haemostasis, or a combination of both. If I considered after 30 minutes of resection that optimal resection of a large prostate would require a prolonged resection time, it was my usual practice to limit the resection, such as to one lateral lobe +/- the median lobe of the prostate. It was also my usual practice to request serum biochemistry to be performed if I was approaching one hour's resection time. If the serum sodium levels were normal, and I felt I could complete the procedure within 15 minutes, my normal practice was to continue to complete the procedure. I have no recollection of any TURP procedure coming close to the two hours resection time as alleged by Mr Hagan. Moreover, the audit of the incidence of hyponatraemia complicating TUR prostate and bladder tumours undertaken in 2014 found no correlation between resection time and glycine absorption [TRU-396014 – TRU-396017].

57. The only severe TUR syndrome that I have ever been aware of was a complicated resection of a very large prostate by a consultant urologist in Dublin in 1987 when I was a registrar in urology there. The patient suffered pulmonary oedema from which he made a complete recovery with no lasting consequence. I had performed over 400 prostatic resections prior to appointment as a consultant urologist in 1992. By 2000, when Mr Hagan was hoping to increase the number of TURP operations he had performed towards a target of 100 during his six months' rotation, I had already performed over 1,000 prostatic resections. I have performed over 3,000 TURP operations throughout my career. I would estimate that I may have experienced a maximum of three or four potentially symptomatic cases of TUR syndrome during my consultant career. I believe that such a low incidence has been attributable to much improved operative techniques, such as the use of video magnification and continuous intraoperative irrigating resectoscopes, as well as increasing experience. These patients had transient symptoms which resolved completely in the recovery ward. I cannot recall ever having been aware of any severe TURP syndrome affecting any patient under my care, or under the care of any colleague. I have never known of a mortality associated with glycine absorption complicating TURP. I am unaware of any evidence that my practice in respect of TURP procedures was associated with any more complications than any other consultant.

4.2 This was the technology available when I arrived in the Unit, having been used to a flexible laser fibre during my training.

4.3 I personally found the ureteric probe had to be handled with care and would instruct registrars very precisely on its use and techniques, namely single pulses, using as low an energy level as possible and location of the probe upon the stone.

4.4 I also instructed registrars to have a safety guidewire in position before performing any fragmentation; this was to aid vision and the ureteroscope direction for the EHL probe at endoscopy. It also was in place so that a stent could be inserted if there was any issue such as loss of vision, an extravasation of contrast or perforation. In addition, during endoscopy I performed these procedures with x-ray screening.

(b) Did you consider Mr O'Brien's approach to ureteric stone treatment to be 'very different'? If so, please explain, providing full details.

4.5 I found Mr O'Brien's approach was different in that he did not use a safety guidewire nor x-ray screening for ureteroscopy in my early days as a Consultant. X-ray screening was one of the earliest features I introduced and Mr O'Brien in due course moved to using the x-ray screening. I am unsure as to whether he ever moved to using a safety guidewire.

4.6 Other than the above, I did not find Mr O'Brien's approach to be very different in respect to the timing of intervention. For inpatient admissions with colic there will be a discussion between clinician and patient on their care-pathway with regards to a conservative *vs.* an interventional approach. I believe that the use of medication to aid ureteric stone passage did not come into vogue until mid-to late 2000s.

(c) Please provide any further comments you may have in respect of Mr Hagan's comments regarding the use of lithoclast.

4.7 I agree with Mr Hagan that the Lithoclast has a better safety history, however no ureteric procedure is without the risk of perforation. Even with the modern modalities of lasertripsy there is still a risk and it should be noted on all current

me, he told me to use the EHL probe to break up the stone. As instructed, I did this and the discharge of the energy source caused a very large perforation in the upper third of the ureter. Mr. O'Brien took over the case and was unable to negotiate a ureteric stent into the kidney due to the size of the defect. This then required the patient to have an open surgical repair of his ureter. I was very distressed by this complication, as I felt very much to blame for it, even though I had carried out the instructions of the supervising Consultant. Mr. O'Brien spoke to the patient afterwards, as he was ultimately responsible for the operation. I was not present. I don't know what Mr. O'Brien said to the patient. With hindsight, it is clear to me that the direction I received from the supervising Consultant, to use the EHL, was not appropriate in the situation and that this was an entirely avoidable complication.

V. **Paediatric Urology.** I recall, during my rotation, Mr. O'Brien expressing the view that Craigavon District General Hospital (DGH) Urology unit should be able to carry out the majority of urological procedures, including paediatric urologic procedures. There is nothing necessarily wrong with that view per se, but sub-specialisation in urology was becoming very common and for many years paediatric urology had generally been performed by paediatric trained urologists working in paediatric units. In Northern Ireland, there is a paediatric urology team in the Royal Belfast Hospital for Sick Children (RBHSC). At that time in urology, around 2000, it was generally accepted that minor procedures such as testicular torsion and circumcision in children could be safely performed in DGHs, but more complex procedures should be performed in specialist centres, such as RBHSC. Mr. O'Brien however had acquired a set of paediatric cystoscopes. I thought this was very unusual as there are very few indications for cystoscopy in a child, and usually it will be in children with congenital conditions or vesico-ureteric reflux (both of which would be managed in tertiary specialist centres). I did not see Mr. O'Brien ever perform a cystoscopy in a child, and cannot say if he ever did. I can recall one case of a child who had nocturnal eneuresis. Mr. O'Brien and I disagreed over the management of the child's condition. Standard treatment then was the use of desmospray or desmotabs, as this condition usually settled with age. There is often no need for investigations, other than perhaps an ultrasound of the kidneys and

"I have no memory of contacting Mr. Hagan regarding this matter following the introduction of The Policy on the Surgical Management of Endoscopic Tissue Resection HSS(MD)14/2015 because I believe that it did not happen."

Ureteric Stones

62. Mr Hagan in his statement at WIT-98848 raised two separate issues under the above heading. I will deal with these separately:

63. Issue 1

(i) Mr Hagan said the following at WIT-98848:

"Mr. O'Brien's approach to ureteric stone management was very different and his preference was to intervene surgically at a very early stage. When discussing patient management with Mr. O'Brien, I challenged him in relation to this approach, as I felt that suitable stones should be allowed to pass naturally. This is because intervention carries risks, including sepsis and ureteric perforation. Mr. O'Brien however referred to his training in Tallaght Hospital in Dublin, and that this was how he managed stones. Generally, I found Mr. O'Brien to be dismissive of me when I raised concerns. He was clear that it was an appropriate course of treatment."

(ii) Again, I have no recollection of any patients whom Mr Hagan considered were inappropriately managed and have not been provided with any details and / or medical records relating to any such patients to assist me in responding to Mr Hagan's comments. I have no recollection of Mr Hagan ever discussing this issue with me at any time.

(iii) I do not accept that I had a preference to intervene surgically at a very early stage, other than when clinically indicated. The criteria for early endoscopic management of ureteric calculi are well established. It may be the case that Mr Hagan's understanding of this treatment at the time was simplistic given his position as a trainee.

(iv) I further note that Mr Hagan referred to my training at Tallaght Hospital in Dublin. I was trained in the endoscopic management of ureteric stones at St. James's, Meath, Beaumont and Mater Hospitals in Dublin from 1985 to 1991. It may be of interest to the Inquiry to note that I never undertook any training at Tallaght Hospital. Moreover, Tallaght hospital did not open until 1998, which was six years after I commenced my employment with the SHSCT in Craigavon.

64. Issue 2

(i) At paragraph 31.iv (WIT-98848), Mr Hagan stated that:

"The second issue related to the energy source used in the destruction of stones. Destruction of ureteric stones requires an energy source. In 2000, there were a number of sources commonly used when operating on the ureter, such as laser and pneumatic devices (such as the swiss lithoclast). Both these types of energy sources had good safety profiles. Mr. O'Brien's preference however was to use an electrohydraulic (EHL) energy source. It was powerful and unpredictable. EHL has uses for large bladder stones and kidney stones, where its use is safe, but, in the ureter, it carries a very high risk of ureteric perforation. I discussed this risk with Mr. O'Brien, as I felt this was a high-risk energy source to use in the ureter, with real safety risks. I described my experience with the lithoclast, which has a zero risk of perforation, and questioned why he would not use it, as it was very cheap technology. Again, I found Mr. O'Brien to be dismissive of my concerns. Mr. O'Brien did not accept my view. Unfortunately, when carrying out a left ureteric stone case, with Mr. O'Brien directly supervising me, he told me to use the EHL probe to break up the stone. As instructed, I did this and the discharge of the energy source caused a very large perforation in the upper third of the ureter. Mr. O'Brien took over the case and was unable to negotiate a ureteric stent into the kidney due to the size of the defect. This then required the patient to have an open surgical repair of his ureter. I was very distressed by this complication, as I felt very much to blame for it, even though I had carried out the

OPERATION NOTES

HOSPITAL ..... CAH

Operations Performed
(L) URETEROSCOPIC LITHOTRIPSY

Date

Surgeon CHRIS HANAN

Anaesthetist

Assistant

Sister

Incision

Blood

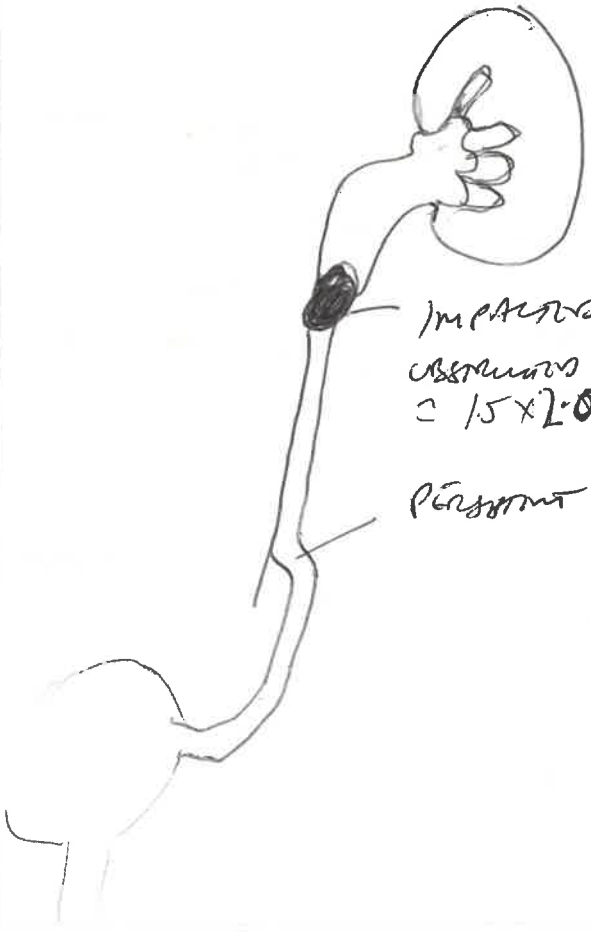
Findings non-functioning kidney
— IMPACTED STONE UPPER 1/3 (L) URETER
* URETERIC PERFORATION *

Drains

Packs

PROCEDURE FAILED JJ STENT

120mg IV Gent



IMPACTED OBSTRUCTING STONE ; OEDEMATOUS MUCOSA
c 1.5 x 2.0 cm.

PERFORATION MID URETERIC 1/3RD

PTD

Signature of Surgeon _____

Trimprint, Armagh

NSV Ref. No. WWW439

- CYSTO - URETHROSCOPY - NORMAL
- (L) JJ AWKWARDLY PLACED POSTERIOR - CAUDALLY IN BLADDER
- DIFFICULT URETHROSCOPY DUE TO KINK MIDURETER
- STONE REACHED; IMPOSSIBLE TO GET GUIDE WIRE BEYOND STONE
- 3F EHL PROBE; SINGLE PULSE; MEDIUM POWER STONE VERY SOFT BROKEN UP. MARKED OEDEMA + SWELLING OF URETER
- NEGOTIATED THROUGH AREA OF STONE IMPACTION
- GUIDE WIRE PLACED
- ON WITHDRAWING SCOPE, POSTERIOR URETERAL PERFORATION SEEN
- ~~PROCEDURE~~ STOPPED
- ATTEMPTED JJ (6.26) ~~EHL~~ STENT INSERTION - FAILED DUE TO KINK IN URETER & PLACEMENT OF (L) JJ
- ATTEMPTED URETEROSCOPIC INSERTION OF 5.26 STENT: IMPOSSIBLE TO NEGOTIATE URETERIC INJURY DUE TO CUT
- PROCEDURE STOPPED
- 16+ URINARY CATHETER
- FOR (L) NEPHROSTOMY INSERTION - DR HALL CONTACTED
- MR O'BRIEN INFORMED
- IV CIPROXIN 400mg IV bd.

Signature of Surgeon _____

instructions of the supervising Consultant. Mr. O'Brien spoke to the patient afterwards, as he was ultimately responsible for the operation. I was not present. I don't know what Mr. O'Brien said to the patient. With hindsight, it is clear to me that the direction I received from the supervising Consultant, to use the EHL, was not appropriate in the situation and that this was an entirely avoidable complication."

(ii) The Inquiry has since been advised on 19 December 2023 that the Trust has investigated this issue and has been able to locate the chart and the operation note in respect of the person the Trust believes to be the patient in question [TRU-320239 – TRU-320241]. The Trust has provided redacted copies of the operation note written by Mr Hagan on 06 May 2010 [TRU-320247) and the discharge summary dictated by me on 03 August 2010 [TRU-320245 – TRU-320246]. There was no record in the operation note of my being present at all during the operation and there was no record of my supervising the operation. On the contrary, Mr Hagan recorded at the end of the operation that I was informed of the proceedings.

Note: As per email (WIT-107947) received on 8th April 2024 the dates highlighted at paragraph 64 (ii) should read "06 May 2000" and "03 August 2000" instead of 2010. Annotated by the Urology Services Inquiry.

(iii) Moreover, the Trust has established that alternative energy sources were unavailable at that time, the Holmium YAG Laser not available until April 2006 and the Swiss Lithoclast not available until March 2014 [TRU-320243 – TRU-320244].

Paediatric Urology

65. At WIT-98849, Mr Hagan relates his surprise to finding that I had acquired a set of paediatric cystoscopes. Having been a Clinical Fellow in Paediatric Urology in Bristol from 1991 to 1992, I appreciated the diagnostic value of being able to examine the lower urinary tract endoscopically. I was for that reason that I acquired a paediatric cystoscope and a resectoscope. They were rarely used, and if used they were usually used for treating older children.

66. Mr Hagan sets out his recollection of another patient, a child, who he alleges I was of the view required invasive testing such as urodynamic studies for nocturnal enuresis. Mr Hagan sets out his view that he felt this was over-investigating, although he accepts that he cannot recall whether the invasive testing actually took place. Mr Hagan again states that he disagreed with me on the course to be undertaken.

67. I have no recollection of Mr Hagan ever discussing this patient with me. I have no recollection of the patient that he refers to. I have not been provided with any clinical details or medical records to allow me to properly comment on the allegation.

Radical Prostatectomy and High PSA

68. At WIT-98850, Mr Hagan relates the concerns he had in 2010 with regard to my performing radical prostatectomies for prostate cancer on men who had very high serum PSA levels at the time of diagnosis.

69. I note that he implies that my patients may not have had staging performed by MRI scanning prior to surgery. In fact, I had staging undertaken by MRI scanning for all patients considered for radical prostatectomy. I was able to have MRI scanning performed at the Royal Victoria Hospital in Belfast for years prior to MRI scanning becoming available at Craigavon Area Hospital.

70. Moreover, staging by MRI scanning was undertaken prior to any patients being prescribed neo-adjuvant androgen deprivation therapy which was not initiated in order to reduce serum PSA levels but instead to prevent disease progression while awaiting surgery.

Priapism and Penile Disassembly

71. At WIT-98851 Mr Hagan provides details of a patient suffering from a priapism. He states the following:

<[redacted]>
Cc: McArdle, SiobhanM <[redacted]>; McKenna, Michelle <[redacted]>; Lindsay, Steven <[redacted]>
Subject: RE: - Lumenis Laser asset 149184 MAINT. OF LASER EQUIPMENT – 1700604 CCBMS31560

Dear Sr. Latimer

- The greenlight laser asset 326415 was purchased January 2017 under PO NO CC01135 @ £66900
- Verapulse Holmium YAG asset 149184 was put into use in April 2006, according to the database, cost £176,194 we have no information on the purchase order no.
- EMS Swiss Lithoclast Laser, asset 311035 was purchased March 2014 under PO NO CC00382 @ £41,992
- Cyber HO 60 asset 341332 was purchased in February 2021 under CC02000 @ £62,500 but was replaced with upgraded version asset 346420 Cyber HO 100W @ £36,900 under CB168513

I trust this information is of assistance.

Kind Regards,

Madonna Haughian
Admin Business Manager Non-Medical Assets and Contracts
Estates Building | Lurgan Hospital
Internal/External Tel: [redacted] | Working Pattern: Monday – Thrusday 8:00am to 6:00pm
[redacted]
svsvdvsdvsdvdv3

Welcome to the MICAD HD Customer Portal
Medical Technical Services - Home

From: Latimer, Charlene <[redacted]>
Sent: 12 October 2023 02:50
To: Haughian, Madonna <[redacted]>; Lindsay, Steven

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

does not go away). Once a priapism has been established for more than 24 to 48 hours, surgical decompression or haematoma evacuation will not be successful as the haematoma will have organised and erectile function will be lost. Andrologists (physicians who specialise in treating men's reproductive-related issues) in Great Britain were recommending early referral to London for insertion of artificial penile prosthesis for management of this rare condition. However, in the case I remember, Mr. O'Brien took the patient to theatre and performed what I can only describe as a penile disassembly by separating the corporal cavernosum and spongiosum tissues. I was not myself "scrubbed" in for the procedure along with Mr. O'Brien, and whoever was assisting him, but I just remember being present in the theatre at some point and wondering what Mr. O'Brien was trying to achieve. I remember being concerned that the procedure could risk compromising the vascular supply to the penis. I remember leaving the theatre as I did not want to watch what was happening. I never found a description of the procedure in any text. My recollection is that when the patient returned to the ward there was concern in respect of ischaemia of parts of the penis. I do not know the final outcome for this patient as I left CAH to return to BCH as part of the urology rotation. This patient will have been on the Urology ward for a period of time post his operation, so it may well be Mr. Young or others will recall the case because of its unusual features.

