that some patients/former patients or their families may have concerns about identifying themselves by name etc on the questionnaire. We would however reassure you that any personal details noted will only be seen by those parties, organisations or the core participants involved in our investigations who need to see it for the purpose of progressing Inquiry business. All core participants must adhere to the terms of our Restriction Orders which are now in place and available to view on our website. The term "core participant" is also defined on our website under the heading "Frequently Asked Questions – FAQ's". Our USI website address is noted below: www.urologyservicesinquiry.org.uk.
- We would encourage you to fill out your personal details as fully as possible in Section A as it will increase the value of the information to our investigative work and may also enhance your potential input to the Inquiry. We would reassure you that your name and personal details will be protected and will be anonymised unless you consent to them being made public. Your personal information will be handled in compliance with the applicable legislation including the Data Protection Act 2018 and the General Data Protection Regulations 2018.
- Please note that it is not the intention of this Inquiry to publish the questionnaires that are submitted to assist us with our work, although the report may refer to some of the content.
- If you require assistance completing this questionnaire please do not hesitate to contact our office directly on telephone number: **028 90251005**.

- The work of this Inquiry is entirely independent of all other organisations including healthcare providers, regulators and government departments.
- Only certain sections of the form will apply to you. We would ask everyone to complete Section A but thereafter please only complete those sections which apply to you.
- When you have completed the relevant sections please complete Section F and then ensure you have signed the completed questionnaire at Section G.

SECTION A – Personal Details

Name	[redacted]
Address	[redacted]
Contact Telephone Number	[redacted]
Mobile Phone Number	[redacted]
Email Address	[redacted]
HSC Number (if known)	[redacted]

	Yes/No
With regard to Section A above, have you read the '**Personal Details**' section of the 'Guide to Completing the USI Questionnaire'?	YES
Are you completing this questionnaire as a patient/former patient? (If your answer is Yes, go to Section B)	YES

Are you completing this questionnaire as a relative of a patient/former patient?	
If you are completing this questionnaire as a **relative of a patient/former patient**, do you have the express authority of the patient to engage with the Inquiry and provide information that relates to their care and treatment? (If your answer is Yes, go to Section B)	
If you are completing this questionnaire as **a relative of a deceased patient**, have you discussed providing information concerning the deceased patient with other relatives/former next of kin and no objection is being raised. (If your answer is Yes, go to Section B)	

If you are completing this questionnaire and you are not the patient/former patient or a relative of one please state your role.	

SECTION B – Contact with Urology Services

Please complete the table below setting out details of each occasion when you accessed urology services. Provide details of the dates attended, relevant consultant, hospital/clinic etc and a brief description of the reason for the visit/treatment received. If you cannot remember exact dates then please give approximate dates where possible.

Date(s)	Seen By (e.g. name of consultant/healthcare professional)	Location (e.g. Craigavon Area Hospital)	Brief description of reason for visit and/or treatment received
29/5/96	MR AIDAN O'BRIEN	C.A.H	Haematuria + Dysuria See P.4 MR DAWSONS' REPORT
14/8/97	DRJ HAMILL SHO TO A.O.BRIEN	CAH	REVIEW See P5 DAWSONS REPORT
16/10/97	Urology Registrar	CAH	REVIEW P5 DAWSONS REPORT
-/5/98	Urology Registrar	CAH	URINARY MICROSCOPY P6 DAWSONS REPORT
16/6/98	MR AIDAN O'BRIEN	CAH	REVIEW P6 DAWSONS REPORT
26/1/01	MR WILSON	BANBRIDGE POLYCLINIC	REVIEW + DISCHARGE TO G.P. P6 DAWSONS' REPORT
28/7/16	DR Personal Information redacted by the USI G.P.	Personal Information redacted by the USI	REFERAL TO UROLOGY AS ROUTINE P6 DAWSONS'
31/1/17	MR JACOB	CAH	FLEXIBLE CYSTOSCOPY P7 DAWSONS
22/2/17	MR JACOB	CAH	CYSTOSCOPY + TURBT P7 DAWSONS
-/3/17	MR GLACKIN	CAH	PROGNOSIS + DIAGNOSIS
5/4/17	MR J KEANE	B.C.H	DISCUSSION OF DIAGNOSIS P8 DAWSONS
5/5/17	MR J KEANE	BCH	OPERATON 2WKS in HOSP. P8 DAWSONS
-/9/17	CT SCAN	BCH	CT SCAN P9 DAWSONS
20/4/18	CT SCAN	BCH	CT SCAN P9 DAWSONS
30/11/18	CT SCAN	BCH	CT SCAN P9 DAWSONS
2/4/20	CT SCAN	BCH	CT SCAN P9 DAWSONS

Continue on a separate sheet if necessary

SECTION C – Details of concerns raised/complaints reported

1. Please provide full details of any concerns and/or complaints raised by you, specifying the nature of those concerns in as much detail as possible.

Mr Wilson, urologist, seen me in Banbridge Polyclinic on 26/1/01 and discharged me back to my G.P.'s care stating that I had discontinued Cyclophosphamide tablets and urinary symptons had improved, this is incorrect because I was still taking Cyclophosphamide and still had slight pain urinating. Faloon + Co, Solicitors, Dungannon, have my last pack of Cycloplosphamide tablets with the correct date in my notes in their Dungannon office.

Page 18 mr Dawsons' Report

There was a failure of the urology team in C.A. Hospital to organise a cystoscopy for me from 1996 to mr wilsons' discharge back to my GP. on 26/1/01

Page 18 mr Dawsons' Report

After an appointment with my G.P. Mr [redacted] on 28/7/16 I told him I passed a lot of bloody urine one night in July'16. It only happened once, he said he would have to get urology to check this, prostate was fine he said after inspection In early January 2017 I went to [redacted] to tell him I hadnt got a reply from urology yet, he said he would look into it. Within a week I recieved a letter from C.A.H to goto Thorndale unit on 31/1/17.

Page 19 Mr Dawsons Report

2.	Please specify the date when any concern or complaint was raised and if you cannot recall date(s) please try to indicate an approximate timescale.
Because I waited from 28/7/16 to 31/1/17 to hear back from urology C.A.H.	
3.	Please note the name and/or position held of the person you raised any concern with or reported any complaint to at the time.
Dr [redacted] G.P., had made the appeal on 28/7/16 to urology, so when I hadnt heard from urology I then went back to my G.P. in early January 2017 to tell him of my concerns.	
4.	Please advise for each occasion a concern or complaint was raised whether this was done verbally or in writing (e.g. via letter/email etc).
Verbally	

5.	If your concern or complaint was made in writing, please provide copies of that correspondence if possible.
	N/A
6.	Please advise if you received any acknowledgment or response (whether a holding response or a detailed response) to your complaint. If so, can you please provide copies?
	Pages 11, 12, 13 Mr C Dawsons' Report
7.	Please advise the outcome of any concern made or complaint raised by you.
	N/A

SECTION D - Details of concerns held but NOT raised/reported

1.	Please provide full details of any concerns you held at the relevant time specifying the nature of those concerns in as much detail as possible.

I was concerned with the delay in getting an urology app. after blood in my urine in July 2016. I also believe that if I had not returned to my G.P. in early January 2017 to complain of no response from urology when would I have been seen by Urology? with my history of cyclophosphamide useage (being on 120mgs daily orally) I should have been seen within 2 wks of attending my G.P. in July 2016.

2.	Please explain why you did not raise your concern(s) at the time and state if there was something that prevented you from raising your concern(s).

N/A

SECTION E – Personal impact/additional information

Please outline the personal impact that the treatment received, which forms the basis of your complaint(s), has had on the patient/deceased patient and provide any additional information which you feel may be of assistance to this Inquiry.

Personally this life changing episode in my life has left me anxious, and suicidal at times. From stoma bags leaking and destroying clothes, beds and my self esteem also. to my wife leaving our marital bed because of getting no intimacy and usually drenched in my urine from the stoma leaking this has been so hard for me and [Patient 13's wife] because we are best friends and have lost the intimate side of our marriage. I started receiving telephone calls from people from admin at Southern Health Trust, one was a lady called Patricia Kingsnorth, she gave me a number, [Personal Information redacted by the USI] she told me there was a SAI ongoing, I received possibly 2 more phone calls from SHT. usually different ladies, one told me on a friday possibly in 2019/2020, that I shouldn't be concerned by what I would be reading in the papers that next Monday about Urology at C.A.H as It didn't apply to me, confused and anxious after this the next call from S.H.T the lady said that the team examining Mr O Briens Conduct had concluded that I was not involved in this and I should have no worries and enjoy life. I was so incensed I just said to her you know nothing about what I have went through and still going through in my life and that I will never be able to enjoy life again. She realised how upset I was and asked would I like to see one of the Doctors who had wrote up the report on me, I said I would so she said she would get this set up for me. Mr Haynes, urologist, saw me in November 2020 with a lady taking notes. He listened to my concerns and answered all my questions

(See additional page please)

Additional sheets, if needed, can be attached

Page 10 continued — 1

Mr Haynes said that my G.P. possibly hit the wrong button on his computer and sent my referral through to urology C.A.H as routine. I was taking aback by this comment and asked him was it my G.P's fault for the delay? He said it was v. easily to make that mistake on a computer. I asked him if I hadnt have went back to my GP in early January 2017 to find out what was the delay in urology contacting me when did he think I would have been called by urology he didnt answer but ther seem to have oncology expertise as "I have had a good oncological outcome from this treatment"

page 11 mr Dawsons Report

Mr Haynes told me after I asked him did the delay in my diagnosis have an adverse outcome on the extent of my operation, was it possible that the prostrate or left kidney could have been saved if I had been seen by urology in July 2016 his response seemed to indicate that he had expertise in bladder cancer pathology, stating that although there was a delay in my referal in July 2016 until Jan 2017 "the ultimate treatment which (I) He required with a radical cystoprostatecomy and nephroureterectomy would have been recommended at the point of initial referral".

Page 12 mr Dawsons' Report

After my Diagnosis in november 1995 Personal information redacted by the USI

Personal information redacted by the USI I was treated in Quinhouse, RVH on atleast 3 occasions, staying from 10-14 days at a time, Mr Victor Patterson and Mr Michael Watt, neurologists, treatment involved steroids and Cyclophosphamide 150mgs, taken orally which increases considerably the risk of bladder cancer, even after 15-20yrs since last administered. I asked Mr Haynes was this a possible reason for my bladder cancer diagnosis he said he wasnt sure because he didnt

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know the doseage of Cyclophosphamide I was taking page 13 mr Dawsons' Report, I was taking 150mgs of cyclophosphamide and prednisolone 60mgs from 1996 until atleast 2001. This dose of medication according to John Hopkins' Vasculitis webpage – Cyclophosphamide ↓ "for patients followed up for upto 15yrs', the projected incidence of bladder cancer was as high as 16% therefore patients who have been treated with cyclophosphamide need to be followed undefinitely...for the possibility of bladder complications of the treatment...." I put this to Mr Haynes and he replied . page 10 mr Dawsons Report. that there was no law saying that I should have been monitored closely because of having taken high doses of cyclophosphamide and that I had been investigated for haematuria prior to my referral in 2016 and in the late 1990's and investigations at this time were satisfactory page 13 Mr Dawsons report.

I found this answer unadequate considering the high toxicity of this drug but he replied that I had smoked prior to my diagnosis and this was the biggest cause of bladder cancer (smoking) even though I was a light casual smoker (10 cigs per day). I should have been kept under close observations every 3-6 mths by urology and they should have been told this by Mr Michael Watt, neurologist RVH, who administered cyclophosphamide for my [redacted]. We ended our meeting when Mr Haynes told me, regarding my cyclophosphamide treatment, he would write to the Neurology team in Belfast Trust requesting they review me to discuss my concerns, as of today, 15/5/22 I have had no correspondance with them.

Personal information redacted by the USI

NEXT PAGE →

Finally I would like to say that Mr John Keane, urologist, B.C.H. was and is a great Doctor and I will be forever grateful to him and his Team. The young female nurse who drew where the stoma was to be fitted on my stomach drew it V near my belly button hence after my op and to this very day because of the in dent of the belly button this causes the stoma bag to leak very often, I feel that if it had been drew 2-3cms further away from belly button I wouldnt be having this problem which causes so much anxiety for me.

Also on march 2017 my wife and I attended C.A.H Thorndale unit to discuss and find out what my prognosis was, Mr Glackin, Urologist, CAH told us the terrible news, I was speechless I then asked mr Glackin how long had it been in my body (the cancer) he replied - " 2 weeks, 2 months, 2 years I dont know" and shrugged his shoulders, we both broke down in tears at his coldness I asked him had cyclophosphamide been a reason for my cancer and he turned and faced his Computer and didnt reply.

The urologists and neurologists comment in mr Dawsons Report that I had bladder problems before Commencing Cyclophosphamide this is true broadly speaking, but my bladder problems pre cyclophosphamide were being Caused by the onset of [redacted] thinking I was wetting myself. post cyclophosphamide and during its administration it was more painful passing water and more frequent passing urine and very small amounts being passed, waking me out of my sleep 2-3 times a night, I feel that I had different Symptons Pre + Post, Present taking cyclophosphamide

yours Sincerely [redacted]

SECTION F – Sharing information / Other related reviews

The Inquiry may consider that the information you have provided is more relevant to one of the other organisations carrying out a review or investigation as detailed in the 'Guide to Completing the USI Questionnaire' under the heading 'Other Related Reviews'.

	Yes/No
Would you be content for the Inquiry to share the contents of this questionnaire with other relevant organisations?	yes
Would you like to discuss this in more detail with the Inquiry before making a decision on the sharing of information?	yes

SECTION G – Signature

Signed:	Patient 13 [redacted]
Name in Block Capitals:	Patient 13 [redacted]
Date:	15/5/22

SECTION H - Returning your Questionnaire

Please ensure that you have enclosed the following items:

- A fully completed questionnaire.
  (Check the questionnaire has been signed and dated).
- All supporting documentation and/or correspondence.
  (Please provide copies and **NOT** originals of your supporting material).
- If you require additional sheets to complete your responses to this questionnaire, please ensure that they are securely attached.
- If you require assistance completing this questionnaire please do not hesitate to contact our office directly on telephone number: **028 90251005.**

Completed questionnaires can be emailed to evidence@usi.org.uk or returned by post to:-

The Urology Services Inquiry

1st Floor Bradford Court

1 Bradford Court

Belfast

BT8 6RB

his team did the bladder examination?

A. Yeah, yeah, yeah.

60 Q. ...and did some biopsies. Then at 1997, according to the paperwork, on PAT-000447 there was a recommendation that you should have another bladder examination? 10:34

A. Yes.

61 Q. At an interval. But I don't think that ever happened, is that correct?

A. No.

10 62 Q. So did you chase that? What is your recollection about 10:34 that, you just felt that...

A. I never chased it now. The GP never mentioned it to me. I think Mr. Hackett was still living then. So I still would have had the symptoms for it now, but there was no follow-up appointment. As I say, 10:35 Mr. Wilson, he ended it all in 2001.

63 Q. I think there was --

A. You mean to say I should have maybe enquired?

64 Q. No, I'm not saying that, I wonder if you had communication from the Trust? 10:35

A. I don't think I had, no. No. Any appointment I would have went to it. Never cancelled any appointment and I have had quite a few.

65 Q. Absolutely yes, thank you. So then moving ahead to 2017, you had had the operation at Craigavon. They had 10:35 removed the tumour, or at least some of it through the telescope, and I think you saw Mr. Glackin. And this is PAT-000481. And you make a comment that that was quite a traumatic interview and you were told the

initial diagnosis?

A. Yes, it was for me and my wife.

66 Q. It was a shock, a new cancer diagnosis. Did you, apart from Mr. Glackin, were you offered any other individuals to see for more support at that time? 10:36

A. I'd say I was. The nurses would have maybe mentioned the Macmillan and different... I went to Charis in Cookstown which helped me. I went on my own steam, me and [redacted]. So we went up to Charis Cancer Centre and we had, just 10:36 maybe once-a-week, you know, just for a bit of a therapy and a bit of pipe music or whatever they call it, that panpipes. It's was a great wee place for the cancer.

67 Q. So you had some, you felt you were supported at that 10:36 time?

A. Yes.

68 Q. Which is good, okay, thank you?

A. I never hear tell of Macmillan though. I think I wrote to them or sent something, but I have yet to hear 10:36 anything from Macmillan or financial help or anything.

69 Q. All right, thank you. Then things moved fairly quickly and you saw Mr. Keane in Belfast after that.

A. Yeah.

70 Q. Did you, I wasn't sure whether you had any chemotherapy 10:37 leading up to that or?

A. Mr. Keane mentioned maybe a dose of chemotherapy, but then he said because of the one kidney, and he said it would probably lead to kidney dialysis later, I suppose

Southern Health and Social Care Trust

Acute Governance

Patient 13

Armagh Community Hospital

25th November 2020

PRESENT: Mr Mark Haynes Consultant Urologist

Patient 13

Mrs Carly Connolly

Mr Haynes welcomed Patient 13 and advised the meeting today was for him so that he could ask questions about his care.

Patient 13 thanked Mr Haynes for meeting with him today and asked what he know.

Mr Haynes advised he was on the review panel advising he was not the chair of the review but was a panel member and provided a urology expert opinion. Mr Haynes advised Patient 13 he has kept an eye on his care and progress over this period of time.

Patient 13 advised he is more than happy with the care he has received from Mr Keane and Mr John.

Mr Haynes advised Mr Keane will be moving on now to new employment.

Patient 13 advised he would be a big loss.

Mr Haynes advised he has worked with Mr Keane after Mr Keane's father retired and agreed he would be a big loss.

Patient 13 described his time in 1995/1996 when he developed muscle disease dermatomyositis; he was treated by Mr Watt in Quinn House in Belfast. Dr Watt prescribed the drug cyclophosphamide, which he did not know at the time could potentially lead to bladder cancer. Patient 13 advised he is aware there was a delay in referral to Thorndale, that he attended his GP as he was passing blood in his urine, he explained that he had his PSA checked regularly, and this was good. GP advised him to come back. At this appointment his GP asked if he had received word from anyone from the hospital to which Patient 13 advised he had not. His GP followed up and by the Friday he had received a letter.

Mr Haynes advised these are 2 issues: 1. Cyclophosphamide and 2. The process. Mr Haynes advised the SAI process recognised the delay; Patient 13 was initially referred in July 2016 due to blood in his urine, which is an indicator for suspect cancer. The cancer pathway is a red flag referral. Mr Haynes advised that when cases are reviewed and when something has gone wrong there is generally always more than one thing that has gone wrong in the care.

DRAFT

Mr Haynes advised Patient 13 his GP referral was intended to be a red flag referral, however it was mistakenly sent as a routine referral. Mr Haynes advised there are fail safe mechanisms in place, all referral letters received by the Trust are triaged by consultants to ensure they have the correct urgency assigned to them. In Patient 13 's situation he had blood in his your urine and although it was sent as routine referral it should have been triaged and upgraded to a red flag. Unfortunately triage did not take place in his case.

Patient 13 advised he was seen within 2 weeks once the error was identified.

Mr Haynes advised that when errors happen in health care there is usually more than one thing that goes wrong. Mr Haynes used the Swiss cheese model to demonstrate how multiple errors can happen and reflected Patient 13 's case.

Patient 13 advised he was not aware the GP mistakenly sent the referral as routine. The GP has since left the practice. Patient 13 advised all the doctors in the practice were very good and would not fault them.

Mr Haynes advised it was not intentional explaining there is a drop down menu on the system for selecting referral type; if you inevitably press the arrow it may select the wrong referral type.

Patient 13 asked would it have made a difference, the letter he received advised it would not as he was now 2 years free of bladder cancer. Would the delay have made a difference to the situation he is in now, explaining this has been life changing for him.

Mr Haynes advised with bladder cancer we would look at 2 factors, 1 the outcome, the prospect of survival. 2. What treatment you required. Mr Haynes advised that although his name was not attached to the letter he was involved in the wording referring to cancer survival. Mr Haynes explained that with some cancers there is very clear evidence that delay in symptoms can reduce the chance of long term survival. With bladder cancer time is important. The letter received recognised the referral made by the GP in June /July and identified the delay did Patient 13 at risk. However because some time has passed since treatment and Patient 13 was still her today reflects a good outcome. In most cases bladder cancer would re-occur within the first year of treatment. It is now 3 years on since treatment and Patient 13 has had no re-occurrence, advising he is lucky. At that point of treatment Patient 13 had a 2 year survival rate 50/50, however if he had been treated earlier the survival rate would have been 60/50. Fortunately the delay has not impacted him as he has had no re-occurrence at this stage down the line.

Patient 13 asked about treatment/surgery, would it have been different if treated earlier.

Mr Haynes advised what is known about bladder cancer is that if invasive it can be aggressive from the outset. The location of the cancer was always going to be invasive and Patient 13 was going to require a bag even if seen earlier. Mr Haynes advised Patient 13 he had cancer cells and either way the best treatment was the operation. When bladder cancer develops there is a further risk of cancer aggression if treatment is delayed.

DRAFT

Patient 13 advised that he had a tumour in his bladder and that one night he went to the toilet and there was blood everywhere and was advised that was his kidney giving up. Patient 13 asked if he had had the surgery earlier would this have saved his kidney and stopped it going into his prostate, he was told he had stage 4.

Mr Haynes advised he did not have stage 4 cancer explaining staging is done in 2 ways. Staging defines where the cancer is located, if it has spread or affecting other parts of the body. Stage 4 cancer would mean spread everywhere, Marsden meaning all over the body. Mr Haynes explained the TNM staging process used specifically for cancer in the bladder.

Patient 13 said the cancer did not grow into his muscle.

Mr Haynes advised it did not grow into the muscle, (Mr Haynes drew a diagram to demonstrate cancer progression in bladder and surrounding areas).Mr Haynes explained bladder cancer on the surface of the bladder is referred to as TAT1, cancer in the muscle T2, cancer in the fat T3, if it the cancer grows outside i.e. to another organ such as the prostate T4A, or the bowel T4 B. The cancer was on the surface of the bladder T1 the recommended treatment was always going to be surgery, at the time he had a non-functioning kidney and although he always has a low threshold for removing a kidney it was necessary in the case, there was cancer in the pipe leading to kidney and cancer in the urothelial.

Patient 13 said it was all taken out but he did not require chemotherapy.

Mr Haynes advised there is an additional risk with chemotherapy, there is a risk of delaying surgery before chemotherapy. Mr Haynes advised the chance of Patient 13 's position in July not requiring surgery would have been exceedingly small, he still would have had to have the surgery.

Patient 13 asked even the kidney and all.

Mr Haynes advised he believed so but advised he could not guarantee.

Patient 13 asked about the drug is this still used.

Mr Haynes advised yes it still used for some blood cancers, breast cancer and leukaemia, the risks are known.

Patient 13 talked about the time when he had dermatomyositis he had his blood washed three times. At a stage in his care he cut down on the steroids as he was on a serious dose. Patient 13 advised this drug was known to cause bladder problems. Patient 13 showed a letter from Mr O Brien who he attended and asked why did urology reviews stop.

Mr Haynes said he had blood in his water in the 1990's.

Patient 13 advised yes and he seen Mr O'Brien at the time, (Patient 13 presented a letter from Mr O Brien. Patient 13 asked should he not have been kept on the list for review even annually whilst on this drug, given the risk of bladder cancer.

DRAFT

Mr Haynes advised if there is blood in the urine then yes we would investigate, a urine dip test is not a good test for bladder cancer. Research publicised identified potential screening options for risk of bladder cancer, like patients on certain drugs the advice was to focus on patients presenting with symptoms only. In [redacted] 's case he had blood in his urine and he was referred by his GP.

[redacted] said he was never told that the drug cyclophosphamide was a chemotherapy drug. He was taking this drug for 4/5 years orally which is slightly worse than intravenously. [redacted] advised he was not griping but advised he was concerned for other people who may be taking this drug, and believed they should be kept under review.

Mr Haynes advised there is recognition of secondary cancer but from a urology perspective they do not routinely check everyone on this drug.

[redacted] said he had no symptoms.

Mr Haynes advised he had blood in his urine which was a symptom of bladder cancer.

[redacted] advised he had attended an appointment with Mr Glackin and asked about the drug and how long had he the cancer and was advised by Mr Glackin it was unknown that it could be 2 weeks or 2 years. Mr Glackin asked if he smoked or if he was a mechanic.

Mr Haynes advised there is an increased risk 2-4% of developing bladder cancer on cyclophosphamide; a smoker would have a higher risk factor. Recent publication from Sheffield underlined heavy metal, hydrocarbons, dye and chemical engineering were all linked specifically to bladder cancers. These chemicals are taken through the body.

[redacted] said he was a smoker, not a smoker now but still believes they should surveillance people on this drug. He was not advised this was a side effect.

Mr Hayes advised they did not have the knowledge 20 years ago that they do now. Today people are advised of risks, consent gained, there are different processes in place today that would not have been there 20/25 years ago. Smokers are at an even greater risk of bladder cancer and they are not routinely scanned either.

[redacted] asked the only option for bladder cancer was to take his bladder out.

Mr Haynes advised it's important they check his right kidney and pipes regularly should the cancer develop, it's important to ensure cancer does not come back.

[redacted] advised that was good and that he were happy to get scans done.

Mr Haynes advised [redacted] he has done really well and has had a good outcome.

DRAFT

Personal Information redacted by USI, Patient 13 **requested confirmation there would have been no different surgery if seen earlier.**

Mr Haynes advised no different surgery would have been performed. There was a delay and fortunately in his case the outcome has being a good one, surgery would have been always recommended.

Patient 13 **advised it was 3 years now.**

Mr Haynes reoccurrence would most likely show up in 1st year, as years go by there is a lower chance of re-occurrence.

Patient 13 **said it was good to hear this as he does not get talking to Mr Keane.**
Patient 13 **asked if his kidney could have been saved if treated earlier.**

Mr Haynes advised unlikely as there was cancer in the pipe.

Patient 13 **mentioned Mr Glackin's comment of when cancer present, could be 2 weeks or 2 years.**

Mr Haynes advised generally they don't know when cancer starts, if there was blood in July then it is likely the cancer was there but we don't know if it was there in March or July. The bleeding would have come from the bladder.

Patient 13 **said the 2 week or 2 year comment annoyed him and that he was concerned cyclophosphamide was a factor for his cancer.** Patient 13 **advised he thought he should not have been cut off for urology review.**

Mr Haynes advised it would not be practical to follow up on every drug.

Patient 13 **asked until you pass blood.** Patient 13 **advised it has been life changing for him, and specified the consequences of having to manage a stoma bag particularly at night time and relationship with his wife.**

Mr Haynes advised because of the subtype of cancer the treatment was always going to be the same, i.e. surgery.

Patient 13 **advised Mr Watt put him on a drug and asked was this right drug.**

Mr Haynes advised he did not know.

Patient 13 **asked where he goes now, he has been treated by both doctors who are currently under review.**

Mr Haynes advised he could not comment on his neurology care, aside from the delay in the urology referral and upgrade there was nothing from a urology perspective that was out of the normal. The urology treatment received was the correct treatment. The referral was a lost opportunity to be seen earlier. Mr Haynes advised he had bladder cancer, the subtype meant the prostate was always going to come away, the kidney possible saved but there was cancer in the pipe and the kidney was non-functioning. Surveillance is important following surgery in case of re-occurrence.

Patient 13 **advised he is due another scan.**

DRAFT

Mr Haynes advised it's one of those things that must be done and acts as a reminder.

Patient 13 thanked Mr Haynes for taking the time to speak to him today.

Mr Haynes thanked Patient 13.

DRAFT

Governance Office, Ground Floor, The Maples
Craigavon Area Hospital
Tel: Personal Information redacted by the USI
E-mail acute.governance@southerntrust.hscni.net

Southern Health and Social Care Trust

APPENDIX 6

Revised November 2016 (Version 1.1)

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by USI

Date of Incident/Event: January 2016 – September 2016

HSCB Unique Case Identifier: Personal information redacted by the USI

Service User Details: (*complete where relevant*)

Responsible Lead Officer: Dr J R Johnston

Designation: Consultant Medical Advisor

Report Author: The Review Team

Date report signed off: 22 May 2020

1.0 EXECUTIVE SUMMARY

During an internal review in 2016, following an Index Case, the Trust identified a number of GP Urology referrals who were not triaged by one particular Consultant Urologist; 30 patients should have been red-flag referrals and of these 4 had cancer. A fifth patient Patient 15, discovered during an outpatient clinic, was included as he was also not triaged and subsequently had a cancer confirmed.

Patient 15 a 68-year-old male was referred to Urology Outpatients on 30 August 2015 for assessment and advice for an elevated Prostate specific antigen (PSA) (The blood level of PSA is often elevated in men with prostate cancer). The referral was marked Routine by the GP. The referral was not triaged on receipt. However, a second GP referral was received on 29 January 2016 marked Suspected Cancer Red Flag and had received a red flag appointment. Following this referral, he was seen in clinic on 8 February 2016 (D153). On day 166, Patient 15 was diagnosed with a confirmed cancer; a resultant 6-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 14 a 63-year-old male was referred to Urology Outpatients on 3 June 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review, the referral was upgraded to Red Flag and was seen in clinic on day 246. On day 304, the patient had a confirmed cancer diagnosis. There has been a resultant 10-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 11 a 68-year-old male was referred to Urology Outpatients on 28 July 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of an internal review the referral was upgraded to Red Flag and seen in clinic on day 217. On day 258, Patient 11 was diagnosed with a confirmed cancer; a resultant 9-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 13 – a 51-year-old male referred to Urology following an episode of haematuria on 28 July 2016. The referral was marked Routine by the GP. The letter was not triaged and Patient 13 was placed on a routine waiting list on 30 September 2016. As part of an internal review this patient's referral letter was upgraded to a Red Flag referral. Patient 13 was reviewed at OPD on 31January 2017. Subsequent investigations diagnosed with bladder and prostate cancer. Patient 13 has locally advanced bladder cancer. There has been a resultant 6-month significant delay in obtaining a diagnosis and a recommendation of treatment for his bladder cancer.

Patient 12 a 73-year-old male was referred to Urology Outpatients on 8 Sept 2016 for assessment and advice on lower tract symptoms and elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review the referral was upgraded to Red Flag and was seen in clinic on day 152. On day 215, Patient 12 had a confirmed cancer diagnosis T3a with no nodal metastases. There has been a resultant 8-month delay in

obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Causal Factors

1. Referral letters did not have their clinical priority accurately assigned by the GP.

Referral letters were not triaged following receipt by the Hospital.

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely

manner.

Recommendation 8

The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

Recommendation 9

Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10

The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with 'difficult colleagues' and 'difficult issues', ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11

Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12

Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

2.0 THE REVIEW TEAM

Dr J R Johnston - Consultant Medical Adviser - Chair

Mr M Haynes - Consultant Urologist

Mrs K Robinson - Booking & Contact Centre Manager

Mrs T Reid - Acute Clinical & Social Care Governance Coordinator

3.0 SAI REVIEW TERMS OF REFERENCE

1. To undertake an initial investigation/review of the care and treatment of patients Patient 15, "Patient 13", Patient 12, Patient 14 and Patient 11, in the period after referral to the SHSCT Urology service using

3.0 SAI REVIEW TERMS OF REFERENCE

National Patient Safety Agency root cause analysis methodology.

2. To determine whether there were any factors in the health & social care services interventions delivered or omitted to Patient 15, Patient 13, Patient 12, Patient 14 and Patient 11 that resulted in an unnecessary delay in treatment and care.
3. The investigation / Review Team will provide a draft report for the Director of Acute Services. This report will include the outcome of the Team's investigation/review, identifying any lessons learned and setting out their agreed recommendations and actions to be considered by the Trust and others.
4. The Trust will share or disseminate the outcomes of the investigation/review with all relevant parties internally and externally including the service user and relevant family member(s) (where appropriate).

4.0 REVIEW METHODOLOGY

The Review Team will undertake an analysis of the information gathered using RCA tools and may make recommendations in order that sustainable solutions can minimise any recurrence of this type of incident. The Review Team will request, collate, analyse and make recommendations on such information as is relevant under its Terms of Reference in respect of the incident outlined above.

Gather and review all relevant information

- Inpatient notes Craigavon Hospital.
- Information from the Northern Ireland Emergency Care Record (NIECR) and Patient Administration System.
- Information from laboratory systems.
- Information obtained from relevant medical, nursing and management staff.
- Review of Relevant Reports, Procedures, Guidelines.

Information mapping

- Timeline analysis
- Change analysis for problem identification and prioritisation of care delivery problems and service delivery problems as well as identifying contributory factors.

5.0 DESCRIPTION OF INCIDENT/CASE

5.1 Triage of GP referrals - background

The general public expect that, when they engage with their GP complaining of symptoms that are potentially due to a cancer, they will be referred to the appropriate secondary care services promptly and that they will respond, also promptly, to confirm or exclude the diagnosis of cancer.

5.0 DESCRIPTION OF INCIDENT/CASE

The DHSSPSNI **Service Framework for cancer prevention, treatment and care** (Standard 13) of 2011 indicates, "*All people with signs and symptoms that might suggest cancer should be appropriately assessed by their GP and referred promptly on to hospital for further tests if needed*".

Cancer specialists, working in networks, have formulated lists of symptom and sign triggers which can signify the development of a cancer. Using these lists, primary care doctors can refer patients into secondary care; triaging a large number of patients by assigning them to different degrees of urgency (Routine, Urgent and Red-flag). If these are used as designed, this can provide an efficient referral system.

NICE have been instrumental in ensuring uniformity and the validity of these cancer recognition and referral lists of symptoms and signs. They have also formulated guidance regarding how safety nets should be setup to ensure patients are not missed. Local programmes, using this type of guidance, have been established, under the auspices of NICaN and the HSCB, to set up these triage pathways and safety nets.

5.2 Triage of GP referrals – Northern Ireland

NI Referral Guidance for Suspected Cancer (2012)

The Northern Ireland Referral Guidance for Suspected Cancer 2012 is based on the NICE clinical guideline, CG 27 - *Referral guidelines for suspected cancer,* published in June 2005. This has a section on Urological Cancer. It was introduced to GPs by HSCB correspondence (30/12/2012), revealing the new red-flag process and indicating in appendix A that, "*triaging will take place in a timely manner, within 72 hours of receipt of referral or the referral should continue with the GP Prioritisation".*

This is still the only set of referral guidance for suspected urological cancer available online on the NICaN website (last accessed 18/11/2018).

However, the 2005 CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* published in June 2015. This was endorsed by the Department of Health (NI) with HSC (SQSD) (NICE NG12) 29/15 on the 19th August 2015 which instructed the HSCB / PHA to send out the guidance to the appropriate Family Practitioners. This particular kind of guidance requires the HSCB to circulate regionally endorsed NICE guidelines to Trusts and GPs for implementation. Trusts are expected to review guidance against a base line assessment and provide HSCB with an assurance that the guidance has been implemented. If a Trust is unable to fully implement the guidance within the one-year period without regional co-ordination and/or additional resources, they should provide a formal assurance to HSCB, and this is to be managed as part of the risk management process. This assurance process does not however apply to primary care and GP's.

5.0 DESCRIPTION OF INCIDENT/CASE

NICaN Urology Cancer Clinical Guideline (2016)

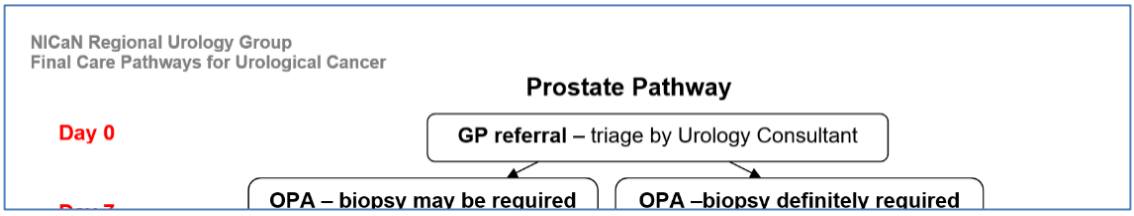
The NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016), was produced regionally to support the diagnosis, treatment and management of urological cancer. This version included amendments, to replace the previous red flag guidelines, with those from NICE NG12; the document was signed off on behalf of the NICaN by Consultant Urologist, Cons1.

The Review Team's evaluation of the advantages of NICE NG12 (2015) over the CG27 (2005) guidelines reveals fewer cases would be red-flagged for Urology, as a result of,

- a reduction in number of non-visible haematuria patients; and
- increases in age criteria of 45 years and over.

However, rollout of NG12 by the HSCB does not appear to have happened. The Review Team understands that the reason NG12 has not been implemented lies with ongoing discussions between the HSCB and GPs.

Appendix 2 of the NICaN Urology Cancer Clinical Guideline guidelines highlights the Urology Care pathways. Cons1 was present at the workshop discussing those on 02/10/2008. It clearly indicates that, for the Prostate pathway, the GP referral would be triaged by the Urology Consultant.



5.3 Triage of GP referrals – SHSCT

The process of Urology triage in CAH is based upon the NI Referral Guidance for Suspected Cancer of 2012 as described above i.e. it is based on the 2005 NICE CG27 guidelines and not the more up to date 2012 NG12. In CAH, triage of referrals is performed by the Consultant Urologist of the week.

The SHSCT Urological Cancer multi-disciplinary team (MDT) was led at the time by Consultant 1 (Cons1), who was also a joint chair.

Over a period of decades, within the SHSCT and Craigavon AH, there were occasions when triage was not performed; and this varied between consultants and specialities. Acute Services had a particular problem with this issue. Preliminary discussions by the Review Team revealed that triaging within Acute Services was a, "*very haphazard process going back for approximately 25 years. There were many Consultants who would not triage but Consultant 1 was the most persistent and there were multiple attempts to tackle this issue*".

5.0 DESCRIPTION OF INCIDENT/CASE

Interview with Associate Medical Director (AMD1)

AMD1 first became aware of waiting list problems with Cons1 in 1996–8 when AMD1 was the lead clinician in outpatients. Cons1's OPD letters were being kept in a ring binder and were not on any waiting list. Once challenged, Cons1 would stop this practice and improve but would then slip back. There were further non-triage meetings with Cons1 when AMD1 was the Clinical Director of Surgery.

Interview with Director of Acute Services (DAS2)

In 2007, DAS2 (while in previous post in CAH) found a waiting list which was 10 years long. They worked on this with the Consultant, Cons1, and cleaned it up; they found no serious patient related issues.

Interview with Director of Acute Services (DAS1)

DAS1 indicated that the Urology Services were under various kinds of pressure during her time as Director. There was a regional transformation project in place for Regional Urology Services under Mr M. Fordham; this generated an element of pressure to modernise and change. Along with this and other issues, including the triage problem, Consultant 1 struggled to adapt to these changes and to comply with the other issues and triaging. DAS1 paints a picture of many issues with Cons1, triaging being only one of many issues but, in her opinion, not the most important issue.

Nevertheless, in April 2010, Consultant 1 (Cons1) was put under pressure to complete his triage list. The surgical Associate Medical Director (AMD1) brought concerns to DAS1. The other Urologists had been 'covering' triaging for Cons1; the Head of Service Surgery had informed AMD1 of this. They met Cons1 the next day. The European Association of Urology meeting was in Spain the following day and Cons1 wished to attend. DAS1 and AMD1 informed Cons1 he would not be attending the meeting unless he triaged all his referrals immediately. Cons1 duly addressed the triage backlog, completing them that evening. From that time on, AMD1 and the Head of Service (HoS1) monitored that Cons 1 was triaging the GP referral letters. However, DAS1 commented that the HoS1 had a difficult job managing Cons1.

Following interview with Head of Service (HoS1)

The Head of Service for Urology (HoS1) indicated that she inherited the problem upon appointment although she was aware that it was a long running issue, going back perhaps 25 years. She highlighted this was an ongoing issue with Cons1. He had the longest backlog and took longest to triage. There were issues with other Consultants who, on occasion, did not triage but Cons1 was the only one, when asked to triage, didn't do it. This came to head in 2010 (referred to above) and again in 2014.

Informal Default Triage (IDT) process

In May 2014, after escalation to HoS1, an Informal Default Triage (IDT) process was put in place by the Trust's booking centre. This process allowed the booking office to allocate

5.0 DESCRIPTION OF INCIDENT/CASE

patients, who had not been triaged in time, to be allocated to a 'waiting list' using the GP triage category. Therefore, this IDT process of putting patients on the waiting list without triage meant that they did not get missed. However, some patients, who should have been triaged as a red flag, waited on the waiting list with their 'incorrect' GP triage category. After much discussion, this detailed process was formally circulated to all specialties on the 6th November 2015 by the Assistant Director of Support Services (ADSS1).

When questioned about this IDT process, the DAS2 was not aware of it even though it started during her time in post i.e. May '14. When asked about its potential problem of leaving incorrectly triaged (by their GP) patients on a waiting list she stated, "*Completely ridiculous, because would allow a cancer patient who should have been red flagged by their GP to go unchallenged by a Consultant triage process i.e. could have to wait for 11 months*".

5.4 Index case

In 2016, the SHSC Trust investigated (RCA ID [redacted]), in what subsequently became an 'Index case' for the cases in this RCA, the treatment and care of [redacted]. [redacted] was a patient who had had Ca Colon (2010), breast carcinoma (2013) and then developed renal carcinoma. During review for her Breast Ca in June 2014, a CT Scan revealed that, previously noted, renal cysts had increased in size. Further investigation by a MRI scan was reported in a limited and incomplete fashion; resulting in a 'routine' referral GP letter on 29/10/2014.

During the investigation, the Review Team identified that [redacted]'s GP referral letter had not been triaged; the Consultant Urologist with responsibility that week for triage duties was Cons1. This referral therefore waited as a 'new routine' referral till January 2016 to be seen by a Consultant Urologist.

The index case Review Panel agreed 3 main contributing factors led directly to [redacted]'s delay in diagnosis. Firstly, the content of the MRI report; secondly a letter following a CT scan did not mention important information and thirdly, the opportunity to upgrade the referral to red flag was lost by the omission of triage; this resulted in a 64-week delay to diagnosis of a suspicious renal mass.

The index case Review Panel concluded in March 2017 that, ".... *a significant number of letters within Urology are not being triaged by the minority of the Team. It is clear that the default triage management process (*vide infra*) continues to be initiated secondary to the omission of Triage by individual members of the urology team and not the entire Urology Team*".

Of the 2 lessons learnt, one indicated that,

> "*Triage of GP referral letters remains a key element in validating appropriate utilisation of specialist services and ensuring patient safety. Triage also serves as an opportunity for early intervention for patients at risk of malignant disease or clinical deterioration*."

5.0 DESCRIPTION OF INCIDENT/CASE

This led to a recommendation that,

> "*This SAI has demonstrated that patients will be at an increased risk of harm when the opportunity for early intervention at Triage is omitted. The Review Panel recommend that the Trust reviews the process which enables the clinical triaging and escalation of triage non-compliance in accordance with the Integrated Elective Access Protocol (IEAP).*
>
> *In particular the fundamental issue of triaging GP referral letters remains a challenge within Urology. The Urology operational and medical management teams immediately need to address the issue of un-triaged referrals not being processed in accordance with IEAP.*"

The findings of this investigation, chaired by Consultant Urologist 2 (Cons2), were made available in December 2016 and formally signed off on the 15th March 2017. A letter highlighting a number of concerns was sent to the (then) lead for Acute Governance for Acute Services (AGAS1), on the 15th December 2016.

The letter pointed out that the IDT process implied that triage non-compliance was to be expected but that this process did not have a clear escalation plan to include the individual Consultant and, indeed, had not been effective in addressing triage non-compliance. Furthermore, the letter pointed out that, from July 2015 till October 2016, there were 318 non-triaged letters which the Trust could not provide assurance that patients were not being exposed to harm by waiting as a routine or urgent appointment i.e. when they should have been red-flagged.

It is not absolutely clear who wrote this letter as it has no signature, but it appears to have been written by, or on behalf of, Cons2. On the 10th January 2017, Cons2 was requested by the Medical Director (MD3) to share the report with the 2 key Consultants involved in the SAI. One of these was Cons1. Cons2 refused, stating that he was Cons1's colleague and not his manager.

This letter was escalated to the Director of Acute Services (DAS3) and the Assistant Director of Anaesthetics & Surgery. This was further escalated to the Chief Executive of the SHSCT.

Cons1 was written to by AMD1 on the 23rd March 2016, acknowledging his hard work as a Consultant Urologist but pointing out that there were governance and patient safety concerns with regard to untriaged letters dating back over 2 years, and other important issues. Cons1 was asked to respond with a commitment and immediate plan to address these issues.

The Review Panel also determined that there were 7 other patients who were not triaged that week along with Patient 10. They subsequently performed a 'look-back' exercise (number 1) of these referrals. Of the seven referrals, six charts were available and each patient had an appropriate

5.0 DESCRIPTION OF INCIDENT/CASE

management plan. One set of notes were missing and efforts were made to find them.

Cons1 provided his personal review, dated 25/01/2017, of the Index Case to the Chairman of this Review Team. It provides an argued retrospective rationale that a timely triage by himself would not have altered the referral grading. However, it does not provide a sound reason for his actual lack of triage. His report is consistent in arguing his view that he does not have time to perform both Consultant of the Week (CoW) duties and triaging of non-red flag referrals.

5.5 Look back exercise #2

Upon realisation that the 'look-back' exercise #1 had resulted from non-triage over the week beginning the 30/10/2014, further efforts were made to investigate the size of this non-triage issue and to find missing referral letters. Cons1 was contacted and the Head of Service for Urology (HoS1) obtained permission to look for missing GP referral letters in his filing cabinet. Cons1 stated that there were referral letters in a filing cabinet in his office. During interview, he stated that he kept the referrals to ensure they would not be missed or overlooked. The Head of Service for Urology retrieved these referral letters, which numbered over 700 along with the triage lists from the booking centre.

These referrals were then reviewed by the Urology Consultant Team revealing 30 patient referrals should have been red-flagged and four of these patients, following review, were diagnosed with cancer, becoming the subject of this review.

This (RCS Personal Information redacted by the) Review Team reviewed the clinical notes from these 4 patients and following discussion, under the Urological guidance of AMD1, detailed the clinical course and made the following conclusions.

Patient 14

03/06/2016 - 63-year-old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
09/08/2016 - added to W/L Urgent.
27/01/2017, as part of the internal review #2, the referral was upgraded to R/F and was seen in clinic on day 246. Therefore, this was an incorrect GP referral.
05/04/2017 (D304), following U/S guided biopsy, the patient obtained a confirmed cancer diagnosis and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 10-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 11

28/07/2016 - 68-year-old male referred to Urology Outpatients by GP for assessment and advice, concerning elevated PSA.
The referral was marked Urgent by the GP.

5.0 DESCRIPTION OF INCIDENT/CASE

The referral was not triaged on receipt.
30/09/2016 - added to W/L Urgent.
18/01/2017 - as part of an internal review #2, upgraded to R/F. Therefore, this was an incorrect GP referral.
20/02/2017 (D207) seen at R/F appointment. Sent for MRI and prostate biopsy.
11/04/2017 (D258) - diagnosed with a confirmed low risk prostate cancer and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 9-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 13 28/07/2016 - 51-year-old male referred to Urology by GP following an episode of haematuria.
The referral was marked Routine by the GP.
The letter was not triaged.
30/09/2016 - Patient 13 was placed on a Routine waiting list.
19/01/2017 - As part of an internal review #2, upgraded to a R/F referral. Therefore, this was an incorrect GP referral.
31/01/2017 (188d) - reviewed at OPD and flexible cystoscopy.
22/02/2017 TURBT/TURP - diagnosed with bladder (locally advanced) and prostate cancer and there was a recommendation of treatment for his bladder cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is clinically significant; time will tell*.

* The Review Team referred to an expert for advice.
Delay in definitive surgical treatment beyond 12 weeks conferred an increased risk of disease-specific and all-cause mortality among subjects with stage II bladder cancer. He remains disease free as of September 2018.

1. John L. Gore, Julie Lai, Claude M. Setodji, Mark S. Litwin, Christopher S. Saigal, and the Urologic Diseases in America Project. Mortality increases when radical cystectomy is delayed more than 12 weeks. Results from a surveillance, epidemiology, and end results–Medicare analysis. Cancer March 1, 2009.
2. Nader M. Fahmy, Salaheddin Mahmud, Armen G. Aprikian. Delay in the surgical treatment of bladder cancer and survival: Systematic Review of the Literature. *European Urology 50 (2006) 1176–1182.*

Patient 12 08/09/2016 - 73-year-old male was referred to Urology Outpatients on for assessment and advice on lower tract symptoms and elevated PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
27/01/2017 – further GP letter – please upgrade to R/F.
30/01/2017 - as part of the internal review #2, upgraded to R/F.

5.0 DESCRIPTION OF INCIDENT/CASE

06/02/2017 - seen in clinic on day 152.
11/04/2017 (D215) - confirmed cancer diagnosis T3a with no nodal metastases – high risk and there was a recommendation of treatment for a locally advanced non-metastatic prostate cancer.

Conclusions

Resultant 8-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is not clinically significant.

At a later date, towards the end of 2018, another patient came to the attention of the Review Team – Patient 15. This patient could also have been one of those found in Cons1 filing cabinet but appeared at an outpatient clinic before the outworking of the look back exercise #2. A Consultant Urologist realised in the clinic that this was also a Cons1 non-triaged patient who was incorrectly referred by their GP.

Patient 15 30/08/2015 - 63-year-old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Routine by the GP.
The referral was not triaged on receipt.
29/01/2016 2nd GP referral marked as Suspected Cancer – Red flag; Patient 15 was added to W/L R/F following this referral.
As part of the internal look back #2, the referral was noted.
Patient 15 had already received an appointment and was seen in clinic on day 153. Therefore, 1st GP referral was incorrect; the 2nd was a correct GP referral.
11/02/2016 (D166), following a prostate biopsy, the patient obtained a confirmed cancer diagnosis T3a and there was a recommendation for treatment of a prostate cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is felt that the delay is unlikely to be clinically significant.

7.0 CONCLUSIONS

The Review Team interviewed a number of Trust staff including Directors (past and present), an Assistant Director, Head of Service and an Associate Medical Director as part of the review process. These interviews, along with clinical documents and health records systems, have helped inform the conclusions by providing the evidence and also corroboration where there appeared to be differences of opinion.

The Review Team and everybody interviewed, including Cons1, provided affirmation that a timely, efficient triage system which checked the initial GP referral was very important to patients. Comments made when interviewees were asked about the importance of triage and where the process of triaging a potential cancer patient ranked alongside other issues such as probity, patient experience and performance, were consistent,

"Very significant". Very high up the list in terms of importance".
"It is fundamental people are seen in the appropriate time".
"Very important" ... "Important for the patient".
"Vital" ... "Very significant .. patients are often anxious and depend on the system to work".

Cons1 replied,

"It is a serious issue, very important"..... "Number one ranking in overall scheme of things"

The Review Team established that there were factors in HSC service delivery to the 5 patients under examination that resulted in an unnecessary delay in treatment and care. In 4 patients the delay was thought not to be clinically significant but in 1 [redacted] there probably was a significant delay.

Consideration of the causative factors to the patients' delays reveal,

- Referral letters did not have the clinical priority accurately assigned by the GP; and
- Referral letters were not triaged following receipt by the Hospital.

7.1 Referral letters did not have the clinical priority accurately assigned by the GP.

Contributory factors

Task Factors (policy and guidelines)

The Review Team reviewed the GP referrals regarding the five patients listed above. They concluded, as judged from the Northern Ireland Cancer Network (NICaN) Referral Guidance for Suspected Cancer (December 2012), that all five patients should have been referred to Urology by the GP's as red flag referrals (suspected cancer) i.e. incorrect triage.

Task Factors (decision aids)

The current decision aid for GPs is the NI Referral Guidance for Suspected Cancer 2012 based on NICE CG 27 *Referral guidelines for suspected cancer* published in June 2005. It is clear that Secondary care, in the form of Consultant Urologists, should triage these GP referrals; by doing so, 11% of GP referrals are changed (from Review Team member). It is also clear that Cons1 would have been in no doubt as to his responsibilities; he was intimately

involved in setting this standard and signed off the NICaN clinical guidelines.

However, it is clear this very important and critical triage safety net, work can be considered onerous and other electronic methods which GPs can use might be more efficient and help to reduce that load.

According the HoS1, most patient referrals by GPs to Trusts for outpatient appointments are now made through the electronic Clinical Communication Gateway (CCG). However, some paper referrals are still received. CCG is a digital referral system for Primary care which can contain referral criteria that meet NICE and NICaN guidance. This would enable appropriate clinical triaging of referrals to be performed as part of the selection of referral reasons and/or symptom description.

Using the electronic CCG pathway, some clinical specialties, such as gynaecology, have worked closely with the Public Health Authority to develop a better GP referral tool e.g. using 'banner guidance' (a specialty specific banner, listing symptoms and signs) which complies with NICE/NICaN guidance. This 'banner guidance' helps by directing clinicians to use the NICE/NICaN referral criteria which allow for timely and appropriate triage of patients to clinically appropriate appointment types. It is possible when red flag symptoms are chosen that an immediate alert could go to the Red Flag booking team, to allow the appointment booking process to begin immediately. However, currently, the referral criteria fields are optional i.e. not mandatory, so opening up the possibility that fields are not completed, leading to error and delay.

NICE NG12
The reference CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* but, despite being endorsed by the DHSSPSNI and accepted by the Regional Urologists, it has yet to be implemented. Its use as a triage standard should result in fewer red-flagged cases which should ease some of the pressure on waiting lists. Its adoption would take place in primary care and should form the basis of the electronic CCG referral tool.

There was a consistent medical staff view from the Review Team, the AMD1, and indeed Cons1, that GP's have a crucial and important responsibility in getting the referral criteria/urgency category correct. If the GP does not provide enough, or the correct information, the NI Electronic Care Record (NIECR) needs to be checked and that slows the whole triage process down. It was clear that the triage system works best when the initial GP referral is usually correct and the Secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

7.2 Referral letters were not triaged following receipt by the hospital.

Contributory factor

Task Factors (policy and guidelines)

The Integrated Elective Access Protocol (IEAP) (DHSSPS, April 2008) defines the roles and responsibilities of staff (in both primary and secondary care) when patients enter an elective care pathway. It states,

> '*…an Executive Director will take lead responsibility for ensuring all aspects of this Protocol are adhered to…. Patients will be treated on the basis of their clinical urgency with urgent patients seen and treated first*'.

The Principles for booking Cancer Pathway patients states,

> "Clinical *teams must ensure triage is undertaken daily, irrespective of leave, in order to initiate booking patients*".

and,

> "*Referrals will be received, registered within one working day and forwarded to Consultants for prioritisation*".

However, the IEAP states,

> *"…if clinical priority is not received from Consultants within 72 hours, processes should be in place to initiate booking of urgent patients according to the GP's classification of urgency".*

Following on from the IEAP of 2008, national and regional policies and guidelines, already referred to above, have been introduced which have outlined the detailed role of the Urology Consultant in triaging referrals that have come in from Primary care e.g.,

- Service Framework for cancer prevention, treatment and care (Standard 13) 2011;
- NI Referral Guidance for Suspected Cancer 2012; and
- NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016).

These have provided agreed lists of the critical symptomatology of Urological cancers and the roles and responsibilities of Primary and Secondary care staff in ensuring patients receive prompt recognition and treatment of their cancer.

Review of Adult Urology Services in Northern Ireland

In March 2009, a *Review of Adult Urology Services in Northern Ireland - A modernisation and investment plan* was published. Its External Advisor was Mr Mark Fordham. SHSCT Consultant Urologists were represented on the committee.

Recommendation 4 states, "*Trusts must review the process for internal Consultant to Consultant referrals to Urology to ensure that there are no undue delays in the system".* Consultants indicated that they would routinely upgrade a significant number of routine and urgent referrals (GP) to urgent or red flag. It was noted that the development of agreed referral guidelines/criteria for suspected Urological cancers was a priority piece of work for the recently formed NICaN Group. That work was led by Cons1; see page 6.

Section 3.31 of the report indicates that, "*Consultant Urologists unanimously consider that referral triage should be led by Consultants. With over 40% of referrals being cancer related*

(and with many not red flagged or marked urgent) they believe that they are best placed and skilled to undertake the triage process. They also believe that despite the volume of referrals, this is not a particularly time consuming process."

Contributory factor

Staff factor

It is obvious from reading the documents referred to above that Cons1 has been aware of developments in this field and, indeed has been party to the discussions and signed some of them off. Cons1 was chair of NICaN (Urology) and was involved in drafting the NICaN regional Urology guidance, and therefore was very familiar with the requirement to triage GP referrals.

Despite all of this, and even though Cons1 agreed that this triaging role was, "*very important*", …. it was, "*a very serious matter not to be minimised, very serious"* he stated he would not triage non-red flag referrals.

When asked, *"Does triage still need done?"* Cons1 answered*, "a procedure is needed to highlight when it needs done and who does it".* When further asked, *"Who was involved in SHSCT Urology service in setting up triage"?* Cons1 answered for urological cancer, "*I was the Lead"*.

He felt triage of referral letters was too time consuming and the amount of time spent on triage, in his opinion, rendered inpatient care unsafe. He highlighted that he had previously escalated his concerns about work load to management teams and medical directors.

In relation to triage, Cons1 stated, '*I would love if we had a Trust Urology agreement on the type of triage to be conducted*'. When it was pointed out that, "*Consultant colleagues did triage for you. How did they do it?"* He stated, "*It depends on how you do it"* ..... "*Not all do advanced / enhanced triage, they compromise. It is a spectrum"... "They have not done it in the detail I felt it needed for routine/urgent non-red flag case".*

When questioned further, regarding his way of organising his own work load, Cons1 stated, '*....yes I did it my way – I wasn't cognisant of being unbending, I am very particular*'.

Cons1 highlighted to the Review Team that he currently takes annual leave each Friday and spends the weekend triaging. He stated that it is impossible to be Urologist of the Week and triage referrals appropriately. He stated he still can't do triage and everything else. He stated, '*I do triage entirely in my own time to allow me to do it properly'*.

When asked about using the NIECR - Electronic Referral using the Clinical Communication Gateway (CCG) method, Cons1 stated found the new CCG triage system*, "Very, very good, I wish all information was available on ECR. It is less time consuming. ECR makes it easier to check information".*

The Review Team concluded that there was a serious inconsistency between the guideline

standard that a Consultant should triage GP referrals (which Cons1 helped to construct) along with his stated view of the crucial importance of triage and Cons1's actual practice.

Cons1's chosen method of triage was beyond what is required. His triage is the equivalent of a virtual clinic where he reviews NIECR and books investigations for patients. While the Review Team recognised this was a detailed triage process, they concluded that his prioritisation of work and attention to detail meant that some patients got a higher standard of triage/care, while, crucially, others were not triaged, leading to a potentially critical delay in assessment and treatment for those patients. Cons1 is aware of this.

The Review Team concluded that Cons1's prioritisation of work and attention to detail led to some patients receiving a high standard of care, while others ran the real risk of having a cancer diagnosis delayed till it was dangerously late.

Contributory factor

Work load/scheduling

In 2008, when the IEAP was published, there was a maximum waiting time of 9 weeks for a first Outpatient appointment. On 30th September 2016, there were 2012 patients on the routine Urology outpatient waiting list, with 597 patients showing as waiting 52 weeks and over. The longest waiting time was 554 days (80 weeks). Therefore, if patient referrals are incorrectly referred, or not triaged and continue to use the GP's classification of urgency, there will be a significant wait. Cons1 is aware of this reality.

The Review Team considered the Consultant of the Week (CoW) work load, including ward rounds, clinics, emergency theatre sessions as a contributory factor. Cons1 has consistently argued that he cannot triage non-red flag referrals and carry out the duties of the CoW. He has not indicated who else should carry out the triage duties. However, the Review Team note that the other Consultant Urologists were able to manage this work load and triage referral letters in a timely fashion, with other members of the consultant team also ordering investigations, providing treatment recommendations and adding patients directly to waiting lists, similar to outcomes achieved from Cons1's 'advanced triage'.

Contributory factor

Organisational

The Review Team concluded that the non-triage of Urology referrals by Cons1 has been an ongoing problem in the Trust for many years, possibly decades. While there were pockets of non-compliance by other Consultants, when escalated, compliance improved. However, the Review Team note that Cons1 consistently did not return triage information on referrals thus not allowing the appropriate prioritisation of appointments by clinical need.

Interviews with 2 previous and the current Director of Acute Services, AMD1 and the Head of Surgery Service have highlighted that on many occasions, over a prolonged period, attempts had been made by the Trust's officers to address Cons1's non-compliance with triage. These

attempts encompassed both direct face to face conversations which were often heated, correspondence and, as in 2010, study leave refusal until there was compliance. These interventions all resulted in a familiar pattern of response; temporary improvement in compliance with triage, followed by a return to non-compliance.

In 2014, due to continuing non-compliance, the Trust implemented an 'Informal' Default Triage Process to manage the referrals which were not being triaged and returned to the Booking Centre. The Review Team considered the intention of this process was to prevent any delay in patients being added to the waiting list. However, this meant the 'non-return of triage' was not individually addressed with the non-compliant clinicians. Furthermore, and most importantly, it allowed patients, who should have been red-flagged, to remain on a waiting list until review.

In 2014, the Director of Acute Service 2 (DAS2) discussed non-compliance with Cons1 and agreed that Cons1 would no longer triage referral letters. Cons1 was heavily involved with formulating the NICaN Urology guidelines at the time and was grateful to the extent that he thanked DAS2.This task was delegated to other Urology Consultants for a time. However, Cons1 does not recollect having to formally stop triage. At interview, DAS2 was not aware that he had resumed those duties; she remembered that their Cancer performance figures improved when Cons1 was not triaging.

Escalation within Organisation
At every interview, questions were asked whether Cons1's consistent and prolonged non-compliance with triaging was referred upwards to executive level i.e. the Medical Director and Chief Executive.

Director DAS1 considered that the problem was being managed at Service level, although as it was only one of a series of issues and considered to be a 'minor' one, it did not predominate at higher level meetings with the Medical Director (MD1); to the extent that he may not have been aware of it.

Director DAS2 considered that the problem was dealt with by agreeing with Cons1 to stop triaging. There were other issues that were flagged up to MD2, but she was not able to remember whether MD2 was made aware of the triage problem.

During DAS3's current tenure Executive members certainly knew; at CAH Oversight meeting level and at the time of the look back exercise #2 which ultimately led onto this SAI and RCA process. The Medical Director (MD3) was directly involved in the RCA process and the CEO was aware. At Trust Board level, it is thought that a non-Executive member was asked to examine the situation which would indicate that it had also reached that level.

Overall, the Review Team in considering whether there was a satisfactory escalation of this 'non-triage' issue have concluded that there was no evidence of consistent and proactive escalation of 'non-return of triage' either to the Medical Director or the Chief Executive until the look back exercise #2 basically forced the seriousness of the issue out into the open. Indeed,

they do not appear to have appreciated the importance of triage, certainly from the patient's perspective. The Trust's officers made efforts to address Cons1's non-triage over time but were consistently thwarted by Cons1's refusal to comply. The Trust failed to put systems, processes and fail safes in place to ensure Cons1's consistently triaged patient referrals until 2017.

Systems and processes have now been put in place so that the Head of Service for Urology reviews Cons1's compliance with triage. HoS1 will check all Urology triage on an adhoc basis but, with Cons1, she will check daily when he is the Consultant of the Week. Any non-compliance with returning referrals without triage is addressed immediately. However, this process is heavily dependent on HoS1 who, when she is on leave, often has to recover non-triaged cases upon her return.

8.0 LESSONS LEARNED

1. The clinical urgency category allocated by GPs to 30 patients referred to Urology were incorrect. The referrals using NICaN guidance should have been referred as a Red Flag. Four (plus 1) of these patients were subsequently shown to have cancer.

2. The process of triaging Urology cancer referrals from Primary Care to Secondary Care, under the direction of the HSCB, appears to be less efficient than it could be, bearing in mind that NICE NG12 guidance has not been adopted and electronic referral using CCG is not being used as efficiently as it could.

3. GP's are not mandated to provide HSCB with an assurance that they comply with the most up to date NICE or other guidelines. Therefore, HSCB are unaware of any risks consequent upon the non-compliance with NICE and other guidance within GP practices.

4. GP's are not mandated to refer patients using CCG clinical criteria banners; this can lead to error and delay.

5. There is no Regional or Trust guidance or policy on what is expected of clinicians when triaging referral letters. Triage of patient referrals is obviously viewed as extremely important but does not seem to be at an equivalent level of importance when ranked alongside other clinical governance issues. Despite being an evident problem for decades and requiring considerable time and effort to find a solution, it only really surfaced within the Trust after an Index case forced the situation out into the open.

6. Despite it being absolutely clear to Consultant 1 (based upon his close proximity to the development and signing off of regional guidance) of the consequences of non-triage, he did not routinely triage referral letters. The Review Team consider that Cons1's refusal to triage to a level similar to other clinicians, led to patients not being triaged,

and this resulted in delays in assessment and treatment. This may have harmed one patient.

7. Cons1 confirmed that despite the Trust reminding him of the requirement to triage, he did not consistently triage referrals. He argued that, due to time pressures, he felt he was unable to perform the duties of the Consultant of the Week and his triaging duties. He has highlighted those views to Trust operational and management teams over a number of years.

8. The Trust made efforts to address Cons1's non-triage over time. However, the Trust failed to put systems, processes and fail safes in place to ensure Cons1 consistently triaged patient referrals until 2017. However, this safeguarding process is heavily dependent on the Head of Service checking triage is completed when Cons1 is Consultant of the Week.

9. The Informal Default Triage process allows patients who should be red flagged to remain on a waiting list of routine or urgent cases.

10. From examining the triaging issue over the length of time it has existed, it is obvious that there is an unwillingness or inability within the medical hierarchy to tackle its 'difficult colleague' problem. The reasons behind this probably include not taking ownership of its own problems and poor support from senior medical management perhaps resulting in issues not being referred upwards.

9.0 RECOMMENDATIONS AND ACTION PLANNING

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely manner.

Recommendation 8

The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 9

Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10

The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with 'difficult colleagues' and 'difficult issues', ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11

Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12

Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

10.0 DISTRIBUTION LIST

In addition to the Review Team, the following.

Mr S Devlin, Chief Executive SHSCT.

Dr Maria O'Kane, Medical Director, SHSCT.

Mrs Melanie McClements Interim Director of Acute Services.

Health & Social Care Board (HSCB).

Chairs of Morbidity & Mortality Groups SHSCT.

Southern Health and Social Care Trust

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information redacted by the USI

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	✓	
	Comment: 5 ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**	✓	**NO**		
	If **YES**, insert **date informed**:19.2.18				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	✓
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			✓

Southern Health and Social Care Trust

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2							
INFORMING THE CORONERS OFFICE **(under section 7 of the Coroners Act (Northern Ireland) 1959)** ***(complete this section for all death related SAIs)***							
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date report shared**:						
	If **NO**, please provide details:						
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**
	If **YES**, insert **date informed**:						
	If **NO**, please provide details:						

DATE CHECKLIST COMPLETED	**22.5.2020**

[1] *Service User or their nominated representative*

Southern Health and Social Care Trust

Quality Care - for you, with you

19 February 2018 **Our Ref:** [redacted]

Private & Confidential

Mr [redacted]
[redacted]

Dear [redacted]

The Southern Health and Social Care Trust received a urology referral from your GP. There was a delay in the processing of this GP referral.

When the Trust identified this delay it commissioned a Serious Adverse Incident (SAI) review. The purpose of the SAI review is to establish what happened, why it happened, impact if any on patients and what learning could be obtained. In order to have a degree of independence and integrity, the SAI review is chaired by senior doctor not directly involved in the patient's care.

An integral part of this SAI review is to engage and inform those patients included in the review. To this end The Trust would encourage your participation in the SAI review whilst fully understanding and respecting if you choose not to participate.

Mr Mulgrew if your preference is to wait until the SAI review is completed I will write to you again to offer the sharing of the draft report and provide you with an opportunity to comment on the report.

However should you wish to take up this opportunity or require additional information please contact Mrs Trudy Reid on [redacted]

Yours sincerely,

[redacted]

Mrs Esther Gishkori
Director of Acute Services

Now, we know from the papers that you were referred in on the 28th July of 2016 and this letter is coming to you then in February 2018?

A. Oh, yes, with the SAI.

20 Q. Yes. 10:17

A. Yes.

21 Q. And it then goes on, I'm not going to go into the details, but it explained to you in that letter what a Serious Adverse Incident Review entailed.

A. Yeah. 10:17

22 Q. It gave you the opportunity to participate in that investigation and encouraged you to do that. And it also then said it was your preference to wait until the SAI Report was complete, and did you contact the Trust at all when you got that letter about that SAI? 10:18

A. No, I just received the letters and I think I did maybe mention to Dr. Brannigan about it, the GP. I was just more concerned about trying to get better and trying to cope with what happened to me. I was just letting this SAI, it wasn't actually in my head every day like this here is, you know. 10:18

23 Q. Yes, you were just letting it take its course?

A. Just letting it take its course. I was more concerned about Dr. Brannigan, I was seeing him regularly, even Dr. Joe Hackett before that, I had been up maybe, I don't know how many times a year, just to keep an eye on my CK readings because I had told him about the muscle problem. And [redacted] was the same, I would have seen him regularly. 10:18

A. I met Mr. Haynes.
34 Q. And he certainly was able to answer all the questions, I think that was in November 2020 you met with him?
A. That's right, yeah.
35 Q. And he was able to answer all the questions that you asked about your treatment, about your bladder cancer, about the drugs -- 10:23
A. Oh yes, he was very informed so he was, and he is a very good doctor too because he saved my Personal Information redacted by USI [redacted] a few years ago and Personal Information redacted by USI [redacted]. I have good regards for Aidan as well and Michael Watt, they done their best for me I thought at the time, you know. Obviously they were snowed in with work too maybe. 10:23
36 Q. But certainly in regards to the communication with Mr. Haynes, you felt that he was able to answer the questions that you were asking and that you wanted answers to? 10:23
A. Well, he answered the questions. But if they were satisfactory for me, I don't think they were, because I would have looked at some of them a different way but... 10:24
37 Q. I think one of the things that you were concerned about was whether or not the drug that you had been on had actually caused the cancer? 10:24
A. That's correct.
38 Q. Wasn't that the big worry?
A. Yeah, it was Mr. John Keane actually said it to me in the City Hospital that he done the -- he was the

surgeon and it was him said to me about the Cyclophosphamide, he mentioned. Anybody that I've went to, even the glaucoma in my eyes from 2000, Mr. Sharkey, the Ophthalmologist, whatever you call them, he highlights the Cyclophosphamide. Every doctor or anything I've went to, this Cyclophosphamide keeps hitting me, you know, and nobody seemed to follow anything up, you know, I'm on such a high dose of it. 150 milligrams-a-day, 50 in the morning, 100 at night or whatever it was. 10:24 10:25

39 Q. Just in relation to Mr. Haynes, there was one question, according to what you told us in your questionnaire and that's at PAT-000479, you had asked him if you hadn't gone back to your GP in early January 2017 to find out what was the delay in Urology contacting you, when did he think you would have been called and he didn't answer? 10:25

A. That's correct.

40 Q. But he seemed to give you reassurance that the delay hadn't adversely affected your bladder cancer? 10:25

A. That's correct.

41 Q. And that your treatment path would have been the same?

A. Would have been the same, yeah. But he did mention it could be something to do about the invasive, something to do with the muscle, possibly could be one or the other I think in that letter too, type of a bladder cancer. Non-invasive or invasive, I'm not sure. I don't know if it's in the thing, maybe you have it in the letter there. But he answered the questions that 10:25

I asked him anyway.

I mentioned to him about this Cyclophosphamide again and he said that it was, smoking is the biggest cause of bladder cancer, and he said, do you smoke? And I says, well I did smoke until I got my diagnosis and I smoked about 10-a-day. So he seemed to be blaming more on the smoking end of it than being on that drug. 10:26

42 Q. Well I'm not a medical expert, I wouldn't like to comment at all on that. But did you ever, when you were told that there was this Serious Adverse Incident Investigation being carried out, you were told that in February 2018? 10:26

A. Mm-hmm.

43 Q. But you didn't get a report until two years after that, did you ever question the delay? 10:26

A. I was just more worried in living and trying to cope with the condition I was left with. And scans, and hoping scans, hoping the phone doesn't ring after you get a scan and things like that. 10:27

CHAIR: That's fine. Well [redacted], thank you very much. I don't have any more questions that I want to ask you, but I'm going to hand over to my co-panellist here, Dr. Swart, and she may have something that she wishes to ask. 10:27

DR. SWART: So thank you very much for telling us how it has impacted on you so far and I am sure you will have more to tell us. I'm interested in what information you were given at various stages about the

Southern Health and Social Care Trust

26 November 2018 **Our Ref:** [redacted]

Private & Confidential

[redacted]

Dear [redacted]

I refer to my letter of 19 February 2018. Unfortunately there has been a delay in the review of your GP referral to Urology. I regret this review has taken longer than we had hoped. Please accept my apologies for this delay.

We would hope to be providing you with a copy of the report as soon as possible however in the interim if you wish to speak to Mrs Trudy Reid who is coordinating this review please telephone [redacted] or email acute.governance@southerntrust.hscni.net.

Yours sincerely

[redacted]

Mrs Esther Gishkori
Director of Acute Services

Clinical and Social Care Governance Team
Directorate of Acute Services
Ground Floor, The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: [redacted]
Email: acute.governance@southerntrust.hscni.net

Southern Health and Social Care Trust

Our Ref: Personal Information redacted by the USI

Private & Confidential

Patient 13
Personal Information redacted by USI

Dear Patient 13

The Trust contacted you on 19 February 2018 to advise that we were reviewing your care in relation to urology referral delay.

Firstly let me apologise sincerely for the delay in completing this review as it involved a number of patients.

I can advise that the Trust has completed its review in relation to a delay in the referral process to Urology. The panel assessed medical evidence regarding the potential impact of delays in treatment for your condition and found that there is evidence that the delay you experienced placed you at a higher risk of that treatment being unsuccessful. However, having undergone your treatment you have subsequently been followed up for almost 3 years and have been free of bladder cancer and therefore in your case this delay has not affected your outcome from treatment.

I hope you are keeping well and send my best wishes.

Yours sincerely

Personal Information redacted by USI

Mrs Melanie McClements
Interim Director of Acute Services

Working together Excellence Openness & Honesty Compassion

Clinical and Social Care Governance Team
Directorate of Acute Services
The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by USI
E-Mail: Acute.governsnce@southerntrust.hscni.net

I think even in December '16 I was up with him, he checked my prostate and all, he said everything was grand. Then I went up after Christmas, that was January '17 and I told him that I had got no word from the Urology and I don't think he really answered me at all. And then I think that was a Tuesday and then by that Friday I got the letter to say Thorndale Unit the 31st of January.

24 Q. And that was --

A. So I think only I had said it, that's how I feel, only I mentioned it to my GP who obviously had got in touch with them again, maybe he realised about the button issue, the routine on the... So I think if I hadn't have highlighted it, when was it going to be highlighted. 10:19

25 Q. Yes.

A. Until it was all spread through me?

26 Q. So you feel that if you hadn't gone to your GP, you feel he went back to the Trust on your behalf?

A. Obviously. Yes, that's how I feel and I still feel to this day. If I hadn't have been going to him so often and seeing my doctor, because I was worried about my health, I don't know when I would have gotten my referral, two/three years? 10:19

27 Q. Well, it is possible that the Trust were looking at cases that hadn't been triaged, that hadn't been looked at, the referrals letters hadn't been looked at, at the same time as your doctor maybe was ringing in and the two maybe coincided, we can look at that? 10:20

investigations, providing treatment recommendations and adding patients directly to waiting lists, similar to outcomes achieved from Cons 1's advanced triage'.

Nevertheless, I believe that this recommendation should be amended. I believe that I should triage in the manner agreed with and expected by the Trust in a written policy for urological referral. That way, there will be no room for variance in how or when triage is conducted, and the trust will bear responsibility for any negative consequences, provided clinicians have conducted triage in accordance with the agreed policy. In doing so, Recommendation 12 will have been complied with.

Conclusions

I do agree with the Recommendations contained in the Report, with a number of caveats. I do believe that it is crucially important that Recommendation be amended to ensure that the Trust develop a clear, agreed, written policy of its expectations, duties and performance of the Urologist of the Week, before it consider whether it is feasible to undertake triage while Urologist of the Week. Qualitatively and quantitatively defining and describing its expectations of the complexity of triage without firstly doing so for UOW will lead to a fudged failure.

I believe that no Consultant Urologist should be expected to concern him or herself with reviewing their conduct of triage to align themselves with his or her colleagues, especially when the colleagues claim to be conducting triage in a similar manner. That proposal will be replaced by a clear, agreed, written policy of the Trust concerning the conduction of triage. Then each Consultant only has to comply with the policy, and not with conduct of his or her colleagues, real or imagined.

Lastly, the report should include a Recommendation concerning the establishment of systems enabling clinicians, and particularly clinical departments, deal with difficult or dysfunctional management.

I look forward to receiving a revised report in due course. I have little confidence that it will have been significantly amended. I have less confidence that any of its Recommendations will be implemented.

Aidan O'Brien

11 December 2019

Received from Tughans OBO Mr Aidan O'Brien on 20/12/21. Annotated by the Urology Services Inquiry.

Comments concerning the RCA Report on Review of SAI [redacted]

In submitting this commentary regarding the RCA Report of SAI [redacted] I have reviewed all retained correspondence relating to the issue of triage, all retained documentation relating to other issues impacting upon triage and all retained documentation relating to other issues referred to by others interviewed during the course of the Root Cause Analysis. Having done so, I believe that the Recommendations outlined in the Report are its most important component, though I believe that at least one additional recommendation is required to ensure that the others could be effectively implemented. I have endeavoured to be concise.

Having been interviewed by Dr. Johnston and having read the above Report, I do believe that the singular and significant flaw of the Review has been to investigate the failure to triage urgent and routine referrals in isolation of other pressures and clinical priorities which I believe are evidently more important. As a clinician and a clinical department, I believe that these greater clinical priorities cannot be compromised for the sake of triage, as they have been and continue to be.

Urologist / Consultant of the Week

While agreeing that triage is indeed a serious issue and very important, I was concerned to being expected to agree that triage of referrals has 'number one ranking in the overall scheme of things'. I believe that it is vitally important to fully appreciate the significance of this claim, especially as triage has been aligned with the duties of the Urologist of the Week (UOW). If, as has been my experience during my last week as UOW, one does a ward round from 09.00 am to 11.30 am, prior to going to theatre to undertake seven emergency / urgent operations, is triage the most important concern that day, or the day after, if it is similar?

I most earnestly urge the Review Team to review the wording of Recommendation 6, urging the Trust to re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW. I believe that it is important to appreciate that the Trust has never examined or assured itself in the first place, never mind do so again. I believe that it is crucially important that the duties and priorities of the CoW and the expectations of the Trust of the CoW in the conduct of those duties and priorities, be clearly agreed and expressed in a written Memorandum of Understanding, or similar. I do so as there has been an ambiguity since its inception as to those duties and priorities.

Following a long period of gestational discussion, the UOW came into existence in late 2014. The major reason for the length of that gestational discussion was the belief, particularly on the part of our Lead Clinician, that the duties of the UOW could not possibly take up a whole day. This belief was borne out of his perception that the UOW would essentially be on call. When subsequently persuaded and convinced that it would be a good for inpatient management that the UOW would conduct an ward round each morning, it was then proposed that we could then undertake a clinic in the afternoon each day, as the duties of UOW could be confined to the morning, as one would rarely be called to theatre in an emergency. When successfully disabused of that proposal which would have necessitated the disorderly cancellation of outpatient attendances, the proposal of

Received from Tughans OBO Mr Aidan O'Brien on 20/12/21. Annotated by the Urology Services Inquiry.

on the subject?

A. Once again, I think that -- I mean, I'm not dismissing the significance of triage. I contributed greatly to, at a regional level, emphasising at that point in time back then, let's say 10 to 13 years ago, that perhaps 12:05
consultant urologists were those people best able to undertake triage rather than considering others like junior staff, staff grades or clinical nurse specialists. I do appreciate everything that you are saying in that regard, but what I'm also saying is 12:06
I found the situation whereby, as urologist of the week, if you started a ward round at nine o'clock, if you had 32 patients in a ward, if you actually had to go and see 10 outliers during the course of which you had to deal with referrals of an acute nature from two 12:06
other hospitals in your geographical area, and take five cases to theatre and leave at two o'clock in the morning in order to get some sleep. Now, the alternative is that you defer the surgeries in order to do that meaningful triage. I appreciate everything 12:07
you're saying. Or you don't do the ward round, or you don't go to theatre. And that's how it was done and I didn't believe to be right. I wasn't the only one who felt that was not the raison d'être, the whole purpose of being urologist of the week. The whole 12:07
purpose of being urologist was to try to ameliorate, to try to mitigate the risks that Catherine Hunter described. It was not -- it was unfortunate. I agreed to it actively to include triage as urologist of the

week in order to get urologist of the week across the line, because at least it was a better option than doing a clinic because the clinic is at a fixed time whereas, whereas at least you could triage at two o'clock in the morning. 12:08

So, I do appreciate the perspective that has been formed. As an individual I have worked very, very hard and I have always had patient care at the centre, but the most important patients that you have as urologist 12:08 of the week are the inpatients. They are the critically ill. You should not be sending a junior registrar to deal with those people whilst you triage. There's something fundamentally wrong about that. 12:08

So by, I think it was March, I don't have a record of the meeting when we all met and when we were informed of the informal default process, and I made it very, very clear that I had found it impossible.

60 Q. I want to come to that aspect of the narrative later. 12:09 Could I ask you this just in terms of the impossibility, as you put it. There is always an opportunity, is there not, to work in a different way to bring different methods, different levels of intensity to the task at hand. Your colleagues, and 12:09 you may look unfavourably at their approach to triage, but whatever standard they brought to it, they were getting it done, they were processing the cases. As the SAI suggests, they were in many cases organising

5.0 DESCRIPTION OF INCIDENT/CASE

06/02/2017 - seen in clinic on day 152.
11/04/2017 (D215) - confirmed cancer diagnosis T3a with no nodal metastases – high risk and there was a recommendation of treatment for a locally advanced non-metastatic prostate cancer.

Conclusions

Resultant 8-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is not clinically significant.

At a later date, towards the end of 2018, another patient came to the attention of the Review Team – Patient 15. This patient could also have been one of those found in Cons1 filing cabinet but appeared at an outpatient clinic before the outworking of the look back exercise #2. A Consultant Urologist realised in the clinic that this was also a Cons1 non-triaged patient who was incorrectly referred by their GP.

