Urology Services Inquiry

UROLOGY SERVICES INQUIRY

USI Ref: S21 No.60 of 2022
Date of Notice: 7th June 2022

Witness Statement of: David Connolly

I, David Connolly, will say as follows:-

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 you, meetings attended by you, 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 I started in Southern Health and Social Care Trust (hereafter 'SHSCT') as a Consultant Urologist in September 2012 and left to join Belfast Health and Social Care Trust in March 2013. This was my first consultant job and was always going to be a short-term appointment for me as I planned to move to Belfast Health and Social Care Trust. As a new consultant, I only had a basic knowledge of the processes behind running a Consultant practice, managing a rapidly expanding service and the Governance structure of a Health Trust.

1.2 I was a standard core urologist with responsibilities as outlined in Paragraphs 5 to 8. I did not take on any other management roles nor did I get involved in the long term planning for the unit as I and within a few months, my Consultant colleagues knew that I was leaving.

1.3 I thought it was a very good unit and there was excellent collaboration and working relationships between Consultants, junior medical staff, ward nurses and nurse specialists, managers and administrative staff as outlined in Paragraphs 22 to 28.

1.4 I thought the Governance structures at SHSCT were satisfactory at the time. As stated above, this was my first Consultant post and the processes and Governance Structure of a Health Trust were all very new to me. There

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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: 1st August, 2022.

Received from David Connolly on 11/08/2022. Annotated by the Urology Services Inquiry.

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7.2. Any issues relating to clinical care, patient safety, administration and governance would have been raised with my Clinical Lead, Mr. Young. I do not recall ever having any such issues that I had to discuss with him.

8. It would be helpful for the Inquiry for you to explain how those aspects of your role and responsibilities which were relevant to the operation and governance of Urology Services, differed from and/or overlapped with the roles of the Clinical Lead, Clinical Director, Medical Director, Associate Medical Director, and Head of Urology Service or with any other role which had governance responsibility.

8.1. I was a standard Consultant Urologist and did not feel that I had any higher level of governance responsibility which would have overlapped with my Clinical Lead, Clinical Director, Medical Director, Associate Medical Director, or the Head of Urology Service. I did feel that I could have raised any issues or concerns with my Clinical Lead or Service manager however this never occurred during my employment within SHSCT.

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9. For the purposes of your tenure, in April 2008, the SHSCT published the *'Integrated Elective Access Protocol'*, the introduction of which set out the background purpose of the Protocol as follows:

> **1.1 INTRODUCTION**
> **1.1.1 This protocol has been developed to encompass the elective pathway within a hospital environment. The principles can be applied to primary and community settings, however it is recommended that guidance is developed which recognises the specific needs of the care pathway provided in these settings.**
>
> **1.1.2 The length of time a patient needs to wait for elective treatment is an important quality issue and is a visible public indicator of the efficiency of the hospital services provided by the Trust. The successful management of patients who wait for outpatient assessments, diagnostic investigations and elective inpatient or day case treatment is the responsibility of a number of key individuals within the organisation. General Practitioners, commissioners, hospital medical staff, managers and clerical staff have an important role in ensuring access for patients in line with maximum waiting time guarantees, managing waiting lists effectively, treating patients**

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53.1. I was not aware of any concerns regarding Mr. O'Brien when I was employed by SHSCT.

53.2. I first became aware of potential issues when I was speaking to Mr. O'Brien after he retired. I believe this was late July or early August, 2020. He informed me of his perceived poor treatment by SHSCT after his retirement (at the end of a telephone conversation about one of his SHSCT patients who he had planned to refer to BHSCT for a metallic stent (Personal Information redacted by the USI, Personal Information redacted by the USI). Mr. O'Brien was aware that this patient was a family friend of mine and he didn't want his care being delayed with his retirement. He was also aware that I had already been helping the patient understand his illness and make decisions regarding his treatment with Mr. O'Brien). He advised that he had a verbal agreement with SHSCT that he would return to work on a part time basis after his formal retirement. When he contacted SHSCT to arrange his return, he was advised that SHSCT did not want him to return to work as he had an outstanding grievance against the Trust management. He felt this was unlawful and he advised that he planned to sue the SHSCT. Mr. O'Brien informed me that he believed that SHSCT began an investigation into his clinical practice after he brought an unfair dismissal claim against SHSCT.