VIII. **Out-patient practice.** Mr. O'Brien's outpatient clinics were busy with large numbers of patients. I assisted with those clinics during my rotation. As a trainee, I generally saw review patients and Mr. O'Brien tended to see new patients. I remember coming across review patients who were on repeat follow up appointments with no clear rationale for this, at least not that I could see. I would therefore try and discharge as many patients as I could to improve clinic efficiency. I recall one specific patient who I discharged from clinic in Banbridge for this reason, but who was then back at the clinic the following month. His symptoms had not deteriorated or changed and I asked him how he had been re-appointed. The patient told me that he had phoned Mr. O'Brien's wife (who I believe assisted Mr. O'Brien with his private patients) who arranged (presumably with the clinic's appointment secretary) for him to be re-instated on the clinic. I was very surprised

that this had happened but was concerned that perhaps something would be said to me for having discharged the patient in the first place. Mr. O'Brien never mentioned it to me. As I reflect on this now for the purposes of this statement, I realise that was an unusual practice that was occurring.

IX. **Administration delays.** As I reflect on Mr. O'Brien's administrative processes, having subsequently had many years in practice myself, it would be fair to say that I look back on Mr. O'Brien's administrative processes as appearing disorganised and chaotic. I accept it may have been a symptom of his workload, but his office was always full of patient charts awaiting dictation which, as I recall, often took a considerable time to process. His secretary would complain about it. The delays were probably compounded by what I now, with hindsight, consider to be his tendency to over investigate patients. However, he also wrote what seemed to me to be extremely long letters, which often seemed to struggle to get to the point. This will have added to the turnaround time. It is of course easy to criticise the practice of others, but it is obviously important, when writing letters to GPs, that they are timely, and that the diagnosis and management plan is succinct and clear.

Raising concerns as a trainee

32. As I have indicated earlier in this statement, I did raise issues with Mr. O'Brien about his practice during my time as a surgical trainee in Craigavon Area Hospital. Mr. O'Brien did not agree with me and was essentially dismissive. I did also raise issues about Mr. O'Brien with his Consultant colleague, Mr. Young, during my rotation. This would have been in an informal manner, and I would not have recorded them in written form. It just would not have occurred to me at the time to do that. It means that I cannot now say precisely what I raised with Mr. Young, or how I precisely I said it. My recollection was that Mr. Young's response to what I said was "that's just Aidan". Mr. Young did not give me the impression that he had any major concerns about the matters I was raising. I don't know if Mr. Young spoke to Mr. O'Brien about any of them, or if Mr. Young spoke to anyone else about them. I certainly thought at the time that I was brave in speaking to both the consultant himself, and to his consultant colleague. In my experience, it certainly was very unusual for trainees in 2000 to raise concerns about consultants and their practice. There were a number of reasons for

"Andrologists (physicians who specialise in treating men's reproductive-related issues) in Great Britain were recommending early referral to London for insertion of artificial penile prosthesis for management of this rare condition. However, in the case I remember, Mr. O'Brien took the patient to theatre and performed what I can only describe as a penile disassembly by separating the corporal cavernosum and spongiosum tissues. I was not myself "scrubbed" in for the procedure along with Mr. O'Brien, and whoever was assisting him, but I just remember being present in the theatre at some point and wondering what Mr. O'Brien was trying to achieve. I remember being concerned that the procedure could risk compromising the vascular supply to the penis. I remember leaving the theatre as I did not want to watch what was happening. I never found a description of the procedure in any text. My recollection is that when the patient returned to the ward there was concern in respect of ischaemia of parts of the penis. I do not know the final outcome for this patient as I left CAH to return to BCH as part of the urology rotation. This patient will have been on the Urology ward for a period of time post his operation, so it may well be Mr. Young or others will recall the case because of its unusual features."

72. I have no recollection of this case, nor have I been provided with any clinical details or medical records in respect of this patient to assist my recollection. I note that in his evidence to the Inquiry, Mr Young had no recollection of this incident ever being raised with him by Mr Hagan [TRA-09686 & WIT-103605].

Outpatient Practice

73. At WIT-98851, Mr Hagan describes his efforts to discharge patients from outpatient review when he considered that they did not require to remain under review. In doing so, he recalls:

"one specific patient who I discharged from clinic in Banbridge for this reason, but who was then back at the clinic the following month. His symptoms had not deteriorated or changed and I asked him how he had been re-appointed. The patient told me that he had phoned Mr.

consent forms. It should also be acknowledged that the Lithoclast is a straight, rigid instrument and that it does not work when flexed i.e., for upper ureteric or renal stones via the ureteric approach.

4.8 All of the instruments mentioned above cost money. The Trust did purchase an ultrasound disintegrator (a version of the lithoclast) for renal surgery in January 2006. However, the main goal for the stone service in Craigavon Area Hospital was to purchase a Holmium laser which was the safest and most efficient modality to use in any part of the urinary tract. A Holmium laser machine was purchased in 2006 and the same laser machine has been in use in the department ever since. I remember discussing with registrars, (and this would have included Mr Hagan), over the preceding years my plans for purchasing a laser and noting the expense.

4.9 EHL has not been used by any urologists for ureteric stone procedures since the Holmium laser arrived to the best of my knowledge.

5. At WIT-98850, Mr Hagan describes a case involving priapism and penile disassembly which caused him concern. He states: *'This patient will have been on the Urology ward for a period of time post his operation, so it may well be that Mr Young or others will recall the case because of its unusual features.'*

(a) Were you aware of this case at the time? If so, please provide full details of your knowledge and indicate whether this case gave you cause for concern, and, if it did, why?

(b) Do you recall discussing this case with anyone? If so, please provide details of all conversations in respect of same.

(c) If you were not aware of this case at the time, please explain how you would not have been so aware if the patient had spent a period of time on the ward, as suggested by Mr Hagan.

5.1 a) I have no recollection of this case.

5.2 b) Since I do not recall the case, further comment is not possible.

O'Brien's wife (who I believe assisted Mr. O'Brien with his private patients) who arranged (presumably with the clinic's appointment secretary) for him to be re-instated on the clinic. I was very surprised that this had happened but was concerned that perhaps something would be said to me for having discharged the patient in the first place. Mr. O'Brien never mentioned it to me. As I reflect on this now for the purposes of this statement, I realise that was an unusual practice that was occurring."

74. I have no recollection of this event or this patient. Nevertheless, I both strongly resent and refute the allegation that this, or any, patient phoned my wife with a view to having a review appointment re-arranged, or even more importantly, that she arranged it. It was not a rarity for patients to attempt to contact me by phoning my home as my telephone number was not ex-directory. While it was the case that patients contacted my home to arrange private appointments, patients waiting long periods of time for review or for admission, would also have done so. If I was not at home, as I usually was not, my wife would have answered the phone. She would have taken a message and contact details so that I could deal with the issue. My wife never arranged any review or any other service of any kind for any patient who contacted me by calling my home; my wife would simply take a message and contact details.

75. It may have been that a patient was dissatisfied by some aspect of his review by Mr Hagan. It may be that I requested that another review be arranged for him. In any case, I have no recollection of either patient or event.

Administration Delays

76. At WIT-98852, Mr Hagan looks back on my administrative processes as appearing disorganized and chaotic. Perhaps they only appeared so. He is of the view that the contributory factors may have included a tendency to over investigate patients. I have not previously been aware of any other person's consideration that I over investigated patients.

77. Mr Hagan also expresses the view that I wrote, what seemed to him, extremely long letters which often seemed to struggle to get to the point. He considers that it is obviously important, when writing letters to GPs, that they are timely, and that the diagnosis and management plan are succinct and clear.

78. I do appreciate that others may consider the length of a letter, such as that which I dictated to the GP of the patient who suffered the left ureteric perforation in addition to a ureteric stenosis requiring surgical repair, to be long or too long [TRU-320245]. However, I believe that such a letter was an appropriate record of the patient's diagnoses and management at that time. I do not believe that it struggled to get to the point, as I believe the point was to provide the GP with a record of the patient's management, and to have such a record for future reference by others. It may be that it did contribute to administrative delays, but I considered it better to have a properly informative record than to have one that was timely but not adequately informative.

Transfer of Patients for Radical Pelvic Cancer Surgery in September 2010

79. At paragraphs 40 to 43 [WIT-98856 to WIT-98863], Mr Hagan relates the sudden and unexpected transfer of five patients from the Southern Trust to the Belfast Trust for radical pelvic surgery in September 2010, three for bladder cancer and two for prostate cancer. Mr Hagan raises concerns regarding the three patients who were transferred for radical surgery for bladder cancer.

80. At paragraph 43.1 [WIT-98857], he relates the history of this male patient who had been found to have non-muscle invasive, non-metastatic, sarcomatoid carcinoma of his urinary bladder in July 2010. I recall this patient well as I continued to review him until my employment with the Southern Trust terminated in July 2020. Mr Hagan stated that:

"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

it not, for trainees to be as vocal as he claims to be in his statement? In other words, he claims to have raised, both with you and with Mr. O'Brien, a range of issues of concern. That would be unusual for a junior?

A. It would be unusual for a junior. I haven't had any other juniors raising such a list of questions. 10:16

5 Q. Yes. While you don't recall precisely, it being 23 years ago, do you recall Mr. Hagan as being a particularly interested and perhaps vocal trainee in terms of raising issues? 10:16

A. Mr. Hagan's demeanour of putting a question across, sometimes you didn't realise if he was asking a question or making a statement. That's maybe just a personality thing at the time. I do agree that, as a registrar, as I was a year or two before that, 10:17 sometimes it is hard to raise things and it takes a bit of courage to actually challenge something, so I do agree with that statement.

6 Q. Do you also agree that in terms of the descriptions that he provides, conscious that you don't have access 10:17 to the particulars, you now don't have access to the particulars of these individual cases, but going on his descriptions, a TURP taking nearly two hours to perform before the case is closed, a penile disassembly, an injury to a ureter in circumstances where the 10:18 protections that you would usually use for stone fragmentation are not in place, as I say, a benign cystectomy, are those the kinds of cases that would qualify as serious concerns, at least on the face of

up. But it is conveying that Mr. O'Brien has certain ways of doing things and that's his plan, that's his policy, that's the way he looks after certain things and I think everybody has their own wee sort of foibles of how they do things.

10 Q. Maybe we shouldn't read too much into that kind of phrasing, but is it suggestive that in certain circumstances Mr. O'Brien is acting in an unconventional manner outwith what would be expected?

A. Unconventional, I wouldn't accept that. I think there's certain ways people go about doing things. I think if I had seen something that was unconventional, then that would be challenged; if that's fair enough.

11 Q. Well, not doing triage is unconventional, would you say 'that's just Aidan' or would you say that's...

A. Well, it's proving to be that way.

12 Q. You go on, at 3.6, just that as you say:

"I have no recollection of having discussions around this issue with others."

But you do recall being generally aware that Mr. O'Brien had on occasions taken more than one hour for a TURP. You believe you're aware of this informally through theatre tearoom chat?

A. Yes.

13 Q. Does that suggest that those participating in theatre with Mr. O'Brien, because you would hardly be in

theatre with Mr. O'Brien, are bringing this out as an unusual feature of his approach? In other words, it was so significant that it warranted discussion as an unusual feature in the tea room, is that what you are putting across there? 10:28

A. I'm putting across that if the nurses are talking in theatre that a procedure has taken a long length of time or longer than usual, or if a theatre list has run over because of an excess time attached to a particular procedure. Yes, so it is a topic that maybe somebody has brought up and it may be observed that Mr. O'Brien is performing TURPs for longer than an hour, maybe more than the other team members. 10:28

14 Q. I would venture to suggest that the Panel are not particularly interested in the minutiae of these individual incidents, I would say. What they are interested in, and no doubt you'll hear from them this afternoon with some questions, what they are probably interested in is where you have clinical issues raised such as this, so that they become part of your awareness, whether they come through Mr. Hagan or whether they come through tearoom chat, they're all pointing in the direction of a problem or a potential problem, one that needs investigated and potentially addressed. Did you ever raise excessive time performing TURPs with Mr. O'Brien? 10:29 10:30

A. No, I don't believe that I have. I mean, if a TURP is going to go on between 15 minutes and 10 or 15 minutes over the hour, that's to complete the operative

for the next ten years that we're talking about.

16 Q. I think you would accept that the longer the TURP procedure goes on, the greater the risk of hyponatremia? It is one factor that should be controlled in order to reduce the risk. Sometimes, as you say, it is not possible to conclude within the hour, shouldn't be dogmatic about that, but it is a risk factor and in Mr. O'Brien's practice it appears to have been a factor that people were talking about? 10:35

A. Yes, I agree with that. Beyond the hour increases risk of complication and, yes, here we have this. But the question is did the complication occur? It increases the risk of it but the important point is did it happen and was the length of the operation due to a safety issue of, for instance, was the patient bleeding. But, yes, I agree, it is a wee bit of an alarm bell to say here is somebody that keeps on operating beyond the hour. 10:36

17 Q. If it's an alarm bell, I suppose the question arises from a governance perspective, what is the clinical lead doing about it? 10:36

A. Well, it's observing if there was a complication. Again, it comes back to how long is a piece of string? An operation starts and finishes. You know, you have to get all the joined up writing in the middle of that. I'm not entirely sure my responsibility of what you're saying here. I mean, this is a team approach. There's the recovery staff, there's the admissions to intensive care, there's the anaesthetic service. It is all very 10:37

live and observing. Are cases like this brought to the Patient Safety Meeting, you know, if there was a complication as such. So I understand what you're saying. There could be a conversation held: Yes, Mr. O'Brien, why are you being observed to be operating for more than an hour? An answer could be: I was completing the operation, you know, and I haven't had any problems. So I'm not certain if, you know, this was one point and, as you're saying, you're adding up all the points together and trying to put the jigsaw together, I understand that. 10:38 10:38

18 Q. Mr. Hagan drew the Inquiry's attention to the use of IV antibiotics and fluids with particular patients. If we just pull up his statement in that respect, WIT-98845. Just scroll down to 31. This is the first of the concerns he set out: 10:39

"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 in-patient 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 six 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 10:39

His concern about it may have crystallised somewhat later, we don't know. In 2000, did you have a concern, did you have any concern about the practice at in point before The Trust raised it in 2009?

A. In 2000 I wouldn't have, myself, partaken in that approach to treating patients, so I would agree with Mr. Hagan that it was maybe not standard practice in the way of treating a patient with such a condition. 10:45

22 Q. And it not being a standard practice, you being aware that it's happening on the ward, you do a joint ward round with Mr. O'Brien on a Thursday, you're aware of each other's patients. Is it something you raised with him, discussed with him, got to understand? 10:46

A. We would have discussed it on the ward round, about patients having the treatment but it's a two-way conversation. He had felt this was a way of looking after patients with such infections. I agree, I hadn't used that policy in my training in Belfast, it was different. But he was trying to approach a clinical situation. I don't know if Mr. O'Brien had used this in his training in Dublin, for instance. But it was a clinical approach to looking after a condition and I was observing if it was working or not. But, I agree, it's not the standard practice, and I agree with Mr. Hagan making comments on that. So, yes, I do agree with what I was trying to explain earlier, but -- 10:46 10:47 10:47

23 Q. But you didn't so it was a different, unconventional might be an appropriate word. You didn't challenge it?

A. I would have challenged it on the ward rounds about

asking about why you're taking this approach. But there's a conversation coming back and whether you accept that or not, that's a clinical decision.

24 Q. You've gone on to say in your answer a moment or two that you went on to develop a practice of bringing patients in for IV antibiotic management. I'm interested to know whether there's a distinction between your approach and that of Mr. O'Brien. Before I come to that question, let me just bring up on the screen your statement in this respect. WIT-51814, and at paragraph 63.1 you're saying: 10:48 10:48

"My first awareness that The Trust had issues of concern regarding Mr. O'Brien was in 2009."

10:49

I just park that for a moment. We saw yesterday that you were aware of concerns around triage in 2008, I think Mrs. Cunningham's email was fed up to you. But this you are describing was your first awareness that The Trust had concerns with Mr. O'Brien. 2009, he is admitting patients who had a chronic history of urinary tract infections on an elective basis for IV antibiotics and fluids. You say: 10:49 10:49

"It should be noted that I also admitted patients for intravenous antibiotics but they either had infections present or were symptomatic. The Medical Director at the time, Dr. Loughran, commissioned an external review of this practice. This resulted in the elective 10:49

giving of their expert opinion. And that person said, you know, the notion that patients need to have intravenous hydration and antibiotic therapy when they can drink normally is nonsense, and that's one of my criticisms that I have submitted in my recent addendum, 11:35
and that is that that expert, and indeed going back to Mr. Hagan, they weren't patients who could drink normally or adequately because they were continuously nauseated. And in my original witness statement I think Mr. Young and I would agree that we had been so 11:36
successful in dealing with this cohort of patients over a long period of time that we probably actually could have, and did, then shed a significant number of them, because they no longer needed to be treated in this manner. But still leaving a cohort of severe cases 11:36
who, as I have articulated quite clearly in the recent addendum, are people who were admitted electively when they had the prodromal symptoms of emerging infection, including nausea, including vomiting, including not being able to drink normally, and we admitted them in 11:36
the knowledge, with certainty, that one week or two weeks later they would be admitted acutely, more severely ill, more severely dehydrated, septic, and needing the same treatment for a longer period of time.