Patient 15 30/08/2015 - 63-year-old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Routine by the GP.
The referral was not triaged on receipt.
29/01/2016 2nd GP referral marked as Suspected Cancer – Red flag; Patient 15 was added to W/L R/F following this referral.
As part of the internal look back #2, the referral was noted.
Patient 15 had already received an appointment and was seen in clinic on day 153. Therefore, 1st GP referral was incorrect; the 2nd was a correct GP referral.
11/02/2016 (D166), following a prostate biopsy, the patient obtained a confirmed cancer diagnosis T3a and there was a recommendation for treatment of a prostate cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is felt that the delay is unlikely to be clinically significant.

My father was referred to urology for raised PSA in August of 2015 but no response was received from the Urology Department until over six months later in February of 2016. This response only came after my fathers GP, Personal Information redacted by the USI sent a follow up letter querying the lack of communication from the Urology Department.

Any delay in treatment relating to cancer is obviously concerning and my father was extremely worried during this period of silence as there was no communication or guidance on what action would be taken.

When the diagnosis of prostate cancer came in February of 2016 with a Gleason grade 4+5, the concern was the cancer was more severe than would have been the case without the six month delay.

2. Please explain why you did not raise your concern(s) at the time and state if there was something that prevented you from raising your concern(s).

No concerns were raised at the time because my father, having faith in the NHS, assumed this was a normal timeline for treatment.

He was unaware of what is now public knowledge in relation to the delay.

SECTION E – Personal impact/additional information

Please outline the personal impact that the treatment received, which forms the basis of your complaint(s), has had on the patient/deceased patient and provide any additional information which you feel may be of assistance to this Inquiry.

My father was understandably upset when told that he had a raised PSA count and was being referred to Urology and the longer the silence lasted after the referral the more worried he became. Having been told that you need specialist attention for what could become a potentially life-threatening problem was stressful for my father and my mother. As a result of Urology ignoring the referral for 6 months, our family saw a very pronounced change for the worse in my father's personality and demeanour; he was much quieter and more withdrawn than we ever knew him to be. We only attribute this to him worrying about his condition.

When prostate cancer was eventually confirmed my father was acutely aware that the length of time which had passed could only have made things worse and he feared that he would not survive. He spoke to me about preparing for the worst possible outcome and he genuinely believed that he was not going to survive. This was an immensely stressful time for my father as he dealt with these fears and it was also an extremely anxious time for my mother.

Treatment for the prostate cancer was ultimately successful in June of 2017, almost two years after being referred but we question why the process took so long and if the cancer and treatment would have been as severe if my father's case had been reviewed sooner. When he did eventually get the all clear, he was a changed man. He returned to being the happy man we knew before this all started. We believe there were an additional six months of unnecessary stress due to Urology's inaction.

My father passed away in Personal Information redacted by the USI. On the 19th of May 2021 my mother received a call (which I witnessed) from Mr Mark Haines on behalf of the Trust to advise that an article would be running in the Irish News about Mr Aiden O'Brien and that my mother should basically disregard anything in the article. He framed the piece as a witch hunt and there was nothing relevant to my father's case and despite the delay in diagnosis this that would not have affected his treatment. As a family we were unaware that Mr O'Brien was involved in any stage of my father's treatment or diagnosis and so accepted this at face value but noted with Mr Haines that the additional months of unnecessary stress took its toll on both my father and my family. This call is to date the singular contact from the Trust. We read the Irish News article with interest along with the media reports which followed. There were reportedly five cases which were undiagnosed which turned out to be positive for cancer and therefore assume that my father was one of those five. We also assume that Mr Haines did not call round hundreds of people to put the Trusts 'spin' on the Irish News article.

In hindsight, this phone call appears to have been an appalling attempt to obscure the truth of what was going on and the patronising manner which was used with my mother was unacceptable. His attitude came across as treatment was successful therefore you can ignore what has happened.

With the information available to us we believe that not only was Mr O'Brien negligent in failing to review my father's case but the Trust were also negligent as it appears they have been aware for years of the concerns around Mr O'Brien's practices yet took no action to address his performance. Furthermore, Mr Haines attempt to deflect attention casts a shadow over the Trust's moral and ethical standards. We also note that this inquiry did not contact my mother until the second round of contacts which suggests that information was withheld by the Trust.

Additional sheets, if needed, can be attached

father received, whether that was the appropriate treatment for him or not. Others both in the Trust and in the General Medical Council have been looking at the care of patients and after I have asked you some questions then, Dr. Swart may have some questions, Mr. Hanbury may have some and I will hand over again to Ms. Treanor in case there is anything she wants to ask you. But I will try to cover all the matters that we need to ask you about and in the meantime, I'm now going to ask you, Patient 15's son, if you wouldn't mind taking the oath. 10:21 10:21

THE WITNESS: Yes, sure.

PATIENT 15'S SON, HAVING BEEN SWORN, GAVE HIS EVIDENCE TO THE INQUIRY AS FOLLOWS: 10:21

1 Q. CHAIR: Thank you. Now, Patient 15's son, as we've already heard from Ms. Treanor, your father was referred by his GP in August 2015 and then having heard nothing, he then went back to the GP and got the GP to contact the Trust again, isn't that correct? 10:22

A. That's correct. So there was the initial referral because of the elevated PSA levels and then, in a way, my father was one of those people who didn't complain, so whenever there was a delay it was just this is the way things were. But eventually the worry of it brought him back to the GP and it was a worry for him, for my mother, for myself and my sister, and that's at the point that things started to move, I suppose. But 10:22

that initial six-month delay was the main thing, you know.

2 Q. Would I be right in thinking that that is the main thing that you and the family are concerned about?

A. Concerned about not only the delay but the impact. I know you say that this isn't looking at, you know, outcomes and things from a medical point of view, but we believe it impacted his health. We certainly know that the PSA levels were increased six months down the line, things like that. So we do believe it had an impact on his life. And I notice one of the phrases used, not only for my father but for other patients, was things weren't clinically significant. But I believe I noted "clinical significance" defined as a real genuine, palpable effect on daily life. So it was certainly was clinically significant from a mental health point of view, from stress levels and the impact on my mother and sister, so. 10:22 10:23 10:23

3 Q. So there really was -- that six-month delay did have an impact on you and your father and your family? 10:23

A. It really did. Again, as I said in my submission in the questionnaire, I mean, it seems to be a very unnecessary additional six months of worry and stress but it didn't need to be. It shouldn't have been.

4 Q. We know that he was then referred back and this time, the designation on the referral letter was one of red flag and he was seen then and treated by Mr. O'Donoghue in the Trust? 10:24

A. Yes, my father spoke very highly of him, and my mother

time went on, and the delay went on, the treatment went on, the treatment was hard on him. He was a fairly elderly man and the treatment, did it need to be so severe eventually when it came? You know, he was up and down to Belfast every day on the train early in the morning. It had an impact on him, and my mother as well. But there's such a change in his character. Dad was the life and soul, that's how I would describe him.

9 Q. The diagnosis itself had an affect?

A. The diagnosis itself but, again, what I think was difficult for him was, as time went on, haven't heard anything, we're into another year, and everybody knows the whole thing; the earlier you catch these things, the more successful treatment generally is and he was fully aware of that and I believe, just the silence of that first six months was very difficult for him, for everybody, waiting, what's going to happen? And I know that he spoke to me whenever the diagnosis came through in January, or February, that he spoke to me basically going, we need to make arrangements now for what happens next, because this is it. 10:26 10:26 10:27 10:27

10 Q. He was expecting the worst?

A. He absolutely expected the worst. As I said in submissions, whenever the all clear eventually did come through, back to normal, it was like years being lifted off people, that's exactly what it was. So I remember that well, the day that he came back with the good news and the big grin. 10:27

11 Q. And as you said, treatment was successful?

Southern Health
and Social Care Trust

Quality Care - for you, with you

19 February 2018 **Our Ref:**

Private & Confidential

Patient 15
Personal Information redacted by USI

Dear Patient 15

The Southern Health and Social Care Trust received a urology referral from your GP. There was a delay in the processing of this GP referral.

When the Trust identified this delay it commissioned a Serious Adverse Incident (SAI) review. The purpose of the SAI review is to establish what happened, why it happened, impact if any on patients and what learning could be obtained. In order to have a degree of independence and integrity, the SAI review is chaired by senior doctor not directly involved in the patient's care.

An integral part of this SAI review is to engage and inform those patients included in the review. To this end The Trust would encourage your participation in the SAI review whilst fully understanding and respecting if you choose not to participate.

Patient 15 if your preference is to wait until the SAI review is completed I will write to you again to offer the sharing of the draft report and provide you with an opportunity to comment on the report.

However should you wish to take up this opportunity or require additional information please contact Mrs Trudy Reid on Personal Information redacted by USI

Yours sincerely,

Personal Information redacted by USI

Mrs Esther Gishkori
Director of Acute Services

7 October 2020 **Our Ref:**

Private & Confidential

Patient 15
Personal Information redacted by USI

Dear Patient 15

In the spirit of openness and transparency I am writing to advise you that as part of a look back exercise, the Trust reviewed a number of cases where there was a delay in referral to the urology clinic.

I can advise that the Trust has completed its review in relation to a delay in the referral process to Urology and they have concluded that although there was a delay in your diagnosis and subsequent treatment for prostate cancer, medical evidence suggests that this will not have had any impact on your treatment or outcome.

Yours sincerely,

_____

Mrs Melanie McClements
Interim Director of Acute Services

Our Ref:

Private & Confidential

Personal Information redacted by USI

Dear Patient 15's Wife

Please accept my sincere condolences on the loss of your husband Patient 15. I hope you are keeping well.

In an effort of being open and transparent, I wanted to contact you with some information you may wish to know. Firstly I want to apologise if the phone call you received from the Trust, caused you some distress and confusion. This was not my intention.

I was hoping to meet with you face to face to advise you that the Trust conducted a review of the urology services in relation to the triage of letters to the urology service. This was part of a wider review in to the care provided by one of our retired consultant urologists and involved a small number of patients (5 in total).

The review team looked at your husband's care in 2016 in relation a delay in actioning a referral letter from his GP until he was assessed by the urology team. The review team identified that although there was a delay in your late husband getting an appointment to the Urology services, the review team concluded that it did not have any influence on your late husband's subsequent diagnosis or treatment received.

I would still like to discuss this with you for clarification and to offer you the opportunity to discuss it with me. If this is acceptable I can arrange for you to attend my clinic to discuss this further. You are welcome to bring someone with you as support.

Yours sincerely

_____

Mr John O'Donaghue
Consultant Urologist

King, Dawn

From: Farrell, Roisin
Sent: 21 November 2018 08:24
To: Reid, Trudy
Cc: McAloran, Paula
Subject: FW: Outstanding Notifications, Acknowledgements & Holding letters for approval
Attachments: Advising family report is complete reviewed.doc; Advising family report is complete reviewed.doc; Acknowledgement to family re deceased relative.docx; Acknowledgement to family re deceased relative.docx; HOLDING LETTER.doc; HOLDING LETTER.doc; Acknowledgement to family re deceased relative.docx; Appendix 1 - Notification Form.docx; HOLDING LETTER.doc; HOLDING LETTER.doc; HOLDING LETTER.doc; HOLDING LETTER.doc; HOLDING LETTER.doc; HOLDING LETTER.doc; Acknowledgement letter.docx; Acknowledgement to Patient.docx; Acknowledgement to family re deceased relative.docx; Appendix 1 - Notification Form.docx; Acknowledgement to family re deceased relative.docx; Acknowledgement to family re deceased relative.docx

Importance: High

Trudy
Did you get a chance to review these outstanding acknowledgments, holding letter and notifications for approval

Kind Regards

Roisin Farrell
Clinical & Social Care Governance Team
Directorate of Acute Services
The Maples
Craigavon Area Hospital

Extension Number Personal Information redacted by the USI

From: Farrell, Roisin
Sent: 02 November 2018 12:50
To: Reid, Trudy
Cc: McAloran, Paula Personal Information redacted by the USI
Subject: Outstanding Notifications, Acknowledgements & Holding letters for approval
Importance: High

Trudy
Please see attached for approval

Personal Information redacted by USI – Letter advising report complete, but to date it has not been sent to HSCB. – in the meantime will I issue a holding letter?
Personal Information redacted by USI – Letter advising report complete, but to date it has not been sent to HSCB. – in the meantime will I issue a holding letter?
Personal Information redacted by USI – Email to family advising response to queries almost complete, awaiting approval 31.10.18

Patient 16 – Urology - Holding letter issued 31.10.18
Personal Information redacted by USI was not informed about the SAI. Please see attached acknowledgment. Notification to HSCB on 2.8.18
Personal Information redacted by USI – Internal acknowledgment attached for your approval
Personal Information redacted by USI – Holding letter attached for your approval
Personal Information redacted by USI – Holding letter attached for your approval
Patient 90 – Acknowledgment attached for approval
I have attached notification for your approval too
Personal Information redacted by USI – Holding letter attached for your approval
Patient 13 – Urology – Holding letter attached for your approval
Patient 12 – Urology – Holding letter attached for your approval
Patient 14 – Urology – Holding letter attached for your approval
Patient 11 – Urology – Holding letter attached for your approval
Patient 15 – Urology – attached is acknowledgment for your approval, this is the only Urology patient that hasn't been advised of the SAI
Personal Information redacted by USI – Will I send Personal Information redacted by USI a holding letter, Can we please discuss as Personal Information redacted by USI has not been sent the 2 report and CYP have not nominated anybody
Personal Information redacted by USI – Notification & Acknowledgment for approval
Personal Information redacted by USI – Holding letter attached for your approval
Patient 91 – Internal review, Acknowledgement attached for approval
Personal Information redacted by USI – Acknowledgement attached for approval. NOK on PAS as brother

Kind Regards

Roisin Farrell
Clinical & Social Care Governance Team
Directorate of Acute Services
The Maples
Craigavon Area Hospital

Extension Personal Information
Number Personal Information redacted by the USI

went out and a bought a pencil, the receipt would be put into the filing cabinet. There's receipts going back to the sixties for rent, you, know. It's incredible. And not only that but my mother and my father worked as a team. There was nothing hidden. It would have been incredibly out of character if my father had received a letter and not shared it and not filed it. And on top of that, my sister, after my father died, my sister was going through various things like this and this is the sort of thing that stands out and she doesn't recall ever seeing it. So we're not aware of it, is the way I'd phrase it. 10:36 10:36

25 Q. Then if I can just move on to the next one, which is PAT-001137?

A. Yeah. Again that's an identical letter and it's dated 1st November 2018. This is where the question of confusing comes in because again, if we go become to PAT-001216. 10:36

26 Q. This is an e-mail, an internal e-mail chain within the Southern Trust? 10:37

A. And towards the end of that, where my father's name is mentioned.

27 Q. If you just scroll down, please, and you'll see that there are a number of patients referred to.

A. Yeah. 10:37

28 Q. And then we have highlighted your father's name there.

A. Yeah. It clearly states:

"This is the only urology patient that hasn't been

advised of the SAI."

And this is 2018.

29 Q. That's the 2nd November 2018?

A. Yeah. So that PAT-001137 is dated 1st November so we're assuming that that's the letter that was sent for your approval, as is mentioned in PAT-001217 there. 10:37

30 Q. Can I just ask you, though, did your mother or did any of you ever remember that letter being received?

A. No. 10:38

31 Q. And again, it wasn't filed by your father?

A. No, and it's two identical letters, one is signed, one is not. I don't know whether the fact that there's no reference number on them, if that's relevant or if that's normal, but we're not aware of that letter. 10:38 Even in my notes, I have red dots on these four letters here.

32 Q. Then I think there's another draft, certainly a draft letter at PAT-001138?

A. Yes. And again this one talks about a lookback exercise, which presumably is different to an SAI, but again, we're not aware of this letter. Now that letter was dated the day before my father died. So whether something arrived and it was missed in the few weeks after my father's death, I don't know. 10:38 10:38

33 Q. Certainly, what we have been given is not signed by anyone, which would suggest that it's a draft, and again there's no reference on it.

A. Again, no reference, no signature and if that had come

TRU-157737

The Regulation and Quality Improvement Authority

RQIA Review of the Urology Structured Case Record Review Southern Health and Social Care Trust

September 2022

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating, inspecting and reviewing the quality and availability of health and social care services in Northern Ireland. RQIA's reviews identify best practice, highlight gaps or shortfalls in services requiring improvement and protect the public interest. Reviews are supported by a core team of staff and by independent assessors, who are either experienced practitioners or experts by experience. Our reports are submitted to the Minister for Health and are available on our website at www.rqia.org.uk.

RQIA is committed to conducting inspections and reviews, taking into consideration our four key domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well-led?

Membership of the Expert Review Team

Professor Aneez Esmail	Professor of General Practice (Emeritus), Centre for Primary Care and Health Services Research, University of Manchester
Mr Hall Graham	Professional Advisor, Regulation and Quality Improvement Authority
Dr Leanne Morgan	Clinical Lead, Regulation and Quality Improvement Authority
Mr Brian O'Hagan	Lay Representative and Independent Expert Advisor to the review

Membership of the Project Team

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Helen Hamilton	Project Manager, RQIA
Emer Hopkins	Interim Director of Improvement, RQIA
Dr Leanne Morgan	Clinical Lead, RQIA

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

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Appendix 1: Terms of Reference for the Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

Appendix 2: Structured Judgement Review

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Received from SHSCT on 13/09/2022. Annotated by the Urology Services Inquiry.

Section 1 Introduction

1.1 Background and Context

On 31 July 2020, the Southern Health and Social Care Trust (SHSCT) contacted the Department of Health (DoH) to report an early alert concerning the clinical practice of a Urology Consultant (referred to in this report as Consultant A).

An initial review, which considered cases over an 18-month period of the consultant's work in SHSCT from 1 January 2019 to 30 June 2020, focussed on whether patients had had a stent inserted during a particular procedure and if the stent had been removed within the clinically recommended time frame. The initial review identified concerns with 46 cases out of a total of 147 patients who had the procedure and were listed as being under the care of the consultant during the period addressed by the initial look-back exercise[i]. The findings were significant and led the Minister for Health, Robin Swann MLA, to announce on 24 November 2020 that a statutory public inquiry would be established under the Inquiries Act 2005. The Urology Services Inquiry, which is currently ongoing, is chaired by Ms Christine Smith QC.

In parallel, yet separate, to the work of the public inquiry, SHSCT subsequently established a review group to assess the further findings of the initial review exercise and to explore the need for a further look-back review in the context of additional concerns.

Areas of concern were identified relating to:

- Elective and emergency activity;
- Radiology;
- Pathology and cytology results;
- Patients whose cases were considered in multidisciplinary team meetings;
- Oncology; and
- The safe prescribing of an anti-androgen drug outside established NICE guidance in the management of prostate cancer.

Nine cases were identified that met the threshold for a Serious Adverse Incident (SAI) review. Following the completion of these initial nine SAI reviews in 2021, the Trust was advised by DoH that the SAI process should not be used to review subsequent potential issues in care identified by the lookback process.

As a result, SHSCT developed a Structured Case Record Review (SCRR) process based on the Structured Judgement Review methodology as developed by the Royal College of Physicians. The aim of the SCRR process was to identify any areas of learning where patient safety could be improved.

In March 2022 SHSCT asked RQIA to undertake:

[i] Ministerial Statement by Health Minister to the Northern Ireland Assembly, 24th November 2020

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- A review of the choice of Structured Judgement Review methodology to underpin their SCRR process.
- A review of the Trust SCRR process in relation to its effectiveness in identifying learning.

It was further agreed that, in the event that the SCRR process was not considered to be appropriate the Trust would like RQIA to suggest an alternative approach.

1.2 Terms of Reference

Although RQIA was requested to review the suitability of the Trust's SCRR process, we considered that the scope of the review should be wider. It would not be appropriate to only assess the tools involved but we should also assess the surrounding process within which the SCRR operates. Therefore the following Terms of Reference were agreed with SHSCT.

1. To assess the suitability of the Structured Judgement Review methodology as the basis for the Trust SCRR process.

2. To assess the specific Trust SCRR methodology in relation to its effectiveness in identifying learning.

3. To assess the overall trust process/framework for conduct of its record review.

4. To make recommendations in relation to the overall process and if the SCRR process is not considered to be appropriate suggest an alternative approach.

1.3 Review Methodology

RQIA used a PRINCE project management approach to underpin this review. The review utilised a range of methodologies to obtain supporting information to inform our assessment:

- We undertook a review of the literature around the use of the Structured Judgement Review Method to help identify key themes and areas of focus.
- We designed and issued structured questionnaires to the Southern Health and Social Care Trust.
- We analysed information returned to us and used this to develop Key Lines of Enquiry for meetings with the Trust.
- Our Expert Review Team (ERT) conducted focus groups and meetings with the independent panel of reviewers, senior staff and other relevant staff from the Trust.
- We analysed the information gathered through our structured pre review questionnaires, meetings, focus groups and staff questionnaire responses in order to determine our key findings and recommendations.

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Section 2 Findings

In assessing the effectiveness of all aspects of the SCRR process we considered the overall process in respect of a number of component parts.

2.1 OVERALL TRUST PROCESS AND FRAMEWORK FOR SCRR

2.1.1 Background to the Structured Case Record Review

The provision of background and contextual information is vital to the understanding of the rationale and purpose of the Structured Clinical Records Review process. This information was provided by SHSCT, in conjunction with a Structured Case Review proposal document and was explored further by the Expert Review Team during fieldwork sessions with Trust representatives.

During fieldwork, the Expert Review Team heard how the Inquiry was announced unexpectedly in November 2020 during what was a difficult time for SHSCT, when it was grappling not just with the emerging issues within Urology Services but also with the COVID-19 pandemic and its associated pressures for service; this contextual information provided the Expert Review Team with a valuable insight into the challenges faced. At the point of announcement of the Inquiry Terms of Reference (see Appendix 1) SHSCT had already commenced a Lookback Review and through this had identified a significant number of patients meeting the threshold for an SAI review under the regional SAI procedure[1].

Due to the volume of patients identified, the time and resource required to progress SAI reviews, and the limited additional value of repeatedly reviewing the same type of incident via the SAI process, it was suggested that an alternative methodology is used to derive learning from these cases. The decision to use the SCRR approach, as an alternative to SAI methodology, was taken in conjunction with SPPG and DoH's Urology Assurance Group. The Expert Review Team considers that this decision was the correct one, and that Structured Judgement Reviews methodology, such as that developed by the Royal College of Physicians, is a robust method of assessing the quality of care and treatment of individual cases, when applied as intended. As such, the Expert Review Team endorses the decision to adopt an alternative approach to undertaking repeated SAI reviews in such circumstances.

Although the decision to proceed with the SCRR was taken prior to the announcement of the Public Inquiry, the Expert Review Team noted that SHSCT continually referenced the SCRR process within the context of their broader work to meet the requirements of the Inquiry. However, the Expert Review Team considers that the Inquiry and the SCRR are separate processes.

The Inquiry is an independent statutory process, supported by underpinning legislation, to deliver on its Terms of Reference; whereas the SCRR is a Trust and DoH-initiated process to establish themes of learning with a view to improving Trust systems to reduce the likelihood of similar incidents happening in the future. Whilst running in parallel to the Inquiry, the SCRR should not be influenced by the Inquiry's agenda or timescales, but instead should be focused on the need to derive learning and implement the necessary improvement.

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During fieldwork, Trust representatives accurately described this distinction between the differing roles and purposes of the Inquiry and SCRR, the relationship between the differing processes and the arrangements for sharing information with the Inquiry Team. However, upon reviewing Trust documentation, although the rationale for the SCRR is clearly stated, the Expert Review Team identified a lack of clear documentation explaining the role, purpose and remit of the SCRR and, in particular, that it is an entirely separate process to the Inquiry.

Similarly, SHSCT SCRR documentation does not make clear whether the cases selected for SCRR are being reviewed on behalf of the Inquiry, or whether all or some of these cases could be subject to a second review by the Inquiry team, and whether patients and families are aware of the potential for conflicting findings. This is likely to cause confusion since the Inquiry Terms of Reference (ToR) include:

> (c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within SHSCT's urology specialty.

The Expert Review Team considered that, although Trust representatives demonstrated a good understanding of the distinction between these two processes, which is further mitigated by the fact that at the time of drafting this report, the Inquiry methodology for ToR (c) has not yet been announced, and the patient / family information materials and Trust documentation require improvement. In the current format, the versions provided to the Expert Review Team do not fully and accurately inform patients and families and, thus, have the potential to inadvertently cause confusion and compound anxiety and distress.

We were informed that SHSCT, in light of recent criticism regarding factually inaccurate information contained in patient letters, regarding the Inquiry's purpose, has sought to improve the clarity and accuracy of documentation. The Expert Review Team was provided with a copy of a "Patient Letters Investigation" report which outline a thorough investigation undertaken by an experienced Director independent from the SHSCT and is accompanied by a number of sensible recommendations. The Expert Review Team commends this report and welcomes these improvement efforts. In addition to these, the Expert Review Team is of the view that SHSCT would benefit from improving their systems for developing and quality assuring patient / family information or indeed any documentation that is publicly accessible or likely to enter the public domain. Such arrangements should include the involvement of a lay person / service user representative and those with communications expertise within SHSCT. Where there is a pending or ongoing Public Inquiry, legal input should also be considered.

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Recommendation 1

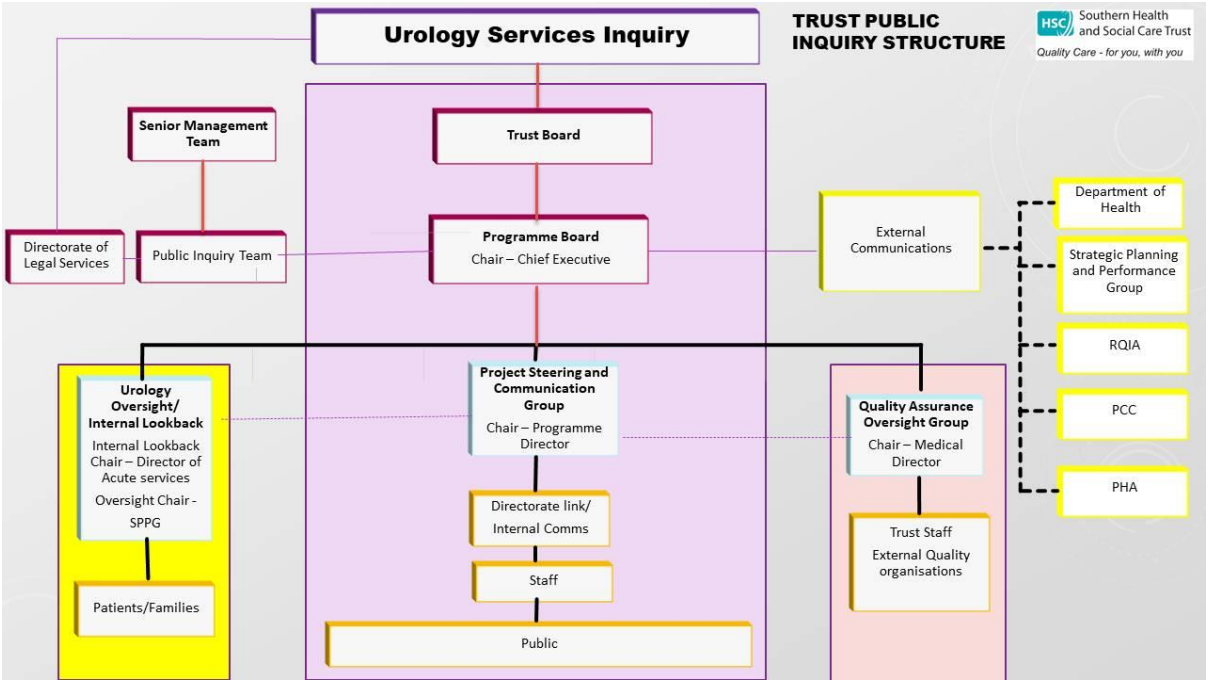
SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

2.1.2 Review Structure

Robust structures are essential for ensuring effective delivery, assurance and accountability. SHSCT provided details of the Review Structure and advised that the SCRR process sits within its current Trust governance structures.

Figure 1. Current Review Structure



We were informed that the Review Structure is presently overseen by SHSCT Internal Urology Lookback Group. SHSCT Public Inquiry Programme Board is chaired by the Chief Executive. The Programme Board members act on behalf of SHSCT Board to oversee the work of the:

- Public Inquiry Response and Communications Group;
- Public Inquiry Urology Oversight / Lookback Steering Group; and
- Quality Assurance and Improvement Oversight Group

The Lookback Review is included on the Corporate and Acute Services Risk Registers. External oversight of the process is provided by the fortnightly Service

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Planning and Performance Group (SPPG) Meeting and Department of Health led Urology Oversight Group.

ToR were provided for the Public Inquiry Programme Board, Trust Internal Urology Lookback Group and Health and Social Care Board[ii] (HSCB) Urology Group. The Expert Review Team noted the broad remit of oversight and co-ordination groups and considered that some of the committees were very large, with overlapping membership. The Expert Review Team noted that the composition of the Lookback Review Steering Group (referred to as the Urology Oversight / Internal Lookback Group) does not reflect the Regional Guidance for Implementing a Lookback Review Process (July 2021)[2] which suggests inclusion of:

> "a Non-Executive Director, the Director of service/speciality concerned, relevant professional Executive Director(s), Risk and Governance representative, Head of Communications, Information Technology manager, Medical Records manager and senior service, representatives with expertise Public Health Agency (PHA) representative and an Health and Social Care Board (HSCB) representative (in the case where the Lookback Review has been identified as an SAI, the role on the Steering Group will be clearly identified to ensure that the independence of the PHA/ HSCB is not jeopardised). The organisation may also wish to consider a member of a relevant service user representative/advocacy group is included as a member of the Steering Group."

The Expert Review Team acknowledged the challenges and sensitivities of including a service user / advocacy representative who has been impacted by or has a vested interest in the matter of concern. However the inclusion of a lay member, not impacted by SHSCT Urology concerns, but nonetheless with previous experience of representing the interests of service users / the public on similar pieces of work, can be hugely valuable and should be considered by SHSCT. The benefits include enhanced public confidence in the process, improved adherence to the statutory duty of Personal Public Involvement (PPI), provision of advice on patient / family / public messaging and on the fulfilment of a duty of candour.

The Expert Review Team considered that there was a lack of clarity surrounding leadership / responsibility and arrangements for accountability and reporting. During fieldwork, we were advised that the Chief Executive has ultimate accountability for the SCRR and that recent work had been undertaken to improve oversight, reporting and ensure clear lines of accountability. This resulted in a proposed new structure for oversight of the SCRR process. The Expert Review Team is of the view that any new structure should also be designed to support SHSCT to fulfil its responsibilities in respect of all Urology work, to deliver on SCRR objectives and should avoid creating unnecessary duplication or complexity.

The Expert Review Team was informed that the new structure exists in shadow form at present with the Operational Team being chaired by the seconded Director in a holding position until the new Director responsible for surgery takes up post.

[ii]The Health and Social Care Board was replaced by the Service Planning and Performance Group (SPPG) April 2022.

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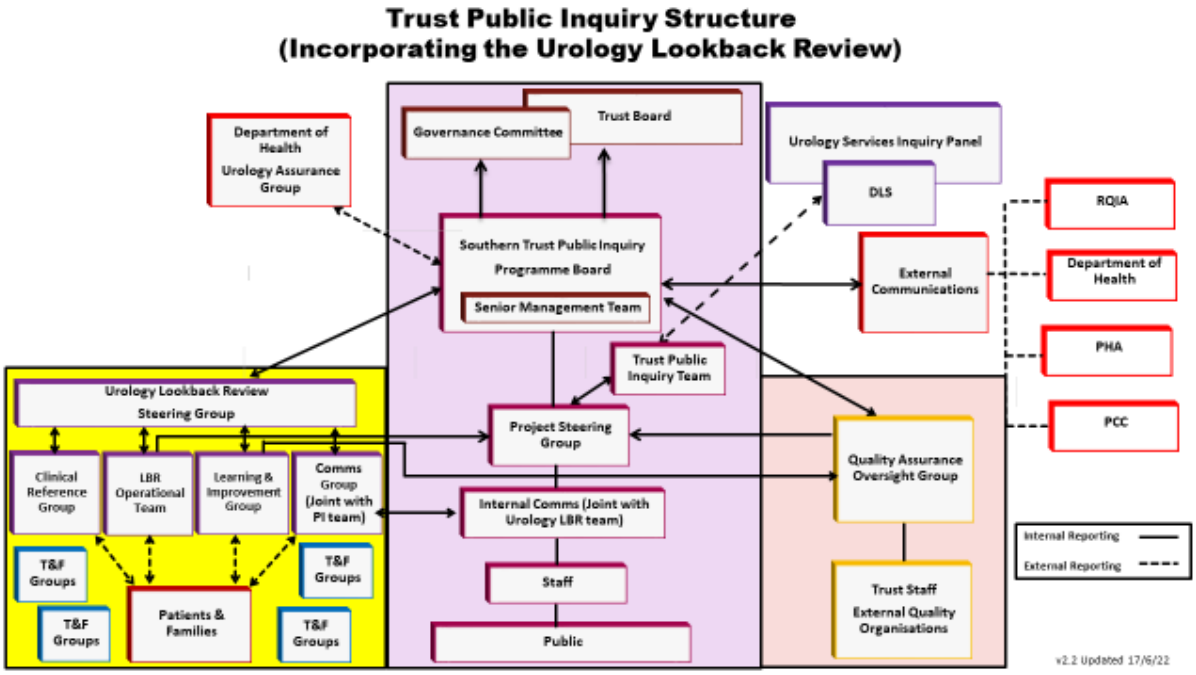
Figure 2. Proposed New Review Structure (draft document at the time of the Review)



Although the Expert Review Team welcomes improvements to the overarching review structure, it is of the view that, given the sizeable undertaking and complexity of the work, the operational arrangements for management and co-ordination of the SCRR and potentially the Lookback Review itself, would benefit from the establishment of a dedicated project team. It was noted that one individual was seconded from another Trust to support SHSCT with its work and this was a welcome development; however, no other Trust representative attending the fieldwork sessions reported having experience of conducting Lookback Reviews. This represents a considerable lack of skill and experience, which can occur when there has been recent turnover or change within the management structures of an organisation. In light of this shortfall, the dedicated project team should include people with previous experience in undertaking similar work, who can draw upon a wide network of 'critical friends' to provide support, advice and guidance.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

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2.1.3 Project Management

Effective project management is crucial in ensuring a well-co-ordinated delivery of objectives within acceptable timescales; this is best implemented with the support of a project manager accredited in using validated project management methodology such as PRINCE / PRINCE 2.

SHSCT SCRR project is currently managed as a sub-workstream of SHSCT corporate lookback process rather than by an individual with project management expertise supported by dedicated project team. Furthermore, the process does not use a specific project management methodology and has followed an iterative approach in terms of its design, signoff and deployment.

To ensure identified project actions are undertaken, minutes are kept of screening and lookback meetings and these are carried forward into future meetings. Individual case records for SCRR are tracked to the relevant Expert Reviewer; ensuring updates can be sought on progress.

The Expert Review Team considered that, whilst these arrangements might suffice for small numbers of cases, they are not sufficiently robust for managing a large volume of work. The Expert Review Team is of the view that a dedicated project team for the co-ordination and management of the Lookback Review and SCRR process, should include a Project Manager; ideally such an individual should have previous experience in managing a Lookback Review or, in the absence of previous experience, should have an understanding of the process and should be supported by a network of people who have the requisite skills and expertise.

The Expert Review Team was advised that a proposal paper outlining an updated Lookback Review structure, process and accountability has been submitted to SHSCT Programme Board. In this paper it states that the Urology Lookback Review is a project and should be constructed as such in terms of purpose, ToRs, reporting lines, risk register etc., including the identification of / clarity on who is the Senior Reporting Officer (SRO) for the project; suggesting this should sit at Director level.

SHSCT further advised that this includes a review of the associated Project Management arrangements in order to ensure that the project progresses swiftly and with clear accountability. The Expert Review Team welcomes this approach.

Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

2.1.4 Terms of Reference / Objectives of the SCRR

A clear Terms of Reference (ToR) or, in lieu of a ToR, a set of specific objectives serves to focus the minds of those undertaking the Structured Clinical Record Review process on the purpose, remit and what needs to be achieved during the

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course of the process. Providing a framework for monitoring progress and accountability for delivery, it is also helpful in communicating the scope of work in a clear, open and transparent way; a Terms of Reference can also assist in conveying information about the process to interested parties, such as DoH, SPPG / PHA, Health and Social Care (HSC) Trusts, patients / families / carers and the public.

Unfortunately, there were no ToR / Objectives provided by SHSCT relating to the SCRR process itself. The Expert Review Team considers that a ToR should be drafted and agreed as soon as possible. Trust representatives were keen that this should adequately convey the clinical elements of the SCRR.

In light of this, a possible ToR could include:

1. To assess the quality of care and treatment provided by Consultant A, using Structured Judgement Review methodology which gives specific consideration to the following:

- Triage;
- Initial assessment;
- Diagnostic investigations;
- Outpatient care;
- Inpatient care;
- Perioperative care;
- Care during any medical or surgical procedure (excluding IV cannulation);
- Communication with colleagues, MDT and primary care;
- Communication with patient and families; and
- Discharge plan and follow-up arrangements.

2. To review the findings of the individual Structured Judgement Reviews and produce a thematic analysis report.

3. To identify learning and make recommendations for improvement.

The Expert Review Team also considered that it would helpful for SHSCT to explicitly state the purpose of the SCRR. It is referenced within the Review Methodology Section of the proposal document provided by SHSCT that “the objective of the SJR method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about the hospital systems where care goes well and to identify points where there may be gaps, problems or difficulty in the care process”. This is closely aligned to the purpose of the SCRR, which is ultimately for SHSCT to define, but may best be described as serving “to assess the quality of care and treatment, in order to identify learning and implement improvement”. Clearly setting out the purpose in this way would also help to differentiate the SCRR from the Inquiry.

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Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

2.1.5 Time period for inclusion of cases for SCRR

All cases reviewed as part of the current Lookback Review undergo screening for consideration for inclusion in the SCRR process; those meeting the SAI threshold are 'screened in'. The scope of the Lookback Review pertains to all patients that were under the care of Consultant A during the time period 1 January 2019 – 30 June 2020. The Expert Review Team explored the rationale for this time period with Trust representatives. When concerns first came to light, this period was chosen as it was believed that this was when patients were most at risk from aberrant clinical practice.

The Expert Review Team acknowledges that no lookback exercise can review all cases at once, that there has to be a starting point, and that a phased approach is preferable in order to expedite learning and facilitate reflection; furthermore, to start with those patients identified as being most at risk is sensible, justified and in keeping with regional guidance. However, the Expert Review Team was informed that since then, it has been identified, by examination of historical care through the Patient Casenote Review process, that patients treated by Consultant A prior to 2019 may also have received substandard care. This is unsurprising; it is the Expert Review Team's experience that problems with a clinician's practice tend to be longstanding and not restricted to a particular period of time. We were advised that in light of this finding, the Royal College of Surgeons (RCS) is currently undertaking a review of a sample of 100 cases from 2015 in order to identify whether there were problems present at this stage

The Expert Review Team is of the view that if there is already enough evidence to inform a risk assessment that patient groups receiving treatment prior to 2019 are at risk of harm, SHSCT should not wait for the RCS work to conclude and should proceed as a matter of urgency to extend their Lookback Review to identify and recall at risk patients under the care of Consultant A prior to 2019. This can be done using a phased, risk-stratified approach based on the learning gathered to date. It can then be extended and scaled up further, following receipt of the RCS findings, should this be required. However, regardless of the approach adopted, given the risk posed to live patients, it is imperative that a further phase of the Lookback is commenced as a matter of priority.

Since this is likely to be a considerable undertaking, requiring suitable expertise to offer advice and guidance, it is vital that SHSCT is adequately supported by its partners across the HSC system, including DoH/ Urology Assurance Group / SPPG and PHA. As this work is scaled up, an independent assessment of the current Urology Lookback Review arrangements would serve to provide assurance regarding its effectiveness and identify any areas that need strengthened; this assessment could be undertaken by RQIA as a 'Part 2' to this review of the SCRR. Assurance of the current lookback arrangements would serve to strengthen the

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foundations in place for extending the time period and scaling up to include additional patient subgroups.

Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

As there is a need to prioritise the Lookback Review, to ensure that patients at risk are promptly reviewed and that ongoing care and treatment is arranged, it may be preferable for an external body, such as the Royal College of Physicians, to undertake the SCRR on behalf of SHSCT. Not only would this allow Trust teams to focus on the Lookback Review whilst maintaining a safe level of care provision for its current and new patients, it would mean that the SCRR is conducted by an independent organisation that has the requisite expertise, governance structures, well tested processes and quality assurance mechanisms in place to support this type of work; consequently, the output may be more expedient and performed to a higher standard. However, the Expert Review Team acknowledges that commissioning an independent body may not be possible either due to a lack of agreement, resources or time, in which case the recommendations outlined in this report should support SHSCT itself to facilitate the SCRR.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

2.1.6 Case selection

Appropriate case selection is important to ensure effective use of time and resources, which should be prioritised towards cases where there is likely to be learning.

During fieldwork, Trust representatives outlined the process for case selection. All service users who were under the care of Consultant A between January 2019 and June 2020 were reviewed using a 10-question Patient Review form either internally by SHSCT or an external consultant urologist commissioned for this purpose. This 10-question Patient Review Form explored current as well as historical care. At a point in time, this list of questions was shortened to 4 questions which explored current care, following discussions with SPPG (formerly HSCB) who were keen that it mirror the approach used by the Belfast HSC Trust Neurology recall. It reverted back to 10 questions at the request of the Trust (and with agreement by SPPG) with all relevant case notes being assessed retrospectively to ensure consistency.

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Where concerns regarding the quality of care are identified, these cases are then considered at a screening meeting, attended by the Trust's acute directorate governance and clinical staff, to establish if the concerns meet the threshold set out in the regional SAI procedure. Where the case meets the criteria for an SAI, it is progressed as an SCRR.

The Expert Review Team considered that if the aim is to identify all cases where there is likely to be learning, the use of SAI thresholds may not be the most effective method. This was explored with Trust representatives who were in agreement. We were advised that cases considered for inclusion in the SCRR included the following:

1. SAI threshold met; concerns around the care and treatment in keeping with a theme already identified
2. SAI threshold met; concerns around the care and treatment in keeping with an emerging theme, not previously identified
3. SAI threshold not met; nonetheless, learning identified
4. SAI threshold not met; care and treatment "reasonable"

The Expert Review Team is of the view that it is acceptable to include cases from Group 3. Although a case may not meet the criteria for an SAI review, it may still contain valuable learning from a patient experience or service quality perspective.

To date, 53 cases have been identified that meet the criteria for SCRR. This number is likely to increase further, particularly if the care and treatment of additional patient groups is going to be subject to an extension of the Lookback Review; a total in excess of 90 cases is expected to be identified from this phase alone.

During fieldwork the Expert Review Team heard that of the 53 SCRRs passed to the external SCRR urologists between February and May this year only 20 have been returned to date. This prolonged process poses challenges for the Trust as they are keen to establish the full extent of learning in relation to these cases.

Given time constraints and limited availability of expert reviewers, the Expert Review Team was keen to explore whether a sampling approach had been considered by SHSCT. Such an approach would seek to maximise learning within the constraints of available resources and may lead to improvements being implemented at an earlier stage.

During fieldwork, Trust representatives remarked on the similarity of themes across the cases that have already been reviewed. We were informed that there was very similar learning arising from 19 out of 20 cases reviewed to date. This supports an argument that a point of saturation might be reached and there may be limited additional benefit to reviewing all cases, as was initially intended.

The Expert Review Team recognises that a pragmatic approach to sampling would mark a departure from the original intention and direction of the SCRR. It would be the Expert Review Team's view that such a departure requires a clear rationale to be agreed by the DoH; this would require the purpose, scope and Terms of Reference for the SCRR review to be clearly articulated and defined. DoH should ensure that such an approach is justified when taking into consideration the wider context,

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including the planned work and emergent findings of the Public Inquiry. The Expert Review Team's view is that a sampling approach would expedite learning and would allow an opportunity for earlier improvement to be implemented. However, there are ethical considerations and SHSCT should take steps to ensure that the sampling framework is robust and should be open and honest with patients and families about the approach and its rationale.

Understanding that some patients and families may be disappointed that their case is no longer going to be reviewed, SHSCT may wish to include an option for patients and families to request inclusion in the SCRR. If it is not feasible or reasonable to grant such a request, then the patient or family should be informed of the alternatives available to them, such as submitting a concern to the Urology Public Inquiry, SHSCT Complaints Department, GMC, PSNI or any redress scheme. It would be helpful at this stage for DoH / Urology Assurance Group / SHSCT to liaise with the Urology Public Inquiry to ascertain their intended approach to case identification and proposed methodology for delivering on Inquiry ToR (c). Should the inquiry intend to review all cases for those patients / families approaching the Inquiry Team, this would lessen the expectations on SHSCT, enabling the SCRR work stream to focus on applying a sampling framework with a view to deriving system learning and implementing improvement.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

2.1.7 Ethical Considerations

The application of ethical principles when conducting reviews of a complex and sensitive nature is invaluable to guide decision-making and ensure that the review is conducted in an open, transparent, fair and sensitive way. It can be helpful in ensuring a rigorous approach, adherence to a duty of candour, respect for confidentiality but also autonomy (i.e. right not to know) and in ensuring that specific patient groups are not inadvertently disadvantaged. It is also helpful when considering specific ethical issues that may arise from the process of reviewing patient cases, such as circumstances where previously undiagnosed or undisclosed hereditary conditions are identified.

SHSCT advised that no Clinical Ethics issues were identified for discussion with SHSCT Clinical Ethics Committee. The Expert Review Team is of the firm view that given the scale and sensitivity of the work involved, and the potential for inadvertent harm to be caused by the process, SHSCT would benefit from giving due consideration to the application of Ethical Principles. Advice from SHSCT Clinical Ethics Committee should be urgently sought and, if deemed necessary, this could be assisted by the HSC Regional Clinical Ethics Committee.

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We refer SHSCT to a recently issued Ethical Framework[3], developed specifically for RQIA's Expert Review of Deceased Patients of Dr Watt, which contains overarching themes that are applicable to any lookback or review of this nature:

1. Respect for Persons (which includes Privacy, Confidentiality and Data Protection, and the Right to Know and the Right Not to Know)
2. Transparency and Candour
3. Fairness
4. Responsibility

It was RQIA's experience that the process of discussing ethical principles and deliberating the potential for ethical issues is as valuable as the end product of any framework or ethical paper. In the context of the Expert Review of Deceased Patients of Dr Watt, it had wider benefits beyond ensuring that the methodology and the approach were ethically rigorous, and greatly assisted with the drafting of correspondence to families, and in the interactions with families by the RQIA Family Liaison Team.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

2.1.8 Legal Considerations

A legal perspective on review proposals and arrangements is prudent when undertaking work of this nature.

The Expert Review Team's experience is that it can be helpful across a number of areas including:

- Identifying previously unconsidered pitfalls in relation to correspondence with interested parties, proposed review methodology and approach;
- Ensuring there is appropriate indemnity for reviewers undertaking the SCRR;
- Managing data protection issues;
- Managing legal challenges from solicitors acting on behalf of patients / relatives;
- Managing legal challenges from Consultant A's legal team; and
- Requesting clinical records of patients reviewed by Consultant A in a private a capacity

Trust representatives advised that the Directorate of Legal Services (DLS) is supporting SHSCT with the Inquiry and that an opinion could be sought if required. However, SHSCT advised that legal advice had not been sought as the SCRR is being utilised as an alternative of SAI to establish learning from the situation. The Expert Review Team considered that legal input would be required in order to make this determination and also to consider the potential for future legal ramifications.

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It is the Expert Review Team's view that given the significance and scale of concerns, the likelihood of negligence and that this is a departure from the regional SAI process, a legal perspective should be sought in relation to the arrangements for SCRR.

Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

2.2 METHODOLOGY AND IDENTIFICATION OF LEARNING

2.2.1 Patient and Family Engagement

There is a statutory duty of Personal Public Involvement as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009[4]. Best practice in involvement is to seek the input of service users and families to help shape the review process, particularly around sensitive person-centred communication, the provision of support and a mechanism for sharing concerns. There may be additional valuable information from affected service users / families that will not be evident in the clinical documentation of the clinician under investigation; information from families and carers is particularly vital in those cases where a patient has sadly deceased. Importantly, effective patient and family engagement is crucial in order to adhere to the principles of candour and 'being open'.

The regional SAI procedure stipulates the requirements for patient and family engagement. On 7 July 2022, the report of the RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland[5] was published; this has relevant findings on effective engagement and involvement of families and recommendations for strengthening the regional approach and procedure. Furthermore, a draft 'Statement of Rights' as an output of the O'Hara Inquiry may be helpful in focussing HSC Trusts on the importance of appropriate and sensitive interaction with patients and their families.

Although the SCRR is not an SAI process, the Expert Review Team is of the view that, as a minimum, patients and families should be informed of the purpose of the SCRR, and that those affected should have an opportunity to provide additional information about their care and treatment. SHSCT outlined their process for engaging and involving families. The Expert Review Team is impressed with and commends the significant efforts SHSCT has made in contacting all impacted families, which, given the scale, is a huge undertaking. However, we note recent issues arising regarding the quality of patient information and consider that the arrangements for patient and family involvement in both shaping the process and sharing concerns require improvement.

The Expert Review Team considers that SHSCT PPI team and those external to SHSCT, such as the PHA and Patient Client Council, have been underutilised in ensuring that there are robust arrangements for PPI as part of the Lookback Review and SCRR.

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Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

SHSCT outlined its arrangements for following up and sharing the findings of the SCRR with patients and family members. Although there is a Family Liaison Officer (FLO) available to support patients and families, the findings are primarily shared through postal correspondence. Whilst this may be the preference of a large number of families, many may require additional support to understand and emotionally cope with the findings.

The Expert Review Team consider the following to represent good practice[6,7,8]:

- As far as possible, reports should be quality assured, checked for factual accuracy, and should be written in easy to understand lay language;
- Patients / families should be provided with a range of options on how they wish to receive the report; one option should be a face to face meeting. They also have a right “not to know” the findings;
- The Family Liaison Officer should be accompanied by a medical doctor in relaying the findings of the report;
- Psychological support should be made available to those impacted by the process and findings of the SCRR;
- If further medical follow-up is required by patients or relatives, there should be Trust arrangements in place to facilitate this in a timely manner; and
- There should be opportunities for the FLO to debrief with colleagues and timely access to psychological support for the FLO and any others involved in family engagement.
- Independent advocacy should be considered for patients or families, particularly when cases are complex. The PCC have extensive experience in this area through previous work on SAIs and other Inquiries.

During fieldwork, the Expert Review Team explored the support available for those staff members involved in the review and, in particular, the patient and family engagement. SHSCT described effective provision of support including: senior and peer support, psychological support and access to Inspire Wellbeing Counselling service. The Expert Review Team is content that the arrangements for support appear sufficient but cautions that a substantial proportion of the work appears to be undertaken by one FLO. Given the large number of cases identified, it may be beneficial to increase the capacity of the Family Liaison Team to provide support to those impacted by the Lookback Review and SCRR.

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Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

2.2.2 Methodology & Tool

Structured Judgement Review methodology is a reliable, well validated tool that has been developed by the Royal College of Physicians. It allows for the blending of traditional, clinical-judgement based, review methods with a standard format. The approach requires reviewers to make safety and quality judgements on particulars of care, to make explicit written comments, and to assign a score for the quality of care at each phase. This produces a rich set of information about each case in a form that can be aggregated to produce knowledge about clinical services and systems. SHSCT discussed the use of this tool with the Royal College of Physicians and opted for this methodology to underpin the SCRR process.

The Structured Judgement Review methodology was adapted for the SCRR in order to take into consideration the relevant phases of care. The phases of care assessed are:

- Triage;
- Initial assessment or review;
- Review of Diagnostics;
- Ongoing Outpatient Care;
- Admission and Initial Management;
- Ongoing Inpatient Care;
- Care during a procedure (excluding IV cannulation);
- Perioperative care; and
- Discharge plan of care.

The Expert Review Team is not privy to all the specific clinical concerns therefore cannot be certain that the tool adequately scrutinises all relevant aspects of care. With this caveat in mind, the SCRR tool generally appears reasonable. However, the Expert Review Team did note some areas that SHSCT may wish to address. There is some divergence from the RCP methodology in terms of the data collection instrument. There is no section to assess:

- Quality of documentation in the records;
- Communication between Consultant A and the patient / carer / family; and
- Communication between colleagues, MDT and primary care.

Whilst we were advised that deceased patients are included in the review, there are no sections outlining a review of the death certification or whether a referral to the coroner's service was required.

Of particular value in relation to deceased patients, but of great value for all cases, is the consideration of patient and family concerns. In general, there is a lack of patient

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and family input into the SCRR process. Patients and families were not engaged with in order to shape the review. Equally, there is no consistent mechanism to proactively seek the concerns of patients and families for consideration as part of the individual SCRR. This marks a considerable deficit in the information available to formulate findings. The experience of the Expert Review Team is that, where concerns from patients and families are taken into account, this greatly enhances the learning process and provides information and context that is often not present in the notes. RCP has successfully incorporated patient / family concerns into its review process by asking expert reviewers to review the notes firstly without knowledge of the patient / family concerns and then a second time taking the patient / family concerns into consideration. The complaint can then be judged to be 'upheld', 'partially upheld' or 'not upheld'.

RQIA's experience from the Expert Review of Deceased Patients of Dr Watt is that there is a close correlation between the views of family members and the judgement of the structured judgement tool (SJR), strengthening the argument that there is great benefit in attaining patient and family input. Where there is little or no correlation between the patient / family story and the clinical picture documented in the records, the Review Panel may determine that the family concern is 'not upheld'; of note, this only occurred for two (out of 44) patients included in Phase 2 of the Expert Review of Deceased Patients of Dr Watt.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Whilst Structured Judgement Tools provide an objective assessment of the care and treatment documented within the clinical records, it can only allow for a partial systems perspective. For example, it may tell a story of care and treatment according to the national standards of the time, of the standard and quality of documentation, multidisciplinary involvement, communication between colleagues and communication with family members. Of direct relevance, it will not examine factors such as caseload, working relationships and peer review.

Furthermore, it will not tell us about the governance systems within Urology Services or within SHSCT as a whole. It will not examine the role of external bodies and the wider system in providing oversight and assurance of quality and safety of care.
With this in mind, DoH or SHSCT Board may wish to commission RQIA to undertake a Review of Governance within Urology in Southern Health and Social Care Trust. This would provide an opportunity to identify and remedy any deficits, and to share learning within SHSCT and across the system so that governance systems may be strengthened and future harm prevented.

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Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

2.2.3 Expert Reviewers

Each case is reviewed independently by a 'Subject Matter Expert' (or Expert Reviewer) utilising the SCRR methodology. SHSCT provided details of Expert Reviewers, including a description of the job role and a copy of the guidance provided to reviewers at the outset of the work. The Expert Reviewers are nominated via the British Association of Urological Surgeons (BAUS) for their subject matter expertise. SHSCT ensures that each reviewer is appropriately registered and of good standing with their professional regulator, the General Medical Council (GMC). The Expert Review Team is content that reviewers appeared suitably independent and qualified.

In total, SHSCT approached 13 reviewers of which four Expert Reviewers have been recruited to support this work. Given the difficulty recruiting Consultant Urologists and the time consuming nature of the SCRR process, the Expert Review Team considered whether specialist nurse reviewers or urologists in training could be used instead. A clearly defined protocol with consultant oversight of the process would facilitate this. It was considered that a hierarchical culture within HSC, associated with perceptions amongst the Northern Ireland public that attaches particular significance to reviews undertaken by a consultant, may be a barrier to implementing a non-consultant review process. Therefore, if the work cannot supported by specialist nurses or trainee urologists, consideration should be given to the use of doctors working outside the specialty of urology.

The Expert Review Team noted that no training was provided to Expert Reviewers, who instead were stated to be familiar with SJR tool methodology. In addition, there was no specific manual provided to reviewers; albeit the following guidance was provided:

- Using the Structured Judgement Review method - A guide for reviewers; National Mortality Case Record Review Programme 2019[9]; and
- Structured Judgement Review - Frequently Asked Questions 2019.

Additionally, the process had not been piloted and there was no method of calibration between reviewers to ensure inter-reviewer reliability and consistency. Importantly there is no mechanism for quality assuring the work of reviewers, either by assigning two reviewers to each case or by second-reviewing a sample of the cases.

The Expert Review Team notes that 20 SCRRs had been completed at the time of fieldwork; and while we understand the challenges in delivering quality assurance of reviews within the current limited pool of reviewers it may be beneficial to conduct an independent review by a second expert reviewer to ascertain the degree of reliability and consistency in assessing the quality of care. A panel should then be convened

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to discuss any significant discrepancies in judgement, to gain consensus and provide expert reviewers with an opportunity to standardise their approach.

Even in the absence of discrepancies, it can be helpful for clinical reviewers to have a forum to discuss cases, debrief and avail of emotional or psychological support. Although it was reported that each reviewer can contact SHSCT Deputy Medical Director for Quality and Safety if issues arise, the Expert Review Team is of the view that SHSCT is missing an opportunity to proactively support reviewers, seek feedback on the process and seek reviewers' views on the learning arising.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feed back and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

2.2.4 Review Panel

Good practice dictates that in undertaking a review, an expert panel to deliberate findings and attain consensus on recommendations is preferable to the judgement of one individual expert. A forum for discussion between panel members allows for a sharing of expertise and perspective, brings a deeper and broader understanding of issues, mitigates bias and derives learning more effectively.

SHSCT stated that there is no specific review panel for the SCRR; however, the Trust Lookback Group oversees the overall lookback process that includes the SCRR. On completion of the initial batch of SCRRs, an independent Consultant Urologist will develop a thematic report on the findings.

The Expert Review Team considered that, as SHSCT has rightly identified that a key outcome of the SCRR is a thematic analysis in order to identify learning and inform system improvements, the process would benefit from a dedicated review panel rather than relying on the professional judgement of one individual to collate findings, identify themes and make recommendations. This was explored with Trust representatives during fieldwork, who advised that the RCS and BAUS had both been approached to undertake an independent quality assurance of the SCRR but SHSCT had not been able to secure agreement from either of these bodies. Subsequently SHSCT considered convening a multidisciplinary panel comprising eight individuals but due to limited resource and availability of staff this had not progressed. The Expert Review Team considers that a smaller panel, including

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urology, governance and lay expertise would suffice; encouragingly, Trust representatives were amenable to this model.

The Expert Review Team is of the view that any learning and evidence-based recommendations made by the review panel would require a commitment from SHSCT to implement a clear prioritised action plan within acceptable timescales.

Recommendation 15

A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR process. This panel should include individuals with expertise in urology and governance, and include a lay member.

2.2.5 Identification and Dissemination of Learning

Dissemination of learning is crucial in order to improve systems for delivery of care both within SHSCT and across the region. Any strategy for the dissemination of lessons learned should be supported by DoH / SPPG / PHA and should incorporate an action log of the system improvements required, along with timescales for follow up and review.

SHSCT stated that each SCRR report will be reviewed by a Trust clinician who will identify if there is any previously unidentified learning. The thematic analysis report will also be considered by SHSCT in respect of broader system issues.

SHSCT advised that returned SCRRs are reviewed by a Trust clinician who will decide on the appropriateness of sharing learning more widely; this includes learning that should be shared beyond Trust boundaries. Mechanisms for sharing learning were stated to include:

- Using SHSCT local shared learning template;
- Regional shared learning template;
- Morbidity and Mortality Meetings (Patient Safety Meetings);
- Acute Governance Meetings (Directorate wide); and
- Urology and Cancer Services team meetings.

The Expert Review Team considered that the arrangements for identifying, implementing and disseminating learning required strengthening. The reliance on the professional judgement of one clinician to undertake a thematic analysis, in the absence of a mechanism for the reviewers to discuss and feedback, compounded by the lack of quality assurance of individual reports, risks that important system issues may go unidentified. Similarly, the reliance on a Trust clinician to determine whether learning should be shared wider, lacks independence, and runs the risk that one person acts as a gatekeeper to the implementation of improvement and dissemination of lessons learned.

As stated previously, a review panel with representation from urology, governance and a lay member would serve to ensure that there is a robust mechanism for deriving, implementing and making determinations on the dissemination of learning.

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Where learning is derived, the Expert Review Team would expect that recommendations are made and clear prioritised time-specific action plans are put in place with arrangements for monitoring and accountability. A follow-up review, with defined parameters for assessment around implementation, would provide assurance around the implementation of sustainable improvements.

The information provided by SHSCT indicates that the consideration of dissemination of learning is confined to within Trust boundaries; although a regional shared learning template is referenced, it is not clear whether this in itself would be sufficiently robust to disseminate learning to the relevant stakeholders across the system. SHSCT representatives were of the view that the previous HSCB process for sharing learning from SAIs needs to be adapted or replicated for the SCRR process but that this had not yet commenced. The Expert Review Team is of the view that the mechanisms for sharing learning should be discussed urgently with DoH / SPPG / Urology Assurance Group. Recipients should include Public Inquiry, SHSCT Board, Urology Assurance Group, DoH / SPPG, PHA, and RQIA; under duty of candour principles, it should be considered whether there is an onus to share learning with the public. In any case, an effective strategy for communication with stakeholders would serve to underpin arrangements for the effective dissemination of learning.

Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

2.3 GOVERNANCE OF THE SCRR

2.3.1 Risk Management

Effective risk management relies on the identification, assessment, mitigation and monitoring of risk. All projects incur risks, such as risks associated with timescales, available expertise, budgetary constraints and data protection vulnerabilities. However, projects of this nature can carry considerable additional risk, such as the risk of causing harm to patients / families / public and reputational risk to the health service. It is vital that the structures, systems and processes in place support effective recognition and management of such risk.

The Expert Review Team was advised that the project does not keep a formal risk log; however, risks are recorded and discussed through meetings. At the time of review, there were three risks identified with mitigation actions identified for each.

When the Expert Review Team explored the issue of risk it was advised that the risks associated with the SCRR had progressed to both the directorate risk register for Acute Services and to the Corporate Risk Register.

The Regional Guidance for Implementing a Lookback Review Process (July 2021) states that:

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> "When scoping the nature, extent and complexity of the Lookback Review Process (Section 2.6 – 2.7) the Steering Group should evaluate and escalate the risk in line with the organisation's Risk Management Strategy. This will ensure that the risk(s) identified will be included in either, the organisation's Board Assurance Framework, Corporate Risk Register or Directorate Risk Register and managed in line with the Risk Management Strategy."

The Expert Review Team was further advised that SHSCT is currently transitioning to a revised organisational structure, designed to fully support SHSCT to fulfil its function in respect of the SCRR objectives; this is currently operating in in shadow form. As a consequence, the project will operate under more robust governance structures with a live risk register maintained specifically for the Lookback Review. Issues of risk will also be included in the ToR for the new Urology Lookback Review Steering Group and SHSCT Public Inquiry Programme Board (note these are working titles which may change when the new structure is finalised). The Expert Review Team welcomed these improvements which will serve to strengthen the current arrangements for risk management.

2.3.2 Records Management

Effective management of clinical records requires protocols for retrieving, scanning and sharing records, underpinned by strong governance arrangements. SHSCT described robust arrangements for accessing and sharing of clinical records, which was in keeping with good information governance.

A list of patient names and health and care numbers of those cases identified for SCRR is shared with a dedicated administrator. When a decision is made to proceed with SCRR, the relevant patient records are obtained through normal hospital processes by request of hardcopy notes via the medical records team. Notes in patient charts which are not available on NIECR are copied, scanned and uploaded to Egress Secure Workspace, an electronic platform, for sharing with expert reviewers. Expert reviewers also have secure access to NIECR.

There is a dedicated member of the clinical governance team assigned to support the SCRR process, who is responsible for obtaining the charts, extracting the records for scanning and who also uploads to Egress Secure workplace and notifies and liaises with the external expert reviewers. The Expert Review Team considered this approach to be acceptable.

2.3.3 Data Considerations

SHSCT outlined their arrangements for data protection. Document transfer is managed via SHSCT Egress document sharing platform and also via secure VPN access to NIECR records. Each Expert Reviewer is required to complete a Trust confidentiality agreement and Data protection agreement prior to accessing records.

The Expert Review Team identified a potential General Data Protection Regulation (GDPR) issue with the arrangements for contacting families. SHSCT would benefit

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from further consideration of information governance, and in particular, data protection issues in relation to SCRR.

Given the sizeable number of patients involved, a database is beneficial to track progress of the Lookback Review / SCRR, to analyse demographic and clinical information, and to monitor outcomes. SHSCT is presently developing a new database to store and analyse information in relation to the selected cases. Unlike the previous database which relied on manual population, the new database allows for automatic population, reducing the risk of input error. The Expert Review Team welcomes this development and advises that a statement of purpose should be drafted for the new database, outlining the rationale for transferring data; a copy of the old redundant file should be retained in case it needs to be examined at a later stage. If deemed to be helpful, SHSCT could be signposted to regional experts who recently developed a database as part of the neurology live patient recall.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

2.3.4 Communication with Stakeholders

Effective communication with stakeholders ensures that there is clear, consistent messaging on the purpose, remit, progress and findings of any review. It also facilitates liaison and co-operation regarding specific aspects of the work where external input is required in order to achieve a particular outcome. The need for robust stakeholder communication is referenced within the Regional Guidance for Implementation of a Lookback Review which highlights that the principle of 'no surprises' should be adopted and outlines that there should be:

- An agreed communication plan/liaison plan for other HSC organisations or independent/private providers which might be affected;
- An agreed media/communications management plan if required, that aims to be proactive in disclosure to the general public and considers responses to media enquiries; and
- Engagement with PSNI and coroner's service in line with standard procedures.

In addition to the above stakeholders, there should also be a channel of communication established with the GMC via the HSC Trust's Responsible Officer. All these elements are best considered as part of a comprehensive Communications Strategy developed for the specific Lookback Review.

SHSCT advised that when completed, the SCRRs are planned to be shared with the Urology Public Inquiry along with the thematic review of cases. Additionally, DoH will be provided with updates on the process via the Urology Assurance Group. SHSCT advised that the Coroner will be notified if there is a potential issue identified via the SCRR processes which has not previously been identified via Trust processes.

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The Expert Review Team considers that there is an absence of an overall communication and stakeholder engagement strategy. It is also noted that there is no channel of communication established between SHSCT and PSNI or GMC. The GMC is likely to be interested in the findings, which will be relevant to the Fitness to Practice (FTP) investigation of the consultant concerned. In addition, there is a possibility that the harm found could be of PSNI interest in terms of possible assault, gross negligence, or in extreme cases, manslaughter. The Expert Review Team considers that a Communications Strategy should be developed and examples from recent lookback exercises or similar review work across the region may assist SHSCT in expediting this.

Recommendation 18

SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

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Section 3 Conclusion and Recommendations

3.1 Conclusion

RQIA acknowledges the commitment of SHSCT to ensuring that this work is undertaken a manner that is robust and effective in deriving learning and informing improvements. This was evident, not only by the fact that SHSCT approached RQIA to request this review, with the aim of providing assurance, but also in the Expert Review Team's engagement with Trust representatives and staff during fieldwork. We acknowledge the amount of time and effort that SHSCT staff have given to this piece of work and commend their openness, candour and willingness to learn from the expertise of the Expert Review Team. This positive engagement and 'buy in' will assist SHSCT in implementing the necessary improvements.

RQIA was initially approached to provide independent assurance of the SCRR methodology. During preliminary discussions with SHSCT, we determined that this assurance should be broadened to include the wider process, governance and framework surrounding the SCRR process. This was felt to be particularly important given that the SCRR arose as a result of a significant number of SAIs which were identified through SHSCT Lookback Review, at which point the decision was made to adopt alternative methodology to the SAI process. The Expert Review Team endorses this decision. Structured Judgement Methodology, when applied appropriately, is a reliable, validated methodology which offers an effective means of deriving learning and implementing improvements.

However, when examining the SCRR process within the context of the Lookback Review, it was apparent to the Expert Review Team, that the Lookback in itself is not only a significant undertaking for SHSCT but its progression is a matter of urgent priority. An assessment of the historical care of patients, whose cases had undergone the screening process for SCRR, identified deficits in care and treatment prior to 2019. SHSCT is presently conducting a risk assessment and has commissioned RCS to undertake a review of cases relating to 2015 which should assist SHSCT in determining the future scope and scale of their Lookback. The Expert Review Team is of the firm view that SHSCT should not wait until this work concludes, and based on the evidence SHSCT has gathered to date should proceed to review and recall further groups of patients which it has identified to be at risk of harm.

Understanding that this is a considerable undertaking and that issues have already been identified regarding the availability of expertise and resource to support the Lookback Review, SHSCT will require significant support from the wider HSC system: DoH, SPPG, PHA and RQIA. A dedicated, appropriately resourced and experienced project team should be established as soon as possible to support this work. This may require secondment of additional individuals with the relevant skills and experience to SHSCT. RQIA recognises the efforts SHSCT has already undertaken to improve its lookback arrangements and is keen to support SHSCT with further improvements. As RQIA is best placed to provide assurance on the current arrangements to ensure strong foundations for scaling up and extending the Lookback time period, we recommend that RQIA undertakes a follow-up piece of assurance work looking specifically at the Lookback Review. Going forward, in order

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to allow SHSCT to focus on the Lookback Review, ideally the SCRR should be undertaken by an independent body. The Expert Review Team understands that SHSCT may not be able to secure the support of an external organisation; therefore, we make a number of recommendations to strengthen the existing SCRR process and arrangements.

SHSCT should explicitly state the purpose of the SCRR and draft a Terms of Reference as soon as possible. Caveated with the fact the Expert Review Team is not privy to all specific clinical concerns, the tool itself appears reasonable, but it does deviate from the tool used by RCP and leaves a number of areas unexamined such as quality of documentation. In addition, given that a proportion of patients are deceased, it would be judicious to update the tool to take into consideration death certification and the need for coronial referral. The Expert Review Team advises that SHSCT liaise with RCP to ensure the tool is appropriately aligned and that SHSCT mirrors RCP's approach to considering patient and family concerns as part of the SCRR process.

The arrangements for patient and family involvement require significant strengthening. Inclusion of lay membership on the relevant project groups would ensure SHSCT meets its statutory duty of patient and public involvement. The Expert Review Team also provides advice on best practice in involving, listening to and supporting patients and families through processes such as these in a way that reduces the potential for further harm and serves to restore faith in the health service. Given the scale, complexity and sensitivity of the work involved, due consideration should be given to seeking an ethical perspective on arrangements through SHSCT Clinical Ethics Committee.

RQIA notes the large number of cases that have been identified for SCRR and the difficulty this poses in terms of conducting SCRRs within reasonable timescales, compounded by the limited number of expert reviewers. A sampling approach is pragmatic and effective in deriving learning within the constraints of time and resource. However, this requires a clear purpose; ToR; agreement with DoH / Urology Assurance Group; due consideration of ethical considerations; and considered and sensitive engagement with patients and families. Importantly, where cases are selected for review, this should be done to a high standard.

A document should be developed to guide reviewers through the SCRR process and there should be a mechanism for calibration between reviewers to ensure consistency and inter-reviewer reliability. Additionally, a sample of the cases should be subject to second review for quality assurance. Understanding that this is challenging to achieve within reasonable timescales with a limited number of reviewers, the Expert Review Team recommends that SHSCT considers recruiting non-urology consultants to review the cases, guided by a defined protocol and with appropriate expert oversight.

Whilst the outcome of individual case reviews will be valuable to patients and families in terms of understanding what went wrong and why, it is the overall learning derived from the SCRR process that will assist SHSCT and the region in improving its systems. Therefore, it is vitally important that SHSCT strengthens its arrangements for identification and dissemination of learning. A review panel

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comprising members with expertise in urology and governance, and a lay representative should be established to deliberate findings, derive learning and make evidence-based recommendations. Equally, the mechanisms for sharing learning require an effective dissemination strategy to be agreed with DoH / SPPG and PHA. Underpinning this, communication with stakeholders including GMC, Coroner's Service and PSNI requires to be underpinned by a Communication Strategy and established channels of communication. Furthermore, the arrangements for sharing information with the public under a duty of candour and for developing patient and family information require considerable strengthening. Encouragingly this is already being explored by SHSCT in light of concerns surrounding factual accuracy of previously issued patient correspondence.

On the whole, the challenges facing SHSCT are considerable, complex and require a concerted effort with appropriate involvement of a number of organisations; DoH / SPPG, PHA and RQIA. Retaining the focus on patient safety, the Lookback Review requires urgent support and upscaling. Whilst SCRR will be valuable in establishing deficits within the care and treatment of this patient population, it is limited in terms of deriving systems and governance learning. As such, RQIA advises that a Review of Governance of Urology Services would be crucial in terms of providing assurance around the current service. RQIA is committed to providing both independent assurance and improvement support to SHSCT as it continues its efforts to urgently address deficits in care whilst improving the quality and safety of SHSCT urology services.

3.2 Summary of Recommendations

Recommendation 1

SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

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Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

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Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feedback and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

Recommendation 15

A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR process. This panel

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should include individuals with expertise in urology and governance, and include a lay member.

Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

Recommendation 18

SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

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Appendix 1: Terms of Reference for the Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

(a) To review the Southern Health and Social Care Trust's (the Trust) handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice. The Inquiry shall determine whether there were any related concerns or circumstances which should have alerted the Southern Trust to instigate an earlier and more thorough investigation over and above the extant arrangements for raising concerns and making complaints.

(b) To evaluate the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients seen by the urology consultant Mr Aidan O'Brien (for the period from January 2019 until May 2020). This includes the communication and escalation of the reporting of issues related to potential concerns about patient care and safety within and between the Trust, the Health and Social Care Board, Public Health Agency and the Department. It also includes any other areas which directly bear on patient care and safety and an assessment of the role of the Board of the Trust.

(c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within the Trust's urology specialty.

(d) To afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry.

(e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien. The Inquiry is asked to determine whether the application of this Policy by the Trust was effective and to make recommendations, if required, to strengthen the Policy.

(f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose.

(g) To examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations in fulfilment of these Terms of Reference.

The clinical practice of Mr O'Brien is being investigated by the General Medical Council (GMC) and it would, therefore, be inappropriate for the Inquiry to encroach on the GMC's remit. The Inquiry shall submit a report as soon as practicable to the Minister for Health. Should the Inquiry as part of its investigation establish any issue of concern which it believes needs to be brought to the Minister's immediate attention, then this will be done.

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Appendix 2: Structured Judgement Review[10]

Case note review remains a prime means of retrospectively assessing quality of patient care. Implicit review is based on clinical judgement and is judged to be effective in identifying and recording the detail and nuance of care (both unsatisfactory and good).

Unstructured implicit review was criticised for low inter-rater reliability (high variability) and for potential reviewer bias. Structured implicit review methods require reviewers to use a judgement based structured explicit scale to rate quality of care from very poor to excellent. However, this form of review only provides a scale based quantitative result giving no indication of why a reviewer made a particular judgement. This means that it is useful for large scale monitoring or epidemiological studies of adverse events but is less effective for more detailed review at ward or hospital level of why an event occurred.

To increase the value of structured review in reviewing the whole spectrum of care quality, rather than focussing only on adverse event rates, a methodology was developed where reviewers were required to provide implicit clinical judgements and to write explicit comments to support judgement based quality of care scores: this forms the basis of Structured Judgement Review.

Structured Judgement Review requires reviewers to make safety and quality judgements over phases of care, to make written comments about care for each phase and to score care for each phase.

The objective of this review method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about hospital systems where care goes well and to identify areas where there may be gaps, problems or difficulties with the care process. It can be used for a wide range of hospital based safety and quality reviews across services and specialties and not only for those cases where patients die in hospital. The quality and safety of care may be judged and recorded whatever the outcome of the case and good care is judged and recorded in the same detail as care that may have been problematic.

There are two stages to the review process.

Stage One

Carried out by ‘front line’ reviewers who are trained in the method and who undertake reviews within their own services, for example in Morbidity and Mortality Reviews.

Phases of care – the ‘structure’ part of the process.

Phases of care are shown below but may be varied depending on the type of care or service being reviewed:

- Admission and initial care – first 24 hours
- Ongoing care

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- Care during a procedure
- Perioperative/procedure care
- End of life care (or discharge care)
- Overall assessment of care

Explicit Judgement Comments

Explicit judgement commentaries provide:

- The means for the reviewer to concisely describe how and why they assess the safety and quality of care provided.
- A commentary that other health professionals can really understand if they subsequently look at the completed review.

Phase of Care Scores

Care scores are recorded after judgement comments have been written and the score is itself an overall judgement of the reviewer. Scores range from excellent to very poor.

1. Very poor care
2. Poor care
3. Adequate care
4. Good care
5. Excellent care

Judging the quality of recording in the case notes.

As part of the overall assessment, the reviewer is also asked to record their judgement on the quality and legibility of the records again using a score of 1-5.

Second Stage Review

A score of 1 or 2 is given when the reviewer assesses that care has been poor or very poor. A score at this level should trigger a second stage review through the hospital governance process.

A second stage review also uses the structured judgement method and takes place if a patient has died. If the second stage reviewer broadly agrees with the initial case review a decision may be taken to carry out a further assessment concerning the potential avoidability of the patient's death.

The judgement is framed by a 6 point scale. A score of 1,2 or 3 on the avoidability scale would indicate a governance 'cause for concern'.

1. Definitely avoidable
2. Strong evidence of avoidability
3. Probably avoidable (more then 50:50)
4. Possibly avoidable, but not very likely (less than 50:50)
5. Slight evidence of avoidability

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6. Definitely not avoidable.

Structured Judgement Review can produce learning at two levels:

- The detail captured can identify both poor practice and good practice of individual clinicians.
- When multiple reviews are undertaken within a clinical area or a hospital, a thematic analysis can be performed that may highlight systemic issues in a system.

Quantitative data identify very poor to excellent care in a number of care phases. Qualitative data from explicit judgements may be analysed, for example using word detection software, to identify recurrent themes.

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A. Yeah.

12 Q. And he was in reasonable health then for a while?

A. Yeah.

13 Q. Before, sadly, he died from something unrelated to the cancer? 10:28

A. We wonder how much of an impact it took on his health, those couple of years in total, whether if it was not directly related to the cancer, certainly, but a man of that age and we know that towards the end, part of the reason for his death was stomach ulcers and things like 10:28 that, and they're things that are connected to stress. So whether a connection can be made, and I know it's outside of the scope of the Inquiry, it can't have helped his health in the long run. It can't have, and we don't believe it did. 10:28

14 Q. Can I come on, Patient 15's son, to ask you a little bit about when you first became aware that there was an issue about how the referral was handled within the Trust?

A. The only thing we, as a family, knew about any of this, 10:28 we never heard of SAI or we had never heard of any review, we never heard of any details, was in May of last year whenever my mother received a phone call from the Trust, I presume the hospital, Craigavon, saying: "I believe you have made a complaint about the 10:29 treatment of your husband", and this was confusing. No complaint was made. We didn't know that there was a reason at this time for a complaint to be raised. And then a phone call was arranged for Mr. Haynes to call

back to my mother to speak to her. So that happened later in the week, and during that phone call was the first time any indication that there was any sort of delay, any sort of abnormality or reason for concern in the treatment or triage or anything like that, but for 10:29
the fact that it was going to -- it seems to us but for the fact it was going to be in the media, we wouldn't have received that phone call, and that phone call, despite what some of the evidence there says, if I could point you to PAT-1132. 10:30

15 Q. Is that PAT-001132.

A. PAT-001132.

16 Q. Do you want to maybe call that document up? Perhaps if we can make that a little bit bigger. Sorry, I think that's the wrong number, isn't it? It's PAT-001132. 10:30

A. PAT-001132, yeah. You know, that middle paragraph there:

"19/05/21 I can confirm that Mr. Haynes has telephoned Patient 15's wife this morning and advised that her 10:30
husband was part of the original SIA."

17 Q. If I can just pause you there, Patient 15's son. We're having a little technological difficulty. This is 10:31
what this week is designed to iron out so I hope you will bear with us. I'm not quite sure what has happened. There we go, thank you.

A. So because my mother was notified that that call was

	notified, however Ronan stated that a consensus from the group was required. Patricia to link with Melanie, Maria and Mark. 10/02/21 - Agreement that family would be notified. Update to be secured from Martina Corrigan. 03.03.2021 To email Martina to see if Mr Donaghue has met with patient's family. 14/04/21 - Martina not aware that this needed to be carried out. Carly liaising with Patricia re same. 19/05/21 - I can confirm that Mr Haynes has telephoned Patient 15's Wife this morning and advised her that her husband was part of the original SAI into urology services. He firstly apologised and then advised her about the original review into the triage of GP referral letters. He advised her that the review looked at two aspects. 1. What can be done about the process and the consultant? 2. What impact the delay in referral letters had on the patients overall care. He advised that we would follow up with the learning to the family. We will agree a letter for Melanie to send but I do believe all the patients involved in these cases new and old urology reviews should have a formal apology from the Trust. 26.5.21 Mr Haynes spoke with family. CLOSE
Decision on Level Review Type AND rationale for this:	
Nominated Review Team: *(Consider need / benefit of independent external expertise)*	
Is it appropriate to inform the Medical Executive/Executive Directorate of Nursing?	☐ Yes ☐ NO
Contact for service user and / or designated relatives / carers: *(Either Lead*	

going to happen, she asked me to sort of be there and listen in, and the fact that that mentions or advises that her husband was part of the original SAI in urology services,that's not what we came away with.

18 Q. Can I pause you there? 10:31

A. Yeah, sure.

19 Q. Was that the first time -- were you told that? Do you recall were you told that at that time?

A. We discussed this and neither of us recall SAI or Serious Adverse Incident or anything like that, we 10:31 don't recall the term but it may have been mentioned but it wasn't what the call started for. The call started to let us know that there is going to be a report in the Irish news that there was some attempt by whoever going to be made to block it but that this was 10:31 shining a light on somebody and practices within the Trust. And again, for us not to worry, it didn't affect the treatment or the outcome for my father. I queried that point again, what was said there, any delay did have an impact, both for my father and the 10:32 family. But the impression we were left, after the call, was this was purely a spin exercise. This seemed to be going -- 'There is going to be media attention, just ignore it, don't worry about that, everything is fine. Patient 15 survived.' That seemed to be the 10:32 thing.

