Mr Glackin doesn't feel they are addressing any issues.

Dr Hughes suggested the trust needs a forum to address these issues.

Mr Glackin said their workload is another issue which needs to be recognised. He said they are "carrying more than their peers". Pressures causing risk with under resourcing of urologists and Cancer Nurse Specialist.

Dr Hughes agreed and asked to get data, he suggested if workload an issue causing underlying issues.

Mr Haynes advised here there is 1consultant per 90,000 of population, in England it is a lot lower.

Martina Corrigan advised the Western Trust has taken back their referrals from mid-September.

Mr Young advised the change in volume was only recently due to not being able to cope.

Dr Hughes advised he would share the draft report with MDM.

Kate O'Neill CNS advised she was astounded CNS had not been asked or been met with.

Martina Corrigan advised there was a meeting planned for Monday.

Dr Hughes said she had asked Patricia Thompson to speak with staff.

Kate O'Neill has only been made aware of meeting and thought it would have been formal.

Dr Hughes advised the issues were the absence of Cancer Nurse Specialist which was a deficit to the patients.

Kate O'Neill clarified it was not the fault of the nurses.

Dr Hughes agreed and advised when investigating the issues surrounding the Cancer Nurse Specialist he thought it was due to geographical but this was not the issue.

Martina Corrigan advised it was a fast process and the review team had to arrange to meet all the families involved. She advised both her and Patricia Kingsnorth liaised to arrange a meeting with Cancer Nurse Specialists.

Dr Hughes advised he needed to get the background of the cases before meeting with the Cancer Nurse Specialists. He apologised for the confusion and offered to chat more at the meeting arranged for Monday.

Jenny McMahon CNS said their role was central and provides a failsafe process that is benchmarked with other Trusts. She asked if other Trusts have the same issues as the Southern Trust.

Dr Hughes understands nurses meet patients with consultants or contact details are made available. He said one issue highlighted due to COVID was that patients were

CT chest without contrast.
Findings
No lung mass seen. There is no hilar or mediastinal lymphadenopathy.
No bony lesion visualised.

Conclusion
No thoracic metastasis seen.

Comorbidity Summary
Vertigo

Urology Services Inquiry

18.What, if any, difficulties or hurdles were you or other members of the review team faced with in the conduct of the nine SAI reviews? For each difficulty or hurdle identified, explain what steps were taken to overcome the issue, and/or whether it was possible to overcome the issue.

- The major deficit within the review was the inability to engage with the professional who was the named consultant for all the patients. This would have allowed some insight into variations from expected practice, as defined by regional and national guidelines. Despite repeated communications and extended timelines responses to questions regarding patient care were not received.

  Ref No111. 20200211

- I believe the Professionals in the SHSCT found the SAI review process concerning as the process involved review of patient pathways in a multidisciplinary setting. This moved governance questions from the actions of a single professional to the responsibilities of the wider team. I believe some felt this unfair, but the SAI report was based on expected care and on standards of care evidenced by the SHSCT team to Cancer Peer Review of their service.

- The deficits in care covered a range of cancer types, related to diagnosis, timely staging, and appropriate treatment. Patients were not informed of treatment varying from national guidelines or varying from the recommendations of the SHSCT Urology MDM. They did not give consent for this. This cohort were unsupported by Clinical Nurse Specialists, could not access services when needed and were not appropriately referred onward to oncology and palliative care as expected.

- The driver for the SAI team approach was informed by the experience and expectation of patients and families who were adamant that the SAI process should be independent from those providing service. The engagement with families resulted in questions moving from what happened to how it happened,

19.Having regard to any difficulty identified above, are you of the opinion that it undermined or impacted upon the quality of the SAI review process? If so, elaborate the reasons why you think this is the case.

- I do not believe that non-engagement by the named consultant hindered the “finding of fact” aspect of the SAI process – this was a process of benchmarking patient timelines, patient stories and patient outcomes against regional and national guidelines common to all urology cancer care. It is not unusual for SAI processes to caried out independent of the professional delivering care. We were however unable to ascertain why therapeutic choices were made, often at variance with regional guidelines and recommendations of the SHSCT Urology Cancer MDM. We were aware that a Specialist Urology Nurse was included in care of patients with benign

Southern Health and Social Care Trust

Acute Governance
Cancer Nurse Specialists
22 February 2021 @ 11am
Zoom

PRESENT: **Dr Hughes (Chair)**
Patricia Kingsnorth Acute Clinical Governance Co-Ordinator
Roisin Farrell, Governance Officer
Patricia Thompson
Martina Corrigan
Kate O'Neill
Leanne McCourt
Jenny McMahon
Jason

Patricia Kingsnorth thanked all for attending, she explained she tried to arrange the meeting in January but it had to be cancelled due to COVID. She advised the meeting that the CNS care was not brought into question.

Dr Hughes advised he was asked to chair the review. He advised he was previously Medical Director in the NHSCT and Director of NI Cancer Network. He has a pathology background.
He explained there was a huge deficit with not having Nurse Specialist's involvement in the patients care.
He gave a background to patients involved in the SAI review.

Patient 1 – Prostate cancer patient. His disease progressed and was not referred back or provided palliative care. The patient has since died. He did not get best care pathway.

Patient 9 year old Biochemical, PSA & potential prostate care. TRP came back negative. Variety of reasons things were missed. He later attended ED with query rectal cancer but was diagnosed with prostate cancer. The disease has progressed.

Patient 5 – Had a large renal cancer, he was treated exemplary. He attended ED no PSA or scan, was missed for 8 months. PSA was over 100 he probable had prostate cancer from start. Never got CNS.
Kate O'Neill believes she had met this man late last summer with Mr Haynes.

Patient 4 – High grade cancer. Should have been referred to oncology, didn't happen. Disease progressed and spread. He wasn't referred back to MDM and no referral to palliative.
Dr Hughes believes issues with lack of onward referrals.

Patient 2 – Very good first time care. He has rheumatoid disease and arthritis. He has been diagnosed with testicular cancer, recommendation referral for treatment, was not referred for treatment and was identified by BHSCT. No CNS assigned.

Patient 6 – elderly with possibility of prostate cancer. MDM suggested active surveillance. No CNS for support. No LRH. Doing reasonably well.

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Patient 7 – Renal mass. Multiple consultants involved. No CNS assigned until tissue diagnosis. Did have surgery and doing well. Question is how to support these patients prior to diagnosis. Personal Information redacted by USI and are very angst.

Dr Hughes advised another family Personal Information redacted by USI.

Jenny McMahon asked if patient should have got laparoscopy surgery.

Dr Hughes advised he was not sure. He believes a pathway should been drawn up. Then locums would be aware. There was no attendance at MDM.

Patient 3 – Penile cancer. He received local treatment, as a rare cancer should have been on regional and super regional pathway. There was a delay of 17 weeks from CT scan to diagnosis. Cancer very progressive and patient has died.

Patient 8 – Had TURP, small chippings. Wasn't referred back to MDM, missed for 8 months, don't feel he has come to any harm. Have issues with TURP and incontinence.

Dr Hughes feels the issues are
8 of 9 recommendations from MDM were perfect but none were put in place.
1 query of penile cancer.

Patient 9 – early diagnosis – Referral
Patient 4 – Referral to oncology
Patient 2 – Oncology – missed
Patient 6 – Oncology
Patient 7 – Super regional network earlier.

All should have had input from Nurse Specialists.

Dr Hughes invited staff to speak.

Kate O'Neill asked if the review was from Jan 2019 to 2020.

Dr Hughes advised one started in 2016.

Kate O'Neill advised during that time staffing team consisted of 2 staff. January 2017 an additional 2 more staff was allocated. At interview job description was changed. Had to re-advertise for staff. This did add to the staff but was a management role.

Leanne McCourt advised she was one of the original clinical sisters. She started in April 2017 and was successful and joined CNS 2019.

Kate O'Neill advised they had established 1 staff clinic and had new clinics Monday to Thursday. She advised at the clinic you might have 1 consultant and 2 reg's with 15 – 21 patient to process along with other work in 3 ½ - 4 hours. There were issues with staffing levels, she advised she would work longer on a Thursday. Kate said if there were 21 patients Monday – Thursday and 6 reviews their first priority was the 21 patients.

Dr Hughes advised these were first review patients. He advised they weren't given phone numbers. He needs to know if MrO'B had an issue working with Nurse Specialists or was it a deficit.

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Leanne McCourt doesn't feel he valued the Nurse Specialists. She recalled him asking her in the kitchen what the role of a Nurse Specialists was. He didn't understand the role if a Nurse Specialists.

Dr Hughes advised the Nurse Specialists was signed off in 2016. He advised the reason for Nurse Specialists are for patients. He advised he needs to know if it was a deficit because of work or this particular doctor.

Jenny McMahon said she had a very different experience. She advised she was not sure why MrO'B didn't invite CNS into the room and feels this is a question MrO'B needs to answer. She advised MrO'B spoke very highly of CNS. She recalls MrO'B having review oncology on Friday but she wasn't asked to attend.

Dr Hughes confirmed he had asked MrO'B this question. He asked if it is reasonable to say resources were made available.

Jenny McMahon said yes they would have been made available if support was need on the day but advised nurse specialists were not invited to attend appointments.

Kate O'Neill advised the period during 2019 MrO'B only seen reviews, she asked Martina Corrigan if this was decided.

Martina Corrigan advised no. MrO'B decided to do this himself.

Kate O'Neill advised reviews changed to Tuesdays. She recalled MrO'B contacting her to help with cath etc.

Leanne McCourt agreed MrO'B would approach her to arrange prostate appointments.

Kate O'Neill advised if there was no nurse available other staff was available to assist.

Dr Hughes advised referrals were not made and no numbers given out even though resources were available.

Jenny McMahon felt MrO'B was very supportive of Nurse Specialists.

Dr Hughes advised there are 9 patients in the review and they were not referred to Nurse Specialists and 3 have died. He advised families were not aware of Nurse Specialists. He feels Nurse Specialist should be imbedded.

Jenny McMahon agreed contact details should have been given. She conceded there may not have anyone available on the day but patients should have been given contact details.

Kate O'Neill advised at MDT Nurse Specialists should have been present or available. She advised there was an audit done from March 2019 to March 2020, 88% was given Nurse Specialist contacts.

Dr Hughes asked Kate if she would send the information to him. He advised he wants to be able to say resources were available but patients were not referred. He feels this is a patient's choice whether or not to avail of the support of Nurse Specialists.

Jason advised he worked with MrO'B and his experience was entirely different. He said he may not have been in the room but would have been introduced after but with MrO'B he would not have had as much input. He said MrO'B may have given contact details in the

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room he doesn't know. He said MrO'B was supportive in other ways, he made him aware of other patients.

