Urology Services Inquiry

UROLOGY SERVICES INQUIRY

Note: An addendum amending this statement was received by the Inquiry on 19 May 2023 and can be found at WIT-96617 to WIT-96637. Annotated by the Urology Services Inquiry.

USI Ref: Notice 100 of 2022

Date of Notice: 26 September 2022

Witness Statement of: Tracey Boyce

I, Tracey Boyce, will say as follows:-

SECTION 1 – GENERAL NARRATIVE

General

1. **Having regard to the Terms of Reference of the Inquiry, please provide a narrative account of your involvement in or knowledge of all matters falling within the scope of those Terms. This should include an explanation of your role, responsibilities and duties, and should provide a detailed description of any issues raised with or by you, meetings you attended, and actions or decisions taken by you and others to address any concerns. It would greatly assist the inquiry if you would provide this narrative in numbered paragraphs and in chronological order.**

1.1 From 1st April 2022 to the present day I have been working as an HSC Leadership Associate. Immediately prior to that my role was the Director of Pharmacy and Medicines Management in the Southern Health and Social Care Trust, until I took early retirement on 31st January 2022. From 1st February to the 31st March 2022 I worked for the Southern HSC Trust for 15 hours per week, assisting with the induction of the new Trust Director of Pharmacy and Medicines Management.

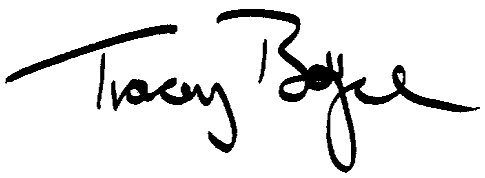
44.7 I do not know if Mrs Gishkori escalated the telephone call and it was never mentioned to me again.

NOTE:

By virtue of section 43(1) of the Inquiries Act 2005, "document" in this context has a very wide interpretation and includes information recorded in any form. This will include, for instance, correspondence, handwritten or typed notes, diary entries and minutes and memoranda. It will also include electronic documents such as emails, text communications and recordings. In turn, this will also include relevant email and text communications sent to or from personal email accounts or telephone numbers, as well as those sent from official or business accounts or numbers. By virtue of section 21(6) of the Inquiries Act 2005, a thing is under a person's control if it is in his possession or if he has a right to possession of it.

Statement of Truth

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

Signed: 

Date: 18th November 2022

Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: Section 21 Notice No.100 of 2022

Date of Notice: 26 September 2022

Addendum Witness Statement of: Dr Tracey Boyce

I, Dr Tracey Boyce, wish to make the following amendments to my existing response, dated 18th November 2022, to Section 21 Notice number 100 of 2022:

Minor Amendments

1. At paragraph 4.10 (WIT-87635) I have stated: "*This allowed me to assist Ms Gishkori, when necessary, with any Non-Executive Directors' questions about Acute Governance issues*."

   This should be amended to state: "*Attending the full meeting ~~This~~ allowed me to assist Ms Gishkori, when necessary, with any Non- Executive Directors' questions about Acute Governance issues."*

2. At paragraph Section 7.1 (c) (WIT-87639) I have stated: "*Four monthly audits of each wards' management.*"

   This should be amended to state: "*Four monthly audits of each wards' Controlled Drug management."*

3. At paragraph 10.2 (WIT-87642) I have stated: "*For financial control my* performance *in leading my team's delivery of the regionally set pharmaceutical savings targets were measured using the "MORE reports," (Attachment 14) in conjunction with the quarterly Medicines Optimisation Resource Efficiency regional accountability meetings with the Department of Health officers*."

   This should be amended to state: "*For financial control my performance in leading my team's delivery of the regionally set pharmaceutical savings targets were*

This was because the Acute Governance team was chronically under resourced for the size of the tasks expected of them."

This should be amended to state: "Overall, in my opinion, the governance arrangements in the Acute Directorate ~~where~~ were not fit for purpose. This was because the Acute Governance team was chronically under resourced for the size of the tasks expected of them."

11. At paragraph 44.1 (WIT-87673) I have stated: "*I would like to add information about a telephone call that I inadvertently witnessed as it I think it may be evidence of some level of pressure on one of the Acute Services Directors who did not fully investigate Mr O'Brien's practice*."

This should be amended to state: "I would like to add information about a telephone call that I inadvertently witnessed as it I think it may be evidence of some level of pressure on one of the Acute Services Directors who did not fully address ~~investigate~~ Mr O'Brien's practice."

Major Amendments

12. At paragraphs 27.11 to 27.13 (WIT-87657 to WIT-87658) I have stated:

> "27.11 On 9th November 2016 one of the lead nurses who had been transferred into the Acute Governance team in 2014, Connie Connelly, gave me a letter of concern *(Attachment 24)* about an SAI that she had been working on *(Attachment 25).* The SAI review was considering the case of Patient 10. Ms Connolly was a panel member in the investigation which was being chaired by Mr Anthony Glackin, Consultant Urologist. The letter was unsigned.
>
> 27.12 The panel's concerns included:
>
> (a) That the root cause of the SAI was Mr O'Brien's lack of action in relation to the triage of Patient 10's referral letter from her GP.

addendum statement of 19 May 2023. I was given to understand by Connie Connolly around this time that it was she who had hand-delivered the letter to my desk. Therefore, I understood that it had come from one or more of the SAI Panel members.

Additional Documents

13. I would also like to attach additional documents in relation to the following areas:-

a. Email

Email from Tracey Boyce to Esther Gishkori and Ronan Carroll dated 16 December 2016 Concerns Raised by an SAI panel (*please see 1. 20161216 Concerns raised by an SAI panel Response from EG*).

b. Correspondence

3-page letter from Mrs Connie Connolly, Lead Nurse Acute Governance dated 15 December 2016 – Letter of SAI Panel Concerns (*please see 2. 20161215 Letter of SAI Panel Concerns*).

c. Trust Board Report

Medicines Governance Reports from SMT Trust Board Governance Committee dated 15 August 2015 (*please see 3a.-3c. 20160815 Medicines Governance Reports for SMT TB Gov Committee, A1 and A2*).

Statement of Truth

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

Signed: Tracey Boyce

Date: 19.05.2023

Urology Services Inquiry

Date	Name
01/04/2007 - 21/05/2008	Mr Jim McCall
01/04/2008 - 30/11/2009	Miss Joy Youart
01/12/2009 - 31/03/2013	Dr Gillian Rankin
01/04/2013 - 31/08/15	Mrs Deborah Burns
17/08/2015 - 06/06/2019	Mrs Esther Gishkori
01/07/2018 - 30/09/2018	Mrs Anita Carroll (acting to cover period of E Gishkori's [redacted]
07/06/2019 - 31/01/22	Mrs Melanie McClements

5.3 I also reported to the Trust's Medical Director who dealt with any professional issues and provided me with professional support if required including when I was acting in my role as the Trust's Accountable Officer.