If SAI was mentioned, it may have been, I don't honestly remember, neither of us can remember those

terms being used. There was mention of a delay and this was the first time we'd had any indication that there'd been any sort of delay or problem with the treatment. It was the very first instance and the only instance until the Inquiry. So there was mention -- he did offer to meet, in fairness, but at the time, Covid was rampant and nobody wanted to go to a hospital in the middle of that, but he said he would follow up and that never happened. That is the only information we had and it seems to be purely the only reason we got it was because there was going to be something in the press. 10:33 10:33

Then the other thing, still in PAT-001132:

10:33

"26/5/21: Mr. Haynes spoke with family. CLOSE."

We're confused by that. He didn't speak to us on the 26th, maybe it refers to the 19th, but why "close" in capital letters? Does he think that's them dealt with, the family doesn't need anything more. We don't need to share anything more? That's something possibly for yourself. 10:33

20 Q. That's something that we can ask the Trust about that and ask for clarity around that, Patient 15's son. Can I just ask, though, it does say that he advised your mother that the review looked at two aspects; what can be done about the process and the Consultant and what impact the delay in referral letters had on the 10:34

through, you'd think we'd be going "what's going on here", as a family, and say is there something we need to know about? But we don't believe we have ever seen that. And PAT-001139...

34 Q. Mm-hmm. 10:39

A. ....is very confusing. Again no reference, no signature, no date. And from Mr. O'Donoghue. It seems to be a very well intentioned letter but what has got us baffled is:

10:39

"Firstly, I want to apologise if the phone call you received from the Trust caused you some distress or confusion. That was not my intention."

How did he know? Where did he get this information 10:39
from? We were only spoke to by Mr. Haynes once. We didn't speak to anybody else to let them know that it had caused distress. Mainly, whenever the Irish news published the article, my mother wasn't in great shape for a couple of weeks after that but..... 10:40

35 Q. But you hadn't actually contacted the Trust after that Irish News?

A. No. We were, between ourselves, debating what should we do next and then we found out Mr. Swann had announced that there'd be an Inquiry. So, you know, 10:40
knowing well that these things need to run their course, I suppose, there's no point in us challenging things now if the Inquiry is going to take over. But this letter, why it's confusing, we don't understand

the background to it, where the information that Mr. O'Donoghue is working from there is coming from and an offer to discuss. As my mother said to me, if for a second she thought at this stage, you know, she could have talked to somebody or we could have talked to somebody, the offer would have been accepted, definitely.

36 Q. So you don't believe that letter was ever received?

A. No. A hundred percent, that's addressed to my mother I'm a hundred percent that that letter was never received. 10:41

37 Q. Is it fair to say that most of the communication and documentation that you received came, in fact, from the Inquiry to the family?

A. Apart from Mr. Haynes' phone call about the press article and that admission that there was a delay, all of our information has come from the Inquiry. All of it. Everything. 10:41

38 Q. Thank you very much, Patient 15's son. Is there anything else that you would wish to say at this stage or wish the Inquiry to know, either about your father or about his care? 10:41

A. Again, just I'm not very good at conveying just how big an impact it did have on him but what is very frustrating for the family, I think, and I don't know if "anger" is the right word because you're at a stage where you are frustrated and everybody, I think, when it comes to this sort of thing, initially you go; 'Well, maybe it was a mistake', but then when you see 10:41

the evidence and you read the media articles, which seem to be reasonably accurate, you're going; 'It's not a mistake and we can't ignore it.' The fact that, you know, we don't see any one individual, there is certainly plenty of individuals who have caused problems but we don't -- we see it as a collective, if there's a failure to triage and then there's a failure to address the failure to triage and it goes back 25 years, I mean, if you or I, we were talking about, anybody in a normal profession was in that position where they were challenged multiple times, something would be done. But even excluding individuals, the Trust has a duty of care, everyone knows that, the Trust has a duty of care and the Trust needs to be grown up and deal with its problems and it hasn't done that. And we're just obviously one of many and God knows how far back it goes. We understand, too, that you know, the medical profession, and I'm sure it's a thankless task at times, and there are many people doing wonderful jobs every day, you know, certainly with my father, the same, you know, very thankful, but, again, it's kind of like football, you're only as good as your last win and whenever you see, you know, if a thousand patients are successfully cured and then a handful are missed because of any sort of action or whatever way you want to describe it, it's not acceptable. I understand there's pressures on every part of the NHS at the minute, financially and all that, but we still need to find ways to do the

10:42 10:42 10:43 10:43 10:43

important things, unfortunately. So...

CHAIR: Thank you, Patient 15's son. Dr. Swart is there anything else you would like to ask?

39 Q. DR. SWART: Thank you very much for sharing your story, it is so important that we hear about how it has made you feel and your family feel and your father feel. I think you have described quite well the impact of the six-month delay and the anxiety that caused. Clearly, there's been some communication, significant communication issues around the Serious Adverse Incident. 10:44 10:44

A. Yeah.

40 Q. If you'd had the offer, would you have been happy as a family to come in and contribute to the Terms of Reference of such an investigation? Did you know about serious incidents about this or did anybody ask you what you'd like it to find out, for example? 10:44

A. You mean, if it had happened back then?

41 Q. Yeah.

A. We would certainly would have taken any offer, if we'd known or if we had been contacted, absolutely we would have engaged with them. 10:44

42 Q. And how did you feel about the fact that nobody explained that to you and the sort of confusion around it? 10:45

A. The frustration, mostly, I'd like to say anger is the wrong word.

43 Q. Mm-hmm.

A. It's that sort of frustration of why, you know? Is it

somebody trying to hide something? Is somebody trying to avoid culpability? Why were we excluded? Why was the information not shared? It's frustrating and it makes you worry about if this has happened to us, what else is happening? You know, you lose faith in the systems which are there, which shouldn't be the case.

44 Q. If you had the opportunity to talk to the Trust Board today and they said, you know: "Patient 15's son, can you give us one piece of advice about the serious incident process in relation to families?", what would that advice be?

A. I think that there needs to be better procedures which you see in the recommendations. There's a start there, but there needs to be better procedures in place to catch things like this. It seems that there is no auditing in the past of these procedures to catch any sort of failure or anything or anybody that would be missed and there is no escalation process. So that is the thing I guess I would say to the Trust; improve your procedures to make it so that this can't happen, you know. I work in IT so we've got procedures and we've got risk assessments and we go, you know, "Can you do this?", blah, blah, blah, and there's always an escalation made and there's also a way to audit and check everything's done right and, you know, those can be annoying and complex, but at least I'm only dealing with computers, you know, not life. So, you know, it's a very different matter. So the fact that those weren't in place is kind of flabbergasting

You explained earlier that this initiative to bring improvement to the cancer arena broadly, as I understood your evidence, is the subject of a separate piece of work within Urology itself, and that's where your improvement role kicks in. Explain to me the mechanism. Do you know - assumedly you do know - what's going on with the Task and Finish Group, and then it's your responsibility or your team's responsibility to ensure that those kinds of initiatives are implemented for Urology? 14:43 14:44

A. So if you go back to the Task and Finish Group membership, included in that membership is the Urology MDT Chair Mr. Glackin and three specialist nurse specialists. So there is Urology input in there in addition to my being a member. So although I wasn't able to attend, there was Urology input into that. 14:44

My role, as you say, is very much to make sure that these things are implemented in Urology. In Urology, as is highlighted there in the second point, Urology was very much used as the first rollout for these things. That audit of outcomes was done for us first and then has been rolled out across others. There's a dashboard that is produced on a monthly basis which gives us our cancer dashboard in terms of waiting times, treatment times. 14:44 14:45

ineffective response, an ineffective governance response. It is that point that I'm focused on. Has the responsiveness or the culture changed around that? If there is an outlier in terms of one of your colleagues, what is the appetite for addressing that at the coal face? Is there a better approach to escalating these matters, or where does your confidence lie in all of that?

A. So it's only -- fortunately, I haven't had to escalate a noncompliance thing, but we do have monitoring that is ongoing of the entire team on a number of issues directly related to some of the failings that have been identified. I've mentioned there that private practice is -- as I say, I know that this is monitored but I haven't had to escalate it. If we look at management of results, we have a monitoring process, we have an escalation process within that, but I haven't had to go beyond the first step of that escalation at any point. That first step of the escalation is me contacting the clinician. Typically that is that they've fallen behind because they've had a period of leave and they are just over two weeks in terms of actioning their results.

If we look at triage, we have a monitoring process in place, we have an escalation process in place. I haven't had to trigger the higher steps of that escalation process because they haven't happened. So I'm confident that we have processes surrounding

a number of the failings that have procedures linked to when there is a failing identified that escalate it through the system and the medical management structure that will identify the problem and enable it to be tackled.

The very first point, though, is that actually lots of it is self-policing, certainly I found with many things. If you are telling your team of consultants this is how well you are doing at this particular thing and you've effectively got a league table, although you may not portray it as a league table, they make sure that they are not the outlier. So it is self-policing. So before anyone needs to escalate, someone will spot that I'm a bit behind, I better pick myself up.

10:17

10:17

10:17

10 Q. Perhaps later we'll look at some, if you like, of the devices or tools that have been constructed to ensure that outlying behaviours are more quickly picked up. Is it not fair to say to while there have been improvements in the development of those kinds of alarm bells or devices, during the whole triage problem, during the whole notes at home era - put it in these terms - the system knew that the rules were being broken. The problem, perhaps, which I'm pointing to was where was the appetite, where was the culture in terms of properly addressing what was known, in other words, the first line manager speaking to, in this case Mr. O'Brien, or escalating as the case might be. It's that, I suppose, I'm asking you to comment upon.

10:18

10:18

that a draft is there of a standard aspect of a letter for that purpose. That piece of work is ongoing.

The preoperative assessment team are engaged and clinically led to try to improve that position. As I've said, within our service our theatre scheduling is done by our scheduler, so where patients haven't been through preoperative assessment, they are not added, or an active decision needs to be made and is made in communication between an anaesthetic team and a surgical team as to whether it is reasonable to proceed without it. Invariably the answer to that is no. 15:28 15:29

I think the position is there. There is ready access to additional, if you like, enhanced anaesthetic assessments with physiological testing, so CPX testing where we can give, for patients who are having more major surgery, and they do get, a very personalised assessment of their risks of undergoing that major surgery. 15:29 15:29

136 Q. Can you ask you briefly, just finishing on this aspect of clinical aspect shortcomings, triage and the area of dictation following reviews or clinical episodes. Taking them together, what work has been done to better keeping a check on those and escalating those issues if there are shortcomings? 15:30

A. So triage is part of that dashboard that I mentioned earlier that we get. So we get along or within that

dashboard detail of triage and time scales for triage. There is a data limitation within how that's obtained, which means that the time scales applied can be complicated by factors like a patient needing registration or the referral going to another Trust first before being redirected, because the time scale is from the point at which the GP presses refer, not the point at which it is passed to the consultant for triage. So there is a limitation in that but it is monitored and there is an escalation process. 15:30 15:31

I neglected to mention earlier when we talked about results but it applies to the dictation and the triage as well. We also have an in-person interface meeting where myself, the head of service, our manager for our admin and support team, and our Cancer Services manager meet on a monthly basis and run through the performance across the team looking at triage, looking at dictations, looking at results management, and if any other things need to be brought up. You mentioned earlier is it fair for a secretary to be the one who contacts the consultant first. It is not only the secretary that does it, it would come to that meeting as well. 15:31 15:31

137 Q. You spoke on the last occasion, and indeed in real time you were speaking to Dr. O'Kane about the shortcomings of the backlog reports that were being utilised to monitor Mr. O'Brien. In general, I think you expressed the view that they would perhaps give the uneducated 15:31

Director for Urology Improvement, we have a weekly audit, exactly as described there, where we have a report generated as to how many outstanding results are awaiting sign-off by the Consultant Urologist. I've developed that in a red, amber, green format so results that are less than two weeks old, results that are two to four weeks old, and results that are over four weeks old. I know that within Urology, we have a system working where all of the Consultants are working utilising the electronic sign-off and the print -- or the result yesterday, the result last week is the only outstanding results are less than two weeks old, so I know that, within Urology, we have developed that system, and I've started speaking across the other Divisional Medical Directors as to how that can be translated across into other Specialties. 14:19 14:20 14:20

122 Q. Yes. I think the Inquiry might accept that sometimes it's more difficult to develop a system-wide solution, you know, that goes through, no doubt, numerous committees and numerous obstacles before you get a solution at the other end, but it's perhaps easier to devise an individualised bespoke solution, so if you know that a particular Clinician is falling foul of the rule that you described earlier as sort of get to these things promptly, then it should be a straightforward matter of including that as part of a monitoring arrangement? 14:20 14:21

A. Yeah. So if you are monitoring arrangements, particularly if you are monitoring arrangement for the

Southern Health and Social Care Trust

PAT-000804

Structured Clinical Record Review title(SCRR)

Section 1

This section should be completed as soon as is possible following identification of the incident
If it is deemed appropriate to complete Section 2, it should be completed within 8 Weeks (56 days)

Patient identification number:	Personal Information redacted by the USI	**Gender:**	Male
Date of birth (dd/mm/yyyy)	Personal Information redacted by the USI	**Age:**	72
Date of Incident	23/11/2021	**Date Incident Reported:**	23/11/2021
Datix Incident Number	Personal Information redacted by the USI		
Date of death (if relevant)	Personal Information redacted by the USI		
Location of death (if relevant)	Personal Information redacted by the USI		
Was the patient identified as being within the last 12 months of life?	Yes palliative Prostate Cancer with multiple metastasis		
Cause of death (if known)	Metastatic Prostate Cancer		
Primary diagnosis, including ICD-10 code (if known)	Prostate Cancer		
Co-morbidities			
Healthcare teams involved in the patient's care at the time of incident			

Patient summary (can be completed by the clinical team)

Highlighted by Prof
Initial diagnosis in 2009 with a Gleason 7 T2 adenocarcinoma of the prostate gland. US guided biopsy in 2012 Gleason 7 was noted and a PSA of 3.9. Lower and unlicensed dose of Bicalutimide. No record of discussion of surgery/ delay in radiotherapy

Concerns from family members or carers about the patient's care (please outline concerns, or state if there were no concerns)	Wife and Son (Personal Information redacted by the USI) concerned as cause of death was prostate cancer.
Concerns from staff about the patient's care (please outline concerns, or state if there were no concerns)	

Time taken to complete Section 1 of this form (minutes): ……

Care Review Tool for Urology

Date of completion: ……

Name of person completing Section 1: local team

Job title of person completing Section 1 ……

Section 2

Please state the information sources used for the review, including the names of the electronic systems accessed:

EGRESS and NIECR

2.1. Phase of care: Triage (where relevant)

- **Was triage conducted in a timely manner?**
- **Was the triage outcome assigned an appropriate level of priority given the information available at the time?**

Please record your explicit judgements about the triage process and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Initial Triage correct following GP referral with abnormal PSA 3.47 and small volume prostate

Repeat PSA 4.22 leading to prostate biopsies performed at time of partial nephrectomy

Could have had prostate biopsies earlier as an independent procedure to ensure early diagnosis, PSA marginally elevated so delay not clinically significant

Subsequent management of prostate cancer inappropriate but no triage issues

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☒ 1 Very poor care ☐

Section not applicable ☐

2.2. Phase of care: Initial assessment or review (where relevant)

- **Were the investigations, prescribing, diagnosis and clinical management approach and communications with patient, primary care and MDT teams appropriate?**
- **Were diagnostic tests or investigations requested in a timely manner and with sufficient clinical information to allow appropriate onward prioritisation?**

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Initial assessment of elevated PSA inappropriate, should have had US guided biopsies but instead had delayed biopsies at time of partial nephrectomy. These biopsies were performed blind via the perineum and proved positive for cancer in 3 of 5 cores revealing Gleason 3+7 prostate cancer

The oncology MDT recommended staging but there was no management recommendation – other than OPC review. Mr O'Brien was chair of the MDT and I am not sure if an Oncologist was present.

There was no subsequent discussion of treatment options which would have included radical prostatectomy and radical radiotherapy. The patient was then age 59y and active surveillance would not be standard recommendation for Gleason 7 prostate cancer in a fit man.

This is a serious failing to provide active prostate cancer treatment option with curative intent and the MDT outcome was inadequate with no guidance.

Active surveillance was incorrect advice as was starting Bicalutamide in 2013 following a PSA rise. Hormone monotherapy for localised disease was inappropriate at that time and the dose of 50mg is not recognised or licensed for the treatment of patients with localised prostate cancer.

He finally received radical treatment in the form of radiotherapy in 2014 after further MDT review, but could have had treatment in 2009

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

2.3. Phase of care: Review of Diagnostics (where relevant)

- **Were diagnostic tests or investigations reviewed in a timely manner with appropriate further actions taken?**
- **Were any required actions adequately communicated to patient / primary care / MDT teams?**
- **Please list medication if known and relevant, and comment on medication monitoring where appropriate**

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Diagnostic tests were delayed but correct. Clinical management and treatment were incorrect

No treatment outcome from MDT in 2009 at time of initial diagnosis. Finally referred in 2014 when referral for radiotherapy recommended.

No record of treatment options discussed with patient in 2009. Why he was not offered radical treatment at that time remains unexplained.

The patient had no opportunity to discuss the result of diagnostic tests and subsequent treatment options. He was denied the opportunity of curative active treatment for his localised prostate cancer.

I am concerned that Mr O'Brien was chair of the Oncology MDM at that time and was making incorrect prostate cancer recommendations without challenge.

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

2.4. Phase of care: Ongoing Outpatient Care (where relevant)

- **Were ongoing reviews scheduled at appropriate intervals?**
- **Were referrals made to other teams / professionals appropriately and in a timely manner?**

- **Where any further required tests / investigations requested and performed in line with good current practice?**
- **Please list medication if known and relevant, and comment on medication monitoring where appropriate**

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Review was timely but prostate cancer treatment advice fell well below that would be expected.
Active surveillance inappropriate
Standard treatment for 59-year-old man diagnosed with T2 Gleason 7 prostate cancer is active treatment (surgery or radiotherapy according to patient preference)
Age 59y at time of diagnosis in 2009

Bicalutamide 50mg monotherapy 2013 inappropriate

MDT outcome 2019 unsatisfactory

Please rate the care received by the patient during this phase as:
5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

2.5. Phase of care: Admission and Initial Management (approximately the first 24 hours) (where relevant)
Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Not applicable

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☒

2.6. Phase of care: Ongoing Inpatient Care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

In patient care relates to partial nephrectomy and TURP
No issues to address

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☒

2.7. Phase of care: Care during a procedure (excluding IV cannulation) (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided

Please also include any other information that you think is important or relevant.

Not Applicable

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☒

2.8. Phase of care: Perioperative care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Not Applicable

Please rate the care received by the patient during this phase as:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☒

2.9. Phase of care: Discharge plan of care (where relevant)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Not applicable

Please rate the care received by the patient during this phase:

5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐

Section not applicable ☒

2.10. Other area of care (please specify)

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.
Please also include any other information that you think is important or relevant.

Not Applicable
Please rate the care received by the patient during this phase as: 5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☐ Section not applicable ☒

2.11. Overall care

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.
Areas identified where learning could occur, including areas of good practice, should be included in addition to any potential areas of further investigation.
Please also include any other information that you think is important or relevant.

Localised Prostate cancer treatment not in accordance with standard practice

No offer of radical treatment for a fit 59yo patient with localised T2 Gleason 7 prostate cancer

Radical treatment given 5 years later in the form of radical radiotherapy

This delay may well have had a significant adverse impact on cancer specific survival

Inappropriate use of bicalutamide monotherapy

Poor communication with patient and MDT

Cancer treatment guidelines were not followed, patient denied potential curative treatment option

The patient developed metastatic disease in 2019 with bone metastases. His suboptimal management may have contributed to early progression of disease.

Please rate the care received by the patient during this phase as:
5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☐ 1 Very poor care ☒

Section not applicable ☐

2.12. If care was below an acceptable standard, did it lead to harm?

If yes, please provide details and state an action plan

Yes, 5 year delay in radical treatment reduced the chance of curative radiotherapy being successful. It is difficult to quantify the exact impact on prognosis.

Side effects of inappropriate bicalutamide monotherapy could have been avoided.

2.13. If the patient died is it considered more likely than not to have resulted from problems in care delivery or service provision?
If yes, please provide details and state an action plan (consider whether a serious incident investigation is required).

Patient died with metastatic prostate cancer in Personal Information redacted by the USI. Although radical treatment in 2009 may not of been curative, earlier treatment would likely have improved prognosis. It is very difficult to quantify the extent which is overall survival was compromised

2.14. If a family member, carer, or staff raised concerns, please outline any feedback provided and state who was responsible for providing this feedback. Please state further action required.
If no feedback was provided, please consider how the outcome of this review should be fed back to the relevant people, considering the duty of candour principle.

The family should be informed that the patient did not receive standard care for localised prostate cancer diagnosed in 2009. At that point his case should have been fully discussed at the MDT meeting with and been offered active radical treatment in the form of either radical prostatectomy or radical radiotherapy. For some reason this did not take place and the patient was placed on active surveillance which would only be appropriate in the presence of extensive comorbidities limiting life expectancy.

The family should be informed that the use of bicalutamide monotherapy was inappropriate. Radiotherapy finally went ahead in 2014 but the delay in receiving radical treatment may have compromised his prognosis

2.15. Were the patient records adequate for the purpose of the review?	Yes ☒ No ☐

Please outline any difficulties in accessing appropriate information:

Time taken to complete Section 2 of this form (minutes): …90……

Date of completion: ……12/4/22……

Name of person completing Section 2: ……D Thomas……

Job title of person completing Section 2: ……Urologist……

Assessment of problems in healthcare for Urology patients

In this section, the reviewer is asked to comment on whether one or more specific types of problem(s) were identified and, if so, to indicate whether any led to harm. Please circle correct response.

Problem types

1. Problem in assessment, investigation or diagnosis	**Yes** **Delay to biopsy**
Did the problem lead to harm?	**Uncertain**
In which phase(s) did the problem occur?	**Triage** **Initial assessment or review yes** **Review of Diagnostics** **Ongoing Outpatient Care** **Admission and Initial Management** **Ongoing Inpatient Care** **Care during a procedure (excluding IV cannulation)** **Perioperative care** **Discharge plan of care** **Other area of care**

2. Problem with medication / IV fluids / electrolytes / oxygen	**Yes**
Did the problem lead to harm?	**Unlicensed use of Bicalutamide 50mg for localised prostate cancer** **Uncertain**
In which phase(s) did the problem occur?	**Triage** **Initial assessment or review** **Review of Diagnostics** **Ongoing Outpatient Care yes** **Admission and Initial Management** **Ongoing Inpatient Care** **Care during a procedure (excluding IV cannulation)** **Perioperative care** **Discharge plan of care** **Other area of care**

3. Problem related to treatment and management plan **Did the problem lead to harm?** **In which phase(s) did the problem occur?**	**Yes** **Delayed radical treatment for localised prostate cancer** **Yes** **Triage** **Initial assessment or review** **Review of Diagnostics** **Ongoing Outpatient Care yes** **Admission and Initial Management** **Ongoing Inpatient Care** **Care during a procedure (excluding IV cannulation)** **Perioperative care** **Discharge plan of care** **Other area of care**
4. Problem related to operation / invasive procedure *(other than infection control)* **Did the problem lead to harm?** **In which phase(s) did the problem occur?**	**No** **No Uncertain Yes** **Triage** **Initial assessment or review** **Review of Diagnostics** **Ongoing Outpatient Care** **Admission and Initial Management** **Ongoing Inpatient Care** **Care during a procedure (excluding IV cannulation)** **Perioperative care** **Discharge plan of care** **Other area of care**
5. Problem with infection management **Did the problem lead to harm?** **In which phase(s) did the problem occur?**	**No** **No Uncertain Yes** **Triage** **Initial assessment or review** **Review of Diagnostics** **Ongoing Outpatient Care** **Admission and Initial Management** **Ongoing Inpatient Care**

	Care during a procedure (excluding IV cannulation) **Perioperative care** **Discharge plan of care** **Other area of care**
6. Problem in clinical monitoring (including failure to plan, to undertake, or to recognise and respond to changes)	**No**
Did the problem lead to harm?	**No Uncertain Yes**
In which phase(s) did the problem occur?	**Triage** **Initial assessment or review** **Review of Diagnostics** **Ongoing Outpatient Care** **Admission and Initial Management** **Ongoing Inpatient Care** **Care during a procedure (excluding IV cannulation)** **Perioperative care** **Discharge plan of care** **Other area of care**
7. Problem in resuscitation following a cardiac or respiratory arrest (including cardiopulmonary resuscitation (CPR))	**No**
Did the problem lead to harm?	**No Uncertain Yes**
In which phase(s) did the problem occur?	**Triage** **Initial assessment or review** **Review of Diagnostics** **Ongoing Outpatient Care** **Admission and Initial Management** **Ongoing Inpatient Care** **Care during a procedure (excluding IV cannulation)** **Perioperative care** **Discharge plan of care** **Other area of care**
8. Problem of any other type not fitting the categories above (including patient records and documentation, informed consent, communication with patients and carers and organisational issues)	**No**
Did the problem lead to harm?	**No Uncertain Yes**
In which phase(s) did the problem occur?	**Triage** **Initial assessment or review** **Review of Diagnostics**

	Ongoing Outpatient Care **Admission and Initial Management** **Ongoing Inpatient Care** **Care during a procedure (excluding IV cannulation)** **Perioperative care** **Discharge plan of care** **Other area of care**

Southern Health and Social Care Trust

Quality Care - for you, with you

Chair
Eileen Mullan

Chief Executive
Shane Devlin

31 December 2021

Healthcare Ref: Personal Information redacted by USI

Private & Confidential

Patient 35's Wife
Personal Information redacted by the USI

Dear Patient 35's Wife

RE: Urology Record Review

RE: Patient 35

On the 31st August 2021 the Minister for Health announced in the Assembly that he was commissioning a Public Inquiry under the Inquires Act 2005 into the circumstances surrounding Urology Services in the Southern Health and Social Care Trust (Southern Trust).

As the Chief Executive of the Southern Trust I instructed that a lookback exercise of all patients under the care of Mr Aidan O'Brien for the period January 2019 to June 2020, when Mr O Brien retired be undertaken. All the patients who were under Mr O'Brien's care during this 18 month period have been shared with the Urology Services Inquiry (USI). I advise you of this as you may receive communication from the USI.

In order to provide the necessary assurance for this lookback exercise we commissioned Consultant Urologists who were external and independent to the Trust to undertake a review of your Husband Patient 35's medical records. I can now advise following this review, aspects have been identified that require a further review. This means an independent Consultant will complete a Structured Clinical Record Review

(SCRR) of your Husband Patient 35's care. We have included a leaflet to explain this process in further detail.

The external independent Consultant has determined that the treatment plan your Husband was given in 2009 was potentially not appropriate. This treatment plan will be reviewed in the SCRR. Once this is complete we will write to you to inform you of the outcome.

We appreciate that up until you have received this letter this may have been a worrying time. The leaflet included with this letter outlines the support services available to you. Dedicated Trust Liaison Officers who are trained professional staff are available for any queries, concerns or questions you may have. This is a strictly confidential service for the purpose of this review process.

I apologise it has taken some time to complete. This was due to the volume of patients involved and wanting to assure ourselves that every patient record was reviewed fully. Finally you have the right to expect the very best care and treatment every time you use our services, for this expectation not being met I apologise.

Yours Sincerely
Shane Devlin
CHIEF EXECUTIVE

Southern Health and Social Care Trust

Quality Care - for you, with you

23 June 2022

Private & Confidential

Patient 35's Wife
Personal Information redacted by the USI

Dear Patient 35's Wife

RE: Patient 35 - H&C Personal Information redacted by USI

I refer to correspondence dated 31 December 2021 from my predecessor Mr Shane Devlin, Chief Executive, advising that the Trust was undertaking a Lookback Review exercise of patients who were under the care of Mr Aidan O'Brien, Consultant Urologist.

At the outset, I would like to express my sincere condolences on the death of your beloved husband in December 2019. Losing a loved one is never easy; I recognise this must be a particularly difficult time for you and your family and receiving a letter regarding Patient 35's past medical care may cause even further distress. I apologise unreservedly if that is the case.

In reference to Mr Devlin's letter referenced above, as the Trust's Lookback Review identified concerns with Patient 35's care, we were having a Structured Clinical Record Review (SCRR) undertaken to establish if there were themes and learning from his care.

An experienced NHS Consultant Urologist from outside Northern Ireland, who is a member of the British Association of Urological Surgeons (BAUS), has completed the SCRR and has now returned his report.

I would like for the detail of this report to be shared with you in person so that it can be explained in depth and any questions that you may have can be answered directly. We will follow up that meeting with a written summary of the report for your records.

If you are agreeable to this approach we will arrange a meeting as soon as possible with Mr M Haynes, Senior Urology Consultant and Divisional Medical Director, together with a senior manager from the Trust. If you would prefer not to meet with us at this time we can provide you with written update and an open invitation to meet us at a later date.

I would be grateful if you would make contact with Sarah Ward, Head of Service for the Lookback Review on Personal Information redacted by USI and advise on how you would like to proceed.

I would also like to take the opportunity and use this correspondence to update you on an inaccuracy contained in Mr Devlin's of 31 December 2021.

Mr Devlin's letter informed you that there was to be an Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust. This was correct however, the information pertaining to the Inquiry in Mr Devlin's letter was incorrect and because of this, you have been misinformed.

I very sorry that this was the case. I would like at this time to correct the error and clarify the situation.

Mr Devlin advised that the Minister of Health, Mr Swann, announced his intention to have a public inquiry into Urology Services on 31 August 2021. This was incorrect. The actual date that Minister Swann announced to the Assembly his intent to set up a statutory public inquiry into the Urology Service in the Southern Health and Social Care Trust under the Inquiries Act 2005, was in fact 24 November 2020.

I can confirm the Urology Services Inquiry commenced on 6 September 2021. The Chair of the Inquiry is Christine Smith QC.

As Patient 35 was patient within the timeframe of the Trust's Lookback Review we have shared his details with the Urology Services Inquiry team. Ms Smith may have already written to you directly as your husband's next-of-kin as I understand she was doing so with the next-of-kin of all deceased patient's.

If you would like further information about the Urology Services Inquiry, more detail is available on the Inquiry's website at www.urologyservicesinquiry.org.uk.

Finally, I would like to thank you for your patience as we have progressed with the Urology Lookback Review.

Yours Sincerely

Personal Information redacted by USI

Dr Maria O'Kane
Chief Executive

Information Line Contact Record Form	
Date of Call	27.6.2022
Name of Caller	Patient 35's Son
Patient Name	Patient 35
Patient DOB	Personal Information redacted by USI
Detail of Call	- Returning call on behalf of mum to letter offering f2f review to discuss findings of SCRR.
Action Required/ Taken	- discussed options + agreed would like letter 1st + then will contact me to arrange review. - agreed to email letter to son also as lives in Personal Information redacted by the USI and mum lives alone. - advised if he cannot get home we will support virtual link to be with mum [clinician.
Completed By	Personal Information redacted by USI

All completed forms to be retained and attached to the individual patients review form/ letters and filed.

29.6.22 @1500 - following convo with margaret - Letter to be reviewed and signed by the chief executive To advise son of Cx on leave so may take 2weeks to get this.

1537 - Son happy with explanation + offered if mum wants to chat to give my mobile number. Advised I will ring him on day of posting, + having Cx oversight is priority on return.

Southern Health and Social Care Trust

Quality Care - for you, with you

Chair
Eileen Mullan

Chief Executive
Dr Maria O'Kane

27 July 2022

PRIVATE & CONFIDENTIAL

Patient 35's Wife
Personal Information redacted by USI

Dear Patient 35's Wife

RE: Patient 35 **- H&C** Personal Information redacted by USI

I refer to my letter dated 23 June 2022 regarding the Structured Clinical Record Review (SCRR) into the urology care of your late husband, Patient 35. I am sorry for the delay in me writing to you again, I was on leave for a period in July and it has taken me some time to get caught up.

I am aware your son Personal Information redacted by USI contacted Sarah Ward on Monday 27 June 2022 and explained that in the first instance you would like us to provide detail of the SCRR report in writing. I am aware you and family members may wish to follow this up with the meeting previously proposed, with Mr Haynes and a senior manager from the Trust.

I respect your wishes in this regard and will endeavour to summarise the SCRR report in an understandable way.

For information, a copy of this letter has been emailed to Patient 35's Son at his request.

I regret to advise that the SCRR report has highlighted that Patient 35 did not receive the correct treatment for prostate cancer when he was diagnosed with this disease in 2009.

The report states that when your husband was first diagnosed his case should have been fully discussed at a urology cancer multidisciplinary team (MDT) meeting. He should have been offered active radical treatment in the form of either a radical prostatectomy, which is surgically removing the prostate gland including the cancer, or radical radiotherapy which uses external beam radiation to kill off the cancer cells.

This did not happen and instead Patient 35 was placed on "active surveillance" which is treatment that would only have been appropriate if your husband had extensive past medical history impacting on his life expectancy, which was not the case.

The SCRR report notes that radical radiotherapy was undertaken five years later in 2014. It states that the delay in receiving radical treatment may have compromised your husband's prognosis and that this suboptimal management may have contributed to early progression of the disease.

The report further advises that the hormone medication i.e. Bicalutamide 50mg which Patient 35 was prescribed in 2013 was an inappropriate treatment.

To summarise, the SCRR report has highlighted that Patient 35 did not receive treatment in accordance with standard clinical practice and that cancer guidelines for the treatment for localised prostate cancer were not followed despite him being a fit 59 year old gentleman. This resulted in your husband being denied potentially curative treatment for prostate cancer.

On behalf of the Trust I would like to offer an unreserved apology to you and your family that the service your late husband received was well below the required standard.

Furthermore, I deeply regret that Patient 35 experienced a five year delay in receiving the appropriate treatment for his condition which may have had a bearing on how his disease progressed.

I recognise this letter must be very upsetting for you to read; I expect you and your family will have many questions about the SCRR findings and Patient 35's treatment and care.

If you would like to meet with us to discuss the SCRR Report's findings Sarah will arrange that meeting. I am aware Patient 35's Son lives in Personal Information redacted by the USI and he will want to be present. We will be flexible with the date and venue (to include a zoom meeting if that is more convenient) to ensure it is an easy as possible for this meeting to take place.

For ease of reference, Sarah's mobile number is Personal Information redacted by USI, she is currently on leave returning Monday 1 August 2022.

We are committed to supporting you and your family at this time. However, if you would like independent and confidential advice and support you can contact the Patient Client Council. Their contact number is Freephone 08009170222.

Finally, I would like to pass on my best wishes to you and your family at this very difficult time.

Yours sincerely

Personal Information redacted by USI

DR MARIA O'KANE
CHIEF EXECUTIVE

Information Line Contact Record Form

Date of Call	1 8.2022
Name of Caller	Patient 35's Son
Patient Name	Patient 35
Patient DOB	Personal Information redacted by USI
Detail of Call	Received SCRR report letter. Mum flew out to Personal Information redacted by the USI prior to it arriving with her and they both read to emailed letter together. keen to have a meeting with consultant; virtually while mum is in Personal Information redacted by USI (until 13th Aug) I asked if there was anything I could answer at this time; Patient 35's Son advised the letter was well written and easy to understand, and there was nothing particular to the letter at this time; but Patient 35's Son stated he did have questions for eg relating to end of life care. I suggested they make note of these and if they wish send them to me and I will aim to have info if possible available for the meeting. I advised Patient 35's Son Mr Haynes would be the clinician we would advise is best placed to meet with them and I will go to secure date/time of meeting and will be in touch. Patient 35's Son was happy with this. I passed on my regards to [redacted]
Action Required/ Taken	
Completed By	Patient 35's Wife and again advised Patient 35's Son to ring me at anytime.

All completed forms to be retained and attached to the individual patients review form/ letters and filed.

2.8.22 @ 11.20 am - Mr Haynes on leave until thursday. Spoke to secretary and advised in Belfast operating on Thurs/Fri. Updated Patient 35's Son on Mr Haynes unavailable until Thursday and will be in contact soon.

(S. WARD) Personal Information redacted by USI

Southern Health and Social Care Trust

Date of Meeting: 10th August 2022 at 11:30am via Zoom.

Attendees of Meeting: Patient 35's Son, Patient 35's Wife, Mr Mark Haynes (Consultant Urologist), Margaret O'Hagan (Director of Urology Lookback Review) and Sarah Ward (Head of Service for Urology Lookback Review Team).

Purpose of Meeting: To offer apologies to Patient 35's Wife and Son on behalf of the Chief Executive and the Southern Health and Social Care Trust, for the below standard of urology treatment Patient 35 received To also allow an opportunity for any questions to be raised and answered by Patient 35's wife and son in relation to the findings reported in the Structured Clinical Record Review.

Summary of the Meeting

Mr Haynes (Mark), Margaret O'Hagan (Margaret) and Sarah Ward (Sarah) each introduced themselves to Patient 35's Wife and Patient 35's Son. The purpose of the meeting was explained and an apology was issued at this time on behalf of the Trust and the Chief Executive by Margaret, the opportunity for questions to be raised and advising that further meetings can be accommodated in the future was expressed.

Margaret outlined the process of this Urology Lookback Review and advised that there was an Independent Public Inquiry into Urology Services also ongoing as a parallel process. Mark explained the review process that allowed the issues in Patient 35's care to be discovered.

Patient 35's Son asked why his dad was not discussed at an MDM in 2009 when he was first diagnosed with Prostate Cancer. Mark advised he could not confirm at this time if the "Multidisciplinary Team Meetings (MDM)" had been functioning in 2009. Northern Ireland was slower to implement this process but there is a thought it was potentially around 2010 that MDM's were introduced.

Action: Patient 35's Son and Patient 35's Wife to be advised of the exact date that the Urology MDM's commenced in the Trust to be confirmed and.

In terms of treatment, Mark advised that in 2008 NICE (National Institute for Clinical Excellence) published guidelines and recommendations for treatment of Prostate Cancer.

In Patient 35's case, with a diagnosis of intermediate risk localised prostate cancer the recommendations were for Radical Prostatectomy or Radical Radiotherapy. There is no record of a discussion of these treatment recommendations with Patient 35 at his initial diagnosis and it appears he was placed on a surveillance pathway initially instead before commencing hormone therapy.

Patient 35's Wife advised in 2009 following this diagnosis they were advised that this was "non-aggressive cancer" and "doing nothing for a year will make no difference" and he will be reviewed in a year. Mark confirmed this was not in line with NICE guidelines and highlighted that later when Patient 35 was prescribed an unlicensed dose of hormone treatment (Bicalutamide) at 50mg for a prolonged period of time, this was also outside of NICE guidelines. Patient 35's Son asked in regards to the 2013 records of discussions about his dad's treatment options. Mark advised the notes do not record a discussion with Patient 35 but indicate a decision to "start treatment". It was recorded that a referral for radiotherapy was to be completed when Patient 35 's "PSA was less than 1". Mark explained this is not standard practice.

In May 2014, the MDM discussion records recommended action to refer to the Oncology Team. This referral to Oncology was not actioned until October 2014. Patient 35's Son queried of the hormone treatment his dad was on at that time was correct. Mark advised the dose was increased to a correct dose in Oct 2013 but this would have had no effect on reducing the PSA.

Mark confirmed from the start of the Oncology Teams input in 2014 to completion of radiotherapy, there were no concerns identified with the care Patient 35 received from the Oncology team.

In 2019 a CT scan reported a significant spread of disease, noting this in both bones and lung. Mark advised that standard practice is to advise the patient of the seriousness of this finding, what treatment options are available and the non-curative intent of any treatment i.e. this disease cannot be cured and is considered palliative.

Patient 35's Wife advised this was not the case of her husband and described that she was under the impression that the addition of a hormone injection was all that was required at that time. Both Patient 35's Son and Patient 35's Wife described their shock and devastation when they were informed within minutes of being reviewed by an oncologist in Daisy Hill Hospital in October 2009 that Patient 35 was "palliative" as his condition was never described like this before.

Patient 35's Son asked if Chemotherapy could have been an option for his dad at this point. Mark explained that Prostate Cancer care has developed extensively in the past 5 to 10 years. He explained the role of chemotherapy in conjunction with hormone therapy and the important role of the oncologist in considering this treatment option. Patient 35's Wife noted that the "injection" he received around this time made him worse. Mark outlined the MDM discussion in August 2019 recommended a change to LHRA analogue and refer to Oncology. Regarding the injection, Mark outlined the potential side effects patients may experience from this treatment. Mark also explained that it is possible that Patient 35 was so unwell at this time due to either the effect of the treatment or as a result of the progression of his cancer. Mark thought the most likely reason was that the reason Patient 35 was so unwell at this time was most likely due to the rapid progression of his cancer.

Patient 35's Son asked in the 5 years from 2009 to 2014 when his dad did not receive potentially curative treatment, how much of an impact could this have had. Mark explained he could

not give a definitive answer. However, the evidence is that the delay in receiving curative treatment would have reduced his likelihood of a positive long-term outcome (i.e. cure). Mark went on to explain that in his experience, as a practicing urologist at this time, if he were treating a patient similar to Patient 35 he would have certainly recommended surgical treatment, and outlined the potential role of salvage radiotherapy in the event that the prostate cancer returned after surgery.

In summing up the meeting Margaret commented on how the Trust was determined to improve services for urology patients and referenced that there was ongoing service improvement being progressed at the same time as the Lookback Review continues rather than waiting until the end of the Lookback Process. She referenced specific changes to the Trust MDM meetings not only for urology but also for all cancer tumour groups. She offered to share a summary of improvements if Patient 35's Wife and Patient 35's Son wish to receive a copy

Action: Clarify if cancer MDM summary document

Patient 35's Son expressed his gratitude for the time taken for the meeting and for apology given. He advised this meeting has helped them to understand what happened. Patient 35's Wife expressed the devastation she felt at losing Patient 35 then receiving the news that there was issues with his care.

Margaret explained she hoped that both Patient 35's Wife and Patient 35's Son could understand the approach we took to inform them of the findings as we felt it would cause too much upset and distress in a letter without offering the option to speak first. Patient 35's Wife and Patient 35's Son both agreed they were grateful of the options given to them.

Conclusion

Mark expressed his hope that Patient 35's Wife and Patient 35's Son now had a better understanding of Mr Patient 35's care and appreciated the difficulty in hearing the issues that had been found.

Margaret also reiterated that the offer of further meetings is always open at any time and again offered a further sincere apology to Patient 35's Wife and Patient 35's Son on behalf of the Trust for the care Patient 35 received.

Next Steps

- Sarah will draft a summary of the meeting today and send to Patient 35's Wife and Patient 35's Son for review and comment before being finalised
- When this summary is finalised it will be formally issued to Patient 35's Wife and Patient 35's Son as a record of the meeting. This will include a copy changes made to improve the effectiveness of the MDMs if desired.
- The Team will ascertain when the MDM Process officially commenced in Northern Ireland and feedback to Patient 35's Wife and Patient 35's Son

Southern Trust. What you are reflecting is that Mr. O'Brien had different ways of working compared with others. This is 61.1. It was apparent that many of these were embedded in his working patterns and widely accepted across the Trust as "his way". 10:56

You go on at 61.2 to give an example of the lack of Clinical information, which we have seen in one of the incidents we looked at yesterday. You talk about the voicing of concerns would have occurred during informal 10:57
conversations and within Departmental meetings, including with the Head of Service but, as you observed a moment or two ago, in the context of private patients, the managerial response to this was at best ineffective. Amongst colleagues, that's yourself, 10:57
Mr. Young, Mr. O'Donoghue by this point and Mr. Glackin, I think Mr. Suresh as well -- he left when? In 2016, I think?

A. I can't remember.

42 Q. But amongst colleagues you talk about informal 10:58
meetings. Was there any attempt on the part of the Urology team as a group, the group of people who collaboratively are delivering this Service and who are, no doubt, impacted by these behaviours that you have outlined, was there no challenge coming from the 10:58
group?

A. As I say, it was certainly discussed within meetings. I don't have documented recollections of it but I have included in my statements, I certainly recall when

a discussion about contemporaneous GP letters came up in one such meeting, Mr. O'Brien expressing an opinion that the only two people that needed to know the outcome of the consultation was him and the patient as his justification for why nothing else was needed.

43 Q. Does that suggest that, however frequently issues were raised with him and he rebuffed the challenge and nothing more was done, it was -- was it a group shrug of the shoulders, that's just Mr. O'Brien and we can't do much about it?

A. I think we had attempted to let him know our concerns, you know, even to the point of where if we were doing Clinics to see long waiting patients who had been seen by him before, we weren't able to see as many as we might see if we were doing a long waiting list of patients in Clinic who had been under the care of someone else because we didn't have the documented decision-making processes leading up to that, that we could quickly review, and so the process of reviewing patients took longer. Did we collectively as a group shrug our shoulders? I think I certainly continued -- well, I certainly had raised concerns and I did raise concerns where it impacted.

44 Q. You were, in raising concerns, looking to the systems and Management to take those concerns seriously and make appropriate challenge and escalation if the challenge was rebuffed?

A. Yeah. We, as a group, had made an informal challenge of, you know, this is an issue for us.

addendum and in the evidence that I am giving today, to outline for you, as best I can, the reasons for the manner in which I managed patients.

182 Q. Yes. One final point around this. We see in Patient 1's case and Patient 6's case, that the recommendation common to each of those cases was that, in the -- in the event of divergence from an MDT decision, it should be properly documented? 14:14

A. Hmm.

183 Q. In other words, you would send out the reasons for the approach that you're taking, what you've discussed with your patient, and the reasons for the management plan, if you consider it to have diverged, and you would validate it with further MDM discussion. I think we've had the debate about the practicality of further MDM discussion earlier. When you reflect upon it, do you think the quality of your note-keeping or recording of your prostate cancer management decisions following review of your patient after the MDT was all that it should have been? 14:15 14:15

A. In handwriting, no, because what I -- I took it for granted, you know, my practice was -- the reason why I am reviewing this patient today following an MDM discussion is for all of the reasons that I have outlined previously. You know, I used my handwritten notes as an aide-mémoire to enable me to detail the other features, like the number of times a person was getting up at night, or whatever particular issues that they had to contend with, or what their priorities were 14:16

and so forth. And hopefully that was reflected in the letter that I would subsequently dictate.

In the case of Patient 6, I need to be reminded of what the MDM outcome was, because I do not instantly know in what manner I diverged from it. 14:16

184 Q. The reference is DOH-00078. Hopefully, that might help us. So I think the key feature of it was, and we possibly don't have the material in front of us to -- if we go back to 77 I've been told with some optimism, I think. 14:17

A. Yes, that's it. "MDM recommendation" -- if that's the right patient -- on 8th August 2019.

185 Q. Yes.

A. " Surveillance or radiotherapy with curative intent." 14:17

186 Q. That was the case where, I think it was Mr. Haynes was the -- is that the case where Mr. Haynes was the reviewer? It wasn't an MDM itself?

A. Okay. So, in any case, this man is the patient who was anxious in the first instance and for whom I prescribed Bicalutamide 50mgs. This man had significant lower urinary tract symptoms, and as I think I detailed in my commentary, or in the clinical history that has been shared with the Inquiry, it is one of the recommendations in the NICE guidelines that the patient would be offered investigation and management of his lower urinary tract symptoms prior to referral for radiotherapy, as the outcome following radiotherapy, then followed by the management of quite frequently 14:18 14:18

deteriorated symptoms, or worsening symptoms is much worse than if you manage it beforehand, followed by radiotherapy. So, here, I would dissent from the view that I hadn't followed the MDM recommendation. So in the first instance, you know, this man was actually being worked up for referral for radical radiotherapy. As you know he didn't have urodynamics done twice and, as you know, then he subsequently stopped his Bicalutamide I think because of some gastric symptoms, and then when he was reviewed by Mr. Haynes subsequently he didn't want to have any treatment. So -- so I -- 14:19 14:19

187 Q. I think your point is that you disagree with the proposition that you diverged from the recommendations?

A. Yes, because the recommendations in the NICE guidelines are that you offer assessment and management of lower urinary tract symptoms when they are of significance prior to radical radiotherapy, in order to achieve an optimal outcome. 14:19

188 Q. Yes. I'm not sure that's the point. The point is, whether you diverged from the MDM recommendation as opposed to what you think NICE was informing you of? 14:20

A. Well, it's not what I think NICE was informing me of; that is what NICE recommends.

189 Q. And the point is, if you're taking the patient down a route, which you think is appropriate or legitimate, but if it departs from what your MDM, or the notional MDM is telling you, then the recommendation here, the criticism here, is that it's got to be adequately 14:20

recorded and invalidated by reference back to the MDM?

A. Well, as we have discussed earlier, I would have no difficulty in doing that whatsoever, and would have been robustly asserting that this patient should be offered the assessment and management of his lower urinary tract symptoms prior to referral for radical radiotherapy.

190 Q. But the point is, that didn't happen?

A. The point is, that didn't happen, yes.

191 Q. Let me move to my next topic. It's an issue connected with Patient 139. 14:21

A. Mm-hmm.

192 Q. And I wish to explore with you whether you had any hand in inappropriately accessing that patient's records in order to advance an argument before this Inquiry? 14:21

A. Hmm.

193 Q. The context for this is as follows: Mr. Glackin was due before this Inquiry on 20th September?

A. Mm-hmm.

194 Q. And your legal team submitted questions to the Inquiry, entirely appropriately -- 14:22

A. Mm-hmm.

195 Q. -- in order to be directed to Mr. Glackin, and one of those sets of questions involved enquiries into whether and why Mr. Glackin had continued a regime of low dose Bicalutamide -- 14:22

A. Hmm.

196 Q. -- for that patient.

A. Hmm.

SECTION C – Details of concerns raised/complaints reported

1. Please provide full details of any concerns and/or complaints raised by you, specifying the nature of those concerns in as much detail as possible.
We did not keep a record of appointment dates or treatments received by Patient 35 so are mostly recollecting from memory. In 2009 Mr O'Brien performed an operation on Patient 35, where he removed a lesion from his left kidney. Patient 35 was informed that he had Prostate Cancer and Mr O'Brien advised that as the cancer was not aggressive, he did not need any procedure at that time other than medication in the form of a tablet. Patient 35 suffered severe abdominal pain in his left side from the time of this operation in 2009 and was in constant pain with this until he passed away in 2019. Patient 35 made Mr O'Brien and colleagues aware of the severe abdominal pain he was having and over the years was referred to many Pain Clinics and Doctors to try to help with his pain. He attended many Private Pain Clinics to try to get relief. As a result of this pain he was prescribed ever stronger pain killers which impaired his quality of life and, in our opinion, prevented his recognising the subsequent return of his cancer. In 2010, Patient 35 received a letter informing that a CT scan had revealed that a lesion, similar to the one removed the year previously, had been identified. However, we have no recollection of any further treatment until 2014 when Patient 35 had Radiotherapy in Belfast City Hospital. He received daily treatments of radiotherapy from 4 November until 24 December. In 2019 after having a series of tests and scans Patient 35 was told that his cancer had come back and spread into his bones. In Craigavon Hospital at end of August 2019, Mr O'Brien told Patient 35 and myself that the cancer had spread but he was optimistic with the treatment he had prescribed a few months prior which had reduced his PSA levels and with new medication in the form of a monthly injection he would be fine. As a non-medical person I can only say that this injection had an adverse effect on my husband, his PSA levels went up and his movement was restricted from the second month. The loss of my husband has been terrible and had a detrimental effect on my own health, having to witness his suffering over 10 years has been truly awful as you can imagine. The pain he endured had a massive effect on his quality of life over all those years. Patient 35, or the family, never made a formal complaint to the Trust as at the time we had total faith in the system. It has therefore been very distressing to learn about the Inquiry into Mr O'Brien who was overseeing Patient 35's care for over 10 years. Furthermore, it came as a huge shock to learn in the recent letter that the Independent Consultant found that the treatment plan Patient 35 received in 2009 may have been inappropriate. That said, we welcome the investigation into these matters but hope that the inquiry is executed immediately and thoroughly. Also, we hope that the findings are communicated clearly and with full transparency to the relatives.

out of that, that operation, and obviously the other output from that was that, like, the diagnosis on the cancer, so it was established then at that point that he had prostate cancer. And, yeah, I mean, you're right, like, nothing really happened then, you know. 14:08
Like, I spoke to my mom and it was sort of explained at the time that this is non-aggressive and that we have, we don't really need to do anything immediate here with this, this cancer. And so, you know, "we'll keep an eye on it", basically and, sort of like, you know, once 14:09
you're reading all this back now, maybe it's like a moment where I wish that you could go back in time and sort of, like, you know, sort of -- but I suppose throughout this entire process like, you know, there was no reason for us -- there was complete trust on the 14:09
part of my Dad and the rest of us that, do you know everything, the advice, everything he was getting was -- well, there was no reason to doubt it. And actually at that time as well, you know, really, the pain that he was now experiencing in his side was actually the 14:09
thing that was most prominent and the thing then, it was almost taking his primary focus, if you know what I mean, you know. He was told that the cancer piece, "you don't need to worry about that, we'll keep an eye on things, it's fine." But it was the pain that was 14:09
causing him such trouble day in day day out that, you know, that kind of distracted, I suppose, as well, him and my Mum's attention away from that other piece.

76 Q. He received radiotherapy in 2014, that was some five

years after he'd been diagnosed with the prostate cancer.

A. That's right, yeah. So he -- like, to be honest, I don't know the full, I mean, I've read back the same information that you had access to and I've sort of spoken to my Mum on this. But effectively, yes, in or around 2013, I believe, there were, like, observations on his PSA again that sort of prompted action. He went on to a hormone therapy tablets which, again the lookback has established was not correct, I believe, in terms of dosage and using that as a way of treating this particular disease. 14:10 14:11

Even then, I'm not quite sure why, but it took until, like -- so this was 2013 when these things were observed and then it was, like, he finished the radiotherapy treatment on Christmas Eve 2014, it still took another almost two years for that to work its way through, you know, the process and for him to receive that treatment. 14:11 14:11

77 Q. You subsequently discovered that your father's cancer was terminal. Can you recall what the circumstances of finding that out were?

A. So after 2014 he was then, you know, he was again monitored every maybe -- he got a PSA test taken every three months or so and for the most part there was -- at least if you were to look at that as a metric of whether he was healthy or sick, those scores were good until 2019 when, you know, it shot up quite 14:12

significantly then and it was sort of springtime of 2019. So he had to go and get various sort of tests and scans and whatever done then and I think it was like around about August 2019, him and my Mum went to Craigavon to meet Mr. O'Brien and it was then when he told them that, you know, he sort of put it like: "There's good news and bad news. The bad news is that the cancer has returned and it's spread to the bone and the lung, but the good news is that the tablet, the treatment that we've been putting you on for the last two months or so has significantly reduced the PSA values down." And so whilst my Mum, or as soon as she heard, like, you know, that it was in the bone, you know, she kind of almost had a breakdown there and then in the hospital room or whatever but it wasn't, you know -- I don't believe they left that meeting with -- well, they didn't leave that meeting with the understanding that it was like this was a terminal condition, that it was now just a matter of how long. It was explained that had it not have been for this PSA coming down, he would have needed chemotherapy immediately and we could be looking at one-and-a-half years of life expectancy. However, because of this positive reaction that we don't need to look at chemo immediately and there's nothing really to be that worried about in terms of immediate, you know, urgency and they were advised to go on holiday, they were booked to go for a month on holiday. He received another hormone, analogue treatment there and then in

14:12 14:13 14:13 14:14 14:14

the hospital, it was delivered, like, through an injection, and that didn't really react very well with him and by the time they came home from hospital, he was in pretty bad shape, actually, because I went back to visit them then and I was very shocked by kind of what I was walking into because, like, I had seen him maybe two or three months previous to that, and the change in that space of time was really quite significant. So, like, do you know it wasn't really -- I know there's a balance to be had between optimism and sort of doom and gloom, you know, you can't just tell somebody that game's over here, but I don't think that the full severity of the situation was properly explained there and, you know, not that it would have changed anything but it might have -- it would have changed how those last few months were spent, you know, and they didn't really talk about the fact that he wasn't going to be here, he was trying to stay positive and saying "I can beat this", but, like, in hindsight, even reading all the material that's there, it was fairly obvious he had no chance of beating this. It was like, it was very sort of ominous, as the text put it in some of those letters.

14:15
14:15
14:15
14:16

78 Q. When did you actually discover then, or did your family discover, or your father, that the cancer was terminal and that he wasn't going to beat it, as you say? How did that come about?

14:16

A. Well, I kind of pieced it together when -- he was checked into Daisy Hill Hospital one time I was at home

and the night before I went back, he just was in really bad shape and we got an ambulance and so he went to Daisy Hill that night and was taken into a ward and the next day, a Consultant Oncologist was there and was able to see him and look at the same data, I presume, 14:17
that was available, you know, from the previous meetings and it was kind of his tone, the language he was using and, you know, "we just got to get your Dad comfortable." He used the word "palliative", which was the first time I heard that. I actually had to Google 14:17
it to make sure my interpretation of what it meant was correct, and even he didn't -- it was almost like he kind of assumed that we knew. You know, it wasn't like he said, you know, your Dad, I am sure, is only -- he never talked about a timeline or "terminal" or anything 14:17
but it was almost like he would have assumed that this was known to me and my Mum, that this is just something we have to manage now; it's not something that you're going to win, to beat.

79 Q. How did you and your Mum and your father feel when you 14:18
discovered this?

A. Well, I mean, to be honest I didn't -- like, I kind of figured it out a little bit but it was almost like because my Dad was still so... I kind of knew in my heart, let's say, but he was still -- because no-one 14:18
had actually told him that, I didn't want to -- I wasn't going to be the person to sort of say, do you know -- like, he was still being as positive as he could. So it wasn't really spoken about, to be honest.

And, you know, it was kind of like always this: "Well, we're seeing this consultant in a week, we're seeing this person then." You know, it was kind of like a week by week sort of a process and, like, in the end it all happened very quickly. But there wasn't really ever a conversation about, like, this is now, this is kind of, you know, that "terminal" thing, which is strange when you sort of say it out loud now but it wasn't. Like I said, it was kind of like, maybe it's something that -- like, I mean, I didn't feel comfortable in bringing that up to him just based on this sort of inference that I had heard from this, if you know what I mean, from this particular doctor. 14:19 14:19

80 Q. Yeah. Well, when were you first told that there was an issue regarding the treatment that your father had received? 14:19

A. It was really as a result of this whole process and the lookback review, you know, throughout -- with the exception of that moment in the Daisy Hill Hospital where I was like why, you know, why is this guy saying one thing and Mr. O'Brien hadn't really spelled this out? There wasn't really any moment along this entire, like, that ten-year span that there was any reason for us to have anything other than complete trust in the care that he was receiving, you know, everything surrounding that. And even after he died, you know, it was -- you kind of just were: 'Well, he was unlucky, you know, and there was nothing that could be done', and whatever, and it was only really when this process 14:20 14:20

came through and in the last few moments when there was, you know, the findings of the investigation that these issues had been presented where, you know, it sort of appears that had different things been done at different times then, you know, we could have had a very different outcome and that's really just in the last few months we've become aware of that.

81 Q. And finding that out, how did you actually find out? What was the method of communication?

A. So there were letters sent throughout the lookback process and I suppose they start with a, like, you know: 'Because your Dad has been in the care of the Trust and Mr. O'Brien in this period, then he's been selected for review.' Then was it in, like, January, December/January of last, like around last Christmas, there was a letter sent to say, well, that the initial filtering process has found some issues and that was a letter with not so much detail but just that it is significant enough to warrant it going to the next stage. So that's when you start to think; 'Oh, okay, what's going on here? And then sort of in the summer time then we got a phone call, there was a phone call or letter to say that, you know, there has been, you know, the review, the findings from the independent urologist have come back and, you know, we can -- so in the end we chose to have a letter sent, first of all, which sort of summarised the findings and then we had a meeting with them and we did it remotely, my Mum was actually with me and we both, like, had a Zoom meeting

He also then spoke about, you know, that, I can't pronounce -- Bical....

86 Q. Bicalutamide?

A. Yes. That that treatment wasn't really appropriate at that time either in 2013, it was the wrong dose and that even then, you know, I think there was, like, you know, there was this thing where, well, we need to get the PSA down under 1 before we can do radiotherapy and that type of thing, which again he didn't agree with things like that. So it was a very informative meeting, I suppose, to ask a lot of questions and to hear I suppose more on the medical side. Margaret did apologise upfront, you know, on behalf of the Trust in terms of, like, you know, for the below standard of care that my Dad received and we didn't, I suppose, dive into too much of, like, the governance around, like, why these decisions, like who was making the decisions, why were they not again these MDM meetings going on and checks and measures and stuff like that. It was more the sort of looking at the lookback review and the findings and giving us a chance to ask some questions around that. 14:24 14:25 14:25 14:26

87 Q. There was some discussion, was there not, though, about when MDMs became operational in the Trust and the Trust undertook to tell you when the MDM team was set up and the meetings happened? 14:26

A. Yeah, we're still waiting to hear on that, when it was. I think Leah might have found out something separately but I haven't been told.

least we had some time in our own sort of environment to process that information and think about what questions we wanted to answer and everything.

95 Q. Did you feel the need to ring the Patient/Client Council or did you have enough support, do you think, in dealing with the contents of that letter? 14:38

A. Yeah, I didn't personally, we didn't ring -- that option was made. We were made aware of that. We didn't feel we needed to, so I can't really comment on that. You know, I think it was helpful that the two of us were together at that time so that we could kind of talk about it and not -- you know, we were still able to sort of say: "Look, you know, we've got this meeting and there's no point in worrying about it until ... Let's just go and have the meeting." And in fairness, in the meeting, I got the feeling that, you know, that the individuals there were not trying to hide or, like, offer any excuses or anything. They were being brutally honest. They gave their own opinion on matters where we asked it. They were critical and, you know, agreed with the findings that were found. They weren't trying to sort of, like, wriggle out of anything, or anything like that. So I don't really have any major issues with how that whole communication side of things has been managed here. 14:39 14:39 14:40

96 Q. And were you a bit shocked about the fact that the MDT decisions weren't particularly tracked and things of that nature? Did that strike you as odd or...?

A. Yeah, I suppose you kind of, like, I don't know, it's

88 Q. You haven't had any communication since that meeting. That meeting, I think, was in August of this year so it wasn't that long ago.

A. Correct.

89 Q. But you haven't as yet had any update from the Trust about that? 14:26

A. We have exchanged a few e-mails on the notes, the notes have been sent over and we have reviewed them. There's one or two little updates to be made and then I also asked today, actually, I asked about the MDM meetings. 14:26 So they're still to come back on that one.

90 Q. And the other thing that they said at that meeting that they would come back to you on is to explain to you what improvements the Trust had made to MDM meetings since all of this came to light, isn't that correct? 14:27

A. Yeah. Funny, yeah, I haven't heard on that either. Maybe was I supposed to follow that? Was I to supposed to ask them that one? I'm not sure. But either way, there hasn't been any sharing of that information either. 14:27

91 Q. Can I just ask you, I mean, because this has all come to light as a result of the lookback review and it is fairly recent information for you and your family, how have you felt to learn that there is an issue with the care that your father received? 14:27

A. Yeah, I mean it's been, you know, I suppose, like, it's -- well, obviously it's difficult to lose someone. You know, for me and my Mum it was a hard time back in 2019. They were very, very close and so it was very

tough for her, you know, even more so. So you're starting to just come to terms with this loss and then it is quite distressing, very distressing whenever this news comes out again and I suppose there's all this information is starting to get dug up and, you know, 14:28
memories are evoked again and wounds that maybe are starting to heal are opened. So it has been a very emotional and distressing time, for my Mum in particular. And then whenever you find out that, like, you know, whenever you read what the findings are and 14:29
you sort of hear how critical they have been and I suppose there's, like, a sense of it could have been avoided and, like, all the pain, especially at the end, the pain that he was in and endured, like, you know, to feel that that could have been prevented, maybe he 14:29
could still be with us today had, you know, just the right checks and measures been in place. That's heart breaking and it's really tough to come to terms with that and, you know, if you dwell too much on it, you would sort of like, you know -- well, you can't dwell 14:29
too much on it because it is, it's so sort of sad. And, you know, I suppose, like, on the back of that, at times you maybe feel angry. You want to sort of maybe -- like, I'm keen to know what went wrong, how did these things happen ,what's been done to make sure 14:30
it doesn't happen again? Was it like a cultural thing or what? Because, like, I mean, even for me, like reading that, you know, last week, one night last week I sat and read all of the pack that you sent, you know,

from start to finish and there was a lot of letters in it back and forth and, like, that was, you know, quite emotional, it's almost like reading a book where you, you know, your Dad is like the main character in it and you kind of -- you know how it ends and you sort of just put yourself in his shoes as you go through that. And, like, you know, so that's difficult and it sort of just brings it all back. To me, you know, I didn't know the half of it, I suppose, of what he was going through because he kept so much of it to himself. But, like, you sort of -- yeah, so it's tough like that. I mean, at times you kind of feel like a little bit -- like I say, there was so much trust put in it. You sort of read, like, you know, he had this prostate cancer diagnosis and, like, we sort of just took it at face value that yeah, well, you don't need to do anything. So you kind of feel a little bit almost like a little bit of guilt and regret as well that you didn't sort of poke him and, you know, sort of question my Dad and sort of, you know, give him a harder time about: "Are you sure, like? Should we not research this ourselves or go and ask somebody for another opinion or whatever?" We kind of went along with it. So there's an element of guilt in there as well. And, yeah, I suppose it's just not nice, obviously, I'm sure, for anyone in this position. But I think one other thing when I read through that was, like, for me, I would like to know why because, you know, on each of these letters back and forth to various consultants

14:30 14:31 14:31 14:31 14:32

along the way, it was almost like a summary at the top of each of these letters of what his history was, the key points, and when the cancer returned, it was almost like this amazement of how could this -- shock, how could this clever cancer have come back? You know. 14:33
And there was some conversations my Mum and Dad had with various consultants that they would have talked to, with this sort of language that made them feel quite, I don't know, sort of belittling almost that, you know, these clever consultants have done everything 14:33
they possibly could and yet this thing had outwitted them and it's unlucky, sort of thing. When in fact surely they all knew that by looking, you know, that they themselves were partly culpable here and had they -- you know, there was never a mention of, like, 14:33
maybe we could have done something different or, you know, self-reflection or anything. It was, you know, there was one or two moments towards the end where I would say the lowest points were coming, having met some consultants who kind of spoke to them with that 14:34
sort of language which kind of to this day my Mum still talks about having, you know, left a very sort of negative impression.

So, yeah. So, I don't know, it's almost like, you 14:34
know, there wasn't any sort of culture of looking at what had been done and what they can learn from it and instead it was like, you know, this must be the cleverest cancer ever if it has outwitted us.

CHAIR: Thank you, Patient 35's son. I really appreciate you taking the time to come up and speak to us. I'm going to ask Dr. Swart if she has anything that she would like to ask you, but we do appreciate all that you've told us. 14:34

THE WITNESS: Thank you.

92 Q. DR. SWART: Thank you. Before I ask you anything, I just want to thank you for reminding us about two really important things; one is the guilt that patients and their families often feel with cancer. It's quite 14:35 a complicated thing, but it does underlie this and thank you for reminding us about that. And the other is the need for humility on the part of the medical profession. Patients usually teach us that and it's very, very important because without it, we don't 14:35 learn. So thank you.

I wanted to ask you, there's a big role in cancer treatment in multidisciplinary meetings which you will now be aware of, having read your book. How aware of 14:35 that was the family during your father's treatment? Did people explain the role of that to you?

A. No. The first we became aware of these meetings would have been just through this process when the findings were made. Like, that meeting was with the Trust 14:36 basically in the summer just a couple of months ago.

93 Q. Okay. In the later phases when you describe your father deteriorating and the difficult encounter with the Oncologist at Daisy Hill Hospital, were you given

not something I've really thought about before as to how these decisions are made and, you know, it is disappointing now to hear that, like, well, you know, was it the Wild West or was it just like, you know, when the most senior person in the room just gets to 14:40
make a decision and no-one... There isn't like a culture where people can challenge or have a debate or whatever and I know that's what those meetings were there for; to drive that sort of quality and make sure the right decisions were being made. Obviously, like, 14:41
they weren't happening for whatever reason -- or either they weren't happening or didn't happen in the case of my Dad at that time. And, you know, I don't think that's a healthy environment where just there's too much responsibility if it's just on one person to make 14:41
these decisions, it should be experts from different viewpoints are considered. But, like, yeah, I mean that's...

97 Q. The meeting with Mr. Haynes, though, you were reassured, I think, that the Trust was trying to 14:41
improve matters and had indeed already made improvements; is that the case?

A. Yeah, well, it sounds as if these meetings are happening now, which is good, or happened even soon after 2009. I guess, you know, the one question 14:41
I still have is how are they being run effectively and I mean, I have no insight so I don't know. But, yeah, it sounded as if measures had been taken but it's certainly a learning there. Even if the meetings are

happening, you know, are all the right people there and do they have -- is there an environment where they feel its safe for them to speak their opinion and, you know, challenge a decision or an opinion even if it's that of -- it all boils down to culture, ultimately, and I guess so many people inside of that environment would be able to answer that. 14:42

98 Q. I mean, those are exactly the right questions and observations, you know, in this situation and I'm hopeful, you know, that all the comments we have from the patients and families and so on will be fed back. So it's really useful to hear your perspective, having come to it quite fresh, if you like. We are all used to these terms. So thank you very much. That's all from me. 14:42 14:43

A. Okay.

CHAIR: Mr. Hanbury?

99 Q. MR. HANBURY: Thank you very much, Patient 35's son, it's very striking evidence and a few of my questions have already been answered so thank you for that. 14:43

I'd just like to run over a couple of events in a little bit more detail. Obviously, I appreciate there's a lot history of flank pain. Many clinicians, apart from the urologists, struggle to diagnose that. But when your father came back and had seen Mr. O'Brien after the big kidney operation and had the positive prostate cancer biopsy, I'm not sure if you were with him at the time or did your father recollect having any 14:43

other treatment options given to him apart from just having kept an eye on him? Do you remember that?

A. No, there's certainly not to my knowledge and it wasn't like he came home and spoke about having radiotherapy or having the prostate taken out and, like, I don't think he would have, like, not mentioned that. I mean when it was then mentioned later, five years later, he took it. It wasn't that, you know, if somebody was to tell him there's no need to worry about this or whatever, you know, he would have totally believed them and taken that easy way out, in a sense. But if they had have told him, well, we need to do something and there's these two options, then I believe he would have acted on those. So not to my knowledge was there any talk of any other treatment options at that time. And, indeed, I mean, my Mum spoke to Mr. O'Brien on the phone back there before when she was concerned, like, you know: "Is it okay for us to go on holidays, like a two-week holiday?" And he said: "Yes, not at all, this is not an aggressive cancer. If we did nothing for another year, it'll be fine, nothing to worry about." It was another four or five years before anything of note happened. 14:44 14:44 14:44 14:45

100 Q. Thank you. So just running forward until, I think your father had some "waterworks" trouble that was getting worse at the time which sort of complicated the issue and had a second set of biopsies in 2012. Do you remember how the results were presented to your father then? Was there an opinion whether things were worse 14:45

whether I think from our reading, the cancer nurses weren't seemingly involved at that time but he may not have been someone who would have engaged with them or would you have thought otherwise?

A. I think he would have. I mean, yeah, I think if it had have been offered, he would have because, like, he was seeing lots of different doctors and nurses. So, yeah, I mean, if there had have been a person available, I'm sure he would have availed of that. 14:48

106 Q. Thank you, that's interesting. I think again moving forward with the communication issues when, five years later, obviously, there's a few things when things, on paper at least, are relatively well controlled between 2015 and 2018. But then things go wrong that summer and Mr. O'Brien sort of gives your father the bad news, the family bad news then about it having spread. 14:48

I mean, apart from Mr. O'Brien, was there anyone else there to support? Because that really would have been the time that another person in the room might have helped, professionally. 14:49

A. Yeah. Well, I don't think so. My Mum was with him that time. I mean, again I wasn't there so I can't say. I don't believe there was anybody else in the room but, I mean, I could be wrong. But I don't -- like, I spoke to my Mum about this and I don't know. As far as I'm aware, there wasn't. That's not much of answer, sorry. 14:49

MR. HANBURY: You've done brilliantly. Thank you very much.

5.0 DESCRIPTION OF INCIDENT/CASE

advised of the outcome of the MDM by letter.

XX was reviewed by Dr.1 on 23 September 2019 and was told that he had high-risk prostate cancer. No staging investigations were requested. Instead, he was prescribed Bicalutamide150mgs once daily and Tamoxifen 10mgs once daily in order to minimise the risk of breast tenderness a possible side-effect of the anti-androgen.

XX received a follow up phone call from Dr.1 on 14 October 2019 following a request for advice regarding the potential side effects to his medication. Dr.1 reported that XX was experiencing some light headedness and dizziness, which was affecting his ability to drive. Dr.1 advised XX to cease both hormonal medications. However, although XX's PSA was noted to be rising (21.8ng/ml), a plan was made to re-check the PSA level. The bone scan and CT scans were also arranged. XX was advised to recommence Bicalutamide at a lower dose (50mgs once daily) from 1 November 2019.

XX was discussed again at MDM on 31 October 2019. His bone scan and CT scan showed no metastatic spread of disease outside the prostate. A recommendation to commence androgen deprivation therapy (a LHRH analogue) and refer for an opinion from a Clinical Oncologist regarding external beam radiation therapy (EBRT) was agreed.

XX attended his outpatient appointment with Dr.1 on 11 November 2019. His lower urinary tract symptoms were unchanged. His PSA result had fallen to 3.84ng/ml. Dr.1 described in a letter to XX's GP that if the PSA level did not decrease further at a subsequent check, "*it may be necessary to take an incremental approach to increased androgen blockade by increasing the dose of bicalutamide to 50mgs twice daily, and hopefully subsequently to taking the higher dose of 150mgs once again…. I suspect that the addition of an LHRH agonist may be more intolerable".*

A review on 27 January 2020 took place as planned. The PSA was noted to be 2.23nmol/ml, but XX's urinary symptoms including nocturia continued. XX was asked to increase the Bicalutamide to 100mgs once daily.

On 7 March 2020, XX received a telephone call from Dr.1, who advised that the PSA level had increased to 5.37ng/ml. The dose of bicalutamide was increased to150mgs once daily.

A planned review appointment for 27 April 2020 had been made however, on 23 March 2020 XX attended the Emergency Department in South West Acute Hospital Enniskillen (SWAH) complaining of difficulty passing urine. He was assessed and sent home. XX re-attended on 7 April 2020 and was found to be in urinary retention. A urethral catheter was fitted.

On 1 June 2020, Dr.1 informed XX in a telephone conversation that the PSA level had risen to 12.08ng/ml and advised the commencement of Leuprorelin (a LHRH analogue) subcutaneous injection be administered monthly by the practice nurse at the GP surgery.

To try and remove the urethral catheter, arrangements were made for a transurethral resection of prostate (TURP) at Daisy Hill Hospital (DHH). He was advised to self-

Personal Information redacted by the USI

multidisciplinary meeting, the second one after all the scans had been done?

A. Yes.

57 Q. A lot of drugs we prescribe do have side effects including the Bicalutamide, so on that one do you have a recollection that he was, that that was explained or there was an offer made of an alternative hormone treatment? 11:58

A. I don't remember my Dad discussing an alternative treatment being recommended to him. I'm sorry to jump ahead, but the only thing that I can recall was further down the line I think it was in the turn of the year he had mentioned the possibility of brachytherapy and Dad had sort of explained to me that that was, that might be an option for him. But in terms of, you know, a hormone deprivation therapy, then no. I mean, I wasn't present at those but certainly nothing like that was ever communicated to me afterwards, yeah. 11:58 11:59

58 Q. Again at that consultation with respect to the radiotherapy which you've already said, was there a conversation about the timing of a referral? Was your father -- he would have been happy to have been referred at that point, there was nothing that you perceived that he was reluctant in any way? 11:59

A. Absolutely not, no. He understood that he would be getting his PSA level down to a certain level and at that point he would be receiving radiotherapy. I know that there is reference in his diary entries, if you want me to take you to the relevant page. 11:59

59 Q. No.
A. I know you've read it. That he was being referred to an oncologist in the January and it does state that quite clearly, "refer to oncologist", and I think that's backed up by the clinical notes. 12:00
60 Q. I think the anticipation was but the reality --
A. Yes, he was told he was being referred, yeah.
61 Q. Okay, thank you. And we also know that prostate cancer, there often are options and it's helpful to have someone else in the room to help with the 12:00 decision-making. Again it brings us back to the Cancer Nurse Specialist role. I mean were you aware that was offered or he saw anybody else to have any additional support?
A. I'm not aware of it. As I say, I was, like a lot of 12:00 people, off the radar a bit during that time in terms of being actually present and calling in, as I normally would have done. But certainly my father never mentioned it. I know if he could have got somebody on the end of a phone who could have spoke to him about 12:01 the fact that he had a catheter in that he absolutely did not want, he would have explored that, he would have been straight on to them. So, no, I don't believe he ever had access to that service at that stage.
62 Q. Okay, thank you. So, can I now bring you on to the 12:01 time when your father sadly went into urinary retention and had to be catheterised and those conversations there.
A. Yes.

When I spoke with him by telephone, I found him to be somewhat vague. I do believe that he does have some, probably significant degree of memory loss. He did not appreciate that he had been referred to the Cancer Centre at Altnagelvin Area Hospital, and did not fully appreciate that any radiotherapy would be for the malignancy of his prostate gland. I do believe that there is some global deterioration in cognitive function since I first met him in July 2019. Whether it was denial or lack of insight, he did not particularly wish to have any treatment for his prostatic carcinoma in late 2019, preferring to go on holiday in December 2019, deferring initiation of any treatment until after he returned. While he was able to convince me that he had been taking the Bicalutamide daily recently, he could not remember having that first injection of Leuprorelin during the 1st week of June 2020.

A provisional report of the histopathological examination of recently resected prostatic tissue has found that he now does have Gleason 5+5 adenocarcinoma involving approximately 60% of resected prostatic tissue. I have advised Patient 1 that his prostatic carcinoma is now appearing to be more aggressive than it had been in August 2019.

In order to ensure that he is administered the Decapeptyl 11.25mgs injection intramuscularly, I took the liberty of contacting your Practice, requesting that the prescription be issued and transferred to Personal Information redacted by the USI. Your receptionist ensured that she would then arrange for Patient 1 to have the injection administered, and his serum PSA level repeated, by the Practice Nurse during the week commencing Monday the 29th of June 2020.

I do hope that there will be no evidence of any metastatic disease on scanning, and that Patient 1 may proceed to have radical radiotherapy. I believe that it would be preferable for him to be free of indwelling urethral catheterisation prior to any radical radiotherapy. If Patient 1 is unable to pass urine following catheter removal, or is unable to achieve satisfactory bladder voiding, it would be preferable for him to be taught self-catheterisation prior to radical radiotherapy. I have written to Kathy Travers, Urology Nurse Specialist asking her to consider introducing Patient 1 to self-catheterisation in the event of satisfactory bladder voiding not being achieved.

Yours sincerely

Dictated but not signed by

Mr A O'Brien FRCS
Consultant Urological Surgeon

c.c. Sister Kathy Travers,
Urology Nurse Specialist
South West Acute Hospital
124 Irvinestown Rd,
Enniskillen
BT74 6DN

Date Dictated: 26/06/20	**Date Typed:** 02/07/20-NE

xxiv. Why did [redacted] have to rely on ED attendances, at the SWAH, to secure medical assistance and treatment from March 2020 onwards, rather than being cared for under the aegis of the Urology Department?

xxv. Why did Mr O'Brien have an opportunity to contact the family of the Deceased, in the aftermath of his death? It is the family's opinion that they were mislead by Mr O'Brien in the course of that telephone call whilst they were in a vulnerable and emotional state.

xxvi. In correspondence directed to the GP by Mr O'Brien on 2nd July 2020, Mr O'Brien suggests that it appeared that [redacted] was suffering from a cognitive deficit. The family refute that assertion and consider that the suggestions made by Mr O'Brien amount to little more than "victim blaming". The family have serious concerns that the allegations made by Mr O'Brien were in some way attempting to "cover his tracks" relating to the substandard care.

xxvii. Why is it that the entire responsibility for the management of [redacted]'s care pathway was delegated to Mr O'Brien with no independent scrutiny or surveillance by any other person?

xxviii. Did [redacted] die as a consequence of the documented substandard care?

2. Please explain why you did not raise your concern(s) at the time and state if there was something that prevented you from raising your concern(s).

The patient and the family placed faith and belief in the clinical practitioners in this case. They considered the clinicians had the patient's best interests at heart in the course of care. They did not think that substandard care had impacted on his treatment and the possibility of same was, to them, unbearable.

When they became aware of the concerns in relation to care in July 2020 they were too caught up in the day to day requirements of dealing with a family member at end of life to see beyond that narrow focus. The business of caring for a dying relative trumped the immediate concerns in respect of care.

They were then falsely reassured by Mr O'Brien in relation to the quality of care in the immediate aftermath of [redacted]s death when they were clearly in an extremely vulnerable and emotional state.

1st July 2020 – injection at GP. Nurse unable to administer

6TH July 2020 – Collection of new injection

7th July 2020 – Injection and PSA check

9th July 2020 – Scan Craigavon

14th July 2020 –Met with Mr Mark Haynes Urologist for the results of the CT scan. This appointment only happened on foot of pressure by family members as there was obviously anxiety around the results. Mr Haynes informed [Patient 1], [Patient 1's wife] and [Patient 1's Daughter] that the cancer had spread. He said that there were signs of the disease progression for some time – the first being the requirement for a catheter in March/April. He informed them that the spread was significant. [Patient 1] was shocked, we simply could not take the news in. A cancer nurse specialist was present who indicated her surprise that [Patient 1] had never been allocated to a cancer nurse specialist from the outset. We explained that no, from February –June his only access to care was through A&E despite repeated attempts to access Urology Services. [Patient 1] explained that Mr O'Brien had felt his prognosis was a good one so he really could not believe what he was being told. Mr Haynes explained that he was going to lodge a complaint by in relation to this matter. We weren't particularly interested in that as the reality was, [Patient 1] was going to die and we had to deal with whether now lay ahead for us. [Patient 1] asked what his prognosis was and it was explained that it was difficult to say however he was optimistically looking at around 18 months. His only treatment option was likely to be chemotherapy. [Patient 1] simply could not understand why he was never given radiotherapy and how on earth he had ended up in this position. Mr Hayes explained that treatment options could be discussed in more detail tomorrow with Dr Darren Brady, Consultant Urological Oncologist at the Cancer Centre in Altnagelvin.