Dr Hughes advised families didn't know this service was available. Patients were unsupported and didn't have an understanding of their care.

Patricia Kingsnorth asked Jason if he followed up on patients results.

Jason said no patients were told to contact if needed.

Dr Hughes asked if they all get the opportunity to attend MDM.

Jenny McMahon advised no she hadn't linked for 1 year.

Dr Hughes asked if they can put patients on for discussion.

All said yes.

Kate O'Neill gave an example of contact from a patient. She was never questioned when she added to MDM.

Dr Hughes suggested they didn't have a seamless pathway.

Kate O'Neill asked if the SAI is to be closed at the end of the wee will be inclusive of MrO'B response.

Dr Hughes advised the draft report is to be completed to see if there is any early learning. He advised draft reports would be sent to the families. He advised families are more interested in how this happened. He added the report will include referrals not made and no contact details made available. He said this can't be done if referrals are not made.

Leanne McCourt advised in the year 19/20 they had 2016 patients. 14 from MrO'B. She advised they may have had a call later and took into process.

Dr Hughes asked staff to share their experiences.

Patricia Kingsnorth asked Leanne to clarify. Were those 14 from MrO'B.

Leanne McCourt advised these may not have been from MrO'B. She agreed to check for Patricia.

Dr Hughes asked if staff had any other questions.

Kate O'Neill advised it would be nice to work in an environment doing one job at a time. Reflected work load.

Dr Hughes acknowledged doctors have a work plan. He asked if they have a job plan.

Kate O'Neill advised it's to do what needs done on the day. If theatres need covered their day would change.

Dr Hughes advised there is no criticism of Nurse Specialists. The issues are with the person not refering patients which is best practice. He advised this review has highlighted the importance of Nurse Specialists. These issues are not of Nurse Specialists doing.

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Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

Meeting with Mrs Heather Trouton Executive Director of Nursing SHSCT
Dr Dermot Hughes – Chair of SAI review

Note taker – Patricia Kingsnorth Acute Clinical Governance Coordinator

23 February 2021 at 13:30 via zoom

Patricia welcomed Mrs Trouton and introduced her to Dr Hughes and explained that he was chairing the SAI review and that he had some questions he needed clarification for.

Dr Hughes provided a summary of the urology review to date in relation to meeting 8 of the 9 the families twice and understanding their experiences of their care.

He explained that the main concern was around the patient's access to a cancer nurse specialist. None of the 9 patients received the services of a cancer nurse specialist and therefore they were not supported on their cancer journey which for some caused serious distress.

Dr Hughes explained that as part of the review the quality of care provided was not in question as patients did not receive any care.

He explained that the NICAN guidance recommended that every patient with a cancer diagnosis was provided support from a cancer nurse specialist. This assurance was provided to the peer review in 2017 that additional specialist nurses were resourced to provide this service. This was signed off by the chief executive. But the reality was that Mr OB patients were not given access to a specialist nurse. There were no checks and balances in the system to quality assure that this was happening.

Mrs Trouton advised that she was assistant director of Surgical and Elective Care until March 2016 when she moved to IMWH division. She advised that she was not in post when the NICAN guidance was implemented and could not comment on it. She advised that prior to leaving her post there were only two specialist nurses in post. One who was responsible for cystoscopy and one who was responsible for cancer care.

She went on to advise that as a Director of nursing she would expect any nurse to provide care in their professional role. Dr Hughes advised that he did not have an issue with the standard of care that the specialist nurses provided. His issue was that they did not receive any referrals from Mr O'Brien and therefore did not provide any care. Mrs Trouton asked if Dr Hughes thought that they should have sought referrals He replied that they should not but there should have been a system of checks and balances in place to ensure that Mr'OBrien's patients were being referred.

Dr Hughes advised that this was about the patients not getting access to a nurse and he wanted to understand how that could happen. He advised that this resulted in

SAI Urology Review

Meeting with Dr Joe O'Sullivan
Monday 4 January 2021 via zoom at 11:15

Attendees
Dr Dermot Hughes and Mrs Patricia Kingsnorth

Dermot Hughes (DH)
Dr Joe O'Sullivan (JOS)

DH thanks JOS for meeting with him and explained the process to date regarding the SAI review involving 9 patients (one with penile cancer, 1 testicular cancer, 5 prostate cancers and 2 renal cancers).

He asked if JOS was aware of any issues regarding the practice of Mr AOB?
JOS advised that when he came into post initially about 17 years ago, he had concerns in relation to the use of bicalutamide and that they had frequently challenged him about the treatment. He made recommendations in clinic letters questioning the use of bicalutamide 50mgs instead of the standard 150mgs or LHRH agonist therapy. In the cases he had seen, the dose of bicalutamide would not have resulted in a major detriment to the patient's therapy/outcome and therefore wasn't escalated further. JOS said he was aware that his colleague D M (as MDT Chair) had raised our concerns about AOB's bicalutamide prescribing with the then CD for Oncology, SMcA, probably in 2011.

JOS said that the MDT improved with the attendance of two of the newer consultants about 7 years ago.

DH advised that there were a number of delays of people being referred for oncology/ palliative care.

DH said that there were issues regarding lack of oncologist attending MDM as it was on the same time as lung MDM and that there was inadequate cover for CAH MDM.

JOS agreed he did want it recognised that there was a lot of good work from urologist in CAH and good involvement in MDT in particular he named two consultants Mr MH and Mr AG.

DH wanted to assure JOS that the SAI review will also recognise the good work the MDT are doing and recognised that the concerns relate to one person's practice. It would seem he worked in isolation despite being involved in a multi-disciplinary team. JOS said that was his impression of Mr AOB

Southern Health and Social Care Trust

Acute Governance
Darren Mitchell
Telephone call
23.02.2021

PRESENT: Dr Darren Mitchell
Dr Dermot Hughes
Mrs P Kingsnorth

Dr Hughes thanked Dr Mitchell for taking time out to talk to him today. Dr Hughes highlighted the reviews concerns identified in the SAI, explaining there was non-adherence to MDT recommendations, non-referral to oncology services for potential curative therapy, prescribing issues.
He asked if there was any knowledge regarding the concerns mentioned.

Dr Mitchell advised aware of issues going back decade in relation to hormone therapy prescribing, prescribing outside guidelines, Bicalutamide. Dr Mitchell advised he took over as chair of the regional urology MDM in 2015. He advised that they had challenged Mr OB on his use of bicalutamide as part of the development of clinical guidelines whilst Mr OB was chair of the NICAN urology group in 2015. Dr Mitchell wrote the regional guidelines for the use of hormone therapy. This was done in the hope this would address the issues around off-licence prescribing of Bicalutamide. This guideline was circulated and presented when Mr OB was chair of the NICAN urology group and he signed off on the guidelines.

Dr Hughes asked Dr Mitchell to share the guidelines mentioned. Dr Hughes advised a number of patients were to be referred to oncology and this was not done.

Dr Mitchell mentioned a radical bladder cancer case in 2016, Personal Information redacted by USI and Personal Information redacted by USI noted there was a significant delay in treatment whilst waiting for a bone scan, this case was flagged back to SHSCT. Dr Mitchell believes Mr OB was chair of the southern urology MDM at that stage.

Dr Hughes advised the review was looking at 9 cases, there are significant findings, delays in treatment and care, MDT recommendations were not implemented, referrals to oncology were never made for potential curative treatment, and patients were not brought back to MDT for review. Dr Hughes advised there were systematic issues. The recommendations will include structured review process of MDT processes. NICE guidelines were not adhered to regarding prescribing of bicalutamide. There was very poor oncology support at MDT, oncology attendance at MDT was rare. Dr Mitchell described issues

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trying to support the MDT in SHSCT it was a busy practice and they had difficult recruiting to cover this role.

Dr Hughes asked if MDT chair had questioned prescribing methods in accordance with NICE guidelines. Patients did not know, there were no onward referrals. One case of penile cancer was not referred to the super regional MDT for discussion following diagnosis.

Dr Mitchell asked about the testicular cancer case that was brought to his attention.

Dr Hughes advised the consultant did not refer, the oncology centre identified this patient and booked him, there was a delay in treatment.

Dr Hughes advised the consultants prescribing was against NICE/ NICAN guidance and would be grateful if he could forward a copy of the guidance signed off by the consultant.

Dr Mitchell agreed to forward this. Dr Mitchell advised he emailed the consultant in 2016/2017 about his prescribing outside recommended guidelines and highlighting it was his GMC duty to inform patients they were being treated outside the recommended guidelines. The patients were misled.

Dr Hughes advised recommendations of the SAI will reflect this issue. Discussions should be had with patients if treatment is outside the recommended guidelines and reason explained to them in and signed off by peers at MDT. He suspects that the issues around Mr OB were extensive and wide ranging. Dr Hughes advised families are asking the question why no one else knew.

Dr Hughes thanked Dr Mitchell for talking with him today.

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Received from Dr Dermot Hughes on 08/11/2022. Annotated by the Urology Services Inquiry.

disease but were unable to ascertain why those with malignant disease were not offered the same support.

- I believe that the most the most important aspect of the SAI was the experience of patients and families who experienced care delivered in a uni-professional fashion and different from that experienced by other patients attending SHSCT Urology Cancer Services. The major issue throughout the reviews was the finding of care deficits that were professional specific but happened within a multidisciplinary setting. An SAI is ultimately a learning and improvement tool – the weakness of this process was that those responsible for managing care and service did not have the opportunity to meet the patients and families and contextualize the deficits. The families had offered to be part of the assurance process which considering the trauma suffered was brave and constructive. I ensured this was included within the recommendations but acknowledge that some may have found this challenging.

20.Outline the nature and extent of any interaction you or other members of the review team had with (a) the Trust's Board, (b) the Health and Social Care Board and (c) the Public Health Agency in connection with the reviews, whether before you commenced, during the course of, or after completion of the reviews.

- I had no involvement with the SHSCT Trust Board, the Health and Social Care Board or the Public Health Agency directly. Mrs. Patrricia Kingsnorth managed these interfaces and the sole feedback received related to expected timelines for completion. There was no feedback regarding findings of fact or recommendations from these bodies.

Structured Clinical Record Review Process & Further Actions

21.What, if anything, were you told about the decision of the SHSCT to adopt a Structured Clinical Record Review process ("SCRR") in respect of other cases, apart from the nine you reviewed, which met the threshold for an SAI review? Specifically, address:

a. When and in what circumstances you became so aware of the intention to adopt a SCRR methodology.

- I became aware of this proposal from the Medical Director SHSCT towards the end of the SAI process that I was chairing. I had kept a distance from the SHSCT in-house triage process for patients reaching a threshold for SAI review, as I believed that information on ongoing governance processes could be perceived to inappropriately influence the independent aspect of the SAI process.

b.What, if any, view did you express to the SHSCT in writing or orally on the merits of this decision, or generally.

