6.0 FINDINGS

- Patient 3 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 Patient 3 may have had could not have been addressed outside the consultant reviews.

- Without a CNS, Patient 3 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 Patient 3 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. Patient 3 was not offered this opportunity. The Review Team has learned of the sudden death of Patient 3 and wish to extend their sincere condolences to his wife and family.

Personal Information

8.0 LESSONS LEARNED

- The MDM should be quorate.
- If the MDM is not quorate, an accountable Chair should ensure, through appropriate Quality Assurance (QA), that every patient's potential management options are fully discussed and that the MDM's decisions are documented as having been communicated with the patient, their family, and their GP.
- A MDM Chair should ensure appropriate and a comprehensive Quality Assurance (QA) programme, that ensures adequate compliance with the MDM's published guidelines.
- All patients should be independently assigned a Key Worker, usually a cancer nurse specialist, to guide and advise them of their options.
- The MDM should regularly revisit their guidelines and policies to ensure best practice continues to be followed.
- The MDM should agree and audit, as part of QA, the indicative timings for the stages in cancer management.
- All patients whose disease fits the criteria for referral to a specialist MDT should be referred for advice and management at the completion of staging.
- Specialist urological cancer interventions should be delivered by appropriately experienced clinicians, normally at a specialist centre, who continue to demonstrate audited outcomes.

References

1. EAU guidelines for penile cancer: section 6.2.1 (2019)
2. NICE improving outcomes in urological cancer (2002)
3. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).
4. Peer review Self-Assessment report for NICaN 2017.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

A MDM Chair should develop an appropriate and comprehensive Quality Assurance programme that ensures adequate compliance with the MDM's published guidelines.

Recommendation 2

The MDM should agree and audit, as part of QA, the indicative timings for the stages in cancer management.

Personal Information

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 3

The MDM should regularly revisit their guidelines and policies to ensure best practice continues to be followed. This needs to be audited annually.

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

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

Personal Information

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**:26 October 2020						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exeXXise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			x
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exeXXise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

16 March 2021 **Our Ref:** Personal Information redacted by the **Your Ref:**

Private & Confidential

Patient 3's Wife

Dear Patient 3's Wife

I have previously been in contact with you about a review that the Southern Trust has been carrying out into the care your late husband Patient 3 received.

As advised at the meeting with you on 19 February 2021 the team has concluded their review.

Please find enclosed a draft copy of the SAI report for you to consider. Mr O'Brien has asked that a copy of correspondence he has issued to the Trust be enclosed with the draft report. This is also attached.

I also enclose a feedback form which we would be grateful if you would return to the Acute Governance Team within 2 weeks of receipt of this letter. This form details the two options now available.

1. If after reviewing the report you have no further comment and indicate this to us, we will forward a final draft to both you and the Health and Social Care Board.

2. Alternatively if you would like to discuss the findings and outcome of this review further, please state this on the attached form and a member of the Governance Team will be in contact with you.

If after 2 weeks the Acute Governance Team has not received a response from you the report will be finalised and issued to both the family and Health and Social Care Board in its final format.

I look forward to hearing from you in due course.

Yours sincerely

Personal Information redacted by the USI

Mrs Melanie McClements
Director of Acute Services

encs

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

Telephone: Patient 3
E-Mail: Patient 3

Sharing of Draft SAI Report

Patient/Family Feedback Form

Please complete the form below and return to the Acute Clinical Governance Team in the enclosed return envelope or email to acute.governance@southerntrust.hscni.net within 2 weeks of receipt of the report.

I _____ (name) confirm I have read the draft SAI report Personal Information redacted by the .

Please tick one of the two boxes below.

I confirm I have read and approve the draft report to be issued as the final report. ☐

or

I confirm I have read the draft SAI report and I would like to discuss it further. ☐

Signed: _____

Date: _____ Telephone: _____

Working together Excellence Openness & Honesty Compassion

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: Personal Information redacted by the USI

Date of Incident/Event: 18 April 2019

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

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

Patient 3 was referred to urology services on 20 February 2019 in view of a growth on his foreskin. He was referred for urgent circumcision which was performed on 10 April 2019. Histology confirmed squamous cell carcinoma. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease at presentation or subsequently. The MDM – which was a virtual meeting conducted by a single urologist recommendation was that Dr 1 would review Patient 3 and arrange for a CT scan of Patient 3's chest, abdomen, and pelvis to complete staging.

He was referred to the regional penile cancer service in February 2020.

On Personal Information redacted by the USI Patient 3 passed away. The review team wish to extend their sincere sympathies to his wife and family.

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 report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Family/ Staff involved in the care.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

The Review of the Northern Ireland Electronic Care Records

Family Engagement

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 3 was referred by his General Practitioner (GP) to the urology service on 20 February 2019. The GP documented that a firm mass was arising from under the left side of the foreskin and that there was pain on attempted retraction. It was noted that although the symptoms had been present for three months or more, Patient 3 had been reluctant to attend the GP. He had seen a locum GP two weeks previously and was prescribed a trial of miconazole and clarithromycin. Patient 3 re-attended as advised as the problem had not resolved.

On 2 April 2019, Patient 3 attended the urology outpatient clinic and was seen by Dr 2 (a specialist urology trainee) who noted the abnormal penile growth under the foreskin which was unable to be retracted. Dr.2 recorded that there were no palpable lesions in the penile shaft or either inguinal (groin) area. Patient 3's case was discussed with Dr.1 (Consultant Urologist) who examined Patient 3 and confirmed these findings. It was noted that Patient 3 needed a red flag (urgent) circumcision and he was asked to come in for operation on 10 April 2019.

The circumcision was carried out as planned by Dr 1 who subsequently advised the GP that in the course of the procedure it was evident that the lesion was confined to the glans (inner) aspect of the foreskin. Dr 1 noted that there was no suspicion of any glans penis involvement and that he anticipated that the circumcision had been curative. The specimen had been submitted for histology and the findings would be discussed at the Multi-Disciplinary Meeting (MDM) of 18 April 2019 with a review appointment to be subsequently arranged.

At the meeting on 18 April 2019, Patient 3's case was discussed. Histology had confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease at presentation or subsequently. The MDM – which was a virtual meeting conducted by a single urologist - recommendation was that Dr 1 would review Patient 3 and arrange for a CT scan of Patient 3's chest, abdomen, and pelvis to complete

5.0 DESCRIPTION OF INCIDENT/CASE

staging.

Patient 3 was reviewed by Dr 1 on 24 May 2019 and was advised of the histology. Dr 1 found Patient 3 to be keeping very well and to be satisfied with the cosmetic appearance of the circumcision. He advised Patient 3 that he had requested the CT appointment and that he would arrange an outpatient review when the report was available.

The CT (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no suspicion or evidence of any metastatic disease.

Dr 1 reviewed Patient 3 with this result on 23 August 2019. On clinical examination, Dr 1 was unable to palpate any left inguinal lymphadenopathy, but he arranged for an ultrasound guided, needle biopsy of the abnormal node to be performed on 6 September 2019 and for further management to be discussed at the urology MDM.

Cytology confirmed metastatic squamous cell carcinoma. At a MDM (12 September 2019) it was agreed that Patient 3 should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Patient 3 to a supra-regional penile cancer multi-disciplinary team. On 20 September 2019, when Dr 1 reviewed Patient 3, he was informed of the plan for him to return on 9 October 2019 for left inguinal lymphadenectomy. This was duly performed by Dr 1. Patient 3 was fit for discharge, four days later on 13 October 2019, but left hospital with an indwelling drain remaining on continuous drainage to prevent the development of a lymphocele.

Patient 3's case was discussed again on 17 October 2019 at the MDM and it was noted that the inguinal node dissection showed 2 of 5 nodes involved with metastatic disease. The MDM plan was that Dr 1 would review Patient 3 in outpatients and arrange a follow-up CT abdomen and pelvis.

Dr 1 reviewed Patient 3 twice weekly after discharge and found that significant volumes of lymphatic fluid drained daily from the left groin. Dr 1 incrementally withdrew the drain until it was removed altogether on 5 November 2019. He arranged to review Patient 3 on 8 November 2019 when he was able to aspirate 250mls of lymphatic fluid from Patient 3's groin; a volume that had accumulated over a period of three days.

Dr 1 arranged for Patient 3 to return to outpatients on Wednesday 13 November 2019 for further review and in the interim asked the GP to issue a prescription for antibiotics to be taken until the review, even though there was no suspicion of any infective complication. Dr 1 also requested a further staging CT scan for January 2020 and listed him for discussion at the Urology MDM with the result.

Patient 3 had a CT chest, abdomen and pelvis carried out on 22 January 2020 which showed a fluid collection and possible lymph node enlargement in the left groin. Furthermore, abnormal lymph node enlargement was seen within the pelvis and in front of the hip joint.

Patient 3 was discussed at the Urology MDM on 6 February 2020 when the new lymph node abnormalities were noted. The MDM recommended that Dr 1 would review Patient 3 in outpatients and refer him to the supra-regional penile cancer group for further

5.0 DESCRIPTION OF INCIDENT/CASE

management.

Patient 3 was seen by Dr 1 on 14 February 2020. He was referred to the penile cancer MDT at the Western Health and Social Care Trust on 17 February 2020.

Patient 3 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 Personal Information redacted by the USI .

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 Patient 3's management.
- The treatment provided to Patient 3 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 Patient 3 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 Patient 3 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.
- 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 Patient 3'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

6.0 FINDINGS

successfully.

- Patient 3 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 Patient 3 may have had could not have been addressed outside the consultant reviews.

- Without a CNS, Patient 3 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 Patient 3'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 to the Regional / Supra-Regional Penile Cancer Specialist Network for all subsequent management.

Penile cancer is an unpredictable disease, but in this case appropriate management could have provided a 90% 5-year survival. Patient 3 was not offered this opportunity. The Review Team has learned of the sudden death of Patient 3 and wish to extend their sincere condolences to his wife and family.

8.0 LESSONS LEARNED

- The MDM should be quorate.
- If the MDM is not quorate, an accountable Chair should ensure, through appropriate Quality Assurance (QA), that every patient's potential management options are fully discussed and that the MDM's decisions are documented as having been communicated with the patient, their family, and their GP.
- A MDM Chair should ensure appropriate and a comprehensive Quality Assurance (QA) programme, that ensures adequate compliance with the MDM's published guidelines.
- All patients should be independently assigned a Key Worker, usually a cancer nurse specialist, to guide and advise them of their options.
- The MDM should regularly revisit their guidelines and policies to ensure best practice continues to be followed.
- The MDM should agree and audit, as part of QA, the indicative timings for the stages in cancer management.
- All patients whose disease fits the criteria for referral to a specialist MDT should be referred for advice and management at the completion of staging.
- Specialist urological cancer interventions should be delivered by appropriately experienced clinicians, normally at a specialist centre, who continue to demonstrate audited outcomes.

References

1. EAU guidelines for penile cancer: section 6.2.1 (2019)
2. NICE improving outcomes in urological cancer (2002)
3. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).
4. Peer review Self-Assessment report for NICaN 2017.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

A MDM Chair should develop an appropriate and comprehensive Quality Assurance programme that ensures adequate compliance with the MDM's published guidelines.

Recommendation 2

The MDM should agree and audit, as part of QA, the indicative timings for the stages in cancer management.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 3

The MDM should regularly revisit their guidelines and policies to ensure best practice continues to be followed. This needs to be audited annually.

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

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HSCB

PHA

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report <u>for all levels of SAI reviews)</u>

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**:26 October 2020						
	If **NO**, please select <u>**only one**</u> rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exeXXise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						

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

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert date informed:			
	If **NO**, please select <u>**only one**</u> rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			x
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exeXXise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 18 April 2019

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

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

Patient 3 was referred to urology services on 20 February 2019 in view of a growth on his foreskin. He was referred for urgent circumcision which was performed on 10 April 2019. Histology confirmed squamous cell carcinoma. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease at presentation or subsequently. The MDM – which was a virtual meeting conducted by a single urologist recommendation was that Dr 1 would review Patient 3 and arrange for a CT scan of Patient 3's chest, abdomen, and pelvis to complete staging.

He was referred to the regional penile cancer service in February 2020.

On Personal Information redacted by the USI Patient 3 passed away. The review team wish to extend their sincere sympathies to his wife and family.

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 report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/ Family/ Staff involved in the care.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

The Review of the Northern Ireland Electronic Care Records

Family Engagement

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 3 was referred by his General Practitioner (GP) to the urology service on 20 February 2019. The GP documented that a firm mass was arising from under the left side of the foreskin and that there was pain on attempted retraction. It was noted that although the symptoms had been present for three months or more, Patient 3 had been reluctant to attend the GP. He had seen a locum GP two weeks previously and was prescribed a trial of miconazole and clarithromycin. Patient 3 re-attended as advised as the problem had not resolved.

On 2 April 2019, Patient 3 attended the urology outpatient clinic and was seen by Dr 2 (a specialist urology trainee) who noted the abnormal penile growth under the foreskin which was unable to be retracted. Dr.2 recorded that there were no palpable lesions in the penile shaft or either inguinal (groin) area. Patient 3's case was discussed with Dr.1 (Consultant Urologist) who examined Patient 3 and confirmed these findings. It was noted that Patient 3 needed a red flag (urgent) circumcision and he was asked to come in for operation on 10 April 2019.

The circumcision was carried out as planned by Dr 1 who subsequently advised the GP that in the course of the procedure it was evident that the lesion was confined to the glans (inner) aspect of the foreskin. Dr 1 noted that there was no suspicion of any glans penis involvement and that he anticipated that the circumcision had been curative. The specimen had been submitted for histology and the findings would be discussed at the Multi-Disciplinary Meeting (MDM) of 18 April 2019 with a review appointment to be subsequently arranged.

At the meeting on 18 April 2019, Patient 3's case was discussed. Histology had confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease at presentation or subsequently. The MDM – which was a virtual meeting conducted by a single urologist - recommendation was that Dr 1 would review Patient 3 and arrange for a CT scan of Patient 3's chest, abdomen, and pelvis to complete staging.

Patient 3 was reviewed by Dr 1 on 24 May 2019 and was advised of the histology. Dr 1 found Patient 3 to be keeping very well and to be satisfied with the cosmetic appearance of

5.0 DESCRIPTION OF INCIDENT/CASE

the circumcision. He advised Patient 3 that he had requested the CT appointment and that he would arrange an outpatient review when the report was available.

The CT (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no suspicion or evidence of any metastatic disease.

Dr 1 reviewed Patient 3 with this result on 23 August 2019. On clinical examination, Dr 1 was unable to palpate any left inguinal lymphadenopathy, but he arranged for an ultrasound guided, needle biopsy of the abnormal node to be performed on 6 September 2019 and for further management to be discussed at the urology MDM.

Cytology confirmed metastatic squamous cell carcinoma. At a MDM (12 September 2019) it was agreed that Patient 3 should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Patient 3 to a supra-regional penile cancer multi-disciplinary team. On 20 September 2019, when Dr 1 reviewed Patient 3, he was informed of the plan for him to return on 9 October 2019 for left inguinal lymphadenectomy. This was duly performed by Dr 1. Patient 3 was fit for discharge, four days later on 13 October 2019, but left hospital with an indwelling drain remaining on continuous drainage to prevent the development of a lymphocele.

Patient 3's case was discussed again on 17 October 2019 at the MDM and it was noted that the inguinal node dissection showed 2 of 5 nodes involved with metastatic disease. The MDM plan was that Dr 1 would review Patient 3 in outpatients and arrange a follow-up CT abdomen and pelvis.

Dr 1 reviewed Patient 3 twice weekly after discharge and found that significant volumes of lymphatic fluid drained daily from the left groin. Dr 1 incrementally withdrew the drain until it was removed altogether on 5 November 2019. He arranged to review Patient 3 on 8 November 2019 when he was able to aspirate 250mls of lymphatic fluid from Patient 3's groin; a volume that had accumulated over a period of three days.

Dr 1 arranged for Patient 3 to return to outpatients on Wednesday 13 November 2019 for further review and in the interim asked the GP to issue a prescription for antibiotics to be taken until the review, even though there was no suspicion of any infective complication. Dr 1 also requested a further staging CT scan for January 2020 and listed him for discussion at the Urology MDM with the result.

Patient 3 had a CT chest, abdomen and pelvis carried out on 22 January 2020 which showed a fluid collection and possible lymph node enlargement in the left groin. Furthermore, abnormal lymph node enlargement was seen within the pelvis and in front of the hip joint.

Patient 3 was discussed at the Urology MDM on 6 February 2020 when the new lymph node abnormalities were noted. The MDM recommended that Dr 1 would review Patient 3 in outpatients and refer him to the supra-regional penile cancer group for further management.

Patient 3 was seen by Dr 1 on 14 February 2020. He was referred to the penile cancer MDT

5.0 DESCRIPTION OF INCIDENT/CASE

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

Patient 3 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 Personal Information redacted by the USI .

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 Patient 3's management.
- The treatment provided to Patient 3 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 Patient 3 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 Patient 3 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.
- Patient 3 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 Patient 3'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

- Patient 3 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 Patient 3 may have had could not have been addressed outside the consultant reviews.

- Without a CNS, Patient 3 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 Patient 3 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. Patient 3 was not offered this opportunity. The Review Team has learned of the sudden death of Patient 3 and wish to extend their sincere condolences to his wife and family.

8.0 LESSONS LEARNED

- The MDM should be quorate.
- If the MDM is not quorate, an accountable Chair should ensure, through appropriate Quality Assurance (QA), that every patient's potential management options are fully discussed and that the MDM's decisions are documented as having been communicated with the patient, their family, and their GP.
- A MDM Chair should ensure appropriate and a comprehensive Quality Assurance (QA) programme, that ensures adequate compliance with the MDM's published guidelines.
- All patients should be independently assigned a Key Worker, usually a cancer nurse specialist, to guide and advise them of their options.
- The MDM should regularly revisit their guidelines and policies to ensure best practice continues to be followed.
- The MDM should agree and audit, as part of QA, the indicative timings for the stages in cancer management.
- All patients whose disease fits the criteria for referral to a specialist MDT should be referred for advice and management at the completion of staging.
- Specialist urological cancer interventions should be delivered by appropriately experienced clinicians, normally at a specialist centre, who continue to demonstrate audited outcomes.

References

1. EAU guidelines for penile cancer: section 6.2.1 (2019)
2. NICE improving outcomes in urological cancer (2002)
3. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).
4. Peer review Self-Assessment report for NICaN 2017.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

A MDM Chair should develop an appropriate and comprehensive Quality Assurance programme that ensures adequate compliance with the MDM's published guidelines.

Recommendation 2

The MDM should agree and audit, as part of QA, the indicative timings for the stages in cancer management.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 3

The MDM should regularly revisit their guidelines and policies to ensure best practice continues to be followed. This needs to be audited annually.

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

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**:26 October 2020						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exeXXise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			x
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exeXXise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

24 May 2021 **Our Ref:** Personal Information redacted by the USI

Private & Confidential

Patient 5's Daughter

Dear Ms Patient 5's Daughter

Further to your discussions with Mrs Kingsnorth, the requested amendment to page 5 of the SAI report has been made and I enclose the final report for your reference.

I can confirm the amendment has been shared with the Health & Social Care Board.

Yours sincerely

Personal Information redacted by the USI

Mrs Melanie McClements
Director of Acute Services

enc

Working together Excellence Openness & Honesty Compassion

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

Telephone: Personal Information redacted by the USI
E-Mail: Patient 3

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: Personal Information redacted by the USI

Date of Incident/Event: 28 July 2020

HSCB Unique Case Identifier:

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

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

Patient 5

1.0 EXECUTIVE SUMMARY

Patient 5 was an Personal Information redacted by the old gentleman when he first presented with haematuria to Emergency Department (ED) in Craigavon Area Hospital (CAH) on 12 December 2018. He complained of low back pain. There was no evidence of urinary tract infection. He was referred to urology services and was reviewed by Dr 1 in January 2019.

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 from 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 report with the Director of Acute Services / Medical Director of SHSCT / HSCB / Patient / Staff involved.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 5, an Personal Information redacted by the -old gentleman, presented with haematuria to the Emergency Department (ED) at Craigavon Area Hospital (CAH) on 12 December 2018. He complained of low back pain. There was no evidence of urinary tract infection. A digital rectal examination (DRE) showed a smooth prostate gland query right side bigger than left but no rectal bleeding was seen. He was referred as an outpatient to the urology services as a red flag referral. A PSA blood test was not requested. Dr.1 (Consultant Urologist) arranged a CT scan of chest and CT urogram which were performed on 4 January 2019 prior to an expedited review at urology outpatients as Red Flag.

The CT scan showed a large right kidney tumour measuring 15cms in diameter with possible vein involvement. There was no evidence of metastatic disease. His case was discussed on 17 January 2019 at the multidisciplinary team meeting (MDM) when it was recommended that Patient 5 was reviewed by Dr.1 in outpatients to discuss management options.

Patient 5 was reviewed by Dr.1 on 18 January 2019 and the findings of the scan were explained to him. A MRI venogram, to assess if any extensive involvement of the major vessels, and a DMSA scan, to quantify the function of the left kidney, were both requested. At the same time an echocardiogram and an anaesthetic referral were arranged to assess the risk factors for surgery.

On 5 February 2019, Patient 5 attended for a DMSA which showed that “the function left kidney 63%; right kidney 37% function. The MRI venogram confirmed a tumour in the right renal vein but this did not extend into the inferior vena cava.

On 8 February 2019, Patient 5 attended for the anaesthetic review with Dr.2 (Consultant Intensivist) and a stay on the High Dependency Unit following surgery was recommended. Patient 5 was noted to be keen for surgery.

On 14 February 2019, Patient 5 was discussed at the MDM when the imaging results were noted. The pre-operative assessment was also discussed and noted a high risk of mortality and morbidity in the post-operative period. It was planned for Dr.1 to review Patient 5 with his family, to ensure that surgery was in his best interest.

5.0 DESCRIPTION OF INCIDENT/CASE

On 19 February 2019, Patient 5, accompanied by his two daughters, was reviewed by Dr.1 when the risks and benefits of the surgery were explained: Patient 5 opted for surgical intervention. Precise pre-operative instructions and arrangements for bridging anti-coagulation were given to Patient 5.

On 6 March 2019, Patient 5 was admitted for an elective radical nephrectomy. The procedure was undertaken as planned and he was transferred to the Intensive Care Unit (ICU) as he needed blood pressure support. He was transferred to the ward on 8 March 2019. He developed a bacteraemia (infection) which was managed with antibiotic therapy following advice from the microbiology team.

On 14 March 2019, Patient 5's case and progress were presented at MDM. The recommendation was for a CT scan 3 months post operatively. He was discharged home on 17 March 2019.

On 29 March 2019, Dr.1 reviewed Patient 5 in outpatients and noted him to be well. A plan for CT scan chest abdomen and pelvis was arranged for June 2019 with a clinic review planned at the urology clinic in July 2019. A post-operative anaemia was treated.

On 11 June 2019, a CT scan of chest abdomen and pelvis was performed. There was no change in comparison from previous scans.

28 October 2019 Dr 3 (Consultant Cardiologist) reviewed Patient 5 at a cardiology appointment following a private referral. Patient 5 was noted to have increased fatigue and dyspnoea. He was also noted to have anaemia and deranged renal function. He was admitted for observation and investigation. Dr.1 was advised of the admission. Patient 5 was discharged on 31 October 2019. Subsequently, Dr.1 telephoned Patient 5 to inform him that a CT scan of the chest, abdomen and pelvis would be arranged in December at South Tyrone Hospital. Review was planned for January 2020.

On 17 December 2019 a CT scan of chest abdomen and pelvis was performed the results showed a possible sclerotic metastasis in the L1 vertebral body. The scan report was available on 11 January 2020.

On 28 July 2020 following a telephone conversation between Dr.4 (Consultant Urologist) and Patient 5's daughter, a letter was sent to Patient 5 to advise of the CT result and to apologise for the delay of 6 months. Dr.4 advised of a possible abnormality on the CT scan that required further investigation with a bone scan.

The bone scan (6 August 2020) confirmed new sclerotic abnormalities in the spine, pelvis, the ribs and the left femur. His PSA was noted to be 138 ng/L. On this basis metastatic prostate cancer was confirmed.

On 12 August 2020, Patient 5, accompanied by his daughters, was reviewed by Dr.4 in outpatients and his treatment options were discussed. Androgen deprivation therapy was commenced and a referral to the Oncology Service was made.

5.0 DESCRIPTION OF INCIDENT/CASE

Dr.4 noted in his clinic letter that the scan performed in December 2019 had not been followed up and that there had been no communication with Patient 5 about the results.

A review was planned for November 2020.

6.0 FINDINGS

- Patient 5's 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 Patient 5 appeared to be lost to follow up.
- In a letter to Patient 5 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 was present for the meetings.
- The MDM was quorate 11% 2017, 22% 2018 and 0% 2019 and 5% in 2020.
- Patient 5 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 Patient 5'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 Patient 5 presented in ED with urinary symptoms a PSA was not undertaken. It would appear from the electronic records that a PSA test was not 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.

7.0 CONCLUSIONS

The management of Patient 5'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**.**

Reference: Peer Review Self-Assessment Report for NICAN (2017).

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

APPENDIX 1
QUESTIONS FROM FAMILY

On 12 December in ED

Q1 Was a referral made from A&E to Urology?

Answer: A red flag referral was made in ED to urology services.

Q 2) Was this routine or urgent?

Answer: Red flag

Q 3) Was a PSA test considered in A&E and if not why not?

Answer: Our expert doesn't agree that a PSA should have been carried out in ED. This might have been considered when your father was referred to urology services.

Q4) Should Patient 5 have been asked if he ever had a PSA test or informed to contact his GP for PSA test?

Answer: Our expert believes this might have been considered at his first consultation, but the diagnosis of a large renal tumour, which explained his presentation, had already been made.

4th January 2019 - CT Scan [Chest & Urogram]

Q 5) Did this CT scan include the prostate?

Answer: Yes, but a CT scan is not a satisfactory way of imaging the prostate. A CT is appropriate for detecting lymph node enlargement (indicating spread of any cancer) and has some value in assessing the skeleton for metastatic deposits. The skeleton is best assessed by a whole body radionucleotide bone scan. The prostate is best imaged with a MRI scan.

Q 6) If so, was there any evidence of prostate cancer?

Answer: No

At MDM on 17th January 20191

Q7) Was the possibility of prostate cancer raised?

Answer: No, a renal cancer that explained his presentation had been made.

Q8) Was a PSA Test discussed?

Answer: There was no indication at this stage for considering a diagnosis of prostate cancer.

Q9) Which professionals were present at the MDM?

Answer: Urologists/ Radiographer/ Cancer Nurse Specialist/ Pathologist/ Tracker

Q10) Was a liaison/key nurse present at MDT?

Answer: Yes

Q11) Was it noted at the meeting that Patient 5 had not been allocated a liaison/key nurse?

Answer: No

When tumour was identified on 18th January 2019

Q12) Should a liaison/key nurse have been assigned to Patient 5 at this point, if not why not?

Answer**:** It would be normal to offer a key worker/ CNS appointment or at least contact details when the mass was diagnosed, that is, at the original appointment.

13) Who was responsible for allocating a liaison/key nurse?

Answer: The Consultant in charge of the patient's care makes a referral to the CNS.

At MDM 14 February 2019

Q14) Was PSA raised in discussions?

Answer: There was no reason to suspect the presence of significant prostate cancer.

Q15) Was liaison nurse raised at this point?

Answer: No

Q16) Were the MDM in agreement with Patient 5 proceeding to have the surgery?

Answer: The MDM advised to discuss the risks and benefits of surgery with your father.

29th March 2019

The family left the appointment feeling positive with respect to the outcome of the surgery and were looking forward to Patient 5's full recovery.

Comment from expert: Full recovery for an elderly gentleman with significant co-morbidities would have been very unlikely.

June 19 scans CT Chest, abdomen and pelvis.

Q17) Was there any indication of prostate cancer on scans?

Answer: the scans were reviewed by an independent radiology consultant and confirms there was no evidence of metastases on the previous scans.

7th October GP appointment

Q18) Why was a PSA test not undertaken as a result of the symptoms indicated by Patient 5?

Answer: Patient 5 should have expected a protracted recovery. His symptoms can be entirely attributed to the renal cancer and its management. A CNS or Key Worker would have been

reassuring at this time. The prostate cancer would have been very unlikely to have caused these symptoms, which can be attributed to the surgery, the anaemia and the co-morbidities.

28 October referral to cardiology and on to ED

Q19) Was this a missed opportunity for additional tests including a PSA test and additional scans to be undertaken to explore any underlying issues or causes contributing to Patient 5 's lack of recovery from his operation in March 2019 and the presenting health issues in A&E?

Answer: No. There were sufficient causes to explain any perceived lack of progress. The prostate cancer would not be contributing to this. It should be borne in mind that urologists are often presented with a dilemma in weighing up the pros and cons of starting treatment for prostate cancer as the side-effects can outweigh any benefit.

17th December 2019

Q20) Following CT scan taking place what was the sequence of events in terms of reporting:

- **When was the scan uploaded to NIPACS**
  Answer: The scan was uploaded on the 11 January 2020. Following an audit trail we can confirm that no one accessed the report. An email had been sent to Mr O'Brien and his secretary to advise of the abnormal scan report.

- **When was Mr O'Brien notified of the scan results by the system?**

  Answer: The email notification is generated at the same time the report is available on NIPACS

- **If the scan results were available on 11 January, were they accessed by Mr O'Brien and indicated in the medical chart?**

  Answer: No not until 12 July 2020.

- **Were any automated reminders sent to Mr O'Brien or any other member of the MD team?**

  Answer: It is the responsibility of the requesting doctor to follow up on the results.

- **What processes were in place to ensure that there were no delays in follow-ups of scan results and that no results are missed?**

  Answer: It is the responsibility of the requesting doctor to follow up on the results.

From January to July

Q21) Following Patient 5 's CT Scan results (available 11th January 2020) was he discussed at any further MDMs?

Answer: Not until his care was taken over in July 2020 by Mr Haynes

Comments from Patient 5

Patien

Patient 5 would like it noted in the conclusion of his report that he is grateful for the "exemplary care" received in the management of his kidney tumour".

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER						
1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**	
	Comment: ***If multiple service users involved please indicate the number involved***					
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI?	**YES**		**NO**			
	If **YES**, insert **date informed**:					
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the					

Patient 5

Please select as appropriate (✓)	Service User / Family / Carer that the incident was being investigated as a SAI	
	a) No contact or Next of Kin details or Unable to contact	
	b) Not applicable as this SAI is not 'patient/service user' related	
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user	
	d) Case involved suspected or actual abuse by family	
	e) Case identified as a result of review exercise	
	f) Case is environmental or infrastructure related with no harm to patient/service user	
	g) Other rationale	
	If you selected c), d), e), f) or g) above please provide further details:	

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			
	f) Withdrew fully from the SAI process			
	g) Participated in SAI process but declined review report			
	(if you select any of the options below please also complete 'l' below)			
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer			
	i) case involved suspected or actual abuse by family			
	j) identified as a result of review exercise			
	k) other rationale			
	l) If you have selected **c), h), i), j), or k)** above please provide further details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE

(under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

Patient 5

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: Personal Information redacted by the USI

Date of Incident/Event: 28 July 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

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: (Draft) 1 March 2021

1.0 EXECUTIVE SUMMARY

Patient 5 was an Personal Information redacted by the USI old gentleman when he first presented with haematuria to Emergency Department (ED) in Craigavon Area Hospital (CAH) on 12 December 2018. He complained of low back pain. There was no evidence of urinary tract infection. He was referred to urology services and was reviewed by Dr 1 in January 2019.

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 from 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 report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/Patient/ Staff involved.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 5, an Personal Information redacted by the -old gentleman, presented with haematuria to the Emergency Department (ED) at Craigavon Area Hospital (CAH) on 12 December 2018. He complained of low back pain There was no evidence of urinary tract infection. A digital rectal examination (DRE) showed a smooth prostate gland query right side bigger than left but no rectal bleeding was seen. He was referred as an outpatient to the urology services as a red flag referral. A PSA blood test was not requested. The patient's family contacted Dr.1's secretary and requested a private appointment. However, Dr.1 (Consultant Urologist) arranged a CT scan of chest and CT urogram which were performed on 4 January 2019 prior to an expedited review at urology outpatients as urgent.
The CT scan showed a large right kidney tumour measuring 15cms in diameter with possible vein involvement. There was no evidence of metastatic disease. His case was discussed on 17 January 2019 at the multidisciplinary team meeting (MDM) when it was recommended that Patient 5 was reviewed by Dr.1 in outpatients to discuss management options.

Patient 5 was reviewed by Dr.1 on 18 January 2019 and the findings of the scan were explained to him. A MRI venogram, to assess if any extensive involvement of the major vessels, and a DMSA scan, to quantify the function of the left kidney, were both requested. At the same time an echocardiogram and an anaesthetic referral were arranged to assess the risk factors for surgery.

On 5 February 2019, Patient 5 attended for a DMSA which showed that "the function left kidney 63%; right kidney 37% function. The MRI venogram confirmed a tumour in the right renal vein but this did not extend into the inferior vena cava.

On 8 February 2019, Patient 5 attended for the anaesthetic review with Dr.2 (Consultant Intensivist) and a stay on the High Dependency Unit following surgery was recommended. Patient 5 was noted to be keen for surgery.

On 14 February 2019, Patient 5 was discussed at the MDM when the imaging results were noted. The pre-operative assessment was also discussed and noted a high risk of mortality and morbidity in the post-operative period. It was planned for Dr.1 to review Patient 5, with his family, to ensure that surgery was in his best interest.

On 19 February 2019, Patient 5, accompanied by his two daughters, was reviewed by Dr.1 when the risks and benefits of the surgery were explained: Patient 5 opted for surgical intervention. Precise pre-operative instructions and arrangements for bridging anti-coagulation were given to Patient 5.

On 6 March 2019, Patient 5 was admitted for an elective radical nephrectomy. The

5.0 DESCRIPTION OF INCIDENT/CASE

procedure was undertaken as planned and he was transferred to the intensive care unit (ICU) as he needed blood pressure support. He was, that day, later transferred to the ward. He developed a bacteraemia (infection) which was managed with antibiotic therapy following advice from the microbiology team.

On 14 March 2019, Patient 5's case and progress were presented at MDM. The recommendation was for a CT scan 3 months post operatively. He was discharged home on 17 March 2019.

On 29 March 2019, Dr.1 reviewed Patient 5 in outpatient and noted him to be well. A plan for CT scan chest abdomen and pelvis was arranged for June 2019 with a clinic review planned at the urology clinic in July 2019. A post-operative anaemia was treated.

On 11 June 2019, a CT scan of chest abdomen and pelvis was performed. There was no change in comparison from previous scans.

28 October 2019 Dr 3 (Consultant Cardiologist) reviewed Patient 5 at a cardiology appointment following a referral from his GP. Patient 5 was noted to have increased fatigue and dyspnoea. He was also noted to have anaemia and deranged renal function. He was admitted for observation and investigation. Dr.1 was advised of the admission. Patient 5 was discharged on 31 October 2019. Subsequently, Dr.1 telephoned Patient 5 to inform him that a CT scan of the chest, abdomen and pelvis would be arranged in December at South Tyrone Hospital. Review was planned for January 2020.

On 17 December 2019 a CT scan of chest abdomen and pelvis was performed the results showed a possible sclerotic metastasis in the L1 vertebral body. The scan report was available on 11 January 2020.

On 28 July 2020 following a telephone conversation between Dr.4 (Consultant Urologist) and Patient 5's daughter, a letter was sent to Patient 5 to advise of the CT result and to apologise for the delay. Dr.4 advised of a possible abnormality on the CT scan that required further investigation with a bone scan.

The bone scan (6 August 2020) confirmed new sclerotic abnormalities in the spine, pelvis, the ribs and the left femur. His PSA was noted to be 138 ng/L. On this basis metastatic prostate cancer was confirmed.

On 12 August 2020, Patient 5, accompanied by his daughters, was reviewed by Dr.4 in outpatients and his treatment options were discussed. Androgen deprivation therapy was commenced and a referral to the Oncology Service was made.

Dr.4 noted in his clinic letter that the scan performed in December 2019 had not been followed up and that there had been no communication with Patient 5 about the results.

A review was planned for November 2020.

6.0 FINDINGS

- Patient 5 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 Patient 5 appeared to be lost to follow up.

- In a letter to Patient 5 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.

- Patient 5 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 Patient 5 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 overall impact of the delay to action a CT scan in January 2020 resulted in a 6 month delay in recognition of prostate cancer and therefore treatment. There is the possibility that had a PSA been carried out in January 2019, prostate cancer may have been detected earlier. (you may wish to reword this Dermot/ Hugh).

7.0 CONCLUSIONS

The management of Patient 5'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

9.0 RECOMMENDATIONS AND ACTION PLANNING

References:

1. **Peer Review Self-Assessment Report for NICAN (2017).**

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	1	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**: **26 October 2020**						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

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

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	**x**
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 2 July 2020

HSCB Unique Case Identifier:

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

Responsible Lead Officer: Dr Dermot Hughes

Designation: Retired Medical Director

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 5 was an Personal Information redacted by the old gentleman when he first presented with haematuria to Emergency Department (ED) in Craigavon Area Hospital (CAH) on 12 December 2018. He complained of low back pain. There was no evidence of urinary tract infection. He was referred to urology services and was reviewed by Dr 1 in January 2019.

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 (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 SHSCT/ HSCB/Patient/ Staff involved.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 5, an Personal Information redacted by the -old gentleman, presented with haematuria to the Emergency Department (ED) at Craigavon Area Hospital (CAH) on 12 December 2018. He complained of low back pain. There was no evidence of urinary tract infection. He was referred as an outpatient to the urology services as a routine referral. A PSA blood test was not requested. The patient's family contacted Dr.1's secretary and requested a private appointment. However, Dr.1 (Consultant Urologist) arranged a CT scan of chest and CT urogram which were performed on 4 January 2019 prior to an expedited review at urology outpatients as urgent.
The CT scan showed a large right kidney tumour measuring 15cms in diameter with possible vein involvement. There was no evidence of metastatic disease.
His case was discussed on 17 January 2019 at the multidisciplinary team meeting (MDM) when it was recommended that Patient 5 was reviewed by Dr.1 in outpatients to discuss management options.

Patient 5 was reviewed by Dr.1 on 18 January 2019 and the findings of the scan were explained to him. A MRI venogram, to assess if any extensive involvement of the major vessels, and a DMSA scan, to quantify the function of the left kidney, were both requested. At the same time an echocardiogram and an anaesthetic referral were arranged to assess the risk factors for surgery.
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On 8 February, Patient 5 attended for the anaesthetic review with Dr.2 (Consultant Intensivist) and a stay on the High Dependency Unit following surgery was recommended. Patient 5 was noted to be keen for surgery.

On 14 February 2019, Patient 5 was discussed at the MDM when the imaging results were noted. The pre-operative assessment was also discussed and noted a high risk of mortality and morbidity in the post-operative period. It was planned to forDr.1 to review the patient, with his family, to ensure that surgery was in his best interest.

On 19 February, Patient 5, accompanied by his two daughters, was reviewed by Dr.1 when the risks and benefits of the surgery were explained: Patient 5 opted for surgical intervention. Precise pre-operative instructions and arrangements for bridging anti-coagulation were given to Patient 5.

On 6 March 2019, Patient 5 was admitted for an elective radical nephrectomy. The procedure was undertaken as planned and he was transferred to the intensive care unit (ICU) as he needed blood pressure support. He was, that day, later transferred to the ward. He developed a bacteraemia (infection) which was managed with antibiotic therapy following advice from the microbiology team.

On 14 March 2019, Patient 5 case and progress were presented at MDM. The

5.0 DESCRIPTION OF INCIDENT/CASE

recommendation was for a CT scan 3 months post operatively. He was discharged home on 17 March 2019.

On 29 March 2019, Dr.1 reviewed Patient 5 in outpatient and noted him to be well. A plan for CT scan chest abdomen and pelvis was arranged for June 2019 with a clinic review planned at the urology clinic in July 2019. A post-operative anaemia was treated.

On 11 June 2019, a CT scan of chest abdomen and pelvis was performed. There was no change in comparison from previous scans.

28 October 2019 Dr 3 (Consultant Cardiologist) reviewed Patient 5 at a cardiology appointment following a referral from his GP. Patient 5 was noted to have increased fatigue and dyspnoea. He was also noted to have anaemia and deranged renal function. He was admitted for observation and investigation. Dr.1 was advised of the admission. Patient 5 was discharged on 31 October 2019. Subsequently, Dr.1 telephoned Patient 5 to inform him that a CT scan of the chest, abdomen and pelvis would be arranged in December at South Tyrone Hospital. Review was planned for January 2020.

On 17 December 2019 a CT scan of chest abdomen and pelvis was performed the results showed a possible sclerotic metastasis in the L1 vertebral body. The scan report was available on 11 January 2019.

On 28 July 2020 following a telephone conversation between Dr.4 (Consultant Urologist) and Patient 5 's daughter, a letter was sent to Patient 5 to advise of the CT result and to apologise for the delay. Dr.4 advised of a possible abnormality on the CT scan that required further investigation with a bone scan.

The bone scan (6 August 2020) confirmed new sclerotic abnormalities in the spine, pelvis, the ribs and the left femur. His PSA was noted to be 138 ng/L. On this basis metastatic prostate cancer was confirmed.

On 12 August 2020, Patient 5 , accompanied by his daughters, was reviewed by Dr.4 in outpatients and his treatment options were discussed. Androgen deprivation therapy was commenced and a referral to the Oncology Service was made.

Dr.4 noted in his clinic letter that the scan performed in December 2019 had not been followed up and that there had been no communication with Patient 5 about the results.

A review was planned for November 2020.

6.0 FINDINGS

The review team find that the treatment and care in relation management of the renal tumour was of a high standard. High risk surgery was performed successfully following informed consent as to the risks and benefits of the surgery. The surgery

6.0 FINDINGS

was performed on 6 March 2019.

- Mr Patient 5 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 Mr Patient 5 appeared to be lost to follow up.

- In a letter to the Patient 5 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.

- Patient 5 did not have access from a Cancer Nurse Specialist or Keyworker to support him with his diagnosis. 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"(ref) This did not happen and was detrimental to the patients 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 Patient 5 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.

Considerations

What are the administrative mechanisms in place to alert clinicians to abnormal results?
What tracking arrangements are in place to ensure that MDM recommendations are actioned?

7.0 CONCLUSIONS
The management of Patient 5 '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.

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

APPENDIX 1
QUESTIONS FROM FAMILY

On 12 December in ED

Q1 Was a referral made from A&E to Urology?
Answer: **Yes a routine referral was made, our expert suggests this should have been a red flag**

Q 2) Was this routine or urgent?
Answer: **Routine**

Q 3) Was a PSA test considered in A&E and if not why not?
Answer: **Our expert doesn't agree that a PSA should have been carried out in ED. This might have been considered when your father was referred to urology services.**

Q4) Should Patient 5 have been asked if he ever had a PSA test or informed to contact his GP for PSA test?
Answer: **Our expert believes this might have been considered at his first consultation, but the diagnosis of a large renal tumour, which explained his presentation, had already been made.**

4th January 2019 CT Scan [Chest & Urogram].

Q 5) Did this CT scan include the prostate?

Answer: **Yes, but a CT scan is not a satisfactory way of imaging the prostate. A CT is appropriate for detecting lymph node enlargement (indicating spread of any cancer) and has some value in assessing the skeleton for metastatic deposits. The skeleton is best assessed by a whole body radionucleotide bone scan. The prostate is best imaged with a MRI scan.**
Q 6) If so, was there any evidence of prostate cancer?

At MDM on 17th January 20191

Q7) Was the possibility of prostate cancer raised?
Answer: **No, a renal cancer that explained his presentation had been made.**

Q8) Was a PSA Test discussed?
Answer: **There was no indication at this stage for considering a diagnosis of prostate cancer.**

Q9) Which professionals were present at the MDM?
Urologists/ Radiographer/ Cancer Nurse Specialist/ Pathologist/ Tracker

Q10) Was a liaison/key nurse present at MDT?
Answer: **Yes**

Q11) Was it noted at the meeting that Patient 5 had not been allocated a liaison/key nurse?
Answer: **No**

When tumour was identified on 18th January 2019

Q12) Should a liaison/key nurse have been assigned to Patient 5 at this point, if not why not?