71 Q. Did you recognise in 2000, when you were engaging in 11:37
this therapy with this group of patients, that your approach was novel, unconventional perhaps, not practised elsewhere?

A. Yes, I did. Oh, sorry.

72 Q. And did you think it was an efficacious thing, something that should be, if you like, used more widely?

A. I did, and for which reason we reported it in the manner in which we did. 11:37

73 Q. But that was to be 11/12 years later that you reported it?

A. Yes. Yes, yes.

74 Q. I suppose Mr. Hagan, young trainee, you don't have any recollection of explaining to him the rational for your 11:37 treatment?

A. I don't have any recollection of explaining to him the rational for the treatment.

75 Q. Yes. Yes. When did the therapy commence? When did you commence using it? 11:38

A. Well, if we were doing it in 2000, I presume it may have been -- I don't think actually I started doing that prior to Mr. Young's appointment. So it probably would have been maybe just a year or two prior to then.

76 Q. Yes. And your rational, as I think you've expressed 11:38 it, you've expressed it variously, but in a nutshell it was, from your perspective, to prevent the acute admission of this group of patients in a worse clinical condition?

A. That's right. 11:38

77 Q. Having, I suppose, tried using pre-emptive oral antibiotics in the community to address their needs, and recognising that that was ineffective or less effective than admission electively at predicted times

Northern Ireland Assembly

Parliament Buildings
Belfast BT4 3XX

Mr Michael McGimpsey MLA
Minister of Health, Social Services and Public Safety
Castle Buildings
Stormont
Belfast
BT4 3SG

12 MAR 2009

6th March 2009

Dear Mr McGimpsey,

RE: Meeting Request for Self Care Proposal in the Community

I am writing to request a meeting with you following a discussion with two women, [redacted] and [redacted] You may recall my raising the issue of self care in the community with you in relation to these women on Monday the 2nd of March in the Members Coffee Bar.

To give you some of the background medical history; [redacted] picked up a hospital acquired coliform infection following several gynaecological surgeries, and [redacted] too suffers from chronic and persistent coliform infections of the urinary system following a hysterectomy and oepherectomy.

Due to the severity of their conditions they are required to attend hospital every 6 to 8 weeks for a period of five days to flush out their urinary system to suppress the symptoms of urinary infection. As you can imagine the negative impact that this has on these women physically and emotionally is considerable, the effect and pressure these hospital visits has on their families is also extensive.

Ideally these women would wish to receive medical treatment in their own homes. Three proposal is supported by their Consultant Urologist, Mr. Aidan O'Brien and the Staff on Ward 2 South Urology at Craigavon Area Hospital. Undoubtedly treatment at home would improve their quality of life, lessen their exposure to other Healthcare Acquired Infection, and free up much needed acute hospital beds.

I very much hope you will facilitate a meeting to discuss the proposal of care in the community further for these women and I look forward to your response.

Yours sincerely,

[redacted]

Carmel Hanna MLA
SDLP South Belfast

SDLP South Belfast Constituency Office: 393A Lisburn Road Belfast BT9 7EW
[redacted]

SDLP
Social Democratic and Labour Party

Appendix B

NOTES OF MEETING
10th March, 2008

Mr A O'Brien

Meeting with Mrs Joy Youart.

Joy believes that she has discovered a cohort where 34 patients were re-admitted to Craigavon Area Hospital for intravenous fluids and antibiotic therapy and she is not sure what the indications for this treatment are.

Joy discovered this cohort as the result of a routine patient flow exercise to find out the bed usage within different specialties.

I agreed to get further information from Dr Tracey Boyce in Pharmacy about the antibiotic usage and check with Dr Damani whether or not the Antibiotic usage fell within the Trust's guidelines.

I further agreed that I would take this information back directly to Mr O'Brien so we can determine the background to this treatment and its appropriateness or otherwise.

Unknown. This unit was within the Acute Services Directorate, and therefore the day-to-day running was within that part of its system and responsibilities, under the Director of Acute Services

26. *"What, if any role did you have in staff performance reviews? "*

    I was not involved with the Urology staff in this regard.

27. *"Was your role subject to a performance review or appraisal? If so, please explain how and by whom and provide any relevant documentation including details of your agreed objectives for this role, and any guidance or framework documents relevant to the conduct of performance review or appraisal."*

    From the best of my recollection, my performance was reviewed annually by the Chief Executive. I was provided with a list of objectives and expected outcomes prior to the meeting. I set out my responses to these and discussed the questions/answers at a face-to-face meeting. I attach the 2010 copy in the appendix 6 as it is the only record I have, and I believe it was my final performance review. Appendix 6 Dr Patrick Loughran 2009-10 pdf, for reference. Document can be located in *S21 No 30 of 2022/Dr Patrick Loughran IPR 2009-10.*
    My Medical Appraisal was a separate annual event, undertaken by the Medical Director in the Western Health and Social Care Trust with my last being in or around the Summer of 2010. This was my final medical appraisal before I retired in July 2011. The guidance and framework that was followed was as set out by the Department of Health for medical appraisal at that time. I do not have a copy of this and I am unable to recall the specific details of what the guidance and framework contained. There were no objectives in Medical Appraisal at the time.

Engagement with unit staff

28. *.Describe how you engaged with all staff within the unit. It would be helpful if you could indicate the level of your involvement, as well as the kinds of issues which you were involved with or responsible for within urology services, on a day to day, week to week and month to month basis. You might explain the level of your involvement in percentage terms, over periods of time, if that assists.*

    My engagement with staff within the unit was primarily with the Consultant medical staff. I would describe this engagement as very infrequent (much less than 1% of my time). I recall meetings regarding Junior Doctors' hours of work and the European Working Time Directive. I was responsible for Trust wide compliance with the EWTD. This was routine and did not raise governance issues. I also recall engaging with Consultants in regard to anti-biotic stewardship in relation to my overall remit for Infection Protection and Control ('IPC'). In or around April 2009 the Director of Acute Services identified a cohort of 35 patients who were receiving inpatient treatments and I was asked to assess the need to admit these patients. After initial consideration and discussion with the Associate Medical Director covering Urology (Mr Mackle), I decided that the treatments - which included several days admission, bed rest, intravenous fluids and intravenous anti-biotics - needed closer

consideration and scrutiny. I contacted a senior Urologist in Liverpool [Mr Mark Fordham] and a senior Microbiologist [D J O Driscoll] in Stoke Mandeville by phone. Both independent experts advised that there was no scientific basis for the treatment. I relayed this to Mr O'Brien in person, but he remained of the opinion that the treatment was safe and proper. Mr O'Brien and I agreed that the experts would be asked to look at some patient clinical notes. This was organised and the outcome report was the same as the verbal report. On foot of this, I directed that the Acute Services would cease to provide the treatment.

29. *Please set out the details of any weekly, monthly or daily scheduled meetings with any urology unit/services staff and how long those meetings typically lasted. Please provide any minutes of such meetings.*

    I did not have regular scheduled meeting with the Urologists. My meetings were limited to addressing the matters above.

30. *During your tenure did medical and professional managers in urology work well together? Whether your answer is yes or no, please explain by way of examples regarding urology.*

    My overall impression from memory was that the working relationships were tense at times but always civil. I was aware that the medical and professional managerial staff worked through some difficult issues such as bed occupancy and antibiotic stewardship. One example was when the Acute Service Director wanted to reduce the number of beds available to Urology and the Consultants objected to this, which created tension in the relationship.

Governance – generally

31. *What was your role regarding the consultants and other clinicians in the unit, including in matters of clinical governance?*

    I had no direct role in managing the Urology consultants and clinicians in the unit. In relation to clinical governance I would have received or had sight of reports of incidents, 'near misses', complaints and compliments as generated by the governance structures, and made available for me through the Datix system

32. *Who oversaw the clinical governance arrangements of the unit and how was this done? As relevant to your role, how did you assure yourself that this was being done appropriately?*

    Oversight responsibilities were within the Acute Service directorate. I was aware that the Director of Acute Services [Mrs Youart and then Dr Rankin] and the Associate Medical director [Mr Mackle] had agreed arrangements in place, however I am unable to recall the details of what these arrangements entailed. I felt assured because the practice and expectation were that any important incident or poor outcome would be reported from the affected Directorate to me. For example, Infection Protection and Control (IPC) was within my remit and I exercised this through the IPC team. We developed an antibiotic formulary and monitored the adherence to the prescribing rules very strictly. My general assurance that governance was being undertake appropriately was based on trusting the professional and managerial staff and understanding that each had a duty to provide

Note of a phone call M Young 21 4 09 at 4pm
PL explained the 3 issues and meeting 20 th April – views as lead clinician ??

Alternative to IV therapy is to wait till patients get clinical infection - quoted a patient who does very well and family are very keen to get prophylaxis.
"low bacterial count not 10 to the power 5 as required by Dr D etc"
Expects the evidence base is not there to support the therapy but clinical experience supports use.
He expects an independ inspection will not support the therapy but then patients will be unhappy.

Notes of a phone call to Dr Jean O Driscoll Microbiologist
1145 22 4 09
PL explained the situation as per meeting on Monday
PL explained that ND believes the IV therapy is inappropriate
ND describes the existence of oral prophylaxis, and the identification and treatment of symptomatic patients using cultures.

JOD agrees – she has never heard of the IV therapy used for prophylaxis – is familiar with the oral regimen. She has recently given a lecture on urinary infections and researched prior to that lecture. She will check with some colleagues in Bristol, look again at the literature, and send me a summary email.

Notes of call aob 22 4 09
6pm
Pl explained he had contacted jod and no backing for treatment
Aob said the rx was because of the cohort morbidity 18 cases – only evidence is our draft paper he agreed to look at converting some cases to orap proh
Pl asked if he would look at all cases for alternative treatments
Aob wants an in depth look at the cohort.. not just telephone contact with specialists

Southern Health and Social Care Trust

Medical Directorate

12 May 2009 Our Ref: PL/tc

Mr Aiden O'Brien
Urology Department
CAH

Dear Aiden

At our meeting on 21 April we discussed the cohort of patients who are elective admissions to receive IV fluids and antibiotics.

I have searched the NICE Guidelines for the current position on the prevention of recurrent UTI and have turned up clinical guidance for UTI in children – and therefore not relevant. The NICE guidance on Chronic Kidney Disease does not deal with infection.

I have contacted Dr Corrigan, on behalf of our commissioner. In the absence of NICE or other peer reviewed support for IV antibiotics and/or IV fluids, the commissioner would not support the provision of this at home. Dr Corrigan and I have therefore agreed that this Trust should immediately seek independent advice on how such patients are treated in other Trusts in N Ireland and other parts of the UK.

I have received a copy of the paper on the work you are doing in relation to this treatment. I have contacted Jean O'Driscoll who is a consultant microbiologist in the East of England who has carried out a literature search for me. This search did not show any evidence in support of intravenous fluids and IV antibiotics as a recognised prophylaxis,

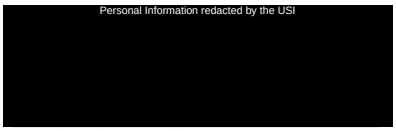
I am awaiting a return call from Mr Mark Fordham who is a Consultant urologist in Manchester and who is very familiar with the NI urology service. I am hoping to ask for his independent views on the IV therapies.

Cont'd. …….

I spoke to Mr Young on the afternoon of 21 April, as the lead clinician, to make him aware of the background to our meeting and the expectation of an Independent inspection of the IV therapy.

I will keep in touch by letter and telephone as required.

Yours sincerely



Dr Patrick Loughran
Medical Director

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
Personal Information redacted by the USI

Southern Health and Social Care Trust

Medical Directorate

18 May 2009 Our Ref: PL/TC/lw

Mr Aiden O'Brien
Urology Department
CAH

Dear Aiden

I have now contacted and spoken to Mr Mark Fordham at length. I explained to him that we have patients who are being admitted for IV fluids and antibiotics. I gave him your viewpoint as best I could. He said that while he understood that you are doing your best for this group of patients, he did not know of any evidence base which would support these therapies.

We went on to a more detailed discussion about his practice and a widely accepted approach to recurrent urinary infections. He felt that once such patients had the initial standard investigations carried out, that they should be managed in primary care with no further hospital interventions. He talked about voiding techniques, advice to patients about oral hydration and the use of night time oral antibiotics. He also talked about the specifics in relation to females, and local oestrogen therapy and advising patients in relation to personal care. He also felt that if patients needed particular advice and reassurance that a once weekly MSSU provided at the hospital for 6 successive weeks would indicate that 90% of these patients did not have urinary infections and had what he described as "abacterial "cystitis.

I explained that we have a very strong antibiotic guideline in place. He supported the use of such a guideline and went on to say that he believes that such circumstances need bacteriological evidence before antibiotics should be commenced.

<u>Summary</u>

Over the last 6 weeks, I have spoken and written to you about a cohort of about 30 patients who are admitted for IV antibiotics and IV fluids as a prophylaxis for recurrent UTI's.

We have had a letter from a politician asking for the treatment to be provided at home. Our CX is taking this forward with Mrs C Hanna, MLA.

Cont'd. ……

I have discussed the situation with a senior microbiologist from Stoke Mandeville who believes there is no evidence base to support the treatments.

In the above paragraphs I have described the reaction of a senior urological surgeon from Manchester who also believes there is no evidence to support the treatment.

Our commissioner has expressed concern and asked me to seek independent advice so that an evidence based discussion could take place around the continuation or discontinuation of such therapies.

I would now like to meet with you immediately to take this forward. In advance of the meeting perhaps you could reflect on the possibility of changing these patients to oral therapy with an MSSU taken at the hospital at a regular interval. As on previous occasions, I have copied this to Michael Young, whose opinion on the way forward might also be valuable.

Dr Patrick Loughran
Medical Director

cc Mr Michael Young, Consultant
Mr Colm Donaghy, Chief Execurive

Southern Health and Social Care Trust

Medical Directorate

2 June 2009 Our Ref: PL/lw

Mr Aiden O'Brien
Urology Department
CAH

Dear Aiden

Thank you very much for meeting with me today. We agreed that you:

- would provide me with a complete list of the patients who are currently on the IV programme.
- will accept an independent assessment of this IV therapy.

I will arrange terms of reference with Mr Mark Fordham and speak to Jean O'Driscoll the Micro-biologist again.

I will also speak to Michael Young in due course.

Regards

Personal Information redacted by the USI

Dr Patrick Loughran
Medical Director

cc Mr Michael Young, Consultant
Mr Colm Donaghy, Chief Executive

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
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please set out in full the nature of the concern, who, if anyone, you spoke to about it and what, if anything, happened next. You should include details of all meetings, contacts and outcomes. Was the concern resolved to your satisfaction? Please explain in full.

26.1 Yes. I raised a concern that related to "triage in urology," as set out in my response to Question 24 at 24.2., after it was brought to my attention by a member of the Acute Governance team on 9th November 2016. Please see my response to Question 27 27.10 to 27.18 for further details about this concern.

27. Did you have concerns regarding the practice of any practitioner in urology? If so, did you speak to anyone and what was the outcome? Please explain your answer in full, providing documentation as relevant. If you were aware of concerns but did not report them, please explain why not.

27.1 Yes. I had two concerns regarding Mr Aidan O'Brien during my employment in the Trust.

27.2 The first concern involved the prescribing and administration of gentamicin to urology patients. One of the experienced clinical pharmacists, who was based on the Craigavon Area Hospital (CAH) surgical wards, asked to speak to me about a clinical concern that she had not been able to resolve herself. She was aware of a number of patients who had been admitted for five or more days to receive an infusion of gentamicin, at Mr Aidan O'Brien's request.

27.3 Gentamicin is an aminoglycoside antibiotic used to treat serious infections, such as sepsis and acute pyelonephritis. It has a number of serious side effects including ototoxicity and nephrotoxicity.

27.4 The pharmacist's concerns were that the dose of gentamicin being prescribed was subtherapeutic and that she could not find any record or sig that

the patient was being treated for an infection. The patients all appeared to be clinically well. She had spoken to the nursing and junior medical staff on the ward and they had confirmed that the admission and the dose to be used was specified by Mr O'Brien.

27.5 In my view her concerns were valid. Patients were being exposed to the side effects of the medicine unnecessarily, being cannulated for no reason and being put at risk of acquiring an infection whilst in hospital. Further, by giving low doses of the antibiotic, there was a risk that antimicrobial resistance could develop which would render that antibiotic ineffective if they actually needed it in the future. In addition to this, the Trust was under huge pressure for beds at the time and these patients were taking up a valuable resources unnecessarily.

27.6 I escalated this issue by raising it with Dr Patrick Loughran who was the Medical Director of the Trust at that time (2007 – 2011). I believe I escalated this concern sometime between January 2008 and December 2010. I apologise that I cannot give an exact date for this meeting and there are no notes of the meeting either, as it was raised as part of a conversation. Dr Loughran may be able to give a more accurate date.

27.7 I believe that Dr Loughran took the concern seriously. He asked me to leave the issue with him and he assured me that he would investigate it further.

