Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Notice …6… of 2023

Date of Notice: 17 April 2023

Witness Statement of: Dr Darren Mitchell

I, Darren Mitchell, will say as follows:-

1. You were interviewed by Dr Dermot Hughes on 23 February 2021 in relation to the investigation of a number of SAIs concerning former patients of Mr Aidan O'Brien. The record of that interview states as follows (relevant extracts underlined):

'Dr Mitchell advised aware of issues going back decade in relation to hormone therapy prescribing, prescribing outside guidelines, Bicalutamide. Dr Mitchell advised he took over as chair of the regional urology MDM in 2015. He advised that they had challenged Mr OB on his use of bicalutamide as part of the development of clinical guidelines whilst Mr OB was chair of the NICAN urology group in 2015.' [TRU-162276]

(i) Confirm whether the above is an accurate record of the discussion during interview. To the extent that it is not, please identify any alleged inaccuracies and offer clarification of same.

1(i) I accept that this is an accurate record of the discussion during the interview. I would note that I was appointed to regional MDM chair in August 2014.

(ii) Please explicitly state what, to your knowledge or in your view, the 'issues … in relation to

a. hormone therapy prescribing,

b. prescribing outside guidelines,

c. Bicalutamide were.

1(ii) a *hormone therapy prescribing*

Urology Services Inquiry

10 To the extent that you have any knowledge of potential governance problems regarding the referral and screening of patients to Regional Urology, Belfast City Hospital, please provide details.

10 As an Oncologist I am not aware of any potential governance problems regarding the referral and screening of patients to regional urology, Belfast.

11. Please provide any further details which you consider may be relevant to the Inquiry Terms of Reference.

11 I have no further details

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed: ____ [redacted] _____

Date: __18/05/2023_____

Southern Health and Social Care Trust

Acute Governance
Darren Mitchell
Telephone call
23.02.2021

PRESENT: **Dr Darren Mitchell**
Dr Dermot Hughes
Mrs P Kingsnorth

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

Dr Mitchell advised aware of issues going back decade in relation to immunotherapy prescribing, prescribing outside guidelines, bicalutamide. Dr Mitchell advised he took over as chair of the cancer group in 2015. He advised that they had challenged Mr OB on his use of bicalutamide. He escalated this to his clinical lead (Chris Hagan) and the decision was made to develop a guideline for the use of ADT in the hope this would address the issues. This guideline was presented when Mr OB was chair of the NICAN urology group and he signed off on the guidelines.

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

Dr Mitchell mentioned a radical bladder cancer case in 2016, Chris Hagan and Gillian Traub noted there was a significant delay in treatment, this case was flagged back to SHSCT.

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

Governance Office, Ground Floor, The Maples
Craigavon Area Hospital
Tel: Personal Information redacted by the USI
E-mail Personal Information redacted by the USI

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.

WIT-96678
AOB2

MailMeter
Message ID - 292349e8743d4571b4a2c28b2d725874 - 146321847
Archived on 20/11/2014 13:47:53. Printed on 18/05/2023 05:20:41.

Time Sent 20/11/2014 13:38:19
Time Received 20/11/2014 13:38:19
Time Archived 20/11/2014 13:47:53
From: mitchell, darren < Personal Information redacted by the USI >
To jellett, lucy Personal Information redacted by the USI >
CC 'joe.osullivan@ Personal Information redacted by the USI suneil jain Personal Information redacted by the USI
Subject: FW: Patient 126

Lucy (Joe & Suneil) – I've emailed Aidan to open discussion on this case.

Copy below for your information only.

DMM

Dr DM Mitchell FRCR
Consultant in Clinical Oncology
Northern Ireland Cancer Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB

☎ - Personal Information redacted by the USI
✉ - Personal Information redacted by the USI
Secretary - Personal Information redacted by the USI

From: Mitchell, Darren
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 w

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 monc

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

(ix) Please give details of any discussions you had with Dr Mitchell regarding shared concerns.

Dr. Mitchell, as chair of the Urology MDT raised concerns in 2014 to Mr. O'Brien in relation to a particular case which had been referred to the MDT and was receiving bicalutamide 50mg daily as monotherapy for prostate cancer. At that time, I mentioned to Dr. Mitchell about the historical cases I had remembered from my early years as a consultant in Belfast. This discussion would have taken place at one of our Thursday morning pre-clinic meetings at the Northern Ireland Cancer Centre.

(x) Were you aware of others who had knowledge of these issues or who may have shared similar concerns? Please provide details.

I can't recall any specific discussion but I believe there was a general awareness of the issue amongst the oncology team treating prostate cancer.

(xi) Please identify every occasion on which you escalated concerns regarding Mr O'Brien's prescribing practices in respect of Bicalutamide and identify the individual(s) to whom your concerns were escalated. If it is the case that you did not escalate your concerns, please indicate why.

I did not escalate my concerns as I felt there was no substantial harm to patients from the bicalutamide prescribing I had encountered in my practice.

2. **The Inquiry is aware of significant issues around the quoracy of SHSCT Urology MDMs, particularly in terms of Oncology attendance. On this issue, the record of the interview of 4 January 2021 (at TRU-162262) states: 'JOS said that the MDT improved with the attendance of two of the newer consultants about 7 years ago.' Please explain this further and offer any further comments or observations which may assist the Inquiry in understanding this issue.**

I do not have a detailed knowledge of the oncology cover at the Southern Trust. This was a general comment in which I was referring to my personal understanding of the oncology presence at the Southern Trust Urology MDT. I understood that oncology cover had been absent or patchy for a period of time but that there had been new oncology consultants appointed who were job-planned to attend the MDT.

3. **During the interview referred to above (at TRU-162262), in response to a comment by Dr Hughes to the effect that 'it would seem he [Mr O'Brien] worked in isolation despite being involved in a multi-disciplinary team', it is recorded: 'JOS said that was his impression of Mr AOB.' What led you to have this impression of Mr O'Brien? Please provide full details.**

This impression was based on my experience with the cases that had been prescribed bicalutamide 50mg as monotherapy. My view was that an MDT would be unlikely to recommend this therapy and that it was probably the decision of Mr. O'Brien alone.

4. In his Section 21 Statement to the Inquiry, at [WIT-84157] in reference to you and Dr Mitchell, Dr Hughes states: 'They had also written to him [Mr O'Brien] directly about his

Urology Services Inquiry

3 (iv) Did you seek to discuss this case with Mr O'Brien at any stage? To the extent that the answer is 'yes', please give full details. If no, why not?

3 (iv) Yes – as noted above Mr O'Brien was emailed about the case.

4. A further extract of the record of the interview with Dr Hughes of 23 February 2021, further states the following (at TRU-162277):

'Dr Mitchell advised he emailed the consultant in 2016/17 about his prescribing outside recommended guidelines and highlighting it was his GMC duty to inform patients they were being treated outside the recommended guidelines. The patients were misled.'

4 (i) Provide the Inquiry with a copy of this email and any response(s) received.

4 (i) The email referenced in the interview with Dr Hughes was actually sent in 2014 and has been discussed in section 1. I did not receive any response. (***AOB1***)

4 (ii) Did you take any further action in respect of this apparent concern? To the extent that the answer is 'yes', provide full details. If your answer is no, why not?

4(ii) As per my response in section 1, I wrote the androgen deprivation guidelines and presented these to the NICAN urology group in 2015. When I was made aware of the cases seen by Prof Jain in 2019 and 2020 I spoke to and emailed Mr Haynes. (***AOB4, AOB12***)

4 (iii) The Inquiry notes the statement 'The patients were misled'. Please confirm whether this is your belief and, if so, how and why you consider that patients were misled? If not your belief, why did you say it to Dr Hughes?

4 (iii) I do believe patients were being misled. The hyperlink included in my 2014 email to Mr O'Brien leads to guidance on off-licence prescribing. This outlines our responsibilities as prescribers to use medication within licence and if a decision is made to use a medication outside its licenced indication or dose then good practice would be to make the patient aware of the reason for this decision in their case. In the cases identified in my statement I could see no evidence that the patients had been advised about the off-licence use of Bicalutamide 50mg monotherapy.

The delayed referral to oncology in the cases in my statement meant that these men waited longer than other men in a similar situation to have an oncology opinion.

5 (i) Please give details of any discussions you had with Dr O'Sullivan regarding shared concerns.

5 (i) The discussions with Prof O'Sullivan would have been as part of the joint Thursday morning outpatient case note review. I believe there would have been a number of cases discussed at that meeting with off licence prescription or perceived delayed referral.

2 (ii) This approach was taken in the knowledge that Mr O'Brien would be required to formally review and accept the guidelines in his role as NICAN Chair. I was aware that the guidelines would be discussed at a subsequent NICAN Urology meeting and that would both allow me to formally raise the point as outlined 1(ix) and give Mr O'Brien an opportunity to discuss this off licence practise. I hope that the guidelines and the verbal point as 1 (xi) above would be a prompt for Mr O'Brien to address the off-licence prescription of Bicalutamide 50mg monotherapy.

2 (iii) In your view, ought these guidelines have been subject to audit within individual Trusts? Please explain your answer.

2 (iii) These guidelines could have been audited within each trust. If my belief that Mr O'Brien was the only person in the region using Bicalutamide 50mg monotherapy is correct then it would in essence have been an audit of his hormone therapy prescriptions in the southern trust. The guidelines were written to encourage good practice and provide a point of reference if there were future cases identified with this off-licence prescribing.

2 (iv) Please provide any further relevant comments you may have in relation to the development of these guidelines and the process leading to their approval.

2 (iv) I am not aware that the guidelines were ever formally approved by Mr O'Brien.

3 (i) Please provide this patient's HCN.

3. (i) Patient 127

3 (ii) Please explain the significance of this case, giving further details as to the particular concern raised by Mr Hagan and Ms Traub.

3 (ii) Mr Hagan raised concern to Ms Davinia Lee who I believe was the cancer services manager at the time about avoidable delays in the management of a muscle invasive bladder case referred to him from Craigavon. His concern was around multiple discussions at the southern trust MDM prior to the patient being referred for discussion at the regional meeting and he was concerned that the delays would adversely affect the outcome in this case. Mr Hagans email also identified the use of isotope bone scans as being outside the guidance for staging in muscle invasive bladder cancer. (***AOB11***)

3 (iii) How was this case 'flagged back to SHSCT'? Please identify the mechanism by which this was raised with the Southern Trust and identify any relevant individual(s).