5.4 The Medical Directors that I worked under were:

(a) Providing specialist advice to the Trust Board, Chief Executive and other Director colleagues and their teams on all areas of Pharmacy and Medicines Management across the organisation.

(b) Responsibility for the delivery and clinical governance of the Pharmacy service and all aspects of the management of Pharmacy staff throughout the Trust including the hospitals and community sectors.

(c) Responsibility for managing the procurement of medicines and associated pharmaceutical products to ensure pharmaceutical clinical effectiveness was in line with accepted best practice standards

(d) Responsibility for research and development, quality improvement and clinical audit activity within the Pharmacy Department.

(e) Achieving outcomes which improved patient and service user experience, provided safe services and improved the environment to provide excellent patient care.

4.3 I also held the position of Controlled Drug Accountable Officer for the Trust under the Controlled Drugs (Supervision of Management and Use) Regulations 2013. I was responsible for the management of controlled drugs, the related governance issues in the organisation and also compliance with the legislation in relation to production of quarterly Occurrence Reports and representing the Trust at the regional confidential Local Intelligence Network meetings.

4.4 In October 2014 I was asked by the then Director of Acute services, Mrs Deborah Burns, to manage the Acute Governance team for a few weeks while the Acute Governance Lead post was being recruited. This was because the previous post holder, Margaret Marshal, had moved into the Corporate Governance Lead role. I was asked to take this on as, out of the six Assistant Directors in the Acute Directorate, I had the most governance experience. I had set up the Northern Ireland Medicines Governance Pharmacist Team in a previous post and I also completed a post graduate Doctor of Pharmacy practice on the subject of medication related patient safety.

were those concerns and with whom did you raise them and what, if anything, was done?

43.1 Overall, in my opinion, the governance arrangements in the Acute Directorate where not fit for purpose. This was because the Acute Governance team was chronically under resourced for the size of the tasks expected of them.

43.2 The clinical staff also did not have protected time for governance activities. When they were under severe patient flow/bed pressures, as often experienced in the Southern Trust Acute Service, the governance activity had to be put on hold.

43.4 When I was asked to look after the Acute Governance team for a period of time in October 2014 I realised that there was a back a backlog of unopened incident reports on Datix *(Attachment 32).* This backlog had not been escalated before and was unknown to the Director (Debbie Burns). These incidents, once reviewed, led to a backlog of SAI reviews.

43.5 The fact that the Governance Lead post had been given up as a saving in 2014 also demonstrated a lack of understanding of the importance of good clinical governance in my opinion. It was impossible for me to take on the full role of the governance lead on top of my substantive post as the Director of Pharmacy. As my registration as a pharmacist could have been at risk if I did not ensure the safe running of the pharmacy service, the best I could do was to offer every Tuesday morning in my diary to assist the members of the Acute Governance team as best as I could.

43.6 The two Band 7 governance officers on the team at the time were very inexperienced as they had been redeployed at short notice after the lead nurse role was stood down at that time too. I had to identify training for them to try to get them up to speed with incident investigation and report writing skills as quickly as possible.

4.5 Shortly after this I was told at an Acute team meeting that the Acute Governance lead was not going to be replaced as the salary had been given up as a cost efficiency saving. I was not happy about this decision as I had been told that I would be managing the team on a temporary basis until the post had been filled. I already had an extremely large workload as Director of Pharmacy and Trust Accountable Officer.

4.6 In February 2016 the Director of Acute Services at the time, Esther Gishkori agreed to the replacement of the Acute Governance Lead *(Attachment 2)* and Trudy Reid was recruited into the role. She started this role on 4th April 2016.

4.7 Ms Gishkori was not prepared to take back direct responsibility for interfacing with the Acute Governance Lead despite it being part of her remit. I was told of this decision verbally at one of my 1:1 meetings with the Director. I do not believe that there is a note of what was said at this meeting. Therefore I continued to mentor and support the Governance Lead as they needed someone to facilitate their work. This involved meeting Trudy Reid every Tuesday morning to discuss any issues the team were having and accompanying her to brief Ms Gishkori on Governance issues once per week.

4.8 I put this weekly governance briefing meeting into Ms Gishkori's diary when I realised that she was not going to take back the Director's responsibility for Governance. I decided that the meetings were necessary as Ms Gishkori was attending Senior Management Team meetings where issues of governance and risk were being discussed. In my opinion she needed to be briefed to be able to represent the Acute Directorate position accurately. Unfortunately the meetings were often cancelled by Ms Gishkori. I do not have any notes of these meetings, as they would have been in my paper diary for the year which I no longer have in my possession. Ms Reid may be able to provide notes of these meetings.

know, to report back on it. Or they would have looked at -- I was very keen at looking at trends and patterns, for example, in relation to incidents or near misses, because that will tell you if there's something wrong in an area around one particular person or whatever. When I say a governance team, I mean that that team would have dealt with all of those things being pulled together. Good governance, as I said before, is everyone's business and we should all, everyone who practices, make sure that they deliver good evidence-based practice. 14:43 14:43

369 Q. You've explained in your statement that there was resource available for you to --

A. Yes.

370 Q. -- to fill that gap? 14:44

A. There was. That's right.

371 Q. What exactly did you do?

A. Governance was the only thing that I didn't have an Assistant Director to report to me on, and I felt that was very important because I wanted to keep all of my service the same. So actually Kieran Donaghy, who was the previous Director of Human Resources, told me -- he was very helpful in the beginning, and he told me that Tracey Boyce, who was the Director of Pharmacy, had just done a Diploma in Governance, a postgrad Diploma, I think, I am sorry, it may have been a postgrad, but it was a postgrad, anyway, qualification in Governance and he said: "You know, you should use that as a starting point." So I spoke to Tracy and she was 14:44 14:44

43.7 I raised my concerns with the Director of Acute Services throughout this period, as did the other Assistant Directors within the Acute Services team and we submitted a number of proposals to augment the Acute Governance team *(Attachments 33 to 42)* during this time.

43.8 Part of the proposals included protected paid time and additional governance training for a number of consultants, who could then develop experience in chairing SAIs and other governance activities, as it became increasingly difficult to engage the medical staff in such governance activities when it was not part of their job plans.

43.9 As outlined in my response to Question 5, at 4.7, funding was found to reinstate the Acute Governance Lead post in February 2016.

