Southern Health and Social Care Trust

Quality Care - for you, with you

Urology Cancer MDT Operational Policy - Agreement Cover Sheet

This MDT Operational Policy has been agreed by:

Position	Director of Acute Services
Name	Mrs Esther Gishkori
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by the USI

Position	Clinical Director Cancer Services
Name	Dr Rory Convery
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by the USI

Position	MDT Lead Clinician (on behalf of MDT members)
Name	Mr Anthony Glackin
Organisation	Southern Health & Social Care Trust
Date Agreed	1st September 2017
Signed	Personal Information redacted by the USI

The MDT members agreed this Operational Policy on:

Date Agreed	**1st September 2017**
Operational Policy Review Date	**1st September 2018**

SECTION 1: STRUCTURE AND FUNCTION OF THE MDT

1.0 Purpose of the MDT

MDTs bring together staff with the necessary knowledge, skills and experience to ensure high quality diagnosis, treatment and care for patients with cancer. MDT working has been advocated in each of the NICE Improving Outcomes Guidance and is strongly supported by clinicians.

The primary aim of the SHSCT Urology Cancer MDT is to ensure equal access to diagnosis and treatment for all patients in the agreed catchment area with Urological cancer. In order to achieve this aim we provide a high standard of care for all patients including: efficient and accurate diagnosis, treatment and ensuring continuity of care.

The MDT ensures a formal mechanism for multidisciplinary input into treatment planning and ongoing management and care of patients with Urological cancer with the aim of improving outcomes and to:

- Provide an opportunity for multidisciplinary discussion of all new cases of Urological cancer presenting to the team
- To assess newly diagnosed cancers and determine, in the light of all available information and evidence, the most appropriate treatment and care plan for each individual patient
- Ensure care is delivered according to recognised guidelines
- Ensure that the MDT work effectively together as a team regarding all aspects of diagnosis, treatment and care
- Facilitate communication with other professional groups within the hospital and between the MDT and other agencies e.g. primary care, palliative care
- Facilitate collection and analysis of high quality data to inform clinical decision making and to support clinical governance/audit
- Promote multidisciplinary decision making regarding the team's operational policies
- Support implementation of service improvement initiatives
- Ensure incorporation of new research and best practice into patient care
- Ensure mechanisms are in place to support entry of eligible patients into clinical trials, subject to patients fully informed consent
- Provide education to senior and junior medical, nursing and allied health staff.

1.1 Membership Arrangements

Core and extended membership of the Urology cancer MDT is detailed below:

Core Membership **(14-2G-101)**

Position	Name	Cover
Consultant Urological Surgeon*/**	Anthony Glackin	Aidan O'Brien Mark Haynes

1.5 Chairing of meetings

The chairing of MDMs has been shared by Mr Glackin, Mr O'Brien and Mr Haynes on a rotational basis. Mr O'Donoghue joined in chairing on a rotational basis during 2016. The person appointed to chair each MDM is decided at least one month previously, when a period of time equivalent to one session is allocated to the appointed Chair to preview all cases one day prior to the MDM. Adequate preparation time is included in Job Plans and in a pro rata, annualised, quantitative manner.

1.6 MDT Review (14-2G-103)

The MDM takes place every Thursday, unless otherwise notified, and begins promptly at 14:15 in the tutorial room, Medical Education Centre in Craigavon Area Hospital. The meeting takes place in a room with video conferencing facilities, enabling communication by video to Daisy Hill Hospital, Newry, and with the Specialist MDM in Belfast.

Video conferencing with the Specialist MDT is scheduled to take place at 3.30 pm, or as soon as is mutually convenient thereafter.
It is the policy of the Southern MDT that all MDMs should finish by 5 pm at the latest. It has been the experience of the MDT that the number of cases to be discussed has had to be limited to 40 in order to enable the MDM to finish by 5 pm.

All new cases of Urological cancer and those following Urological biopsy will be discussed. Patients with disease progression or treatment related complications will also be discussed and a treatment plan agreed. Patient's holistic needs will be taken into account as part of the multidisciplinary discussion. The Clinician who has dealt with the patient will represent the patient and family concerns and ensure the discussion is patient-centred.

All meetings are supported and organised by the MDT Coordinator. The MDT Coordinator is responsible for collating the information on all patients being discussed and ensuring that all the necessary information is available to enable clinical decisions to be made.

Responsibilities of the MDT Coordinator:

- Ensuring all cancer patients are discussed at the MDT meeting
- Inserting notes onto the pro forma and ensuring it has been signed-off as being a correct record of the meeting's discussion (this forms the main body of the MDT letter to GP)
- Insertion of clinical summaries and updates onto CaPPs
- Filing the pro forma into the relevant notes and forwarding a copy to the oncology department of those patients who need to be referred to the oncologists
- Posting a summary sheet or the pro forma to the referring General Practitioner within 24 hours of the MDT discussion taking place
- Recording the MDT attendance for every meeting
- Adding any patient on the MDT list not discussed (notes, films or results missing, lack of time), to the following week's list

Why was that relevant from a benchmarking perspective?

A. DR. HUGHES: It's really to show the principles of how a functional MDT should work and how they should deliver care for patients.

97 Q. Yes. In terms of the dual work that you were carrying out, that's more relevant for the governance side, for your side of the house, Dr. Hughes? 12:17

A. DR. HUGHES: Yes.

98 Q. Is there anything in particular in that document that you wish to refer us to? I know that, within your reports, you talk about difficulties within the MDT, cases not being referred back, failure to escalate, deficits in care, these kinds of things? 12:17

A. DR. HUGHES: I think the overarching findings were that absence of Clinical Nurse Specialists meant that there was no overarching view of MDT recommendations being implemented. 12:17

99 Q. Yes.

A. DR. HUGHES: There is a requirement, if you don't implement an MDT recommendation, that you would bring it back to your colleagues and discuss it, and agree how that would be achieved. I think the other issues are that, because the team focused on first diagnosis and first treatment, patients weren't being brought back to the MDT for discussion as their care needs changed, and because a cohort of patients were not also being cared for by a nurse specialist, it meant that they had a major deficit in their care. 12:18 12:18

100 Q. There's a series of documents cited by you as having

5.0 DESCRIPTION OF INCIDENT/CASE

advised of the outcome of the MDM by letter.

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

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

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

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

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

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

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

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

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

5.0 DESCRIPTION OF INCIDENT/CASE

chest, abdomen and pelvis.