15th July 2020 – We attended at the Cancer centre. A 6am start from [Personal Information redacted by the USI]. [Patient 1] was extremely weak and had to be carried from the car by his brother in law. With difficulty, due to Covid protocols, the Cancer Centre agreed that [Patient 1's Daughter] could attend this appointment with [Patient 1]. He was recommended for Abiraterone , an oral drug used to treat advanced prostate cancer. An 18 month prognosis was given. He spoke to [Patient 1's wife] and [Patient 1's Daughter] and told them he felt that he "had been thrown under a bus" by the health care system. He and we simply could not believe that he was now in this position.

22nd July 2020 - Admitted to SWAH for treatment for urinary infection. GP would not visit home due to Coved so [Patient 1's Daughter] took a urine sample from the catheter bag and brought it to the GP practice for testing [Patient 1's Daughter] advised by GP – [Personal Information redacted by the USI] advised that unless [Patient 1] was admitted to hospital there was a good chance he would die at home. Visiting was not permitted whilst [Patient 1] was in hospital and [Patient 1] was in a lot of distress throughout this period, telephoning [Patient 1's Daughter] frequently.

3rd August 2020 – Patient 1 re-attended at the cancer centre with Dr Brady. Dr Brady was shocked at how he was presenting. He was extremely weak and underweight and was struggling to walk. There was blood in his catheter bag. It was noted that it would be difficult to commence him on his treatment with him at clearly such a low ebb. He was given a half dosage of the recommended mediation.

The period of the next 10 days - Patient 1's health took a serious decline. It was clear that he was seriously ill. He was unable to mobilise unaided, he was trying to mobilise but was falling frequently and both Patient 1's wife and Patient 1's Daughter (who had been granted leave from her job) had to care for him 24 hours per day. We had no access to carers or district nurses. We contacted Palliative care and an assessment was done. We also contacted Social Services and an assessment was done. No care was forthcoming. Marie Curie were unable to help. The local cancer charities were unable to assist as what they could provide was so restricted during Covid. Family members and neighbours were drafted in and a rota was established to provide 24 hour care but Patient 1's health continued to deteriorate. We wanted to care for him at home as he was terrified that an admission hospital would mean he would never see us again. He developed another very serious infection and Patient 1's Daughter organised for the rapid response team to attend at the home and antibiotics were administered 3 times per day intravenously.

13th August 2020 – GP – Personal Information redacted by the USI attended and agreed with family that Patient 1 needed to be admitted to hospital. He was still demonstrating signs of infection and was unable to have a bowel movement. Patient 1 was extremely reluctant to go and said he knew if he went he would be "returning in a box". He was admitted in an ambulance, accompanied by Patient 1's Daughter (only 1 person was allowed) who stayed with him for 6 hours in A&E holding his hand as he cried in distress. The following day Patient 1's Daughter and Patient 1's wife met with the Consultant and it was agreed that should the antibiotics not be effective and if Patient 1 became unconscious that he would not be resuscitated. Patient 1's condition continued to deteriorate. He was extremely confused and agitated as a result of the ongoing infection, not recognising either Patient 1's Daughter or Patient 1's wife when they were allowed to briefly attend with him. He was unable to eat and despite being spoon fed by the Consultant in a final bid to boost his energy levels, it was clear that the person we knew and loved was slipping away.

Personal Information redacted by the USI 6am urgent call received from SWAH advising Patient 1 was seriously ill and for family to attend as soon as possible.

Personal Information redacted by the USI – 1:15 pm Patient 1 died in SWAH.

Personal Information redacted by the USI – Social worker contacted Patient 1's Daughter to advise that at last a care package has been granted for Patient 1. It was too late.

Personal Information redacted by the USI – Patient 1's funeral at Personal Information redacted by the USI.

In the days following Patient 1's death (she cannot be precise as to the actual date) Patient 1's Daughter received a call from Mr O'Brien. The call was within a week of the death.

Patient 1's Daughter was grateful for the call. He expressed his condolences and said that he was very fond of Patient 1. Patient 1's Daughter said that the feeling had been mutual but that we were so shocked that he had ended up in the position he did. Mr O'Brien said he was happy to ask any questions that Patient 1's Daughter might have had. Patient 1's Daughter's first question was why when Patient 1 began to experience urinary retention had the matter not been red flagged at that stage. Mr O'Brien asked for clarification of that. Patient 1's Daughter explained that if that was, as we now know, the first sign that the disease may be progressing then why wasn't [redacted]'s treatment re-assessed at that stage. Patient 1's Daughter also asked why a scan wasn't taken out prior to the TURP procedure being carried out and if it had shown disease progression would the procedure have still been carried out? Patient 1's Daughter also asked was there any chance whatsoever that the medication prescribed might have by any chance caused the tumour to flare and therefore accelerated the disease. Mr O'Brien answered all these questions thoroughly explaining that the spread of cancer had been "phenomenal" and that nothing, beyond the treatment he received, would have made any difference. Lastly Patient 1's Daughter asked would Patient 1 therefore have been a candidate for surgery – using the rationale that if the cancer could not be treated but had been contained would a radical prostatectomy have been an alternative option. Mr O'Brien replied no.

Patient 1's Daughter accepted what Mr O'Brien had said. It was much easier for Patient 1's Daughter and Patient 1's wife to believe that the best care had been given to Patient 1, that he had been given every opportunity to have the disease cured than to entertain any other narrative. We wanted to believe that this had been a natural progression of the disease and that the end result of Patient 1 dying, had been inevitable. Entertaining any alternative was simply too painful to bear.

No concerns or complaints were raised to The Southern Trust by Patient 1's Daughter or Patient 1's wife following Patient 1's death, their preference being that he rest in peace allowing them an opportunity to process what had happened and to grieve their loss.

In late September Patient 1's Daughter received a call from Mrs Patricia Kingsnorth, the then Acting Acute Clinical Governance Coordinator in the Southern Trust. She advised that there was an article being printed in that day's edition of the "Irish News" regarding an investigation into Patient 1's Consultant, Mr Aidan O'Brien and they wanted to give the heads up. She stated that she and Doctor Dermot Hughes would like to meet with Patient 1's Daughter and Patient 1's wife to discuss issues that they had identified with Patient 1's care. She informed Patient 1's Daughter that Patient 1's care was the subject of a Level 3 Serious Adverse Incident review.

The SAI report had been made available to the Tribunal and the findings of that review and included therein. A further copy is attached for the Tribunals ease of reference.

2. Please specify the date when any concern or complaint was raised and if you cannot recall date(s) please try to indicate an approximate timescale.

6.0	FINDINGS

discussed with the patient.

- XX could not and did not give informed consent for this action.

- XX did not have a Cancer Nurse Specialist (CNS) or Key Worker to support his care. The SHSCT had invested in additional resource to provide Specialist Nurses to all urology cancer patients. The SHSCT had indicated to Cancer Peer Review (2017) that all patients had access to this resource. The review team have been informed that Dr.1 excluded all CNSs from the care of his patients at clinics. This was contrary to the regional guidance and contrary to the multidisciplinary ethos of cancer care.

- The review team found that without appropriate CNS support, XX and his family had difficulties in accessing support and care, especially in the community. This resource was provided by the SHSCT but was denied to XX by the exclusion of CNS involvement. XX's family tried their best to address this deficit, with input from family, extended family and friends.

- The review team noted that XX's case was not re-discussed at the MDM despite clear progression of the disease. This meant there was no opportunity for XX to benefit from the multi-disciplinary care, other urologists, oncology and especially palliative care, that underpins Improving Outcomes Guidance (2002). The absence of any CNS input to XX's care meant that they were unaware of the disease progression and could not refer back to the MDM independently.

- The review team concluded that XX received uni-professional treatment and care despite multi-professional resources being available. His care did not follow regional guidance and treatment recommendations from the MDM were ignored. XX was denied the opportunity of multidisciplinary professional referral and care: initially from a clinical oncologist when radical therapy should have been considered; and subsequently from high quality palliative care when it became necessary.

- XX developed metastases whilst being inadequately treated for high-risk prostate cancer. The opportunity to offer him radical (with curative intent) treatment was lost.

Family Engagement.

- The review panel met with XX's family. They were advised that XX did not have a CNS to support him through his cancer diagnosis. XX's daughter was planning to get married next year and brought her wedding forward to November when they learned of XX disease progression. But XX died sooner than they expected.

- The family highlighted the huge impact of the indwelling catheter problems caused to Patient 1 from March/ April 2020. The family described his difficulties in trying to contact Dr 1 and his secretary. Had a CNS been introduced to Patient 1 at his initial diagnosis, he would have been provided with contact details. He

Personal Information redacted by the USI

6.0 FINDINGS

would also have been sign posted to other community services to alleviate any potential physical or psychological problems, resulting from this diagnosis and complications.

- The family described how difficult it was to access district nursing and palliative care services during the pandemic, which resulted in XX's admission to hospital and subsequent passing. They had tried to support him at home by recruiting family and friends to assist with the basic caring needs. The challenges the family experienced due to restricted visiting times caused additional stresses to the family.

Questions from the Family

The family wished to explore if the initial biopsy of the 20 August 2019 is representative of an aggressive cancer from this date. The review team have scrutinised the report and find that the biopsy sample was adequate and comprised appropriate numbers of biopsy cores of both lobes of the prostate. It concludes the biopsy was conducted properly

The biopsy was signed off by the SHSCT consultant pathologists with specific interest in urological cancer.

The biopsy was deemed representative off XX's tumour which was graded as Gleason 4+3.

The review team would suggest there is no evidence to support the contention that the biopsy may not have been representative.

7.0 CONCLUSIONS

XX was investigated appropriately up to and including the original biopsies. The staging scans (bone and CT) would normally be expected to have been performed with a degree of urgency. These would have demonstrated no metastases and this should have led to a referral to a Clinical Oncologist as it would have been reasonable to consider radical treatment with external beam radiotherapy. Conventionally this would have been preceded by at least 4 months of neo-adjuvant ADT and this could have been started before the results of the scans were available.
XX suffered disease progression whilst being inadequately treated for high-risk prostate cancer. The opportunity to offer him radical treatment (with curative intent) was recommended by the MDM, but not actioned by those responsible for his care. The local progression of the disease should have been considered in the light of both the symptomatic deterioration and PSA changes.

Personal Information redacted by the USI

SECTION E – Personal impact/additional information

Please outline the personal impact that the treatment received, which forms the basis of your complaint(s), has had on the patient/deceased patient and provide any additional information which you feel may be of assistance to this Inquiry.

Patient 1 is gone and we are broken-hearted. His loss in our lives is immeasurable.

His diagnosis was a shock however he had done the "sensible" thing by requesting a PSA test and upon learning that the cancer had not spread, we and more importantly, he, felt that he was in safe hands. We were going to deal with this and come out the other side of it. He was young at heart and had lots of life left to live and was making plans for the future.

The events that overtook those plans commenced, in our view, in March 2020. Patient 1 lost control of his bladder and never regained it. With no access to (or indeed knowledge that he should've been provided access to one) a Cancer Nurse Specialist he was treated exclusively at A&E from March – June 2020. The negative impact that this void in care and the reality of having to live with a urinary catheter had on Patient 1, cannot be overstated. He suffered considerably in those months. He was prescribed antidepressants (with no previous history of mental illness) anti-anxiety mediation and sleeping tablets. He was crying out for help but couldn't get it. He thought he was losing in mind. In reality he was extremely ill unbeknownst to us all. All of this was compounded by the isolation of the ongoing Covid restrictions.

After he died, we realised the true extent of his anxieties and suffering throughout those months; We found handwritten notes in his car detailing whom he wanted to carry his coffin at his funeral and what hymns he wanted played. It caused us unbearable pain to think of the distress that he must've been in given that these would've been written prior to him being told that his disease was terminal in the July of 2020.

The weeks that followed after our meeting with Mr Haynes on 14th July 2020 until Patient 1's death on Personal Information redacted by the USI will remain etched on our memories forever. The lack of support and care from across the board of the medical profession and the ancillary professions meant we were left to care for a terminally ill patient with complex needs, at home, with zero input from anyone outside of our family. Whilst it was our privilege to care for Patient 1 throughout this period it came at a huge personal cost for both him and us. He was stripped of his dignity and felt entirely abandoned and unsupported to endure the cruel and unrelenting symptoms of his

disease. A disease which only one year earlier he believed he had every chance of securing a recovery from.

Upon hearing [redacted]'s terminal prognosis [redacted] brought her wedding forward to the end of October, 2020 in the hope that [redacted] would be there to walk her down the aisle or at the very least be present to witness the day. It was not to be as [redacted] died within 5 weeks of hearing the bad news. The wedding went ahead at the end of November with 25 guests and no reception (having been postponed for one month after we had been contacted by the Southern Trust and advised of the Investigations into Mr O'Brien/The Southern Trust). Two days before the wedding, immediately prior to being presented with a gift from all her colleagues, [redacted] learned that there would be a Public Inquiry held in relation to the practices of Mr O'Brien and The Southern Trust. Another major blow and shock in the midst of what was already an incredibly difficult, painful time

The wedding went ahead. The day, whilst a celebration of love, was bittersweet without [redacted] present. Now with the knowledge that the Southern Trust believed there had been major failings in [redacted]'s care the day was underpinned by a sense of shock and horror at what we had learned. The wedding was held in [redacted] – a church in which [redacted] was a lifelong member. His absence was painfully felt by us all, given that [redacted]'s funeral had taken place in the same building only [redacted] earlier. He was nowhere and yet everywhere at the same time.

His death, having coincided with the Covid restrictions which were in place meant that we lost out on being able to visit [redacted] in hospital as often as we would've liked and indeed as often as he needed and we had to deal with [redacted]'s obvious upset and distress around that. We lost out on the rituals of mourning that usually sustain and carry grieving people, following a loved one's death. A "normal" wake was not possible. Attendance at the funeral was restricted. His last days in hospital were without the constant security of us by his side.

We have received extensive counselling following [redacted]'s untimely death. With the support of those Counsellors, we have tried to find a way to move forward. That has proven to be impossible given the nature of the investigations that are ongoing and indeed the inevitable media coverage that they have attracted. The natural grieving process has been altered and impacted greatly by these circumstances. We have been unable to heal or find a sense of peace in [redacted]'s passing and we endure ongoing trauma and pain as a result of what we have learned regarding the apparent failings in his care. Due to the findings of the SAI we feel that we have

been robbed of our loved one and him of us. We believe we will have to carry that sense of loss with us for the rest of our lives.

We do however remain open minded as to what will transpire throughout the course of the Public inquiry and via the other investigatory processes. We understand that there will be various narratives submitted by the interested parties and these accounts will require careful consideration. We welcome the opportunity for those accounts to be given in an open, transparent manner.

We will assist in this Inquiry in so far as we are able, making no comment beyond the telling of ours and Patient 1 s lived experience. We endeavour to continue to carry the pain of Patient 1 's loss with courage and dignity.

Additional sheets, if needed, can be attached

A. It just absolutely didn't help matters at all and it was very difficult because when we realised he was terminally ill, his disease and his decline progressed extremely quickly. And, you know, we wanted to do our best for him to try to care for him at home insofar as we could but his disease was complex, it was hard to manage. And unfortunately there was this element of if I go into hospital I'm not going to be able to see you and I'm going to die and I'm not going to come back out and I'll never get to speak to you again. That was a real fear and that was something that we certainly struggled with. And ultimately in his final days, whilst I had been raising concerns because I could see that my Dad was deteriorating rapidly and was being reassured about that and, I mean, they were short staffed, they were doing their best. But, you know, ultimately I suppose it just meant that the final conversation you had with him was a lot sooner than it necessarily would have been, had you have been able to have been there with him more. That was a great difficulty for us and for him. And indeed when he was in hospital in Daisy Hill for a week in June that was difficult for him because we weren't able to get in. He actually lay in the back of the car on the way down because he really was in quite a state at that stage. He phoned me a number of times whilst he had been admitted, he was crying, he was in pain, the TURP procedure didn't appear to have worked. They tried to remove the catheter which he was extremely keen to try

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travelled. The way Dad had put it to me was 'I think they are going to try to map a way forward for me and we'll see where we go'.

12 Q. Can I just pause you there now, can you recall who that call came from? 11:28

A. I think it was a female as I understand it. I don't think it was Mr. O'Brien. I don't think it was Mr. Haynes. I don't think my Dad necessarily knew their name but -- I don't, being honest. But we then went to Craigavon to meet with Mr. Haynes, both myself 11:28 and my Mum and my Dad, on the 14th July.

13 Q. And that was the first time that you understood that his disease was in fact terminal?

A. It was, absolutely. I mean in retrospect you look back and you think, you know, how could it not have been 11:28 more obvious? I think my Dad knew there was something seriously wrong with him. I think he thought he was going mad, to be perfectly honest, because he felt terrible, we now know why but he hadn't been told that he was as ill as he indeed was. He had been through 11:29 surgery so, you know, we'd nothing really outside what he was telling us to believe that he was indeed that ill. And Mr. Haynes had communicated to us that the disease had spread. He said the first sign of that really would have been when he had required the urinary 11:29 catheter in the March of 2020, that that would have been the first sign that this disease was progressing. He'd had weight loss, so really the signs had been there. At that stage he had explained to Dad that,

look, you know, radiotherapy isn't an option, your chance for curative treatment here, it is no longer on the table. We asked for a prognosis. Dad had asked why he hadn't been given or received radiotherapy, would that have made a difference? I think he sort of 11:29
struggled to accept that radiotherapy was no longer on the table. He gave him a prognosis, doing the best he could, of in or around about 18 months. But he said we would be going to Altnagelvin the next day to meet with the urological oncologist and that we could discuss 11:30
that in further detail. That was a really, really, really difficult day for us and for Dad. He just kept saying 'I don't know how I have ended up in this situation, I thought it was going to get sorted out' and I think he was reasonable in that belief. 11:30

14 Q. When you say he was reasonable in that belief, is that because of what he had been led to believe as it were?

A. Well, I mean we weren't naive, it's a vicious, unpredictable disease. But, you know, the way it had been communicated to me was, look, you know, I'm here, 11:30
I'm in good hands, I'm in the right place, I have done the right thing, I have got diagnosed, you know, I have a good chance of getting to the other side of it. You know, it would be nicer if I had been further down the Gleason Scale but I'm not but, you know, I'm in the 11:31
system and I'm getting my treatment and hopefully we'll be able to get it sorted out. I don't think he took it as a guarantee of course but I think he had a reasonable belief that he had a good shot at curative

treatment.

15 Q. And just in terms of the treatment before the operation in June, we know that he was prescribed Bicalutamide?

A. Yes.

16 Q. Can you maybe describe some of the effects of that on him? 11:31

A. I can. As soon as he started to take it he felt really terrible. He was feeling dizzy. He was feeling sick. If I'm honest we didn't over indulge those concerns. We were telling him look, you've been prescribed them, 11:31 you have got to take it, it's in your interest. He, I understand, had communicated that to Mr. O'Brien. I do remember going to the house one evening and Dad being quite annoyed because he had received a letter from Mr. O'Brien, it isn't within the bundle. As I remember 11:32 reading it, and I can't quote it, but I do remember the gist of it was that the symptoms that my Dad had been experiencing he had found to be unusual and not what he would have expected and having been practising for quite some time he'd never really heard those 11:32 particular concerns. I think my father felt his hair was thinning, there was other things, and my Dad was quite annoyed about that because I think he had found it dismissive, but albeit he sort of tried to tolerate it as best as he could and that's what he did. I know 11:32 he had asked to stop taking it for a short period of time when they were going on holiday at the end of November of 2019, but apart from that he took his medication.

17 Q. Can I just ask do you still have that letter at all?
A. I haven't come across it since he has died but I could have a look for it. I do have the hospital notes, I just never really wanted to go through them, to be honest, but I could probably make enquiries about that. 11:33
18 Q. I appreciate that, Patient 1's Daughter, and if you do come across it, if you could share it with the Inquiry we would be grateful?
A. Yes, no problem.
19 Q. You describe how you then saw the oncologist on 15th July? 11:33
A. Yes.
20 Q. And how difficult that appointment was for you as a family. At that stage you were told by the Cancer Nurse Specialist at that meeting, do you recall that, or was it then? 11:33
A. I think that was on 14th July when we met with Mr. Haynes. There was a Cancer Nurse Specialist present at that meeting and that was the first I'd heard about a Cancer Nurse Specialist. 11:33
21 Q. Your father had never been assigned a Cancer Nurse Specialist?
A. No.
22 Q. From diagnosis?
A. No. I never heard him mention it. I mean that would have been presumably his first port of call whenever the catheter had gone in and, you know, I never was aware of anybody being assigned to him in that regard. 11:33
23 Q. There was a Urology Nurse Specialist with whom he had

some contact?

A. Yes. I'd seen that in his diary entries but, to be honest, throughout that time, I mean I didn't live with my Mum and Dad and the Government advice at the time was to stay away so really through that period of time from April to probably the end of May my contact with my Dad was standing in a garage bringing food a couple of times a week, do you know. So, you know, I know he was very upset through that time. I know every day you would speak to him and it would be 'have you heard from Mr. O'Brien? 'I haven't heard from Mr. O'Brien'. And that, that seemed to go on for a long time. And he was making trips to A&E which we were trying to discourage him to do because of Covid and little did we know that Covid probably didn't pose much of a risk to him as what he was dealing with, you know, but hindsight's a wonderful thing. 11:34 11:34 11:35

24 Q. Well, sadly, he did deteriorate quite rapidly and died unfortunately in [redacted]?

A. Yeah. 11:35

25 Q. During the days shortly after his death you talk about a telephone call that you received. Could you tell us a little about that please?

A. Sure. I can't be precise as to when that telephone call was. I think it was -- I don't think I was back at work because I went back to work about three and a half weeks after Dad had died, it was certainly before that, and I remember there being a number of people in our house at the time which would make me think it was 11:35

relatively soon thereafter. He had spoken to my Mum initially and my Mum had put me on. I think she was worried that he would start talking --

26 Q. When you say he?

A. Sorry, Mr. O'Brien, sorry. And I think that my Mum was concerned that she wouldn't be able to communicate with him and understand the medical terms and she had put me on. It was strange, if I can just set the scene for it, because all I had heard from March 2020 to June 2020 was my Dad wanting to hear from Mr. O'Brien and here I was having a conversation with him after all of those months, albeit I appreciate he had seen him in the interim time. My Dad was now dead and I was sitting having that telephone call outside the room that his coffin had lay in only maybe a week or so beforehand. So that was a really strange thing and all I could think of was you need to speak to Dad because he's the person that really needs to have the questions answered. And, whatever about this conversation, we can't reverse time, we are where we are. And I remember that was sort of my feeling about it. He expressed his condolences and he had said he was particularly fond of my Dad and I had said my Dad had felt the same, maybe not albeit towards the end of his treatment, end of his life, but I think it is important that I do say that, that he, his interactions with him on a personal level had only ever been anything but positive and reassuring and I appreciated him expressing his condolences to us. He told me some

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personal stories. We talked a bit about loss generally and then he asked me if I had any questions about the care that my father had received. I had asked him, sorry, Mr. O'Brien, if -- we now know that the first sign that the disease was progressing when he required 11:37
the urinary catheter in March 2020, why did that not then precipitate some sort of action or a restaging? I don't think I necessarily put it like that at the time, but I suppose I was saying why was he not red-flagged, I think that was the terminology I had used. He asked 11:38
me what I meant by that and I just really repeated the same thing to him again. I would be doing the conversation a disservice to say that I really remember what his answers were in any great detail, albeit that the gist of it was that he had had appropriate care and 11:38
really little beyond what he had had would have made any difference. I appreciate we're not here to discuss issues of causation, but that's really probably, if I'm honest, what I wanted to hear because any alternative I couldn't have really lived with. We are, as it turns 11:38
out, but certainly at that time I had -- I'm fairly certain that I had asked him about whether or not, knowing what we know now, that he was almost certainly terminally ill at the time that the procedure was carried out. You know, should that really have 11:38
happened? Should he have been rescanned before that? And if they had found that he had been terminally ill at that stage, you know, would that still have been recommended treatment because it struck me as being

futile and that my Dad had been put through that operation entirely unnecessarily. That was a question that I had, I asked him that as well. I do appreciate that my Dad was particularly keen to have the catheter removed. I mean I think we're all in agreement about 11:39
that, he was, he just absolutely detested having that. He found it undignified and he really, really struggled with it. But albeit if there wasn't, you know, a really good chance that he could have had a successful removal of it, I still think he would have opted not to 11:39
have it removed. I asked him that and then I asked him as well about maybe had the cancer been more aggressive from the outset because I was starting to wonder whether or not my Dad had tried to protect me on some level by sort of, you know, downplaying, you know, the 11:40
prognosis and diagnosis that he had been given. He did explain to me that, no, that the biopsy was representative. He went into a lot of detail about how a biopsy is carried out and the samples that are taken, how it is done and that they were satisfied that that 11:40
was representative. And then I had mentioned to him about we knew that then there was Gleason 10 Grade, I'm not going to pretend to know anything about this, but, you know, later on in the samples that had been taken after the TURP procedure and I think, you know, I had 11:40
wondered after that conversation, albeit I don't think that Mr. O'Brien was saying that my Dad's disease had been more aggressive at the outset than they originally thought, I think I took that, just being fair, having

recollected on that telephone conversation and that's why I had then asked for the initial sample to be retested, but I don't think he was saying that. I don't think he is saying that. And that's something maybe that I should have corrected at a later stage but, you know, I'm saying that now.

27 Q. Fair enough. You describe how you found that conversation with Mr. O'Brien reassuring?

A. Yeah.

28 Q. And you appreciated him ringing at that time? 11:41

A. I did, yeah.

29 Q. And do you still feel that way now?

A. I don't know if I'm honest. We were vulnerable. We were emotional. We were in shock, to be perfectly honest. I took it for what it was at the time and I did appreciate, I did appreciate it as to why it was made or, whether or not it was genuine, I think that's a matter for Mr. O'Brien. 11:41

30 Q. Well, you were later contacted by the Trust and I think that was in September 2020. Can you describe how that first contact came about? 11:42

A. Yeah, I can. I had gone back to the office and I had received a call from Patricia Kingsnorth and she had communicated to me that she said you'll recall that when we had met with Mr. Haynes in July, 14th July, that he had indicated that he would be making a report in relation to the care that Dad had received. I think the way it was communicated to me was that there had been a leak within the Trust to the media, that there 11:42

were concerns over Mr. O'Brien's practices and that that was on the front page of the Irish News and they want to give us a heads up. That was the first communication that I had. So of course I left the office and went and bought the Irish News. She had said that they wanted to meet with Mum and I and they were really reluctant to give us any information until we met with her and Dr. Dermot Hughes in [redacted] a few weeks after that.

31 Q. I think you, in fact, had two meetings with the Trust but at that first meeting, when did you first learn that your father's care was the subject of a Serious Adverse Incident? 11:43

A. At the first meeting with the Southern Trust.

32 Q. And was the SAI process explained to you? 11:43

A. Yes, it was.

33 Q. And were you invited to be involved in that process, for example were the Terms of Reference of the Serious Adverse Incident, did you have any input into that?

A. I don't think we did, no. 11:43

34 Q. But they did certainly explain to you what would be happening in terms of that?

A. Yes.

35 Q. And how did you find that meeting and the communication that surrounded that? 11:44

A. I understood why we couldn't be told anything in advance, albeit it was frustrating, but when we met with them they were very transparent. I would say, that was Patricia Kingsnorth and Dermot Hughes, and to

the point probably of blunt about the failures in the care that my father had received. It was quite confronting to have to receive that information to the extent, and it's not within the records, but Dr. Hughes had communicated to Mum and I that the Bicalutamide medication can sometimes cause a tumour flare and that that's what they believed could possibly have happened. Now, I didn't expect to see it anywhere written down afterwards, and I haven't, but that's what was said. We were told that there were concerns with the practices for a long time, albeit maybe I played slight devil's advocate with that. I couldn't understand if there had been concerns for so long and they were so serious then, you know, why were they only being highlighted now and why were they continuing to employ somebody if this was their view of their practices? It just didn't make an awful lot of sense to me.

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36 Q. You then had a later meeting, I think in November 2020?

A. Yeah.

37 Q. And, again, that was before the SAI report was concluded and can you recall that meeting and --

11:45

A. I can, although for some reason I can't recall it in any great detail. It was on Zoom. I don't know, I was actually getting married only a couple of weeks after that and that felt like a particularly nightmarish time is the only way I can describe it. I don't have any particular -- I have read the notes of it but as for what was said and what was discussed, I couldn't tell you.

11:46

38 Q. But you have no reason to disagree with the notes that you received?

A. No, no.

39 Q. Then it was in Spring 2021 that you received the SAI report? 11:46

A. Yes.

40 Q. And the conclusions of that. And, again, can I just ask you about the effect that that had on you as a family when you received that?

A. Yeah. It was horrendous. It's the stuff of nightmares 11:46 to be perfectly honest. It just had a devastating effect on us both. We were still in lockdowns at that stage. We were grieving. The loss and then we had this additional layer and the person that we really wanted to speak to about it is no longer here and, you 11:47 know, it was too little too late is the best way I could put it. We understood why that needed to be communicated to us. We welcomed the transparency and the fact that it was done in that frank manner but really any outcome that didn't result in my Dad being 11:47 taken back to the summer of 2019 and given a second run at his treatment, you know, just there was nothing good could come of this for us. It's been a very, very difficult thing to have to live with it, albeit we try.

41 Q. I appreciate that. Can I just check with you, after 11:47 the report was received did you have a further meeting with members of the Trust and perhaps with the representatives of the Department of Health to discuss that and to discuss the Inquiry being set up?

had seen that letter before, I couldn't be specific about when but no, it was before we received the bundle.

47 Q. There is a particular paragraph which is actually on the screen in front of you, it's at the top of that page? 11:50

A. Yes.

48 Q. That I know that you wanted to say something about?

A. I do. I'm aware of that conversation between Mr. O'Brien and my father. I should say, although it reflects differently in the SAI, I don't dispute that he found him vague, that's really for him to make that determination. I don't actually doubt that he was vague because he was in a really poor condition at that stage. I do, however, wish to challenge the suggestion that he was displaying a significant degree of memory loss. I'm not sure you could make that determination in a short conversation in any event, but I really don't think that was the case for my father. I don't accept that there was any sort of cognitive decline. I think we have to appreciate he was speaking, Mr. O'Brien was speaking to somebody there who was extremely ill and their only access to healthcare, apart from the TURP procedure, between March 2020 and June of 2020 was via A&E. So, I was disappointed to read that characterisation and we don't accept that there was a deterioration in cognitive function, no. 11:50 11:50 11:50 11:51

The point following on from that where it's stated that

he did not particularly wish to have any treatment for his prostatic carcinoma in late 2019, preferring to go [redacted] in [redacted] 2019, deferring initiation of any treatment until after he returned, I would challenge that as well. I don't think it's clear as to whether or not the treatment Mr. O'Brien is referring to is the Bicalutamide, which he shouldn't have been on in any event, or the commencement of radiotherapy. But I do remember my father speaking to me after that appointment and stating that I've asked Mr. O'Brien is it okay for me to go [redacted], they went away for [redacted] at the end of [redacted] 2019, and would that interfere with anything. He said no, this is how my Dad put it to me, you'll not be starting your radiotherapy until probably the early spring, because you're on this medication and the idea is we want to get your PSA driven down through the floor before you would commence that. So if he is referencing radiotherapy there, I think that's disingenuous and it wouldn't have prevented him from making the referral to the radiological oncologist anyway. I was disappointed to note that. I haven't seen any contemporaneous note that my father had asked for his treatment to be deferred. I accept it's in the diary entries and I remember him saying that he wanted to stop taking it for a short period of time whilst he was going on holiday. But it's the characterisation of him being in denial or lacking insight. My Dad was diagnosed on foot of him being diligent enough to ask for a PSA

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test, that's how this diagnosis came about. This wasn't somebody who was flippant with their health or that was in denial or lacking insight. He knew he had prostate cancer and I want to be really clear about that. If he had have been told you are going to see an oncologist the following week he would have been there. If he had been told you're commencing radiotherapy next week, let me tell you he'd have been the first person in that cancer centre 11:53

49 Q. Thank you very much, Patient 1's Daughter Is there anything that we haven't covered or that isn't covered in the bundle of papers that we have that you wanted to let the Inquiry know or say at this stage, this is your opportunity? 11:54

A. I think I've covered everything and thank you for the opportunity today. 11:54

50 Q. We really do very much appreciate you coming along and speaking to us because we know it isn't easy.

A. Thank you.

CHAIR: I'm going to hand over and ask Dr. Swart if she has anything she would like to ask you. 11:54

51 Q. DR. SWART: Thank you. Thanks again, it gives significant colour to hear from people, but your notes are very good anyway.

11:54

You describe the meeting with the Trust about the Serious Incident, you had several meetings, and then the report. I can imagine that would have been very shocking for you and difficult?

A. Mmm.

52 Q. What, in those meetings, shocked you the most about the care, as it was described? What was the biggest thing that sort of really wrenched at you?

A. The use of the unlicensed medication. That was the most shocking thing. Because that, of course, was the only treatment that my father ever received. So, to be told that, at best, it wasn't going to do anything for him and, at worst, it had in actual fact made things worse for him, I think that was the most shocking thing. 11:55

53 Q. And what about the whole issue of the multidisciplinary team meetings, had you been aware of those until that time?

A. No, I hadn't. My father had never discussed it. I wasn't aware of what the treatment plan would have been beyond what my father had understood it to be. So I didn't know what recommendations had been made or what should have been done on foot of those recommendations, I had no idea until that meeting. 11:55

54 Q. And when it came through to the report, and the lessons learnt are fairly clearly set out and stark and there was quite a lot of emphasis on that Multidisciplinary Team meeting, wasn't there, and the recommendations. How did you feel about that, when you read that, the fact that the right things had been recommended but didn't happen, what impact did it have on you? 11:56

A. It shocked me. And I wouldn't say I was particularly naive or anything like that. But it did shock me and I

remember saying at the time, he's not the first person who has presented with prostate cancer or prostate cancer at this stage. You know, it's not formulaic but also it's not, this isn't unchartered territory either. There should have been a plan in place and you would have expected those fairly basic measures to have been implemented. I was shocked. I knew other people who had came to our home after my Dad had been diagnosed and treated by Mr. O'Brien successfully and had absolutely nothing negative to say about him or their experiences with the Southern Trust, so this was quite a shock. 11:56 11:57

55 Q. And if you were sitting with the Trust Board today and you had to give them three recommendations, what would you choose to highlight to them about things that you feel perhaps they need to understand more about? Is there anything you'd like to say, 'please know this', in addition to the pain and suffering that the family has had which is obviously shocking? 11:57

A. If I'm honest no, because I think it's known to them already. I don't think there's anything new in any of this and that's my belief. 11:57

DR. SWART: Thank you.

CHAIR: Mr. Hanbury?

56 Q. MR. HANBURY: Thank you very much, Patient 1's Daughter, for your evidence, very compelling. 11:58

I just want to dig a bit deeper on the consultation your father had with Mr. O'Brien after the

in Personal information redacted by the USI following your father's death, you've explained in your evidence that the broad gist of it was that Mr. O'Brien had delivered all appropriate treatment and nothing else would have made a difference; is that the broad gist of it? 12:12

A. It is. I should add to that that I did ask a question at the end, I remember thinking about it, that if nothing could have made any difference was taking his prostate out an option, was surgery an option? I now realise it probably wasn't at his age, it's not for me 12:13 to comment on that. I did ask that question and he replied 'no'.

86 Q. So, did you, during that conversation, get into the radiotherapy issue with him?

A. I'm fairly sure I did ask would it have made any 12:13 difference if he'd had radiotherapy sooner. And, again, the broad gist of the answer was no. And then there was a discussion around the fact that he had required the urinary catheter which would have caused difficulties for him receiving radiotherapy. He did 12:13 give me, Mr. O'Brien did give me a fair bit of detail around that but I would be doing it a disservice to try and recall it in any detail.

87 Q. So is it fair to say, Patient 1's Daughter, knowing what the multidisciplinary meeting prescribed as the recommended 12:14 form of treatment for your father, is it your family's fundamental question: Why didn't that happen and how could the Trust have failed to realise until quite late in the day that it hadn't happened?

A. Yes, indeed.

88 Q. Is that fundamental to you?

A. Very fundamental.

MR. WOLFE KC: Thank you.

CHAIR: Patient 1's Daughter and Patient 1's Wife, Patients 1's Son-in-Law, thank you all very much for attending today. We do very much appreciate you taking the time to come and speak to us and hopefully whenever we do reach our conclusions and make recommendations, what you have told us will bear fruit in those recommendations, so thank you very much indeed. If you don't mind I'm going to ask if Ms. Marshall will take you from the room, I have some housekeeping matters that I need to deal with the representatives. Thank you. 12:14 12:15

THE WITNESS: No problem. Thank you. 12:15

DISCUSSION RE HOUSEKEEPING

MR. MILLAR: There was a point that arose this morning in the evidence that I just wanted to clarify. If you look at line 10.1, just after that, 10.1, 10.2. 12:16

CHAIR: We don't have CaseView in front of us Mr. Millar, if you maybe want to read the portion.

MR. MILLAR: I think the question you raised, Madam Chair, was whether in June Patient 1 was prescribed Bicalutamide in advance of his operation. 12:16

CHAIR: I don't believe that was my question but I'm subject to what is in the transcript.

MR. MILLAR: The point is I think there was just a

difficulty understanding each other's communication. To aid her understanding of dad's medication I showed her the written repeat prescription sheet that I had brought with me. Dad informed her *that his allergies were; penicillin, nickel, leather and inadine, he informed her about his heart attack* and stents, and that his cardiologist stopped plavix one week ago. The anaesthetist requested that the TV be turned off and I got up to close the treatment room door. The nurse took dads blood pressure which was not a concern to either nurse or anaesthetist. Then the surgeon (Mr Thwaini) came in and introduced himself. He informed us that there were no medical notes, but he has retrieved some information from the computer and then proceeded to take a detailed history and retrieve consent. He highlighted the risks of surgery in great detail, to the extend I asked "are you confident to proceed without my dad's notes" to which he replied that he had worked in CAH with Mr O'Brien and that the procedure was relatively straight forward and that dad had provided him with very good information.

At 9.30 I received a call to return to the ward; on my return I was informed that dad had a cardiac episode and that they were working with him. In the mean time the sister at Downpatrick hospital called the senior anaesthetist and informed me they were doing their best for dad. A member of Downpatrick nursing staff told me that someone with complex cardiac history like dads should never have been referred from the acute hospital as Downpatrick has no cardiac backup, thus leading to hospital transfer.

He was then transferred to the Ulster Hospital via ambulance and the senior anaesthetist travelled with him. It was at the Ulster Hospital that I was told that there was no pre-operative ECG and without this they had nothing to compare following this episode and that they would treat dad as he presented in the absent of the cardiac history. At this point I learned that we almost lost dad.

The Ulster hospital had dad confined to bed and he required oxygen, IV diuretics, catherization and pain relief. They restarted plavix and he warranted an Echo cardiogram in the Ulster Hospital and an angiogram in the City Hospital.

It is my understanding that both surgeon and anaesthetist from 352 visited dad at the Ulster hospital and that the anaesthetist told dad that he did not tell her about all his allergies. This is not the case as there was a nurse present at the time, who should have also recorded the allergies, as was I.

What are my concerns?

1. No consultation about transfer to 352 or consent given
2. Inadequate information RE: surgery and appointment letter
3. Letter from 352 made no reference to stopping medication, even though admission staff is advising patients to stop medication.
4. Admission staff advising on medication prescription
5. No pre operative assessment at 352
6. No sharing of information between CAH and 352
7. CAH and 352 failure to recognise my father's complex cardiac history
8. Proceeding without notes (surgery/clinics not prepared)
9. Communication barriers between professional and patients
10. No privacy when discussing information with patient

11. And most importantly NO ONE has offered any feedback as to what went wrong at 352 in Downpatrick.

This begs the question what drugs where administered that lead to a reaction, given that heart investigation didn't show a heart attack as we were first informed.

Today I have also written to 352 requesting a list of medication administered as to prevent a further episode

Having attended an appointment with the coronary prevention nurse at CAH they had no information on file RE 352 episode and investigations at the Ulster and City Hospital. She was also unable to obtain any informative information from dads GP as he has no information either. Despite a CAH letter on 11/07/2012 advising that all treatment would be recorded in CAH notes. It would appear that Mr O'Brien is unaware of this entire episode that my father was exposed to.

Dad remains with his urology problem which causes his urge and disturbs his sleep. He has been told not to proceed with further intervention without explanations as to what happened.

Further to writing this letter, I attended a follow up appointment for my own medical condition in CAH and when asked was there any family history of a reaction to an anaesthetic, I informed the nurse of my dad's episode. She said that she would not be able to excess my father notes as there is no transfer of notes between the private company and CAH, despite a previous letter informing me that all information would be passed between the two sites.

Can someone please enlighten me as to what exactly is happening?

Yours Sincerely

[redacted]
Patient 82's Daughter

CC John Wilson 352 Down Patrick Hospital.

3fivetwo
HEALTHCARE

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e. admin@3fivetwo.com

23 January 2013

Patient 82
Personal Information redacted by USI
Personal Information redacted by USI

Dear Patient 82

I am writing in response to correspondence from your daughter, Patient 82's Daughter in relation to your treatment with 3fivetwo Healthcare. 3fivetwo Healthcare take all complaints seriously and an investigation was instigated.

3fivetwo Healthcare work in partnership with the Southern Health and Social Care Trust under a scheme called the Waiting List Initiative. You were transferred to 3fivetwo Healthcare for a urology procedure which you had been placed on a waiting list within the Southern Health and Social Care Trust for. When you were placed on this waiting list for this procedure you were deemed fit to proceed to surgery which is why you did not see a consultant at 3fivetwo Healthcare or have a pre-operative assessment. Unfortunately, I am unable to comment on the decision taken by the Southern Trust regarding your transfer to 3fivetwo Healthcare.

Your daughter kindly contacted 3fivetwo Healthcare on 07 September 2012 to organise your procedure and it was during this telephone conversation that your procedure date was confirmed for 15 September 2012.

Following this, a confirmation letter was issued advising of the date, time and location of your appointment. The letter requested that you bring all your current medication with you to the appointment and advised that if you were taking Warfarin that you should have your INR levels assessed 2 – 3 days prior to date of your surgery. Further to this, it advised that as part of the procedure you would be undergoing general anaesthetic which would require you to fast for up to 6 hours before your scheduled appointment.

On 13 September 2012 your daughter contacted 3fivetwo Healthcare by telephone to clarify what steps you had to take prior to surgery with regards to discontinuing medication. I understand she was provided with conflicting information by 3fivetwo Healthcare staff from that advised by staff at your pre-operative assessment at Craigavon Area Hospital. 3fivetwo Healthcare strive to provide a high quality of care to all of our patients so I would like to sincerely apologise that you feel you were provided with differing information and any confusion this may have caused.

I can advise that your previous medical history was not passed to 3fivetwo Healthcare at the time of your referral and you were booked for your procedure with the information that was provided to us.

With regards to the decision to proceed with surgery, pleased find attached a report from Dr Olga Mala, the anaesthetist present at Downe Hospital on the day of your procedure.

There's a letter from Mr. Thwani that says Daddy was to have watchful surveillance. Had he have had them notes and seen his notes, his letter that he had sent at the time, he might have questioned why Daddy at this time was on the Bicalutamide and the tamoxifen, but he didn't have the notes at that point. He says, look, I've worked with Mr. O'Brien, I know what needs to be done, I've got some computer access here and I'm happy. But he give a big spiel about the risks of surgery and then I started, oh, he's a bit over the top. 11:32

I questioned him then and I said are you sure you can do this safely and he's going to be okay, and he says yes. I says, hmm, right. Faced with the option of going on a waiting list again against the possibility that something might not happen, we proceeded. 11:32

MR. HANBURY: We know that Mr. O'Brien, with the admission papers of the Trust, was very specific about the cardiac history and the stents.

A. Yes, he knew. He knew. 11:32

MR. HANBURY: It doesn't sound as though the anaesthetist had access to that.

A. When we came back to clinic, I said to Mr. O'Brien "Why would you have passed Daddy's file out of Craigavon Hospital; he should have stayed within the acute service because of his heart". Mr. O'Brien says my files were taken, it was nothing to do with me; the list was nothing to do with me. Which, you know, I thought, well, like who decided who was the 11:32

appropriate person to go forward to 352 and who should stay in the hospital?

Then 352, they decided -- as I said to them, did you operate just off a list? They had no notes either. They didn't write back to Craigavon Hospital to say we don't know the first thing about this man that you sent on a list. They didn't get the notes. 11:32

MR. HANBURY: Just to go back to your comment about all treatments have risks and the radiotherapy stirring up the bladder. Mr. O'Brien saw your father a lot over that 10 year period. Was there any time that that conversation about the Bicalutamide and the risk of heart disease was raised by Mr. O'Brien over that period? 11:32

A. Well, there never was a question of should we stop the Bicalutamide and the tamoxifen. If that was a discussion, the anxiety would have rose in me like it did the day Mr. Haynes asked to take it off. I was going, oh heavens, if they stop this, what will happen? 11:32 But I wouldn't have been adverse to having stopping it if it was explained why it should stop. I mean, I think all medication should be reviewed. But, I mean, there was a GP writing that prescription every month, did he not think about the standard clinical 11:32 practice and the long-term use of a hormone treatment? I mean, I definitely questioned Daddy's having fatigue and he's having dizziness and he's talking about hot flushes.

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10 April 2025

Ms Anne Donelly

Solicitor to the Urology Services Inquiry

Urology Services Inquiry

info@USI.org.uk

Dear Ms Donnelly,

Thank you for providing 3fivetwo Healthcare, Kingsbridge Healthcare Group, the opportunity to provide comment and feedback relating to this section 21 notice.

Given the length the time that has passed since this patient's appointment with 3fivetwo Healthcare it has been challenging to provide much more information than was provided at the time of response to the compliant.

We have aimed to provide additional comments and context to the questions raised where we have been able to.

Please find responses detailed below to the questions posed.

Q1. No consultation about transfer to 3fivetwo healthcare (sic) or consent given

R1. As part of the patient transfer process from referring trust's to 3fivetwo healthcare it would have been standard practice that the referring trust would either write to or phone patients to inform them of their transfer to the independent sector provider. This would have been managed by the individual trust and as such we are unable to say if this process took place on this occasion.

Q2. Inadequate information RE: Surgery and appointment letter

R2. In line with the patient's daughter statement and the compliant response issued by 3fivetwo healthcare at the time it was recognised that the pre-operative information provided prior to surgery was not adequate. It was documented in the complaint response that additional measures and training were introduced to improve the quality and consistency of the pre-operative assessment process.

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Q3. Letter from 3fivetwo Healthcare made no reference to stopping medication, even though admission staff is advising patients to stop medication

R3. It was recognised at the time of this complaint that pre-operative process was not adequate in relation to this patient. It was documented in the complaint response that additional measures and training were introduced to improve the quality and consistency of the pre-operative assessment process, specific reference was made regarding pre-operative management of existing medication of patients. Kingsbridge Healthcare Group continues to provide a full and comprehensive anaesthetic pre-assessment service.

Q4. Admission staff advising on medication prescription

R4. It would be common practice that admission staff would relay specific pre-operative advice including instruction on medication to patients prior to an admission on direct instruction from the Surgeon and or Anaesthetist. As was originally documented it was evident that this process appeared to be confusing for the patient and their daughter and as result it was documented in the complaint response that additional measures and training were introduced to improve the quality and consistency of the pre-operative assessment process, specific reference was made regarding pre-operative management of existing medication of patients. Kingsbridge Healthcare Group continues to provide a full and comprehensive anaesthetic pre-assessment service.

Q5. No preoperative assessment at 3fivetwo Healthcare

R5. Given the patients' previous medical conditions, age and pre-existing medical condition this patient should have had pre-operative assessment completed prior to admission. This was recognised in the complaint response at the time.

Q6. No sharing of information between Craigavon Area Hospital and 3fivetwo Healthcare.

R6. As part of the patient transfer process, it would have been standard to have received appropriate referral information from the referring hospital. This information at the time would have been held within a physical chart that would have been sent to each appointment. It was standard practice that appointment outcome information was then reported by 3fivetwo healthcare to the referring trust at the time this reporting was provided using excel reports. Once a patient pathway was completed or the patient was discharged copies of all relevant clinical notes were shared with the referring hospital for filing within their NHS records.

Q7. Craigavon Area Hospital and 3fivetwo healthcare failure to recognise my father's complex cardiac history.

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R7. Given the patients complex cardiac history he should have undergone a pre-operative assessment in advance of his admission for surgery. On the date of admission, it was clear that physical chart could not be located at the facility. The surgeon has referred to having access to the patient's electronic care record that would likely have provided details on their past medical history. If there was any concern about proceeding with the surgery, it would be standard practice for Surgeon or Anaesthetist to cancel and postpone the procedure.

Q8. Preceding without notes (surgery/clinics not prepared)

R8. At the time of this patients surgery 3fivetwo healthcare would have prepared and delivered sets of patient charts to the location of the clinics and theatres. On the date of admission, as documented the physical chart could not be located at the facility. The surgeon has referred to having access to the patient's electronic care record that would likely have provided details on the past medical history. If there was any concern about the proceeding with the surgery, it would be standard practice for Surgeon or anaesthetist to cancel and postpone the procedure.

Q9. Communication barriers between professional and patients

R9. Kingsbridge Healthcare group work to promote and encourage open communication between clinical professionals and patients. It is evident in this circumstance the patient and daughter felt that there had been barriers in the communication. It is difficult to provide a more detailed response given the length and time since this incident and the information available.

Q10. No privacy when discussing information with patient

R10. This appointment took place in Downpatrick hospital through an insourcing initiative. Given the length of time since the incident and the lack of information available as to the flow on the day it is difficult to comment. Privacy and patient dignity is a core aspect of patient the centred care that (3fivetwo) Kingsbridge Healthcare group deliver within its hospitals these principles are upheld and are regularly inspected by the RQIA.

Q11. And most importantly NO One has offered any feedback as to what went wrong at 3fivetwo Healthcare in Downpatrick

R11. Based on the response provided by 3fivetwo Healthcare Oct 2013, a response detailing the clinical circumstances of the incident were provided. The length of time to provide this response was not in line with normal or existing response time frames for such complaints or incident investigations.

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2. Please review the attached extract of the oral evidence of Patient 82's daughter most specifically, the references to 3fivetwo healthcare at TRA-01856, TRA-01858, TRA-01861

(i) Transfer of her father's care to 3fivetwo Healthcare without pre-operative assessment.

R. As part of the patient transfer process from referring trust's to 3fivetwo healthcare it would have been standard practice that the referring trust would either write to or phone patients to inform them of their transfer to the independent sector provider. This would have been managed by the individual trust and as such we are unable to say if this process took place on this occasion.

(ii) Transfer of her father's care to 3fivetwo Healthcare without pre-operative assessment

As part of the patient transfer process, it would have been standard to have received appropriate referral information from the referring hospital. This information at the time would have been held within a physical chart that would have been sent to each appointment. It was standard practice that appointment outcome information was then reported by 3fivetwo healthcare to the referring trust at the time this reporting was provided using excel reports. Once a patient pathway was completed or the patient was discharged copies of all relevant clinical notes were shared with the referring hospital for filing within their NHS records.

At the time of this patient's surgery 3fivetwo healthcare would have prepared and delivered sets of patient charts to the location of the clinics and theatres. On the date of admission, as documented the physical chart could not be located at the facility. The surgeon has referred to having access to the patient's electronic care record that would likely have provided details on the past medical history. If there was any concern about the proceeding with the surgery, it would be standard practice for Surgeon or anaesthetist to cancel and postpone the procedure.

(iii) The adequacy of the explanation provided by 3fivetwo Healthcare

Based on the response provided by 3fivetwo Healthcare Oct 2013, a response detailing the clinical circumstances of the incident were provided. This response did not address the 11 points that the patient's daughter had outlined. The response provided was not in line with normal or existing response time frames for such complaints or incident investigations.

(iv) The alleged discrepancies in 3fivetwo healthcare's reply to Patient 82's Daughter 's complaint.

Based on the transcript and documentation provided it does not outline what these alleged discrepancies are.

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3. Please add any further information or responses which you may have on the issues raised by [redacted] Patient 82's Daughter *and which may not already be before the inquiry panel.*

There is no further information to add.

Yours sincerely

Raymond Macsorley
KHG Chief Commercial Officer

Southern Health and Social Care Trust

10 June 2013 **Our Ref:** AS224.12/13 **Your Ref:**

Private & Confidential

Patient 82's Daughter
Personal Information redacted by USI

Dear Patient 82's Daughter

I refer to your complaint in respect of the provision of urology care to your father, Mr Patient 82 Patient 82 by an Independent Sector Provider on behalf of the Trust. Thank you for taking the time to highlight your concerns and for providing me with the opportunity to address them.

At the outset I wish to provide you with my sincerest apology for the inordinate length of time it has taken to deal with your concerns.

I understand you have been written to directly by 3fivetwo Healthcare about your father's experience and I appreciate that you have further concerns you wish to be addressed. Given the information available to the Trust, I have asked that a full and thorough investigation be carried out into the circumstances of your father's case and we will be appointing a team of persons not directly involved with your father's care to take this forward. We will also be inviting representatives from 3fivetwo Healthcare to participate in this also.

We would normally aim to have such detailed investigations completed within 12 weeks and it would be normal practice to share the findings and learning from the investigation with the family after that period by inviting them to a meeting to discuss the outcome. I trust you will be happy with this approach.

Finally, I am pleased to note that your father has been returned to the Trust under the care of Mr O'Brien and I am pleased to learn that he has had his procedure and I do hope he is keeping well after this.

I will be in contact again in due course, however if in the meantime you have any queries please do not hesitate to contact the Directorate's Clinical and Social Care Governance Team on Personal Information redacted by the USI

Yours sincerely

Personal Information redacted by USI

DEBORAH BURNS (Mrs)
Interim Director of Acute Services

for Mairead McAlinden, Chief Executive

Clinical and Social Care Governance Team
Directorate of Acute Services
Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by USI

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice 2 of 2025
Date of Notice: 24th March 2025

Witness Statement of: Dr Ian Menown

I, Dr Ian Menown, Consultant Cardiologist, Southern Trust, will say as follows:-

1.01 Patient 82 attended me for elective cardiac catheterisation for angina symptoms on 05/02/2010 and then returned for planned stenting in a staged fashion to the right coronary artery on 17/05/2010, to the left anterior descending artery on 08/09/2010, and to the left circumflex artery on 04/04/2011. Good stent results were obtained on each occasion.

1.02 I saw Patient 82 once more for outpatient review on 13/4/2012 when it was documented that he was “feeling well with no further chest discomfort. He is troubled by bladder complaints. He is easily fatigued.” I noted that his heart rate was relatively low (57bpm) and that his blood pressure was relatively low (116/52mmHg), both of which could contribute to fatigue. Thus, I asked his GP to reduce the dose of his beta-blocker (Bisoprolol) from 5mg to 2.5mg od. As his angina had resolved, I discharged him back to the care of his GP.

1.03 Regarding TRA-01870: Bicalutamide or tamoxifen were prescribed by urology for prostate cancer and he was already under ongoing urology review for these. Assessing the indication and tolerability these drugs, including side effects and any contribution or otherwise to fatigue is outside of the expertise of a cardiologist.

1.04 Patient 82 subsequently saw two other cardiology consultants (NH, Belfast trust and CH, South Eastern trust) following a peri-procedural “vasovagal” episode in September 2012. Cardiac echo showed his heart strength remained normal (EF 61%), repeat angiogram showed his stents remained patent, and of note, neither commented on his urology treatment.

Urology Services Inquiry

Statement of Truth

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

Signed: [redacted]
Personal information redacted by the USI

Date: 31/3/25

From: Ali Thwaini
To: Benson, Shauna; Donnelly, Anne
Subject: Fwd: Urgent Section 21 Dr Thwaini
Date: 20 April 2025 19:23:03

CAUTION – This email has been received from outside the NICS network. If you have any concerns, please report for investigation.

FYI

Many thanks

Ali

Sent from my iPhone

Begin forwarded message:

From: Ali Thwaini <Personal Information redacted by the USI>
Date: 14 April 2025 at 8:34:30 AM GST
To: Raymond Macsorley <Personal Information redacted by the USI>
Subject: Re: Urgent Section 21 Dr Thwaini

Dear Raymond,

Many thanks for your email regarding Patient 82, whom I seemingly treated in 2013 as part of the waiting to initiative.

Just to give you an update about my current situation, I have actually left the UK a few years back and I actually really relinquished my GMC license as I don't have intention to come back in the foreseeable future to work for the NHS.

I am really sorry for what Patient 82 's family have gone through.

As you can imagine, it's been more than a decade since Patient 82 was under my care for that particular weekend as part of the waiting list initiative.

Patients who are on the NHS used to have have physical notes. Some of them are very large, however thankfully we were greatly helped by the electronic care records of the NHS patients that contains their letters, laboratory, and radiological investigations. Therefore, generally, in the absence of the physical notes, clinicians would be able to access the relevant information from the electronic care records that are generally very sufficient.

While I'm trying to refresh my memory, I vaguely remember looking after him as he came for a seemingly minor procedure, as per his daughter's letter, however, after the induction of anesthesia. He reacted badly to the anesthesia hence, the procedure was stopped even before I started my operation.

He was managed by the Anaesthetist colleague, and after being stabilized, he was transferred to Ulcer hospital and as far as I remember, he fully recovered from that incident.

I am sorry to learn that he passed away about a decade later, and I can only assume that his passing was most likely unrelated to that incident.

I'm not sure if my email was helpful, but I'd be happy to help within the space of my capabilities Personal Information redacted by the USI .

All the very best

Ali

Sent from my iPhone

On 4 Apr 2025, at 10:48 AM, Raymond Macsorley <Personal Information redacted by the USI> wrote:

Dear Mr Thwaini,

I am forwarding you the attached correspondence on behalf of Shauna Benson, Deputy Solicitor from Urology Service Inquiry. This relates to one patient treated through WLI Urology

service commissioned on behalf of Southern Health and Social Care Trust under a contract with 3fivetwo Healthcare in September 20212.

If this correspondence is received, I would appreciate if you could confirm receipt of this.

Kind regards,

Raymond

Raymond MacSorley
Chief Commercial Officer
Kingsbridge Healthcare Group
Danesfort Building,
221 Stranmillls Road,
Belfast, BT9 5UB
Personal Information redacted by the USI
Personal Information redacted by the USI

From: Benson, Shauna <Personal Information redacted by the USI>
Sent: 24 March 2025 17:02
To: Governance <Personal Information redacted by the USI>
Subject: Urgent Section 21 Dr Thwaini

[EXTERNAL EMAIL] Treat attachments with caution
Urgent

Private

and Confidential

Dear Sirs

Re: Urology Services Inquiry - Section 21 Notice 3 of 2025 requiring the production of a witness statement from Dr Ali Thwaini

Please find attached Cover Letter and Section 21 Notice 3 of 2025, requiring Dr Ali Thwaini to provide a written statement to the Urology Services Inquiry by noon on the 14th April 2025.

We appreciate that Dr Thwaini, may have moved on to other posts at this stage but he was working for your organisation at the time and we therefore expect you to liaise directly with him to ensure that he has received this Notice and is made aware of the timescale for replying to same.

Should Dr Thwaini have any difficulties completing his statement, please let me know at the earliest opportunity and no later than the 7th April 2025.

Please also find attached the following documents to assist with completion of the statement.

1. Urology Services Inquiry, Terms of Reference (TOR)
2. Guidance notes for completing a S21 response
3. Template Witness statement
4. Extracts referred to in the Section 21 Notice

Should you require any assistance in relation to this Notice then please do not hesitate to contact me on my number noted below. I look forward to hearing from you within the timescale stipulated.

Many thanks,

Shauna Benson
Deputy Solicitor
Urology Services Inquiry
Contact Personal Information redacted by the USI | Tel: Personal Information redacted by the USI | Ext: Personal Information redacted by the USI

<image001.png>

<Section 21 Mr Thwaini.pdf>
<USI-Terms-of-Reference.pdf>
<GUIDANCE NOTES FOR THE SECTION 21 NOTICE.pdf>

<USI Witness Statement Template - Dec 2021.docx>
<USI Witness Statement Template - Dec 2021.docx>
<TRA-01856 - TRA-01871.pdf>
<Cover Letter Dr Ali Thwaini .pdf>
<Patient 82 Relevant Correspondence with 3fivetwo..pdf>

was 20 weeks, and that I would be invited to a meeting.
CHAIR: Did that happen?
A. No, you know. And as an employee of The Trust as well, as I say, it wasn't to make a complaint really, it was to say, look, you know, people need to be assessed before they go for surgery and there needs to be sharing of information, and if this isn't done, you know, it will be to the detriment of further patients. That was where I was trying to go. Thankfully, Daddy was okay from the event. You know, he didn't suffer.
CHAIR: Just so that I can be sure that I've got it clear, Patient 82's Daughter, your father's surgery was outsourced to 352 by the Trust. Our understanding is his notes and records didn't go with him, as it were, from the Trust?
A. No, no, no.
CHAIR: So 352 were in the dark, as it were, in terms of what treatment he had had?
A. Yes. I suppose even on that morning, when I arrived in Downpatrick Hospital, it was like a ghost town. There wasn't even a receptionist in the foyer. We went upstairs to the area where we were supposed to be and I observed, as I felt at the time, the anesthetist walking around and being shown round; she didn't know where she was, she was finding her way. Then a nurse came in and she started to take information from Daddy, and in the middle of that the anaethetist took over and really dismissed the nurse, from memory.

CHAIR: Unfortunately, your father would appear to have a reaction of the drug that he was given?

A. Yes. I had forgotten my glasses that day and I left to go and buy a pair. I got a call, it wouldn't have been half an hour, to come back, Daddy had deteriorated. 10:27
I was asked -- I got into the ward. They said he took a heart attack and I was asked to call the rest of the family. I called them, and then we just were in the corridor waiting to see what was going to happen.
Then, when we did get in to see Daddy, he was sitting 10:27
up quite bright and he said he was all right, but at that stage they decided he needed to go to the Ulster. I mean, he was in there for three/four days. He was on drips and he was on heart monitors, and he was moved
from there to the City to have an angiogram. Out of 10:28
that had come that, you know, his heart was okay, so they come to the conclusion that possibly he had got the anaesthetic too quick.

CHAIR: This was obviously a very upsetting and worrying time for you and your family, and you were 10:28
concerned to try to ensure that it didn't happen again to anyone else, which is why you wrote then to the Trust?

A. Yes, that was why I wrote to the Trust.

CHAIR: And to 352. 10:28

A. Because once we got Daddy out of the hospital we realised he was okay and there wasn't going to be long-term harm, barring the fact that he didn't yet have his Botox injection and it was still needed. So,

WEDNESDAY 31st OCTOBER 2012
Ref: [redacted]

[redacted]

HOSP.NO.: [redacted]
D.O.B.: [redacted]
G.P.: [redacted]

H&C No: [redacted]

Dear [redacted]

I wish to confirm the appointment which you made to attend The UROLOGY CLINIC

on Friday 9th November 2012 at ~~12:30 pm~~ 1.30 p.m

This clinic is held in the:
THORNDALE UNIT, CRAIGAVON AREA HOSPITAL,
LURGAN ROAD, PORTADOWN.

MR A O'BRIEN is the Consultant-in-Charge of this Clinic.

Please make every effort to attend this appointment. If you are UNABLE TO ATTEND, please contact the Referral & Booking Centre on 028 38613406, 028 38613410 or 028 38613420 as soon as possible. If you do not attend this appointment and fail to notify the Appointments Department in advance you will not be offered any further appointments in accordance with Trust policy.

If you are attending the Ophthalmology (Eye) Clinic please bring a driver with you as we may need to put eye drops in your eyes to dilate them and you will not be allowed to drive home.

PLEASE BRING WITH YOU:

1) This letter
2) A list of any medication that you are currently taking.
3) Your Medical Card
4) Your inhaler(s) if attending the Respiratory Clinic

Yours sincerely,

APPOINTMENTS BOOKING CLERK

9/11/12 Seen MR O Brian.
Blood taken for PSA
result 1Wk to GP.
Previous result 67
any increase PSA ∧ Med start radiotherapy
No radiotherapy until irritable bladder
problem solved
MR O Brian to check med given @ DPH
and decide best way forward

PAT-001859

RV 2 10 2020

MR Haynes

SK Kate ONeill

Bicalutamide x Tamoxifen

show new research not effective

risk to heart, stroke, memory ↓

energy ↓ cognitive - low dose

Hormone not effect. cure 1st

course of action in early ↓

Plan - Stop medication

- base line PSA 2·11·20

- Rtn Feb 2021

PSA ↓ 10 monitor No treatment

10-20 monitor how quick

↑ consider large dose

Hormone injection intermittent

↑ 20 PSA treat ? Radiotherapy

Irrelevant information redacted by USI

Ultersound bladder x2

+ catherization NAD

Stop intermittent

Catherization.

Urine sample obtained

Southern Health and Social Care Trust

Quality Care - for you, with you

Personal Information redacted by USI

KEYWORKER

Thorndale Unit

Telephone: Personal Information redacted by USI

Mon-Fri 9-5pm

Routine bloods

Code AN10C

Southern Health and Social Care Trust

Quality Care - for you, with you

Chair
Eileen Mullan

Chief Executive
Shane Devlin

31 January 2022

Healthcare Ref: [redacted]

Private & Confidential

[redacted]

Dear [redacted]

RE: Urology Record Review

RE: [redacted]

On the 31st August 2021 the Minister for Health announced in the Assembly that he was commissioning a Public Inquiry under the Inquires Act 2005 into the circumstances surrounding Urology Services in the Southern Health and Social Care Trust (Southern Trust).

As the Chief Executive of the Southern Trust I instructed that a lookback exercise of all patients under the care of Mr Aidan O'Brien for the period January 2019 to June 2020, when Mr O Brien retired be undertaken. All the patients who were under Mr O'Brien's care during this 18 month period have been shared with the Urology Services Inquiry (USI). I advise you of this as you may receive communication from the USI.

In order to provide the necessary assurance for this lookback exercise we commissioned Consultant Urologists who were external and independent to the Trust to undertake a review of your Fathers medical records. I can now advise following this review of your Fathers care, aspects have been identified that require a further review. This means an independent Consultant will complete a Structured Clinical Record

Review (SCRR) of your Fathers care. We have included a leaflet to explain this process in further detail.

The external independent Consultant has determined that the treatment plan your father was given in 2010/ 2011 was potentially not appropriate. This treatment plan will be reviewed in the SCRR. Once this is complete we will write to you to inform you of the outcome. Structured Clinical Record RIV.

I note your father was initially diagnosed with prostate cancer in 2010 under the care of Mr O'Brien. Mr Haynes, Consultant Urologist reviewed him in November 2020 and he advised that at the time of diagnosis he did not recall being advised of the treatment options of radiotherapy or a surveillance pathway involving monitoring of his PSA (prostate specific antigen blood test which indicates possible prostate cancer or progression of cancer). Mr Haynes advised that a medication was commenced (Bicalutimide) which was at a potentially lower dose than should have been for the management of the prostate cancer and there was no discussion of radiotherapy or surveillance options. Mr Haynes discussed the options going forward and agreed with your father that the medication should stop and a surveillance pathway be commenced. I note Patient 82 [redacted] PSA was being monitored 3 monthly and the results indicated this was stable within normal range.

We appreciate that up until you have received this letter this may have been a worrying time. The leaflet included with this letter outlines the support services available to you. Dedicated Trust Liaison Officers who are trained professional staff are available for any queries, concerns or questions you may have. This is a strictly confidential service for the purpose of this review process.

I apologise it has taken some time to complete. This was due to the volume of patients involved and wanting to assure ourselves that every patient record was reviewed fully. Finally you have the right to expect the very best care and treatment every time you use our services, for this expectation not being met I apologise.

Yours Sincerely

Shane Devlin

CHIEF EXECUTIVE

I was working and I was busy, you know. I had rang and I had tried to speak to people and they weren't available and they didn't ring back.

CHAIR: You basically just gave up?

A. Yeah, I gave up. You know, Daddy was annoyed because Daddy was going, "Sure, nothing happened to me, I'm all right". 10:30

CHAIR: So he didn't want you to pursue it either?

A. No.

CHAIR: Certainly, as far as the Inquiry is concerned, nine and a half years after you received a holding letter saying that the Trust was going to investigate, you received no further communication from them? 10:30

A. No. No.

CHAIR: You were saying your father, thankfully, had no adverse outcome as a result of what happened, as a result of the waiting list initiative incident. When did you discover that there was a further difficulty with the treatment that your father had received? 10:31

10:31

First of all, sorry, just to interrupt, I just want to make it clear that Mr. O'Brien also tried to find out information on behalf of you and the family; isn't that correct?

A. Yes, he did. Yes, Mr. O'Brien wrote to a lady, Corrigan, copied her into a letter that he had wrote, I think to Mr. Thwani, asking for information on what had happened. I don't think -- well, I certainly didn't get any reply or I don't think he 10:31

got a reply from Mr. Thwani about what had taken place. I thought that it was significant that the head of service and Mr. O'Brien didn't have discussions about what had taken place. He seemed to say in one of the letters, Mr. O'Brien, that he hadn't seen our complaint. In another paragraph, he was proceeding with the spinal because he didn't expect to get an answer. Well, you know, why would you not expect to get an answer?

10:32

CHAIR: But you then discover that there is a further difficulty with the care that your father had received?

10:32

A. Yes.

CHAIR: When did you discover that?

A. That sort of come to light -- well, I suppose the first bit that come to light was when we met Mr. Haynes in Craigavon. On reflection now when I think of it, I did feel "What's going on here", because normally we would have only met Mr. O'Brien at clinic. Nurses out and about but when we in for the consultations, it was Mr. O'Brien. But Sister O'Neill was there. When you're on the spot and asked to recall information, I couldn't think. And Mr. Haynes said to the effect that there was new research that Bicalutamide and tamoxifen were not effective and that their use increased the risk of heart attacks, heart problems, stroke, decrease in memory, decrease in energy, decrease in cognitive decline on a low dose, and the hormone treatment was not effective, and cure was the first course of action in early diagnosis. The plan

10:32

10:33

10:33

well-qualified people, better than myself, that could have queried that Bicalutamide or tamoxifen.

CHAIR: Certainly those are questions that we will be asking.

A. So it is. I think the Trust is in a very bad light over the 352 business. I think it is just about clearing a waiting list and they didn't do their assessments properly, and they didn't... It's terrible when you are putting out a helping hand and that helping hand is not taken. That's what I feel. Thank you. 11:32 11:32

CHAIR: Well, thank you again, [redacted]. We appreciate you coming along.

(The witness withdrew) 11:32

CHAIR: We will reconvene at two o'clock this afternoon then.

THE INQUIRY ADJOURNED UNTIL 2.00 P.M. 11:32

CHAIR: Good afternoon, everyone. Good afternoon, [redacted].

14:09

Just before we continue with this afternoon's session, can I ask the lawyers present to remain for a little while after [redacted] concludes her evidence. You will recall, I think it was 27th September, we had

SECTION E – Personal impact/additional information

Please outline the personal impact that the treatment received, which forms the basis of your complaint(s), has had on the patient/deceased patient and provide any additional information which you feel may be of assistance to this Inquiry.

(1) Shock & fear as I was advised to call extended family by staff @ Downpatrick as they thought Dad might die.

(2) Dad was very anxious to understand what had taken place and greatful as we were to those who saved his life. A second senior anaesthetist was called to assist by the theater Sister.

(3) Frustration @ delay in further treatment due to failure of 3fiveTwo or Southern trust to make available name of drug involved in incident. Which should have been immediately available to the Medication Kardex. Neither GP or Dr O Brien could obtain the name nor were they informed of the event

(4) Dad and family were extremely anxious when the procedure did eventually take place @ CAH. However Mr O Brien & the Anaesthetist did their very bes to resolve our fears.

(5) Frustration at the duration of time to resolve the complaint alot of thankyou & sorry for the delay but very little openess and transparency.

Additional sheets, if needed, can be attached

2.	Please specify the date when any concern or complaint was raised and if you cannot recall date(s) please try to indicate an approximate timescale.

26·Oct 2012 written complaint following teleptone complaint September 2012 with Sinead Corr, Pauline McElorn, Martina Corrigan. copy attached for your reference
Also copy forwarded to John Wilson 3fivetwo personel.

3.	Please note the name and/or position held of the person you raised any concern with or reported any complaint to at the time.

Sinead Corr
Pauline Mc Elorn
Martina Corrigan
> CAH

John Wilson > 3fiveTwo

4.	Please advise for each occasion a concern or complaint was raised whether this was done verbally or in writing (e.g. via letter/email etc).

My complaint was initially verbal and followup in writing. Replies to the complaint raised more questions for me than answers. As a working member of the trust at the time my only aim was to improve services ensuring the same would not happen again but lost faith in the process I considered it a WHITE WASH More about self protection than openess and transparency.

Section 2

Please state the information sources used for the review, including the names of the electronic systems accessed:

EGRESS and NIECR

2.1. Phase of care: Triage (where relevant)

- **Was triage conducted in a timely manner?**
- **Was the triage outcome assigned an appropriate level of priority given the information available at the time?**

Please record your explicit judgements about the triage process and whether it was in accordance with current good practice at the time the care was provided
Please also include any other information that you think is important or relevant.

Patient referred from general surgery with an elevated PSA of 10.8 for and a firm irregular prostate. Mr O'Brien triaged the letter to routine prostate clinic which does not seem appropriate. The initial referral letter gave a firm indication that this was likely to be a cancer diagnosis and as such the patient has had been brought to an urgent prostate cancer diagnosis clinic.

The only confounding variable was that the patient was scheduled for cardiac stents to be placed on the 17th May and it is possible that his cardiac treatment was taking priority and delayed his prostate investigations.

Patient seen in prostate clinic on the 11th of May and referred for prostate biopsies with advice requested from cardiology regarding stopping clopidogrel and timing of biopsies.

Prostate biopsies confirm low volume intermediate risk prostate cancer T2 Gleason 3+4. Biopsies taken 27th July 2010

Given ongoing cardiac care delay in diagnostic investigations could be defended but initial triage decision seems inappropriate.

Received from SHSCT on 31/05/2022. Annotated by the Urology Services Inquiry.

2.11. Overall care

Please record your explicit judgements about the quality of care the patient received and whether it was in accordance with current good practice.
Areas identified where learning could occur, including areas of good practice, should be included in addition to any potential areas of further investigation.
Please also include any other information that you think is important or relevant.

Overall care was poor and not in keeping with good practice.

Failure to discuss treatment options with patient
No record of MDT discusssion
In correct decision to implement hormone ablation therapy in 2011
In correct choice of medication with bicalutamide 50 mg once daily, not registered for monotherapy
No offer radical radiotherapy although may have not been appropriate based on performance status
Following MDT review in 2021 hormone ablation therapy immediately discontinued and patient started on a watchful waiting programme

Patient died Personal Information redacted by the but not of prostate cancer. PSA at that time normal at 0.23
Comorbidities with COVID and pneumonia.

Please rate the care received by the patient during this phase as:
5 Excellent care ☐ 4 Good care ☐ 3 Adequate care ☐ 2 Poor care ☒ 1 Very poor care ☐

Section not applicable ☐

2.12. If care was below an acceptable standard, did it lead to harm?

If yes, please provide details and state an action plan

Received from SHSCT on 31/05/2022. Annotated by the Urology Services Inquiry.

Potential harm could have ensued from a long period of inappropriate hormone ablation therapy. This would have led to increase cardiac risk factors, osteoporosis, weight gain and lethargy. Any of these side effects could potentially have been avoided through a watchful waiting policy.

If the patient has elected for radical radiotherapy there may have been a survival advantage although this is very difficult to predict on account of his cardiac comorbidities. On balance I think the benefits of radiotherapy would be minimal.

2.13. If the patient died is it considered more likely than not to have resulted from problems in care delivery or service provision?
If yes, please provide details and state an action plan (consider whether a serious incident investigation is required).

Not applicable

2.14. If a family member, carer, or staff raised concerns, please outline any feedback provided and state who was responsible for providing this feedback. Please state further action required.
If no feedback was provided, please consider how the outcome of this review should be fed back to the relevant people, considering the duty of candour principle.

The family should be informed that the patient did not receive standard treatment at that time and could have avoided a long period of hormone ablation therapy. The family should also be aware that the patient did not have a balanced discussion regarding treatment options.

It should be stressed that it is very difficult to determine whether prognosis has been affected however I suspect quality of life has.

2.15. Were the patient records adequate for the purpose of the review?	Yes ☒ No ☐

Please outline any difficulties in accessing appropriate information:

Received from SHSCT on 31/05/2022. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

Quality Care - for you, with you

Chair
Eileen Mullan

Chief Executive
Shane Devlin

4 January 2022 Healthcare Ref: Personal Information redacted by USI

Private & Confidential

Patient 82's Daughter
Personal Information redacted by USI

Dear Patient 82's Daughter

RE: Urology Record Review

RE: Patient 82

On the 31st August 2021 the Minister for Health announced in the Assembly that he was commissioning a Public Inquiry under the Inquires Act 2005 into the circumstances surrounding Urology Services in the Southern Health and Social Care Trust (Southern Trust).

As the Chief Executive of the Southern Trust I instructed that a lookback exercise of all patients under the care of Mr Aidan O'Brien for the period January 2019 to June 2020, when Mr O Brien retired be undertaken. All the patients who were under Mr O'Brien's care during this 18 month period have been shared with the Urology Services Inquiry (USI). I advise you of this as you may receive communication from the USI.

In order to provide the necessary assurance for this lookback exercise we commissioned Consultant Urologists who were external and independent to the Trust to undertake a review of your Fathers medical records. I can now advise following this review of your Fathers care, aspects have been identified that require a further review. This means an independent Consultant will complete a Structured Clinical Record

Review (SCRR) of your Fathers care. We have included a leaflet to explain this process in further detail.

The external independent Consultant has determined that the treatment plan Patient 82 was given in 2010 was potentially not appropriate. This treatment plan will be reviewed in the SCRR. Once this is complete we will write to you to inform you of the outcome.

Firstly can I pass on my condolences on the passing of Patient 82 in Personal Information redacted by the HSI this year.

I note Patient 82 was initially diagnosed with prostate cancer in 2010 under the care of Mr O'Brien. Mr Haynes, Consultant Urologist reviewed him in November 2020 and he advised that at the time of diagnosis he did not recall being advised of the treatment options of radiotherapy or a surveillance pathway involving monitoring of his PSA (prostate specific antigen blood test which indicates possible prostate cancer or progression of cancer). Mr Haynes advised that you were commenced on a medication only (Bicalutimide) which was at a potentially lower dose than should have been for the management of the prostate cancer. Mr Haynes discussed the options going forward and agreed with you that the medication should stop and a surveillance pathway be commenced. I note Patient 82 PSA was being monitored 3 monthly and the results indicated this was stable within normal range.

We appreciate that up until you have received this letter this may have been a worrying time. The Liaison Team attempted to contact you on the 8th, 9th and 15th December to discuss this letter prior to sending. The leaflet included with this letter outlines the support services available to you. Dedicated Trust Liaison Officers who are trained professional staff are available for any queries, concerns or questions you may have. This is a strictly confidential service for the purpose of this review process.

I apologise it has taken some time to complete. This was due to the volume of patients involved and wanting to assure ourselves that every patient record was reviewed fully.

Finally you have the right to expect the very best care and treatment every time you use our services, for this expectation not being met I apologise.

Yours Sincerely
Shane Devlin
CHIEF EXECUTIVE

that --

A. Yes.

MS. TREANOR: If we could just pull up a second letter then, PAT-001631. This is a letter, again to you, dated 20th June 2022. If we scroll down to the next page, we can see that that letter is from Dr. O'Kane, who has taken over as Chief Executive at that time. Could we just scroll go back to 1631. That letter sets out the detail of the outcome of the SCRR review. 11:32

A. Yes. 11:32

MS. TREANOR: You'll see about halfway down it sets out the history of your father's care and the issues around Bicalutamide.

A. Yes.

MS. TREANOR: At 1632 it offers you an opportunity to meet with Mr. Haynes in his capacity as a senior urology consultant and divisional medical director and a senior manager to discuss the situation further. Did you ever meet with anyone from the Trust? 11:32

A. Well, I never got that letter. 11:32

MS. TREANOR: You never received this letter?

A. No.

MS. TREANOR: How sure are you?

A. Well, like, I've all them letters. I mean, there was a number -- as I said to you, there was about 20 pages missing from my bundle. Of those 20 pages, I could replace them all, with the exception of that letter and the letter from Shane Devlin, which isn't the exact letter you're asking me for but it's a similar letter. 11:32

Southern Health and Social Care Trust

Quality Care - for you, with you

20 June 2022

Private & Confidential

Healthcare Ref: [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Dear [redacted]

RE: [redacted]

I refer to correspondence dated 4 January 2022 from my predecessor Mr Shane Devlin, Chief Executive, advising that the Trust was undertaking a Lookback Review exercise of all patients who were under the care of Mr Aidan O'Brien, Consultant Urologist.

Mr Devlin's letter further advised that as the Trust's Lookback Review identified concerns with your father, [redacted] care, we were having a Structured Clinical Record Review (SCRR) undertaken to establish if there were themes and learning from his care.

An experienced NHS Consultant Urologist from outside Northern Ireland, who is a member of the British Association of Urological Surgeons (BAUS), has completed the SCRR and has now returned his report. I would now like to share the detail of this with you.

Before I progress on to describe the findings of the SCRR, I would like to to express my sincere condolences on the death of your beloved father in [redacted] last year. Losing a loved one is never easy; I recognise that receiving this letter regarding his past medical care may cause further distress. I apologise unreservedly if that is the case.

When your father was initially diagnosed with prostate cancer in 2010 Mr O'Brien commenced him on a drug called Bicalutamide, which is a type of hormone drug, at a dose of 50mg. [redacted] remained on this until it was correctly discontinued by Mr Haynes in November 2020. The SCRR report has highlighted that Bicalutamide 50mg was inappropriate treatment for a number of reasons; it is not registered as a treatment for localised prostate cancer and any form of hormone treatment represented an additional risk for your father due to his history of significant cardiovascular disease. The treatment your father received was not in keeping with standard clinical practice.

The SCRR also found that no evidence that your father's case was discussed with the Urology Cancer Multidisciplinary Team in 2010 or any time since. This is expected for all newly diagnosed cancer patients as it is in this forum where the wider clinical team discusses the case and collectively decide on what the best treatment options could be.