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

13) Who was responsible for allocating a liaison/key nurse?
Answer**: The Consultant in charge of the patient's care makes a referral to the CNS.**

At MDM 14 February 2019

Q14) Was PSA raised in discussions?
Answer: **There was no reason to suspect the presence of significant prostate cancer.**

Q15) Was liaison nurse raised at this point?
Answer: **No**

Q16) Were the MDM in agreement with Patient 5 proceeding to have the surgery?

29th March 2019
The family left the appointment feeling positive with respect to the outcome of the surgery and were looking forward to Patient 5 's full recovery.

Comment from expert: **Full recovery for an elderly gentleman with significant co-morbidities would have been very unlikely.**

June 19 scans CT Chest, abdomen and pelvis.
Q17) Was there any indication of prostate cancer on scans?
Answer: the scans were reviewed by an independent radiology consultant and confirms there was no evidence of metastases on the previous scans.

7th October GP appointment
Q18) Why was a PSA test not undertaken as a result of the symptoms indicated by Patient 5 ?
Answer: Patient 5 **should have expected a protracted recovery. His symptoms can be entirely attributed to the renal cancer and its management.**
A CNS or Key Worker would have been reassuring at this time.
The prostate cancer would have been very unlikely to have caused these symptoms, which can be attributed to the surgery, the anaemia and the co-morbidities.

28 October referral to cardiology and on to ED
Q19) Was this a missed opportunity for additional tests including a PSA test and additional scans to be undertaken to explore any underlying issues or causes contributing to Patient 5 's lack of recovery from his operation in March 2019 and the presenting health issues in A&E?
Answer: **No. There were sufficient causes to explain any perceived lack of progress. The prostate cancer would not be contributing to this. It should be borne in mind that urologists are often presented with a dilemma in weighing up the pros and cons of starting treatment for prostate cancer as the side-effects can outweigh any benefit.**

17th December 2019

Q20) Following CT scan taking place what was the sequence of events in terms of reporting:

- When was the scan uploaded to NIPACS?-
- Answer: **The scan was uploaded on the 11 January 2020. Following an audit trail we can confirm that no one accessed the report. An email had been sent to Mr O'Brien and his secretary to advise of the abnormal scan report.**

- When was Mr O'Brien notified of the scan results by the system?

[1]*Service User or their nominated representative*

- Answer: **The email notification is generated at the same time the report is available on NIPACS**

- If the scan results were available on 11 January, were they accessed by Mr O'Brien and indicated in the medical chart?
- Answer: **No not until 12 July 2020.**

- Were any automated reminders sent to Mr O'Brien or any other member of the MD team?
- Answer: **It is the responsibility of the requesting doctor to follow up on the results.**

- What processes were in place to ensure that there were no delays in follow-ups of scan results and that no results are missed?

- Answer: **It is the responsibility of the requesting doctor to follow up on the results.**

From January to July

Q21) Following Patient 5 's CT Scan results (available 11th January 2020) was he discussed at any further MDMs?
Answer: **Not until his care was taken over in July 2020 by Mr Haynes**

[1]*Service User or their nominated representative*

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER							
1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**			**NO**			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed **(*if you select this option please also complete 'I' below*)**			
Continued overleaf	**d)** No contact or Next of Kin or Unable to contact			
	e) No response to correspondence			
	f) Withdrew fully from the SAI process			
	g) Participated in SAI process but declined review report			
	(if you select any of the options below please also complete 'I' below)			
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer			
	i) case involved suspected or actual abuse by family			
	j) identified as a result of review exercise			
	k) other rationale			
	l) If you have selected **c), h), i), j), or k)** above please provide further details:			

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

DATE CHECKLIST COMPLETED	

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Southern Health and Social Care Trust

27 April 2021 **Our Ref:** Personal Information redacted by the USI

Private & Confidential

Patient 1's Daughter

Dear Mrs Patient 1's Daughter

On behalf of the Trust I would like to take this opportunity to apologise to you and your family for the identified failures in the care to your late father Patient 1 which has had a devastating effect on you and your family.

I wish to offer my sincere condolences on the passing of your late father Patient 1

I can assure you that as a Trust we are working towards progressing the recommendations of the SAI review to improve patient safety and prevent reoccurrence.

I would like to extend my sincere thanks for your participation in the SAI review, which was greatly appreciated by the review team and I.

Please find attached copy of the final SAI report.

As advised in my letter to you dated 16 March 2021 a copy of the final report will be issued to the Health & Social Care Board.

Yours sincerely

Personal Information redacted by the USI

Mrs Melanie McClements
Director of Acute Services

Enc

Working together Excellence Openness & Honesty Compassion

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

Telephone: Patient 5
E-Mail: Patient 5

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: Personal Information redacted by the USI

Date of Incident/Event: 2 July 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

Patient 9, a Personal Information redacted by the -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 Patient 9 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. Patient 9 was able to pass urine prior to discharge home. A routine review for September 2019 did not happen. Patient 9 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 Patient 9 had advanced prostate cancer. Patient 9 is now terminally ill.

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 (SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical and Social Care Governance Coordinator (SHSCT)

3.0 SAI REVIEW TERMS OF REFERENCE

The terms of reference for the review of the care and treatment provided to Patient 9 were:

- To carry out a systematic review in the process used in the diagnosis, MDT decision making and subsequent follow up provided, using a Root Cause Analysis (RCA) Methodology.
- To use a multidisciplinary team approach to the review.
- To identify those factors which may have had an influence, or may have contributed to the process.
- To engage with Patient 9 ensuring where possible, questions presented to the review team are addressed.
- To agree the outcome of the review and subsequent recommendations.
- To action any recommendations and disseminate any lessons to be learnt.
- To report the findings and the recommendations of the review through the

Director of Acute Services SHSCT, Medical Director of SHSCT and disseminate to the staff involved and Patient 9.

Review of Medical Notes Interviews with Staff Family Engagement – discussion with patient MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

At presentation, Patient 9 was a Personal Information redacted by the -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.

He 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, Patient 9 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 Patient 9 was able to pass urine prior to discharge home.

Patient 9 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.

5.0 DESCRIPTION OF INCIDENT/CASE

No appointment is recorded until Patient 9 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 bleeding and tenesmus (an uncomfortable feeling or pain indicating a need to open the bowels). He was reviewed by Dr.2 (a specialist surgical trainee, ST4) who documented that Patient 9 was known to urology services and queried if he had been lost to follow up. On digital rectal examination Dr.2 felt a rectal mass and suspected prostate cancer. Bloods for a PSA level was taken. Patient 9 was catheterised and allowed home with a referral to both urology and colo-rectal surgery.

According to a letter, dated 12 May 2020, from Dr.1 to Patient 9 following a virtual clinic review, Doctor 1 prescribed bicalutamide (50mg) for the suspected prostate cancer, in addition to tamsulosin (0.4mg) for the urinary symptoms. He had asked for Patient 9's GP to arrange for the district nurse/ practice nurse to review Patient 9 on 18 May 2020 for a TROC.

On 18 May 2020 Patient 9 attended for the TROC as arranged. He was unable to void urine and as a bladder scan showed 500mls of residual urine a catheter was reinserted. He was reviewed by DR.3 (specialist urology trainee, ST3) who noted that the serum PSA level (9.5ng/ml) was elevated. DR.3 also noted that during Patient 9's attendance at ED Dr.2 had recorded that the prostate felt malignant. Dr.3 requested a MRI scan of the prostate and pelvis and wrote a referral letter to request an outpatient review by Dr.1. In addition, a red flag referral to general surgery was made and a letter for information was sent to Patient 9's GP.

On 27 May 2020, Patient 9 attended for the MRI scan, which demonstrated a pelvic mass that was highly suspicious of prostate cancer causing a urethro-rectal fistula.

On 12 June 2020, Patient 9 attended for a CT scan which showed a large rectal mass with small volume groin nodes but no distant metastasis.

Patient 9 was reviewed by Dr.4 (General Surgery Consultant) on 30 June 2020 who performed a biopsy of the mass *per rectum*. Histology confirmed poorly-differentiated (aggressive) prostate adenocarcinoma (Gleason 9/10).

Patient 9's case was discussed at the urology MDM (2 July 2020) which noted a locally advanced prostate cancer. The MDM recommended prompt urology review, to commence androgen deprivation therapy (ADT), and that a bone scan was arranged.

Dr.5 (Consultant Urologist) saw Patient 9 (6 July 2020) and found that he continued with rectal bleeding and tenesmus. Patient 9 had stopped his bicalutamide (May 2020) and, so, was on no treatment for his prostate cancer. The MDM recommendations were followed. Further discussion at MDM was planned for when the bone scan results were available. It was intended that if there was no metastatic disease, he would be referred to oncology.

Patient 9 attended the ED (27 July 2020) with ongoing problems with his urinary catheter which was changed earlier in the day but was still not draining. His catheter was changed again and he was commenced on oral antibiotics. He was discharged home.

5.0 DESCRIPTION OF INCIDENT/CASE

Two days later (29 July 2020) Patient 9 returned to the ED with urinary retention after again having his catheter changed in the community. He was noted to have a very low urine output through the catheter despite good hydration. Patient 9 reported passing urine per rectum. Faeces were seen in the catheter bag.

Patient 9 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.

Patient 9 was reviewed by the acute oncology service during this admission; palliative treatment was recommended. It was decided that Patient 9 would need a defunctioning faecal stoma and possibly an ileal conduit (stoma bag for the bladder). Patient 9 was reviewed by the stoma nurse regarding future stoma.

The surgeons planned surgery for the defunctioning colostomy when Patient 9 felt able: he wanted to return home to recuperate before undergoing any further intervention. He was discharged home on 1 August 2020.

Patient 9'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 Patient 9's surgery and he was to remain on hormone therapy.

On 13 August 2020 Patient 9 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 Patient 9 was reviewed by Dr.5 (Consultant Urologist), it was noted that Patient 9 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

Patient 9 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,

6.0	FINDINGS

there was no intention to consider this further until 3 months after presentation.

- Although the possibility of prostate cancer was considered from the time of presentation - the PSA was elevated - there was no record in the medical notes of a digital rectal examination (DRE).

- During the operation further signs might have been elicited and appropriate (ultrasound guided needle) biopsies could have been performed. A transrectal biopsy, performed at the time of the TURP, would have secured the diagnosis.

- TURP is not an adequate way to biopsy the prostate gland. NICAN Urology Clinical Guidelines 2016 indicate that TURP is a poor clinical tool for cancer diagnosis and recommend prostate biopsy by the trans-rectal or trans-perineal approach.

- The Review Team conclude that the signs of localised prostate cancer were apparent from the time of presentation and that the correct course of action would have been to arrange appropriate staging scans and biopsies . Patient 9 should have undergone investigation with a MRI scan of the prostate and pelvis together with a bone scan.

- Arrangement could then have been made to start androgen deprivation therapy (a LHRH analogue) before referral on to a clinical oncologist for consideration of external beam radiotherapy (ERBT) with a realistic prospect of effective disease control.

- Dr.1 still suspected cancer within the prostate gland in a GP letter (dated 24 May 2019) but deferred definitive investigation until a review planned for September 2019.

- Patient 9's appointment in September was not made and he was lost to follow up.

- Patient 9 presented to Emergency Department (ED) on 8 May 2020 with urinary tract symptoms and signs of locally progressive prostate disease.

- After interactions with Urology and Lower Gastro-intestinal surgical colleagues, Patient 9 was diagnosed with high grade carcinoma of ~~prostate~~ prostatic origin, Gleason score 9. The patient had locally advanced disease and a colo-vesical fistula.

- When Patient 9 was reviewed at a virtual clinic in May 2020 by Dr 1, he was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment.

- The review team note that this treatment was not in adherence with 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 Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017).

6.0 FINDINGS

- This guidance was issued when Dr.1 was the regional chair of this group and had full knowledge of its contents.

- The review team note that following discussion with Patient 9, he was unaware that his care given was at variance with regionally recommended best practice.

- The review team believe that Patient 9 could not and did not give informed consent to this alternative pathway.

- A Urology Cancer Nurse Specialist was not appointed to support Patient 9 and his family, despite Patient 9's delayed diagnosis and immediate complex needs.

- The review team met with Patient 9 and his wife as part of the family engagement for the SAI. He described feeling isolated with no guidance on how to seek support or further care when he needed it. This resulted in numerous attendances to the Emergency Department with blocked catheters and urinary retention which Patient 9 found to be quite distressing. He was advised that the ED was the wrong place for him and that he should seek help from his GP. His experience in ED was further compounded by the Covid-19 restrictions.

- The review team acknowledge that the ED was not the most appropriate route for him to access. However, Patient 9 did not have access to a urology CNS to support him and his family with his diagnosis and despite having complex healthcare needs.

- The Southern Health and Social Care Trust Urology Cancer Peer Review submission 2017 states “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” (Peer review Self-Assessment report for NICaN 2017).

<u>Multidisciplinary Team Meetings</u>

- Patient 9 was not referred to MDM in a timely fashion because of non-adherence to diagnostic pathways Northern Ireland Cancer Network (NICAN) Urology Cancer clinical Guidelines 2016) and a delayed diagnosis of cancer.

6.0 FINDINGS

7.0 CONCLUSIONS

The possibility of localised prostate cancer should have been considered from the time of presentation; although there is no record of a digital rectal examination the PSA was elevated. Further, signs should have been elicited during the TURP and appropriate biopsies could have been performed. TURP does not provide an adequate biopsy the prostate gland.

A MRI scan prompted by a digital rectal examination together with the elevated PSA might have revealed the need for biopsy. A transrectal biopsy performed either before or at the time of the TURP would have secured the diagnosis. Arrangements could have been made to start appropriate hormone therapy (a LHRH analogue) prior to referral to a clinical oncologist for an opinion on external beam radiotherapy with a realistic prospect of effective disease control.

To compound this, the patient was apparently lost to follow up after his appointment in July 2019.

Patient 9 is likely to have suffered an unnecessary outcome owing to delays in the investigation of his symptoms and signs, the unconventional treatment of prostate cancer, and failures in follow up procedures.

Had the appropriate investigations and treatment been instituted in a timely fashion, there is likelihood that Patient 9 would have enjoyed a good quality of life for an extended period.

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 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. Any other function is secondary to, and if necessary be sacrificed to, this aim.

The multi-disciplinary team meeting should be quorate, and all participants must feel able to

contribute to discussion.

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

The MDT should audit all aspects of its primary function.

The clinical record should include the reason for any deferments 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

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

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	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 31/10/2019

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

Pati ent

1.0 EXECUTIVE SUMMARY

Patient 1, a Personal Information redacted by the 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. Patient 1 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. Patient 1's disease progressed and he passed away Personal Information redacted by the USI. The Review Team would like to extend their sincere condolences to his wife and family.

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.

Pati ent

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement

Review of Northern Ireland Health Care Records

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines.

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 1, a Personal Information redacted by the -old gentleman, was referred by his GP to the urology service at the Western Trust on 13 June 2019; he had a raised PSA (19ng/ml) which is a blood test used to assess the risk of the presence of prostate cancer. His past medical history included Personal Information redacted by the USI

The 'red flag' urgent referral was received on 14 June 2019 and triaged by Dr.1 (Consultant Urologist) on 17 June 2019. A MRI scan of the prostate and pelvis was requested to be done prior to an appointment scheduled for 22 July 2019.

The MRI scan (10 July 2019) showed some benign enlargement in the central zone of the prostate and, at the front of the gland, a moderately suspicious (PIRADS 3) area of possible prostate cancer, but also some highly suspicious changes (PIRADS 5) in the peripheral zone.

Patient 1 was reviewed by Dr.1 on 22 July 2019 and was advised that he may have a malignancy of his prostate gland and that further investigations would be required. An ultrasound scan of the bladder and urinary tract and an appointment for prostate biopsies were arranged.

On 20 August 2019, Patient 1 attended the Prostate Biopsy Clinic under the care of Nurse 1. The procedure was completed without complication and the samples were sent to histopathology. The results of the biopsy, reported on 28 August 2019, showed adenocarcinoma of prostate (Gleason 4+3), but there was no evidence of perineural infiltration, lymphovascular invasion or extracapsular extension.

The ultrasound scan of the urinary tract, performed on 21 August 2019, showed normal kidneys and normal bladder appearance although there was a post void residual of 204mls of urine.

Patient 1's case was discussed at the Urology Multidisciplinary Meeting (MDM) on 29 August 2019. He was noted to have been taking Finasteride 5mgs since 2010. A radioisotope bone scan and a CT scan of chest, abdomen and pelvis were recommended to stage the prostate cancer. Patient 1's General Practitioner (GP) was

Pati ent

5.0 DESCRIPTION OF INCIDENT/CASE

advised of the outcome of the MDM by letter.

Patient 1 was reviewed by Dr.1 on 23 September 2019 and was told that he had high-risk prostate cancer. No staging investigations were requested. Instead, he was prescribed Bicalutamide150mgs once daily and Tamoxifen 10mgs once daily in order to minimise the risk of breast tenderness a possible side-effect of the anti-androgen.

Patient 1 received a follow up phone call from Dr.1 on 14 October 2019 following a request for advice regarding the potential side effects to his medication. Dr.1 reported that Patient 1 was experiencing some light headedness and dizziness, which was affecting his ability to drive. Dr.1 advised Patient 1 to cease both hormonal medications. However, although Patient 1's PSA was noted to be rising (21.8ng/ml), a plan was made to re-check the PSA level. The bone scan and CT scans were also arranged. Patient 1 was advised to recommence Bicalutamide at a lower dose (50mgs once daily) from 1 November 2019.

Patient 1 was discussed again at MDM on 31 October 2019. His bone scan and CT scan showed no metastatic spread of disease outside the prostate. A recommendation to commence androgen deprivation therapy (a LHRH analogue) and refer for an opinion from a Clinical Oncologist regarding external beam radiation therapy (EBRT) was agreed.

Patient 1 attended his outpatient appointment with Dr.1 on 11 November 2019. His lower urinary tract symptoms were unchanged. His PSA result had fallen to 3.84ng/ml. Dr.1 described in a letter to Patient 1's GP that if the PSA level did not decrease further at a subsequent check, "*it may be necessary to take an incremental approach to increased androgen blockade by increasing the dose of bicalutamide to 50mgs twice daily, and hopefully subsequently to taking the higher dose of 150mgs once again…. I suspect that the addition of an LHRH agonist may be more intolerable".*

A review on 27 January 2020 took place as planned. The PSA was noted to be 2.23ng/ml, but Patient 1's urinary symptoms including nocturia continued. Patient 1 was asked to increase the Bicalutamide to 100mgs once daily.

On 7 March 2020, Patient 1 received a telephone call from Dr.1, who advised that the PSA level had increased to 5.37ng/ml. The dose of bicalutamide was increased to150mgs once daily.

A planned review appointment for 27 April 2020 had been made however, on 23 March 2020 Patient 1 attended the Emergency Department in South West Hospital Enniskillen (SWAH) complaining of difficulty passing urine. He was assessed and sent home. Patient 1 re-attended on 7 April 2020 and was found to be in urinary retention. A urethral catheter was fitted.

On 1 June 2020, Dr.1 informed Patient 1 in a telephone conversation that the PSA level had risen to 12.08ng/ml and advised the commencement of Leuprorelin (a LHRH analogue) subcutaneous injection be administered monthly by the practice nurse at the GP surgery.

To try and remove the urethral catheter, arrangements were made for a transurethral resection of prostate (TURP) at Daisy Hill Hospital (DHH). He was advised to self-

5.0 DESCRIPTION OF INCIDENT/CASE

isolate until his surgery and to have a Covid-19 test two days prior to admission.

On 17 June 2020, Patient 1 was admitted and at operation was noted to have a large obstructive prostate gland. The procedure was carried out by Dr.1. Patient 1 developed a pyrexia (high temperature) and bradycardia (low pulse) post-operatively, which was appropriately and efficiently treated. The subsequent removal of the catheter was unsuccessful and so a plan was made for Patient 1 to have a second trial of voiding at his local hospital. Patient 1 was discharged on 22 June 2020.

Histology of the resected specimen showed adenocarcinoma (Gleason 5+5) with peri-neural and lympho-vascular invasion.

On 22 June 2020 Dr.2 (Consultant Urologist) dictated a letter (typed on 26 June 2020) advising Patient 1's GP of his admission for TURP and the unsuccessful trial removal of the catheter. Dr.2 expressed thanks for commencing Patient 1 on the LHRH analogue and noted that the next dose (due 29th June) would provide an opportunity to switch to a 12-weekly preparation. Dr.2 advised of Patient 1's referral to the Oncology Team. A referral letter was sent on the same day by Dr.2 to Nurse 1 asking to arrange a further trial of voiding two weeks later.

Dr.1 sent a letter to Patient 1's GP on 2 July 2020 advising of the rise in PSA from 22.22ng/ml (3 June 2020) to 29.5ng/ ml (12 June 2020) and the need for trial removal of catheter by Nurse 1 as indicated by Dr.2's letter. The plan for a CT and a bone scan to update staging and allow appropriate referral to the Oncology Team in Altnagelvin Hospital was explained. Dr.1 described a conversation with Patient 1 in which he found him to be "somewhat vague" stating that he thought there may have been some "significant degree of memory loss" and that Patient 1 could not remember commencing his Leuprorelin during the first week in June 2020. Patient 1's GP was advised that histology had shown Gleason 5+5 adenocarcinoma. Dr.1 requested if Decapeptyl 11.25mgs injections could be made available for administration by the practice nurse.

On 15 July 2020 Patient 1 was reviewed by Dr.3 (Consultant Oncologist) in Altnagelvin Area Hospital. The oncologist's opinion was the Patient 1 had become too unfit to consider any treatment option with curative intent. He was commenced palliative treatment and was prescribed Abiratherone.

On 23 July 2020, Patient 1 was admitted to South West Area Hospital following an Emergency Department attendance with decreased oral intake, diarrhoea and abdominal pain. He recently had his catheter changed and the GP had tested the urine which was positive for coliforms. He had been commenced on trimethoprim in the community with no improvement. Patient 1 was found to have an acute kidney injury (AKI) initially thought to be due to infection and was treated for sepsis. After an ultrasound showed left hydronephrosis, a CT scan, performed on the advice of urology, showed prostate cancer progression in the pelvis that was causing the left obstructive uropathy. He improved clinically and was keen for discharge home on oral antibiotics.

On Personal Information redacted by the USI Patient 1 passed away in Personal Information redacted by the

6.0 FINDINGS

- The review team found that the initial assessment of Patient 1 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 treatment did not conform with 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 this case was not discussed with Patient 1. 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 MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% in 2020.

- 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 discussed with the patient.

- Patient 1 could not and did not give informed consent for this action.

- Patient 1 did not have a Cancer Nurse Specialist (CNS) or Key Worker to support his care. The SHSCT had invested in additional resource to provide Specialist Nurses to all urology cancer patients. The SHSCT had indicated to Cancer Peer Review (2017) that all patients had access to this resource. The review team have been informed that Dr.1 excluded all CNSs from the care of his

Pati ent

6.0 FINDINGS

patients at clinics. This was contrary to the regional guidance and contrary to the multidisciplinary ethos of cancer care.

- The review team found that without appropriate CNS support, Patient 1 and his family had difficulties in accessing support and care, especially in the community. This resource was provided by the SHSCT but was denied to Patient 1 by the exclusion of CNS involvement. Patient 1's family tried their best to address this deficit, with input from family, extended family and friends.

- The review team noted that Patient 1's case was not re-discussed at the MDM despite clear progression of the disease. This meant there was no opportunity for Patient 1 to benefit from the multi-disciplinary care, other urologists, oncology and especially palliative care, that underpins Improving Outcomes Guidance (2002). The absence of any CNS input to Patient 1's care meant that they were unaware of the disease progression and could not refer back to the MDM independently.

- The review team concluded that Patient 1 received uni-professional treatment and care despite multi-professional resources being available. His care did not follow regional guidance and treatment recommendations from the MDM were ignored. Patient 1 was denied the opportunity of multidisciplinary professional referral and care: initially from a clinical oncologist when radical therapy should have been considered; and subsequently from high quality palliative care when it became necessary.

- Patient 1 developed metastases whilst being inadequately treated for high-risk prostate cancer. By this time the opportunity to consider potentially curative treatment had been lost.

- **Family Engagement.**

- The review panel met with Patient 1's family. They were advised that Patient 1 did not have a CNS to support him through his cancer diagnosis. Patient 1's daughter was planning [redacted] to [redacted] when they learned of Patient 1's disease progression. But Patient 1 died sooner than they expected.

- The family highlighted the huge impact of the indwelling catheter problems caused to Patient 1 from March/ April 2020. The family described his difficulties in trying to contact Dr 1 and his secretary. Had a CNS been introduced to Patient 1 at his initial diagnosis, he would have been provided with contact details. He 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 Patient 1'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

Patient

6.0 FINDINGS

additional stresses to the family.

- Had Patient 1 been given the opportunity to have access to a clinical nurse specialist his experience may have had a different experience.

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 Patient 1's tumour which was graded as Gleason 4+3.

The review team suggest there is no evidence to support the contention that the biopsy may not have been representative.

7.0 CONCLUSIONS

Patient 1 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.

Patient 1 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.

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 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. Any other function is secondary to, and if necessary be sacrificed to, this aim.

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

- After any patient interaction, best practice includes the prompt communication with the patient (and their General Practitioner) in plain English 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.

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

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

Recommendation 2

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients. This will be achieved by - Urology Cancer Care delivered through 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.

Recommendation 3

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

Recommendation 4

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.

Recommendation 5

The Southern Health and Social Care Trust must ensure that patients are discussed

9.0 RECOMMENDATIONS AND ACTION PLANNING

appropriately at MDM and by the appropriate professionals, especially as disease progresses.

Recommendation 6

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.

Recommendation 7

Each MDM requires a Chair responsible for the audit and quality assurance of all aspects of its primary function.

Recommendation 8

The multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.

Recommendation 9

The clinical record should include the reason for any deferments or variation in MDM management decisions.

Reference:

1. **Peer Review Self-Assessment Report for NICAN (2017).**

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE
(under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 31/10/2019

HSCB Unique Case Identifier:

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: Retired Medical Director

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

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 Clinical Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Review NIECR records

Interviews with Staff

Family Engagement

MDT pathway for Cancer Management

Relevant guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 1 a Personal Information redacted by the -old gentleman, was referred by his GP to the urology service at in Western Trust on 13 June 2019; he had a raised PSA (19ng/ml) which is a blood test used to assess the risk of the presence of prostate cancer. His past medical history included Personal Information redacted by the USI

The 'red flag' urgent referral was received on 14 June 2019 and triaged by Dr.1 (Consultant Urologist) on 17 June 2019. A MRI scan of the prostate and pelvis was requested to be done prior to an appointment scheduled for 22 July 2019.

The MRI scan (10 July 2019) showed some benign enlargement in the central zone of the prostate and, at the front of the gland, a moderately suspicious (PIRADS 3) area of possible prostate cancer, but also some highly suspicious changes (PIRADS 5) in the peripheral zone.

Patient 1 was reviewed by Dr.1 on 22 July 2019 and was advised that he may have a malignancy of his prostate gland and that further investigations would be required. An ultrasound scan of the bladder and urinary tract and an appointment for prostate biopsies were arranged.

On 20 August 2019, Patient 1 attended the Prostate Biopsy clinic under the care of Nurse 1. The procedure was completed without complication and the samples were sent to histopathology. The results of the biopsy, reported on 28 August 2019, showed adenocarcinoma of prostate (Gleason 4+3), but there was no evidence of perineural infiltration, lymphovascular invasion or extracapsular extension.

The ultrasound scan of the urinary tract, performed on 21 August 2019, showed normal kidneys and normal bladder appearance although there was a post void residual of 204mls of urine.

Patient 1's case was discussed at the Urology Multidisciplinary Meeting (MDM) on 29 August 2019. He was noted to have been taking Finasteride 5mgs since 2010. A radioisotope bone scan and a CT scan of chest, abdomen and pelvis were recommended to stage the prostate cancer. Patient 1's General Practitioner (GP) was advised of the outcome of the MDM by letter.

Patient 1 was reviewed by Dr.1 on 23 September 2019 and was told that he had high-risk prostate cancer. No staging investigations were requested. Instead, he was prescribed Bicalutamide150mgs once daily and Tamoxifen 10mgs once daily in order to minimise the risk of breast tenderness a possible side-effect of the anti-androgen.

Patient 1 received a follow up phone call from Dr.1 on 14 October 2019 following a request for advice regarding the potential side effects to his medication. Dr.1 reported that Patient 1 was experiencing some light headedness and dizziness, which was affecting his ability to drive. Dr.1 advised Patient 1 to cease both hormonal medications. However, although Patient 1's PSA was noted to be rising (21.8ng/ml), a plan was made to re-check the PSA level. The bone scan and CT scans were also arranged. Patient 1 was advised to

5.0 DESCRIPTION OF INCIDENT/CASE

recommence Bicalutamide at a lower dose (50mgs once daily) from 1 November 2019.

Patient 1 was discussed again at MDM on 31 October 2019. His bone scan and CT scan showed no metastatic spread of disease outside the prostate. A recommendation to commence androgen deprivation therapy (a LHRH analogue) and refer for an opinion from a Clinical Oncologists regarding external beam radiation therapy (EBRT) was agreed.

Patient 1 attended his outpatient appointment with Dr.1 on 11 November 2019. His lower urinary tract symptoms were unchanged. His PSA result had fallen to 3.84ng/ml. Dr.1 described in a letter to Patient 1's GP that if the PSA level did not decrease further at a subsequent check, "*it may be necessary to take an incremental approach to increased androgen blockade by increasing the dose of bicalutamide to 50mgs twice daily, and hopefully subsequently to taking the higher dose of 150mgs once again…. I suspect that the addition of an LHRH agonist may be more intolerable".*

A review on 27 January 2020 took place as planned. The PSA was noted to be 2.23nmol/ml, but Patient 1's urinary symptoms included nocturia continued. Patient 1 was asked to increase the Bicalutamide to 100mgs once daily.

On 7 March, Patient 1 received a telephone call from Dr.1, who advised that the PSA level had increased to 5.37ng/ml. The dose of bicalutamide was increased to150mgs once daily.

A planned review appointment for 27 April 2020 had been made, but on 23 March Patient 1 attended the Emergency Department in South West Hospital Enniskillen (SWAH) complaining of difficulty passing urine. He was assessed and sent home. Patient 1 re-attended on 7 April 2020 and was found to be in urinary retention. A urethral catheter was fitted.

On 1 June 2020, Dr.1 informed Patient 1 in a telephone conversation that the PSA level had risen to 12.08ng/ml and advised the commencement of Leuprorelin (a LHRH analogue) subcutaneous injection be administered monthly by the practice nurse at the GP surgery.

To try and remove the urethral catheter, arrangements were made for a transurethral resection of prostate (TURP) at Daisy Hill Hospital (DHH). He was advised to self-isolate until his surgery and to have a Covid-19 test two days prior to admission.

On 17 June 2020, Patient 1 was admitted and at operation was noted to have a large obstructive prostate gland. The procedure was carried out by Dr.1. Patient 1 developed a pyrexia (high temperature) and bradycardia (low pulse) post-operatively, which was appropriately and efficiently treated. The subsequent removal of the catheter was unsuccessful and so a plan was made for Patient 1 to have a second trial of voiding at his local hospital. Patient 1 was discharged on 22 June 2020.

Histology of the resected specimen showed adenocarcinoma (Gleason 5+5) with peri-neural and lympho-vascular invasion.

On 22 June 2020 Dr.2 (Consultant Urologist) dictated a letter (typed on 26 June 2020)

5.0 DESCRIPTION OF INCIDENT/CASE

advising Patient 1's GP of his admission for TURP and the unsuccessful trial removal of the catheter. Dr.2 expressed thanks for commencing Patient 1 on the LHRH analogue and noted that the next dose (due 29th June) would provide an opportunity to switch to a 12-weekly preparation. Dr.2 advised of Patient 1's referral to the Oncology Team. A referral letter was sent on the same day by Dr.2 to Nurse 1 asking to arrange a further trial of voiding two weeks later.

Dr.1 sent a letter to Patient 1's GP on 2/7/2020 advising of the rise in PSA from 22.22ng/ml (3 June 2020) to 29.5mg/ ml (12 June 2020) and the need for trial removal of catheter by Nurse 1 as indicated by Dr.2 letter. The plan for a CT and a bone scan to update staging and allow appropriate referral to the oncology team in Altnagelvin Hospital was explained. Dr.1 described a conversation with Patient 1 in which he found him to be "somewhat vague" stating that he thought there may have been some "significant degree of memory loss" and that Patient 1 could not remember commencing his Leuprorelin during the first week in June 2020. Patient 1's GP was advised that histology had shown Gleason 5+5 adenocarcinoma. Dr.1 requested if Decapeptyl 11.25mgs injections could be made available for administration by the practice nurse.

15 July 2020 Patient 1 was reviewed by Dr.3 (Consultant Oncologist) in Altnagelvin Area Hospital. He was deemed not fit for any other treatment option.

On 23 July 2020, Patient 1 was admitted to South West Area Hospital following an Emergency Department attendance with decreased oral intake, diarrhoea and abdominal pain. He recently had his catheter changed and the GP had tested the urine which was positive for coliforms. He had been commenced on trimethoprim in the community with no improvement. Patient 1 was found to have an acute kidney injury (AKI) initially thought to be due to infection and was treated for sepsis. After an ultrasound showed left hydronephrosis, a CT scan, performed on the advice of urology, showed prostate cancer progression in the pelvis that was causing the left obstructive uropathy. He improved clinically and was keen for discharge home on oral antibiotics.

Personal Information redacted by the USI Patient 1 passed away in Personal Information redacted by the .

6.0 FINDINGS

Causal Factors

- The review team suggested that the initial assessment of Patient 1 was satisfactory although rather prolonged.
- The prescribed androgen deprivation therapy (ADT) did not conform with the northern Ireland cancer network (NICAN) guidance (2016).
- This guidance was signed off by the Southern Health and Social Care Trust (SHSCT) urology multidisciplinary meeting, as their standard of cancer care for Cancer Peer Review (2017).

6.0 FINDINGS

- This guidance was issued when Dr 1 was the Chair of the Regional Urology Cancer Group and should have had full knowledge of the contents.

- 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 definitive hormonal (LHRH analogue) treatment.

- Bicalutamide monotherapy (150mg) is not licensed for use as a continuing treatment for prostate cancer as it has been shown to reduce survival in comparison to LHRH treatment.

- Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1 nmol/l), which is best accomplished by the use of a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.

- Following discussion with the families, the review team have noted that there was not discussion with Patient 1 that the treatment given was at variance with regionally recommended practice.

- Patient 1 could not and did not give informed consent to his alternative care pathway.

Contributed Factors

<u>Multidisciplinary Team Meetings</u>

- The review team have identified that during the multidisciplinary team meetings (MDM) that a quorate had not been met. This was due to the absence of oncologists 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 recommendations made by the MDT (31 October 2019) to use LHRHa and to refer to oncology for external beam radiotherapy were not actioned by Dr 1. There is no noted rationale for this inaction nor was it discussed with the patient.

- Patient 1 could not and did not give informed consent for this action.

<u>Specialist Nurses</u>

- Patient 1 did not have a Urology Cancer Specialist Nurse to support his care. The SHSCT had invested in additional resource to provide Specialist Nurses to all urology cancer patients. The SHSCT had indicated to Cancer Peer Review (2017) that all patients had access to this resource.

- The review team found that Dr 1 excluded specialist nurses from the care of his patients. This was contrary to the regional guidance and contrary to the multidisciplinary ethos of cancer care.

6.0 FINDINGS

- The review team found that without appropriate Specialist Nurse support, Patient 1 and his family had difficulties in accessing support and care, especially in the community. Patient 1's family tried their best to address this deficit. The review team note that this should not have been the case as the resource was present in the SHSCT and its urology care catchment area. It was not made available.

- The review team noted that Patient 1's case was not re-discussed at the Multidisciplinary Team Meeting despite clear progression of the disease. This meant there was no opportunity for input from other urologists, oncology and especially palliative care.

- Absence of Urology Cancer Specialist Nurse input to care meant that they were unaware of the disease progression and could not independently refer patients back to the MDM.

- The review team concluded that Patient 1 received uni-professional treatment and care despite multi-professional resources being available.

- His care did not follow regional guidance and treatment recommendations from the local multidisciplinary team were ignored.

- Patient 1 was not given the opportunity to have appropriate professional input from oncology/ palliative care and urology nurse specialist.

- Patient 1 developed metastases whilst being inadequately treated for high-risk prostate cancer. The opportunity to offer him radical (with curative intent) treatment was unnecessarily delayed.

Family Engagement.

- The review panel met with Patient 1's family. They were advised that Patient 1 did not have a specialist nurse to support him through his cancer diagnosis. Patient 1's [redacted] when they learned of Patient 1's disease progression. But Patient 1 died sooner than they expected

- The family described how difficult it was to access district nursing and palliative care services and during the pandemic which resulted in Patient 1'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.

1. What role was played by the MDM in ensuring compliance with its recommendations.
2. The treatment offered is likely to have accelerated the tumours de-differentiation development of metastases (REF)

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Diagnosis
Staging

6.0 FINDINGS

MDT
Patient support
Referral to oncology
Compliance to guidelines
discussion

7.0 CONCLUSIONS

Patient 1 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.

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 6 October 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

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

Personal Information

1.0 EXECUTIVE SUMMARY

Patient 6 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

Personal Information

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 3 May 2019, Patient 6's General Practitioner (GP) referred him to urology with a confirmed elevation of prostate specific antigen (PSA) of greater than 11ng/ml. The GP noted that Patient 6 got out of bed 5 times every night to pass urine with a poor flow. A digital rectal examination (DRE) had showed a mildly enlarged prostate, but no suggestion of prostate cancer. The GP also noted that Patient 6 had a poor appetite and had 7 pounds weight loss over two months.

The GP reported that Patient 6's past medical history included Personal Information redacted by the USI Personal Information redacted by the USI Personal Information redacted by the USI .

On 7 May 2019 Dr.1 (Consultant Urologist) requested an ultrasound scan of Patient 6's urinary tract (8 May 2019), which was unremarkable save for a moderately (50g) enlarged prostate; the bladder was empty after micturition.

Patient 6 was reviewed at the urology clinic on 28 May 2019 by Dr.2 (Locum Consultant Urologist). It was recorded that Patient 6 had had lower urinary tract symptoms for a long time and that his main symptom was that he awoke 4-5 times at night to pass urine. The elevated PSA and moderately enlarged prostate were noted. On this occasion the PSA density was calculated to be 0.225, indicating a significant risk of the presence of prostate cancer. This was supported by the digital rectal examination that suggested the possibility of a nodule in the left lateral lobe of his prostate. At that clinic, a urinary flow rate and a measurement of the residual urine carried out was consistent with bladder outlet obstruction due to an enlarged prostate. Dr.2 prescribed Tamsulosin (a prostate relaxant medicine) to ease the symptoms and organised an MRI of the prostate gland to further assess the risk of prostate cancer.

The MRI was carried out on 13 June 2019 and concluded that there was a probable tumour within the posterolateral peripheral zone of the left mid gland, but there was no pelvic lymphadenopathy or any suspicious bone lesion in the pelvis or lumbar spine.

On 19 July 2019 Patient 6 was seen by Dr.1 at the Urology Clinic when he reported hesitancy of micturition, a poor urinary flow and post-micturitional incontinence in addition to the severe nocturia (passing urine at night). Dr.1 advised Patient 6 that it would be prudent to proceed with prostatic biopsies in view of the MRI findings. Patient 6 expressed some concern and anxiety regarding the risk of progression of any prostatic carcinoma whilst awaiting prostatic biopsies. Therefore, after repeating his serum PSA level and assessing his serum testosterone level Dr.1 requested that Patient 6 be prescribed Bicalutamide 50mg (once daily), until advised otherwise, whilst he

Personal Information

5.0 DESCRIPTION OF INCIDENT/CASE

awaited trans-rectal, ultrasound-guided prostatic biopsies which had been scheduled for 30 July 2019.

Dr. 1 wrote to Patient 6's GP to update him on the urology review and confirmed Patient 6's further management would be discussed at the urology multidisciplinary meeting (MDM) as soon as the histopathology report was available.

On 30 July 2019 Patient 6 had his ultrasound guided biopsy prostate carried out which confirmed that there was prostatic adenocarcinoma (Gleason 7) indicating an intermediate risk of progression (spread). (The Gleason sum is the most common system doctors use to indicate the aggressiveness of prostate cancer).

Patient 6 was discussed at the MDM on 8 August 2019. It was agreed that Patient 6 had an intermediate risk but apparently organ confined prostate cancer. Dr.1 was to review Patient 6 in outpatients and discuss management with curative intent or surveillance.

Patient 6 was advised by Dr.1 of the histological diagnosis at review on 3 September 2019. It was noted that Patient 6's PSA level had decreased to 8.41ng/ml, which Dr.1 deemed acceptable.

Dr.1 advised Patient 6 that it would be prudent to further assess his lower urinary tract symptoms with a flexible cystoscopy and urodynamic studies. It was agreed that this would take place on 27 September 2019.

Following the appointment on 27 September 2019, Dr.1 wrote to Patient 6's GP to advise it had proved inconvenient to proceed as Patient 6 was attending a funeral later that day. Dr.1 noted that Patient 6 had found bicalutamide entirely tolerable, with no associated toxicity, and that Patient 6 was of the impression that the [partial] androgen blockade may already have resulted in slight improvement in his urinary symptoms. At this time his serum PSA level had decreased further to 6.37ng/ml. Dr.1 asked the GP to prescribe modified release oxybutynin in the hope of some improvement in his lower urinary tract symptoms. Dr.1 asked for Patient 6's serum PSA level to be repeated during the first week of November 2019 so that the result would be available for the next outpatient review on 8 November 2019.

On 8 November 2019. Dr.1 noted that Patient 6's serum PSA level had decreased further to 4.51ng/ml. Patient 6 reported the development of some tenderness of his right breast. Dr.1 therefore requested that the GP additionally prescribe Tamoxifen 10mgs (once daily). As Patient 6 had also reported some digestive symptoms, Dr. 1 requested that Omeprazole (once daily) be prescribed. Patient 6 reported that his urinary symptoms had worsened significantly since previous review in September 2019 and in particular, he reported that he was having to awake 7 or 8 times each night to pass urine. Dr.1 recommended that Patient 6 should have the flexible cystoscopy and urodynamic studies performed, and Patient 6 agreed to return on 13 December 2019 to have both carried out.

When Patient 6 returned on 13 December 2019, he declined to have any invasive procedures performed. He reported that his nocturia had improved and he was only having to awaken 3 times each night. The serum PSA level was repeated and found not to have decreased (4.35ng/ml). Dr.1 advised the GP that it was evident that the [minimal] androgen blockade (bicalutamide, 50mgs daily) was inadequate and asked

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5.0 DESCRIPTION OF INCIDENT/CASE

for the dose to be increased to 150mgs daily.

On 2 January 2020 Dr.1 spoke with Patient 6 by telephone and was noted to be well. Dr. 1 asked Patient 6 to make an appointment with the GP's Practice Nurse to have his serum PSA level repeated during the first week of March 2020 so that the result would be available at review later that month.

On 4 September 2020, Dr.3 (Locum Consultant Urologist) wrote to Patient 6 asking him to attend his GP to have his serum PSA rechecked.

On 2 October 2020, Patient 6 was reviewed by Dr.4 (Consultant Urologist) who noted that Patient 6 had discontinued Bicalutamide since his last prescription in February 2020. His most recent serum PSA was noted as 15ng/ml. Dr.4 re-discussed with Patient 6 his prostate cancer diagnosis and the available treatment options. Patient 6 did not recall any conversation about external beam radiotherapy (EBRT) as a radical treatment or discussion of surveillance as an option.

Dr.4 noted from the discussion Patient 6 would prefer no treatment at present and to go on to surveillance with a view to radiotherapy if his serum PSA increased or there was other evidence of progression. Dr.4 noted that Patient 6 planned a repeat serum PSA in December 2020.

At the appointment Dr.4 had a conversation with Patient 6 about his initial treatment and highlighted that the initial treatment with bicalutamide (50mg) is not recommended for the continuing treatment of prostate cancer.