3 (iii) This case was flagged back to Mr O'Brien by email on 26th of August 2016 (***AOB10***) suggesting case note review and consideration of shared learning either locally or regionally. The urology MDM co-ordinator Shauna McVeigh at the southern trust was copied to that email.

Urology Network Site Specific Group Meeting
Friday 18th September 2015
2.30pm-4.30pm, Conference room 4, Linenhall Street, Belfast

Record of Discussion & Agreed Actions

In Attendance	Aidan O'Brien (SHSCT), Darren Mitchell (BHSCT), Edel Aughey (NICaN), Ali Thwaini (BHSCT), Hugh O'Kane (BHSCT), Ruth Johnston (BHSCT), Colin Mulholland (WHSCT), Wilma Boyd Carson (SET), Robin Gray (PPI Rep), Mark Haines (SHSCT),
Videoconference	Gareth McClean (SHSCT), Kate O'Neill (SHSCT)
Apologies	Fiona Reddick (SHSCT), Davinia Lee(BHSCT), Elizabeth England (WHSCT), Teresa Majury (PPI Rep), Harry Lockhart (PPI Rep), Samantha Thompson (BHSCT), Mary Haughey (NICaN), Mary Jo Thompson (PHA/NICaN), Chris Hagan (BHSCT), Kerry Chambers (WHSCT), Declan O'Rourke (BHSCT), Thamra Ayton (BHSCT), Suneil Jain (BHSCT), Pat Sheils (BHSCT), Jacque Warwick (BHSCT)

	Item	Responsibility / Date
	Welcome & Introductions Aidan O'Brien welcomed everyone to the meeting and apologies were recorded as above.	
1.	**Minutes of last meeting** **The minutes of the last meeting were agreed.** **Matters arising:** **i)** Meeting with DLA Advisory Board: Mr O'Brien advised that the meeting with ATOS Director regard the lasting impacts of cancer with a particular focus on fatigue has not yet taken place but will be arranged and he will update the group at the next meeting. **Action point 1:** Mr O'Brien to arrange a meeting with ATOS and to invite key people to attend. ii) Regional Urology meeting: Mr O'Brien provided update. There have been a number of regional meetings but the local meetings have not taken place as yet. Mr O'Brien would be keen that the NICaN network group would take on one of the sub group roles particularly with regard reviewing and updating clinical management guidelines for suitability of	

Urology Network Site Specific Group Meeting
Friday 30th January 2015
2.30pm-4.30pm, Conference room 2, Linenhall Street

Record of Discussion & Agreed Actions

In Attendance	Aidan O'Brien, Mary Haughey, Mary Jo Thompson, Edel Aughey, Robin Gray, Suneil Jain, Darren Mitchell, Teresa Majury, Pat Sheils, Alison Downey, Rae Browne, Patricia Thompson, Lin Shum, Rae Browne, Karen Parsons, Kate White,
Teleconference	Fiona Reddick, Kate O'Neill, Gareth McClean, Gerry Millar
Apologies	Elizabeth England, Moyra Mills, Kerry Chambers, Jackie Harney, Thamra Ayton, Harry Lockhart, Hugh O'Kane, Ali Thwaini, Karen Johnston, Wilma Boyd Carson, Davinia Lee

	Item	Responsibility / Date
1.	**Welcome, Introductions & Apologies** Mr Aidan O'Brien welcomed everyone to the meeting and invited members to introduce themselves. Edel Aughey advised of her role as Macmillan Service Improvement Lead for Patient information and the Recovery Package. Alison Downey, SHO, was there to present the outcomes of cystectomy for bladder cancer 2012-2014.	
2.	**Minutes of Last Meeting** Minutes of the last meeting were read and agreed. **Matters Arising:** **AP1 Letter to DLA Advisory Board:** Mr O'Brien advised that he has written a letter to the DLA Advisory Board highlighting the significance of fatigue for people with cancer and referenced the statistics from the information presented by Anna Gavin at the last network meeting. Mr O'Brien offered to meet with the DLA Advisory Board along with Dr Gerry Millar. To date, there has been no response.	

	A task and finish group has been established to assess the current pathway for patients with gastro-intestinal consequences following pelvic radiotherapy treatment. Ms Edel Aughey will support the group in her new role. It was also noted that Dr Suneil Jain will be invited to be involved in the group from an oncology perspective. Further updates will be provided at future network meetings. All other matters will be covered on the agenda.	
3.	**Urology guidelines & pathways** **Regional hormone therapy guideline & pathway:** Mr O'Brien extended thanks to Dr Darren Mitchell and Dr Suneil Jain for their work in taking this forward. Dr Mitchell advised that the draft guideline has been circulated to oncology colleagues for comment and to pharmacy to advise regard licensing restrictions. It was proposed that the guideline and pathway would also be circulated to the Urology Network Group for consultation. A deadline date of end of February 2015 was agreed. Mr O'Brien queried if bone densitometry testing should be considered within the guidance. Dr Mitchell advised that he would review guidance regard this. **AP1: All members to forward comments on the draft guideline and pathway by end of February 2015** **Patient Care pathways**: Mr O'Brien advised that he is currently reviewing and updating all pathways. **Clinical management guidelines:** <u>Surgical</u>: Mr Ali Thwaini is currently developing new surgical guidelines and will have them completed for the next Urology network meeting. <u>Imaging</u>: Ms Haughey advised that Dr Arthur Grey has proposed that the updated Yorkshire network imaging guidelines are adopted by the network group – this has been agreed by Dr Stephen Vallely and Dr Eoin Napier. It was agreed that the imaging guidelines would be circulated to all members for information. **AP2: Ms Haughey to circulated Yorkshire imaging guidelines to all members.** <u>Pathology</u>: Dr Gareth Mc Clean advised that he had reviewed the EAU guidelines which detailed some sections on pathology. He highlighted that the Royal College of Pathologists has produced datasets across all sites and it may be appropriate to reference these as opposed to providing a large amount of detail within the guidelines. Mr O'Brien concurred as long as there is assurance of compliance here to the datasets. Ms Haughey advised that reference to datasets was provided for some of the other tumour sites and agreed to forward an example to Dr McClean. **AP3: Ms Haughey to forward an example of a pathology guideline from another tumour site to Dr McClean** <u>Radiotherapy protocol:</u> Need to check about including this protocol within the guidelines	**All members by end of Feb'15** **Ms Haughey** **Ms Haughey**

	Nursing section: Ms Kate O'Neill, Ms Patricia Thompson and Ms Kerry Chambers to work together on developing a nursing section within the guideline to include reference to the inclusion of the recovery package. **AP4: Ms O'Neill, Ms Thompson and Ms Chambers to develop nursing section for inclusion in the guidelines before next network meeting.** Follow up section: All TCFU pathways to be included. Mr O'Brien updated members on the outpatient model which is being followed in SHSCT. CT scans / tests are arranged for patients prior to attending their outpatient appointment. This ensures that the outpatient visit is definitive; the patient will either be discharged or placed on a waiting list for a therapeutic procedure. The key worker is also introduced to the patient at the first visit. The patient is usually seen within 2-3 weeks with most tests already completed. Dr Gerry Millar advised there is a need to improve information flow to patients and GPs as there is still uncertainty regard what is going to happen and when and this would help to manage patient's fears. Communicating with patients in a timely manner can be an issue as patients are reluctant to answer phone if it is a withheld number. It was suggested that it would be useful to do an audit of the new system against the previous system to see if it works. It was noted that the model only works if there is good tracking as this will help to identify dates for surgery within the 62 day timeline. NICE consultations: there are currently two consultations out regard bladder cancer and the draft prostate quality standards. Mr O'Brien noted the increasing reference of MRI scanning prior to first biopsy in the draft prostate guidance. It was observed that more MRI capacity is required to make this change and that this issue has been flagged with commissioners.	**Ms O'Neill, Ms Thompson & Ms Chambers**
4.	**Targeted Service Improvement Activity** Ms Mary Jo Thompson advised that Ms Lynne Charlton is currently leading the review of the regional urology service and has been linking with individual teams regard taking this forward. Ms Charlton had indicated there was an indicative 40% increase in red flag referrals and would be keen to understand what this is reflective off and queried if there were any changes to the microscopic haematuria pathway or any other reasons. Ms Thompson suggested that the Be Clear on Cancer ''Blood in Pee'' campaign may have impacted on an increase in referrals. Dr Millar highlighted the difficulty by GPs in accessing investigations e.g. ultrasounds, and there could be a reduction of referrals to secondary care if there was better and timely access to diagnostic testing.	
5.	**Audit** **i) Audit of patient outcomes following radical cystectomy** Mr O'Brien invited Alison Downey to present the audit of patient outcomes following radical cystectomy. Hard copies of the audit were circulated to all members for information. Data included source of referral, timing from TURBT to radical surgery, indications, peri-	

	operative outcomes, incidental prostate cancer, complications, re-admissions and survival. 110 patients were identified in the timeframe from 04/01/2012 to 22/07/2014, gender breakdown of 95 male patients, 15 female patients and median age of 66 years. Following the presentation, Mr O'Brien thanked Ms Downey and asked for questions / comments from members: ➢ It was noted that there was no chart review of patients, data was retrieved from PAS,ECR, Link Labs, BAUS database and CaPPS ➢ Oldest patient was aged early 80's ➢ Average length of stay was 2.5 months and it was noted that there is more disease progression if stay is delayed beyond 3 months ➢ Mortality rates are consistent with national figures: 34% death rate, 66% survivor rate ➢ Greater number of lymph nodes retrieved – 20-30 lymph nodes, survival marginal benefit is equivalent to neo-adjuvant chemotherapy ➢ Dr Suneil Jain suggested looking at some standards in relation to the audit e.g. reported rates of neo-adjuvant chemotherapy ➢ There were a significant number unrecorded for pre-op neo-adjuvant chemotherapy and form of urinary diversion - though it was noted that there was no access to COHIS. This highlights the need for clinical teams to document information. ➢ Approximately one third of patients undergoing lymph node resection were node positive – members queried if this was higher than should be? ➢ Pre-op staging provides 5-10% increase of survival benefit ➢ A pathological based audit is required to look at the management of all patients with muscle invasive disease ➢ Radical radiotherapy for bladder – survival comparable for 50% of patients, should be re-run for neo-adjuvant patients ➢ CT scanning is difficult to use for staging bladder cancer, MRI should be considered ➢ For the data which was not on ECR, Mr O'Brien suggested contacting Mr Ali Thwaini to gain access to Lablinks which has a repository of histologies in BHSCT **AP5: Ms Downey to send the database, without patient names, to Dr Darren Mitchell, and he will re-run audit for neo-adjuvant patients** ii) **Erectile & lower urinary tract dysfunction following radical prostactectomy audit** **AP6: Mr Hugh O'Kane will present audit findings at the next network meeting.**	
6.	**Peer review** Ms Haughey advised that upload of documentation is the 18th May and the peer review visits are scheduled for the weeks of 15th and 22nd June across different trusts. Ms Haughey outlined the structure of the visit and timescale for resulting reports. Peer review training is taking place on Thursday 16th April 2015 and members should book a place through their Trust Cancer Manager.	