27.8 A few weeks later Dr Loughran gave me an update about the actions he had taken. Again, as this was an informal conversation, I unfortunately do not have a record of the date or any meeting notes that I can share with the Inquiry. I recall that he told me that he had spoken to Mr O'Brien and told him that his practice of prescribing an infusion of gentamicin to patients was to cease immediately. He advised that he had also spoken to the Ward Managers to make them aware that Mr O'Brien was no longer allowed to admit such patients.

would usually have been acutely readmitted to our department once again, at the request of their GP, or on presenting to the Emergency Department at Craigavon Area or Daisy Hill Hospitals. A common feature of these patients was that they would have been dehydrated to varying degrees due to nausea or vomiting persisting for days prior to admission. In addition, they may have been painful, febrile and hypotensive. Their immediate management included intravenous rehydration as they were unable to tolerate an adequate oral fluid intake. It also would have included intravenous antibiotic therapy, either pre-emptively or following identification of the antibiotic sensitivities of the infecting organism. We typically found that 5 days of intravenous hydration and antibiotic therapy was required to achieve optimal clinical outcomes, with patients rendered asymptomatic and with negative urinary cultures.

419. However, we saw these patients being repeatedly acutely readmitted after varying periods of time, usually of the order of 2 to 3 months. One might have expected that they would not have been as severely symptomatic as previously, having derived benefit from their previous infection. However, a common feature was that they tended to be as severely symptomatic as previously, if not worse. One would have anticipated that they may have had a lower threshold for readmission due to having been made well from previous admissions. However, we found this cohort of stoical patients to have made every effort to avoid or defer having to spend another 5 days in hospital. By the time of their acute readmission, they were more unwell than previously.

420. We wondered whether we could prevent these patients becoming repeatedly so acutely unwell, requiring acute re-admission, by having them electively readmitted prior to acute readmission. By analysing the periods of time that had elapsed between acute readmissions, we were able to determine a planned date for elective re-admission for intravenous hydration and antibiotic therapy. Prior to doing so, we had already found that pre-emptive oral antibiotic therapy in the community had been ineffective and had only delayed their acute re-admission. So, we electively re-admitted patients, usually 2 weeks prior to their otherwise, anticipated acute re-admission. We also hoped that by doing so,

we would be able to lengthen the periods of time between elective re-admissions, while hopefully preventing acute re-admission.

421. Overall, over a period of time, we found this to be effective. Most patients reported that they considered that the most important component of their elective management was the intravenous hydration. We certainly found that intravenous antibiotic therapy without intravenous hydration was either not effective at all or took longer to be so. We also frequently found that patients had positive urinary cultures on elective readmission, though they had not yet become symptomatic. We were able to increase the periods of time between elective readmissions. We were able to do so without finding evidence of emerging antibiotic resistance. However, we were unable to prevent acute readmission in a minority of patients.

422. The practice of elective readmission of these patients came under scrutiny in 2010 when Mr Young and I were directed that the practice had to end, and that the further management of these patients had to be undertaken by a multidisciplinary team (MDT), including a consultant microbiologist. Dr Rankin, the then Director of Acute Services, prohibited us individually from communicating directly with these patients, with any communication having to come from the MDT instead [see AOB-00191]. By this time, the majority of patients had been managed so successfully by elective readmission that they continued to be managed successfully in the community by having urinary cultures repeated regularly and by having therapeutic courses of oral antibiotic therapy, or by antibiotic prophylaxis, or by a combination of both. However, a minority of patients were left to be acutely readmitted when they became unwell enough to warrant admission. This minority proved to be increasingly difficult to manage due to progressive deterioration in peripheral venous access, occasionally requiring central venous lines. One or more of these patients required acute admission to intensive care because of the severity of their bacteraemia / septicaemia, and these patients were still being acutely readmitted prior to the end of my employment with the Trust.

admission of these patients stopping, with a new Trust pathway being put in place."

You're differentiating your practice from Mr. O'Brien's practice in this respect. What is the distinction that you're highlighting here? 10:50

A. Mr. O'Brien would have electively admitted patients for the fluids and antibiotics. My approach was for patients that weren't -- that had an infection, that had been through the use of prophylactic antibiotics where they had been stopped and the patient had developed a urinary tract infection again and again and again, and the use of oral antibiotics weren't working properly to treat their infection, I would have admitted them for intravenous gentamicin. Now, the other aspect of that is patients may -- there are several patients have commented on 'I've been on oral antibiotics for a long time here but when I get the intravenous antibiotics, it lasts six months'; they are getting a good amount of time out of the use of the intravenous approach to it. 10:50 10:51 10:51

The other -- although I did have a planned admission for some people, I did try to target their time of admission to be similar to when they were recording that their infections were coming back. So if somebody noted that they had been on a course of antibiotics for three months -- sorry, and got three months out of it, then I would be trying to pinpoint their admission to 10:51

actually be at the three-month spell. So I was using it to try to target patients when they were having their recurrent infections, and to give them a proper dose of an antibiotic.

25 Q. So is it your suggestion that Mr. O'Brien was admitting patients who did not have evidence of urinary infection and symptoms, whereas your approach was focused on patients who either had infection present, who were symptomatic or, taking your three-month approach who were likely to be symptomatic around that point in time? 10:52 10:53

A. Yes. I was trying to target the therapy to be of the right antibiotic to treat it for the right length of time, and I was very focused on the patients who were symptomatic. 10:53

There are some patients actually, although there was two patients I know of that, although I was planning a date to come in, they had attended casualty and one lady had come in on that planned three months, for instance, and she was well when she came in but got septic on the award, for instance, so I did have it timed right. But it's getting the right antibiotic. 10:53

26 Q. Just to be clear, are you saying Mr. O'Brien's patients, in your experience did not have evidence of the presence of infection or had not developed symptoms of emerging infection whereas, by contrast, yours did? 10:54

A. Sorry, I was answering for myself there. Certainly my observation of Mr. O'Brien's patients is that they were

more often admitted electively without a proven infection. Some may still have had a urine culture done that had been positive but it's the symptomatic nature. So that was my observation, that his set of patients were more likely to be elective. 10:54

27 Q. So you were, for a period of some years, aware of Mr. O'Brien admitting patients electively without -- and commencing the treatment without proof of infection?

A. Yes, our unit did a paper on this and it did show that this plan of action did reduce the number of acute admissions to the ward. So there was some science behind it but it probably could have been at a higher level. 10:55

CHAIR: Sorry to interrupt, Mr. Wolfe. Forgive me, Mr. Young, I'm trying to get this clear in my head. I'm not entirely clear what you mean by Mr. O'Brien admitting patients electively and how that differed from what you were doing by scheduling an admission in three months' time. So can you please explain, just for my understanding, the difference? 10:55 10:56

A. I was observing that patients had a time frame between having a treatment and then coming --

CHAIR: Needing it again?

A. -- and then when they would have had an infection again and I was trying to plan that. And sometimes that planning, the patient was ahead of me and would be admitted via casualty. So I was trying to focus more on the patients that were going to get an infection, a 10:56

So do you follow his distinction and do you think it's a valid distinction?

A. I don't think actually -- I mean I listened to it carefully and I think that his, do you know, this is like semantics, but his were still elective admissions. 11:44
The reality is, is that if you had put this patient on a waiting list to be electively re-admitted in let's say eight weeks time, based upon the intervals between previous infections, and you rang them up on week, at the end of Week 7 and say "How are you?", and they say 11:45
"I'm wonderful", there's not one of them wanted to come in one week later. I think that mine would have been symptomatic. And the symptoms were not typically those pertaining or arising from the urinary tract.
Remarkably they were more general than that. I recall 11:45
after this controversy, as you put it, arose, getting an email from Mr. Mackle sort of being critical that I hadn't taken on board that I wasn't allowed to admit someone electively without consulting with the Clinical Director and the Clinical Microbiologist at that time, 11:45
and I had -- I got this about maybe two or three hours after I had received a phone call from a general practitioner, who has long since retired, about one of our patients in this cohort, he was ringing from her home because she was so dehydrated because she had been 11:46
nauseous and vomiting for two days, and asked me if he could admit her, and I said "Of course you can admit her." So.

88 Q. Well, I want to come to this in the proper order. I

Notes of meeting 20-4-09
Pl, AOB,CMcA, ND
Loughran office

Three related topics were addressed

1. Compliance with Trust Antibiotic Guidance, as set out in covering letter (attached).

Mr O B said that his personal experience would support the antibiotic use as he currently followed and he was not persuaded to adopt the Trust advice.
Dr Loughran felt that the Trust had circulated the guidance for comment and was anxious that the Urology team had not joined the consultation.
The evidence base of the guidelines especially as applied to Gentamycin was debated, and all agreed should be discussed separately.
Dr McA said many clinicians were reluctant to take advice in relation to long held beliefs and habits but the adoption of guidance and then measuring outcomes was the best way forward.

It was agreed that Dr D and some or all of the urology team will meet in the immediate future to agree the Guidelines as applied to urology. Dr L asked for the final agreement to be evidence based

2. The Trust has identified a cohort of about 30 patients who are admitted as elective cases for IV antibiotics and IV fluids as a prophylaxis for recurrent UTIs. The evidence base for this was described by AOB, and he described a study of outcome which was being prepared for publication.

3. The third related issue is the letter from Mrs C Hanna MLA to Mr M McGimpsey MLA asking for the above treatment to be made available at the homes of two patients.

Dr L agreed that he would contact the Commissioner (Dr Corrigan).

Wright, Elaine

From: White, Laura [redacted]
Sent: 17 July 2009 13:22
To: 'Wilson, Roberta2'; 'Donaghy, Colm'
Cc: 'Wright, Elaine'
Subject: Ltr to Mr Aiden O'Brien
Attachments: 20090717_Ltr_AO'Brien_UrologyPatients_PLlw.doc

Roberta and Colm
Please find attached copy of letter re Urology Patients sent to Mr Aiden O'Brien in internal post today as he doesn't open e-mails.
Laura

Ms Laura White
Personal Assistant to
Dr Patrick Loughran
Medical Director
Southern Health & Social Care Trust
College of Nursing
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

Tel: [redacted]
Fax: [redacted]
E-mail: laura.white[redacted]

P Please consider the environment before printing this e-mail.

Southern Health and Social Care Trust

Medical Directorate

17 July 2009 Ref: PL/lw

Mr Aiden O'Brien, Consultant Urologist
SHSCT, Urology Department
Level 2 South, CAH

Dear Aiden

I refer to our previous conversations and correspondence, and my expectation that you would provide me with the list/cohort of patients who were in the programme for repeated IV fluids and antibiotics. I have now obtained the list from the Director of Acute services.

I have advised the Chief Executive that I have considered:

- The contents of correspondence and the meetings with you,
- The informal phone calls between me and Dr O Driscoll and Mr Mark Fordam
- Your belief that these therapies are evidence based
- The commissioner's uncertainty of the evidence base of the therapies
- Your reluctance to consider alternative non IV therapies

I am now bound to take an independent assessment of the whole situation to allow me to advise the Chief Executive of the safety and efficacy of the treatment.

I have written to Dr O Driscoll and Mr Mark Fordam to ask them to provide a formal assessment.

I expect to agree terms of reference for the investigation in the immediate future.

I would ask you to take this final opportunity to consider if there is an alternative way to treat these patients.

I would be very happy to speak with you and Mr Young to discuss this cohort of patients. I am on leave at present returning on Monday 3rd August, and I will make myself available at any time that week.

Yours sincerely

Personal Information redacted by the USI

Dr Patrick Loughran
Medical Director
c.c. Michael Young, Colm Donaghy, Roberta Wilson

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
Tel: (028) Personal Information / Fax: (028) Personal Information / Email: patrick.loughran Personal Information redacted by the USI

Southern Health and Social Care Trust

Office of the Medical Director

Dr Jean O'Driscoll
Consultant Microbiologist and Director of Infection Prevention and Control
Buckinghamshire Hospitals Trust
Stoke Mandeville Hospital
Mandeville Rd,
Aylesbury
HP21 8AL

17/07/09

Dear Dr O'Driscoll

Re Urology Clinical Practice

Further to our recent conversations regarding local urology clinical practice and your email of 29/05/09

The matter I discussed with you was as follows.

I had initial concerns that in our urology service a cohort of around 30 patients were identified that receive a regime of intravenous fluids and antibiotics as a preventative treatment for recurrent / chronic urinary infections. This treatment is given over a five day period on a regular basis.

When we spoke by phone on 22/04/09 indicated that there was no evidence base to support the above clinical practice. You indicated at that time that you may be able to consult with your colleagues in Bristol, undertake a brief literature search and provide me with a summary of your findings by email. I understand that you were unable to do this because of the pressure of your own work.

I subsequently also agreed to contact Mr Mark Fordham a consultant Urologist in Manchester. In discussing this matter with him he also indicated that he did not believe that there was an evidence base for this clinical practice.

I have continued to negotiate with the consultants involved to see if they would discontinue this practice without any success. Unfortunately they remain unconvinced that their practice is an unconventional method of treatment and of limited or no benefit to the patients.

I have advised them that the Trust now needs to seek independent professional advice on the matter and they are both agreeable to this.

Southern Trust Headquarters, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ
Personal Information redacted by the USI

You can appreciate that this is a very sensitive issue and is likely to be difficult for the patients and doctors concerned and also the Trust. For example one of the consultants agreed to forward me the list of patients receiving the IV therapy, despite a number of reminders over a four week period this information was not provided. (I have now obtained these details from the Director of Acute Services who has responsibility for this service)

If you are wiling I would be very pleased for you to accept my invitation to provide an in-depth assessment of this clinical practice. The key aspects of this assessment would involve the following:

1. A review of the evidence base for the treatment of recurrent / chronic urinary infections in a similar patient cohort. Cohorts include;
    a. Congenital urinary tract abnormalities
    b. Post operative urinary reconstruction surgery including urinary conduits
    c. No obvious predisposition to urinary infections.
2. Current practice for the management of such types of patients including prophylaxis regimes.
3. Advice or suggestions on the future management of these types of patients.

In order to assist you I would be able to provide you with a sample of case notes for review. I was considering a sample of between 9-12 records but would be guided by you as to your requirements.

I appreciate that it may be difficult to co-ordinate this piece of work over the summer months due to holiday commitments. I will be on holidays from 21 July to 03 August and 08 August to 17 August. I have briefed my governance lead who is willing to act as a point of contact for your in the first instance. She can be contacted at:

Personal Information redacted by the USI or by email at Roberta.wilson Personal Information redacted by the USI .

Many thanks for your assistance in this difficult matter.

Yours sincerely

Personal Information redacted by the USI

Patrick Loughran
Medical Director

Southern Health and Social Care Trust

Office of the Medical Director

Mr Mark Fordham
Consultant Urological Surgeon
12 Leigh Road
West Kirby
Wirral
CH48 5DY

17/07/09

Dear Mr Fordham

Re Urology Clinical Practice

Further to our recent conversations regarding local urology clinical practice

I had initial concerns that in our urology service a cohort of around 30 patients were identified that receive a regime of intravenous fluids and antibiotics as a preventative treatment for recurrent / chronic urinary infections. This treatment is given over a five day period on a regular basis.

I have also contacted Dr Jean O'Driscoll a consultant Microbiologist in Stoke Mandeville Hospital. In discussing this matter with her she also indicated that she did not believe that there was an evidence base for this clinical practice.

I have continued to negotiate with the consultants involved to see if they would discontinue this practice without any success. Unfortunately they remain unconvinced that their practice is an unconventional method of treatment and of limited or no benefit to the patients.

I have advised them that the Trust now needs to seek independent professional advice on the matter and they are both agreeable to this.

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In order to assist you I would be able to provide you with a sample of case notes for review. I was considering a sample of between 9-12 records but would be guided by you as to your requirements.

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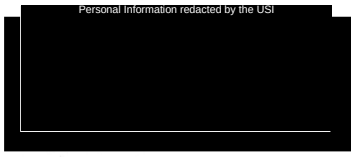
Personal Information redacted by the USI or by email at Roberta.wilson Personal Information redacted by the USI.

Many thanks for your assistance in this difficult matter.

Yours sincerely



Patrick Loughran
Medical Director

Meeting re Urology Clinical Practice

Date: 4th August 2009

In attendance: Dr Patrick Loughran, Medical Director
Mr Aiden O'Brien, Consultant Urologist
Mr Michael Young, Consulant Urologist

Previous positions re the treatment of the identified cohorts of patients discussed. Dr Loughran explained that the Trust had engaged two experts Mr Mark Fordham (Urologist) and Dr Jean O'Driscoll (Microbiologist) to provide an opinion on the efficacy of the present intravenous regimes. They would review the charts of a number of patients and current urology and microbiology practices.

After further explanation of each others positions the following was agreed:

1. A further meeting to take place in September

2. A meaningful active and accurate list of patient details to be provided by Friday 7th August by Mr O'Brien and Mr Young.

3. Each surgeon will personally review the current treatment regime for each patient on the list.

4. A multidisciplinary group would be convened to review the reduced list of patents and agree a treatment plan for each patient. This group would consist of microbiology and urology consultants.

c.c. Dr Nazim Damani
Mr Colm Donaghy

Update: 7th August 2009

Dr Loughran met with Dr Damani today. Dr Damani has agreed to be a member of the multidisciplinary team.

Southern Health and Social Care Trust

Medical Directorate

Memorandum

Our ref:	PL/lw	**Your ref:**	
To:	Dr Gillian Rankin, Interim Director of Acute Services		
From:	Dr Patrick Loughran, Medical Director		
c.c.	Mr Eamon Mackle, AMD for Elective Care/Surgery Division, Acute Roberta Wilson, Governance Lead		
Date:	2nd September 2010		
Subject:	Urology Services		

Dear Gillian

Since the end of March 2009 the Trust has been examining the practice of IV antibiotic and fluid therapy as a prophylaxis for recurrent UTI's. I have received expert advice from Mr Mark Fordham (an acknowledged expert from Manchester) and Dr Jean O'Driscoll Consultant Microbiologist in Stoke Mandeville Hospital.