6.0 FINDINGS

- The diagnostic pathway was rather prolonged.
- The MDM recommendation of 8 August 2019 – surveillance or radiotherapy with curative intent. This recommendation was not followed with neither option being offered. Bicalutamide was continued.
- No further opinion regarding the management of his disease was offered to the patient, which should have happened as a matter of course either by a recorded discussion with an oncologist at the MDM, by an appointment at a Joint Oncology Clinic or by urgent direct referral.
- The treatment did not conform to the "NICAN Regional Hormone Therapy Guidelines for Prostate Cancer" 2016. This was singed off by Dr 1 as chair of the NICAN Urology Cancer Clinical reference Group.

Personal Information

6.0 FINDINGS

- The Review team note that following discussion with Patient 6 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 Patient 6 stopped the bicalutamide as they "didn't agree with his stomach".
- The patient and family were left unsupported.

Contributory factors

- Patient 6 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 Patient 6 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.

Personal Information

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.

Personal Information

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

Personal Information

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report <u>for all levels of SAI reviews)</u>

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**: 26 October 2020						
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	✓
	If **YES**, insert date informed:			
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			✓
	c) Report not shared but contents discussed **(*if you select this option please also complete 'I' below*)**			
	d) No contact or Next of Kin or Unable to contact			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 6 October 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

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

Personal Information

1.0 EXECUTIVE SUMMARY

Patient 6 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

Personal Information

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 3 May 2019, Patient 6's General Practitioner (GP) referred him to urology with a confirmed elevation of prostate specific antigen (PSA) of greater than 11ng/ml. The GP noted that Patient 6 got out of bed 5 times every night to pass urine with a poor flow. A digital rectal examination (DRE) had showed a mildly enlarged prostate, but no suggestion of prostate cancer. The GP also noted that Patient 6 had a poor appetite and had 7 pounds weight loss over two months.

The GP reported that Patient 6's past medical history included Personal Information redacted by the USI Personal Information redacted by the USI Personal Information redacted by the USI .

On 7 May 2019 Dr.1 (Consultant Urologist) requested an ultrasound scan of Patient 6's urinary tract (8 May 2019), which was unremarkable save for a moderately (50g) enlarged prostate; the bladder was empty after micturition.

Patient 6 was reviewed at the urology clinic on 28 May 2019 by Dr.2 (Locum Consultant Urologist). It was recorded that Patient 6 had had lower urinary tract symptoms for a long time and that his main symptom was that he awoke 4-5 times at night to pass urine. The elevated PSA and moderately enlarged prostate were noted. On this occasion the PSA density was calculated to be 0.225, indicating a significant risk of the presence of prostate cancer. This was supported by the digital rectal examination that suggested the possibility of a nodule in the left lateral lobe of his prostate. At that clinic, a urinary flow rate and a measurement of the residual urine carried out was consistent with bladder outlet obstruction due to an enlarged prostate. Dr.2 prescribed Tamsulosin (a prostate relaxant medicine) to ease the symptoms and organised an MRI of the prostate gland to further assess the risk of prostate cancer.

The MRI was carried out on 13 June 2019 and concluded that there was a probable tumour within the posterolateral peripheral zone of the left mid gland, but there was no pelvic lymphadenopathy or any suspicious bone lesion in the pelvis or lumbar spine.

On 19 July 2019 Patient 6 was seen by Dr.1 at the Urology Clinic when he reported hesitancy of micturition, a poor urinary flow and post-micturitional incontinence in addition to the severe nocturia (passing urine at night). Dr.1 advised Patient 6 that it would be prudent to proceed with prostatic biopsies in view of the MRI findings. Patient 6 expressed some concern and anxiety regarding the risk of progression of any prostatic carcinoma whilst awaiting prostatic biopsies. Therefore, after repeating his serum PSA level and assessing his serum testosterone level Dr.1 requested that Patient 6 be prescribed Bicalutamide 50mg (once daily), until advised otherwise, whilst he

Personal Information

5.0 DESCRIPTION OF INCIDENT/CASE

awaited trans-rectal, ultrasound-guided prostatic biopsies which had been scheduled for 30 July 2019.

Dr. 1 wrote to Patient 6's GP to update him on the urology review and confirmed Patient 6's further management would be discussed at the urology multidisciplinary meeting (MDM) as soon as the histopathology report was available.

On 30 July 2019 Patient 6 had his ultrasound guided biopsy prostate carried out which confirmed that there was prostatic adenocarcinoma (Gleason 7) indicating an intermediate risk of progression (spread). (The Gleason sum is the most common system doctors use to indicate the aggressiveness of prostate cancer).

Patient 6 was discussed at the MDM on 8 August 2019. It was agreed that Patient 6 had an intermediate risk but apparently organ confined prostate cancer. Dr.1 was to review Patient 6 in outpatients and discuss management with curative intent or surveillance.

Patient 6 was advised by Dr.1 of the histological diagnosis at review on 3 September 2019. It was noted that Patient 6's PSA level had decreased to 8.41ng/ml, which Dr.1 deemed acceptable.

Dr.1 advised Patient 6 that it would be prudent to further assess his lower urinary tract symptoms with a flexible cystoscopy and urodynamic studies. It was agreed that this would take place on 27 September 2019.

Following the appointment on 27 September 2019, Dr.1 wrote to Patient 6's GP to advise it had proved inconvenient to proceed as Patient 6 was attending a funeral later that day. Dr.1 noted that Patient 6 had found bicalutamide entirely tolerable, with no associated toxicity, and that Patient 6 was of the impression that the [partial] androgen blockade may already have resulted in slight improvement in his urinary symptoms. At this time his serum PSA level had decreased further to 6.37ng/ml. Dr.1 asked the GP to prescribe modified release oxybutynin in the hope of some improvement in his lower urinary tract symptoms. Dr.1 asked for Patient 6's serum PSA level to be repeated during the first week of November 2019 so that the result would be available for the next outpatient review on 8 November 2019.

On 8 November 2019. Dr.1 noted that Patient 6's serum PSA level had decreased further to 4.51ng/ml. Patient 6 reported the development of some tenderness of his right breast. Dr.1 therefore requested that the GP additionally prescribe Tamoxifen 10mgs (once daily). As Patient 6 had also reported some digestive symptoms, Dr. 1 requested that Omeprazole (once daily) be prescribed. Patient 6 reported that his urinary symptoms had worsened significantly since previous review in September 2019 and in particular, he reported that he was having to awake 7 or 8 times each night to pass urine. Dr.1 recommended that Patient 6 should have the flexible cystoscopy and urodynamic studies performed, and Patient 6 agreed to return on 13 December 2019 to have both carried out.

When Patient 6 returned on 13 December 2019, he declined to have any invasive procedures performed. He reported that his nocturia had improved and he was only having to awaken 3 times each night. The serum PSA level was repeated and found not to have decreased (4.35ng/ml). Dr.1 advised the GP that it was evident that the [minimal] androgen blockade (bicalutamide, 50mgs daily) was inadequate and asked

Personal Information

5.0 DESCRIPTION OF INCIDENT/CASE

for the dose to be increased to 150mgs daily.

On 2 January 2020 Dr.1 spoke with Patient 6 by telephone and was noted to be well. Dr. 1 asked Patient 6 to make an appointment with the GP's Practice Nurse to have his serum PSA level repeated during the first week of March 2020 so that the result would be available at review later that month.

On 4 September 2020, Dr.3 (Locum Consultant Urologist) wrote to Patient 6 asking him to attend his GP to have his serum PSA rechecked.

On 2 October 2020, Patient 6 was reviewed by Dr.4 (Consultant Urologist) who noted that Patient 6 had discontinued Bicalutamide since his last prescription in February 2020. His most recent serum PSA was noted as 15ng/ml. Dr.4 re-discussed with Patient 6 his prostate cancer diagnosis and the available treatment options. Patient 6 did not recall any conversation about external beam radiotherapy (EBRT) as a radical treatment or discussion of surveillance as an option.

Dr.4 noted from the discussion Patient 6 would prefer no treatment at present and to go on to surveillance with a view to radiotherapy if his serum PSA increased or there was other evidence of progression. Dr.4 noted that Patient 6 planned a repeat serum PSA in December 2020.

At the appointment Dr.4 had a conversation with Patient 6 about his initial treatment and highlighted that the initial treatment with bicalutamide (50mg) is not recommended for the continuing treatment of prostate cancer.

6.0 FINDINGS

- The diagnostic pathway was rather prolonged.
- The MDM recommendation of 8 August 2019 – surveillance or radiotherapy with curative intent. This recommendation was not followed with neither option being offered. Bicalutamide was continued.
- No further opinion regarding the management of his disease was offered to the patient, which should have happened as a matter of course either by a recorded discussion with an oncologist at the MDM, by an appointment at a Joint Oncology Clinic or by urgent direct referral.
- The treatment did not conform to the "NICAN Regional Hormone Therapy Guidelines for Prostate Cancer" 2016. This was singed off by Dr 1 as chair of the NICAN Urology Cancer Clinical reference Group.

Personal Information

6.0 FINDINGS

- The Review team note that following discussion with Patient 6 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 Patient 6 stopped the bicalutamide as they "didn't agree with his stomach".
- The patient and family were left unsupported.

Contributory factors

- Patient 6 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 Patient 6 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.

Personal Information

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.

Personal Information

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

Personal Information

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report <u>for all levels of SAI reviews)</u>

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**: 26 October 2020						
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed **(*if you select this option please also complete 'I' below*)**			
	d) No contact or Next of Kin or Unable to contact			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 6 October 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

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

Patient 6 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)
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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.
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- 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

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 3 May 2019, Patient 6's General Practitioner (GP) referred him to urology with a confirmed elevation of prostate specific antigen (PSA) of greater than 11ng/ml. The GP noted that Patient 6 got out of bed 5 times every night to pass urine with a poor flow. A digital rectal examination (DRE) had showed a mildly enlarged prostate, but no suggestion of prostate cancer. The GP also noted that Patient 6 had a poor appetite and had 7 pounds weight loss over two months.

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awaited trans-rectal, ultrasound-guided prostatic biopsies which had been scheduled for 30 July 2019.

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Patient 6 was advised by Dr.1 of the histological diagnosis at review on 3 September 2019. It was noted that Patient 6's PSA level had decreased to 8.41ng/ml, which Dr.1 deemed acceptable.

Dr.1 advised Patient 6 that it would be prudent to further assess his lower urinary tract symptoms with a flexible cystoscopy and urodynamic studies. It was agreed that this would take place on 27 September 2019.

Following the appointment on 27 September 2019, Dr.1 wrote to Patient 6's GP to advise it had proved inconvenient to proceed as Patient 6 was attending a funeral later that day. Dr.1 noted that Patient 6 had found bicalutamide entirely tolerable, with no associated toxicity, and that Patient 6 was of the impression that the [partial] androgen blockade may already have resulted in slight improvement in his urinary symptoms. At this time his serum PSA level had decreased further to 6.37ng/ml. Dr.1 asked the GP to prescribe modified release oxybutynin in the hope of some improvement in his lower urinary tract symptoms. Dr.1 asked for Patient 6's serum PSA level to be repeated during the first week of November 2019 so that the result would be available for the next outpatient review on 8 November 2019.

On 8 November 2019. Dr.1 noted that Patient 6's serum PSA level had decreased further to 4.51ng/ml. Patient 6 reported the development of some tenderness of his right breast. Dr.1 therefore requested that the GP additionally prescribe Tamoxifen 10mgs (once daily). As Patient 6 had also reported some digestive symptoms, Dr. 1 requested that Omeprazole (once daily) be prescribed. Patient 6 reported that his urinary symptoms had worsened significantly since previous review in September 2019 and in particular, he reported that he was having to awake 7 or 8 times each night to pass urine. Dr.1 recommended that Patient 6 should have the flexible cystoscopy and urodynamic studies performed, and Patient 6 agreed to return on 13 December 2019 to have both carried out.

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5.0 DESCRIPTION OF INCIDENT/CASE

for the dose to be increased to 150mgs daily.

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On 2 October 2020, Patient 6 was reviewed by Dr.4 (Consultant Urologist) who noted that Patient 6 had discontinued Bicalutamide since his last prescription in February 2020. His most recent serum PSA was noted as 15ng/ml. Dr.4 re-discussed with Patient 6 his prostate cancer diagnosis and the available treatment options. Patient 6 did not recall any conversation about external beam radiotherapy (EBRT) as a radical treatment or discussion of surveillance as an option.

Dr.4 noted from the discussion Patient 6 would prefer no treatment at present and to go on to surveillance with a view to radiotherapy if his serum PSA increased or there was other evidence of progression. Dr.4 noted that Patient 6 planned a repeat serum PSA in December 2020.

At the appointment Dr.4 had a conversation with Patient 6 about his initial treatment and highlighted that the initial treatment with bicalutamide (50mg) is not recommended for the continuing treatment of prostate cancer.

6.0 FINDINGS

- The diagnostic pathway was rather prolonged.
- The MDM recommendation of 8 August 2019 – surveillance or radiotherapy with curative intent. This recommendation was not followed with neither option being offered. Bicalutamide was continued.
- No further opinion regarding the management of his disease was offered to the patient, which should have happened as a matter of course either by a recorded discussion with an oncologist at the MDM, by an appointment at a Joint Oncology Clinic or by urgent direct referral.
- The treatment did not conform to the "NICAN Regional Hormone Therapy Guidelines for Prostate Cancer" 2016. This was singed off by Dr 1 as chair of the NICAN Urology Cancer Clinical reference Group.

6.0 FINDINGS

- The Review team note that following discussion with Patient 6 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 Patient 6 stopped the bicalutamide as they "didn't agree with his stomach".
- The patient and family were left unsupported.

Contributory factors

- Patient 6 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 Patient 6 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.

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.

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**: 26 October 2020						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 6 October 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 6 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

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 3 May 2019, Patient 6's General Practitioner (GP) referred him to urology with a confirmed elevation of prostate specific antigen (PSA) of greater than 11ng/ml. The GP noted that Patient 6 got out of bed 5 times every night to pass urine with a poor flow. A digital rectal examination (DRE) had showed a mildly enlarged prostate, but no suggestion of prostate cancer. The GP also noted that Patient 6 had a poor appetite and had 7 pounds weight loss over two months.

The GP reported that Patient 6's past medical history included Personal Information redacted by the USI [redacted].

On 7 May 2019 Dr.1 (Consultant Urologist) requested an ultrasound scan of Patient 6's urinary tract (8 May 2019), which was unremarkable save for a moderately (50g) enlarged prostate; the bladder was empty after micturition.

Patient 6 was reviewed at the urology clinic on 28 May 2019 by Dr.2 (Locum Consultant Urologist). It was recorded that Patient 6 had had lower urinary tract symptoms for a long time and that his main symptom was that he awoke 4-5 times at night to pass urine. The elevated PSA and moderately enlarged prostate were noted. On this occasion the PSA density was calculated to be 0.225, indicating a significant risk of the presence of prostate cancer. This was supported by the digital rectal examination that suggested the possibility of a nodule in the left lateral lobe of his prostate. At that clinic, a urinary flow rate and a measurement of the residual urine carried out was consistent with bladder outlet obstruction due to an enlarged prostate. Dr.2 prescribed Tamsulosin (a prostate relaxant medicine) to ease the symptoms and organised an MRI of the prostate gland to further assess the risk of prostate cancer.

The MRI was carried out on 13 June 2019 and concluded that there was a probable tumour within the posterolateral peripheral zone of the left mid gland, but there was no pelvic lymphadenopathy or any suspicious bone lesion in the pelvis or lumbar spine.

On 19 July 2019 Patient 6 was seen by Dr.1 at the Urology Clinic when he reported hesitancy of micturition, a poor urinary flow and post-micturitional incontinence in addition to the severe nocturia (passing urine at night). Dr.1 advised Patient 6 that it would be prudent to proceed with prostatic biopsies in view of the MRI findings. Patient 6 expressed some concern and anxiety regarding the risk of progression of any prostatic carcinoma whilst awaiting prostatic biopsies. Therefore, after repeating his serum PSA level and assessing his serum testosterone level Dr.1 requested that Patient 6 be prescribed Bicalutamide 50mg (once daily), until advised otherwise, whilst

5.0 DESCRIPTION OF INCIDENT/CASE

he awaited trans-rectal, ultrasound-guided prostatic biopsies which had been scheduled for 30 July 2019.

Dr. 1 wrote to Patient 6's GP to update him on the urology review and confirmed Patient 6's further management would be discussed at the urology multidisciplinary meeting (MDM) as soon as the histopathology report was available.

On 30 July 2019 Patient 6 had his ultrasound guided biopsy prostate carried out which confirmed that there was prostatic adenocarcinoma (Gleason 7) indicating an intermediate risk of progression (spread). (The Gleason sum is the most common system doctors use to indicate the aggressiveness of prostate cancer).

Patient 6 was discussed at the MDM on 8 August 2020. It was agreed that Patient 6 had an intermediate risk but apparently organ confined prostate cancer. Dr.1 was to review Patient 6 in outpatients and discuss management with curative intent or surveillance.

Patient 6 was advised by Dr.1 of the histological diagnosis at review on 3 September 2019. It was noted that Patient 6's PSA level had decreased to 8.41ng/ml, which Dr.1 deemed acceptable.

Dr.1 advised Patient 6 that it would be prudent to further assess his lower urinary tract symptoms with a flexible cystoscopy and urodynamic studies. It was agreed that this would take place on 27 September 2019.

Following the appointment on 27 September 2019, Dr.1 wrote to Patient 6's GP to advise it had proved inconvenient to proceed as Patient 6 was attending a funeral later that day. Dr.1 noted that Patient 6 had found bicalutamide entirely tolerable, with no associated toxicity, and that Patient 6 was of the impression that the [partial] androgen blockade may already have resulted in slight improvement in his urinary symptoms. At this time his serum PSA level had decreased further to 6.37ng/ml. Dr.1 asked the GP to prescribe modified release oxybutynin in the hope of some improvement in his lower urinary tract symptoms. Dr.1 asked for Patient 6's serum PSA level to be repeated during the first week of November 2019 so that the result would be available for the next outpatient review on 8 November 2019.

On 8 November 2019. Dr.1 noted that Patient 6's serum PSA level had decreased further to 4.51ng/ml. Patient 6 reported the development of some tenderness of his right breast. Dr.1 therefore requested that the GP additionally prescribe Tamoxifen 10mgs (once daily). As Patient 6 had also reported some digestive symptoms, Dr. 1 requested that Omeprazole (once daily) be prescribed. Patient 6 reported that his urinary symptoms had worsened significantly since previous review in September 2019 and in particular, he reported that he was having to awake 7 or 8 times each night to pass urine. Dr.1 recommended that Patient 6 should have the flexible cystoscopy and urodynamic studies performed, and Patient 6 agreed to return on 13 December 2019 to have both carried out.

When Patient 6 returned on 13 December 2019, he declined to have any invasive procedures performed. He reported that his nocturia had improved and he was only having to awaken 3 times each night. The serum PSA level was repeated and found not to have decreased (4.35ng/ml). Dr.1 advised the GP that it was evident that the

5.0 DESCRIPTION OF INCIDENT/CASE

[minimal] androgen blockade (bicalutamide, 50mgs daily) was inadequate and asked for the dose to be increased to 150mgs daily.

On 2 January 2020 Dr.1 spoke with Patient 6 by telephone and was noted to be well. Dr. 1 asked Patient 6 to make an appointment with the GP's Practice Nurse to have his serum PSA level repeated during the first week of March 2020 so that the result would be available at review later that month.

On 4 September 2020, Dr.3 (Locum Consultant Urologist) wrote to Patient 6 asking him to attend his GP to have his serum PSA rechecked.

On 2 October 2020, Patient 6 was reviewed by Dr.4 (Consultant Urologist) who noted that Patient 6 had discontinued Bicalutamide since his last prescription in February 2020. His most recent serum PSA was noted as 15ng/ml. Dr.4 re-discussed with Patient 6 his prostate cancer diagnosis and the available treatment options. Patient 6 did not recall any conversation about external beam radiotherapy (EBRT) as a radical treatment or discussion of surveillance as an option.

Dr.4 noted from the discussion Patient 6 would prefer no treatment at present and to go on to surveillance with a view to radiotherapy if his serum PSA increased or there was other evidence of progression. Dr.4 noted that Patient 6 planned a repeat serum PSA in December 2020.

At the appointment Dr.4 had a conversation with Patient 6 about his initial treatment and highlighted that the initial treatment with bicalutamide (50mg) is not recommended for the continuing treatment of prostate cancer.

6.0 FINDINGS

- The diagnostic pathway was rather prolonged.
- The MDM recommendation of 8 August 2019 – surveillance or radiotherapy with curative intent. This recommendation was not followed with neither option being offered. Bicalutamide was continued.
- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% 2020
- No further opinion regarding the management of his disease was offered to the patient, which should have happened as a matter of course either by a recorded discussion with an oncologist at the MDM, by an appointment at a Joint Oncology Clinic or by urgent direct referral.
- The treatment did not conform to the "NICAN Regional Hormone Therapy Guidelines for Prostate Cancer" 2016. This was signed off by Dr 1 as chair of

the NICAN Urology Cancer Clinical reference Group.

- The Review team note that following discussion with Patient 6 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 Patient 6 stopped the bicalutamide as they "didn't agree with his stomach".
- The patient and family were left unsupported.
- Patient 6 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 Patient 6 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 Patient 6 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.

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.

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

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.

Recommendation 4

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.

9.0 RECOMMENDATIONS AND ACTION PLANNING
Recommendation 5 The MDM must have an open supportive culture allowing members to raise clinical concerns. **Recommendation 6** 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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 6 October 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 6 was commenced on a low dose (sub therapeutic) dose of bicalutamide for prostate cancer. This was subsequently increased which is not a licensed option for reducing testosterone levels in the management of 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).

Comment [HG1]: Please delete this

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 (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Statements from Staff

Family Engagement

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

On 3 May 2019, Patient 6 's General Practitioner (GP) referred him to urology with a confirmed elevation of prostate specific antigen (PSA) of greater than 11ng/ml. The GP noted that Patient 6 got out of bed 5 times every night to pass urine with a poor flow. A digital rectal examination (DRE) had showed a mildly enlarged prostrate, but no suggestion of prostate cancer. The GP also noted that Patient 6 had a poor appetite and had 7 pounds weight loss over two months.

The GP reported that Patient 6 's past medical history include Personal Information redacted by the USI [redacted]

On 7 May 2019 Dr.1 (Consultant Urologist) requested an ultrasound scan of Patient 6 's urinary tract (8 May 2019), which was unremarkable save for a moderately (50g) enlarged prostrate; the bladder was empty after micturition.

Patient 6 was reviewed at the urology clinic on 28 May 2019 by Dr.2 (Locum Consultant Urologist). It was recorded that Patient 6 had had lower urinary tract symptoms for a long time and that his main symptom was that he awoke 4-5 times at night to pass urine. The elevated PSA and moderately enlarged prostate were noted. On this occasion the PSA density was calculated to be 0.225, indicating a significant risk of the presence of prostate cancer. This was supported by the digital rectal examination that suggested the possibility of a nodule in the left lateral lobe of his prostate. At that clinic, a urinary flow rate and a measurement of the residual urine carried out was consistent with bladder outlet obstruction due to an enlarged prostate. Dr.2 started Patient 6 on Tamsulosin (a prostate relaxant medicine) to ease the symptoms and organised an MRI of the prostate gland to further assess the risk of prostate cancer.

The MRI was carried out on 13 June 2019 and concluded that there was a probable tumour within the posterolateral peripheral zone of the left mid gland, but there was no pelvic lymphadenopathy or any suspicious bone lesion in the pelvis or lumbar spine.

On 19 July 2019 Patient 6 was seen by Dr.1 at the Urology Clinic when he reported hesitancy of micturition, a poor urinary flow and post-micturitional incontinence in addition to the severe nocturia. Dr.1 advised Patient 6 that it would be prudent to proceed with prostatic biopsies in view of the MRI findings. Patient 6 expressed some concern and anxiety regarding the risk of progression of any prostatic carcinoma whilst awaiting prostatic biopsies. Therefore, after repeating his serum PSA level and assessing his serum testosterone level Dr.1 requested that Patient 6 be prescribed Bicalutamide 50mg (once daily), until advised otherwise, whilst he awaited trans-rectal, ultrasound-guided prostatic biopsies which had been scheduled for 30 July 2019.

Doctor 1 wrote to Patient 6 's GP to update him on the urology review and confirmed Patient 6 's further management would be discussed at the urology multidisciplinary meeting (MDM) as soon as the histopathological report was available.

On 30 July 2019 Patient 6 had his ultrasound guided biopsy prostrate carried out which confirmed that there was prostatic adenocarcinoma (Gleason 7) indicating an intermediate risk of progression (spread). (The Gleason sum is the most common

5.0 DESCRIPTION OF INCIDENT/CASE

system doctors use to indicate the aggressiveness of prostate cancer.)

Patient 6 was discussed at the MDM on 8 August 2020. It was agreed that Patient 6 had an intermediate risk but apparently organ confined prostate cancer. Dr.1 was to review Patient 6 in outpatients and discuss management with curative intent or surveillance.

Patient 6 was advised by Dr.1 of the histological diagnosis at review on 3 September 2019. It was noted that Patient 6's PSA level had decreased to 8.41ng/ml, which Dr.1 deemed acceptable.

Dr.1 advised Patient 6 that it would be prudent to further assess of his lower urinary tract symptoms with a flexible cystoscopy and urodynamic studies. It was agreed that this would take place on 27 September 2019.

Following the appointment on 27 September 2019, DR.1 wrote to Patient 6's GP to advise it had proved inconvenient to proceed as Patient 6 was attending a funeral later that day. Dr.1 noted that Patient 6 had found bicalutamide entirely tolerable, with no associated toxicity, and that Patient 6 was of the impression that the [partial] androgen blockade may already have resulted in slight improvement in his urinary symptoms. At this time his serum PSA level had decreased further to 6.37ng/ml. Dr.1 asked the GP to prescribe modified release oxybutynin in the hope of some improvement in his lower urinary tract symptoms. Dr.1 asked for Patient 6's serum PSA level to be repeated during the first week of November 2019 so that the result would be available for the next outpatient review on 8 November 2019.

On 8 November 2019. Dr.1 noted that Patient 6's serum PSA level had decreased further to 4.51ng/ml. Patient 6 reported the development of some tenderness of his right breast. Dr.1 therefore requested that the GP additionally prescribe Tamoxifen 10mgs (once daily). As Patient 6 had also reported some digestive symptoms, Doctor 1 requested that Omeprazole (once daily) be prescribed. Patient 6 also reported that his urinary symptoms had worsened significantly since previous review in September 2019 and in particular, he reported that he was having to awake 7 or 8 times each night to pass urine. Dr.1 recommended that Patient 6 should have the flexible cystoscopy and urodynamic studies performed, and Patient 6 agreed to return on 13 December 2019 to have both carried out.

When Patient 6 returned on 13 December 2019, he declined to have any invasive procedures performed. He reported that his nocturia had improved and he was only having to awaken 3 times each night. The serum PSA level was repeated and found not to have decreased (4.35ng/ml). Dr.1 advised the GP that it was evident that the [minimal] androgen blockade (bicalutamide, 50mgs daily) was inadequate and asked for the dose to be increased to 150mgs daily.

On 2 January 2020 Dr.1 spoke with Patient 6 by telephone and was noted to be well. Doctor 1 asked Patient 6 to make an appointment with the GP Nurse to have his serum PSA level repeated during the first week of March 2020 so that the result would be available at review later that month.

On 4 September 2020, Dr.3 (Locum Consultant Urologist) wrote to Patient 6 asking him

5.0 DESCRIPTION OF INCIDENT/CASE

to attend his GP to have his serum PSA rechecked.

On 2 October 2020, Patient 6 was reviewed by Dr.4 (Consultant Urologist) who noted that Patient 6 had discontinued Bicalutamide since his last prescription in February 2020. His most recent serum PSA was noted as 15ng/ml. Dr.4 re-discussed with Patient 6 his prostate cancer diagnosis and the available treatment options. Patient 6 did not recall any conversation about external beam radiotherapy (EBRT) as a radical treatment or discussion of surveillance as an option.

Comment [HG2]: here

Dr.4 noted from the discussion Patient 6 would prefer no treatment at present and to go on to surveillance with a view to radiotherapy if his serum PSA increased or there was other evidence of progression. Dr.4 noted that Patient 6 planned a repeat serum PSA in December 2020.

At the appointment Dr.4 had a conversation with Patient 6 about his initial treatment and highlighted that the initial treatment with bicalutamide (50mg) is not recommended for the continuing treatment of prostate cancer.

6.0 FINDINGS

- The diagnostic pathway was rather prolonged.
- The MDM recommendation of 8 August 2019 – surveillance or radiotherapy with curative intent – was not offered to the patient.
- No further opinion regarding the management of his disease was offered to the patient, which should have happened as a matter of course either by a recorded discussion with an oncologist at the MDM, by an appointment at a Joint Oncology Clinic or by urgent direct referral.
- The review team have established that the hormone (bicalutamide 50mgs) prescribed was did not conform to the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guideline (2016). This guidance was signed off by Southern Health and Social Care Trust (SHSCT) Urology MDM as their standard for Cancer Peer review 2017.
- This guidance was issued when Dr.1 was the Chair of the Northern Ireland Regional Urology Cancer Group and should have full knowledge of its detail.

Contributory factors

6.0 FINDINGS

- Patient 6 did not have access to a Urology Cancer Nurse Specialist (CNS).
- The review team have established that a CNS was available but there is no record of Patient 6 being allowed access to this support service.
- Dr.1 practiced without input of urology CNS providing a different level of care compared to the other consultant urologists in the MDM.
- 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 lacks pathway quality assurance audits.
- There is a reluctance to escalate issues.
- The MDM lacks leadership with a rotating Chair of SHSCT allowing a lack of clarity in responsibilities.

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 (a LHRH analogue) as neo-adjuvant treatment at the same time as referring on for an opinion from a clinical oncologist.

Contributory factors

- Patient 6 did not have access to a urology Cancer Nurse Specialist (CNS).
- The review team have established that a CNS was available but there is no record of Patient 6 being allowed access to this support service.
- Dr.1 practiced without input of urology CNSs providing a different level of care compared to the other consultant urologists in the MDM.
- 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 lacks pathway quality assurance audits.
- There is a reluctance to escalate issues.
- The MDM lacks leadership with a rotating Chair of SHSCT allowing a lack of clarity in responsibilities.

7.0 CONCLUSIONS

The review team note that following discussion with Patient 6, 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 (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment.
In this case Patient 6 stopped the bicalutamide as they "didn't agree with his stomach".
The Patient and family were left unsupported.

8.0 LESSONS LEARNED

The MDM should be quorate.

The MDM should be chaired by a named clinician with responsibility for ensuring adequate discussion of every patient.

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

Consideration should be given to ensuring that all patients and their GP's receive a plain-English copy of the MDM discussion.

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.

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.

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.

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER							
1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved**						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)***				
3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 6 October 2020

HSCB Unique Case Identifier: Personal Information redacted by the USI

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

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 6 was commenced on a low dose (sub therapeutic) dose of bicalutamide for prostate cancer. This was subsequently increased which is not a licensed option for reducing testosterone levels in the management of 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 (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of Northern Ireland Electronic Care Record

MDT pathway for Cancer Management and appropriate guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 3 May 2019, Patient 6 's General Practitioner (GP) referred him to urology with a confirmed elevation of prostate specific antigen (PSA) of greater than 11ng/ml. The GP noted that Patient 6 got out of bed 5 times every night to pass urine with a poor flow. A digital rectal examination (DRE) had showed a mildly enlarged prostrate, but no suggestion of prostate cancer. The GP also noted that Patient 6 had a poor appetite and had 7 pounds weight loss over two months.

The GP reported that Patient 6 's past medical history included Personal Information redacted by the USI

On 7 May 2019 Dr.1 (Consultant Urologist) requested an ultrasound scan of Patient 6 's urinary tract (8 May 2019), which was unremarkable save for a moderately (50g) enlarged prostrate; the bladder was empty after micturition.

Patient 6 was reviewed at the urology clinic on 28 May 2019 by Dr.2 (Locum Consultant Urologist). It was recorded that Patient 6 had had lower urinary tract symptoms for a long time and that his main symptom was that he awoke 4-5 times at night to pass urine. The elevated PSA and moderately enlarged prostate were noted. On this occasion the PSA density was calculated to be 0.225, indicating a significant risk of the presence of prostate cancer. This was supported by the digital rectal examination that suggested the possibility of a nodule in the left lateral lobe of his prostate. At that clinic, a urinary flow rate and a measurement of the residual urine carried out was consistent with bladder outlet obstruction due to an enlarged prostate. Dr.2 started Patient 6 on Tamsulosin (a prostate relaxant medicine) to ease the symptoms and organised an MRI of the prostate gland to further assess the risk of prostate cancer.

The MRI was carried out on 13 June 2019 and concluded that there was a probable tumour within the posterolateral peripheral zone of the left mid gland, but there was no pelvic lymphadenopathy or any suspicious bone lesion in the pelvis or lumbar spine.

On 19 July 2019 Patient 6 was seen by Dr.1 at the Urology Clinic when he reported hesitancy of micturition, a poor urinary flow and post-micturitional incontinence in addition to the severe nocturia. Dr.1 advised Patient 6 that it would be prudent to proceed with prostatic biopsies in view of the MRI findings. Patient 6 expressed some concern and anxiety regarding the risk of progression of any prostatic carcinoma whilst awaiting prostatic biopsies. Therefore, after repeating his serum PSA level and assessing his serum testosterone level Dr.1 requested that Patient 6 be prescribed Bicalutamide 50mg (once daily), until advised otherwise, whilst he awaited trans-rectal, ultrasound-guided prostatic biopsies which had been scheduled for 30 July 2019.

Doctor 1 wrote to Patient 6 's GP to update him on the urology review and confirmed Patient 6 's further management would be discussed at the urology multidisciplinary meeting (MDM) as soon as the histopathological report was available.

On 30 July 2019 Patient 6 had his ultrasound guided biopsy prostrate carried out which confirmed that there was prostatic adenocarcinoma (Gleason 7) indicating an intermediate risk of progression (spread). (The Gleason sum is the most common

5.0 DESCRIPTION OF INCIDENT/CASE

system doctors use to indicate the aggressiveness of prostate cancer.)

Patient 6 was discussed at the MDM on 8 August 2019. It was agreed that Patient 6 had an intermediate risk but apparently organ confined prostate cancer. Dr.1 was to review Patient 6 in outpatients and discuss management with curative intent or surveillance.

Patient 6 was advised by Dr.1 of the histological diagnosis at review on 3 September 2019. It was noted that Patient 6's PSA level had decreased to 8.41ng/ml, which Dr.1 deemed acceptable.

Dr.1 advised Patient 6 that it would be prudent to further assess of his lower urinary tract symptoms with a flexible cystoscopy and urodynamic studies. It was agreed that this would take place on 27 September 2019.

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When Patient 6 returned on 13 December 2019, he declined to have any invasive procedures performed. He reported that his nocturia had improved and he was only having to awaken 3 times each night. The serum PSA level was repeated and found not to have decreased (4.35ng/ml). Dr.1 advised the GP that it was evident that the [minimal] androgen blockade (bicalutamide, 50mgs daily) was inadequate and asked for the dose to be increased to 150mgs daily.

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5.0 DESCRIPTION OF INCIDENT/CASE

to attend his GP to have his serum PSA rechecked.

On 2 October 2020, Patient 6 was reviewed by Dr.4 (Consultant Urologist) who noted that Patient 6 had discontinued Bicalutamide since his last prescription in February 2020. His most recent serum PSA was noted as 15ng/ml. Dr.4 re-discussed with Patient 6 his prostate cancer diagnosis and the available treatment options. Patient 6 did not recall any conversation about external beam radiotherapy (EBRT) as a radical treatment or discussion of surveillance as an option.

Dr.4 noted from the discussion Patient 6 would prefer no treatment at present and to go on to surveillance with a view to radiotherapy if his serum PSA increased or there was other evidence of progression. Dr.4 noted that Patient 6 planned a repeat serum PSA in December 2020.

At the appointment Dr.4 had a conversation with Patient 6 about his initial treatment and highlighted that the initial treatment with bicalutamide (50mg) is not recommended for the continuing treatment of prostate cancer.

6.0 FINDINGS

- The diagnostic pathway was rather prolonged.
- The MDM recommendation of 8 August 2019 – surveillance or radiotherapy with curative intent – was not offered to the patient. Neither offered and bicalutamide continued.
- No further opinion regarding the management of his disease was offered to the patient, which should have happened as a matter of course either by a recorded discussion with an oncologist at the MDM, by an appointment at a Joint Oncology Clinic or by urgent direct referral.
- The review team have established that the hormone (bicalutamide 50mgs) prescribed was did not conform to the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guideline (2016). This guidance was signed off by Southern Health and Social Care Trust (SHSCT) Urology MDM as their standard for Cancer Peer review 2017.
- This guidance was issued when Dr.1 was the Chair of the Northern Ireland Regional Urology Cancer Group and should have full knowledge of its detail.

<u>Contributory factors</u>

6.0 FINDINGS

- Patient 6 did not have access to a Urology Cancer Nurse Specialist (CNS).
- The review team have established that a CNS was available but there is no record of Patient 6 being allowed access to this support service.
- Dr.1 practiced without input of urology CNS providing a different level of care compared to the other consultant urologists in the MDM.
- 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 lacks pathway quality assurance audits.
- There is a reluctance to escalate issues.
- The MDM lacks leadership with a rotating Chair of SHSCT allowing a lack of clarity in responsibilities.

For clarification

1. **Why did AO consider bicalutamide (50 mg) a reasonable alternative to the options agreed by the MDM?**

2. **Has the MDM conducted any audits of its cancer pathways?**

Hugh's comments

A standard pathway for this man was followed up to and including the first MDM discussion was appropriate. 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 (a LHRH analogue) as neo-adjuvant treatment at the same time as referring on for an opinion from a clinical oncologist.

- The diagnostic pathway was rather prolonged.
- The MDM recommendation of 8 August 2019 – surveillance or radiotherapy with curative intent – was not offered to the patient. Neither offered and bicalutamide continued.
- No further opinion regarding the management of his disease was offered to the patient, which should have happened as a matter of course either by a recorded discussion with an oncologist at the MDM, by an appointment at a Joint Oncology Clinic or by urgent direct referral.
- The review team have established that the hormonal prescribed was did not conform to the Northern Ireland Cancer Network (Urology Cancer Guidance) (March 2016). This guidance was signed off by Southern Health and Social Care Trust (SHSCT)

Urology MDM as their standard of care for Cancer Peer review 2017.

- The review team note that following discussion with Patient 6, 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 (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment.
- In this case Patient 6 stopped the bicalutamide as they "didn't agree with his stomach".
- The Patient and family were left unsupported.

Contributory factors

- Patient 6 did not have access to a urology Cancer Nurse Specialist (CNS).
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- There was no oncology referral.
- The MDM lacks pathway quality assurance audits.
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- The MDM lacks leadership with a rotating Chair of SHSCT allowing a lack of clarity in responsibilities.

For clarification

3. Why did AO consider bicalutamide (50 mg) a reasonable alternative to the options agreed by the MDM?

Has the MDM conducted any audits of its cancer pathways?

7.0 CONCLUSIONS

The review team note that following discussion with Patient 6, 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 (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment.
In this case Patient 6 stopped the bicalutamide as they "didn't agree with his stomach".
The Patient and family were left unsupported.

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*				
	f)	Withdrew fully from the SAI process		
	g)	Participated in SAI process but declined review report		
	(if you select any of the options below please also complete 'l' below)			
	h)	concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer		
	i)	case involved suspected or actual abuse by family		
	j)	identified as a result of review exercise		
	k)	other rationale		
	l)	If you have selected **c), h), i), j), or k)** above please provide further details:		
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: [redacted]

Date of Incident/Event: 20 August 2019

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M
Age: [redacted]

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

[redacted]

1.0 EXXXUTIVE SUMMARY

Patient 4 an Personal Information redacted by the USI old gentleman who presented to the Emergency Department (ED) in Craigavon Area Hospital (CAH) on 24 December 2018 complaining of urinary symptoms and pain passing urine. He was referred to the urology services and was subsequently diagnosed with prostate cancer. His treatment and care provided was at variance with regional Northern Ireland Cancer Network Guidance.

Patient 4 passed away on Personal Information redacted by the USI. The Review Team wish to extend their sincere condolences to his widow and family.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director of the Northern Ireland Cancer Network (NICAN). Former Medical Director Western Health and Social Care Trust.
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 Urology (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 report with the Director of Acute Services/ Medical Director of the SHSCT/ HSCB/ Family of Patient 4 / Staff involved in his care

Personal Information

Review of Medical Notes

Interviews with Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 4, an Personal Information redacted by the USI old gentleman with a past medical history of Personal Information redacted by the USI attended the Emergency Department (ED) at Craigavon Area Hospital (CAH) on 24 December 2018 complaining of urinary symptoms and pain passing urine. Urinary retention was diagnosed and treated with the insertion of a urinary catheter. His kidney function was normal and a plan was made to return to urology outpatients after two weeks for a trial removal of catheter (TROC). An appointment was given and Patient 4 was discharged home.

On 18 January 2019 Patient 4 attended urology outpatient for the TROC. He was reviewed by Specialist Nurse 1. His urine sample, sent for microscopy on 24 January 2019, was noted to be clear. His PSA test was noted to be 2.79 ng/L. A post void bladder scan showed a residual of 300mls urine. Following discussion with Dr.1 a plan was made to add Patient 4 to the urgent waiting list for transurethral resection of prostate (TURP). He was re-catheterised and referred to the district nursing continence service for supplies.

28 March 2019 Patient 4 attended for preoperative assessment and was noted to be mildly deficient in iron, folate and vitamin B12. He was prescribed oral iron therapy.

Patient 4 attended his GP on 3 June 2019 complaining of frank haematuria (blood in urine). A red flag referral was made to urology.

On 19 June 2019 Patient 4 underwent a TURP. The procedure notes describe the prostate tissue as having “endoscopic appearances of prostatic carcinoma”. Histology confirmed adenocarcinoma (Gleason score 5+5) in 90% of the resected tissue. He continued to be deficient in Vitamin B_{12} and Folic Acid, which was treated on the first postoperative day and he continued an oral iron preparation. Patient 4 was able to pass urine satisfactorily following catheter removal, and was fit for discharge on the 24 June 2019.

Patient 4’s case was discussed at the multidisciplinary meeting (MDM) on 25 July 2019 who

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noted there was no evidence of metastases on a CT abdomen and pelvis but recommended a CT scan of chest and a bone scan. The recommended treatment was to commence an LHRH analogue.

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Dr. 1 prescribed Bicalutamide (50mgs once daily), in order to 'assess its tolerability in a generally frail man' and in the 'light of the low presenting PSA'

A letter to his GP dictated on 5 October 2019 described the clinic attendance on 20 August 2019 and a subsequent telephone conversation between Patient 4 and Dr.1, which identified some persistent bladder problems. Patient 4 had commenced self-catheterisation. In view of this, Dr.1 advised Patient 4 to attend the outpatient's department for a flexible cystoscopy and urodynamics studies.

On 23 October 2019 an USS showed a right hydronephrosis and 263ml residual bladder volume. There was echogenic debris in bladder.

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On 27 November 2019 Patient 4 attended for a CT scan of his chest. This showed a small left pleural effusion. Patient 4 was also noted to have some features of pulmonary fibrosis. There was no evidence of metastatic disease.

A planned review was arranged for December 2019 to assess Patient 4's lower urinary tract symptomatic status and to arrange a spinal MRI.

On 13 December 2019 Patient 4 was reviewed by Dr.1 who noted a PSA level of 0.86ng/L. Patient 4 was noted to be doing well and continued self-catheterisation twice daily with small volumes (approximately 80mls) of residual urine.

On 23 January 2020 Patient 4 attended the Emergency Department in CAH with acute urinary retention, frank haematuria (blood in urine) and impaired renal function. He was admitted to the ward under the care of Dr.2 (Consultant Urologist). He required bladder irrigation an ultrasound scan showed bilateral hydronephrosis. His kidney function was monitored and a plan to have ureteric stents in theatre was planned.