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

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

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

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

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

6.0 FINDINGS

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

SECTION 3: PATIENT EXPERIENCE

3.1 Key Worker (14-2G-113)

The identification of the Key Worker(s) will be the responsibility of the designated MDT Core Nurse member.

It is the joint responsibility of the MDT Clinical Lead and of the MDT Core Nurse Member to ensure that each Urology cancer patient has an identified Key Worker and that this is documented in the agreed Record of Patient Management. In the majority of cases, the Key Worker will be a Urology Clinical Nurse Specialist (Band 7) or Practitioner (Band 6). It is the intent that all Key Workers will have attended the Advanced Communications Skills Course.

Patients and families should be informed of the role of the Key Worker. Contact details are given with written information, and in the Record of Patient Management.

As patients progress along the care pathway, the Key Worker may change. Where possible, these changes should be kept to a minimum. It is the responsibility of the Key Worker to identify the most appropriate healthcare professional to be the patient's next Key Worker. Any changes should be negotiated with the patient and carer prior to implementation, and a clear handover provided to the next Key Worker.

Urology Clinical Nurse Specialists and Practitioners should be present or available at all patient consultations where the patient is informed of a diagnosis of cancer, and should be available for the patient to have a further period of discussion and support following consultation with the clinician, if required or requested. They may also be present, and should be available, when patients attend for further consultations along their pathway.

Key responsibilities of the Key Worker:

- Act as the main contact person for the patient and carer at a specific point in the pathway
- Should be present when the cancer diagnosis is discussed and any other key points in the patients journey
- Offer support, advice and provide information for the patient and their carers, referring to Macmillan Information and Support Service as appropriate to enable access to services
- Ensure continuity of care along the patients pathway and that all relevant plans are communicated to all members of the MDT involved in the patients care
- Ensure that the patient and carer have their contact details, that these contact details are documented and available to all professionals involved in that patients care

6.0	FINDINGS

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 as 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 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 according to NICAN Urology cancer guidelines 2016 but a

6.0	FINDINGS

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 the case and was known to be so.
- 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

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

XX 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, XX 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. XX re-attended as advised as the problem had not resolved.

On 2 April 2019, XX 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. XX's case was discussed with Dr.1 (Consultant Urologist) who examined XX and confirmed these findings. It was noted that XX 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, XX'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 XX and arrange for a CT scan of XX's chest, abdomen, and pelvis to complete staging.

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

6.0 FINDINGS

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

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

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

- The recommendations from MDT indicate "all newly diagnosed patients have a Key Worker appointed, a Holistic Needs Assessment conducted, adequate communication and information, advice and support given, and all recorded in a Permanent Record of Patient Management which will be shared and filed in a timely manner".[(4)] This did not happen.

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

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

7.0 CONCLUSIONS

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

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

appropriate surgical procedure that he performed. Although undoubtedly there were some considerable delays in the management of this individual, very few of these can be directly ascribed to Mr O'Brien himself. Instead, the main issues seem to reflect the fact that the patient first presented to his GP having suffered from some symptoms for some time and the fact that the urological service of the Southern Trust has been under significant pressure as a result of longstanding under-resourcing and under-staffing.

It is worth reanalysing step-by-step the individual causes of delay over the course of this patient's management:

A crucial initial delay in the cancer diagnosis stemmed from the delay in patient SUH's presentation to his GP. His symptoms of a painful mass beneath the foreskin accompanied by intermittent bleeding had been present for at least three months, according to his GP, and at least six months, according to the patient himself, before he presented to his local practice in February 2019. In all probability it was during that period, and/or during the 5-week delay between the GP referral and him actually being seen in clinic, that his cancer micro-metastasised from the penis to the regional and supra-regional lymph nodes. Even when he did present, there was a further two-week delay while a locum GP inappropriately prescribed miconazole and clarithromycin, advising the patient to return in two weeks if the symptoms persisted. Eventually an appropriate "red flag" referral was made to urology at CAH on 19 February. Unfortunately, another 5 weeks elapsed before he was actually seen first in clinic on 2 April 2019, jointly by Mr Hiew and Mr O'Brien. This initial delay was presumably due to a lack of available clinic slots, even for "red flag" cases. When he was eventually seen in early April 2019, the clinically correct decision was made to proceed to an urgent radical circumcision. This was performed expeditiously one week later on 10 April 2019 – not by Mr O'Brien himself, but instead by Mr Evans.

Histology became available for an MDM review by Mr O'Brien promptly on 18 April 2019 confirming complete excision of an intermediate risk squamous cell carcinoma. At this point the decision was made to review the patient and organise a CT scan, which was anticipated in all likelihood to confirm no evidence of metastatic spread. Mr O'Brien reviewed the patient on 24 May 2019. His clinical note then confirmed his plan to proceed with CT CAP (chest, abdomen and pelvis) followed by further review in clinic in June 2019.

Unfortunately, this staging investigation was not performed until 26 July 2019. The CT scan rather unexpectedly revealed a solitary enlarged left inguinal lymph node measuring 1.3cms, suggestive of secondary spread of the penile squamous cell carcinoma. Mr O'Brien himself was not able to see the patient in clinic again until 23 August 2019, again presumably because of booking delays within the system. At that juncture he made the clinically correct decision to request an ultrasound guided biopsy of the enlarged lymph node.

Following this request, the US-guided biopsy took place expeditiously on 6 September 2019. Histopathology from the specimen confirmed the presence of metastatic squamous cell carcinoma within the enlarged node.

SUH's case was then discussed promptly at the Urology MDM on 12 September 2019. The findings of metastatic squamous cell cancer in the biopsy were noted and a recommendation made then for a left inguinal lymph node dissection to be undertaken.

Mr O'Brien reviewed the patient in clinic one week later on 20 September 2019 and, according to him, after explaining the risks and benefits of the procedure (unfortunately this discussion with the patient was not recorded in the notes), he proceeded with appropriate haste to perform a left inguinal lymphadenectomy on 9 October 2019 . The patient was discharged home 4 days later on 13 October 2019. Histology from the left inguinal lymph node dissection became available on 16 October 2019 and confirmed metastatic squamous cell carcinoma in 2 out of 5 lymph nodes harvested.

The case was then discussed again at the Urology MDM the following day on 17 October 2019 when a correct decision was made to organise a further CT scan in order to rule out the possibility of more distant metastases.