As a result of the expert external opinions and following several meetings and related correspondence with Mr O'Brien and Mr Young, I met with the 2 Urologists on 4th August 2009. During this meeting the surgeons agreed:

a) to compile an accurate list of patients who were on the IV programme
b) that each surgeon would review the treatment regime for each patient
c) that a multi-disciplinary group would be convened to look at a treatment plan for each patient. The core of this treatment plan would be to convert the patient from IV to oral therapy or another non-intravenous treatment (review/watchful waiting ??).

On 7th August 2009 Dr Damani and I agreed that he would provide Microbiology support for point's b and c above.

In the intervening period I understand that there has been a significant reduction in the number of patients within the cohort. I had expected that the number of patients would be extremely small by now and that the patients with central venous lines or long peripheral lines would have had the lines removed. You, Mr Mackle and I met on Wednesday 1st September 2010 and discussed the progress of this matter.

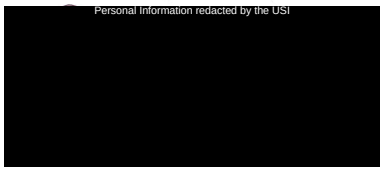
It is of concern to me that the agreement as set out above has not been followed by Mr Young and Mr O'Brien. In particular I understand that there are at least 7 patients remaining on the IV treatment and that 2 (and possibly 3) have permanent intra venous access. We agreed that Mr Young and Mr O'Brien should be informed of the meeting on Tuesday and should also be informed that I remain concerned that <u>any</u> patient is receiving this intra venous treatment.

I believe that it is my responsibility to have this unusual treatment subject to a formal independent review of its appropriateness and in the meantime I want to discuss an immediate cessation of those patients who remain on the treatment. I expect that this will come as no surprise to Mr Young and Mr O'Brien as I have made it clear from the middle of last year that this was the only course which would be open to me in the event of them not ceasing the treatment in an orderly fashion.

I would be grateful if you would arrange to meet with Mr Young and Mr O'Brien and I would suggest that Mr Mackle should accompany you during that meeting. The purpose of the meeting should be to determine which patients remain on the IV therapy list and if there are any patients with central venous access. I would hope that the surgeons would agree to cease the therapy forthwith and see that the venous access lines are removed safely. I would expect that the meeting would be arranged in the next few days.

I would be happy that this memo should be copied to the 2 surgeons as an accurate record of our meeting on Tuesday and a record of my concerns for these patients safety.

Regards



Dr Patrick Loughran
Medical Director

Southern Health and Social Care Trust

Meeting re Urology Service

Tuesday 1 December 2009

Action Notes

Present:
Mrs Mairead McAlinden, Acting Chief Executive
Dr Patrick Loughran, Medical Director
Mr Eamon Mackle, AMD – Surgery & Elective Care
Mrs Paula Clarke, Acting Director of Performance & Reform
Mrs Deborah Burns, Assistant Director of Performance
Mrs Heather Trouton, Acting Assistant Director of Acute Services (S&E Care)
Dr Gillian Rankin, Interim Director of Acute Services

1. **Demand & Capacity**
   Service model not yet agreed, outpatients and day patients not finalised, no confidence that this will be finalised. Theatre lists not currently optimised and recent reduction in number of flexible cystoscopies per list. Recent indication that availability for lists in December 2009 will be reduced.

   Action
   - Sarah Tedford to be requested to benchmark service with UK recognised centres regarding numbers, casemix, throughput (eg cystoscopies per list). **Action – urgent within 1 week.**

   - Team/individual job plans to be drafted – Debbie Burns/Mr Mackle/Zoe Parks, for approval at meeting on 11 December 2009. To be sent to consultants and a meeting to be held within a week with consultants, Mr Mackle, Heather Trouton and Dr Rankin.

2. **<u>Quality & Safety</u>**

   <u>Key Issues</u>:-

   1. Evidence-base for current practice of IV antibiotics for up to 7 days repeated regularly requires urgent validation. Current cohort of 38 patients even though this clinical practice appeared to change after commitment given to Dr Loughran at end July 2009.

Action:-

- Dr Loughran to have phone discussion with Mr Mark Fordham to get urgent professional opinion on appropriateness and safety of current practice. Mr Mackle will meet Mr Fordham next week (w/c 7 December 2009) and report to be ready for discussion

- Discuss outcomes at meeting to be arranged for 11 December 2009

- Depending on the outcome of the professional assessment, management actions may be required as follows:-

    - Commissioner to be informed if practice not safe
    - Letter to be issued to relevant consultants regarding requirement to change clinical practice, with clear indication of sanctions if this change were not to happen
    - Professional assessment of full cohort of patients (38)

2. Triage of Referrals
   Undertaken by 1 of the 3 consultants within required timescale. 1 consultant's triage is 3 weeks and he appears to refuse to change to meet current standard of 72 hours.

3. Red Flag Requirements for Cancer Patients
   1 consultant refuses to adopt the regional standard that all potential cancers require a red flag and are tracked separately. This results in patients with potential cancers not being clinically managed within agreed timescales.

4. Chronological Management of Lists for Theatre
   1 consultant keeps patients' details locked in the desk and refuses to make this available. Current breaches of up to 24 weeks which may or may not include urgent patients, while non-urgent vasectomies are booked for 2 weeks after listing.

Actions for Points 2, 3 & 4:-

- Written approach from Dr Gillian Rankin, Interim Director of Acute Services to consultants to require patient lists/details to be made available immediately, in order that all urgent patients can be booked (Debbie Burns to draft). Safe management of patients is a requirement in the consultants' contracts.
- If no compliance, further written correspondence to be drafted on issues of lack of conformance with triage and red flag requirements, clearly setting out the implications of referral to NCAS if appropriate clinical action not taken.

- Dr Loughran, Kieran Donaghy & Dr Rankin to agree relevant correspondence

2. Other Issues

- Dr Loughran to ensure circulation of recently adopted policies to all consultants (SPA, full job planning, WLI)
- Funding base and recruitment process for Clinical Fellows in Urology to be reviewed before proceeding to any further appointments

Appendix L

Key points from discussions with Dr Mark Fordham

Date 02 12 09

1 The management of these patients can be challenging.

2 They have normal life expectancy (non cancer patients)

3 They can become psychologically dependent on hospital services even in the absence of specific clinical needs.

4 Clinically diagnosed urinary tract infections are best confirmed by laboratory urine cultures but urine cultures from bowel based urine reservoirs or conduits need to be interpreted with care.

5 The local urology regimes for these patients do not have a scientific evidence base.

6 There is no need to treat patients with IV fluids who are able to drink normally.

7 The use of IV antibiotics should be reserved for patients with multiresistant urinary infections or severe pyelonephritis

8 Care can be provided with the support of primary care using various treatments relating to out patient oral antibiotic regimes.

9 These patients sometimes require unplanned admission when acutely unwell.

Montgomery, Ruth

From: Loughran, Patrick [redacted]
Sent: 11 August 2010 18:43
To: Brennan, Anne
Subject: Re: IV Antibiotics in Urology

Anne
Roberta has all our info on this. Will discuss tomorrow - I raised this with Gillian last Thurs 5th
Paddy

----- Original Message -----
From: Brennan, Anne
To: Loughran, Patrick
Sent: Tue Aug 10 22:11:23 2010
Subject: Fw: IV Antibiotics in Urology

Paddy did u discuss with eamon

----- Original Message -----
From: Mackle, Mr E
To: Brennan, Anne
Sent: Mon Jul 19 15:09:22 2010
Subject: IV Antibiotics in Urology

Anne

Paddy as you know had a report from Mark Fordham regarding the use of long term IV antibiotics for urology patients. I mentioned to Paddy recently that I understood that they were still not adhering to the guidance which he gave to them (in conjunction with advice from Dr Damani). Paddy stated that I should check the numbers concerned and then if necessary meet with them. I have discovered there are 13 or 14 patients still getting IV treatment. I am organising a meeting but would appreciate if you could forward me a copy of Mark Fordham's report and if there were minutes of his meeting with Urology so I can be sure I am singing from the same hymn sheet.

Eamon

HSC Public Health Agency

South Office
Tower Hill
ARMAGH
Co Armagh
BT61 9DR

Tel : Personal Information redacted by the USI
Fax :
Web Site : www.publichealth.hscni.net

Dr P Loughran
Medical Director
Southern Trust HQs
College of Nursing
68 Lurgan Road
PORTADOWN
BT63 5QQ

CONFIDENTIAL

1 September 2010

Dear Dr Loughran

In the context of the Urology Review implementation process, I was present at a recent meeting with Trust staff to discuss progress. I had already noted from the written submission that there appeared to be a high proportion of elective urology episodes at CAH which did not have an operative procedure. This is being explored further, but in a brief discussion with the Clinical Director for Surgery it appeared that the practice of some urologists of admitting patients for intravenous fluids and antibiotics as a treatment for chronic urinary tract infections has not ceased. If I understood the position correctly, some patients may now be receiving this treatment via central lines. I would be very concerned if this was the case. I forwarded to Mr Mackle the email correspondence to your secretary which set out my opinion on this practice back in January. I had assumed steps were being taken to bring this to an end.

Following the recent meeting I re-read the external expert reports relating to the use of IV therapies at CAH (Appendices of the draft document I was asked to comment on last January). There was one sentence which read "Whether these patients have been well served by the major bladder surgery they have undergone is difficult to say as the records do not include the original letters leading up to the surgery." In the context of my unease at the ongoing use of a treatment at CAH which had not been supported

by external experts, I informed Mr Mackle that I intended to seek NI-wide information on the numbers of cystectomies and ileal conduit procedures carried out by Unit and consultant across NI. I was seeking assurance that the use of operative intervention in patients with chronic cystitis at CAH was in keeping with that in other units.

I enclose data from 2005/06 to 2009/10 from all hospitals in NI, including CAH. The search criteria selected elective admissions of patients who had either cystectomy or ileal conduit formation recorded as the primary procedure code. The primary diagnosis is shown alongside. The information has been checked to exclude duplicate patients. These data have to be interpreted with caution as they are dependent on coding quality and the total numbers are very small. I have considered the possibility that patients who had had these procedures done in the past and who were admitted for another purpose might have been recorded incorrectly as having the procedures a second time, thus inflating the total numbers, but the check for duplicate cases would have been expected to minimise this possibility. If this is primarily a coding error then this would indicate a need to review coding practice in the Trust.

From this information it appears that cystectomy and conduit creation is done in the great majority of cases in NI for malignant disease. There appear to be small numbers done for other reasons, though in some cases the diagnostic coding is too vague to be sure what the true underlying diagnosis might have been, e.g. when recorded as 'peritonitis, faecal incontinence, mycobacterial infection or attention to openings of urinary tract'. The role of the regional centre seems to have become more prominent over the five year period, with cessation of cystectomy work at Altnagelvin and the Mater Hospitals. The specialist role in treating patients with spinal problems/neuropathic bladders is reflected in the BCH data.

There is no clear pattern throughout the five-year period in relation to cystectomies done for cystitis, though perhaps the first two years of that period would indicate higher proportions than expected at CAH. In 2005/06 and 2006/07 the cystectomy and/or ileal conduit creation operations recorded across NI were 32 and 41 respectively. The numbers done for reasons other than malignant disease (as per the ICD coding) were 9 and 7 respectively. Four of the 9 done in 2005/06 were for cystitis, of

whom 3 of the four had their operation at CAH. In 2006/07 three of the seven non-malignant patients operated on in NI were coded as having a primary diagnosis of cystitis, all three of whom had their operation at CAH.

From 2007 onwards the number of procedures done for non-malignant indications at CAH fell to 2, 2 and 4. In that group of 8 cases, one was for UTI unspecified and one for mycobacterial infection but none specifically for cystitis.

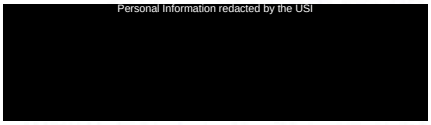
I have asked for information for the five years preceding 2005 and will forward that to you when it becomes available. In the meantime, I would be grateful if the Trust would review this information with a view to checking its accuracy, i.e. that the coding of these cases is correct. Your information department may wish to re-run the data but if they wish to cross-check this version by casenote number the latter can be made available.

Until the data have been verified it may be premature to take any further steps, however depending on the outcome the Trust might wish to consider whether it would be appropriate to seek additional advice from the GB experts who provided the earlier reports.

Following the Urology Review decision, as of March 2010 radical pelvic urology surgery for malignant disease should no longer be being done in SHSCT. This would include cystectomy. Trust staff discussed the process for cancer cases recently at a meeting chaired by Beth Malloy from PMSI Directorate of the HSCB. The rationale for this policy decision, which is in line with IOG guidance, was to concentrate the relatively small number of such cases in the hands of a small number of surgeons who could maintain specialist skills. No specific reference was made in the Urology Review to radical pelvic surgery for non-malignant disease. It was perhaps assumed to be implicit that the even smaller volume of this type of work would also be centralised. I would be grateful for an assurance that the urology team at CAH is now referring on all patients being considered for radical pelvic surgery regardless of the underlying diagnosis.

Lastly, I would be grateful for a report from the Trust detailing what steps are being taken to manage the ongoing risks associated with delivering IV therapies to the original cohort of patients. As a first step, it would be helpful to have an assurance that none are receiving this treatment via a central line. It would also be helpful to have a position statement detailing how many patients are still on this form of treatment and the expected timeframe for this to cease.

Yours sincerely



Dr D Corrigan
Consultant in PHM

Enc

cc Dr G Rankin, Director of Acute Services, SHSCT
Mr E Mackle, Clinical Director of Surgical Services

Sent: 13 September 2010 09:13
To: Stinson, Emma M
Subject: FW: Urology letter from Dr Corrigan

Emma please let me have the 3 individual papers which we tabled for the separate meetings with urology surgeons last Thursday. I will email to Dr L for his response,
Thanks
Gillian

-----Original Message-----
From: McAlinden, Mairead
Sent: 11 September 2010 23:25
To: Loughran, Patrick
Cc: Rankin, Gillian
Subject: Urology letter from Dr Corrigan

Paddy, are you intending to respond to Diane's letter and share with her the review brief agreed with Gillian? If so, would you copy to us both please.

Mairead

Private & Confidential

Local Review into the incidence of cystectomies

The Public Health Agency (the Agency)has written to the Medical Director of the Southern Health and Social Care Trust (the Trust) identifying that there is a higher than expected proportion of cystectomies undertaken for cystitis in Craigavon Area Hospital over a five year period.

In order to respond to the Agency and provide assurance to the Trust that the diagnosis, treatment and outcomes for those patients, who have undergone cystectomies, for reasons other than malignant disease, is appropriate and proportionate, the Trust has asked that a preliminary review be undertaken by the Associate Medical Director for Surgery and Elective Care.

The first stage of this process will be a case note review of those patients who have undergone cystectomies for non malignant disease within the last 5-10 years, with independent advice where appropriate. Following the conclusion of this preliminary review the AMD will provide a report to the Interim Director of Acute Services and the Medical Director.

In order to undertake this preliminary review the Associate Medical Director for Surgery and Elective Care will have access to all notes and staff whom he deems appropriate.

September 10

Southern Health and Social Care Trust

Quality Care - for you, with you

Process to review all cases of people currently and intermittently receiving IV fluids and antibiotics for recurrent UTIs.

Steps required:

- Each patient who is currently on a regular or intermittent regime of IV antibiotics to have a case review, in order to agree a management plan which may require oral antibiotics but not IV antibiotics and not regular admission as an inpatient.

- The case review meeting will be chaired by Ms S Sloan, Clinical Director for Surgery & Elective Care, and minuted by Mrs M Corrigan, Head of Urology. The relevant urologist will present each case and Dr Damani, Consultant Microbiologist, will provide expert advice on appropriate antimicrobial therapy.

- If agreement cannot be reached for a particular patient on oral therapy, a further meeting will be held to involve Mr E Mackle, Associate Medical Director for Surgery and Elective Care, and involving the same team as before.

- Please note that there are unlikely to be circumstances accepted by the Commissioner or the Southern Trust where the use of IV fluids and antibiotics is an evidence based or acceptable treatment for a patient with recurrent UTIs.

9th September 2010

Southern Health and Social Care Trust

Quality Care - for you, with you

Urology Pathways

Recurrent Urinary Tract Infections

Step 1 Nurse Led Service

Urine cultures- frequency to be determined by Consultant Nurse to obtain and monitor results and liaise with Consultant regarding any change to pathway including frequency of sample.

Oral antibiotic regime prescribed and altered by Consultant Urologist as per culture with input when necessary from Bacteriology

Step 2

If the symptoms cannot be controlled through Step 1, a case discussion is required involving:

- Consultant Urologist
- Consultant Microbiologist
- Specialist Nurse
- Clinical Director for Surgery and Elective Care

Under no circumstances is central venous access to be used for treatment of recurrent UTIs.

9th September 2010

Southern Health and Social Care Trust

DIRECTORATE OF ACUTE SERVICES
Interim Director: Dr Gillian Rankin
Tel: 38-612510

MEETING RE IV FLUIDS AND ANTIBIOTICS AND CYSTECTOMIES

Date: Thursday 9th September 2010
Time: 5.00 pm
Venue: Meeting Room, Admin Floor

NOTES FROM MEETING

1. Dr Rankin and Mr Mackle outlined the issue raised by Dr D Corrigan's letter (Commissioner) to Dr Loughran regarding the continued use of IV fluids and antibiotics for patients with recurrent UTIs. The statement in the letter that the use of central venous access for such therapy would be of serious concern was discussed.