Dr.2 advised that Patient 4 had the clinical features consistent with a locally advanced prostate cancer and invasion of the trigone of the bladder and consequently had developed bilateral ureteric obstruction. This had caused significant renal impairment and required tumour resection and insertion of bilateral ureteric stents. On 29 January

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Dr.1 received a telephone call from Patient 4's wife advising that Patient 4 had deteriorated since the nephrostomy tube was capped and was unable to self-catheterise because of pain. He was admitted to the inpatient ward in CAH for the right nephrostomy to be uncapped. A plan was made for the GP to continue to prescribe Degarelix (80mg) and to start Dexamethasone 500mg twice daily. Dr.1 requested the Palliative Care Nurse to arrange an assessment of Patient 4's holistic needs. A plan was made to admit Patient 4 if clinically appropriate to have replacement of the permanent indwelling nephrostomy drain in May 2020.

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Patient 4 returned on 14 May 2020 as nephrostomy drain was blocked and it was successfully exchanged. After a blood transfusion and adjustments to his insulin administration, Patient 4 was discharged home on 17 May 2020.

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Personal Information

6.0 FINDINGS

- The review team could not locate any record regarding digital rectal examination being performed in the medical notes at any point during Patient 4's medical treatment. This would have provided evidence to support the malignant nature of the prostate gland prompting biopsy. The low PSA was falsely reassuring and should not have been relied upon. Whether or not this would have led to the appropriate management is not certain at this stage.

- Patient 4 was discussed at MDM on 27 July 2019 where the recommendation for androgen deprivation therapy (LHRH analogue) was made. Patient 4 should have been started on this hormonal therapy to achieve castrate testosterone levels as soon as the diagnosis of poorly differentiated prostate cancer was made.

- The MDM should have recommended urgent referral to an Oncologist, irrespective of any staging results.

- Hormone therapies (ADT) and radiotherapy might have been used in controlling Patient 4's disease, but these were all denied to him.

- Instead he was started on an inadequate dose of a drug (bicalutamide) which is not licensed for the treatment of prostate cancer.

- This therapy was not in adherence with the Northern Ireland Cancer Network (NICAN) guidance (2016) which was signed off by the Southern health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their standard protocols for Cancer Peer Review (2017).

- The treatment did not conform to the "NICAN Regional Hormone Therapy Guidelines for Prostate Cancer 2016". This was signed off by Dr.1 as of the NICAN Urology Cancer Clinical Reference Group.

- There was no evidence in the medical notes or from speaking with Patient 4' family of informed consent to this alternative care pathway.

- The pursuit of staging scans was too protracted. The MDM recommended a bone scan and a CT chest in late July, but these were not completed until the November. Similarly a MRI spine was recommended by a Radiologist; advice which was not acted upon.

- In late January 2020, Patient 4 presented as an emergency with clearly progressing disease, but his case was not referred to the MDM and the opportunity to alter his treatment was not taken.

<u>Multidisciplinary Team Meetings</u>

- The review team note that oncology presence and MDM was poor (approx. 11% in this timeframe). This was due to lack of resource at the SHSCT and a heavy clinic oncology workload covering lung and urology cancer on the same day. This however, did not prevent referral of patients to a clinical appointment.

Personal Information

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 Patient 4 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 Patient 4'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, Patient 4's care was not coordinated with the palliative care team.
- Patient 4 presented as an emergency admission requiring urgent surgery- despite the aggressive nature of his cancer and evidence of clinical progression, Patient 4'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>

- Patient 4 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

Patient 4 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.

Personal Information

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.

Personal Information

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 3

The multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to any discussion.

Recommendation 4

A joint oncology clinic appointment should be available and offered to all patients with a new cancer diagnosis. This should include the opportunity to reflect with an independent Key Worker.

Recommendation 5

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

Recommendation 6

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

Personal Information

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SXXTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**: **26 October 2020**						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						

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

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			x
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this sXXtion where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*				
	f)	Withdrew fully from the SAI process		
	g)	Participated in SAI process but declined review report		
	(if you select any of the options below please also complete 'l' below)			
	h)	concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer		
	i)	case involved suspected or actual abuse by family		
	j)	identified as a result of review exercise		
	k)	other rationale		
	l)	If you have selected **c), h), i), j), or k)** above please provide further details:		
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SXXTION 2

INFORMING THE CORONER'S OFFICE (under sXXtion 7 of the Coroners Act (Northern Ireland) 1959) *(complete this sXXtion for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

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Southern Health and Social Care Trust

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- The treatment did not conform to the "NICAN Regional Hormone Therapy Guidelines for Prostate Cancer 2016". This was signed off by Dr.1 as of the NICAN Urology Cancer Clinical Reference Group.

- There was no evidence in the medical notes or from speaking with Patient 4' family of informed consent to this alternative care pathway.

- The pursuit of staging scans was too protracted. The MDM recommended a bone scan and a CT chest in late July, but these were not completed until the November. Similarly a MRI spine was recommended by a Radiologist; advice which was not acted upon.

- In late January 2020, Patient 4 presented as an emergency with clearly progressing disease, but his case was not referred to the MDM and the opportunity to alter his treatment was not taken.

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6.0 FINDINGS

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 Patient 4 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.

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- Patient 4 presented as an emergency admission requiring urgent surgery- despite the aggressive nature of his cancer and evidence of clinical progression, Patient 4's case was not brought back to the MDM for consideration of Specialist Nurse input, oncology input or palliative care input.

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- Patient 4 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

Patient 4 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.
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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.

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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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SXXTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert **date informed**: **26 October 2020**						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			x
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this sXXtion where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
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	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SXXTION 2

INFORMING THE CORONER'S OFFICE (under sXXtion 7 of the Coroners Act (Northern Ireland) 1959) *(complete this sXXtion for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

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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: [redacted]

Date of Incident/Event: 20 August 2019

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M
Age: [redacted]

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

[redacted]

1.0 EXXXUTIVE SUMMARY

Patient 4 an Personal Information redacted by the USI old gentleman who presented to the Emergency Department (ED) in Craigavon Area Hospital (CAH) on 24 December 2018 complaining of urinary symptoms and pain passing urine. He was referred to the urology services and was subsequently diagnosed with prostate cancer. His treatment and care provided was at variance with regional Northern Ireland Cancer Network Guidance.

Patient 4 passed away on Personal Information redacted by the USI. The Review Team wish to extend their sincere condolences to his widow and family.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair: Former Medical Director of the Northern Ireland Cancer Network (NICAN). Former Medical Director Western Health and Social Care Trust.
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 Urology (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 report with the Director of Acute Services/ Medical Director of the SHSCT/ HSCB/ Family of Patient 4 / Staff involved in his care

Personal Information

Review of Medical Notes

Interviews with Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 4, an Personal Information redacted by the USI old gentleman with a past medical history of Personal Information redacted by the USI, attended the Emergency Department (ED) at Craigavon Area Hospital (CAH) on 24 December 2018 complaining of urinary symptoms and pain passing urine. Urinary retention was diagnosed and treated with the insertion of a urinary catheter. His kidney function was normal and a plan was made to return to urology outpatients after two weeks for a trial removal of catheter (TROC). An appointment was given and Patient 4 was discharged home.

On 18 January 2019 Patient 4 attended urology outpatient for the TROC. He was reviewed by Specialist Nurse 1. His urine sample, sent for microscopy on 24 January 2019, was noted to be clear. His PSA test was noted to be 2.79 ng/L. A post void bladder scan showed a residual of 300mls urine. Following discussion with Dr.1 a plan was made to add Patient 4 to the urgent waiting list for transurethral resection of prostate (TURP). He was re-catheterised and referred to the district nursing continence service for supplies.

28 March 2019 Patient 4 attended for preoperative assessment and was noted to be mildly deficient in iron, folate and vitamin B12. He was prescribed oral iron therapy.

Patient 4 attended his GP on 3 June 2019 complaining of frank haematuria (blood in urine). A red flag referral was made to urology.

On 19 June 2019 Patient 4 underwent a TURP. The procedure notes describe the prostate tissue as having “endoscopic appearances of prostatic carcinoma”. Histology confirmed adenocarcinoma (Gleason score 5+5) in 90% of the resected tissue. He continued to be deficient in Vitamin B_{12} and Folic Acid, which was treated on the first postoperative day and he continued an oral iron preparation. Patient 4 was able to pass urine satisfactorily following catheter removal, and was fit for discharge on the 24 June 2019.

Patient 4’s case was discussed at the multidisciplinary meeting (MDM) on 25 July 2019 who

Personal Information

5.0 DESCRIPTION OF INCIDENT/CASE

noted there was no evidence of metastases on a CT abdomen and pelvis but recommended a CT scan of chest and a bone scan. The recommended treatment was to commence an LHRH analogue.

On 20 August 2019, Patient 4 was reviewed by Dr.1 in the urology clinic. The bone scan and CT scan were requested to check for spread outside the prostate. An ultrasound scan of the urinary tract was also requested to assess bladder emptying.

Dr. 1 prescribed Bicalutamide (50mgs once daily), in order to 'assess its tolerability in a generally frail man' and in the 'light of the low presenting PSA'

A letter to his GP dictated on 5 October 2019 described the clinic attendance on 20 August 2019 and a subsequent telephone conversation between Patient 4 and Dr.1, which identified some persistent bladder problems. Patient 4 had commenced self-catheterisation. In view of this, Dr.1 advised Patient 4 to attend the outpatient's department for a flexible cystoscopy and urodynamics studies.

On 23 October 2019 an USS showed a right hydronephrosis and 263ml residual bladder volume. There was echogenic debris in bladder.

On 1 November 2019 Patient 4 attended for a flexible cystoscopy. Consequently Dr.1 recommended an increase in self-catheterisation to twice daily.

The bone scan carried out on 15 November 2019 showed some increased uptake of radioisotope at the superior aspect of the 11th thoracic vertebrae as well as an area of osteopenia in the posterior cervical spine. Both appearances were not thought to be in keeping with metastatic disease; however a spinal MRI was suggested by the Radiologist.

On 27 November 2019 Patient 4 attended for a CT scan of his chest. This showed a small left pleural effusion. Patient 4 was also noted to have some features of pulmonary fibrosis. There was no evidence of metastatic disease.

A planned review was arranged for December 2019 to assess Patient 4's lower urinary tract symptomatic status and to arrange a spinal MRI.

On 13 December 2019 Patient 4 was reviewed by Dr.1 who noted a PSA level of 0.86ng/L. Patient 4 was noted to be doing well and continued self-catheterisation twice daily with small volumes (approximately 80mls) of residual urine.

On 23 January 2020 Patient 4 attended the Emergency Department in CAH with acute urinary retention, frank haematuria (blood in urine) and impaired renal function. He was admitted to the ward under the care of Dr.2 (Consultant Urologist). He required bladder irrigation an ultrasound scan showed bilateral hydronephrosis. His kidney function was monitored and a plan to have ureteric stents in theatre was planned.

Dr.2 advised that Patient 4 had the clinical features consistent with a locally advanced prostate cancer and invasion of the trigone of the bladder and consequently had developed bilateral ureteric obstruction. This had caused significant renal impairment and required tumour resection and insertion of bilateral ureteric stents. On 29 January

Personal Information

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2020, Patient 4 went to theatre for a re-do TURP and the insertion of ureteric stents. The left stent was inserted, but Dr 2 was not able to locate the right ureter due to the tumour, and noted that Patient 4 may require a right nephrostomy tube if the kidney function did not improve or if there were signs of sepsis. Patient 4 remained under observation in hospital and required the insertion of a right nephrostomy tube on 6 February 2020. His renal function tests then improved, and the nephrostomy tube was noted to be working well. Having received an initial dose of Degarelix (240mg) on 28 January 2020, he was discharged on 11 February 2020 and was referred to the district nursing services.

On 27 February 2020, Patient 4, accompanied by his wife and two children, was reviewed by Dr.1 at an outpatient clinic. Patient 4s family expressed concern about his general decline, weight loss and lack of appetite. As planned Dr.1 capped the nephrostomy drain and administered the first maintenance dose of 80mgs of Degarelix. Dr 1 reviewed Patient 4's blood results and advised his GP that the cancer was progressing and had resulted in ureteric obstruction.

Dr.1 received a telephone call from Patient 4's wife advising that Patient 4 had deteriorated since the nephrostomy tube was capped and was unable to self-catheterise because of pain. He was admitted to the inpatient ward in CAH for the right nephrostomy to be uncapped. A plan was made for the GP to continue to prescribe Degarelix (80mg) and to start Dexamethasone 500mg twice daily. Dr.1 requested the Palliative Care Nurse to arrange an assessment of Patient 4's holistic needs. A plan was made to admit Patient 4 if clinically appropriate to have replacement of the permanent indwelling nephrostomy drain in May 2020.

On 2 March 2020 Patient 4 was admitted via ED to the urology ward with urosepsis. He was treated with intravenous antibiotics. He remained on the ward until his discharge on 19 March 2020. A plan was made to return for removal of stents in 2 weeks and for exchange of the nephrostomy drain in 3 months.

On 7 May 2020 Patient 4 attended for removal of the stents, but this was not performed as a Covid-19 swab had not been taken in time.

Patient 4 returned on 14 May 2020 as nephrostomy drain was blocked and it was successfully exchanged. After a blood transfusion and adjustments to his insulin administration, Patient 4 was discharged home on 17 May 2020.

On Personal Information redacted by the USI Patient 4 died peaceful at home surrounded by his family.

Personal Information

6.0 FINDINGS

- The review team could not locate any record regarding digital rectal examination being performed in the medical notes at any point during Patient 4's medical treatment. This would have provided evidence to support the malignant nature of the prostate gland prompting biopsy. The low PSA was falsely reassuring and should not have been relied upon. Whether or not this would have led to the appropriate management is not certain at this stage.

- Patient 4 was discussed at MDM on 27 July 2019 where the recommendation for androgen deprivation therapy (LHRH analogue) was made. Patient 4 should have been started on this hormonal therapy to achieve castrate testosterone levels as soon as the diagnosis of poorly differentiated prostate cancer was made.

- The MDM should have recommended urgent referral to an Oncologist, irrespective of any staging results.

- Hormone therapies (ADT) and radiotherapy might have been used in controlling Patient 4's disease, but these were all denied to him.

- Instead he was started on an inadequate dose of a drug (bicalutamide) which is not licensed for the treatment of prostate cancer.

- This therapy was not in adherence with the Northern Ireland Cancer Network (NICAN) guidance (2016) which was signed off by the Southern health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their standard protocols for Cancer Peer Review (2017).

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

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Continued overleaf	**e)** No response to correspondence			

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SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this sXXtion where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
	f) Withdrew fully from the SAI process	
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	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: [redacted]

Date of Incident/Event: 03/09/2020

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted]

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

[redacted]

1.0 EXECUTIVE SUMMARY

Patient 7 had a small renal mass since 2016 which was under surveillance by Urology. At an outpatient's review clinic on 29 March 2019 Patient 7 was advised that his renal mass was stable and he was for surveillance. This is despite the urology multi-disciplinary team meeting outcome of the previous day advising that Patient 7 should have the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risk discussed.

On 13 November 2019 Patient 7 had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a subsequent delay in the follow up process for cancer care management.

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

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/ Patient/ Staff involved.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of Northern Ireland Electronic Care Record

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 28 June 2016, Patient 7 was urgently referred as a 'red flag 'to the urology services at Craigavon Area Hospital (CAH), because an abdominal ultrasound scan, requested to investigate raised liver enzymes, had shown a renal lesion. A subsequent CT scan (16 June 2016) confirmed a mildly enhancing renal lesion. The CT scan also showed mesenteric lymphadenopathy suspicious of lymphoma and a simultaneous 'red flag' referral was made to haematology.

On 19 July 2016, Patient 7 was seen by Dr.1 (Consultant Urologist) at an outpatient clinic at which the CT images were explained and discussed. Dr.1 advised of the presence of a solid lesion, measuring 2.5cms in diameter, which was partly protruding out of the anteromedial cortex of the lower pole of the left kidney's outer surface. The lesion was described as mildly enhancing and being rather homogeneous in appearance. Dr.1 explained that the lesion could very well be a papillary renal cell carcinoma and advised that its location did not allow biopsy without significant risk.

Patient 7 was discussed at the urology multidisciplinary meeting (MDM) on 28 July 2016. The MDM recommended active surveillance and that Dr.1 should review Patient 7 in a further 4 months with the results of a CT scan to assess both the mesenteric nodes and the renal mass.

On 12 August 2016, Patient 7 was reviewed by Dr.1 at an outpatient clinic and found him to remain "entirely well" and that he was happy with the plan, and to have the left renal lesion and the mesenteric lymphadenopathy reassessed by CT scan in November 2016. Dr.1 also advised an outpatient appointment for December 2016 to review the CT images and report. Patient 7 was also to be followed up by the haematology team.

Patient 7 had a repeat CT scan on 7 December 2016 and on 6 January 2017 was reviewed in outpatients by Dr.2 (Locum Consultant Urologist) who noted that the CT scan had shown a slight increase in the size of the kidney mass, but the mesenteric lymph nodes were unchanged. Of note, there was no new retroperitoneal or pelvic lymph node enlargement, nor any bony lesions. Dr.2 noted that Patient 7 had been doing well since his last outpatient review and had no lower urinary tract symptoms or haematuria. Dr.2's planned to re-discuss Patient 7 at the urology MDM in January, but

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5.0 DESCRIPTION OF INCIDENT/CASE

provisionally requested a repeat CT scan and outpatient review in a further 4 months.

On 19 January 2017, Patient 7's case was discussed at the MDM, which noted that the first repeat CT scan showed minimal changes to the renal mass. There were no changes in the mesenteric appearances, which were now felt to be not significant. A follow up MRI scan of the kidney was recommended.

A second repeat CT was carried out on 23 March 2017.

On 11 April 2017, Dr.2 (Locum Consultant Urologist) wrote to Patient 7's GP to advise on the findings on the latest CT scan. Some mild bilateral apical pleural thickening and a 4mm right basal pulmonary nodule, which had been described on the previous CT had now resolved. All else was reportedly normal and Dr.2 noted that Patient 7 awaited an MRI of his kidney which had been booked for 8 May 2017.

The MRI of the kidney was said to show no change in size of the left kidney mass when compared with the CT of December 2016. It was noted that the MRI radiologist's report described the lesion as non-specific and may have represented a papillary renal cell carcinoma. As Patient 7 remained on active surveillance, Dr.2 listed the case for discussion at MDM to agree which modality (CT/MRI) and what intervals for further reimaging were appropriate in this case.

On 25 May 2017, Patient 7's case was presented to the MDM by Dr.1 and after discussion the plan was for Dr.1 to review Patient 7 in outpatients and organise a further CT scan in a further 12 months.

On 9 June 2017, Patient 7 was reviewed by Dr.1 who noted that a further renal CT scan was to be performed during November 2017.

On 5 January 2018, Dr.1 reviewed Patient 7 at an outpatient clinic. Dr.1 noted, in relation to latest CT scan (November 2017) that "I consider it to have increased by 2mm in maximum diameter up to 2.8cm".

Dr.1 recommended proceeding to partial nephrectomy if the left renal lesion became closer to 3cms in diameter than it had been on first assessment in June 2016. A CT scan was requested for August 2018 with the intention of discussion at the Regional Small Renal Masses MDM.

On 25 July 2018, a CT scan was performed which showed a slight increase in the size of the left kidney mass. Further, it was commented that it did not appear suitable for ablative therapy.

23 August 2018 Patient 7's case was again discussed at MDM. The July scan was reviewed which now showed the lesion to measure 3.0cm and it was recommended that, at an imminent review, both continuing active surveillance and open partial nephrectomy should be discussed. Furthermore, Patient 7 case should be discussed at the Regional Small Masses MDM.

On 14 September 2018, Dr.1 reviewed Patient 7 at outpatients when Patient 7 remained undecided, and it was concluded that a further CT scan should be performed in March

5.0 DESCRIPTION OF INCIDENT/CASE

2019 and that Patient 7 would proceed to partial nephrectomy if a further increase in the size of the left kidney mass was confirmed.

On 28 March 2019, on discussion at MDM the left kidney mass was noted to be enlarging and it was recommended that Dr.1 discussed laparoscopic radical nephrectomy in relation to continued surveillance with its attendant risks.

On 29 March 2019 Patient 7 was reviewed by Dr.3 (Locum Consultant Urologist). It was noted that Patient 7 had had a 3.1cms left sided kidney mass since July 2018, which was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 6 July 2019, a routine referral to the surgical team was made for Patient 7 after he complained of some months of intermittent right lower abdominal swelling.

13 November 2019, a CT scan was performed which showed an increase in size (3.5 cm) of lesion. No urology review was noted.

On 19 November 2019, Patient 7 was reviewed at the cardiology clinic and it was noted his condition was stable from a cardiac perspective. There was no plan for any further investigation other than an echocardiogram as Patient 7 was under review with urology and, according to his wife, was due an operation. On 14 January 2020 a letter to Patient 7's GP indicated that the result of the echocardiogram was normal.

Patient 7 was seen at the surgical clinic on 21 January 2020 when it was confirmed he had a right inguinal hernia and agreed to treat on an expectant basis.

On 14 August 2020 Patient 7 CT scan result was reviewed by Dr.4 (Locum Consultant Urologist). The CT scans were reviewed and it was noted that the kidney mass was 3.1 cms in March 2019 and had increased to 3.5 cms in November 2019. A plan was made for MDM discussion.

On 3 September 2020, Patient 7 case was discussed at MDM. It was noted that he had a 3.5cm lesion at the centre of his left kidney which had been slowly increasing in size since 2017. The MDT recommended that Patient 7 needed an up-to-date staging CT chest scan and renal function scans. Bloods to be taken for urea and electrolytes. To be reviewed by Dr.5 (Consultant Urologist) to discuss his suitability for radical nephrectomy.

On 26 October 2020, Patient 7 was reviewed by Dr.5 when there were further discussions about a laparoscopic radical nephrectomy and an agreement to discuss the way forward with Patient 7's daughter.

Patient 7 underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021Dr. 5 reviewed Patient 7. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

6.0 FINDINGS

- The review team acknowledge that Patient 7 was on a surveillance pathway for a renal mass below 4cm.
- The plan in 2017 was to proceed to partial nephrectomy if the tumour size increased to 3.0cm.
- The review team note that following discussions, Patient 7 remained undecided regarding surgery. [Patient 7 does not recall the discussions taking place regarding his surgery].
- The review team found that the planning of the intervals and imaging modalities was reactive, with no obvious proactive scheduling.
- In cases such as these, a referral to the Small Renal Mass MDM would be expected according to the NICAN Urology Cancer Clinical Guidelines (2016). This was recommended on two separate occasions by the MDM. Dr.1 advised that he would make the referral, but this was not actioned.
- Patient 7 case was brought repeatedly back to MDM at the request of locum surgeons to clarify the follow up surveillance protocol. The review team found that the MDM did not question why regional policy was not followed and why an appropriate opinion was not sought from the small renal mass MDM.
- Patient 7 was reviewed at MDMs 28/7/2016, 19/01/2017/ 28/08/2018, 28/3/2019/ 3/09/2020. All these meetings were non quorate due to the absence of an oncologist. Patient 7 case comprised of complex decisions based on tumour size and interpretation of radiological images. The review team note that a radiologist was present to provide additional interpretation of radiological images on all occasions except 23/8/2018.
- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% 2020
- Patient 7 was seen by Dr.1 and by 2 different locum consultants over this surveillance period, which led to somewhat fragmented care, inconsistency in investigations and a poor experience. Locum staff did not attend MDM and so did not feedback on the patient reviewed at outpatients.
- The review team believe a key worker or cancer specialist nurse would have improved the coordination of care, allowed a better understanding of the options available, and provided more consistent support to Patient 7 who was living with a potential and presumed diagnosis of cancer.
- The review team questions why it is not current practice for the SHSCT urology team to provide specialist nurses/ key worker to patients in a renal mass surveillance programme: whilst a histological diagnosis has not been made, the patient is fully aware of the high likelihood of cancer.
- The review team believes that Dr.1 had ample opportunities to refer Patient 7 for a

6.0 FINDINGS

specialist opinion and questioned why he decided to vary from established guidelines practice and MDM recommendations.

- The MDM is only funded to track 31 and 62 day targets - Patient 7 had not received a tissue diagnosis of cancer he would not fall within the remit. Similarly appointment of a CNS would occur at time of cancer diagnosis. This resource was not allocated prior to this. Complex tracking of this case was in essence outside the MDM structures.

7.0 CONCLUSIONS

The likelihood of long-term harm of a 35mm tumour is low [(1).] The ideal pathway for Patient 7 would have been to present the full details of his presentation, medical history, investigations and proposed management to the specialist MDT responsible advising on the management of small renal masses. The patient should have been fully informed of the presumed diagnosis of renal cell carcinoma (a 90% likelihood) and so should have been allocated a Key Worker. Active surveillance was a reasonable management, option but should have been proactively planned so that even if there was a lack of continuity in overall responsibility for care, the timing and type imaging modality was clear. Even so, further prompt MDT discussions, informed by the patient's expectations and health status, should have been arranged whenever there was any change in the surveillance findings. [This was not facilitated by the absence of locum urologists from the MDT].

8.0 LESSONS LEARNED

- The management of small renal masses should all be referred to a specialist MDM to guide management.
- The surgical management of small renal masses should be the responsibility of clinicians with the appropriate experience, normally at the specialist centre.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

The MDM should appoint a Chair responsible for the regular review and auditing of patient pathways to ensure a common and collaborative approach.

Recommendation 2

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9.0 RECOMMENDATIONS AND ACTION PLANNING

Individualised protocols for surveillance – especially the frequency and modality of imaging - should be clarified with the specialist MDT, which should be informed of any variation.

Recommendation 3

Any patient with a potential cancer diagnosis to be managed by surveillance should be independently allocated a Key Worker, usually a cancer nurse specialist, responsible for supporting and co-ordinating their care.

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.

References

1. **Age, Tumour Size and Relative Survival of Patients with Localized Renal Cell Carcinoma: A Surveillance, Epidemiology and End Results Analysis.** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2703466/

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:	Personal Information	**HSCB Ref Number:**	Personal Information

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**	x	**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: **This part of an overarching report involving multiple service users.** ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**	x			
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related	x					
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	✓
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned	✓		
	c) Report not shared but contents discussed **(*if you select this option please also complete 'I' below*)**			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

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Southern Health and Social Care Trust

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Date of Incident/Event: 03/09/2020

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted]

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

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On 13 November 2019 Patient 7 had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a subsequent delay in the follow up process for cancer care management.

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On 19 January 2017, Patient 7 's case was discussed at the MDM, which noted that the first repeat CT scan showed minimal changes to the renal mass. There were no changes in the mesenteric appearances, which were now felt to be not significant. A follow up MRI scan of the kidney was recommended.

A second repeat CT was carried out on 23 March 2017.

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Comment [KP1]: Family said this wasn't an appointment .

Comment [HG2]: That is why I have said the CT was reviewed, perhaps if… CT scan result was noted by Dr 4

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6.0 FINDINGS

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- The plan in 2017 was to proceed to partial nephrectomy if the tumour size increased to 3cm.
- The review team note that following discussions, Patient 7 remained undecided regarding surgery. [Mr Patient 7 does not recall the discussions taking place regarding his surgery].
- The review team found that the planning of the intervals and imaging modalities was reactive, with no obvious proactive scheduling.
- In cases such as these, a referral to the Small Renal Mass MDM would be expected according to the NICAN Urology Cancer Clinical Guidelines (2016). This was recommended on two separate occasions by the MDM. Dr.1 advised that he would make the referral, but this was not actioned.
- Patient 7 case was brought repeatedly back to MDM at the request of locum surgeons to clarify the follow up surveillance protocol. The review team found that the MDM did not question why regional policy was not followed and why an appropriate opinion was not sought from the Small Renal Mass MDM.
- Patient 7 was reviewed at MDMs 28/7/2016, 19/01/2017, 28/08/2018, 28/3/2019, 3/09/2020. All these meetings were non quorate due to absence of an oncologist. Patient 7 case comprised complex decisions based on tumour size and interpretation of radiological images. The review team note that a radiologist was present to provide additional interpretation of radiological images on all occasions except 23/8/2018.
- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% 2020.
- Patient 7 was seen by Dr.1 and by 2 different locum consultants over this surveillance period, which led to somewhat fragmented care, inconsistency in investigations and a poor experience. Locum staff did not attend MDM and so did not feedback on the patient reviewed at outpatients.
- The review team believe a key worker or cancer specialist nurse would have improved the coordination of care, allowed a better understanding of the options available, and provided more consistent support to Patient 7 who was living with a potential and presumed diagnosis of cancer.
- The review team questions why it is not current practice for the SHSCT urology team to provide specialist nurses/ key worker to patients in a renal mass surveillance programme: whilst a histological diagnosis has not been made, the patient is fully aware of the high likelihood of cancer.
- The review team believes that Dr.1 had ample opportunities to refer Patient 7 for a specialist opinion and questioned why he decided to vary from established

Comment [KP3]: Do you want a discussion here about Mr Patient 7 disputes being advised about being informed about the scans possibility of cancer or by being advised about surgery let alone being undecided about surgery.

Comment [HG4]: Could we put this in square brackets to show that this is a comment from outside the clinical record

6.0 FINDINGS

guidelines practice and MDM recommendations.

- The MDM is only funded to track 31 and 62 day targets - Patient 7 had not received a tissue diagnosis of cancer he would not fall within the remit. Similarly appointment of a CNS would occur at time of cancer diagnosis. This resource was not allocated prior to this. Complex tracking of this case was in essence outside the MDM structures.

7.0 CONCLUSIONS

The likelihood of long-term harm of a 32mm tumour is low)[1]. The ideal pathway for Patient 7 would have been to present the full details of his presentation, medical history, investigations and proposed management to the specialist MDT responsible advising on the management of small renal masses. The patient was fully informed of the presumed diagnosis of renal cell carcinoma (90% likelihood) and so should have been allocated a Key Worker. Active surveillance was a reasonable management option but should have been proactively planned so that even if there was a lack of continuity in overall responsibility for care, the timing and type of imaging modality was clear. Even so, further prompt MDT discussions, informed by the patient's expectations and health status, should have been arranged whenever there was any change in the surveillance findings. [This was not facilitated by the absence of locum urologists from the MDT]

Comment [KP5]: Hugh should we put this sentence back in again. It may go some way to reassuring the patient and family.

Comment [HG6]: amended

Comment [KP7]: Do we ned to put something in here again about the locums not being involved in the MDT discussions being a risk?

8.0 LESSONS LEARNED

- The management of small renal masses should all be referred to a specialist MDM to guide management.
- The surgical management of small renal masses should be the responsibility of clinicians with the appropriate experience, normally at the specialist centre.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

The MDM should appoint a Chair responsible for the regular review and auditing of patient pathways to ensure a common and collaborative approach.

Recommendation 2

Individualised protocols for surveillance – especially the frequency and modality of imaging - should be clarified with the specialist MDT, which should be informed of any variation.

Recommendation 3

9.0 RECOMMENDATIONS AND ACTION PLANNING

Any patient with a potential cancer diagnosis to be managed by surveillance should be independently allocated a Key Worker, usually a cancer nurse specialist, responsible for supporting and co-ordinating their care.

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.

References

1. **Age, Tumor Size and Relative Survival of Patients With Localized Renal Cell Carcinoma: A Surveillance, Epidemiology and End Results Analysis.** https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2703466/

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER							
1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**			**NO**			
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**			**NO**			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)***				
3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: [redacted]

Date of Incident/Event: 03/09/2020

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted]

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

Patient 7 had a small renal mass since 2016 which was under surveillance by Urology. At an outpatient's review clinic on 29 March 2019 Patient 7 was advised that his renal mass was stable and he was for surveillance. This is despite the urology multi-disciplinary team meeting outcome of the previous day advising that Patient 7 should have the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risk discussed.

On 13 November 2019 Patient 7 had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a subsequent delay in the follow up process for cancer care management.

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

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/ Patient/ Staff involved.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of Northern Ireland Electronic Care Record

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

On 28 June 2016, Patient 7 was urgently referred as a 'red flag 'to the urology services at Craigavon Area Hospital (CAH), because an abdominal ultrasound scan, requested to investigate raised liver enzymes, had shown a renal lesion. A subsequent CT scan (16 June 2016) confirmed a mildly enhancing renal lesion. The CT scan also showed mesenteric lymphadenopathy suspicious of lymphoma and a simultaneous 'red flag' referral was made to haematology.

On 19 July 2016, Patient 7 was seen by Dr.1 (Consultant Urologist) at an outpatient clinic at which the CT images were explained and discussed. Dr.1 advised of the presence of a solid lesion, measuring 2.5cms in diameter, which was partly protruding out of the anteromedial cortex of the lower pole of the left kidney's outer surface. The lesion was described as mildly enhancing and being rather homogeneous in appearance. Dr.1 explained that the lesion could very well be a papillary renal cell carcinoma and advised that its location did not allow biopsy without significant risk.

Patient 7 was discussed at the urology multidisciplinary meeting (MDM) on 28 July 2016. The MDM recommended active surveillance and that Dr.1 should review Patient 7 in a further 4 months with the results of a CT scan to assess both the mesenteric nodes and the renal mass.

On 12 August 2016, Patient 7 was reviewed by Dr.1 at an outpatient clinic and found him to remain "entirely well" and that he was happy with the plan, and to have the left renal lesion and the mesenteric lymphadenopathy reassessed by CT scan in November 2016. Dr.1 also advised an outpatient appointment for December 2016 to review the CT images and report. Patient 7 was also to be followed up by the haematology team.

Patient 7 had a repeat CT scan on 7 December 2016 and on 6 January 2017 was reviewed in outpatients by Dr.2 (Locum Consultant Urologist) who noted that the CT scan had shown a slight increase in the size of the kidney mass, but the mesenteric lymph nodes were unchanged. Of note, there was no new retroperitoneal or pelvic lymph node enlargement, nor any bony lesions. Dr.2 noted that Patient 7 had been doing well since his last outpatient review and had no lower urinary tract symptoms or haematuria. Dr.2 planned to re-discuss Patient 7 at the urology MDM in January, but provisionally requested a repeat CT scan and outpatient review in a further 4 months.

5.0 DESCRIPTION OF INCIDENT/CASE

On 19 January 2017, Patient 7 's case was discussed at the MDM, which noted that the first repeat CT scan showed minimal changes to the renal mass. There were no changes in the mesenteric appearances, which were now felt to be not significant. A follow up MRI scan of the kidney was recommended.

A second repeat CT was carried out on 23 March 2017.

On 11 April 2017, Dr.2 (Locum Consultant Urologist) wrote to Patient 7 's GP to advise on the findings on the latest CT scan. Some mild bilateral apical pleural thickening and a 4mm right basal pulmonary nodule, which had been described on the previous CT had now resolved. All else was reportedly normal and Dr.2 noted that Patient 7 awaited an MRI of his kidney which had been booked for 8 May 2017.

The MRI of the kidney was said to show no change in size of the left kidney mass when compared with the CT of December 2016. It was noted that the MRI radiologist's report described the lesion as non-specific and may have represented a papillary renal cell carcinoma. As Patient 7 remained on active surveillance, Dr.2 listed the case for discussion at MDM to agree which modality (CT/MRI) and what intervals for further reimaging were appropriate in this case.

On 25 May 2017, Patient 7 's case was presented to the MDM by Dr.1 and after discussion the plan was for Dr.1 to review Patient 7 in outpatients and organise a further CT scan in a further 12 months.

On 9 June 2017, Patient 7 was reviewed by Dr.1 who noted that a further renal CT scan was to be performed during November 2017.

On 5 January 2018, Dr.1 reviewed Patient 7 at an outpatient clinic. Dr.1 noted, in relation to latest CT scan (November 2017) that "I consider it to have increased by 2mm in maximum diameter up to 2.8cm".

Dr.1 recommended proceeding to partial nephrectomy if the left renal lesion became closer to 3cms in diameter than it had been on first assessment in June 2016. A CT scan was requested for August 2018 with the intention of discussion at the Regional Small Renal Masses MDM.

On 25 July 2018, a CT scan was performed which showed a slight increase in the size of the left kidney mass. Further, it was commented that it did not appear suitable for ablative therapy.

23 August 2018 Patient 7 's case was again discussed at MDM. The July scan was reviewed which now showed the lesion to measure 3.0cm and it was recommended that, at an imminent review, both continuing active surveillance and open partial nephrectomy should be discussed. Furthermore, Patient 7 case should be discussed at the Regional Small Masses MDM.

On 14 September 2018, Dr.1 reviewed Patient 7 at outpatients when Patient 7 remained undecided, and it was concluded that a further CT scan should be performed in March 2019 and that Patient 7 would proceed to partial nephrectomy if a further increase in the

5.0 DESCRIPTION OF INCIDENT/CASE

size of the left kidney mass was confirmed.

On 28 March 2019, on discussion at MDM the left kidney mass was noted to be enlarging and it was recommended that Dr.1 discussed laparoscopic radical nephrectomy in relation to continued surveillance with its attendant risks.

On 29 March 2019 Patient 7 was reviewed by Dr.3 (Locum Consultant Urologist). It was noted that Patient 7 had had a 3.1cms left sided kidney mass since July 2018, which was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 6 July 2019, a routine referral to the surgical team was made for Patient 7 after he complained of some months of intermittent right lower abdominal swelling.

On 13 November 2019, a CT scan was performed which showed an increase in size (3.5 cm) of lesion. No urology review was noted.

On 19 November 2019, Patient 7 was reviewed at the cardiology clinic and it was noted his condition was stable from a cardiac perspective. There was no plan for any further investigation other than an echocardiogram as Patient 7 was under review with urology and, according to his wife, was due an operation. On 14 January 2020 a letter to Patient 7's GP indicated that the result of the echocardiogram was normal.

Patient 7 was seen at the surgical clinic on 21 January 2020 when it was confirmed he had a right inguinal hernia and agreed to treat on an expectant basis.

On 14 August 2020 Patient 7's CT scan was reviewed by Dr.4 (Locum Consultant Urologist). It was noted that the kidney mass was 3.1 cms in March 2019 and had increased to 3.5 cms in November 2019. A plan was made for MDM discussion.

On 3 September 2020, Patient 7 case was discussed at MDM. It was noted that he had a 3.5cm lesion at the centre of his left kidney which had been slowly increasing in size since 2017. The MDT recommended that Patient 7 needed an up-to-date staging CT chest scan and renal function scans. Bloods to be taken for urea and electrolytes. To be reviewed by Dr.5 (Consultant Urologist) to discuss his suitability for radical nephrectomy.

On 26 October 2020, Patient 7 was reviewed by Dr.5 when there were further discussions about a laparoscopic radical nephrectomy and an agreement to discuss the way forward with Patient 7's daughter.

Patient 7 underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021 Dr.5 reviewed Patient 7. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

6.0 FINDINGS

- The review team acknowledge that Patient 7 was on a surveillance pathway for a renal mass below 4cm.
- The plan in 2017 was to proceed to partial nephrectomy if the tumour size increased to 3cm.
- The review team note that following discussions, Patient 7 remained undecided regarding surgery. Mr Patient 7 does not recall the discussions taking place regarding his surgery.
- The review team found that the planning of the intervals and imaging modalities was reactive, with no obvious proactive scheduling.
- In cases such as these, a referral to the Small Renal Mass MDM would be expected according to the NICAN Urology Cancer Clinical Guidelines (2016). This was recommended on two separate occasions by the MDM. Dr.1 advised that he would make the referral, but this was not actioned.
- Patient 7 case was brought repeatedly back to MDM at the request of locum surgeons to clarify the follow up surveillance protocol. The review team found that the MDM did not question why regional policy was not followed and why an appropriate opinion was not sought from the Small Renal Mass MDM.
- Patient 7 was reviewed at MDMs 28/7/2016, 19/01/2017, 28/08/2018, 28/3/2019, 3/09/2020. All these meetings were non quorate due to absence of an oncologist. Patient 7 case comprised complex decisions based on tumour size and interpretation of radiological images. The review team note that a radiologist was present to provide additional interpretation of radiological images on all occasions except 23/8/2018.
- The MDM was quorate 11% 2017, 22% 2018, 0% 2019 and 5% 2020.
- Patient 7 was seen by Dr.1 and by 2 different locum consultants over this surveillance period, which led to somewhat fragmented care, inconsistency in investigations and a poor experience. Locum staff did not attend MDM and so did not feedback on the patient reviewed at outpatients.
- The review team believe a key worker or cancer specialist nurse would have improved the coordination of care, allowed a better understanding of the options available, and provided more consistent support to Patient 7 who was living with a potential and presumed diagnosis of cancer.
- The review team questions why it is not current practice for the SHSCT urology team to provide specialist nurses/ key worker to patients in a renal mass surveillance programme: whilst a histological diagnosis has not been made, the patient is fully aware of the high likelihood of cancer.
- The review team believes that Dr.1 had ample opportunities to refer Patient 7 for a specialist opinion and questioned why he decided to vary from established

Comment [KP1]: Do you want a discussion here about Mr Patient 7 disputes being advised about being informed about the scans possibility of cancer or by being advised about surgery let alone being undecided about surgery.

6.0 FINDINGS

guidelines practice and MDM recommendations.

- The MDM is only funded to track 31 and 62 day targets - Patient 7 had not received a tissue diagnosis of cancer he would not fall within the remit. Similarly appointment of a CNS would occur at time of cancer diagnosis. This resource was not allocated prior to this. Complex tracking of this case was in essence outside the MDM structures.

7.0 CONCLUSIONS

The ideal pathway for Patient 7 would have been to present the full details of his presentation, medical history, investigations and proposed management to the specialist MDT responsible advising on the management of small renal masses. The patient was fully informed of the presumed diagnosis of renal cell carcinoma (a 90% likelihood) and so should have been allocated a Key Worker. Active surveillance was a reasonable management option but should have been proactively planned so that even if there was a lack of continuity in overall responsibility for care, the timing and type of imaging modality was clear. Even so, further prompt MDT discussions, informed by the patient's expectations and health status, should have been arranged whenever there was any change in the surveillance findings.

8.0 LESSONS LEARNED

- The management of small renal masses should all be referred to a specialist MDM to guide management.
- The surgical management of small renal masses should be the responsibility of clinicians with the appropriate experience, normally at the specialist centre.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 1

The MDM should appoint a Chair responsible for the regular review and auditing of patient pathways to ensure a common and collaborative approach.

Recommendation 2

Individualised protocols for surveillance – especially the frequency and modality of imaging - should be clarified with the specialist MDT, which should be informed of any variation.

Recommendation 3

Any patient with a potential cancer diagnosis to be managed by surveillance should be independently allocated a Key Worker, usually a cancer nurse specialist,

9.0 RECOMMENDATIONS AND ACTION PLANNING
responsible for supporting and co-ordinating their care. **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.

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER							
1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved**						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**			**NO**			
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**			**NO**			

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER ***(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)***				
3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
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	d) No contact or Next of Kin or Unable to contact			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: [redacted]

Date of Incident/Event: 03/09/2020

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted]

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 7 had a small renal mass since 2017 which was under surveillance by Urology. At an outpatient's review clinic on 29 March 2019 Patient 7 was advised that his renal mass was stable and he was for surveillance. This is despite the urology multi-disciplinary team meeting outcome of the previous day advising that Patient 7 should have the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risk discussed.

On 13 November 2019 Patient 7 had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a subsequent delay in the follow up process for cancer care management.

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 Clinical Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

On 28 June 2016, Patient 7 was urgently referred as a 'red flag 'to the urology services at Craigavon Area Hospital (CAH), because an abdominal ultrasound scan, requested to investigate raised liver enzymes, had shown a renal lesion. A subsequent CT scan (16 June 2016) confirmed a mildly enhancing renal lesion. The CT scan also showed mesenteric lymphadenopathy suspicious of lymphoma and a simultaneous 'red flag' referral was made to haematology.

On 19 July 2016, Patient 7 was seen by Dr.1 (Consultant Urologist) at an outpatient clinic at which the CT images were explained and discussed. Dr.1 advised of the presence of a solid lesion, measuring 2.5cms in diameter, which was partly protruding out of the anteromedial cortex of the lower pole of the left kidney's outer surface. The lesion was described as mildly enhancing and being rather homogeneous in appearance. Dr.1 explained that the lesion could very well be a papillary renal cell carcinoma and advised that its location did not allow biopsy without significant risk.