7.	**TCFU Prostate Sub group** Ms Thompson referenced the progress report on prostate follow-up implementation which was circulated prior to the meeting. This provided an update on prostate cancer patients moving onto shared care / nurse led pathways across all of the Trusts. It was noted that the follow-up pathways are being implemented at varying degrees and Prostate cancer follow-up has come a long way to moving patients to nurse led follow up. Ms Thompson also provided an update on the PSA IT Tracking feature within RISOH. The triggers are set at disease level though further work is required with the developers to ensure functionality. The tracking feature is allocated an identifier reflective of the PSA tracking category, including a prefix to indicate what trust. A search can also be initiated via the patient health and care number. Customised reports can be written to facilitate reporting requirements and letters can be set up for correspondence. It is envisaged that the RISOH system will go live from 20th April in BHSCT for oncology moving on to other trust sites over a five week period with a final go live on 15th June for haematology. Staff can start to utilise once go live. PAS virtual clinics to be developed within trusts to facilitate timely monitoring and training for staff will be rolled out. **Stage 3 TCFU evaluation: –** PWC has completed the evaluation. The draft report is currently out for comment and when finalised, it will be issued to stakeholders.	
8.	**Updates** **Clinical Trials:** Dr Suneil Jain advised that 8 trials are due to open in next year for local and metastatic prostate cancer and these will help to improve access to new therapies. Members highlighted the importance of dedicated staff within trusts to support recruitment of suitable patients for trials. **Cancer Patient Experience Survey:** Ms Haughey advised that the survey will be issued within the next week or two and will be sent to over 5,000 patients who received treatment for cancer over a defined six month period. It is hoped that interim trust reports will be available prior to peer review upload. It was also acknowledged that trusts are carrying out their own surveys to capture patient experience and feedback for peer review. **Prostate Cancer UK research:** Ms Haughey advised that PCUK carried out a nursing survey and a report will be published in March. Ms Haughey advised that PCUK researcher, Morven Masterson, has offered to present the finding of the study at a future network group meeting. **PCUK BHSCT Physiotherapy pilot:** Ms Thamra Ayton was unable to attend the meeting but has advised that her-self and Alison Robinson started the 18 month pilot on 19th January 2015. The next few months will involve background work: setting up the service, pathways, patient recruitment, assessment forms, outcome measures and meeting with nursing and medical colleagues. A further update will be provided at the next meeting.	

9.	**Emerging Issues** **Presentation of completed audits:** It was agreed that it would be useful to present findings / recommendations from completed Trust audits at the next network meeting. Completed audits include the Brachytherapy audit, Patient history audit, the Docetaxel neutropenic sepsis audit, and possibly a Bladder chemo audit. **AP7: Dr Darren Mitchell and Dr Lin Shum to contact relevant audit personnel regard summaries of completed audits for presentation at the next network meeting**	**Drs' Darren Mitchell & Lin Shum**
10.	**Date of Next Meeting** **Friday 17 April 2015 at 2.30pm – 4.30pm in Conference room 4, Linenhall Street, Belfast.**	

Urology Network Site Specific Group Meeting
Friday 17th April 2015
2.30pm-4.30pm, Conference room 4, Linenhall Street, Belfast

Record of Discussion & Agreed Actions

In Attendance	Aidan O'Brien (SHSCT), Mary Haughey (NICaN), Suneil Jain (BHSCT), Darren Mitchell (BHSCT), Mary Jo Thompson (PHA/NICaN), Edel Aughey (NICaN), Chris Hagan (BHSCT), Ali Thwaini (BHSCT), Thamra Ayton (BHSCT), Hugh O'Kane (BHSCT), Pat Sheils (BHSCT),Jacque Warwick (BHSCT), Karen Parsons (BHSCT), Melanie Blackwood (BHSCT), Ruth Johnston (BHSCT)
Teleconference	Moyra Mills (NHSCT)
Videoconference	Gareth McClean (SHSCT), Kate O'Neill (SHSCT)
Apologies	Fiona Reddick (SHSCT), Davinia Lee(BHSCT), Patricia Thompson, Elizabeth England(WHSCT), Robin Gray(PPI rep), Teresa Majury(PPI Rep), Harry Lockhart (PPI Rep), Samantha Thompson (BHSCT)

	Item	Responsibility / Date
1.	**Welcome & Introductions** Aidan O'Brien welcomed everyone to the meeting and apologies were recorded as above.	
2.	**Minutes of last meeting** **The minutes of the last meeting were** **Matters arising:** i) <u>Letter to DLA Advisory Board:</u> Mr O'Brien advised that he had spoken to the ATOS Director and she welcomed an opportunity for the network group to make representation regard the lasting impacts of cancer with a particular focus on fatigue. The Director proposed a meeting is set up with herself and the medical assessor before the end of June to discuss further. Mr O'Brien suggested that an oncologist and a GP should also attend the meeting. Ms Edel Aughey highlighted the fatigue management programme and the need for further promotion to clinicians. Ms Thamra Ayton advised that she would speak to Jane Rankin regard AHP representation and to Janet Morrison, Macmillan Information Manager.	

	Action point 1: Mr O'Brien to arrange a meeting with ATOS before end of June and to invite key people to attend as highlighted above. ii) Regional Urology meeting: Ms Mary Jo Thompson advised that Ms Lynne Charlton & Ms Sara Long are facilitating a Regional urology meeting on 30th April 2015 in Linenhall Street, chaired by Mr Dean Sullivan. Mr O'Brien advised that he would be attending in his capacity as SHSCT MDM Chair but it was agreed that it would be useful to have further representation on behalf of the Network Group. **Action point 2:** Ms Mary Jo Thompson to contact Lynne Charlton to seek Urology network group representation at the meeting iii) Audit of patient outomes following radical cystectomy: This audit was presented by Ms Alison Downey at the last meeting. Mr Darren Mitchell advised that he had not received the database to re-run the audit for neo-adjuvant patients. **Action point 3:** Mr Hugh O'Kane agreed to follow this up. iv) Audit on erectile & lower urinary tract dysfunction following radical prostactectomy: Mr Hugh O'Kane advised that this audit is on-going and will be presented at the regional Urology audit meeting next month. He advised that a registrar could present at a future network meeting. **Action point 4**: Mr Hugh O'Kane to arrange for presentation of audit at next network meeting.	**Aidan O'Brien** **Mary Jo Thompson** **Hugh O'Kane** **Hugh O'Kane**
3.	**Urology guidelines & pathways** **Regional hormone therapy guideline & pathway:** Following the last network meeting, the guideline and pathway were circulated to all network members for comment. Dr Darren Mitchell advised that he had received no comments to date. Mr O'Brien queried the term 'shared care' used in the pathway and thought that this may require clarification as it implies shared care with GPs. **Action point 5**: Ms Mary Jo Thompson agreed to review and define the term. **Action point 6:** Dr Mitchell advised that he will send the guideline to pharmacy colleagues to clarify licensing restrictions and following this, the document will be ready for final sign off. **Clinical Management Guidelines:** A draft version of the guidelines was circulated to members prior to the meeting. It was noted that Mr Ali Thwaini has done extensive work in reviewing and developing guidelines for Bladder, Prostate, Penile, Renal Cell, Testicular & Upper Urinary Tract Urothelial Cell Carcinomas, using the EAU guidelines as a template and including others from BAUS, NICE, NHS England and the Improvement of Outcomes Guidelines (IOG).	**Mary Jo Thompson** **Darren Mitchell**

	Mr Thwaini advised that he would need to circulate the draft document to other colleagues for review and to ensure it is in accordance with other appropriate guidelines. Ms Mary Haughey advised that the updated Yorkshire Imaging guideline were adopted following review by the lead authors. Dr Gareth McClean advised that he had consulted with colleagues to adopt the Royal College of Pathologists datasets. Ms Haughey advised that the existing SACT and Radiotherapy guidelines / protocols have been referenced in the document. Ms Kate O'Neill in partnership with nursing colleagues has developed the nursing section and it was also noted that the TCFU Prostate follow up documents have been included in the document. It was noted that the network should consider follow up pathways for other groups of patients besides prostate patients. There was discussion on whether Mr Thwaini should remove the chemotherapy and radiotherapy sections from his sections as they are already referenced under the relevant sections. Ms Haughey advised that the network group needs to agree guidelines and pathways which are circulated to trust MDTs – this needs to happen before the peer review documentation upload on 18th May. As there will not be a network meeting before this, it was agreed that the most up to date version would be sent to trusts with a rider that the document was still under review. **Action point 7:** Mr Ali Thwaini to circulate guidelines to relevant colleagues for review and comment. **Pathways:** Mr O'Brien advised that there are referral pathways, patient pathways and follow-up pathways. He has reviewed all the Urology care pathways and is content that they do not require any further update at this time. **Follow up:** It was highlighted that follow up pathways should be considered for other groups of patients besides prostate patients. There was discussion on the need to review all national guidance in relation to a number of procedures that are not currently available in Northern Ireland. Mr Chris Hagan suggested that the Urology CMGs should consider the inclusion of unique solutions to problems of managing cancer in NI when there are smaller volumes. Reference was made to the fact that patients currently travel to England for robotic prostatectomy under current commissioning arrangements and that a proposal for robotic surgery is being developed by BHSCT.	**Mr Ali Thwaini**
4.	**Clinical Trials** Dr Suneil Jain referred to the annual report on urology cancer trial activity 2014 which was developed by Melanie Morris from the NI Cancer Trials Network and was circulated to members prior to the meeting. Dr Jain highlighted that during 2014, 1415 participants, (16.6%) of incidental cancers, were recruited into regional cancer clinical trials, 2.7% of participants (235) received interventional, systemic or radiotherapy treatment. There were 14 urological cancer trials open to recruitment during this time and a total of 495 participants were recruited into urology cancer studies, with 59 participants into interventional trials. There were ten prostate trials which recruited 144	