2. A statement setting out a case review process chaired by Ms Sloan, Clinical Director of SEC, involving Dr Damani, consultant Microbiologist was tabled. Mr Young agreed to be involved in this process of clinical review of each of their patients currently or intermittently receiving IV fluids and antibiotics. The process will commence in the next few days, reviewing those with central venous access as a priority.

3. A pathway outlining the treatment of people with recurrent UTIs by oral therapy was tabled. The pathway outlines that if there is future consideration of IV fluids/antibiotics there requires to be a case review as outlined in paragraph 2 above.

4. The further issue raised by the Commissioner of the disproportionate rate of cystectomy undertaken in Craigavon Area Hospital was set out by Dr Rankin and Mr Mackle. A statement setting out the screening process which the Trust proposes to commence was tabled. The results will be made available to Mr Young when the screening is complete.

5. Mr Young offered to provide a case summary of each patient in the last 10 years for whom cystectomy had been performed. Mr Mackle thanked Mr Young for the offer but replied that he needed to review each case by casenote review and as needed seek the engagement of an independent expert.

Southern Health and Social Care Trust

DIRECTORATE OF ACUTE SERVICES
Interim Director: Dr Gillian Rankin
Tel: Personal Information redacted by the USI

MEETING RE IV FLUIDS AND ANTIBIOTICS AND CYSTECTOMIES

Date: Thursday 9th September 2010
Time: 6.00 pm
Venue: Meeting Room, Admin Floor

NOTES FROM MEETING

1. Dr Rankin and Mr Mackle outlined the issue raised by Dr D Corrigan's letter (Commissioner) to Dr Loughran regarding the continued use of IV fluids and antibiotics for patients with recurrent UTIs. The statement in the letter that the use of central venous access for such therapy would be of serious concern was discussed.

2. A statement setting out a case review process chaired by Ms Sloan, Clinical Director of SEC, involving Dr Damani, consultant Microbiologist was tabled. Mr O'Brien stated that patients may become less well as a result of withdrawal of IV antibiotics. He agreed to remove the PICC line in a patient who is due to have surgery in 2 week's time. The process of case review will commence in the next few days, reviewing those with central venous access as a priority.

3. A pathway outlining the treatment of people with recurrent UTIs by oral therapy was tabled. The pathway outlines that if there is future consideration of IV fluids/antibiotics there requires to be a case review as outlined in paragraph 2 above.

4. The further issue raised by the Commissioner of the disproportionate rate of cystectomy undertaken in Craigavon Area Hospital was set out by Dr Rankin and Mr Mackle. A statement setting out the screening process which the Trust proposes to commence was tabled. The results will be made available to Mr O'Brien when the screening is complete.

5. Mr O'Brien stated that he would not wish to meet Mr M F under any circumstances and that he hoped that another urologist would be found if an independent expert was required.

Southern Health and Social Care Trust

Medical Directorate

15th September 2010 Ref: PL/AB/lw

Dr Diane Corrigan
Public Health Agency
South Office
Tower Hill
ARMAGH
BT61 9DR

Dear Dr Corrigan

UROLOGY at Craigavon Area Hospital

Thank you for your letter dated 1st September 2010 in relation to the above.

IV Therapy (IVT)

It is true that this has not ceased. Despite my understanding that this would be ceased under the guidance of a Multi-Disciplinary Team, in early 2010, I now understand that a smaller number of the original cohort continue to receive the therapy.

About 10 patients were identified, 3 of whom had central or long peripheral line for the sole purpose of this treatment. Dr Rankin and Mr Mackle have now identified each patient on IVT. I have been reassured that the 2 surgeons in charge of these patients have accepted the need to cease the therapy and they have agreed to follow the process which is included with this letter and dated 9th September 2010 (Appendix A).

I will be informally provided with a progress report each week and a formal written report on the last Thursday of each month until all IVT has ceased. No further patients can be commenced on this treatment and under no circumstances can central venous access be used for treatment of recurrent urinary tract infections (Appendix B).

Cystectomies

In relation to the cystectomies our Chief Executive convened a meeting on 9th September 2010. At that meeting it was agreed that we would initially look at the last 10 years data in relation to cystectomy or ileal conduit as the primary procedure. Individual charts under those criteria will be reviewed by the Associate Medical Director (AMD) Mr Mackle, to confirm that we are working from an accurate data base.

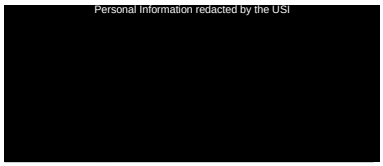
Cont'd. ……

When the appropriate charts have been identified Mr Mackle will enlist an expert to assist him in deciding exactly what the indication for surgery was.

In order that the surgeons concerned with these patients are fully informed, a remit for this local review was agreed and I have attached it as Appendix C. This remit was shared with the 2 urological surgeons concerned. Advising the surgeons of the review and sharing the terms of Mr Mackle's responsibility is in keeping with good practice. (Maintaining High Professional Standards in the Modern HPSS November 2005).

In response to your e-mail dated 9th September 2010 I can confirm that there are definite arrangements in place to ensure that no further radical pelvic surgery cases are completed at the Trust. I understand that you discussed this with Dr Gillian Rankin on 15th September 2010.

Yours sincerely



Dr Patrick Loughran
Medical Director

Encs

Strictly Private and Confidential

Clinical Issues in Urology Service
Briefing Note for Trust Board Confidential

Background on IV Fluids and Antibiotics

The clinical practice of managing recurrent urinary tract infections (UTIs) by intravenous (IV) fluids and antibiotics has become part of local urological practice over many years. This was discovered in Spring 2009 during an audit of bed usage, and was considered to be unusual. At that time the therapy was discussed with the clinicians involved and the Trust subsequently took expert advice and was persuaded that this therapy is not evidence based. About 35 patients were in the cohort, and following discussions with the commissioner, the Director of Acute Services at that time, and the clinicians, it was agreed that each member of the cohort would be reviewed with a view to ceasing IV therapy.

This patient group, who have repeated episodes of therapy, ultimately become difficult with regard to venous access. This may result in the need for placement of a central venous line as the only alternative for IV therapy. This procedure carries risks in that the line is left inserted semi-permanently. Equally the patient has difficult peripheral venous access.

The cohort of patients who have received this method of treatment has been reduced considerably to approximately 10 since January 2010.

Current Action

The Trust received a letter from the Commissioner seeking an assurance that this treatment had ceased and that no patient had central venous access. The Director of Acute Services and Associate Medical Director of Surgery and Elective Care have met the two surgeons individually to require an immediate review of each patient in the remaining cohort of 10. The review will be chaired by the Clinical Director of Surgery and Elective Care and will also involve Dr Damani, Consultant Microbiologist, to advise on optimum antimicrobial therapy. All potential future patients for IV therapy will also be reviewed in this manner. Both surgeons agreed to participate in this process which is now underway.

Strictly Private and Confidential

Background on Cystectomies

The Commissioner has also drawn to the Trust's attention to a slightly increased rate of cystectomy for benign pathology in CAH when compared with the rest of the NI region. Cystectomy is the surgical excision of bladder. The numbers of patients identified are of the order to 2-4 per year.

Current Action

In line with guidance provided by the document "Maintaining High Professional Standards in the HPSS" the Trust has commenced a local review. This process includes a case note review of each patient who has undergone cystectomy in the past 10 years. The review will be undertaken by the Associate Medical Director for Surgery and Elective Care, who also has a remit to seek professional advice from an appropriate expert.

The result of this screening review will guide the next step – no further action or the requirement for a deeper investigation.

In keeping with best practice the 2 clinicians have been kept fully informed.

Regional Urology Review

One of the requirements of the implementation of the review is that all radical pelvic urological surgery is moved to the Belfast Trust. This now explicitly covers radical pelvic surgery for both malignant and benign conditions. The Trust is in discussion currently with HSCB and Belfast Trust regarding each individual case during the transition period.

Dr Gillian Rankin
Interim Director of Acute Services
September 2010

Southern Health and Social Care Trust

Quality Care - for you, with you

Minutes of the confidential meeting of the Board of Directors held on Thursday, 30th September 2010 at 10.00 a.m. in the Boardroom, Daisy Hill Hospital, Newry

PRESENT:

Mrs A Balmer, Chairman
Mrs M McAlinden, Acting Chief Executive
Mrs D Blakely, Non Executive Director
Mrs R Brownlee, Non Executive Director
Mr E Graham, Non Executive Director
Mr A Joynes, Non Executive Director
Mrs H Kelly, Non Executive Director
Mrs E Mahood, Non Executive Director
Dr R Mullan, Non Executive Director
Mr B Dornan, Director of Children and Young People's Services/Executive Director of Social Work
Dr P Loughran, Medical Director
Mr S McNally, Acting Director of Finance and Procurement

IN ATTENDANCE:

Dr G Rankin, Interim Director of Acute Services
Mr K Donaghy, Director of Human Resources and Organisational Development
Mrs P Clarke, Acting Director of Performance and Reform
Mrs A McVeigh, Acting Director of Older People and Primary Care
Mrs J Holmes, Board Secretary
Mrs R Rogers, Head of Communications
Mrs S Judt, Committee Secretary (Minutes)

1. APOLOGIES

Apologies were recorded from Mr F Rice, Director of Mental Health and Disability Services/Executive Director of Nursing.

2. **MINUTES OF PREVIOUS MEETING**

The minutes of the meeting held on 26th June 2010 were agreed as an accurate record and duly signed by the Chairman.

3. **MATTERS ARISING**

Irrelevant information redacted by the USI

[redacted]

4.

5.

6. Irrelevant information redacted by the USI

7. **CLINICAL ISSUES IN UROLOGY SERVICE**

Dr Rankin outlined the clinical issues in the Urology Service as detailed in the briefing note and the action being taken:-

IV Fluids and Antibiotics

An immediate review is underway of a cohort of 10 patients who are receiving IV therapy.

Cystectomies

The Commissioner had drawn to the Trust's attention a slightly increased rate of cystectomy for benign pathology in Craigavon Hospital compared with the rest of the NI region. The Associate Medical Director for Surgery and Elective Care has commenced a review, which includes a case note review of each patient who has undergone cystectomy in the past 10 years.

Regional Urology Review

One of the requirements of the implementation of the review is that all radical pelvic urological surgery is moved to the Belfast

ANNUAL APPRAISAL 2010 MR. AIDAN O'BRIEN

FORM 4 - SUMMARY OF APPRAISAL DISCUSSION WITH AGREED ACTION AND PERSONAL DEVELOPMENT PLAN

The aim of this section is to provide an agreed summary of the appraisal discussion based on the documents listed on **Form 3** and a description of the action agreed in the course of the appraisal, including those forming the personal development plan.

This form should be completed by the appraiser and agreed by the appraisee. Under each heading the appraiser should explain which of the documents listed in **Form 3** informed this part of the discussion, the conclusion reached and say what if any action has been agreed.

SUMMARY OF APPRAISAL DISCUSSION

1. Good medical care

Commentary:

Aidan qualified in 1978, holds full GMC registration and has been in the same Consultant Urologist post since 1992. He is a Fellow of the RCS in Ireland, and is a member of several general and urological societies. Description of his job reflects a broad urological practice. This includes MDM oncology involvement and a special interest in lower urinary tract dysfunction. Current rota is 1:3. The population base covered is geographically wide, and hence patients are from both urban and rural backgrounds.

A log of individual list of operations performed for 2008, 2009 and 2010 is impressively long, defining a constant and hard working pattern.

No formal complaints nor critical incidents are logged by the Trust. The Trust however has had discussions with reference to patients being treated with IV fluids and antibiotics. This has been satisfactorily concluded.

An audit of prostate biopsy outcomes is recorded. Several of the hospital mandatory courses have been attended.

Action agreed: For next appraisal

- log of total volume of outpatient activity, day cases and operations.
- audits in current time frame
- log Defence Organisation
- formally log mandatory courses

8. Any other points

Aidan is the Principal Investigator at Craigavon Area Hospital of an international study into a new drug treatment for Angiomyolipoma (Ref 09/H0502/82).

IV fluids/Antibiotic issue

Aidan has regarded the changes resulting from the ward reconfigurations of 2009 as particularly disruptive, since it had taken many years to build and had predicted the deleterious effects of such changes. Eventual restoration to a definitive urology unit has been a very important point, and for the Trust to recognise this precise point.

A further major change in practice has been the centralisation of radical pelvic cancer surgery imposed by the Department of Health. This has resulted in the loss of this provision at Craigavon Area Hospital, and negative consequences for patients. There is general discontentment in the decision making process conducted by the recent Regional Review of Urology. Aidan has concerns that this will have significant knock on effects for services in the area in the future.

Action agreed:

IV fluids/Antibiotic issue has been improved by a new care-pathway defined by the Trust.

A. Yes.

228 Q. Was it your understanding that clearly based on that, there was a resistance to adopt the new process that had been put in place, presumably as clinically appropriate but also as a safety valve? 14:14

A. Yes, there definitely was resistance and it was very difficult to completely eradicate this. I think by the autumn of 2010, we had it largely eradicated. We put in place a couple of strands of work. One was the multidisciplinary approach involving Dr. Damani and the 14:14 Clinical Director, of whom there were three in succession who handled this. We also, aligned to that, asked the ward to identify to Mrs. Corrigan if they knew of a patient who had a planned admission for IV antibiotics. So, that became an action that was put in 14:14 place so we were aware then if there was a planned admission and we could then take appropriate action to ensure that there had been a multidisciplinary discussion and, if not, there was one put in place.

14:15

The other main action that we put in place was a new pathway agreed with Mr. O'Brien and the other two consultants, that there would be a community pathway for oral antibiotics which then the patients went through. 14:15

Set against that, part of the dilemma here was that some of these patients had actually become dependent on this as a treatment that they actually phoned looking

21. It is my view that, that an independent review process would have been considerably more robust had the Trust provided the independent reviewers with an opportunity to consult with the clinicians who managed these patients who would have accurately informed the experts of the reason and purpose of their management. It remains incomprehensible to me how any responsible clinicians could deny to patients an effective form of treatment to prevent their worsening conditions requiring their acute admissions for the same treatment for longer periods of time, all other usual preventative treatments having been found to be ineffective. In that regard, I found it concerning that Dr Loughran could advise that "*admission to the ward is possible but only if outpatient or day case management fails – usually in cases of severe sepsis*" [PHA-00174].

22. It is also concerning that Dr Corrigan et al did not appreciate that radical pelvic urological surgery was a term used throughout the world to refer to surgery for malignancy, such as radical cystectomy and radical prostatectomy [PHA-00453]. The use of the adjective 'radical' by the urologists working in the Southern Trust was not sophistry, nor was it due to a lack of common sense as she attributed to us [PHA-00490]. Instead, she instructed that simple cystectomy would no longer be performed in the Southern Trust before she had even validated the data, never mind attempting to understand the reasons for simple cystectomies being performed.

23. I believe that the manner in which these issues were addressed was an example of personnel providing opinions and making decisions without being fully informed and, more importantly, without having any intent or making any effort to be fully informed by consulting with the clinicians directly involved in the issues, and most importantly, consulting with the patients directly involved.

And Dr. Damani agreed that he would provide microbiological support for Items B and C.

Now, is that your understanding of the step that was taken... 12:03

A. Yes.

96 Q. In meeting with the two of you?

A. Yes. Yes.

97 Q. Did that microbiology group or that multi-disciplinary group meet? 12:03

A. No.

98 Q. Between 2009 and 2010?

A. No. I don't think we ever met. I think that what we had to do as clinicians was to consult with the Clinical Director and to consult with a microbiologist, 12:03 not necessarily Dr. Damani, but his colleague as well, if we wanted to electively admit. I think actually the need for a multi-disciplinary team meeting was very much obviated by the establishment of Shirley Tedford, who was our ward manager, as a person who would manage 12:04 these patients on all our behalves, as it were, insofar as it was possible for her to do.

99 Q. So that was to be the arrangement that these, this current cohort of patients were to be the subject of scrutiny with microbiology. 12:04

A. Mmm.

100 Q. When you think about it now, Mr. O'Brien, should this intervention, this form of therapy, have been pursued by you without seeking the approval of your employer?

A. I think actually we saved lives by it, quite frankly. If we had sought approval we may not have had it approved and people would have died, I've no doubt. I can name those who would have died. So it wasn't the intent at the time, but the old adage sometimes, it's better to seek forgiveness than to seek permission.

101 Q. Is that the long way around of saying that you would have understood the process at the time should have been to seek approval for a form of treatment that wasn't commissioned and wasn't recognised, before doing it, but the benefit of not seeking permission was the outcomes that you refer to? 12:05

A. No, prospectively it never crossed my mind to seek permission.

102 Q. Yes. Looking back on it now, I think you're recognising that you should have? 12:06

A. Not necessarily.

103 Q. Well, I think the Panel would appreciate a straight answer to a straight question. Given your understanding of the norms of the time, before engaging in therapy for patients that wasn't commissioned and didn't belong on any recognised patient care pathway, should you have sought permission before engaging on it? 12:06

A. Ehm, well, when you frame it in that way, yes. I think that patients would have suffered and patients would have died as a consequence, and I've no doubt about that. 12:06

104 Q. July 2010, Mrs. Corrigan provides Mrs. Rankin,

Journal of Infection (2011) xx, 1–3

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LETTER TO THE EDITOR

Preliminary assessment of regular short-term intravenous fluids and antibiotic therapy in recurrent UTI

Dear Sir,

We read with interest on the article by Falagas et al., concerning antibiotic treatment in women with uncomplicated cystitis.[1] In this context, the management of recurrent urinary tract infection (rUTI) remains a therapeutic challenge. Within our department, we have identified a cohort of patients with rUTI, who have had multiple emergency admissions for severe rUTI episodes requiring intravenous fluid and antibiotic therapy. For years, these patients have been treated appropriately with multiple oral antibiotics treatment and prophylactic antibiotic courses by their GP, but with little success since their symptoms, in particular nausea and generally unwell being, have prevented compliance to oral antibiotic therapy and adequate oral rehydration. As a consequence, their condition deteriorates and inevitably leading to the need for emergency hospital admission.