Patient 7 was discussed at the urology multidisciplinary meeting (MDM) on 28 July 2016. The MDM recommended active surveillance and that Dr.1 should review Patient 7 in a further 4 months with the results of a CT scan to assess both the mesenteric nodes and the renal mass.

On 12 August 2016, Patient 7 was reviewed by Dr.1 at an outpatient clinic and found him to remain "entirely well" and that he was happy with the plan, and to have the left renal lesion and the mesenteric lymphadenopathy reassessed by CT scan in November 2016. Dr.1 also advised an outpatient appointment for December 2016 to review the CT images and report. Patient 7 was also to be followed up by the haematology team.

Patient 7 had a repeat CT scan on 7 December 2017 and on 6 January 2017 was reviewed in outpatients by Dr.2 (Locum Consultant Urologist) who noted that the CT scan had shown a slight increase in the size of the kidney mass, but the mesenteric lymph nodes were unchanged. Of note, there was no new retroperitoneal or pelvic lymph node enlargement, nor any bony lesions. Dr.2 noted that Patient 7 had been doing well since his last outpatient review and had no lower urinary tract symptoms or haematuria. Dr.2's planned to re-discuss Patient 7 at the urology MDM in January, but provisionally requested a repeat CT scan and outpatient review in a further 4 months.

On 19 January 2017, Patient 7 's case was discussed at the MDM, which noted that the first repeat CT scan showed minimal changes to the renal mass. There were no changes in the mesenteric appearances, which were now felt to be not significant. A follow up MRI scan of the kidney was recommended.

A second repeat CT was carried out on 23 March 2017.

On 11 April 2017, Dr.2 (Locum Consultant Urologist) wrote to Patient 7 's GP to advise on the findings on the latest CT scan. Some mild bilateral apical pleural thickening

5.0 DESCRIPTION OF INCIDENT/CASE

and a 4mm right basal pulmonary nodule, which had been described on the previous CT had now resolved. All else was reported normally and Dr.2 noted that Patient 7 awaited an MRI of his kidney which had been booked for 8 May 2017.

The MRI of the kidney was said to show no change in size of the left kidney mass when compared with the CT of December 2016. It was noted that the MRI radiologist's report described the lesion as non-specific and may have represented a papillary renal cell carcinoma. As Patient 7 remained on active surveillance, Dr.2 listed the case for discussion at MDM to agree which modality (CT/MRI) and what intervals for further reimaging were appropriate in this case.

On 25 May 2017, Patient 7 's case was presented to the MDM by Dr.1 and after discussion the plan was for Dr.1 to review Patient 7 in outpatients and organise a further CT scan in a further 12 months.

On 9 June 2017, Patient 7 was reviewed by Dr.1 who noted that a further renal CT scan was to be performed during November 2017.

On 5 January 2018, Dr.1 reviewed Patient 7 at an outpatient clinic. Dr.1 noted, in relation to latest CT scan (November 2017) that "I consider it to have increased by 2mm in maximum diameter up to 2.8cm".

Dr.1 recommended proceeding to partial nephrectomy if the left renal lesion became closer to 3cms in diameter than it had been on first assessment in June 2016. A CT scan was requested for August 2018 with the intention of discussion at the Regional Small Renal Masses MDM.

On 25 July 2018, a CT scan was performed which showed a slight increase in the size of the left kidney mass. Further, it was commented that it did not appear suitable for ablative therapy.

23 August 2018 Patient 7 's case was again discussed at MDM. The July scan was reviewed which now showed the lesion to measure 3.0cm and it was recommended that, at an imminent review, both continuing active surveillance and open partial nephrectomy should be discussed. Furthermore, Patient 7 case should be discussed at the Regional Small Masses MDM.

On 14 September 2018, Dr.1 reviewed Patient 7 at outpatients when Patient 7 remained undecided, and it was concluded that a further CT scan should be performed in March 2019 and that Patient 7 would proceed to partial nephrectomy if a further increase in the size of the left kidney mass was confirmed.

On 28 March 2019, on discussion at MDM the left kidney mass was noted to be enlarging and it was recommended that Dr.1 discussed laparoscopic radical nephrectomy in relation to continued surveillance with its attendant risks.
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On 29 March 2019 Patient 7 was reviewed by Dr.3 (Locum Consultant Urologist). It was noted that Patient 7 had had a 3.1cms left sided kidney mass since July 2018, which was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

5.0 DESCRIPTION OF INCIDENT/CASE

On 6 July 2019, a routine referral to the surgical team was made for Patient 7 after he complained of some months of intermittent right lower abdominal swelling.

13 November 2019, a CT scan was performed which showed an increase in size (3.5 cm) of lesion. No urology review was noted until 14 August 2020.

On 19 November 2019, Patient 7 was reviewed at the cardiology clinic and it was noted his condition was stable from a cardiac perspective. There was no plan for any further investigation other than an echocardiogram as Patient 7 was under review with urology and, according to his wife, was due an operation. On 14 January 2020 a letter to Patient 7's GP indicated that the result of the echocardiogram was normal.

Patient 7 was seen at the surgical clinic on 21 January 2020 when it was confirmed he had a right inguinal hernia and agreed to treat on an expectant basis.

On 14 August 2020 Patient 7 was reviewed by Dr.4 (Locum Consultant Urologist). The CT scans were reviewed and it was noted that the kidney mass was 3.1 cms in March 2019 and had increased to 3.5 cms in November 2019. A plan was made for MDM discussion.

On 3 September 2020, Patient 7 case was discussed at MDM. It was noted that he had a 3.5cm lesion at the centre of his left kidney which had been slowly increasing in size since 2017. The MDT recommended that Patient 7 needed an up-to-date staging CT chest scan and renal function scans. Bloods to be taken for urea and electrolytes. To be reviewed by Dr.5 (Consultant Urologist) to discuss his suitability for radical nephrectomy.

On 26 October 2020, Patient 7 was reviewed by Dr.5 when there were further discussions about a laparoscopic radical nephrectomy and an agreement to discuss the way forward with Patient 7's daughter.

Patient 7 underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. Histopathology confirmed the left kidney mass was…..
Patient 7 is scheduled for laparoscopic radical nephrectomy on 25 November 2020. Pathology reports showed……. And Patient 7 was discharged on 27 November 2020 with a planned follow up.

6.0 FINDINGS

Multidisciplinary Team Meetings

- The review team acknowledge that Patient 7 was on a surveillance pathway for a renal mass below 4cms.
- The review team acknowledged that there were slight changes to tumour identified on CT scan. The plan in 2017 was to proceed to partial nephrectomy if the tumour size increases to 3.0cms.

- The review team note that following discussions, Mr Patient 7 remained

6.0 FINDINGS

undecided regarding surgery the partial nephrectomy, without invasive procedures.

- In cases such as these, a referral to the small renal mass MDM would be recommended according to the NI regional urology cancer guidance (2016, page 84).
- The review team recognises that the lesion was in a difficult position to proceed with Dr 1 had advised the MDT he would make the referral to the regional group.
- This referral was not actioned.
- Mr Patient 7 case brought repeatedly back to MDM as part of a small renal mass surveillance follow up.
- The review team found that the MDM did not question why regional policy was not followed and why an appropriate opinion was not sought from the small renal mass team.
- Mr Patient 7 was reviewed at Multidisciplinary Team Meetings (MDM) on 28/7/2016, 19/01/2017, 28/08/2018, 28/3/2019, 03/09/2020. All these meeting were non quorate due to absence of oncologists.
- Mr Patient 7 case comprised complex decisions based on tumour size and interpretation of radiological images. The review team note that a radiologist was present to provide additional interpretation of radiological images on all occasions except 23/8/2018.
- Mr Patient 7 was seen by Dr 1 and in addition by 3 locum consultants over his period of surveillance- this lead to somewhat fragmented care, differing investigations of the renal mass and poor experience.
- Locum staff did not attend MDM and did not feedback on the patient reviewed at outpatients.

<u>Specialist Nurses</u>

- The Review team believe a Urology Cancer Specialist Nurse would have improved coordination of care, understanding of options by a patient and provided support to Mr Patient 7 who was living with a potential and presumed diagnosis of cancer.
- The review team note that it is not current practice in SHSCT urology team to provide Urology Cancer Specialist Nurses to patients in a renal mass surveillance programme as they do not have a definitive diagnosis of cancer.

Need an addendum to explain completion of therapy.

1. Wasn't referred to small renal masses.

7.0 CONCLUSIONS

The ideal pathway for Mr Patient 7 would have been to present the full details of his presentation, medical history, investigations and proposed management to the specialist MDT responsible advising on the management of small renal masses. The patient should have been fully informed of the presumed diagnosis of renal cell

carcinoma (a 90% likelihood) and so should have been allocated a Key Worker. Active surveillance was a reasonable management, option but should have been proactively planned so that even if there was a lack of continuity in overall responsibility for care, the timing and type imaging modality was clear. Even so, further prompt MDT discussions, informed by the patient's expectations and health status, should have been arranged whenever there was any change in the surveillance findings.

The review team are aware that Patient 7 had had a radical nephrectomy in November 2020

The likelihood of long-term harm is low. However, this case raises some concerns about the ability of the MDM to ensure that its recommendations are followed, which would be reduced if a Cancer Nurse Specialist was allocated to all patients with a cancer diagnosis.

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

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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: [redacted]

Date of Incident/Event: 03/09/2020

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted]

Responsible Lead Officer: Dr Dermot Hughes

Designation: Former Medical Director

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 7 had a small renal mass since 2017 which was under surveillance by Urology. At an outpatient's review clinic on 29 March 2019 Patient 7 was advised that his renal mass was stable and he was for surveillance. This is despite the urology multi-disciplinary team meeting outcome of the previous day advising that Patient 7 should have the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risk discussed.

On 13 November 2019 Patient 7 had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a subsequent delay in the follow up process for cancer care management.

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 (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.
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- Examine any areas of good practice and opportunities for sharing learning from the incidents

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of Northern Ireland Electronic Care Record

MDT pathway for Cancer Management and appropriate guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

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On 26 October 2020, Patient 7 was reviewed by Dr.5 when there were further discussions about a laparoscopic radical nephrectomy and an agreement to discuss the way forward with Patient 7's daughter.

Patient 7 underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021Dr. 5 reviewed Patient 7. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

6.0 FINDINGS

Multidisciplinary Team Meetings

- The review team acknowledge that Patient 7 was on a surveillance pathway for a renal mass below 4cms.
- The review team acknowledged that there were slight changes to tumour identified on CT scan. The plan in 2017 was to proceed to partial nephrectomy if the tumour size increases to 3.0cms.
- The review team note that following discussions, Mr Patient 7 remained

6.0 FINDINGS

undecided regarding surgery the partial nephrectomy, without invasive procedures.

- In cases such as these, a referral to the small renal mass MDM would be recommended according to the NI regional urology cancer guidance (2016, page 84).
- The review team recognises that the lesion was in a difficult position to proceed with Dr 1 had advised the MDT he would make the referral to the regional group.
- This referral was not actioned.
- Mr Patient 7 case brought repeatedly back to MDM as part of a small renal mass surveillance follow up.
- The review team found that the MDM did not question why regional policy was not followed and why an appropriate opinion was not sought from the small renal mass team.
- Mr Patient 7 was reviewed at Multidisciplinary Team Meetings (MDM) on 28/7/2016, 19/01/2017, 28/08/2018, 28/3/2019, 03/09/2020. All these meeting were non quorate due to absence of oncologists.
- Mr Patient 7 case comprised complex decisions based on tumour size and interpretation of radiological images. The review team note that a radiologist was present to provide additional interpretation of radiological images on all occasions except 23/8/2018.
- Mr Patient 7 was seen by Dr 1 and in addition by 3 locum consultants over his period of surveillance- this lead to somewhat fragmented care, differing investigations of the renal mass and poor experience.
- Locum staff did not attend MDM and did not feedback on the patient reviewed at outpatients.

<u>Specialist Nurses</u>

- The Review team believe a Urology Cancer Specialist Nurse would have improved coordination of care, understanding of options by a patient and provided support to Mr Patient 7 who was living with a potential and presumed diagnosis of cancer.
- The review team note that it is not current practice in SHSCT urology team to provide Urology Cancer Specialist Nurses to patients in a renal mass surveillance programme as they do not have a definitive diagnosis of cancer.

Need an addendum to explain completion of therapy.

1. Wasn't referred to small renal masses.

6.0 FINDINGS

Hugh's Findings

The ideal pathway for this man, would have been to present the full details of his presentation, medical history, investigations and proposed management to the specialist MDT responsible advising on the management of small renal masses. The patient should have been fully informed of the presumed diagnosis of renal cell carcinoma (a 90% likelihood) and so should have been allocated a Key Worker. Active surveillance was a reasonable management ,option but should have been proactively planned so that even if there was a lack of continuity in overall responsibility for care, the timing and type imaging modality was clear. Even so, further prompt MDT discussions, informed by the patient's expectations and health status, should have been arranged whenever there was any change in the surveillance findings.

-The review team acknowledge that Patient 7 was on a surveillance pathway for a renal mass below 4cms

-The plan in 2017 was to proceed to partial nephrectomy if the tumour size increased to 3.0cms.

- The review team note that following discussions, Mr Patient 7 remained undecided regarding surgery.

- The review team found that the planning of the intervals and imaging modalities was reactive, with no obvious proactive scheduling.

- in cases such as these, a referral to the Small Renal Mass MDM would be expected according to the NI regional urology cancer guidance (2016). This was recommended on two separate occasions by the MDM. Dr.1 advised that he would make the referral, but this was not actioned.

- Mr Patient 7 case was brought repeatedly back to MDM at the request of locum surgeons to clarify the follow up surveillance protocol. The review team found that the MDM did not question why regional policy was not followed and why an appropriate opinion was not sought from the small renal mass MDM.

- Mr Patient 7 was reviewed at MDMs 28/7/2016, 19/01/2017/ 28/08/2018, 28/3/2019/ 3/09/2020. All these meetings were non quorate due to absence of an oncologist. Mr Patient 7 case comprised complex decisions based on tumour size and interpretation of radiological images. The review team note that a radiologist was present to provide additional interpretation of radiological images on all occasions except 23/8/2018.

- Mr Patient 7 was seen by Dr.1 and by 3 different locum consultants over this surveillance period, which led to somewhat fragmented care, inconsistency in investigations and a poor experience. Locum staff did not attend MDM and so did not feedback on the patient reviewed at outpatients.

- the review team believe a key worker or cancer specialist nurse would have improved the coordination of care, allowed a better understanding of the options available, and provided more consistent support to Patient 7 who was living with a potential and presumed diagnosis of cancer.

- the review team questions why it is not current practice for the SHSCT urology team to provide specialist nurses/ key worker to patients in a renal mass surveillance programme: whilst a histological diagnosis has not been made, the patient is fully aware of the high likelihood of cancer.

- the review team believes that Dr.1 had ample opportunities to refer Patient 7 for a specialist opinion and questioned why he decided to vary from established guidelines practice and MDM recommendations.

Considerations

1. The means of communicating and recording MDM decisions promptly should be reviewed.
2. The guidelines and means by which cases are referred to Regional MDMs should be reviewed.
3. A Key Worker would have provided continuity of care and enhanced the patient's experience whilst reducing the risk of delayed action.
4. Consideration should be given to ensuring that sufficient tracking capacity is available to the MDM
5. All small renal masses should be referred to the dedicated (Small Renal Mass) MDM.

7.0 CONCLUSIONS

The ideal pathway for Mr Patient 7 would have been to present the full details of his presentation, medical history, investigations and proposed management to the specialist MDT responsible advising on the management of small renal masses. The patient should have been fully informed of the presumed diagnosis of renal cell carcinoma (a 90% likelihood) and so should have been allocated a Key Worker. Active surveillance was a reasonable management, option but should have been proactively planned so that even if there was a lack of continuity in overall responsibility for care, the timing and type imaging modality was clear. Even so, further prompt MDT discussions, informed by the patient's expectations and health status, should have been arranged whenever there was any change in the surveillance findings.

The review team are aware that Patient 7 had had a radical nephrectomy in November 2020

The likelihood of long-term harm is low. However, this case raises some concerns about the ability of the MDM to ensure that its recommendations are followed, which would be reduced if a Cancer Nurse Specialist was allocated to all patients with a cancer diagnosis.

8.0 LESSONS LEARNED

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report <u>for all levels of SAI reviews)</u>

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

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

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
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	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

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16 March 2021 **Our Ref:** Personal Information redacted by the USI **Your Ref:**

Private & Confidential

Patient 2

Dear Mr Patient 2

I have previously been in contact with you about a review that the Southern Trust has been carrying out into the care you received.

As advised at the meeting with you on 18 February 2021 the team has concluded their review.

Please find enclosed a draft copy of the SAI report for you to consider. Mr O'Brien has asked that a copy of correspondence he has issued to the Trust be enclosed with the draft report. This is also attached.

I also enclose a feedback form which we would be grateful if you would return to the Acute Governance Team within 2 weeks of receipt of this letter. This form details the two options now available.

1. If you would like to discuss the findings and outcome of this review further with Dr Hughes, please state this on the attached form and a member of the Governance Team will be in contact with you.

2. Alternatively if after reviewing the report you have no further comment and indicate this to us, we will forward a final draft to both you and the Health and Social Care Board.

If after 2 weeks the Acute Governance Team has not received a response from you the report will be finalised and issued to both the family and Health and Social Care Board in its final format.

I look forward to hearing from you in due course.

Yours sincerely

Personal Information redacted by the USI

Mrs Melanie McClements
Director of Acute Services

encs

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

Telephone: Personal Information redacted by the USI
E-Mail: Personal Information redacted by the USI

Sharing of Draft SAI Report

Patient/Family Feedback Form

Please complete the form below and return to the Acute Clinical Governance Team in the enclosed return envelope or email to acute.governance@southerntrust.hscni.net within 2 weeks of receipt of the report

---

I _____ (name) confirm I have read the draft SAI report Personal Information redacted by the USI.

Please tick one of the two boxes below.

I confirm I have read and approve the draft report to be issued as the final report. ☐

or

I confirm I have read the draft SAI report and I would like to discuss it further. ☐

Signed: _____

Date: _____ Telephone: _____

Working together Excellence Openness & Honesty Compassion

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: [redacted]

Date of Incident/Event: 25 July 2019

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M Age: [redacted]

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

[redacted]

1.0 EXECUTIVE SUMMARY

Patient 2, a Personal Information redacted by the IIP man was referred by his General Practitioner (GP) in November 2018 for assessment and management of left scrotal pain which had been attributed to chronic left epididymitis, and which he had had for some years. A subsequent request was made for Patient 2's appointment to be expedited. This took place in June 2019 when it was confirmed that Patient 2 had a testicular tumour which was removed in July 2019.

Patient 2 was subsequently referred to the Cancer Centre at Belfast City Hospital with a view to consideration of adjuvant chemotherapy. Patient 2 was made aware that as the treatment would be delivered outside the recommended 12 week mark from surgery, the exact benefit in terms of reduction and relapse was uncertain.

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 report with the Director of Acute Services/ Medical Director of SHSCT/ HSCB/Family/ staff involved.
- To share the report with Director of Acute Services/ Medical Director SHSCT/HSCB/Patient/ Staff involved.

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Review of the Northern Ireland Electronic Care Record

Family Engagement

MDT pathway for Cancer Management

Comparative analysis against Regional and National Guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 2, a Personal Information redacted by the USI-old, was referred by his GP on 8 November 2018 to Craigavon Area Hospital (CAH) with chronic epididymitis (an inflammation of the epididymis which is a tube located at the back of the testicles that stores and carries sperm) for which he had been on months of antibiotics to no benefit. The GP noted that Patient 2 had been in continuous pain for a number of years, that there was no discharge and on examination, there was tenderness left testicle. This referral was triaged as routine.

On 25 March 2019, Patient 2, who had a history of psoriatic arthritis, had an appointment with his Rheumatology Nurse Specialist who subsequently wrote to the Urology Team at the South West Acute Hospital (SWAH) asking if his appointment could be expedited as she noted that Patient 2 was on continuous Trimethoprim and had to suspend the Methotrexate treatment that eased his arthritis.

On 29 April 2019 Patient 2 attended the urology nurse clinic where it became evident that a specialist medical urology assessment was required. The Urology Nurse Specialist apologised to Patient 2 and returned the Rheumatology Nurse Specialist's referral letter to Southern Trust Booking Centre. This was received on 7 May 2019 and was subsequently annotated by Dr.1 asking for urology appointment in SWAH on 24 June 2019.

On 13 May 2019, Dr.1 wrote to Patient 2 to inform him of the appointment planned for 24 June 2019 and to advise him that he was being referred for an ultrasound scan of his left testicle. This took place on 17 June 2019 and was reported and issued the following day, noted that most of the left testicle had been replaced by solid tissue. On review of the result Dr.1 noted this lesion was not present on an ultrasound scanning performed in 2012. Though the appearances were possibly due to chronic epididymitis, it was advised that a testicular tumour should also be considered.

Dr.1 reviewed Patient 2 on 24 June 2019 when he found Patient 2's left testis to be very indurated (firm) on palpation. He discussed with Patient 2 the differential diagnosis of chronic epididymitis and a testicular tumour and advised orchidectomy to confirm the diagnosis. Dr.1 requested serum testicular tumour marker levels (the LDH level was marginally elevated, whilst AFP and HCG levels were normal) and requested a CT scan of the chest, abdomen and pelvis.

5.0 DESCRIPTION OF INCIDENT/CASE

The CT (9 July 2019) demonstrated no evidence of metastases (cancer spread). The following day Patient 2 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 Patient 2'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 Patient 2 in outpatients and refer him to the regional testicular cancer oncology service.

At Patient 2'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 Patient 2 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 Patient 2 was referred to a medical oncologist. Patient 2 was discussed at the urology MDM the following day when the referral onwards to medical oncology was noted. Patient 2 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 Patient 2 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.
- Patient 2 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 care Trust stated in peer review in 2017 "*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*"(2) .

7.0 CONCLUSIONS

This presentation was unusual and the progress of Patient 2's investigation and treatment up to and including the orchidectomy was of an expected standard. However, the delay in his referral to a medical oncologist complicated treatment options, but whether this will compromise the long-term outcome remains uncertain. Adjuvant treatment is recommended to be given within 6 weeks of histological confirmation of the diagnosis (1,2,3).

Patient 2 received suboptimal treatment for testicular cancer as a consequence of a delay in onward referral.

8.0 LESSONS LEARNED

- Although the initial diagnostic of testicular cancer falls within the remit of the General Urologists, the continuing management, in every respect, is within the expertise of a Specialist Medical Oncologist. Prompt referral after staging and orchidectomy are mandatory.
- The effective management of urological cancers requires co-operative local and specialist multi-disciplinary teams, 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 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 multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.
- The primary function of an MDT is to ensure the appropriate management of patients with urological cancer.
- The patient's clinical record should include the reason for any delay or variation 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.

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

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

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

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

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Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
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	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
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	If **NO**, please provide details:			
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	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

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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: Personal Information redacted by the USI

Date of Incident/Event: 25 July 2019

HSCB Unique Case Identifier:

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 and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

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Patient 2 was subsequently referred to the Cancer Centre at Belfast City Hospital with a view to consideration of adjuvant chemotherapy. Patient 2 was made aware that as the treatment would be delivered outside the recommended 12 week mark from surgery, the exact benefit in terms of reduction and relapse was uncertain.

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4.0 REVIEW METHODOLOGY

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5.0 DESCRIPTION OF INCIDENT/CASE

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5.0 DESCRIPTION OF INCIDENT/CASE

chronic epididymitis and testicular tumour and advised orchidectomy to confirm the diagnosis. Dr.1 requested serum testicular tumour marker levels (the LDH level was marginally elevated, whilst AFP and HCG levels were normal) and requested a CT scan of the chest, abdomen and pelvis.

The CT (9 July 2019) demonstrated no evidence of metastases (cancer spread). The following day Patient 2 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.

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Patient 2 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

This presentation was unusual and the progress of Patient 2's investigation and treatment up to and including the orchiectomy was of an expected standard. However, the delay in his referral to a medical oncologist complicated treatment options, but whether this will compromise the long-term outcome remains uncertain. Adjuvant treatment is recommended to be given within 6 weeks of histological confirmation of the diagnosis.[KP1]

- The review team acknowledge that there is limited oncology presence within the urology MDT and on the day that Patient 2 was discussed there was no oncologist present.

- The MD 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.
- Patient 2 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 care Trust stated in peer review in 2017 "*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*"(2) .

This presentation was unusual and the progress of Patient 2's investigation and treatment up to and including the orchidectomy was of an expected standard. However, the delay in his referral to a medical oncologist complicated treatment options, but whether this will compromise the long-term outcome remains uncertain. Adjuvant treatment is recommended to be given within 6 weeks of histological confirmation of the diagnosis (1)

This man received suboptimal treatment for testicular cancer as a consequence of a delay in onward referral.

Patient 2 Version 3

8.0 LESSONS LEARNED

- Although the initial diagnostic of testicular cancer falls within the remit of the General Urologists, the continuing management, in every respect, is within the expertise of a Specialist Medical Oncologist. Prompt referral after staging and orchidectomy are mandatory.
- The effective management of urological cancers requires co-operative local and specialist multi-disciplinary teams, 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 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 multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.
- The primary function of an MDT is to ensure the appropriate management of patients with urological cancer.
- The patient's clinical record should include the reason for any delay or variation 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.

Reference

1.

2. Peer review Self-Assessment report for NICaN 2017).

9.0 RECOMMENDATIONS AND ACTION PLANNING

- 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.
- Any divergence from a MDT recommendation should be justified by further MDT discussion and the informed consent of the patient.
- An operational system with sufficient administrative personnel to allow the prompt scheduling of any investigations or appointments should be available during all clinical interactions.
- 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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 25 July 2019

HSCB Unique Case Identifier:

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 and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 2, a Personal Information redacted by the USI man was referred by his General Practitioner (GP) in November 2018 for assessment and management of left scrotal pain which had been attributed to chronic left epididymitis, and which he had had for some years. A subsequent request for made for Patient 2's appointment to be expedited. This took place in June 2019 when it was confirmed that Patient 2 had a testicular tumour which was removed in July 2019.

Patient 2 was subsequently referred to the Cancer Centre at Belfast City Hospital with a view to consideration of adjuvant chemotherapy. Patient 2 was made aware that as the treatment would be delivered outside the recommended 12 week mark from surgery, the exact benefit in terms of reduction and relapse was uncertain.

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 (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement – discussion with patient

Review of Northern Ireland Electronic Care Record

MDT pathway for Cancer Management and appropriate guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 2, a Personal Information redacted by the USI-old, was referred by his GP on 8 November 2018 to Craigavon Area Hospital (CAH) with chronic Epididymitis (an inflammation of the epididymis which is a tube located at the back of the testicles that stores and carries sperm) for which he had been on months of antibiotics to no benefit. The GP noted that Patient 2 had been in continuous pain for a number of years, that there was no discharge and, on examination, there was tenderness left testicle. This referral was triaged as routine.

On 25 March 2019, Patient 2, who had a history of psoriatic arthritis, had an appointment with his Rheumatology Nurse Specialist who subsequently wrote to the Urology Team at the South West Acute Hospital (SWAH) asking if his appointment could be as she noted that Patient 2 was on continuing Trimethoprim and had had to suspend the Methotrexate treatment that eased his arthritis.

On 29 April 2019 Patient 2 attended the urology nurse clinic where it became evident that a specialist medical urology assessment was required. The Urology Nurse Specialist apologised to Patient 2 and returned the Rheumatology Nurse Specialist's referral letter to Southern Trust Booking Centre. This was received on 7 May 2019 and was subsequently annotated by Dr.1 asking for urology appointment in SWAH on 24 June 2019.

On 13 May 2019, Dr.1 wrote to Patient 2 to inform him of the appointment planned for 24 June 2019 and to advise him that he was being referred for an ultrasound scan of his left testicle. This took place on 17 June 2019 and was report, issued the following day noted that most of the normal left testicle had been replaced by solid tissue. On review of the result Dr.1 noted this lesion had not present on an ultrasound scanning performed in 2012. Though the appearances were possibly be due to chronic epididymitis, it was advised that a testicular tumour should also be considered.

Dr.1 reviewed Patient 2 on 24 June 2019 when he found Patient 2's left testis to be very indurated (firm) on palpation. He discussed with Patient 2 the differential diagnosis of chronic epididymitis and testicular tumour and advised orchidectomy to confirm the diagnosis. Dr.1 requested serum testicular tumour marker levels (the LDH level was marginally elevated, whilst AFP and HCG levels were normal) and requested a CT scan of the chest, abdomen and pelvis.

The CT (9 July 2019) demonstrated no evidence of metastases (cancer spread). The following day Patient 2 underwent a left inguinal orchidectomy; the removal of left testicle and full spermatic cord. The histopathology confirmed that the tumour was a classical seminoma measuring 2.6cms across. Though 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 Patient 2's case discussed at the urology Multidisciplinary Meeting (MDM) on 18 July 2019. This took place on 25 July 2019 with the recommendation

5.0 DESCRIPTION OF INCIDENT/CASE

for Dr.1 to review Patient 2 in outpatients and refer him to the regional testicular cancer oncology service.

At Patient 2'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 Patient 2 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 Dr.1 referred Patient 2 to a medical oncologist. Patient 2 was discussed at the urology MDM the following day when the referral onwards to medical oncology was noted.

Patient 2 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

- This presentation was unusual and the progress of Patient 2's investigation and treatment up to and including the orchiectomy was of an expected standard. However, the delay in his referral to a medical oncologist complicated treatment options, but whether this will compromise the long-term outcome remains uncertain. Adjuvant treatment is recommended to be given within 6 weeks of histological confirmation of the diagnosis (reference).

- The review team acknowledge that there is limited oncology presence within the urology MDT and on the day that Patient 2 was discussed there was no oncologist present. (the figure of attendance)- need up to date figure.

- The majority of the urology MDM at the Southern Trust is non quorate due to the absence of oncologist and does not meet the existing guidelines of the MDT. (annual figure for 2019)

- 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.

- A Key Worker or Cancer Nurse Specialist would support the patient on their journey and ensure key actions take place. The Southern Health and Social care Trust stated in peer review in 2017 "*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".(ref)

Considerations

- Has an operational policy for the referral of testicular cancer cases to the Regional Testis MDT been agreed? If so, why was this patient excluded?
- Does the MDM have adequate administrative support to allow effective patient tracking?
- Does the MDM hold business meetings in which QA is addressed?

This presentation was unusual and the progress of Patient 2's investigation and treatment up to and including the orchidectomy was of an expected standard. However, the delay in his referral to a medical oncologist complicated treatment options, but whether this will compromise the long-term outcome remains uncertain. Adjuvant treatment is recommended to be given within 6 weeks of histological confirmation of the diagnosis (reference).

This man received suboptimal treatment for testicular cancer as a consequence of a delay in onward referral.

Patient 2 Version 3

8.0 LESSONS LEARNED

The is no failsafe – key worker would have provided a failsafe

The patients of AOB did not have access to a key worker.

MDT systems

Oncology

Administration process

31/ 62 target – Fiona to update.

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

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	If **YES**, insert **date informed**:						
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For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
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Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

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	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 25 July 2019

HSCB Unique Case Identifier:

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 and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 2, a Personal Information redacted by the USI man was referred by his General Practitioner (GP) in November 2018 for assessment and management of left scrotal pain which had been attributed to chronic left epididymitis, and which he had had for some years. A subsequent request for made for Patient 2's appointment to be expedited. This took place in June 2019 when it was confirmed that Patient 2 had a testicular tumour which was removed in July 2019.

Patient 2 was subsequently referred to the Cancer Centre at Belfast City Hospital with a view to consideration of adjuvant chemotherapy. Patient 2 was made aware that as the treatment would be delivered outside the recommended 12 week mark from surgery, the exact benefit in terms of reduction and relapse was uncertain.

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 Clinical Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 2, a Personal Information redacted by the USI old patient was referred by his GP on 8 November 2018 to Craigavon Area Hospital (CAH) with chronic Epididymitis (is an inflammation of the epididymis which is a tube located at the back of the testicles that stores and carries sperm) for which he had been on months of antibiotics without any result. The GP noted that Patient 2 was in ongoing pain for a number of years. There was no discharge and on examination there was long term tenderness left testicle. This referral was triaged as routine.

On 25 March 2019, Patient 2 had an appointment with his Rheumatology Nurse Specialist who subsequently wrote to the Urology Team at the South West Acute Hospital (SWAH) asking if an appointment could be expedited for Patient 2 who had a history of psoriatic arthritis. It was noted that Patient 2 was on Trimethoprim 200mg twice daily and that he had to suspend his Methotrexate treatment for his arthritis throughout the period of his infection.

On 29 April 2019 Patient 2 attended the Urology Nurse and it became evident that specialist medical urology assessment was required. The Urology Nurse Specialist apologised to Patient 2 and returned the Rheumatology Nurse Specialist's referral letter to Southern Trust Booking Centre. This was received on 7 May 2019 and was subsequently annotated by Doctor 1 asking for urology appointment in SWAH on 24 June 2019.

On 13 May 2019 Doctor 1 wrote to Patient 2 to inform him of the appointment planned for 24 June 2019 and to advise Patient 2 that he was being referred for an ultrasound scan of his left testicle. This took place on 17 June 2019 and was reported the following day. It noted that most of the left testicle had been replaced by solid tissue. On review of the result Doctor 1 noted this lesion was not present on ultrasound scanning performed in 2012. Though the appearances were considered to possible be due to a chronic epididymitis, it was equally advised that a testicular tumour may also be present.

Doctor 1 reviewed Patient 2 as planned on 24 June 2019 when he found Patient 2's left testis to be very indurated (firm) on palpation. He discussed with Patient 2 the differential diagnosis of chronic epididymitis and testicular tumour and advised if it was known to be a testicular tumour it would warrant resection. Doctor 1 undertook assessment of testicular tumour markers, finding his serum LDH level to be marginally elevated, while serum alpha beta protein and beta HCG levels were normal. Doctor 1 requested a CT scan of Patient 2's chest, abdomen and pelvis.

Patient 2 attended for his CT chest, abdomen and pelvis on 9 July 2019 which indicated no evidence of metastases (cancer spread). The following day Patient 2 had a left inguinal orchidectomy (removal of left testicle and full spermatic cord) carried out. Pathology of the resection specimen found that the tumour was entirely a classical seminoma

5.0 DESCRIPTION OF INCIDENT/CASE

measuring 2.6cms across. Though the tumour was confined to the testes, it did involve the exit tubules from the testis (rete testis) and was also found to have intratubular germ cell neoplasia. These findings indicate a small increased risk of spread.

Doctor 1 planned to have Patient 2's case discussed at the Urology Multidisciplinary Meeting on 18 July 2019. This took place on 25 July 2019. The plan was for Doctor 1 to review Patient 2 in outpatients and refer him to oncology.

Patient 2's outpatient review with Doctor 1 took place on 23 August 2019 and it was noted that Patient 2 had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that Patient 2 would be reviewed in SWAH again in February 2020 by Doctor 1 to determine if Patient 2 wished to have a testicular prosthesis implanted.

On 25 September 2019 Doctor 1 referred Patient 2 to oncology. Patient 2 was then discussed at the Urology Multi-Disciplinary Meeting the following day when it was noted that he had been referred onwards to oncology for discussions around adjuvant chemotherapy.

Patient 2 was subsequently seen at the Cancer Centre at Belfast City Hospital on 1 October 2019 and his cycle of adjuvant chemotherapy started on 10 October 2019.

6.0 FINDINGS

Causal factors

Delay in referral to Oncology

- This presentation was unusual and the progress of Patient 2's investigation and treatment up to the orchidectomy was of a high standard.
- However, the delay in his referral to a Medical Oncologist complicated treatment choices.
- Whether this will compromise the long-term outcome is uncertain as this treatment is recommended to be given within 6 weeks as per the designated protocol. (reference).

Contributory factor

Multidisciplinary Team Meetings

- The review team acknowledge that there is limited oncology presence within the urology MDT and the date when Patient 2 case was discussed there was no oncologist present. (the figure of attendance) 90%.
- The vast majority of the urology MDT within the Southern Trust is non quorate due to the absence of oncologist and does not meet the existing guidelines of the MDT. (annual figure for 2019).
- It is the primary responsibility for the consultant in charge to make the referral to oncology. The normal failsafe mechanism would include administration

6.0 FINDINGS

tracker to ensure agreed actions take place.

Allocation of Specialist Nurse

- The presence of a Urology Cancer Specialist Nurse would support the patient on their journey as well as ensure key actions take place. The Southern Health and Social care Trust declared in peer review in 2017 "*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".*(ref) that this was their standard Dr 1 did not avail of this resource.
- The Cancer Specialist Nurse would also provide a failsafe to ensure that all recommendations from the MDT are actioned.

There is a CAPPS cancer patient pathway system (generates all MDT letters and patient information. – check Fiona how the process works.
No oncologist in 90% of cases.

To consider
1. There is no record of the Testis MDM having received any communication. What is the usual means of informing it of a new case?
2. Cases, such as this, benefit from having a Key Worker (usually a Cancer Nurse Specialist) who can follow the patient across specialities. Is there any provision for this?
3. Should the MDM monitor its recommendation and request explanations for any deviations from conventional and timely treatment?

Conclusion
Patient was known to Belfast Trust – how.

MDT
Discussion.
Family question – when Patient 2 received the letter it was dated 25/9/2020 he believes that the oncology team came looking for him. – why?

Why was there a delay in the referral?

Considerations

1. Has an operational policy for the referral of testicular cancer cases to the Regional Testis MDT been agreed?

2. Does the MDM have adequate administrative support to allow effective patient tracking? Check with Fiona – if all scans were done?

3. Does the MDM hold business meetings in which QA is addressed?

This man may have received suboptimal treatment for testicular cancer as a consequence of an inexplicable delay in onward referral.

Patient 2 Version 3

8.0 LESSONS LEARNED
The is no failsafe – key worker would have provided a failsafe The patients of AOB did not have access to a key worker. MDT systems Oncology Administration process 31/ 62 target – Fiona to update.

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 25 July 2019

HSCB Unique Case Identifier:

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 and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 2, a Personal Information redacted by the USI man was referred by his General Practitioner (GP) in November 2018 for assessment and management of left scrotal pain which had been attributed to chronic left epididymitis, and which he had had for some years. A subsequent request for made for Patient 2's appointment to be expedited. This took place in June 2019 when it was confirmed that Patient 2 had a testicular tumour which was removed in July 2019.

Patient 2 was subsequently referred to the Cancer Centre at Belfast City Hospital with a view to consideration of adjuvant chemotherapy. Patient 2 was made aware that as the treatment would be delivered outside the recommended 12 week mark from surgery, the exact benefit in terms of reduction and relapse was uncertain.

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 Clinical Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Review of NIECR records

Interviews with Staff

Family Engagement

MDT pathway for Cancer Management

Relevant guidelines

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 2, a Personal Information redacted by the USI-old, was referred by his GP on 8 November 2018 to Craigavon Area Hospital (CAH) with chronic Epididymitis (an inflammation of the epididymis which is a tube located at the back of the testicles that stores and carries sperm) for which he had been on months of antibiotics to no benefit. The GP noted that Patient 2 had been in continuous pain for a number of years, that there was no discharge and, on examination, there was tenderness left testicle. This referral was triaged as routine.

On 25 March 2019, Patient 2, who had a history of psoriatic arthritis, had an appointment with his Rheumatology Nurse Specialist who subsequently wrote to the Urology Team at the South West Acute Hospital (SWAH) asking if his appointment could be as she noted that Patient 2 was on continuing Trimethoprim and had had to suspend the Methotrexate treatment that eased his arthritis.

On 29 April 2019 Patient 2 attended the urology nurse clinic where it became evident that a specialist medical urology assessment was required. The Urology Nurse Specialist apologised to Patient 2 and returned the Rheumatology Nurse Specialist's referral letter to Southern Trust Booking Centre. This was received on 7 May 2019 and was subsequently annotated by Dr.1 asking for urology appointment in SWAH on 24 June 2019.

On 13 May 2019, Dr.1 wrote to Patient 2 to inform him of the appointment planned for 24 June 2019 and to advise him that he was being referred for an ultrasound scan of his left testicle. This took place on 17 June 2019 and was report, issued the following day noted that most of the normal left testicle had been replaced by solid tissue. On review of the result Dr.1 noted this lesion had not present on an ultrasound scanning performed in 2012. Though the appearances were possibly be due to chronic epididymitis, it was advised that a testicular tumour should also be considered.

Dr.1 reviewed Patient 2 on 24 June 2019 when he found Patient 2's left testis to be very indurated (firm) on palpation. He discussed with Patient 2 the differential diagnosis of chronic epididymitis and testicular tumour and advised orchidectomy to confirm the diagnosis. Dr.1 requested serum testicular tumour marker levels (the LDH level was marginally elevated, whilst AFP and HCG levels were normal) and requested a CT scan of the chest, abdomen and pelvis.

The CT (9 July 2019) demonstrated no evidence of metastases (cancer spread). The following day Patient 2 underwent a left inguinal orchidectomy; the removal of left testicle and full spermatic cord. The histopathology confirmed that the tumour was a classical seminoma measuring 2.6cms across. Though the tumour was confined to the testes,

5.0 DESCRIPTION OF INCIDENT/CASE

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 Patient 2'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 Patient 2 in outpatients and refer him to the regional testicular cancer oncology service.

At Patient 2'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 Patient 2 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 Dr.1 referred Patient 2 to a medical oncologist. Patient 2 was discussed at the urology MDM the following day when the referral onwards to medical oncology was noted.

Patient 2 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

Causal factors

<u>Delay in referral to Oncology</u>

- This presentation was unusual and the progress of Patient 2's investigation and treatment up to the orchidectomy was of a high standard.
- However, the delay in his referral to a Medical Oncologist complicated treatment choices.
- Whether this will compromise the long-term outcome is uncertain as this treatment is recommended to be given within 6 weeks as per the designated protocol. (reference).

Contributory factor

<u>Multidisciplinary Team Meetings</u>

- The review team acknowledge that there is limited oncology presence within the urology MDT and the date when Patient 2 case was discussed there was no oncologist present.
- During this timeframe oncology presence was limited and usually restricted to

6.0 FINDINGS

clinical oncology. (need up to date 2019 attendance)

- The vast majority of the urology MDT within the Southern Trust is non quorate due to the absence of oncologist and does not meet the existing guidelines of the MDT. (annual figure for 2019).

- Absence of the Oncology presence at MDT does not however preclude timely Written referrals to the service. This is especially true for patients who require time critical interventions.

- It is the primary responsibility for the consultant in charge to make the referral to oncology.

- The normal failsafe mechanism would include administration tracker to ensure agreed actions take place. This was not in place in the SHSCT.

Allocation of Specialist Nurse

- Dr 1 did not work with Urology Cancer Nurse Specialists nor provide input for them to his patients.

- This was contrary to the Northern Ireland Cancer Network Urology Cancer Guidelines (2016) on the critical role of Specialist Nursing- 10.0 page 11.

- The presence of a Urology Cancer Specialist Nurse would support the patient on their journey as well as ensure key actions take place. The Southern Health and Social care Trust declared in peer review in 2017 "*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*" (ref).

- The Cancer Specialist Nurse would also provide a fail-safe mechanism to ensure that all recommendations from the MDT are actioned.

There is a CAPPS cancer patient pathway system (generates all MDT letters and patient information. – check Fiona how the process works.
No oncologist in 90% of cases.

To consider
1. There is no record of the Testis MDM having received any communication. What is the usual means of informing it of a new case?
2. Cases, such as this, benefit from having a Key Worker (usually a Cancer Nurse Specialist) who can follow the patient across specialities. Is there any provision for this?
3. Should the MDM monitor its recommendation and request explanations for any deviations from conventional and timely treatment?

Conclusion
Patient was known to Belfast Trust – how.

MDT
Discussion.
Family question – when Patient 2 received the letter it was dated 25/9/2020 he believes that the oncology team came looking for him. – why?

Why was there a delay in the referral?

Considerations

1. Has an operational policy for the referral of testicular cancer cases to the Regional Testis MDT been agreed?

2. Does the MDM have adequate administrative support to allow effective patient tracking? Check with Fiona – if all scans were done?

