From the Deputy Chief Medical Officer
Dr Paddy Woods

HSS(MD)14 /2015

Department of
Health, Social Services and Public Safety
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Your Ref:
Our Ref: HSS(MD)14 /2015
Date: 18 August 2015

For Action:

Chief Executives HSC Trusts
Chief Executive HSCB
Chief Executive PHA
Chief Executive RQIA *(for dissemination to independent sector organisations)*

Dear Colleague

POLICY ON THE SURGICAL MANAGEMENT OF ENDOSCOPIC TISSUE RESECTION

ACTION REQUIRED

1. HSC Trusts and independent providers should process this regional policy template for endorsement by the organisational board, or equivalent;

2. HSC Trusts and independent providers should develop action plans to implement the various elements of the endorsed policy;

3. HSC Trusts should work with commissioners to address resource issues arising from these implementation plans in a phased, consistent and timely manner; and

4. the Public Health Agency should report on progress by 30 November 2015.

As a result of the verdict of the Coroner into the cause of death of Personal Information redacted by USI in October 2013, work was commissioned on ensuring the safe and effective management of procedures involving the use of distending fluids in endoscopic procedures. In recognition of the limited guidance available on the management of these procedures, local work was commissioned, led by Dr Julian Johnston, Assistant Medical Director in Belfast Health and Social Care Trust.

The attached outline policy is the product of that work and we are now commending it for regional implementation.

Corrigan, Martina

From: O'Brien, Aidan [redacted]
Sent: 07 February 2016 21:22
To: Corrigan, Martina; Glackin, Anthony; Haynes, Mark; ODonoghue, JohnP; Suresh, Ram; Young, Michael
Subject: RE: Standard Operating Procedure for Fluid Management during Urology surgery

Dear All,

I suspect that any comments from me will be perceived to have been prejudicial.
However, I honestly did approach using the much hailed Olympus with a view to giving it a fair wind.
And was I bowled over?
No!
I resected two small prostates.
I found it deficient in two respects:

1. It is my understanding that there is no blended current on cutting with the result that haemostasis was inferior to monopolar during cutting
   You resect, it bleeds and you coagulate.
   This slowed the resection.
   It also had me wondering whether one would have increased fluid absorption as a consequence.

2. The rate of irrigation was much slower than with the monopolar resectoscopic, with the result that there was an intermittent fog which I had to stop resecting to wait for it to clear.

I was so glad that neither prostate was large, as I certainly would not have used the Bipolar.

The Audit asks the question whether the trialist would be 'happy' to use it.
My answer was a definite 'No'.
I will do if I have to.
I just do hope that the Operating procedure will allow me to continue to use Monopolar, as it is very much superior,

Aidan

From: Corrigan, Martina
Sent: 07 February 2016 17:55
To: Glackin, Anthony; Haynes, Mark; O'Brien, Aidan; ODonoghue, JohnP; Suresh, Ram; Young, Michael
Subject: FW: Standard Operating Procedure for Fluid Management during Urology surgery

Any comments?

Martina

Martina Corrigan
Head of ENT, Urology and Outpatients
Southern Health and Social Care Trust
Craigavon Area Hospital

Telephone: [redacted]
Mobile: [redacted]
Email: [redacted]

Corrigan, Martina

From: O'Brien, Aidan [redacted]
Sent: 30 March 2016 16:17
To: Young, Michael; Corrigan, Martina
Cc: Glackin, Anthony; Suresh, Ram; Haynes, Mark; ODonoghue, JohnP
Subject: Bipolar Resection

Michael and Martina,

I wish to take the opportunity to update you on my experience of trying bipolar resection systems.
I have tried the models on trial to date, and did so having disabused myself of any prejudice against their use.
As reported previously, I found their performance inferior to monopolar mainly as a consequence of the intermittency of the current, the lack of any small vessel fulguration whilst cutting and the much reduced rate of continuous irrigation.
I last use bipolar two weeks ago to resect the moderately enlarged prostate gland of an elderly patient.
I had to abandon bipolar resection after 10 minutes because of bleeding, poor irrigation and visualisation.
The intraoperative comparison of both systems was remarkable.
Bipolar resection placed this patient in intraoperative danger, and salvaged by monopolar resection.

I have therefore pledged not to do so again.
I will not use or try bipolar resection again,

Aidan.

Purely on the ease of use principal, excluding other criteria (i.e. cost and CSSD), the option came down to either STORZ or the OLYMPUS system, the other two being excluded. Four surgeons voted for the STORZ, one electing for the OLYMPUS. Mr Haynes was not present for this vote but on subsequent conversation later in the day, Mr Young put the same question to Mr Haynes asking for his comments on ease of use and again he had no particular preference and was happy to run with the global opinion.

On reviewing the various costs, it was noted that the disposables did have a variable range. It was accepted that loop quality did vary and that loops could be purchased from different sources. We all felt that this was not a particularly focused point for making a decision (namely cost of loop).