Mr O'Brien himself reviewed the patient expeditiously on 8 November 2019 and aspirated 250mls of lymphatic fluid from his groin. Mr O'Brien then arranged for the patient to reattend on 13 November 2019. At that stage Mr O'Brien requested a further CT staging scan of the chest, abdomen and pelvis to be performed in January 2020.

This CT CAP scan was performed on 22 January 2020. This scan revealed multiple lymphadenopathy consistent with widespread metastases from the original squamous cell carcinoma.

Mr O'Brien then saw the patient promptly on 14 February 2020 and then recorded his intention to refer the patient to the Department of Urology at Altnagelvin Hospital, which had recently been set up as the reference centre for management of penile carcinoma. It is important to emphasise that this supra-regional service, in conjunction with the Christie Hospital in Manchester, was only established in December 2019.

The patient was subsequently seen in Altnagelvin Hospital by a Consultant Urologist, Mr Mulholland, on 25 February 2020 who organised a PET CT scan and oncology referral.

Sadly, in spite of chemotherapy and radiotherapy, the patient suffered a fall at home and was admitted to hospital having suffered a fractured femur in Personal Information redacted by the USI and passed away on Personal Information redacted by the USI.

Chronology of diagnosis and treatment indicating points and periods of delay:

1. **Autumn 2018**: Symptoms of a penile mass developed with bleeding (at least 3 months, delay)
2. **19 February 2019:** Referral by GP
3. **2 April 2019:** First seen at CAH by Mr O'Brien (5 weeks delay)
4. **10 April 2019:** Circumcision performed (8 days later)
5. **18 April 2019:** MDM review – Mr O'Brien – complete excision achieved, CT recommended (1 week later)
6. **24 May: 2019:** Seen in Clinic

7. **28 July 2019:** CT performed (9 week delay)
8. **23 August 2019:** Outpatient review and lymph node biopsy requested (5 week delay)
9. **6 September 2019:** Biopsy performed – positive for cancer (2 week delay)
10. **12 September 2019:** MDM – plan lymph node dissection
11. **9 October 2019:** Lymph node dissection performed (4 week delay)
12. **13 November 2019:** Further CT requested (5 week delay)
13. **22 January 2020:** CT performed – multiple metastases detected (10 week delay)
14. **14 February 2020:** Seen by Mr O'Brien in outpatients, referred on (3 week delay)

It is apparent that many of the unacceptable delays in the management of this case can be attributed to CAH's lack of outpatient slots and reflect an overloaded urology service in the Southern Health and Social Care Trust. During the 12-month interval between the original referral by the GP and Mr O'Brien's onward referral to a specialist in penile cancer and oncology, only steps 7 and 12 above can be legitimately considered to be directly under Mr O'Brien's control. The CT scan was not requested on the 24 May (step 7) as intended and therefore not performed until 28 July (9 week delay). If this had been done the patient could have been reviewed with the report in July 2019 at the latest, thereby expediting his further management by a month. The delay between step 12 and 13 (10 week delay) was also attributable to Mr O'Brien, but the understandable rationale for this was that the restaging CT scan should be performed during January 2020 in order to provide time for resolution of reactive lymphadenopathy to resolve. The performance of a follow-up CT scan very soon after surgery to the groin can certainly lead to confusion because of the local swelling and reactive changes in the lymph nodes which can easily result in misdiagnosis. The remaining delays - including bookings for out-patient review - were clearly beyond Mr O'Brien's control and the responsibility lies with the Trust not the individual clinician.

The second criticism of Mr O'Brien stems from the lack of written informed consent from the patient concerning the risks and benefits of the two procedures performed. It is acknowledged that the consent form did not contain details in respect of the risks / intended benefits of the procedure. However, the circumcision itself was not undertaken by Mr O'Brien, but instead by Mr Evans. Before he performed the lymphadenectomy Mr O'Brien maintains that he did provide the requisite information to the patient verbally and a signed consent form is present in the patient's notes.

The third criticism directed at Mr O'Brien is his failure to refer the patient promptly onwards to a supra-regional penile cancer group. However, Mr O'Brien has clarified that the supra-regional penile cancer group, which included the Christie Hospital in Manchester, was not in fact established at the time of the MDM on 12 September 2019 when the diagnosis of metastatic penile cancer was made, and was not in fact set up until December 2019.

The lack of a functioning supra-regional penile cancer network in Northern Ireland until December 2019 largely provides the explanation for the fact that local and national guidelines were not adhered to in this case in terms of the timing of interventions. However, it should be remembered that guidelines are established to provide guidance and should not be regarded as prescriptive. All the sequential steps in the diagnosis and treatment of

I had been referred a few prostate cancer patients by Mr O'Brien who had been commenced on an unlicensed dose of Bicalutamide hormone therapy prior to referral to oncology.

1(ii) b *prescribing outside guidelines*

The licenced doses for Bicalutamide are either 150mg once daily as a monotherapy, or 50mg once daily when used in combination with hormone therapy injections known as luteinizing hormone releasing hormone agonists. There are no licenced indications that I am aware of for Bicalutamide 50mg once daily as a monotherapy. As such I viewed the used of the Bicalutamide 50mg once daily as a monotherapy as being outside the licenced indications.

Mr O'Brien in his position as chair of the NICAN Urology group in 2015 had asked for guidelines to be written for each urology disease sub-site. I wrote the androgen deprivation therapy guidelines in 2015 to accurately define our regional use of hormone therapy at that stage in line with the licenced indications. I hoped that this would standardise practise with the appropriate of dose Bicalutamide being used within our regional guidance document. Following discussion at the NICAN urology group meeting on a number of occasions in 2015 a final version was sent to Mr O'Brien on 10/10/2016 (***AOB3***)

1(ii) c *Bicalutamide*

As outlined above

(iii) How, in your view, did these issues differ from normal medical practice?

1(iii) Normal practise would have been to prescribe a dose of Bicalutamide that was within the licenced indications or to refer to oncology for discussion and allow the oncology team to discuss treatment options including the use of hormone therapies such as Bicalutamide.

(iv) If they differed, what, if any, action was taken by you or others? If none, why not?