In your father's case the SCRR found there was no evidence of any patient discussion regarding treatment options, risks and benefits. Again, this was not the standard of care expected for patients.

The Consultant who undertook the SCRR has described Patient 82 treatment and care as "poor care". I apologise unreservedly for this poor care.

I recognise this might be a lot of information for you to understand and that you may have further questions at this time. If you would like to meet with Mr Haynes (in his capacity as a Senior Urology Consultant and Divisional Medical Director) and a senior manager, to discuss the situation further this can be arranged by contacting Sarah Ward, Head of Service for the Lookback Review on Personal Information redacted by USI.

As previously advised, the Trust has set up a Urology Helpline to inform and support patients and families during the Trust's Lookback Review process.

This Helpline remains available should you have any queries about the Lookback Review in general or your father's case specifically. The contact details are: freephone 08004148520 weekdays 10am – 3pm and / or email urologylookback@southerntrust.hscni.net.

I would also like to use this correspondence to update you on an inaccuracy contained in Mr Devlin's of 4 January 2022.

Mr Devlin's letter informed you that there was to be an Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust. This was correct however, the information pertaining to the Inquiry in Mr Devlin's letter was incorrect and because of this, you have been misinformed.

I very sorry that this was the case. I would like at this time to correct the error and clarify the situation.

Mr Devlin advised that the Minister of Health, Mr Swann, announced his intention to have a public inquiry into Urology Services on 31 August 2021. This was incorrect. The actual date that Minister Swann announced to the Assembly his intent to set up a statutory public inquiry into the Urology Service in the Southern Health and Social Care Trust under the Inquiries Act 2005, was in fact 24 November 2020.

I can confirm the Urology Services Inquiry commenced on 6 September 2021. The Chair of the Inquiry is Christine Smith QC.

As your father was patient within the timeframe of the Trust's Lookback Review we have shared his details with the Urology Services Inquiry team. Ms Smith may have already written to you directly as your father's next of kin as I understand she was doing so with all deceased patient's next of kin.

If you would like further information about the Urology Services Inquiry, more detail is available on the Inquiry's website at www.urologyservicesinquiry.org.uk.

Finally, I would like to thank you for your patience as we have progressed with the Urology Lookback Review.

Yours Sincerely

Personal Information redacted by USI

Dr Maria O'Kane
Chief Executive

COVID on [redacted] and he didn't die until the [redacted]

But, you know, there again, I would ask the question. Mr. Haynes had said a hormone injection but there's a letter there from somebody to say that any hormone treatment would be detrimental to Daddy with his heart problems, so was even that right? I just don't know.

CHAIR: If I can just sum up. The first you were aware that there was an issue about -- just to be clear, your father was on Bicalutamide and tamoxifen for about ten years? 10:38

A. Yes.

CHAIR: The first you became aware that that was maybe not the appropriate treatment for your father is when you received communication from Mr. Haynes at a clinic that he took rather than Mr. O'Brien; is that right? 10:38

A. Yes.

CHAIR: And you haven't received any communication from the Trust other than what Mr. Haynes told you at the clinic? 10:38

A. No.

CHAIR: There was no letter came out saying, "We have reviewed the records" or anything like that?

A. I only knew that there even was a review taking place when I heard about it on UTV News, which again aggrieved me because I felt, you know, the Trust had responsibility for our care; there was an investigation taken into it. I know all about confidentiality but it 10:38

obviously was out there when it was in the news. I think the Trust should have took the opportunity when they had us to have said, look, there is a review also taking place here; we can't go into the ins and outs of it. I could have accepted that but at least I would have been informed, I wouldn't have had to hear it on UTV News.

You know, we talk about openness and transparency and keeping the patients informed. Certainly, I wasn't informed. 10:39

But it's funny, on reflection, I did sense the two people in the room that day had something more going on with them, which I think is a poor reflection of the Trust again. 10:39

CHAIR: You felt that they knew that there was -- that your father was part of this look-back exercise and weren't even tell you then?

A. Yes, on hindsight. When I went into that room that day, I thought "What's going on here"? I expected to see Mr. O'Brien. He wasn't there. I was told he had left and this was the new doctor and there was new research. But underpinning that all was a public inquiry, which I think the words could have been said - "There's a public inquiry taking place here, we can't discuss it but at the minute here's what we need to do with your daddy", and there would not have been any breach of public confidentiality, I don't feel. 10:40 10:40

CHAIR: Obviously there's the issue over the nine and a half years' lack of response from the Trust to your complaint, which you say was not designed to get anybody into trouble as such --

A. No.

CHAIR: -- but rather to help others.

A. Improve service.

CHAIR: So there's that issue about communication.

A. Yes.

CHAIR: But if I've heard what you're telling me correctly, you're saying that you were pretty dissatisfied with the level of communication generally from the Trust with patients and families; would that be fair?

A. Yes, yes. I find you write in a complaint and they write back to you what you wrote in. "I wish to complain"; "I see you want to complain", or "You have a complaint; I acknowledge your complaint". But they tell you nothing about the complaint, they don't answer the complaint.

CHAIR: Or give you answers as to maybe what happened in the individual circumstances?

A. Yes.

In terms of the Bicalutamide, you know, somebody has mentioned a -- just to I get all this terminology -- a pathway, a clinical -- a standard for clinical practice.

CHAIR: Sorry, you're reading from a document there,

you, Patient 82's Daughter. I'm going to hand you over to, first of all, Dr. Swart, and also Mr. Hanbury in due course. Thank you.

DR. SWART: Let's go back to the complaint process. You wrote a letter to the Trust. Did anybody from The Trust ring you up and talk to you about what you wanted to achieve with the complaint? 11:31

A. No. I rang in several times to speak to people, and people were to ring me back but never phoned back, so then I put it in writing. Before I put it in writing, I made a phone call to say I wanted to speak to somebody. 11:31

DR. SWART: But did you get a phone call to say "We've received your written complaint. It would be helpful to discuss the main points of it so we can give you a good answer", or anything like that? 11:31

A. No, no, no. I sent them the letter telling them what my issues were and nobody from the Trust ever came back to discuss those.

DR. SWART: You worked in the hospital, you said? 11:31

A. I worked on community at the time.

DR. SWART: You worked for the Trust. What has this left you in terms of a feeling about complaint processes in general? If you could go to the Trust and say, look, you know, I would like you to consider a different way of doing it, what would your suggestions be? 11:31

A. Well, I think when a complaint comes in it, is all about self-preservation and protection of yourself. Or

themselves.
DR. SWART: What would it take to change that? What are some suggestions? If you were to go in a quiet room with someone and say look?
A. Well, it's hard to beat face-to-face. 11:31
DR. SWART: We have heard your story today and we can see the impact it has had.
A. It is hard to beat the face-to-face. You know, I think if you can't meet someone, a colleague, to discuss a complaint, it doesn't say much for the general public 11:31 trying to make a complaint.
DR. SWART: When we come on to the meeting with Mr. Haynes and the nurse where you had this kind of odd feeling, as you describe it --
A. Yes. 11:31
DR. SWART: -- were you given the opportunity to ring up and speak to them after? The nurse, in particular. Did they say just ring us if you have got anything?
A. In fairness to Sister O'Neill, she did give us her card. 11:31
DR. SWART: Did you ring her?
A. No, I didn't.
DR. SWART: How were you feeling at that point after you came out of that consultation? Can you remember how you felt? 11:31
A. Worried because I thought -- well, I mean, Health Service in crisis, can't get in to see doctors and what happens if this cancer takes off? Is it going to be monitored or are we not going to be getting the bloods

[redacted] Patient 82's Daughter ?

A. No, it's my own words.

CHAIR: Sorry, your own notes.

A. It refers to standard clinical practice for Daddy's management, so I presume that's something that's written down that doctors are meant to follow. I would have expected Dr. Thwani and Mr. Tyson and Mr. O'Brien to have known that. Yet, Mr. Thwani and Mr. Tyson seen Daddy's medication and never queried why he was on a low dose of Bicalutamide. 10:42

CHAIR: There's some water there, if you need it, [redacted] Patient 82's Daughter .

A. Sorry.

CHAIR: You're okay, don't worry.

A. It looks like to me that there were two other doctors with knowledge of urology that should have questioned the use of Bicalutamide and tamoxifen in Daddy, and didn't. 10:43

Daddy took a dizzy spell one day in the main street in [redacted] Personal Information redacted by USI and he was referred to a geriatrician. I understood that to be an expert in the care of the elderly and medicine suitable to that age group. He never questioned it. In fact, he actually reduced furosemide and clopidogrel at that review, and never questioned. 10:43 10:44

Daddy would have complained about hot flushes, and I could say on three occasions I have spoken to the GP

practices and been told, well, that's his cancer medication, you know, so we're not going to touch that. But nobody thought to ring or write to Mr. O'Brien and say is this still essential, is it appropriate to continue with this, he's having hot flushes? 11:31

CHAIR: Can I just ask, the hot flushes would be a side effect of the medication?

A. Dizziness.

CHAIR: Were you aware of any other side effects that he had in the ten years that he was on the drugs? 11:31

A. He would have had breast tissue, I would have felt. Fatigue. You know, there again he seen a cardiologist, Mr. Menown, and complained of fatigue, and there was no mention of it being down to Bicalutamide or tamoxifen, it wasn't questioned. From, I mean, a cardiologist -- 11:31 right, if hormone treatment is detrimental to somebody with Daddy's acknowledged cardiac condition, was the cardiologist not concerned that Daddy was being prescribed a drug from another practitioner and yet didn't consult with that practitioner to say, well, 11:31 look, you know, his heart condition is causing me concern, does he really need to be on this or can we do something different?

There didn't seem to be any of that correspondence 11:31 between either of those two people.

CHAIR: So, not only are you saying that the communication from the Trust to you as a family was less than satisfactory, but you're saying that the

4. Upon review of my witness disclosure bundle, I have noted at WIT-13114 that Mr Carroll has stated that I was the Standards and Guidelines Lead. In relation to this reference by Ronan Carroll I would say as follows:

I was the Standards and Guidelines Lead for 'Benign Urology', the Cancer related Guidelines were incorporated into the roles of Mr Glackin and Mr Haynes for their specialist roles with Cancer Services and the Cancer MDM. I undertook my role from 24th October 2021 until July 2023. The role was for mainly Urology Stone related guidelines to help transform the Stone Pathways for the SHSCT and development of regional ESWL stone service.

5. Upon review of my attendance record for MDM's from January 2022 until May 2022 (WIT-24251), I would make the following comment:

Attendance at MDM was affected by annual leave, Personal information redacted by USI, occasional elective theatre list and a possible virtual attendance episode not recorded. I am no longer part of the Cancer MDM due to my sub-specialist role and development of regional stone services.

6. Upon review of Patient 82's notes and records and specifically the discharge letter at PAT-00176, I would like to make the following comments:

I was involved in this case from the perspective of a first year Urology Trainee in 2013, undertaking a supervised injection of Intravesical Botox into the bladder for treatment of bladder storage symptoms under Mr O'Brien. I note a written discharge from Mr O'Brien was provided to the patient and GP upon discharge from the procedure. A further dictated discharge was provided by myself for the procedure as a typed letter. My typed letter states I note the patient to be on 50mgs Bicalutamide and Tamoxifen, which will be from reading the paper discharge summary, my role was to provide a discharge summary for the procedure of Intravesical Botox to the bladder, undertaken as a first year Urology Trainee.

The perceived delay in dictation may relate to the time it took the notes to arrive to Mr O'Brien's secretary's office for dictation, possible annual leave, on-call commitment or the date dictated recorded on the letter may also be inaccurate. This was done at the time on a Tape Recorded Dictaphone and it was the role of the registrar to provide dictated discharge letters for inpatient activity, both acute and elective admissions.

A. No. But I clearly have done a discharge documenting it!

101 Q. Yes, yes, and it's really just to unpick the procedure around that. The Inquiry is looking at governance and perhaps how things get repeated or where there may be fault lines that could inform any of their recommendations. So it's just to see the way in which the procedure operated for the family we have raised this as an issue as well, obviously, and we just want to just understand. So from what you've said so far, you look at the patient's notes and you dictate the discharge letter based on the notes and is it the case that, in your position as a registrar and your knowledge at the time, that there was nothing to trigger a query from you around Bicalutamide 50 being prescribed as it was in this letter? 12:08 12:08 12:09

A. There was nothing at the time, as a first year registrar, for me to suddenly go "There's a pattern, there's something going on." It's a first year registrar doing a discharge for someone who has come in to have intravesical botox to the bladder, reading the paper, discharge summary of medication, and then also then moving on to the next summary of discharge, because our role at that point was to discharge -- to do dictated letters on all the inpatient activity. So I am sat there with lots of notes, going "Right, next one...". so I'm now looking at the function of that interaction, which was to come in and have botox in the bladder, and noting they are on medication and 12:09 12:09

done? And, you know, the Bicalutamide was very simple to take; it didn't inconvenience Daddy in terms of having to travel for radiotherapy sessions. Yes, it had its side effects but radiotherapy would have its side effects. You know, even the injection, which I'm not sure now even was appropriate either. I mean -- 11:31

DR. SWART: From your perspective, you had confidence in something that was keeping the cancer under control and that confidence was then removed; is that what you are telling us? 11:31

A. Yes. Yes.

DR. SWART: How could that have been done differently, do you think?

A. How could that have been done differently?

DR. SWART: Yes. What would have made that easier for you, because it is quite easy to understand that that was hard. I mean, you have mentioned that you thought there was a lack of openness and transparency about things. 11:31

A. Well, if it had have been said it was the totally wrong medicine that he had been on for ten years, then I would have started to sit up and take notice, whereas I thought somebody else is coming in now and there's a bit of new research, you know. Well, as it was put to me when Daddy got the anaesthetic, the old head was better than the young. It was implied that the young anaesthetist had given the aesthetic too quick, whereas the older anaethetist that did do the eventual procedure said I would be going extremely very slow. 11:31

There is a notion of go low and go slow when medications are being introduced sometimes. I was thinking, well, we're not on the maximum dose so maybe it will be safer.

DR. SWART: In terms of the whole urology clinic setup and this thing going on over years and everything you now know, what advice would you give the Department now as a patient in terms of making things better for the future for patients and families? 11:32

A. Well, obviously there was some lack of governance in terms of -- well, was Mr. O'Brien operating solely on his own? I mean, that's not recommended. It is recommended that a multi-disciplinary team approach is taken. There is documentation and reference to a multi-disciplinary meeting which discusses watchful surveillance. I honestly can't recall that being discussed with us. 11:32

I think possibly surgery was mentioned but because of Daddy's heart, that was a big risk, and since this cancer wasn't going to kill him, why would you go down that route? Radiotherapy was mentioned. Again, I have to say I can't recall that conversation. But when I would have went to clinics at the last - when I got the letter to invite me - I would have maybe wrote the outcome of it. On the night of the 11th/12th, "no radiotherapy until bladder problem resolved". So radiotherapy obviously was discussed, in my thinking. 11:32

we haven't covered, either in the papers that you received from the Inquiry or in anything that we have asked you today?

A. I don't know. It's very disappointing, like, you know. I just thought he was being well looked after and it turns out he hasn't, and I sort of feel I should have been smarter myself. Awful, so it is, you know. But the Health Service is under a lot of pressure and this is what happens when it isn't managed correctly. 11:32

CHAIR: We'll certainly be paying attention to all that you have told us and we'll be bearing it in mind as we look through other evidence. Thank you very much indeed. 11:32

A. Just there's files and files of paper and, really, how much of it really is read when people are reviewing, you know, clinics and that. 11:32

CHAIR: Certainly anything that is coming through our door is being looked at and being analysed. If you do need assurance that the Inquiry is looking at it in detail, we are. 11:32

A. But it is the Trust that need to be looking in detail, you know. Like, why did the other urologists not question it? Why did the GP not question it? You know, like, I'm told as a nurse if a doctor writes a medicine and a dose and I don't think it's right or it isn't right, that I'm asked to speak to the doctor, "Is this what you want the patient to have". If I still think it is not what should be given, I'm not supposed to give it. To me, there was a lot of 11:32

well-qualified people, better than myself, that could have queried that Bicalutamide or tamoxifen.

CHAIR: Certainly those are questions that we will be asking.

A. So it is. I think the Trust is in a very bad light over the 352 business. I think it is just about clearing a waiting list and they didn't do their assessments properly, and they didn't... It's terrible when you are putting out a helping hand and that helping hand is not taken. That's what I feel. Thank you. 11:32 11:32

CHAIR: Well, thank you again, [redacted]. We appreciate you coming along.

(The witness withdrew) 11:32

CHAIR: We will reconvene at two o'clock this afternoon then.

THE INQUIRY ADJOURNED UNTIL 2.00 P.M. 11:32

CHAIR: Good afternoon, everyone. Good afternoon, [redacted].

14:09

Just before we continue with this afternoon's session, can I ask the lawyers present to remain for a little while after [redacted] concludes her evidence. You will recall, I think it was 27th September, we had

SUC had CT scanning performed on 17 December 2019. It was reported on 11 January 2020. There was no evidence of any recurrence or progression of renal cell carcinoma on CT scanning. However, it was reported that a new area of ill-defined sclerosis was present within the left side of the first lumbar vertebra, and slightly extending into the pedicle. This was not evident on previous CT scans, and sclerotic metastasis was within the differential diagnosis. A dedicated radioisotope bone scan was advised for further evaluation.

My secretary had retained SUC's hospital chart in her office to await the report of the CT scan performed on 17 December 2019, so that his chart would be available for his intended review in January 2020. She transferred the chart with the report of the CT scan to my office on some unspecified date following receipt of the report. As she did not track the transfer of the chart from her office to mine, it has not been possible to determine when it occurred. It is probable that it was during February 2020 due, once again, to my not being able to review SUC during January 2020 due to the inadequacy of outpatient review capacity. In fact, he still remained on the list for review at my oncology review clinic in June 2019.

I always returned to my office each evening of every working day in the hospital. On doing so, I could find that my secretary had left a hierarchy of administrative tasks requiring attention. The most urgent could be positioned on my chair so that I could not sit down without being aware of it. I would find a number of hospital charts would be left on my desk, some which I had requested, others accompanied by the reports of investigations which had been requested. In addition, there would be a much greater number of hard copy reports of investigations without hospital charts, particularly the large numbers of reports of investigations requested during triage of referrals, as well as messages, queries and requests to contact patients or their relatives etc. I would firstly review the reports accompanied by hospital charts as that released most desk top space at which to begin working. I would then place the hospital charts on a shelf in my office to deal with at a later time when available. This was a necessity so that I could log on to my computer to address those tasks sent by email, and all this after attending firstly to those administrative tasks involved in arranging future admissions etc.

While I do not have a record of the date, I believe that it was either in late February 2020 or early March 2020 when I reviewed the report of the CT scan and the recommendation of a radioisotope bone scan. I do so as my dominant concern was with regard to exposing SUC to the risk of Covid by having him attend Craigavon Area Hospital for scanning. I called with the radiographers in the Department of Nuclear Medicine to enquire whether they were continuing to arrange radioisotope

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scans and what measures were in place to minimise the risk of Covid to patients attending. I considered that arranging for SUC to attend a rather confined department at Craigavon Area Hospital at that time, initially for intravenous injection of radioisotope, and to return later for scanning, exposed a vulnerable, comorbid, 89 year old man to a potentially lethal risk greater than deferring further assessment of the recently reported CT findings.

I later considered arranging further CT scanning to be performed at South Tyrone Hospital in April 2020. However, by then, society was heading towards lockdown due to the Covid pandemic, and elective clinical services were being progressively cancelled. Outpatient clinics were cancelled to eliminate the risk of Covid posed to patients and staff attending, as well as facilitating redeployment of staff to other more urgent needs. Again, rightly or wrongly, it was my overwhelming concern that SUC was at greater risk by being requested to attend hospitals for scanning during that first wave of the pandemic than by deferring such scans until such time as the associated risks may have been reduced.

The risks associated with attending hospitals for scans and other investigative procedures were considered to have been reduced significantly by June 2020, mainly as a consequence of the Trust having managed to divert specific clinical services to Covid light locations, though the risks were not completely eliminated. The advent of warm summer weather also helped. This was evident to me as I had been scheduled to undertake an elective list of flexible cystoscopies at South Tyrone Hospital on Tuesday 09 June 2020.

I had advised the Trust in March 2020 of my intention to retire from full time employment with the Trust on 30 June 2020 and to return to part time employment from Monday 03 August 2020. My return to part time employment was supported by both operational and professional managers. However, I was informed by telephone on 08 June 2020 that my return to part time employment in August 2020 would not be facilitated. As I would not have considered retiring from full time employment had I been informed that my return to part time employment would not be facilitated, I therefore revoked my intention to retire from full time employment on 09 June 2020. I was subsequently informed by the Trust on 18 June 2020 that I was not entitled to revoke my intention to retire. On 23 June 2020, my legal representatives submitted pre-action correspondence concerning possible injunctive relief to prevent the Trust terminating my contract of full time employment. The Trust then extended my contract of employment to 17 July 2020, citing the need for more time to seek legal advice in responding to the pre-action correspondence. Though it did, when I sought to continue to be scheduled for

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Southern Health
and Social Care Trust
Quality Care - for you, with you

11 July 2020

STRICTLY PRIVATE & CONFIDENTIAL

Mr A O'Brien
Personal Information redacted by USI

Via E-Mail only Personal Information redacted by USI

Dear Mr O'Brien

I am writing to advise you of a number of concerns that have arisen in respect of your practice as a Consultant Urologist.

On 7th June 2020 at 22.25, you sent an email which was copied to me, in which you explained that you had added 10 patients to the Trust's list for urgent admission. On my initial review of the list of patients in my capacity as AMD, I noted that 2 of the patients were stated to have been listed on 11th September 2019 and 11th February 2020, both requiring *"Removal/Replacement of Stent and Right Flexible Ureteroscopic Laser Lithotripsy".*

It appeared to me that these patients had been assessed on the dates given by you, but the outcomes of these assessments did not appear to have been actioned by you as required with the patients being added to the inpatient waiting list on the Trust's Patient Administration System. These patients therefore appeared on the face of it to fall outside the Trust's systems with all the potentially very serious clinical risks attendant on that.

Since this has come to light, the Trust has been seeking as a matter of urgency to establish the position in relation to these 2 specific patients and also to clarify whether any other patients are similarly affected. A review of records back to January 2019 has been undertaken.

At this stage, I enclose a summary of the concerns following initial review of patient records dating back to January 2019.

Southern Health & Social Care Trust
Craigavon Area Hospital
68 Lurgan Road, PORTADOWN BT63 5QQ
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The concerns identified will be managed in line with the '*Maintaining High Professional Standards in the Modern HPSS*' Framework (MHPS). I have enclosed a copy of this document for your information.

We are at the initial enquiry stage of the process and I would like to offer you the opportunity at this point to make any initial representations on the concerns outlined in the attached document.

Once we have concluded our initial enquiries, a determination will be made about the next steps in the process. The possible actions following initial enquiries are set out in detail within the MHPS Framework at Section I Paragraph 15.

The Medical Director has been in contact with NHS Resolution (formerly National Clinical Assessment service (NCAS)) regarding this matter to seek advice on the management of your case. This is a normal part of any MHPS process. I enclose a copy of the letter received from NHS Resolution, for your information, and would draw to your attention, that you can contact them directly to discuss your case confidentially with an advisor.

In line with MHPS Section I paragraph 18, and following advice from NHS Resolution, the Medical Director and I have considered any necessary restrictions. We believe, that given our level of concern at this stage of preliminary enquiries, that it is necessary to put in place the following restrictions with immediate effect:

1. **That you are no longer to undertake clinical work.**

2. **That you do not access or process patient information either in person or through others either in hard copy or electronically.**

I would invite you to consider the underlying principle in Section II paragraph 22, and request that you voluntarily undertake to refrain from seeing any private patients at your home or any other setting. I would request confirmation of this undertaking, by return, via email.

I would also request that you notify me via email of any patient / clinical related information, reports and files which you have in your possession at home so that we can make the necessary arrangements to have them returned to assist us with our preliminary enquiries, and ensure any appropriate patient follow up.

I must also advise you that given the existing referral to the GMC in respect of the outstanding MHPS case, the Medical Director has informed the GMC's Employment Liaison Officer regarding these most recent concerns.

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In summary, I seek confirmation by email, **by return,** your voluntary undertaking in respect of private patients, and confirmation as to any patient related information and or files in your personal possession.

If you have any representations that you wish to make regarding the concerns highlighted above, I would request these **by no later than 17th July 2020**.

I fully acknowledge that this will undoubtedly be a difficult time for you, and wish to highlight to you that the services of the Trust's Occupational Health Department or the staff counselling service, Carecall are available to you. You can contact Occupational Health on [redacted] or CareCall on 0808 800 0002.

Yours sincerely

[redacted]

Mr Mark Haynes
Associate Medical Director
Surgery and Elective Care

Enc. 'Maintaining High Professional Standards in the Modern HPSS' Framework (MHPS)

NHS Resolution - correspondence

Summary of concerns

Received from Tughans OBO Mr Aidan O'Brien on 20/12/21. Annotated by the Urology Services Inquiry.

7.0 CONCLUSIONS

The management of XX's renal tumour was exemplary. The abnormal findings on the post-operative review scan should have been noted and acted upon. It would be unusual for a renal cell carcinoma to produce a sclerotic metastatic bone deposit and other options should have been considered.

8.0 LESSONS LEARNED

- An acknowledgement mechanism for email alerts to adverse radiological reports should have been in place.
- The MDM tracking capacity was insufficient to provide an additional safety net for patient follow up.
- Absence of a Urology Cancer Nurse Specialist is an additional risk for successful patient follow up.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

All patients receiving care from the SHSCT Urology Cancer Services should be appropriately supported and informed about their cancer care. This should meet the standards set out in Regional and National Guidance and meet the expectation of Cancer Peer Review. This must be supported by a Urology Cancer Nurse Specialist at an early point in their surveillance journey**.**

Recommendation 2

The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals. In this case it would be essential to improve radiological resource.

Recommendation 3

The Southern Health and Social Care Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations / actions are completed. This should be supported by a clinical nurse specialist, a radiology alert system and the consultant.

Recommendation 4

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance). This includes onward referral for appropriate advice

Personal Information redacted by HSCI

I just remind you that we can't make any decision about the individual care that your father received and we are looking at issues wider than that, but it is very important that we hear from people like yourself about what happened either to themselves personally or to their loved one. Can I, on behalf of the Inquiry, express our condolences on the loss of your father. I know it is [redacted] and I know you must still be missing him. 14:11

A. Thank you very much.

CHAIR: Having said all that, [redacted], can I ask you just to tell us in your own words what it is that you want the Inquiry to know about the care that your father received in the Southern Health and Social Care Trust. If you want to start in your own words. I can have a conversation with you as we go along. 14:11

A. I'm very nervous. It is a story of two halves for Daddy, for my father. I would describe the care that he received in terms of his kidney cancer, the nephrectomy was excellent. Mr. O'Brien was so supportive of us a family. He presented as a very intelligent, articulate, knowledgeable man. He seemed to have a genuineness, a genuine interest in Daddy. He, you know, had a great sense of engagement and was able to build up a rapport with Daddy and us as a family. We trusted him and we valued that support, and we are... you know, Daddy was very clear that he was very grateful to Mr. O'Brien. He felt that he had 14:12 14:12

exemplary care in terms of his kidney. You know, we felt at that juncture Daddy's life had been saved as a result of the nephrectomy. So, I could not fault the care around Daddy's kidney and the nephrectomy.

CHAIR: Your father had other health issues at the time of the kidney removal? 14:13

A. Yes.

CHAIR: And the risks were fully explained by Mr. O'Brien at that time?

A. The risks were fully explained to Daddy. Daddy was an intelligent, articulate man. He understood the risks. The risks were reiterated again by the anaesthetist during the assessment -- or by the anaesthetist who undertook the assessment. We read around the risks; they were very, very clear. But Daddy was a very determined man and he made the choice that he would prefer to undertake the operation knowing about the risk, because my understanding is that it was a 14/15 centimetre tumour; it was very large on his kidney; it was near a major vein, vena cava. We supported Daddy in making that decision. It was his right, it was his choice, and he was very clear about that. 14:13 14:13

CHAIR: And that went well?

A. That went well, yes. It was a success. You know, we had a follow-up meeting with Mr. O'Brien. At that point in time, you know, we were feeling very positive. We have under no illusion that there could be microscopic spread and that it could come back again and it was very close to the vena cava vein, but 14:14

cardiologist. He had a short stay in hospital. His medication, I think, was realigned, he was rehydrated, etcetera. I don't know the detail but obviously it would be there. We thought, okay, that's okay.

14:16

Daddy had his scan, follow-up scan, in December '19 and it was available from 11th January. Daddy was clear at that point in time that he -- in the previous instance, my sister had phoned up for the result of the scan and then it had been followed up by a letter. Daddy was 14:16
clear at that point in time that he didn't want us to call, ring up about the scan. He had complete trust in Mr. O'Brien and felt that if there were any concerns, that Mr. O'Brien would be in touch. That was his view and we had to respect that. 14:16

We did not know anything about the result of the scan until we were contacted by Mr. Haynes, which I think was towards the end of July. He phoned my sister, who then said you need to speak to our Patient 5's Daughter. I suppose 14:17
the background that I come from, you know, speak to me. He explained to me that there was a suspicion, something suspicious on Daddy's scan. From memory, I was very distressed, very upset, very angry. You know, Mark Haynes was the ultimate gentlemen and calmed 14:17
me down and talked me through everything and the ramifications. My first thought was had there been microscopic spread and had Daddy's kidney cancer spread. Mr. Haynes explained that that was unlikely,

that it was potentially a prostate cancer. I was completely shocked. I guess I had a naive approach, thinking if Daddy had been scanned before and he has been in hospital, you know, why was this not discovered, number 1, before; and, number 2, why has the scan not been followed up in a seven to eight-month period.

I guess with my background, I read a lot. I started to do some generic reading around radiological investigations in Northern Ireland and prostate cancer, you know, diagnosis. I emerged myself in the world of PSA tests, the gold standard being a PSA test and an MRI; the pros and cons of the false negatives and the false positives. But also I read the RQIA previous investigations into review of radiological investigations in Northern Ireland, where the issues seemed to be the delay in investigations were at the juncture from the Radiology Department to the clinician, not from the juncture of the clinician once it had been delivered virtually. So, I had assumed that that potentially was what had happened.

CHAIR: Just to interrupt you, if you don't mind, Patient 5's Daughter, just to check when was this? When were you first made aware? This was in July '20?

A. July '20, yes.

CHAIR: The scan had been in December or January?

A. December. Yeah, the date is there. The scan was --

CHAIR: That's right, it is December the 17th.

explained that this would be looked at in terms of a Serious Adverse Incident?

A. Yes. It was a telephone conversation, yes.

CHAIR: Then if you can just maybe -- I'm sorry I interrupted you. If you can continue on with what happened next, as it were. 14:20

A. Then Daddy went for - was it a bone scan - for a scan. You know, we were absolutely terrified. You know, Daddy was completely shocked, distressed and anxious when we heard about a potential prostate cancer. The fact it had metastasised in his bones, we knew this was extremely serious. He was worried sick and we were worried sick that it would have spread in the interim because of the delay. That was just our human view rather than based on any clinical information. 14:21 14:21

Daddy went for his scan. You know, it indicated further spread. We had a follow-up meeting with Mr. Haynes, who explained, you know, the next -- the way forward for Daddy. Daddy was trying to be positive, to look at treatment options. You know, he didn't have -- you know, I don't know how he dealt with it mentally or emotionally because it was so traumatic, but he was focused on what are my options now moving forward, what is my treatment going to be, and what do I have to deal with. 14:21 14:22

Then treatment started for Daddy, and we were in the trauma of regular PSA tests. You were just waiting all

6.0 FINDINGS

- XX case was appropriately discussed at the multidisciplinary meetings pre- and post-surgery.

- A urology review was planned for July 2019 following the CT scan report in June, but this did not happen. The review team note that XX appeared to be lost to follow up.

- In a letter to XX dated 30 November 2019, Dr.1 advised that he was arranging a further CT scan to be performed in December and to reviewing him at the urology clinic in January 2020.

- The review team note that the scan was performed on 17 December 2019 and reported by the radiology team on 4 January 2020, but no follow up occurred.

- The review team have identified that the MDM was not quorate as no oncologist present for the meetings.

- XX was not referred to a Cancer Nurse Specialist or Keyworker to support him with his diagnosis. Nor was any contact details given to him. The Northern Ireland Cancer Services recommendations for Peer Review include that "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner"(1). This did not happen and was detrimental to the patient's experience.

- The review team are of the opinion that a specialist nurse would also have been a failsafe for identifying the delayed scan report and bringing it back to the MDM sooner.

  The review team are mindful that the family have concerns that when XX presented in ED with urinary symptoms a PSA was not undertaken. It would appear from the electronic records that a PSA test was never undertaken until August 2020.

- The CT scan, performed in January 2020, was not actioned until July 2020. Fortunately, no significant metastasis related event occurred in this 6 month period so will probably have no long-term effect on the disease's progress.

Personal Information redacted by HSCI

symptoms.

I will say, reflecting back on our experience of not having a clinical nurse specialist when Daddy had his kidney cancer, compared to having two clinical nurse specialists when Daddy had his prostate cancer and his bowel cancer, there was no comparison. We were able to ring the nurses and ask them for advice and support. It was an absolutely amazing service. I don't feel -- I think it was alluded to in the SAI report that the scans may have been followed up quicker. I think the role of a clinical nurse specialist is so much more than that. It is about holistic assessment of your needs; it is about having a port of call, someone to advise, someone to support. Having been able to compare and contrast the two experiences, they were absolutely phenomenal, and I cannot thank them enough for the support that they gave us and Daddy. 14:24 14:24 14:24

CHAIR: That was one of the things that the Inquiry just wanted to be clear. When your father underwent the nephrectomy for the kidney cancer, there was no clinical nurse specialist assigned to him at that point? 14:25

A. No.

CHAIR: And that differed from when the prostate cancer was actually diagnosed? 14:25

A. Yes.

CHAIR: I assume that you would have had discussions with the clinical nurse specialists. The SAI report is

clear that had there been one, there may have been someone to chase up the scan and make sure that it was resulted, or that the results were looked at, I should say.

A. Yes. I think that is one aspect of it, in tandem with the support services that we were provided. Having someone to call, you know, you are not feeling as if you're a ship without a rudder, you have someone you can speak to. Even about minor issues such as, you know, is sage useful for hot flushes. You know, Daddy is feeling a bit under the weather, there's some nausea. Having that port of call when are you going through this horrific journey was of great benefit to us. 14:25 14:25

CHAIR: Sorry I keep interrupting you, Patient 5's Daughter. 14:26

Just in terms of the SAI, Mr. Haynes told you that your father's case was going to be looked at in an SAI.

A. Yes.

CHAIR: Whenever that happened, what level of contact was there between yourselves and the Trust during the SAI process? Were you kept informed? 14:26

A. Yes. So we were -- we were contacted initially, I think, on 26th October. Patricia Kingsnorth phoned me. At that point Daddy had given his permission for me to be involved -- Personal Information redacted by USI to be involved in the SAI. She rang and explained the process and said that she would like to meet. I think it was followed up with a letter from Melanie McClements on 14:26

28th October outlining the purpose of the SAI. They would be keen to meet and for Daddy to sign a consent form. At that juncture, Daddy changed his mind. He was weary, he was tired, he had so much going on. He said I just want to leave it for now, which I respected. 14:27

He subsequently then reflected on it and changed his mind, primarily because he felt it was important to find out what went wrong, and to prevent this from happening to other patients in the future was his motivation and that was our motivation. 14:27

So I contacted Mrs. Kingsnorth on, I think around 3rd January. We met with her -- Personal Information redacted by USI met with her and Dr. Hughes on 11th January '21. 14:27

CHAIR: We have seen the notes of that meeting with him but it certainly seemed from my reading of it - and I'm interested to know your view - it certainly seemed a frank discussion that you had with both of them where you were able to put the family's views and ask the questions that you wanted answers to? 14:28

A. Absolutely. I mean, it was a difficult situation. You know, COVID was under way. We went over to the Trust for a face-to-face. You are sitting across a large room with face masks on. You can't pick up on nonverbal cues or reassuring smiles. You know, I cried a lot throughout it. I'm the crier in the family. I found it very, very difficult and very, very 14:28

distressing, and very difficult to control my emotions, but at the same time [redacted] had answers that we felt needed to be answered to protect -- to find out what had happened to Daddy but also to protect patients in the future, I suppose, are the two reasons for that. 14:28

We were able to be open and honest in terms of our feelings. We could not have felt more supported. You know, Dr. Hughes and Patricia Kingsnorth could not have been more empathic. They gave us time, they did not 14:29 rush us, they did not take over the meeting. Everything was explained carefully to us and it was as positive as it could have been.

CHAIR: Just in terms of once they had done their work and the SAI was reported, what level of communication 14:29 was there at that point in time with the Trust?

A. After our first meeting, we put together a family timeline because it felt to me that there were some gaps. I didn't know what level of research had been done into Daddy's case at that juncture, so we decided 14:29 to consolidate our thinking in terms of questions that we would like to be answered, which we annotated, which I'm sure you have seen.

CHAIR: Yes, we have that as well.

A. At the second meeting, all of our questions were 14:29 answered and commented on in depth. I think there were several versions of the SAI form. I think we went back and suggested some amendments, and then there was an issue that required clarification around a metastic

incident or a comment that Mr. Gilbert had made in terms of Daddy's circumstances. We asked for that to be clarified because we were unclear what that meant. It will be in the papers, it was due to a research paper that indicated that there may have been, you know, a resultant paralysis or some type of impact on Daddy as a result of the delay in the treatment. Sorry, I'm not a medic so I don't know. The general thing was that an event could have occurred within that timeframe and it was lucky that it didn't. 14:30

So, it was very -- we appreciated that clarity. Then I think we made a further change about we felt it was important for the MDM non-quorate issues to be included in the report. 14:31

I cannot fault the contact from the Trust and the support that we experienced throughout the SAI process. I don't think there's anything. You know, COVID got in the way. Having two virtual consultations is always very difficult as well. Dr. Hughes and Patricia had face masks on during the virtual meeting, so it is more difficult and it is more stressful but they made it as easy as possible for us, and they did everything they could to clarify circumstances for us, took on board our feedback and acted accordingly. So, I was very impressed by the process. 14:31 14:31

CHAIR: In terms of the impact on you and your father, how did you as a family, how did you feel when all this

came to light?

A. I'm not going to get upset; I promised that I wouldn't. I think we're appreciative of all the apologies that have been given in the hearings to date, and the language used is "anxiety and distress". For me, it doesn't cut it. For me it was harrowing, it was horrific, it was traumatic, it was distressing, it was long term, it was an emotional roller coaster, it was devastating, it was shocking. It was all of those emotions. It was difficult for us to deal with as a family. Daddy was our life; our life revolved around him. He reared us as a single parent. So, you know, he was part of our lives 24/7. 14:32 14:32

Coming from the background that I come from, I just could not understand how it could have happened. I had a lot of questions and was reading and reading and reading to try to make sense of protocols and safeguards that were in place and yet this happened, and why. Our biggest concern was for Daddy. Daddy went into lockdown in March '20. In lockdown, no physical contact with his family, apart from my sister going in just to leave his food literally at the kitchen door. He was in lockdown; he was isolated. You know, we were protecting him. And in tandem with that, he had undiagnosed cancers on top of his recovery from his nephrectomy. That is horrific in itself. I don't know how Daddy had the strength to deal with what he did but he was resilient. Coming here today to 14:32 14:33 14:33

speak to the Panel is nothing compared to what he went through. It was the most traumatic and horrific experience of our lives as a family, I think.

CHAIR: I know that you were deeply concerned about the governance issues. 14:34

A. Yes.

CHAIR: I mean, you expressed that to the Trust through the Zoom meetings that you had and through the timeline you put together, and asked for those concerns to be addressed. 14:34

A. Yes.

CHAIR: You actually went a stage further and became involved in the -- I think it is called the Task and Finish Group.

A. Task and Finish, a service user group, yes. 14:34

CHAIR: I know that you are happy to talk about that in general terms without going into the details of what the group is doing.

A. Yes, yes.

CHAIR: Would you like to tell the Inquiry a little bit about that? 14:34

A. I mean, the motivation for becoming involved in the group was my background in [redacted] for many years, but also that sense of responsibility and duty, and Daddy saying put your education to good use, go and take part in this group, do as much as you can to ensure this does not happen to other patients and their families in the future, you know? 14:34

The group, I have never met such a more open, warm and welcoming group of professionals. I felt I wasn't there as a silent partner. I felt very much listened to. You will know from looking at the minutes that I wasn't shy in terms of putting my personal opinions forward in terms of governance, in terms of issues, in terms of the action plan generally. I think they are a very, very committed group who really want to make a difference and ensure that the correct governance, policies and procedures are in place; that the action plan is clearly mapped to current policy and procedure expectations, benchmarks and standards; and also - which I think is particularly important - that there is a clear evidence base on which to measure the success of the action plan and the enhancements in situ. 14:35 14:35 14:35

Sarah Ward was my contact for the group, and Mr. Ronan Carroll chaired the group. I feel that I was there as a layperson, in effect, as a daughter of a patient, and I think I would defer to the clinical and governance experts to give an overview of the progress to date. There was regular updating, and I know there were regular reports to the overarching urology quality assurance group. I would not suggest anything different in terms of how I was treated, welcomed in terms of the conduct of the group and in terms of their embracing me working as a partner within that group. 14:36 14:36

I had great support from the family liaison officers, from the PPI staff. You know, it was a very, very positive experience but it was a difficult experience because this affected us and our family and our story. 14:37
But that made me more motivated to ask questions and to probe and to make suggestions.
CHAIR: It's good to hear that it has been such a positive experience for you on a personal level.
A. Yes. 14:37
CHAIR: Can I ask you maybe what your reflection might be on the involvement generally of service users of patients and families in issues of governance and the involvement in the SAI process? Your experience certainly seems to have been a positive one; would you 14:37
like to see that for all patients and families?
A. Absolutely. I think, you know, there are guidelines in terms of approaches to service user involvement in SAIs and groups. I think it is really, really important that -- I hate the term "service user" and I hate the 14:37
term "lessons to be learned." I think they dehumanise the situation. We are people, we are real families and we need a voice. I think, moving forward, I know that the urology group had suggested disbanding the Task and Finish Group after 12 months at the last meeting. At 14:38
the last meeting I said I didn't feel that was appropriate. I felt that service users' families needed to continue to be involved in the action plan and involved, you know, in the progress to date and to

continue to be updated, that it shouldn't just stop at that juncture. So, it was agreed that the group would meet again at regular intervals, which I was really pleased about.

14:38

I think, moving forward, families need a voice at the table, whatever table that is. That is reviewing, monitoring and critiquing the effectiveness of the action plan moving forward, and also identifying any further enhancements and changes that need to be raised 14:38 or changed as a result of the evidence base moving forward. I think we have a unique voice in that we have experienced it. I think we have the opportunity to raise issues as non-employees of the Trust and to give that kind of objective viewpoint which I think is 14:39 really, really important.

CHAIR: [redacted], thank you. I'm not going to ask you anything more at the moment. I'm going to hand over to my two colleagues here in a moment and they will have some questions for you. I am aware that at 14:39 the end of that, there is something you would wish to read to the Inquiry. Just so you know we are aware of that.

Dr. Swart. 14:39

DR. SWART: Thank you very much. I agree it is very important to hear from people as individual people, patients, so much more than a service user.

You describe a harrowing experience, being shocked, and we have all the papers in front of us. What, of all of this, shocked you the most? What was the biggest moment where you were pulled up short and thought I can't believe this has been allowed to happen? 14:40

A. Where Daddy's scan was not acted upon over a seven to eight-month period, and the subsequent diagnosis of prostate cancer.

DR. SWART: Going back to that, you had a look and you looked at the RQIA report which is a similar thing. You will be aware this is not an unusual series incident in the UK actually, not just in Northern Ireland. What is your reflection on -- why is it that you think those reports and the recommendations from them haven't got traction and these things still happen? Do you have any observations for us? 14:40

A. Yes. I mean, this morning I was reading over the second RQIA report and thinking that one of the recommendations articulates really clearly that scans or whatever should be followed up and disseminated quickly; that the Trusts should have systems and processes in place for the effective tracking and monitoring of those scans but, more importantly, clinician follow-up. For me, that is a concern for me. When the NIPACS system came into fruition in Northern Ireland, I think in 2010, you know, one of the aspects that were heralded was that instantaneous ability to click a mouse and you would be able to see a scan to 14:40 14:41

prevent any delay in follow-up, not relying on paper and hard copies. That was supposed to be a system which was foolproof and which would enhance the governance and, I suppose, the timely dissemination of scans and results moving forward. For me, the Department of Health spent an awful lot of money on that. I read in one digital health article, it was £50 million for the new phase, perhaps between 100 and 132 million for a five-year contract. If you are spending that amount of money - which I know it was BSO who commissioned it, I know there's a leading NIPACS coordinator within BSO and one within the Trust - if you are spending that amount of money on the system, I would like to think - and I don't know anything about its functionality - but you would like to think that there would be some way of monitoring clinician follow-up. 14:41 14:42 14:42

I think reflecting on the evidence to date within the Inquiry, the DARO system, I don't understand why there's a separate system. It sounds as though the systems within the Trust are not talking to each other. I'm not an IT expert but, for me, I still have concerns about the ineffectiveness of the follow-up and tracking mechanisms in terms of clinicians looking at a scan, because the DARO process for me seems to rely on human intervention, whereas I feel with the technology that we have available to us now, why was there not an escalating opportunity where, if a scan had not been 14:42 14:42

looked at, that that would have been escalated to another level within the Trust immediately and the issue would have been addressed. So there's a system issue for me as well.

DR. SWART: It is hard to understand, I agree with you. 14:43

Do you think it has just been lost in lots of important things and nobody has given it the priority --

A. No.

DR. SWART: -- or do you think that people haven't tried hard enough? How does that strike you? 14:43

A. Sorry, could you repeat the question?

DR. SWART: Do you think it has been lost because there are so many competing priorities, or do you think people have not tried hard enough to make that system foolproof? What sense have you got from it? 14:43

A. Looking at it as a layperson, there's an imaging board for Northern Ireland, there's an imaging strategy for Northern Ireland. There's so much importance out there about the importance of CT scans, imaging standards, expectations, key issues around protecting and safeguarding service users. You know, it is clear: If a scan is not followed up quickly, that is a risk to the patient. It is not an administrative issue, it is a risk to a patient. 14:44

I personally feel that more could have been done to drill down to the actual processes and systems and whether they were fit for purpose, would be my personal view. 14:44

DR. SWART: Keeping on that theme because I think it is a very important theme, in your service user group following up the actions from the SAI, did you have the opportunity to keep talking about this?

A. Yes. 14:44

DR. SWART: Is it your view that, as a result of your involvement in that group, the right things were in place to make that happen now?

A. I think I would talk about it generically that work is being done by the Trust, but I think it would be up to 14:45 the chair of the meeting to give that --

DR. SWART: You haven't had assurance in that group that this is now fixed?

A. I think what I do know is that extensive work has been undertaken and it is still in process. I think it is 14:45 more than a Trust issue, I think this is a regional issue, I think it is a systems issue. You know, I think it's an issue in terms of, you know, why do we have NIPACS but then we have DARO. I think it is an infrastructural issue that needs to be -- it is 14:45 a bigger conversation because it affects thousands and thousands of patients. I know the Trust have invested, and now it is moving on to pathology results, isn't it, NIPACS? I'm not an IT expert but I do think that the IT systems and the monitoring systems do need a bigger 14:45 look at external to the Trust. I think that's something that the Department of Health should do as that overarching agency. I think that's a core responsibility of theirs.

Southern Health and Social Care Trust

Acute Governance

Patient 5

Meeting Room, Trust HQ, CAH
Monday 11 January 2021

PRESENT: **Dr Dermot Hughes**
Mrs Patricia Kingsnorth
Mrs Roisin Farrell – Via Zoom
Patient 5's Daughter
Patient 5's Daughter

Patricia introduced Dr Hughes to Patient 5's Daughters and thanked them both for taking the time to meet with us to discuss their father's story.
Dr Hughes explained who the team members were and what his role was. He is a former Medical Director of the Western Trust. Mr Hugh Gilbert is our expert opinion who is based in England and has is totally independent of urology services in Northern Ireland. Patricia Thompson is a specialist Nurse who is new to the Southern Trust and previously worked in the South Eastern Trust. She does not know the consultant involved and is independent from that aspect but can bring insight and clarity around specialist nurses roles. Fiona Reddick is the Head of Cancer Services and can provide clarity around the process of cancer services Patricia Kingsnorth – head of clinical and social care Governance.

Dr Hughes explained about the review and how it came about after the retirement of the said consultant and the identification of patients when other consultants took over their care. He explained that these 9 patient's care were reviewed and screened for SAI and deemed to reach the threshold for SAI review.
The review will involve the treatment and care of 9 patients – 5 prostate cancers, 2 renal cancers, 1 testicular cancer and 1 penile cancer. He advised that he doesn't believe these will be the only patients affected. He assured Patient 5's Daughters that the process will be open and honest and transparent and that the learning will be shared and made available to the independent enquiry. Dr Hughes confirmed Mr Hugh Gilbert will be reviewing all cases. He explained the public enquiry being done by the Department would be more in-depth and may take a longer period of time.
Patient 5's Daughter advised that she was well versed in the process and had reviewed Robin Swan's statement.
Patient 5's Daughter Said it seems pretty clear given the back ground. She asked if the initial review was looking at stent procedures. She recalled hearing that a named consultant had retired and when he retired his cases were passed to other consultants and some came back with concerns. She asked was there any indication of his practice before he retired.
Dr Hughes advised he was contacted in August to review cases and when he started more cases came to light. He explained they will review their father's cancer care and assured the family the review would be open and transparent. He acknowledged their father suffered and apologised for this.
Patient 5's Daughter – stated an apology wasn't enough.

Dr Hughes advised that clinicians shouldn't work in isolation; they should work as part of a multidisciplinary team. This keeps the patient safe and the staff safe as there is someone who can check their work and follow up any gaps. He advised that the Southern Trust signed up to accepting the recommendations from the peer review in 2017. He advised this was a regional pathway for cancer services that was signed off by the Trust which included the health professionals and senior managers. This is the agreed cancer pathway which should be followed but it was not followed by this particular consultant.

Dr Hughes explained that during this review to date we have identified that Multidisciplinary recommendations were not followed and that none of the patients involved had been offered support from a specialist nurse/ key worker. Their job would have been to support the patient through their pathway. The specialist nurse would have acted as a failsafe to ensure all recommendations were actioned and that diagnostic tests were followed up. This was unique to this professional. Dr Hughes explained at the review in 2017 stated regional policies and was signed off to have access to specialist nurses.

Dr Hughes acknowledged their father was unsupported in his care. He missed follow-up scan and was lost. There was no safety net with no key worker/ specialist nurse to support him.
Dr Hughes explained that the review will look at the causal factors – mainly the consultant but also any contributory factors which will look at the systems and process in place.

Patient 5's Daughter – asked if this was being monitored / benchmarked through audit?

Dr Hughes advised this was a good question and it is what we are asking also. He advised that we had met with senior staff and have questioned the processes and what assurances are in place and where is evidence of audits. These audits if carried out on every consultants work, keeps everyone safe and ensures consistency. This will be a recommendation from the review.

Patient 5's Daughter – Confirmed her father has specialist cancer nurses now but no key worker.
Dr Hughes advised they are one and the same. He advised when it comes to decisions about care this should be liaised with key worker for follow-up discussions with patient.

Patient 5's Daughter advised she was a Personal information redacted by USI. She has read all the policies and protocols and can see multiple failures.

Dr Hughes said that the documentation in the notes was not luminous and he welcomed the families' contribution to the review.

She asked if their father should have had a key worker when he went to ED.
Dr Hughes said yes he should have been given a key worker when his cancer was diagnosed.

Dr Hughes advised he had spoken to other families and said he would be presenting each family the draft report.
Daughter – Asked for their father's timeline.
Dr Hughes provided a copy of the timeline. He suggested if the family have questions needing answered the review team were happy to facilitate. He acknowledged the review team doesn't have their father's journey.

Daughter - agreed to send any queries they have from the timeline.

Dr Hughes asked why their father hadn't a PSA test done when he was in ED.

Patient 5's Daughter – advised her father was very happy with the care provided by Mr O'Brien until he got the call from Mr Haynes. She asked if the CT scan her father got was not viewed or actioned. (an audit search has shown the CT scan report was not viewed).
Dr Hughes advised he had requested clarification from Mr O'Brien and the request was going through his solicitor.

Patient 5's Daughter - recalled 3 years ago her father presenting to ED for an INR test. She recalled the doctor going through her father's past medical history and asked if he had been in contact with chemicals. She believes the doctor realised her father hadn't a simple infection as her father was obviously in pain, the family left feeling reassured as he was being referred to urology. Patient 5's Daughter advised that following their father's ED attendance, she rang Mr OB secretary requesting a private appointment for their father, but Mr OB initiated an urgent review and arranged for their father to be seen urgently in December 2018. The kidney tumour was diagnosed. Her father was sick and he put his faith in the Trust.

Patient 5's Daughter - acknowledged her father is 90 years old and that this has had a phenomenal impact on him. Her father had come through a lot. She continued to advise that her father had lost his Personal information redacted by USI to cancer. Patient 5 sang Mr O'Brien's praises. Patient 5's Daughter advised their father had been shielded for 5 month due to COVID. They recall coming from an appointment in March 2019 thinking their father was cancer free. They didn't know he had prostate cancer until Mr Haynes phoned their father. This distressed them thinking that their father was fine and safe when he had cancer. They advised it was shocking news to receive. They questioned the governance processes in place. Who was monitoring Mr OB appraisals?
Dr Hughes agreed and advised these will be looked in a separate process with the GMC and external professionals.

Dr Hughes acknowledged the traumatic impact this had on the family. He advised Mr O'Brien is polite and personable but he gave the wrong advice, he seemed to work as an individual.

Patient 5's Daughter - recalled how their father was given a stress test by anaesthetics in preparation for their father's surgery. They put an 88 year old man with an Personal information redacted by th and asked why would you do that?
She advised that due to the anaesthetic risk the surgery was deemed too risky, but their father was willing to take the chance. Patient 5's Daughter said that each patient should be looked at as a holistic individual. She recounted that on two occasions, whilst in ED her, ECG leads were put on her father's Personal information redacted by even though it was obvious.

Patient 5's Daughter recalled they were asked to attend a meeting with Mr Haynes. They attended the room to be told staff were meeting there and they had to move to another area in the hospital causing even more stress to their father. They felt this reflected poorly on the Trust. Patient 5's Daughter feels the meeting could have been moved and not the family. They described how their father is a very intelligent fully independent 90 year old.
Patient 5's Daughter said they never felt their father would have a second cancer.

Dr Hughes advised prostate cancer is very slow growing and does sometimes link with liver cancer. He advised the scan showed bony lesions but he is not sure if Mr O'Brien reviewed the scans but will checking the audit trail on NIECR.

Patient 5's Daughter - asked if Mr O'Brien went against MDT advice.
Dr Hughes said no regarding their father's renal tumour. This care was very good but Mr O'Brien didn't action the scan done in December.

Dr Hughes advised in terms of their father's care he needed surgical input to be at the MDT meeting, and oncology following his surgery. He acknowledged that oncology was not represented at the MDM. He said the Southern Trust were disadvantaged disproportionately regarding oncology services. That an oncologist was provided by Belfast for lung MDM which meets on a Thursday morning and urology is in the afternoon and often no oncologist is available to attend. There are known staffing issues within oncology and these will be addressed in the review.

Patient 5's Daughter - advised she has no confidence in the Trust.
Dr Hughes advised that the Trust has allowed him to conduct the review unhindered and have cooperated with him and are keen to identify learning to make it better for people going forward.
Dr Hughes will be asking why a specialist nurse wasn't aligned to Patient 5 and why MDT advise was not taken forward.

Patient 5's Daughter – asked was this issue localised to one profession?

Dr Hughes feels it is but he doesn't have the evidence to support that. This has been discussed with the cancer managers, going forward they will be running assurance audits on all staff. He said when reviewing Mr O'Brien the focus was around him as he had no nursing support.

Patient 5's Daughter - has spoken to her father and he had asked if it was all older people involved?
Dr Hughes advised there was one younger man and most patients are younger than Patient 5.
Patient 5's Daughter - believes most GP's dismiss older patients.
Dr Hughes believes the family have a valid point and questioned if it was ageism. He said it was a question around uni professional care given to patients.

Patient 5's Daughter - asked why would you want to do this and asked how Mr O'Brien got away with it?
Dr Hughes suggested it is better to share patient care and responsibility with other medics for both support and feedback. That is what the MDT is about.

Patient 5's Daughter - asked what the guidelines were audited.

Dr Hughes said the guidelines were for bladder cancer was regularly audit. But there was no audit on other urological cancers. He said there were a variety of issues, how people are diagnosed, prescriptions, support and referred back to MDT.

Patient 5's Daughter - recalled after her father's discharge there was no support the family had to care for his wound. She believes the doctor should have coordinated their father's care. She advised their father is not getting any better and his energy levels are low.
Dr Hughes suggested the family should have had named nurse to support the family.

Daughter - knew he wasn't getting any better so contacted the locum GP. They got a call to say he had fluid on the heart. He was referred to cardiology. The family arranged a private appointment with Dr McEneaney. Dr McEneaney sent their father to ED for assessment. They advised that at first the ED team didn't want to admit him. Patient 5's Daughter stated they felt hostility from ED and high to fight their father's corner.. ED then agreed to admit him; he got his kidney function up again. Patient 5 was referred back to urology.
Dr Hughes advised they would audit all referrals.

Patient 5's Daughter said- Mr O'Brien found out their father was in hospital and prescribed him folic acid. She recalls at a GP appointment their father was asked how "his flow" she questioned what kind of question is that to ask an 90 year old man? What does that mean? Patient 5 advised he was "going to the toilet a wee bit more" and thought it was old age. Patient 5 had pain but he put it down to arthritis. She said their father is always sleeping.

Dr Hughes asked if Patient 5 got a PSA test done.
Patient 5's Daughter - advised he hadn't.
Mrs Kingsnorth check on the system, the first PSA was done 10 August 2020.
Dr Hughes suggested all older patients should get a PSA test done and is generally offered by GP's.

Patient 5's Daughter - asked how common is it to get two cancers?
Dr Hughes advised it is not uncommon but in certain family groups it can be more common.
Mrs Kingsnorth confirmed Patient 5's PSA was reported as normal.
Patient 5's Daughter - asked was it a qualified radiologist that reviewed the scans.
Mrs Kingsnorth confirmed it was.
Patient 5's Daughter asked if it was a staff member or locum who reviewed the scans.

Mrs Kingsnorth said it could have been a locum as this is most radiological investigations are outsourced by the Trust. (Patricia can confirm it was a consultant staff member who reported on the results)
Dr Hughes agreed to check.

Daughter - feels there was a deficit in their fathers care in December. She asked if her father could have had the cancer earlier.
Mrs Kingsnorth assured the family she would ask for a review of the previous scan reports to check if there was any abnormality detected. But assured them we were not defending anything that has happened. (We have had the radiology consultant lead to review and compare the previous scans. There was no evidence of metastases on the previous scans).

Patient 5's Daughter - expressed how angry she is. There were multiple failures in their father's care.

Dr Hughes said that the review expert would not agree with that and added that Mr Gilbert suggests that their father received very good care regarding his surgery and outcomes the problem was with the follow up of the scan result.

Dr Hughes advised he was ashamed as a health professional for what their father and the family have gone through. There is a clear pathway which wasn't followed.
Patient 5's Daughter said that her father was exhausted and the treatment has taken its toll on him. Dr Hughes advised that the hormone therapy does make you feel exhausted.

Patient 5's Daughter said that her father is a very philosophical who didn't want to come forward. He is very loyal to Mr OB. She said the older generation put their Trust in the health professionals and that his daughters are his advocates.

Mrs Kingsnorth said all patients/ families spoken to were the same and were very shocked when they were advised of the review.

Patient 5's Daughter - believes older generations are more loyal to medical staff and believes their father may not have been here if he didn't have the support of his family. She said that patients should be given information leaflets about the services at the start of their journey.

Dr Hughes agreed and said some patients have no one to advocate or support them. He said none of the patients had a specialist nurse aligned to them for support.

Dr Hughes advised most of the patients were in their first cancer journey and wouldn't have been aware of the specialist nurse's role.
Mrs Kingsnorth confirmed this was unique to this professional as all other consultants availed of the specialist nurses. Mrs Kingsnorth said they will be asking Mr O'Brien why he didn't use specialist nurses.

Dr Hughes suggested it was more important to provide the right care and Patient 5 didn't get the right care.
Dr Hughes asked how their father was.

Patient 5's Daughter - advised he was doing well, very tired but doing his best but he is suffering from hot flushes. They are afraid the cancer has spread. He is still waiting to get more PSA results.
Dr Hughes asked if he had received his COVID vaccination.
Daughter - spoke to the GP they haven't received their supply yet.
Mrs Kingsnorth said Patient 5 should be one of the first to receive his vaccination.

Patient 5's Daughter - asked if the missed prostate cancer had been picked up earlier would it have prevented spreading.
Mrs Kingsnorth advised this would be looked at in the review.

Patient 5's Daughter – said there were so many missed opportunities for the Trust and expressed serious concerns about the governance oversight.

Dr Hughes recapped about the process and advised there would be 9 separate SAI reports relating to each patient. The patient/ family would see the draft report and have input into this review. There will also be an overarching report which will include short aspects of each of the 9 patient's care. The patient will be referred to anonymously. Patients/ Families will also be shared the overarching report.

Dr Hughes advised there were 6 major cancers in urology. Some patients that's disease progressed were not brought back. He said all these issues well be reflected in the overarching report.

Patient 5's Daughter - asked if there would be education coming out from the review especially in relation to the ED attendances.
Dr Hughes said there would be feedback to ED.

Dr Hughes advised the case would be presented to M&M.

Patient 5's Daughter - asked if there was a timeframe for the completion of the report.

Mrs Kingsnorth advised the timeframe was pushed back due to the pressures of COVID to March, it was initially due end of January.
Dr Hughes advised a draft of the report would be sent to the family.

Patient 5's Daughter - asked if Dr McEneaney asked for their father to be reviewed at urology.
Mrs Kingsnorth said it is possible that Dr McEneaney did refer their father back to urology. (Patricia has since checked and can confirm a referral was sent to Mr OB from the surgical team in level 3).
She added they have asked Mr O'Brien if Patient 5 was for review in September this did not take place until November. Scan not actioned on.

Patient 5's Daughter - recalled their father felt having no contact meant no new was good news.
Dr Hughes believes if their father had a specialist nurse this may not have happened.

Patient 5's Daughter - confirmed they were receiving updates from the department.
Mrs Kingsnorth advised the review is a separate process from the department enquiry.
Dr Hughes advised he would be prepared to provide evidence to the public enquiry.
Patient 5's Daughter said that she would like the review to know their father as an individual not another statistic.
Dr Hughes is happy to use their fathers name in the report (Patient 5) if required. He also suggested to the family if they wanted they could give a background into their father.
Patient 5's Daughter - advised she was Personal Information redacted by the USI and feels she would have to answer to her registration.
Mrs Kingsnorth advised this was a different process, the SAI process is for learning.
Dr Hughes advised Mr O'Brien has been suspended until the process has been complete.
Dr Hughes advised some immediate learning has been shared with the operational teams to take forward.

Mrs Kingsnorth thanked the family for attending the meeting and advised the meeting does help shape the report.

Patient 5's Daughter - feels they have changed their minds of Mr O'Brien after his daughter set up a support AOB on Facebook saying it was a witch hunt against her father.
Daughter advised they were not told by the Trust but was informed by the news.
Mrs Kingsnorth advised the Trust was under instruction from the Department not to say anything until an agreed time. The Irish News broke the story before the Trust were allowed to discuss it, that is why Mrs Kingsnorth phoned them to advise about their father's involvement the day the story broke.

Mrs Kingsnorth advised all patients thought Mr O'Brien was a lovely man so it was quite a shocked to them.

Dr Hughes advised independent enquiries are not set up lightly and has powers SAI reviews haven't.
Daughter - recalled Mr Robin Swann in the assembly say a small number were affected but each person is a family member.

Mrs Kingsnorth confirmed the family had her contact details and confirmed they would share the draft report for approval. She confirmed the TOR would be from first attendance in ED to Patient 5's diagnosis. She confirmed the review would be happy to review the 2 attendance in ED.

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 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 Feb 24 and 2 x April 24 • Physician Associate – advertised, offered and declined. Back out to advertise. Temp initially until recurrent funding is secured • Urology CNS – non-recurrent funding received for 1.8wte, 0.8wte in post. Recurrent funding in IPT We will continue with one Locum Consultant until all Substantive Consultant posts are filled.	Complete		

Received from the SHSCT on 11/06/2024. Annotated by the Urology Services Inquiry.

From: Avril Frizell [redacted] >
Sent: 06 May 2025 15:45
To: Donnelly, Anne [redacted]; Benson, Shauna [redacted]
Cc: Emmet Fox <[redacted]
Subject: Urology Consultant Staffing

CAUTION – This email has been received from outside the NICS network. If you have any concerns, please report for investigation.

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

Dear Anne

Further to your email last week, I have been able to take instructions on the Urology services employing Doctors from over seas. The Trust has provided the following staffing update:

Consultant	Status	Comment	Additional information
Mark Haynes	Permanent	Shared with Belfast Trust	
Anthony Glackin	Permanent	Leaving mid June 2025	Scrutiny form just approved to replace with Locum until permanent
John O'Donoghue	Permanent	Off night oncall from May 25	Remains on day oncall
Nasir Khan	Locum	Long term locum and will remain with the team	
Sartaj Khan	IMR started 19/2/2024	Leaving August 2025	Going to England - family reasons
Abdelazem Elsherbeny	IMR started 3/5/2024		
Srini Ganesan	IMR started 1/6/2024	Left end of April 2025	Went back to family home

* IMR means Individual Medical Readiness.

In respect of ongoing Recruitment, the Trust has received Approval to replace up coming consultant vacancies with Locums, while waiting on permanent replacement.

Interviews for one replacement scheduled to take place later this month. It is hoped Ms Doherty the current Registrar who has just qualified will be able to commence post in September 2025.

I hope this deals with your queries.

Yours faithfully,

Avril Frizell
Consultant Solicitor
Inquiries & Inquests Team
Legal Services (DLS)

Directorate of Operations

2 Franklin Street | Belfast| BT2 8DQ
Direct Line: Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI

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

HSC Business Services Organisation

Working together · Excellence · Openness & Honesty · Compassion

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DR. SWART: As a patient and as a family member, you have been able to highlight that in the action group. In that group, what have you personally learned about the way the Trust works and the pressures people are under in the Trust? What revelations have you had as part of that group? 14:46

A. I think we all know that there are resourcing issues within the Trust. You know, I think this doesn't necessarily come from the group. I think around the general reading I have done, we know there is a shortage of urologists and oncologists. My personal view is that there needs to be a specific recruitment campaign. A two-pronged approach, really, I think maybe for international recruitment of urologists and oncologists, but I think we can also start at that pretraining level perhaps, where there are bursaries and incentives put in place for the new doctors of the future that would incentivise them to work within a urology discipline. I think much more could be done in terms of that. 14:46 14:47

DR. SWART: Did you learn anything surprising about the way the hospital works or doesn't work as a result of your involvement in that group? Was there anything that struck you as something you never would have thought of? 14:47

A. I suppose I didn't have an understanding, really, of the infrastructure within governance within an organisation. I didn't know how huge it was; I didn't know how many policies, procedures and standards. It

is a massive, massive arena and I think it is one that should be resourced effectively. I would say that all Trusts could do with as many resources as possible to track and to ensure that there are effective governance arrangements in place. That would be in terms of 14:47
people having time to do that; it would be time to reflect and critique and measure against standards. It would also be the structures around the supporting technology and the supporting administration. I think it is a whole arena within itself and it is much vaster 14:48
than I thought it was.

DR. SWART: Thank you very much. That's all from me. That's really helpful.

CHAIR: Mr. Hanbury.

MR. HANBURY: Thank you very much. I would just like 14:48
to ask you a couple of things on a similar theme. Your father got through a really very high-risk nephrectomy, and I'm sure the family were really relieved at that point. Just to go back to the follow-up arrangements, which is where a lot of this 14:48
hangs.

Mr. O'Brien arranged a follow-up CT in June after the initial one in March and then, I think, to see your father after that? 14:48

A. Sorry?

MR. HANBURY: Then to see your father after that, with the results.

A. Yes.

cancer nurse specialists.

A. Yes.

CHAIR: Whenever your father was treated for his kidney cancer, was there ever any suggestion or -- how did you know that there was a difference? I am not being very clear on this, but you weren't given a cancer nurse specialist when he was diagnosed with the kidney cancer yet you were when he was diagnosed with prostate cancer. I know you had two, but was that cancer nurse specialist present at the meeting with Mr. Haynes the first time? 14:53

A. Yes.

CHAIR: Were you aware of the existence of cancer nurse specialists before that?

A. No, at that juncture I wasn't aware. You'd think that I would know that in terms of my background but no, I wasn't aware of the existence of clinical nurse specialists or their role and function and how important it was until it was mentioned at the SAI meeting, and then I read up on the role and function and recognised that, you know -- I think, you know, people say why did you not complain. If you don't know what the baseline expectations are in terms of what you're entitled to, then you don't complain. If we had known that, if it had have been indicated to us that your dad should have a clinical nurse specialist allocated to him, if that hadn't been done, we would have followed that up but that was not indicated to us at any juncture. But certainly the two nurses, the 14:53 14:53 14:54

urology nurse and the colorectal nurse, were both allocated promptly and were present at the meetings to support us throughout Daddy's journey.

CHAIR: [redacted], thank you very much. Ms. Treanor, do you have any questions? 14:54

THE WITNESS WAS QUESTIONED BY MS. TREANOR AS FOLLOWS:

MS. TREANOR: [redacted], I just wanted to ask you about an answer that you gave to Dr. Swart. You said 14:54 that one of the things that you were most shocked by was the failure to act on the CT scan and your father's diagnosis of prostate cancer. I just want to take you very briefly to one of the pages in the bundle. It is from your second meeting with the SAI review team. It 14:55 is at PAT-001972.

A. Yes.

MS. TREANOR: If you just look at the second paragraph for me. We can see there I think this was you had challenged the review team to explain whether there had 14:55 been disease progression and whether earlier action may have prevented the spread of the cancer. Dr. Hughes, in response to you, said he would get oncology and Mr. Gilbert to advise. I just want to ask you, do you feel the SAI answered that question for you? 14:55

A. I have no memory of an oncologist being consulted or feedback from an oncologist. My memory is Mr. Gilbert commented on the impact on prognosis. I do know, having listened to the previous hearings, that there

MDM was quorate 11% 2017, 22%, and so on. That paragraph seems to have been added into this copy.

A. Yes.

MS. TREANOR: I just wanted to check with you which version was sent to you as the final version, if you can recall. 14:58

A. That version. I think we may have -- I think there was a letter received from Mrs. McClements identifying that the final version of the report was sent to us with the change made on page 5. I felt it was important to note that the multi-disciplinary team, the attendance and the quorate levels was of great concern to me. 14:58

I cannot remember if we suggested that that be added into the report or not, I cannot remember. But that was the final version we were sent. 14:58

Thank you very much. I believe you have something further.

A. Thank you very much.

I have written a statement that I would like to read out and hope that I don't get upset and weepy. I think it is really important that, you know, we are able to put forward our views today and I really appreciate the Panel giving me the opportunity, and everyone here in the room for taking the time to give me the opportunity today to reflect on Daddy's circumstances and to reflect on the poor care that he did receive with regard to the follow-up and action of the scan. 14:59 14:59

Chair and Panel members and everyone present here today, thank you for giving me the opportunity to tell my father's story and the impact that these events had on my father and my family. I would therefore like to read out the statement pertaining to the failings on my father Patient 5 's cancer journey, who sadly passed away on Personal Information redacted by USI

I feel that my father, Patient 5 , was failed by Mr. O'Brien, the Department of Health, and the Southern Health and Social Care Trust. Initially as a family we were indeed aware that after my father's kidney removal, there was no guarantee there had been no microscopic spread from his tumour which could become evident at a future date. Fortunately, a June 19th CT scan revealed no sign of disease. At this time we were all unaware that my father also had an undiagnosed prostate cancer.

Whilst we appreciate the extensive evidence presented in this Inquiry and the detailed response by Mr. O'Brien, we still don't have an answer to our main concern: Did the lack of prompt action and follow-up with my father's CT scan on 17 December '19 affect his prognosis? My father's cancer metastasised further in intervening months. We are not talking seven to eight weeks, nor seven to eight days, we are talking seven to eight months.

Mr. O'Brien, in his statement, which I received yesterday, described how this delay came about, detailing his administrative processes and his rationale. He suggested he reviewed the scan results in late February or early March 2020. However, at a very minimum the results of the scan should have been communicated to my father once the scan had been reviewed. Surely he had a right to know at that juncture rather than not being informed until late July 2020. 15:01 15:01

My father should have been allowed to make an informed choice on whether to attend for an additional scan. We appreciate that COVID-19 measures also came into effect. 15:01

When I reflect on my father's circumstances, he was neither protected nor safeguarded and was not reviewed post-CT scan, even though there were clear governance policies and procedures. These serious governance issues and failings need to be addressed by the Department of Health, and the Trust. An arm's length approach to governance does not seem to be working when I reflect on my father's circumstances. More rigorous oversight by the Department of Health of governance in the Trust is required, in my opinion. 15:01

In addition, if unannounced inspections do not

currently take place across Trusts with regard to governance, doing so would provide a realtime snapshot of practice.

The longevity of the concerns with regards to the lack of prompt follow-up of scans is worrying, harrowing and upsetting. Had they been addressed or resolved, we perhaps might not be where we are today, in the middle of another public inquiry. It was the first noticed almost ten years ago that scans were not being followed up promptly, yet it has happened to my father again. In my opinion, and based on the hearings to date, there appears to be ineffective leadership in the Trust at different levels where risk factors were not sufficiently addressed, escalated, and dealt with appropriately. Chief executives should have taken ownership and responsibility of addressing serious concerns in order to maintain public confidence in the Trust. 15:02 15:02 15:02

In terms of Trust culture, work needs to be done in changing the Trust culture to ensure the staff are not afraid to raise professional practice issues and feel supported to do so. The systems tracking patient scans and monitoring the follow-up scans by clinicians is not fit for purpose, in my opinion, and should be reviewed. Remember, patients and their families are not just a number, a statistic on a PowerPoint reflecting lessons to be learned. Instead of lessons to be 15:02

learned, it should be mandatory changes and enhancements required, closely monitored by the Department of Health and its associated arm's length organisations to safeguard patients.

We no longer have my father in our lives. We continue to grieve and mourn him every day. The public inquiry, although necessary, is difficult and distressing for us as a family. We hope that eventually it will provide closure and will make a difference and safeguard patients in the future, which was Patient 5's wish. 15:03

CHAIR: Patient 5's Daughter, thank you very much. We do appreciate how difficult it has been for you to come and speak to us and I know that from the correspondence that you directed to me a year ago. We do really appreciate you coming along to speak to us. 15:03

What we hope to be able to do at the end of our work is to make recommendations that will make a difference to patient safety overall. So, thank you again. 15:04

A. Thank you very much. Thank you.

(The witness withdrew)

CHAIR: Ladies and gentlemen, we're going to take a break now until 3.30 when I hope that we will able to deal with the one remaining issue on the patient list today. 15:04

legislation?

A. I think that would be a fair comment. I think the challenge for us is that essentially the way in which the legislation is caveated means that there is an opportunity there to involve the PCC and to pay due regard to our views. However, other bodies are essentially free to ignore it and the PCC doesn't have control over ensuring that we are involved, when we're involved and ensuring that that is done consistently. You can see that reflected at times in areas of work where we might expect to be involved or are written into it without knowledge of it. I think that is definitely a challenge. 10:36 10:37

I think the picture across the system for engagement and involvement of the public is confusing. There is quite a lot of resource and structures go into engagement involving the public but I think we would welcome greater clarity on some of those rules and functions and particularly alignment of resource to the functions of the PCC with respect to some of that. I think there is opportunity to look at that. 10:37 10:37

29 Q. We'll look at some specific examples of where PCC may have been readily available or potentially keen to become involved in some of the issues relevant to this Inquiry in a moment, which may provide some context for that particular answer. Just in relation to the comment on the functions, if we look at how the PCC carries out its functions. I just want to draw 10:37

to set out, I suppose, a plan of support around how we begin to address that issue. That, in terms of advocacy, can be right through from advice and information or an issue that might be resolved in a matter of days, or it might be something that requires more in-depth case work. Unfortunately that can also extend into the formal complaints process, SAIs, engagement with NIPSO and other bodies as well. So we try to look at that issue in the person that's coming to us holistically and address the issues in that space. 10:42 10:43

It may be also be that somebody is coming through to us where they have advocacy needs but they may also want to be engaged around some of our programmes of work, in which case we'll make that linkage to the staff who are facilitating those programmes of engagement. Across the board, we seek to take the information we are hearing through our advocacy case work and the engagement and then ask what is that telling us about what we're hearing from the public and how should that influence particular policy programmes or be highlighting issues to the system. 10:43 10:43

32 Q. That's a very helpful answer, there's a lot of information there. If I could just sum it up: Depending on the nature of the query or the contact, you've got multiple different pathways, including pathways out of the organisation to other organisations; pathways into the Trusts; if you need to 10:43

comprehensive in setting out the expectations of a complaints procedure, but in reality what we are hearing from people who come to PCC for support is that there is regional inconsistency in terms of how people are experiencing the complaints process, the length of time that it takes for a complaints process to be undertaken, the fact that they experience it as a largely administrative process which often doesn't address the issues that they have originally raised a complaint about. I think that's why the PCC has sought to adopt a more early resolution approach that involves conversations and upstream addressing of issues at an earlier stage. 10:59 10:59

I think that if you reflect on recommendations that are made from other inquiries, this is already picked up. Aside from the experience the PCC is seeing, I would be aware of recommendations from the Neurology Inquiry, for example, that set out recommendations around looking at the complaints guidance from the Department, and looking to have a refocus or ensuring that it addresses outcomes for people, as opposed to a focus on compliance with procedure or a process or the administration of complaints. I think, again, that independent assurance for Trust boards and for the system that people's experience of a process is front and centre would be really welcome. 11:00 11:00

39 Q. The Panel heard yesterday from RQIA where they explained that when they inspect or review, they

to issues. There was a recommendation around, I believe, a database of clinicians practising privately to keep a record of their private patients and the diagnosis and treatments, and they had to provide that as part of lookback reviews. I think that would be very welcome if implemented, because I think increasingly the way treatment is going is that people are increasingly turning to the private sector, and I think there is a significant risk with respect to patient safety if there isn't consideration given to how that intelligence is sought, understood and triangulated with HSC and the rest of the intelligence. Also from the patient perspective and where the PCC is coming from, how the public are adequately supported when issues in the private sector go wrong, and where they turn to for support with respect to that and what the procedures and guidance are governing it. 12:45 12:45 12:46 12:46

MR. HANBURY: Thank you very much. I have no further questions.

CHAIR: Thank you, Mr. Hanbury. Dr. Swart? 12:46

96 Q. DR. SWART: The complaints process, first of all. You had a sort of statement that you didn't think the Trust staff were always adequately trained in the procedures. What did you see as the biggest deficit in their understanding? 12:46

A. I think our comment is based on the experience we see from members of the public coming to us for support and their experience of the complaints process. I think timeliness of response, understanding of the

expectation of responding to complainants and what they are trying to seek from that process. Understanding from people's experience in the process. Often what we see is trying to -- a focus less on the outcomes and how people experience a complaints process as opposed to the administration of a complaint. I think greater training and awareness around the impact of why somebody is coming to complain, what patient experience might at an earlier stage feed in to an awareness would really assist, as opposed to an administrative response to complaints, which is about following a process and maybe losing the person in the middle of that. 12:47 12:47

97 Q. So you have the information from the patients and families, not from the Trust staff, just to get that clear? 12:47

A. That would be the case. Or our experience of then supporting patients and engaging directly with the Trust where, at times, our staff would report finding regional inconsistency with respect to the response they are getting from Trust staff, their understanding of the complaints process, the expectation, the role of PCC, etcetera. So it would be twofold, directly from patients and our experience of the staff. 12:47

98 Q. As far as I can see, most of the oversight of complaints really does focus on the time scales more than anything else, not particularly customer satisfaction, shall I say, or outcome? 12:48

A. Yes.

represented throughout. We would provide advocacy support throughout an SAI to the family members working directly with the panel, with family liaison officers within the Trust, if those were in place; working with the family to set out the questions that may have; to 11:07
have facilitated conversations with panel members, with senior members within the Trust; receiving draft reports. In the work that I have done directly in SAIs, I have engaged directly with a number of panel members throughout the process. Providing constructive 11:08
challenge as well throughout where family members perhaps don't feel - which is a consistent theme - that there is parity of voice in the SAI process for those who have been victims of the SAI, or who have had a loved one or somebody experience the SAI process. 11:08

In our work, I suppose, we seek for that to extend beyond the actual conclusion of the SAI itself. Whenever there is a draft report, unfortunately our experience in a lot of our case work has been that we 11:08
have had experience of cases where the family members have withdrawn from the SAI process partway through because they haven't been satisfied with how the SAI process is being undertaken, or the direction of travel. 11:08

We have worked directly with SPPG and the Trusts to try to resolve some of those issues. Where we haven't been able to seek resolution or, I suppose, agreement

that answer your question?

88 Q. Yes, I think so. Thank you. You made a comment about, and we've also noticed how long the SAI reports took. Did you collect data on the length of time complaints took from a family making a complaint or a patient making a complaint to resolution? 12:39

A. Last year, I think, in our outcome report we looked at the -- we had set an output with respect to the length of time it took to resolve a complaint for PCC. The challenge in that for us was that often the resolution of a complaint is very much dependent on the response of the Trust and therefore we didn't continue to look at that sort of data because we were finding that we had little control to an extent over the length of time that was taking. I suppose what that reflects is that we would find that complaints often take a lot longer than what is maybe expected within the Complaints Direction. But that would be anecdotal, I couldn't speak to the evidence at this stage with respect to that. 12:39 12:40

89 Q. Okay, thank you. Moving on to the SAIs, you said an interesting thing, that some families engage with you initially and then pull out or fade away. What's your thoughts about that? Why does that happen?