	participants, there were two open testicular trials and only one randomised controlled trial (STAR) available for renal cell cancer, which was halted due to limited staff and will re-open for recruitment in April 2015. Urological cancer clinical trial activity is increasing at the Cancer Units, not only in identifying patients but also supporting full trial activity for studies such as UKGPC and HaBio. Dr Jain advised that further information on all open urological trials in 2014 was detailed in the report.	
5.	**Peer review update** All trusts are preparing documentation for upload on the 18th May. Visits are scheduled for weeks of 15th and 22nd June 2015. Some members attended the peer review training on 16th April 2015 and feedback was that it was very informative. It was noted that that there may be network actions after the peer review visits which may need discussion / action at the next network group meeting.	
6.	**TCFU Prostate sub group** **Implementation of pathways:** Ms Mary Jo Thompson advised that the TCFU project team finished in December 2014 and work is on-going within trusts to implement the prostate pathways though it was noted that the focus has been on surgical rather than oncology. Ms Thompson advised that Macmillan Service Improvement Leads posts for trusts are being recruited to support the transformation of cancer services. Ms Thompson also advised that the HSCB and PHA have been requested to develop a risk-based, prioritised, incremental development plan to address the gaps in the specialist cancer nursing workforce. This plan will be supported through charitable organisations using a pump prime model. A recent workshop in March has begun the discussion with key stakeholders on how this programme will be managed and prioritised across the region and across tumour sites. It was noted that there needs to be flexibility of how these nurse roles are utilised to ensure best use of time and cost effectiveness and consideration of skill mix. Chemotherapy prescribing nurses will be looked at through the chemotherapy review work stream. It was also highlighted that Friends of the Cancer Centre in partnership with Belfast trust have a CNS development programme currently underway. The TCFU evaluation report has been signed off and will be circulated to key stakeholders. Ms Edel Aughey advised that a Gastro-Intestinal (GI) Consequences of Pelvic Radiotherapy task and finish group has been set up following a workshop held last year, to assess the current pathway for patients with gastro-intestinal consequences following pelvic radiotherapy treatment and to bring forward recommendations to improve the pathway and patients' experience. The first meeting took place in February 2015, and the group is establishing a baseline of patients affected, identifying clinical champions in each trust, implementing a redesigned pathway to include patient information, raising awareness with GPs and introducing a treatment summary record. They are also going to explore the way forward for patients with complex cases. It was noted that a PSA tracking functionality has been developed for the RISOH system and currently this functionality is being tested.	

7.	**Updates** **Cancer Patient Experience Survey:** There has been a 62% response rate to the survey which was issued in February 2015 and is closing today. Interim data reports will be available for those MDTs that are being reviewed this year by late April and the full CPES reports will be available by late May 2015. **Prostate Cancer UK funded programmes:** Dr Jain advised that Charis Integrated Cancer Care had delivered two successful pilot programmes of education and support to individuals affected by prostate cancer and their families from diagnosis onwards. Dr Maura O'Neill advised that the second session took place in Causeway Hospital and was well attended **Physiotherapy programme** Ms Thamra Ayton advised that the 18 month pilot started on 19th January 2015. Work has been on-going to set up the service, including developing pathways and assessment forms, recruiting patients and agreeing outcome measures. To date 30 patients were identified from the pre-op surgery clinic, 50% were post-op patients, 17% were historical patients. The aim of the programme is to ensure that patients are doing their pelvic floor exercises correctly. From the 10 patients from the pre-op clinic, 4 were doing it correctly, 5 were doing it wrong. Of the 14 post-op patients assessed, 7 could do reasonably well, 7 were doing the exercises wrong and 1 patient was over active, so in this case it is best that they don't do. Ms Ayton advised that referral rates have been good to date and patients are assessed by DRE.	
8.	**Emerging Issues** There were no emerging issues. **Date of next meeting** Friday 18th September 2015, 2.30pm-4.30pm, Conference room 4, Linenhall Street, Belfast.	

Mitchell, Darren

From: Hagan, Chris
Sent: 18 August 2016 09:29
To: Mitchell, Darren; Traub, Gillian; Lee, Davinia; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Follow Up Flag: Follow up
Flag Status: Completed

The issue for me is the regional shared learning, and clinician to clinician may not capture this. Raising it as an IR1 and hoping ST then escalate to SAI may not happen and therefore no regional learning will follow. I think we should ensure that this is shared regionally.
I agree it would be useful to look back at referrals for MIBC and their timelines
The NICAN urology chair is part of the ST MDT and NICAN should also be involved in this
chris

From: Mitchell, Darren
Sent: 17 August 2016 18:42
To: Traub, Gillian; Lee, Davinia; Hagan, Chris; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Route 1 seems best. I think I would add weight to the discussion if we saw this as a trend and had evidence to that effect.

I suspect we'd see a longer lag than would be expected.

DMM

Sent from my Windows Phone

From: Traub, Gillian
Sent: 17/08/2016 18:28
To: Lee, Davinia; Mitchell, Darren; Hagan, Chris; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Hi Davinia, thanks for following this up.

I would add 2 points:

a) There should be a Consultant to Consultant discussion as Carol Anne says but should this discussion be with the MDT chair in SHSCT rather than with the individual Consultant Urologist, if the plan for this patient was agreed at MDT, rather than being the patient's urologist own treatment plan?
b) In past experience with interface incidents (which must meet criteria for an SAI) they are not the most palatable route. We could do a 3rd way – completion of a BHSCT incident report, with discussion with SHSCT clinician, and then incident report shared with them and they are asked to investigate. It also gets shared between corporate governance teams so it is formally logged. If the SHSCT then investigate it and find that it meets SAI criteria, it would then be incumbent on them to declare an SAI.

Gillian

From: Lee, Davinia
Sent: 17 August 2016 17:39
To: Mitchell, Darren; Hagan, Chris; Traub, Gillian; Crawford, Jena
Cc: Waring, Tracey
Subject: RE: query

Thanks Darren. I have chatted to Carol Anne and she says there are two options to raise this with Southern Trust

1) Speak directly to the colleague in the SHSCT who referred the patient (she advised discussion should be consultant to consultant) and advise of the concerns below and ask them to take forward an investigation locally
2) Report this as an interface incident with HSCB. In this scenario we complete a one page summary and submit to HSCB and they then contact the SHSCT for investigation. In either option we will need to have a discussion with the Southern Trust referrer.

Chris/Darren – would be keen to see if you have a preference?

I will ask Tracey to pull the MDT data for Jan-June 16 and pull out the muscle invasive bladder cancers – do you want to look at all Trusts or just Southern?

Thanks
Davinia

From: Mitchell, Darren
Sent: 17 August 2016 15:47
To: Lee, Davinia; Hagan, Chris; Traub, Gillian; Crawford, Jena
Subject: RE: query

Chris – I agree there is no recommendation for isotope bone scan in the regional guidelines or NICE guidelines.

1.2.8 Consider further TURBT within 6 weeks if the first specimen does not include detrusor muscle.

1.2.9 Offer CT or MRI staging to people diagnosed with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer that is being assessed for radical treatment.

1.2.10 Consider CT urography, carried out with other planned CT imaging if possible, to detect upper tract involvement in people with new or recurrent high-risk non-muscle-invasive or muscle-invasive bladder cancer.

1.2.11 Consider CT of the thorax, carried out with other planned CT imaging if possible, to detect thoracic malignancy in people with muscle-invasive bladder cancer.

1.2.12 Consider fluorodeoxyglucose positron emission tomography (FDG PET)-CT for people with muscle-invasive bladder cancer or high-risk non-muscle-invasive bladder cancer before radical treatment if there are indeterminate findings on CT or MRI, or a high risk of metastatic disease (for example, T3b disease).

I think this should be flagged back to the southern trust and I would suggest to all non-regional MDTs that any muscle invasive bladder cancer on pathology should be discussed at the regional meeting at the earliest opportunity to allow early surgical assessment and guidance on role of neo-adjuvant chemo or suitability for XRT/ ChemoXRT. Scans as per guidance can occur in tandem.

The outcomes from muscle invasive bladder cancer are poor and as you have demonstrated early intervention is crucial.

Perhaps the southern team would wish to do a case note review – either as part of an MDT process review or SAI.

SAI might be more appropriate if we see this as a consistent trend – So I also agree that a review of timelines for the last 30-50 muscle invasive cases coming to central-MDT could be reviewed to identify trends.??

Happy to discuss further.

DMM

Dr DM Mitchell FRCR
Consultant in Clinical Oncology
Northern Ireland Cancer Centre
Belfast City Hospital
Lisburn Road
Belfast BT9 7AB

☎ - Personal Information redacted by the USI
✉ - darren.mitchel Personal Information redacted by the USI
Secretary - elizabeth.burgess Personal Information redacted by the USI

From: Hagan, Chris
Sent: 16 August 2016 11:01
To: Lee, Davinia; Crawford, Jena
Cc: Traub, Gillian
Subject: RE: query

Davinia – it may be more appropriate for the MDM lead to comment.