1(iv) Firstly - I emailed Mr O'Brien in November 2014 (***AOB1***) highlighting a case that had been passed to me as the new chair of the regional urology MDM. The patient had been commenced on Bicalutamide 50mg once daily as a monotherapy. In that email I outlined the standard of care that we as oncologists would have offered in terms of hormone therapy. I advised that I was writing the regional guidelines to standardise the approach to hormone therapy prescription across the region, and pasted a link to guidance on off label prescription, good practise recommendations and our responsibilities within that. I offered further discussion on this.

Secondly I wrote the regional guidelines on androgen deprivation therapy and passed these through to Mr O'Brien as the NICAN urology chair and the NICAN urology group for sign off. These guidelines reflected the licenced indications and doses of hormone therapy.

Angela Kerr

From: Mitchell, Darren < Personal Information redacted by the USI >
Sent: 20 November 2014 13:35
To: O'Brien, Aidan
Subject: Patient 126

Aidan –could I ask you to have a look at this case which was passed to me as the regional MDT chair.

Looks like young man with high grade organ confined disease from 2012. From my prospective he would have been considered for neo-adjuvant hormones for 3-6months followed by EBRT in early 2013. He may have been suitable for combined EBRT + BT (pending LUTS assessment). His high grade disease would have encouraged us to offer him 2-3years of adjuvant hormonal therapy after EBRT depending on 2008 or 2014 NICE guidelines and pt tolerance.

I'm not aware of any of his co-morbidities or performance status.

As hormonal therapy in this case we would use LHRHa or occasionally Bicalutamide 150mg OD monotherapy.

I'm told he has only just been referred for radiotherapy at 2 years after initial MDT presentation.

I'm not aware of supportive research for 24months of neo-adjuvant hormones prior to EBRT but the trans-tasmin group 0 vs 3 vs 6 and the Canadian 3 vs 8 are already quoted in our radiotherapy protocol and based on those studies we typically think of 6 months neo-adjuvantly in this kind of case.

6 months of LHRHa prior to EBRT is also recommended in the STAMPEDE protocol for men with high risk non-metastatic disease who are for radical radiotherapy.

I'm also told that he was on Bicalutamide 50mg OD for the first year of his management.

The NICAN hormone protocol (in process) would be useful in standardising our therapy across the region but Bicalutamide 50mg is not licenced for mono-therapy use and will not be recommended in the protocol other than within the licenced context for the management of flare with LHRHa.

The MRHA site provides information on 'off-label' prescribing and our responsibilities within that.

http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON087990

Happy to discuss this further.

REGIONAL HORMONE THERAPY GUIDELINE

The regional guidelines on hormonal therapy for prostate cancer are drawn from the extensive research in this region and broadly adhere to the EAU guidelines (1) and NICE guidelines (2) on this topic.

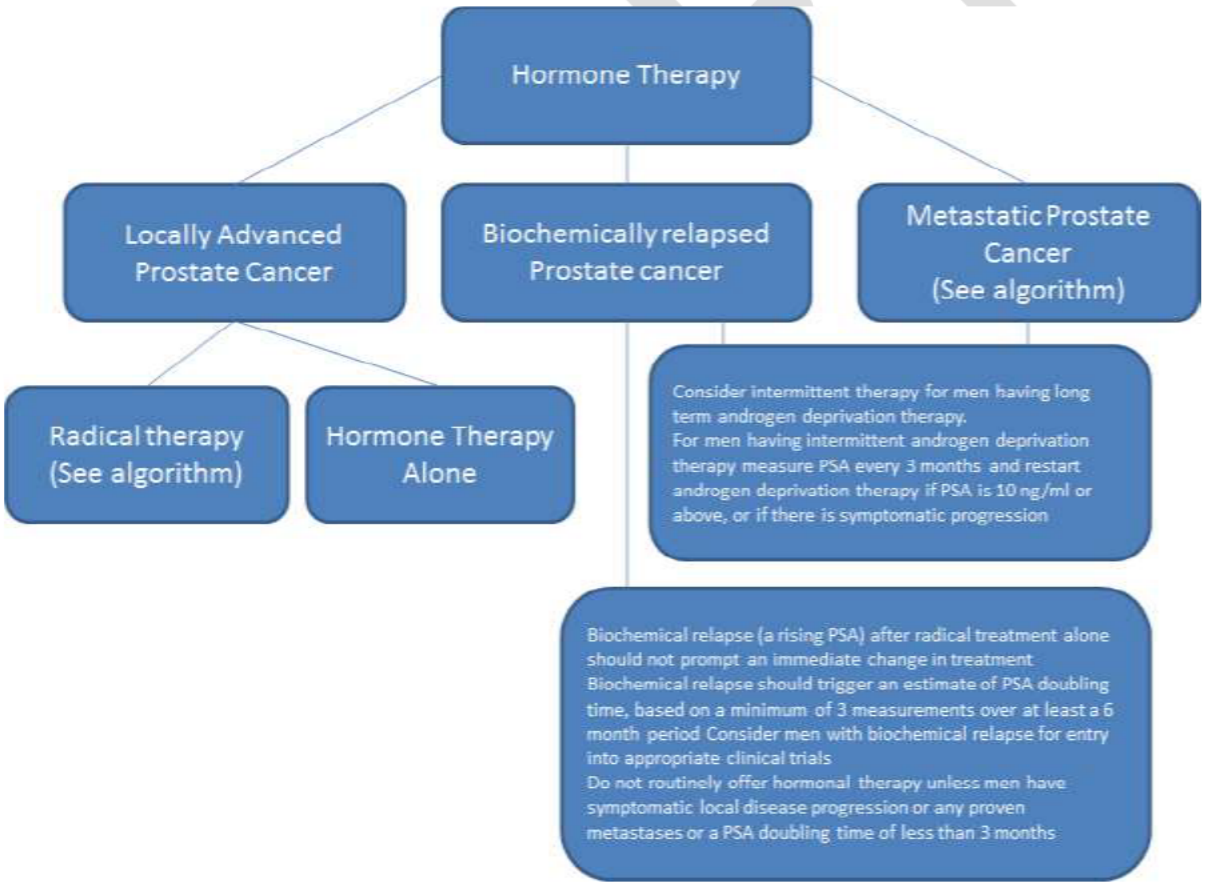
The role of hormonal manipulation in men with prostate cancer is well established and fits within 3 broad groups.

1) Neo-adjuvant, concurrent and adjuvant hormone therapy with radical treatment.

2) Treatment of biochemical failure after radical treatment.

3) Treatment of metastatic disease.