Attachment 32 20141104 Governance Agenda and papers

Attachment 33 Acute Governance Structure email Oct 2014

Attachment 34 Acute Governance Structure proposal Oct 15

Attachment 35 Acute Governance structure email April 2016

Attachment 36 Acute Governance Structure proposal April 16

Attachment 37 Email re Governance structure proposals to Acute Director April 2016

Attachment 38 Acute Governance Structure proposal April 16

Attachment 39 Acute Governance Structure proposal Oct 17

Attachment 40 email re Acute governance structures Oct 2017

Attachment 41 Acute Governance Enhanced Structure proposal 31 May 2018

Attachment 42 Acute Governance Structure proposal Aug 2018

happy enough to do it, based on the fact that hers was a very busy job as well. But she then was able to appoint an 8B and then, more importantly, three Band 7s who did the "legwork", if you like, of the governance team. They were the people who went and gathered the information and brought it together and got the review team sorted out, et cetera. Then there was a team below that of, you know, 4s, 5s, 6s, and they were admin and all those people.

372 Q. Can you give us a practical example of a governance shortcoming that existed when you came into post that you were able to solve and pursue a better course as a result of the action that you took? 14:45

A. Well, there was a few that I didn't manage to crack and, to be honest with you, those were important, I felt, but I did speak to the two medical directors in turn. But, for example, when I came in to my position, there were more than 200 Serious Adverse Incidents that hadn't been reported on, more than 200. So this team began very quickly to look at those Serious Adverse Incidents, get teams together. It was difficult because there had to be one of the surgeons or physicians, whoever it was on the team. So by the time I pulled the team together and then they sat, they looked into it and they followed the SAI procedure, and by the time I left, most of those SAIs had been reported on or were being dealt with. I resurrected the Friday morning governance meeting that had been set up by Dr. Gillian Rankin, because it had sort of gone 14:45 14:46 14:46

Urology Services Inquiry

44. If not specifically asked in this Notice, please provide any other information or views on the issues raised in this Notice. Alternatively, please take this opportunity to state anything you consider relevant to the Inquiry's Terms of Reference and which you consider may assist the Inquiry.

44.1 I would like to add information about a telephone call that I inadvertently witnessed as it I think it may be evidence of some level of pressure on one of the Acute Services Directors who did not fully investigate Mr O'Brien's practice.

44.2 I cannot remember the date of the meeting and I did not make a note of the incident at the time. However, I know that it must have been after the concern in relation to Mr O'Brien's triage practice was identified, as I understood the context of the call without it having to be explained.

44.3 I was in a 1:1 meeting with Mrs Esther Gishkori, Director of Acute Services, in her office on the CAH Administration floor, updating her on my pharmacy responsibilities. The telephone rang and Mrs Gishkori answered it whilst I was in the room. I realised she was speaking to the Chair of the Trust (Mrs Roberta Brownlee) and, while I indicated to Mrs Gishkori that I would leave the room to give her privacy, she told me to stay.

44.4 I could not hear what Mrs Brownlee was saying however I recall that Mrs Gishkori did not say very much in response to Mrs Brownlee during the call and that she became very flustered.

44.5 When the call ended Mrs Gishkori told me that the Chair had asked her to *"leave Mr O'Brien alone"* as he was an excellent doctor and a good friend of hers who had saved the life of one of her friends.

44.6 I remember saying to Mrs Gishkori that I thought that the Chair's behaviour was unacceptable and that she should document the call and speak to the Chief Executive about it, as her line manager.

TRU-164694

inappropriate

Roberta :- omitted / delay :-
?? have date :-
errors

Update → Tracey →
Ask Tracey
!!! Defensive language → percentage

and harassment towards Mr O'Brien and that he needed to step back from managing him. I was not present when Mr Mackle was told this but he came straight to me after this happened, told me about it, and was visibly annoyed and shaken and said to me that he would no longer be able to manage Mr O'Brien. I also understand that, in mid-2016, Mrs Gishkori received a phone call from the then Chair of the Trust, Mrs Brownlee, and was requested to stop an investigation into Mr O'Brien's practice. Once again, I did not witness this but I was told later by Mr Carroll that it happened as my understanding is that Mrs Gishkori had told some of her team.

Governance – generally

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

31.1 My role in governance for all my areas was to promote and ensure that there was high quality and effective care offered to all patients and to ensure that services were maintained at safe and effective levels. I can confirm that I didn't have a direct management role regarding the consultants and other clinicians in the Thorndale Unit.

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?

32.1 The Director of Acute Services had overall responsibility for the governance arrangements in the Urology Service. During my tenure the Directors were:

a. Dr Gillian Rankin;
b. Mrs Debbie Burns - supported by Dr Tracey Boyce (Director of Pharmacy);
c. Mrs Esther Gishkori – supported by Dr Tracey Boyce (Director of Pharmacy);

WIT-90984

19/11/19

Meeting c̄ Mark Haynes.
① AOB letter.
② JP — finalise | Mr McNabee
③ Ned. + speaking to him about retirement
④. backlog importance in response by 22nd.
⑤ Desist notices in surgery
⑥ Discussed IRS Spring RCS
→ wording of desist ←.
→ Surgeons

⑦ ENT — ° beds for elective paeds
— ~~no beds for electives~~
?. ambulatory pathways.
Paediatric pressures — not booking paeds for next 2/52

— Where are you got pressures?
— Are all ambulatory pathways in place?
What are mitigations for impact on elective
→ ? 8 Theatres for paeds??

OxF → we got this wrong?
Acknowledgement of decision.
Pathways ⊛.

⑧. Mark's JP

OAG meeting

— c/s meeting.
— D/W →. Civility saves lives
→. ?
→ RCS | RCOG. →
→ working well together.
training today
→ Appraisals.
3rd date for next cohort.

— Date for wider
→ Prescreening → 4th Dec [redacted]
→ Aorfe. ⊛. C
→.

— Whistleblowing
— 4th / 6th Dec
Am.

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.

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

Urology Outcome Sheet

(9)

(for face to face appointments and advice)

Consultants name: MR O'BRIEN

Date: 25/10/2016

Patient Name	H & C or Hospital Number	DOB	Source of Referral	New or Review	Action: Add to op w/l list, add to inpt w/l, discharge etc	Type of Contact: Face to Face/Telephone/Email
Personal Information redacted by the USI			13/10 Personal Information redacted by USI			
			23/10 Personal Information redacted by USI			
			23/10 Personal Information redacted by USI			
			24/10 Personal Information redacted by USI			
			24/10 Personal Information redacted by USI			
			24/10 Personal Information redacted by USI			
			24/10			
			24/10 Personal Information redacted by USI			

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BIAM British Infection Association

www.elsevierhealth.com/journals/jinf

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

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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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

36.2 When Mr Haynes became the AMD we attended the same Acute Clinical Governance meetings each month and, from my experience, we had a good working relationship.

37. In your experience, did medical (clinical) managers and non-medical (operational) managers in urology work well together? Whether your answer is yes or no, please explain with examples.

37.1 My experience of their working relationship was limited to my observations during Acute Clinical Governance meetings, as this was the only time that I would have seen the senior clinical and operations managers responsible for the urology interacting.