Urology Services Inquiry

Ref No3. 2020522

11.With regard to the steps taken and processes adopted by the review team to complete its work. Further, outline, in broad terms,: to each of the nine cases subject to SAI review, generally describe

1. Your specific role in conducting the reviews and actions taken by yourself.

- I was the Independent Chair of the SAI Review process and was responsible for the SAI review, the Root cause analysis, patient timelines and leading on Family Engagement. The External Expert Clinical advisor to the SAI process provided the independent clinical opinion on each case, based on patient records, MDT records and feedback from families. This was benchmarked against regional and national

  standards declared to External Peer Review as the Standard of care by the SHSCT Urology Cancer Services. Variances from expected best practice were identified, formed the learning within each SAI and resulted in an overarching arching plan.

2. What documentation was made available to the review team?

- The review team had full access to the patient record of care. This included radiology scans, laboratory results and multidisciplinary meeting notes and agreed care pathways. Patient and family experience along with patients and family questions were included in this record as care was often delivered by a single professional without recourse to other members of the multidisciplinary team. The review team considered the clinical care and pathways for all 9 patients. The Investigation team wrote to Mr A O'B with specific questions for clarification. These questions were not responded to despite extension of deadlines.

  Ref No4. 20200211

3. What relevant personnel, including management staff, clinicians and nursing staff;

   i. Did the review team meet with?

- Associate Medical Director and Clinical lead for Cancer Services SHSCT
  Ref No5. 20210111
  Ref No6. 20210107

- Assistant Director for Surgical Services SHSCT
  Ref No7. 20210204

- Nursing Director SHSCT

11 December 2020 **Our Ref:**

Private & Confidential

Dear Aidan

As you may be aware, I am the External Chair of the SAI processes into 9 patients who were previously under your care.

As part of the normal SAI process we have been carrying out interviews with all relevant members of staff who have been involved in these patients' care.
The interviews are based on the patient's journey and are aimed at identifying learning and making recommendations for future care. We are seeking to complete the staff interviews before Christmas in order to keep the timeframes of the review.

We would be keen to have your input into this process and would like to agree an appropriate time (in person/ zoom/ telephone).

Yours sincerely

Dermot

Dr Dermot Hughes
Chair of the SAI Panel

Dr Dermot F C Hughes MB BCH BAO FRCPath Dip Med Ed

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Dr Dermot Hughes
Co SHSCT

Our Ref: AFA/

Your Ref:

Date: 23 December 2020

By email to; Kingsnorth, Patricia < [redacted] >

Dear Dr Hughes

SAI's
Mr Aidan O'Brien

I have been instructed by the Medical Protection Society on behalf of Mr Aidan O'Brien. Your letter to Mr O'Brien of 11 December 2020 has been passed to me. I have already explained to Miss Kingsnorth that our energies were diverted in relation to dealing with an Interim Orders Application before the Medical Practitioners Tribunal this week, hence the delay in responding to you. Mr O'Brien has also been unwell which has contributed to the delay in me receiving instructions.

Your letter has advised that you are the External Chair of a panel appointed to review Serious Adverse Incidents concerning nine patients previously under the care of Mr. O'Brien. You have invited Mr O'Brien's input into the process of your review. However, your letter is unclear in relation to what input you shall be requesting. It would be helpful if you could provide clarification.

If you are requesting information from Mr O'Brien in relation to the clinical care he has provided to the patients it will be necessary for him to be provided with:

1. The terms of reference;
2. The review methodology;

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3. A description of the incident/case;
4. The timeline drafted by the SAI group;
5. The threshold criteria for each SAI engaged;
6. Specific issues which you are inviting Mr O'Brien to address on a case-by-case basis;
7. Complete photocopies of hard copy records and complete data available on NIECR for each patient. To date Mr O'Brien has received only copies of the hard copy data in relation to 2 patients who appear to be the subject of the SAI's (referred to by the Trust as Service Users A and B) however in those cases he has not been provided with the NIECR records which are required to understand the complete chronology.

I look forward to hearing from you. Can you please let me have your response by no later than the 8th of January?

Yours sincerely

Andrew Anthony

ANDREW ANTHONY

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11 January 2021 **Our Ref:**

Private & Confidential

Dear Mr Anthony

As requested, please see attached questions for Mr O'Brien. I have arranged for copies of the notes for each patient to be sent to your offices. They will be sent recorded delivery.

I have attached the terms of reference and review methodology as requested
I have also enclosed a brief description with the questions. Unfortunately I can't paginate all the pages, but have put them into order for you.

As we are facing time constraints from the HSCB, I would ask that we receive the answers to my questions by close of play 29 January 2021.

The remaining requests you have asked for will need to be submitted by the Trust as they are beyond my remit as chair.

Yours faithfully

Dermot Hughes

Dr Dermot Hughes
Chair of the SAI Panel

Dr Dermot F C Hughes MB BCH BAO FRCPath Dip Med Ed

Questions for Mr O'Brien

Service User A

A Patient diagnosed with prostatic cancer (Gleason 4+3)

- Can you advise why the recommendation from the MDM (31.10.2019) was not followed regarding commencement of androgen deprivation according to regional NICAN guidance (2016)?
- The patient had no allocated specialist nurse to support his journey despite peer review and annual report documents indicating that these were available to all patients. Can you advise why this patient was unable to avail himself of this service?
- Why did you prescribe bicalutamide 50mgs?

Servicer user B

A Patient diagnosed with advanced prostate cancer when he presented in ED CAH in March 2020 despite benign pathology in June 2019.

- In a patient with biochemical and clinical evidence of prostate cancer- why was a TURP sample of 2g taken to indicate the absence of cancer?
- Why was the NICAN urology clinical guidance pathway for diagnosis not followed?
- If there was a clinical assumption of cancer, why was bicalutamide prescribed instead of adhering to the NICAN regional guidance regarding androgen deprivation therapy?
- The patient had no allocated specialist nurse to support his complex and difficult journey despite peer review and annual report documents indicating that these were available to all patients. Can you advise why this patient was not able to avail himself of this service?

Service User C

A Patient diagnosed with a renal tumour. He had a CT scan on 17 December 2019. The scan result was not followed up despite being abnormal.

- Can you advise why his CT scan result was not followed up in December 2019?
- Can you advise why the patient was not allocated a specialist nurse despite peer review and annual report documents indicating that these were available to all patients?

Service User D

A Patient diagnosed with prostate cancer (Gleason 5+5)

- Why was this patient not referred to oncology?
- When his disease progressed, why was he not re-referred to the MDT?
- Why wasn't he prescribed ADT as per protocol?
- The patient had no allocated specialist nurse to support his journey despite peer review and annual report documents indicating that these were available to all patients. Can you advise why this was unable to avail himself of this service?

Tughans

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Dr Dermot Hughes
C/o Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital

Our Ref: AFA/AK/00003911.100

Your Ref:

Date: 22 January 2021

BY EMAIL

Patricia.Kingsnorth[redacted]

Dear Dr Hughes

MR AIDAN O'BRIEN

I write further to my correspondence with you last week. As you will be aware Mr O'Brien [redacted] on Monday 18 January 2021. That followed a [redacted] before Christmas. In those circumstances it was not possible or appropriate for me to endeavour to take instructions from Mr O'Brien last week.

In order for me to obtain instructions with a view to replying to your letter of 11 January 2021 (sent by email on the 12th) I will need additional information and time to obtain instructions.

The following request for documentation and/or information arises from the documentation you have provided entitled "Level 3 Serious Adverse Incident Review Urology Services".

Please provide the following:-

1. The Datix Forms referred to on the front page. I note there appear to be eight Datix Forms yet nine cases. Is there an additional Datix Form missing?

2. The Terms of Reference are said to be "proposed draft Terms of Reference". Can you please confirm the Terms of Reference are still in draft or have they been finalised? Clearly, we need to be working from a finalised Terms of Reference. If they have not been finalised when will that occur?

3. I note the Terms of Reference may be amended "pending engagement with all affected patients and families". Has that engagement now occurred if not when will it occur?

4. Has any consideration been given to engagement with Mr O'Brien in relation to the Terms of Reference and, in particular, to seek his views in relation to the system within which he was

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E law@tughans.com

Aimee Crilly

From: Andrew Anthony <[redacted]>
Sent: 19 February 2021 16:06
To: Kingsnorth, Patricia
Subject: RE: Confidential response [TS-Live.FID694915]

Dear Ms Kingsnorth,

Thanks for your email, I did receive your below email.

Mr O'Brien is working through the voluminous documentation provided. The only manageable way to deal with this is on a case by case basis. We are progressing well with comments on Service Users A and B. I am on leave for the early part of next week. I hope to have comments to you on these two cases by the end of next week or at the latest early the following week. Perhaps you would be good enough to update Dr Hughes.

Would it be possible for you to forward to me the IR 1's upon which the Datix reports were based?

Kind regards,

Andrew

ANDREW ANTHONY
Partner
[redacted]
T: [redacted]
M: [redacted]
D: [redacted]

Tughans / Marlborough House, 30 Victoria Street, Belfast BT1 3GG

From: Kingsnorth, Patricia <[redacted]>
Sent: 19 February 2021 10:39
To: Andrew Anthony <[redacted]>
Subject: FW: Confidential response

Dear Mr Anthony
Please can you confirm if you received my email sent on 10th February as I didn't receive an acknowledgement.
If not please see attached response.
Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital

HSC Business Services Organisation

Directorate of Legal Services

2 Franklin Street, Belfast, BT2 8DQ

Via email [redacted]

Mr Andrew Anthony
Tughans Solicitors
Marlborough House
30 Victoria Street
Belfast

Date: 5th March 2021 Our ref: ERLS104/03 Your ref: AFA/AK/9MP28112

Dear Mr Anthony,

RE: YOUR CLIENT: MR AIDAN O'BRIEN
OUR CLIENT: SOUTHERN HSC TRUST

As per previous communications from my client please find enclosed copies of draft Serious Adverse Incident reports conducted by Dr Dermot Hughes. These remain as draft reports pending any final comments from relevant parties.

As you are aware, your client was offered the opportunity to contribute to these reviews, however to date no response has been forthcoming. At this stage, it is my client's intention to progress as per the regional procedure for the reporting and follow up of Serious Adverse Incidents. This will include:

- Sharing the relevant draft patient report and draft overarching report recommendations with each patient / family. My client intends to send these documents out by post on Monday 8th March 2021
- Sharing all of the overarching draft report and the recommendations from the patient specific draft reports with the Trust Urology and Specialist Cancer team on Monday 8th March 2021
- Upon finalisation of the Serious Adverse Incident reports, sharing the final reports with the regulator the General Medical Council
- Where appropriate, my client will share the finalised Serious Adverse Incident reports with relevant coronial services (in Northern Ireland and the Republic of Ireland as appropriate)

I would be grateful if you could share this information with your client.