The price of the individual resectoscope systems was recorded noting that the OLYMPUS system was significantly more expensive in totality. The OLYMPUS system would have to be purchased completely whereas the STORZ system could be involve both new scopes and modification of current sets. (The costs set out for this meeting were significantly in favour of the STORZ system but it was appreciated that if a STORZ completely new systems was to be included that this information was to be presented to the forum before a final decision was made).

A further significant contributor to decision making was the generator needed for the electrical input. Although the OLYMPUS company was going to offer a free £40,000 generator, we did record that we may need up to three generators in view of the amount of urology sessions occurring at the same time. (The forum did not know if the company would supply three free generators. They felt it unlikely but enquiries would be made). The current generator system available within the Trust is multifunctional and therefore would already suit the STORZ system more appropriately. Even with the OLYMPUS generator system, this would result in increased machinery parking within the theatre environment. Overall this was regarded as a fairly substantive pointer in favour of the STORZ system.

CONCLUSION

In concluding, the vote on several aspects namely ease of use, cost, generator type were all in favour of the STORZ system. All the urologists have backed this decision with a unanimous vote.

This decision was based on the information supplied with a final decision pending the outstanding enquiries, namely the cost of a completely new STORZ resectoscope system and the cost of the OLYMPUS cystoscope. This would give a truly like for like comparison. The additional enquiry related to the OLYMPUS generator issue.

Mr Young will add an addendum to this document when the above information becomes available before final sign off.

The paperwork with regards to this has been forwarded to the Service Administrator, Martina Corrigan and to Pamela Johnston, Theatre Manager.

M Young
22nd September 2016
Chair of Session

theatre nursing staff, had adequate time and numbers of cases with each resectoscope system to make a meaningful assessment. There were some supply issues from the companies regarding the equipment which contributed to the protracted period of assessment. We regarded that our appraisal was robust for ease of use, effectiveness, and taking into account the cost of these systems. We noted that the interchange of equipment with our existing glycine system was a feature we wished to maintain, as we had noted the coagulation mode for the saline system was not as efficient as the glycine system in our initial assessment. This would therefore allow the surgeon to switch mid-procedure, if necessary. This was a specific safety point raised by Mr O'Brien but we felt it was a safety feature that should be available for all the surgical team in the unit. *See:*

11.-13. 20161012 Urology Department Minutes 22 9 2016, A1-A2

6.6 We all realised that there was an adaptation to our surgical technique to be required but, overall, the majority observed that it wasn't a major issue.

(e) When did the Southern Trust direct the cessation of monopolar procedures?

6.7 To the best of my knowledge I am not aware of the Southern Trust ever directing cessation of monopolar procedures. There was a delay in the supply of the resectoscopes due to purchasing issues from the Trust. In December 2017 we had a Urology Departmental meeting at which we agreed that we would stop doing TURP until the new saline equipment was in place. Please see correspondence from myself to Ronan Carroll relating to this (*see 14. 20171116 - E MY - saline TURP issue*). The scopes system was eventually installed in April 2018. There was however a proviso that saline was the principle medium to be used but if, for example, the surgeon felt there was a tissue coagulation issue at the time of surgery, this could be changed to glycine. This was to accommodate all members of the team.

(f) Did you continue to undertake monopolar resection in glycine beyond this point?

7.0 CONCLUSIONS

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

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

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

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

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

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

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

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

304. I met with Dr Richard Wright, then Medical Director, in April 2016 when we discussed the issue of the inability of the Department of Radiology to ensure the attendance of a uroradiologist at all MDMs. While this did result in some improvement for a period of time, it was inadequate. As with the failure of attendance of clinical oncologists, the essential constraint was the regional shortage of radiologists and oncologists.

305. This issue is highlighted in the SAI reports which are dealt with at Question 79. For example, in the SAI Report regarding Patient SUB [S18333 see AOB-61216 – AOB-61226], it was noted at page 7 that the MDM was quorate 11% in 2017, 22% in 2018, 0% in 2019, and 5% in 2020. There was evidently a failure on the part of the Trust to ensure that the MDMs were quorate, and that undoubtedly reduced their effectiveness, and arguably their legitimacy. The poor MDM quoracy is but another feature of an inadequate urological service provided by the Trust over many years. It should also be noted that the Trust's Urology Cancer MDT's Operational Policy, agreed in September 2017 [AOB-03859] expressly states that the MDT should be quorate for at least 95% of MDMs. That policy was evidently not complied with by the Trust.