However, from the guidance:

1. I can see no role for bone scan and we do not routinely do this in Belfast. I would ask them to justify this – from the guidance:

CT imaging for local staging of MIBC: The advantages of CT include high spatial resolution, shorter acquisition time, wider coverage in a single breath hold, and lower susceptibility to variable patient factors. Computed tomography is unable to differentiate between stages Ta and T3a tumours, but it is useful for detecting invasion into the perivesical fat (T3b) and adjacent organs. The accuracy of CT in determining extravesical tumour extension varies from 55% to 92% and increases with more advanced disease.
MRI for local staging of invasive bladder cancer: Magnetic resonance imaging has superior soft tissue contrast resolution compared with CT, but poorer spatial 32 V1.3

resolution. In studies performed before the availability of multidetector CT, MRI was reported as more accurate in local assessment. The accuracy of MRI for primary tumour staging varies from 73% to 96% (mean 85%). These values were 10-33% (mean 19%) higher than those obtained with CT. Dynamic contrast-enhanced (DCE) MRI may help to differentiate bladder tumour from surrounding tissues or post-biopsy reaction, because enhancement of the tumour occurs earlier than that of the normal bladder wall, due to neovascularisation. In 2006, a link was established between the use of gadolinium-based contrast agents and nephrogenic systemic fibrosis (NSF), which may result in fatal or severely debilitating systemic fibrosis. Patients with impaired renal function are at risk of developing NSF and the non-ionic linear gadolinium-based contrast agents should be avoided (gadodiamide, gadopentetate dimeglumine and gadoversetamide). A stable macrocyclic contrast agent

should be used (gadobutrol, gadoterate meglumine or gadoteridol). Alternatively, contrast-enhanced CT could be performed using iodinated contrast media (LE: 4).

2. **Timing and delay of cystectomy:**
   Patients treated > 90 days after the primary diagnosis showed a significant increase in extravesical disease (81 vs 52%). Delay in cystectomy affects treatment outcome and the type of urinary diversion. In organ-confined urothelial cancer of the bladder, the average time from primary diagnosis to cystectomy was 12.2 months in patients who received a neobladder and 19.1 months in those who received an ileal conduit. This was even more noticeable with organ-confined invasive cancer; the average time to surgery was 3.1 months with a neobladder and 15.1 months with an ileal conduit (8). Similar results have been observed in a series of 247 patients: recurrence-free survival and OS were significantly better in patients treated before 90 days compared to others treated after 90 days.

Happy to discuss further. It may well be worth looking at other ITTs for cystectomy
chris

From: Lee, Davinia
Sent: 15 August 2016 16:08
To: Hagan, Chris; Crawford, Jena
Cc: Traub, Gillian
Subject: FW: query

Hi Chris,

Can I check if you have had an opportunity to review this patients pathway, and whether you still have concerns we need to follow up on?

Thanks
Davinia

From: Lee, Davinia
Sent: 22 June 2016 17:19
To: Hagan, Chris
Cc: Crawford, Jena; Traub, Gillian
Subject: RE: query

Hi Chris

I have had a look at the patients pathway from CaPPS, see attached.

I have compared it against the NICaN pathway (page 125 of the clinical guidelines) and the guidance is for muscle invasive bladder cancer to send to CT chest abdomen before MDT discussion, however in this case it was discussed at MDT first. There was then a delay to the bone scan and it took over a month for the CT after the first MDM and nearly 2 months from the original report of the pathology. They then discussed at local MDT again on 28/4/16 and decided on a plain film of left shoulder and central MDM discussion. The first discussion at the regional MDT was following this on 12/5 at which a CT was recommended of the shoulder. An MRI was carried out as recommended by the radiologist on 26/5 and then was discussed centrally again and transferred on 9/6/16.

Would you have a look at the pathway prior to the first central MDM discussion on 12/5 for me? It looks like a CT should have been requested following the original path on 29/2 in line with the pathway attached which would have

saved at least a month, but would welcome your clinical view as to what should have happened post original resection and pre specialist MDT discussion before we decide on how to proceed.

Thanks
Davinia

From: Hagan, Chris
Sent: 22 June 2016 10:01
To: Lee, Davinia
Subject: RE: query

Sorry its: Patient 127
chris

From: Lee, Davinia
Sent: 22 June 2016 09:13
To: Hagan, Chris
Subject: RE: query

Hi Chris

We can't find anything for patient Personal Information redacted by the USI on CaPPS or ECR – is the HCN definitely correct? What is the patients name?

Thanks
Davinia

From: Hagan, Chris
Sent: 21 June 2016 16:24
To: Lee, Davinia
Cc: Crawford, Jena
Subject: query

Davinia
I'm very concerned about delays in ITT from Craigavon and how we raise this – is it possibly an interface SAI?

patient Personal Information redacted by the USI muscle invasive bladder cancer.
Original resection16.02.206 with multiple local MDT discussions before a regional discussion 09.06.2016 and I see her today 21.06.2016. In my view there are multiple avoidable delays which will potentially lead to an adverse outcome – she is not fit for cystectomy today.

Contrast this with an exemplar. Patient Personal Information redacted by the USI TURBT 25/05/2016 in Derry. Muscle invasive bladder cancer; discussed regional MDT 09/06/2016 and seen today with radical surgery next week.

What do you think?

happy to discuss

Chris

I spoke to Mr McAleer I believe in 2019 at the point of initial discussion with Mr Haynes and then again in 2020 at the point of being asked to contribute to the look back exercise.

(viii) Were you aware of others who had knowledge of these issues or who may have shared similar concerns? Please give full details.

1(viii) I believe the oncologists providing support as part of their job plan to the Craigavon urology service would have routinely been referred cases from Mr O'Brien and may have come across this off license prescribing. This would include Dr Jonathan McAleese, Professor David Stewart and Dr Fionnuala Houghton. I am not aware of any discussions they had if they had concerns.

(ix) Please provide further details in respect of the suggestion that the MDM 'challenged' Mr O'Brien on his use of Bicalutamide in 2015. In particular, please set out:

(a) the nature and form of the said challenge,

(b) who was present or otherwise involved in same, and

(c) Mr O'Brien's response.

Please provide the Inquiry with copies of any relevant contemporaneous documentation (record, note, email, minute or otherwise) relating to this.

1(ix) I believe this to relate to the discussions at the NICAN urology group meeting on the androgen deprivation guidelines that had been circulated to the group. I was chair of the regional urology MDM at that stage and attended the NICAN meeting in that role. I believe I raised the point at the NICAN urology meeting on 3/1/2015 that the androgen deprivation guidelines were to standardise the prescription of hormone therapy and stop the use of off licence Bicalutamide 50mg monotherapy, however the minutes of the NICAN meetings have not recorded this. (***AOB7, AOB8, AOB9***)

I remember there being a prolonged pause following my point, before Mr O'Brien "extended thanks to Dr Darren Mitchell and Dr Suneil Jain for their work in taking this forward"

2 (i) Please confirm whether the Regional Hormone Therapy guidelines referred to were developed in direct response to concerns about Mr O'Brien's prescribing practices in respect of Bicalutamide.

2 (i) The guidelines were in large part written to address concerns over off licence prescription of Bicalutamide 50mg monotherapy by Mr O'Brien.

(ii) To the extent that the answer to (i) above is 'yes', please explain why this approach was taken, explaining how, if at all, it was intended that the guidelines should address the issues/concerns around off-licence prescribing of Bicalutamide.

2 (ii) This approach was taken in the knowledge that Mr O'Brien would be required to formally review and accept the guidelines in his role as NICAN Chair. I was aware that the guidelines would be discussed at a subsequent NICAN Urology meeting and that would both allow me to formally raise the point as outlined 1(ix) and give Mr O'Brien an opportunity to discuss this off licence practise. I hope that the guidelines and the verbal point as 1 (xi) above would be a prompt for Mr O'Brien to address the off-licence prescription of Bicalutamide 50mg monotherapy.

2 (iii) In your view, ought these guidelines have been subject to audit within individual Trusts? Please explain your answer.

2 (iii) These guidelines could have been audited within each trust. If my belief that Mr O'Brien was the only person in the region using Bicalutamide 50mg monotherapy is correct then it would in essence have been an audit of his hormone therapy prescriptions in the southern trust. The guidelines were written to encourage good practice and provide a point of reference if there were future cases identified with this off-licence prescribing.

2 (iv) Please provide any further relevant comments you may have in relation to the development of these guidelines and the process leading to their approval.

2 (iv) I am not aware that the guidelines were ever formally approved by Mr O'Brien.

3 (i) Please provide this patient's HCN.

3. (i) Patient 127

3 (ii) Please explain the significance of this case, giving further details as to the particular concern raised by Mr Hagan and Ms Traub.

3 (ii) Mr Hagan raised concern to Ms Davinia Lee who I believe was the cancer services manager at the time about avoidable delays in the management of a muscle invasive bladder case referred to him from Craigavon. His concern was around multiple discussions at the southern trust MDM prior to the patient being referred for discussion at the regional meeting and he was concerned that the delays would adversely affect the outcome in this case. Mr Hagans email also identified the use of isotope bone scans as being outside the guidance for staging in muscle invasive bladder cancer. (***AOB11***)

3 (iii) How was this case 'flagged back to SHSCT'? Please identify the mechanism by which this was raised with the Southern Trust and identify any relevant individual(s).

3 (iii) This case was flagged back to Mr O'Brien by email on 26th of August 2016 (***AOB10***) suggesting case note review and consideration of shared learning either locally or regionally. The urology MDM co-ordinator Shauna McVeigh at the southern trust was copied to that email.

Urology Services Inquiry

3 (iv) Did you seek to discuss this case with Mr O'Brien at any stage? To the extent that the answer is 'yes', please give full details. If no, why not?

3 (iv) Yes – as noted above Mr O'Brien was emailed about the case.

4. A further extract of the record of the interview with Dr Hughes of 23 February 2021, further states the following (at TRU-162277):

'Dr Mitchell advised he emailed the consultant in 2016/17 about his prescribing outside recommended guidelines and highlighting it was his GMC duty to inform patients they were being treated outside the recommended guidelines. The patients were misled.'

4 (i) Provide the Inquiry with a copy of this email and any response(s) received.

4 (i) The email referenced in the interview with Dr Hughes was actually sent in 2014 and has been discussed in section 1. I did not receive any response. (***AOB1***)

4 (ii) Did you take any further action in respect of this apparent concern? To the extent that the answer is 'yes', provide full details. If your answer is no, why not?