Yours sincerely,

June Turkington
Assistant Chief Legal Adviser

Phone: Personal Information redacted by USI
Email: Personal Information redacted by USI

PAT-001481

Urology MDM @ The Southern Trust

RE: Patient 1 Personal Information redacted by the USI

DOB: Personal Information redacted by the USI, Hospital Number: CAHE Personal Information redacted by the USI , HCN: Personal Information redacted by the USI

CONSULTANT MR O'BRIEN: This Personal Information redacted by the USI year old man was referred in June 2019 with serum PSA levels of 19.16 ng/ml in May 2019 and of 19.81 ng/ml in June 2019. He reported mild urinary symptoms at review in July 2019, consisting of a sensation of unsatisfactory voiding following micturition, and of nocturia, having to rise once or twice each night to pass urine. He was noted to have been taking Finasteride since 2010 and Oxybutynin since 2016. He was found to have an indurated prostate gland on examination. He was reported to have a prostatic volume of 40 ml on MRI scanning in July 2019, when it was reported that he had a PIRADS 3 lesion within the anterior transition zone, and PIRADS 5 features with the peripheral zones of both lateral lobes.

An ultrasound scan of urinary tract and transrectal, ultrasound guided, prostatic biopsies were requested.

TRUS biopsy, 20.08.19 -
Prostatic adenocarcinoma of overall Gleason sum score 4 + 3 = is present in 7 of 20 cores with a maximum tumour length of 6 mm. The tumour occupies approximately 8% of the total tissue volume.

Discussed at Urology MDM 29.08.19.
Patient 1 has high risk prostate cancer. For review with Mr O'Brien to organise a Bone Scan, CT Chest, Abdomen and Pelvis. For further discussion at MDM with radiology results.

Patient 1 was advised of the histopathological diagnosis of prostatic carcinoma on 23 September 2019 when his serum PSA had increased to 21.8 ng/ml and his serum testosterone was 19.3 nmol/L. He was prescribed Bicalutamide 150 mg daily and Tamoxifen 10 mg daily while awaiting completion of imaging. The medication was accompanied by intolerable adverse toxicity, mainly in the form of light headedness, and to the extent that he lost the confidence to drive. He was advised to discontinue taking both on 14 October 2019, and to resume taking Bicalutamide 50 mg daily alone on 01 November 2019. A bone scan and CT scan of chest, abdomen and pelvis were requested. A review on 11 November 2019 was arranged.

CT, 28.10.19 - No evidence of metastatic disease.

Bone scan, 31.10.19.

MDM Plan:

PAT-001482

Urology MDM @ The Southern Trust

RE: Patient 1
Personal Information redacted by the USI

DOB: Personal Information redacted by the USI, Hospital Number: CAHE Personal Information redacted by the USI , HCN: Personal Information redacted by the USI

Discussed at Urology MDM 31.10.19.
Review with Mr O'Brien as arranged.
Patient 1 has intermediate risk prostate cancer to start ADT and refer for ERBT.

If you have any queries or require further information, please do not hesitate to contact us.

Yours sincerely,

Chairman of Urology MDM
Mr John O'Donoghue
Consultant Urologist

PAT-001453

78/CA.2/1

IN-PATIENT FOLLOW-UP AND OUT-PATIENT NOTES

Affix Label or Enter in Block Letters
Full Name
Date of Birth
Unit No.
Ward/Dept.
Address
Consultant

CAHE Personal Information redacted by the USI
HCN Personal Information redacted by the USI
Patient 1
Personal Information redacted by the USI

Personal Information redacted by the USI
HCN

NOTES

When used for In-patient follow-up ignore left-hand column

Out-Patient Use Only	Date	Clinical Notes
→		
Age		• MDM
URINE Protein Sugar Acetone		
WEIGHT kg.		
→	11/11/19	MR. A. O'BRIEN UROLOGY OPD CAN
Age		
URINE Protein Sugar Acetone		LUTS UNCHANGED
WEIGHT kg.		PLAN
→		• PSA = ↓ 3.84
Age		• ? CBRT / REVIEW
URINE Protein Sugar Acetone		
WEIGHT kg.		

30723

Southern Health and Social Care Trust

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

Organisation's Unique Case Identifier: 121045

Date of Incident/Event: 31/10/2019

HSCB Unique Case Identifier: S18317

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M
Age: Personal Information redacted by the USI

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off: 26 February 2021

Date submitted to HSCB: 1 March 2021

1.0 EXECUTIVE SUMMARY

XX a[redacted]year old man was diagnosed with a Gleason 4+3 prostate cancer on 28 August 2019. There was no evidence of perineural infiltration, lymphovascular invasion or extracapsular extension.

He was discussed at MDM on 31 October 2019, his bone scan and CT scan showed no metastatic spread outside the prostate. A recommendation to commence LHRH analogue and refer for an opinion from a clinical oncologist regarding external beam radiation therapy (EBRT) was agreed. This was not actioned. XX was commenced on Bicalutamide 50mgs once daily. He was commenced on LHRH analogue on 1 June 2020 and was referred to oncology on 22 June 2020. XX's disease progressed and he passed away on 18 August 2020.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS.
Mrs Fiona Reddick – Head of Cancer Services (SHSCT).
Ms Patricia Thompson – Clinical Nurse Specialist (Formally SET and recently SHSCT).
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator.

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

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

6.0 FINDINGS

This patient 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.

- The review team found that the initial assessment of XX was satisfactory although rather prolonged.
- The initial treatment should have been reversible ADT – most commonly a LHRH analogue – pending the results of the staging scans.
- The prescribed hormone therapy did not conform to the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (2016), which was signed off by the Southern Health and Social Care Trust (SHSCT) urology multidisciplinary meeting, as their protocols for cancer care for Cancer Peer Review (2017).
- This prescribing did not conform with the NICAN "Hormone Therapy Guidelines for Prostate Cancer 2016" which was signed off by Dr 1 as Chair of the Regional Urology Cancer Clinical Reference Group.
- The subsequent management with unlicensed anti-androgenic treatment (bicalutamide) at best delayed definitive treatment. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before ADT. Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1.7 nmol/l), which is best accomplished with ADT through a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.
- Following discussion with the families, the review team have noted that the variance from regional care pathways and the anti-androgen dosage used in his case was not discussed with XX. He could not and did not give informed consent to this alternative care pathway.
- The family also informed the Review Team that Patient 1 had not exhibited any of the vagueness implied by Dr 1.
- Of relevance to this case, the review team have identified that the MDMs were not quorate due to the absence of an oncologist at the meetings. During this timeframe 11% of meetings had oncology presence due to the lack of resource at SHSCT and a heavy clinical workload.
- The specific MDM recommendation of 31 October 2019, to prescribe a LHRH analogue and to refer to clinical oncology for external beam radiotherapy were not actioned. Dr.1 neither provided a noted rationale for this inaction nor was it

Southern Health and Social Care Trust

CRAIGAVON AREA HOSPITAL
68 LURGAN ROAD
PORTADOWN, BT63 5QQ

UROLOGY DEPARTMENT
Telephone: Personal Information redacted by the USI
E mail: noleen.elliott Personal Information redacted by the USI
Secretary: Mrs N. Elliott

DR S. LEONARD
LAKESIDE MED PRACT
ERNE ROAD
ENNISKILLEN BT74 6NN

Dear DR LEONARD

Re: Patient Name: Patient 1
D.O.B.: Personal Information redacted by the USI
Address: Personal Information redacted by the USI
Hospital No: CAHE Personal Information redacted by the USI **HCN:** Personal Information redacted by the USI

Date/Time of Clinic: 11/11/19	**Follow Up:** Review 27/1/20

I last wrote to you in October 2019 when I requested that you prescribe for Patient 1 the lower daily dose of 50mgs of Bicalutamide as he had been intolerant of the higher dose of 150mgs due to a sensation of lightheadedness. When I reviewed Patient 1 on the 11th of November 2019, I was pleased to find him keeping somewhat better, and able to tolerate the lower dose of Bicalutamide. He undertook to continue to take that lower dose until his further review, and whilst Personal Information redacted by the USI.

I have been able to speak with Patient 1 by telephone on the 2nd of January 2020, and was pleased to advise him that I had found his serum PSA level to have decreased further to 3.84ng/ml on the 11th of November 2019. I have asked Patient 1 to arrange an appointment with your Practice Nurse to have his serum PSA level repeated and so that the result will be available when he returns for further review on Monday the 27th of January 2020.

It would be ideal for Patient 1 to have an optimal biochemical response to androgen blockade or androgen deprivation prior to consideration of radical radiotherapy. If his serum PSA level has not decreased further, it may be necessary to take an incremental approach to increased androgen blockade by increasing the dose of Bicalutamide to 50mg twice daily, and hopefully subsequently to taking the higher dose of 150mgs once again, as I suspect that the addition of a LHRH agonist may be more intolerable.

In any case, I look forward to reviewing him with the recent result of a further serum PSA level, and I will advise you in due course of plans for his further management.

Yours sincerely

Dictated but not signed by

Mr A O'Brien FRCS
Consultant Urological Surgeon

Date Dictated: 02/01/19	**Date Typed:** 10/01/20-NE

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.

clinical oncologist when radical radiotherapy should have been considered". Again, as detailed in the clinical history and above, this statement is incorrect. Radical radiotherapy was considered at MDM on 31 October 2019, and again at review of the patient on 11 November 2019. However, at that time, the patient was just beginning to tolerate ADT and did not wish to consider any further hormonal treatment until his further review in January 2020. Thereafter, his disease progressed while he proceeded to tolerate optimal, safe androgen deprivation with neo-adjuvant and adjuvant intent.

(14) The allegation that he "*developed metastases while being inadequately treated for high risk prostate cancer"* [PAT-001310] risks the inference that he developed metastases *because* he was inadequately treated. It was as a consequence of the experience of adverse toxicity to his initial treatment that his subsequent treatment may have been considered by the Review Team to have been 'inadequate' for a period of time. However, that 'inadequate' treatment resulted in an impressive biochemical disease response initially. Biochemical evidence of rapid disease progression emerged while his treatment returned to 'adequacy' and persisted after it had done so. The "*opportunity to offer him radical treatment with curative intent was lost*" due to his experience of adverse effects of the adequate hormonal treatment initially prescribed in September 2019. Thereafter, I do not believe that radical treatment with curative intent would have been curative, even if available despite Covid-19.