54. Did you raise any concerns about the conduct/performance of Mr O'Brien? If yes:

(a) Outline the nature of concerns you raised, and why they were raised?

(b) Who did you raise it with and when?

(c) What action was taken by you and others, if any, after the issue was raised?

(d) What was the outcome of raising the issue?

If you did not raise any concerns about the conduct/performance of Mr. O'Brien which were known to you, please explain why you did not?

54.1. I was not aware of, nor did I raise, any concerns regarding Mr. O'Brien when I was employed by SHSCT.

55. As relevant, please detail all discussions (including meetings) in which you were involved which considered concerns about Mr. O'Brien,

and delivering a high quality, efficient and responsive service. Ensuring prompt timely and accurate communications with patients is a core responsibility of the hospital and the wider local health community.

1.1.3 The purpose of this protocol is to define those roles and responsibilities, to document how data should be collected, recorded and reported, and to establish a number of good practice guidelines to assist staff with the effective management of outpatient, diagnostic and inpatient waiting lists. It will be a step-by-step guide to staff, and act as a reference work, for the successful management of patients waiting for hospital treatment.

1.1.4 This protocol will be updated, as a minimum, on an annual basis to ensure that Trusts' polices *(sic)* and procedures remain up to date, and reflect best practice locally and nationally. Trusts will ensure a flexible approach to getting patients treated, which will deliver a quick response to the changing nature of waiting lists, and their successful management.

1.1.5 This protocol will be available to all staff via Trusts' Intranet.

During your time working in Urology services, was the *'Integrated Elective Access Protocol'* provided to you or its contents made known to you in any way by the SHSCT? If yes, how and by whom was this done? If not, how, if at all, were you made aware of your *role and responsibilities* as a Consultant urologist as *to how data should be collected, recorded and reported ... to establish good practice guidelines to assist staff with the effective management of outpatient, diagnostic and inpatient waiting lists for the successful management of patients waiting for hospital treatment*?

9.1. I was aware of the Integrated Elective Access Protocol (hereafter 'IEAP'), most probably from Mr. Young and Martina Corrigan. I do not recall if I was ever given the full document or signposted to it on the Trust intranet. I was informed from an early part of my employment (Sept or Oct 2012) that the main focus of the IEAP in the urology unit was trying to decrease the waiting times for all patients so that the target times were met. As a new Consultant in a new post, on a practical basis this meant taking the longest waiters from other consultant's waiting lists and operating on them. I was aware of the importance of reducing waiting times and of ensuring no patients were waiting longer than the agreed target times for their planned out-patient review or surgical intervention.

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59. What, if any, metrics were used in monitoring and assessing the effectiveness of any agreed way forward or any measures introduced to address the concerns? How did these measures differ from what existed before? Who was responsible for overseeing any agreed way forward, how was this done, where was record of the oversight recorded, and how long did this oversight last? Please include any documentation (unless already provided) and/or indicate where the Inquiry may find a record of any oversight.

59.1. Not applicable.

60. As relevant, how did you assure yourself that any systems and agreements put in place to address concerns (if this was done) were sufficiently robust and comprehensive and were working as anticipated? What methods of review were used? Against what standards were methods assessed? Are there records of you having assured yourself that systems and agreements put in place, to address concerns, were effective?

60.1. Not applicable.

61. Did any such agreements and systems which were put in place operate to remedy the concerns? If yes, please explain. If not, why do you think that was the case? What, in your view, could have been done differently?

61.1. Not applicable.

62. Did Mr O'Brien raise any concerns with you regarding, for example, patient care and safety, risk, clinical governance or administrative issues or any matter which might impact on those issues? If yes, what concerns did he raise (and if not with you, with whom), and when and in what context did he raise them?