4(ii) As per my response in section 1, I wrote the androgen deprivation guidelines and presented these to the NICAN urology group in 2015. When I was made aware of the cases seen by Prof Jain in 2019 and 2020 I spoke to and emailed Mr Haynes. (***AOB4, AOB12***)

4 (iii) The Inquiry notes the statement 'The patients were misled'. Please confirm whether this is your belief and, if so, how and why you consider that patients were misled? If not your belief, why did you say it to Dr Hughes?

4 (iii) I do believe patients were being misled. The hyperlink included in my 2014 email to Mr O'Brien leads to guidance on off-licence prescribing. This outlines our responsibilities as prescribers to use medication within licence and if a decision is made to use a medication outside its licenced indication or dose then good practice would be to make the patient aware of the reason for this decision in their case. In the cases identified in my statement I could see no evidence that the patients had been advised about the off-licence use of Bicalutamide 50mg monotherapy.

The delayed referral to oncology in the cases in my statement meant that these men waited longer than other men in a similar situation to have an oncology opinion.

5 (i) Please give details of any discussions you had with Dr O'Sullivan regarding shared concerns.

5 (i) The discussions with Prof O'Sullivan would have been as part of the joint Thursday morning outpatient case note review. I believe there would have been a number of cases discussed at that meeting with off licence prescription or perceived delayed referral.

Urology Services Inquiry

5 (ii) How and when did you raise these concerns with the CD Dr McAleer? Please provide full details, together with copies of any relevant contemporaneous documentation.

5 (ii) I believe my first discussion with Dr McAleer occurred at the time of the informal discussions with Mr Haynes in 2019 outlined above. I advised Dr McAleer that I was contributing to a process of investigation of Mr O'Brien's practice and that I anticipated that as it evolved that it was likely I would have to provide evidence to any subsequent investigation within the southern trust. When I was invited to a case review meeting with the southern trust on 1/10/2020 I also advised Dr McAleer of my role in this at that time. I have no documentation from these discussions.

5 (iii) Did you discuss or raise these concerns with anyone else? If so, please provide all details, including names, dates and contents of all discussions.

5 (iii) At the time of my discussions in 2020 with Dr McAleer there were a number of people aware, including those from the southern trust listed on the meeting for 1/10/2020 and I had also advised Prof O'Sullivan and Prof Jain that I was taking part in a formal investigation process.

5 (iv) What was the outcome of your engagement with Dr McAleer?

5 (iv) I have no documentation from these discussions but remember Dr McAleer agreeing that it was appropriate for me to contribute to this process.

5 (v) Was this the only occasion on which you raised concerns with Dr McAleer? To the extent that the answer is 'no', please provide further details of any other occasions on which concerns were raised with the Clinical Director.

5 (v) I believe I spoke to Dr McAleer twice as outlined in 5 (ii) above

6. Please consider the email of 20 November 2014 at AOB-71990.

(i) Please explain the context and purpose of this email.

6 (i) The email referenced (***AOB-71990***) is the same email discussed in section 1

The purpose was to outline standard of care for this case and to make him aware of his responsibilities as a prescriber when using off licence medication.

6 (ii) Please provide a copy of any response received.

6 (ii) I did not receive a response.

6 (iii) To the extent that this email may be said to demonstrate concern, please indicate whether, at any stage, these concerns were discussed with others or otherwise escalated.

Urology Services Inquiry

6 (iii) A copy of the email sent to Mr O'Brien in 2014 (***AOB2***) was copied to Prof O'Sullivan, Prof Jain as well as Dr Lucy Jellet, who may have been covering the Craigavon urology oncology clinic in a temporary capacity.

7 (i) To the best of your recollection, please provide all details of every occasion on which you wrote directly to Mr O'Brien about his practice and, where possible, provide copies of this correspondence together with any response received.

7 (i) The email sent in November 2014 (***AOB1***) regarding off licence prescription and the email sent in August 2016 about the muscle invasive bladder cancer case (***AOB10***) are I believe the only 2 times that I wrote to Mr O'Brien about his practice. I do not believe I received a response from either email.

7 (ii) Please explain why the issue was never escalated to SHSCT, providing details of any real or perceived obstacles to such escalation?

7 (ii) This was escalated to Mr Haynes in 2020.

7 (iii) Please provide any further comments/ reflections you may have on the failure to escalate, setting out what might perhaps have been done differently.

7(iii) On reflection my hope that Mr O'Brien had taken note of the email sent in 2014 and ADT guideline discussion at the NICAN was misplaced. If the ADT guidelines had been signed off then some form of audit may have identified ongoing off licence prescription.

8. Please indicate whether, at any stage, you had concerns about or knowledge of issues around the use of Clinical Nurse Specialists. To the extent that your answer is affirmative, please provide further details.

8 I had no knowledge of any issues around the use of clinical nurse specialists.

9 The Inquiry is aware of significant issues around the quoracy of SHSCT Urology MDMs, particularly in terms of Oncology attendance. On this issue, the record of the interview of 23 February 2021, at TRU-162276-77, indicates that you:

'described issues trying to support the MDT in SHSCT it was a busy practice and they had difficult [sic] in recruiting to cover this role.'

Please further explain the difficulties from your perspective and offer any further comments or observations which may assist the Inquiry in understanding this issue.

9 The oncology post formally supporting the urology service in the southern trust had been occupied by non-substantive consultants for a period of time. As part of the job plan for those posts it was not always possible for an oncologist to be present at the southern trust MDM. I believe the substantive post was advertised on a number of occasions. I believe this would have been raised by SHSCT with the clinical director in clinical oncology.

Therapeutic doses of anti-androgen monotherapy with bicalutamide are prescribed at recommended dose (150 mg).	100%	Discussions with patient / Clinical rationale	NICE guideline NG131 Prostate Cancer: Diagnosis and Management

Audit Methodology

The following audit methodology will be followed:

- HSCB to provide information on primary care prescriptions of the medication Bicalutamide
- Southern Health and Social Care Trust patients to be identified and a consultant led review of prescribing to take place to identify prescribing of Bicalutamide that is outside of that prescribed in NICE guideline NG131 Prostate Cancer: Diagnosis and Management

A review of each patient's electronic care record, for patients from the Southern, Western and Northern Trust areas (as patients from these areas urological care was provided by the Southern Trust urology service at this time) was conducted by Mr Haynes whose responsibility was ~~in order~~ to determine if the prescription of Bicalutamide 50mg was in line with the licenced indications / standard practice / guidelines. 'Standard practice' being defined as;

- Short course Bicalutamide 50mg OD to cover testosterone flare immediately before and after first LHRH analogue (hormone) injection
- Bicalutamide 50mg in addition to LHRHa (hormone) as combined androgen blockade (which may be as primary Androgen Deprivation Therapy for metastatic disease or as addition to LHRHa monotherapy upon development of a rising Prostatic Cancer Marker, Prostate Specific Antigen).
- In line with British Association of Urological Surgeons (BAUS) COVID-19 pandemic response guidelines during initial wave of COVID-19.
- Where clinical justification of low dose use given in correspondence.

Low Dose Bicalutamide Prescribing (50mg)

A total of 466 patients was identified from the Western, Northern and Southern Local Commissioning Group areas as having received a prescription for Bicalutamide 50mg.

34 of these patients were identified as being on the incorrect treatment as determined by the clinical indications above. 2 patients had been commenced on the medication by services outside of NI Urology (1 by GP, 1 in South Africa in 2005 and continued following move to NI).

Of the remaining 32 patients 31 had been commenced on the low dose Bicalutamide by Mr O'Brien. 1 patient had been correctly commenced by Mr O'Brien on combined androgen blockade (LHRHa and 50mg bicalutamide) and had been switched to intermittent treatment by another Southern Trust Locum Consultant Urologist (Mr Thomas Jacob) on review. However only the LHRHa (rather than both treatments) had been stopped at the time of this switch.

This patient has since been reviewed by the oncology team and the Bicalutamide discontinued.

From the remaining 31 patients, 2 (Patient 6 DOB Personal Information redacted by the USI and Patient 4 DOB Personal Information redacted by the USI) were subjects of 2020 SAIs (conducted by Dr Dermot

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Section 21 - No 11 of 2023 Mr. Christopher Hagan

Date of Notice: 6th June 2023

Witness Statement of: Mr. Christopher Hagan

I, Chris Hagan, Consultant Urologist and Medical Director of the Belfast Health and Social Care Trust (Belfast Trust), will say as follows:

1. This is my first witness statement to the Urology Services Inquiry.

2. The documents that I refer to in this witness statement can be found in the exhibit bundle marked “CH1”.

3. I have been asked by the Urology Services Inquiry (USI) to address a number of questions set out in a section 21 notice dated 6 June 2023. I endeavour to address those questions in this witness statement. The USI has also provided me with a number of documents that bear on those questions. The section 21 notice and accompanying documents can be found behind Tab 1 in the exhibit bundle.

4. I am happy to try and assist the USI in any way I can. I have set out my recollections below to the best of my present ability. My specific direct experience of Mr O’Brien was over a 6 months period in excess of 20 years ago, and so I do not think that I now have a full and complete recollection of that period, simply due to the passage of time, but I have done my best to set out what I recall.

Belfast to changing their equipment and technique, but over time there was a gradual adoption of bipolar TURP and other safe techniques such as laser prostatectomy.

59. Some years after this policy was developed I was contacted by phone by Dr Charlie McAllister, a consultant anaesthetist in CAH. I cannot be sure when exactly I received this call, but I believe it was sometime between 2017 and 2019. Dr McAllister wished to discuss TUR surgery, TUR syndrome and use of bipolar resection. He explained that they had an issue in CAH with an individual surgeon carrying out prolonged TURP resections with glycine and some "bad" TUR syndromes. He did not name the surgeon specifically. He wanted to know my experience with introducing TURP in saline. I explained that the experience in Belfast was good, that the technique was similar to monopolar TURP with glycine and that with modern equipment, in my view, it was unjustified and unsafe to continue to use glycine due to the safety profile of it as an irrigating fluid. From a personal perspective, I have carried out TURP in saline for around 10 years and see no justification for the use of glycine.

60. I cannot myself provide more detail in relation to this issue, but I have referred to it lest it is relevant to the Terms of Reference of the USI and the open questions that have been asked of me.