Men within each group should be advised of the role of hormonal therapy in the management of their cancer and where appropriate PSA trigger points should be given.
Men should be advised of alert signs and symptoms of cancer progression which should be reported to the supervising clinical team and rapid access arrangements explained.



Southern Health and Social Care Trust

UROLOGY
OUTPATIENTS LETTER

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

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

Personal Information redacted by the USI

Dear Personal Information redacted by the USI

Re: Patient Name: Patient 82
D.O.B.: Personal Information redacted by the USI
Address: Personal Information redacted by the USI
Hospital No: Personal Information redacted by the USI **HCN:** Personal Information redacted by the USI

Date/Time of Clinic: 02/11/20	**Follow Up:** PSA February 2021

Diagnosis:
Localised intermediate risk prostate cancer initially diagnosed 2010 and commenced on low dose Bicalutamide 50mg and Tamoxifen 10mg February 2011

Outcome:
Stop Bicalutamide/Tamoxifen
Check PSA and write with result. (At Patient 82 request I have also checked a number of other bloods as he says he has not had his diabetes blood test checked for a while)
Check PSA February 2021 and write with result

Patient 82 came to see me in the outpatient department following review of his notes. He has been treated with a low dose of Bicalutamide since diagnosis with a localised intermediate risk prostate cancer back 2010. From memory Patient 82 or his daughter could not recall having any discussion regarding alternative radical treatment options such as radiotherapy nor any discussions of active surveillance/watchful waiting.

I have explained the rationale behind reviewing his prostate cancer treatment and have explained the concerns associated with longterm anti-androgen treatment, in addition I have explained the dose of Bicalutamide he was on is below the recommended treatment dose and studies have shown a worse outcome for men treated with this dose of Bicalutamide as monotherapy.

Assessing his prostate cancer it may well be that he does not need any treatment for his prostate cancer and I have recommended in the first instance we stop his Bicalutamide and Tamoxifen and monitor his PSA. I have advised that if his PSA

needed any hormone treatment, or if they weren't having brachytherapy, if they were having some other treatment, then I would have written back to the GP, copied the referring consultant to say that I was keeping them on Bicalutamide but at a correct dose of 150mg. At least that's my memory of how I would have phrased the reply letter. I would have taken the patients then through their chosen treatment. 10:23

16 Q. So, in relation to sequencing, we'll go to the 2014 e-mail just in a moment. The context that led to that was that you were getting referrals from patients who were on Bicalutamide 50. As you've said, you adjusted the dose to 150? 10:24

A. (Witness Nods).

17 Q. And we'll look at that in a moment. But that was an indication in 2014, when you thought about it you realised that this issue had been going back to 2008. Is that what your evidence is? 10:24

A. Reflecting back, I suspect there were a number of cases that fitted that particular pathway of Bicalutamide 50, coming for consultation, a correct dose being offered. But I don't think I would have noticed it at the time of seeing them, other than believing it was a prescription error. 10:24

18 Q. Well, just as a baseline for your evidence, what's your understanding of the dosage that should be prescribed in relation to Bicalutamide? 10:24

A. So, the Bicalutamide falls into two doses; we have 150mg once a day, which can be used as a monotherapy,

Southern Health & Social Care Trust

Findings of the Root Cause Analysis – Patient 95
Incident Ref - [redacted]
Personal information redacted by USI

October 2010

6 ANALYSIS

This section of the report summarises the analysis conducted during this investigation, which has been complied from a review of the materials generated as a result of the activities outlined in Sections 5.1 to 5.3 of this report. The analysis contained in this report focuses in detail on the immediate postoperative period. The analysis undertaken supports the conclusions reached by the investigation team and the recommendations identified in Section 7 of this report.

The primary issue in this incident is clearly the retention of a swab following surgery. Although the surgeon is ultimately responsible for what happens during surgery the responsibility for ensuring that the swabs are correctly counted prior, during and at the end is delegated to the scrub nurse. The outcome of the inquiry on this occasion highlighted the count was not correct. Because this was a long procedure there was a change of Scrub Nurse and it is unclear from the record which of the scrub nurses was responsible when the error was made. In addition the method of counting the swabs when a swab is left in the patient's cavity was not standardised across all theatres. The method used on that day in that theatre is unclear.

The second issue was the delay in diagnosis; There was a three-month follow up CT Scan of abdomen performed on the 1st October 2009. A diagnosis of retained swab was not made on this scan but the reporting consultant radiologist described a mass measuring 6.5cm in the region of the right renal bed. The differential given for this mass included a seroma or local recurrence. The high-density areas within the mass lesion were described as multiple surgical clips.

Although a diagnosis of a retained swab was not made on the CT Scan report a pathological abnormality was described, however this report was not seen by the consultant urologist as it is his routine practice to review Radiological and Laboratory reports when the patient returns for post-operative follow up. The planned four-month follow up never took place due to the waiting times for review at Outpatients.

Patient 95 subsequently presented and was admitted medically on the 6th (discharged on the 12th when eating and drinking normally) and again on the 14th with symptoms of sub-acute bowel obstruction. A further CT scan of abdomen was performed on the 7th July 2010. This was reported by the same consultant radiologist as showing an unusual appearance to a loop of colon within the pelvis that contained faecalent material and intraluminal linear high-density material suggestive of surgical clips. The reporting consultant radiologist and a consultant physician reviewed this scan and the diagnosis was of small bowel loops in the pelvis and a possible adhesion. She was discharged following surgical review and resolution of symptoms on the 12th July 2010.

Patient 95 was readmitted medically on the 14th July 2010 with cough and green sputum for 24 hours. On the 16th July abdominal x-rays were reviewed by the Surgical SHO on call and noted no obvious obstruction.

She continued to have episodes of vomiting. A further surgical review by Dr 2, a Surgical Core Trainee was undertaken on the 19th July at 03.00 again regarding evidence of obstruction. There was no evidence of same initially, but he felt that there was evidence of a foreign body within the pelvis aside from surgical clips

I will need assistance when replying to this email.