306. The quality of chairmanship of MDMs is critical to the outcomes of MDM discussions and to the recommendations agreed. It is essential that the Chair, or indeed whoever presents the case, has adequately previewed the cases so that the members will be optimally informed. The inclusiveness of discussion is dependent upon the Chair. The Chair should not have a predetermined view as to the next step or be resistant to a change in his or her view. Of greater concern over recent years has been the increasing tendency of the MDT members at MDM finding themselves agreeing to management recommendations which had not only already been recommended to the patient by the consultant urologist and core member but had already been implemented. In most cases, the MDM would have agreed in retrospect with the recommendations already shared with the patient, if not already implemented. As I recall, this applied particularly to patients being recommended with regard to the management of upper urinary tract pathology, and even of patients having undergone renal surgery without previous

discussion at MDM, as occurred in the case of Patient 10 [PAT 000001 – 000055].

307. It has been reported that it is of critical importance that the agreed recommendation should be audibly dictated by the Chair to and recorded by the Cancer Tracker. It has been my experience that the language used in expressing the agreed recommendation is of critical importance, particularly when there are management options to be considered with the patient at review, as is often the case. Sometimes, the recommendations more importantly specified management options which were not to be recommended, rather than those which could be recommended. While not all of these features were characteristic of all rotating Chairs at all times, overall, I would have considered the MDMs to have been effective within the constraints placed upon them

308. Please see the Trust's Urology Cancer MDT's Operational Policy, agreed in September 2017 [AOB-03859]

(Q 41)

309. Decisions were generally unanimous because most cases discussed were straightforward in terms of the recommended next steps. There was certainly an opportunity within MDMs for differing views regarding patient next steps to be discussed and debated. My view was that the focus at the MDMs was always on recommending the right approach for each patient, and as stated above I never felt that anyone felt inhibited from expressing their views at the MDMs.

310. The decisions made at MDM with regard to any patient were the agreed recommendations which would be considered and discussed with the patient at review. The agreed recommendations have been variously referred to as MDM outcomes and MDM plans. Irrespective of those labels, the agreed next steps are recommendations to be considered, shared and discussed with patients, and, with the patients' consent, with those accompanying them, when reviewed

THE HEARING ADJOURNED FOR LUNCH AND RESUMED AS FOLLOWS

CHAIR: Thank you everyone, Mr. Wolfe.

MR. WOLFE: We were examining, just before the break Dr. O'Kane, the content of Recommendation 5, I think it was, of the outworking from the SAI recommendations, which provided for and appears to have embedded some form of auditing across a number of the concerns that Dr. Hughes had. You mentioned, and just before we go to the evidence for the auditing, you mentioned in part of your answer that this system of auditing might have the potential to pick up on failure to refer into the MDT process, and if I picked up your answer correctly, you seem to suggest that with regards to Mr. O'Brien there was information, or it was your belief perhaps, that he had a history of failing to refer patients into the Urology MDT. Is that your understanding? 13:58 13:59 13:59

A. Yes. Certainly from the Lookback Review in relation to the 10 questions that we have undertaken in reviewing all of that, there's a suggestion that patients came through the system, had a diagnosis of cancer, and weren't always referred to the MDT. And for others, were referred to the MDT but may not have had their results enacted. 14:00

126 Q. Yes. Certainly - we can look at that, we can look again at the lookback as regards the first part of your answer. Certainly there is indication through the Dr. Hughes's SAIs, if I can call them that, that patients having come through the MDT didn't get their 14:00

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

Section not applicable ☐

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

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

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

There is no evidence that the patients condition was discussed in MDT, the patient was started on suboptimal and unlicenced dose of Bicalutamide of 50mg rather than complete Androgen deprivation.

This treatment dose gave the patient no clinical benefit but only the side effects of AntiAndrogens.

There was a very long delay in referring the patient to the oncology team for consideration of Radiotherapy

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

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

Section not applicable ☐

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

- **Were ongoing reviews scheduled at appropriate intervals?**
- **Were referrals made to other teams / professionals appropriately and in a timely manner?**
- **Where any further required tests / investigations requested and performed in line with good current practice?**
- **Please list medication if known and relevant, and comment on medication monitoring where appropriate**

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

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

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

4 Good Care

Section not applicable ☐ **Please record above why this section is Not Applicable**

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

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

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

On 14.11.11 patient with wife was seen by a SpR and diagnosis of high risk Gleason 4+5 Ca prostate given and need for staging investigations and MDT review.

MDT did not happen, which should have and instead the patient was seen by AoB, diagnosed with T2/3 N0M0 and started on 50mg Bicalutamide and 10mg tamoxifen. There appears to have been no discussion at this point of referral for consideration of DXT. This was inappropriate management with use of an off-licence dose.

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

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

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

documented. So while protecting the patient, it also protects the surgeon?