3. Does the MDM hold business meetings in which QA is addressed?

This presentation was unusual and the progress of Patient 2's investigation and treatment up to and including the orchidectomy was of an expected standard. However, the delay in his referral to a medical oncologist complicated treatment options, but whether this will compromise the long-term outcome remains uncertain. Adjuvant treatment is recommended to be given within 6 weeks of histological confirmation of the diagnosis (reference).

Patient 2 Version 3

8.0 LESSONS LEARNED

The is no failsafe – key worker would have provided a failsafe

The patients of AOB did not have access to a key worker.

MDT systems

Oncology

Administration process

31/ 62 target – Fiona to update.

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: Personal Information redacted by the USI

Date of Incident/Event: 25 July 2019

HSCB Unique Case Identifier:

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 and Chair of the Northern Ireland Cancer Network

Report Author: The Review Team

Date report signed off:

Date submitted to HSCB:

1.0 EXECUTIVE SUMMARY

Patient 2, a Personal Information redacted by the USI man was referred by his General Practitioner (GP) in November 2018 for assessment and management of left scrotal pain which had been attributed to chronic left epididymitis, and which he had had for some years. A subsequent request for made for Patient 2's appointment to be expedited. This took place in June 2019 when it was confirmed that Patient 2 had a testicular tumour which was removed in July 2019.

Patient 2 was subsequently referred to the Cancer Centre at Belfast City Hospital with a view to consideration of adjuvant chemotherapy. Patient 2 was made aware that as the treatment would be delivered outside the recommended 12 week mark from surgery, the exact benefit in terms of reduction and relapse was uncertain.

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 Clinical Cancer Services (SHSCT)
Ms Patricia Thompson – Clinical Nurse Specialist (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

4.0 REVIEW METHODOLOGY

Review of Medical Notes

Interviews with Staff

Family Engagement

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 2, a Personal Information redacted by the USI -old, was referred by his GP on 8 November 2018 to Craigavon Area Hospital (CAH) with chronic Epididymitis (~~is~~ an inflammation of the epididymis which is a tube located at the back of the testicles that stores and carries sperm) for which he had been on months of antibiotics ~~without any result~~to no benefit. The GP noted that Patient 2 ~~was in~~had been in ~~ongoing~~ continuous pain for a number of years, that ~~. T~~there was no discharge and, on examination, there was ~~long term~~ tenderness left testicle. This referral was triaged as routine.

On 25 March 2019, Patient 2, who had a history of psoriatic arthritis, had an appointment with his Rheumatology Nurse Specialist who subsequently wrote to the Urology Team at the South West Acute Hospital (SWAH) asking if ~~an~~ his appointment could be ~~expedited for~~ Patient 2 ~~who had a history of psoriatic arthritis.~~as she ~~It was~~ noted that Patient 2 was on continuing Trimethoprim ~~200mg twice daily~~ and ~~that he~~ had had to suspend ~~his~~ the Methotrexate treatment that eased his arthritis.~~for his arthritis throughout the period of his infection.~~

On 29 April 2019 Patient 2 attended the ~~Urology~~ urology ~~Nurse~~nurse clinic where ~~and~~ it became evident that a specialist medical urology assessment was required. The Urology Nurse Specialist apologised to Patient 2 and returned the Rheumatology Nurse Specialist's referral letter to Southern Trust Booking Centre. This was received on 7 May 2019 and was subsequently annotated by Dr.1~~octor 1~~ asking for urology appointment in SWAH on 24 June 2019.

On 13 May 2019, Dr.1 ~~Doctor 1~~ wrote to Patient 2 to inform him of the appointment planned for 24 June 2019 and to advise Patient 2 -him that he was being referred for an ultrasound scan of his left testicle. This took place on 17 June 2019 and was ~~reported~~ report, issued the following day~~the following day. It~~ noted that most of the normal left testicle had been replaced by solid tissue. On review of the result ~~Doctor 1~~Dr.1 noted this lesion ~~was~~ had not present on an ultrasound scanning performed in 2012. Though the appearances were ~~considered to~~ possibly~~e~~ be due to ~~a~~ chronic epididymitis, it was ~~equally~~ advised that a testicular tumour ~~may also be present~~should also be considered.

~~Doctor 1~~Dr.1 reviewed Patient 2 ~~as planned~~ on 24 June 2019 when he found Patient 2's left testis to be very indurated (firm) on palpation. He discussed with Patient 2 the differential diagnosis of chronic epididymitis and testicular tumour and advised ~~if it was known to be a testicular tumour it would warrant resection~~orchidectomy to confirm the diagnosis. ~~Doctor 1~~Dr.1 ~~undertook assessment of~~requested serum testicular tumour ~~markers~~marker levels (~~, finding his serum~~ the LDH level ~~to be~~was marginally elevated, ~~while~~ whilst~~serum alpha beta protein and beta~~ AFP and HCG levels were normal) and ~~. Doctor 1~~ requested a CT scan of Patient 2 ~~'s~~ the chest, abdomen and pelvis.

Patient 2 ~~attended for his~~The CT ~~chest, abdomen and pelvis on~~(~~–~~9 July 2019) ~~which indicated~~ demonstrated no evidence of metastases (cancer spread). The following day Patient 2 ~~had~~ underwent a left inguinal orchidectomy; the ~~(~~ removal of left testicle and full spermatic cord~~)~~ ~~carried out~~. The histop~~P~~athology ~~of the resection specimen found~~confirmed that the tumour was ~~entirely~~ a classical seminoma measuring 2.6cms across. Though the tumour was confined to the testes, it did involve the exit tubules from the testis (rete testis) and ~~was also found to have~~ intratubular germ cell neoplasia was also found. These findings indicate a small increased risk of pre-existing spread.

5.0 DESCRIPTION OF INCIDENT/CASE

~~Doctor 1~~Dr.1 planned to have Patient 2's case discussed at the ~~Urology Multidisciplinary~~urology Multidisciplinary Meeting (MDM) on 18 July 2019. This took place on 25 July 2019 with the recommendation ~~. The plan was~~ for ~~Doctor 1~~Dr.1 to review Patient 2 in outpatients and refer him to the regional testicular cancer oncology service.

At Patient 2's outpatient review with ~~Doctor 1~~Dr.1 ~~took place~~ on 23 August 2019 ~~and~~ it was noted that Patient 2 ~~he~~ had had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that Patient 2 would be reviewed in SWAH again in February 2020 by ~~Doctor 1~~Dr.1 to determine if Patient 2 ~~he~~ wished to have a testicular prosthesis~~. implanted.~~

On 25 September 2019 ~~Doctor 1~~Dr.1 referred Patient 2 to a medical ~~oncology~~oncologist. Patient 2 was ~~then~~ discussed at the ~~Urology~~ urology MDM~~Multi-Disciplinary Meeting~~ the following day ~~when it was noted that he had been~~when the ~~referred~~ referral onwards to medical oncology ~~for discussions around adjuvant chemotherapy~~was noted.

Patient 2 was ~~subsequently~~ seen at the Cancer Centre at Belfast City Hospital on 1 October 2019 and his ~~cycle of~~ adjuvant chemotherapy started on 10 October 2019.

6.0 FINDINGS

~~Causal factors~~

This presentation was unusual and the progress of Patient 2's investigation and treatment up to and including the orchidectomy was of an expected ~~high~~ standard. However, the delay in his referral to a ~~Medical~~ medical ~~Oncologist~~ oncologist complicated treatment ~~choices~~options, but~~. Whether~~ whether this will compromise the long-term outcome ~~is~~ remains uncertain~~.~~ ~~as this~~Adjuvant treatment is recommended to be given within 6 weeks ~~as per the designated protocol.~~of histological confirmation of the diagnosis (reference).

~~Contributory factor~~

- The review team acknowledge that there is limited oncology presence within the urology MDT and on the ~~date~~ day that~~when~~ Patient 2 ~~case~~ was discussed there was no oncologist present. (the figure of attendance) 90%

- The ~~vast~~ majority of the urology ~~MDT~~ MDM at~~within~~ the Southern Trust is non quorate due to the absence of oncologist and does not meet the existing guidelines of the MDT. (annual figure for 2019)

- It is the primary responsibility for the consultant in charge to make the referral to oncology. However, t~~T~~he normal failsafe mechanism would include an administration tracker or a Key Worker to ensure agreed actions, such as onward referral, take place.

- ~~The presence of~~ A~~a~~ Key Worker~~/~~ or Cancer ~~Specialist~~ Nurse Specialist would support the patient on their journey ~~as well as~~and ensure key actions take place. The Southern Health and Social care Trust ~~declared~~ stated in peer review in 2017 "*all newly diagnosed patients have a Key Worker appointed, a Holistic Needs*

6.0 FINDINGS

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".(ref) ~~that this was their standard Dr 1 did not avail of this resource.~~

-

~~There is a CAPPS cancer patient pathway system (generates all MDT letters and patient information. – check Fiona how the process works.~~
~~No oncologist in 90% of cases.~~

~~To consider~~

~~1. There is no record of the Testis MDM having received any communication. What is the usual means of informing it of a new case?~~
~~2. Cases, such as this, benefit from having a Key Worker (usually a Cancer Nurse Specialist) who can follow the patient across specialities. Is there any provision for this?~~
~~3. Should the MDM monitor its recommendation and request explanations for any deviations from conventional and timely treatment?~~

~~Conclusion~~
~~Patient was known to Belfast Trust – how.~~

~~MDT~~
~~Discussion.~~
~~Family question – when~~ Patient 2 ~~received the letter it was dated 25/9/2020 he believes that the oncology team came looking for him. – why?~~

~~Why was there a delay in the referral?~~
Considerations

1. Has an operational policy for the referral of testicular cancer cases to the Regional Testis MDT been agreed? If so, why was this patient excluded?

2. Does the MDM have adequate administrative support to allow effective patient tracking? ~~Check with Fiona – if all scans were done?~~

3. Does the MDM hold business meetings in which QA is addressed?

7.0 CONCLUSIONS

This man ~~may have~~ received suboptimal treatment for testicular cancer as a consequence of ~~an inexplicable~~a delay in onward referral.

~~Delay in referral~~

8.0 LESSONS LEARNED
~~The is no failsafe – key worker would have provided a failsafe~~ ~~The patients of AOB did not have access to a key worker.~~ ~~MDT systems~~ ~~Oncology~~ ~~Administration process~~ ~~31/ 62 target – Fiona to update.~~

9.0 RECOMMENDATIONS AND ACTION PLANNING

10.0 DISTRIBUTION LIST

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

Reporting Organisation SAI Ref Number:		**HSCB Ref Number:**	

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***		**HSC Child Death Notification only**		
	Comment: ****If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			
Continued overleaf	**e)** No response to correspondence			

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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

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

	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**

Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959)

(complete this section for all death related SAIs)

1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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 – Personal Information redacted by the USI 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 has Personal Information redacted by the 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.

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

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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Kate O'Neill asked if this will be reflected in the report.

Both Dr Hughes and Patricia Kingsnorth said yes.

Jenny McMahon said she feels much better supported now, but back years it took all consultants a while to engage. She added in 2019 all resources were there it is indefensible not to provide contact details.

Dr Hughes advised the report will be written without any criticism of Nurse Specialists but will highlight resource issues.

Jenny McMahon asked if the report could be share with CNS.

Patricia Kingsnorth advised not at this stage it is just shared with staff involved.

Dr Hughes agreed to share the part of the report that refers to Nurse Specialists.

Patricia Kingsnorth suggested Patricia Thompson could share that part of the report.

Dr Hughes read the part referring to CNS from the draft report. He advised he wants to say what happened is against regional guidelines and what the Trust signed up to.

Dr Hughes thanked staff for attending the meeting.

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

Connolly, Carly

From: Dermot Hughes <[redacted]>
Sent: 28 January 2021 17:07
To: Kingsnorth, Patricia

Dear Patricia

This is the Guidance in the NICAN Urological Cancer Guidelines march 2016 referring to Specialist Urology cancer Nursing and palliative care

This will be used to benchmark the patients experience etc

Again critical aspects of care that are regional recommendation

10.0 UROLOGICAL NURSING

It is well-documented that the CNS plays an essential role within the cancer multidisciplinary team (MDT) in providing high-quality care from diagnosis throughout the patient journey (National Peer Review Programme, 2014). The National Institute for Clinical Excellence (NICE) (2002) called for major changes in improving outcomes for patients with Urological Cancers. In particular they recommended that the CNS should have specific knowledge and expertise and should be trained in advanced communication skills. More recently, NICE (2014) emphasised that the CNS can ensure that patients have information that is tailored to their individual needs, therefore enhancing shared decision making. The CNS is also in an excellent position to provide individualised care following treatment which promotes cancer survivorship (National Cancer Survivorship Initiative, 2011). A recent Macmillan census on specialist nurses workforce in Northern Ireland (2014) has highlighted that cancer care teams of the future will need to have more flexibility working with people who are living with cancer. This census emphasised that the role of the CNS must be optimised to support those living in the community with a diagnosis of cancer.

The combination of improved life expectancy, advancements in diagnostics and treatment, and increased use of PSA testing in primary Care have all contributed to a significant rise in Urological cancer diagnosis. In Northern Ireland the number of new cases of Urological cancers diagnosed annually has increased and the associated workload creating significant challenges for Urological cancer teams and further demands on Uro-Oncology Clinical Nurse Specialists (CNS).

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10.1 Responsibilities of the Uro-oncology Specialist Nurses

All patients should be assigned a key worker (usually a CNS) at the time of diagnosis, and appropriate arrangements should be in place to facilitate easy access to the key worker during working hours and an appropriate source of advice in his/her absence, as per National Cancer Peer Review standards. All patients should be offered a holistic needs assessment (HNA) at diagnosis and subsequently if their disease status changes. Patients should be offered advice and support to address any immediate concerns – physical, mental, spiritual or financial – on completion of the HNA with onward referrals made as necessary.

The responsibilities of the uro-oncology CNS include, ensuring patients undergoing investigations for suspected cancers have adequate information and support. On diagnosis, the CNS has a supportive role and will help ensure that the patient and significant others are equipped to make informed decisions regarding their ongoing treatment and care. The CNS may have a role in the review of patients following treatment for urological cancer. The CNS also has a key role in equipping the patient to live with and beyond the urological cancer, as advocated by the National Cancer Survivorship Initiative (2011). National Cancer Survivorship Initiative (2011) has also recommended the use of Holistic Needs Assessment (HNA) by the CNS to assess patient's needs for physical, psychological, social, spiritual and financial support at key points of their journey. A structured pack has been provided for use by professionals to assist with this process (NCAT, 2010). This HNA approach and subsequent care planning is a process which would ensure that people's needs are met in a timely and appropriate way and that resources are targeted to those who need them most. As a result of the HNA patients should be appropriately referred or signposted to any required support services.

Where cystectomy is considered, the involvement of the Stoma Therapist and/or Urology Clinical Nurse Specialist soon after diagnosis is essential. Patients should be offered the opportunity to meet a patient who has had a cystectomy and urinary diversion to help the decision making process. Patients who may have problems with urinary incontinence should be given information about local continence services.

11.0 SUPPORTIVE AND PALLIATIVE CARE

Supportive care is available to people with cancer and their carers throughout the patient pathway, from pre-diagnosis onwards and is a term used to describe all services that may be required to support people with cancer and their carers(NICE,2004). It is identified by NICE (2004) that patients and carers may have a series of problems preceding diagnosis (when cancer is suspected) which may include physical and anxiety related symptoms which require appropriate management, and information should be available for patients at this stage if they require it. As recognised by NICE (2004) supportive care is the responsibility of all health and social care professionals involved in delivering care and effective communication within teams will enable a seamless transition from one service to another if and when required.

Patients with advanced urological cancer may benefit from supportive and palliative care. Palliative care is defined by the World Health Organization (WHO, 2014) as an approach that improves the quality of life of patients and their families, facing the problems associated with life threatening illness. Uncontrolled symptoms can adversely affect quality of life and a patient's ability to cope with their illness, therefore, early identification, thorough assessment and treatment of pain and other problems, physical, psychological and spiritual, is essential (WHO 2014). The overall goal of palliative care is to help manage the symptoms and difficulties that may arise with disease progression, through appropriate support and intervention.

Palliative Care is an integral part of the multidisciplinary team and patients may require palliative care at different stages of the patient pathway (NICE, 2004). Generalist palliative care is the level of care required by most people and is provided by non-palliative/ end of life care specialist's i.e. primary and secondary health care teams (Living Matters, Dying Matters, 2010). Specialist palliative care may be required for those patients with more demanding care needs, i.e. unresolved symptoms and complex psychosocial, end of life and bereavement issues (Living Matters, Dying Matters, 2010).Referral to Specialist Palliative Care may be made at any time in the course of the disease when the patient wishes and would benefit from it.

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References:

Living Matters, Dying Matters (2010) A Palliative and End of Life Care Strategy for Adults in Northern Ireland www.dhsspsni.gov.uk

Macmillan (2014) Specialist adult cancer Nurses in Northern Ireland: A census of the specialist adult cancer nursing workforce in the UK, 2014. Macmillan Cancer Support.

National Cancer Action Team (2010) Holistive Needs Assessment for people with cancer: a practical guide for health care professionals. www.ncsi.org.uk

National Cancer Survivorship Initiative (2011) Consequences of Cancer Treatment. National Cancer Survivorship Initiative: London.

National Institute for Clinical Excellence (2002) Guidance on Cancer Services Improving Outcomes in Urological Cancers. NICE.

National Institute for Clinical Excellence (2004) Guidance on Cancer Services. Improving Supportive and Palliative Care for Adults with Cancer. London: NICE.

National Institute for Clinical Excellence (2014) Prostate Cancer: diagnosis and treatment. NICE: London.

National Peer Review Programme (2014) Manual for Cancer Services- Urology Measures.

World Health Organisation (2014) http://www.who.int./cancer/palliative/definition/en/

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

Personal Information redacted by the USI

Connolly, Carly

From: Kingsnorth, Patricia
Sent: 10 May 2021 13:28
To: Patient 5's Daughter
Subject: RE: re REPORT. Confidential

Dear Patient 5's Daughter
No problem at all. He was very happy to clarify for you.
I will get the amended report out to you and the board.
Please see my best wishes to your father and Patient 5's Daughter

Kind regards
Patricia

Patricia Kingsnorth
Acting Acute Clinical Governance Coordinator
Governance Office
Room 53
The Rowans
Craigavon Area Hospital
Personal Information redacted by the USI

From: Patient 5's Daughter
Sent: 10 May 2021 13:26
To: Kingsnorth, Patricia
Subject: Re: re REPORT. Confidential

Thanks very much Patricia, it is really helpful to have the explanation.I am very grateful for you going back to Mr Gilbert. Please extend my thanks to him for taking the time to provide clarification.
Kind regards
Patient 5's Daughter

Sent from my iPad

On 10 May 2021, at 10:48, Kingsnorth, Patricia <Personal Information redacted by USI> wrote:

> Dear Patient 5's Daughter
> Please see comments below. Does this answer your query regarding the significant metastases?
>
> Kind regards
> Patricia

2 The first page of the appendix is missing, it starts from question 13. Was this intentional or an error ?

Not sure

3 In terms of the added comment below which was not included in the draft report
" 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 ."
As indicated in the report .
"the bone scan 6 August 2020 confirmed new sclerotic abnormalities in the spine,pelvis,the ribs and the left femur"

We would like to know how the term "significant metastasis" is defined. In the time frame between the scan which took place in December 19 which was not followed up in January 20 (when it was available) and the body scan which took place in August 20 the cancer had spread further to other bone sites. I still hope that eventually we will ascertain how an earlier diagnosis of prostrate cancer via a PSA test and the starting of treatment earlier may have prevented any spread.

I think Hugh would best comment

Collective family report
1 We had requested that the number of months daddy's scan had been overlooked and not followed up should be added to the report (Patient 5)
As stated in the report
" Patient 5 had a delayed diagnosis of a metastatic prostrate cancer following successful treatment of renal cancer. This was due to non action on a follow up scan report."
The number of months delay should have been added here.

Happy to ammend with number of months

2 Recomendation 10, is the group still taking place which family members were asked to join Personal Information redacted by USI to have oversight of the new governance arrangements. I don't think sending families updated reports alone would be sufficiently robust. Maybe the group is still going ahead and I have misinterpreted this statement.

I made a recommendation for family involvement but cannot really prescribe how this is done - personal view is that they can act as expert by experience similar to lay role in Peer Review - really think getting this sorted may help with future reviews etc.

3 Was the independent expert writing a report at the end of this process and will this be shared with families ? We had indicated previously the importance of " impact " on the 9 family members and the families which was to be possibly included in the subject experts report.

No there is no additionality outside this process

Thank you to both of you for your patience as always .
Kind regards
Patient 5's Daughter

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

Organisation's Unique Case Identifier: [redacted]

Date of Incident/Event: Multiple dates

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: Male Age:

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. EXECUTIVE SUMMARY

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 to the patients identified and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided. Nine patients have been identified as potentially suffering harm. This review will examine the timelines of each individual case and analyse if any deficits in treatment or care has occurred. As part of the review the cancer

pathways will be used to determine where learning can be extracted.

The SHSCT recognise the life changing and devastating consequences to the 9 families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care they received.

1. THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair former Chair of the NICAN. Former Medical Director Western Health and Social Care Trust.
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 from SET / recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical Governance Coordinator (SHSCT)

1. 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/ Patients and families involved/ Staff involved.

1. REVIEW METHODOLOGY

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

1. DESCRIPTION OF INCIDENT/CASE

The review team conducted individual reviews on 9 patients on their treatment and care. A summary of each case is discussed within this report.

Causal deficits in their care and contributory factors were identified.

Service User A

Service User A was diagnosed with prostate cancer and was started on an anti-androgen therapy as opposed to Androgen Deprivation Therapy (ADT). This did not adhere to the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016). These Guidelines had been signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-Disciplinary Meeting (MDM), as their protocols for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. Following discussion with the families, the review team noted that there was no discussion with Service User A that the treatment given was at variance with regionally recommended practice. There was no evidence of informed consent to this alternative care pathway.

The review team have identified that during the MDM that a quorum had not been met. This was due to the absence of an oncologist from these meetings. Even so, the recommendations made by the MDM were not actioned by Dr 1. Members of the MDT may not have been aware of this, but similar practice in prescribing an anti-androgen had been challenged. Any challenges made regarding the appropriateness of treatment options were not minuted nor was the issue escalated.

The Review Team suggested that the initial assessment of Service User A was satisfactory although rather prolonged, the subsequent management with unlicensed anti-androgenic treatment (Bicalutamide) at best delayed definitive treatment. Bicalutamide (50mg) is currently only indicated before (as an anti-flare agent) or in combination with a LHRH analogue (Complete Androgen Blockade) Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer (reference is EAU guidelines), and further it decreases overall survival. Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1.7 nmol/l), which is best accomplished by the use of a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.

Service User A did not have Urology Cancer Nurse Specialist allocated to his care. The review team questioned this and it was established that whilst there were no resources for a Urology Cancer Nurse Specialist to attend any outreach clinics, their contact numbers should have been provided to the patient.

The Review Team conclude that Service User A received unconventional and inadequate treatment. The expected multi-professional involvement in his care was

omitted. Service User A's disease progressed whilst being inadequately treated. The opportunity to offer him radical treatment with curative intent was lost.

Service User B

Service User B was diagnosed clinically and biochemically with prostate cancer, and was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent (or in combination with a LHRH analogue) and is only prescribed before definitive hormonal (LHRH analogue) treatment. The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016), which was signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017). This guidance was issued when Doctor 1 was the chair of this group and had full knowledge of its contents. The review team note that, following discussion with Service User B, 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.

A biopsy result taken at the time of transurethral resection of prostate (TURP) showed benign disease (low volume sample 2g from central area of prostate). There were no further investigations to explore the clinical suspicion of prostate cancer.

The possibility of localised prostate cancer was considered from the time of presentation because the PSA was elevated; however, there was no record in the medical notes of any digital rectal examination (DRE) findings. During the operation further signs might have been elicited and appropriate biopsies could have been performed. TURP is not an adequate way to biopsy the prostate gland for suspected prostate cancer. The Review Team conclude that sufficient evidence of localised prostate cancer was apparent from the time of presentation. A correct course of action would have been to arrange appropriate staging scans and biopsies. Service User B should have undergone investigation with a MRI scan of the prostate and pelvis and a bone scan should have been considered. A transrectal biopsy performed either at the time of the TURP or separately, would have secured the diagnosis.

Arrangement could then have been made to start conventional Androgen Deprivation Therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (EBRT) potentially with radical intent. However, the patient was apparently lost to follow up after his appointment in July 2019.

Service User C

Service User C was referred to urology service following a visit to ED in December 2018. He was reviewed promptly by Dr 1 in January 2019. Investigations were arranged and a diagnosis of a large right-sided renal carcinoma was made. He was counselled regarding the risks and benefits of surgical intervention and chose to proceed with the high-risk surgery.

On 6 March 2019 Service User C was admitted for an elective radical nephrectomy.

The procedure was undertaken as planned and he was transferred to the intensive care unit (ICU) to support his blood pressure. He was later transferred to the ward. He developed a bacteraemia (infection) which was successfully managed with the advice of the microbiology team. Follow up CT scans were performed in June with a planned follow up in July 2019. This did not happen. Service User C was admitted to Ward 3 North following an ED admission. He was reviewed again via telephone in November 2019 by Dr 1 who arranged for a repeat CT scan to be performed on 17 December 2019 with a plan for review in January 2020. This did not happen.

The CT scan report was available on 11 January 2020 which showed a possible sclerotic metastasis in a vertebral body which had not been present on the previous CT scans. This report was not actioned until July 2020 when a new consultant reviewed the care. Service User C was subsequently diagnosed with prostate cancer.

The Review Team find that the treatment and care in relation to management of the renal tumour was of a high standard. High-risk surgery was performed successfully following informed consent as to the risks and benefits of the surgery. A urology review was planned for July 2019 following the CT scan report in June but this didn't happen. Service User C appeared to be lost to review. The scan performed in December 2019 with a plan to review in January was not actioned and the plan for review did not happen. This resulted in a delay in diagnosis of a prostate cancer.

Service User D

Service User D attended ED on 24 December 2018 with retention of urine. A urinary catheter was inserted, and a urology consultant review was planned to coincide with a trial removal of catheter with a specialist nurse. Service User D was placed on the waiting list for a TURP. A normal PSA result (2.79 ng/l) was noted.

On 19 June 2019 Service User D underwent a TURP. The procedure notes describe the prostate tissue as having "endoscopic appearances of prostatic carcinoma". Histology confirmed adenocarcinoma (Gleason score 5+5) in 90% of the resected tissue. His case was discussed at MDM on 25 July 2019 who noted there was no evidence of metastases on a CT abdomen and pelvis. It recommended a CT scan of chest and a bone scan to check for spread outside the prostate. Further, a LHRH agonist as ADT should be commenced. In August 2019 a bone scan and CT scan were requested together with an ultrasound scan of the urinary tract to assess bladder emptying. Doctor 1 prescribed Bicalutamide (50mgs once daily), in order to 'assess its tolerability in a generally frail man' and in the 'light of the low presenting PSA'.

The Review Team could not locate any record in the medical notes of a digital rectal examination being performed at any point during this patient's medical treatment. This may well have provided evidence to support the malignant nature of the prostate gland prompting a swifter biopsy.

The patient was discussed at MDM on 25 July 2019 when the recommendation for ADT (a LHRH analogue) was made. He should have been started on this hormonal therapy to achieve "castration testosterone levels" as soon as the diagnosis of poorly differentiated prostate cancer was made. Instead he was started on an inadequate

dose of a drug (bicalutamide) which was not licensed for the treatment of prostate cancer and was contrary to the recommendations at MDM. This therapy was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Clinical Guidelines (2016) which were signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Team, as their standard of care for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. There was no evidence in the medical notes or from speaking with Service User D's family of informed consent to this alternative care pathway.

Service User D should have been referred to an oncologist to at least allow consideration of other treatment options. His care was not coordinated with the palliative care team. The diagnosis of possible metastasis which would not have changed best practice was nevertheless pursued in a dilatory fashion. The Review Team suggested that when the patient developed anaemia consideration should have been given to the possibility of this being due to malignant involvement of the bone marrow, rather than an effect of severe chronic disease, could have been considered.

The Review Team noted that Service User D's case was not brought back to MDM for rediscussion and multi-disciplinary input despite disease progression.

Service User E

Service User E was diagnosed with testicular cancer. His case was discussed at MDM.He attended for CT chest, abdomen and pelvis on 9 July 2019 which indicated no evidence of metastases (cancer spread). The following day the patient had a left inguinal orchidectomy (removal of left testicle and full spermatic cord) carried out. Pathology of the resection specimen found that the tumour was a classical seminoma measuring 2.6cm across. Although the tumour was confined to the testes, it did involve the rete testis (exit tubules from the testis) and , in addition, intratubular germ cell neoplasia was seen. These findings indicate an increased risk of spread. Service User E's case was discussed at the Urology MDM on 25 July 2019. The plan was for Doctor 1 to review the patient in outpatients and refer him to oncology.

The patient was reviewed on 23 August 2019 and it was noted that Servicer User E had an uncomplicated recovery and his operative wound had healed satisfactorily. It was agreed that he would be reviewed in SWAH again in February 2020 by Doctor 1 to determine if the patient wished to have a testicular prosthesis implanted. The referral to oncology was made on 25 September 2019.

Although, this presentation was unusual, the progress of the patient's investigation and treatment up to the orchidectomy was of a high standard. However, the 2 month delay in his referral to a Medical Oncologist complicated treatment choices. Whether this will compromise the long-term outcome is uncertain as this treatment is recommended to be given within 6 weeks as per the designated protocol.[1,2,3]

The Review Team acknowledge that there is limited oncology presence within the Urology MDT and the date when the patient's case was discussed there was no oncologist present.

The vast majority of the Urology MDMs within the Southern Trust are non-quorate due to the absence of an oncologist and does not meet the existing guidelines. (0% quorate for 2019). (There is a regional deficit of Oncology Consultants in NI and this is recognised by HSCB. During the past 2 years, HSCB have produced a stabilisation plan for Oncology / Haematology. Southern Trust has engaged in this process. A costed plan has been prepared and is currently being considered for funding. In the interim period, the Southern Trust has worked closely with Belfast Trust to secure as much Oncology cover for MDMs as possible, whilst recognising the regional pressures in this specialty. More recently Southern Trust has advertised a shared Oncology Consultant post with Belfast and this trawl has been successful with the post to be filed in the summer 2021. This will improve cover for MDMs but significant~~ome~~ gaps will remain.)

Whilst it was the primary responsibility for the consultant in charge to make the referral to oncology a failsafe mechanism to ensure agreed actions took place, such as an MDM administration tracker, was not in place. Cancer Services Division would welcome the establishment of an MDM administrator role; however it would be helpful if the report clarified that this is not yet a commissioned role in the Trust.

Alternatively, the allocation of a Urology Cancer Specialist Nurse as a Key Worker would have supported the patient on his journey as well as having ensured key actions had taken place. Service User E was not referred to a Urology Cancer Nurse Specialist nor was any contact details provided to him. The MDM 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"[4]. This did not happen. A Key Worker/ Urology Cancer Nurse Specialist would have prompted the oncology referral sooner.

Service User F

Service User F presented with possible prostate cancer and was commenced on bicalutamide 50mgs indefinitely or until biopsy results were available. The diagnosis of prostate cancer was confirmed by biopsy in July 2019. The patient was discussed at the MDM on 8 August 2020. The diagnosis of intermediate-risk organ confined prostate cancer was agreed. The plan was that Doctor 1 should review the patient and discuss management by surveillance or by active treatment with curative intent.

When Service User F was reviewed by a locum consultant in October 2020 the patient did not recall any conversation about the options of external beam radiotherapy (EBRT) as a radical treatment and Active Surveillance. A Urology Cancer Nurse Specialist was appointed as the Key Worker at this review, not having one at time of diagnosis.

Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent and is only prescribed before definitive hormonal (LHRH analogue) treatment. Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer.

The presence of a Urology Cancer Nurse Specialist would support the patient on his journey as well as ensure key actions had taken place. Service User F was not

referred to a Cancer Nurse Specialist. This is in contrast to declaration for Cancer Peer Review 2017 “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.

Service User G

Service User G was diagnosed in June 2016 with a renal mass measuring 2.5 cms in diameter on the anteromedial cortex of the lower pole of the left kidney. The case was presented to MDM in July 2016, and the recommendation was for active surveillance with interval CT scans. These were carried out at the scheduled times.

On 23 August 2018 his case was discussed at MDM. The July 2018 scan was reviewed and now showed the lesion to measure 3.0cm. The MDM recommended to review and discuss with the patient the options of continuing active surveillance or open partial nephrectomy. The case was to be discussed at the Regional Small Masses MDM.

On 28 March 2019 at MDM the renal mass was noted to be enlarging. A further recommendation for Dr 1 to discuss the options of laparoscopic radical nephrectomy versus continued surveillance with its attendant risks was made.

On 29 March 2019 the patient was reviewed by a Locum Consultant Urologist. It was noted that the patient had a 3.1cms left sided kidney mass since July 2018 and this mass was increasing slowly in size. It was noted that the CT would be repeated in November 2019.

On 13 November 2019 a CT scan was performed which showed a further increase in size of lesion to 3.5 cms. No action was taken.

The overall progress of this patient’s management was, on balance, acceptable even though the result of the November 2019 CT scan was not acted on.

The Regional Small Renal Mass MDM was developed to oversee the management of this group of patients. An appropriate referral to this group was omitted, despite the MDM’s recommendation on at least two occasions.

The patient was reviewed in 29 March 2019 by locum consultant who appears not to have had an update from the MDM held on 28 March 2019.

The patient underwent laparoscopic radical nephrectomy on 25 November 2020 and was discharged on 27 November 2020 with a planned follow up. On 15 January 2021 Dr. 5 reviewed Service User G. He was noted to be doing well. Histopathology confirmed the left kidney mass was pT1a grade 3 papillary carcinoma (mixed oncocytic and type 2) kidney cancer. A plan for CT chest abdomen and pelvis in 12 month was agreed.

Service User H

Service User H was diagnosed with penile cancer. The pathology confirmed squamous cell carcinoma of the prepuce. There was both lymphovascular invasion and perineural infiltration, both of which are associated with an increased risk of metastatic disease, at presentation and subsequently.

The MDM was a virtual meeting conducted by a single urologist. Its plan was that Doctor 2 would review the patient and arrange for a CT scan of the Service User's chest, abdomen and pelvis to complete staging. The CT scan (26 July 2019) showed a single enlarged, left inguinal lymph node measuring 1.3cms in its short axis. Otherwise, there was no evidence of metastatic disease.

At the MDM of 12 September 2019 it was agreed that the Service User H should undergo a left inguinal lymphadenectomy. There does not appear to have been any discussion regarding the referral of Service User H to a supra-regional penile cancer MDT.

The Review Team found that the MDM recommendations did not follow NICE guidance for the management of penile cancer [6,7,8] and that there was an opportunity at each meeting to intervene and question Service User H's management.

The treatment provided to this patient was contrary to the NICAN Urology Cancer Clinical Guidelines (2016) for Penile Cancer where it states that local care is restricted to diagnosis. This Guidance was adopted by the SHSCT Urology MDT and evidenced by them as their protocols for cancer peer review 2017. Dr 1 was chair of the NICAN Urology Tumour Speciality Group when the guidance was issued.

The initial clinical assessment of Service User H would have benefited from staging imaging either before or immediately after the original circumcision. All cases of penile cancer should be discussed by the supra-network MDT as soon as the diagnosis is confirmed by biopsy.

The clinical stage G2 pT1 should have led to a consideration of surgical staging with either a bilateral inguinal lymph node dissection (ILND) or sentinel node biopsy (SNB). This omission reduced the likelihood of Service User H's 5 year survival from 90% to less than 40%. The left ILND yielded only 5 nodes, which might be considered at the lower limit of that expected in experienced hands.

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.

Service User I

Service User I was seen on 27 October 2014 with lower urinary tract symptoms that continued despite medical treatment. Doctor 1 discussed options with Service User I and he decided to proceed to surgery (TURP).

A letter dated 11 November 2016 Service User I's General Practitioner asked for

Service User I TURP to be expedited.

The Patient underwent TURP on 29 January 20 and histology confirmed prostatic adenocarcinoma.

Collation of Multidisciplinary meetings should have a fail-safe whereby lists of all urological cancers by site and SNOMED code are generated weekly. This system was not in place. Cancer Services can confirm that these reports would have been produced up to approx. 5 years ago by an experienced Biomedical Scientist in the Lab in CAH. These reports took a long time to produce and feedback from the MDMs was that they were of limited value. Cancer Services have confirmed that some labs in NI still produce these reports but not all do. Cancer Services believe that new Failsafe reports could be included with the scope of an MDM administrator role if this could be established.

Although Doctor 1 planned to review the patient in April 2020, he was not seen until August 2020 at an appointment arranged by another doctor who has continued care. The patient had done well following his TURP. The histology was explained as an incidental finding that required continuing surveillance with an up to date serum PSA level and a prostate MRI scan.

Service User I was informed on 9 September 2020 that the serum PSA level was within the normal range and that the MRI scan did not show any features of prostate cancer. The prostate cancer was considered unlikely to represent a threat during the patient's life expectancy and would not be anticipated to require any treatment other than surveillance with PSA monitoring.

1. FINDINGS

Diagnosis and Staging

- 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).
- 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.
- Service User F had a slow initial diagnostic pathway which was outside expected cancer care time-frames.
- 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. Cancer Services can confirm that the patient attend clinic on 25/05/2019 and it was noted that the CT was to be requested. The request was not raised until 08/07/2019 as an urgent referral (not Red Flag). The CT was completed 18 days after the CT was requested.
- 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.

Targets

- Three of the nine patients were said to have met one of their 31 / 62 day targets.
- Service User I was said to have met his diagnostic target for 31 days despite his tissue cancer diagnosis being missed and the patient suffering an 8 month delay. The 31 pathway for this patient has been checked against regional guidance and was met. The delays for this patient were outside the 31 day pathway and outside the scope of Cancer Trackers at this time.
- Service User H was said to have met his 62 day (1st treatment) target but had been referred down an incorrect pathway.
- Service User B was said to have met his diagnostic target of 31 days despite having a delay from initial presentation of 15 months. The 31 pathway for this patient has been checked against regional guidance and was met. The delays for this patient were outside the 31 day pathway and outside the scope of Cancer Trackers at this time.

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 follow agreed regional and supra-regional pathways for penile cancer.
- 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 for initial biopsy. Cancer Services can confirm that these reports would have been produced up to approx. 5 years ago by an experienced Biomedical Scientist in the Lab in CAH. These reports took a long time to produce and feedback from the MDMs was that they were of limited value. Cancer Services have confirmed that some labs in NI still produce these reports but not all do. Cancer Services believe that new Failsafe reports could be included with the scope of an MDM administrator role if one was to be established.
- The patient's care was through a Multidisciplinary Team process but unfortunately they did not benefit from it. The Multidisciplinary Meeting failed in its primary purpose to ensure patients received best care as defined by Regional and National Guidelines.
- The Urology MDM was under resourced and frequently non quorate

due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent Quality Assurance of images by a second radiologist prior to MDM. There is a regional deficit of Oncology Consultants in NI and this is recognised by HSCB. During the past 2 years, HSCB have produced a stabilisation plan for Oncology / Haematology. Southern Trust has engaged in this process. A costed plan has been prepared and is currently being considered for funding. In the interim period, the Southern Trust has worked closely with Belfast Trust to secure as much Oncology cover for MDMs as possible, whilst recognising the regional pressures in this specialty. More recently Southern Trust has advertised a shared Oncology Consultant post with Belfast and this trawl has been successful with the post to be filed in the summer 2021. This will improve cover for MDMs but significant~~ome~~ gaps will remain. In relation to Radiology attendance at MDMs, Cancer and Clinical Services have been working as a priority in recent years to fill vacant consultant Radiology posts. In 2016, there were 10 vacant posts and this has now been reduced down to 2 vacancies. Consultant Radiologist with a sub specialty interest in Urology continues to be one of the 'hard to fill' posts, however efforts continue to try and fill this gap. One substantive Radiologist has retrained in Urology to support the other Radiologist who attends the Urology MDM. Cover had improved during 2019, however this has been further impacted during COVID19. Cancer and Clinical Services will continue to work as a priority to improve Radiology cover to the Urology and other MDMs.

- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31 and 62 day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care. The Cancer Trackers continue to track in the same way as other Trackers across NI with the exception of Western Trust. The Cancer Tracker roles are standardised across NI and are in line with what has been commissioned to date. If the scope of the tracking is to change, this should be agreed regionally through NICAN and should be funded by the commissioner.
- Safe cancer patient care and pathway tracking is usually delivered by a three pronged approach of MDT tracking, Consultants and their secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that ~~these~~ these 9 patients were not referred to Specialist Nurses and telephone numbers were not given. The MDM tracking system was limited. The tracking is currently in line with what has been commissioned to date and is in line with tracking in other Trusts in NI with the exception of Western Trust – this has been confirmed with other Cancer Managers in NI and with the Assistant Director for Cancer Commissioning in NI The consultant / secretary led

process was variable and resulted in deficits. The weakness of the latter component was known from previous review.

- 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.

Multidisciplinary working and referral

- The review team noted repeated failure to appropriately refer patients
- 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.
- Patients were not aware that the care given varied from Regional Standards and MDM recommendations. They could not have given informed consent to this.
- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non referral was an unknown to others within the MDM.

Patient Support and Experience

All patients or families reported a positive experience with their treating consultant initially.

All patients and families were unaware of the additional support available to other patients.

Where patients had disease progression, they expressed concern at the disjointed nature of service provision and the inability to access supportive care. As they were unaware of the normal support mechanisms they believed this to be the normal standard of care or a standard that had been compromised by Covid 19 Pandemic.

All patients and their families were shocked by the fact that their care was not supported and that the care did not follow MDM recommendations. This was especially true when appropriate care should have entailed onward referral to oncology or palliative care.

Affects of Covid

- Some patient's planned review appointments did not go ahead but were rescheduled virtually. Some of the patients did not have their planned review in March / April 2020.

- The review team after speaking with the families and hearing their stories learned that for many of these patients they could not access services in their locality due to the covid restrictions. At the time two families described having difficulty accessing district nursing services for intravenous antibiotics in the community as services were stood down. One family expressed dismay at having difficulties visiting their loved one prior to his passing in hospital due to the covid restrictions and the emotional impact this has had on their grieving process. Others described how when catheters blocked they could not access support from their GP and where hence referred to the Emergency Department which the review team agree was not the best place for them. The review team are of the opinion that access to a specialist nurse could have offered support for these families and provide direction to the appropriate services.

Governance / Leadership

- The review team considered the treatment and care of 9 patients who were treated under the care of Dr 1 Consultant Urologist. Individual reviews were conducted on each patient. The review team identified a number of recurrent themes following each review.
- 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.
- The Urology MDM made recommendations that were deemed appropriate in 8 of 9 cases and were made with contribution and knowledge of Dr.1. Many of the recommendations were not actioned or alternative therapies given. There was no system to track if recommendations were appropriately completed. Cancer Trackers will track patients on the 31 and 62 day pathways in line with what has been commissioned. This is confirmed to be the case in other Trusts in NI with the exception of Western Trust. The responsibility for following

up other actions sits with the clinician and his / her secretary.

- 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.
- The review team considered if this was endemic within the Multidisciplinary Team and concluded that it was not. Patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.
- Statements to Urology Cancer Peer Review (2017) indicated that all patients had access to a Key worker / Urology Cancer Nurse Specialist. This was not the case and was known to be so. It would be helpful if the report stated who was aware of this issue.
- The Urology Cancer Nurse Specialist play an integral role of the MDT and should be facilitated on all the MDM to advocate on patient's best interest throughout the patient's journey. This should include independently referring and discussing patients at MDT.
- The Review Team regard absence of Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and the Professional Leads. The Review team have heard differing reports around escalation of this issue but are clear that patients suffered significant deficit because of non inclusion of nurses in their care. While this is the primary responsibility of the referring consultant, there is a responsibility on the SHSCT to know about the issue and address it. It would be helpful if the report stated who was aware of this issue.
- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered. Additional capacity for targeted assurance audits would be useful for MDMs and for Cancer Services.
- Because of resource~~,~~ the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31 and 62 day targets. Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were,in essence absent. It is important to state that the Cancer Trackers are commissioned to track patients on the 31 and 62 day pathways. It is incorrect to suggest that the scope of tracking was limited due to resources or due to the process being flawed. The Trackers perform this function in line with what has been commissioned and it is in line with other Trusts in NI with the exception

of Western Trust. Changes to the scope of tracking should be agreed regionally through NICAN and be consistent across Trusts in NI.

- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report. Cancer Services agree that additional capacity to support compliance audits would be helpful.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM, but did not escalate other issues. Comments noted above provide evidence of actions taken by Cancer Services to help address deficits in Oncology and Radiology input to MDMS – therefore we would suggest that this parapraph is incorrect.
- The Review team found that issues around prescribing and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.
- The Review team were concerned that the leadership roles focused on service delivery while having a limited process to benchmark quality, identify deficiencies and escalate concerns as appropriate. Senior managers and clinical leaders in medicine and nursing were unaware of the issues detailed in this report.
- There had been a previous SAI signed off in May 2020 regarding adherence to Cancer Red Flag referral Pathways. The SAI process started in July 2016. The review team is concerned that, as part of early learning, assurances regarding other aspects of the cancer pathway were not sought. Clinical Leadership within Cancer Services were unaware of issues leading to the SAI in 2016.
- Patients in this review were not referred back appropriately to MDM as their diseased progressed. This meant there was no access to oncology and palliative care for many patients, when needed. Care needs within the community were unmet and patients left isolated.

1. 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.

1. LESSONS LEARNED

The review identified Cancer Care given by Dr 1 that did not follow agreed MDM recommendations nor follow regional or national best practice guidance. It was care given without other input from Cancer Specialist Nurses, Oncology and palliative care. It was inappropriate, did not meet patient need and was the antithesis of quality multidisciplinary cancer care.

Ensure all patients receive appropriately supported high quality cancer care irrespective of the professional delivering care.

Ensure all cancer care is multidisciplinary and centred on patients physical and emotional need.

Have processes in place to provide assurances to patients and public that care meets these requirements.

That the role of the Multidisciplinary Meeting Chair is defined by a Job Description with specific reference to Governance, Safe Care and Quality Care. It should be resourced to provide this needed oversight.

1. RECOMMENDATIONS AND ACTION PLANNING

The recommendations represent an enhanced level of assurance. They are in response to findings from nine patients where Dr 1 did not adhere to agreed recommendations, varied from best practice guidance and did not involve other specialist appropriately in care. They are to address what was asked of the Review by families - "that this does not happen again".

Recommendation 1.

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients.

This will be achieved by - Urology Cancer Care delivered through 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.

Timescale – Immediate (suggest the timescale reflects the time to plan and implement the peer review process– possibly 3 months)

Assurance - Comprehensive Pathway audit of all patients care and experience. This should be externally benchmarked within a year by Cancer Peer Review / External Service Review by Royal College.

Recommendation 2.

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 will be achieved by - Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent.

Timescale - Immediate

Assurance - Comprehensive Cancer Pathway audit and Patient experience.

Recommendation 3.

The SHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely.

This will be achieved by - Ensuring a culture primarily focused on patient safety and respect for the opinions of all members. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical Cancer Services oversight fortnightly agenda. There must be action on issues escalated.

Cancer Services suggest that the MDM chair is the main point of escalation in the first instance where it is suggested that patient safety is compromised. The MDM chair should then address the issue and involve the CD/AMD for the specialty and also the CD/AMD for Cancer. The recommendation refers to a fortnightly cancer services meeting. The Cancer Service meeting is actually a monthly meeting with the AMD, CD, AD and HOS present. We believe the fortnightly meeting may be a reference to a COVID rebuild Friday PM meeting which is not the correct forum for raising issues of this nature.

Furthermore, Cancer Services recommend that a quarterly Cancer Services Oversight Group be established to oversee delivery of cancer care. This was proposed pre-COVID 19 as a forum to raise the profile of Cancer Services with a focus on service improvement. With the learning from these SAIs, we believe the TOF for this group should be revisited and a governance role included.

Cancer Services believe governance around delivery of cancer care could be improved by:

- Reviewing the role of chair of MDMs
- Reviewing the role of all AMDs, CDs, ADs and HOS involved in delivery cancer care
- Closer working between the chair of MDMs, other Divisions and Cancer Services
- Additional capacity for clinical audit to support assurance audits
- Establishment of MDM administrator and a new failsafe function for histopathology
- Additional support for tracking

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Timescale – Immediate (suggest this work may take 3-6 months to complete)

Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, numbers of issues outstanding.

Recommendation 4.

The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.

This will be achieved by - All MDMs being quorate with professionals having appropriate time in job plans.This is not solely related to first diagnosis and treatment targets. Re-discussion of patients, as disease progresses is essential to facilitate best multidisciplinary decisions and onward referral (e.g. Oncology, Palliative care, Community Services).

Cancer Service agrees that we should be aiming to have all MDMs quorate as soon as possible. We do need to acknowledge that some of the gaps are due to regional deficits in workforce – Oncology and Radiology being two examples of this. Cancer and Clinical Services are working to address the Radiology gap as noted above in this report. The Oncology gap is more difficult to address as this support is mainly provided to the Trust by Belfast Trust.

Timescale - 3 months (given that this is a regional gap, it may take much longer than 3 months to address this – possible up to 1 year)

Assurance - Quorate meetings, sufficient radiology input to facilitate pre MDM QA of images - Cancer Patient pathway Audit - Audit of Recurrent MDM discussion - Onward referral audit of patients to Oncology / Palliative Care etc.

Recommendation 5.

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 will be achieved by - Appropriate resourcing of the MDM tracking team to encompass a new role comprising whole pathway tracking, pathway audit and pathway assurance. This should be supported by fail-safe mechanisms from laboratory services and Clinical Nurse Specialists as Key Workers A report should be generated weekly and made available to the MDT. The role should reflect the enhanced need for ongoing audit / assurance. It is essential that current limited clinical resource is focused on patient care.

As stated in the feedback above, the Cancer Trackers currently track patients on the 31 and 62 day pathways. This is in line with what has been commissioned to date. If the tracking role is to change, we suggest that this will need to be considered regionally and endorsed through NICAN. If full pathway tracking was to be introduced for all tumour sites, this would require a major investment - possibly seeing the current tracking team double and possibly triple in size from 8wte to between 16 and 24 Band 4 staff. Given the workforce / financial implications of this, we may need to consider putting this in place for Urology in the first instance and then looking to expand further in due course

Timescale - 3 months (given the lead in time for securing funding, recruitment and training, it would be more realistic to state 6 months for this recommendation and that would be for Urology MDM only)

Assurance - Comprehensive Cancer care Pathway audit - Exception Reporting and escalation

Recommendation 6.

The Southern Health and Social Care Trust must ensure that there is an appropriate Governance Structure supporting cancer care based on patient need, patient experience and patient outcomes.

This will be achieved by - Developing a proactive governance structure based on comprehensive ongoing Quality Assurance Audits of care pathways and patient experience for all. It should be proactive and supported by adequate resources.This should have an exception reporting process with discussion and potential escalation of deficits. It must be multidisciplinary to reflect the nature of cancer and work with other directorates.

Comments for recommendation 3 above also apply to this recommendation.

Timescale - 3 months

Assurance - Cancer Pathway Audit outcomes with exception discussion and escalation. Data should be declared externally to Cancer Peer Review

Recommendation 7.

The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.

See comments for recommendation 3 above. Cancer Services believe it would be prudent to review the Job Descriptions for the chair of the MDMs alongside those for the AMDs, CDs, ADs and HOS involved in delivery cancer care. This is necessary to have complete clarity around the clinical governance function for Cancer Care and also the escalation arrangements where there are concerns in relation to patient safety.

Timescale - 3 months

Recommendation 8.

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

This will be achieved by - Ensuring the multi-disciplinary team meeting is the primary 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.

Timescale - Immediate

Assurance - Variance from accepted Care Guidelines and MDM recommendations should form part of Cancer Pathway audit. Exception reporting and escalation would only apply to cases without appropriate peer discussion.

Recommendation 9.

The roles of the Clinical Lead Cancer Services and Associate Medical Director Cancer Services should be reviewed. The SHSCT must consider how these roles can redress Governance and Quality Assurance deficits identified within the report.

See comments against recommendation 7 above. Same comments apply to recommendation 9.

Timescale - 3 months

Recommendation 10.

--This recommendation will be agreed following discussion with families.

Recommendation 11

The Southern Health and Social Care Trust should consider if assurance mechanisms detailed above, should be applied to patients or a subset of patients retrospectively.

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. https://uroweb.org/guideline/testicular-cancer/note_127-129 (accessed 26/02/2021)

4. Peer review Self-Assessment report for NICaN 2017

5. Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016)

6. EAU guidelines for penile cancer: section 6.2.1 (2019)

1. NICE improving outcomes in urological cancer (2002)

1. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).

1. 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 AMPs

PHA

HSCB

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report <u>for all levels of SAI reviews)</u>

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER						
1. Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**	
	Comment: ***If multiple service users involved please indicate the number involved***					
1. Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**			
	If **YES**, insert **date informed**:					
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI					
	a. No contact or Next of Kin details or Unable to contact					
	a. Not applicable as this SAI is not 'patient/service user' related					
	a. Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user					
	a. Case involved suspected or actual abuse by family					
	a. Case identified as a result of review exercise					
	a. Case is environmental or infrastructure related					

	with no harm to patient/service user	
	a. Other rationale	
	If you selected c), d), e), f) or g) above please provide further details:	

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

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

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

1. Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**	**x**	**NO**	
	If **YES**, insert date informed: **all informed 26 October 2020**			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a. Draft review report has been shared and further engagement planned to share final report			
	a. Plan to share final review report at a later date and further engagement planned			
	a. Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	a. No contact or Next of Kin or Unable to contact			
	a. No response to correspondence			
	a. Withdrew fully from the SAI process			
Continued overleaf	a. Participated in SAI process but declined review report			
	(if you select any of the options below please also complete 'I' below)			
	a. concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer			
	a. case involved suspected or actual abuse by family			
	a. identified as a result of review exercise			
	a. other rationale			

	a. If you have selected **c), h), i), j), or k)** above please provide further details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2

INFORMING THE CORONER S OFFICE **(under section 7 of the Coroners Act (Northern Ireland) 1959)** ***(complete this section for all death related SAIs)***				
1. Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
1. Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
1. If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

1.“There is a regional deficit of Oncology Consultants in NI and this is recognised by HSCB. During the past 2 years, HSCB have produced a stabilisation plan for Oncology / Haematology. Southern Trust has engaged in this process. A costed plan has been prepared and is currently being considered for funding. In the interim period, the Southern Trust has worked closely with Belfast Trust to secure as much Oncology cover for MDMs as possible, whilst recognising the regional pressures in this specialty. More recently Southern Trust has advertised a shared Oncology Consultant post with Belfast and this trawl has been successful with the post to be filed in the summer 2021. This will improve cover for MDMs but significant gaps will remain.”

The review team does not accept a differential service for patients based on geography and the report is based on what should be present. It is expected that the out-workings of the SAI will result in better and appropriate resourcing for patients of the SHSCT.

2. “Cancer Services Division would welcome the establishment of an MDM administrator role; however it would be helpful if the report clarified that this is not yet a commissioned role in the Trust.”

This is not the experience of the external members of the review team elsewhere in NI and the UK. The review is based on what is best regional and national practice and that which results in the safest possible service for patients. Commissioning within trust resource or regional resource is not within the remit of a Serious Adverse Incident Review.

3 “Cancer Services can confirm that these reports would have been produced up to approx. 5 years ago by an experienced Biomedical Scientist in the Lab in CAH. These reports took a long time to produce and feedback from the MDMs was that they were of limited value. Cancer Services have confirmed that some labs in NI still produce these reports but not all do. Cancer Services believe that new Failsafe reports could be included with the scope of an MDM administrator role if this could be established”

This is not the experience of the external members of the SAI review team. The fail-safe cancer lists are generated by T site codes and M diagnosis codes for malignancy (xxxx3) weekly, by clerical staff who liaise with MDM trackers. It provides additional assurance and would have been of benefit in cases where patients are lost to follow. Critically it also ensures rapid referral of patients to MDM and better adherence to 31 and 62 day targets.

4. “Cancer Services can confirm that the patient attend clinic on 25/05/2019 and it was noted that the CT was to be requested. The request was not raised until 08/07/2019 as an urgent referral (not Red Flag). The CT was completed 18 days after the CT was requested”

The review included the overarching CT timeline, as the critical issue was that the patient had a potentially aggressive tumour and should have been on an appropriately timed pathway that was supported by tracking and assurance mechanisms. The 17week delay should not have happened and ideally systems would have been in place to prevent this.

The recommendations in the over-arching SAI review propose patient pathways should be tracked in real time and prevent such delays.

5. “Cancer Trackers will track patients on the 31 and 62 day pathways in line with what has been commissioned. This is confirmed to be the case in other Trusts in NI with the exception of Western Trust. The responsibility for following up other actions sits with the clinician and his / her secretary.”

This is not the experience of the external members of the SAI review team in NI and UK. Critically the resource in SHSCT Urology MDM was unable to meet patient tacking need in these 9 SAIs and in a previous SAI of 2016. Patients came to harm. The review team believe it essential that enhanced resource is in place to improve MDM tracking, in concert with Key workers (usually Urology Cancer Nurse Specialists) and consultant secretaries. This has been shared with the Urology MDM and welcomed, given that several members had previous experience of this approach from the UK.

6 and 7 “It would be helpful if the report stated who was aware of this issue.”

“With the appointment of two more Nurses to the Thorndale Unit and Clerical Staff, 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. It is intended that patients newly diagnosed as inpatients will also be included.”

The above statement was made on behalf of the SHSCT to Urology Cancer Peer Review 2017 – it has proven to be inaccurate and not based on an assurance audit process. The review team appreciated the candour of those who admitted to being aware that not all care was supported by Cancer Nurse Specialists. They do expect that governance processes are enhanced to ensure that no patients receive cancer care unsupported and without linkages to other critical services.

8 ”Additional capacity for targeted assurance audits would be useful for MDMs and for Cancer Services.”

The review team have considered this in the recommendations going forward. They believe prospect assurance audit must be supported by resource and infrastructure. However between 2017 and 2020 assurance audit was limited in the Urology Service and much led by Urology Nurse Specialists. There was no evidence of targeted audit work in areas of known problems or concerns. Appropriate resourcing of audit should be within the remit of Cancer Service Management and Clinical leadership.

9.”It is important to state that the Cancer Trackers are commissioned to track patients on the 31 and 62 day pathways. It is incorrect to suggest that the scope of tracking was limited due to resources or due to the process being flawed. The Trackers perform this function in line with what has been commissioned and it is in line with other Trusts in NI with the exception of Western Trust. Changes to the scope of tracking should be agreed regionally through NICAN and be consistent across Trusts in NI”

The 9 SAI reports detailed wide ranging delays and deficits in care that were not and could not be detected with the current tracking resource within SHSCT Urology Cancer MDT. The external members of the SAI review team have different experiences of cancer tracking, something which is shared by several consultant members of the Urology MDT with UK experience. Patients came to harm which could have been prevented by enhanced tracking. The SHSCT is responsible for governance of this service and resource must meet clinical risk and patient need.

10.Cancer Services agree that additional capacity to support compliance audits would be helpful.

No comment.

11. Comments noted above provide evidence of actions taken by Cancer Services to help address deficits in Oncology and Radiology input to MDMS – therefore we would suggest that this paragraph is incorrect.

The Chair of the SAI review would dispute this as it is not based on data – attendance at MDM by oncology had become progressively worse in the year 2020 (5%) and radiology is still single handed without appropriate pre- MDM independent review of images. This was a live concern and frustration of the SHSCT Urology MDM 18th February 2021.

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: [redacted]
Personal Information redacted by USI

Date of Incident/Event: Multiple dates

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: Male Age:

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

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 to the patients identified and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided. Nine patients have been identified as potentially suffering harm. This review will examine the timelines of each individual case and analyse if any deficits in treatment or care has occurred. As part of the review the cancer pathways will be used to determine where learning can be extracted.

The SHSCT recognise the life changing and devastating consequences to the 9 families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care they received.

2.0 THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair, former Chair of the NICAN. Former Medical Director Western Health and Social Care Trust.
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 from SET / recently SHSCT).
Mrs Patricia Kingsnorth – Acting Acute Clinical 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.

3.0 SAI REVIEW TERMS OF REFERENCE

- To share the report with the Director of Acute Services / Medical Director of SHSCT / HSCB / Patients and families involved / Staff involved.

4.0 REVIEW METHODOLOGY

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

5.0 DESCRIPTION OF INCIDENT/CASE

The review team conducted individual reviews on nine patients on their treatment and care. A summary of the findings of each case is discussed within this report.

6.0 FINDINGS

Diagnosis and Staging

- 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).
- 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.
- Service User F had a slow initial diagnostic pathway which was outside expected cancer care time-frames.
- 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

6.0	FINDINGS

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.

Targets

- Three of the nine patients were said to have met one of their 31 / 62 day targets.
- Service User I was said to have met his diagnostic target for 31 days despite his tissue cancer diagnosis being missed and the patient suffering an 8 month delay.
- Service User H was said to have met his 62 day (1st treatment) target but had been referred down a pathway that did not meet the NICAN Urology Cancer Guidelines 2016. A Regional Penile Cancer Pathway was agreed in January 2020.
- Service User B was said to have met his diagnostic target of 31 days despite having a delay from initial presentation of 15 months.

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

6.0	FINDINGS

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. A Regional Penile Cancer Pathway was only agreed in January 2020.
- 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 for initial biopsy.
- The patient's care was through a Multidisciplinary Team process but unfortunately they did not benefit from it. The Multidisciplinary Meeting failed in its primary purpose to ensure patients received best care as defined by Regional and National Guidelines.
- The Urology MDM was under resourced and frequently non quorate due to lack of professionals. The MDM had quorate rates of 11% in 2017, 22% in 2018 0% in 2019 and 5% in 2020. This was usually due to lack of clinical oncology and medical oncology. Radiology had only one Urology Cancer Specialist Radiologist impacting on attendance but critically meaning there was no independent quality assurance of images by a second radiologist prior to MDM.
- The Urology MDM was under resourced for appropriate patient pathway tracking. The Review Team found that patient tracking related only to diagnosis and first treatment (that is 31 and 62 day targets). It did not function as a whole system and whole pathway tacking process. This resulted in preventable delays and deficits in care.
- Safe cancer patient care and pathway tracking is usually delivered by a three pronged approach of MDT tracking, Consultants and their Secretaries and Urology Specialist Nurses, in a Key Worker role. The Review found that these 9 patients were not referred to Specialist Nurses and contact telephone numbers were not given. Therefore the CNS were not given the opportunity to provide support and discharge duties to the 9 patients who suffered as a consequence. The MDM tracking system was limited. The consultant / secretary led process was variable and resulted in deficits. The weakness of the latter component was known from previous review.
- As patients were not re-discussed at MDM and Urology Cancer Nurse

6.0 FINDINGS

Specialist were not involved in care, non implementation of these MDM recommendations was unknown to others in the MDM. One patient [redacted] presented as an emergency and his care was changed to the MDM recommendation by another consultant.

Multidisciplinary working and referral

- The review team noted repeated failure to appropriately refer patients.
- 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 Regnional Penile Cancer Pathway was only agreed in January 2020.
- Patients were not aware that the care given varied from regional standards and MDM recommendations. They could not have given informed consent to this.
- All patients were not referred to Urology Cancer Nurse Specialists despite this resource being increased by the Southern Health and Social Care Trust. Peer Review 2017 was informed that this resource was available to all. Their contact numbers were not made available.
- As patients were not re-discussed at MDM and Urology Cancer Nurse Specialist were not involved in care, non referral was an unknown to others within the MDM.

Patient Support and Experience

All patients or families reported a positive experience with their treating consultant initially. All patients and families were unaware of the additional support available to other patients.

Where patients had disease progression, they expressed concern at the disjointed nature of service provision and the inability to access supportive care. As they were unaware of the normal support mechanisms they believed this to be the normal standard of care or a standard that had been compromised by Covid 19 Pandemic.

All patients and their families were shocked by the fact that their care was not supported and that the care did not follow MDM recommendations. This was especially true when appropriate care should have entailed onward referral to oncology or palliative care.

Effects of Covid

- Some patient's planned review appointments did not go ahead but were

6.0	FINDINGS

rescheduled virtually. Some of the patients did not have their planned review in March / April 2020.

- The review team after speaking with the families and hearing their stories learned that for many of these patients they could not access services in their locality due to the covid restrictions. At the time two families described having difficulty accessing district nursing services for intravenous antibiotics in the community as services were stood down. One family expressed dismay at having difficulties visiting their loved one prior to his passing in hospital due to the covid restrictions and the emotional impact this has had on their grieving process. Others described how when catheters blocked they could not access support from their GP and where hence referred to the Emergency Department which the review team agree was not the best place for them. The review team are of the opinion that access to a specialist nurse could have offered support for these families and provide direction to the appropriate services.

Governance / Leadership

- The review team considered the treatment and care of 9 patients who were treated under the care of Dr 1 Consultant Urologist. Individual reviews were conducted on each patient. The review team identified a number of recurrent themes following each review.
- 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.
- The Urology MDM made recommendations that were deemed appropriate in 8 of 9 cases and were made with contribution and knowledge of Dr.1. Many of the recommendations were not actioned or alternative therapies given. There was no system to track if recommendations were appropriately completed.
- 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.
- The review team considered if this was endemic within the Multidisciplinary Team and concluded that it was not. Patients booked under other consultant urologists had access to a specialist nurse to assist them with their cancer journey.
- Statements to Urology Cancer Peer Review (2017) indicated that all patients had access to a Key worker / Urology Cancer Nurse Specialist. This was not

6.0	FINDINGS

the case and was known to be so.

- The Urology Cancer Nurse Specialists play an integral role of the MDT and should be facilitated on all the MDM to advocate on patient's best interest throughout the patient's journey. This should include independently referring and discussing patients at MDT.
- The Review Team regard absence of Specialist Nurse from care to be a clinical risk which was not fully understood by Senior Service Managers and the Professional Leads. The Review team have heard differing reports around escalation of this issue but are clear that patients suffered significant deficit because of non inclusion of nurses in their care. While this is the primary responsibility of the referring consultant, there is a responsibility on the SHSCT to know about the issue and address it.
- Assurance audits of patient pathways within the Urology Cancer Services were limited between 2017 and 2020. They could not have provided assurance about the care delivered.
- Because of resource, the MDM was very focused on first presentation at MDM and did not have a role in tracking subsequent actions if it lay outside 31 and 62 day targets. Tracking of patients was flawed by limitations within the MDM systems and the lack of Specialist Urology Nurses from their Key Worked role. Two of the three normal safety nets for patient pathway completion were,in essence absent. A collaborative approach did not appear to be actively encouraged within the MDT.
- Annual business meetings had an expressed role in identifying service deficits and drawing up an annual work plan to address them. Cancer Patient Pathway compliance audits were limited and did not identify the issues within this report.
- Governance of professionals within the MDT ran through their own directorates but there was no functioning process within Cancer Services to at least be aware of concerns - even if the responsibility for action lay elsewhere within the Southern Health and Social Care Trust. There was disconnect between the Urology MDT and Cancer Services Management. The MDT highlighted inaction by Cancer Services on Oncology and radiology attendance at MDM, but did not escalate other issues.
- The Review team found that issues around prescribing and the use of Clinical Nurse Specialists were of long standing. They were known internally and in the case of prescribing externally (Regional Oncology Services). The Northern Ireland Cancer Network drew up specific Guidance on Hormonal Therapy in Prostate Cancer in 2016 following concerns about this issue. The Guidance was not subject to audit within the Southern Health and Social Care Trust.
- The Review team were concerned that the leadership roles focused on service delivery while having a limited process to benchmark quality, identify deficiencies and escalate concerns as appropriate. Senior managers and clinical leaders in medicine and nursing were unaware of the issues detailed in this report.
- There had been a previous SAI signed off in May 2020 regarding adherence to Cancer Red Flag referral Pathways. The SAI process started in July 2016. The

6.0 FINDINGS

review team is concerned that, as part of early learning, assurances regarding other aspects of the cancer pathway were not sought. Clinical Leadership within Cancer Services were unaware of issues leading to the SAI in 2016.

- Patients in this review were not referred back appropriately to MDM as their diseased progressed. This meant there was no access to oncology and palliative care for many patients, when needed. Care needs within the community were unmet and patients left isolated.

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 from Dr 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.

8.0 LESSONS LEARNED

The review identified Cancer Care given by Dr 1 that did not follow agreed MDM recommendations nor follow regional or national best practice guidance. It was care given without other input from Cancer Specialist Nurses, Oncology and palliative care. It was inappropriate, did not meet patient need and was the antithesis of quality multidisciplinary cancer care.

Ensure all patients receive appropriately supported high quality cancer care irrespective of the professional delivering care.

Ensure all cancer care is multidisciplinary and centred on patients physical and emotional need.

Have processes in place to provide assurances to patients and public that care meets these requirements.

That the role of the Multidisciplinary Meeting Chair is defined by a Job Description with specific reference to Governance, Safe Care and Quality Care. It should be resourced to provide this needed oversight.

9.0 RECOMMENDATIONS AND ACTION PLANNING

The recommendations represent an enhanced level of assurance. They are in response to findings from nine patients where Dr 1 did not adhere to agreed recommendations, varied from best practice guidance and did not involve other specialist appropriately in care. They are to address what was asked of the Review by families - "that this does not happen again".

Recommendation 1.

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients.

This will be achieved by - Urology Cancer Care delivered through 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.

Timescale – Immediate and ongoing

Assurance - Comprehensive Pathway audit of all patients care and experience. This

9.0 RECOMMENDATIONS AND ACTION PLANNING

should be externally benchmarked within a year by Cancer Peer Review / External Service Review by Royal College.

Recommendation 2.

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 will be achieved by - Ensuring all patients receive multidisciplinary, easily accessible information about the diagnosis and treatment pathway. This should be verbally and supported by documentation. Patients should understand all treatment options recommended by the MDM and be in a position to give fully informed consent.

Timescale - Immediate and ongoing

Assurance - Comprehensive Cancer Pathway audit and Patient experience.

Recommendation 3.

The SHSCT must promote and encourage a culture that allows all staff to raise concerns openly and safely.

This will be achieved by - Ensuring a culture primarily focused on patient safety and respect for the opinions of all members. The SHSCT must take action if it thinks that patient safety, dignity or comfort is or may be compromised. Issues raised must be included in the Clinical Cancer Services oversight fortnightly agenda. There must be action on issues escalated.

Timescale – Immediate and ongoing

Assurance - Numbers of issues raised through Cancer Services, Datix Incidents identified, numbers of issues resolved, numbers of issues outstanding.

Recommendation 4.

The Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals.

This will be achieved by - All MDMs being quorate with professionals having appropriate time in job plans.This is not solely related to first diagnosis and treatment targets. Re-discussion of patients, as disease progresses is essential to facilitate best multidisciplinary decisions and onward referral (e.g. Oncology, Palliative care, Community Services).

Timescale - 3 months and ongoing

Assurance - Quorate meetings, sufficient radiology input to facilitate pre MDM QA of images - Cancer Patient pathway Audit - Audit of Recurrent MDM discussion - Onward referral audit of patients to Oncology / Palliative Care etc.

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 5.

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 will be achieved by - Appropriate resourcing of the MDM tracking team to encompass a new role comprising whole pathway tracking, pathway audit and pathway assurance. This should be supported by fail-safe mechanisms from laboratory services and Clinical Nurse Specialists as Key Workers. A report should be generated weekly and made available to the MDT. The role should reflect the enhanced need for ongoing audit / assurance. It is essential that current limited clinical resource is focused on patient care.

Timescale - 3 months

Assurance - Comprehensive Cancer care Pathway audit - Exception Reporting and escalation.

Recommendation 6.

The Southern Health and Social Care Trust must ensure that there is an appropriate Governance Structure supporting cancer care based on patient need, patient experience and patient outcomes.

This will be achieved by - Developing a proactive governance structure based on comprehensive ongoing Quality Assurance Audits of care pathways and patient experience for all. It should be proactive and supported by adequate resources.This should have an exception reporting process with discussion and potential escalation of deficits. It must be multidisciplinary to reflect the nature of cancer and work with other directorates.

Timescale - 3 months

Assurance - Cancer Pathway Audit outcomes with exception discussion and escalation. Data should be declared externally to Cancer Peer Review

Recommendation 7.

The role of the Chair of the MDT should be described in a Job Description, funded appropriately and have an enhanced role in Multidisciplinary Care Governance.

Timescale - 3 months

Recommendation 8.

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

This will be achieved by - Ensuring the Multi-Disciplinary Team meeting is the primary 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

9.0 RECOMMENDATIONS AND ACTION PLANNING

defer to the opinion of his / her peers or justify any variation through the patient's documented informed consent.

Timescale – Immediate and ongoing

Assurance - Variance from accepted Care Guidelines and MDM recommendations should form part of Cancer Pathway audit. Exception reporting and escalation would only apply to cases without appropriate peer discussion.

Recommendation 9.

The roles of the Clinical Lead Cancer Services and Associate Medical Director Cancer Services should be reviewed. The SHSCT must consider how these roles can redress Governance and Quality Assurance deficits identified within the report.

Timescale - 3 months

Recommendation 10.

The families working as "Experts by Experience" have agreed to support implementation of the recommendations by receiving updates on assurances at 3, 6 and 12monthly intervals.

Recommendation 11

The Southern Health and Social Care Trust should consider if assurance mechanisms detailed above, should be applied to patients or a subset of patients retrospectively.

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. https://uroweb.org/guideline/testicular-cancer/note_127-129 (accessed 26/02/2021)

4. Peer review Self-Assessment report for NICaN 2017

5. Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016)

6. EAU guidelines for penile cancer: section 6.2.1 (2019)

7. NICE improving outcomes in urological cancer (2002)

8. NICAN Urology Cancer Clinical Guidelines (March 2016), Penile Cancer treatment Section 9.3 (3).

9.0	RECOMMENDATIONS AND ACTION PLANNING

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 AMPs

PHA

HSCB

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report <u>for all levels of SAI reviews)</u>

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**		
	Comment: ***If multiple service users involved please indicate the number involved***						
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**		**NO**				
	If **YES**, insert **date informed**:						
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI						
	a) No contact or Next of Kin details or Unable to contact						
	b) Not applicable as this SAI is not 'patient/service user' related						
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user						
	d) Case involved suspected or actual abuse by family						
	e) Case identified as a result of review exercise						
	f) Case is environmental or infrastructure related with no harm to patient/service user						
	g) Other rationale						
	If you selected c), d), e), f) or g) above please provide further details:						
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**							
Content with rationale?	**YES**		**NO**				

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**	x	**NO**				
	If **YES**, insert date informed: **all informed 26 October 2020**						
	If **NO**, please select **<u>only one</u>** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer						
	a) Draft review report has been shared and further engagement planned to share final report						
	b) Plan to share final review report at a later date and further engagement planned						
	c) Report not shared but contents discussed **(*if you select this option please also complete 'l' below*)**						

[1]*Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**d)** No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	**1.3.2021**

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: [redacted]

Date of Incident/Event: 31/10/2019

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M
Age: ([redacted])

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

Patient 1 a Personal Information redacted by the USI 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. Patient 1 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. Patient 1's disease progressed and he passed away on Personal Information redacted by the USI.

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.

Review of Medical Notes

Interviews with Staff

Family Engagement

Review of Northern Ireland Health Care Records

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 1, a Personal Information redacted by the USI-old gentleman, was referred by his GP to the urology service at in Western Trust on 13 June 2019; he had a raised PSA (19ng/ml) which is a blood test used to assess the risk of the presence of prostate cancer. His past medical history included Personal Information redacted by the USI

The 'red flag' urgent referral was received on 14 June 2019 and triaged by Dr.1 (Consultant Urologist) on 17 June 2019. A MRI scan of the prostate and pelvis was requested to be done prior to an appointment scheduled for 22 July 2019.

the prostate and, at the front of the gland, a moderately suspicious (PIRADS 3) area of possible prostate cancer, but also some highly suspicious changes (PIRADS 5) in the peripheral zone.

Patient 1 was reviewed by Dr.1 on 22 July 2019 and was advised that he may have a malignancy of his prostate gland and that further investigations would be required. An ultrasound scan of the bladder and urinary tract and an appointment for prostate biopsies were arranged.

On 20 August 2019, Patient 1 attended the Prostate Biopsy Clinic under the care of Nurse 1. The procedure was completed without complication and the samples were sent to histopathology. The results of the biopsy, reported on 28 August 2019, showed adenocarcinoma of prostate (Gleason 4+3), but there was no evidence of perineural infiltration, lymphovascular invasion or extracapsular extension.

The ultrasound scan of the urinary tract, performed on 21 August 2019, showed normal kidneys and normal bladder appearance although there was a post void residual of 204mls of urine.

Patient 1's case was discussed at the Urology Multidisciplinary Meeting (MDM) on 29 August 2019. He was noted to have been taking Finasteride 5mgs since 2010. A radioisotope bone scan and a CT scan of chest, abdomen and pelvis were recommended to stage the prostate cancer. Patient 1's General Practitioner (GP) was

5.0 DESCRIPTION OF INCIDENT/CASE

advised of the outcome of the MDM by letter.

Patient 1 was reviewed by Dr.1 on 23 September 2019 and was told that he had high-risk prostate cancer. No staging investigations were requested. Instead, he was prescribed Bicalutamide150mgs once daily and Tamoxifen 10mgs once daily in order to minimise the risk of breast tenderness a possible side-effect of the anti-androgen.

Patient 1 received a follow up phone call from Dr.1 on 14 October 2019 following a request for advice regarding the potential side effects to his medication. Dr.1 reported that Patient 1 was experiencing some light headedness and dizziness, which was affecting his ability to drive. Dr.1 advised Patient 1 to cease both hormonal medications. However, although Patient 1's PSA was noted to be rising (21.8ng/ml), a plan was made to re-check the PSA level. The bone scan and CT scans were also arranged. Patient 1 was advised to recommence Bicalutamide at a lower dose (50mgs once daily) from 1 November 2019.

Patient 1 was discussed again at MDM on 31 October 2019. His bone scan and CT scan showed no metastatic spread of disease outside the prostate. A recommendation to commence androgen deprivation therapy (a LHRH analogue) and refer for an opinion from a Clinical Oncologist regarding external beam radiation therapy (EBRT) was agreed.

Patient 1 attended his outpatient appointment with Dr.1 on 11 November 2019. His lower urinary tract symptoms were unchanged. His PSA result had fallen to 3.84ng/ml. Dr.1 described in a letter to Patient 1's GP that if the PSA level did not decrease further at a subsequent check, "*it may be necessary to take an incremental approach to increased androgen blockade by increasing the dose of bicalutamide to 50mgs twice daily, and hopefully subsequently to taking the higher dose of 150mgs once again…. I suspect that the addition of an LHRH agonist may be more intolerable".*

A review on 27 January 2020 took place as planned. The PSA was noted to be 2.23nmol/ml, but Patient 1's urinary symptoms including nocturia continued. Patient 1 was asked to increase the Bicalutamide to 100mgs once daily.

On 7 March 2020, Patient 1 received a telephone call from Dr.1, who advised that the PSA level had increased to 5.37ng/ml. The dose of bicalutamide was increased to150mgs once daily.

A planned review appointment for 27 April 2020 had been made however, on 23 March 2020 Patient 1 attended the Emergency Department in South West Acute Hospital Enniskillen (SWAH) complaining of difficulty passing urine. He was assessed and sent home. Patient 1 re-attended on 7 April 2020 and was found to be in urinary retention. A urethral catheter was fitted.

On 1 June 2020, Dr.1 informed Patient 1 in a telephone conversation that the PSA level had risen to 12.08ng/ml and advised the commencement of Leuprorelin (a LHRH analogue) subcutaneous injection be administered monthly by the practice nurse at the GP surgery.

To try and remove the urethral catheter, arrangements were made for a transurethral resection of prostate (TURP) at Daisy Hill Hospital (DHH). He was advised to self-

5.0 DESCRIPTION OF INCIDENT/CASE

isolate until his surgery and to have a Covid-19 test two days prior to admission.

On 17 June 2020, Patient 1 was admitted and at operation was noted to have a large obstructive prostate gland. The procedure was carried out by Dr.1. Patient 1 developed a pyrexia (high temperature) and bradycardia (low pulse) post-operatively, which was appropriately and efficiently treated. The subsequent removal of the catheter was unsuccessful and so a plan was made for Patient 1 to have a second trial of voiding at his local hospital. Patient 1 was discharged on 22 June 2020.

Histology of the resected specimen showed adenocarcinoma (Gleason 5+5) with peri-neural and lympho-vascular invasion.

On 22 June 2020 Dr.2 (Consultant Urologist) dictated a letter (typed on 26 June 2020) advising Patient 1's GP of his admission for TURP and the unsuccessful trial removal of the catheter. Dr.2 expressed thanks for commencing Patient 1 on the LHRH analogue and noted that the next dose (due 29th June 2020) would provide an opportunity to switch to a 12-weekly preparation. Dr.2 advised of Patient 1's referral to the Oncology Team. A referral letter was sent on the same day by Dr.2 to Nurse 1 asking to arrange a further trial of voiding two weeks later.

Dr.1 sent a letter to Patient 1's GP on 2 July 2020 advising of the rise in PSA from 22.22ng/ml (3 June 2020) to 29.5mg/ ml (12 June 2020) and the need for trial removal of catheter by Nurse 1 as indicated by Dr.2 letter. The plan for a CT and a bone scan to update staging and allow appropriate referral to the oncology team in Altnagelvin Hospital was explained. Dr.1 described a conversation with Patient 1 in which he found him to be "somewhat vague" stating that he thought there may have been some "significant degree of memory loss" and that Patient 1 could not remember commencing his Leuprorelin during the first week in June 2020. Patient 1's GP was advised that histology had shown Gleason 5+5 adenocarcinoma. Dr.1 requested if Decapeptyl 11.25mgs injections could be made available for administration by the practice nurse.

On 15 July 2020 Patient 1 was reviewed by Dr.3 (Consultant Oncologist) in Altnagelvin Area Hospital. The oncologist's opinion was that Patient 1 had become too unfit to consider any treatment option with curative intent. He was commenced palliative treatment and was prescribed Abiratherone.

On 23 July 2020, Patient 1 was admitted to South West Acute Hospital following an Emergency Department attendance with decreased oral intake, diarrhoea and abdominal pain. He recently had his catheter changed and the GP had tested the urine which was positive for coliforms. He had been commenced on Trimethoprim in the community with no improvement. Patient 1 was found to have an acute kidney injury (AKI) initially thought to be due to infection and was treated for sepsis. After an ultrasound showed left hydronephrosis, a CT scan, performed on the advice of urology, showed prostate cancer progression in the pelvis that was causing the left obstructive uropathy. He improved clinically and was keen for discharge home on oral antibiotics.

Personal Information redacted by the USI Patient 1 passed away in SWAH.

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 Patient 1 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 Patient 1. 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

6.0 FINDINGS

discussed with the patient.

- Patient 1 could not and did not give informed consent for this action.
- Patient 1 did not have a Cancer Nurse Specialist (CNS) or Key Worker to support his care. The SHSCT had invested in additional resource to provide Specialist Nurses to all urology cancer patients. The SHSCT had indicated to Cancer Peer Review (2017) that all patients had access to this resource. The review team have been informed that Dr.1 excluded all CNSs from the care of his patients at clinics. This was contrary to the regional guidance and contrary to the multidisciplinary ethos of cancer care.
- The review team found that without appropriate CNS support, Patient 1 and his family had difficulties in accessing support and care, especially in the community. This resource was provided by the SHSCT but was denied to Patient 1 by the exclusion of CNS involvement. Patient 1's family tried their best to address this deficit, with input from family, extended family and friends.
- The review team noted that Patient 1's case was not re-discussed at the MDM despite clear progression of the disease. This meant there was no opportunity for Patient 1 to benefit from the multi-disciplinary care, other urologists, oncology and especially palliative care, that underpins Improving Outcomes Guidance (2002). The absence of any CNS input to Patient 1's care meant that they were unaware of the disease progression and could not refer back to the MDM independently.
- The review team concluded that Patient 1 received uni-professional treatment and care despite multi-professional resources being available. His care did not follow regional guidance and treatment recommendations from the MDM were ignored. Patient 1 was denied the opportunity of multidisciplinary professional referral and care: initially from a clinical oncologist when radical therapy should have been considered; and subsequently from high quality palliative care when it became necessary.
- Patient 1 developed metastases whilst being inadequately treated for high-risk prostate cancer. The opportunity to offer him radical (with curative intent) treatment was lost.

Family Engagement.

- The review panel met with Patient 1's family. They were advised that Patient 1 did not have a CNS to support him through his cancer diagnosis. Patient 1's daughter was Personal Information redacted by USI when they learned of Patient 1 disease progression. But Patient 1 died sooner than they expected.
- The family highlighted the huge impact of the indwelling catheter problems caused to Patient 1 from March/ April 2020. The family described his difficulties in trying to contact Dr 1 and his secretary. Had a CNS been introduced to Patient 1 at his initial diagnosis, he would have been provided with contact details. He

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 Patient 1'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 Patient 1'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

Patient 1 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.
Patient 1 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.

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 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. Any other function is secondary to, and if necessary be sacrificed to, this aim.
- The multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.
- Any divergence from a MDT recommendation should be justified by further MDT discussion and the informed consent of the patient.
- Each MDM requires a Chair responsible for the audit and quality assurance of all aspects of its primary function.
- The clinical record should include the reason for any deferments or variation in MDM management decisions.
- After any patient interaction, best practice includes the prompt communication with the patient (and their General Practitioner) in plain English 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

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

Recommendation 2

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients. This will be achieved by - Urology Cancer Care delivered through a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis,

9.0 RECOMMENDATIONS AND ACTION PLANNING

treatment planning and completion and survivorship.

Recommendation 3

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

Recommendation 4

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.

Recommendation 5

The Southern Health and Social Care Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals, especially as disease progresses.

Recommendation 6

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.

Recommendation 7

Each MDM requires a Chair responsible for the audit and quality assurance of all aspects of its primary function.

Recommendation 8

The multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.

Recommendation 9

The clinical record should include the reason for any deferments or variation in MDM management decisions.

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**	
	Comment: **There are 9 individual reports and one over arching report** ***If multiple service users involved please indicate the number involved***					
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**			
	If **YES**, 26 October 2020					
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI					
	a) No contact or Next of Kin details or Unable to contact					
	b) Not applicable as this SAI is not 'patient/service user' related					
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user					
	d) Case involved suspected or actual abuse by family					
	e) Case identified as a result of review exercise					
	f) Case is environmental or infrastructure related with no harm to patient/service user					
	g) Other rationale					
	If you selected c), d), e), f) or g) above please provide further details:					

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

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**	x	**NO**	
	If **YES**, 1 March 2021			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report	x		
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**	x	**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

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: [redacted]

Date of Incident/Event: 31/10/2019

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: M
Age: [redacted]

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

Patient 1 a Personal Information redacted by the USI 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. Patient 1 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. Patient 1's disease progressed and he passed away on Personal Information redacted by the USI.

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.

Review of Medical Notes

Interviews with Staff

Family Engagement

Review of Northern Ireland Health Care Records

MDT pathway for Cancer Management

5.0 DESCRIPTION OF INCIDENT/CASE

Patient 1, a Personal Information redacted by the USI-old gentleman, was referred by his GP to the urology service at in Western Trust on 13 June 2019; he had a raised PSA (19ng/ml) which is a blood test used to assess the risk of the presence of prostate cancer. His past medical history included Personal Information redacted by the USI

The 'red flag' urgent referral was received on 14 June 2019 and triaged by Dr.1 (Consultant Urologist) on 17 June 2019. A MRI scan of the prostate and pelvis was requested to be done prior to an appointment scheduled for 22 July 2019.

the prostate and, at the front of the gland, a moderately suspicious (PIRADS 3) area of possible prostate cancer, but also some highly suspicious changes (PIRADS 5) in the peripheral zone.

Patient 1 was reviewed by Dr.1 on 22 July 2019 and was advised that he may have a malignancy of his prostate gland and that further investigations would be required. An ultrasound scan of the bladder and urinary tract and an appointment for prostate biopsies were arranged.