A. Just to clarify, that point was in relation to families engaging with the SAI process and then deciding at a point in that process to disengage from the process rather than from PCC support. That, in our experience, has been because families have been dissatisfied with 12:40

the SAI process and feel a loss of confidence in the process addressing the issue that is subject of the SAI, or how the process is being undertaken, or the outcomes they are seeing. Often it is also the case - in case work I've been involved in - that families feel 12:40
that there isn't parity of voice or they're experiencing a necessary weight being given to that within the SAI process. Often you are talking about family members who have been pushing and have been engaged in trying to understand what went wrong, to 12:41
seek acknowledgment of that and to also seek recommendations around what would change that fundamentally to ensure that other family members don't have the same experience. It's an incredibly arduous process that places a huge burden on family members. 12:41

What I have seen is the tenacity required can often be too much for family members. They are dealing with a lot of other things going on as well and there's a repeat trauma associated with consistently revisiting 12:41
that issue. So we have found that the process itself can be retraumatising for people and, as a result, some family members have lost confidence in the process and have disengaged. That is generally with the process as opposed to than PCC support. 12:42

90 Q. That is more a reflection of how Trusts are engaging or not with the families, you're saying?

A. Yes, how they are experiencing the process of the SAI review, yes.

Serious Adverse Clinical Incident Investigation

33. Compliance with investigation procedures should be the personal responsibility of the Trust Chief Executive.

34. The most serious adverse clinical incidents should be investigated by wholly independent investigators (i.e. an investigation unit from outside Northern Ireland) with authority to seize evidence and interview witnesses.

35. Failure to co-operate with investigation should be a disciplinary offence.

36. Trust employees who investigate and accident should not be involved with related Trust preparation for inquest or litigation.

37. Trusts should seek to maximise the involvement of families in SAI investigations and in particular:

    (i) Trusts should publish a statement of patient and family rights in relation to all SAI processes including complaints.

    (ii) Families should be given the opportunity to become involved in setting the terms of reference for an investigation.

    (iii) Families should, if they so wish, engage with the investigation and receive feedback on progress.

    (iv) A fully funded Patient Advocacy Service should be established, independent of individual Trusts, to assist families in the process. It should be allowed funded access to independent expert advice in complex cases.

    (v) Families in cases of SAI related child death should be entitled to see relevant documentation, including all records, written communication between healthcare professionals and expert reports.

between the family and the panel in terms of the content of the SAI report, we have sought to work with families to put together a family statement, and to work with panels to ensure that family statement is reflected in the overall SAI report. 11:09

Beyond that process itself, I mean for family members it doesn't stop at the point where the SAI final report is produced. Ultimately they are seeking to understand what went wrong and to ensure that there is 11:09 acknowledgment of that, where appropriate, and that changes are made in the system to ensure that other families don't have the same experience. Our independent advocates would also work with families beyond the point of the submission of the report to 11:09 engage with Trusts. For example, in the past we had presentations to Trust Boards; facilitated conversations directly between family members and chief executives in the Trusts or senior staff; on some occasions sought presentations or assurances from the 11:10 Trust six months, or in a time period beyond the SAI, to feed back to family members about how changes or recommendations have been implemented.

What I would say is that independent advocacy in SAIs 11:10 require specialist practitioners, it requires dedicated time, it is painstaking work. You are dealing with not only the SAI process but also mediating and advocating with family members and panels, with individuals who

are often experiencing multi levels of trauma and are perhaps still going through grief and bereavement with respect to the issue. So it requires quite a lot of expertise and time.

11:10

As I said, the only way in which PCC has been able to support families in SAIs over the last three years -- and you can see from the stats I provided, I mean we dealt with 33 new SAIs last year and the bulk of our SAIs tend to be at Level 3 of complexity. The only way 11:11
we have been able to do that is by having senior members of the staff involved in those cases, and that has included myself as Head of Operations at the time, the Chief Executive. I still have a number of cases that I am supporting directly, given the nature of the 11:11
complexity, the sensitivity, the engagement at senior levels with other bodies, and directly with SPPG in the Department. So we're not resourced to do that at all, and I think what we would seek to see is full implementation of the IHRD recommendation in terms of 11:11
a funded advocacy service in SAIs. Did I cover all your questions?

43 Q. I think it does, yes, it is very helpful. Just for the Panel's note, the number of SAIs can be found at WIT-106701 at paragraph 189. It shows, as you say, an 11:12
upward trend, number of new SAIs 2018/19 was 16, 2019/20 was 26, 2020/2021 31, 2021/2022 the number is 25, 2022/2023 is 33. That's the number engaging with PCC, obviously, rather than for the SAI process.

199. There are significant issues with the operation of the SAI process which the PCC hope the current review by the Department of the process will address. The PCC view is that there is a need to implement the recommendations of the Hyponatraemia Inquiry set out at paragraph 100 101 above.

200. To set in context the examples of SAI practice experience it is essential to understand the starting point for the PCC. The majority of the public who seek support from the PCC have experienced harm resulting from the service received from statutory providers. They have described a negative and distressing engagement experience when trying to find a resolution with the statutory body. Whilst this may not be true for all service users, it is for the those who have availed of the PCC advocacy service.

201. The PCC reached out to families in advance of completing this Corporate Witness Statement requesting permission to highlight their experiences. Paragraph 97 details one family's experience over a 5-year period with the PCC assisting them to engage across the system, including the SHSCT. The second family experienced a Level 2 SAI review which was conducted following the death of daughter / sibling by suicide, while under the care of the Southern Trust. The following sets out their experience on being advised that an SAI was to take place;

- No information was provided as to how Trust/GP records could be obtained, this would have made the initial meeting with the Chair of the review panel more productive.
- SAI was deemed Level 2 without any discussion with the family.
- Terms of reference of the SAI were presented to the family but at the early stage of the process it was not made clear that these could be challenged,
- The family had no independent advice.
- Initial contact person within the governance office was absent for a prolonged period of time, and the family were not provided with a suitably senior alternative in his absence.

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- The family had requested a meeting with the lead professional, prior to issue of the draft SAI report, this request was never passed to him by the governance office.
- There was a lack of regular updates thus had to constantly seek information.
- Family input was not considered to be an integral part of the review process,
- Support from PCC at this time was intermittent as the officer worked part time and then left on maternity leave.
- Lack of confirmation that draft report would be available on the date promised.
- The Trust insisted on meeting with us to explain the report content despite the family telling them on multiple occasions that we would take the report, read it, respond and then ask for a meeting.
- A series of meetings with the Southern Trust, facilitated by the PCC eventually took place, virtually, including a meeting with a new Chair of the SAI panel.
- Following the finalisation of the SAI, the family were offered an opportunity to escalate our concerns with the office of the Public Service Ombudsman.
- The Ombudsman accepted our case for investigation.
- The SAI process certainly caused further harm to my family, not the investigation itself but the lack of engagement and communication, lack of openness and willingness to answer all questions asked. We were not treated as equals.
- On reading the RQIA review of the systems and processes for learning from SAIs (June 2022) it is obvious that what we were asking for from the Trust should have been delivered, we were not asking for anything that was unreasonable.
- Many straightforward questions remain unanswered in the final SAI report.
- The family requested that their response to the draft report be included as an Appendix to the final report, this did not occur.

202. The timeframes of SAI's usually relate to the actual time required to complete an SAI Review. This does not take into consideration the timeframe to

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168. Of the remaining 18 cases, which were not under the care of Mr O'Brien; 10 related to waiting times or delays in procedures, with the remaining covering issues concerning diagnosis, vaginal mesh and care quality. From the evidence available in the case files no concerns have been identified regarding how the cases were actioned in line with PCC practice guidance.

169. Of the **7 cases identified from 2019 – present**, none referred to Mr O'Brien. 3 cases related to waiting times or delays in procedures; 2 concerned support and information provision regarding SAIs. A further case was a general query from a third party concerning the Urology Inquiry. Advice was provided regarding PCC services and support, however, no direct support from PCC was sought by the third party or a member of the public. The final case related to a patient who wished to complain about care and treatment during a day procedure. The patient did not follow up on initial contact, or respond to PCC, and the case was closed. From the evidence available in the case files no concerns have been identified regarding how the cases were actioned in line with PCC practice guidance.

170. In conclusion, from our analysis of the limited number of cases relating to Urology services, which span over a 20-year period in the SHSCT area, it would be difficult if not impossible to have identified systemic issues in general, and specifically to the Urology Services Inquiry's Terms of Reference. The concerns raised regarding waiting times, delays in procedures and quality of care, were similar to those shared across all programmes of care and Trusts in Northern Ireland.

171. On the basis of the evidence available to the PCC only a small number of complainants have approached the PCC seeking assistance in raising a complaint about Urology services in the Southern Trust. The nature of most of these complaints is typical of complaints about other services particularly in relation to waiting lists and waiting times for example. On the basis of the evidence provided to the Inquiry, the majority of the concerns about Urology and Mr O'Brien were identified by management and through reviews of cases by the Trust through lookback exercise and clinical records reviews. These cases would not have come to the notice of the PCC in our role under the complaints

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111 Q. CHAIR: I think most of the questions I was going to ask you have been asked. One thing, you talked about the lack of resource, and obviously that is an issue across the piste in the health setting at the moment. Assuming that you have to work within the resource that you have at the minute, what one change -- you've talked about the recommendations of the Neurology Inquiry and the recommendations of the Hyponatraemia Inquiry. What one recommendation do you feel would make a difference to patients in Northern Ireland that this Inquiry could make that is different to those that have already been made? Is there one? 12:59 12:59

A. I mean, I suppose I've touched on the statutory footing of advocacy in Northern Ireland in general, and that isn't touched upon in other recommendations from the inquiries. I mean, IHRD talks about having a fully funded patient advocacy service, but until you have a statutory right to advocacy, as there is in Scotland and in other places, in Northern Ireland I think that there will always be a challenge. Therefore, what I would see as a fundamental change could be both that legislative standing for advocacy. But changes in the interim to guidance and direction that demonstrated an affirmative commitment from the Department and the health Trusts to the role advocacy plays in being a fundamental part of governance and assurance in terms of the quality of services that patients get, and supporting patients to engage around that, I think would make a difference, not just within the health 12:59 13:00 13:00

sphere but right across the board in terms of third sector organisations and the experience of the public generally when they have issues that they need to address right across public services. I think that could be a fundamental change. 13:00

CHAIR: Thank you very much.

I think that's it, Ms. McMahon, unless there are any other questions?

MS. McMAHON BL: No, thank you. 13:00

CHAIR: Thank you for coming and speaking to us, Ms. Monaghan.

That is us until ten o'clock tomorrow morning, ladies and gentlemen. See you then. 13:01

THE INQUIRY ADJOURNED TO 10:00 A.M. ON THURSDAY 22ND FEBRUARY 2024

INQ-20218

Parliamentary and Health Service Ombudsman

Broken trust: making patient safety more than just a promise

HC 1444

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Annotated by the Urology Services Inquiry

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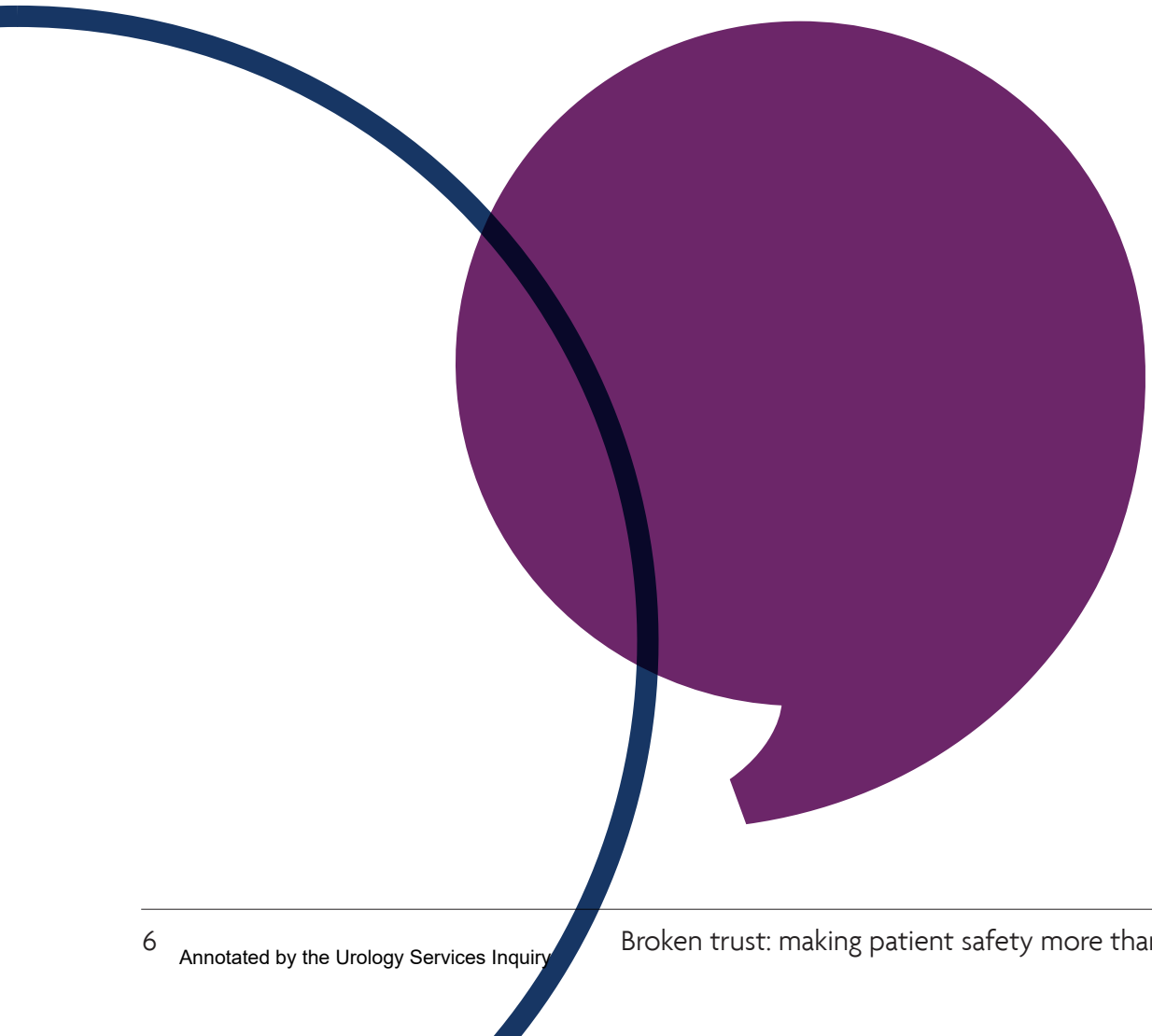
About us

The Parliamentary and Health Service Ombudsman (PHSO) makes final decisions on complaints that have not been resolved by the NHS in England, UK government departments and other public organisations.

When we investigate, we gather all relevant information from the person who made the complaint and the organisation they are complaining about. This will include relevant clinical records and information, such as a complaint file. We may get advice from experienced clinical professionals who are specialists in particular areas of care. We weigh up all the evidence impartially to reach a decision. In cases we uphold, we can make recommendations to put things right for the individuals involved.

We share insight from our casework to help improve public services and complaint handling. This includes highlighting failings in systems and failures to follow guidance if complaints show there is a need for further learning.



Foreword from the Ombudsman

'This must never happen again.' That phrase is uttered every time an NHS scandal hits the papers. But as we saw in the similarities between inquiries into maternity services in East Kent and Morecambe Bay seven years earlier, lessons are not always learned. It is as vital as ever that my Office continues to call for action to improve learning, accountability and, ultimately, safety.

The last ten years have seen significant activity from policymakers to improve patient safety. We have the NHS Patient Safety Strategy and welcome the introduction of the Patient Safety Incident Response Framework, which recognises the complexity of systems and the risks to staff and patients of a blame culture.

And yet, it is clear from the analysis of our most serious patient safety cases through this report that there is a gaping hole between best practice policy and consistent real-life practice. We may have a very sophisticated understanding of how to prevent patient safety incidents and avoid compounding harm for patients, families and staff when things do go wrong. But our evidence suggests that, on the ground, this is regrettably not always implemented.

Sadly, but perhaps inevitably, mistakes will happen in a complex health system that relies on human judgement. But every time my Office rules that a patient died in avoidable circumstances, it means that incident was not adequately investigated or acknowledged by the Trust. It also means staff, patients and their families had to go through an unacceptably long and painful process to make sure action was taken to address shortcomings and justice was achieved for the patient.

In this report, we consider the reasons for the continued failures to accept mistakes and take accountability for turning learning into action and improvement. We pose questions on how to embed an honest, open and unafraid culture in our healthcare system that supports staff and patients to challenge and learn.

Complex systems need robust regulation and oversight to recognise good practice and identify poor systems. When regulation and oversight work well, they also serve to keep people safe from harm. We need to see less fragmentation of the patient safety landscape. This report will have failed if it prompts the creation of yet another patient safety body or initiative. What we need is a streamlined system that works together, with real leadership from Government.

But the biggest threat to patient safety is a system at breaking point. In this report, we recognise that the NHS itself can only go so far in improving patient safety. We need to see concerted and sustained action from Government to make sure NHS leaders have the tools to prioritise the safety of patients and are accountable for doing so. This means getting past politics to put patient safety at the very top of the agenda.

Rob Behrens CBE
Parliamentary and Health Service Ombudsman

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Executive summary

There have been significant developments in patient safety over the last decade. But there is a concerning disconnect between increasing activity and progress made to embed a just and learning culture across the NHS. Recognising the challenging operational context for the NHS, this report draws on findings from our investigations. It asks what more must be done to close the gap between ambitious patient safety objectives and the reality of frontline practice.

We identified 22 NHS complaint investigations closed over the past three years where we found a death was – more likely than not – avoidable. We analysed these cases for common themes and conducted in-depth interviews with the families involved.

What we found

We found that the physical harm patients experienced was too often made worse by inadequate, defensive and insensitive responses from NHS organisations when concerns were raised.

When we looked at the direct causes of harm, we identified four broad themes of clinical failings leading to avoidable death:

- failure to make the right diagnosis
- delays in providing treatment
- poor handovers between clinicians
- failure to listen to the concerns of patients or their families.

We also looked at the further harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of losing a loved one, try to understand what has happened but are met with a poor response from NHS organisations. We identified several factors that contribute to compounded harm:

- a failure to be honest when things go wrong
- a lack of support to navigate systems after an incident
- poor-quality investigations
- a failure to respond to complaints in a timely and compassionate way
- inadequate apologies
- unsatisfactory learning responses.

Our recommendations

Recognising the complexity of the issues identified, and the lack of easy solutions, our recommendations focus on two areas.

1. Accountability for a robust and compassionate response to harm, which supports learning for systems and healing for families

The Patient Safety Incident Response Framework (PSIRF) offers a new approach to patient safety investigations. It holds great promise but needs to be accompanied by sufficient monitoring and better support for families. We recommend that:

- Integrated care boards, with oversight from NHS England, should closely monitor the impact of the PSIRF to identify any negative consequences of the new flexibility it offers, which gives Trusts more autonomy to decide when a patient safety investigation is needed. This should include paying special attention to the balance of patient safety investigations versus other learning responses in Trusts (or service areas of a Trust) where there are poor Care Quality Commission (CQC) ratings for safety and leadership, or where other national bodies have raised concerns (recommendation 1).
- As part of their quality monitoring role, the PSIRF executive lead on each Board should look at any discrepancies between local and PHSO investigations, or other independent investigations, and make sure the Board discusses them. This should include where local investigations did not take place, or did not find that things went wrong, but PHSO or another independent oversight body later identified failings (recommendation 2).
- The Department of Health and Social Care and NHS England should further scrutinise the lack of compliance with duty of candour. They should review the operation of duty of candour to assess its effectiveness and make recommendations for improvement (recommendation 3).
- The Department of Health and Social Care should commit to funding further independent advocacy to support harmed patients, families and carers when they raise concerns or look for answers after an incident (recommendation 4).

2. Evidencing that patient safety is a top Government and NHS priority

NHS leaders and frontline staff need to be in no doubt of the priority placed on patient safety. But patient voice and leadership for patient safety are fractured. Political leaders have created a confusing landscape of organisations, often in knee-jerk reaction to patient safety crisis points. The Healthcare Safety Investigation Branch (HSIB), the Patient Safety Commissioner, PHSO, NHS England, NHS Resolution and at least a dozen different health and care regulators all play important roles in patient safety. But there are significant overlaps in functions, which create uncertainty about who is responsible for what. The Government must consider the case for streamlining some of these functions, for the benefit of people who use the NHS, their families and carers. This is not about reducing investment in patient safety. It is about creating a system that is coherent and easier to navigate, based on evidence and engagement with patients, families, NHS staff and leaders. We recommend that:

- The Department of Health and Social Care should commission an independent review of what an effective set of patient safety oversight bodies would look like. The review must include meaningful engagement with NHS leaders, staff, patients and families (recommendation 5).

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Patient safety must be a consistent priority over the long term. It must not be subject to changes of emphasis or importance each time there is a new minister or leadership change in the NHS. We recommend that:

- The Government should seek cross-party support for commitments to embedding patient safety and the culture and leadership needed to support it as a long-term priority (recommendation 6).

It is not possible to prioritise patient safety while avoiding difficult decisions about the workforce the NHS needs. Patient safety will always be at risk in environments that are understaffed and where staff are exhausted and under unsustainable pressure.

Tackling workforce shortages goes beyond political decisions about resourcing. It is about making the NHS a place where people want to work and stay because they feel valued, not just because it is a vocation. We must break down the false dichotomy between the interests of patients and staff, recognising that a system that does not treat its workforce with humanity and compassion will struggle to extend these qualities to patients and families.

We recognise the Government has promised to publish a new NHS workforce strategy. At the time of writing, this is expected 'shortly'. But for this to properly address the underlying causes of NHS staffing pressures, it needs cross-party consensus. In a sector where it can take nearly two decades to train a consultant doctor, a workforce strategy will only succeed if there is support from across the political spectrum, and far beyond one parliamentary term.

We recommend that:

- The Government should urgently produce its long-awaited long-term workforce strategy, with cross-party support, to increase the numbers entering and staying in the workforce across clinical and non-clinical roles. This strategy must:
    - include independent, evidence-based and fully costed projections of future workforce requirements
    - include detailed plans for training and recruiting new staff, retaining staff already working in the NHS and attracting those who have left to return
    - take account of the mix of different professional skills required, rather than just total numbers in the workforce, and how existing professional skills can be deployed where they are most needed (recommendation 7).

The Department of Health and Social Care should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 3, 4, 5, 6 and 7.

NHS England should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 1 and 3.

Introduction

It is ten years since the landmark Francis Inquiry into failings of care at Mid Staffordshire NHS Foundation Trust. The final report identified a system that should have picked up on appalling deficiencies in quality and safety of care, but 'failed in its primary duty to protect patients and maintain confidence in the healthcare system'.[1] The report also argued that a fundamental culture shift was needed, to make sure 'the patient is put first day in and day out.'[2]

The Francis report was a wake-up call for healthcare systems. In the decade that followed, the patient safety landscape has undergone significant change. Globally, there has been greater recognition of the importance of safety science in healthcare and a strategic approach to patient safety. In 2020, patient safety was included as one of the five priorities of G20 Health Ministers, and 2021 saw the publication of the World Health Organisation Global Patient Safety Action Plan.

The NHS developed an NHS Patient Safety Strategy in 2019, with an updated version expected this year. The strategy has a vision to save 1,000 lives and £100 million per year and has seen some concrete successes in specific areas, such as improved care of premature babies and reductions in prescribing opioids (pain-relieving medicines that have a serious risk of addiction).[3] This year, the NHS will roll out the Patient Safety Incident Response Framework (PSIRF), marking a major change in the approach to recording and learning from patient safety incidents. There are also plans to expand the roll-out of medical examiners to provide independent scrutiny of the causes of deaths. This should provide answers for bereaved relatives and help NHS organisations to learn and improve the care of future patients.

On issues of transparency, there is now a legal duty of candour requiring organisations to be honest with families when they make mistakes. And there are freedom to speak up guardians to give staff a route to report patient safety issues in each hospital. There is greater recognition of the insights that patients, families and carers hold, with a Patient Safety Partner role set up to use these insights in managing patient safety.

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[1] Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive summary (February 2013).

[2] As above.

[3] Statistics on impact shared with us by the Patient Safety Strategy team. Improved care of premature babies through optimal cord management (delaying cutting the cord after a baby is born) has saved up to 417 lives since 2020. There have been up to 347 lives saved over two years and 2,152 fewer cases of short-term harm each year, as a result of fewer people with chronic pain being prescribed long-term opioid pain relief compared to 2021. (Figures calculated in March 2023.)

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Following the recommendation of the Independent Medicines and Medical Devices Safety Review, the role of Patient Safety Commissioner has been created to amplify the views of patients in relation to medicines and medical devices.

There has also been an important transition to a more widespread understanding of patient safety as a systems issue. As the NHS Patient Safety Strategy recognises, failings in care often result from systems and processes that allow errors to happen, rather than from people who lack the skills to care, or who deliberately cause harm. The national conversation around patient safety now focuses on learning, rather than seeking to blame individuals. And it recognises the huge complexity in healthcare processes, which means to understand when things go wrong, we must look at all the environmental and organisational factors that affect behaviour at work, not just the specific incident. This approach is now supported by the work of HSIB, drawing out national safety recommendations from its investigations.[4]

It is clear there is no shortage of programmes, policies, new initiatives and roles to try to reduce instances of avoidable harm. But there is a disconnect between the increasing levels of activity and consciousness about patient safety and the level of progress we see on the frontline. The statistics about patient harm remain stark. There are an estimated 11,000 avoidable deaths every year in the NHS due to patient safety failings, with thousands more patients seriously harmed.[5] Behind these numbers are the stories of individuals and their families and friends, whose lives have been shattered as a result of avoidable harm.

There is a well-recognised 'implementation gap' – the difference between what we know improves patient safety and what is done in practice.[6] Overcoming this represents a huge challenge. The NHS is an incredibly complex and sometimes fragmented system, making it challenging to embed changes to working practices and cultures. The structural changes brought in by the 2022 Health and Care Act offer the potential for better collaboration at a regional and local level through Integrated Care Systems and place-based partnerships. But such structural change brings the risk of disruption as local leaders divert attention to building new organisations and relationships. There is also good reason to be concerned about the prospects for reducing avoidable harm when attention is focused overwhelmingly on throughput, and the people and systems that make up the NHS are under growing pressure.

We know there is a long way to go to embed working cultures that can learn and improve in response to failings in some parts of the NHS. In the latest NHS Staff Survey, nearly 40% reported they did not feel safe to speak up about anything that concerns them in their organisation. More worrying still, less than half of staff felt confident their organisation would address their concern.[7]

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[4] From October 2023, HSIB will become the Health Services Safety Investigations Body (HSSIB), an independent public body under the Health and Care Act 2022, with its own 'safe space' for confidential investigations. The CQC will host HSIB's maternity programme.

[5] NHS England and NHS Improvement (July 2019), 'The NHS Patient Safety Strategy: Safer culture, safer systems, safer patients'.

[6] Patient Safety Learning (April 2022), 'Mind the implementation gap: the persistence of avoidable harm in the NHS'.

[7] NHS Staff Survey 2022: National results briefing, March 2023.

In clinical safety specifically, more than a quarter of staff did not feel secure raising concerns about unsafe clinical practice and nearly 40% did not feel confident their organisation would address their concern about unsafe practices. These two measures have worsened in the last two years.[8] This polling is a reminder of the gap between the 'learning not blaming' vision of national strategies and the day-to-day experience of frontline NHS professionals.

Concerns about progress in patient safety need to be considered against a backdrop of intensifying workforce pressures, creating further risks. Latest data from NHS England shows there are more than 8,000 doctor vacancies and more than 40,000 nursing vacancies across the NHS.[9] The CQC, in its latest State of Care report, said that 'continuing understaffing in the NHS poses a serious risk to staff and patient safety, both for routine and emergency care'.[10]

The latest data from the British Social Attitudes Survey shows the cracks are growing. Although the British public remain committed to the founding principles of the NHS as a universal service, funded by taxation and provided free at the point of contact, public satisfaction with the service is now at just 29%. This is seven percentage points lower than the year before and the lowest level since the survey began in 1983.[11]

The NHS cannot wait any longer. Nor can the people who use it or work in it. We must see urgent action and sustained commitment to address the root causes of problems that result in patient harm.

About this report

Recognising this challenging context, we have developed this report to share learning from our investigations into complaints about serious avoidable harm in the NHS.

Our intention is not to further demoralise NHS staff and leaders at a time of extreme pressure. We recognise that the vast majority of NHS staff are highly motivated to provide excellent care and never intend to cause harm. And we know that involvement in patient safety incidents can be traumatic for staff too.[12]

The Ombudsman has a unique position in the patient safety landscape. We investigate impartially and do not take sides or speak on behalf of patients or clinicians. Our role is to objectively and independently understand what happened. Where we find failings, we make recommendations for learning to improve services and protect patients. The cases we see highlight persistent clinical failings and, perhaps even more importantly, persistent failure to respond to patients and families in a compassionate way when they raise complaints.

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[8] NHS Staff Survey 2022: National results briefing, March 2023.

[9] NHS Vacancy Statistics, England, April 2015 - December 2022, Experimental Statistics.

[10] CQC (October 2022), State of Care 2022, Summary.

[11] The Kings Fund (March 2023), Public satisfaction with the NHS.

[12] See, for example, research outlined in BMJ (2015), 'Supporting "second victims" is a system-wide responsibility'.

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This report builds on the detailed and extensive work of countless others over the past ten years. In recognition of that, we have engaged with policymakers, oversight bodies, regulators, professional bodies and advocacy organisations to test and refine our conclusions and recommendations.

By analysing the unique evidence of complaints we have investigated, we have identified two sets of findings. First, we reflect on common themes that emerge when clinical failings have led to avoidable harm. Despite the diversity in the cases we looked at – some involving babies a few days old, others older adult patients; situations that progressed in a matter of hours and others over a number of years – there are issues that come up repeatedly.

Second, we look at the additional harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of avoidable harm, try to understand what has happened to their loved ones but are met with a poor response from NHS organisations.

In the final section, we suggest the wider changes needed to see the improvements that patients, families and clinicians deserve when it comes to serious avoidable harm.

How we developed this report

To develop this report, we undertook a qualitative analysis of over 400 detailed health complaint investigations from the past three years. We identified 22 cases where someone had died and we found that the death was – more likely than not – avoidable. We know that relatively few families, having been through a local complaints process while dealing with their own grief, will feel able to keep going and bring their case to us. So these 22 cases are a significant sample of what is likely to be a much bigger problem.

In these cases, we found that the patients would not have died if they had received the right care and treatment at the right time. This happened mainly in inpatient settings in NHS acute trusts, including emergency departments, intensive care units (ICUs) and general medical wards.

We analysed the cases in more detail to develop the themes in this report. We conducted four interviews with families who brought the cases to us, to hear from them directly about their experience of raising concerns with Trusts. We supplemented this with a review of secondary literature on patient safety to put our evidence in context.

Words we use in this report

Throughout this report, we use **clinical failings** to refer to clinical care and treatment that a patient should have received but did not receive.

We use **avoidable harm** to refer to clinical harm that a patient suffers because they did not receive the right care and treatment at the right time.

Our casework evidence on avoidable harm

Clinical failings leading to avoidable harm

Patient harm is a global phenomenon[13] that happens everywhere patient care takes place. Over 1.25 million staff in the NHS[14] have 1.5 million patient interactions every day,[15] so it is inevitable that mistakes will happen. But, despite improvements over the last ten years, the estimated number of 11,000 avoidable deaths every year is shocking.

After analysing the 22 cases where we found that a death was avoidable, we identified four broad themes of clinical failings leading to avoidable harm:

- failure to make the right diagnosis
- delays in providing treatment
- poor handovers between clinicians
- failure to listen to the concerns of patients or their families.

Failure to make the right diagnosis

In more than half of the cases we looked at, we found that a failure to diagnose directly led to or significantly contributed to the avoidable death of a patient. In these cases, the right diagnosis could have been made at the right time. If this had happened and the correct treatment had been provided, it is likely the patient would not have died.

A range of factors and circumstances can lead to clinicians not making the right diagnosis at the right time, especially when a patient's condition is complex or critical. In our casework analysis, failures to make the right diagnosis were mainly the result of:

- not seeking more senior or specialist input where that would be appropriate
- not observing or monitoring someone at regular enough intervals to recognise deteriorating health or new issues
- failings in imaging, such as failing to follow up on an unexpected finding.[16]

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[13] Bennett, S. A. (2020), 'Avoidable deaths in Britain's National Health Service - A systems-thinking informed analysis using data garnered from government agencies, representative bodies, private canvassing and public inquiries'. International Journal of Healthcare Technology and Management, 18 (1–2), pp. 95–110.

[14] NHS Workforce Statistics - December 2022.

[15] The King's Fund (October 2022), Activity in the NHS.

[16] For a more detailed analysis of failings in imaging, see our 2021 report, 'Unlocking Solutions in Imaging: working together to learn from failings in the NHS'.

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In one case we looked at, the patient's National Early Warning Score (NEWS score)[17] showed he was very unwell and should have been reviewed by a more senior clinician with the knowledge and experience to diagnose and treat him while his condition was getting worse. The Trust should have asked for an urgent review by a more senior clinician, but this did not happen. When the patient's condition got worse, the Trust delayed asking for an urgent review, and there were further delays in reviewing the patient. This meant the Trust failed to recognise the patient had sepsis and did not give him the right treatment. The patient suffered a cardiac arrest (when the heart stops pumping blood around the body) and died.

We identified the importance of appropriate and timely senior input in our report on sepsis, 'Time to Act', noting that 'the skills necessary for early identification of patients at risk of severe sepsis are high level and develop with long experience'.[18] It is concerning that a decade after this report, and following huge efforts to improve the early recognition and treatment of sepsis, we still see these kinds of failings.

[17] NEWS is the National Early Warning Score designed to standardise the assessment of and response to acute illness. It combines scores along six physiological measures: respiration rate, oxygen level, blood pressure, pulse rate, level of consciousness or new confusion and temperature. It was updated in 2017 and NEWS2 is endorsed by NHS England as the early warning system for use in all secondary care and ambulance services.

[18] PHSO (2013), 'Time to Act', p. 43.

Case study: failure to diagnose pulmonary embolism

- A man contacted an out-of-hours GP service because he had been suffering from shortness of breath for over a month and had a fever. The GP diagnosed a chest infection and prescribed steroid medication.
- The patient's family called for an ambulance the same evening because his breathlessness had started to get worse. The ambulance crew arrived and took him to hospital.
- The patient's observations showed a fast heart rate, raised rate of breathing and a low level of oxygen in his blood. Staff gave him a nebuliser and his oxygen levels improved.
- A doctor reviewed the patient. An X-ray did not show any concerns. The doctor diagnosed pneumonia, prescribed antibiotics and decided not to admit the patient.
- The following day, a GP visited the patient at home and prescribed an inhaler. They suggested the patient should return to the hospital.
- Later that day, the patient's family called an ambulance because they were concerned about his condition. When the ambulance arrived, the patient was conscious but short of breath.
- The patient suffered a cardiac arrest and the paramedics tried to resuscitate him. Unfortunately, they could not do so and the patient died. The cause of death was a pulmonary embolism (a blocked blood vessel in the lungs).
- We found the doctors failed to follow the relevant guidance when they reviewed the patient at the hospital.
- The clinical signs the patient presented suggested a pulmonary embolism was the likely cause of their breathlessness, high heart rate, high respiratory rate and low oxygen. Doctors should have arranged a specific blood test, but this did not happen. Instead, the patient was sent home without the right treatment.
- The doctors made a diagnosis of pneumonia (inflammation of the lungs) but the chest X-ray results showed the patient's lungs were clear and there was no evidence of blood tests to confirm a diagnosis of infection.
- We found it likely the patient would have survived had he received the right treatment after the doctor reviewed him. This would likely have led to the diagnosis of pulmonary embolism and successful treatment with the right medication.[19]

[19] In its report on the diagnosis of pulmonary embolism in emergency departments, HSIB identified a safety risk in missed diagnosis and treatment of pulmonary embolism, given its atypical symptoms: HSIB (2022), 'Clinical decision making: diagnosis of pulmonary embolism in emergency departments'.

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We spoke to the patient's mother who described her and her family's experience of seeing the patient die at home:

'My son came home with absolutely no information whatsoever ... He should have been in hospital, he should have been on a ward. He died in his bedroom and I had to hear it ... My grandson was in the room next door with me and he heard him die too. It's not something that you would want for anybody.'

Failing to observe or monitor someone at regular enough intervals can result in missed opportunities to recognise deteriorating health or new issues. In one case we looked at, a man was admitted to the Trust's emergency department with chest pains. His condition got worse in hospital but staff did not carry out observations to monitor him as frequently as they should have done. This resulted in a missed opportunity to notice the patient's health getting worse due to sepsis and to involve critical care. It delayed the diagnosis and treatment of sepsis for over ten hours. We found that if the patient had been monitored at appropriate intervals, it is likely his worsening health would have been identified, he would have received treatment for sepsis and, more likely than not, he would have survived.

In another case, a mental health Trust did not observe a long-term inpatient as frequently and as closely as it should have done. The woman attempted to harm herself in a way that could have led to her death on two occasions. Staff managed to stop her from harming herself both times. The Trust should have updated the risk assessment to include actions to reduce any risks and minimise harm, including risks posed by ligature points (anything that could be used to attach a cord, rope or other material for the purpose of self-harm). The following day, the patient was found unresponsive and died because of a hypoxic brain injury (when the brain does not get enough oxygen). We found that if the Trust had observed the patient more closely and frequently and taken action to address ligature points, it was unlikely the suicide attempt would have been completed. If the patient had been monitored more frequently, it is likely there would have been the opportunity to intervene in time and prevent the woman's death.

We spoke with the patient's sister who told us the Trust did not manage to keep her sister safe:

> 'It was supposed to be a place of safety and it clearly wasn't. My sister shouldn't have died in the hospital.'

Case study: failure to carry out repeat risk assessments

- A patient went to a Trust's emergency department with a swollen left hand. The patient had cellulitis (a bacterial skin infection that causes swelling) and gout (a build-up of uric acid causing swelling in the joints).
- The Trust admitted the patient to the hospital and considered their risk of developing venous thromboembolism (VTE, a condition that happens when a blood clot forms in a vein).
- The Trust decided there was no risk and did not carry out any further risk assessments. Staff treated the patient, which included elevating their arm and giving them antibiotics.
- A couple of days later, the patient started experiencing chest pains and tightness in their chest. The Trust carried out an electrocardiogram (ECG, a test to check the heart's rhythm and electrical activity) and provided medication. Later that day, the patient became sick and collapsed.

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- The doctor planned to move the patient to a bed with more monitoring. But, before this could happen, the patient suffered a cardiac arrest. The Trust resuscitated the patient and gave them medication to break down blood clots.
- After this, the patient remained stable for a short time during which they were moved to the intensive care unit. Sadly, their condition did not improve and they died that evening. The Trust carried out an autopsy which confirmed the cause of death as a pulmonary embolism (blockage of a lung artery).
- We found the Trust failed to carry out a full assessment of the patient's risk of developing VTE, and then failed to reassess them 24 hours later as outlined in NICE guidance. It missed two opportunities to provide appropriate and timely treatment to prevent a pulmonary embolism.
- Had the Trust given the right treatment on time, it is more likely it could have prevented the pulmonary embolism and avoided the patient's death.

Delays in the treatment response

Our casework shows that serious harm can be caused by delays in providing treatment. In our analysis, we found that these delays often relate to:

- a diagnosis being made but then not being acted on properly or quickly enough
- not acting quickly enough on observations.

In one of the complaints we looked at, the Trust appropriately and quickly diagnosed a woman with vasculitis (inflammation of the blood vessels). Vasculitis is a condition that needs urgent treatment. But the Trust did not prescribe the medication needed for another 16 hours after the diagnosis. After prescribing the medication, the Trust did not give it to the patient for another 11 hours. The Trust significantly delayed giving the patient the life-saving treatment she needed for 27 hours. Our investigation found the patient could have survived if she been given the correct medication in time. It is more likely than not that her death could have been avoided.

When there is evidence that a patient's health is getting worse it is vital to respond quickly, but we found instances where this did not happen. For example, in a case where the on-call doctor did not attend when requested to, we found that the way they were contacted (via a 'bleep') did not include information about the urgency of the request. The Trust explained the system does not give any sign of urgency unless the doctor is being called to attend a cardiac arrest. Our investigation report highlighted that this is a problematic system because it does not allow clinicians to prioritise their patients' needs. We argued that it undermines the benefits of a warning system like NEWS if clinicians are not meaningfully empowered to act quickly in response.

This is a well-known issue. It is highlighted, for example, in a recent national investigation report by HSIB on recognising and responding to critically unwell patients. The report notes that early warning scores 'can place a high demand on medical staff and the current escalation protocols may not be achievable owing to a task versus resource mismatch'.[20] Clearly, monitoring is only useful if there are enough staff to respond when deterioration is detected.

Case study: failure to provide timely sepsis treatment

- A patient went to hospital for a hysteroscopy (a procedure to examine the inside of the womb).
- The procedure was completed without incident and the plan was for her to stay in hospital to be monitored.
- After being transferred to the ward, she felt unwell. Staff carried out assessments to examine her symptoms. The results showed abnormal blood tests, including a very low white blood cell count.
- The patient was referred to and reviewed by the emergency medical response team. The doctors considered sepsis as one of several possibilities for explaining the clinical findings. But they thought this was unlikely so they did not prescribe antibiotics.
- The patient was transferred to the acute medical unit for closer monitoring. The doctor who reviewed her recommended an immediate dose of antibiotics.
- Unfortunately, she did not receive the antibiotics until four hours later. Her health deteriorated significantly in that time.
- This delay in receiving antibiotics meant the patient did not receive timely treatment for sepsis in line with the NICE sepsis guidance.
- Staff performed a CT scan (a computerised tomography scan, which creates detailed images of the inside of the body) the following morning. They prescribed another dose of antibiotics, reviewed the patient and transferred her to the intensive care unit to receive medication to support circulation.
- The patient's condition did not improve. Doctors explained to her family they could give no further treatment and started end of life care. Sadly, she died that evening.
- We found that the delays in starting antibiotic treatment and admitting the patient to the intensive care unit (to support her circulation) significantly affected her chances of survival.
- If the Trust had done what it should have done, it was more likely that the patient would not have died.

[20] HSIB (2021), 'Recognising and responding to critically unwell patients'.

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Poor handovers

Good communication between clinicians and appropriate handover between teams is an essential part of patient safety. General Medical Council guidance[21] to doctors, for example, stresses the importance of working collaboratively, communicating effectively and sharing information between teams. Equally, the Nursing and Midwifery Council Code of Practice highlights the need to maintain effective communication and keep health and care professionals informed when sharing the care of individuals, to 'preserve the safety of those receiving care'.[22] This includes the need for timely and appropriate handovers between teams. Research has identified that transfers into or out of intensive care units and when information has to be communicated to other teams during a critical care stay can be risk points for patient safety incidents.[23]

In almost half of the cases we analysed, we found failings in communication between different clinicians and teams. In one case, for example, we could not find any evidence that the Trust followed a clear and coordinated clinical management plan when a man in his seventies attended the Trust's emergency department with a twisted bowel. We found that poor communication between teams contributed significantly to the Trust failing to take urgent action to reduce the risk of bowel perforation. When investigating another case, we could not find evidence of a documented handover between teams. This meant we could not understand what actions the Trust had taken at the time to make sure the patient continued to receive adequate care.

[21] General Medical Council, 'Domain 3: Communication partnership and teamwork', Good medical practice.

[22] Nursing and Midwifery Council, The Code.

[23] Thomas, A.N., and MacDonald, J.J. (2016), 'Patient safety incidents associated with failures in communication reported from critical care units in the North West of England between 2009 and 2014'. Journal of Intensive Care Society, 17 (2), pp. 129-135.

Case study: failure to diagnose and lack of handover between teams

- A patient went to a Trust's emergency department after an out-of-hours GP told them to call 999. The patient said they had a racing heart, felt generally unwell and had pain in their forearms.
- The Trust carried out a series of checks and found them to be within normal limits. The doctor prescribed an antibiotic and discharged the patient.
- A few days later, the patient was admitted to a medical assessment unit after a GP referral for a respiratory opinion.
- A consultant reviewed them and noted they might have a blood clot and fluid around the lung.
- The consultant requested a troponin test (a blood test that can help assess heart damage), echocardiogram (a scan to look at the heart and nearby blood vessels) and repeat ECG, and prescribed a blood-thinning injection to treat the suspected clot.
- Another doctor reviewed the patient and considered a pleural effusion (when excess fluid builds up in the space between the lungs and the chest wall) rather than a blood clot. Staff gave the patient antibiotics and drained the fluid around the lung. The following day, the doctor noted the patient's symptoms were improving.
- A couple of days later, a consultant respiratory physician noted that the patient had aching pain in both arms, breathlessness and difficulty breathing when lying down. They reviewed the test results and considered the patient had congestive heart failure (when the heart cannot pump blood around the body properly), which was probably secondary to a recent heart attack.
- The consultant asked for an ECG and troponin test and prescribed medication. They left instructions for staff to triage the patient as a cardiology patient and arrange an ECG to check the heart's rhythm and electrical activity.
- The next day, the patient was moved to a ward and nurses noted that a doctor needed to do a medical review, including reviewing the ECG results.
- Sadly, the patient died the next day after suffering a cardiac arrest.
- We found multiple failings in relation to the patient's care.
- The Trust had not carried out the troponin test and echochadiogram the first time a consultant requested them, and staff did not act on early warning observations when they should have alerted a doctor.
- There was evidence of a heart attack in the ECG results, but this did not get an urgent medical review. And no medical review was carried out after the patient was transferred to the ward.

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- If the Trust had made a timely diagnosis and given appropriate treatment, there would have been an improved chance of the patient surviving. It missed an opportunity to provide potentially lifesaving treatment. It was more likely than not that the patient's death was avoidable.
- We found that communication with the patient's next of kin was flawed and incomplete, and there were failings in the Trust's complaint handling that caused them distress and frustration.

Failure to listen to the concerns of patients and their families

Listening to patients and their families is a vital part of providing good quality care and treatment that puts the patient front and centre. In our casework, we identified a small number of cases where failures to listen to the concerns of patients and their families had a clinical impact.

For example, a man who was admitted to hospital with abdominal pain raised concerns with clinical staff on multiple occasions about his care and treatment. During our investigation we found evidence that he was concerned he did not feel well enough to leave the hospital. Despite this, the Trust still considered him well enough to go home and discharged him on the same day. Two days later, he returned to hospital and died shortly after being admitted due to gastric aspiration (where vomit enters the larynx and lungs). Our investigation found that the Trust should have carried out an urgent CT scan, which would have led to the patient having lifesaving surgery.

In another example, a complainant described how he had to persuade staff to admit his mother after she had attended the Trust's emergency department multiple times. During our investigation, we found evidence that staff doubted the patient's symptoms and failed to appreciate the serious nature of her condition. Understandably, this was upsetting for the complainant who could see that his mother was very unwell. The complainant's mother died after having a stroke in hospital. This could have been avoided if she had been diagnosed correctly and treated during an earlier admission.

Summary

The themes we have identified around clinical failings are wide-ranging but will be very familiar to anyone with experience in patient safety. The caseworkers who worked on these cases observed that they reflect the types of issues we see in most of our health casework, not just those that resulted in the most serious possible outcome of a patient's avoidable death.

Although a lot can be done to reduce clinical harm and improve patient safety, and certain incidents can be prevented entirely with the right processes, systems and cultures in place, it is unrealistic to expect that all clinical errors and omissions can be eliminated. But it should always be possible to respond well, with compassion, and in a way that shows learning and accountability when avoidable harm has happened. In the next section we look at the evidence from our casework about the impact on families when this does not happen.

The ongoing impact of clinical harm: compounded harm to families

All too often in our casework, we see families who have already experienced the devastating consequences of avoidable harm suffer further distress because of the response they get from healthcare organisations. This additional harm that people experience when interactions following patient safety incidents feel closed and defensive is known as 'compounded harm'.[24] Researchers have recognised the impact of compounded harm, 'especially when people feel unheard or invalidated'.[25]

Although the idea of compounded harm is not new, it is often neglected in the process of understanding the impact of avoidable serious harm. In this section, we look at evidence of compounded harm in our casework. We highlight the experiences of families who brought cases to us, as they described it during our interviews with them.

When we looked at our casework, we identified the following scenarios that are likely to contribute to compounded harm:

- failure to be honest when things go wrong
- a lack of support to navigate systems in the aftermath of an incident
- poor-quality investigations
- failure to respond to complaints in a timely and compassionate way
- inadequate apologies
- unsatisfactory learning responses.

A failure to be open and honest when things go wrong

The duty of candour requires organisations to be open and honest with patients as soon as possible after they realise something has gone wrong. But we know from our casework that this duty is not always met. In one example, we found the Trust did not disclose the contradictory opinions it had received from different reviewers when determining whether a delay to an operation had resulted in avoidable harm. We judged that this review should have triggered action under the duty of candour, but there was no evidence the Trust had considered its responsibilities to inform the family.

In a case where a baby died after antibiotics were not given quickly enough, we found the Trust had not properly equipped its staff to acknowledge what had gone wrong. Important details about the sequence of events and the nature of the infection were not given to the parents until seven weeks after their son died. Staff even discussed deleting a recording made during a meeting when the parents temporarily stepped out of the room, because they realised what they had said might get the Trust into difficulty. This complete failure of transparency created understandable mistrust and worsened the pain and distress of the family in their grief.

[24] This term features in the Patient Safety Incident Response Framework guidance on engaging with and involving families, patients and staff following a patient safety incident.

[25] Wailling, J., Kooijman, A., Hughes, J., and O'Hara, J. (2022), 'Humanizing harm: Using a restorative approach to heal and learn from adverse events'. Health Expectations, 25 (4), pp. 1192-1199.

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Duty of candour

The underlying principle of the duty of candour is that when something goes wrong in the provision of health and care services, patients and families have a right to receive a meaningful apology and explanations for what happened as soon as possible.

The statutory duty of candour was introduced in 2014 in regulations to the Health and Social Care Act 2008.

Regulation 20 puts a legal duty on health and social care to be open and transparent with people using services and their families. It sets out actions that providers must take when a 'notifiable safety incident' happens. Notifiable safety incidents:

- are unintended or unexpected
- happen during the provision of an activity the CQC regulates
- are incidents that – in the reasonable opinion of a healthcare professional – could, or already appear to have, resulted in death or severe or moderate harm to the person receiving care.

As soon as a notifiable safety incident has been identified, organisations must act promptly and are expected to:

- tell the relevant person, face-to-face, that a notifiable safety incident has taken place
- say sorry
- provide a true account of what happened, explaining what is known at that point
- explain what further enquiries or investigations will take place
- follow up by providing this information and the apology in writing, and giving an update on any enquiries
- keep a secure written record of all meetings and communications with the relevant person.

The CQC regulates compliance with the statutory duty of candour. Organisations must have clear policies and procedures in place and make sure staff understand their responsibilities. The CQC also expects senior managers to show they have a safe culture where staff feel able to speak up and are supported to carry out the duty of candour. Failure to comply with the duty can result in enforcement activity ranging from warning or requirement notices to criminal prosecution.

Lack of support to navigate systems in the aftermath of an incident

All our interviewees spoke about the difficulties they had in knowing how to raise concerns about what happened to their family member. A lack of information was a common experience. One complainant explained: 'we didn't get any information in regards to letting them [the Trust] know about our experience, how we felt about my mum's care; all of that was sorted by me and I didn't get any family support either. I literally did it all by myself'.

Another commented:

> 'Nobody gave me any information at all. I went online and googled what to do and that was it. Nobody gave me any advice on how to complain, on what to say, or anything like that.'

We also heard some concerns about a lack of independent advice, if it came from the same organisation where the incident took place:

'I feel like it was a very distressing situation, there was no sort of advice around the complaint. I first complained to PALS which work in the hospital. I don't actually think that this is a good way for patients to complain about the hospital because the people they complain to work within the hospital.'

Where complainants were able to access independent advocacy services, this was a positive experience:

> 'I did find an organisation that supported me called POhWER, they were really helpful. I was really upset and distressed and the first lady was very patient with me, very kind, very helpful, she told me the steps to complain. Then that lady left and they gave me another advocate and she was also really helpful ... she read every single page with me, and she literally held my hand all the way through the process. So the advocates were helpful, but in regards to the hospital, there was no help from them.'

Local authorities have a statutory duty to fund independent NHS complaints advocacy. This type of advocacy is provided by trained, professional advocates who can give information, signposting and support with the complaints process. Professional advocacy can be a source of valuable information and guidance, and a way of supporting complainants through what can be a long and difficult process, although emotional or psychological support is not part of the role of professional NHS complaints advocates.

As we highlighted in 'Making Complaints Count', NHS complaints advocacy services are limited to helping people navigate the NHS complaints process. Complaints advocacy providers cannot give advice on the clinical parts of a complaint or other processes a complainant might be involved in or considering, such as coroner inquests or making a claim.[26]

[26] PHSO, Making Complaints Count, p. 32.

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The benefit of access to advocacy is something the Harmed Patients Alliance recognised in a recent report. It said: 'well-advised and supported people are more likely to take an active part in investigations without suffering compounded harm', as well as being better able to take part 'in a meaningful way in a patient safety investigation under the Patient Safety Incident Response Framework (PSIRF)'.[27]

Poor-quality investigations

Organisations should provide clear, evidence-based explanations in response to concerns, provide reasons for their decisions, and consider the impact of any failings. We routinely see Trusts fail to accept errors or the extent of what has happened and its impact. In most cases where we found a death was avoidable, the Trust had not conducted a serious incident investigation. And there were no instances of Trusts themselves reaching the same conclusion as our investigation that errors in care led to the death of the patient. Because we use evidence that organisations would have had access to, it is reasonable to expect those organisations should also have been able to identify these errors.

In one case, after delaying its response by a whole year, the Trust responded to a complainant about her mother's death by summarising what was said in a local resolution meeting (a meeting between the Trust and the complainant). We saw no evidence that the Trust conducted a full investigation into the complainant's concerns or attempted to address them in any detail. In another case, there were contradictions in the Trust's written responses and inaccuracies in its account of the care and treatment provided to the complainant's wife, who had died of a brain tumour. The Trust provided two responses a year apart. The first response accepted there was a delay in identifying that the tumour was growing, while the second response explained events differently.

Some investigations are not as thorough as they should be and crucial parts are missed out. For example, a case in which a senior house officer failed to attend when bleeped was a significant moment in understanding failures in care and treatment. But the senior house officer was not interviewed as part of the serious incident investigation that followed. Nursing staff were asked to give statements, but the senior house officer was not. This meant the Trust was unable to explain why there was a delay in responding to the bleep and missed an opportunity to understand the context of the failing. This added to the distress felt by the patient's partner, who was left with no answers to this important part of the incident.

In some instances, we found the Trust identified the clinical failings correctly but the local investigation failed to consider the impact of them. In one case, the Trust carried out an investigation and correctly identified the clinical failings that led to a mother's death from sepsis. It made an action plan for improving process, which showed it aimed to learn from the incident, but it did not consider the impact of the failings, which was that the patient's death would not have happened if they had received the right treatment at the right time. In another case, the Trust initially refused to accept that it should have identified clear abnormalities on an X-ray and did not believe this represented a missed diagnosis.

[27] Harmed Patients Alliance (2022), Signpost to Nowhere, p. 4.

Trusts can sometimes use comorbidities (when someone has more than one, often chronic or long-term, disease or condition at the same time) to minimise the impact of any failings or omissions. For example, in a case where there was a significant delay in giving antibiotics, the Trust said the patient's history of cardiac problems and low blood pressure would have limited the patient's response to sepsis. But our critical care advisor said this was not supported by the information available. Examples like these suggest an ingrained defensiveness and lack of curiosity about the causes of harm, which is sadly still prevalent in some Trusts.

Case study: failure to make the right diagnosis and poor-quality investigation

- A patient with a long-standing autoimmune disease went to a Trust's emergency department with symptoms including dizziness, poor balance and blurred vision. The Trust kept the patient overnight for further investigations.
- A doctor carried out a brief initial assessment of the patient and noted they looked unwell and pale. Later in the evening, a nurse took blood samples for testing and examined the patient using a MEWS score (Modified Early Warning Score, an early warning system based on clinical observations). This was recorded as 1.
- The Trust transferred the patient to the acute medical unit to wait for a full medical assessment.
- Later in the night, a doctor assessed the patient and noted nystagmus (involuntary flickering eye movements) in addition to earlier symptoms including blurring of vision and dizziness.
- The doctor made a working initial diagnosis of dehydration. The doctor started a care plan to continue with IV fluids, to monitor IV fluids in and urine out, and to refer the patient to the ophthalmic team if the visual changes did not improve with rehydration.
- Afterwards, the nursing team noted further heart rate increase and that the patient had not passed urine since they went to the acute medical unit. The Trust recorded a MEWS score of 4 – 1 for the increased heart rate and 3 for the lack of urine output.
- The patient told the doctor who attended for review that they were unable to pass urine. The patient was catheterised for urine drainage, which eased their discomfort.
- The following morning, a family member reported a rapid change in the patient's condition. They were concerned about the patient becoming drowsy and unable to speak. This prompted the immediate escalation of their treatment.
- Tests and scans were ordered to try to identify the underlying cause of the change. Shortly after, the patient's condition suddenly got worse and they eventually lost consciousness.

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- The CT head scan results showed signs of hydrocephalus (fluid pressure in the brain caused by a blockage stopping fluid from draining out of the skull) and a bleed on the brain. The patient was immediately transferred to the nearest Regional Neurosurgical Department for surgery to relieve the pressure and stop the bleed.
- Despite having two operations to try saving their life, sadly the patient never regained consciousness and died a few days later.
- The surgeon's notes show they found a growth in the brain during surgery, which caused the hydrocephalus and eventually had also been the source of a bleed on the brain.
- We found several failings in the care the Trust gave the patient.
- We found a failing to complete a full neurological assessment and order a CT head scan in response to signs of nystagmus noted by the doctor at the acute medical unit. Although the nystagmus was identified correctly, the doctor missed the significance.
- This led to a missed opportunity to diagnose and treat the patient's condition and potentially avoid their death.
- We found there was failure to make sure the MEWS score was monitored hourly following the MEWS score of 4 being recorded.
- We also found that the Trust's complaint investigation failed to identify and address these issues, which added to the distress and grief suffered by the patient's family.

The Patient Safety Incident Response Framework (PSIRF)

The PSIRF is being rolled out across the NHS, with a deadline for implementation of autumn 2023. While this is too recent to be relevant to the cases in this report, it represents the future for the approach to patient safety in the NHS.

What the PSIRF is changing

The PSIRF replaces the Serious Incident Framework. Unlike the Serious Incident Framework, it is not an investigation framework that prescribes what to investigate (although there are still circumstances where a patient safety investigation will be mandatory: incidents meeting the 'learning from deaths' criteria; Never Events[28] – safety events that are 'wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers'; deaths of patients detailed under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies).

Instead, the PSIRF promotes a range of system-based approaches for learning from patient safety incidents. This includes alternatives to an investigation such as a multidisciplinary team review and a 'swarm huddle' – when staff gather to quickly analyse what happened immediately after an incident and decide how to reduce future risks.

The PSIRF is intended to be more flexible, allowing organisations to tailor their response to patient safety so that it is relevant for their contexts and the populations they serve. This flexibility will allow organisations to focus resources on where they can really make an impact, rather than having to always conduct an investigation where that might not lead to new learning or create change. The framework represents a move away from root cause analysis and towards approaches that look at the wider system and human factors.

Under the framework, NHS organisations need to develop a plan and a policy outlining how they will respond to patient safety incidents. There is a focus on compassionate engagement with patients and families, with specific guidance on how to do this well.

In terms of oversight, the framework requires a PSIRF executive lead on each NHS Board, as well as an integrated care board lead who will work with providers on their responses to patient safety. The suggestion is that oversight focuses more on collaborative working and collecting qualitative data, rather than requiring lots of quantitative measures. As stated in the guidance, it 'focuses on engagement and empowerment rather than the more traditional command and control'.[29]

Who the PSIRF applies to

The PSIRF is a contractual requirement under the NHS Standard Contract so it will be mandatory for acute, ambulance, mental health and community healthcare providers. This includes maternity and all specialised services. Primary care providers (for example, GPs) may adopt the PSIRF but are not required to at this stage.

[28] NHS (2018), 'Never Events policy and framework'.
[29] NHS England, Patient Safety Incident Response Framework supporting guidance: Oversight roles and responsibilities specification, August 2022.

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Failure to respond to complaints in a timely and compassionate way

As we are the final stage for unresolved complaints in the NHS, we usually expect people to complain to the organisation they are unhappy with first. This gives the organisation the chance to look into the concerns and, where needed, put things right. We frequently see examples of unacceptable and unreasonable delays in responding to complaints, and failures to keep families informed and updated about the progress of their case. These delays and failings in communication often cause more distress and frustration for complainants and their families at a difficult time.

Case study: failings in care and poor complaint handling

- A patient with bipolar disorder (a mental health condition that affects your moods) attended a hospital's emergency department by ambulance, due to shortness of breath they had been experiencing for a few days.
- Staff arranged a chest X-ray and diagnosed inflammation of the lungs. This inflammation caused impaired oxygen absorption which resulted in respiratory failure. This resulted in low oxygen levels causing the patient to be confused and agitated.
- The patient was admitted to the intensive care unit and prescribed antibiotics and continuous positive airway pressure (CPAP, a type of breathing support).
- A few days later, the patient could breathe without respiratory support and maintain oxygen levels. The consultants considered the patient to be medically stable and transferred them to a ward.
- A couple of days later, the patient had a cardiac arrest. The doctors resuscitated the patient and transferred them back to the intensive care unit.
- Staff carried out an electrical brain wave test, which showed irreversible brain damage. A neurology assessment also confirmed that recovery was unlikely.
- The consultant decided to withdraw critical care support. The patient died later that week. The cause of death was recorded as severe hypoxic brain injury (when the brain does not get enough oxygen) and cardio-respiratory arrest (loss of breathing and heart function).
- We found that staff failed to observe the patient as frequently as they should have. If this had happened, they may have recognised the patient's health deteriorating earlier and called for senior medical input before the cardiac arrest happened.
- We also found the Trust failed to provide planned, focused, one-to-one care for the patient during their time on the ward. If the Trust had provided one-to-one care, staff would have identified the patient's cardiac arrest much sooner.

- If this had happened, it is likely the patient would have been resuscitated without suffering the irreversible brain damage that led to their death. It is likely the patient's death could have been avoided.
- We also found failings in the way the Trust handled the complaint.
- When the patient's daughter complained, the Trust took over six months to arrange an initial meeting to discuss it and failed to provide a written response.
- Before we began our investigation, we asked the Trust to provide a written response. It agreed to do this by the end of the following month but did not provide it until a year later. This meant the complainant only received a response to her complaint about her mother's death two years after complaining to the Trust.

In one case, a man who complained about the death of his wife from a brain tumour had to wait two years for the Trust to conclude its investigation.

In interviews we conducted, complainants described the process of trying to resolve their complaint with Trusts as 'long and torturous', 'a long, dragging sequence of events' and 'very lengthy and distressing'.

Often, Trusts will explain that the complaint department was understaffed or dealing with high staff turnover. We know from previous research that complaint handlers in the NHS may not be sufficiently empowered or trained to resolve a complaint.[30]

Treating complainants with dignity and compassion is an essential part of resolving a complaint, but we found instances where organisations failed to do this. For example, in one of the complainant interviews, a mother whose son died of a pulmonary embolism told us:

> 'At some point a doctor from the Trust phoned my [other] son to tell him that his brother would have died anyway and there was really no point in carrying on with this.'

The same complainant told us she felt the Trust 'just weren't interested. It was over, it was done with, and they didn't want to know'.

In another interview, the complainant told us their first meeting with the Trust took place in the same ward where her mother had recently died.

[30] PHSO (2020), 'Making Complaints Count: Supporting complaints handling in the NHS and UK Government Departments'.

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The complainant said this was so insensitive to her and her family that 'it felt cruel'. The same complainant told us she did not feel like the Trust was interested in what she had to say:

> 'I didn't think they were interested. I felt like my mum had passed away and so it wasn't a concern for them. It was almost like, you know, she's gone now and that was it.'

NHS Complaint Standards

We are committed to supporting and improving frontline complaint handling. We developed the NHS Complaint Standards to support organisations to provide a quicker, simpler and more streamlined complaint handling service. The Standards apply to NHS organisations in England and independent healthcare providers that deliver NHS-funded care.

The Standards have a strong focus on:

- early resolution by empowered and well-trained people
- all staff, particularly senior staff, regularly reviewing what learning can be taken from complaints
- how all staff, particularly senior staff, should use this learning to improve services.

The Complaint Standards are based on 'My Expectations', which sets out what patients want to happen when they make a complaint about health or social care services.[31] The Standards and the guidance modules describe how staff can meet those expectations.

We worked with 11 pilot sites and over 70 'early adopters' across the NHS in 2021-22 to help test how the Standards, supporting materials and training can support frontline complaint handling.

Feedback from the pilot has been overwhelmingly positive, with NHS staff telling us the support on offer will make a real, practical difference and promote consistency. Throughout 2023, we will be working to embed the Standards across the NHS.

Inadequate apologies

Guidance from NHS Resolution makes it clear that apologising is not an admission of fault or liability.[32] The same guidance highlights that organisations must make meaningful apologies when things go wrong. It states that a meaningful apology 'is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them'.

[31] PHSO (2014), 'My expectations for raising concerns and complaints'.

[32] NHS Resolution, 'Saying sorry': 'The Compensation Act 2006 states; "An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty"'.

But we still see organisations that fail to give a genuine apology. Organisations may say sorry and accept that failings happened, but it is rarer that they offer a clear and unreserved apology that shows they have understood the impact of those failings on the patient. In 'Making Complaints Count', we identified how a culture of defensiveness can result in staff feeling like they are not allowed to say sorry. Advocates also told us they often see organisations send apology letters that say 'I'm sorry if you felt that...' rather than offering a sincere apology.[33]

In one case, the apology letter repeated that the Trust had been asked to accept the failings we found, but it did not go on to do this. Instead, it referred to what the Ombudsman 'felt', which suggests a lack of acceptance of our findings and the learning they offer. The apology letter did not accept responsibility for what happened or even refer to the patient or the fact that they died. In another case, we considered that the Trust's apology letter did not accept that its failings led to avoidable serious harm. In its first apology letter to the complainant, the Trust only apologised for the complainant having 'had cause to raise concerns'. It was clear the Trust did not accept responsibility and had not apologised for the impact of the failings. It was only after repeated contact with the Trust on the content of the apology letter that it gave the complainant an unreserved apology for the avoidable serious harm it caused to the patient.

One complainant told us that after our investigation they felt the 'Trust finally had to accept that they had got it wrong'. But they also said:

> 'I don't think that they did it with a good grace. I think it was just a formula ... They weren't sorry that they'd done it, they were sorry they'd been caught.'

Unsatisfactory learning responses

Most complainants want assurances that something is being done to prevent the same mistakes from happening again. In our recent research on motivations for complaining, 93% of respondents said 'ensuring that others don't face the same issues in the future' was either very important or important in their decision to complain.[34] Similarly, in our interviews with complainants, they all said part of the reason why they complained was to make sure the same thing does not happen to other patients, families and carers.

Being able to show that learning has happened is vital if families are to feel their complaint has achieved its purpose. Responses that do not feel meaningful can leave families feeling badly let down and frustrated.

While we do see good examples of thorough action plans, we frequently see less robust responses. These are a missed opportunity for learning from avoidable serious harm and taking action to prevent it from happening again. In one case, we had to follow up multiple times to make sure we were satisfied with the proposed action plan. The Trust did not plan to audit its proposed new processes, so there would be no way of knowing if they were effective.

[33] PHSO (2020), Making Complaints Count, p. 14.

[34] PHSO (2023), Outreach Research.

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In one interview, the complainant told us:

> 'I knew that all the things they said they were going to implement to change things, wouldn't change the way the ward was operated and the way nurses behaved, or the way that the actual patients on the ward felt. It was all just more rules, and probably just more bits of paper for the nurses to fill in, but not translating to an effect on the ward.'

Another complainant told us:

> 'I don't believe they've learned one lesson.'

It is clear that, far from being a process that promotes learning and provides resolution and healing, the response to families following an incident frequently creates further harm and distress. This is completely unacceptable. Reducing compounded harm must be an urgent priority for everyone working to improve patient safety.

Our recommendations

The issues we have identified are complex. They reflect the fact that healthcare is a web of interactions, behaviours and processes, underpinned by deeply ingrained cultures. If there were readily available, easy solutions to tackle clinical failures and end compounded harm, they would have been implemented long ago.

Facing up to this complexity, we have focused on two themes in our recommendations.

1. Accountability for a robust and compassionate response to harm, which supports learning for systems and healing for families

Our casework shows that many local investigations are not good enough. It cannot be right that in so many instances, the Ombudsman finds errors that the Trust has not identified at an earlier stage. The gap between the findings of local investigations and the findings of our investigations suggests how defensive some NHS cultures can be. In some Trusts, there is still an embedded lack of curiosity about what has happened and what can be learned.

It is important to recognise that our evidence base is just one snapshot in a much bigger picture. We understand that few people will have the energy to keep going and bring their case to the Ombudsman, having been through the trauma of grief, an investigation and a complaints process. This means what we see through our casework is likely to be the tip of the iceberg.

We must improve investigation quality and practices so they aid learning and promote healing, rather than adding to compounded harm. The HSIB has done important work to upskill NHS staff in best practice investigation methodologies, and the PSIRF is an excellent framework to take this even further. There is a lot to welcome in the framework's systems-based approach and emphasis on compassionate engagement.

While we want to endorse the approach the PSIRF outlines, we need to be realistic about how far there is still to go. There is a gap between the welcome rhetoric in PSIRF guidance documents and the defensive behaviours from some NHS leaders we still see in our casework, as evidenced in this report.

The additional flexibility the PSIRF offers (giving Trusts more autonomy to decide when a safety investigation is needed) might present a risk that Trusts with poor cultures do not carry out safety incident investigations when they should. This possibility is not acknowledged in the PSIRF oversight guidance. Rather, the emphasis on 'proportionate responses' focuses more on making sure unnecessary investigations are not conducted if they would repeat old ground or would not lead to learning.

The PSIRF needs to be accompanied by sufficient monitoring and support for families.

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We recommend that:

- **Integrated care boards, with oversight from NHS England, should closely monitor the impact of the PSIRF to identify any negative consequences of the new flexibility it offers, which gives Trusts more autonomy to decide when a patient safety investigation is needed. This should include paying special attention to the balance of patient safety investigations versus other learning responses in Trusts (or service areas of a Trust) where there are poor CQC ratings for safety and leadership, or where other national bodies have raised concerns (recommendation 1).**
- **As part of their quality monitoring role, the PSIRF executive lead on each Board should look at any discrepancies between local and PHSO investigations, or other independent investigations, and make sure the Board discusses them. This should include where local investigations did not take place, or did not find that things went wrong, but PHSO or another independent oversight body later identified failings (recommendation 2).**

The PSIRF recognises that genuine apologies are critical to avoid compounded harm. As we found in cases we analysed, apologies are often still not good enough and duty of candour is not always implemented as it should be. It is unacceptable that Trusts still fail in this duty nearly a decade after it was introduced. Again, this is symptomatic of a defensive culture in some Trusts. Duty of candour is the right policy, but it needs more attention and monitoring.

We recommend that:

- **The Department of Health and Social Care and NHS England should further scrutinise the lack of compliance with duty of candour. They should review the operation of duty of candour to assess its effectiveness and make recommendations for improvement (recommendation 3).**

We welcome the model of family engagement outlined in the PSIRF. But we know that, for the foreseeable future, it will continue to be very challenging for families affected by safety incidents to navigate the complex NHS landscape when they raise concerns and seek answers. They are often very aware of the power imbalances in dealing with professionals who are familiar with the processes and systems that they are coming to for the first time. In this context, advocacy is an essential service, not a 'nice to have'.

While there is a statutory duty for local authorities to commission NHS complaints advocacy, these services are often limited to helping people navigate the NHS complaints process. As we noted in 'Making Complaints Count', there are concerning gaps in access to more specialist services that may be important for families affected by patient safety incidents.

We recommend that:

- **The Department of Health and Social Care should commit to funding further independent advocacy to support harmed patients, families and carers when they raise concerns or seek answers after an incident (recommendation 4).**

2. Evidencing that patient safety is a top Government and NHS priority

The right patient safety framework is not enough on its own to drive change. NHS leaders and frontline staff need to be in no doubt of the priority placed on patient safety.

In some ways it is strange that this should need emphasis: patient safety is about the NHS' core purpose to do no harm. But there are clear signs that patient safety is not prioritised at the moment, however much rhetoric there is to suggest otherwise.

First, we are becoming too used to seeing repeated failings. This is especially stark in maternity services. In his inquiry in East Kent, Bill Kirkup acknowledged the disappointing familiarity of the findings to those he made in Morecambe Bay seven years earlier. The fact that inquiries many years apart find the same failings is met with dismay, but not always outrage or even surprise. There is almost an acceptance that this is 'how things are'. This inertia undermines the difficult work underway to change cultures and manage patient safety more effectively.

Second, political leaders have created a confusing landscape of organisations, often in knee-jerk rection to patient safety crisis points. HSIB, the Patient Safety Commissioner, PHSO, NHS England, NHS Resolution and more than a dozen different health and care regulators all play important roles in patient safety. But there are significant overlaps in functions, which create uncertainty about who is responsible for what. This means patient safety voice and leadership are fractured. This is not due to a lack of dedication and professionalism from those tasked with championing patient safety. The problem is structural.

The Government must consider the case for streamlining some of these functions, for the benefit of people who use the NHS, their families and carers. This is not about reducing investment in patient safety. It is about creating a system that is coherent and easier to navigate, based on evidence and engagement with patients, families, NHS staff and leaders. We recommend that:

- **The Department of Health and Social Care should commission an independent review of what an effective set of patient safety oversight bodies would look like. The review must include meaningful engagement with NHS leaders, staff, patients and families (recommendation 5).**

Patient safety must be a consistent priority over the long term. It must not be subject to changes of emphasis or importance each time there is a new minister or leadership change in the NHS. We recommend that:

- **The Government should seek cross-party support for embedding patient safety and the culture and leadership needed to support it as a long-term priority (recommendation 6).**

Third, it is not possible to claim to prioritise patient safety while avoiding difficult political decisions about the workforce the NHS needs. Patient safety will always be at risk in environments that are understaffed and where staff are exhausted and under unsustainable pressure. No matter how effective the safety systems and process, it is not possible to run a safe service without the right numbers of staff. Many patient safety commentators draw parallels between the NHS and aviation. In aviation, a plane would not take off without the right number of staff, with the rights skills, who have had enough rest, support and training to be able to operate safely.

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Tackling workforce shortages goes beyond political decisions about resourcing. It is about making the NHS a place where people want to work and stay because it is somewhere they feel valued, not just because it is a vocation. We must break down the false dichotomy between the interests of patients and staff, recognising that a system that does not treat its workforce with humanity and compassion will struggle to extend these qualities to patients and families.

We recognise the Government has promised to publish a new NHS workforce strategy. At the time of writing, this is expected 'shortly'. But for this to properly address the underlying causes of NHS staffing pressures, it needs cross-party consensus. In a sector where it can take nearly two decades to train a consultant doctor, a workforce strategy will only succeed if there is support from across the political spectrum, and far beyond one parliamentary term.

We recommend that:

- **The Government should urgently produce its long-awaited long-term workforce strategy, with cross-party support, to increase the numbers entering and staying in the workforce across clinical and non-clinical roles. This strategy must:**
    - **include independent, evidence-based and fully costed projections of future workforce requirements**
    - **include detailed plans for training and recruiting new staff, retaining staff already working in the NHS and attracting those who have left to return**
    - **take account of the mix of different professional skills required, rather than just total numbers in the workforce, and how existing professional skills can be deployed where they are most needed (recommendation 7).**

The Department of Health and Social Care should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 3, 4, 5, 6 and 7.

NHS England should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 1 and 3.

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The Regulation and Quality Improvement Authority

RQIA Review of the Urology Structured Case Record Review Southern Health and Social Care Trust

May 2023

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The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating, inspecting and reviewing the quality and availability of health and social care services in Northern Ireland. RQIA's reviews identify best practice, highlight gaps or shortfalls in services requiring improvement and protect the public interest. Reviews are supported by a core team of staff and by independent assessors, who are either experienced practitioners or experts by experience. Our reports are submitted to the Minister for Health and are available on our website at www.rqia.org.uk.

RQIA is committed to conducting inspections and reviews, taking into consideration our four key domains:

- Is care safe?
- Is care effective?
- Is care compassionate?
- Is the service well-led?

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Appendix 1: Terms of Reference for the Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

Appendix 2: Structured Judgement Review

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Section 1 Introduction

1.1 Background and Context

On 31 July 2020, the Southern Health and Social Care Trust (SHSCT) contacted the Department of Health (DoH) to report an early alert concerning the clinical practice of a Urology Consultant (referred to in this report as Consultant A).

An initial review, which considered cases over an 18-month period of the consultant's work in SHSCT from 1 January 2019 to 30 June 2020, focussed on whether patients had had a stent inserted during a particular procedure and if the stent had been removed within the clinically recommended time frame. The initial review identified concerns with 46 cases out of a total of 147 patients who had the procedure and were listed as being under the care of the consultant during the period addressed by the initial look-back exercise[i]. The findings were significant and led the Minister for Health, Robin Swann MLA, to announce on 24 November 2020 that a statutory public inquiry would be established under the Inquiries Act 2005.

The Urology Services Inquiry, which is currently ongoing, is chaired by Ms Christine Smith QC has been charged with: (a) reviewing SHCT's handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice; (b) evaluating the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients (c) examining the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate; (d) afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry; (e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien; (f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose and (g) examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations.

In parallel, yet entirely separate, to the work of the Urology Services Inquiry, SHSCT subsequently established a review group to assess the further findings of the initial review exercise and to explore the need for a further look-back review in the context of additional concerns.

Areas of concern were identified relating to:

- Elective and emergency activity;
- Radiology;
- Pathology and cytology results;
- Patients whose cases were considered in multidisciplinary team meetings;
- Oncology; and

[i] Ministerial Statement by Health Minister to the Northern Ireland Assembly, 24th November 2020

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- The safe prescribing of an anti-androgen drug outside established NICE guidance in the management of prostate cancer.

Nine cases were identified that met the threshold for a Serious Adverse Incident (SAI) review. Following the completion of these initial nine SAI reviews in 2021, the Trust was advised by DoH that the SAI process should not be used to review subsequent potential issues in care identified by the lookback process.

As a result, SHSCT developed a Structured Case Record Review (SCRR) process based on the Structured Judgement Review methodology as developed by the Royal College of Physicians. The aim of the SCRR process was to identify any areas of learning where patient safety could be improved.

In March 2022 SHSCT asked RQIA to undertake:

- A review of the choice of Structured Judgement Review methodology to underpin their SCRR process.
- A review of the Trust SCRR process in relation to its effectiveness in identifying learning.

It was further agreed that, in the event that the SCRR process was not considered to be appropriate the Trust would like RQIA to suggest an alternative approach.

1.2 Terms of Reference

Although RQIA was requested to review the suitability of the Trust's SCRR process, we considered that the scope of the review should be wider. It would not be appropriate to only assess the tools involved but we should also assess the surrounding process within which the SCRR operates. Therefore, the following Terms of Reference were agreed with SHSCT.

1. To assess the suitability of the Structured Judgement Review methodology as the basis for the Trust SCRR process.

2. To assess the specific Trust SCRR methodology in relation to its effectiveness in identifying learning.

3. To assess the overall trust process/framework for conduct of its record review.

4. To make recommendations in relation to the overall process and if the SCRR process is not considered to be appropriate suggest an alternative approach.

1.3 Review Methodology

RQIA used a PRINCE project management approach to underpin this review. The review utilised a range of methodologies to obtain supporting information to inform our assessment:

- We undertook a review of the literature around the use of the Structured Judgement Review Method to help identify key themes and areas of focus.

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- We designed and issued structured questionnaires to the Southern Health and Social Care Trust.
- We analysed information returned to us and used this to develop Key Lines of Enquiry for meetings with the Trust.
- Our Expert Review Team (ERT) conducted focus groups and meetings with the independent panel of reviewers, senior staff and other relevant staff from the Trust.
- We analysed the information gathered through our structured pre review questionnaires, meetings, focus groups and staff questionnaire responses in order to determine our key findings and recommendations.

Section 2 Findings

In assessing the effectiveness of all aspects of the SCRR process we considered the overall process in respect of a number of component parts.

2.1 OVERALL TRUST PROCESS AND FRAMEWORK FOR SCRR

2.1.1 Background to the Structured Case Record Review

The provision of background and contextual information is vital to the understanding of the rationale and purpose of the Structured Clinical Records Review process. This information was provided by SHSCT, in conjunction with a Structured Case Review proposal document and was explored further by the Expert Review Team during fieldwork sessions with Trust representatives.

During fieldwork, the Expert Review Team heard the Urology Services Inquiry was announced unexpectedly in November 2020 during what was a difficult time for SHSCT, when it was grappling not just with the emerging issues within Urology Services but also with the COVID-19 pandemic and its associated pressures for service; this contextual information provided the Expert Review Team with a valuable insight into the challenges faced. At the point of announcement of the Inquiry Terms of Reference (see Appendix 1) SHSCT had already commenced a Lookback Review and through this had identified a significant number of patients meeting the threshold for an SAI review under the regional SAI procedure[1].

Due to the volume of patients identified, the time and resource required to progress SAI reviews, and the limited additional value of repeatedly reviewing the same type of incident via the SAI process, it was suggested that an alternative methodology is used to derive learning from these cases. The decision to use the SCRR approach, as an alternative to SAI methodology, was taken in conjunction with SPPG and DoH's Urology Assurance Group. The Expert Review Team considers that this decision was the correct one, and that Structured Judgement Reviews methodology, such as that developed by the Royal College of Physicians, is a robust method of assessing the quality of care and treatment of individual cases, when applied as intended. As such, the Expert Review Team endorses the decision to adopt an alternative approach to undertaking repeated SAI reviews in such circumstances.