Thanks

Martina

Martina Corrigan
Head of ENT and Urology
Craigavon Area Hospital

Tel: Personal Information redacted by USI (Direct Dial)
Mobile: Personal Information redacted by USI
Email: Personal Information redacted by USI

From: aidanpobrien Personal Information redacted by the USI [mailto: Personal Information redacted by the USI]
Sent: 25 August 2011 15:37
To: Corrigan, Martina
Subject: Re: Results and Reports of Investigations

Martina,

I write in response to email informing us that there is an expectation that investigative results and reports to be reviewed as soon as they become available, and that one does not wait until patients' review appointments. I presume that this relates to outpatients, and arises as a consequence of patients not being reviewed when intended. I am concerned for several reasons:

- Is the consultant to review all results and reports relating to patients under his / her care, irrespective of who requested the investigation(s), or only those requested by the consultant?
- Are all results or reports to be reviewed, irrespective of their normality or abnormality?
- Are they results or reports to be presented to the reviewer in paper or digital form?
- Who is responsible for presentation of results and reports for review?
- Will reports and results be presented with patients' charts for review?
- How much time will the exercise of presentation take?
- Are there other resource implications to presentation of results and reports for review?
- Is the consultant to report / communicate / inform following review of results and reports?
- What actions are to be taken in cases of abnormality?
- How much time will review take?
- Are there legal implications to this proposed action?

I believe that all of these issues need to be addressed,

Aidan.

-----Original Message-----
From: Corrigan, Martina < Personal Information redacted by USI >
To: Aidanpobrien Personal Information redacted by the USI ; Personal Information redacted by USI >; Akhtar, Mehmood Personal Information redacted by USI >; O'Brien, Aidan < Personal Information redacted by USI >; Young, Michael < Personal Information redacted by USI >
CC: Dignam, Paulette < Personal Information redacted by USI >; Hanvey, Leanne < Personal Information redacted by USI >; McCorry, Monica < Personal Information redacted by USI >; Troughton, Elizabeth Personal Information redacted by USI >
Sent: Wed, 27 Jul 2011 5:30
Subject: FW: Results
Dear all

LEVEL 1 – SIGNIFICANT EVENT AUDIT INCLUDING LEARNING SUMMARY REPORT AND SERVICE USER/FAMILY/CARER ENGAGEMENT CHECKLIST

SECTION 1

1. ORGANISATION: SHSCT	**2. UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE:** Personal Information redacted by the
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE: S Personal Information redacted by the	**4. DATE OF INCIDENT/ EVENT: 17 July 2018**
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: No	**6. IF 'YES' TO 5. PLEASE PROVDE DETAILS:**

7. DATE OF SEA MEETING / INCIDENT DEBRIEF: 07 August 2019

8. SUMMARY OF EVENT:

Patient 92 was referred to Craigavon Area Hospital Emergency Department on 2 November 2017 by her GP for a productive cough, lethargy, sweats and back pain for 2 months. Patient 92 was admitted to the ward and treated for a urinary tract infection (UTI) and poor diabetic control. Patient 92 was discharged home the following day with a plan for an outpatient renal tract ultrasound scan (USS). Patient 92 had her USS on 16 November 2017 which reported further investigation was required to exclude renal malignancy.

Patient 92 had a follow up CT renal abdominal scan on the 28 November 2017. The CT scan reported that appearances most likely represented areas of renal inflammation, and likely infected renal cysts with probable abscess formation and that the appearances were not typical for underlying malignancy (cancer).

Patient 92 was contacted and advised to attend CAH ED for treatment of same. Patient 92 attended CAH ED and was admitted to the ward for treatment of an infected renal cyst. Prior to her discharge a follow up outpatient urology review appointment was arranged for 6 weeks and a repeat CT renal abdominal scan in 3 months' time.

Patient 92 never received a follow up urology outpatient review appointment. Patient 92 had a repeat CT scan on 13 March 2018 which reported a solid nodule suspicious of renal cell carcinoma. There was no follow up following CT report.

Patient 92 attended her GP on the 10 July 2018 complaining of right sided abdominal pain. Patient 92's GP noted the overlooked CT report and immediately forwarded a red flag urology referral to Craigavon Area Hospital.

SECTION 2

9. SEA FACILITATOR / LEAD OFFICER: Dr D Gormley, Consultant Physician	**10. TEAM MEMBERS PRESENT:** Ms W Clayton, Head of Service Mrs K Robinson, Booking & Contact Centre Manager Mrs C Connolly, Clinical Governance Manager

13. Why did it happen?

As part of the review process the chair of the review met with Patient 92 to discuss treatment and care prior to Patient 92's partial nephrectomy. Patient 92 advised that when she attended CAH with symptoms she felt staff did not listen to her concerns. Patient 92 believed her symptoms were more than a UTI and warranted further investigation at the time of presentation and not at a later date.

The review team reviewed Patient 92's first CAH ED attendance on 3 November 2017. The Review Team concluded treatment and care provided in CAH ED and on the ward was appropriate given Patient 92 presenting symptoms and the plan for an outpatient ultrasound scan was considered appropriate. The Review Team acknowledges Patient 92 had her ultrasound scan 13 days post discharge. This was considered by the Review Team an appropriate time frame for follow up.

The Review Team recognise the result of the ultrasound scan was appropriately followed up the following day by Dr 2 and arrangements were made for Patient 92 to have an urgent CT abdomen and pelvis scan to exclude renal malignancy on the 28 November 2017. The report was available the following day.

The Review Team identified Patient 92 was appropriately referred on to the cancer tracker system on the 23 November but unfortunately did not attend her appointment on 4 December 2017 due to her inpatient status under the care of the Urology Team.

The review team has reviewed Patient 92's medical notes from her admission on 29 November 2017 to her discharge on the 7 December 2017, and considers treatment and care during this period was appropriate. The Review Team recognises results were appropriately followed up by doctor 2 and appropriate arrangements were made for Patient 92 to re-attend CAH ED and to be admitted under the care of the urology team. Patient 92 was admitted to the Gynecology ward under the care of doctor 3, Consultant Urologist. Patient 92 was treated for an infected renal cyst with antibiotics. Patient 92 was discharged home with antibiotics on the 7 December 2017 with a plan to be followed up at Dr 3's outpatient clinic in six weeks and a follow up CT rena scar in three months' time. The Review Team has concluded a differential diagnosis of an infected renal cyst was appropriate following the CT report on 29 November 2017 and has therefore considered treatment and care, and discharge arrangements were all appropriate at the time.