62.1. I cannot recall the specific details, however, I do remember that Mr. O'Brien had long standing concerns regarding the perception or support of Urology by the General Surgical management in SHSCT. This would have been discussed informally during conversations at break times and during meetings with the whole consultant team about the restructuring of urology services. There were no specific patient safety concerns raised, it was more about the perception of and resource given to urology compared to other services. Specifically, I recall that he did not have a good relationship with Mr. Eamon Mackle (Associate Medical Director). I recall that Mr O'Brien felt that

Mr. Mackle did not take Urology seriously and would always make decisions that prioritised general surgery over Urology.

63. How, if at all, were those concerns considered and what, if anything, was done about them and by whom? If nothing was done, who was the person responsible for doing something? How far would you expect those concerns to escalate through the chain of management?

63.1. I was unsure if this was a real concern or just a clash of personalities. I was never aware if this was actually raised as a formal concern by Mr. O'Brien. In any case, Urology has just expanded to 5 consultants and would have a far greater input in SHSCT and I would have expected these concerns to improve over time.

64. What support was provided by you and the Trust specifically to Mr. O'Brien given the concerns identified by him and others? Did you engage with other Trust staff to discuss support options, such as, for example, Human Resources? If yes, please explain in full. If not, please explain why not.

64.1. I did not provide support as I did not feel that Mr. O'Brien needed formal support at that time. I was unaware if the Trust were aware of any concerns of Mr. O'Brien nor if any support was given to him.

65. How, if at all, were the concerns raised by Mr. O'Brien and others reflected in Trust governance documents, such as the Risk Register? Please provide any documents referred to, unless already provided. If the concerns raised were not reflected in governance documents and raised in meetings relevant to governance, please explain why not.

65.1. I am not aware if a formal concern / compliant was raised by Mr. O'Brien nor how this was managed, if so.

<u>Learning</u>

66. Are you now aware of governance concerns arising out of the provision of Urology Services, which you were not aware of during your tenure? Identify any governance concerns which fall into this category and state whether you could and should have been made aware and why.

66.1. No, the only formal information that I am aware of surrounding the concerns raised about Mr. O'Brien relates to that which I have seen or read on

Aimee Crilly

From: Young, Michael <Personal Information redacted by the USI>
Sent: 26 November 2012 11:13
To: Connolly, David; O'Brien, Aidan; Pahuja, Ajay; Glackin, Anthony
Subject: RE: Emergency list

What exactly is this = completely unaware of this Will investigate MY

From: Connolly, David
Sent: 25 November 2012 12:30
To: O'Brien, Aidan; Pahuja, Ajay; Young, Michael; Glackin, Anthony
Subject: Emergency list

Hi,

Was anyone aware of the way that emergency lists are now running? What I was told is the Surgeon of the Week reviews the list and prioritises it, giving time limits that the cases need to be performed in (1 hour, 4 hours, 12 hours, 24 hours etc.) I did not receive any communication about this as far as I know but it appears to have been implemented from last week.

I have just had a case bumped down the list without any communication from the surgical team – bilateral ureteric stones with hydro, luckily she is not septic and renal function is OK – but when I went down, I was told that their case had to be done within 4 hours so got prioritised. Just slightly annoyed that this seems to have happened without any input from the other specialities which also use the emergency list.

David

Received from Tughans OBO Mr Aidan O'Brien on 10/04/2022. Annotated by the Urology Services Inquiry

the news. I have specifically not spoken to Mr. O'Brien given the potential that I may have to give evidence during the USI.

67. Having had the opportunity to reflect, do you have an explanation as to what went wrong within Urology Services and why?