685. It is clear that the SAI report contains numerous serious errors in respect of my management of SUA. I can only reiterate the prejudice that has been caused to me, as well as to the family of SUA, by the failure to allow me a reasonable opportunity to provide comment to inform the SAI report in respect of the treatment I provided to SUA. This represents a recurrent theme of a Trust which has followed processes which are manifestly unfair and unreasonable, and thus produced a report which is replete with errors both clinical and factual.

686. It should also be noted that, notwithstanding the comments I have provided in

Southern Health and Social Care Trust

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

Organisation's Unique Case Identifier: 121851

Date of Incident/Event: 31/10/2019

HSCB Unique Case Identifier: S18333

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information redacted by USI

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB: 1 March 2021

1.0 EXECUTIVE SUMMARY

XX, a Personal information redacted (s40 FOI) year-old man, was referred to urology services in Craigavon Area Hospital (CAH) via the Emergency Department (ED) following an episode of retention of urine in May 2019. He was reviewed by Dr.1 who noted a raised PSA. Suspicious of prostate cancer, Dr.1 commenced XX on Bicalutamide (50mgs od) whilst awaiting transurethral resection of the prostate (TURP).

A TURP was performed. The findings were thought to be in keeping with bladder outlet obstruction due to bladder neck hypertrophy (enlargement). The bladder neck and prostate gland were partially resected and histology showed benign disease only. XX was able to pass urine prior to discharge home. A routine review for September 2019 did not happen. XX presented in ED in May 2020 complaining of abdominal pain and urinary retention. Following digital rectal examination an initial diagnosis of bowel cancer was made; histological examination later concluded XX had advanced prostate cancer.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally SET recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

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

respect of SUA, I am concerned by the contents of the Acute Governance Meeting with SUA's family on 9 November 2020 [PAT-001318]. This meeting was prior to the SAI report being prepared. It was prior to the Trust receiving any input whatsoever from me in respect of SUA. It is clear from the content of the notes of the meeting that a pre-determined view had been taken, which is not appropriate in the context of a review into a patient which had not at that point been completed.

SUB

687. I would make the following comments in respect of the SAI report regarding SUB:

(1) At page 3 of the SAI report it is stated that in my letter to the patient's GP following review on 2 July 2019 I deferred a prostatic biopsy until a planned review in September 2019. While I had indicated September 2019 in my clinical note, the letter in fact indicated that I hoped to review SUB in August 2019.

(2) In respect of this planned review, the report states that the "*appointment in September was not made and he was lost to follow up"*. The Executive Summary section of the report simply states that a "*routine review for September 2019 did not happen*". The report provides no analysis of why that occurred, which is surprising given how vitally important it is to the care that was provided to SUB. SUB should have been reviewed in August 2019, as I had hoped to do. If the Trust had ensured the provision of an adequate outpatient review service, SUB would have been reviewed, and he would have been found to have been as well as he subsequently claimed to be. He would have had prostatic biopsies, following by MDM discussion. If the Trust had ensured the provision of an adequate urology outpatient service, he would have been reviewed in August 2019, and would have proceeded to have prostate cancer safely diagnosed and appropriately managed. That is the single most significant issue in respect of the care provided to SUB and it is surprising that there is no reference to why that review appointment

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of the Northern Ireland Health Care Record

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

At presentation, XX was a Personal Information redacted by the USI year-old gentleman who attended the Emergency Department (ED) in Craigavon Area Hospital (CAH) on 1 May 2019 complaining of severe abdominal pain and urinary retention. He was catheterised and referred to urology.

XX was seen on 24 May 2019 by Dr.1 (Consultant Urologist) who noted a history of lower urinary tract symptoms and a failed trial removal of catheter (TROC). A serum prostate specific antigen (PSA), (which is a blood test that indicates the risk of the presence of prostate cancer), was elevated. Following examination, Dr.1 was suspicious of the presence of significant prostate cancer. He initiated partial androgen blockade by prescribing bicalutamide (50mgs, once daily) whilst awaiting a prostatic resection which was arranged for 12 June 2019.

On 12 June 2019, XX attended for TURP. The procedure was performed by Dr.1 who noted that the prostate gland did not look “particularly enlarged or obstructive”. Severe bladder neck hypertrophy and a trabeculated bladder were seen, (trabeculation represents bladder muscle that has thickened over time, possibly, but not exclusively as a result of obstruction to outflow of urine). The findings were thought to be in keeping with bladder outlet obstruction due to bladder neck hypertrophy (enlargement). The bladder neck and prostate gland were partially resected and XX was able to pass urine prior to discharge home.

XX was reviewed on 2 July 2019 when he was noted to have suffered an increase in urinary symptoms since discharge. It was noted there was no evidence of malignancy on histopathological examination, however, Dr.1 documented in the patient’s GP letter that he suspected there may be a cancer in the unresected prostate gland and therefore arranged a repeat PSA level, an ultrasound scan of the urinary tract and a MRI scan of the prostate. Depending on the PSA result, Dr.1 stated in the GP letter that he was considering performing a prostatic biopsy of the gland remnant but deferred this until a planned review in September 2019.

No appointment is recorded until XX attended the Emergency Department (ED) at CAH on 8 May 2020. He complained of severe urinary symptoms and was found to be in retention of urine. He was also noted to have some diarrhoea with associated rectal

5.0 DESCRIPTION OF INCIDENT/CASE

output through the catheter despite good hydration. XX reported passing urine per rectum. Faeces were seen in the catheter bag.

XX was admitted under the care of Dr.6 (Consultant Urologist) as he was in painful urinary retention, but the urology team were unable to pass a urethral catheter. He was taken to theatre for the open insertion of a suprapubic catheter under general anaesthetic.

A bone scan did not show metastases.

XX was reviewed by the acute oncology service during this admission; palliative treatment was recommended. It was decided that XX would need a defunctioning faecal stoma and possibly an ileal conduit (stoma bag for the bladder). XX was reviewed by the stoma nurse regarding future stoma.

The surgeons planned surgery for the defunctioning colostomy when XX felt able: he wanted to return home to recuperate before undergoing any further intervention. He was discharged home on 1 August 2020.

XX's case was discussed at MDM on 6 August 2020. The recommendation for de-functioning colostomy was confirmed, but the supra pubic catheter was to be maintained for urinary drainage. Palliative radiotherapy could be considered after XX's surgery and he was to remain on hormone therapy.

On 13 August 2020 XX attended the ED complaining of severe abdominal pain and was noted to have a recto-vesical fistula. He was admitted under the general surgical team and underwent an emergency laparotomy and defunctioning sigmoid loop colostomy on 14 August 2020. He was discharged home with a planned review by the urology team.

On 19 October 2020 XX was reviewed by Dr.5 (Consultant Urologist), it was noted that XX was having intermittent episodes of diarrhoea and penile discomfort. His PSA was noted to have risen to 17.30ng/ml and a referral was made to Clinical Oncology in Belfast City Hospital for further assessment.

6.0 FINDINGS

XX presented in urinary retention and demonstrated features of possible prostate cancer. This possibility should have been pursued by the request of a MRI of the prostate and pelvis and ultrasound guided needle biopsy of the gland. Alternatively, an urgent TURP and the needle biopsies could have been performed simultaneously after the MRI scan. This would have established the diagnosis and, following staging with a bone scan, the patient could have been referred for a specialist opinion on radical therapy.

- The review team believe that Dr.1 suspected prostate cancer based on clinical examination and raised PSA. Following TURP, which showed benign disease, there was no intention to consider this further until 3 months after presentation.

did not take place in the SAI report. I further find the term "*lost to follow up*" to be at best misleading and at worse disingenuous. SUB was not lost to follow up. He was not followed up within a reasonable or adequate timeframe because the Trust failed to provide an outpatient service that was fit for purpose. The service provided by the Trust exposed patients to considerable risks and caused harm to innumerable patients over the course of many years, and SUB is but one of that cohort of individuals so affected.

(3) When SUB was reviewed by oncology at the Cancer Centre in Belfast City Hospital on 5 November 2020, he was prescribed Bicalutamide 50mg daily, contrary to the assertion by the Review Team that Bicalutamide 50mg daily is only indicated for the prevention of tumour flare associated with the first injection of a LHRH agonist.

(4) The Report found that there '*was no record in the medical notes of a digital rectal examination (DRE)*'. This is incorrect as '*DRE: T3 ?T4 CaP'* is recorded in my handwritten note of the consultation on 24 May 2019.

SUF

688. I have appended my detailed comments in respect of SUF's clinical history and the SAI report in respect of Patient SUF to this statement [see supplemental October bundle pages 784 - 799]. However, I wish to reiterate the following points:

(1) The Executive Summary makes two statements. The first asserts that SUF was commenced on a low (sub-therapeutic) dose of Bicalutamide for prostate cancer. This is incorrect as he was commenced on Bicalutamide 50 mg daily to relieve his concern regarding the risk of progression of any presumed prostate cancer while awaiting confirmation of its presence by biopsy. The second asserts that there was no documentary evidence of any discussion of the radical treatment options for prostate cancer recommended by the Multidisciplinary Meeting (8 August 2020 [sic]). This

Southern Health and Social Care Trust

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

Organisation's Unique Case Identifier: 125819

Date of Incident/Event: 6 October 2020

HSCB Unique Case Identifier: S18793

Service User Details: (*complete where relevant*)
D.O.B: Personal Information redacted by the USI Gender: M Age: Personal Information redacted by USI

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN)

Report Author: The Review Team

Date report signed off: 26 February 2021

Date submitted to HSCB: 1 March 2021

1.0 EXECUTIVE SUMMARY

XX was commenced on a low dose (sub therapeutic) dose of bicalutamide for prostate cancer. There was no documentary evidence of any discussion of the radical treatment options for prostate cancer recommended by the Multidisciplinary Meeting (8 August 2020).

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director Western Health and Social Care Trust. Former Medical Director of the Northern Ireland Cancer Network (NICAN).
Mr Hugh Gilbert - Expert External Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick – Head of Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (Formally of the SET and recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The aims and objectives of this review are to:

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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Statements from Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement

6.0 FINDINGS

- The Review team note that following discussion with XX he was unaware that his care given was at variance with regionally recommended best practice.
- There was no evidence of informed consent to this alternative care pathway.
- Bicalutamide (50mgs is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH) analogue) treatment.
- In this case XX stopped the bicalutamide as they "didn't agree with his stomach".
- The patient and family were left unsupported.

Contributory factors

- XX was not referred to a Urology Cancer Nurse Specialist (CNS) to support and discuss treatment options. Their phone number was not made available to the patient.
- The review team have established that a CNS was available but there is no record of XX being referred to this support service.
- Dr.1 provided uni-professional care despite multi-disciplinary input. This left the patients unsupported especially as their disease progressed.
- There was no oncology referral.
- The MDM is not funded to provide appropriate tracking and focus only on 31 and 62 day targets. This combined with the absence of a Urology Cancer Nurse Specialist represents a major risk. There was no effective fail-safe mechanism.
- Use of bicalutamide was known to the MDM and was challenged. It was not minuted or escalated. This practice was also known externally within Oncology.