A. Yes, absolutely right. That's more and more important in an increasingly litigious society.

154 Q. One other thing just in relation to -- we were talking about actioning scans. Would you accept that if the waiting lists are long and a review appointment cannot be held as soon as the clinician would like them to be, it is more incumbent upon the clinician to check scans as soon as they come back, or results as soon as they come back? 15:37 15:37

A. Yes, I mean, ideally what we need is a joined-up electronic system. The technology is there now to do remote consultations, order scans online, look at the results online and, you know, action urgent cases, you know, literally within a few days. It could be done but the problem is that we're dealing with such an overloaded system. It is quite hard to change things within the system because doctors are brought up to do things in a certain way. We were all brought up in the sort of paper era where we had to have the notes and the patient in front of us, but now suddenly all these things can be done online. You can see that there are all sorts of issues. Dealing with the very senior surgeons in the department can be the trickiest issue, really. It is hard to get them to change. 15:37 15:37 15:38

155 Q. Clearly in the 2,000 or so pages that you've read and your conversation with a colleague, you formed an opinion of Mr. O'Brien. I just wonder if you would

share some of these views; that he was someone who worked in isolation rather than as a team player?

A. Yes, I think he obviously did. To his detriment, I think, to the patient's detriment. He didn't seem to want to collaborate with his colleagues as well as he should have done, especially the radiotherapists in Belfast. That would have been -- a close relationship would have been ideal. And he had his own way of doing things and perhaps was reluctant to change. I think a lot of energy has been wasted in battles about who should do the triage and who should be the urologist on call and the urologist of the week, and how should we run the MDTs, instead of dealing with the issues. They were allowed to sort of spiral out of control. 15:38 15:38 15:39

That does raise the issue, if you have a problem within a department within a hospital, it shouldn't be left just to deteriorate further and further and further and end up with an inquiry. A lot of these problems could have been addressed and dealt with at a much lower level than what's happened now. 15:39

156 Q. You may well be right and we'll certainly be reflecting on that when we come to write our report.

Thank you very much, Prof. Kirby. You're not getting away just yet. Mr. Wolfe wants to speak to you again. 15:39

were waiting on a first outpatient appointment. I would have requested 50 – 100 investigations during the course of triaging during and after being UOW. Moreover, I believe that the expectation to follow up on the reports of these investigations proved to be a disincentive for others to similarly request investigations on triaging.

543. Urological practice generates investigations in the majority of patients who attend outpatient clinics. To have expected consultants to follow up on the reports of all of these investigations without provision of any or sufficient time to do so was unfair. I believe that to additionally jeopardise the patients' review was irresponsible. To transfer all responsibility to the clinician in the process was consistent with the approach of the Trust to its failure to provide a sufficiently safe service.

(xiii)

544. At no point during my years of clinical practice as a consultant urologist within the Trust, from 1992 until 2020, was any concern raised with me in respect of the manner in which I prescribed Bicalutamide. Indeed, it was well known within both the urology service and the oncology service that Bicalutamide was being prescribed, and how it was being prescribed. No issues were ever raised with me in that regard. The first time concerns were made known to me in respect of my prescribing Bicalutamide was when the Directorate of Legal Services wrote to my solicitors by letter dated 25 October 2020 [AOB-02772].

545. I note that the SAI report in respect of SUF states that the use of Bicalutamide was known to the MDM, was challenged, was not minuted, and was not escalated. I entirely refute that. The reason it was never minuted at an MDM as having been challenged, or escalated, is that it was never challenged or escalated. Indeed, in MDMs such as that regarding SUF, the fact that the patient had been prescribed Bicalutamide 50mg was specifically noted on the patient's MDM clinical history and when this was reviewed by Mr Haynes in August 2019

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

Note: S21 Notice No. 68 of 2022 can be found at WIT-82399 to WIT-82657. Addendum No. 2 can be found at WIT-107564 to WIT-107623. Annotated by the Urology Services Inquiry.

USI Ref: Notice 68 of 2022

Date of Notice: 23 August 2022

Addendum Witness Statement of: MR AIDAN O'BRIEN

I, Aidan O'Brien, wish to make the following amendments to my existing response, dated 2nd November 2022, to Section 21 Notice number 68 of 2022.

1. At Paragraph 135 I stated "*I did express concerns in relation to DARO in an email exchange in January/February 2009 primarily between Colette McCaul and me. [see AOB-07566-AOB-07567]".* This should be amended to state: "*I did express concerns in relation to DARO in an email exchange in January/February 2019 primarily between Colette McCaul and me. [see AOB-07566-AOB-07567]".*

2. At Paragraph 544 I stated that *"At no point during my years of clinical practice as a consultant urologist within the Trust, from 1992 until 2020, was any concern raised with me in respect of the manner in which I prescribed Bicalutamide."* At Paragraph 563 I stated that "*No concerns were ever raised during my tenure in respect of the use of Bicalutamide."* At Paragraph 587, I stated that "*It could not be said that any issue in respect of my prescribing Bicalutamide recurred during my tenure, as no issue was ever raised with me in respect of my prescribing that medication during my tenure as a consultant urologist with the Trust."*

   Since submitting my Section 21 response dated 2 November 2022, I have come across an email sent to me by Dr Darren Mitchell, Consultant in Clinical Oncology at the Cancer Centre in Belfast (AOB-71990), on 20 November 2014, asking me to look into the case of a man who had been prescribed and remained

41. In the case of Patient 6, I prescribed Bicalutamide 50 mg at his review in July 2019 due to his anxiety and concern that his presumed prostate cancer would progress while awaiting prostatic biopsies later that month. Though prescribed prior to histopathological confirmation of prostate cancer, the off-licence indication was similar to that recommended by BAUS in March 2020 to relieve the similar anxieties and concerns of men whose definitive treatment was deferred due to Covid 19. Its efficacy was reflected in his serum PSA level having decreased from 13.44ng/ml in July 2019 to 8.4ng/ml by September 2019.