67.1. When I started in the urology unit in SHSCT I felt it was a good Unit, with good working relationships between staff members including Consultants, trainees, nursing staff (both ward and nurse specialists), secretaries and unit managers. The Unit had significant backlogs and waiting times and this would have taken time and effort from all staff to organise and resolve. With the expansion of Consultant numbers and the upcoming rebuilding of a dedicated Urology 'one-stop' clinic, there was a lot of good will and excitement about the future of the unit. In the intervening years, I, and a number of other staff members, have moved on and I understand that there has been difficulties with recruiting and retaining fulltime staff. The SHCST have advertised on a number of occasions for substantive Consultant urologists and have not successfully appointed anyone. I suspect that this has led to increased pressure on the remaining staff and the services have become stretched and pressurised. I expect that this has likely led to worsening interpersonal relationships between individual Consultants, admin staff and management. It also leaves less time for the usual governance structures to work robustly. With COVID, these problems have exacerbated the underlying issues so that the service now has difficulty managing even its core work.

67.2. At the time, I felt it was a well-run unit with good engagement and organisation between the medical staff and management. Like other units I have worked in, there were appropriate formal processes of risk management, clinical governance and patient safety. Any issues tended to be managed informally and almost on an ad hoc basis. There was however very little true structure to governance meetings and there tended to be no agenda and the meetings were not minuted. Any patient safety issues, complaints and incidents tended to be managed by the individual consultants involved. Therefore there was the potential for a lack of independence or oversight. This is not an exclusive issue with SHSCT and I suspect this was normal practice at that time. Indeed, it is only since the Dr. Michael Watt case in Belfast Trust where I have seen this change so that these governance processes are now more formal and documented with independent oversight.

68. What do you consider the learning to have been from a governance perspective regarding the issues of concern within Urology Services and the unit, and regarding the concerns involving Mr. O'Brien in particular?

administrative team. I felt I had sufficient administrative support. I did not have any concerns.

26. As Consultant urologist, how did you assure yourself regarding patient risk and safety and clinical care in Urology Services in general? What systems were in place to assure you that appropriate standards were being met and maintained?

26.1. As this was my first Consultant post (and I had not planned to stay in the Unit on a long term basis), I did not have a good grasp of the clinical governance structure and processes at the time. On appointment, I believed that the Trust governance structures were already in place and I was happy to fully engage with them. I was aware of the Unit's M&M meetings, grand ward rounds, audit meetings, complaints management, Critical incident reporting (IR1), risk register and MDT (and appraisal had I stayed longer). This provided me reassurance that patient safety and minimising risk were an important part of the unit's standard work.

27. Who was in overall charge of the day to day running of the Urology unit? To whom did that person answer? Give the names and job titles for each of the persons in charge of the overall day to day running of the unit and to whom that person answered throughout your tenure. Identify the person/role to whom you were answerable.

27.1. Mr. Young was my clinical lead. He was answerable to the Clinical Director, Mr Robin Brown the Associate Medical Director, Mr Eamon Mackle and the Medical Director, Dr John Simpson. Mrs. Martina Corrigan was the Head of Surgical Service. She was answerable to the the Assistant Directors, Mrs Heather Trouton, Assistant Director of Surgery and Elective Care, Mr Ronan Carroll Assistant Director of Cancer and Clinical Services and the Director of Acute Services, Dr Gillian Rankin.

28. During your tenure did medical managers and non-medical managers in Urology work well together? Whether your answer is yes or no, please explain with examples.

28.1. Yes, I thought they worked very well together. This was a time of great change in the Unit and there were regular meetings between the Consultants and Managers about restructuring and improving services which always appeared very productive to me. There was a monthly scheduling meeting chaired jointly with Mr. Young and Martina Corrigan and this was always very amicable and friendly.

31.2. There was also a weekly x-ray meeting (my recollection is that this occurred every Tuesday) which lasted one hour. Minutes were not taken however individual Consultants would have made a plan for their patients which were discussed. There was a monthly M&M audit meeting as part of the rolling audit calendar which lasted approximately 3 to 4 hours. I believe minutes were taken for the M&M meetings but I do not have access to any of these. SHSCT may have records from M&M meetings from that time.