7.0 CONCLUSIONS

A standard pathway for this man was followed up to and including the first MDM discussion. At that point acceptable practice should have been to discuss the options available as recommended by the MDT. Most urological centres would have requested a bone scan to complete staging. Should the patient have chosen to pursue radical therapy it would have been reasonable to start ADT (an LHRH analogue) as neo-adjuvant treatment at the same time as referring on for an opinion from a Clinical Oncologist.

(5) The report finds that I provided uni-professional care despite multi-disciplinary input, and that this left the patient unsupported especially as their disease progressed. This is incorrect. There was no multi-disciplinary input as there had not been a multidisciplinary discussion of his diagnosis at a properly or adequately constituted MDM, as a CNS had failed to provide an input and as there was no evidence of disease progression while under my care.

(6) The report finds that there was no oncology referral. This is correct as I considered it inappropriate to refer SUF for radical radiotherapy until he had undergone assessment and management of his severe lower urinary tract symptoms, in compliance with NICE Guidelines [NG131 Paragraph 1.3.4].

(7) The report finds that the use of Bicalutamide was known to the MDM, was challenged, was not minuted, was not escalated and was known externally within Oncology. It is true that the use of Bicalutamide was known to the MDT and was certainly recorded in all cases at MDM when prescribed by me, such as would have been the case with SUF if he had been discussed at a MDM. I certainly have no recollection of it ever having been challenged, and I don't believe there is any record of it ever being challenged. In respect of this specific patient, Bicalutamide 50mg had already been prescribed in July 2019 prior to the 'MDM' in August 2019 (which was in fact simply an online review by Mr Haynes). The fact that Bicalutamide 50mg had been prescribed was noted on the MDM record under the section 'MDM Update'. No issue was raised by Mr Haynes in respect of the prescription of that medication.

(8) The report concludes that "*at that point, acceptable practice should have been to discuss the options available as recommended by the MDT".* Even though the options were not recommended by the MDT following discussion at a MDM, I would have discussed both options recommended by Mr Haynes, though advising SUF that all of the features of his confirmed

prostate cancer indicated that he would be best served by proceeding with management with curative intent. I would not have recommended active surveillance and did not recommend it. I recommended androgen deprivation prior to radical radiotherapy, as indicated in my letter to the patient's GP dated 27 October 2019.

(9) A letter from Mr Haynes to the Patient's GP dated 2 October 2020 refers to the patient indicating he did not recall any conversation about external beam radiotherapy as a radical treatment or discussion of surveillance as an option. I entirely refute that as both options were discussed with the patient by me.

(10) I initially prescribed Bicalutamide 50mg in July 2019 as the patient expressed some anxiety in respect of disease progression while awaiting prostatic biopsy. I then increased that to 150mg following review of the patient in December 2019. In view of the pronounced and bothersome urinary symptoms, especially the need for him to get out of bed 7 times each night, this therapeutic intervention and delay in referral to Oncology with a view to radiotherapy was perfectly justified and appropriate and in accordance with NICE guidelines.

(11) The patient was subsequently followed-up with regular PSA determinations and the possibility of radiation treatment was discussed with him by other clinicians, but he declined treatment on several occasions and so far as I can tell active surveillance has continued to date without adverse consequences. There is no conclusive evidence to suggest that active surveillance followed by delayed radiotherapy preceded by hormonal treatment with a LHRH analogue provides inferior outcomes to earlier radiation therapy. In many cases such as this, radiotherapy, preceded by LHRH analogue therapy, with all its attendant side-effects, especially in patients with pre-existing lower urinary tract symptoms, can be avoided and

8.0 LESSONS LEARNED

- The MDM should be chaired by a named clinician with responsibility for ensuring adequate discussion of every patient.
- Consideration should be given to ensuring that all patients and their GP's receive a plain-English copy of the MDM discussion.
- A Key Worker, usually a cancer nurse specialist, should be independently assigned to each patient with a new cancer diagnosis.
- All patients and their families should be offered an out-patient or telephone consultation with their Key Worker to allow reflection on their options.
- Patients should be invited to a joint oncology outpatient appointment at which all the treatment options available should be explained by the most appropriate clinician.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

A MDM chair's responsibilities must include regular quality assurance activity.

Recommendation 2

The MDM should be quorate.

Recommendation 3

The rationale for any decision to diverge from the MDM plan must be explained to the patient, documented in the communication with their GP, and subsequently validated by further MDM discussion.

Recommendation 4

The MDM must have an open supportive culture allowing members to raise clinical concerns.

Recommendation 5

The Southern Health and Social Care Trust must develop cancer service governance processes to identify deficits in care and to escalate these appropriately.

Urology Services Inquiry

Ref No8. 20210208

- Urology Cancer MDT including Consultant Urologists
  Ref No9. 20210218
- Clinical Lead NICAN Urology Cancer Tumour Group
  Ref No10. 20210225
- Urology Services Manager
  Ref No11. 20210225
- Urology Cancer Nurse Specialist team
  Ref No12. 210222
- Clinical Director Regional Cancer Centre BHSCT
  Ref No13. 20210106
- Clinical Oncologist BHSCT / Past Chair of NICAN Urology Cancer Tumour Group
  Ref No14. 20210223

ii. At what stage in the process were those individuals met with?

- The meetings took place throughout the SAI process, initially they were with core members of the Multidisciplinary Team providing the service to understand context of care within the SHSCT. Meetings with management and clinicians with managerial roles followed. This was, after identification of initial clinical deficits, in an attempt to understand governance of care and governance of those providing care.

iii. What was the purpose of speaking to those individuals?

- This was to gain a detailed understanding how cancer patient pathways were delivered in Urology Services SHSCT and to reflect how these related to SAI team members experience elsewhere. The meetings also sought assurance regarding how others delivered care within the urology service given the clinical deficits identified. This was critical to provide assurance regarding ongoing care quality. This would be a requirement of any SAI review. Discussions with managers and clinicians with managerial responsibility focused on governance of care and governance of those who provided care. Lastly, the meetings were to discuss how the care experienced by the patients under review varied from best practice and that provided by other members in the Urology Cancer Services Team.

iv. What was the outcome of speaking to those individuals?

Cancer, the assistant clinical lead for cancer and an Assistant director of Surgery. I asked that this was withdrawn by the SHSCT as editing rights had been restricted to the SAI team. I was conscious of the family discussions which focused on independence from those delivering service and those responsible for managing service. I believe this related to a lack of understanding on how Serious Adverse Incident Reviews and how level 3 SAI reviews are carried out. The amendments were edited into a separate document, and these were reviewed by me, shared with the SAI team and forwarded to the Cancer Management Team as a response – please see response to comments in Question 12.

Ref No95. 20210331
Ref No96. 20210421

15.Outline, in broad terms, the key themes, trends, findings or conclusions which the review team reached across the nine SAI reviews with regard to both patient safety and governance issues. It may assist you to refer the Inquiry to particular sections of the review reports.

- International best practice indicates that cancer care is best delivered on an agreed evidenced base by teams of professionals with differing but complementary skill sets. This should ensure patients are partners in care, informed about their care and supported throughout their journey – including the palliative phase of disease. Cancer Care in Norther Ireland has been resourced to a considerable degree to achieve these outcomes. Each cancer type has a regional group which includes patients, to determine best treatment pathways for each aspect of care – this is founded on research and international, national, and regional guidelines. The guidelines explain best care and how it should be delivered. Adherence to such guidelines is delivered at Trust / Hospital levels through patient discussion at the multidisciplinary team meeting.

  Ref No97. 20200817
  Ref No98. 20210125
  Ref No99. 20201230
  Ref No100. 20200910
  Ref No101. 20201229
  Ref No102. 20200202

- The SAI Review indicated that the above standards were not met and raised a range of Patient Safety and Governance issues. This related to a range of cancer types, timely diagnosis, staging, and appropriate treatment. Patients were not informed of treatment varying from national guidelines or varying from the recommendations of the SHSCT Urology MDM. They did not give consent for this. This cohort were unsupported by Clinical Nurse Specialists, could not access services when needed and were not appropriately referred onward to oncology and palliative care as expected.

- I believed that this approach would be constructive, providing patient and family engagement was adequately addressed.

  I have experience of this approach in another setting, and it can deliver high quality review of care – especially when there are expected care pathways to benchmark outcomes. It can be performed external to local service which provides greater public assurance and allows local service to continue for patients. The process of finding fact does not alter how a trust or professionals managing a service should interact with families and patients. My experience is that the Structured Review of notes should be only part of the process and the structure should include additional reviews considering patient and family stories. This can, to some degree, address the concerns that clinical notes, if incomplete, may result in flawed conclusions.

22.Since your participation in the series of SAI reviews in 2020, have you performed any additional work for the SHSCT in connection with Urology Services or governance generally, or have you been asked to do so? If applicable, outline what work you have undertaken or specify what work you have been asked to do.

- I had been asked by the SHSCT Governance Lead to be a critical Friend to the service and the Urology Cancer Service Manager did write to ask me to join the Urology Cancer Services team to help implement Recommendations. I considered this request but believed that if I took up such a role the recommendations might be viewed as “my recommendations” and not owned by the SHSCT. I decided not to undertake this role and explained my rationale to the Medical Director.

Learning & Reflections

23.Having had the opportunity to reflect upon the nine SAI reviews you were involved in, is there anything that would wish to say about the cases which you reviewed, the conduct of the review processes and the outcomes of the SAI reviews themselves, which is not already reflected in the respective reports?

- The SAI Review Team had an essential external component did include professionals from the SHSCT who discharged their duties in an exemplary manner. This was despite a potential perceived conflict of interest by some. I believe the local governance team were able to establish and maintain very positive relationships with patients and families, despite the traumatic nature of some of the findings. Although I met families on three occasions, the local team had ongoing interactions with patients and families ensuring details that would not otherwise have been known were included in the reports.