42. Concern regarding compromise or loss of erectile function has been a significant issue for many patients embarking upon androgen deprivation therapy. For example, it was the reason for initially prescribing tadalafil for a period of three weeks prior to prescribing Bicalutamide 50 mg daily for Patient 35 in February 2013 in the hope of maintaining his erectile function which he was so keen to preserve.

43. Most importantly, when the patient has been optimally informed of the anticipated benefits of differing management options and of the comparative risks associated with those options, it has been my experience that a great proportion of men, probably the majority, were most keen to embark upon a journey to achieve the benefits while incurring the least risks. It has been in that context that androgen deprivation using Bicalutamide has been prescribed, irrespective of the dose initially used.

44. I have never initiated ADT of any form for any patient with non-metastatic prostate cancer with the intent that it would be their sole, indefinite management. Bicalutamide was always initiated with the intent that it would be a prelude to radical radiotherapy to which the patient had agreed in principle. However, on numerous occasions, when patients were informed of the biochemical response to ADT, I have been asked whether they were obliged or compelled to proceed with radiotherapy at that time. I advised them that they were of course under no such obligation. It was for that reason that ADT, using Bicalutamide, initiated with neo-adjuvant intent, incrementally became long-term monotherapy. Such was the case of Patient 139 who had a

Angela Kerr

From: Mitchell, Darren <[redacted]>
Sent: 20 November 2014 13:35
To: O'Brien, Aidan
Subject: [redacted]

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.

NEO-ADJUVANT, CONCURRENT AND ADJUVANT HORMONE THERAPY WITH RADICAL TREATMENT.

There is clear randomised evidence supporting the addition of hormone therapy to radical radiotherapy in men with non-metastatic prostate cancer. The majority of this evidence is for hormone therapy in men with an increased risk of systemic disease and is based on pre-treatment clinical and pathological features.

Men with intermediate or high risk prostate cancer should be offered neo-adjuvant hormone therapy for at least 3 months before the commencement of radical radiotherapy.
For very large prostate glands or patients with high risk prostate cancer or pelvic node positive prostate cancer a longer period of neo-adjuvant hormone therapy may be required (3, 4).
Cyto-reductive hormone therapy is also considered for men with large prostate's prior to their prostate brachytherapy volume study.

Men with intermediate or high risk prostate cancer should continue their hormone therapy through the course of radiotherapy.

Men with Intermediate risk prostate cancer should receive a total of 6 months of hormone therapy before, during and after their radiotherapy is complete (6-9)

Up to 3 years of adjuvant hormone therapy after radical radiotherapy should be considered for men with high risk prostate cancer. The benefits and risks of long term androgen deprivation therapy should be discussed. [NICE 2014] (5)

Hormone therapies options with radical radiotherapy include

LHRH agonists:-
Zoladex (goserelin) 3.6mg subcut every 4 weeks or
Prostap (leuproreline) 3.75 mg IM every 4 weeks or
Decapeptyl (triptorelin) 3mg IM every 4 weeks

Consider transferring to the 12weekly preparation of androgen deprivation therapy if the 4weekly preparation is tolerated and the intention is to proceed with longer term therapy.

In order to prevent testosterone flare, anti-androgen cover with Bicalutamide 50mg is given for 3 weeks in total with the first LHRHa given 1week after the start of the Bicalutamide.

The anti-androgen - Bicalutamide 150mg OD mono-therapy can be used as neo-adjuvant hormone therapy especially in men where preservation of physical capacity or sexual function is important or in those who may not tolerate hot flushes.

The cardiovascular and metabolic toxicities of LHRHa should be discussed and the patient advised to address cardiovascular risk factors with their GP.

The use of concurrent and adjuvant androgen deprivation with adjuvant and salvage radiotherapy post prostatectomy remains undefined. It is currently being assessed as part of the RADICALs study. Use is therefore at the discretion of the treating clinician.

Limited evidence suggested that the patients who may gain most benefit from the addition of hormone therapy to adjuvant post-prostatectomy radiotherapy have Gleason scores of ≥8 (13) or positive nodes at the

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.