<u>Governance</u>

32. During your tenure, who did you understand as overseeing the quality of Services in Urology? If not you, who was responsible for this and how did they provide you with assurances regarding the quality of Services?

32.1. I believe that I had individual responsibility for ensuring that I was providing good quality care for my patients. This would have been assured through the Trust governance structure such as IR1s, complaints, audit or M&M meetings and the risk register, for example. This would have been overseen by my clinical lead, Mr. Young, and my service manager Martina Corrigan. I do not recall any issues regarding the quality of care that I provided being raised during my time in SHSCT. I was never aware of any issue with any of the wider Urology service.

33. Who oversaw the clinical governance arrangements of the unit and how was this done? As Consultant urologist, how did you assure yourself that this was being done properly? How, if at all, were you as Consultant urologist provided with assurances regarding the quality of urology services?

33.1. As per my answer to Question 32, I believed that the clinical lead and service manager were responsible for overseeing the clinical governance arrangements of the unit. I am not aware of how this was undertaken, however, I assume that there were open lines of communication between Mr. Young and Martina Corrigan and that they had access to all of the governance data that the Trust obtained, such as IR1s, complaints, appraisal and the risk register.

33.2. I took personal responsibility for my practice and continued personal development. I ensured that I kept up to date and was aware of and followed current guidelines. I assumed other consultants did the same as this was expected as part of our annual appraisal. I never asked for, nor was I ever provided with, any assurances regarding the governance structure of the Urology Unit.

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39. How did you ensure that you were appraised of any concerns generally within or relating to Urology Services?

39.1. Had any issues been raised, I would have expected these to be discussed during the dedicated governance day (Thursday); either around the discussions during the Grand ward round, during the lunchtime meetings or during Cancer MDT. There were also ad-hoc meetings between the Consultant team to discuss the proposed service changes which would have provided a further opportunity for concerns to be raised. I never asked for, nor was I ever provided with, any assurances regarding the quality of Urological care under any consultant.

40. How, if at all, were any concerns raised or identified by you or others reflected in Trust governance documents, such as Governance meeting minutes or notes, or in the Risk Register? Please provide any documents referred to (unless provided already by the Trust).

40.1. Not applicable. Any such concerns were not raised by me during my tenure, or by others, to the best of my knowledge and recollection.

41. What systems were in place for collecting patient data in Urology Services? How did those systems help identify concerns, if at all?

41.1 Data would have been automatically collected as part of each Consultants' Appraisal, for example, the number of elective or emergency admissions, the number of readmissions within 30 days, the number or rate of mortality, the number of patients seen at OPC with New Review ratio. I was never sent this data as I left the Trust before I did an Appraisal. I would have expected that this would also have included information on Complaints, IR1 and Serious Adverse Incidents (SAIs), as these data are routinely included in my Annual Appraisal in Belfast Trust. Data would also have been collected for M&M or audit meetings. These data should have been able to identify patterns of concern if these existed. Waiting time data was also regularly collected and presented to the Consultant team as part of IEAP.

42. What is your view of the efficacy of those systems? Did those systems change over time and, if so, what were the changes?

The other Consultant Urologists were Mr. Aidan O'Brien, Mr. Tony Glackin, and Mr. Ajay Pahuja.

I trained with Mr. Glackin and Mr. Pahuja and I considered them to be my contemporaries. I would have been comfortable raising clinical concerns directly with them. Mr. O'Brien was my supervising Consultant both when I was a locum registrar in Craigavon (2004 to 2007) and when I started my higher training in Urology (Urology ST3, 2007 to 2008). I would not have felt comfortable going directly to Mr. O'Brien if I had concerns as he only knew me when I was very junior and inexperienced, and we did not have time to build a stronger relationship before I left. In any event, I did not have any concerns to raise.

I have no relevant documentation.