- Much of the SAI Reviews are framed in terms of what care and support patients did or did not receive. Patients with urological cancers often fall within the older age group and may be more often be passive recipients of decisions and advice. They may not have been able to seek independent information for themselves. They all had faith in the health service but were not given the opportunity to discuss their care or more importantly how their care varied from practice of others. Individual decisions of a single professional took precedence over patient’s rights to best care based on evidence and best supported care. This was not “patients as partners in care” and my

2.0 NETWORK CONFIGURATION OF THE UROLOGY CANCER SERVICES

Northern Ireland Cancer Network has three cancer MDTs which diagnose and treat patients with urological cancers. These are held at the following locations:

- Craigavon Area Hospital – Southern HSC Trust
- Belfast City Hospital – combined team for Belfast HSC Trust and South Eastern HSC Trust
- Altnagelvin Hospital – combined team for Western HSC Trust & Northern HSC Trust

The catchment populations of these MDTs are shown below:

Urology MDT	**Catchment**[1]
SHSCT	366,000
Combined for: BHSCT and SEHSCT	 366,000 341,085
Combined for: WHSCT and NHSCT	 297,000 467,000 *Of note the population base for urology is 480,000 representing the upper two thirds of both the NHSCT & WHSCT*
Total	**1,830,000**

Each MDT meets on a weekly basis. All MDTs have named surgeons who deal with urological cancers.

[1] *Source: NISRA, 2013 MYEs*

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

7.0 CONCLUSIONS

The Review Team would like to thank the patients and their families for their contribution to the report and their willingness to share their experiences. The process was difficult and at times traumatic for them.The review team acknowledge that this report may cause distress to the patient and their families, however the team has endeavoured to produce a complete and transparent account of each patient's journey.

The Review of nine patients has detailed significant healthcare deficits while under the care of one individual in a system. The learning and recommendations are focused on improving systems of multidisciplinary care and it's governance. It is designed to deliver what was asked of the Review Team by patients and families -" *to ensure that this does not happen again or that another patient suffers".*

The Patients in this review received uni-professional care despite a multidisciplinary resource being available to all others. Best Practice Guidance was not followed and recommendations from MDM were frequently not implemented or alternative treatments chosen. There was knowledge of that prescribing practice varied from regional and national guidelines in the Southern Health and Social care Trust, as well as more widely across the Cancer Network. This was challenged locally and regionally, but not effectively, to provide safe care for all patients. Inappropriate non referral of patients to oncology and palliative care was unknown.

The primary duty of all doctors, nurses and healthcare professionals is for the care and safety of patients. Whatever their role, they must raise and act on concerns about patient safety. This did not happen over a period of years resulting in MDM recommendations not being actioned, off guidance therapy being given and patients not being appropriately referred to specialists for care. Patients were unaware that their care varied form recommendations and guidance. They could not and did not give informed consent to this.

The systems of governance within the Urology SHSCT Cancer Services were ineffective and did not provide assurance regarding the care and experience of the nine patients in the review. Assurance audits were limited, did not represent whole patient journey and did not focus on areas of known concern. Assurances given to Peer review were not based on systematic audit of care given by all.

While it is of little solace to the patients and families in this review, The Review team sought and received assurances that care provided to others adhered to recommendations on MDM and Regional / National Guidance.

Four of the nine patients suffered serious and significant deficits in their care. All patients had sub-optimal care that varied from regional and national guidelines.

As part of the Serious Adverse Incident process, the Review Team had requested input fromDr 1. This related to the timelines of care, for the nine patients involved in the SAI reviews and specifically formed part of the root cause analysis. This fell under professional requirements to contribute to and comply with systems to protect patients and to respond to risks to safety. To date a response has not been received.

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.

Urology Services Inquiry

Themes, Trends, Findings and Conclusions

The Overarching SAI report reference exemplifies the themes along the patient journey –

Ref No103. 20210419

All information supporting the identified themes are extracts from the Overarching SAI report.

Professional delivering care without multidisciplinary professional input

- The MDT guidelines indicate "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". None of the 9 patients had access to a Key Worker or Cancer Nurse Specialist. The use of a CNS is common for all other urologists in the SHSCT urology multidisciplinary team allowing any questions or concerns that patients' have, to be addressed. This did not happen.

Failure of onward referral of patients to Oncology / Palliative care

- Service User A should have been referred to oncology initially and then to palliative care as his disease progressed.
- Service User B should have had an earlier diagnosis and referral to oncology.
- Service User D should have been referred to oncology and palliative care.
- Service User E should have been referred to oncology for time critical care.
- Service User F should have been referred to oncology.
- Service User G should have been referred to the Small Renal Mass Team.
- Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 but a Regional Penile Cancer Pathway was only agreed in January 2020.

Prolonged Treatment Pathways

- 5 of the 9 patients in this review experienced significant delay in diagnosis of their cancer. This was related to patients with prostate cancer and reflected variable adherence to regionally agreed prostate cancer diagnostic pathways, NIACN Urology Cancer Clinical Guidelines (2016).

  Ref No104. 20200817
- Service User B had a delay of over 15 months from presentation.

- The review team could not find evidence of a Digital Rectal Examination in the notes of Service User D - potentially missing an opportunity to detect his high grade cancer earlier in his pathway.

5.0 DESCRIPTION OF INCIDENT/CASE

at the Western Health and Social Care Trust on 17 February 2020.

XX was admitted to hospital in December 2020 following a fall at home which resulted in a fractured femur. His disease had progressed and he passed away on 16 January 2021.

6.0 FINDINGS

- The review team state that the MDM recommendations did not follow NICE guidance for the management of penile cancer [1,2] and there were opportunities at each meeting to intervene and question XX's management.
- The treatment provided to XX was contrary to the NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 [3]. This Guidance was adopted by the SHSCT Urology MDT and evidenced by them as their protocols for Cancer Peer Review (2017).
- This Guidance was issued following Dr 1's chairmanship of the NICAN Urology Clinical Cancer Reference Group.
- The initial clinical assessment of XX would have benefited from staging imaging either before or immediately after the original circumcision. The 17 week wait between the MDM recommending a staging CT and informing XX of the result was unacceptable.
- All cases of penile cancer should be discussed by the supra-network multidisciplinary team (MDT) as soon as the diagnosis is confirmed by biopsy.
- XX should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.
- The clinical stage G2 pT1 should have led to a consideration of surgical staging with either a bilateral Inguinal Lymph Node Dissection or sentinel node biopsy. This omission reduced the likelihood of XX's 5-year survival from 90% to less than 40%.
- The left Inguinal Lymph Node Dissection yielded only 5 nodes, which might be considered at the lower limit of that expected in experienced hands (raising the risk of under - staging).
- The consent form signed by the surgeon and patient is inadequate as it does not state the rationale for the procedure nor the potential complications.
- The timings between the steps in treatment and management were unduly long and failed to the show the urgency needed to manage penile cancer successfully.

6.0 FINDINGS

- XX was not referred to a Urology Cancer Specialist Nurse (CNS) nor was he provided with their contact details. The use of a specialist nurses is common for all other urologists in the SHSCT Urology Multidisciplinary Team.

- Without a CNS, any questions or concerns that XX may have had could not have been addressed outside the consultant reviews.

- Without a CNS, XX and his family were unable to access the multi-disciplinary support available to patients with cancer.

- The recommendations from MDT indicate "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".[(4)] This did not happen.

- The MDM was non-quorate due to the absence of an oncologist. The initial meeting held on 18 April 2019, after which XX's management deviated from the expected, was a virtual meeting and no record of attendance was kept. A virtual meeting is when a case is brought forward to initiate referral to the pathway. It occurs when there is no Multidisciplinary meeting occurring to avoid delay.

- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% in 2020.

7.0 CONCLUSIONS

Although there was a 5-week delay between referral and initial appointment, the management of this case was appropriate up to the MDM on 18 April 2019. At this point the MDM should have recommended an urgent staging CT scan and simultaneous referral onward either to the Regional / Supra-Regional Penile Cancer Specialist Group, or to a surgeon with the appropriate expertise, for all subsequent management.

Penile cancer is an unpredictable disease, but in this case appropriate management could have provided a 90% 5-year survival. XX was not offered this opportunity. The Review Team has learned of the sudden death of XX and wish to extend their sincere condolences to his wife and family.

6.0 FINDINGS

- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% 2020
- The diagnosis of possible metastasis which would not have changed best practice was nevertheless pursued outwith expected timeframes.
- The review team note that there was no effective mechanism to track whether staging scans etc had been completed and actioned. The MDM is only funded to track 31 and 62 day targets.
- The review team suggests that when XX developed anaemia this should have been confirmed either as due to malignant involvement of the bone marrow or as an effect of severe chronic disease.
- The review team note that XX's case was not brought back to MDM for discussion and multi-disciplinary input despite high grade cancer and disease progression. As a result of this inaction, XX's care was not coordinated with the palliative care team.
- XX presented as an emergency admission requiring urgent surgery- despite the aggressive nature of his cancer and evidence of clinical progression, XX's case was not brought back to the MDM for consideration of Specialist Nurse input, oncology input or palliative care input.

<u>Specialist Nurses</u>

- XX was not referred to a Urology Cancer Nurse Specialist, nor was their phone number made available. Absence of a Cancer Nurse Specialist resulted in uncoordinated care and difficulty accessing support in the community.
- This was contrary to regional best practice guidance NICAN Urology Cancer Clinical Guidelines 2016 and contrary to the fundamentals of Multidisciplinary cancer care.

7.0 CONCLUSIONS

XX presented in acute urinary retention. The initial assessment of this should have included a digital rectal examination. The TURP was expedited by the significant development of haematuria rather than clinical judgement. The histology was an indicator of poor prognosis disease, and urgent staging including a CT chest/abdomen and pelvis together with a bone scan should have been reported within 4 weeks of the diagnosis. The information from these investigations should have been presented at an MDM whose recommendation should have included, even if not present, an urgent referral onwards to an oncologist for expert consideration of appropriate hormone therapy (ADT) and external beam radiotherapy.

Through inadequate treatment this gentleman's poorly differentiated prostate cancer was allowed to progress and cause him severe and unnecessary distress. There is a chance that despite this the clinical course might not have been any different, but he should have been given every opportunity to consider proper and adequate treatment options.

8.0 LESSONS LEARNED

- The effective management of urological cancers requires a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis, treatment planning and completion and survivorship.
- A single member of the team should not choose to, or be expected to, manage all the clinical, supportive, and administrative steps of a patient's care.
- A key worker, usually a cancer nurse specialist, should be independently assigned to every patient learning of a new cancer diagnosis.
- The clinical record should include the reasons for any delay in management decisions.
- After any patient interaction, best practice includes the prompt communication, with the patient and their General Practitioner, of the rationale for any decisions made.
- An operational system that allows the future scheduling of any investigations or appointments should be available during all clinical interactions.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

The multi-disciplinary team meeting is primarily a forum in which the relative merits of all appropriate treatment options for the management of their disease can be discussed. As such, a clinician should either defer to the opinion of his/ her peers or justify any variation through the patient's documented informed consent.

Recommendation 2

The audit and quality assurance of all aspects of the MDTs primary function should be assigned to an elected Chair.