6.0 FINDINGS

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

Contributory factors

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

7.0 CONCLUSIONS

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

Southern Health and Social Care Trust

UROLOGY
OUTPATIENTS LETTER

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

Personal Information redacted by the USI

Dear Personal Information redacted by the USI

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

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

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

Current Management: Bicalutamide 50mg once daily, Tamoxifen 10mg once daily.

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

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

Yours sincerely

Mr AJ Glackin, MD FRCSI (Urol)
Consultant Urologist

Results
PSA 1.02ng/ml

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

Southern Health and Social Care Trust

UROLOGY

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

04/03/16

Mr O'Brien,
Consultant Urologist,
CAH

Dear Mr O'Brien,

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

I saw Patient 139 in my long waiters clinic on Monday evening 22nd February. He is doing very well. With your kind permission I will take on his follow up. Kind regards.

Yours sincerely

Mr AJ Glackin, MD FRCSI (Urol)
Consultant Urologist

Date Dictated: 26/02/2016	Date Typed: 04/03/16 – ET

Southern Health and Social Care Trust

UROLOGY
RESULTS LETTER

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

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

05/05/20

Personal Information redacted by the USI

Dear Personal Information redacted by the USI

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

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

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

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

Yours sincerely

Dictated but not signed by

Mr AJ Glackin, MD FRCSI (Urol)
Consultant Urologist

My colleague Patricia Rooney has been in touch with you in relation to the two NHS patient records which Mr O'Brien had in his possession. Mr. O'Brien has confirmed that these have been collected from his home. He has no further records.

Yours sincerely,

ANDREW ANTHONY
Partner
Personal Information redacted by the USI
T: +44 (0) Personal Information redacted by the USI
M:+44 (0)
D: +44 (0)
Tughans / Marlborough House, 30 Victoria Street, Belfast BT1 3GG

From:	Avril Frizell
To:	Donnelly, Anne; Murphy, Eoin; Benson, Shauna
Cc:	Emmet Fox; Keeva Wilson
Subject:	Issue for AOB regarding Patient 139
Date:	21 March 2024 16:46:56
Attachments:	emails Avril to Anne of 5.2.24 and response of Anne 13.2.24.docx 20200825 Email from M Corrigan to M O"Kane re AOB-NE contact.pdf s-sheet - Results to Trust 20240201.xlsx s-sheet - patient access (1).xlsx 20200731 - E Mr O"Brien return items to Trust (003).pdf TRU 252938- TRU 252940.pdf
Importance:	High

Dear Anne

Further to our email exchange on 5 February and 13 February, I have taken further instructions on this issue from the Southern Trust, and I understand that Mr Lunny KC has raised this matter directly with Mr Wolfe KC. By way of summary, I can confirm:

1. On 18.9.23 Mr Wolfe KC raised with Donal Lunny KC an issue re Mr Glackin's involvement with Patient 139 from 2016. The issue had been raised with Mr Wolke KC by AOB's lawyers. Mr Wolfe KC cited a document at WIT-04624 when raising the issue with Mr Lunny KC. Mr Lunny KC reverted to ask what the basis was for believing Mr Glackin had any involvement as WIT-04624 did not disclose any such involvement. Mr Wolfe KC replied quoting precisely what AOB's lawyers had said in the points they wanted Mr Wolfe KC to raise with Mr Glackin:

   > '…It would appear that Patient 139 (WIT04624) remained on Bicalutamide 50mg daily and Tamoxifen 10 mg daily since recommended by Mr O'Brien in 2010 for organ confined, intermediate risk prostate 5 cancer with apparently good effect. The patient remained under your care after you reviewed him in 2016.
   >
   > Did you find that he remained well since 2016?'

2. When Mr Lunny KC pressed the point with Mr Wolfe KC (and Mr Wolfe KC in turn pressed it with Mr Millar BL on behalf of AOB), Mr Millar BL provided 3 letters to Mr Wolfe KC. Those 3 letters can be described as follows:

   a. They are 3 letters relating to Patient 139 from Mr Glackin to Dr Gudyma (the GP);
   b. The first was dictated on 22.2.16. The second and third are dated 4.3.16 and 5.5.20 respectively.

3. The Trust quickly satisfied itself that none of the 3 letters was contained in any discovery provided by it or by AOB to the Inquiry.