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Although the decision to proceed with the SCRR was taken prior to the announcement of the Urology Services Inquiry, the Expert Review Team noted that SHSCT continually referenced the SCRR process within the context of their broader work to meet the requirements of the Inquiry. However, the Expert Review Team understands that the Inquiry and the SCRR are separate processes and that these references to the Inquiry were likely to give rise to confusion.

The Urology Services Inquiry is an independent statutory process, supported by underpinning legislation, to deliver on its Terms of Reference; whereas the SCRR is a Trust and DoH-initiated process to establish themes of learning with a view to improving Trust systems to reduce the likelihood of similar incidents happening in the future. Whilst running in parallel to the Inquiry, the SCRR is an entirely separate process and is intended to derive learning and implement the necessary improvement to protect current patients.

During fieldwork, Trust representatives accurately described this distinction between the differing roles and purposes of the Urology Services Inquiry and SCRR, the relationship between the differing processes and the arrangements for sharing information with the Inquiry Team. However, upon reviewing Trust documentation, although the rationale for the SCRR is clearly stated, the Expert Review Team identified a lack of clarity in the documentation explaining the role, purpose and remit of the SCRR and, in particular, reinforcing that it is an entirely separate process to the Urology Services Inquiry.

Similarly, SHSCT SCRR documentation does not make clear whether the cases selected for SCRR are being reviewed on behalf of the Urology Services Inquiry.

This lack of clarity has potential to cause confusion since the Urology Services Inquiry Terms of Reference (ToR) include:

> (c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within SHSCT's urology specialty.

The Expert Review Team considered that, although Trust representatives demonstrated a good understanding of the distinction between these two processes, the patient / family information materials and Trust documentation were not clear. In the current format, the versions provided to the Expert Review Team do not adequately inform patients and families of the clear distinction between the Urology Services Inquiry and SCCR process, thus, have the potential to inadvertently cause confusion and compound anxiety and distress.

We were informed that SHSCT, in light of recent criticism regarding factually inaccurate information contained in patient letters, regarding the Urology Services Inquiry's purpose, has sought to improve the clarity and accuracy of documentation. The Expert Review Team was provided with a copy of a "Patient Letters Investigation" report which outline a thorough investigation undertaken by an experienced Director independent from the SHSCT and is accompanied by a number of sensible

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recommendations. The Expert Review Team commends this report and welcomes these improvement efforts. In addition to these, the Expert Review Team is of the view that SHSCT would benefit from improving their systems for developing and quality assuring patient / family information or indeed any documentation that is publicly accessible or likely to enter the public domain. Such arrangements should include the involvement of a lay person / service user representative and those with communications expertise within SHSCT. Where there is a pending or ongoing Public Inquiry, legal input could be considered to avoid confusion in interpretation of roles and remits.

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Recommendation 1

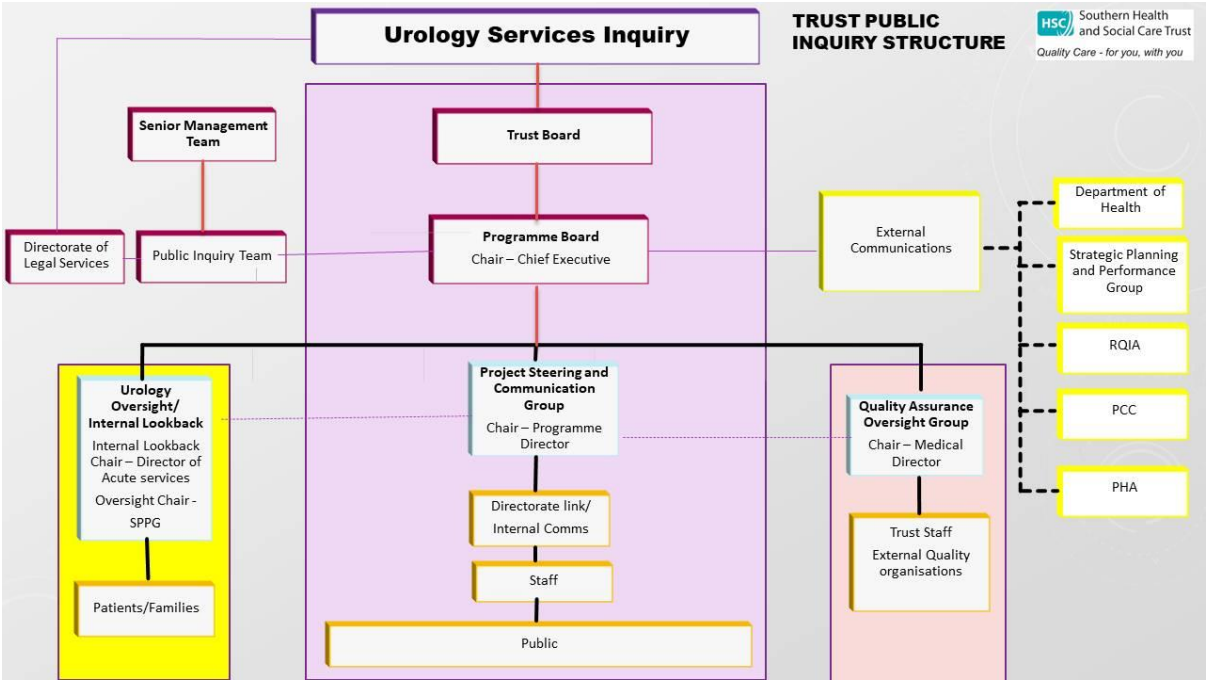
SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

2.1.2 Review Structure

Robust structures are essential for ensuring effective delivery, assurance and accountability. SHSCT provided details of the Review Structure and advised that the SCRR process sits within its current Trust governance structures.

Figure 1. Current Review Structure



We were informed that the Review Structure is presently overseen by SHSCT Internal Urology Lookback Group. SHSCT Public Inquiry Programme Board is chaired by the Chief Executive. The Programme Board members act on behalf of SHSCT Board to oversee the work of the:

- Public Inquiry Response and Communications Group;
- Public Inquiry Urology Oversight / Lookback Steering Group; and
- Quality Assurance and Improvement Oversight Group

The Lookback Review is included on the Corporate and Acute Services Risk Registers. External oversight of the process is provided by the fortnightly Service

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Planning and Performance Group (SPPG) Meeting and Department of Health led Urology Oversight Group.

ToR were provided for the Urology Services Inquiry Programme Board, Trust Internal Urology Lookback Group and Health and Social Care Board[ii] (HSCB) Urology Group. The Expert Review Team noted the broad remit of oversight and co-ordination groups and considered that some of the committees were very large, with overlapping membership. The Expert Review Team noted that the composition of the Lookback Review Steering Group (referred to as the Urology Oversight / Internal Lookback Group) does not reflect the Regional Guidance for Implementing a Lookback Review Process (July 2021)[2] which suggests inclusion of:

> "a Non-Executive Director, the Director of service/speciality concerned, relevant professional Executive Director(s), Risk and Governance representative, Head of Communications, Information Technology manager, Medical Records manager and senior service, representatives with expertise Public Health Agency (PHA) representative and an Health and Social Care Board (HSCB) representative (in the case where the Lookback Review has been identified as an SAI, the role on the Steering Group will be clearly identified to ensure that the independence of the PHA/ HSCB is not jeopardised). The organisation may also wish to consider a member of a relevant service user representative/advocacy group is included as a member of the Steering Group."

The Expert Review Team acknowledged the challenges and sensitivities of including a service user / advocacy representative who has been impacted by or has a vested interest in the matter of concern. However, the inclusion of a lay member, not impacted by SHSCT Urology concerns, but nonetheless with previous experience of representing the interests of service users / the public on similar pieces of work, can be hugely valuable and should be considered by SHSCT. The benefits include enhanced public confidence in the process, improved adherence to the statutory duty of Personal Public Involvement (PPI), provision of advice on patient / family / public messaging and on the fulfilment of a duty of candour.

The Expert Review Team considered that there was a lack of clarity surrounding leadership / responsibility and arrangements for accountability and reporting. During fieldwork, we were advised that the Chief Executive has ultimate accountability for the SCRR and that recent work had been undertaken to improve oversight, reporting and ensure clear lines of accountability. This resulted in a proposed new structure for oversight of the SCRR process. The Expert Review Team is of the view that any new structure should also be designed to support SHSCT to fulfil its responsibilities in respect of all Urology work, to deliver on SCRR objectives and should avoid creating unnecessary duplication or complexity.

The Expert Review Team was informed that the new structure exists in shadow form at present with the Operational Team being chaired by the seconded Director in a holding position until the new Director responsible for surgery takes up post.

Figure 2. Proposed New Review Structure (draft document at the time of the Review)

[ii]The Health and Social Care Board was replaced by the Service Planning and Performance Group (SPPG) April 2022.

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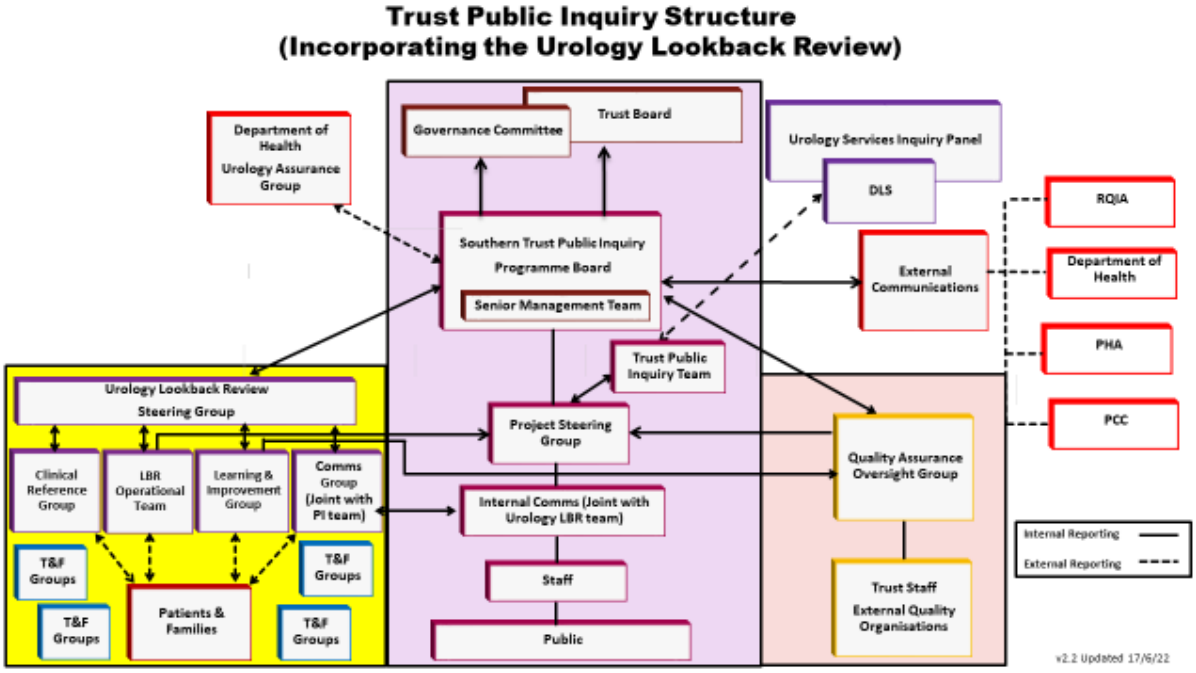

Although the Expert Review Team welcomes improvements to the overarching review structure, it is of the view that, given the sizeable undertaking and complexity of the work, the operational arrangements for management and co-ordination of the SCRR and potentially the Lookback Review itself, would benefit from the establishment of a dedicated project team. It was noted that one individual was seconded from another Trust to support SHSCT with its work and this was a welcome development; however, no other Trust representative attending the fieldwork sessions reported having experience of conducting Lookback Reviews. This represents a considerable lack of skill and experience, which can occur when there has been recent turnover or change within the management structures of an organisation. In light of this shortfall, the dedicated project team should include people with previous experience in undertaking similar work, who can draw upon a wide network of 'critical friends' to provide support, advice and guidance.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

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2.1.3 Project Management

Effective project management is crucial in ensuring a well-co-ordinated delivery of objectives within acceptable timescales; this is best implemented with the support of a project manager accredited in using validated project management methodology such as PRINCE / PRINCE 2.

SHSCT SCRR project is currently managed as a sub-workstream of SHSCT corporate lookback process rather than by an individual with project management expertise supported by dedicated project team. Furthermore, the process does not use a specific project management methodology and has followed an iterative approach in terms of its design, signoff and deployment.

To ensure identified project actions are undertaken, minutes are kept of screening and lookback meetings and these are carried forward into future meetings. Individual case records for SCRR are tracked to the relevant Expert Reviewer; ensuring updates can be sought on progress.

The Expert Review Team considered that, whilst these arrangements might suffice for small numbers of cases, they are not sufficiently robust for managing a large volume of work. The Expert Review Team is of the view that a dedicated project team for the co-ordination and management of the Lookback Review and SCRR process, should include a Project Manager; ideally such an individual should have previous experience in managing a Lookback Review or, in the absence of previous experience, should have an understanding of the process and should be supported by a network of people who have the requisite skills and expertise.

The Expert Review Team was advised that a proposal paper outlining an updated Lookback Review structure, process and accountability has been submitted to SHSCT Programme Board. In this paper it states that the Urology Lookback Review is a project and should be constructed as such in terms of purpose, ToRs, reporting lines, risk register etc., including the identification of / clarity on who is the Senior Reporting Officer (SRO) for the project; suggesting this should sit at Director level.

SHSCT further advised that this includes a review of the associated Project Management arrangements in order to ensure that the project progresses swiftly and with clear accountability. The Expert Review Team welcomes this approach.

Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

2.1.4 Terms of Reference / Objectives of the SCRR

A clear Terms of Reference (ToR) or, in lieu of a ToR, a set of specific objectives serves to focus the minds of those undertaking the Structured Clinical Record Review process on the purpose, remit and what needs to be achieved during the course of the

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process. Providing a framework for monitoring progress and accountability for delivery, it is also helpful in communicating the scope of work in a clear, open and transparent way; a Terms of Reference can also assist in conveying information about the process to interested parties, such as DoH, SPPG / PHA, Health and Social Care (HSC) Trusts, patients / families / carers and the public.

Unfortunately, there were no ToR / Objectives provided by SHSCT relating to the SCRR process itself. The Expert Review Team considers that a ToR should be drafted and agreed as soon as possible. Trust representatives were keen that this should adequately convey the clinical elements of the SCRR.

In light of this, a possible ToR could include:

1. To assess the quality of care and treatment provided by Consultant A, using Structured Judgement Review methodology which gives specific consideration to the following:

- Triage;
- Initial assessment;
- Diagnostic investigations;
- Outpatient care;
- Inpatient care;
- Perioperative care;
- Care during any medical or surgical procedure (excluding IV cannulation);
- Communication with colleagues, MDT and primary care;
- Communication with patient and families; and
- Discharge plan and follow-up arrangements.

2. To review the findings of the individual Structured Judgement Reviews and produce a thematic analysis report.

3. To identify learning and make recommendations for improvement.

The Expert Review Team also considered that it would helpful for SHSCT to explicitly state the purpose of the SCRR. It is referenced within the Review Methodology Section of the proposal document provided by SHSCT that “the objective of the SJR method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about the hospital systems where care goes well and to identify points where there may be gaps, problems or difficulty in the care process”. This is closely aligned to the purpose of the SCRR, which is ultimately for SHSCT to define, but may best be described as serving “to assess the quality of care and treatment, in order to identify learning and implement improvement”.

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Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

2.1.5 Time period for inclusion of cases for SCRR

All cases reviewed as part of the current Lookback Review undergo screening for consideration for inclusion in the SCRR process; those meeting the SAI threshold are 'screened in'. The scope of the Lookback Review pertains to all patients that were under the care of Consultant A during the time period 1 January 2019 – 30 June 2020. The Expert Review Team explored the rationale for this time period with Trust representatives. When concerns first came to light, this period was chosen as it was believed that this was when patients were most at risk from aberrant clinical practice.

The Expert Review Team acknowledges that no lookback exercise can review all cases at once, that there has to be a starting point, and that a phased approach is preferable in order to expedite learning and facilitate reflection; furthermore, to start with those patients identified as being most at risk is sensible, justified and in keeping with regional guidance. However, the Expert Review Team was informed that since then, it has been identified, by examination of historical care through the Patient Casenote Review process, that patients treated by Consultant A prior to 2019 may also have received substandard care. This is unsurprising; it is the Expert Review Team's experience that problems with a clinician's practice tend to be longstanding and not restricted to a particular period of time. We were advised that in light of this finding, the Royal College of Surgeons (RCS) is currently undertaking a review of a sample of 100 cases from 2015 in order to identify whether there were problems present at this stage

The Expert Review Team is of the view that if there is already enough evidence to inform a risk assessment that patient groups receiving treatment prior to 2019 are at risk of harm, SHSCT should not wait for the RCS work to conclude and should proceed as a matter of urgency to extend their Lookback Review to identify and recall at risk patients under the care of Consultant A prior to 2019. This can be done using a phased, risk-stratified approach based on the learning gathered to date. It can then be extended and scaled up further, following receipt of the RCS findings, should this be required. However, regardless of the approach adopted, given the risk posed to live patients, it is imperative that a further phase of the Lookback is commenced as a matter of priority.

Since this is likely to be a considerable undertaking, requiring suitable expertise to offer advice and guidance, it is vital that SHSCT is adequately supported by its partners across the HSC system, including DoH/ Urology Assurance Group / SPPG and PHA. As this work is scaled up, an independent assessment of the current Urology Lookback Review arrangements would serve to provide assurance regarding its effectiveness and identify any areas that need strengthened; this assessment could be undertaken by RQIA as a 'Part 2' to this review of the SCRR. Assurance of the current lookback arrangements would serve to strengthen the foundations in place for extending the time period and scaling up to include additional patient subgroups.

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Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

As there is a need to prioritise the Lookback Review, to ensure that patients at risk are promptly reviewed and that ongoing care and treatment is arranged, it may be preferable for an external body, such as the Royal College of Physicians, to undertake the SCRR on behalf of SHSCT. Not only would this allow Trust teams to focus on the Lookback Review whilst maintaining a safe level of care provision for its current and new patients, it would mean that the SCRR is conducted by an independent organisation that has the requisite expertise, governance structures, well tested processes and quality assurance mechanisms in place to support this type of work; consequently, the output may be more expedient and performed to a higher standard. However, the Expert Review Team acknowledges that commissioning an independent body may not be possible either due to a lack of agreement, resources or time, in which case the recommendations outlined in this report should support SHSCT itself to facilitate the SCRR.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

2.1.6 Case selection

Appropriate case selection is important to ensure effective use of time and resources, which should be prioritised towards cases where there is likely to be learning.

During fieldwork, Trust representatives outlined the process for case selection. All service users who were under the care of Consultant A between January 2019 and June 2020 were reviewed using a 10-question Patient Review form either internally by SHSCT or an external consultant urologist commissioned for this purpose. This 10-question Patient Review Form explored current as well as historical care. At a point in time, this list of questions was shortened to 4 questions which explored current care, following discussions with SPPG (formerly HSCB) who were keen that it mirror the approach used by the Belfast HSC Trust Neurology recall. It reverted back to 10 questions at the request of the Trust (and with agreement by SPPG) with all relevant case notes being assessed retrospectively to ensure consistency.

Where concerns regarding the quality of care are identified, these cases are then considered at a screening meeting, attended by the Trust's acute directorate governance and clinical staff, to establish if the concerns meet the threshold set out in

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the regional SAI procedure. Where the case meets the criteria for an SAI, it is progressed as an SCRR.

The Expert Review Team considered that if the aim is to identify all cases where there is likely to be learning, the use of SAI thresholds may not be the most effective method. This was explored with Trust representatives who were in agreement. We were advised that cases considered for inclusion in the SCRR included the following:

1. SAI threshold met; concerns around the care and treatment in keeping with a theme already identified
2. SAI threshold met; concerns around the care and treatment in keeping with an emerging theme, not previously identified
3. SAI threshold not met; nonetheless, learning identified
4. SAI threshold not met; care and treatment "reasonable"

The Expert Review Team is of the view that it is acceptable to include cases from Group 3. Although a case may not meet the criteria for an SAI review, it may still contain valuable learning from a patient experience or service quality perspective.

To date, 53 cases have been identified that meet the criteria for SCRR. This number is likely to increase further, particularly if the care and treatment of additional patient groups is going to be subject to an extension of the Lookback Review; a total in excess of 90 cases is expected to be identified from this phase alone.

During fieldwork the Expert Review Team heard that of the 53 SCRRs passed to the external SCRR urologists between February and May this year only 20 have been returned to date. This prolonged process poses challenges for the Trust as they are keen to establish the full extent of learning in relation to these cases.

Given time constraints and limited availability of expert reviewers, the Expert Review Team was keen to explore whether a sampling approach had been considered by SHSCT. Such an approach would seek to maximise learning within the constraints of available resources and may lead to improvements being implemented at an earlier stage.

During fieldwork, Trust representatives remarked on the similarity of themes across the cases that have already been reviewed. We were informed that there was very similar learning arising from 19 out of 20 cases reviewed to date. This supports an argument that a point of saturation might be reached and there may be limited additional benefit to reviewing all cases, as was initially intended.

The Expert Review Team recognises that a pragmatic approach to sampling would mark a departure from the original intention and direction of the SCRR. It would be the Expert Review Team's view that such a departure requires a clear rationale to be agreed by the DoH; this would require the purpose, scope and Terms of Reference for the SCRR review to be clearly articulated and defined. DoH should ensure that such an approach is justified when taking into consideration the wider context, including the planned work and emergent findings of the Urology Services Inquiry. The Expert Review Team's view is that a sampling approach would expedite learning and would allow an opportunity for earlier improvement to be implemented. However, there are

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ethical considerations and SHSCT should take steps to ensure that the sampling framework is robust and should be open and honest with patients and families about the approach and its rationale.

Understanding that some patients and families may be disappointed that their case is no longer going to be reviewed, SHSCT may wish to include an option for patients and families to request inclusion in the SCRR. If it is not feasible or reasonable to grant such a request, then the patient or family should be informed of the additional routes available to them, such as submitting a concern to the SHSCT Complaints Department, GMC, PSNI or any redress scheme. They should additionally be informed about the Urology Services Inquiry and directed to it's website for further information.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

2.1.7 Ethical Considerations

The application of ethical principles when conducting reviews of a complex and sensitive nature is invaluable to guide decision-making and ensure that the review is conducted in an open, transparent, fair and sensitive way. It can be helpful in ensuring a rigorous approach, adherence to a duty of candour, respect for confidentiality but also autonomy (i.e. right not to know) and in ensuring that specific patient groups are not inadvertently disadvantaged. It is also helpful when considering specific ethical issues that may arise from the process of reviewing patient cases, such as circumstances where previously undiagnosed or undisclosed hereditary conditions are identified.

SHSCT advised that no Clinical Ethics issues were identified for discussion with SHSCT Clinical Ethics Committee. The Expert Review Team is of the firm view that given the scale and sensitivity of the work involved, and the potential for inadvertent harm to be caused by the process, SHSCT would benefit from giving due consideration to the application of Ethical Principles. Advice from SHSCT Clinical Ethics Committee should be urgently sought and, if deemed necessary, this could be assisted by the HSC Regional Clinical Ethics Committee.

We refer SHSCT to a recently issued Ethical Framework[3], developed specifically for RQIA's Expert Review of Deceased Patients of Dr Watt, which contains overarching themes that are applicable to any lookback or review of this nature:

1. Respect for Persons (which includes Privacy, Confidentiality and Data Protection, and the Right to Know and the Right Not to Know)
2. Transparency and Candour

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3. Fairness
4. Responsibility

It was RQIA's experience that the process of discussing ethical principles and deliberating the potential for ethical issues is as valuable as the end product of any framework or ethical paper. In the context of the Expert Review of Deceased Patients of Dr Watt, it had wider benefits beyond ensuring that the methodology and the approach were ethically rigorous, and greatly assisted with the drafting of correspondence to families, and in the interactions with families by the RQIA Family Liaison Team.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

2.1.8 Legal Considerations

A legal perspective on review proposals and arrangements is prudent when undertaking work of this nature.

The Expert Review Team's experience is that it can be helpful across a number of areas including:

- Identifying previously unconsidered pitfalls in relation to correspondence with interested parties, proposed review methodology and approach;
- Ensuring there is appropriate indemnity for reviewers undertaking the SCRR;
- Managing data protection issues;
- Managing legal challenges from solicitors acting on behalf of patients / relatives;
- Managing legal challenges from Consultant A's legal team; and
- Requesting clinical records of patients reviewed by Consultant A in a private a capacity

Trust representatives advised that the Directorate of Legal Services (DLS) is supporting SHSCT with the Urology Services Inquiry and that an opinion could be sought if required. However, SHSCT advised that legal advice had not been sought as the SCRR is being utilised as an alternative of SAI to establish learning from the situation. The Expert Review Team considered that legal input would be required in order to make this determination and also to consider the potential for future legal ramifications.

It is the Expert Review Team's view that given the significance and scale of concerns, the likelihood of negligence and that this is a departure from the regional SAI process, a legal perspective should be sought in relation to the arrangements for SCRR.

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Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

2.2 METHODOLOGY AND IDENTIFICATION OF LEARNING

2.2.1 Patient and Family Engagement

There is a statutory duty of Personal Public Involvement as set out in the Health and Social Care (Reform) Act (Northern Ireland) 2009[4]. Best practice in involvement is to seek the input of service users and families to help shape the review process, particularly around sensitive person-centred communication, the provision of support and a mechanism for sharing concerns. There may be additional valuable information from affected service users / families that will not be evident in the clinical documentation of the clinician under investigation; information from families and carers is particularly vital in those cases where a patient has sadly deceased. Importantly, effective patient and family engagement is crucial in order to adhere to the principles of candour and 'being open'.

The regional SAI procedure stipulates the requirements for patient and family engagement. On 7 July 2022, the report of the RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland[5] was published; this has relevant findings on effective engagement and involvement of families and recommendations for strengthening the regional approach and procedure. Furthermore, a draft 'Statement of Rights' as an output of the O'Hara Inquiry may be helpful in focussing HSC Trusts on the importance of appropriate and sensitive interaction with patients and their families.

Although the SCRR is not an SAI process, the Expert Review Team is of the view that, as a minimum, patients and families should be informed of the purpose of the SCRR, and that those affected should have an opportunity to provide additional information about their care and treatment. SHSCT outlined their process for engaging and involving families. The Expert Review Team is impressed with and commends the significant efforts SHSCT has made in contacting all impacted families, which, given the scale, is a huge undertaking. However, we note recent issues arising regarding the quality of patient information and consider that the arrangements for patient and family involvement in both shaping the process and sharing concerns require improvement.

The Expert Review Team considers that SHSCT PPI team and those external to SHSCT, such as the PHA and Patient Client Council, have been underutilised in ensuring that there are robust arrangements for PPI as part of the Lookback Review and SCRR.

Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external

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partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

SHSCT outlined its arrangements for following up and sharing the findings of the SCRR with patients and family members. Although there is a Family Liaison Officer (FLO) available to support patients and families, the findings are primarily shared through postal correspondence. Whilst this may be the preference of a large number of families, many may require additional support to understand and emotionally cope with the findings.

The Expert Review Team consider the following to represent good practice[6,7,8]:

- As far as possible, reports should be quality assured, checked for factual accuracy, and should be written in easy to understand lay language;
- Patients / families should be provided with a range of options on how they wish to receive the report; one option should be a face to face meeting. They also have a right "not to know" the findings;
- The Family Liaison Officer should be accompanied by a medical doctor in relaying the findings of the report;
- Psychological support should be made available to those impacted by the process and findings of the SCRR;
- If further medical follow-up is required by patients or relatives, there should be Trust arrangements in place to facilitate this in a timely manner; and
- There should be opportunities for the FLO to debrief with colleagues and timely access to psychological support for the FLO and any others involved in family engagement.
- Independent advocacy should be considered for patients or families, particularly when cases are complex. The PCC have extensive experience in this area through previous work on SAIs and other Inquiries.

During fieldwork, the Expert Review Team explored the support available for those staff members involved in the review and, in particular, the patient and family engagement. SHSCT described effective provision of support including: senior and peer support, psychological support and access to Inspire Wellbeing Counselling service. The Expert Review Team is content that the arrangements for support appear sufficient but cautions that a substantial proportion of the work appears to be undertaken by one FLO. Given the large number of cases identified, it may be beneficial to increase the capacity of the Family Liaison Team to provide support to those impacted by the Lookback Review and SCRR.

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Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

2.2.2 Methodology & Tool

Structured Judgement Review methodology is a reliable, well validated tool that has been developed by the Royal College of Physicians. It allows for the blending of traditional, clinical-judgement based, review methods with a standard format. The approach requires reviewers to make safety and quality judgements on particulars of care, to make explicit written comments, and to assign a score for the quality of care at each phase. This produces a rich set of information about each case in a form that can be aggregated to produce knowledge about clinical services and systems.
SHSCT discussed the use of this tool with the Royal College of Physicians and opted for this methodology to underpin the SCRR process.

The Structured Judgement Review methodology was adapted for the SCRR in order to take into consideration the relevant phases of care. The phases of care assessed are:

- Triage;
- Initial assessment or review;
- Review of Diagnostics;
- Ongoing Outpatient Care;
- Admission and Initial Management;
- Ongoing Inpatient Care;
- Care during a procedure (excluding IV cannulation);
- Perioperative care; and
- Discharge plan of care.

The Expert Review Team is not privy to all the specific clinical concerns therefore cannot be certain that the tool adequately scrutinises all relevant aspects of care. With this caveat in mind, the SCRR tool generally appears reasonable. However, the Expert Review Team did note some areas that SHSCT may wish to address. There is some divergence from the RCP methodology in terms of the data collection instrument. There is no section to assess:

- Quality of documentation in the records;
- Communication between Consultant A and the patient / carer / family; and
- Communication between colleagues, MDT and primary care.

Whilst we were advised that deceased patients are included in the review, there are no sections outlining a review of the death certification or whether a referral to the coroner's service was required.

Of particular value in relation to deceased patients, but of great value for all cases, is the consideration of patient and family concerns. In general, there is a lack of patient

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and family input into the SCRR process. Patients and families were not engaged with in order to shape the review. Equally, there is no consistent mechanism to proactively seek the concerns of patients and families for consideration as part of the individual SCRR. This marks a considerable deficit in the information available to formulate findings. The experience of the Expert Review Team is that, where concerns from patients and families are taken into account, this greatly enhances the learning process and provides information and context that is often not present in the notes. RCP has successfully incorporated patient / family concerns into its review process by asking expert reviewers to review the notes firstly without knowledge of the patient / family concerns and then a second time taking the patient / family concerns into consideration. The complaint can then be judged to be 'upheld', 'partially upheld' or 'not upheld'.

RQIA's experience from the Expert Review of Deceased Patients of Dr Watt is that there is a close correlation between the views of family members and the judgement of the structured judgement tool (SJR), strengthening the argument that there is great benefit in attaining patient and family input. Where there is little or no correlation between the patient / family story and the clinical picture documented in the records, the Review Panel may determine that the family concern is 'not upheld'; of note, this only occurred for two (out of 44) patients included in Phase 2 of the Expert Review of Deceased Patients of Dr Watt.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Whilst Structured Judgement Tools provide an objective assessment of the care and treatment documented within the clinical records, it can only allow for a partial systems perspective. For example, it may tell a story of care and treatment according to the national standards of the time, of the standard and quality of documentation, multidisciplinary involvement, communication between colleagues and communication with family members. Of direct relevance, it will not examine factors such as caseload, working relationships and peer review.

Furthermore, it will not tell us about the governance systems within Urology Services or within SHSCT as a whole. It will not examine the role of external bodies and the wider system in providing oversight and assurance of quality and safety of care.
With this in mind, DoH or SHSCT Board may wish to commission RQIA to undertake a Review of Governance within Urology in Southern Health and Social Care Trust. This would provide an opportunity to identify and remedy any deficits, and to share learning within SHSCT and across the system so that governance systems may be strengthened and future harm prevented.

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Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

2.2.3 Expert Reviewers

Each case is reviewed independently by a 'Subject Matter Expert' (or Expert Reviewer) utilising the SCRR methodology. SHSCT provided details of Expert Reviewers, including a description of the job role and a copy of the guidance provided to reviewers at the outset of the work. The Expert Reviewers are nominated via the British Association of Urological Surgeons (BAUS) for their subject matter expertise. SHSCT ensures that each reviewer is appropriately registered and of good standing with their professional regulator, the General Medical Council (GMC). The Expert Review Team is content that reviewers appeared suitably independent and qualified.

In total, SHSCT approached 13 reviewers of which four Expert Reviewers have been recruited to support this work. Given the difficulty recruiting Consultant Urologists and the time consuming nature of the SCRR process, the Expert Review Team considered whether specialist nurse reviewers or urologists in training could be used instead. A clearly defined protocol with consultant oversight of the process would facilitate this. It was considered that a hierarchical culture within HSC, associated with perceptions amongst the Northern Ireland public that attaches particular significance to reviews undertaken by a consultant, may be a barrier to implementing a non-consultant review process. Therefore, if the work cannot be supported by specialist nurses or trainee urologists, consideration should be given to the use of doctors working outside the specialty of urology.

The Expert Review Team noted that no training was provided to Expert Reviewers, who instead were stated to be familiar with SJR tool methodology. In addition, there was no specific manual provided to reviewers; albeit the following guidance was provided:

- Using the Structured Judgement Review method - A guide for reviewers; National Mortality Case Record Review Programme 2019[9]; and
- Structured Judgement Review - Frequently Asked Questions 2019.

Additionally, the process had not been piloted and there was no method of calibration between reviewers to ensure inter-reviewer reliability and consistency. Importantly there is no mechanism for quality assuring the work of reviewers, either by assigning two reviewers to each case or by second-reviewing a sample of the cases.

The Expert Review Team notes that 20 SCRRs had been completed at the time of fieldwork; and while we understand the challenges in delivering quality assurance of reviews within the current limited pool of reviewers it may be beneficial to conduct an independent review by a second expert reviewer to ascertain the degree of reliability and consistency in assessing the quality of care. A panel should then be convened to discuss any significant discrepancies in judgement, to gain consensus and provide expert reviewers with an opportunity to standardise their approach.

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Even in the absence of discrepancies, it can be helpful for clinical reviewers to have a forum to discuss cases, debrief and avail of emotional or psychological support. Although it was reported that each reviewer can contact SHSCT Deputy Medical Director for Quality and Safety if issues arise, the Expert Review Team is of the view that SHSCT is missing an opportunity to proactively support reviewers, seek feedback on the process and seek reviewers' views on the learning arising.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feedback and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

2.2.4 Review Panel

Good practice dictates that in undertaking a review, an expert panel to deliberate findings and attain consensus on recommendations is preferable to the judgement of one individual expert. A forum for discussion between panel members allows for a sharing of expertise and perspective, brings a deeper and broader understanding of issues, mitigates bias and derives learning more effectively.

SHSCT stated that there is no specific review panel for the SCRR; however, the Trust Lookback Group oversees the overall lookback process that includes the SCRR. On completion of the initial batch of SCRRs, an independent Consultant Urologist will develop a thematic report on the findings.

The Expert Review Team considered that, as SHSCT has rightly identified that a key outcome of the SCRR is a thematic analysis in order to identify learning and inform system improvements, the process would benefit from a dedicated review panel rather than relying on the professional judgement of one individual to collate findings, identify themes and make recommendations. This was explored with Trust representatives during fieldwork, who advised that the RCS and BAUS had both been approached to undertake an independent quality assurance of the SCRR but SHSCT had not been able to secure agreement from either of these bodies. Subsequently SHSCT considered convening a multidisciplinary panel comprising eight individuals but due to limited resource and availability of staff this had not progressed. The Expert Review Team considers that a smaller panel, including urology, governance and lay expertise would suffice; encouragingly, Trust representatives were amenable to this model.

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The Expert Review Team is of the view that any learning and evidence-based recommendations made by the review panel would require a commitment from SHSCT to implement a clear prioritised action plan within acceptable timescales.

Recommendation 15

A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR process. This panel should include individuals with expertise in urology and governance, and include a lay member.

2.2.5 Identification and Dissemination of Learning

Dissemination of learning is crucial in order to improve systems for delivery of care both within SHSCT and across the region. Any strategy for the dissemination of lessons learned should be supported by DoH / SPPG / PHA and should incorporate an action log of the system improvements required, along with timescales for follow up and review.

SHSCT stated that each SCRR report will be reviewed by a Trust clinician who will identify if there is any previously unidentified learning. The thematic analysis report will also be considered by SHSCT in respect of broader system issues.

SHSCT advised that returned SCRRs are reviewed by a Trust clinician who will decide on the appropriateness of sharing learning more widely; this includes learning that should be shared beyond Trust boundaries. Mechanisms for sharing learning were stated to include:

- Using SHSCT local shared learning template;
- Regional shared learning template;
- Morbidity and Mortality Meetings (Patient Safety Meetings);
- Acute Governance Meetings (Directorate wide); and
- Urology and Cancer Services team meetings.

The Expert Review Team considered that the arrangements for identifying, implementing and disseminating learning required strengthening. The reliance on the professional judgement of one clinician to undertake a thematic analysis, in the absence of a mechanism for the reviewers to discuss and feedback, compounded by the lack of quality assurance of individual reports, risks that important system issues may go unidentified. Similarly, the reliance on a Trust clinician to determine whether learning should be shared wider, lacks independence, and runs the risk that one person acts as a gatekeeper to the implementation of improvement and dissemination of lessons learned.

As stated previously, a review panel with representation from urology, governance and a lay member would serve to ensure that there is a robust mechanism for deriving, implementing and making determinations on the dissemination of learning. Where learning is derived, the Expert Review Team would expect that recommendations are made and clear prioritised time-specific action plans are put in place with arrangements for monitoring and accountability. A follow-up review, with defined

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parameters for assessment around implementation, would provide assurance around the implementation of sustainable improvements.

The information provided by SHSCT indicates that the consideration of dissemination of learning is confined to within Trust boundaries; although a regional shared learning template is referenced, it is not clear whether this in itself would be sufficiently robust to disseminate learning to the relevant stakeholders across the system. SHSCT representatives were of the view that the previous HSCB process for sharing learning from SAIs needs to be adapted or replicated for the SCRR process but that this had not yet commenced. The Expert Review Team is of the view that the mechanisms for sharing learning should be discussed urgently with DoH / SPPG / Urology Assurance Group. Recipients should include Urology Services Inquiry, SHSCT Board, Urology Assurance Group, DoH / SPPG, PHA, and RQIA; under duty of candour principles, it should be considered whether there is an onus to share learning with the public. In any case, an effective strategy for communication with stakeholders would serve to underpin arrangements for the effective dissemination of learning.

Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

2.3 GOVERNANCE OF THE SCRR

2.3.1 Risk Management

Effective risk management relies on the identification, assessment, mitigation and monitoring of risk. All projects incur risks, such as risks associated with timescales, available expertise, budgetary constraints and data protection vulnerabilities. However, projects of this nature can carry considerable additional risk, such as the risk of causing harm to patients / families / public and reputational risk to the health service. It is vital that the structures, systems and processes in place support effective recognition and management of such risk.

The Expert Review Team was advised that the project does not keep a formal risk log; however, risks are recorded and discussed through meetings. At the time of review, there were three risks identified with mitigation actions identified for each.

When the Expert Review Team explored the issue of risk it was advised that the risks associated with the SCRR had progressed to both the directorate risk register for Acute Services and to the Corporate Risk Register.

The Regional Guidance for Implementing a Lookback Review Process (July 2021) states that:

> "When scoping the nature, extent and complexity of the Lookback Review Process (Section 2.6 – 2.7) the Steering Group should evaluate and escalate the risk in line with the organisation's Risk Management Strategy. This will

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ensure that the risk(s) identified will be included in either, the organisation's Board Assurance Framework, Corporate Risk Register or Directorate Risk Register and managed in line with the Risk Management Strategy."

The Expert Review Team was further advised that SHSCT is currently transitioning to a revised organisational structure, designed to fully support SHSCT to fulfil its function in respect of the SCRR objectives; this is currently operating in in shadow form. As a consequence, the project will operate under more robust governance structures with a live risk register maintained specifically for the Lookback Review. Issues of risk will also be included in the ToR for the new Urology Lookback Review Steering Group and SHSCT Public Inquiry Programme Board (note these are working titles which may change when the new structure is finalised). The Expert Review Team welcomed these improvements which will serve to strengthen the current arrangements for risk management.

2.3.2 Records Management

Effective management of clinical records requires protocols for retrieving, scanning and sharing records, underpinned by strong governance arrangements. SHSCT described robust arrangements for accessing and sharing of clinical records, which was in keeping with good information governance.

A list of patient names and health and care numbers of those cases identified for SCRR is shared with a dedicated administrator. When a decision is made to proceed with SCRR, the relevant patient records are obtained through normal hospital processes by request of hardcopy notes via the medical records team. Notes in patient charts which are not available on NIECR are copied, scanned and uploaded to Egress Secure Workspace, an electronic platform, for sharing with expert reviewers. Expert reviewers also have secure access to NIECR.

There is a dedicated member of the clinical governance team assigned to support the SCRR process, who is responsible for obtaining the charts, extracting the records for scanning and who also uploads to Egress Secure workplace and notifies and liaises with the external expert reviewers. The Expert Review Team considered this approach to be acceptable.

2.3.3 Data Considerations

SHSCT outlined their arrangements for data protection. Document transfer is managed via SHSCT Egress document sharing platform and also via secure VPN access to NIECR records. Each Expert Reviewer is required to complete a Trust confidentiality agreement and Data protection agreement prior to accessing records.

The Expert Review Team identified a potential General Data Protection Regulation (GDPR) issue with the arrangements for contacting families. SHSCT would benefit from further consideration of information governance, and in particular, data protection issues in relation to SCRR.

Given the sizeable number of patients involved, a database is beneficial to track progress of the Lookback Review / SCRR, to analyse demographic and clinical

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information, and to monitor outcomes. SHSCT is presently developing a new database to store and analyse information in relation to the selected cases. Unlike the previous database which relied on manual population, the new database allows for automatic population, reducing the risk of input error. The Expert Review Team welcomes this development and advises that a statement of purpose should be drafted for the new database, outlining the rationale for transferring data; a copy of the old redundant file should be retained in case it needs to be examined at a later stage. If deemed to be helpful, SHSCT could be signposted to regional experts who recently developed a database as part of the neurology live patient recall.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

2.3.4 Communication with Stakeholders

Effective communication with stakeholders ensures that there is clear, consistent messaging on the purpose, remit, progress and findings of any review. It also facilitates liaison and co-operation regarding specific aspects of the work where external input is required in order to achieve a particular outcome. The need for robust stakeholder communication is referenced within the Regional Guidance for Implementation of a Lookback Review which highlights that the principle of 'no surprises' should be adopted and outlines that there should be:

- An agreed communication plan/liaison plan for other HSC organisations or independent/private providers which might be affected;
- An agreed media/communications management plan if required, that aims to be proactive in disclosure to the general public and considers responses to media enquiries; and
- Engagement with PSNI and coroner's service in line with standard procedures.

In addition to the above stakeholders, there should also be a channel of communication established with the GMC via the HSC Trust's Responsible Officer. All these elements are best considered as part of a comprehensive Communications Strategy developed for the specific Lookback Review.

SHSCT advised that when completed, the SCRRs are planned to be shared with the Urology Services Inquiry along with the thematic review of cases. Additionally, DoH will be provided with updates on the process via the Urology Assurance Group. SHSCT advised that the Coroner will be notified if there is a potential issue identified via the SCRR processes which has not previously been identified via Trust processes.

The Expert Review Team considers that there is an absence of an overall communication and stakeholder engagement strategy. It is also noted that there is no channel of communication established between SHSCT and PSNI or GMC. The GMC is likely to be interested in the findings, which will be relevant to the Fitness to Practice (FTP) investigation of the consultant concerned. In addition, there is a possibility that the harm found could be of PSNI interest in terms of possible assault, gross negligence, or in extreme cases, manslaughter. The Expert Review Team considers

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that a Communications Strategy should be developed and examples from recent lookback exercises or similar review work across the region may assist SHSCT in expediting this.

Recommendation 18

SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

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Section 3 Conclusion and Recommendations

3.1 Conclusion

RQIA acknowledges the commitment of SHSCT to ensuring that this work is undertaken a manner that is robust and effective in deriving learning and informing improvements. This was evident, not only by the fact that SHSCT approached RQIA to request this review, with the aim of providing assurance, but also in the Expert Review Team's engagement with Trust representatives and staff during fieldwork. We acknowledge the amount of time and effort that SHSCT staff have given to this piece of work and commend their openness, candour and willingness to learn from the expertise of the Expert Review Team. This positive engagement and 'buy in' will assist SHSCT in implementing the necessary improvements.

RQIA was initially approached to provide independent assurance of the SCRR methodology. During preliminary discussions with SHSCT, we determined that this assurance should be broadened to include the wider process, governance and framework surrounding the SCRR process. This was felt to be particularly important given that the SCRR arose as a result of a significant number of SAIs which were identified through SHSCT Lookback Review, at which point the decision was made to adopt alternative methodology to the SAI process. The Expert Review Team endorses this decision. Structured Judgement Methodology, when applied appropriately, is a reliable, validated methodology which offers an effective means of deriving learning and implementing improvements.

However, when examining the SCRR process within the context of the Lookback Review, it was apparent to the Expert Review Team, that the Lookback in itself is not only a significant undertaking for SHSCT but its progression is a matter of urgent priority. An assessment of the historical care of patients, whose cases had undergone the screening process for SCRR, identified deficits in care and treatment prior to 2019. SHSCT is presently conducting a risk assessment and has commissioned RCS to undertake a review of cases relating to 2015 which should assist SHSCT in determining the future scope and scale of their Lookback. The Expert Review Team is of the firm view that SHSCT should not wait until this work concludes, and based on the evidence SHSCT has gathered to date should proceed to review and recall further groups of patients which it has identified to be at risk of harm.

Understanding that this is a considerable undertaking and that issues have already been identified regarding the availability of expertise and resource to support the Lookback Review, SHSCT will require significant support from the wider HSC system: DoH, SPPG, PHA and RQIA. A dedicated, appropriately resourced and experienced project team should be established as soon as possible to support this work. This may require secondment of additional individuals with the relevant skills and experience to SHSCT. RQIA recognises the efforts SHSCT has already undertaken to improve its lookback arrangements and is keen to support SHSCT with further improvements. As RQIA is best placed to provide assurance on the current arrangements to ensure strong foundations for scaling up and extending the Lookback time period, we recommend that RQIA undertakes a follow-up piece of assurance work looking specifically at the Lookback Review. Going forward, in order to allow SHSCT to focus on the Lookback Review, ideally the SCRR should be undertaken by an independent

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body. The Expert Review Team understands that SHSCT may not be able to secure the support of an external organisation; therefore, we make a number of recommendations to strengthen the existing SCRR process and arrangements.

SHSCT should explicitly state the purpose of the SCRR and draft a Terms of Reference as soon as possible. Caveated with the fact the Expert Review Team is not privy to all specific clinical concerns, the tool itself appears reasonable, but it does deviate from the tool used by RCP and leaves a number of areas unexamined such as quality of documentation. In addition, given that a proportion of patients are deceased, it would be judicious to update the tool to take into consideration death certification and the need for coronial referral. The Expert Review Team advises that SHSCT liaise with RCP to ensure the tool is appropriately aligned and that SHSCT mirrors RCP's approach to considering patient and family concerns as part of the SCRR process.

The arrangements for patient and family involvement require significant strengthening. Inclusion of lay membership on the relevant project groups would ensure SHSCT meets its statutory duty of patient and public involvement. The Expert Review Team also provides advice on best practice in involving, listening to and supporting patients and families through processes such as these in a way that reduces the potential for further harm and serves to restore faith in the health service. Given the scale, complexity and sensitivity of the work involved, due consideration should be given to seeking an ethical perspective on arrangements through SHSCT Clinical Ethics Committee.

RQIA notes the large number of cases that have been identified for SCRR and the difficulty this poses in terms of conducting SCRRs within reasonable timescales, compounded by the limited number of expert reviewers. A sampling approach is pragmatic and effective in deriving learning within the constraints of time and resource. However, this requires a clear purpose; ToR; agreement with DoH / Urology Assurance Group; due consideration of ethical considerations; and considered and sensitive engagement with patients and families. Importantly, where cases are selected for review, this should be done to a high standard.

A document should be developed to guide reviewers through the SCRR process and there should be a mechanism for calibration between reviewers to ensure consistency and inter-reviewer reliability. Additionally, a sample of the cases should be subject to second review for quality assurance. Understanding that this is challenging to achieve within reasonable timescales with a limited number of reviewers, the Expert Review Team recommends that SHSCT considers recruiting non-urology consultants to review the cases, guided by a defined protocol and with appropriate expert oversight.

Whilst the outcome of individual case reviews will be valuable to patients and families in terms of understanding what went wrong and why, it is the overall learning derived from the SCRR process that will assist SHSCT and the region in improving its systems. Therefore, it is vitally important that SHSCT strengthens its arrangements for identification and dissemination of learning. A review panel comprising members with expertise in urology and governance, and a lay representative should be established to deliberate findings, derive learning and make evidence-based recommendations. Equally, the mechanisms for sharing learning require an effective dissemination

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strategy to be agreed with DoH / SPPG and PHA. Underpinning this, communication with stakeholders including GMC, Coroner's Service and PSNI requires to be underpinned by a Communication Strategy and established channels of communication. Furthermore, the arrangements for sharing information with the public under a duty of candour and for developing patient and family information require considerable strengthening. Encouragingly this is already being explored by SHSCT in light of concerns surrounding factual accuracy of previously issued patient correspondence.

On the whole, the challenges facing SHSCT are considerable, complex and require a concerted effort with appropriate involvement of a number of organisations; DoH / SPPG, PHA and RQIA. Retaining the focus on patient safety, the Lookback Review requires urgent support and upscaling. Whilst SCRR will be valuable in establishing deficits within the care and treatment of this patient population, it is limited in terms of deriving systems and governance learning. As such, RQIA advises that a Review of Governance of Urology Services would be crucial in terms of providing assurance around the current service. RQIA is committed to providing both independent assurance and improvement support to SHSCT as it continues its efforts to urgently address deficits in care whilst improving the quality and safety of SHSCT urology services.

3.2 Summary of Recommendations

Recommendation 1

SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.

SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.

Recommendation 2

SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for Implementing a Lookback Review Process; in particular, consideration should be given to the inclusion of a lay representative.

SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.

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Recommendation 3

Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.

Recommendation 4

SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be agreed and referenced within the relevant Trust documentation.

Recommendation 5

SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.

RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.

Recommendation 6

SHSCT should consider commissioning an independent body to undertake the SCRR process on its behalf.

Recommendation 7

SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT.

Recommendation 8

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.

Recommendation 9

SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.

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Recommendation 10

SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback Review and SCRR.

Recommendation 11

SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the Expert Review Team in this report.

Recommendation 12

SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT should consider facilitating the consideration of patient / family concerns as part of the SCRR to mirror the approach undertaken by RCP.

Recommendation 13

DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.

Recommendation 14

SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feedback and avail of emotional / psychological support if required.

A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.

A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and consistency. Consideration should be given to quality assurance of a defined sample of cases for the remainder of the SCRR.

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Recommendation 16

SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is shared regionally with all relevant stakeholders and the public is effectively informed under duty of candour principles.

Recommendation 17

SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant file on record.

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SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process.

A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.

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Appendix 1: Terms of Reference for the Statutory Independent Public Inquiry into Urology Services in the Southern Health and Social Care Trust

(a) To review the Southern Health and Social Care Trust's (the Trust) handling of relevant complaints or concerns identified or received prior to May 2020 and its participation in processes to maintain standards of professional practice. The Inquiry shall determine whether there were any related concerns or circumstances which should have alerted the Southern Trust to instigate an earlier and more thorough investigation over and above the extant arrangements for raising concerns and making complaints.

(b) To evaluate the corporate and clinical governance procedures and arrangements within the Trust in relation to the circumstances which led to the Trust conducting a "lookback review" of patients seen by the urology consultant Mr Aidan O'Brien (for the period from January 2019 until May 2020). This includes the communication and escalation of the reporting of issues related to potential concerns about patient care and safety within and between the Trust, the Health and Social Care Board, Public Health Agency and the Department. It also includes any other areas which directly bear on patient care and safety and an assessment of the role of the Board of the Trust.

(c) To examine the clinical aspect of the cases identified by the date of commencement of the Inquiry as meeting the threshold for a Serious Adverse Incident (SAI) and any further cases which the Inquiry considers appropriate, in order to provide a comprehensive report of findings related to the governance of patient care and safety within the Trust's urology specialty.

(d) To afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry.

(e) To review the implementation of the Department of Health's "Maintaining High Professional Standards Policy" by the Trust in relation to the investigation related to Mr O'Brien. The Inquiry is asked to determine whether the application of this Policy by the Trust was effective and to make recommendations, if required, to strengthen the Policy.

(f) To identify any learning points and make appropriate recommendations as to whether the framework for clinical and social care governance and its application are fit for purpose.

(g) To examine and report on any other matters which the Chairman considers arise in connection with the Inquiry's investigations in fulfilment of these Terms of Reference.

The clinical practice of Mr O'Brien is being investigated by the General Medical Council (GMC) and it would, therefore, be inappropriate for the Inquiry to encroach on the GMC's remit. The Inquiry shall submit a report as soon as practicable to the Minister for Health. Should the Inquiry as part of its investigation establish any issue of concern which it believes needs to be brought to the Minister's immediate attention, then this will be done.

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Appendix 2: Structured Judgement Review[10]

Case note review remains a prime means of retrospectively assessing quality of patient care. Implicit review is based on clinical judgement and is judged to be effective in identifying and recording the detail and nuance of care (both unsatisfactory and good).

Unstructured implicit review was criticised for low inter-rater reliability (high variability) and for potential reviewer bias. Structured implicit review methods require reviewers to use a judgement based structured explicit scale to rate quality of care from very poor to excellent. However, this form of review only provides a scale based quantitative result giving no indication of why a reviewer made a particular judgement. This means that it is useful for large scale monitoring or epidemiological studies of adverse events but is less effective for more detailed review at ward or hospital level of why an event occurred.

To increase the value of structured review in reviewing the whole spectrum of care quality, rather than focussing only on adverse event rates, a methodology was developed where reviewers were required to provide implicit clinical judgements and to write explicit comments to support judgement based quality of care scores: this forms the basis of Structured Judgement Review.

Structured Judgement Review requires reviewers to make safety and quality judgements over phases of care, to make written comments about care for each phase and to score care for each phase.

The objective of this review method is to look for strengths and weaknesses in the caring process, to provide information about what can be learnt about hospital systems where care goes well and to identify areas where there may be gaps, problems or difficulties with the care process. It can be used for a wide range of hospital based safety and quality reviews across services and specialties and not only for those cases where patients die in hospital. The quality and safety of care may be judged and recorded whatever the outcome of the case and good care is judged and recorded in the same detail as care that may have been problematic.

There are two stages to the review process.

Stage One

Carried out by ‘front line’ reviewers who are trained in the method and who undertake reviews within their own services, for example in Morbidity and Mortality Reviews.

Phases of care – the ‘structure’ part of the process.

Phases of care are shown below but may be varied depending on the type of care or service being reviewed:

- Admission and initial care – first 24 hours
- Ongoing care
- Care during a procedure

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- Perioperative/procedure care
- End of life care (or discharge care)
- Overall assessment of care

Explicit Judgement Comments

Explicit judgement commentaries provide:

- The means for the reviewer to concisely describe how and why they assess the safety and quality of care provided.
- A commentary that other health professionals can really understand if they subsequently look at the completed review.

Phase of Care Scores

Care scores are recorded after judgement comments have been written and the score is itself an overall judgement of the reviewer. Scores range from excellent to very poor.

1. Very poor care
2. Poor care
3. Adequate care
4. Good care
5. Excellent care

Judging the quality of recording in the case notes.

As part of the overall assessment, the reviewer is also asked to record their judgement on the quality and legibility of the records again using a score of 1-5.

Second Stage Review

A score of 1 or 2 is given when the reviewer assesses that care has been poor or very poor. A score at this level should trigger a second stage review through the hospital governance process.

A second stage review also uses the structured judgement method and takes place if a patient has died. If the second stage reviewer broadly agrees with the initial case review a decision may be taken to carry out a further assessment concerning the potential avoidability of the patient's death.

The judgement is framed by a 6 point scale. A score of 1,2 or 3 on the avoidability scale would indicate a governance 'cause for concern'.

1. Definitely avoidable
2. Strong evidence of avoidability
3. Probably avoidable (more then 50:50)
4. Possibly avoidable, but not very likely (less than 50:50)
5. Slight evidence of avoidability
6. Definitely not avoidable.

Received from Briege Donaghy 15/01/2024. Annotated by the Urology Services Inquiry.

Structured Judgement Review can produce learning at two levels:

- The detail captured can identify both poor practice and good practice of individual clinicians.
- When multiple reviews are undertaken within a clinical area or a hospital, a thematic analysis can be performed that may highlight systemic issues in a system.

Quantitative data identify very poor to excellent care in a number of care phases. Qualitative data from explicit judgements may be analysed, for example using word detection software, to identify recurrent themes.

Received from Briege Donaghy 15/01/2024. Annotated by the Urology Services Inquiry.

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[3] Ethical Framework to Inform Phase Two of the Expert Review of Records of Deceased Patients of Dr Watt April 2021. Available at b996b934-f707-4206-b1c9-1e7d706bd5ec.pdf (rqia.org.uk) Cited July 2022

[4] Health and Social Care (Reform) Act (Northern Ireland) 2009. Available at Health and Social Care (Reform) Act (Northern Ireland) 2009 (legislation.gov.uk) Cited July 2022

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[6] IHRD Workstream 5: What you should expect in relation to a Serious Adverse Incident Review in a Health and Social Care setting (Version 2: February 2019). Available at IHRD Workstream 5 - Serious Adverse Incidents - What to Expect irt SAI Review.pdf (health-ni.gov.uk) Cited July 2022

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[8] Involvement Tools and Guides. Available at Involvement Tools and Guides - Engage (hscni.net) Cited July 2022

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[10] Information taken from the Royal College of Physicians: Using the structured judgement review method. Guide for reviewers (England). Available at https://www.rcplondon.ac.uk/sites/default/files/media/Documents/NMCRR%20guide%20England_0.pdf Cited July 2022

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The Regulation and Quality Improvement Authority

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RQIA SCRR Review Recommendations

Action Plan

Summary

Total Number of Trust Actions = 25

Date	Progress RAG Rating	Number
24/10/22		8
		14
		3
18/11/22		9
		13
		3
16/12/22		18
		5
		2

Southern Health and Social Care Trust

Quality Care - for you, with you

RQIA SCRR REVIEW RECOMMENDATIONS IMPLEMENTATION PLAN

RECOMMENDATION 1				
1 (a) SHSCT should urgently update all relevant documentation to ensure that there is clarity regarding the SCRR including a description of the SCRR purpose, remit and process; explicitly stating that it is a separate process to any parallel Inquiries or investigations.				
Action Required to Deliver Recommendation(s)	**Responsible Officer[1]?**	**Update**	**Status RAG**	**Evidence pf Completion**
Update PID – with detail and purpose of SCRR,	LBR Project Manager (LE)	**20/10/22** – work commenced on this **18/11/22** - draft complete being reviewed prior to being finalised **16/12/22 -** Complete	Complete	Report
Draft a "stand-alone" summary of the background, purpose, objectives and process of SCRR	LBR Project Manager (LE)	**20/10/22** – work commenced **18/11/22** - draft complete being reviewed prior to being finalised **16/12/22 -** Complete	Complete	Report
1(b) SHSCT should review their arrangements for developing and quality assuring patient / family information materials and publicly accessible information to ensure there is adequate lay / service user involvement, communications expertise and, where beneficial, legal input.				
Add lay representation to the Urology Lookback Review steering and operational group.	Head of the Lookback Review (SW)	**20/10/22** – Lay representation sought via PPI team in Trust **18/11/22** - no further progress **16/12/22** – Two lay reps identified and joining Operational & Steering Groups	Complete	Emails confirming TOR
Patient / family information materials required for Phase 2 to be activity considered by Lay representatives and tested within other PPI forums either internal or external to Trust.	This is an action for the future – will be addressed and evidenced in phase 2			

[1] Responsibility for delivery this action plan sits with the SRO for the LBR who is chair of the LBR Steering Group (MOH)

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 2				
2(a) SHSCT should consider reviewing the composition of Lookback Review steering group to reflect that which is stated within Regional Guidance for				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Reorganise structures for the LBR process and reset role and function of steering group including membership	Chair of Steering Group (MOH)	**20/10/22** – complete	Closed	- Terms of Reference for Steering Group - Diagram of new structure
2(b) SHSCT should establish a dedicated project team for the management and co-ordination of SCRR. SHSCT should recruit people with the skills and experience who, if required, can seek the advice and guidance of experts from across the region.				
Lookback Review in line with project management principles and processes. Draft PID to summaries the LBR process	Chair of Steering Group (MOH)	**20/10/22** – complete – new structure and process	Closed	- PID - New structure and process in place to include clarity on reporting and accountability

RECOMMENDATION 3				
Considering the need for dedicated co-ordination and management of the Lookback Review and the SCRR process; SHSCT should prioritise the appointment of a suitably qualified Project Manager.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Appoint project manager to oversee the implementation of the Lookback Review in line with project management principles and processes	Chair of Steering Group (MOH)	20/10/22 – complete LE in post from 1 September 2022	Closed	- Staff in post

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 4				
4(a) SHSCT should define and explicitly state the purpose of the SCRR process. Furthermore, a clear Terms of Reference / set of objectives should be				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Same as per recommendation 1(a) above	See recommendation 1(a) above	**20/10/22** – work commenced **18/11/22** - draft complete being reviewed prior to being finalised **16/12/22 -** Complete	Complete	Report

RECOMMENDATION 5				
5(a) SHSCT should give urgent consideration to extending their Lookback Review to identify and recall further groups of patients. DoH / Urology Assurance Group / SPPG, PHA and RQIA should work together to support SHSCT with the Lookback Review.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Draft options paper for extending the Urology Lookback Review and progress with option agreed by UAG.	Chair of Steering Group (MOH)	**20/10/22** – work commenced **18/11/22 –** Options paper shared with UAG on 17 November	Complete	Options paper
5(b) RQIA should consider undertaking an independent assessment of Trust arrangements for the Urology Lookback Review in order to provide assurance on its effectiveness and identify any areas for improvement.				
RQIA to action not Trust				

RECOMMENDATION 6

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RSC requested – not accepted SCRR process is currently outsourced to individual external urologists accessed via BAUS. Request to be made to RCP	Dep MD (DG)	**20/10/22** – unable to secure RCS to undertake this work, **18/11/22 –** IS (3FiveTwo) sourced – IS contract being urgently drawn up to commission this work **16/12/22 –** Complete		Emails from RSC Emails with BAUS First tranche (14 cases) passed to IS on 13 December

RECOMMENDATION 7				
SHSCT should consider implementing a sampling approach to case selection for SCRR. Such an approach should be agreed with DoH / Urology Assurance Group / SPPG. SHSCT should be clear on the rationale, its benefits and limitations and ensure that there is openness and transparency in communication with patients, families and the public. SHSCT should engage the Clinical Ethics Committee to consider any ethical issues arising from such an approach which can then be addressed and mitigated by SHSCT				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Sampling approach to case selection for SCRR to be included in the options paper on progressing with the SCRR process for consideration by UAG	Chair of Steering Group (MOH)	**20/10/22** – work commenced – **18/11/22** – to be further clarified when IS contract in place **16/12/22** – All of the outstanding cases (29) of the original 53 cases will be passed to IS. Consideration will be given to sampling the remaining 38 plus any new SCRRs added at screening in the NY	Ongoing	

RECOMMENDATION 8

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

SHSCT should request SHSCT Clinical Ethics Committee to review both current and proposed arrangements for the Lookback Review and SCRR. Where ethical issues are identified, SHSCT should give this due consideration and, where required, adapt the methodology and approach for the review.				
Action Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence of Completion**
Papers on SCRR and extending the Lookback Review to be shared with Trust ethic committee when complete	TBA	**20/10/22** - Not yet commenced – to discuss with new Medical Director when he takes up post **18/11/22 –** no update **16/12/22** – no update	Not started	

RECOMMENDATION 9				
SHSCT should engage with Trust legal representation to obtain a legal perspective on the arrangements for the SCRR.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Share SCRR related papers with DLS	Chair of Steering Group (MOH)	**20/10/22** - Current SCRR process arrangement shared with DLS. The options paper on the way forward re SCRR will be shared with DLS when complete and prior to discussion with UAG. **18/11/22** – to be further considered if SCRR to change when IS contract in place. **16/12/22** – unchanged	Ongoing	

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 10				
SHSCT should review their arrangements for the involvement of patients and families to ensure that it fulfils its statutory duty of Personal Public Involvement. SHSCT should consider engaging those with Personal Public Involvement expertise and external partners such as the PHA who have PPI training resources for staff and the PCC who could provide advice and support in the involvement of patients and families as part of the Lookback				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
As per recommendation 1(b) add Lay representation to the Urology Lookback Review steering and operational group. Provide information and bespoke induction of new Lay representatives to assist in contributing to the Lookback Review	Head of the Lookback Review (SW)	**20/10/22** – Lay representation sought via PPI team in Trust **18/11/22 –** no update while Head of LBR is unavailable **16/12/22** – Two lay reps identified and joining Operational & Steering Groups	Complete	Meeting with Head of LBR and 2 lay reps Information pack

RECOMMENDATION 11				
SHSCT should review their arrangements for sharing SCRR findings with patients and families giving consideration to good practice as outlined by the				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Share current process for communicating with patients / families re SCRR outcomes with DLS for feedback and advice.	Chair of Steering Group (MOH)	**20/10/22** – As per DLS advice for an individual patient –patients to be offered either report in full or summary from section 2.11. Letter also includes opportunity to discuss the finding with clinical team face to face and separately an offer of a clinical appointment with consultant urologist. Also includes an unreserved apology from the CX on behalf of the Trust	Completed & Closed	Email from DLS (21/7/22)

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 12				
SHSCT should liaise with RCP and consider amending the Structured Clinical Record Review tool to include an assessment of the quality of documentation and an assessment of the documented communication with patients and families; the clinical team, MDT and primary care. SHSCT				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Consider the above recommendation	Chair of Steering Group (MOH)	**20/10/22** – recommendation considered and decision taken not to change SCRR inter-process as calls into question the validity the work done previously.	Closed see below re next phase of LBR	
SCRR process to be reviewed - if being utilised for the extended cohort of patients. This recommendation to be applies at that time.	This is an action for the future – will be addressed and evidenced in phase 2			

RECOMMENDATION 13				
DoH should commission RQIA to undertake a Review of Governance Arrangements within Urology Services in Southern HSC Trust.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
DOH to action not Trust				

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 14				
14(a) SHSCT should not be limited to consultant urologists when recruiting clinical reviewers to undertake the SCRR process. All Expert Reviewers should be provided with guidance and support, including an opportunity to debrief, feedback and avail of emotional / psychological support if required.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Establish if RCP can facilitate the SCRR process	DMD (DG)	**20/10/22** – await feedback from RCP **18/11/22 –** no further feedback – response chased **16/12/22 –** Complete – IS contract in place	Complete	Contract Returned reports from IS
SCRR process to be reviewed - if being utilised for the extended cohort of patients. This recommendation to be applies at that time.	This is an action for the future – will be addressed and evidenced in phase 2			
14(b) A document should be drafted specific to this particular piece of work to guide reviewers through the process of conducting the SCRR; this should include a defined protocol for the assessment of the quality of care and treatment.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Review the document that currently exists for the SCRR reviewers and update it in terms of good practice identified in RQIA review document as the basis for further review should SCRR continue to be utilised in the extended Lookback Review.	Project Manager (LE)	**20/10/22** – This work has commenced **18/01/22 -** Draft guideline on completing SCRR reports shared with the MDO for feedback	Ongoing	

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

14 (c) A sample of cases already reviewed using the SCRR methodology should undergo a second review to ensure inter-reviewer reliability and				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Consider this action	Chair of Steering Group (MOH)	**20/10/22** – recommendation considered – due to lack of SCRR reviewers it is not possible to undertake a second review of a sample of the returned SCRR reports. For this cohort of patients a comparative analysis of reasons for SCRR verse findings from SCRR has been undertaken and both align	Closed see below re next phase of LBR	SCRR theming analysis
SCRR process to be reviewed - if being utilised for the extended cohort of patients. This recommendation to be applied at that time.	This is an action for the future – will be addressed and evidenced in phase 2			

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 15				
A review panel should be constituted, for the specific purposes of identifying learning and determining recommendations arising from the SCRR				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Commission a "Thematic Review" undertaken when all 53 SCRR reports and complete.	Medical Director	**20/10/22** – an external urologist identified to complete this work when the report are returned. Currently on 24 of the 53 reports have been returned. **18/11/22 –** no further SCRR returned **16/11/22** – Meeting with Dr Sally Williams on 13/12 – Dr Williams agreed to coordinate a thematic Review when SCRR complete	Ongoing	
Provide an analysis of the themes identified by Trust senior doctors through the internal "SCRR Screening" process and complete to themes identified external SCRR urologists	Head of the Lookback Review (SW)	**20/10/22** – Complete and will be kept up to date as reports are returned	Closed	Up to date report available

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 16				
SHSCT should work with DoH / SPPG / PHA to develop an effective dissemination strategy for the Lookback Review and SCRR so that learning is				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Agree and document the process(s) for disseminating regional learning following the Lookback Review for consideration by UAG	Head of the Lookback Review (SW)	**20/10/22** – work commenced **18/11/22 –** no update to report **16/12/22** – no further progress	Ongoing	
Update Communication plan to include this aspect of communication	Project Manager (LE)	**20/10/22** – cannot commence until above action completed **16/12/22** – no change	Not started	

RECOMMENDATION 17				
SHSCT should draft a statement of purpose for the new database, outlining the rationale for transferring data and should retain a copy of the redundant				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Draft a "Statement of Purpose"	Project Manager (LE)	**20/10/22** – Copy in draft awaiting review and sign-off **18/11/22** – no update to report **16/12/22** – not signed off until cross-reference against template requested from BOH (via RQIA) – not yet received **06/03/2022** – awaiting nominations from IG and Informatics to finalise draft document	Ongoing	

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

RECOMMENDATION 18				
18(a) SHSCT should urgently develop and implement a communication strategy specific to the Lookback Review and including the SCRR process				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Draft communications strategy including communication plan	Communications Manager (PT)	**20/10/22** – draft plan complete – awaiting review and sign-off **18/11/22 –** no update to report **16/11/22** – Phase 1 plan complete – will be revised for Phase 2	Complete	PID including phase 1 comms plan
18(b) A channel of communication specific to Urology work streams should be established between SHSCT, PSNI, GMC and Coroner's office; SHSCT should ascertain the thresholds for referral in respect of specific concerns arising out of cases reviewed as part of the SCRR.				
Action(s) Required to Deliver Recommendation(s)	**Responsible Officer?**	**Update**	**Status RAG**	**Evidence pf Completion**
Consider above recommendation		**20/10/22** – channel of communication currently exists with GMC and USI. Communication with PSNI and / or coroner not warranted at this time – this will be established if required in the future.	Closed	Emails and documents shared with GMC and USI.

Received from SHSCT on 21/04/2023. Annotated by the Urology Services Inquiry.

DOH-72508

The Regulation and Quality Improvement Authority

SHSCT Trust Urology Services
Phase II Report
Governance and Assurance Arrangements & Patient Views and Experience

August 2024

Received from Department of Health on 30/09/2024. Annotated by the Urology Services Inquiry.

The Regulation and Quality Improvement Authority

The Regulation and Quality Improvement Authority (RQIA) is the independent body responsible for regulating, inspecting and reviewing the quality and availability of health and social care services in Northern Ireland. RQIA Reviews identify best practice, highlight gaps or shortfalls in services requiring improvement and protect the public interest. Reviews are supported by a core team of staff and by independent assessors, who are either experienced practitioners or experts by experience. Our reports are submitted to the Minister for Health and are available on our website at www.rqia.org.uk.

RQIA Reviews and Inspections must consider the statutory duty on public authorities under Section 75 of the Northern Ireland Act 1998[1] and the European Convention on Human Rights[2]. Methodologies will be developed to ensure that RQIA are compliant with its obligations in this regard.

Phase II

Membership of the Expert Review Team

Dr Julie Ann Walkden	Assistant Director of Reviews, Audit, Governance and Improvement
Dr Andrew Dickinson	Consultant Urologist, National Health Service
Pauline Bagnall	Nurse Specialist, Urology
Brian O'Hagan	Lay Representative and Independent Expert Review Team advisor to the Review

Membership of the Project Team

Briege Donaghy	Chief Executive / Review Lead (from April 24)
Emer Hopkins	RQIA Review Director Lead (to April 24)
Hall Graham	Reviews Advisor
Dr Richard Gamble	Project Manager
Lheanna Kent	Project Support Officer
Anne Wilson	Senior Project Manager

Received from Department of Health on 30/09/2024. Annotated by the Urology Services Inquiry.

We would like to thank all Southern Health and Social Care Trust staff who took time out of their busy schedules to attend meetings with our Review team.

We would also like to thank them for their openness when answering our questions. We recognise the difficulties staff have faced and we commend their dedication, commitment and optimism for the future.

We would also like to thank all service users who took the time to give their views to RQIA staff members.

Received from Department of Health on 30/09/2024. Annotated by the Urology Services Inquiry.

Glossary

Abbreviation	
BAUN	British Association of Urological Nurses
BAUS	British Association of Urological Surgeons
BHSCT	Belfast Health and Social Care Trust
DoH	Department of Health
EAU	European Association of Urology
GIRFT	Getting It Right First Time (NHS National programme)
HSCNI	Health and Social Care Northern Ireland sector
HQIP	Healthcare Quality Improvement Programme
MDT	Multi-Disciplinary Team
MDM	Multi-Disciplinary Meeting
NICE	The National Institute for Health and Care
RQIA	The Regulation and Quality Improvement Authority.
SAI	Serious Adverse Incident
SHSCT	Southern Health and Social Care Trust
ToR	Terms of Reference
USI	Urology Services Inquiry (Public)

Received from Department of Health on 30/09/2024. Annotated by the Urology Services Inquiry.

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Received from Department of Health on 30/09/2024. Annotated by the Urology Services Inquiry.

Executive Summary

Background

On 31 July 2020, the Southern Health and Social Care Trust (the Trust) submitted an Early Alert (Ref EA 182/20) to the Department of Health (DoH) Northern Ireland, in relation to concerns about the practice of a clinician within Urology Services in the Trust.

The Early Alert described an early Review (Lookback) covering a 17-month period, (1 January 2019 - 31 May 2020) which had identified a number of concerns. The Trust became aware that:

- two out of 10 patients listed for surgery under the care of the consultant had not been recorded on the hospital's patient administration system at that time.
- there were concerns about 46 patients who had had a procedure to insert a stent.
- 120 of 334 elective inpatients had a delay in dictation of their consultation appointment letter, of up to 41 weeks.
- 36 patients were identified with no case record on Northern Ireland Electronic Care Record System.

The Minister for Health announced a number of actions that were to be taken:

- the establishment of a Urology Oversight Group, chaired by the Permanent Secretary
- commissioning the Royal College of Surgeons (RCS) to carry out an independent Review of a sample of the clinical cases included in the initial Lookback exercise
- establishment of a public inquiry under the Inquiries Act 2005; the public inquiry was established in March 2021, and was chaired by Christine Smith KC.

The Trust initiated a Lookback exercise to identify patients under the care of the consultant who required a review of their care and then arrange a recall appointment or follow up as appropriate.

Subsequently a number of external assessments were undertaken:

- A root cause analysis of nine patients who had potentially suffered harm.
- Royal College of Surgeons (RCS) review of 100 clinical cases.
- RQIA Review of the Trust structured judgement methodology.
- A Getting It Right First Time (GIRFT) Review.

Received from Department of Health on 30/09/2024. Annotated by the Urology Services Inquiry.

On 11 August 2022, the Chief Medical Officer wrote to RQIA commissioning an independent Review of the Southern Trust Urology Services and Lookback Review relating to patients previously under the care of the consultant. This work was undertaken by RQIA in two phases: the first to Review the Lookback process, which produced an interim report in July 2023, and the second phase assessing the governance arrangements for the oversight and delivery of Urology Services. This report presents the findings and recommendations from Phase 2, in assessing the effectiveness of current arrangements to assure the delivery of safe care within Urology Services in the Southern Health and Social Care Trust, and also to include patient views of their care.

Methodology

As there are no specific local or national Urology standards, the HSC Quality Standards (2006) and associated criteria alone have been used to underpin this Review.
An assurance framework was developed to enable an evidence-based assessment of governance within the Trust Urology service.

- A questionnaire based on the assurance framework was issued to the Trust. Unfortunately, due to many competing pressures, the Trust felt they did not have capacity to complete it.
- An alternative approach was agreed with DoH, resulting in a Trust submission of 720 documents including policies, training logs and standard operating procedures (SOPs).
- We held 6 staff engagement sessions at Craigavon Area Hospital, over a two-day period of fieldwork.
- We held engagement sessions with Trust Urology service users, at the Outpatient services Thorndale Unit, Craigavon Hospital.
- A further clarification meeting took place which included the Trust Medical Director, the Director of Surgery & Clinical Services and the Head of Urology Services.

Findings

As a result of the Urology Services Inquiry (USI), a number of other external Reviews, plus the day to day clinical pressures, including staffing issues and increased clinical complexity of cases, staff told us of the increased pressure they had been working under. We were encouraged to find that despite these major challenges, there was evidence that staff morale remained high and they were optimistic in relation to the future direction of the department.

Staff described how the recent changes in leadership and management structure had introduced a less hierarchical structure within Urology Services, which they considered to be an improvement over the previous structure, as it offered staff of all levels greater opportunities to suggest improvements, speak up and raise any potential concerns. We

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found that these structural changes seemed to be working effectively. However, as at that time the Clinical Director position had not been filled, we considered that the Trust should review its succession planning process, to ensure that lengthy senior leadership vacancies were avoided.

The Trust submitted a copy of its Medical Appraisal and Revalidation Engagement Procedure which clearly set out the expectation of appraisals being completed annually and the consequences for those doctors who fail to participate. At the time of the Review visit, available appraisal rates for the Trust were low, which the Expert Review Team accepted was due to the Covid-19 pandemic. However, recently received appraisal rates for the Urology department were high and we considered that, based on the information we had, the Trust had an effective system for medical appraisal in Urology Services.

Effective appraisal and supervision procedures are important building blocks of any governance system. We found that nursing supervisions were often being carried out informally and not always recorded and nursing appraisal rates were low. The Trust needed therefore to ensure that effective nursing supervision and appraisal processes are in place, that are carried out in line with Trust policy.

A number of external Reviews made recommendations in relation to how MDTs in the Urology department were carried out. We found that the Trust had created a dedicated task and finish group which met monthly and reported to the Urology Oversight Group. This group was responsible for implementing a number of service improvements in relation to the MDT process. During staff meetings, we were also told of positive administration changes that had been put in place. We agreed that the new steps the Trust had introduced were promising and likely to improve the functioning of the MDT, the decisions made and the tracking of these decisions.

We found that, in common with other areas, staffing presented significant challenges for the Urology department, though this had been somewhat mitigated by active recruitment of nursing and administrative staff and of an additional Urology consultant. However, we considered that the Urology department should record instances of staff shortage on Datix.

We were told that all staff were provided with sufficient training opportunities and we considered that the Trust was providing sufficient training opportunities for all nursing staff, both ward staff and specialist nurses. We also considered that based on the information we had, an effective system was in place to track mandatory training for nursing staff and this formed part of reporting to senior staff and to the Trust Board

Risk registers are a critical component of risk management, allowing for tracking of risks from an operational level through to the Trust Board and providing information as to the level of risk and any mitigations in place. We found that work was being undertaken to

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improve the use of risk registers at an operational level but the Trust needed to assure itself that risk registers were being used effectively.

Length of waiting lists is a regional issue and the recent reliance of the Trust on the independent sector was acknowledged to be a short-term strategy to help address excessive waiting times for some procedures. Following the GIRFT review of Urology Services across Northern Ireland, published on 1 December 2023[3], further opportunities for modernisation reform and improved efficiency have been identified at a local and regional level, as part of a range of actions aimed at addressing Northern Ireland's exceptionally long waiting lists. We considered that implementation of these recommendations will be important to safeguard the long-term safety and sustainability of the Trust Urology Services.

We were encouraged by the reported Quality Improvement (QI) ethos in the Trust and the fact that staff were being encouraged to participate in audit and QI. Given the difficulties encountered by the Urology department, we were satisfied with the level of audit and QI activity that was happening, based on the available information we had. However, we considered that planning of the audit and QI programme could be improved by considering incidents, complaints, SAIs and near misses, to more effectively target areas for improvement. The Trust should also assess the effectiveness of its process for delivering improvements suggested by audit and QI projects.

After reviewing progress updates in relation to external Reviews and associated action plans, we considered that the Trust response was comprehensive, identifying any major gaps in oversight that existed. We also considered that the structures established for monitoring the action plan and progress reports provided positive assurance of an ongoing system of review and follow up.

During our fieldwork sessions, clinicians described the process adopted by the wider Trust in respect of recording, monitoring and reviewing clinical guidance across the Trust. This involves maintenance of a centralised spreadsheet, which contains each of the guidelines applicable to the Southern Trust. Overall, we considered that the systems, process and reporting mechanisms that exist currently within the Trust, were working effectively to monitor performance against all the relevant standards.

Staff told us that the number of Datix reports being submitted has increased and that near misses were also being reported. They described the process for analysis and grading of incidents. A number of changes had been made in how incidents were collated and held on the system and also to how the effectiveness of recommendations was being assessed. We considered that based on the available information, the Trust was working hard to improve its system for investigating SAIs, tracking recommendations, disseminating learning and assessing the effectiveness of any

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outcomes. We also considered that, based on the information we had, the Trust had an effective process for dealing with complaints.

A number of staff commented on the pressure that Urology staff had been experiencing as a result of the USI but also as a result of increasing staffing pressures, numbers of patients and increasing acuity of patients. We were also told of psychological support that had been provided by the Trust. We were impressed by the positive attitude of staff, who although admitting how difficult the USI had been, realised that as a result a number of positive changes had taken place and they were optimistic for the future.