When answering this question please name the individual(s) who held each role during your tenure. When addressing this question you should appreciate that the Inquiry is interested to understand how you liaised with these post- holders in matters of concern regarding Urology governance generally, and in particular those governance concerns with the potential to impact on patient care and safety. In providing your answer, please set out in detail the precise nature of how your roles interacted on matters (i) of governance generally, and (ii) specifically with reference to the concerns raised regarding Urology services which are the subject of this Inquiry. You should refer to all relevant documentation (and provide that documentation if not previously provided), dates of meetings, actions taken, etc.

48. Were any concerns ever raised regarding your clinical practice? If so, please provide details.

48.1. No.

49. Did you ever have cause for concern, or were concerns ever reported to you regarding:

(a) The clinical practice of any medical practitioner in Urology Services?

No.

(b) Patient safety in Urology Services?

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70.3. For example, Mr O'Brien (and Mr. Young and Mr. Akhtar) used to regularly admit patients with recurrent urinary tract infections to the Urology ward for 5 to 7 days to be treated with intravenous antibiotics and fluids. I never saw this in any guideline but accepted that this was the standard practice in the unit, which predated my time. I felt that I was never going to change this practice in the short time that I was planning to stay in SHSCT but I was not going to practice in the same way. Similarly, he did not like using intravesical BCG therapy for high-risk non-muscle invasive bladder cancer and preferred Mitomycin therapy. I was informed (I do not recall if this was by Mr. O'Brien himself or someone else), that Mr. O'Brien had a patient soon after BCG was first introduced that developed a small capacity, poorly functioning bladder as a side effect of the BCG treatment and since that time, he did not like using BCG. I did not have this experience and continued to advise BCG for my patients. Over time, there may have been the opportunity for me to challenge some of the differences between our practices but I never felt that was a realistic prospect during my short tenure at Craigavon Area Hospital.

71. Do you think, overall, the governance arrangements were fit for purpose? Did you have concerns about the governance arrangements and did you raise those concerns with anyone? If yes, what were those concerns and with whom did you raise them and what, if anything, was done?

71.1. In hindsight I do not think the Governance arrangements were fit for purpose. I did not appreciate this at the time as this was my first consultant job and the processes in SHSCT appeared to be similar to other units I had worked in during my urology training. As a result, I did not raise this as a concern. As outlined in my answer to Question 67, this was my experience of all the Units I worked in during my Urology training and as a Consultant until the last 5 years or so. I have noted within Belfast Trust in the past 5 years that governance procedures have become far more formalised. The recording and documentation of issues, and the independent oversight of these has greatly improved. I suspect this relates to lessons learned from the Dr. Michael Watt case.

72. Given the Inquiry's terms of reference, is there anything else you would like to add to assist the Inquiry in ensuring it has all the information relevant to those Terms?

72.1. No.

68.1. I am not fully aware of the issues that have been identified in the Urology unit regarding governance procedures and concerns about Mr. O'Brien specifically. I think there has been significant change in Governance structures in Belfast Trust in the past few years and I would expect that the learning from the Dr. Michael Watt inquiry would be shared amongst all Healthcare providers in Northern Ireland to promote these recommendations being implemented regionally.

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

69.1. I do not feel that I have the knowledge of all the events to be able to comment on this. In my view, all the issues which were subsequently identified and managed in SHSCT occurred after I had moved to Belfast Trust.

70. 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 properly utilised to maximum effect? If yes, please explain how and by whom. If not, what could have been done differently/better within the arrangements which existed during your tenure?

70.1. No. I do not believe that I made any mistakes in handling concerns at the time. I did not identify any significant concerns during my time in SHSCT, nor were any concerns ever raised with me by any other staff members.

70.2. In my time working with Mr. O'Brien, I found him to be very similar to other older Consultants that I had worked with during my training. He had a wealth of experience and was technically a very good surgeon. He was a good teacher and was very patient with trainees. His patients were very fond of him, even to the point where they preferred to see Mr O'Brien personally instead of other Consultants or trainees and they respected his opinion above all others. He did, however, have idiosyncrasies to his practice that I did not understand. As a new Consultant and having recently passed the FRCS (Urol) exit exam, I was very guideline and evidence focused and I practised as closely to what I had learned during my training as possible. Mr. O'Brien had changed his practice based on his experience and anecdotal cases.