4. The letters have since been given the Bates numbers AOB-82836, AOB-82837, and AOB-

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

1st July 2020 – injection at GP. Nurse unable to administer

6TH July 2020 – Collection of new injection

7th July 2020 – Injection and PSA check

9th July 2020 – Scan Craigavon

14th July 2020 –Met with Mr Mark Haynes Urologist for the results of the CT scan. This appointment only happened on foot of pressure by family members as there was obviously anxiety around the results. Mr Haynes informed [Patient 1], [Patient's Family] that the cancer had spread. He said that there were signs of the disease progression for some time – the first being the requirement for a catheter in March/April. He informed them that the spread was significant. [Patient 1] was shocked, we simply could not take the news in. A cancer nurse specialist was present who indicated her surprise that [Patient 1] had never been allocated to a cancer nurse specialist from the outset. We explained that no, from February –June his only access to care was through A&E despite repeated attempts to access Urology Services. [Patient 1] explained that Mr O'Brien had felt his prognosis was a good one so he really could not believe what he was being told. Mr Haynes explained that he was going to lodge a complaint by in relation to this matter. We weren't particularly interested in that as the reality was, [Patient 1] was going to die and we had to deal with whether now lay ahead for us. [Patient 1] asked what his prognosis was and it was explained that it was difficult to say however he was optimistically looking at around 18 months. His only treatment option was likely to be chemotherapy. [Patient 1] simply could not understand why he was never given radiotherapy and how on earth he had ended up in this position. Mr Hayes explained that treatment options could be discussed in more detail tomorrow with Dr Darren Brady, Consultant Urological Oncologist at the Cancer Centre in Altnagelvin.

15th July 2020 – We attended at the Cancer centre. A 6am start from Enniskillen. [Patient 1] was extremely weak and had to be carried from the car by his brother in law. With difficulty, due to Covid protocols, the Cancer Centre agreed that [Patient's Wife] could attend this appointment with [Patient 1] He was recommended for Abiraterone , an oral drug used to treat advanced prostate cancer. An 18 month prognosis was given. He spoke to [Patient's Family] and told them he felt that he "had been thrown under a bus" by the health care system. He and we simply could not believe that he was now in this position.

22nd July 2020 - Admitted to SWAH for treatment for urinary infection. GP would not visit home due to Coved so [Patient's Daughter] took a urine sample from the catheter bag and brought it to the GP practice for testing [Patient's Daughter] advised by GP – Dr Davies advised that unless [Patient 1] was admitted to hospital there was a good chance he would die at home. Visiting was not permitted whilst [Patient 1] was in hospital and [Patient 1] was in a lot of distress throughout this period, telephoning [Patient's Daughter] frequently.

and on 11 February 2020 in the case of Mr Patient 104. Not only is it indisputably so, but there is also much documentation arising from and in further support of both patients being on my waiting list from the appropriate time. Moreover, Mr Haynes was aware of both patients being on the waiting list for admission at various times prior to my email of 7 June 2020.

18. I therefore fail to understand how it could have appeared to Mr. Haynes that these two patients had not been added to the inpatient waiting list when it was plainly evident that both had been. I further find it concerning that it appears that Mr Haynes' misplaced, claimed concern in respect of these patients was the basis in his 11 July 2020 letter for "*a review of records back to January 2019*".

19. It appears that the very trigger for a look back exercise of all of my patients to January 2019 was the totally untrue assertions in this letter about two patients who had been placed on the inpatient waiting list on the Patient Administration System in the ordinary way and which any competent and impartial consideration of the medical records and correspondence held by the Trust would have revealed.

20. It is of further concern that this untrue assertion should have led the Minister of Health to misinform the Northern Ireland Assembly in his Ministerial Statement on 24 November 2020.

21. Throughout my tenure the greatest threat to patient safety in providing safe care to urological patients was due to the inadequacy of the service provided by the Trust.

22. I first became aware of the comparative inadequacy of urological consultant staffing in Northern Ireland when co-opted onto the Council of the Irish Society of Urology for the years 1990-9. I learned that the Republic of Ireland, with a consultant / population ratio of 1:240,000, having 15 consultant urologists, had an inadequate staffing complement compared to the UK which had a consultant /

710. Therefore, in short whilst concerns have been raised they have never been fully or fairly investigated at a Trust level. Clinical concerns are being investigated by the GMC and I continue to liaise with them in relation to same.

(Q 84)

711. There was an abject failure by the Trust, throughout my tenure, to engage in a constructive manner and provide adequate support, management and resources to deal with the inadequate service clinicians could provide to patients. The statistics speak for themselves. The failure to engage left me stretched throughout my tenure, having to prioritise, as best I could, to deliver a service to patients. However, that inevitably led to issues occurring in my practice, as referred to in my response to Question 66. I have set out in detail, in my opening narrative to Question 1-2 and in my comments on Support (Question 73 and 74), the inadequacies of the Trust.

712. I cannot say the extent to which the Trust alone was at fault. On the basis of the respective waiting lists there was a disparity between the manner in which resources were allocated between urology patients and to other services – why was that allowed to be the case when it was clear to all we were failing to meet so many targets? I am quite sure this raises issues also at a regional level – what was the role of the Commissioners and Department of Health in failing to address this? I am quite sure in any other part of the UK a Urology Service, and its patients, would not have been left in the extremely vulnerable situation we were left in.