Conclusion

61. I have endeavoured to assist the USI through the provision of this witness statement. I hope I have answered the various questions posed to me in the section 21 notice. I have to accept that my memory will not be perfect, and consequently I may not have remembered all examples, or even remembered fully those examples that I do recall. However, I have done my best, and I will continue to assist the USI in any way I can.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed: Personal information redacted by the USI _____

Date: 9 August 2023

24. There were two consultants in the Urology unit in CAH, Mr. Aidan O'Brien and Mr. Michael Young. Whilst I had met both of them before at educational events, I had not worked with either of them previously.

25. The Urology department in CAH at that time had its own inpatient ward. I cannot remember precisely, but there were probably around 20 beds on the CAH Urology ward. The ward would have been fully staffed by nurses on a 24/7 rotation. At the time there would have been a ward sister and deputy ward sister for the Urology ward. The consultants were supported by a number of nurse specialists; nurses who specialised in Urology, having had additional urology training.

26. I was the only Urology Specialist Register in CAH during my rotation, but there were a number of other junior grade medical staff (Senior House Officers and Junior House Officers) also there at the time. Like specialist registrars, they will also have changed over time on rotation. My recollection is that the CAH Urology unit was busy with good training opportunities.

27. Whilst Mr. O'Brien and Mr. Young had their own sets of urology patients, they did do a joint Thursday morning ward round together. I attended this. It meant they were involved with each other's patients. They would also have covered for each other, seeing each other's ward patients, on the weekend rotations and for holidays.

28. I have reflected over time, arising from the questions posed by the USI in the section 21 notice, about the 6 months I spent in CAH. As I have done so, I have recalled that there were a number of situations that arose that caused me to feel concerned about some of the practices of Mr. O'Brien. With the passage of time it is not now possible for me to recall all the details. I did not keep a formal record at the time. I am afraid it would not have occurred to me to do so. I did raise issues that concerned me with Mr. O'Brien himself, and also with Mr. Young about Mr. O'Brien, during my 6 months rotation. In 2000 that would have seemed like a brave or courageous step from a higher surgical trainee. I am sure I probably saw it that way at the time. Whereas, with all the more recent and ongoing changes in medical culture (transparency, openness, and the many mechanisms for raising concerns) and the development of clinical governance (introduced into health and social care around 2003), it hardly seems

sufficient by today's standards when the opportunity for trainees to raise concerns are much more organised and available, and their use encouraged. Trainees are now heard and listened to in a way they would not have been in 2000.

29. As I have reflected on my time in CAH for the purposes of providing this statement it is possible to broadly identify 9 areas of concern that I address below. I would not have counted them up at the time in order to regrade them as some form of accumulation, and would not have had the "slow time" thinking about them facilitated by the questions posed by the USI. It is difficult for me to say whether the concerns I now identify, as I reflect back with hindsight, and with awareness of investigations into Mr. O'Brien, were concerns considered by me to be of the extent and nature that I now see them, and I would ask the USI to bear that in mind. It is also the case that how I responded to the matters that concerned me in 2000 would be different from how I would respond to them today, if I were still a trainee, including because the available mechanisms for responding are significantly different.

30. I should also say at the outset that I recognise and acknowledge that Mr. O'Brien was someone, in 2000, who was a senior consultant. He appeared popular with patients, pleasant to staff, and someone who worked hard (including into the evenings). I also acknowledge him assisting me to secure the opportunity to focus on a particular specialism I was interested in when training in Dublin in 2021.

31. The concerns were as follows:

I. **Patients being admitted to the ward for prolonged intravenous fluids and antibiotic therapy.** There was a group of patients that seemed to me to be being regularly admitted to the ward for antibiotics and IV fluids by Mr. O'Brien. My recollection is that these patients would make contact with Mr. O'Brien in some way and be admitted directly to the ward as an inpatient for treatment. When I asked about this practice the ward nurses referred to this treatment as "*Mr. O'Brien's regime*". I would do an unaccompanied ward round every morning during my 6 months rotation when I would come across these patients. It was often not clear to me the reason for this approach, or the evidence base for the treatment. I considered patients who fell into this category could have been managed as

bladder, unless there are unusual daytime features. Mr. O'Brien was of the view that the child required invasive tests such as urodynamics (which requires a general anaesthetic and catheters). In my view at the time this was over-investigating and unnecessary, as the course of treatment would be expected to be the same in any event. I cannot say whether Mr. O'Brien did in fact carry out the invasive tests, I just remember disagreeing with him when he thought this should be the course undertaken.

VI. **Radical Prostatectomy and high PSA.** During my 6 months in Craigavon Area Hospital, Mr. O'Brien performed operations in a small number of pelvic cancer cases, such as radical cystectomy for bladder cancer and radical prostatectomy ("**RRP**") for prostate cancer. His patient selection for RRP differed to what was generally accepted by UK urologists at that time, though I accept there would be some support beyond the UK for the approach Mr. O'Brien advocated. This was at a time before MRI scans were routinely used to assess suitability for surgery. Generally, men with a Prostate Specific Antigen (PSA) test score of less than 10 and no higher than 15, with confirmed prostate cancer, were thought suitable for RRP, as higher PSAs tended to be associated with higher risk of lymph node positive disease or extracapsular disease and were best treated with radical radiotherapy and hormone treatment. Mr. O'Brien however offered RRP to men with very high PSAs and would commence them on hormone treatment prior to surgery to reduce their PSA score. It is likely that men with a high PSA will have micro-metastatic disease. Commencing hormone treatment pre-surgery will lower the PSA before surgery but does not cure metastatic disease and so surgery provides no ultimate benefit. I disagreed with Mr. O'Brien about his approach and argued that the path he was taking may also in fact lead to earlier hormone resistance in the patients, as these men would then not be hormone naïve when they developed symptomatic metastatic disease. Mr. O'Brien did not share my view. My recollection is that Mr. O'Brien did openly disagree with others in the region on the issue of the treatment of prostate cancer.

VII. **Priapism and penile disassembly.** In my last week as a trainee in CAH in 2000, a patient was admitted with a long-standing priapism (an erection of the penis that

asked my legal representative to provide to the USI the details of the three patients I saw so that the USI can consider their cases. I provide a very brief summary below to try to illustrate the issues (the references to Patients 1, 2 and 3, and the text in square brackets are my attempts to ensure anonymity for the patients concerned):

Patient 1

I. Patient 1 was referred to CAH by a GP in June 2010 with haematuria. They underwent TURBT in July 2010 in CAH; histology sarcomatoid bladder cancer with CT scan demonstrating no metastatic disease. The presence of high grade aggressive sarcomatoid bladder cancer should have triggered immediate discussion about cystectomy irrespective of there being no detrusor muscle in the specimen. However, the patient underwent another TURBT in August 2010 which confirmed the same pathology. The patient also had a bone scan in August 2010 which was also negative (bone scan is not a recommended investigation for bladder cancer). The patient was then readmitted to CAH in September 2010 and had another CT scan which demonstrated regrowth of the tumour at which point a decision was made to proceed with cystectomy in Craigavon at the end of September 2010. In Mr O'Brien's letter to the GP he wrote:

> *"As you are now aware, a decision was made by officials in the Department of Health, in conjunction with the Commissioner, to cancel [Patient 1] admission and to have his further management transferred to Mr Hagan, Consultant Urologist at Belfast City Hospital, and with whom I gather that an appointment has been arranged for [date] September 2010. [Patient 1] and [their] family have been gravely distressed by the cancellation of [their] admission. [Patient 1] is suffering gravely from severe lower urinary tract symptoms. I do hope that [their] further management can be expedited as soon as is possible."*

Mr O'Brien further wrote to the patient:

Subject: 20100929 Email correspondence from Chris Hagan to Tony Stevens BHSCST

From: Hagan, Chris
Sent: 04 October 2010 21:15
To: Stevens, Tony <Personal Information redacted by the USI>; Hannon, Ray <Personal Information redacted by the USI>
Subject: RE: urology patients - confidential

Tony,
This is obviously very awkward for me – urology is a small specialty and 2 of the CAH urologists were my trainers!
I think if the surgeons concerned fully engage in the regional MDM then hopefully a lot of these issues can be avoided in the future. This would certainly be my hope. Thankfully, on Thursday, 2 of the 3 CAH urologists tele-linked with the regional MDM and referred 2 patients to Belfast.
However, a private, perhaps "off record" discussion with the CAH MD about some of these issues probably needs to happen even if just to make him aware as it is highly likely that there will be patient/ relative complaints.
Chris

From: Stevens, Tony
Sent: 29 September 2010 16:04
To: Hagan, Chris; Hannon, Ray
Subject: RE: urology patients - confidential
Chris
Thanks for this. If you are comfortable i will write to med director in southern copyying this email. I understand that situation further complicated by advise given by one consultant to patient. If you have detail on this it would be helpful. I am prepared to take strong line on this if continues, to extent of considering need for gmc referral. Happy to discuss.
tony
Sharon please bf when i am in office

Sent from my Windows Mobile® phone.

From: Hagan, Chris <Personal Information redacted by the USI>
Sent: 28 September 2010 15:25
To: Stevens, Tony <Personal Information redacted by the USI>; Hannon, Ray <Personal Information redacted by the USI>
Subject: RE: urology patients - confidential

Tony and Ray,
Whilst the letters sent about these patients were unhelpful, I think it misses the point with these patients and the governance issues that have been raised.
To put in a wider context, in 2002 NICE issued guidance (improving outcomes in urological cancer, IOG) specifically stating that surgeons performing <5 pelvic cancer operations / annum (radical prostatectomy and radical cystectomy) should cease. Furthermore, units performing less than 50 / year of these operations should cease immediately. In addition, there was firm guidance that all new urological cancers should be discussed at an MDT that comprised urologists, oncologists, radiologists, pathologists and CNS.