Southern Health and Social Care Trust

Quality Care - for you, with you

BCG (Bacillus Calmette Guérin) Audit

With reference to the concern raised with regards to Mr O'Brien's use of intravesical BCG treatment for patients with high risk non-muscle invasive urothelial cancers of the bladder, the existing Lookback Review cases have been interrogated. A single case of high risk non muscle invasive bladder cancer was identified where BCG treatment was not offered. For this patient there was clinical justification for the decision to not offer BCG. Therefore, to date the Lookback Review has not identified any concerns regarding the offer of BCG treatment to patients with high risk non muscle invasive bladder cancer. As BCG treatment for high risk non muscle invasive bladder cancer is given after initial diagnosis (and re-resection TURBT) and that following retirement Mr O'Brien's patients' care has been continued by the remaining members of the Southern Trust urology team, we do not have any concern that there is an ongoing patient concern regarding this group of patients not currently receiving appropriate management.

Mr Connolly references the risk of functional side effects of BCG therapy, in particular in the longer term. Bladder function / symptoms factor into decision making for patients, and may be a clinical reason why BCG treatment is not offered – in order to receive BCG treatment patients need to retain the BCG in their bladder for up to 2 hours. Patients who are unable to do this either because of incontinence or severe urgency symptoms would not be suitable for the treatment. In addition, patients' bladder symptoms can become worse during the course of BCG treatment. Approximately 1/3 of patients do not complete 3-year maintenance BCG programmes with the majority of these being because of worsened bladder symptoms. Risk of persistent bladder pain '…sometimes leading to bladder removal' is quoted as 1:50 – 1:250 in the patient information leaflet produced by BAUS for patients receiving BCG treatment. Patients are counselled regarding these risks when their treatment options are discussed with them. Unfortunately, some patients do develop intractable bladder symptoms as described by Mr Connolly as a result of BCG treatment and may subsequently require surgery to remove their bladders to manage these symptoms.

We have considered the guidance for bladder cancer management which was available during the time which Mr Connolly was a consultant in Southern Trust, in order to ascertain if the assertion by Mr Connolly can be evidenced in the treatment patients received. At this time, NICE guidelines had not been published (they were first published in 2015). The available guidance for multidisciplinary teams at this time had been produced by BAUS (January 2013) which recommends 'Intravesical BCG + maintenance 1-3 years' (page 17 of BAUS MDT guidance for the management of bladder cancer 2013) and references the European Association of Urology guidelines for bladder cancer.

A significant factor which has occurred on a number of occasions over the past decade is disruption / unavailability of BCG supplies. This was an issue during the time period 2012 – 2013. This has been a worldwide problem and has meant that at times of unavailability of BCG patients were not able to be offered this treatment and delivery of maintenance BCG for patients has been interrupted and therefore sub-optimal. Supplies of BCG during periods of disruption have been intermittent and

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limited BCG supply. This document states, ***'References about the use of only an induction course (6 weekly instillations without maintenance) are controversial. A recently presented cohort study showed promising results, however meta-analyses have shown induction only BCG to have inferior efficacy compared to intravesical chemotherapy.'*** The recommendations for management of this group of patients when faced with limited BCG supply, as was the case during this time period, included a recommendation to deliver maintenance treatment for 1 year (not up to 3 years, recommendation 3), and recommendation 4 states, ***'In patients with Ta or T1 tumours at intermediate or high risk of recurrence and intermediate risk of progression, adjuvant BCG treatment can be replaced by intravesical chemotherapy which represents an alternative treatment option'.***

Despite the NICE guidelines not being published until 2015, in order to assess the care of patients with non muscle invasive bladder cancer treated in Southern Trust during the time period when Mr Connolly worked as a Consultant in Southern Trust we utilised the audit tool published alongside these guidelines. Unfortunately, the data output from this audit did not provide sufficient insight into the care provided to patients with high risk non muscle invasive bladder cancer to be able to assess Mr O'Brien's utilisation of BCG for patients with high risk non muscle invasive bladder cancer and the concern raised in Mr Connolly's statement.