Over their multiple emergency admissions, we have evolved our treatment strategy to electively administer a combination of short-term intravenous fluids and antibiotics therapy (IVT) regularly to this cohort. The duration of admission for treatment varied dependent on the patient's treatment response and usually ranges between 3 and 5 days. In this select cohort, their nausea symptoms have prevented adequate oral rehydration and hence about 1–2 L per day of intravenous fluid were administered during admission. The antibiotic choice used during IVT is dependent on the most recent MSSU culture sensitivity. When IVT is completed, further oral antibiotics are not given. The rationale for this strategy is to adequately treat any underlying UTI completely prior becoming symptomatically severe and therapeutically difficult to manage. This cohort of rUTI patient usually became symptomatic about 3 months after their emergency admission for severe UTI. The frequency and duration regime is not fixed, but rather flexibly adapted according to patient's symptoms. The intention is to gradually prolong the regularity of this regime, for example every 3 monthly, then 6 monthly and gradually yearly. The ultimate aim is help these rUTI patients achieve independence from IVT and yet maintain a reasonably good quality of life. We report our experience with regular short-term intravenous fluids and antibiotic therapy (IVT) as an adjunctive treatment.

A retrospective cohort analysis was done on 16 patients with rUTI on IVT, and was followed up for an average of 100 months. There were 11 female and 5 male patients with the mean age of 41.2 (SD $\pm$ 15.9) years. Five patients have ileal conduit/urostomy, 2 patients had long-term suprapubic catheter, 4 patients perform ISC, 1 patient has a Mitrofanoff formation and the remaining patient without significant comorbidity. In all patients, extensive and comprehensive investigations have been performed to exclude any urologically treatable conditions that predispose to rUTI. Comparative assessments included emergency admission, urinary culture, antibiotic usage, SF-36 and FACIT-TS quality of life questionnaires, between the period before and during IVT.

There were a total of 206 of IVT admission episodes contributing to a total of 934 days and a mean duration of hospital stay per admission of 4.7 days. The mean duration between each IVT admission was 2.9 months. The number of emergency admission (88 vs 16, $p = 0.001$, X_2) and outpatient clinic reviews (216 vs 5, $p = 0.001$, X_2) have decreased significantly. The IVT for elective admissions predominantly utilised Gentamicin, followed by Co-amoxiclav as shown in Table 1. Similarly in the emergency admissions, intravenous Gentamicin and Co-amoxiclav were the antibiotic of choice. In the outpatient or GP practice setting, the predominant oral antibiotics used were Trimethoprim followed by Ciproxin and Cefelexin. A total of 1050 MSSU culture and direct microscopic results were obtained. Majority of MSSU are obtained at GP setting as shown in Table 2. The most common cultured uropathogen was coliforms, followed by mixed growth, Enterococcus faecalis, Proteus and Pseudomonas. There was significantly more mixed growth culture results obtained during the IVT period comparatively (14.8% vs 4.2%). There was a decreased in ESBL cultures during IVT treatment. Otherwise, the IVT did not significantly change the proportion of the colonising uropathogen type cultured.

There was a complete response rate of 100% to the SF-36 QoL and FACIT-TS questionnaire. The overall negative impact of rUTI on the QoL confirmed the debilitating nature of the disease. There are statistically significant

0163-4453/$36
doi:10.1016/j.jinf.2011.08.010

Please cite this article in press as: Koo V, et al., Preliminary assessment of regular short-term intravenous fluids and antibiotic therapy in recurrent UTI, J Infect (2011), doi:10.1016/j.jinf.2011.08.010

Table 1 Frequency and type of antibiotic usage.

Antibiotic therapy	IVT admission	Emergency admission	OPD & GP
Intravenous			
Gentamicin	45.5%	40.5%	–
Co-amoxiclav	36.8%	38.1%	–
Ciprofloxacin	6.4%	4.8%	–
Cefuroxime	6.4%	9.5%	–
Meropenem	2.3%	2.4%	–
Cefutaxime	1.8%	0	–
Teicoplanin	0.05%	2.4	–
Vancomycin	0.05%	0	–
Netilmicin	0	2.4%	
Oral			
Trimethoprim	–	–	43.9%
Ciprofloxacin	–	–	35.2%
Cefelexin	–	–	10.9%
Co-Amoxiclav	–	–	5.5%
Nitrofurantoin	–	–	3.3%
Ampicillin	–	–	1.1%

improvements after being on the IV regimen in six of the SF-36 domains including the physical functioning (52.3 vs 35.4, $p = 0.05$), social functioning (51.6 vs 27.3, $p = 0.01$), physical role limitation (37.5 vs 4.7, $p = 0.01$), emotional role limitation (58.3 vs 24.9, $p = 0.04$), bodily pain (53.6 vs 30.5, $p = 0.03$) and vitality (42,5 vs 21.9, $p = 0.002$). The FACIT-TS showed an overall treatment satisfaction score of 81.5% and a treatment recommendation score of 95%. There were 3 recurring themes of commentaries from patients via FACIT-TS, and they were: i) IVT is effective, more so than oral antibiotics ii) IVT has significantly improved their quality of life and reduced the rate of emergency hospital admissions iii) IVT would be much better if given in a non-hospital admission setting.

Because the major cost burden was incurred from inpatient hospital stay, one alternative solution is to develop IVT into an outpatient treatment, also known as Outpatient Parenteral Antibiotic Therapy (OPAT) or to develop a home intravenous antibiotic treatment.[2,3] OPAT and home intravenous antibiotic in various infectious conditions has been shown to be clinically efficacious and cost-effective in the United Kingdom National Health Service setting and the Australian healthcare system respectively. Administration of IVT through OPAT represents a potential economically viable option. Further, the carefully selected rUTI patients undergoing IVT are relatively well and require minimal clinical observation.

From our preliminary results, we conclude that IVT is beneficial for a carefully selected patient with rUTI and their treatment should be individually tailored. We do not claim to know the optimal duration of treatment and

Table 2 Admission and urinary culture data.

	Before IVT	During IVT	*p*-value
Mean duration of follow-up (months)	67.1	32.9	–
No. of emergency admission episodes	86	18	0.001, X_2
Mean duration of emergency episode (days)	5.6	5.8	NS
No. of OPD episodes	208	5	0.001, X_2
MSSU culture			
Not significant $<10^4$	219 (40%)	186 (37.0%)	–
No growth	73 (13.3%)	54 (10.7%)	–
Coliforms	145 (26.5%)	80 (15.9%)	–
Mixed growth	23 (4.2%)	74 (14.8%)	–
Enterococcus faecalis	40 (7.3%)	34 (6.8%)	–
Proteus	6 (1.1%)	29 (5.8%)	–
Pseudomonas	11 (2.0%)	16 (3.2%)	–
Escherichia Coli	5 (0.9%)	15 (2.9%)	–
Klebsiella	7 (1.3%)	4 (0.8%)	–
ESBL	8 (1.5%)	2 (0.4%)	–
Enterococcus faecium	2 (0.4%)	4 (0.8%)	–
Enterococci spp.	2 (0.4%)	1 (0.2%)	–
Staphalococcus aureus	2 (0.4%)	2 (0.4%)	–
Candida albicans	2 (0.4%)	0	–
MRSA	0	1 (0.2%)	–
Streptococcus Group A	2 (0.4%)	0	–
Streptococcus Group B	0	1 (0.2%)	–
MSSU origins			
Elective	–	213 (42.3%)	–
Emergency	109 (19.9%)	22 (4.4%)	–
OPD	86 (15.7%)	0	–
GP	352 (64.4%)	268 (53.3%)	–

NS – not statistically significant.

Please cite this article in press as: Koo V, et al., Preliminary assessment of regular short-term intravenous fluids and antibiotic therapy in recurrent UTI, J Infect (2011), doi:10.1016/j.jinf.2011.08.010

regularity of IVT regime, but suggest that it should be adapted to patient's condition. It is hoped that this report will serve as a pilot assessment of its efficacy and proof of concept to allow for future randomised trials.

Funding

None obtained.

Competing interest statement

None declared.

Acknowledgement

The authors would like to thank Mrs Anne Quinn from the Audit Department and Mrs. Monica McCrorry from the Department of Urology in Craigavon Area Hospital, for their assistance in the facilitation of this audit project and the preparation of medical notes.

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Accepted 16 August 2011

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Please cite this article in press as: Koo V, et al., Preliminary assessment of regular short-term intravenous fluids and antibiotic therapy in recurrent UTI, J Infect (2011), doi:10.1016/j.jinf.2011.08.010

Infection to which you, Mr. Young, and Vincent Koo put your names, essentially presented an argument based on your experience in favour of the IV fluid and antibiotic treatment of this cohort of patients with chronic or recurrent UTI, and that was published in circumstances where, ringing in your ears was the Trust's view that it could not endorse this treatment in the way that it was performed by you and Mr. Young. The Commissioner was not lending its support to it, and internally you knew of the opposition of the microbiologists. You're familiar with the expression "two fingers", was this you and Mr. Young giving two fingers to the organisation by publishing this article? 12:31 12:31

A. That's amazing! Absolutely not. What we were doing, in fact... 12:31

122 Q. Sorry, what's amazing about it?

A. Because it never occurred to me that that was even -- that never crossed my mind that we were putting two fingers up to everybody who had their concerns. Not at all. I'm just -- my apologies for the reaction, it's just that didn't occur to me. Vincent Coe was a very talented specialist registrar who published a number of papers whilst he was with us, and is a consultant in England, and all we did actually was -- I'm quite a disciplinarian when it comes to publication, because what we were doing was reporting our experience. It wasn't actually promoting anything. It wasn't expecting the rest of the world to agree with us. We reported our experience, and we reported the efficacy 12:32 12:32

of it, and we particularly reported on the fact that it had not been associated with the emergence of any antibiotic resistance. So it wasn't done in any shape or form to -- I mean we do have academic freedom to report in good faith, accepted by a reputable journal, our experience, and that's what we did.

123 Q. But you didn't report within your article the opposition to your approach?

A. No.

124 Q. The well, some might argue, the well-founded arguments against it or the dangers of the approach? 12:33

A. I can't -- it's some time since I have read it, but we simply reported our experience. And the only, the only word I would change is that in the title again "UTI", because I think it has minimised in the perception of the person who may read the title and not bother to read the actual article or the letter, that we were doing something that was rather extreme for simple recurrent urinary tract infections. 12:33

125 Q. Could I just bring together three further strands of evidence and seek your view on them collectively in the interests of time. Mr. Mackle wrote to you on 15th June 2011. If we could have on the screen, please, TRU-281944, and he is explaining that he has found that you initially plan to admit a patient this week without having discussion with anyone, and then when challenged you only spoke to a Dr. Rajadran, who I assume is part of the microbiology team. Could I invite your answer to that as well as a number of other examples of 12:34 12:34

Maintaining and improving standards of care

Reflecting on your practice

All medical professionals

22. You should regularly reflect on your own performance, your professional values and your contribution to any teams in which you work. You should ask for, and be prepared to act on, feedback from colleagues and patients, including through the outcomes of audits, appraisals and performance reviews (see paragraphs 30 - 32), and through patient complaints and comments.

Medical professionals with extra responsibilities

23. Leading by example, you should promote and encourage a culture that allows all staff to contribute and give constructive feedback on individual and team performance. You should make sure that systems are in place to achieve this.

Ensuring high standards of care

24. Early identification of problems or issues with the performance of individuals, teams or services is essential to help protect patients.

All medical professionals

25. You must take part in regular reviews and audits of the standards and performance of any team you work in, taking steps to resolve any problems.

26. You should be familiar with, and use, the clinical governance and risk management structures and processes within the organisations you work for or to which you are contracted. You must also follow the procedure where you work for reporting adverse incidents and near misses. This is because routinely identifying adverse incidents or near misses at an early stage, can allow issues to be tackled, problems to be put right and lessons to be learnt.

27. You must follow the guidance in *Good medical practice* [5] and *Raising and acting on concerns about patient safety* [4] when you have reason to believe that systems, policies, procedures or colleagues are, or may be, placing patients at risk of harm.

Medical professionals with extra responsibilities

28. If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering

Medical professionals with extra responsibilities

82. If you are responsible for managing resources, or commissioning or delivering health services, you should have detailed knowledge of how management processes work and how they affect the delivery of patient care.

83. You must make sure that you are competent and have the necessary training or advice for any financial responsibilities that are part of your role. You must make sure that those you manage have the necessary skills and advice to fulfil their roles.

Allocating resources

84. All medical professionals must make the care of patients their first concern. However, the treatment options that can be offered to patients may be affected by limits on resources.

All medical professionals

85. If you make decisions about access to treatments on a case by case basis, without referring to agreed policy or guidelines, you risk introducing elements of unfair discrimination or may fail to consider properly the patient's other legal rights. When making decisions about using resources, you must do the following.

1. Provide the best service possible within the resources available, taking account of your responsibilities towards your patients and the wider population.
2. Be familiar with any local and national policies that set out agreed criteria for access to a particular treatment.[21]
3. Make sure that decisions about setting priorities that affect patients are fair and based on clinical need and the likely effectiveness of treatments, and are not based on factors that may introduce discriminatory access to care.[22]
4. Be open and honest with patients[23] and the rest of the healthcare team about the decision-making process and the criteria for setting priorities in individual cases.

86. You should involve colleagues, including other healthcare professionals, in discussions about how to allocate wider resources. If issues or disputes about allocating resources arise, you should try to sort them out by discussing options with, for example, patients, the healthcare team, other colleagues (including other health and social care professionals) and managers. You should be open and honest with patients when resource constraints may affect the treatment options available.[24]

Medical professionals with extra responsibilities

87. If you have a management role or responsibility, you will often have to make judgements about competing demands on available resources. When making these decisions, you must

laboratories, hospital support services such as patient and staff food, domestic and portering and decontamination services.

1.2 Issues in relation to the urology service were raised with me on my first day in post i.e., 1st December 2009. This was through a meeting chaired by the Chief Executive, which alerted me to the current and on-going issues. The regional Review of Urology had reported but was not yet signed off by the Minister. The development of the Implementation Plan for Team South Urology had commenced and I subsequently chaired a weekly /fortnightly meeting with the consultants involved to get agreement on the implementation plan and its implementation.

1.3 In early 2010, I commenced a weekly performance meeting with the full system of Assistant Directors (ADs) and Heads of Service in order to lead the weekly review of how each specialty was delivering on the various clinical elements of the Integrated Elective Access Protocol. This required 'deep dives' by services in terms of data and ensured a daily focus on delivering the activities required by the commissioner, HSCB, and agreed in the Service and Budget Agreement.

1.4 In early 2010, I also commenced two meetings on governance. These were both held monthly. One of these included the Associate Medical Directors and ADs in a review of all the data used in the governance of services. The second meeting included the ADs and used the same reports with a deeper review of the data updated to the previous month.

1.5 These processes of regular meetings reviewing reports and data on both performance and governance provided collective energy and held the system to account in a supportive system for delivery of safe and high quality care. The emphasis was on quality improvement and learning from mistakes and this was evidenced through the Trust Review of Clinical and Social Care Governance led by the Chief Executive in 2010.

1.6 With regards to urology there were several issues regarding the service and some specific issues in relation to a single consultant. The key issues for the service

with each consultant. *Relevant document located at Relevant to Acute, Evidence Added or Renamed 19 01 2022, Acute, Retired Staff, Dr Gillian Rankin, 20101206 Uro Issues re Long Wait Pts*

28.3 Specific meetings not held on a regular basis included the following:

a. 1 December 2009 meetings re range of governance issues chaired by the Chief Executive, with the Medical Director, AMD, AD, Acting Director of Performance and Reform, AD of Performance, Interim Director of Acute Services. The range of issues on the agenda included:
    i Demand and capacity and the need to optimise the use of clinical sessions;
    ii Quality and safety - Medical Director to discuss with Mr Fordham seeking an urgent professional opinion on:
        A The appropriateness and safety of the current practice of IV antibiotics;
        B Triage of referrals and 1 consultant refusing to meet the current standard of triaging within 72 hours;
        C Red flag requirements and 1 consultant refusing to adopt the regional standard that all potential standards require a red flag and are tracked separately;
        D Chronological management of theatre lists for theatre with 1 consultant keeping patients' details locked in the desk.
    iii Action agreed that if there was no compliance, correspondence would be sent regarding the implications of a referral to NCAS if appropriate clinical action was not taken. *The relevant document can be located in S21 No 8 of 2022, 58. 20091201 Uro Service Mtg Notes.*

b. 7 December follow up meeting with Mr Young, Consultant Urologist after 1 December meeting. Key points of discussion are set out. *Document located in Relevant to HR, reference no 35, 20091207 Ref35 - Meeting re Urology Service*

correspondence would be sent regarding the implications of a referral to NICAS if appropriate clinical action was not taken."