On 20 August 2019, Patient 1 attended the Prostate Biopsy Clinic under the care of Nurse 1. The procedure was completed without complication and the samples were sent to histopathology. The results of the biopsy, reported on 28 August 2019, showed adenocarcinoma of prostate (Gleason 4+3), but there was no evidence of perineural infiltration, lymphovascular invasion or extracapsular extension.

The ultrasound scan of the urinary tract, performed on 21 August 2019, showed normal kidneys and normal bladder appearance although there was a post void residual of 204mls of urine.

Patient 1's case was discussed at the Urology Multidisciplinary Meeting (MDM) on 29 August 2019. He was noted to have been taking Finasteride 5mgs since 2010. A radioisotope bone scan and a CT scan of chest, abdomen and pelvis were recommended to stage the prostate cancer. Patient 1's General Practitioner (GP) was

5.0 DESCRIPTION OF INCIDENT/CASE

advised of the outcome of the MDM by letter.

Patient 1 was reviewed by Dr.1 on 23 September 2019 and was told that he had high-risk prostate cancer. No staging investigations were requested. Instead, he was prescribed Bicalutamide150mgs once daily and Tamoxifen 10mgs once daily in order to minimise the risk of breast tenderness a possible side-effect of the anti-androgen.

Patient 1 received a follow up phone call from Dr.1 on 14 October 2019 following a request for advice regarding the potential side effects to his medication. Dr.1 reported that Patient 1 was experiencing some light headedness and dizziness, which was affecting his ability to drive. Dr.1 advised Patient 1 to cease both hormonal medications. However, although Patient 1's PSA was noted to be rising (21.8ng/ml), a plan was made to re-check the PSA level. The bone scan and CT scans were also arranged. Patient 1 was advised to recommence Bicalutamide at a lower dose (50mgs once daily) from 1 November 2019.

Patient 1 was discussed again at MDM on 31 October 2019. His bone scan and CT scan showed no metastatic spread of disease outside the prostate. A recommendation to commence androgen deprivation therapy (a LHRH analogue) and refer for an opinion from a Clinical Oncologist regarding external beam radiation therapy (EBRT) was agreed.

Patient 1 attended his outpatient appointment with Dr.1 on 11 November 2019. His lower urinary tract symptoms were unchanged. His PSA result had fallen to 3.84ng/ml. Dr.1 described in a letter to Patient 1's GP that if the PSA level did not decrease further at a subsequent check, "*it may be necessary to take an incremental approach to increased androgen blockade by increasing the dose of bicalutamide to 50mgs twice daily, and hopefully subsequently to taking the higher dose of 150mgs once again…. I suspect that the addition of an LHRH agonist may be more intolerable".*

A review on 27 January 2020 took place as planned. The PSA was noted to be 2.23nmol/ml, but Patient 1's urinary symptoms including nocturia continued. Patient 1 was asked to increase the Bicalutamide to 100mgs once daily.

On 7 March 2020, Patient 1 received a telephone call from Dr.1, who advised that the PSA level had increased to 5.37ng/ml. The dose of bicalutamide was increased to150mgs once daily.

A planned review appointment for 27 April 2020 had been made however, on 23 March 2020 Patient 1 attended the Emergency Department in South West Acute Hospital Enniskillen (SWAH) complaining of difficulty passing urine. He was assessed and sent home. Patient 1 re-attended on 7 April 2020 and was found to be in urinary retention. A urethral catheter was fitted.

On 1 June 2020, Dr.1 informed Patient 1 in a telephone conversation that the PSA level had risen to 12.08ng/ml and advised the commencement of Leuprorelin (a LHRH analogue) subcutaneous injection be administered monthly by the practice nurse at the GP surgery.

To try and remove the urethral catheter, arrangements were made for a transurethral resection of prostate (TURP) at Daisy Hill Hospital (DHH). He was advised to self-

5.0 DESCRIPTION OF INCIDENT/CASE

isolate until his surgery and to have a Covid-19 test two days prior to admission.

On 17 June 2020, Patient 1 was admitted and at operation was noted to have a large obstructive prostate gland. The procedure was carried out by Dr.1. Patient 1 developed a pyrexia (high temperature) and bradycardia (low pulse) post-operatively, which was appropriately and efficiently treated. The subsequent removal of the catheter was unsuccessful and so a plan was made for Patient 1 to have a second trial of voiding at his local hospital. Patient 1 was discharged on 22 June 2020.

Histology of the resected specimen showed adenocarcinoma (Gleason 5+5) with peri-neural and lympho-vascular invasion.

On 22 June 2020 Dr.2 (Consultant Urologist) dictated a letter (typed on 26 June 2020) advising Patient 1's GP of his admission for TURP and the unsuccessful trial removal of the catheter. Dr.2 expressed thanks for commencing Patient 1 on the LHRH analogue and noted that the next dose (due 29th June 2020) would provide an opportunity to switch to a 12-weekly preparation. Dr.2 advised of Patient 1's referral to the Oncology Team. A referral letter was sent on the same day by Dr.2 to Nurse 1 asking to arrange a further trial of voiding two weeks later.

Dr.1 sent a letter to Patient 1's GP on 2 July 2020 advising of the rise in PSA from 22.22ng/ml (3 June 2020) to 29.5mg/ ml (12 June 2020) and the need for trial removal of catheter by Nurse 1 as indicated by Dr.2 letter. The plan for a CT and a bone scan to update staging and allow appropriate referral to the oncology team in Altnagelvin Hospital was explained. Dr.1 described a conversation with Patient 1 in which he found him to be "somewhat vague" stating that he thought there may have been some "significant degree of memory loss" and that Patient 1 could not remember commencing his Leuprorelin during the first week in June 2020. Patient 1's GP was advised that histology had shown Gleason 5+5 adenocarcinoma. Dr.1 requested if Decapeptyl 11.25mgs injections could be made available for administration by the practice nurse.

On 15 July 2020 Patient 1 was reviewed by Dr.3 (Consultant Oncologist) in Altnagelvin Area Hospital. The oncologist's opinion was that Patient 1 had become too unfit to consider any treatment option with curative intent. He was commenced palliative treatment and was prescribed Abiratherone.

On 23 July 2020, Patient 1 was admitted to South West Acute Hospital following an Emergency Department attendance with decreased oral intake, diarrhoea and abdominal pain. He recently had his catheter changed and the GP had tested the urine which was positive for coliforms. He had been commenced on Trimethoprim in the community with no improvement. Patient 1 was found to have an acute kidney injury (AKI) initially thought to be due to infection and was treated for sepsis. After an ultrasound showed left hydronephrosis, a CT scan, performed on the advice of urology, showed prostate cancer progression in the pelvis that was causing the left obstructive uropathy. He improved clinically and was keen for discharge home on oral antibiotics.

Personal Information redacted by the USI Patient 1 passed away in SWAH.

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 Patient 1 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 Patient 1. 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

6.0 FINDINGS

discussed with the patient.

- Patient 1 could not and did not give informed consent for this action.
- Patient 1 did not have a Cancer Nurse Specialist (CNS) or Key Worker to support his care. The SHSCT had invested in additional resource to provide Specialist Nurses to all urology cancer patients. The SHSCT had indicated to Cancer Peer Review (2017) that all patients had access to this resource. The review team have been informed that Dr.1 excluded all CNSs from the care of his patients at clinics. This was contrary to the regional guidance and contrary to the multidisciplinary ethos of cancer care.
- The review team found that without appropriate CNS support, Patient 1 and his family had difficulties in accessing support and care, especially in the community. This resource was provided by the SHSCT but was denied to Patient 1 by the exclusion of CNS involvement. Patient 1's family tried their best to address this deficit, with input from family, extended family and friends.
- The review team noted that Patient 1's case was not re-discussed at the MDM despite clear progression of the disease. This meant there was no opportunity for Patient 1 to benefit from the multi-disciplinary care, other urologists, oncology and especially palliative care, that underpins Improving Outcomes Guidance (2002). The absence of any CNS input to Patient 1's care meant that they were unaware of the disease progression and could not refer back to the MDM independently.
- The review team concluded that Patient 1 received uni-professional treatment and care despite multi-professional resources being available. His care did not follow regional guidance and treatment recommendations from the MDM were ignored. Patient 1 was denied the opportunity of multidisciplinary professional referral and care: initially from a clinical oncologist when radical therapy should have been considered; and subsequently from high quality palliative care when it became necessary.
- Patient 1 developed metastases whilst being inadequately treated for high-risk prostate cancer. The opportunity to offer him radical (with curative intent) treatment was lost.

Family Engagement.

- The review panel met with Patient 1's family. They were advised that XX did not have a CNS to support him through his cancer diagnosis. Patient 1's Personal Information redacted by USI hen they learned of Patient 1 disease progression. But XX died sooner than they expected.
- The family highlighted the huge impact of the indwelling catheter problems caused to Patient 1 from March/ April 2020. The family described his difficulties in trying to contact Dr 1 and his secretary. Had a CNS been introduced to Patient 1 at his initial diagnosis, he would have been provided with contact details. He

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 Patient 1'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 Patient 1'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

Patient 1 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.
Patient 1 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.

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 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. Any other function is secondary to, and if necessary be sacrificed to, this aim.
- The multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.
- Any divergence from a MDT recommendation should be justified by further MDT discussion and the informed consent of the patient.
- Each MDM requires a Chair responsible for the audit and quality assurance of all aspects of its primary function.
- The clinical record should include the reason for any deferments or variation in MDM management decisions.
- After any patient interaction, best practice includes the prompt communication with the patient (and their General Practitioner) in plain English 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

All patients should receive cancer care based on accepted best care Guidelines (NICAN Regional Guidance, NICE Guidance, Improving Outcome Guidance).

Recommendation 2

The Southern Health and Social Care Trust must provide high quality urological cancer care for all patients. This will be achieved by - Urology Cancer Care delivered through a co-operative multi-disciplinary team, which collectively and inter-dependently ensures the support of all patients and their families through, diagnosis,

9.0 RECOMMENDATIONS AND ACTION PLANNING

treatment planning and completion and survivorship.

Recommendation 3

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

Recommendation 4

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.

Recommendation 5

The Southern Health and Social Care Trust must ensure that patients are discussed appropriately at MDM and by the appropriate professionals, especially as disease progresses.

Recommendation 6

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.

Recommendation 7

Each MDM requires a Chair responsible for the audit and quality assurance of all aspects of its primary function.

Recommendation 8

The multi-disciplinary team meeting should be quorate, and all participants must feel able to contribute to discussion.

Recommendation 9

The clinical record should include the reason for any deferments or variation in MDM management decisions.

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

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

(This checklist should be completed in full and submitted to the HSCB along with the completed SAI Review Report for all levels of SAI reviews)

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

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, a number of service users or if the SAI relates **only** to a HSC Child Death notification *(SAI criterion 4.2.2)* **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	x	**HSC Child Death Notification only**	
	Comment: **There are 9 individual reports and one over arching report** ***If multiple service users involved please indicate the number involved***					
2) Was the Service User[1] / Family / Carer informed the incident was being investigated as a SAI? **Please select as appropriate (✓)**	**YES**	x	**NO**			
	If **YES**, 26 October 2020					
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being investigated as a SAI					
	a) No contact or Next of Kin details or Unable to contact					
	b) Not applicable as this SAI is not 'patient/service user' related					
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user					
	d) Case involved suspected or actual abuse by family					
	e) Case identified as a result of review exercise					
	f) Case is environmental or infrastructure related with no harm to patient/service user					
	g) Other rationale					
	If you selected c), d), e), f) or g) above please provide further details:					

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

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

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

3) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**	x	**NO**	
	If **YES**, 1 March 2021			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer			
	a) Draft review report has been shared and further engagement planned to share final report	x		
	b) Plan to share final review report at a later date and further engagement planned			
	c) Report not shared but contents discussed ***(if you select this option please also complete 'I' below)***			
	d) No contact or Next of Kin or Unable to contact			

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being investigated as a SAI)*		
Continued overleaf	**e)** No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

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

SECTION 2

INFORMING THE CORONER'S OFFICE (under section 7 of the Coroners Act (Northern Ireland) 1959) *(complete this section for all death related SAIs)*				
1) Was there a Statutory Duty to notify the Coroner at the time of death? **Please select as appropriate (✓)**	**YES**		**NO**	x
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
2) Following or during the review of the SAI was there a Statutory Duty to notify the Coroner? **Please select as appropriate (✓)**	**YES**	x	**NO**	
	If **YES**, insert **date informed**:			
	If **NO**, please provide details:			
3) If you have selected 'YES' to any of the above **'1' or '2'** has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**	
	If **YES**, insert **date report shared**:			
	If **NO**, please provide details:			

DATE CHECKLIST COMPLETED	

[1] *Service User or their nominated representative*

This checklist should be completed in line with the HSCB Procedure for the reporting and follow up of SAIs October 2013 and the HSC Guidance for staff on engagement/communication with Service Users[1] / Families/Carers following a SAI

Update on early learning from SAI by Chair Dr Dermot Hughes/ Patricia Kingsnorth
Melanie McClements / Stephen Wallace

Monday 12 January 2021

Dermot provided an update on the early learning from the review to date. He advised the review included 5 prostate cancer patients, I testicular cancer patient, 1 penile cancer patient and 2 renal cancer patients.

He discussed the main issues, that one professional did not adhere to regional guidance and recommendations made by the MDT. This consultant was aware of the regional guidance and was chair the regional NICAN team when the guidelines were developed.

Prostate cancers
Mainly involve issues with diagnostics and treatment including off licence prescriptions. No considerations for timely pathway/
None if his patients had been given a key worker to support them on their cancer journey. This was unique to this professional. The review team initially wondered was it a resource issue, but realised that the resources were there, specialist nurses were excluded from his patient's care.
This resulted in poor timelines for the patients, no safety nets to follow up on scan reports or appointments.
This also resulted in patients being unable to access the service, they often didn't know who to contact and eventually went to ED during covid which was not the right place for them.
This professional worked as a mono professional in a multi-disciplinary team. There was no oversight of the patient's care from other professionals.

The **testicular cancer** patient was not referred to oncology despite a time critical need for chemo therapy.
The **penile cancer** patient was managed locally and not referred to the regional centre as per guidelines
The MDT have written up its annual plan but wording still varies from the regional guidance regarding penile cancers. Dermot advised that the Trust could be criticised for the wording and suggests it is changed. The wording states "that it is **desirable** to manage penile cancers in the regional centre".

The two kidney cancers care was good for kidney cancer, but lost to follow up and then scan showing evidence of metastases not actioned.
The second kidney cancer – should have been discussed at the small masses clinic for advice.

Other issues included
MDT recommendations for patients were not actioned. When there was a challenge from the urology team regarding the use of bicalutamide – this was not minuted.
Dermot advised that following discussion with the cancer leads – AMD and CD
Neither of them were aware of the issues regarding this professional. The escalation occurred within the specialities and not escalated to the Cancer Leads.

Dermot advised that when the patient's disease progressed, they were not brought back to MDT for re-discussion.
Dermot advised that the current system allowed this professional to work in isolation when he didn't adhere to the recommendations set by the MDT. There should be governance oversight in the Cancer leads forums. This should be on the agenda of their meetings and any concerns within the specialities escalated through the Cancer Leads.
2 patients died and were not referred for palliative care
2 patients are dying.

This was distressing for patients and families as they thought they were receiving the best care.

Other learning.
Access to services during covid caused distress for families.
No phone number to contact specialist services left families vulnerable. GPs couldn't help and families left to organise district nursing services themselves.

Dermot described the patients as having personalised care to the exclusion of the right professional. The patients did not have any understanding of the treatments they were prescribed – no informed discussion regarding treatments.
This professional practiced outside his competencies and patients were not afforded the choice.

He advised that the Belfast Trust Oncologist had concerns and escalated to the professional directly. The oncology team changed the prescription for patients to ensure they were on the appropriate therapy.

Dermot advised there needs to be evidence of clinical leadership and audits carried out on all health professionals to ensure compliance.

Patricia advised that one of the families who initially did not want to be part of the SAI review, came forward and advised that there is a support website for AOB and this caused them great distress. They said the members on the group are health professionals. This was the reason the family came forward to be part of the SAI review

We are working through the reviews. Dermot had asked to speak with the MDT team regarding the SAI review.

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Progress Report on Level 3 Urology Services Serious Adverse Incidents

Southern Health and Social Care Trust

Introduction

This paper provides an update on the Level 3 Serious Adverse Incident (SAI) reviews that are being carried out regarding the treatment and care provided by Trust Consultant Urologist who is no longer employed by Health and Social Care Services in Northern Ireland.

SAI Process

In total the quality of care for nine patients who were under the care of Doctor 1 have been identified as meeting the threshold as requiring a SAI review. To ensure a robust and expedient process is conducted to identify learning themes and areas for improvement for all cases is carried out, the Health and Social Care Board (HSCB) and Public Health Agency (PHA) agreed that nine separate SAI's should be conducted supplemented by an overarching SAI report complete with themed recommendations.

The HSCB and PHA agreed that given the similarities between the cases identified and to ensure consistency of approach a single SAI chairperson and nominated panel should conduct each of the SAI's concurrently.

Case Summaries

The table below provides an overview of each of the nine patients identified as part of the SAI review cohort, the table includes details of their clinical summary and current status.

Patient details	Clinical summary	Current status
Patient 9	In May 2019 Patient 9 had an assessment which indicated he had a malignant prostate. Patient 9 was commenced on androgen deprivation therapy (ADT). Reviewed in July 2019 in outpatients and planned for repeat PSA and further review. Patient lost to review and attended Emergency Department in May 2020. Rectal mass	Alive - Palliative

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	investigated and diagnosed as locally advanced prostate cancer.	
Patient 1	Patient 1 was diagnosed with locally advanced prostate cancer in August 2019. An MDT discussion on 31 October 2019 recommended androgen deprivation therapy (ADT) and external beam radiation therapy (EBRT). Patient 1 was not referred for ERBT and his hormone treatment was not as per guidance. Patient commenced bicalutamide. In March 2020 Patient 1's PSA was rising and when restaged in June 2020 Patient 1 had developed metastatic disease.	Deceased
Patient 4	Diagnosed with high grade prostate cancer July 2019. MDM outcome '...commence androgen deprivation therapy (LHRHa), arrange a CT Chest and bone scan and for subsequent MDM review.' MDM recommendations not followed. Patient commenced on bicalutamide. Patient now deceased.	Deceased
Patient 3	Diagnosed with penile cancer, recommended by cancer MDM for CT scan of Chest, Pelvis and Abdomen to complete staging. Patient managed locally by MDT and delay to refer to tertiary centre in Western Trust. Penile Cancers should be managed by specialist team as per NICE guidelines.	Palliative
Patient 5	Patient 5 had a right radical nephrectomy March 2019.He had a follow up CT scan of chest abdomen and pelvis performed on 17 December 2019. The indication for this was restaging of current renal cell carcinoma. The CT scan report noted possible sclerotic metastasis in L1 vertebral body. Result was not actioned. Patient contacted with result on 28 July 2020 and further assessment required diagnosed with prostate cancer.	Alive

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	Delay in diagnosis due to delay in actioning the CT scan result.	
Patient 2	Patient diagnosed with a slow growing testicular cancer (Seminoma) had delayed referral to oncology and therefore delay in commencing chemotherapy.	Alive
Patient 7	Patient has had a small renal mass since 2017 which was under surveillance by Urology. On the 13 November 2019 the patient had a follow up CT renal scan. The report identified an enhancing lesion which had increased slightly in size. There was a delay in the follow up process for cancer care management.	Alive
Patient 8	Patient underwent transurethral resection of prostate (TURP) on 29 January 2020. Pathology reported incidental prostate cancer. There was a delay in the follow up process for cancer care management.	Alive
Patient 6	Patient diagnosed with prostate cancer Gleason 7. MDM 08/08/19- Significant Lower urinary tract symptoms but declined investigations. On maximum androgen blockade - No onward oncology referral was made.	Alive

Identification of Panel Chair

As per Level 3 SAI requirements the Trust has commissioned an external review panel to ensure independence and a robust investigation. HSCB, PHA and patients / families have been informed of the panel membership and have communicated their agreement. The below table provides details of each member.

Panel Member	Role
Dr Dermot Hughes	**External independent Chair**: Former Medical Director Western Health and Social Care Trust. Former Chair of the Northern Ireland Cancer Network (NICAN)

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Mr Hugh Gilbert	Expert External Consultant Clinical Urologist - Clinical Advisor from the British Association of Urological Surgeons BAUS
Mrs Fiona Reddick	Head of Clinical Cancer Services (SHSCT)
Ms Patricia Thompson	Clinical Nurse Specialist (SHSCT)
Mrs Patricia Kingsnorth	Acting Acute Clinical Governance Coordinator To provide facilitation

Terms of Reference

A full term of reference for the reviews can be found in Appendix 1. The terms of reference have been shared and discussed with each of the patients / families and agreed by the HSCB/PHA.

Family Engagement

Trust engagement with families has commenced and is ongoing, key points are below:

- All families have received an initial phone call to advise of the SAI process. Some of the families were made aware of the SAI process previously directly by the clinical team.
- The Chair of the SAI team and the Clinical Governance Coordinator and personally met with all families (with the exception of one who didn't want to meet with the team or be involved in family engagement, however discussions have taken place with his family and the patient wants to wait the outcome of the review).
- The families have been advised about the process, shared terms of reference and told their stories.
- Support in the form of counselling has been provided to those families who wished to avail of the support.

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- For those who didn't want to avail of support, they have contact numbers to the clinical governance coordinator who will update them.

Support for Families (Family Liaison)

The Trust is in the process of recruitment of a Family Liaison Officer. The role of this staff member will be to support families through the SAI process including after the report is completed. An appointment is expected to be made at the beginning of January 2021, a full role description is provided in Appendix 2.

Documentation

All requested documentation that has been requested by the panel has been provided:

- Patient Medical Notes have been reviewed and timelines generated for each of the nine patients and shared with the review team.
- The review team have been provided with the appropriate clinical guidelines and protocols.
- NICAN Urology cancer clinical guidelines (2016)
- The Urology MDT Operational Policy
- SHSCT Urology MDT annual report
- NICE: Suspected cancer recognition and referral: site or type of cancer
- Self-Assessment Peer Review document 2017/ 2019
- Leadership and management for all doctors (GMC)

Staff Interviews

The review team are in the process of interviewing relevant staff members and aim for completion in early January. To date interviews have been carried out with the following staff:

- Trust MDM chairperson

Further interviews are scheduled for January 2021 including:
Lead for Cancer Services

Southern Health and Social Care Trust

AMD for Urology Services

Doctor 1

Doctor 1 has been sent a letter from the panel chairperson offering for him to contribute to the process, a response is awaited. The panel have agreed that if a response is not received by 24th December 2020 written questions will be provided to Doctor 1 via his legal team for consideration and response.

Any Early Findings

To date early learning has identified regarding the prescribing of anti-androgen therapy (Bicalutamide) at low dose, sub therapeutic levels. A review of Bicalutamide prescribing has been undertaken and where required patients whose medication has required review has commenced.

Timescales

The SAI is currently on target for completion end of January.

- A draft copy of the report will be sent to relevant staff for factual accuracy check a response period is normally two weeks for staff to comment.
- Families will be provided with a draft copy of the reports for comments. A period of 3 weeks will be given to families to respond to the report and meet with the chair of the panel to discuss the findings and ask for amendments.
- A draft copy of the report will be shared with the HSCB at the same time as the families pending family engagement. Once comments are received and report finalised the completed report will be submitted to the HSCB.

A Gantt chart featuring key milestones is provided below.

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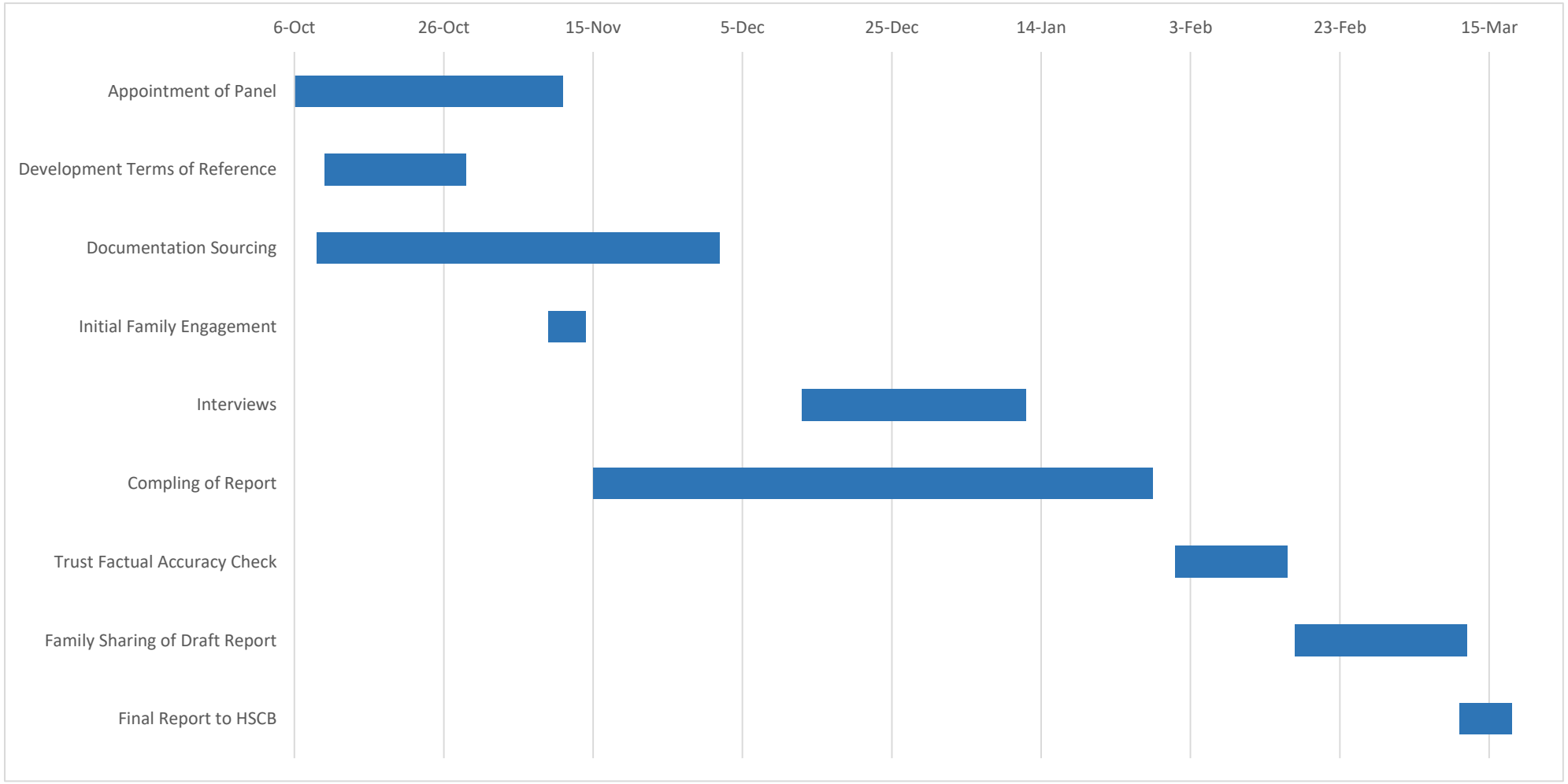

Southern Health and Social Care Trust

Appendix 1 – Terms of Reference

Introduction

The core values of the Southern Health and Social Care Services (Northern Ireland) are of openness, honesty, respect and compassion. In keeping with these values, the Director of Acute Service has commissioned a level 3 SAI review to address the issues referenced above. The draft terms of reference may be amended pending engagement with all affected patients and families.

Purpose of Review

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided.

Scope of Review

As part of an internal review of patients under the care of Doctor 1, a number of patients have been identified as possibly been exposed to increased or unnecessary risk.

Review Team

The proposed review team is as follows:

Chairperson / Lead Reviewer	Dr Dermot Hughes
Independent Consultant Urologist	Mr Hugh Gilbert
Cancer Services Lead	Mrs Fiona Reddick
Clinical Nurse Specialist	Ms Patricia Thompson
Clinical Governance Facilitator	Mrs Patricia Kingsnorth

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Review Aims and Objectives

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.

Review Team Access Arrangements

Through the Review Commissioner, the Review Team will:

- Be afforded the assistance of all relevant staff and other relevant personnel.
- Have access to all relevant files and records (subject to any necessary consent/data protection requirements, where necessary).

Should immediate safety concerns arise, the Lead Reviewer will convey the details of these concerns to the Director of Acute Services / Trust Board (known as Review Commissioner) as soon as possible.

Review Methodology

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to

privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

Recommendations and Implementation

The report, when finalised, will be presented to the Review Commissioner. The Review Commissioner is responsible for ensuring that the local managers responsible for the service where the incident occurred will implement the recommendations of the review report. The Review Commissioner is responsible for communicating regionally applicable recommendations to the relevant services for wider implementation.

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Appendix 2 – Service User Liaison Officer

JOB TITLE	Acute Service User Liaison Officer
BAND	7
DIRECTORATE	Medical Directorate
INITIAL LOCATION	Trustwide

JOB SUMMARY

The post holder will have responsibility for management of the proactive liaison service for service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. The post holder will be the key central point of contact between the affected service users, relatives[1] and carers and will ensure they remain fully supported, including pastoral and tangible supports where required, throughout and following any Trust review processes.

The post holder will ensure the Trust maintains a responsive liaison service for patients, relatives, carers at all times. This will include liaising with internal Trust services and external agencies to ensure that appropriate supports are provided to service users and families who may require access.

KEY RESULT AREAS

1. Provide a central point of contact for service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. The contact may be in person, by telephone, e-mail or written correspondence.

[1] *The definition of family includes any person(s) who may be affected as a result of a healthcare related incident regardless of their personal connection to the services provided*

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2. Facilitate meetings with service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety. This will include dealing with situations which are highly emotive and challenging where information may be of a sensitive and complex clinical nature.

3. Where necessary, advise and support service users to access alternative sources of information, including advocacy services, other healthcare organisations, or voluntary sector services suited to their needs.

4. Keep service users, relatives and carers who have had contact with a serious adverse incident or submitted a complaint to the Trust regarding service user safety continuously informed of Trust review processes and expected timescales for completion.

5. In cases where service users, families or carers require on-going help and support to regarding their contact with a serious adverse incident of complaint, chair liaison meetings between Trust staff and service users, families or carers to discuss any concerns they have.

6. With the consent of service users, families or carers, provide links to Trust services, General Practitioner services or external counselling agencies.

7. Lead on communication with service users, families or carers when sharing sensitive and complex information and with input from clinical subject matter experts the factors that led to adverse events affected them.

8. With operational directorate teams, make objective analysis and assessment of concerns that may be complex and/or sensitive, make judgements and through liaison with chair / reviewer to ensure the appropriate level of reviews are carried out and if required, facilitate negotiations with all concerned to find solutions.

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9. With operational directorate teams, communicate the outcome of any review to individuals in response to concerns or feedback raised, either verbally and/or in writing.

10. Keep accurate and contemporaneous records of all communications with service users, relatives and carers including outcomes and actions and input data onto the Datix system.

11. Work collaboratively with directorates to monitor the progress of action plans as a result of concerns and patient feedback and ensure that lessons are learned and share with affected service users, relatives and carers.

12. Work closely with directorates to embed a culture which views adverse events, complaints, concerns and patient feedback as opportunities for learning and support services to ensure adequately supported and empowered to deal with complaints quickly, effectively and objectively at local level

13. Represent the Trust at regional meetings and forums including the patient and client council regional working group

14. Lead and manage multidisciplinary service improvement projects designed to create improved systems and processes for the identification and dissemination of learning from adverse events and complaints

15. Provide guidance to the Chief Executive, operational directors, senior managers and clinicians on the management of communications with patients, relatives and carers.

16. Using evidence based approaches, design and deliver specialist training for clinical staff to support them when communicating with patients, families and carers.

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17. Lead on the local development of guidance in respect of service user, relative and carer engagement processes by leading on the assessment, interpretation and implementation of national and regional guidance and policies.

18. Lead and oversee an ongoing review of organisational engagement processes with regard to patients, relatives and carers and lead on the development of appropriate levels of staff, public and service user consultations.

19. Lead on the development of quality metrics and targets based on national and regional policies and provide action plan and monitoring information to the Medical Director.

20. Have input in the governance agenda by highlighting patient safety issues raised through concerns, complaints and patient feedback to the AD Clinical and Social Care Governance

21. Assist the AD Clinical and Social Care Governance and Head of Patient Safety Data and improvement analysing trends and themes arising from concerns/complaints or feedback and assist in the production of reports to Care Groups and departments

22. Work to undertake surveys, audits and other projects relevant to the department

23. Ensure that members of the public know how to raise concerns and complaints and that any barriers preventing this are addressed

24. Provide assistance to the AD Clinical and Social Care Governance collating and presenting data in preparation for external audits

25. To contribute to Trust-wide training on customer services including; staff supporting service users; relatives and carers; frontline resolution of concerns and complaints, in order to ensure that staff are supported and enabled to meet patients' needs in practice

Southern Health and Social Care Trust

26. Responsible for maintaining own professional development and to be aware of current practices and developments within the Trust and the Health and Social Care in order to fulfil the role effectively

King, Dawn

From: Dermot Hughes [redacted]
Sent: 31 March 2021 20:41
To: Kingsnorth, Patricia
Subject: Fwd: feedback from Cancer and Clinical Services Division on the draft Overarching Urology SAI report
Attachments: image001.jpg

For info

Regards

Dermot
---------- Forwarded message ---------
From: **Dermot Hughes** [redacted]
Date: Wed, 31 Mar 2021, 20:34
Subject: Re: feedback from Cancer and Clinical Services Division on the draft Overarching Urology SAI report
To: McClements, Melanie [redacted]

Dear Melanie

No I had a good discussion with Maria.

I was concerned about the use of the master copy as evidence editing rights and loss of independence of the process. The process will be subject to a range of external scrutiny.

I have copied you into my responses to what was described as matters of fact. I and Hugh as externals would disagree with this assertion given all 3 individuals had limited knowledge of any of the issues that formed the core of the SAIs and the deficits experienced by the 9 patients.

Our recommendations around tracking, which was referenced to my previous practice in WHSCT is actually normal standard in the UK, and in my previous cancer experience in Washington DC and the National Cancer Institute - these standards are what many Urology team members would welcome and had previously experienced in the UK.

In any event they are what are required to keep patients safe and provide assurances to patients families and the public.

10 "matters of fact" have been addressed in my response but am still concerned about a similar number of issues raised regarding the recommendations.

The recommendations have been shared with families and are regared by the external team as things that should be in place anyway. Assurance mechsnism could be scaled back with time but I am conscious of previous absence of meaningful audit and indeed incorrect declaration to peer review.

The recommendations are limited straight forward and an opportunity to adress staffing issues, improve care and move on.

I have faith in the Urology team to do so if supported.

It really is what patients and families expect

Regards

Dermot

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

On Wed, 31 Mar 2021, 19:00 McClements, Melanie, <[redacted] wrote:

> thanks Dermot
>
> apologies re not being free to ring you earlier, Maria and Patricia have appraised me.
>
> if you still wish to speak to me, please ring me anytime, [redacted], thanks Melanie

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From: Dermot Hughes [redacted]
Sent: 31 March 2021 14:35
To: OKane, Maria; McClements, Melanie
Cc: Kingsnorth, Patricia
Subject: Fwd: feedback from Cancer and Clinical Services Division on the draft Overarching Urology SAI report

Dear Maria

Please see below

I have received tracked changes to an Independent Overarching SAI review.

I wish to raise my concern regarding this, as Independent Chair.

I was assured that the document would be circulated on Egress in read only format with professionals giving comment.

As we have not offered editing rights to other professionals, patients or families, I would ask this to be withdrawn.

I have attached my responses to the comments made.

I have not amended the recommendations as these are to make a service safe and provide enhanced public assurance. I think it unwise to change these while in the process of consolation with patients and families.

Regards

Dermot

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

Personal Information redacted by the USI

Begin forwarded message:

From: "Kingsnorth, Patricia" <Personal Information redacted by the USI>

Subject: FW: feedback from Cancer and Clinical Services Division on the draft Overarching Urology SAI report

Date: March 31, 2021 at 9:28:25 AM GMT+1

To: "Dermot Hughes (Personal Information redacted by the USI)" <Personal Information redacted by the USI>, "hugh.gilbert Personal Information redacted by the USI" <Personal Information redacted by the USI>

Dear Dermot and Hugh

Please see email below and comments in the report for discussion.

Kind regards

Patricia

Patricia Kingsnorth

Acting Acute Clinical Governance Coordinator

Governance Office

Room 53

The Rowans

Craigavon Area Hospital

Personal Information redacted by USI

From: Conway, Barry
Sent: 31 March 2021 09:11
To: Kingsnorth, Patricia
Cc: Tariq, S; McCaul, David; McClements, Melanie; Reddick, Fiona
Subject: feedback from Cancer and Clinical Services Division on the draft Overarching Urology SAI report

Dear Patricia,

Firstly on behalf of the Cancer and Clinical Services Division, we would like to note our sadness and regret in respect of the adverse impact on the nine patients and their families as outlined in the reports. Cancer and Clinical Services Division will work as a priority with other Divisions in Acute Services to implement agreed recommendations to improve our services.

We would also like to acknowledge the huge amount of work that you and the review team have put into all the draft reports. I have no doubt this has been a difficult process.

Dr Tariq, Dr McCaul and I have reviewed the reports and we have attached a tracked version of the Overarching report with our comments. Please note that we have not been able to involve Fiona Reddick in reviewing the draft reports as she is currently [redacted] from late February.

As requested, our feedback is primarily focussed on comments from a factual accuracy perspective, however following recent discussions with Melanie and Maria, we have also included some of our thoughts in relation to how the current governance arrangements could be improved.

Yours sincerely.

Barry.

Mr Barry Conway

Assistant Director – Acute Services – Cancer & Clinical Services / Integrated Maternity & Women's Health

Email – [redacted]

Mobile number - [redacted]

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

Organisation's Unique Case Identifier: [redacted]

Date of Incident/Event: Multiple dates

HSCB Unique Case Identifier:

Service User Details: (*complete where relevant*)
D.O.B: Gender: Male Age:

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. EXECUTIVE SUMMARY

The purpose of the review is to consider the quality of treatment and the care provided by Doctor 1 to the patients identified and to understand if actual or potential harm occurred. The review findings will be used to promote learning, to understand system wide strengths and weaknesses and to improve the quality and safety of care and treatment provided. Nine patients have been identified as potentially suffering harm. This review will examine the timelines of each individual case and analyse if any deficits in treatment or care has occurred. As part of the review the cancer

pathways will be used to determine where learning can be extracted.

The SHSCT recognise the life changing and devastating consequences to the 9 families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care they received.

1. THE REVIEW TEAM

Dr Dermot Hughes – External Independent Chair former Chair of the NICAN. Former Medical Director Western Health and Social Care Trust.
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 from SET / recently SHSCT)
Mrs Patricia Kingsnorth – Acting Acute Clinical Governance Coordinator (SHSCT)

1. 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/ Patients and families involved/ Staff involved.

1. REVIEW METHODOLOGY

The review will follow a review methodology as per the Regional Serious Adverse Incident Framework (2016) and will be cognisant of the rights of all involved to privacy and confidentiality and will follow fair procedures. The review will commence in October 2020 and will be expected to last for a period of 4 months approximately, provided unforeseen circumstances do not arise. Following completion of the review, an anonymised draft report will be prepared by the review team outlining the chronology, findings and recommendations. All who participated in the review will have an opportunity to provide input to the extracts from the report relevant to them to ensure that they are factually accurate and fair from their perspective.

Prior to finalising the report, the Lead Reviewer will ensure that the Review Team apply Trust quality assurance processes to ensure compliance of the review process with regional guidance prior to delivery of the final report to the Review Commissioner. The Review Commissioner will seek assurance that the quality assurance process has been completed.

1. DESCRIPTION OF INCIDENT/CASE

The review team conducted individual reviews on 9 patients on their treatment and care. A summary of each case is discussed within this report.

Causal deficits in their care and contributory factors were identified.

Service User A

Service User A was diagnosed with prostate cancer and was started on an anti-androgen therapy as opposed to Androgen Deprivation Therapy (ADT). This did not adhere to the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016). These Guidelines had been signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-Disciplinary Meeting (MDM), as their protocols for Cancer Peer Review (2017). This guidance was issued when Dr 1 was the regional chair of the Urology Tumour Speciality Group and should have had full knowledge of its contents. Following discussion with the families, the review team noted that there was no discussion with Service User A that the treatment given was at variance with regionally recommended practice. There was no evidence of informed consent to this alternative care pathway.

The review team have identified that during the MDM that a quorum had not been met. This was due to the absence of an oncologist from these meetings. Even so, the recommendations made by the MDM were not actioned by Dr 1. Members of the MDT may not have been aware of this, but similar practice in prescribing an anti-androgen had been challenged. Any challenges made regarding the appropriateness of treatment options were not minuted nor was the issue escalated.

The Review Team suggested that the initial assessment of Service User A was satisfactory although rather prolonged, the subsequent management with unlicensed anti-androgenic treatment (Bicalutamide) at best delayed definitive treatment. Bicalutamide (50mg) is currently only indicated before (as an anti-flare agent) or in combination with a LHRH analogue (Complete Androgen Blockade) Bicalutamide monotherapy (150mg) is not recommended for use as a continuing treatment for intermediate risk localised prostate cancer (reference is EAU guidelines), and further it decreases overall survival. Treatment for prostate cancer is based on achieving biochemical castration (Testosterone <1.7 nmol/l), which is best accomplished by the use of a LHRH analogue, by an LHRH antagonist or by bilateral subcapsular orchidectomy.

Service User A did not have Urology Cancer Nurse Specialist allocated to his care. The review team questioned this and it was established that whilst there were no resources for a Urology Cancer Nurse Specialist to attend any outreach clinics, their contact numbers should have been provided to the patient.

The Review Team conclude that Service User A received unconventional and inadequate treatment. The expected multi-professional involvement in his care was

omitted. Service User A's disease progressed whilst being inadequately treated. The opportunity to offer him radical treatment with curative intent was lost.

Service User B

Service User B was diagnosed clinically and biochemically with prostate cancer, and was commenced on bicalutamide 50mgs. Bicalutamide (50mg) is currently only indicated as a preliminary anti-flare agent (or in combination with a LHRH analogue) and is only prescribed before definitive hormonal (LHRH analogue) treatment. The review team note that this treatment was not in adherence with the Northern Ireland Cancer Network (NICAN) Urology Cancer Guidelines (2016), which was signed off by the Southern Health and Social Care Trust (SHSCT) Urology Multi-disciplinary Meeting, as their protocols for Cancer Peer Review (2017). This guidance was issued when Doctor 1 was the chair of this group and had full knowledge of its contents. The review team note that, following discussion with Service User B, 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.

A biopsy result taken at the time of transurethral resection of prostate (TURP) showed benign disease (low volume sample 2g from central area of prostate). There were no further investigations to explore the clinical suspicion of prostate cancer.

The possibility of localised prostate cancer was considered from the time of presentation because the PSA was elevated; however, there was no record in the medical notes of any digital rectal examination (DRE) findings. During the operation further signs might have been elicited and appropriate biopsies could have been performed. TURP is not an adequate way to biopsy the prostate gland for suspected prostate cancer. The Review Team conclude that sufficient evidence of localised prostate cancer was apparent from the time of presentation. A correct course of action would have been to arrange appropriate staging scans and biopsies. Service User B should have undergone investigation with a MRI scan of the prostate and pelvis and a bone scan should have been considered. A transrectal biopsy performed either at the time of the TURP or separately, would have secured the diagnosis.

Arrangement could then have been made to start conventional Androgen Deprivation Therapy (a LHRH analogue) with referral on to an oncologist for consideration of external beam radiotherapy (EBRT) potentially with radical intent. However, the patient was apparently lost to follow up after his appointment in July 2019.

Service User C

Service User C was referred to urology service following a visit to ED in December 2018. He was reviewed promptly by Dr 1 in January 2019. Investigations were arranged and a diagnosis of a large right-sided renal carcinoma was made. He was counselled regarding the risks and benefits of surgical intervention and chose to proceed with the high-risk surgery.

On 6 March 2019 Service User C was admitted for an elective radical nephrectomy.