- Service User F had a slow initial diagnostic pathway which was outside expected cancer care timeframes.
- Service User C had a delayed diagnosis of a metastatic prostate cancer following successful treatment of Renal Cancer. This was due to non-action on a follow-up CT scan report.
- Patient I had a delayed diagnosis of Prostate cancer due to non-action on a histopathology report at TURP.
- Patient H with penile cancer had a 5 week wait between referral and first appointment. Subsequent time to diagnosis and MDM were appropriate. He had a 17 week wait for a CT scan for staging.
- Service User G was on a renal mass surveillance programme - a recommendation at MDM to discuss his case with the regional small renal lesion team was not actioned and it is not known if they would have suggested earlier intervention.

Care that varied from Regional and National Best Practice Guidance

- The treatment provided to 8 out of 9 patients was contrary to the NICAN Urology Cancer Clinical Guidelines (2016). This Guidance was adopted by the Southern Health and Social Care Trust Urology Multidisciplinary Team and evidenced by them as their protocols for Cancer Peer review (2017). The Guidance was issued following Dr.1 & Chairmanship of the Northern Ireland Cancer Network Urology Cancer Clinical Reference Group.

  Ref No105. 20200202

  Ref No106. 20200910

  Ref No107. 20201229

Care that varied from SHSCT Urology Services Multidisciplinary Team Recommendations

- The MDM made appropriate recommendations for 8 of the 9 patients but there was no mechanism to check actions were implemented - this included, further investigations, staging, treatment, and appropriate onward referral.
- Dr 1 was present for the discussions and party to the recommendations, 8 of which were compliant with National and Regional Guidelines.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non-implementation of these MDM recommendations was unknown to others in the MDM. One patient D presented as an emergency and his care was changed to the MDM recommendation by another consultant.

6.0 FINDINGS

Multidisciplinary Meeting

- The MDM made appropriate recommendations for 8 of the 9 patients but there was no mechanism to check actions were implemented - this included, further investigations, staging, treatment and appropriate onward referral.
- Dr 1 was present for the discussions and party to the recommendations, 8 of which were compliant with National and Regional Guidelines.
- In the case of the 5 patients with Prostate cancer, 5 patients were referred to the Multidisciplinary Meeting and had appropriate MDM recommendations.
- Service User A and Service User D to start Androgen Deprivation Therapy with LHRHa while Service User F was advised to have active surveillance or curative intent radiotherapy. None of these recommendations were implemented.
- NICAN Regional Hormone Therapy Guidelines for Prostate cancer 2016 were not followed.
- Service User B had a delayed diagnosis of prostate cancer and was belatedly seen at the Urology MDM 15 months after his first presentation. The recommendations from this MDM were correct but not implemented. Regional NICAN Hormone Therapy Guidelines for Prostate Cancer 2016 were not followed
- Service User I had an unexpected diagnosis of cancer at TURP. His diagnosis on pathology report was not actioned and he was discussed at MDM 8 months after his surgery and pathological diagnosis of cancer. His subsequent MDM recommendations were correct.
- Two patients had renal cancer. Service User C was initially appropriately discussed at MDM with action on recommendations. However a routine CT scan in December 2019 was not actioned, leading to a delayed re-presentation to MDM with a second primary diagnosis of metastatic prostate cancer.
- Service User G was on a surveillance pathway for a small renal lesion he was appropriately discussed at MDM. The meetings were not always quorate but a radiologist was present on 4 out of 5 occasions. An MDM recommendation to seek input from the regional small lesion group was not actioned.
- Service User E had a testicular tumour and was appropriately discussed at MDM with the recommendation onward referral to the regional testicular oncology team. This recommendation was time critical but did not happen.
- Service User H was appropriately discussed at the local MDM at diagnostic stage. Unfortunately his treatments and further discussions were restricted to local level and did not meet the NICAN Urology Cancer Guidelines 2016. Patient H should have been referred to the Regional / Supra-Regional Penile Cancer Network according to NICAN Urology cancer guidelines 2016 and, although a Regional Penile Cancer Pathway was only agreed in January 2020, referral to a specialist with appropriate experience should have been pursued.
- Collation of MDM lists did not include a fail-safe list from histopathology. This would ensure all tissue diagnoses of cancer were cross checked against clinician declared cases. This would capture unexpected cases of cancer as in case I or as in case B where a delayed diagnosis presented to the GI surgeons

5.0 DESCRIPTION OF INCIDENT/CASE

chest, abdomen and pelvis.

The CT (9 July 2019) demonstrated no evidence of metastases (cancer spread). The following day XX underwent a left inguinal orchidectomy; the removal of left testicle and full spermatic cord). Histopathology confirmed that the tumour was a classical seminoma measuring 2.6cms across. Although the tumour was confined to the testes, it did involve the exit tubules from the testis (rete testis) and intratubular germ cell neoplasia was also found. These findings indicate a small increased risk of pre-existing spread.

Dr.1 planned to have XX's case discussed at the urology Multidisciplinary Meeting (MDM) on 18 July 2019. This took place on 25 July 2019 with the recommendation for Dr.1 to review XX in outpatients and refer him to the regional testicular cancer oncology service.

At XX's outpatient review with Dr.1 on 23 August 2019 it was noted that he had had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that XX would be reviewed in SWAH again in February 2020 by Dr.1 to determine if he wished to have a testicular prosthesis.

On 25 September 2019 XX was referred to a medical oncologist. XX was discussed at the urology MDM the following day when the referral onwards to medical oncology was noted.

XX was seen at the Cancer Centre at Belfast City Hospital on 1 October 2019 and his adjuvant chemotherapy started on 10 October 2019.

6.0 FINDINGS

- The review team acknowledge that there is limited oncology presence within the urology MDT and on the day that XX was discussed there was no oncologist present.
- The MDT was only quorate in 11% of meetings in 2017, 22% of meetings in 2018, on no occasion in 2019 and only 5% in 2020 - this was largely due to absence of oncology.
- It is the primary responsibility for the consultant in charge to make the referral to oncology. However, the normal failsafe mechanism would include an administration tracker or a Key Worker to ensure agreed actions, such as onward referral, take place.
- XX was not referred to a Urology Cancer Nurse Specialist nor was there a phone number made available to him.
- A Key worker or Cancer Nurse Specialist would support the patient on their journey to ensure key actions take place. The Southern Health and Social

with the patient and their General Practitioner, of the rationale for any decisions made.

References:

1. Hoffmann, R., et al. Innovations in health care and mortality trends from five cancers in seven European countries between 1970 and 2005. Int J Public Health, 2014. 59: 341.
2. Oliver, R.T., et al. Radiotherapy versus single-dose carboplatin in adjuvant treatment of stage I seminoma: a randomised trial. Lancet, 2005. 366: 293.
3. Laguna M.P., et al EAU Guidelines: testicular cancer.
4. Peer review Self-Assessment report for NICaN 2017).

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

The MDT should audit all aspects of its primary function, which includes the timings of access to definitive treatment. A Chair should be appointed to oversee the quality assurance of this function.

Recommendation 2

Any divergence from a MDT recommendation should be justified by further MDT discussion and the informed consent of the patient.

Recommendation 3

An operational system with sufficient administrative personnel to allow the prompt scheduling of any investigations or appointments should be available during all clinical interactions.

Recommendation 4

The Southern Health and Social Care Trust must develop cancer service governance processes to identify deficits in care and to escalate these appropriately.

10.0 DISTRIBUTION LIST

Mr Shane Devlin – Chief Executive SHSCT

Mrs Melanie McClements Director of Acute Services SHSCT

Dr Maria O'Kane – Medical Director SHSCT

Mrs Heather Trouton – Executive Director of Nursing Midwifery and AHPs

HSCB

PHA

team. The MDT pathway is a contract between the medical team and the patient. It is based on international best practice guidelines. Individuals do not have the right to deviate from that.

Patient 1's Daughter talked about Personal Information redacted by the USI, it was to be in Personal Information redacted by USI but they brought it forward. She described how her father was so fit and healthy and very clever and well known. People were shocked when they heard.

Dr Hughes advised you may go home and think and you may have more questions you may want to ask. You can contact us at any time.

Patient 1's Daughter advised it has being difficult working full time.

Patricia Kingsnorth offered psychological support to deal with grief and all that has happened.

Patient's 1 Daughter – welcomed this as she was paying privately for psychological support. She advised her mother may also benefit from some support. Patricia will explore and get back to them.

Dr Hughes advised that he would want to include the problems that the covid restrictions placed on Patient 1 and his family within the review.

Patient 1's Daughter advised family were not allowed in to visit her father when he was in Daisy Hill Hospital for 5 days. He was admitted before Personal Information redacted by the USI He was very upset.

Dr Hughes consoled, it must have been hard.

Patient 1's Wife advised that when someone is dying it should be different. Patient 1 thought I had abandoned him. That upset her. She advised about visiting him in the SWAH and that the ward sister let her visit him.

Patricia advised that was the humane thing to do.

Patient 1's Daughter advised they could not get a care package in place. The only nurse available was the rapid response nurse, she went out-side her duties and she washed dad, she went over and above her job. District nurse could not come out.

Dr Hughes agreed covid was caused problems; people won't access care and care stopped in some areas.

Patient 1's Daughter talked about the pressures it has caused on cancer services.

Patient 1's Daughter advised to manage, 2 people would sit with her dad, neighbours and extended family helped with this.

Patricia asked were any of the family or neighbours nurses?

following MDM discussion. Therefore, the agreed recommendations could not dictate the next steps in all cases, as not all patients were agreeable to comply with the recommendations, or the latter may not have been considered appropriate or advisable following a more holistic review of the patient.

311. In that regard, I note that Dr Hughes at PAT-001323 describes the MDT pathway as "*a contract between the medical team and the patient. It is based on international best practice guidelines. Individuals do not have the right to deviate from that."* I was surprised and concerned to read this and even more concerned that the family of SUA had been so advised. Certainly, I am unaware of any contractual relationship arising between the medical team and the patient based on an MDM discussion. Moreover, I have been unaware of any patient having appreciated or having been informed that he/she had entered into such a contractual relationship. Crucially, this statement fails to reflect a fundamental tenet of modern medical care that the patient has autonomy for their treatment decisions. The patient is not present at the MDM. If the patient is advised of a MDM recommendation and, following discussion with their treating consultant, decides not to proceed with the course of treatment recommended by the MDM, there is no question that the patient is entitled to do so. To suggest that the MDM recommendations are in some way mandatory or contractual is to fail to respect the principle of patient autonomy. The patient has the right to deviate from a MDM recommendation and that right must be respected by the consultant treating the patient.

(Q 42)

312. The final decisions regarding next steps are taken forward by the treating consultant when reviewing the patient. The MDT Core Nurse Member, Kate O'Neill, made sure that every patient was reviewed following a MDM. Each consultant would have been responsible for considering, discussing and informing the patients of the recommendations agreed following MDM discussion.