37.2 I did not observe anything at those meetings that made me think there was a problem in their working relationships.

Learning

38. Are you now aware of governance concerns arising out of the provision of urology services which you were not previously aware of? Identify any governance concerns which fall into this category and state whether you could and should have been made aware of the issues at the time they arose and why.

38.1 Yes. I am now aware that Mr O'Brien was recommending the prescription of sub-therapeutic doses of bicalutamide for men diagnosed with prostate cancer. I became aware of this when Mr Mark Haynes, AMD, asked me for Trust pharmacy help in auditing these prescription recommendations.

and Q2 xiv Item 4592 - [redacted] *re Treatment Southern Trust Urology Department 21 March 2022*

xv. Any report or other documentation arising from the Bicalutamide audit as referred to in the minutes of the Urology Assurance Group of 4th December 2020 (per answer 27(c) of No. 4 / 2021).

A copy of the Bicalutamide audit commencement form and narrative of audit outcome is presented below.

Bicalutamide Audit

Following identification that patients had been prescribed low dose (50mg) Bicalutamide outside of licenced indications or standard practice (as a result of the SAIs conducted by Dr Dermot Hughes) contact was made with the Trust Director of Pharmacy, Dr Tracey Boyce, with a view to identifying patients currently receiving a prescription for Bicalutamide 50mg.

The data was provided on 22nd October 2020. The data provided identified all HSC Trusts' patients who received a prescription for Bicalutamide (any dose) between March and August 2020. For each patient their Health and Care Number, Bicalutamide prescription, number of prescription items and quantity (count of tablets) was provided.

Audit Aims

To ensure that the anti-androgen medicine 'Bicalutamide' has been prescribed as licensed and in line with NICE guideline NG131 Prostate Cancer: Diagnosis and Management located in *S21 No. 1 of 2022, Q2 xv Bicalutamide Clinical Audit Form*.

Audit Objectives

- To ensure that where Bicalutamide is prescribed only where indicated and as per licensed usage
- To ensure that where Bicalutamide is prescribed this is prescribed in the correct therapeutic dosages
- To ensure that patients prescribed Bicalutamide is appropriately reviewed as part of the patients ongoing care
- To ensure that any deviations from prescribing guidance is based on sound evidence based clinical rationale

Audit Standards

Audit Criteria	Target	Exceptions	Source of Evidence
Bicalutamide prescribed as per indicated conditions in NICE NG131	100%	Clinical rationale for deviation from guidance	NICE guideline NG131 Prostate Cancer: Diagnosis and Management

(b) That there were 7 other patients' GP letters that were not triaged that week by Mr O'Brien.

(c) That the secretaries appeared to be aware that triage was not being completed and were putting patients onto the routine appointment list as a way of ensuring that they were kept in the system. They had kept a record of those patients which revealed that 318 letters had not been triaged by a Consultant Urologist.

(d) That some patients' notes were missing (despite being tracked to Mr O'Brien).

(e) That there appeared to be delays in the dictation of Mr O'Brien's letters.

27.13 That afternoon, I emailed Mrs Gishkori about the concern *(Attachment 26*) and I subsequently went to the Admin Floor to speak to her and Mr Ronan Carroll (AD for Surgery and Elective Care) about it."

This section, from paragraphs 27.11 to 27.13, should be amended to state:

"27.11 On 9th November 2016 one of the lead nurses who had been transferred into the Acute Governance team in 2014, Connie Conne~~o~~lly, spoke to me at my weekly meeting with the Governance team ~~gave me a letter of concern *(Attachment 24)*~~ about an SAI that she had been working on *(Attachment 25).* The SAI review was considering the case of Patient 10. Ms Connolly was a panel member in the investigation which was being chaired by Mr Anthony Glackin, Consultant Urologist. ~~The letter was unsigned.~~ I believe that Connie informed me that ~~27.12~~ the panel's concerns included:

(a) That the root cause of the SAI was Mr O'Brien's lack of action in relation to the triage of Patient 10's referral letter from her GP.

(b) That there were 7 other patients' GP letters that were not triaged that week by Mr O'Brien.

Stinson, Emma M

From: Boyce, Tracey [redacted]
Sent: 09 November 2016 15:39
To: Gishkori, Esther
Cc: Stinson, Emma M
Subject: FW: Emailing: sc of partial SAI
Attachments: sc of partial SAI.pdf

Importance: High
Sensitivity: Confidential

Hi Esther
I had my weekly update with the governance leads today and they shared a draft of an SAI that is nearing completion as they are concerned about its implications - I have attached the first page to give you the gist. I think we may need to discuss this one with Richard as the cause seems to be directly attributable to one of the consultants (AOB)?

Basically this lady's GP sent in a referral in relation to an incidental finding on a CT in relation to her kidneys - it came in as routine.
The urologist consultant of the week collected that week's letters to do triage, as per the urology arrangements but from what the investigation team has found out that letter was never seen again and no instruction were received re triage appointment booking.

Apparently this had happened before with this consultant so the booking team's way of dealing with these type of 'lost letters' was to book them a routine appointment (because letters were lost before they had started keeping copies to work from). As a result there was a 16 month delay in diagnosing this ladies renal carcinoma. The triage consultant is meant to look at the CT as part of triage process but the SAI team found that it hadn't been looked at. The urologist on the SAI team has said if it had been reviewed at triage it would have been immediately obvious it was a tumour. (there was also an issue in relation to the reporting of a subsequent MRI back in 2014 that meant the GP or breast team did not pick up that it was potentially a red-flag or urgent referral was needed)

Although this was an SAI about a single case it has come to light that the other 7 urology referral letters received that week are also missing - as an initial action I have asked Trudy and Connie to try and track them via PAS to check they have been seen and pull their notes if necessary. I haven't asked the question yet whether we know if any more of that consultants weeks triage letters have been lost - but it is probably something we need to discuss.

I am conscious that I haven't spoken to Ronan about this yet as AOB's AD - but I wanted to get your take on it before I shared it with anyone else.

Kind regards

Tracey

Dr Tracey Boyce
Director of Pharmacy
[redacted]

Gibson, Simon

From: Wright, Richard [redacted]
Sent: 06 December 2016 10:52
To: Gishkori, Esther
Subject: RE: Confidential

Thanks Esther. That sounds very reasonable. Any ideas when that is likely to be? Richard

-----Original Message-----
From: Gishkori, Esther
Sent: 06 December 2016 09:31
To: Wright, Richard
Cc: Toal, Vivienne
Subject: RE: Confidential

Dear Richard,
I can confirm that Mr O'Brien has had surgery and that sick lines are being submitted appropriately. I do not think that an occupational health referral is indicated at this point although it may well be in the coming weeks as Mr O'Brien is likely to return before he is well. We shall see in due course.

Patient notes are being returned as requested from Mr O'Brien however, Trudy Reid (governance facilitator) is not sure if all notes taken off the premises have been returned. The governance team are in the process of checking this out. It is difficult to be completely sure until notes cannot be found but we are doing our best.