The Review Team has reviewed the Patient Administration System (PAS) and confirmed Patient 92 was added to Dr 3's urgent urology outpatient waiting list following discharge on 7 December 2017. The Review Team acknowledges there are demand and capacity issues with Urology outpatient appointments, and waiting lists are extremely lengthy (currently 3 years). The Review Team acknowledge clinics are scheduled in advance, and recognise doctor 3's clinics may not have been scheduled that far ahead. With no outpatient clinic scheduled it would have being impossible for medical staff to ascertain Patient 92 would be appointed an outpatient appointment in six weeks' time. Patient 92 was therefore added to Dr 3's urgent urology waiting list which at the time had a waiting time of 96 weeks. Conversely, the Review Team concluded had Patient 92 been reviewed six weeks post discharge the management plan may not have changed given the recent CT scan result reporting an infected renal cyst and treatment received.

On 13 March 2018 Patient 92 attended CAH X-ray department for a CT renal with contrast. The Review Team note the report was finalised on the 20 March 2018 at 14:05. The Review Team have confirmed communication was emailed to the referring Consultant Urologist Dr 3 and secretary 1 and an additional secretary 2 (secretary1 was off on leave) on the same day 20 March 2018 at 14:54. The email advised all correspondents an urgent report for Patient 92 was available on Sectra Radiology Information System (RIS). The Review Team have identified Patient 92's report was completed in a timely manner and escalated to the referring consultant immediately by the Radiology Team. The Review Team on the other hand cannot confirm Dr 3 read the report. Secretary 2 has advised the Review

assessment. This was due to the androgen deprivation therapy he was receiving. According to the records, the patient underwent a follow-up blood test on 26 October 2020 that confirmed a reduction in the patient's PSA level. In a letter from a consultant urologist to the patient it was noted that: "I am pleased to report this has fallen significantly in response to your prostate injection treatment from a level of 138.3 to a level of 0.53 and this is extremely good news."

A follow up blood test was arranged for January 2021.

By letter dated 24 December 2020 from a consultant urologist to the patient, it was noted that a review of the patient had been planned for November but that the consultant had not been able to see him. It was noted that the patient was 'doing very well' on his injections with occasional side effects such as hot flushes and tiredness. The patient underwent follow-up blood tests as planned on 7 January 2021 and in a letter from a consultant urologist to the patient it was noted: "…this remains extremely low at 0.67 showing a continued good response to your hormone treatment as at present with the regular injections."

Conclusions and Opinion

In my considered opinion, the care of this patient by Mr O'Brien cannot be considered to fall below the expected standard of a reasonably competent consultant urologist. In fact, the surgical management of his sizeable right renal clear cell carcinoma with concomitant renal vein invasion should be regarded as exemplary. The safe and successful surgical excision of a sizeable renal tumour in a patient of Personal Information redacted by the USI of age with significant cardiovascular morbidity is no mean achievement.

Whether or not Mr O'Brien should have requested a PSA test on this patient when he first saw him in clinic on 17th January 2019 is a moot point. In my view this cannot be considered a serious omission for the following reasons: firstly, prostate cancer itself is a rather uncommon cause of haematuria, especially in the absence of significant lower urinary tract symptoms and a benign-feeling prostate on rectal examination (as was the case in this patient). Bladder and kidney cancer, as well as urinary stones, represent a much more common aetiology for this symptom. Secondly, by the time that Mr O'Brien saw the patient, who was by then Personal Information redacted by the USI of age and suffered other significant comorbidities including significant cardiovascular disease, the cause of the bleeding had already been clearly identified as a renal cell carcinoma. Consequently, a request for a PSA was no longer required clinically to establish the cause of the bleeding. It could have been carried out as a "screening investigation" to exclude the possibility of concomitant prostate cancer; however there was no absolute clinical indication for this.

The surgical management of the renal cancer by Mr O'Brien was, as already stated, exemplary, especially in a high-risk patient who was almost a nonagenarian, and the outcome of the surgery was excellent. The subsequent identification of a second significant urological diagnosis, namely metastatic adenocarcinoma of the prostate, was unfortunate – as was the delay in recognising the significance of the sclerotic spinal metastasis on the follow-up CT scan.

However, the blame for this delay cannot be laid entirely at the door of Mr O'Brien: it must be attributed partly to the Trust itself, because of the lack of sufficient outpatient slots available for patient SUC to be seen in clinic in January 2020, as had been envisaged. Had that clinic attendance

SECTION 3 - LEARNING SUMMARY

13. WHAT HAS BEEN LEARNED:

Causative Factor

The review team concluded Patient 90 had an unrecognised haemorrhage post operatively.

The review team note Patient 90's post mortem report. The cause of death was reported after post mortem as 1(a) Intra-abdominal and retroperitoneal haemorrhage following cystoscopy, insertion of ureteric stents and ureterolysis. 11 Cardiomegaly
'The post mortem reported noted 'Death was due to bleeding, or haemorrhage, into the abdominal cavity itself and into the fatty tissues at the back of the abdomen……..The post-mortem examination also revealed that the heart, and in particular its two main pumping chambers the ventricles, was enlarged. Such enlargement of the heart, termed cardiomegaly, would without doubt have made him less able to withstand the stresses place upon the body by the effects of the blood loss. Indeed the severity of his heart disease was such that it could have caused his death at any time. Therefore as his per-existing heart disease would have made him more susceptible to the effects of haemorrhage it would be best regarded as a contributory factor in his death'.

Contributory Factors
Patient factors

Patient 90 had significant comorbidities which included:-
[redacted]
Personal information redacted by the USI

A CT scan in December 2016 noted a *'Potentially haemodynamically significant coronary atheroma',* the review team can find no evidence that follow up investigations were organised for this finding. However, it appears that other findings on the CT scan were actioned for follow up.

Despite the patient discharge letter noting an outpatient echo was required, the review team were unable to identify that the echo was completed prior to surgery, there is no evidence of an outpatient echo being requested, and the last record of an echo being completed was in 2010 (EF 50%). Outpatient clinic letters highlight Patient 90 was under the care of cardiology for heart failure on the background of AF between 2010 and 2012.

There was a suspicion of coronary artery disease (CAD) in 2006 but he has no symptoms suggestive of angina at present.' He had a Direct Current Cardioversion (DC Cardioversion) for AF in 2012 and was on Bisoprolol (medication most commonly used for heart diseases) and aspirin, he had decline warfarinisation. Rate control was decided in 2012 Patient 90 was reviewed by cardiology to until 3 July 2012 when he was discharged from cardiology to his GP's care.

The review team notes the post mortem findings that Patient 90's pre-existing heart disease would have made him more susceptible to the effects of haemorrhage it would be best regarded as a contributory factor in his death.