This audit did enable us to identify those patients who were first diagnosed with high risk non muscle invasive bladder cancer in the 2012-13 and 2013-14 financial years and a subsequent review of all of these cases was undertaken with regards to the offer of intravesical treatment and the MDM recommendations given at the time.

A total of 38 patients were identified with a diagnosis of high risk non muscle invasive bladder cancer on their initial TURBT. Of these 7 patients were upstaged to muscle invasive disease on re-resection TURBT, and 1 patient was found to have metastatic disease on staging. A further 3 patients had severe significant co-morbidities and were managed with palliative intent.

The remaining 27 patients were potentially eligible for BCG treatment. A total of 9 consultants who worked in the Southern Trust urology department during this time period managed these patients. Mr O'Brien was recorded as managing 5 of these patients. The table below details the intravesical treatment offered to these patients.

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	All consultants	Mr O'Brien	All other consultants (excluding Mr O'Brien)
Offered BCG	10/27 = 37%	2/5 = 40%	8/22 = 36%
Offered MMC, BCG noted as unavailable	3/27 = 11%	0/5 = 0%	3/22 = 14%
Offered MMC, BCG availability not recorded	6 = 22%	1/5 = 20%	5/22 = 23%
Not offered intravesical treatment with clinical justification	3 = 11%	0/5 = 0%	3/22 = 14%
Not offered intravesical treatment, no clinical justification recorded	4 = 15%	1/5 = 20%	3/22 = 14%
DNA follow-up	1 = 4%	1/5 = 20%	0/22 = 0%

From the data collected over this time period there is therefore no evidence that patients under the care of Mr O'Brien during this time period were less likely to be offered BCG in the management of their high risk non muscle invasive bladder cancer than patients under the care of the rest of the urology team.

Review of the MDM recommendations made during this time period identifies that for 12 patients the MDM outcome specifically recommends BCG treatment (including availability issues for 3 patients), for 5 patients the outcome recommends MMC therapy alone, 1 outcome recommends 'Intravesical treatment' but does not specify MMC or BCG, 8 outcomes do not make any recommendation of intravesical treatment and for 1 patient no MDM record was identified (Consultant = Mr Brown). Mr O'Brien is listed as the chair of MDM for all of these MDM outcomes. While it is possible that Mr O'Brien expressed the view highlighted by Mr Connolly during MDM discussions, a greater proportion of MDM outcomes recommended BCG treatment than any alternative treatment. For those outcomes that recommended MMC, intravesical therapy or did not recommend any intravesical treatment, it is possible that the MDM discussion considered BCG treatment but that this was not recorded in the outcome detail. For those patients for whom the MDM outcome did not recommend any intravesical treatment, clinical records at the time indicate significant co-morbidity / frailty / co-existent pathology in 7 (of 8) patients. It is also possible that recommendations for MMC were made in the light of BCG supply problems but not referenced in these MDM outcomes.

With regards to current practice within the Southern Trust urology service, we are confident that BCG is being offered to patients with high-risk non muscle invasive bladder cancer as per NICE guidelines from 2015 and we are auditing current practice against the NICE 2015 standards as part of our current departmental audit plan. In addition, more recent EAU guidance has clearly identified sub-groups of high-risk patients who are at a very high risk of progression and in whom radical cystectomy is recommended. This is being utilised as part of MDM recommendations and patient counselling. Currently, supplies of BCG are satisfactory and therefore at present this is not a factor in treatment selection.

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Of note during the process of this review concern has been identified regarding the management of 1 patient (who is now deceased) with metastatic / muscle invasive disease and this has been flagged to the Trust lookback team for further assessment. This concern is not in relation to intravesical treatment.

Mark Haynes

Consultant Urologist

24 November 2023

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