The SAI review continues and will no doubt produce its own recommendations.

I have been having conversations in relation to Mr O'Brien's "return to work" interview. We thought that this would be a good time to set out the ground rules from the start.
Since [redacted] are both off sick, Mark wondered if you and I could do this. Since there are both professional and operational issues here, I feel that this is entirely reasonable.

Will chat to you about it as we will have until the new year to think about it.

Best,
Esther.

Esther Gishkori
Director of Acute Services
Southern Health and Social Care Trust
Office [redacted] Mobile [redacted]
[redacted]

-----Original Message-----
From: Wright, Richard
Sent: 30 November 2016 09:36
To: Gishkori, Esther
Cc: Toal, Vivienne
Subject: Confidential

Hi Esther.

(c) That the secretaries appeared to be aware that triage was not being completed and were putting patients onto the routine appointment list as a way of ensuring that they were kept in the system. They had kept a record of those patients which revealed that 318 letters had not been triaged by a Consultant Urologist.

~~(d) That some patients' notes were missing (despite being tracked to Mr O'Brien).~~

~~(e) That there appeared to be delays in the dictation of Mr O'Brien's letters.~~

27.12~~3~~ Connie informed me that the SAI review was nearing completion and, because of the concern about the implications of the finding that Mr O'Brien had not triaged any of the eight urology referrals that had arrived during the relevant week in 2014, I asked Ms Connolly and Mrs Trudy Reid, Acute Governance Lead, to track the seven patients (other than Patient 10) from that week to ensure that they had not come to harm. That afternoon, I also emailed Mrs Gishkori ~~about~~ to escalate the concern and to advise her of the action I had taken (Attachment 26) ~~and I subsequently went to the Admin Floor to speak to her and Mr Ronan Carroll (AD for Surgery and Elective Care) about it~~.

27.13 On 16th December 2016 I returned to my office and found an envelope on my desk. Inside the envelope was a letter of concern dated 15th December 2016 (Appendix 24) about the Patient 10 SAI and the outcomes of the additional actions that I had requested in relation to the other seven patients who had not been triaged that week. The letter was unsigned (i.e. it lacked its third page, which has subsequently been located and provided to the Inquiry). I emailed a copy of the letter immediately to Esther Gishkori, Acute Director, and Ronan Carroll, Assistant Director responsible for Surgery, suggesting that we needed to meet urgently to discuss (which, I believe, we did the following week). A copy of this email has been supplied with my

15 December 2016

Dear Tracey

As you are aware the SAI review and report in relation to Patient 10 reference number W48461 is complete.

The remit of Patient 10 s Serious Adverse Incident was to fully investigate the circumstances which contributed to her clinical incident. The Review Team was comprised Mr Anthony Glackin Consultant Urologist, Dr Aaron Milligan Consultant Radiologist, Mrs Katherine Robinson Booking and Contact Centre Manager, and Mrs Christine Rankin Booking Manager. To provide context, part of the work included a look-back exercise for 7 Urology patients who managed in the same manner as Patient 10 in October 2014. This was to satisfy the panel that there was a management plan in place and no harm had come to the other 7 patient (letters) which were not triaged on the week ending 30 October 2014. The manual look-back was done using the 6 available patient charts on 14 November 2016. These 6 patients all have been discharged or management plans in place. The 7th (patient initials Patient 99) chart was not able to be found on Trust property at this time. Patient 99 s chart arrived to the Governance office on week commencing 28 November 2016. The look-back exercise was completed on13 December 2016. There is clinical detail within the dictated letter in relation to the Patient 99 s consultation which requires clinical validation. This has been given to Mr Anthony Glackin to review on 15 December 2016.

Upon conclusion, the Review Team agree there are a number of relevant and related issues/themes causing concern for the panel which have been exposed during the SAI investigation. The Panel would like to clarify that all relevant enquiries made while undertaking this report have been solely limited to the information which were independently provided by members of the Review panel in conjunction with Mrs Andrea Cunningham, Service Administrator. There have not been any approaches made directly to the Urology Clerical team, the Urology Head of Service or the Assistant Director of Surgery and Elective Care for any information or evidence of communication.

Discussed ic Roran Tracey
Esther 20/12/16

Hand delivered to TB
Friday 16/12/16

If you have any further questions, do not hesitate to contact me directly.
Sincerely
Connie

Mrs Connie Connolly
Lead Nurse Acute Governance

Issues and Themes of concern include:

- In May 2014, there was an informal process was implemented to monitor/manage Urology letters which had not been returned with management advice (not triaged). It appears that this process was created in an effort to limit risk of harm to the patient. The presence of this process implies that it was accepted that triage non-compliance was to be expected by a minority of consultants within the Urology specialty. On 6 November 2015, an email from the AD of Functional Service formally implementing this process. The Review Panel are anxious that the current process does not have a clear escalation plan which evidences inclusion of the Consultant involved. In addition, this process has not been effective in addressing triage non-compliance. From 28 July 2015 until 5 October 2016, there are 318 patient letters which were not triaged. Currently the Trust cannot provide assurance that the Urology non-triaged patient cohort are not being exposed to harm while waiting 74 weeks for a Routine appointment or 37 weeks for an urgent appointment.

- During the manual look-back exercise on 14 November 2016, Patient 99 [redacted]s patient chart could not be found on Trust premises. Patient 99 [redacted]'s chart did appear in the Acute Governance office the week commencing 28 November 2016. After informal queries, it is understood that patient notes are not transported via Trust vehicles to or from Dr 6's outlying clinics (inc SWAH). This could compound efforts to establish any chart location or outstanding dictation. The Review panel acknowledge that processes should not be drafted to address one issue with one specialist team. On balance, the Review team agree there is sufficient cause for concern that Trust documentation may be leaving Trust facilities and the process of record transportation for this Specialty does need urgently addressed.

- There is clear evidence that this patient Patient 99 [redacted]s letter was not triaged by week ending 30 October 2014. Patient 99 [redacted] was seen in SWAH by Dr 6 in January 2015. The outpatient letter was dictated 11 November 2016 and typed 15 November 2016. The Review panel have grave concerns that there are other Urology patient letters not being dictated in a timely manner. Upon further investigation, the Panel have found that the Trust does monitor the number charts needing audio-typing of dictation but there does not appear to be a robust process to monitor if post-consultation patient dictation has been completed. This has the potential to be compounded if patient charts are leaving the Trust facilities. The SAI Panel are anxious that assurance is sought that there is reasonable compliance in relation to the timely dictation letters by Dr 6.