Now, they were the general issues that were brought to your attention. Was this information from the Chief Executive or was it from the Medical Director at the meeting? Can you recall the way in which the information -- was it just on an agenda and it was discussed generally, or did someone actually speak to a narrative of these issues at that point? 11:55 11:55

A. I don't recall the specifics of the meeting as to who was speaking to each issue. I'm sorry, I don't have that recall. It is first day, and baptism of fire.

123 Q. It certainly seems to be a very specific list of issues and we move on to the detail of some of that. Just in relation to point B, where it says "triage of referrals and one consultant refusing to meet the current standards of triaging within 72 hours", was that a reference to Mr. O'Brien, do you know? Did you know at that time or... 11:56 11:56

A. Almost certainly that was in reference to Mr. O'Brien.

124 Q. Was there any suggestion that rather than him refusing, that it was his view that he just simply was unable to meet referrals within 72 hours due to other competing clinical demands? Was there any context to that sentence at the meeting, or it was simply put forward as a refusal? 11:56

A. I don't recall, I'm sorry.

were the demand and capacity gap which was present and increased during my tenure in post. It was expected that this would be addressed both through the implementation of Team South Urology and through the improvement of clinical practices within the Trust.

1.7 The specific issues in relation to Mr O'Brien related to the need to change behaviour in relation to some clinical practices and some administrative practices. The range of issues included:

a. Triage of red flag referrals i.e., referrals of people with potential cancer and non-urgent referrals.
b. The scheduling of patients for surgery without due regard to urgency and chronological order.
c. The surgical operation of cystectomy.
d. The use of IV antibiotics for inpatients.
e. Referral of patients requiring prostatectomy or cystectomy to the Belfast Trust and the implementation of the regional MDM (Multidisciplinary Meeting) to discuss each patient with cancer and agree their treatment.
f. Service capacity gap which impacted on the waiting time for patients for outpatient clinics, day case surgery, inpatient surgery and review outpatient appointments; and breaches of the 31 day and 62 day standards for patients with diagnosed cancer.
g. Failure to read test results when received and before filing the patient notes, irrespective of whether the patient has an outpatient appointment booked.
h. Disposal of some patient notes and information in the bin of a consultant's office.

1.8 The details of these issues and all communications on these issues are set out in full detail in response to Questions 50, 57 and 67.

1.9 There were a considerable number of meetings, actions and decisions taken by myself and others to address all the issues. These are set out in detail in several

c. Cancer pathways: 14 day for breast cancer, and 31 and 62 pathways for all other cancers;
d. The review backlog numbers and trends.

29.10 Actions by specialty were identified at a high level for more detailed planning after the meeting.

[30] Were there any informal meetings between you and urology staff and management? If so, were any of these informal meetings about patient care and safety and/or governance concerns? If yes, please provide full details and any minute or notes of such meetings?

30.1 Virtually all meetings with urology staff regarding patient care and safety were scheduled meetings due to the need to identify a suitable time which did not impact on the consultants' clinical schedules. These meetings were scheduled with the urgency required and all are detailed in responses to other questions. The only two informal meetings that I can recall are detailed below.

30.2 These two meetings, which were not scheduled but which were required on an urgent basis, were as follows:

a. A meeting at my request of myself as Director, Mr Mackle as AMD and Mr O'Brien, Consultant urologist. The meeting took place at the end of a working day after Mr O'Brien had completed his main theatre list. I had been notified that day that Mr O'Brien had not been triaging his red flag referrals and was travelling to the BAUS Conference in Barcelona the following day. Mr Mackle and myself impressed on Mr O'Brien the requirement and importance of triaging red flag referrals. The permission to attend the conference the following day was refused unless the red flag referrals were triaged before travelling the following day. This resulted in the red flag referrals being triaged and Mr O'Brien travelled to the conference. I have no notes of this short discussion which took place in late April 2010. The red flag referrals continued to be

A. There was no doubt there was a great deal of co-working and cooperation. Whether it was to do with the general busyness of the fact that everybody was dealing with so many issues across the range of services, I can't really say why that didn't happen. I think it should have happened when I look back now and I see the range of issues, and perhaps that should have happened. I mean, we would have had many informal conversations about the Urology Service, and the consultant in particular. It's not that it wasn't known and wasn't in discussion. 16:14 16:15

377 Q. No.

A. But nobody said right, let's put this all down on the table, let's look at this in the round and see what we need to do. 16:15

378 Q. Who should have? Whose job was that, do you think?

A. It would have been a combination of the Medical Director and myself. Either one of us could have said 'time to do this'.

379 Q. Yes. 16:15

A. And neither of us did.

380 Q. Okay. Thank you very much.

CHAIR: I just have a couple of questions. One of the documents that we looked at earlier today was the letter of the consultants in response. I think it was January 2011, maybe, 18th January, about the ward issue. 16:15

A. Yes.

381 Q. I just wondered, the onus was then put on the

1.0 INTRODUCTION AND BACKGROUND

Mr Aidan O'Brien has been employed as a Consultant Urologist by the Southern Health and Social Care Trust from 6 July 1992. He was initially employed as a locum consultant from 31 August 1991.

On 16 June 2011, an incident was reported relating to the inappropriate disposal of confidential patient information normally filed in the patient chart. This was initially reported by a nursing assistant to Sharon McDermott, Ward Clerk who advised the ward sister and her line manager. The nursing assistant said that she had found the material in a confidential waste bin and she returned it to the ward clerk for filing in the patient's chart. The materials included fluid balance, Gentamicin charts, drugs kardexes, etc. The incident was reported to Shirley Telford (Ward Sister) and subsequently to Mr Eamon Mackle, Heather Trouton and Helen Walker.

Because of the seriousness of this allegation, a disciplinary investigation was undertaken. I, Mr Robin Brown, Surgical Director and Mrs Zoe Parks, Medical Staffing Manager were appointed to undertake this investigation.

3.0 ISSUE OF CONCERN/ALLEGATIONS

As a result of the investigation the allegation to be considered is:

That on 15 June 2011, Mr O'Brien disposed in the confidential waste a section of filing from a current patient's chart. This consisted of fluid balance charts, mews charts, TPN prescription forms, Aminoglycosides prescription form and a prescription kardexes.

4.0 FACTS & FINDINGS ESTABLISHED

The findings in relation to the allegations are listed below:

4.1 Zoe Parks and I met with Aidan O'Brien on the afternoon of 24th June 2011. I advised him that there had been a complaint made about the inappropriate disposal of patient confidential information and that the matter was being investigated under the Trust Disciplinary Procedure. I advised him that the material which he had disposed of was not unimportant and the matter was being considered as a case of misconduct. Mr O'Brien agreed that he had acted inappropriately and apologised for his behaviour. He agreed that the material which he had removed from the chart had been of value should a case arise and require subsequent investigation. Further he agreed that he would not act in a similar way in the future. Mr O'Brien went on to describe how he has the utmost respect for patient notes and how he takes a great deal of time filing, reorganising charts and writing lengthy notes in readable handwriting to make sure that there are good and clear patient records. He explained that the reason why he had removed the large amount of material was that the patient's chart had become so bulky that he found it difficult to retrieve important information from the chart and found it difficult to write in the chart. In the end however, he agreed that disposal of the material concerned was inappropriate and that it would not happen again.

Meeting with Shirley Telford 24 June 2011

Zoe Parks and I met with Shirley Telford on the morning of 24t June 2011. Shirley confirmed that materials had been found by a nursing auxiliary in the confidential waste and returned to Sharon (ward clerk) for filing in the patients chart. The materials included fluid balance charts, Gentamicin charts, drugs kardexes etc. Shirley felt that this sort of information would be of use, should there ever be a case of complaint or litigation or the requirement for root cause analysis. Shirley had challenged Mr O'Brien after talking to some of the other nurses and he admitted that he had disposed of the materials in the confidential waste. I invited Shirley to make any other further complaint that she wished to make, but she said that she had nothing further to add. I also

APPENDIX TWO

From: Tedford, Shirley
Sent: 27 June 2011 07:32
To: Parks, Zoe
Subject: meeting last friday

Zoe,

I have been thinking over the weekend about our meeting on Friday, if its not too late can I add something to the notes. I would like it recorded that when I emailed this information to Martina it was information and not as a direct complaint although this is how it has been dealt with.

Can you give me a ring if you haven't already met with Aoidan.

Shirley

From: Corrigan, Martina
Sent: 16 June 2011 15:56
To: Mackle, Eamon; Trouton, Heather; Walker, Helen
Subject: FW: Refiling of binned documents

As discussed

Martina

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

From: Tedford, Shirley
Sent: 16 June 2011 15:07
To: Corrigan, Martina; Scott, Jane M; McDermott, Sharon
Cc: Trouton, Heather
Subject: filing issue

Hi all,

I have spoken with staff at ward level and have ascertained that the person concerned was Mr O'Brien and he has admitted to disposing of the documentation in the bin. I have addressed the issue with him and pointed out that this information is a legal requirement and if there was cause eg RCA this is our evidence for proving the treatment the patient received by whom and when. He stated that as Fluid balance charts are not a legal document and they take up a lot of room in charts he would remove them as he had other bits he wanted to file.

I hope the fact that this has been highlighted to him will deter any future issues of this kind but it could potentially happen again, as Sharon has pointed out this is not the first time this has happened.
Shirley

5.0 CONCLUSION

The investigating team took into account the information provided by Mr O'Brien in relation to this matter and would conclude that the following allegation is proven.

That on 15 June 2011, Mr O'Brien disposed in the confidential waste a section of filing from a patient's chart. This consisted of fluid balance charts, mews charts, TPN prescription forms, Aminoglycosides prescription form and a prescription kardexes.

Mr O'Brien readily admits that he inappropriately disposed of patient information in the confidential waste. He readily admits that this was in error, that he should not have done it and will not do it again. I think that it is also important to note that Mr O'Brien says that he spends more time writing in and filing in charts than probably any other Consultant and from my own personal experience I can confirm that that is the case. Mr O'Brien has the utmost respect for patients, for their information and for the storage of records. This was an unusual behaviour which was the result of frustration from dealing with a large unwieldy chart, difficulties retrieving important information from the chart, and from the difficulty finding anywhere suitable to make good quality records.

The motivation for the incident was honourable in that Mr O'Brien was trying to make an entry in the chart, though the solution to the problem was clearly wrong. I am satisfied that Mr O'Brien has accepted his error and agreed that it will not happen again. I do not think that a formal warning is appropriate to the scale of the case and I would recommend an informal warning, this has effectively already taken place as part of the process.

Mr Robin Brown
Clinical Director
General Surgery

Mrs Zoe Parks
Medical Staffing Manager

the bullying allegation he alleges, we'll come on to in a moment, the context of Mr. Wolfe raising that with Mr. Mackle was to try and explore the possibility that, in some way, you or others who might have noticed some governance concerns, were perhaps blinded by Mr. O'Brien's reputation or his standing or his long tenure in Urology. Would you accept any of that?

A. I will accept that people who have a very good reputation clinically would be able to, to some extent, blind you a little bit for their shortcomings, I would agree with that, yes. 11:31

96 Q. And was that the occasion with you? Did you find you had difficulty or were perhaps, with hindsight, less robust in your investigations around this issue or other issues in relation to Mr. O'Brien than you might have been? 11:31

A. To some extent, I'll accept that, yes.

97 Q. Now, there wasn't any other issue around note disposal or anything on a par with this ever brought to your attention again? 11:32

A. No, I never heard of it happening again.

98 Q. Now, the second occasion that you refer to in your statement where you were asked to engage with Mr. O'Brien, if that's an example of a formal governance process, then this is, perhaps, an example of an informal process that you were involved in, and this occurred around June or July 2013. I'll just read from your statement at WIT-17526, at paragraph 24.3. You say: 11:32

6 ANALYSIS

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

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

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

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

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

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

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

Willis, Lisa

From: Mackle, Eamon
Sent: 16 November 2011 18:07
To: Trouton, Heather
Subject: Fw: Results and Reports of Investigations

Follow Up Flag: Follow up
Flag Status: Flagged

From: Rankin, Gillian
To: Mackle, Eamon
Cc: Corrigan, Martina; Trouton, Heather
Sent: Thu Sep 08 07:29:02 2011
Subject: RE: Results and Reports of Investigations

Dear all,

I am concerned that we have not been able to sort this one out yet despite trying to have a conversation with Mr O'Brien.

Heather I wonder if when you are meeting the 3 surgeons regarding speciality interests this whole area of how results are read when they arrive rather than waiting for review apt could be discussed.
The secretaries need to be given a brief as to what is expected of them and tis would need discussed and agreed.
Perhaps a protocol for secretaries is needed when there is not currently a system in place which I hope is not more widespread.
Can I leave it with you until ~I return?
Thanks,
Gillian

From: Mackle, Eamon
Sent: 26 August 2011 16:37
To: Rankin, Gillian
Cc: Corrigan, Martina
Subject: FW: Results and Reports of Investigations

Gillian

I have been forwarded this email by Martina and I think it raises a Governance issue as to what happen to the results of tests performed on Aidan's patients. It appears that at present he does not review the results until the patient appears back in OPD.

Eamon

From: Corrigan, Martina
Sent: 25 August 2011 16:22
To: Mackle, Eamon
Cc: Trouton, Heather
Subject: FW: Results and Reports of Investigations

Eamon,

I will need assistance when replying to this email.

Thanks

Martina

Martina Corrigan
Head of ENT and Urology
Craigavon Area Hospital

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

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

Martina,

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

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

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

Aidan.

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

Please see below for your information and action

Thanks

Martina

Martina Corrigan

Head of ENT and Urology

Craigavon Area Hospital

Tel: Personal Information redacted by USI (Direct Dial)

Mobile: Personal Information redacted by USI

Email: martina.corrigan@ Personal Information redacted by USI

From: Trouton, Heather

Sent: 25 July 2011 15:07

To: Reid, Trudy; Devlin, Louise; Corrigan, Martina

Cc: Mackle, Eamon; Brown, Robin; Sloan, Samantha

Subject: Results

Dear All

I know I have addressed this verbally with you a few months ago , but just to be sure can you please check with your consultants that investigations which are requested, that the results are reviewed as soon as the result is available and that one does not wait until the review appointment to look at them.

Thank you

Heather

Southern Health & Social Care Trust IT Department Personal Information redacted by the USI

email, and here they are. So you're writing in response, you say, to:

"...an email informing us that there is an expectation that investigative results and reports be reviewed as soon as they become available and that one does not wait until patient's review appointments. I presume this relates to outpatients and arise as a consequence of patients not being reviewed when intended." 15:29

15:29

And you're concerned for several reasons. I suppose those questions, to summarise, are relating to the practical aspects and the responsibilities which flow from that statement of principle which Mrs. Corrigan and her fellow managers had sent your way. Does it not portray -- does your response not portray, at least implicitly, the view that "I'm simply not in a position to review results in all cases when they're available"? 15:29

A. In addition to everything else that, you know, we had to do, that was my concern. And I know that it's been described, this email, as "pushback". I didn't regard it as pushback because I agreed with the principle. I just was concerned about the practicalities of it. How robust would it be? What time would it take to undertake all of this? And, indeed, nowadays, in addition to actually reviewing, we have heard that in addition to that you action it. Do you phone the patient with a quick telephone call to tell them that the x-ray is okay, or do you write to the GP and to the 15:30 15:30

HSC Public Health Agency

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Co Armagh
BT61 9DR

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Fax :
Web Site : www.publichealth.hscni.net

Strictly Confidential

Ms D Burns
Assistant Director Clinical &
Social Care Governance
Southern Health & Social Care Trust
Old College of Nursing
Craigavon Area Hospital
68 Lurgan Road
PORTADOWN
BT63 5QQ

14 November 2011

Dear Ms Burns

I refer to the Trust's report on the Root Cause Analysis of this incident. The report is thorough, clearly identifying the chronology of events and making recommendations on actions to avoid recurrence. As might be expected, the report concentrates on the primary event, which occurred during the patient's operation on 15th July 2009 and the x-ray findings which might have aided detection prior to her emergency admissions in July 2010.

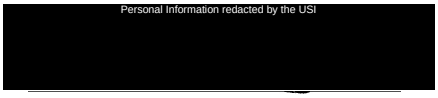
The patient was expected to have an outpatient review four months after her major complex cancer surgery in July 2009. It was also expected that at that review attendance the CT scan, undertaken three months post-operatively, would be available for the consultant urologist to see. This scan was done promptly in early October 2009 and the report identified an abnormality. Although not identified as a retained swab, one of the differential diagnoses was recurrence of the patient's cancer.

The RCA report identifies that, due to a backlog in outpatient reviews, in fact the patient was not seen at outpatients in the 12 months after surgery, at which stage she was admitted as an emergency. The recommendation relating to this issue was that outpatient backlog reviews should be cleared. This recommendation is reasonable, albeit not necessarily easy for the Trust to

implement given the resources required to do so. However, this aspect of the SAI does raise a wider cause for concern which has not been addressed directly in the RCA or the recommendations.

The report records that it was the practice of the patient's consultant urologist not to review laboratory or radiology reports until patients attended their outpatient appointment. There was no further comment on this practice, nor any recommendation relating to this. I believe that this highlights an area where the Trust would have considered action to be appropriate. It is possible that this was not seen as directly relevant to the actions required to minimise the likelihood for further SAIs relating to retained swabs, hence there were no recommendations for action in this particular RCA report. I am writing to ask whether this issue has been taken forward, for example by considering whether there is a need for a formal Trust policy, such as review of all test results by medical staff before filing, whether or not the patient is awaiting outpatient review.

Yours sincerely



Dr D Corrigan
Consultant in Public Health Medicine

cc Dr J Simpson
Dr G Rankin
Mrs J McCulla