Task Factors-Guidelines, Policies and Procedures

Results follow up
The review team note that all findings on the 2016 CT chest, abdomen and pelvis were not followed

up by the clinical teams.
The review team note there is no formal clinical result sign off guidance for the Southern Health and Social Care Trust (SHSCT), the Acute Directorate are developing guidance to implement clinical result sign off. The review team concluded that all results must be signed off and action taken to further investigate or manage findings.

A BNP blood test collected on 3 January 2017 was 1609pg/ml; this result was not documented on the patient discharge letter. The review team are of the opinion that here was no evidence to support if this was actioned.

Preoperative Assessment
Patient 90 was added to Doctor 1 urgent urology waiting list on 9 June 2017 and was pre-admitted for surgery at 15:50 on Thursday 3 May 2018 by Doctor 1's secretary. The review team noted that Patient 90 did not have a formal outpatient preoperative assessment as per Trust and National Institute for Clinical Excellence (NICE) guidance.
Patient 90 was booked for pre-operative assessment on the 4 May 2018. The review team considered that this referral did not give sufficient time to appropriately pre-operatively assess and optimise Patient 90 for surgery.

Patient 90 was in the emergency department of Craigavon Area Hospital on 4 May 2018 and called with the preoperative team at 09:00, as his preoperative assessment appointment was booked for 13:45 they were unable to assess him. He was advised to contact the preoperative team later that day if he was unable to attend his 13:45 appointment. Patient 90 did not attend this appointment. The anaesthetist was informed by the pre-operative team that Patient 90 had not attended.

The review team note that on 3 January 2017 Patient 90 Brain Natriuretic Peptide (BNP) test was 1609 is a blood test that measures levels of a protein called BNP that is made by the heart and blood vessels. BNP levels are higher than normal when you have heart failure). SHSCT echocardiography in the preoperative assessment clinic guidance highlights heart failure (either systolic or diastolic dysfunction) is a major perioperative risk factor. The presence of heart failure doubles the risk of dying after major surgery Patient 90 BNP was 1609pg/ml).
National NICE Chronic heart failure in adults: management (CG108) recommended refer patients with suspected heart failure and a BNP level above 400 pg/ml (116 pmol/litre) or an NTproBNP level above 2000 pg/ml (236 pmol/litre) urgently, to have transthoracic doppler 2D echocardiography and specialist assessment within 2 weeks. This guidance has been superseded by NICE guideline chronic heart failure in adults: diagnosis and management published: 12 September 2018 (nice.org.uk/guidance/ng106). However the review team noted that certain medications and medical conditions such as atrial fibrillation can affect BNP levels even in the absence of heart failure.

NICE guideline routine preoperative tests for elective surgery published: 5 April 2016 (nice.org.uk/guidance/ng45) recommends not routinely offering resting echocardiography before surgery. However, consider resting echocardiography if the person has:
a heart murmur and any cardiac symptom (including breathlessness, pre-syncope, syncope or chest pain) or signs or symptoms of heart failure. SHSCT guidance recommends a patient with known heart failure with a significant change in symptoms and an increase in BNP should have a preoperative echocardiogram.

Consultant 1 noted '*I do not regret the surgery as his quality of life was terrible due to the effects of indwelling ureteric stents. I do however regret not sending him for cardiac workup, including echo*

and coronary angiography. When he did have CT scanning performed in December 2016, he was reported to have gross enlargement of his atrium, and appeared to have a haemodynamically significant, atheromatous plaque in his left main stem'.

The review team considered that waiting lists for elective urology surgery and a cancellation could lead to a significant delay in relisting of a patient, however doctor 2 noted '*There was no push/ pressure to get the case done regardless'*

The review team concluded particularly in view of his comorbidities that Patient 90 should have had a formal preadmission pre-operative assessment with optimisation of his clinical condition prior to surgery. This assessment should have been organised sufficiently in advance of the surgery to allow for all appropriate investigations to be completed. This allows for patient optimisation and discussion regarding specific anaesthetic risk.

The review team noted that the consultant anesthetist Doctor 2 noted on the preoperative assessment on the day of surgery the Patient 90 comorbidities including ischaemic heart disease. The review team noted that Patient 90 had had previous anaesthetics which were uneventful.
Doctor 2 reported that *'induction of anaesthesia and intra-operative progress was largely uneventful'* and that Patient 90 was anaesthetically stable throughout the procedure. *'Blood pressure became more labile in the last 20 minutes of the case, although not to a major degree – he responded to small doses of metaraminol. Emergence from anaesthesia and extubation was uneventful. The patient did not look particularly unwell on transfer to his bed (of note, not clammy/pale.)'*
Doctor 2 highlighted there were serial arterial blood gases that showed that the haemoglobin and lactate were stable throughout the operative procedure. The review team concluded that these blood tests were missing from the notes.

The review team noted doctor 2's preoperative plan for an arterial line and venous access, and the anaesthetic management. The team notes a small amount of inotropes was administered during the procedure but these were not significant. The procedure was relatively long with the total procedure time 3 hours 45 minutes and the anaesthetic time 4 hours 27 minutes. The review team notes that there were no previous clinical notes available to doctor 2 on the day of surgery.
The review team considered that with the information available to the anaesthetist it was reasonable to progress with the surgery, the anaesthetic assessment and management of Patient 90 was appropriate.

Management of Patient 90 post-operative care

Post operatively he developed a labile blood pressure. He subsequently became agitated, tachycardic (fast heart rate) and hypotensive (low blood pressure) (NIBP 51/37). Patient 90 required further boluses of phenylephrine and 2x doses of haloperidol 2.5mg for agitation. Noradrenaline for inotropic support and amiodarone were administered. Patient 90 initially responded well but he developed anuria (no urinary output) and confusion. He was requiring increasing doses of inotropes. Patient 90 was transferred to theatre for intubation and insertion of dialysis line. There was ongoing intensive care including supra-maximal doses of inotropes and other resuscitative measures. Patient 90 was transferred to ICU at approximately 22:30.
The review team note the plan was to attempt to stabilise the patient and transfer to ICU for haemofiltration/ dialysis. However, despite maximal efforts lost cardiac output and cardiopulmonary resuscitation (CPR) was commenced. Despite CPR there was no return to spontaneous circulation and Patient 90 died at 23:10.

The review team noted the clinical team's differential diagnosis of a sudden cardiac event.