We considered that the Trust should positively assess the staff culture in the Urology service and investigate any possible detrimental effects the extra pressures they have been experiencing may have caused. Appropriate staff support should subsequently be put in place. We also considered that the Trust should ensure that all learning arising from the USI and all other external Reviews should be widely disseminated within the Trust and beyond.

The Trust provided its 'Your Right to Raise a Concern '(whistleblowing policy) which the Expert Review Team considered to be comprehensive.

The Expert Review Team commended the efforts of Urology Services staff to encourage an open and transparent culture, whereby staff of all levels feel empowered to speak up should need arise. However, we felt that in the Urology department the Trust should consider assessing the visibility and effectiveness of its process for raising concerns.

The Trust has a number of ways in which feedback is obtained from service users. During meetings with Trust staff, we were first told of the Working Together Strategy, through which individual Trust teams have a mechanism for reporting service user input, especially from frontline services. The Trust participates in the 10,000 voices initiative which gives service users the opportunity to highlight anything important in relation to their care and what they may have liked or disliked. The Trust also makes use of the independent feedback collated and reported by the organisation Care Opinion. This service provides patients and their families with an opportunity to share their experiences of an HSC service via personal stories. We considered however that the Trust should more actively employ a wider range of methods for proactively listening to/gathering patient views and provide examples of how it meets its statutory obligations to involve patients in key decisions about improvement and development of services.

We obtained feedback directly from patients, who were attending a mixture of new and review appointments, which was resoundingly positive. Patients spoke highly of their interaction with staff and confirmed that they had been helpful in facilitating access to the service, offering them a choice of date and time when setting up their appointments. Patients described how having a choice of appointment made it easier for them to plan

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their hospital attendance. Once at their appointment, patients described how staff were approachable and made every effort to ensure they were at ease while being checked in for their appointment.

The report contains 11 recommendations for improvement within the Urology service in the Trust.

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Section 1: Introduction

1.1 The Speciality of Urology

Urology can be broadly defined as the specialty that manages patients presenting with diseases of the male and female urinary tract and of the male reproductive organs. It covers a wide range of common conditions including urinary tract infections, urinary tract stones, problems with bladder emptying, urinary incontinence and erectile dysfunction. Urologists also treat patients with kidney, bladder, prostate, penile and testicular cancer. The last of these typically affects younger men than most cancers; prostate cancer, on the other hand, is most often seen in older patients. Statistics from the charity Prostate Cancer UK have shown that prostate cancer now accounts for the third highest number of cancer deaths in the UK, but also that the mortality rate for prostate cancer dropped by 6% between 2010 and 2015, reflecting growth in the number of men being diagnosed, and living with, the condition.

Unlike most surgical specialties, there is no parallel medical speciality for Urology and fewer than 20% of patients admitted as an emergency under the care of a urologist undergo a surgical intervention during the acute admission. A high proportion of urologists' work is carried out in an outpatient setting, addressing conditions that significantly affect everyday quality of life. While Urologists carry out some major surgical operations, such as removal of the bladder or prostate and open urinary tract reconstructive surgery, much urological surgery can be conducted relatively swiftly and using minimally invasive techniques. This reflects the fact the Urology was amongst the first surgical specialties to introduce endoscopic surgery.

The specialty continues to be at the forefront of technological change and many providers now offer robot-assisted surgery.

1.2 Background to the Review

On 31 July 2020, the Southern Health and Social Care Trust (the Trust) submitted an Early Alert (Ref EA 182/20) to the DoH Northern Ireland, in relation to concerns about the practice of a clinician within Urology Services in the Trust.

The Early Alert advised that on 7 June 2020, the Trust had become aware of potential safety concerns related to delays in the treatment of surgical patients. These patients had been under the care of a consultant urologist, who had been employed by the Trust from 6 July 1992 until his retirement on 17 July 2020. The purpose of this Early Alert was to inform system partners of events and describe early findings derived from scoping of records. The alert contained a commitment to further work to scope the extent of any further look back.

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The Early Alert described an early review (Lookback) covering a 17-month period, (1 January 2019 - 31 May 2020) which had identified a number of concerns. The Trust became aware that:

- two out of 10 patients listed for surgery under the care of the consultant had not been recorded on the hospital's patient administration system at that time.
- there were concerns about 46 patients who had had a procedure to insert a stent.
- 120 of 334 elective inpatients had a delay in dictation of their consultation appointment letter, of up to 41 weeks.
- 36 patients were identified with no case record on Northern Ireland Electronic Care Record System.

A number of cases had subsequently been identified as meeting the threshold for investigation under the Serious Adverse Incident (SAI) procedure.

On 24 November 2020, the Minister for Health made a statement[4] to the Northern Ireland Assembly in which he confirmed that as a result of the initial Lookback, concerns had been identified in relation to elective and emergency activity, radiology, pathology and cytology results, patients whose cases were considered at Multi-Disciplinary Team (MDT) meetings, oncology and the prescribing of an anti-androgen drug outside of established NICE guidance, in the management of prostate cancer.

The Minister announced a number of actions that were to be taken:

- the establishment of a Urology Oversight Group, chaired by the Permanent Secretary that would review the progress of the initial Lookback exercise, consider emerging strategic issues, commission and direct further work as necessary and monitor the impact on Urology and related services in the Southern Trust.
- commissioning the Royal College of Surgeons (RCS) to carry out an independent review of a sample of the clinical cases included in the initial lookback exercise, to determine whether a further, more extensive Lookback or patient recall by the Trust was required.
- establishment of a public inquiry under the Inquiries Act 2005, as the best way of ensuring that the full extent of concerns would be identified and for patients and families involved, to see that all relevant issues were pursued in a transparent and independent way. The public inquiry was established in March 2021, and was chaired by Christine Smith KC.

The Trust initiated a Lookback exercise to identify patients under the care of the consultant who required a review of their care and then arrange a recall appointment or follow up as appropriate.

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The Urology Services Inquiry, established in March 2021, heard closing submissions on 13 June 2024 and will report in the near future. The terms of reference for this public inquiry are available on the Urology Services Inquiry website[5].

A number of other Reviews in relation to Urology Services have also been carried out in the Trust. In March 2021, a report was submitted to the Health and Social Care Board of a root cause analysis of the care of 9 patients who had potentially suffered harm. The RCS was commissioned to carry out an independent review of 100 clinical cases and conditions for patients under Mr O'Brien's care during 2015. This review reported on 29 September 2022. RQIA carried out a Review of the Trust Structured Judgement Review methodology and process which was published in September 2022.

More recently, the Trust has also participated in a regional GIRFT Review[6].

On 11 August 2022, the Chief Medical Officer wrote to RQIA commissioning an independent review of the Trust Urology Services and its Lookback Review relating to patients previously under the care of the consultant.

Following discussion with DoH, it was agreed that the review would be undertaken in two phases. Phase I would consider the Lookback Review process and Phase II would consider the remaining items (Governance and assurance arrangements and patients views and experience).

Phase I of this review assessed the robustness of the Trust Lookback Review process, which included arrangements for its delivery and oversight. This was completed and submitted to DoH and to the Trust on 26 July 2023.

This Phase II report presents the findings and recommendations emerging from Phase II; to assess the effectiveness of current arrangements to assure the delivery of safe care within Urology Services in the Southern Health and Social Care Trust, to include:

- An assessment of the arrangements to monitor the delivery of care against all relevant standards and
- To seek the views and experiences of patients in relation to the care provided from Urology Services in the Southern Health and Social Care Trust, in so far as they relate to item 2.

1.3 Terms of Reference

The Terms of Reference (ToR) for this review were agreed with members of the Urology Assurance Group (UAG) within DoH. DoH sought to ensure that work was completed in an appropriate and timely manner, whilst ensuring the review did not infringe on the work of the USI.

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Phase I

1. Undertake an assessment of the current Southern Health and Social Care Trust Urology Lookback Review process, to include arrangements for its delivery and oversight.
   To include:
   - Progress on the implementation of the recommendations made by the Southern Health and Social Care Trust in relation to the earlier investigation relating to the Urology Lookback Review and assess the robustness of the current Lookback Review.
   - Identify learning which can be applied to any further extension to the current Lookback Review.
   - Assess the extent to which Southern Health and Social Care Trust members of the Urology Assurance Group (UAG) have fulfilled requirements set out within the UAG Terms of Reference.

   Phase I, as described above, was completed and submitted to DoH and the Southern HSC Trust on 26 July 2023.

Phase II

2. Assess the effectiveness of current arrangements to assure the delivery of safe care within Urology Services in the Southern Health and Social Care Trust.
   To include:
   - An assessment of the arrangements to monitor the delivery of care against all relevant standards.
3. To seek the views and experiences of patients in relation to the care provided from Urology Services in the Southern Health and Social Care Trust, in so far as they relate to item 2.
4. To provide a report on the findings and where relevant, make recommendations to DoH by report at the earliest point.
5. To escalate any emerging concerns identified during the course of the Review to DoH and to notify the Southern Health and Social Care Trust of any emerging patient safety concerns.

This Review report focuses on Phase II and includes Terms of Reference 2, 3 ,4 and 5.

1.4 Review Methodology

Phase II was conducted in two parts, part A governance and assurance, and part B patient views and experience.

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Section 2: Part A, Governance and Assurance

2.1 Methodology

The objective of this part of the Review was to seek evidence to determine if the Trust had in place effective arrangements to assure the safety and quality of Urology Services, enabling early and effective action to be taken, where indications of risks to safety and quality had been identified.

These assurance arrangements are part of effective overall governance within the Trust. In 2006[7], in order to contribute to the safety and quality of HSC services, DoH published the Minimum Quality Standards expected for HSC services. The standards were designed to be used by HSC organisations and by RQIA to assess the quality of care provided. The standards contain 5 overall quality themes. Each theme has a title which defines the area on which the standard is focused. A standard statement explains the level of performance to be achieved and a rationale explains why the standard is considered to be important. Finally, a series of criteria are set out which provide the level of detail to enable effective assessment.

The 5 overall quality themes are:

1. Corporate Leadership and Accountability of Organisations.
2. Safe and Effective Care.
3. Accessible, Flexible and Responsive Services.
4. Promoting, Protecting and Improving Health and Social Well-being; and
5. Effective Communication and Information.

In combination with more detailed service specific standards, RQIA may use these quality standards when reviewing, inspecting or investigating matters relating to HSC Services. As there are no specific local or national Urology standards, the quality standards and associated criteria alone have been used to underpin this Review. Each quality theme has multiple associated criteria; a number of these have been selected to assure the effectiveness of governance arrangement is place in the Trust Urology Services.

Selected Criteria

The Review has sought evidence against the following criteria, that the Trust:

- has in place appropriate structures, systems and processes to provide robust delivery of safe and quality Urology Services, through effective oversight and reporting arrangements that enable effective governance.
- has identified specific risks that relate to the safety and quality of Urology Services and can demonstrate active management of those risks, including escalation as appropriate.

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- is kept informed about key indicators of safety and quality, to enable proactive management, and early indications of when things go wrong.

The following criteria have been used:

Assurance relating to:		To be evidenced	HSC 2006 Quality Standard Ref
1	**Organisational Structure & Oversight**	• Organisational structure with clear leadership, through lines of professional and corporate accountability • Evidence of reporting of key governance issues through the governance infrastructure • Role of the Trust Board • Regional oversight, reporting and strategy	Theme 1 Corporate Leadership and Accountability: 4.3 (a) Theme 2 Safe & Effective Care 5.3.3 (i)
2	**Medical Workforce**	• Medical Appraisal • Maintaining High Professional Standards • Multi-Disciplinary Teams • Training including mandatory training • Nursing supervision • Nursing appraisal • Job planning	Theme 1 Corporate Leadership and Accountability: 4.3 (l)
3	**Risk Management**	• Risk Register/s and active Management • Incident reporting, management and applied learning • Trends, analysis and wider learning from incidents • Learning from complaints • Use of locums /agency staff	Theme 1 Corporate Leadership and Accountability: 4.3 (i) Theme 2 Safe & Effective Care 5.3.1 (b) 5.3.2 (a)
4	**Clinical Outcomes**	• Clinical outcomes reviewed to include trends, key patient safety indicators, and benchmarks to appropriate peers • Waiting times for red flag referrals (by service type/ consultant including trends and benchmarks to appropriate peers/ region) • Clinical audit • Quality Improvement initiatives	Theme 2 Safe & Effective Care 5.3.3 (e) 5.3.3 (g) Theme 3 Accessible, Flexible and Responsive Services 6.3.1(f)
5	**Implementation of Recommendations from Key Reports**	• Active implementation of recommendations from Invited Reviews, RQIA Reports, Public Inquiries, knowledge of position achieved and issues arising • Issuing of, and assurance through following up, on adoption of urgent, new, additional clinical guidance • Active audit programme	Theme 2 Safe & Effective Care 5.3.1 (f) 5.3.3 (f) Theme 5 Effective Communication and Information 8.3 (d)

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6	**Culture**	• Process for staff raising concerns, widely known, and evidence of confidence in same and action taken where issues raised • Whistleblowing Policy and procedures • Staff experience/ views on culture in working environment • Effective internal communications, within and across services, teams and organisation	Theme 2 Safe & Effective Care 5.3.1 (f)
7	**Patient Experience**	• Process for patients being involved/ informed and to raise complaints • Evidence of patient experience proactively sought about services acknowledging role in patient safety and prevention of harm • How are Trust staff, managers and the Trust Board aware of patients views and take account of	Theme 2 Safe & Effective Care 5.3.1(b) Theme 3 Accessible, Flexible and Responsive Services 6.3.2(g) Theme 5 Effective Communication and Information 8.3 (a)

Other issues may well be raised during field work/ site visits, speaking with staff and with patients. Additional issues would be included in the Review, as far as relevant to the ToR.

2.2 Data sources which contributed to Part A

Included:

- A robust assurance framework was developed to enable an evidence-based assessment of governance within the Trust Urology service.
- A questionnaire, based on the assurance framework, was issued to the Trust by RQIA. However, as a result of competing factors on resources, which included the USI, a GIRFT Review and service delivery pressures, the Trust was not in a position to respond to the questionnaire within the requested timeframe.
- RQIA subsequently met with the Trust and DoH to agree an alternative approach which did not include completing an RQIA questionnaire based on a robust assurance framework. As part of the alternative approach, the Trust submitted 720 documents which included items such as policies, training logs and Standard Operating Procedures. Following receipt on 18 August 2023, the RQIA Review Team held a workshop to undertake screening of documents submitted by SHSCT. Of the total submission, 70 documents were selected and reviewed on the basis of relevancy to the Review ToR and emerging themes identified through ongoing engagement with the Trust.
- On 30 and 31 August 2023, 6 staff engagement sessions took place at Craigavon Area Hospital, over a two-day period of fieldwork.
- During these engagement sessions, discussions with staff took place, which included progress reports around work arising from the Trust commissioned Root Cause Analysis Review (completed February 2021) and the RQIA Review of the Structured Clinical Case Review (SCCR) (completed September 2022).

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- Engagement sessions with Trust Urology service users, including one-2-one engagement, took place at the Outpatient Services, Thorndale Unit, Craigavon Hospital on 11 September 2023.
- On 27 October 2023, a further clarification meeting took place with the Trust Medical Director, the Director of Surgery & Clinical Services and the Head of Urology Services.
- On 22 February 2024, following a final information request, 3 further documents were provided to RQIA.

2.3 Findings

Findings are presented against the revised Review assessment framework, based on the HSC Quality Standards 2006:

- Urology structure and activity data
- Organisational Structure and Oversight
- Workforce
- Risk Management
- Clinical Outcomes
- Implementing Recommendations from Reviews, SAI, Public Inquiries, and new/updated Guidance
- Culture
- Patient Experience

2.3.1 Southern HSC Trust Urology Services

The Trust 2022/23 Annual Quality Report, (published November 2023), describes that the Trust provides services to a population of 388,688, across a geographical area which covers Armagh City, Banbridge, Craigavon and parts of Newry, Mourne, Down and Mid-Ulster. The Trust has a staffing complement of 14,887, which between April 2022 and March 2023 helped to deliver 199,558 Consultant led outpatient appointments, 69,060 adult day care attendances and 158,854 emergency department attendances.

The Trust Urology Services are based primarily within Craigavon Area Hospital in the outpatient 'Thorndale' unit; however elective and outpatient care is also delivered at Trust sites in South Tyrone, Craigavon Area, Daisy Hill and Armagh Community Hospitals. Complex conditions can be transferred for treatment to the Royal Victoria Hospital in the Belfast Health and Social Care Trust (BHSCT).

The Trust also commissions outpatient activity to be delivered by the Independent Sector on the behalf of the Trust. The service is delivered by a diverse MDT which includes 4.41 whole time equivalent (WTE) Consultants, 2.83 (WTE) Clinical Nurse Specialists and 0.5 WTE Physician Associates[8] among a wide range of other professionals.

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Table 1: Southern HSC Trust Urology Services Activity Data 2022

SOUTHERN HSC TRUST Urology Services Activity data 2022	
Metric	**2022**
Number of Urology elective inpatient spells	472 *IS = 61
Number of Urology day case spells	2851 *IS = I532
Virtual outpatient attendance	Consultant-Led = 1231 New and 6379 Review Nurse-Led = 352 New and 1761 Review Virtual = 650 New and 1100 Review *IS = 2990 New and 753 Review
Number of Urology emergency admissions	901

* IS (independent Sector) activity is not part of Trust's core activity – this activity was contracted to the Acute IS Provider on behalf of the Trust utilising non-recurrent waiting list initiative monies from SPPG.

In 2022, the Trust Urology Services had 472 elective inpatient admissions and 2,851 day cases. Urology services provided 7,610 consultant led; 2113 nurse-led outpatient appointments; and 1,800 virtual out-patient appointments (new and review). Within the Independent Sector 3,743 out-patient appointments (new and review); 61 elective in-patient admissions; and 1,532 day cases were delivered on behalf of the Urology service.

Further metrics provided by the Trust within its Acute SMT performance presentation (6 December 2022) demonstrated that as of 31 October 2022, the total number of patients waiting for Urology outpatients, was 4,162, with an average waiting time of 141 weeks and 2,951 patients had been waiting 52 weeks on the outpatient list (Table 2).

Table 2: SHSCT Outpatient Waiting List Position, 31 October 2022

Specialty Description	Total Volume of Waits	13 + Weeks	26 Weeks	52 Weeks	Longest Wait (weeks)	Average Wait (Weeks)
Urology	4,162	3,423	3,228	2,951	352	141

Data source: Acute SMT Performance presentation, 6 December 2022

Table 3 shows the total number of patients waiting for in patient/day case was 1,748, with the average waiting time in weeks

Table 3: SHSCT Inpatient/Day Case Waiting List Position, 31 October 2022

Specialty Description	Total Volume of Waits	13 C Weeks	52 Weeks	Longest Wait (weeks)	Average Wait (Weeks)
Urology	1,748	1,408	952	429	104

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Data source: Acute SMT Performance presentation, 6 December 2022

Table 4 presents the average wait (in weeks) experienced by patients referred to the Trust Urology outpatient service by priority status as of the 3 January 2024.

Table 4: SHSCT average outpatient wait in weeks, by priority status, January 2024

Priority	Average Wait (Weeks)
Red Flag *	4
Urgent **	19
Routine	153

Data source: SPPG outpatient on-line Dashboard, 3 January 2024

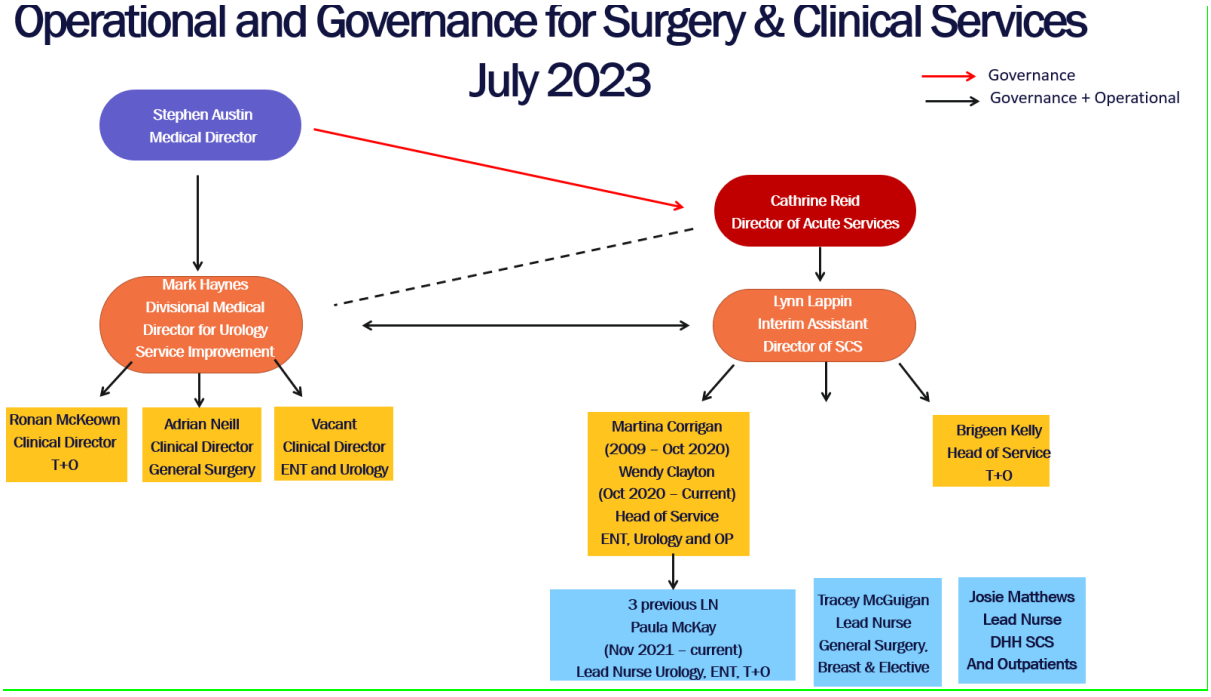
Red Flag: *These appointments are allocated to patients with suspected cancer diagnosis and are the highest priority.*

***Urgent:** These appointments are allocated to patients with urgent care needs other than cancer.*

2.3.2 Organisational Structures and Oversight

The Trust submitted organisational charts which displayed the structure of operational and governance services in the Trust; Figure 1 is an extract from these documents.

Figure 1. SHSCT Urology Services Operational and Governance Structure



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As displayed, in relation to nursing reporting lines, the current structure in Urology Services has a Lead Nurse reporting to a Head of Service, who is responsible for the areas of Urology, outpatients and ear nose and throat (ENT) and ophthalmology. The Head of Service reports to an Interim Assistant Director, who reports to the Director of Surgery and Clinical Services. The Director and Assistant Director interact with the Trust Divisional Medical Director for Urology and Service Improvement who links Directly with the Trust Medical Director. On the medical side, a Clinical Director has responsibility for both ENT and Urology and they report through the Medical Director for Urology Service Development to the Trust Medical Director.

Effective leadership structures, clear lines of reporting and meaningful informed challenge are essential components in assuring that a service is well led and are particularly vital in a service under scrutiny and pressure. Those in leadership roles should be readily accessible, share information freely and mechanisms should be in place which ensure the effective flow of information from service delivery to Trust Board level, to provide effective assurance of the quality of care delivered.

During fieldwork sessions, Trust staff reported that in the past 3 years there had been significant change in the leadership and management structure within Urology Services. Documentation provided by the Trust, identified that during this period the service's governance and operational structure had undergone several changes, including the recent appointment of a new Head of Service, Lead Nurse, Head of the Acute Governance Team and Assistant Director. It was also evident that at the time of this Review, the role of Clinical Director was vacant.

Staff described how the recent changes in leadership and management structure had introduced a less hierarchical structure within Urology Services, which they considered to be an improvement over the previous structure, as it offered staff of all levels greater opportunities to suggest improvements, speak up and raise any potential concerns. Staff commented that they felt this structure allowed for effective leadership across a range of roles and grades and that there was strong evidence of team leadership across Urology Services. Staff who participated in focus groups articulated that they would feel very comfortable raising concerns with members of staff at any level.

Staff reported oversight and communication at a number of levels. Weekly departmental meetings, Urology patient safety meetings and weekly governance meetings were held. Urology sits within a directorate and is not a directorate in itself. Any learning at a directorate level and from other clinical areas is fed through to the Urology department. Patient safety meetings include discussions around mortality, morbidity, complaints and serious adverse incidents (SAIs) and these are attended by junior medical staff. Operational meeting agendas included staffing, recruitment, standard operating procedure (SOP) amendments, policies and procedures, performance, waiting time and incidents such as falls on the ward. Any suggested changes or other safety issues were

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initially presented to the Trust senior leadership team (SLT) and then disseminated to staff at all levels. Staff told us that every team has patient safety discussions. The set-up of the department with a small team and shared offices, facilitated effective communication and this was reinforced by many ad hoc corridor discussions.

We were told that a subcommittee of the Trust Board and a new system of steering groups, with representation from non-executives, had been established, to provide greater oversight of all Trust issues. A Safety and Quality Committee which feeds into the Trust Governance Committee had also been established and this is where any Urology issues could be examined in greater detail.

Trust senior staff told us that the overall aim of these changes was development of better collective leadership, with nurses, clinicians and managers training and working as a collaborative team, to run their division more effectively and safely. This was seen by staff as a fairer structure, compared to a more hierarchical structure with a single director at its head.

Clinical staff informed us that the Urology team was the first in Northern Ireland to carry out trans-perineal biopsies. One of the plans for the department was to recruit more nurse specialists and to investigate different ways of working in Urology. Nurse specialists would be further empowered to be leaders in their own right. We were told by staff that they were excited about the way things were moving and progressing.

The Expert Review Team considered that the structural changes made to the department seemed to be working effectively and we were encouraged that staff felt more empowered and were comfortable with raising concerns at all levels.

At the time of the Review fieldwork, we were concerned that the Clinical Director role had been vacant for some time and would recommend that the Trust assesses its succession planning process, to ensure crucial leadership roles are not vacant for long spells.

Recommendation 1. The Trust should have an effective succession planning process, to ensure that senior leadership roles are filled continuously and prolonged vacancies are avoided.

2.3.3 Workforce

Medical Appraisal

Medical Appraisal is a formal process of protected time once a year, when doctors have the opportunity to focus with a trained colleague, on their scope of work. This includes:

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- Looking back at achievements, challenges and lessons learnt, including the previous year's personal development plan objectives
- Looking forward to their aspirations, learning needs and the recording of new personal development plan objectives

Revalidation is the process by which the General Medical Council confirms the continuation of a doctor's licence to practise. Appraisal is a major component of revalidation.

A copy of the Trust Medical Appraisal and Revalidation Engagement Procedure (January 2023) was submitted. This policy clearly set out the expectation of appraisals being completed annually and the consequences for those doctors who fail to participate in the process, which can range from reminder letters to a request being submitted to the GMC to initiate an early concern procedure.

The Trust told us that they have developed guides and toolkits for completing appraisals and there is a monthly revalidation oversight meeting, at which supporting information would be discussed, decisions taken on whether or not revalidation progresses and any actions required. A letter is sent to each doctor explaining the requirement to revalidate, the need to have appraisals completed by the end of April and the escalation process if all necessary requirements are not met. If a doctor has not prepared their portfolio this would be a red flag. In relation to appraisal, all necessary information is provided to the appraiser in advance. All Datix or auto generated reports are made available and the appraisee completes a declaration form in relation to their private practice, which forms part of their appraisal. It is the responsibility of the appraisee to declare any issues they may have had in relation to their private practice. For the last 2 years the Trust has been operating a 2 sign off system for appraisals, where each appraisal goes to a second appraiser for final sign off.

The Expert Review Team discussed with senior Trust staff as to how they may be made aware of a doctor who is underperforming in some way. Trust staff told us that concerns may be raised informally in the first instance. This would be investigated informally with evidence being gathered, before the doctor was approached and then, if necessary, the Medical Director would be informed. If required, a wider level investigation would be triggered using all available system data. The Trust has a 'supporting doctors' system where cases of concern would be discussed before raising a concern more formally. The Medical Director would also liaise with the General Medical Council (GMC) where appropriate.

At the time of the Review visit, available appraisal rates for the Trust were low, which the Expert Review Team accepted was due to the Covid-19 pandemic. However, recently received appraisal rates for the Urology department were high and we considered that,

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based on the information we had, the Trust had an effective system for medical appraisal in Urology Services.

Nursing Supervision and Appraisal

Nursing supervision provides staff with a means of reflecting on their practice, receiving support and formally recording their achievements, challenges, lessons learnt, and aspirations. It also offers staff an additional opportunity to raise concerns. Supervision should be an ongoing process, with a number of meetings taking place between nursing staff and nominated supervisors.

Appraisal is a more formal, usually annual process to review the previous 12 months' performance, to reflect on practice, to set objectives for the coming year and to plan personal development. Both processes are integral to staff support and development, which in turn contribute to raising standards of service delivery.

A copy of the Trust Reflective Supervision Policy (2023) was submitted as evidence. This policy, which had been informed by the Northern Ireland Practice Education Council (NIPEC) review conducted in 2020, describes the importance of encouraging a culture of sharing, reflection and improvement and highlights the benefits for nurses and midwives as well as those they care for.

The policy sets out the expectation that nursing staff should receive formalised reflective supervision sessions at least twice per year. An appendix in the policy provides a template for the recording of supervision meetings between managers and reporting staff, with a dedicated section for the opportunity to raise concerns.

The Junior Nursing Induction Booklet, submitted as part of this Review was examined which contained detailed information on shift patterns, staffing profile and ward routine but did not mention the process of reflective supervision. We were therefore not clear on the policy expectations of the timeframes and frequency staff can expect to undertake formal supervision.

During fieldwork sessions, we were told that staff should have one formal supervision session between April and September and a second between November and December. Supervision rates were 65%. Nursing staff however reported that in their experience, staff supervisions tended to be informal and acknowledged that they may also be unrecorded. Annual appraisals are also an important opportunity to review progress and development needs for staff. On review of the registered nurse training spreadsheet submitted by the Trust, it was confirmed that (as of July 2023) a significant number of nursing staff had yet to have their annual appraisal completed.

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During discussions with nursing staff, they told us that they recognised the important contribution formal supervision makes towards both personal development and organisational assurance. We were told that it also provides an extremely valuable opportunity for staff to voice issues and concerns; however, nursing staff also told us that they considered that supervision should be formally conducted and recorded in line with the Trust Reflective Supervision Policy.

The Expert Review Team considers that effective appraisal and supervision procedures are important building blocks of any governance system. They provide support and motivation for staff and help to ensure they are developing and maintaining good practice in line with their professional standards. They allow staff to reflect on their performance and progress and enable them to set realistic goals for future development. They also enable managers to ensure that patients are being treated by suitably trained and motivated staff within a positive organisational culture. We accept that these procedures are a joint effort between management and staff, however, we consider that the Trust has an obligation to ensure that effective supervision and appraisal processes are in place, that are carried out in line with Trust policy.

Recommendation 2. The Trust should ensure that records are kept which evidence that relevant clinical staff participate in the process of regular reflective supervisions, which should be conducted and formally recorded in line with its reflective supervision policy.

Recommendation 3. The Trust should ensure all nursing staff are up to date with their appraisals in line with the Trust appraisal policy and that active follow up takes place where appraisals are overdue.

Multi-Disciplinary Meetings

The Trust MDT meeting for cancer services is a key mechanism for consideration of the appropriate treatment options for complex cases, in line with relevant clinical guidelines and standards. The Urology department works closely with cancer services, radiology and allied health professionals (AHPs). The subject of the effective functioning of MDT meetings was significantly focused upon within the Root Cause Analysis Review completed in 2021.

This Review made three specific recommendations in relation to MDTs:

Recommendation 4. The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.

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Recommendation 5. The Trust must ensure that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations / actions are completed.

Recommendation 6. The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multi-Disciplinary Care Governance.

The Root Cause Analysis Review action / progress log submitted by the Trust reported that significant changes had already been made to improve the operation of MDT meetings within Urology Services. The Trust supplied its most recently updated Urology Cancer Services Operational Policy (Sept 2023), which provided a comprehensive overview of the delivery of this function, including roles and responsibilities, recording, monitoring, auditing and linkages with other services. Staff reported that Urology Services now had two operational MDTs which meet on a weekly basis to discuss patient care/ treatment.

The RCS Clinical Records Review also made 3 recommendations in relation to MDT arrangements:

Recommendation 6. The Trust should review the MDT arrangements within the Urology Service to ensure that there is adequate MDT input into the decision making for every patient. All MDT decisions and communication should be adequately documented in each patient's record.

Recommendation 7. It was unclear to the Review Team whether the MDT meetings that surgeon 1 attended and chaired, were local Urology MDT or specialist Urology MDT. The Trust should ensure that complex cancer cases, especially those where major surgery is being considered should always be discussed at a specialist MDT. In the Review Team's opinion, these decisions should not be made purely on a local basis.

Recommendation 8. In addition to recommendations 6 and 7, the Trust should consider whether there are sufficient safeguards in place to monitor decisions made at MDT meetings and to ensure that recommendations are appropriately carried out.

The Trust reported that it had created a dedicated task and finish group which met monthly and reported to the Urology Oversight Group. This group was responsible for implementing a number of service improvements which included:

- Quoracy reports, which were completed monthly to monitor the attendance of staff at each MDT meeting. This report is then shared with senior staff.
- A MDT action log, which recorded each decision agreed, with these actions tracked until first treatment.

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- The MDT action log was then reviewed on a monthly basis, with input from Cancer Service Improvement Leads.
- A rolling audit of MDT decisions which involves five records being audited each week of the month.

During staff meetings we were also told of positive administration changes that had been put in place. Administration staff are now off site and under one directorate. Previously, secretaries had little contact with consultants but now they have a very good working relationship and there are no issues with communication. Staff however told us it is now much more difficult to recruit due to the impact of the USI and there is now more pressure to ensure accuracy. Administration staff, under the Surgical Service Administrator, now carry out spot checks on clinic letters which has resulted in a number of improvements. Administration staff, under the Cancer Services Team, also produce a monthly performance report for each speciality and escalate when targets were not met. Monthly breach reports are prepared and an individual breach reports may be prepared for individual patients. Tumour site reports which were not previously used are now run regularly.
Trust staff with whom we met were very content with this new system and with the extra staffing that had been provided. A band 6 is now dedicated to supporting the work of MDMs and a band 5 and band 4 are now assisting with assurance audits, taking a sample of cases and checking that agreed plans have been implemented.

Staff however told us that there were still significant capacity issues, and there was no failsafe mechanism for radiology similar to that in place for pathology. Staff considered that the present system relies too heavily on the referrer accessing radiology results and they were considering setting up a mini tracking system for radiology.

The Expert Review Team agreed that the new steps the Trust had introduced were promising and likely to improve the functioning of the MDT, the decisions made and the tracking of these decisions

Staffing levels

Appropriate levels of skilled staff are an obvious prerequisite to the delivery of safe and effective care. Continued recruitment, succession planning and longer-term work-force planning are required, to ensure that staffing levels are adequate to meet the current and future needs of patients, staff and the service.

The Urology inpatient ward is an 18-bed ward in Craigavon Hospital shared with ENT. This is smaller than previously, but nursing staff told us this has enabled them to become more specialised and helped to develop both their confidence and competency. Staff also told us that having a dedicated ward has enabled them to have a fully staffed junior medical tier for the first time, with clinical fellows at Senior House Officer (SHO) level.

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During fieldwork, staff reported that there has been ongoing active recruitment and an increase in the number of new nursing and administrative roles, as a direct consequence of the increased demands the Urology service has been experiencing. Staff were pleased with the addition of new team members and efforts to develop succession planning; however, they reported that the induction and training of new staff had been time consuming.

Despite efforts being made to increase nursing staff complement, in common with experiences across the wider health sector, there had been occasions that the Urology service, in particular in-patient wards, had been affected by staff shortages. Historically, in 2013, appropriate staffing levels had been agreed and funded. However, staff told us this agreement was now out of date especially due to the increased acuity of patients and staffing levels on the Urology ward had been reviewed and increased. To illustrate the local difficulties, staff told us that at one time 3 WTE members of staff were on sick leave, two were on maternity leave and 6 others were not available due to a variety of reasons. However, the ward was still showing as being fully staffed. Staff told us that the Trust is working extremely hard to retain existing staff and also to retain student nurses and they have developed a number of initiatives such as a student alignment process to aid retention of staff.

The Trust now employs a cohort of international nurses but it has taken a lot of time and effort to ensure they become effective members of the Trust workforce. They are new to the post, new to the area and in relation to surgery they may be new to this discipline. We were told it may take up to a year to bring this cohort of nursing staff up to speed.

Staff also told us that the CNO is planning to develop a workforce App that could drill down into the number of staff on sick leave at any time as well as quantify the use of bank and agency staff. These data could be used to inform directorate meetings, Board meetings and CNO reports. From the Trust point of view, it would be a useful tool to inform local recruitment. Staff told us that lead nurses spend a lot of time and effort and a significant portion of their time each day, to ensure staffing levels are safe and also spend a lot of time trying to retain both existing staff and students.

The health roster is a discussed by ward sisters every morning, looking at both that day and the next day's potential staffing levels. If sickness is known, staff may be drawn from the nursing bank and if there is no bank availability, agency nurses may be brought in. If there is an urgent immediate shortage, then a ward may ask other wards to help with cover.

Staff reported that finding cover at short notice is exceptionally time consuming, especially if required for night duty, including progressing it through the approval

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process to go from bank to agency. Staff on leave may be contacted but only after exploring agency options.

Staff nurses and nurse leads reported that staffing issues would be reported to the Head of Service and subsequently to higher levels of management; however, staff reflected that these issues may not necessarily be added to the Datix system (incident recording system).

Staffing issues were only added to Datix if there was a significant risk to patient safety. As a result, reports from Datix would not accurately identify all trends associated with staffing, with associated risks.

The Trust has been considering succession planning in a number of ways. It was reported that there are a number of Staff at Agenda for Change Band 5 that are at the stage where they are ready to step up. The system used to be a lot more static but a number of Staff at Band 6 and at Band 7 are moving to other specialisms or into the community. Staff also told us that quite a few young nurses have moved to Australia. The outcome of this is that opportunities have opened up and the Trust is trying to facilitate succession planning by providing a number of training opportunities. The Trust has employed a cohort of nurses from India on permanent contracts. Once their contracts have finished, they might move on, but the Trust plan to encourage them to stay. A retire and return option is also available to nursing staff.

During fieldwork, staff reported that they had encountered difficulties with the recruitment of an additional Urology consultant. A recruitment record submitted by the Trust demonstrated that they had advertised for a new/ replacement consultant urologist(s) on seven separate occasions since March 2021, without success. During a follow-up meeting on October 2023, the Trust reported that they had since secured an additional Urology consultant who would be joining the service, and we were satisfied that the Trust was taking reasonable steps to recruit consultant staff.

Staff told us that a consultant of the week model is in place in the Urology department where their focus is to deliver ward-based care daily. This system is harder to manage within a small team. It is reported that it always going to be challenging within such a small team if one team member goes off on sick leave and a locum may be employed in this case. Admin backup had improved with all consultants now having 1 secretary to 1 consultant with administrative support now also provided to the CNSs.

The Expert Review Team noted the negative impact that staff shortages can have on the delivery of safe care. The Expert Team considered that by recording all instances of staff shortages on the Datix system, below those deemed the minimum required for that service or ward, this would provide the Trust with an additional mechanism which they

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could use to examine trends and patterns in demand and supply and more effectively support the development and analysis of effective staffing patterns.

Recommendation 4. The Trust should ensure that any critical staffing shortages that are likely to impact upon the delivery of safe care are appropriately recorded and monitored.

Staff Training

Staff told us that all new staff receive a Trust induction package with an induction booklet that needs to be signed off. There is subsequent follow up to ensure that induction training has been completed appropriately. Each department has an induction checklist and induction should be included in nursing appraisals.

We were told that the Trust has a Corporate Training Policy and training consists of a mixture of e learning with some face to face. Learning may be accessed in a variety of ways including the HSCNI learn system, staff App, Southern Eye global advertisements and staff newsletters. Each ward has a team training template, which allows for progress to be tracked.

In relation to mandatory training, a clinical education practitioner provides oversight of staff progress. They work with ward staff, as each ward maintains a matrix detailing each staff member's progress in relation to their mandatory training, which is updated weekly. Progress is reported to members of staff via text and email.

Staff told the Expert Review Team that mandatory training is included on the agenda of monthly directorate meetings. Each service's performance is reviewed and Heads of Service are then tasked with addressing any areas where improvement is considered to be necessary. The Head of Service follows up any training deficiencies with individual teams and any individuals involved will get a direct email setting out their requirements.

Managers' report directly to the senior leadership team and detailed data are available on SharePoint and learn SHSCTNI. Mandatory training is one of a suite of governance reports which includes complaints and SAIs.

Staff told us that clinical educators are responsible for keeping staff up to date and informed. A lot of staff access training outside of working hours and they can claim time back for this. It can be hard for them to get time during the working day, as they are often pulled away to deal with queries and to look after patients.

Staff also told us that the Trust is good at facilitating study or extra training and study days are available to attend conferences and forums and to develop specific skills. Staff are well supported by lead nurses and Heads of Service.

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Specific examples were provided where 2 members of staff attended a BAUS conference and 2 attended an AFBI conference. The Trust has an on-site Clinical Education Centre which provides a range of staff training and courses are commissioned through Queens University Belfast (QUB) and the Ulster University (UU). As wards are now better and more consistently staffed, it is hoped the Trust will be able to provide more in-house training and to have more effective rotation, to provide wider skills and experience.

We were also told that there are areas where no formal training is available, such as bladder training. In this case, the system relies on internal training provided by experienced nurses. Leadership and MDT training is provided for specialist nurses, as they are considered by the Trust to be valued members of the MDT, as they may have the best insight into the wider patient journey. However, staff considered that all ward staff are provided with sufficient training opportunities.

In relation to middle grade doctors learning, their education involves a mixture of learning by experience and theoretical knowledge, obtained through clinical papers, conferences etc. We were told that consultant Urology staff will have open learning discussions with junior doctors, going through the pros and cons of various treatment options for a number of cases. All junior staff and clinical fellows attend MDTs whenever their rotas permit. A member of junior staff described how they were very inexperienced when they had joined the Urology department but support from the registrar and consultant staff had shaped their experience and they quickly became much more confident. This was supported by access to MDTs, clinics and teaching. Junior staff felt well supported, had good access to study leave and all felt comfortable about speaking up if they had any issues. A junior doctor gave us an example where they considered that a treatment plan was outside recommended guidelines. They raised their concerns and when challenged they maintained their position and were listened to.

Senior Trust staff told us that the Trust provides a portfolio of leadership modules and programmes. A Trust leadership programme provided the opportunity for Band 6,7 and 8a nursing staff to better develop and manage teams and to develop techniques and support each other to become better leaders. Feedback from attendees was positive and attendees have been using techniques from the programme to more effectively lead and manage their teams. The Trust is now considering delivering this programme at band 5 level.

The Expert Review Team acknowledged the difficulties both the Trust has in providing time for and access to training opportunities and the difficulties staff may have in getting time to train, given how busy wards have become and the increasing acuity of patients, who require more comprehensive nursing care. We consider that the Trust seems to have an effective system for tracking mandatory training and information is passed on to

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senior staff and becomes part of Board reporting. Clinical Education Practitioners provide oversight of training levels and the Clinical Education Centre is an important asset. We considered that the Trust was providing sufficient training opportunities for all nursing staff, both ward staff and specialist nurses.

2.3.4 Risk Management

Identifying and mitigating risks

Effective risk management requires the identification of potential barriers to the delivery of safe care, with proactive steps taken to subsequently control and mitigate risk. The goal is to reduce the possibility of harm occurring, with associated significant consequences.

During fieldwork, the Expert Review Team reviewed the Trust 'Live Risk Register' which included a risk at a divisional level in relation to Urology Services. Urology staff reported that there was no dedicated service level risk register for Urology. Assurances were given that a change in approach to risk register use was being actively considered, with a view to the introduction of Service Level Risk Registers. Upon review of the Divisional Risk Register, the Expert Review Team was concerned that some risks included on the register had predated the formation of the Southern HSC Trust in 2007.

A copy of the Trust Corporate Risk Register (Dated January 2023) was submitted in evidence. Risks relating to The USI and Urology Lookback Review were 2 of the 8 principal risks included on the Corporate Risk Register. Information requests and allowing staff time and support to fully engage with the USI were described as potential risks to patient safety, due to reduction in capacity for clinical delivery. Non-completion of the Urology Lookback Review, was also noted as a risk on the register, due to its reliance on single medical practitioners as reviewers and ongoing cost.

We received copies of minutes from Senior Leadership Meetings and Urology departmental meeting notes as evidence from the Trust. Risk was included as a standing agenda item in Urology department meeting notes reviewed. It was noted in the minutes of one SLT meeting that the action to include the risk register as an agenda item was not suggested until May 2023.

During discussions with staff, we were told that risk registers are designed to be live documents, which should be monitored and updated regularly. It should be clear as to the status of a risk, when it has been reviewed and whether or not it remains unchanged. We were told that staff considered that the corporate risk register was well maintained but that there was still work to do at an organisational level.

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The Expert Review Team welcomed the work that the Trust was undertaking to improve risk management processes and the use of risk registers at an operational level. However, we were concerned that a number of risks contained on a divisional risk register that had been presented to us were historic and it was not clear as to who was responsible for managing specific risks and what mitigations had been put in place. We considered that risk registers are a critical component of risk management and allow tracking of risks from an operational level through to the Trust Board. Risk registers can help to focus attention on the most important issues within the Trust and provide the Board with sufficient information to satisfy itself that management has understood the risks and put in place appropriate mitigation and controls. This contributes to the Trust Board being able to discharge its own responsibilities.

Recommendation 5. The Trust should assure itself that risk registers at all levels are being used effectively, in order to help to facilitate the Trust Board in discharging its oversight responsibilities in relation to risk management.

2.3.5 Performance and Clinical Outcomes

Performance reporting in Urology Services within the Trust focused mainly on waiting times, acknowledging that delays in treatment can contribute to poorer outcomes for some patients. Senior managers, clinicians and frontline staff reported the many challenges they faced in relation to reducing patient waiting times, an issue which they described as pre-dating the Covid-19 pandemic.

A recent GIRFT in review, October 2023, reported on the average Urology waiting times by Health and Social Care Trust in Northern Ireland (based on data at 16 June 2023). This showed that the waiting times in the Southern Trust were longest for all types of referral; 5 weeks for a red flag appointment, 30 weeks for an urgent appointment and 155 weeks for a routine appointment[9].

Ministerial Northern Ireland cancer targets are:

- 95% of patients with an urgent referral for suspected cancer to begin treatment within 62 days.
- 98% of patients commencing first treatment within 31 days of the decision to treat being taken.

Review of the Performance Committee Report for March 2023, shared by the Trust confirmed an increasing length in waiting times against 14 (for breast cancer) and 31-day targets for cancer treatment. The Trust performance against these targets had deteriorated from 2018/19 levels and was below the regional average in 2022/23.
The 'Trust Broader Issues' Performance Report (June 2023) confirmed that the Trust had been experiencing reduced access to theatres and diagnostic services and this coupled

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with a reduction in outpatient capacity, had increased the journey time for those on the cancer pathway. In 2021/22, considering all cancer sites, 49.7% of patients commenced first definitive treatment in 62 days, which had deteriorated to 41.5% in 2022/23. At 23 March 2023, there were 507 people awaiting their first appointment on the 62-day target pathway for urological cancer. The longest wait for urological cancer was 302 days.

The Expert Review Team noted the use of the independent sector to deliver Urology elective cases. The Trust 'Broader Issues' Performance Report (June 2023) noted that an arrangement is also in place between the Trust and the Health and Social Care Board, now SPPG, to secure repatriation of some new referrals back to host Trusts for management as appropriate. The Trust confirmed that an additional £2.5 million had this year been made available to address elective pressures, which included Urology Services; however, the Trust was advised that this funding is non-recurrent and therefore should not be assumed to be available in future years. During staff meetings, we were also told of some successes. Contracts arranged with providers in the Republic of Ireland had meant that a list of catheter patients who may have been waiting for up to 7 years had now been cleared. Patients for planned stenting procedures were now waiting for only a few months compared to a previous twelve-month wait.

In relation to performance reporting to SPPG, a report goes from the Director of Performance to the Trust Performance Committee and meetings are held with SPPG performance and commissioning staff. Information is then cascaded down to the SLT then to directorates, service leads and to individual teams. The Trust Chief Executive meets with the Permanent Secretary on a regular basis to discuss performance.

During a follow up meeting with the Trust in October 2023, managers described how the recent reliance of the Trust on the independent sector was acknowledged to be a short-term strategy to help address excessive waiting times for some procedures. We were also told that staff were concerned about the effectiveness of governance systems between HSC and independent sectors. This was particularly in relation to sharing of information and access to patient records. We consider that as long as independent sector use in Urology continues, the Trust should ensure that governance systems between the two sectors are sufficiently robust.

Following the GIRFT review of Urology Services across Northern Ireland, published on 1 December 2023[10], further opportunities for modernisation reform and improved efficiency have been identified at a local and regional level, as part of a range of actions aimed at addressing Northern Ireland's exceptionally long waiting lists. These include recommendations in respect of workforce, oncology services, facilities, outpatients and diagnostics, urgent and emergency care and specialist services. The Expert Review Team considered that implementation of these recommendations will be important to safeguard the long-term safety and sustainability of the Trust Urology Services.

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Recommendation 6. As long as independent sector use in Urology continues, the Trust should ensure that governance systems are sufficiently robust.

2.3.6 Clinical Outcomes Benchmarking and Peer Review

Using hospital activity data to benchmark services with similar services elsewhere in the UK, is useful to identify where practice or outcomes may not be in line with peers. One such benchmarking programme, used widely across Northern Ireland hospitals, and in which the Trust participates, is the Comparative Health Knowledge System (CHKS). These reports provide service level comparisons in respect of mortality, efficiency, safety and quality. Though it is understood that the Trust does participate in this programme and receives information, reports, which include specific output for Urology, specific Urology reports were not provided as part of this Review.

The Trust also told us that it had participated in the NHS Cancer Services National Peer Review programme when it was previously commissioned and rolled out via the Northern Ireland Cancer Network (NICAN), across all the tumour site specific MDTs (including Urology); however, participation ended in 2019. The NHS Peer Review Programme is in a period of update/review and currently available via testing stage, however, participation in future may be possible, which would provide an additional source of benchmarking and quality monitoring.

2.3.7 Implementing Recommendations from Reviews, SAIs and Inquiries - Adopting and new/updated Clinical Guidelines and Standards

Clinical Audit and Quality Improvement

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria. Audits may provide. insight into issues and concerns, identifying areas that could be improved. Staff reported that they participate widely in local, regional and national audits and junior medical staff were encouraged to undertake audits.

We received copies of the Trust Urology Services 2022/23 and 2023/2024 Annual Clinical Audit Programmes. Audits across each programme had been prioritised at four levels:

1. External 'Must Do' National Audits, NHS England Healthcare Quality Improvement Programme (HQIP) Quality Accounts List, including the national Confidential Enquiry into Patient Outcomes and Deaths (NCPEOD).
2. Other National Audits: National Audits not contained on the HQIP list, clinical risk, re-audit, complaints etc.
3. Divisional Priorities: Local topics important to the division.
4. Clinical / personal interest, education audits.

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In total, eighteen individual audits were listed in the 2022/2023 audit programme; outcomes were available for five of these audits, however, results for two of the external 'must do' topics where not available. One of the 'must do' topics for which there were results, Muscle Invasive Bladder Cancer at Transurethral Resection of Bladder Audit (MITRE) involved the audit of 5 patents.

Staff told us that clinical fellows have two non-clinical slots in which they can carry out audit or quality improvement projects. We were told of a current audit investigating their TP biopsy process to evaluate how accurate the process is in targeting lesions. We were also told that the audit system has developed from being very unstructured to a more structured, effective process.

Staff told us that there was still work to be done in deciding what is to be proactively audited and they also considered that they had not been very good at actually doing something effective with audit results.

In relation to quality improvement, staff considered that the trust overall had a quality improvement ethos and staff were encouraged to participate. Staff told us that they were aware of the Quality Improvement (QI) Team and if they are inexperienced in QI they are encouraged to start with something simpler like a leaflet which may turn out to be as effective as a grander sounding project. We were given examples such as bare clinic walls being covered with patient education and health promotion materials and a smart TV had just been purchased to run patient education videos.

Another example was provided in which a joint Urology/Gynaecology team had carried out a QI project which had resulted in the pathway between referral and diagnostics being process mapped and streamlined.

The Expert Review Team was encouraged by the reported QI ethos in the Trust and the fact that staff were being encouraged to participate in audit and QI. Especially given the difficulties encountered by the Urology department we were satisfied with the level of audit and QI activity that was happening based on the available information we had. However, we considered that planning of the audit and QI programme could be improved by considering incidents, complaints SAIs and near misses to more effectively target areas for improvement. The Trust should also assess the effectiveness of its process for delivering improvements suggested by audit and QI projects.

Recommendation 7. The Trust should assess the effectiveness of its process for planning audit and QI programmes, including consideration of re-audit and its process for subsequently delivering change following audit and QI.

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External Assurance

Invited external or internal review by a team of independent peer reviewers, provides healthcare organisations with independent assurances on the standard of care provided, helps to address potential areas of concern and identifies scope for quality improvement.

An invited clinical record review by the Royal College of Surgeons was completed in September 2022 in respect of a case record review of 100 cases identified by the Lookback Review. This review reported on 29 September 2022 and made 12 urgent recommendations to address patient safety issues and five recommendations for service improvement. These recommendations were being monitored by the Trust.

A Serious Adverse Incident Review, undertaken by an external team, was commissioned by the Trust following the identification of cases of concern. It involved a review of nine cases, resulting in 11 recommendations for the Trust.

RQIA carried out a Review of the Trust Structured Judgement Review methodology and process which was published in September 2022. The Review report made 18 recommendations designed to improve the Structured Review process and made a number of recommendations in relation to the process for the Trust Lookback Review.

More recently, the Trust has also participated in a regional GIRFT Review[11]. The report made 40 national recommendations designed to improve structures and ways of working, in order to improve performance, awareness and governance across Urology Services in Northern Ireland.

Phase I of this Review assessed the robustness of the Trust Lookback Review process, which included arrangements for its delivery and oversight. This was completed and submitted to DoH and to the Trust on 26 July 2023. This report highlighted many of the challenges faced by the Trust in undertaking a Lookback Review among delivery of a busy service, compounded by the Covid-19 Pandemic. It identified findings, such as the requirement to prioritise and identify key safety risks early in the lookback process and then ring-fence and mobilise essential skills and resources at pace, whilst safeguarding the capacity to protect and deliver critical services. Additionally, it highlighted the need to have clarity about roles of different oversight committees and external agencies scrutinising the work. The need for early agreement on what information, data and documentations should be shared to provide external stakeholders with assurance about identification and management of patient risk was an important learning point.

After reviewing the Root Cause Analysis Report and subsequent progress updates and action plans, the Expert Review Team considered that the Trust response was comprehensive, identifying any major gaps in oversight that existed. We also considered

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that the structures established for monitoring the action plan and progress reports provided positive assurance of an ongoing system of review and follow up. It was evident that recommendations remained a key focus of the improvement work within the service and were having an impact.

Clinical Guidelines

As with other specialties, national and regional guidance on the delivery of Urology care is provided by specialist bodies, for example, National Institute of Clinical Excellence (NICE)[12] and the British Association of Urology Surgeons (BAUS)[13].

Failure to properly oversee and assure the implementation of standards and clinical guidelines may result in deviations in the standard of care delivered within a service and may increase the risk of poor outcomes. For this reason, any instances where care/ treatment deviates from best practice, these should be agreed by a MDT and the rationale for doing so recorded.

During engagements clinicians and managers reported that there are numerous guidelines applicable in Urology Services, some of which are followed in their entirety, while others are partially followed, which reflects the specific nature of services offered within the Trust.

During fieldwork sessions, clinicians described the process adopted by the wider Trust in respect of recording, monitoring and reviewing clinical guidance across the Trust. This involves maintenance of a centralised spreadsheet, which contains each of the guidelines applicable to the Trust. The Trust submitted a spreadsheet which included a summary list of NICE Guideline Circulars received by the Trust. This spreadsheet presented for each piece of NICE Guidance the following:

- Title
- Date of issue
- Reference number
- If it was considered applicable to the Trust
- The name of an assigned Change lead

During fieldwork, Trust staff reported that all NICE guidelines recorded on the spreadsheet have been regionally endorsed since the Trust was formed in 2007. Documentation provided further evidence that the specific standards to be used, which had recently been updated further to the work Royal College of Surgeons and BAUS.

Staff reported that the Trust holds a Standards and Guidelines Forum each month, which is attended by senior management including Director, Assistant Director and Governance level staff. At this meeting, data re compliance with guidelines are reviewed prior to being

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submitted to the SPPG), Safety Alerts Teams and the National Institute of Clinical Excellence (NICE) Team, which assesses Trusts' compliance. Staff reported that they frequently run activity reports for the clinical service to support assurance and monitor this process. Overall, the Expert Review Team considered that the systems, process and reporting mechanisms that exist currently within the Trust, were working effectively to monitor performance against all the relevant standards. However, the GIRFT report demonstrates several areas where timely access to care remains a key challenge as a result of barriers attributed to service configuration, facilities and workforce.

SAIs / Complaints / Compliments

Datix is the online system used by HSC services on which all staff should report any incidents, near misses or risks. Trust staff told us that in their system, when a Datix incident is submitted, it is assessed at a weekly screening meeting and graded to identify the seriousness of the incident. In all departments, including Urology, the person submitting the Datix report carries out an initial grading of the incident. A copy goes to the Governance Team where it may be regraded. If considered necessary, a final grading may be carried out at a screening meeting. It is viewed by a number of people, which helps to ensure that each incident is graded and treated appropriately.

Staff told us that the number of Datix reports being submitted has increased, which they consider to be a positive sign of improved openness and that people were more comfortable with reporting incidents and raising concerns. Staff are also using the Datix process for near misses, which again is a positive factor and will help with system improvement. We were also told that the SAI process should be all about learning – it should not be just about apportioning blame.

In order to facilitate learning and improvement, incidents are themed. The system then allows for trend analysis. Staff weren't certain if it was possible to drill down below directorate level. They thought it would be possible to see all surgical incidents but it was perhaps not possible to go down to the level of Urology.

SAI action plans were previously contained in a word document which was held in a number of locations, which did not facilitate a coordinated response. The Trust is now attempting to hold them in one central document, which is widely accessible, so that all recommendations from SAI investigations can be monitored and tracked for outcomes. Staff told us that the Trust is in the process of implementing this system but it has not yet been finalised.

Staff were asked as to how learning from the SAI process was disseminated. Staff considered that it was important to assess the effectiveness of SAI recommendations, or if they were not considered to be effective, then why was this the case. Learning and outcomes from the incident needed to be measurable, with evidence as to how the

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underlying issue had been addressed. If early learning had been identified a template was completed which was then disseminated across directorates.

Previously, there had been an assumption that everything would automatically be corrected following a SAI investigation, with associated recommendations. However, this was not the case and the Trust is going to employ a member of staff (Agenda for Change band 5) to follow up on recommendations, seek evidence as to their effectiveness and subsequently audit to provide more robust assurance. Staff reiterated that they were at the start of a journey and it is still a work in progress. They told us there were still concerns over the volume of SAIs with a number still waiting to be signed off. They were also concerned about being able to obtain evidence of implementation and effectiveness for all SAI recommendations.

The Expert Review Team considered that, based on the available information, the Trust was working hard to improve its system for investigating SAIs, tracking recommendations, disseminating learning and assessing the effectiveness of any outcomes. It also should consider carrying out some audit in this area to assess progress.

In relation to complaints, staff told us that Care Opinion goes around each of the wards obtaining patient views and noting any complaints they may have. There is a post box in all areas and a complaints line is also available. All complaints come to the appropriate Head of Service, who will speak to the clinicians involved, investigate further where necessary and clear the response before it goes back to the complainant. All responses to complaints, MLA questions and possible litigation come from the Chief Executive via the responsible director. All complaints go through the Governance Team and are discussed at weekly and monthly governance meetings. If a response is late, the Governance Team will chase it up. Staff considered that it was vital that complaints didn't get lost. They also told us there is a forum for learning from complaints. Compliments are also captured and disseminated to staff who considered there were lots of examples of good work and it was very important that these were captured and fed back to the individual(s) concerned. Staff told us they received more compliments than they did complaints.

Senior staff told us that the complaints system had been changed two years ago. In the previous iteration of the system, only consultants' names were recorded and other staff wouldn't be identified.

Now any member of staff can be identified and information is aligned and triangulated across Datix. Staff considered that incidents were monitored well at team or ward level but it was more difficult at a service level. If there were any safeguarding issues these would be recorded by ward sisters and escalated to managers where appropriate.

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The Expert Review Team considered that based on the information available the Trust had an effective system for dealing with complaints.

2.3.8 Culture

Staff Support

During discussions, staff described how the previous three years had been a particularly stressful period. In addition to the Covid-19 Pandemic, this period had also involved several external reviews of the service and participation in a public inquiry. Delivery of usual clinical services had taken place in parallel with these but also in conjunction with the Trust Urology lookback exercise. These experiences had accumulated to a point where staff described that they were constantly in 'fight mode' trying to maintain service delivery whilst under high levels of pressure.

However, staff also reported that they considered there had also been positive changes as a result of learning arising from the external scrutiny. For example, staffing levels in administrative services and nursing had been increased. Increased staffing in these areas had provided the service and its staff with opportunities for service improvement which should lead to more robust assurance. For example, administrative staff have undertaken weekly audits of patient records and letters, while nursing staff had led in the development of specialist nurse led clinics.

Nursing staff described the informal support networks they had developed to support their colleagues who were involved in the public inquiry process. Staff in senior management positions were described as accessible and approachable, regardless of the pressures they too were experiencing.

Throughout fieldwork, while those staff we met commented on the positive changes that had happened, they articulated how important they thought it would be for the service and its staff to have time to reflect and digest findings arising from the USI. This time to reflect was considered critical to enable the service and its staff to formulate an action plan that would guide Urology Services into the future.

The Expert Review Team noted during discussions with staff that while the Trust had provided additional support for Urology Services through the allocation of additional resourcing, improvements had generally been led solely by the immediate Urology team and directorate.

A number of staff commented as follows on the pressure that Urology staff had been experiencing as a result of the Inquiry but also as a result of increasing staff pressures, numbers of patients and acuity of patients.

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‘There is so much pressure on a daily basis, as a lead nurse you want to do so much and you know the wards are broken and there’s so much sick leave and short staffing.’
‘It’s the fire fighting and juggling, for example 6 patients on top of 22 coming through and they won’t get placed today. Having to support young staff who are exposed to the stress, you get caught up in managing the moment and supporting staff, so you end up doing the paperwork at night.’

‘Significant impact on nurses. People look to nurses for everything, support, safety, emotional support when patients are vulnerable. A lot is expected of nurses at a daily level to ensure staffing is safe, patients are safe and supported, and manage all of the daily stresses. Need to bring hope and stabilise the workforce and ensure workforce and succession planning.’

However, while acknowledging the pressures staff have been experiencing, a number of staff exhibited a very positive outlook.

‘You have to have a voice to say what’s safe and what’s not – feel I have a voice to speak up if I need to.’

‘There is more acuity now, transformation is long overdue and everyone is feeling that. Things are getting better from a staffing perspective: as a lead nurse I can see where Urology is going to go from the Inquiry and doesn’t have the ability to give to it. Pressures from ED, beds, want to drive so much forward and have a quality improvement and pulled to deal with the pressures on a daily basis and deal with the issues and system when things are not right daily to ensure safety.’

‘Awards in nursing, though not so much for Urology and aware there wasn’t any nominations this year so will be looking at doing this in future years. Noted that experience in a previous role it definitely created a buzz and atmosphere across nurses and also when positive feedback is received.’

‘It shouldn’t be underestimated the affect the Urology Inquiry has had on staff, it has been huge and will be long lasting. And the amount of work put in to change the service and level of patient care. Now is the exciting time, still in some of the hardship and have a bit to go and are coming out of it, it’s the team and they are a credit. You can feel the emotion in the Urology meeting and when staff have to go to the inquiry to speak, also feel like I have a forum to speak. Feels listen to and supported and outpatients have two band 7 and four band 5s which is a result of being listened to and supported and having things acted on’.

‘The learning coming back from the lookback will not just be from outpatients and should extend to ward and have as many shared forums as possible. First Thursday of every month’.

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‘In a different place and thanks and partly to the inquiry. Three years wasn’t positive about the future, didn’t have succession planning, but it has been amazing and there is potential now and nurse led services have now started. A lot of this has been in response to the public inquiry and can see potential and are excited. Staff were always motivated but was never physically possible. But also need to heal now from the impact of the inquiry and daily had to pick up/emotionally support the same staff who negatively impacted by the work through the inquiry. Head of service is very accessible, feel supported and never had issue raising concerns. Even if Head of Service has weight of world on their shoulders they still had time and will take your issue – really high praise from staff about them in their skill and support for staff.’

The Expert Review Team was encouraged to hear the determination of Urology Services staff to improve the service given the pressures they have been operating under. We agreed that given the learning arising from the service’s involvement in the recent Reviews, participation in the USI, and the ongoing delivery of the Urology Lookback Review, there are now clear opportunities for this learning to be collated and shared across the whole Trust and beyond, in a supportive and controlled manner, to provide wider system learning.

During a follow up ‘sense check’ meeting with Trust staff in October 2023, we heard further evidence of number of recent actions taken by the Trust to support staff wellbeing. These included providing access to a psychologist who had recently visited Urology staff to facilitate team building exercises and to discuss methods of how best to manage stress in the workplace. The Expert Review Team considered this was a positive step; however, we questioned whether this was sufficient. During factual accuracy checks the Trust informed us that they have also facilitated Urology Team workshops in March, June and October 2023. The Workshops were led by an independent facilitator to enable to the team to discuss openly and candidly any concerns or anxieties due to the impact the Urology Public Inquiry.

Although staff described the range of learning and improvement that had been implemented within Urology Services, we would encourage the Trust to disseminate this learning more widely, as improvements in governance, assurance and oversight would be applicable across all services.

Recommendation 8. The Trust should assess staff culture in the Urology Service and investigate any possible detrimental effects the extra pressures they have been experiencing may have caused. Appropriate staff support should subsequently be put in place.

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Recommendation 9. The Trust should ensure that all learning arising from the Inquiry, and all other external Reviews, should be widely disseminated within the Trust and beyond.

Raising Concerns

Robust mechanisms which enable staff to escalate concerns quickly and appropriately are a vital component in delivery of a safe and effective service. All staff regardless of their role should be aware of the arrangements of how to raise concerns and of the Trust Whistleblowing Policy.

The importance of encouraging a culture of openness and transparency is well established and highlighted further in recent public inquiries and service reviews. In addition, within the Trust initiated Root Cause Analysis Investigation into a number of Serious Adverse Incidents, a recommendation was made that "the Trust must promote and encourage a culture that allows all staff to raise concerns openly and safely". On examination of documentation provided by the Trust, the Expert Review Team considered that the Trust had implemented several improvements in response to this recommendation.

One such improvement involved Senior Managers/Leaders within Urology Services ensuring they were more visible to staff by conducting ward workarounds. Higher visibility of senior management may help promote a culture of openness and provides frontline staff with further opportunities to ask questions and approach senior managers/leaders to raise any issues and concerns first hand. The Trust also introduced a Clinical Nurse Specialist Forum to encourage peer support and provide an opportunity to raise issues/concerns within cancer care in a safe space with support from senior managers.

The Trust has launched its 'see something say something' initiative where Trust staff are encouraged to raise concerns through their line management structure which would be treated confidentially. Cases involving raising concerns are held in a central log and a comprehensive analysis of outputs, learning etc. form closed cases is held twice a year. The Trust is trying to develop an upstream rather than a downstream approach with learning leading to prevention rather than just dealing with things when they go wrong.

The Expert Review Team commended the efforts of Urology Services staff to encourage an open and transparent culture, whereby staff of all levels feel empowered to speak up should need arise.

The Trust provided its 'Your Right to Raise a Concern '(whistleblowing policy) which the Expert Review Team considered to be comprehensive. It outlined an additional mechanism for staff to raise issues or concerns which may cause serious risk to patient and/or staff safety or provide evidence of potential fraud or corruption.

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During engagement sessions, staff were asked if they were aware of their local whistleblowing contact, whereby staff identified a Director of Human Resources. A Review of the Trust Whistleblowing Policy (issued 2018) confirmed this was indeed the Trust whistleblowing contact. However, staff added that due to the layout of the hospital site, they would be unlikely to interact with this person on a regular basis. Staff told us that they had received training in relation to whistleblowing and they now felt there had been a real culture change and would feel confident in raising a concern in line with the policy. Although the Duty of Candour is not a statutory duty in Northern Ireland, staff were aware that the Trust Chief Executive had an expectation that all staff would be open and honest in everything they did.

The Expert Review Team was reassured that most staff could readily identify their whistleblowing contact and as a result of discussions with staff, staff would be comfortable in raising issues and concerns. Some staff however, weren't sure of the person to approach if they had a concern. Given the recent events in Urology Services, the Expert Review Team considered that the Trust should assess the visibility and effectiveness of its process for raising concerns.

DoH is currently exploring potential actions to embed an open culture across the HSC, through its Duty of Candour work stream, linked with the implementation of the recommendations from the Inquiry into Hyponatraemia Related Deaths (IHRD). In a follow up meeting with senior managers, they voiced their support for the ongoing work overseen by DoH in respect of developing a Being Open Framework. In advance of further clarity being provided as to how this regional work will be implemented, we would encourage the Trust to take any action it can to maintain the progress it has made and to continue to evolve and embed its own policy on whistleblowing and speaking up.

Recommendation 10. The Trust should consider assessing the visibility and effectiveness of its process for raising concerns.

2.3.9 Patient Information and Feedback

Patient Information

The provision of detailed and accessible patient information is a fundamental element of safe, effective and patient centred care. Patients should be considered to be partners throughout their health care experience. During fieldwork sessions, nursing staff reported that patients were provided with written information on their condition, which was most often information that had been created by NICE / BAUS. During engagement sessions, patients confirmed they had received folders containing leaflets of information regarding their diagnoses and treatment plan.

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Patient Feedback

The Trust has a number of ways in which feedback is obtained from service users. During meetings with Trust staff, we were first told of the Working Together Strategy, through which individual Trust teams have a mechanism for reporting service user input, especially from frontline services. Team interactions, individual team members' and service user compliments, concerns or complaints are submitted to a central hub where the information is analysed and then shared back to staff to promote learning and improvement.

The Working Together platform is overseen by the Trust Patient and Client Experience Committee (PCEC) which is a subgroup of the Trust Board. The PCEC is chaired by a non-executive Board member and its membership includes representation from both executive and non-executive Board members. The membership of the committee also includes the Trust CEO and service user and carer representatives. The Trust has a number of peer facilitators, who will engage with patients, obtain their views and subsequently provide feedback. The Trust also participates in the 10,000 voices initiative which gives service users the opportunity to highlight anything important in relation to their care and what they may have liked or disliked.

Care Opinion

The Trust makes use of the independent feedback collated and reported by the organisation Care Opinion. This service provides patients and their families with an opportunity to share their experiences of an HSC service via personal stories. Since Care Opinion was launched in August 2020, the Thorndale Unit at Craigavon Area Hospital has received feedback in the form of 27 service user stories.

These stories have commended the unit's staffing team on their kind and professional approach to delivering care. Staff were also described as being excellent in relation to keeping patients informed and highly accommodating in how they met their needs.
A couple of these stories however reflected on how busy staff were and the waiting times they had experienced prior to getting an appointment. It was notable that each of the stories submitted to Care Opinion had received a customised response from the Trust.

2.3.10 Macmillan Review

In 2022, as part of a review of the Urology Cancer Service in the Trust, staff wished to engage directly with patients of the service, so that their experiences would provide authentic feedback and reflection and help to inform future service improvements. Macmillan Peer Facilitators were invited to support the Review through one to one conversation with patients of the service.

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Patient feedback in relation to the care they had received was overwhelmingly positive. Patients felt they had been well informed about treatment plans and timings, were included in the decision-making process and given options in relation to treatment. They also considered they had been well supported by Trust staff. The prevalent culture, based on the majority of conversations, seemed to be one in which the patient was valued and this culture was consistent from initial diagnosis right through the treatment process to aftercare.

Based on key insights gathered by peer facilitators, the key messages were summarised in the report as follows:

The role of the Clinical Nurse Specialist (CNS) was crucial, with patients reporting that the CNS provided high level care, continuity and reassurance. Some patients however were not aware of the CNS/Key Worker role, with some patients referring to 'Macmillan Nurses.' A small number of patients reported having had no contact with a CNS.

Patients reported that involvement in decision making provided them with a greater sense of choice and control over their care. They felt listened to and their choices were respected, even if their preferred option may not have been the one recommended by the professional. Some patients were however content to defer to the 'experts' and did not seek to be involved in decisions

Telephone appointments and consultations, where considered to be appropriate, were preferred by a significant number of patients. Patients reported that they were aware of the pressures on staff, especially in hospitals.

Waiting times between appointments were long for some patients and when treatment finished, patients could be left feeling insecure and worrying about what the future might bring. In such cases follow up support between appointments or after treatment finished could have provided a greater sense of reassurance to the patients concerned about their care.

Providing the patient with information about their treatment plan was important, including details about timings and stages of treatment. Patients said that if they were aware of everything in advance, this helped them prepare for what was to come. Lack of information about treatment or lack of a treatment plan, could lead to greater levels of uncertainty or even fear, with some patients resorting to the internet to search for information.

The submissions/documents provided by the Trust did not contain specific examples where patient feedback and experience had been used to inform improvement initiatives. The arrangements in place were noted by the Expert Review Team and deemed likely to provide good sources of information to inform improvement and development work. Staff

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told us that they felt that they could do better in demonstrating how patient feedback has been used. We considered that the Trust should explore additional ways for actively listening to/gathering patient views and experiences.

We however considered that it was important that the also Trust actively captures evidence and provides examples of how its user involvement strategy is enabling it to fulfil its statutory obligations to involve patients in key decisions about improvement and development of services.

Recommendation 11. The Trust should employ a wider range of methods for proactively listening to/gathering patient views and provide examples of how it meets its statutory obligations to involve patients in key decisions about improvement and development of services.

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Section 3: Part B, Patient Views and Experience

3.1 Methodology

In order to triangulate the findings from earlier engagements and review of documents, we engaged directly with patients, to seek their views and hear of their experiences in relation to the care provided by Urology Services in the Trust. Over a two-day period in September 2023, RQIA staff and a member of its Expert Review Team visited the Thorndale Unit, to explore with patients their experiences following their appointments.

3.2 Findings

The Thorndale Unit, located in Craigavon Area Hospital is the primary Urology outpatient facility of the Trust and has recently undergone renovation. The unit, which is located close to the main hospital entrance is run by five Clinical Nurse Specialists, with the majority of the Trust clinics taking place in this location.

Upon arriving, the unit was observed to be pleasant and well-appointed in appearance, with recently painted walls and décor. The unit does not have a dedicated reception area; instead, patients arriving for their appointment rely on a member of the staff noticing them in order to be checked in.

Staff on site facilitated the engagement process by asking patients attending the unit if they would consider discussing their experiences following their appointment. Those patients who agreed, engaged in a short interview style conversation, the key lines of enquiry (KLOE) of which explored their experiences of attending the service, which included:

- Appointment waiting times.
- Their experience of receiving care and treatment.
- How they were being kept informed.
- Opportunities to ask questions and raising issues.
- The provision of patient information available.

Feedback from patients, who were attending a mixture of new and review appointments, was resoundingly positive. The majority of patients stated that they had been referred into Urology Services by their GP. Patients spoke highly of their interaction with staff and confirmed that they had been helpful in facilitating access to the service, offering them a choice of date and time when setting up their appointments. Patients described how having a choice of appointment made it easier for them to plan their hospital attendance. Once at their appointment, patients described how staff were approachable and made every effort to ensure they were at ease while being checked in for their appointment.

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Patients who were attending a review appointment, described how they were given the contact details of a key worker within the service, who they could contact outside of their appointment if they had any questions regarding their care. Documentation provided by the Trust described the process of a patient being allocated a key worker (selected at MDM) following MDT diagnosis, a process which had been introduced based on the recommendations of the SAI Review. Patients new to the service and attending their first appointment reported that if they had any questions regarding their condition following their appointment, their first point of contact would be their referring GP.

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Section 4: Conclusions and Summary of Recommendations

Conclusions

This RQIA Review was commissioned by DoH to assess the effectiveness of the current governance arrangements, which contribute to assurance of the delivery of safe care, within the Urology Service in the Southern Health and Social Care Trust (SHSCT). It follows a number of other external Reviews, some of which had been self-commissioned by the Trust, which demonstrates the seriousness with which the Trust took its responsibility to invite external scrutiny and identify learning to improve the service swiftly.

RQIA's normal Review process is to develop an assurance framework using any available standards, guidelines and evidence of good practice, which if complied with, would demonstrate reliable organisational governance and management of risk, which contributes to providing safe and high-quality healthcare. An organisational questionnaire, based on the assessment framework, is then completed by the service/organisation being reviewed. Following analysis of the questionnaire and any supporting information, fieldwork visits are carried out, meeting staff at all levels and service users. Following this, all information is triangulated to produce a report which may contain a number of recommendations to improve the service.

Unfortunately, but understandably, in this case, due to many competing pressures the Trust did not have the capacity to complete a questionnaire and so we had to rely on policy documents submitted by the Trust supported by staff and service user engagement. Any conclusions we have reached are therefore based on the information available to us.

Overall, we observed a local team of clinicians and supporting staff, who were exceptionally committed to implementing learning, and could describe a significant journey of improvement, to ensure the delivery of care in line with expected standards and guidelines and who were confident in speaking up. The service has now been examined in depth from multiple perspectives which has driven improvement and strengthening of clinical governance and quality monitoring.

Staffing is an essential building block of safe care and appropriate staffing levels are essential to offset the increasing numbers and complexity of patients. The Trust has developed a more effective staffing structure, has increased its staff numbers and, based on the information we have, provides ample opportunities for staff training. Supervision and appraisal should be carried out in line with Trust policy.

Governance within Urology Services should go beyond examining Datix reports and complaints. A holistic approach to assurance looks at a wide range of information.

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We considered that the patient voice had not been adequately present and the Trust could perhaps be more effective in this regard.

Participation in audit and quality improvement were encouraged by the Trust but we felt that audit and QI programmes could be informed by a wider range of information. Based on the information we had, the Trust Board is being engaged and informed appropriately, though some work is still required in relation to risk registers.

The Trust has a number of methods for gathering patient experience but we considered that the Trust could widen its methodology and then be more effective in demonstrating how these views and experiences were being used, to effect change and improvement. We talked to a number of service users and they were all very positive about their treatment experience in the Urology department.

A member of staff reported to us that "it still feels raw. Still going through the Inquiry. We are still in fighting mode."

The Urology department has been subject to a number of external Reviews/assessments:

- A root cause analysis of 9 patients who had potentially suffered harm.
- Royal College of Surgeons (RCS) Review of 100 clinical cases.
- RQIA Review of the Trust structured judgement methodology.
- A GIRFT Review.
- The Urology Services Inquiry.

It would have been no surprise if, given this amount of external scrutiny, with associated pressures, staff morale had suffered. However, we were encouraged by the attitude and determination of Urology staff. They had recognised that change was needed and indeed was overdue and positive changes such as increased staffing levels and more effective succession planning had been driven by the USI and by the other Reviews. Staff were now looking forward to the future with a certain amount of optimism. Nursing staff also described the informal networks they had developed, to support their colleagues who were involved in the public inquiry process. Staff we engaged with were also confident that they could raise concerns safely and that their views would be listened to.

We consider that one of the main issues for the Trust is to maintain staff wellbeing and provide appropriate support for staff, which could also be accompanied by training for clinicians and managers on psychological safety, civility and human factors.

On reflecting on this review as a whole, based on the available information, the overall assessment provided should be regarded as positive, showing a service responding to concerns by learning and improving amidst a challenging wider context. We were

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impressed with the professionalism and dedication of the Trust staff with whom we engaged. However, the recently published GIRFT review evidences the extent of the ongoing modernisation, investment and development that is required in Urology Services across Northern Ireland and in the Southern Trust in particular, to support timely access to safe care and optimise outcomes for patients using these services.

As the Trust Urology Service builds further upon the recommendations made by this Review, The GIRFT review, and in future the findings of the Urology Services Inquiry, it is hoped this collated learning will add to strengthening the safety and quality of the care delivered. We would strongly encourage the Trust to share its learning and experience widely across the Trust and with other Trusts across Northern Ireland and beyond.

Summary of Recommendations

Recommendation 1. The Trust should have an effective succession planning process, to ensure that senior leadership roles are filled continuously and prolonged vacancies are avoided.

Recommendation 2. The Trust should ensure that records are kept which evidence that relevant clinical staff participate in the process of regular reflective supervisions, which should be conducted and formally recorded in line with its reflective supervision policy.

Recommendation 3. The Trust should ensure all nursing staff are up to date with their appraisals in line with the Trust appraisal policy and that active follow up takes place where appraisals are overdue.

Recommendation 4. The Trust should ensure that any critical staffing shortages that are likely to impact upon the delivery of safe care are appropriately recorded and monitored.

Recommendation 5. The Trust should assure itself that risk registers at all levels are being used effectively, in order to help to facilitate the Trust Board in discharging its oversight responsibilities in relation to risk management.

Recommendation 6. As long as independent sector use in Urology continues, the Trust should ensure that governance systems are sufficiently robust.

Recommendation 7. The Trust should assess the effectiveness of its process for planning audit and QI programmes, including consideration of re-audit and its process for subsequently delivering change following audit and QI.

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Recommendation 8. The Trust should positively assess the staff culture in the Urology Service and investigate any possible detrimental effects the extra pressures they have been experiencing may have caused. Appropriate staff support should subsequently be put in place.

Recommendation 9. The Trust should ensure that all learning arising from the Inquiry and all other external reviews should be widely disseminated within the Trust and beyond.

Recommendation 10. The Trust should consider assessing the visibility and effectiveness of its process for raising concerns.

Recommendation 11. The trust should actively employ a wider range of methods for proactively listening to/gathering patient views and provide examples of how it meets its statutory obligations to involve patients in key decisions about improvement and development of services.

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