Outside Belfast, NI was slow to adopt these changes due primarily to a combination of hubris and ignorance. However, in 2007/8 with the establishment of NiCAN, NICE recommendations were largely adopted here. Since then, all hospitals bar Craigavon have referred patients to BCH for radical pelvic surgery as we are the only unit treating a population >1M and carrying out approx 80 – 90 procedures per annum. CAH still does not have a properly functioning MDT and has refused to engage with the regional MDM at BCH (all other hospitals either tele-link or attend in person). In the last 2 years, CAH have performed < 10 urological pelvic cancer operations / annum.
The Northern Ireland review of Urology signed off by the Minister of Health further cemented this guidance by stipulating that from March 2010, all urological pelvic cancer surgery should be performed in BCH. Despite this, these 5 patients were the first to be referred to BCH.
Before I saw these 5 patients, they were all discussed at the regional MDM; present were 3 urologists (Hagan/ Keane/ Rajan), 3 oncologists (Harney/ Stewart/ Mitchell), 2 radiologists (Grey / Vallely), 2 pathologists (O'Rourke/ Grey) and 1 CNS (Kelly). There was considerable variance with the management plans proposed by Craigavon Urologists and I think this is where the governance issue lies.
Patient 1. Personal Information redacted. This Personal Information redacted year old Personal Information redacted presented with metastatic bladder cancer and obstructed left kidney. The standard of care in this case would be relief of urinary obstruction followed by palliative chemo. The Craigavon urologist was proposing primary surgery (cystectomy) and chemo after. Reference to a properly constructed MDT would have prevented this error. This patient was admitted to BCH Personal Information redacted by the USI, had nephrostomy today and is due to commence palliative chemo next week. It is highly likely that surgery has no role to play in this Personal Information redacted by the USI palliative care.
Patient 2 Personal Information redacted. This Personal Information redacted year old Personal Information redacted presented with bladder cancer and extensive retroperitoneal nodal disease. The standard of care would be neo-adjuvant chemo and if there is a satisfactory response, then proceed with either surgery or radiotherapy. The Craigavon urologist was proposing primary surgery (cystectomy) and it would appear from the notes that there was not an appreciation of the extensive nodal disease. Again, reference to a properly constructed MDT would have prevented this error. This Personal Information redacted is to see the oncologist in BCH this week and will hopefully start chemo next week.
Patient 3 Personal Information redacted. This unfortunate Personal Information redacted was diagnosed with a highly aggressive sarcomatoid bladder tumour in Personal Information redacted by the USI. At that stage Personal Information redacted should have been offered cystectomy as soon as possible. For some unknown reason, Personal Information redacted was brought back for a second endoscopic resection towards end July / early August by which time the tumour was found to have increases in size. Personal Information redacted remained very symptomatic during August and September and was given a date for cystectomy in CAH Personal Information redacted Personal Information redacted by the USI. It was not clear to the regional MDM why this Personal Information redacted had not been offered definitive surgery sooner and reference to a properly constructed MDT would have prevented this error. Personal Information redacted is having definitive surgery tomorrow.
Patient 4 Personal Information redacted by the USI. This Personal Information redacted has low – intermediate risk prostate cancer and was due to have radical prostatectomy last week in Craigavon. Personal Information redacted operation was cancelled and Personal Information redacted has been in contact with media. There is no issue with the treatment offered. When I met Personal Information redacted on Monday I was going to offer Personal Information redacted a date for surgery Personal Information redacted Personal Information redacted by the USI. However as is customary with patients with prostate cancer there are many options for treatment and after discussion Personal Information redacted has chosen to explore brachytherapy.
Patient 5. This Personal Information redacted has low – intermediate prostate cancer and had been scheduled for radical prostatectomy (no date in CAH). There is no issue with the treatment offered. However, Personal Information redacted is overweight, type II DM, and has had previous endoscopic prostate surgery that would make a radical prostatectomy technically more difficult with poorer outcomes by all measurements (continence, cancer margin status, blood loss, length of stay). After discussion Personal Information redacted has opted for radiation treatment – equally effective but much less morbidity.
The main issues are with the bladder cancer patients. All 3 have had inappropriate management plans that may well have shortened life expectancy. Failure to engage with properly constructed regional MDM would have prevented all these issues occurring. The lack of insight displayed by this surgeon who then wrote letters suggesting that there was a callous disregard for patient welfare is frankly unbelievable given the circumstances and poor management decisions.
I'm unsure if you had planned to discuss this with the CAH MD my own feeling is that he should be made aware of these governance issues and he can then act accordingly.
Chris

From: Welsh, Jennifer
Sent: 28 September 2010 11:59
To: Stevens, Tony; Hannon, Ray
Cc: Hagan, Chris; Armstrong, Brian
Subject: urology patients

Tony

Update re the Urology patients we discussed yesterday.

I spoke to Chris yesterday evening, and he has had detailed discussions with the patients involved. All were discussed thoroughly at last week's regional Urology MDT, and while treatment decision may now be different than had been agreed at SHSCT, all seem to understand why this is the case. Therefore, I don't think we need to seek 2nd opinion.

In addition, Brian Armstrong has spoken to Gillian Rankin and explained about the tone/inference of the letters which were received by Chris and the patients' GPs. Gillian has apologised on behalf of SHSCT, and has advised that Dr Loughran will be writing formally to the consultant in question.

The only actions remaining are:

1) Operational discussion re "swop" of minor or benign procedures to facilitate the fact that we have taken in additional complex patients – Brian will lead on this.
2) Response to Minister's office re one of these patients – Karen McClenaghan is leading on this.

Jennifer

****

Jennifer Welsh
Director of Cancer & Specialist Services
Belfast Health & Social Care Trust
Roe Villa
Knockbracken Healthcare Park
Saintfield Road
Belfast BT8 8BH
Tel: Personal Information redacted by the USI
Fax: Personal Information redacted by the USI
mailto: Personal Information redacted by the USI

would have much preferred to have [their] surgery here at Craigavon Area Hospital and will find the prospect of surgery at Belfast City Hospital all the more detached from [their] tenuous support base. However, even more importantly, [their] present dread is that you would not agree to proceed with cystectomy. I do hope that you will agree to do so. I dread to think of the distress, if you were not to agree."

This assessment contrasted with the CAH MDM discussion at the end of September 2010. Dr McAleese had seen the patient by the date of the MDM in September 2010, commenced Patient 3 on steroids and deemed them unfit for any treatment at that stage. Dr McAleese had planned to review Patient 3 in two weeks.

I also met the patient at the end of September 2010 to discuss their treatment options. Their bladder symptoms were better controlled but unfortunately they had lost a considerable amount of weight, suggestive of systemic metastatic disease. At the meeting with the patient, I explained that the unanimous decision of the regional MDM, given the presence of quite extensive pulmonary metastatic disease, was that palliative chemotherapy was the best option and I explained that unfortunately their bladder cancer was not curable.

Unfortunately, the patient's bladder cancer progressed rapidly and they died in the early part of 2011. Given their poor performance status in the context of metastatic bladder cancer it was my view, supported by the regional MDM, that cystectomy was not appropriate. This is a very major operation that takes many months to recover from and by subjecting a patient to this in the last months of life with no benefit (and likely detriment) I considered to be poor judgement. I have worked as a cystectomy surgeon for 17 years in the regional unit and saw very few patients who may have benefited from palliative cystectomy. In patients in this situation, with intractable urinary symptoms, often a catheter or

Interim Director of Acute Services
Administration Floor
Craigavon Area Hospital

27th September 2010 Ref: GR/pl/lw

Mr A O'Brien
Consultant
CAH

Dear Mr O'Brien

I am in receipt of correspondence in relation to 3 patients. In each case you have written to the patient, the General Practitioner and Mr Hagan Consultant Urologist in Belfast City Hospital.

Each of these patients has been transferred to the City Hospital for further management by Mr Hagan. I understand that you expected and wished to carry out this surgery yourself in Craigavon Area Hospital, but following contact from our Commissioner the Trust was obliged to refer the patients to Belfast.

It is of great concern that you have indicated to a patient, (in advance of a care pathway being agreed) your preferred management of the case. I believe that this puts inappropriate pressure on the receiving team and is regrettable. I understand that the transfer of these patients, with whom you may already have formed a good therapeutic relationship, was somewhat unexpected.

There is another difficult area which we are currently examining – the intravenous therapy (IVT) cohort. Since we have internal agreement that the future care pathway of these patients will be subject to a multi-disciplinary decision I do not want you to write to any of these patients individually. Any outcome of the multi-disciplinary team should be "signed off" by that team and only an agreed communication sent/provided to each patient.

Please acknowledge your agreement by return.

Yours sincerely

Dr Gillian Rankin
Interim Director of Acute Services

Craigavon Area Hospital, 68 Lurgan Road, Portadown, County Armagh, BT63 5QQ Tel No Personal Information redacted by the USI
Fax No Personal Information redacted by the USI Email Address Personal Information redacted by the USI

Subject: 20101004 Email from Tony Stevens to Chris Hagan re chat with Paddy Loughran CAH MD

From: Stevens, Tony
Sent: 04 October 2010 22:34
To: Hagan, Chris <Personal Information redacted by the USI>; Stevens, Tony <Personal Information redacted by the USI>; Hannon, Ray <Personal Information redacted by the USI>
Subject: RE: urology patients - confidential

Chris. I will be content to chat to paddy loughran informally. If that does it fine. If not and if your concerns persist then we would need to consider next steps.
tony

Sent from my Windows Mobile® phone.

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Sent: 04 October 2010 21:15
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Southern Health and Social Care Trust

Medical Directorate

21st October 2010 Our Ref: PL/lw

Dr Tony Stevens
Belfast H&SCT
Knockbracken Healthcare Park
Saintfield Road,
Belfast.
BT8 8BH

Dear Tony

Further to our discussion about one of our Urologists, in private at the conclusion of the Medical Directors meeting, I have done the following:

- The Urologist concerned had witnessed the transfer of a number of patients who required major pelvic surgery as a result of Cancer. He wrote to the patients and their General Practitioner and expressed concern with the transfer, and a very clear view that he would have preferred one particular surgical procedure. I believe that these patients were not subject to a multi-disciplinary discussion between the Belfast and the Southern Trust.

- I was shown the correspondence and given a message that a senior member of the receiving Urology team in your Trust was very upset.

- I agree that our Urologist should not have written to the patients in the manner that he did.

- I have been advised that our AMD in Surgery has been given an undertaking that there will not be a repeat of the above. Any multi-disciplinary decision that is made between the Belfast and the Southern Urologists will be respected by all of our Urologists.

Cont'd. ……

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