Southern Health & Social Care Trust

Oversight Committee
22nd December 2016

Present:
Dr Richard Wright, Medical Director (Chair)
Vivienne Toal, Director of HROD
Ronan Carroll, on behalf of Esther Gishkori, Director of Acute Services

In attendance:
Simon Gibson, Assistant Director, Medical Director's Office
Malcolm Clegg, Medical Staffing Manager
Tracey Boyce, Director of Pharmacy, Acute Services Directorate

Dr A O'Brien

Context
On 13th September 2016, a range of concerns had been identified and considered by the Oversight Committee in relation to Dr O'Brien. A formal investigation was recommended, and advice sought and received from NCAS. It was subsequently identified that a different approach was to be taken, as reported to the Oversight Committee on 12th October.

Dr O'Brien was scheduled to return to work on 2nd January following a period of sick leave, but an ongoing SAI has identified further issues of concern.

Issue one
Dr Boyce summarised an ongoing SAI relating to a Urology patient who may have a poor clinical outcome due to the lengthy period of time taken by Dr O'Brien to undertake triage of GP referrals. Part of this SAI also identified an additional patient who may also have had an unnecessary delay in their treatment for the same reason. It was noted as part of this investigation that Dr O'Brien had been undertaking dictation whilst he was on sick leave.

Ronan Carroll reported to the Oversight Committee that, between July 2015 and Oct 2016, there were 318 letters not triaged, of which 68 were classified as urgent. The range of the delay is from 4 weeks to 72 weeks.

Action
A written action plan to address this issue, with a clear timeline, will be submitted to the Oversight Committee on 10th January 2017
Lead: Ronan Carroll/Colin Weir

Issue two

An issue has been identified that there are notes directly tracked to Dr O'Brien on PAS, and a proportion of these notes may be at his home address. There is a concern that some of the patients seen in SWAH by Dr O'Brien may have had their notes taken by Dr O'Brien back to his home. There is a concern that the clinical management plan for these patients is unclear, and may be delayed.

Action

Casenote tracking needs to be undertaken to quantify the volume of notes tracked to Dr O'Brien, and whether these are located in his office. This will be reported back on 10th January 2017
Lead: Ronan Carroll

Issue three

Ronan Carroll reported that there was a backlog of over 60 undictated clinics going back over 18 months. Approximately 600 patients may not have had their clinic outcomes dictated, so the Trust is unclear what the clinical management plan is for these patients. This also brings with it an issue of contemporaneous dictation, in relation to any clinics which have not been dictated.

Action

A written action plan to address this issue, with a clear timeline will be submitted to the Oversight Committee on 10th January 2017
Lead: Ronan Carroll/Colin Weir

It was agreed to consider any previous IR1's and complaints to identify whether there were any historical concerns raised.
Action: Tracey Boyce

Consideration of the Oversight Committee

In light of the above, combined with the issues previously identified to the Oversight Committee in September, it was agreed by the Oversight Committee that Dr O'Briens administrative practices have led to the strong possibility that patients may have come to harm. Should Dr O'Brien return to work, the potential that his continuing administrative practices could continue to harm patients would still exist. Therefore, it was agreed to exclude Dr O'Brien for the duration of a formal investigation under the MHPS guidelines using an NCAS approach.

It was agreed for Dr Wright to make contact with NCAS to seek confirmation of this approach and aim to meet Dr O'Brien on Friday 30th December to inform him of this decision, and follow this decision up in writing.
Action: Dr Wright/Simon Gibson

The following was agreed:
Case Investigator – Colin Weir
Case Manager – Ahmed Khan

From: Gibson, Simon
Sent: 23 December 2016 11:27
To: Gishkori, Esther; Toal, Vivienne; Wright, Richard
Cc: Carroll, Ronan; Boyce, Tracey; Clegg, Malcolm; Stinson, Emma M; Mallagh-Cassells, Heather; White, Laura; Montgomery, Ruth
Subject: CONFIDENTIAL - Confirmation of further oversight meeting re: Dr AOB - 10th January 1pm, Trust HQ
Attachments: Action note - 22nd December - AOB.docx

Dear Richard, Esther and Viv

I am writing to confirm a follow-up meeting in relation to Dr A O'Brien on

Tuesday 10th January at 1pm – 2pm, Dr Wrights office, Trust HQ

I have included the action note from yesterdays meeting, detailing actions required.

Kind regards

Simon

Simon Gibson
Assistant Director – Medical Directors Office
Southern Health & Social Care Trust
Personal Information redacted by the USI
Mobile: Personal Information redacted by the USI
DHH: Personal Information redacted by the USI Ext Personal Information redacted by the USI

Boyce, Tracey

From: Glackin, Anthony [redacted]
Sent: 10 January 2017 18:36
To: Boyce, Tracey
Cc: Gishkori, Esther; Carroll, Ronan; Corrigan, Martina
Subject: RE: Sharing of SAI report [redacted]

Sensitivity: Confidential

Dear Tracey,
draft 8 of this report was completed this evening.
I will not be sending the report to Mr O'Brien, I am his colleague and not his manager.

Regards

Tony Glackin

Anthony J Glackin MD FRCSI(Urol)
Consultant Urologist
SHSCT

Secretary: Elizabeth Troughton [redacted]

From: Boyce, Tracey
Sent: 10 January 2017 17:45
To: Glackin, Anthony
Cc: Gishkori, Esther; Carroll, Ronan; Corrigan, Martina
Subject: Sharing of SAI report [redacted]
Sensitivity: Confidential

Hi Mr Glackin

At the oversight meeting today the next steps for this SAI report were discussed.

Dr Wright has asked that you, as chair of the SAI panel, now share the report with the two key consultants involved in the SAI so that they have a chance to comment on the report if they wish.

Would you be able to post a hard copy of the report to AOB with a note requesting that he replies with any comments he has by a certain date – I think two weeks from when you send it would be sufficient? Normally we would email reports to consultants however Martina tells me that the only working email address we have for AOB is a personal one, so cannot be used to send a report such as this.

I understand that the consultant radiologist involved in the SAI has now left the Trust, so I will liaise with Heather Trouton about how they wish to handle that.

Thanks for your help with this, it is much appreciated.

Kind regards

Stinson, Emma M

From: Boyce, Tracey [redacted]
Sent: 11 January 2017 12:49
To: Glackin, Anthony
Cc: Gishkori, Esther; Carroll, Ronan; Corrigan, Martina
Subject: RE: Sharing of SAI report [redacted]

Sensitivity: Confidential

Mr Glackin

Totally understand.

The normal process would be that the panel chair shares the report with the key people involved in the SAI – for their comments prior to the final draft going to the AMD governance meeting for approval – however this isn't a 'normal' SAI.

We are being very careful to stay within the Trust SAI guidance but I think that if either Esther or I send the final draft to him and asked for his comments it would still be okay.

I will talk it through with Esther.