(Q 85)

713. I was very disappointed in the Trust's approach to the formal investigation. It is clear that both NCAS and colleagues considered there could have been an action plan put in place as opposed to recourse to disciplinary action. The Trust was well aware that I had been working excessively for years and had fallen

COMMENTS AND CONCERNS REGARDING PROPOSED JOB PLAN

In preparation for Meeting of Facilitation

There are several areas of concern arising from the proposed Job Plan, giving reason for my being unable to agree to it. These are

- Inadequate time for administration relating to direct patient care
- Lack of lunch / rest breaks
- Specialist clinics on Friday mornings
- Availability whilst on – call
- Date of effect of Job Plan

Inadequate time for administration relating to direct patient care

The total amount of time allocated, in the proposed Job Plan, to administration relating to direct patient care is grossly inadequate for the provision of an effective, efficient and safe service, and is markedly divergent from the reality of the total time required. Moreover, the severity of that inadequacy is reflected in there being days when no time at all is allocated for administrative tasks that cannot or should not be deferred. Indeed, the Job Plan includes weeks when several days will pass before time is allocated to administration that needed to be carried out previously. In order to appreciate the totality of administration required, I have detailed below the range of administration required of the Job:

Arrangement of Admissions and Attendances

This consists of the arrangement of all

- Inpatient admissions
- Admissions to Day Surgical Unit
- Flexible cystoscopies
- Urodynamic studies
- Ward attenders for
    - Intravesical therapies
    - Intravenous therapies
    - Trial removals of catheter

Review of Waiting Lists

I review all four waiting lists once weekly to ensure that forthcoming capacity is being offered to those with greatest clinical priorities. These lists comprise a total in excess of 400 patients.

Enquiries from GPs and Patients

My secretary receives more than 40 queries each day relating to patients, a significant proportion of which come from GPs, their practices, community nurses and from patients themselves. She selects and passes on to me 3 to 5 of the most clinically urgent cases to address. These are clinical issues which cannot be addressed by my secretary alone. All are best addressed as soon as is possible. For the safety of the patient, each day there will be some which do need to be addressed on the day on which they arise.

Referrals

We receive personalised referrals on any day for triaging. We receive anonymised referrals during weeks when on call. These include red flag, urgent and routine referrals. I believe that there is an expectation that red flag referrals are triaged daily, and that all referrals are triaged within 3 days (or one week?) of receipt.

Correspondence

There is a considerable amount of correspondence, particularly from oncologists, received weekly, and all of which has to be read, as some requires action, rather than just filing.

Reports and Results

It has recently been proposed that all laboratory results, and radiological and pathological reports, pertaining to outpatients, be read when available, in order to ensure that appropriate action is taken, when indicated and in a timely manner, in order to avoid unsafe delay whilst waiting for patients to be reviewed. This clearly is a major issue of clinical governance. I believe that this is currently conducted on an ad hoc basis only, and that it will require a significant consumption of administrative time if it is to be done completely. I am unable to quantify that amount of time.

Dictation arising from Outpatient Clinics

Particularly due to the increasing volume of patients attending consultant led clinics for oncological review due to inadequate capacity at specialist clinics, it has not been possible to complete dictation on all patients attending. This relates particularly to review of men in the early stages of management of prostate cancer. These patients

are particularly time consuming. This result in increasing amounts of time on dictation outside of clinic time, particularly for onward referral.

Administration arising from Urological Cancer MDT

This relates to administering the implementation of outcomes from MDT, such as requesting scans, arranging admissions, and informing patients of these arrangements. Upon my request, an adequate 30 minutes of administrative time has been allocated following MDT on Thursday afternoons.

Administrative Time arising from Thorndale Unit

This relates specifically and solely to the time required to be consulted by other practitioners regarding the further assessment and management of patients attending the Thorndale Unit. It does not relate to administration arising from Specialist Clinics run by me in the Thorndale Unit. I had requested and had allocated 30 minutes for this purpose on Tuesdays, 1.00 to 1.30 pm, between Day Surgery and Outpatients Clinic. However, for reasons relating to my preference for a break at that time, I would prefer to have it deferred to Fridays when I will be in Thorndale Unit conducting a Specialist Clinic. I would prefer to have administrative time allocated for this purpose following completion of the Specialist Clinic.

Administrative Time required to review Outpatient Backlog

There is a large backlog of patients intended for review, and who have not been reviewed. I spend a minimum of one hour per week, and often twice that time, reviewing the documentation relating to these patients, including updated results and reports, in order to determine their further management.

Since proposed Job Plans were first submitted in July, and particularly since Facilitation was requested on 02/09/2011, I have made note of the actual amounts of time consumed weekly by the above activities. As a result, I am able to submit bare minimum amounts of time consumed by these activities each week:

- Admissions and Waiting Lists — 2.0 hours (usually approx. 3 hours)
- Enquiries from GPs and Patients — 1.0 hour
- Referrals and Correspondence — 1.0 hour (2 HOURS)
- Dictation — 2.0 hours (usually 3 – 4 hours)
- MDT — 0.5 hours
- Thorndale — 0.5 hours
- Results and Reports — to be determined