Thanks for your help

Kind regards

Tracey

Dr Tracey Boyce
Director of Pharmacy/Acute Governance
[redacted]

Learn more about mental health medicines and conditions on the Choiceandmedication website http://www.choiceandmedication.org/hscni/

From: Glackin, Anthony
Sent: 10 January 2017 18:36
To: Boyce, Tracey
Cc: Gishkori, Esther; Carroll, Ronan; Corrigan, Martina

urology services or involving Mr O'Brien in particular. I was not made aware of the outcome of the ongoing investigations prior to my retirement.

40.2. In relation to the 2017 non-triage concern within urology, the learning that I am aware of is that such important parts of the patient care system, that rely on individual actions, should be made visible so that activity can be

monitored regularly so that problems can be identified and addressed quickly. I understand that this was addressed by developing a report that shows triage activity against GP referral letters received for each speciality. The report allows clinical and operational managers to easily monitor such activity and then escalate as needed.

40.3. My personal learning from the urology gentamicin infusion issue was the importance of speaking up when you have a concern and not assuming that others will address it. That was the first time in my career that I had escalated a concern related to a colleague in another profession and I realise that other people working on the wards with that clinical pharmacist must also have known about the patients being admitted for the infusions, yet had not voiced concerns about the practice.

40.4. When Mr Haynes asked me to assist with the audit of bicalutamide in urology outpatient clinics I was not able to help him to collect data due to the paper based prescribing system in use in the Trust. I had to put Mr Haynes in contact with my HSCB colleagues so that they could extract data from the community pharmacy prescription payment database. This is a very cumbersome way of monitoring outpatient prescribing and the learning is that outpatient prescribing needs to be made visible within Trusts by the use of electronic prescribing that allows audit and monitoring. When 'Encompass' is implemented in every Trust this weakness in the system should be resolved.

41. Do you think there was a failure to engage fully with the problems within urology services? If so, please identify who you consider may have failed to engage, what they failed to do, and what they may have done differently. Your answer may, for example, refer to an individual, a group or a particular level of staffing, or a particular discipline.

If your answer is no, please explain in your view how the problems which arose were properly addressed and by whom.

41.1 Yes. In relation to the 2017 triage concern that I was involved in, I do think that there was a failure by the Medical Directors and the Director of Acute Services to engage fully with and address the problems identified at the time.

41.2 In my opinion, both roles (Medical Directors and the Director of Acute Services) had a leadership responsibility to ensure that a robust process and monitoring system were in place and to seek ongoing assurances.

41.3 In relation to the Director of Acute Services think this failure was related to a lack of governance experience of the post holder at that time, Mrs. Gishkori. My view of Mrs Gishkori's lack of governance experience came from my experiences of working with her, supporting her with governance issues and from attending the same Acute and Trust Governance meetings as she did.

41.4 For the Medical Director role, I understood that Dr Wright was very experienced in managing such problems however unfortunately his ill health meant that he was not always available and that he was subsequently required to step down from the post during this period. He was then replaced, on an interim basis, by Dr Khan, who, from my experience of working with him, appeared to be inexperienced in governance matters.

42. Do you consider that, overall, mistakes were made by you or others in handling the concerns identified? If yes, please explain what could have been done differently within the existing governance arrangements during your tenure? Do you consider that those arrangements were

Buckley, LauraC

From: Corrigan, Martina
Sent: 29 September 2019 05:24
To: Hynds, Siobhan
Cc: Buckley, LauraC
Subject: FW: Urology Late Upgrades Update on Pathway

Regards

Martina

Martina Corrigan
Head of ENT, Urology, Ophthalmology & Outpatients
Craigavon Area Hospital

Telephone:
EXT [redacted] (Internal)
[redacted] (External)
[redacted] (Mobile)

From: Carroll, Ronan [redacted]
Sent: 12 June 2017 10:05
To: Chada, Neta; Weir, Colin; Hynds, Siobhan
Subject: FW: Urology Late Upgrades Update on Pathway

Update

From: Boyce, Tracey
Sent: 07 June 2017 12:35
To: Carroll, Ronan; Gishkori, Esther
Subject: RE: Urology Late Upgrades Update on Pathway

Ronan
Our process is that the final draft of the report is shared with the key people involved in the incident – so that they can comment on accuracy, etc.

The final report, as signed off by the Friday morning Acute Clinical Governance meeting should then be shared with all those staff.

Previously this was the relevant AMD's role but the team was getting feedback that this step wasn't happening consistently, so recently, following approval by the AMDs, they have started sending the report to the list of key staff agreed with the panel chair.

I will check what the situation with the original AOB SAI – It may be that the 'performance' work related to the case has affected how the final report was handled. I know that the performance panel authorised the sharing to the draft for his comments.

Kind regards

Tracey

Martina Corrigan

SHSCT Adverse Incident Reporting (IR2) Form -December 2020

The new Regional CCS2 codes which will replace 'Type', 'Category', 'Subcategory', and 'Detail' have been updated.

A full list of these codes can be found here for review.

Incident Details
ID & Status

Incident Reference ID	Personal information
Submitted time (hh:mm)	20:25

Incident IR1 details

Notification email ID number	Personal Information redacted by USI
Incident date (dd/MM/yyyy)	20/11/2014
Time (hh:mm)	17:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	
Does this incident involve a Staff Member?	
Description Enter facts, not opinions. Do not enter names of people	Patient discussed at Urology MDM on 20th November 2014. Recorded outcome Patient 102 s Re-staging MRI scan has shown organ confined prostate cancer for direct referral to Dr H for Radical Radiotherapy. For OP Review with Mr O'B.' Was reviewed by Mr O'B in OP on 28th November 2014. No correspondance created from this appointment. Referral letter from GP received 16th October 2015 stating that Patient 102 had not received any appointments from oncology.
Action taken Enter action taken at the time of the incident	Patient 102 has now been referred to Oncology. This has been done by email and letter. Investigation with MDM team, direct referral was generated at CAH but no record of being received in Belfast.
Learning Initial	
Reported (dd/MM/yyyy)	21/10/2015
Reporter's full name	Mark Haynes
Reporter's SHSCT Email Address	
Opened date (dd/MM/yyyy)	18/11/2015
Last updated	David Cardwell 06/17/2016 09:17:40
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	Patient 102

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Outpatient Clinic
Loc (Exact)	Urology Clinic
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery

Recipients

Message

Message history

Date/Time	Sender	Recipient	Body of Message	Attachments
22/03/2016 12:08:10	Kerr, Vivienne	martina.corrigan Personal Information redacted by the USI	This is a feedback message from Vivienne Kerr. Incident form reference is Personal Information redacted by USI The feedback is: Please see Datix which is now coded under urology. Please go to Personal Information redacted by USI Personal Information redacted by USI	
11/12/2015 14:55:26	Cardwell, David	martina.corrigan Personal Information redacted by the USI	This is a feedback message from David Cardwell. Incident form reference is Personal Information redacted by USI The feedback is: Hi Martina, Helen Forde has asked me to send this to you with the following message: Personal Information redacted by USI Personal Information I think it should go to Martina Corrigan as it says there was no correspondence for the appointment – so it wasn't that the secretary didn't type it – I think it was that it wasn't dictated so that would need to go to Head of Service for urology to discuss with consultant. Regards David Cardwell Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:44	Connolly, Connie	Carroll, Anita	This is a feedback message from Connie Connolly. Incident form reference is Personal Information redacted by USI The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:44	Connolly, Connie	Mark.Haynes Personal Information redacted by the USI	This is a feedback message from Connie Connolly. Incident form reference is Personal Information redacted by USI The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:43	Connolly, Connie	Corrigan, Martina	This is a feedback message from Connie Connolly. Incident form reference is Personal Information redacted by USI The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 14:29:43	Connolly, Connie	Robinson, Katherine	This is a feedback message from Connie Connolly. Incident form reference is W45991. The feedback is: Martina- i have taken this back to SEC as it appears no dictatation was done. Will need review by yourself and governance will support if needed. Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 11:41:44	Connolly, Connie	Mark.Haynes Personal Information redacted by the USI	This is a feedback message from Connie Connolly. Incident form reference is Personal Information redacted by USI The feedback is: Hi all- i have moved this to FSS for investigation and close. There may be 2 teams which cross over in relation to this issue. I wasnt sure so i gave access to all. Moved to review Connie Please go to Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 11:41:43	Connolly, Connie	Robinson, Katherine	This is a feedback message from Connie Connolly. Incident form reference is Personal Information redacted by USI The feedback is: Hi all- i have moved this to FSS for investigation and close. There may be 2 teams which cross over in relation to this issue. I wasnt sure so i gave access to all. Moved to review Connie Please go to http: Personal Information redacted by USI Personal Information redacted by USI	
18/11/2015 11:41:43	Connolly, Connie	Forde, Helen	This is a feedback message from Connie Connolly. Incident form reference is Personal Information redacted by USI The feedback is: Hi all- i have moved this to FSS for investigation and close. There may be 2 teams which cross over in relation to this issue. I wasnt sure so i gave access to all. Moved to review Connie Please go to http Personal Information redacted by USI	

Speciality / Team Urology Surgery

Staff initially notified upon submission

Recipient Name	Recipient E-mail	Date/Time	Contact ID	Telephone Number	Job title	Originated from
No details found for the contact with ID 11592.	sharon.kennedy Personal Information redacted by the USI	21/10/2015 20:26:07	11592			Level 1 Form
No details found for the contact with ID 29029.	Eamon.Mackle Personal Information redacted by the USI	21/10/2015 20:26:07	29029			Level 1 Form
Connolly, Connie	connie.connolly Personal Information redacted by the USI	21/10/2015 20:26:06	9424		Acting Acute Governance Co-Ordinator	Level 1 Form
Mackin, Dawn	dawn.mackin Personal Information redacted by the USI	21/10/2015 20:26:06	10268		Nursing Governance CoOrdinator	Level 1 Form
Young, Michael	Michael.Young Personal Information redacted by the USI	21/10/2015 20:26:05	29046		Consultant	Level 1 Form
Smyth, Paul	paul.smith Personal Information redacted by the USI	21/10/2015 20:26:05	8201		Head of Unscheduled Care	Level 1 Form
Trouton, Heather	heather.trouton Personal Information redacted by the USI	21/10/2015 20:26:05	9418		Assistant Director of Acute Services	Level 1 Form
Glenny, Sharon	sharon.glenny Personal Information redacted by the USI	21/10/2015 20:26:04	9425		Operational Support Lead	Level 1 Form
Nelson, Amie	amie.nelson Personal Information redacted by the USI	21/10/2015 20:26:04	9426		Head of Service	Level 1 Form
Corrigan, Martina	martina.corrigan Personal Information redacted by the USI	21/10/2015 20:26:03	9419		Head of ENT and Urology	Level 1 Form

Management of Incident

Handler
Enter the manager who is handling the review of the incident

Martina Corrigan

Additional/dual handler
If it is practice within your team for two managers to review incidents together use this field to record the second handler

Escalate
You can use this field to note the incident has been escalated to a more senior manager within your Service/Division- select the manager from this list and send an email via the Communication section to notify the manager the

(a) Mr O'Brien was responsible for ensuring his own practice was of the highest standards. If something in the organisation was stopping him from doing this, in my opinion he should have escalated it through the correct channels, whilst continuing to do his best to ensure patient safety until it was resolved. He is a senior member of his profession and, like all registered clinical staff including myself, he is responsible for ensuring his practice was evidence based and in line with current best practice.

(b) Mr O'Brien was a senior member of the medical staff, who had trained may of the other younger consultant staff who had become his colleagues. This led to a reluctance to critically review his practice and challenge him when abnormal practice was identified in my opinion.

(c) Due to Mr O'Brien's seniority, he was well respected by other experienced consultants in specialities outside urology and within the Trust's senior executive team. I believe that those people may have discouraged others from challenging him.

(d) The excessive workload of the clinical and operational managers/leaders within Acute Services meant that staff were often overwhelmed with keeping the service running, which may have given them limited time to focus on governance activities.

(e) The turnover of the Medical Director's and the Director of Acute Services posts led to inconsistencies in experience, approach and the follow-up of concerns.

40. What do you consider the learning to have been from a governance perspective regarding the issues of concern within urology services and, to the extent that you are aware, the concerns involving Mr. O'Brien in particular?

40.1. As I retired from the Trust on 31st January 2022, I am not party to the full extent of the more recent concerns and the associated learning in relation to

38.2 I was not able to assist Mr Haynes with data for this audit as these prescription recommendations were being made at patient's outpatient clinic attendances. At the clinic the patient would be given a paper recommendation note to take to their GP, who would then prescribe the bicalutamide which was then dispensed by a community pharmacy. Therefore, the Trust pharmacy had no records of what had been dispensed and prescribed. A clinic letter, addressed to a patient's GP, would then have been dictated at a later date and sent to the GP.

38.3 I thought that the audit could potentially be carried out by using data from the community pharmacy dispensing payment system, which is held by the Health and Social Care Board. Therefore I contacted Mr Joe Brogan, HSCB lead pharmacist, and put him in contact with Mr Haynes.

38.4 Given that the outpatient prescribing recommendation system in use within the Trust is largely paper based, it is not possible to run reports or audits to identify such problems earlier. In 2015/16 there was work ongoing to implement an electronic prescribing and administration system for medicines across all five of the Trusts. Unfortunately this work was halted as the "Encompass" project was being considered. Once the Encompass project is implemented in all five Trusts, it should be possible to set up electronic surveillance that could identify outliers in prescribing practice quickly.

39. Having had the opportunity to reflect on these governance concerns arising out of the provision of urology services, do you have an explanation as to what went wrong within urology services and why?

39.1 In my opinion there was a combination of factors that I believe contributed to what went wrong within urology services: