Urology Services Inquiry

Oral Hearing

Day 61 – Tuesday, 19th September 2023

Being heard before: **Ms Christine Smith KC (Chair)**

Dr Sonia Swart (Panel Member)

Mr Damian Hanbury (Assessor)

Held at: **Bradford Court, Belfast**

Gwen Malone Stenography Services certify the following to be a verbatim transcript of their stenographic notes in the above-named action.

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THE INQUIRY RESUMED AS FOLLOWS ON TUESDAY, 19TH SEPTEMBER 2023

CHAIR: Morning everyone. Good morning Ms. McMahon.

MS. McMAHON: Chair, this morning we're going to hear evidence from Dr. Darren Mitchell, who is a Clinical Oncologist at the City Hospital in the Belfast Trust. Before that, I have a short opening statement to make to introduce module four and set out aims and objectives of the module and how it fits in with the Terms of Reference. So I'll just read that and then a copy will be available on the website.

OPENING BY MS. McMAHON

MS. McMAHON: Chair, we have now reached the fourth module of the Inquiry's work. This will be an opportunity for the Inquiry to engage with the work of some of the clinicians who served within or who interacted with the Southern Trust's Urology Service.

It will be recalled that during the scene setting phase of the Inquiry's public hearings, which we commenced last November, the Inquiry gained sight of, and explored with witnesses, what the Southern Trust had identified as shortcomings in the clinical practice of Mr. Aidan O'Brien during 2020.

We were able to examine the nature and implications of

those alleged shortcomings by focusing on the outcome of the reviews of nine serious adverse incidents and through receiving oral evidence from a range of witnesses, notably Dr. Hughes and Mr. Gilbert, as well as Mr. Haynes. 10:03

During the Inquiry's second module, which was directed to Part E of the Inquiry's Terms of Reference, we examined the operation of the MHPS framework. In doing so, we also built upon the work of the first phase of 10:03
the Inquiry's public hearings by receiving from witnesses their descriptions of a number of additional concerns associated with Mr. O'Brien's practice, including notably his failure to triage urgent and routine referrals and his backlog of dictation 10:03
following clinical encounters. It was concerns such as these and their implications for patient safety which appear to have caused the Trust to instigate an MHPS investigation in 2017.

10:04

Witnesses suggested that some of those concerns may have been known to management and colleagues within the Trust for many years.

In our last module, Governance in Action, which 10:04
completed last week, the Inquiry explored aspects of the clinical governance arrangements which operated within the Southern Trust. Against the backdrop of the reported shortcomings and concerns, and having regard

to the requirements stipulated within Part B of the Terms of Reference, the Inquiry explored with witnesses whether those governance arrangements have been effective in providing for patient care and safety.

10:04

Taken together, the evidence received by the Inquiry to date will assist you, the panel, to gauge the effectiveness and robustness of the Trust's frameworks for identifying and challenging practice which may depart from acceptable standards and its ability to effectively provide for safe and reliable patient care within the urology specialty.

10:04

The module which commences today and which we plan to run until 4th December, will focus on the practice and delivery of urology services within the Southern Trust. Importantly, it will be possible, indeed necessary, to scrutinise the practice and delivery of those services by reference to the instruments of governance. Those systems and structures, practices and procedures which ought to be in place to underpin patient care and safety.

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10:05

The witnesses who are to be called during this module are clinicians who have engaged with, or worked within the Trust's urology service, and who will be able to describe the practices of that specialty, how it functioned and the difficulties which it faced. They include a number of consultant urologists, as well as

10:05

clinicians from other disciplines who have worked on the front line to deliver urology services for the population served by the Southern Trust. Some of the clinicians who will give evidence, such as Mr. Michael Young, have knowledge of how the service has developed over the past 20 years or so. Each of the witnesses has worked alongside Mr. O'Brien, or in the case of a number of clinicians who work in the Belfast Trust, have received referrals from him. 10:06

I anticipate that each of them will be in a position to assist the Inquiry to better understand the challenges faced by practitioners when delivering urological services against the backdrop of what others have indicated is an ongoing and significant shortfall in capacity. 10:06

The module is directed to a number of overlapping requirements of the Inquiry's Terms of Reference. Part A of the terms of reference encourages interest in whether relevant complaints or concerns existed prior to May 2020 which ought to have alerted the Trust to commence an earlier investigation. 10:06

Part C of the terms of reference places the focus squarely on the governance of patient care and safety within the urology specialty using the vehicle of the serious adverse incident cases and any other cases of concern. 10:07

The evidence to be received during this phase of the Inquiry's work will advance a focused investigation into those parts of your terms of reference and will add greatly to the body of information provided to date. Taken together, those parts of the terms of reference establish a framework for this module. It is one which we shall use to explore with the witnesses across a range of clinical and related issues and attendant governance arrangements, just how the urology service operated on a day-to-day basis. 10:07 10:08

While we hope to bring a focus to these particular aspects of the terms of reference, it is anticipated that the evidence to be provided by the witnesses will be wide ranging in nature. It will be important to establish how the consultants practice in a range of important matters, from triage through to the arrangements for and the conduct of surgery. 10:08 10:08

The Inquiry will wish to understand the extent to which there were variations in practice and approach, whether adherence to best practice was viewed as necessary, and whether the pressures and demands placed on the service compromise the standard of practice which could be delivered and achieved. 10:08

The urology service at Southern Trust was comprised of a small team and we will be keen to explore the

dynamics of how that team worked, the leadership, support and resources it received, and the culture which was promoted. The Inquiry will be particularly interested to understand whether the clinical and governance concerns which prompted the commencement of this Inquiry were known to any members of the team at any time and, if so, what was done about them? 10:09

It will be necessary to investigate whether and how patient safety was promoted by the clinicians who worked within, or engaged with Southern Trust's urology service. We will seek to explore what steps were taken to address risk and to challenge the behaviour which placed patients at risk. 10:09

The Southern Trust urology team had its own instruments for communication, governance and learning. These included departmental meetings, a patient safety committee, and the urology cancer multidisciplinary team meeting. The work of the team was performed within a clinical governance framework which provided a system to report practices or incidents which gave rise to harm or risk of harm. 10:09

The Inquiry will wish to use the further evidence which it will now receive to determine how well these arrangements worked and to support its findings on the governance of patient care and safety. 10:10

As I have said at the outset, this is an opportunity for the Inquiry to engage with the work of the clinicians. It is also vitally important that the clinicians engage fully and frankly with the work of the Inquiry so that it can be best assisted to identify all relevant learning points and to make appropriate and comprehensive recommendations with a view to enhancing the framework for clinical and social care governance. Our engagement with the witnesses to date suggests that they will do their best to assist the Inquiry and will approach the issues to be raised with them forthrightly and with candour. 10:10 10:10

Towards the latter part of the Inquiry's programme for this term, we will hear from a number of witnesses who have contributed to the work of the Trust's Board, notably its current Chair, Ms. Eileen Mullan, and its former Chair, Mrs. Roberta Brownlee. 10:11

The Inquiry Terms of Reference at Part B require an assessment to be made of the role of the Board, particularly in the context of patient care and safety, and we will turn our attention to that during the first week of December. 10:11

Madam Chair, members of the panel, I hope that sets out in broad terms the aims of this module which we are formally opening today and which we will start by hearing the evidence from Dr. Mitchell. 10:11

There is new representation today, as Dr. Mitchell is represented by the Belfast Trust, and Mr. Lavery would like to formally introduce himself for the purposes of the transcript, and his team.

MR. LAVERY: Yes, Madam Chair, Finbar Lavery. I am instructed on behalf of Dr. Mitchell and the Belfast Trust on the instructions of the Directorate of Legal Services along with my instructing solicitor, Sarah Loughran.

CHAIR: Thank you very much, Mr. Lavery. Welcome. Dr. Mitchell.

MS. McMAHON: Dr. Mitchell, I understand you want to take the oath before you give your evidence, so if we do that.

DR. DARREN MITCHELL, HAVING BEEN SWORN, WAS EXAMINED BY MS. MCMAHON AS FOLLOWS

MS. McMAHON: Dr. Mitchell, I know you had the opportunity to look at the chamber before you came to give evidence, so the panel who may ask you questions at the end and other legal representatives, but I'll be taking you through your evidence today. And that evidence starts with your section 21, the notice that you replied to, having been sent that by the Inquiry. So, if we could just have that called up, please. WIT-96666. And that's notice number 6 of 2023, dated 17th April 2023. And we'll go to the end, which is

WIT-96674. And just your signature there at the end. And it's dated 18th May 2023. Is that your signature?

A. Yes, it is.

1 Q. And do you wish to adopt the statement as your evidence to the Inquiry? 10:13

A. Yes, I do.

2 Q. Any amendments or errors that need correcting?

A. No.

3 Q. Just to set out the context of your evidence just before we go into the detail. You were interviewed by 10:13 Dr. Hughes on 23rd February 2021 in relation to a number of SAIs concerning former patients of Mr. O'Brien?

A. Yes.

4 Q. And then you've provided us with your written evidence 10:14 and your section 21. And in that, you set out some issues of interest, potential interest to the Inquiry panel. So it was considered relevant to bring you along to explore those with you in more detail. 10:14

The purpose of today is to ask you about that evidence, with the backdrop being that we have your full statement, that's available to all of the parties, it will be on the website, and the panel have that to consider. So what we want to do today is just draw out 10:14 some of the issues that we need to hear a little bit more about rather than go through that in great detail.

I say that because we have a limited time with you of

half a day, and I appreciate how busy you are, so we hope to get through all that's needed by one o'clock, and we'll do our best. I'll try not to promise anything at this stage, but we'll see how we get on.

10:15

I want to start out just by asking you to fill in some background in relation to your own history as a doctor and your various iterations as you move through your medical career. I know you're quite softly spoken, so if I could ask you either to --

10:15

A. I'll try and speak up.

Q. That's fine. I might need to slow down, and you might need to speak up, but we'll get there. So if I could just ask you to do that, first of all, and then we'll move through the issues in chronological order as best we can. But just to give us a flavour of your expertise?

10:15

A. So I completed my medical training in Dundee in 1995. I returned to Northern Ireland and for the first two or three years worked through a number of medical specialties, before I had an opportunity to work in oncology as a Senior House Officer. That then led to a service position for one year before getting a registrar post in clinical oncology. Having then completed my exams in clinical oncology, I spent four months in Leeds learning about prostate brachytherapy as a technique, subsequently spent four months in New Zealand and, following that, I obtained a fellowship at the Christie Hospital in Manchester for one year as the

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10:16

prostate brachytherapy clinical fellow.

I had a brief few months of locuming in Limerick before obtaining a full substantive post in clinical oncology in Belfast, and that was June 2008, and I've been there since that time.

6 Q. So, 15 years you've been based in the Belfast Trust?
A. Yeah.
7 Q. And what is your particular area of specialty now? What is it that you do? What service do you provide? 10:17
A. So, I am a clinical oncologist with a special interest in urological cancers. As a clinical oncologist, that means I cover both chemotherapy treatments and radiotherapy treatments for prostate, bladder, some renal work, and some testicular radiotherapy work. As a special niche within that radiotherapy, I am one of two prostate brachytherapists working in Northern Ireland, and myself and my colleague would accept referrals across Northern Ireland for patients who are deemed suitable or want consultation on what prostate brachytherapy is. 10:17
8 Q. And who is your colleague in that specialty?
A. It's Prof. Suneil Jain.
9 Q. And the way in which people find their way to you, in particular with your prostate brachytherapy specialty is that either they're referred from other Trusts or through other consultants, is that how your process of people entering your particular area of care works? 10:18
A. So all patients will have been discussed at the multi

disciplinary team, identified for what treatment options are appropriate for their particular tumour demographics and for their personal demographics, and if they express an interest in prostate brachytherapy then they will be referred to me from any of the 10:18
urology centres in Northern Ireland. We would then review those patients, discuss what prostate brachytherapy is, and if they wish to proceed then we'll take them through the implant procedure.

10 Q. And do you have a certain criteria against which you 10:18
apply to assess suitability for individual patients?

A. The criteria are quite strict. So we would have tumour demographics, a certain level of PSA, or prostate-specific antigen, a certain level of aggressiveness, particular findings on imaging, and 10:19
then there will be the personal demographics in terms of the person's fitness for anaesthetic, current urinary function, and then some other unusual things like how being radioactive for a period of time after the implant would affect them personally or their 10:19
family situation.

11 Q. Now, you mentioned that you've been in The City from 2008?

A. (Witness Nods).

12 Q. And that seems to be, from your statement, the 10:19
timeframe, the start of the timeframe of interest for matters that might be relevant for the purposes of the Inquiry, and so I want to look at that. I'll look at the period from which you identify as 2008 to 2014, we

call that the Bicalutamide 50 issue.

A. Yes.

13 Q. We'll move onto the 2014 e-mail to Mr. O'Brien. Then at 2015, you were involved in drafting, or you drafted the Regional Hormone Therapy Guidelines and just a little bit of context about that and the motivation for that. 10:20

A. Yeah.

14 Q. And then in 2016 there was an alleged delay in the muscle invasive bladder cancer case from Craigavon and you again wrote to Mr. O'Brien directly. So, there are three main highlights in relation to your evidence that touch upon the issues that we're interested in. So I want to go straight into the Bicalutamide prescribing issue. And I wonder if we could start off by going to WIT-96819? This is a record of your interview with Dr. Hughes and Patricia Kingsnorth on 23rd February 2021. This is a document I think you're familiar with? 10:20

A. Yes.

15 Q. It was sent to you as well at the time. And this is the, as I said, the background is that they were speaking to you about the SAIs they were involved in looking at at the time. So, just the second paragraph there, the background to your involvement. So when you were speaking to Dr. Hughes you said this note: 10:21

"Dr. Mitchell advised he was aware of issues going back a decade in relation to immunotherapy prescribing, prescribing outside guidelines and Bicalutamide. 10:21

Dr. Mitchell advised he took over as Chair of the cancer group in 2015. He advised that they had challenged Mr. O'Brien on his..."

-- "Mr. OB" it says there: 10:21

"...on his use of Bicalutamide. He escalated this to his clinical lead, Chris Hagan, and the decision was made to develop a guideline for the use of ADT in the hope this would address the issues. This guideline was 10:22 presented when Mr. OB was Chair of the NICaN Urology Group and he signed off on the guidelines."

That paragraph is a pithy explanation of the funneling of the issues. So whenever you first started in 2008, 10:22 as I understand it, you were referred patients who had been or were on Bicalutamide 50 as a monotherapy and this drew your attention to this issue. Could you just give us the context in your own words of how you first became aware of this? 10:22

A. I think if I look at the e-mail in 2014 backwards, so when that case was raised. On reflection I could have thought of a small number of patients who had been referred to me prior to that time who, my memory would have had that they were on Bicalutamide 50mg as a 10:23 monotherapy when they came through for consultation. I don't remember patient names or health care details. I believe there were a small number coming for a brachytherapy opinion and either they wouldn't have

needed any hormone treatment, or if they weren't having brachytherapy, if they were having some other treatment, then I would have written back to the GP, copied the referring consultant to say that I was keeping them on Bicalutamide but at a correct dose of 150mg. At least that's my memory of how I would have phrased the reply letter. I would have taken the patients then through their chosen treatment. 10:23

16 Q. So, in relation to sequencing, we'll go to the 2014 e-mail just in a moment. The context that led to that was that you were getting referrals from patients who were on Bicalutamide 50. As you've said, you adjusted the dose to 150? 10:24

A. (Witness Nods).

17 Q. And we'll look at that in a moment. But that was an indication in 2014, when you thought about it you realised that this issue had been going back to 2008. Is that what your evidence is? 10:24

A. Reflecting back, I suspect there were a number of cases that fitted that particular pathway of Bicalutamide 50, coming for consultation, a correct dose being offered. But I don't think I would have noticed it at the time of seeing them, other than believing it was a prescription error. 10:24

18 Q. Well, just as a baseline for your evidence, what's your understanding of the dosage that should be prescribed in relation to Bicalutamide? 10:24

A. So, the Bicalutamide falls into two doses; we have 150mg once a day, which can be used as a monotherapy,

or Bicalutamide 50mg once a day, but it is really only licensed for use in combination with hormone injections, known as luteinizing hormone, releasing hormone agonists.

10:25

So, there were two clear doses: 50 as a combination treatment or 150mg once daily as a monotherapy.

19 Q. And your concern at the time and on reflection was that some patients were being prescribed Bicalutamide 50 as a monotherapy and your understanding was that that was, was it suboptimal or unlicensed? What was your view on that? 10:25

A. It's not a licensed dose. It's 50mg as a monotherapy.

20 Q. Now, if a patient is given an unlicensed dose, if they're given Bicalutamide 50 as a monotherapy, what's the impact of that? What's the issue for you as a clinician when you see that, if you don't think it's clinically mandated? 10:26

A. So I think it's very difficult to prove in the short-term that it really changes their management, but it has the possibility to induce delay to referral. So we would be keener to see patients and make hormone decisions ourselves rather than a wrong dose be prescribed and a patient referred at a much later date. 10:26

21 Q. How would delay come around because they're on Bicalutamide 50? 10:26

A. Because they should then be referred for a clinical oncology discussion on their management. And if they're being commenced on an incorrect dose but then

not referred, then you begin to worry at what point they're going to be referred, is that going to be at a point of resistance with rising PSA levels whilst on Bicalutamide 50? So, resistance and perhaps poor outcomes with subsequent treatment would be the concern. 10:27

22 Q. Now, you've mentioned resistance. As I understand it, that's almost a tolerance that builds up on long-term low dose monotherapy like Bicalutamide 50, the impact of which is that if the patient does need a higher dose or a greater impact of that at a later stage, that they may be resistant to that clinical regime? 10:27

A. Yeah, less likely to work.

23 Q. Now, just again to set the baseline of your recollection before I ask you some details about what, in particular, issues were. Do you recall any of the patients that you came across who were on this Bicalutamide 50mg monotherapy in what you consider to be an inappropriate drug regime? 10:28

A. No, I couldn't recall the patients between my - I started as consultant in 2014, and as I've been involved in the subsequent discussions it would be quite easily be mixed up with other cases that have been discussed and reflected on. But I couldn't recall patients between 2008 and 2014 specifically. 10:28

24 Q. What you're referring to there, just for the transcript, is your later involvement with Mr. Haynes?

A. Yes.

25 Q. In looking at patients who were on Bicalutamide 50 and

looking at whether that was appropriate treatment regime later on?

A. Yeah.

26 Q. But for the purposes of the period of 2008 to 2014, just in that period, do you recall names of patients? 10:29

A. No.

27 Q. For the record? Do you recall age groups of the patients? It probably lends itself to be older men, does it, or any trigger of any memory at all?

A. No. 10:29

28 Q. No. Do you understand there to be any circumstances in which Bicalutamide 50 is prescribed as monotherapy?

A. No, I'm not aware of any evidence base for Bicalutamide 50 as a monotherapy in prostate cancer management.

29 Q. Now, Bicalutamide 50 can be used in what way? You tell me. What way is that prescribed? 10:29

A. So, it's classically used in two scenarios; inpatients who are being commenced on hormone injections, the LHRHa. There is a small risk that the slight increase in testosterone caused by those injections for the first few days will worsen their clinical situation before the injections have their formal activity of reducing testosterone and thereby shrinking the prostate cancer. That's known as testosterone flare or disease flare. So for patients who are being commenced on those hormone injections, the recommendation is that they receive Bicalutamide 50mg, and that's usually given for three weeks, with the hormone injection given on day three or subsequent to day three to prevent 10:30 10:30

testosterone flare, disease flare, particularly important for patients who have, for example, prostate cancer in their spine, near their spinal cord, where you don't want any growth.

10:31

The second scenario is for patients who are established on those hormone injections typically have advanced prostate cancer or prostate cancer that has spread, in other words metastatic prostate cancer. The hormone injections are beginning to fail, the PSA is rising, and the Bicalutamide 50 can be used as an add-on to those injections, and that's usually referred to as combined androgen blockade or maximum androgen blockade.

10:31

10:31

So, those are the two scenarios where I would see Bicalutamide 50mg prescribed in combination with LHRH antagonists.

30 Q. And although you don't recall anything about the patients who you, on reflection, considered to be being prescribed inappropriately Bicalutamide 50 in monotherapy, they didn't fall within either of those two options that you've just describe?

10:31

A. No, they wouldn't have had a point where they were about to be commenced on a hormone injection, or where they've had failing disease whilst on hormone injections requiring additional treatment, they were coming de novo for discussion of radical therapy.

10:32

31 Q. Now, you've mentioned in your statement that there were

a few patients; do you have any better idea of numbers?

A. I suspect it was two or three cases over the period of the five or six years. But it would have been that small quantity of men within that time.

32 Q. Now, you've timed it to go back at 2008 when you first started at the Trust. Did it go back that far or was it just you thought, "Well, I've moved here at that time and perhaps it started then", but do you have a recollection of a timeframe for us? 10:32

A. I don't remember anything prior to that in my training as a registrar within the oncology system in Northern Ireland. I'm aware that there would be other consultants who were - who had a more formal role in covering the urology service at the Southern Trust and they may have had more experience. But I had no experience prior to 2008. 10:33 10:33

33 Q. Now, you did mention in the very beginning with your answer, you talked about the referrals of the GP and the alteration of the prescription.

A. (Witness Nods). 10:33

34 Q. If you can recall, what was your view when you first saw that prescribed in that way?

A. I think I saw it as a prescription error that simply the wrong dose had been chosen and it should have been correctly 150mg once a day rather than 50. 10:33

35 Q. And would this have been apparent to you by the referral letter from the referring consultant?

A. Yeah, or the patient bringing their medication list with them.

36 Q. And was there one consultant who you noticed a repetition on this issue?
A. Yeah, on reflection, I didn't see any Bicalutamide 50mg coming from other consultants, so, yes, Mr. O'Brien was the only consultant who appeared to be making this error. 10:34
37 Q. And when you saw the first one and you thought that, you know, "That's an error, I'll change that around", you've said the process was for you to send a letter to the GP, effectively ordering a new prescription for the correct dose. 10:34
A. (Witness Nods).
38 Q. And do you copy that letter to, copy that letter to the consultant, the referring consultant?
A. Yes, always. 10:34
39 Q. So if that was the first one that you saw, then when you saw the second one, whenever that was, because we're working in a six year timeframe, whenever you saw the second prescription for Bicalutamide 50, in circumstances in which you considered that that wasn't clinically appropriate, did you have an instinct then or did you have any sense that perhaps this isn't an error or there's another error? What was your response? 10:35
A. Again, it's a long time ago. The cases that I would have seen would have had a time period between them, and on reflection I should have picked it up as a systemic error. But I think I would have listed that as the same error again rather than a frequent 10:35

prescribing inaccuracy.

40 Q. Did Mr. O'Brien ever contact you after you changed the treatment regime?

A. No.

41 Q. Did you ever contact him before 2014? 10:35

A. No.

42 Q. Did you ever have cause to follow-up with these particular patients to find out if they had in fact stayed on your new treatment regime?

A. The patients would have had a very set follow-up, 10:36 either with myself or with the nurse specialist that we were working with. So if they had been on an incorrect dose at subsequent time points, that would have been corrected. But I would believe all those patients would have been moved to the 150mg dose and maintained 10:36 on that for the period of time that they were requested to.

43 Q. You've mentioned two of the possible adverse effects of Bicalutamide 50 monotherapy being prescribed in an inappropriate way, as you say; one is potential delay 10:36 and the other one is resistance. Is there also, given that it is not licensed in that way, is there also the potential that it is suboptimal treatment for people and that they may actually, the disease may progress more rapidly, not be effectively treated? Is this a 10:37 suboptimal, ineffective treatment regime in your view?

A. So that would come back to the point of resistance. I'm not pharma related, but you would expect that a company like AstraZeneca, who were developing

Bicalutamide, or known as Casodex, would have gone through a dose escalation process, looking at safety, looking at efficacy, and if they have decided that the licensed dose should be 150mg then you have to go with that research, that recommendation, rather than use a lower dose. So, the concern as a less effective treatment would still be in terms of delay or development of resistance. 10:37

44 Q. Did you see it as representing any potential for patient harm or risk? 10:38

A. I think because the main issue for me is delay to referral, I don't remember delay to referral in those particular cases. So, it was only when the issues of the dose prescription and the significant delay in referral came through as a discussion in 2014, that it became more important to flag it. 10:38

45 Q. Just to tease that out a little bit more. Just from a sort of a common sense point of view, would there be any potential that people who are not being treated appropriately for the diseases that they have are being placed on a drug regime which has not proven to be effective in the way that it needs to be for them, that that in itself is a patient safety concern? 10:38

A. Retrospectively that systemic error should have been picked up and the practise stopped at an earlier stage. 10:39

46 Q. And should that have been picked up by you?

A. I think I have responsibility within seeing those patients, and when we see a systemic error, then, yes, I should have taken this to a different format rather

than just writing back to the GP and copying the relevant consultant.

47 Q. Now, I know it's a 2008 to 2014 timeframe, things have changed and governance structures have changed, but at that time, what do you think would have been an appropriate response to what you had come across at that time? What do you think you might have done, or should have done, or could have done? 10:39

A. I should have discussed it with my Clinical Director at that time. 10:39

48 Q. And who was that?

A. So there were a number of clinical directors at that time. I think Dr. McAleer, Dr. McAleese would have been two of the -- and Dr. Houston, would have been three of the clinical directors that were in that early phase. 10:40

49 Q. You've mentioned the GP letter; would the dosage of Bicalutamide 50 as a monotherapy, would that be widely known among GPs as perhaps an inappropriate drug regime on its own? 10:40

A. I don't think so. It's quite niche in terms of its use. So, I wouldn't expect a general practitioner to have picked up that 50mg as a standalone therapy was incorrect, or to have looked at the guidance on dose prescription for patients. So I don't think it was a GP's responsibility. 10:40

50 Q. Now, you were starting off your consultancy in 2008; do you recall at that time what the governance processes in place were? Now we have SAIs, IR1s, we've DATIXs.

Do you recall any of those? Are they familiar at that time to you at all?

A. No, my knowledge of governance processes is poor, so I wouldn't recall, and that's why I would speak to someone who had more experience, such as the Clinical Director. 10:41

51 Q. At the time when you were receiving referrals from consultants, including Mr. O'Brien, what was the process by which those referrals were divided up among you and your fellow consultants? Were some of them named to you, for example? 10:41

A. So these patients were coming through for a prostate brachytherapy opinion, initially I would have been the only consultant, so would have been named. I can't quite remember when Prof. Jain returned from his time in Canada doing brachytherapy, but I suspect there would have been named referrals to him as well, but they would have been direct named referrals to me for a brachytherapy opinion. 10:41

52 Q. Do you recall if the ones that you remember being Bicalutamide 50mg, do you remember if they were named to you? 10:42

A. I would expect that they were, but I don't recall.

53 Q. So, there was just the two of you at that time in brachytherapy, is that right? 10:42

A. I was a standalone practitioner for a couple of years, and then laterally Prof. Jain completed training and came back and started.

54 Q. What I'm trying to find out really is the potential for

other people to be receiving referrals with the same, you say, clinical error on it. Are you saying that that's a very limited possibility due to the fact that you only got referrals for your specialism or were there others who might have been receiving letters with the same prescription on them? 10:42

A. So, I would have been seeing a fairly small group of patients who fitted the correct criteria for brachytherapy, and there would have been a number of clinical oncologists who were job planned to provide cover for urology in Craigavon, and they would have seen a greater number of cases. By proportion, I would have expected that they might have seen more cases of Bicalutamide 50. 10:43

55 Q. Did you ever discuss what you had seen with others in and around this timeframe? 10:43

A. Not that I remember. I think having decided it was a prescription error, I didn't necessarily see a point of asking them at that stage.

56 Q. Did anyone mention it to you, come to you and say "Is this something you've noticed?" 10:43

A. So, the 2014 case which prompted the e-mail is the first one that I can really look back and remember discussions. If there were discussions before that, they were informal. But I have no memory of that. 10:44

57 Q. Now, when you changed the treatment regime for these patients to 150, did you explain to the patients that there would be a change in their regime?

A. So, again, I can tell you what my believed practice

was. So, yes, I'd have said that the correct dose is 150mg and it's for this period of time and here's the treatment we're offering. I don't necessarily believe I would have said to them that it was an error or a deliberate action, I would simply have said that it was the correct dose at 150.

58 Q. So, from their perspective, they were getting a new prescription?

A. Yes.

59 Q. As opposed to having their regime corrected? 10:44

A. Increased. Yeah.

60 Q. And were there possible side effects in this increased dose that the patients were now being put on, or adverse effects of any type?

A. No more than the licensed dose. So they were getting the correct dose. And we would have a discussion about the potential impact on them as a person from that treatment. 10:45

61 Q. Now, we'll come on to mention - you used the word "misled", I think? 10:45

A. Hmm.

62 Q. And you believe that the patients were misled. Can you give us a little bit more context to that statement?

A. I think this probably works more around the e-mail in 2014. My subsequent involvement in the cases that were coming through the review process, it didn't appear that patients were informed that Bicalutamide 50mg monotherapy, that they were informed that that was an off licence prescription. So I saw that as the first 10:45

point where they were not informed correctly.

63 Q. Are you speaking about the review, the subsequent review?

A. Yeah.

64 Q. You're not speaking about the 2014? 10:46

A. No.

65 Q. No.

A. So when I look back, and having then met some of the cases who had been on that regime, they had not been informed of the off licence prescribing of 50mg 10:46 monotherapy once a day.

The second point was that the patients that we were seeing, I believe should have been referred to oncology at the point of first consultation post diagnosis. 10:46 They would, therefore, have had the opportunity to discuss all treatments available, and if they weren't being referred through, they weren't being given that opportunity. So that was the second point where I believe that they were misled, they weren't given the 10:46 full information that other patients being seen by other consultants were.

66 Q. And was the delay because the commencement on that treatment was considered a start of a treatment?

A. Yes. 10:47

67 Q. We'll just go to the e-mail of 2014, please. WIT-96668, please. That's your statement. Sorry, my apologies. The e-mail is at, sorry, AOB-71990. That's the reference where you mention the e-mail in your

section 21.

A. Yeah.

68 Q. Hopefully this is the correct... Okay.

A. Yeah.

69 Q. So this is an e-mail that you -- you had received a referral, you were now Regional MDT Chair in 2014. Had you just taken up that post that year? 10:48

A. So, I had been appointed as MDT Chair in August 2014.

70 Q. And this e-mail is dated 20th November.

A. Yeah. 10:48

71 Q. It's from you to Mr. O'Brien. And we can see that patient, the cipher at the top, Patient 126. And it says:

"Aidan, 10:48
Could I ask you to have a look at this case which was passed to me as the Regional MDT Chair? It looks like a young man with high grade organ confined disease from 2012. From my perspective, he would have been considered..." 10:48

-- you'll have to help me with the pronunciation?

A. Neoadjuvant.

72 Q.

"...neoadjuvant hormones for three to six months, followed by EBRT in early 2013. He may have been suitable for combined EBRT plus BT (pending LUTS assessment). His high grade disease would have encouraged us to offer him 2 to 3 years of..." 10:49

-- adjuvant?

A. Adjuvant.

73 Q. "...adjuvant hormonal therapy after EBRT, depending on 2008 or 2014 NICE Guidelines and patient tolerance.

I am not aware of his comorbidities or performance status. 10:49

As hormonal therapy in this case we would use LHRHa or occasionally Bicalutamide 150mg OD monotherapy.

I am told he has only just been referred for radiotherapy at 2 years after initial MDT presentation. 10:49

I am not aware of supportive research for 24 months of neoadjuvant hormones prior to EBRT, but the Trans-Tasman Group 0 versus 3 versus 6 and the Canadian 3 versus 8 are already quoted in our radiotherapy protocol, and based on those studies we typically think of 6 months neoadjuvantly in this kind of case. 10:50

6 months of LHRHa prior to EBRT is also recommended in the stampede protocol for men with high risk non-metastatic disease who are for radical radiotherapy. 10:50

I'm also told that he was on Bicalutamide 50mg OD for

the first year of his management.

The NICaN hormone protocol (in process) would be useful in standardising our therapy across the region but Bicalutamide 50mg is not licensed for monotherapy use and will not be recommended in the protocol other than within the licensed context for the management of flare with LHRHa.

The MHRA site provides information on off-label prescribing and our responsibilities within that." 10:50 10:51

And then you've included, I presume it's a hyperlink to that?

A. Yes. 10:51

74 Q.

"Happy to discuss this further."

And "DMM", that's you?

A. (Witness Nods). 10:51

75 Q. Now, just to - a lot of - just to translate this into English. But just in relation to MHRA site where you have provided the hyperlink, could you just explain what that is?

A. So, my memory of the MHRA document was that my defence union had sent through a quarterly update on a number of cases they were working through as learning points, and I believe that this was quoted within that. I then had opportunity to read through it and realised that 10:51

the practice of 50mg once a day was off licence. The MHRA document is very clear, when I read it, in terms of the responsibilities we have as clinicians to our patients in choosing the right doses of drugs, or if we are using off licence prescriptions then having a conversation with the patient as to your rationale for doing so.

So, it seemed like an appropriate thing to reference when I was sending this e-mail. 10:52

76 Q. So you've set out the history of the clinical presentation of the patient and, also, in relation to our purposes, the Bicalutamide 50, that the patient has been on it, that it is not licensed for monotherapy in the way in which this patient was on it? 10:52

A. (Witness Nods).

77 Q. That there has been - he's been on it for the first year of his management, and there has been - just move up, please: 10:53

"...and the patient has just, only just been referred for radiotherapy at 2 years after initial MDT presentation."

Is this an example of what you had talked about earlier in your evidence where commencing on a treatment regime such as this can result in what appears to be, is it a considerable delay? 10:53

A. Yes. So, the patient has been on hormone treatment

longer than we would have wanted or have any evidence base for when we're giving external beam radiotherapy. So this doesn't fit with any of our protocols.

78 Q. Now, you've said at the top of the e-mail that it's been passed to you, this particular case. Do you remember who it was passed from? 10:53

A. Again, I believe this was Prof. Suneil Jain who had reviewed this case, and as a colleague, a slightly more senior colleague than him, he had brought the case, we'd had a look at it, and I think it's badged as being sent by me as the Regional Chair, but it may be more correctly as a more senior colleague. So, I believe it was Prof. Jain that saw this case initially. 10:54

79 Q. And when this was brought to you, you mentioned earlier this morning that it was on reflection in 2014 that you thought "I've seen this before". Is this the crystallisation of that point? 10:54

A. It was, yeah.

80 Q. Now, in your role as Regional MDT Chair, does it fall under your responsibility to undertake this sort of task of having identified a clinical concern to contact the consultant about that? 10:54

A. I think if there's clinical concern raised through the MDM/MDT process, then we do have responsibility to address those issues. I don't remember this case being discussed through the regional meeting, so technically I don't know that it was a regional share issue. There was, however, potential that there would be other cases which would become important for us as a regional MDT, 10:55

so it still felt appropriate to send it as a badge discussion from Regional Chair.

81 Q. Had you ever had to send an e-mail like this before to a consultant or since?

A. No. When I was able to finally track down the e-mail, since it was archived shortly after this, I was somewhat taken aback at the tone that I had sent the e-mail in. 10:55

82 Q. In what way taken aback?

A. Well, it's not particularly my style to go through an evidence base with a senior colleague, to be as structured as this - I'm not saying I'm not structured, but to have a structure where I'm clearly outlining the correct management for a case, and particularly to hyperlink a reference to good practice in terms of off licence prescribing, I've never sent an e-mail like that to a consultant, other than in this situation. 10:55 10:56

83 Q. And do you reflect on that as being evidence of the strength of your concern, or was it that you wanted to make sure that you were on a firm footing before you sent the e-mail off? 10:56

A. I didn't anticipate that I would be sitting here looking at this e-mail at this stage. It was more that something needed to be done to stop this particular practice and, on reflection, having seen a few previous cases, seeing this one particularly, I felt there was an action. Retrospectively, I think I should have followed up on it more robustly. But, yeah, this is an e-mail which I think if I'd received it, I'd have been 10:56

quite shocked at, at the forthrightness of the approach.

84 Q. I just want to look at the governance issues around this from two different perspectives. The first one really is the way in which it got to you, the way it was brought to you as the Regional MDT Chair. As a governance process, when another clinician identifies a concern, do you think coming to you as the Regional MDT Chair to deal with that is an appropriate response in this scenario? 10:57

A. If it's a non MDT issue then I think it goes to Clinical Director rather than MDT. If it's a problem with an MDT decision, or something that the MDT should have had action on, then we would follow the appropriate channels. And during my tenure as MDM Chair, we had a number of cases that we had to take through the appropriate governance processes. Again, my knowledge of governance is poor, so for those particular cases I'd have gone to the service manager, who was my line manager within the MDM, raised it, and followed the appropriate avenues.

85 Q. I suppose the two examples you've provided, this doesn't fit in either of those. It's not an MDT decision-making issue and it's not one that falls outside the regional MDT framework. This is a clinician having concerns about the clinical package of care, and various aspects of that --

A. Yes.

86 Q. Which we don't need to go into. But certainly the

governance concerns are clear from the language and the content of the e-mail. So I just want to probe a little bit further about how they found its way to you and whether you consider that finding its way to you was the appropriate way for that to be dealt with? 10:59

A. So, again I believe, if my memory is correct, that Prof. Jain had seen this case, had asked me to look at it as a second consultant to confirm his concerns that this was outside standard of care practice. I believe that the case would have been discussed as part of a general discussion at what we would know as the Thursday morning academic rounds - that's an eight o'clock to nine o'clock meeting where we discuss cases coming to clinic later on in the day, and I believe that because I forwarded a copy of this e-mail as a separate attachment to Prof. Jain, Prof. O'Sullivan and to Dr. Jellett. So -- 10:59 10:59

87 Q. We can just look at that, where you forwarded that, just for the panel. WIT-96678. So you sent this e-mail just to Mr. O'Brien, didn't copy anyone, but you then let your colleagues know that "This is what I've done"? 11:00

A. I had acted, yeah.

88 Q. And this is the retrieved e-mail that shows on 20th November. You sent it, as you say, to Lucy Jellett, Joe O'Sullivan, and Dr. Jain, and you say: 11:00

"Lucy, Joe, Suneil,
I have e-mailed Aidan to open a discussion on this

case, copy below for your information."

And just for completeness, if we just go to the e-mail below the panel will see that that's the e-mail to Mr. O'Brien. If you just go back up, please. Now, who was your Clinical Director at that point in November 2014, do you recall? 11:00

A. So, I think if I had just taken over as Chair of MDT, that Prof. O'Sullivan was the MDT Chair prior to me, and he was stepping back from MDT Chair so that he would then take on the role of Clinical Director. I think that's correct. 11:01

89 Q. And so your Clinical Director is aware then, you've copied him in to show him what you have done?

A. (Witness Nods). 11:01

90 Q. Did you have discussions with him or any of the other cc'd individuals prior to sending the e-mail to inform the contents of it or the tone?

A. No, the content and tone was my construct, and I copied these three consultants in because of the, what I believe was a discussion on the Thursday morning to effectively show that I had acted on the discussion. And I don't think I looked at Prof. O'Sullivan within that e-mail as flagging it to my Clinical Director, it was purely as a clinical colleague within the discussions. 11:01

91 Q. But he factually was your Clinical Director?

A. I believe so.

92 Q. And we'll hear from him tomorrow. And I think the

timing is right that he was your Clinical Director at that point?

A. (Witness Nods).

93 Q. Did he ever come to you after and say "Did you get a reply to that e-mail, or if you haven't received a reply I maybe need to speak to my counterpart in the trust, the Southern Trust"? Did those conversations ever take place? 11:02

A. No. And, similarly, I'd be quite quick to reflect that, you know, my clinical work moved on, and this came back to my notice in terms of taking further action and going more formally to him as Clinical Director to flag that it hadn't been moved on. 11:02

94 Q. Well, you've said to your colleagues that you wanted to open discussion on this case. Was it your view that you anticipated either an e-mail in reply, or perhaps a phone call or some communication from Mr. O'Brien to explore some of the suggestions you had made in your e-mail? 11:02

A. So, I expected that there would be some form of contact, given the tone of the e-mail. I also had reference within the original e-mail that I was in the process of writing a hormone protocol, and that was going to be discussed through, presented and ratified by the NICaN Urology Group, of which Mr. O'Brien was Chair. So that was a point where I anticipated there may be some discussion around this prescription practice. 11:03

95 Q. And in some respects, the protocol and the guidelines 11:03

that were anticipated through NICaN were more in the abstract; what was here was a specific patient clinical concern.

A. (Witness Nods).

96 Q. Was there any suggestion from you or any of your colleagues or your Clinical Director, Prof. O'Sullivan, that this needed followed up in the absence of a reply? Did you ever receive a reply? 11:03

A. No.

97 Q. Mr. O'Brien didn't contact you at all about this? 11:04

A. No.

98 Q. In that -- given that, was there any movement at all from you or your colleagues, or did you have a conversation and think, you know, we need to maybe pursue this, or perhaps we need to speak to other consultants and see what's happening? 11:04

A. No, I think naively I had an impression that there were fewer cases coming through, so I perhaps had considered that the e-mail had been taken on board, the practice had stopped, which was in part what I was looking for. But as a direct action on my part to follow this up, no, it was purely an impression. 11:04

99 Q. Can we take from your answer that you've just given that the referrals to you after this e-mail reduced, or -- 11:05

A. I had a sense of that. But, again, I don't have numbers to prove that.

100 Q. Do you recall after this e-mail ever receiving a referral from Mr. O'Brien?

A. I suspect that I did. But the brachytherapy practice, we tend not to use hormone treatments, so the particular prescription issue that we're discussing may not have come through those referrals.

101 Q. So you didn't see another patient with Bicalutamide 50 as a monotherapy post this e-mail? 11:05

A. Not that I remember. And I think it was then the subsequent cases that again were being flagged up by Prof. Jain that then prompted the different avenue of approach. 11:05

102 Q. When you didn't get any more referrals around this issue, is there a possibility that it perhaps engendered a false sense of security that the issue had been dealt with and had simply gone away?

A. I think the answer is yes, in truth, with a busy clinical practice, and this wasn't top of the things that I was doing, and as time went on and not seeing the issue again, it simply moved to the bottom of the list, until the subsequent cases were raised. 11:06

103 Q. Now, if this issue was to materialise as it is now, what would you expect the governance processes, how would you expect it to operate to deal with this? 11:06

A. I think I'm a bit older, a bit wiser, I'd have a bit more of an expectation that this really needs to go further, be more direct, likely have a face-to-face discussion or phone call regarding the prescription error, seeing it as a systemic error and take it to the Clinical Director. So, I would have a different approach now as to what I did ten years ago. 11:06

104 Q. Now, Prof. O'Sullivan does mention a conversation with you in his statement, and if we just go to that at WIT-96650. And just to round off the point about the Thursday morning clinic, at paragraph (ix). So he's asked: 11:07

"Please give details of any discussions you had with Dr. Mitchell regarding shared concerns."

And he says: 11:07

"Dr. Mitchell, as Chair of the Urology MDT, raised concerns in 2014 to Mr. O'Brien in relation to a particular case which had been referred to the MDT and was receiving Bicalutamide 50mg daily as monotherapy 11:07 for prostate cancer. At that time, I mentioned to Dr. Mitchell about the historical cases I had remembered from my early years as a consultant in Belfast. This discussion would have taken place at one of our Thursday morning pre clinic meetings at the 11:08 Northern Ireland Cancer Centre."

Now, we take from that evidence that Prof. O'Sullivan also had historical cases which he remembered, and is it your recollection that they were around the 11:08 Bicalutamide 50 monotherapy issue?

A. I would suspect so, and I think that's why the e-mail in 2014 were formulated, because it became more apparent as a widespread issue, and that particular

case, with the timeframes involved, it wasn't something that could be ignored, it had to be acted on.

105 Q. Did you ever discuss it with him at all after, that there might be a possibility that the suboptimal prescribing of Bicalutamide 50 as a monotherapy was continuing, given the silence, the absence of a reply to the e-mail, and no indication that a discussion was willing to be started from Mr. O'Brien? 11:09

A. I don't remember further discussions on this particular issue after that, that e-mail, and the NICaN discussions. 11:09

106 Q. Just before we move onto the guidelines, you've indicated the guidelines, I think were almost in the back of your mind as a potential route to try and address this in another way; would that be a fair reflection on your thinking at the time? 11:09

A. So, I'd written the majority of the guidelines for urology practice within oncology, and as a guideline type person it made sense to standardise practice by having a hormone therapy guideline. In truth, the guidelines didn't really need to be written. The -- 11:10

107 Q. Well, we'll move on to those just in one second. I don't mean to interrupt you, but just to finish off this point and then we'll look at those, the guidelines, in a bit of detail. It's the patients misled point that I mentioned earlier, I just want to make sure the panel have a reference to that. WIT-96671, and paragraph 4(iii). You're asked the question, this is a comment to Dr. Hughes: 11:10

"The Inquiry notes the statement that patients were misled. Please confirm whether this is your belief and, if so, how, and why you consider that patients were misled? If not your belief, why did you say it to Dr. Hughes?" 11:11

And your reply is:

"I do believe patients were being misled. The hyperlink included in my 2014 e-mail to Mr. O'Brien leads to guidance on off licence prescribing. This outlines our responsibilities as prescribers to use medication within licence and if a decision is made to use a medication outside its licensed indication or dose then good practice would be to make the patient aware of the reason for this decision in their case. 11:11

In the cases identified in my statement I could see no evidence that the patients had been advised about the off licence use of Bicalutamide 50mg monotherapy. 11:11

The delayed referral to oncology in the cases in my statement meant that these men waited longer than other men in a similar situation to have an oncology opinion." 11:11

Now, there's a couple of points in that I just want to clarify. You mention in the second -- the third

sentence:

"This outlines our responsibilities as prescribers to use medication within licence and if a decision is made to use medication outside its licensed indication or dose then good practice may inform the patient of that."

Did you ever explore if Mr. O'Brien had made a decision to use the medication outside its licensed indication for those particular patients and had explained it to them? Did you have any reason to believe that, or did you explore that possibility at all? 11:12

A. So, in the cases who came to see me for consultation at the latter review, I would have asked the patients if they were informed about the dose that they were prescribed, but they weren't informed that this was an off licence prescription. 11:12

108 Q. And that's the latter part of your involvement?

A. Yes. 11:13

109 Q. 2019/2020.

A. Yes.

110 Q. If we go back to your earlier involvement, when you saw the patients that you did in the early years...

A. I wouldn't have explored it at that stage. 11:13

111 Q. Did you form a view at that point of any of those patients that you saw prior to 2014, whether these patients had come to harm due to being prescribed Bicalutamide 50mg daily for a period of time, in your

view?

A. So from the limited memory I have of those cases, I don't remember there being a particular delay in their referral, and I would see the delay as the greater issue than the dose prescription, because we would have had opportunity there because there wasn't delay to make a correction to the dose. 11:13

112 Q. Just come back to your point about what can be given if you step outside the licensed indication for medication. I just want to ask you, do you accept that it is acknowledged that Bicalutamide 150mg daily may be prescribed for patients with metastatic disease and who wish to maintain physical and sexual function but that this is not a licensed indication? 11:14

A. Yes. 11:14

113 Q. You may not be aware of this reference, but I'm going to read the question to you and you can comment. If you don't know then please just say. Do you acknowledge that the section of oncology of the British Association of Urological Surgeons recommended in March 2020 that patients with localised low and intermediate risk prostate cancer could be prescribed Bicalutamide 50mg daily while awaiting definitive management that had been deferred because of the Covid-19 pandemic, even though it was not a licensed indication? 11:14 11:15

A. I'm aware of that and not aware of the evidence on which it was based. And it was during a particularly difficult time period for us as a service.

114 Q. And it doesn't fall within the period that we're

discussing for the purposes of your evidence?

A. No.

115 Q. So, you would accept, therefore, given your answers, that there may be circumstances when it is acceptable to prescribe Bicalutamide for unlicensed conditions? 11:15

A. I don't remember that this particular practice was taken up, despite the recommendations during Covid, and we would likely have seen patients and offered more appropriate hormone treatment rather than the 50mg off licence. 11:16

116 Q. And I think we established earlier in your evidence that the individuals, that although you can't recall the specific details around them, or they manifestly clinically did not lead you to believe that Bicalutamide 50mg as a monotherapy was an appropriate drug regime? 11:16

A. In those early cases, no, it wasn't appropriate for those cases.

117 Q. And that's evidenced by the fact that you changed it?

A. (Witness Nods). 11:16

MS. McMAHON: I'm just going to move on to the guidelines, I wonder if that may be a convenient time?

CHAIR: Yes, we'll come back, ladies and gentlemen, at twenty five to twelve. 11:16

SHORT ADJOURNMENT

CHAIR: Thank you everyone.

MS. McMAHON: Dr. Mitchell, I just want to move on now

to the guidelines we have referred to a couple of times this morning, the Regional Hormone Therapy Guidelines, that's the proper title?

A. Yes.

118 Q. And we're at 2015 at this point. 11:33

A. (Witness Nods).

119 Q. So you've seen a few cases, you've sent the e-mail of 2014, we've now moved on to the Regional Guidelines. And just to put some background in context on this, I just want to go to a couple of extracts from your 11:33 interview with Dr. Hughes in February 2021. The first one is at WIT-96819. Just these paragraphs aren't numbered, so it's a bit more difficult to find. I think we're just at the top of the screen on the second sentence: 11:34

"Dr. Mitchell advised he took over as Chair of the Cancer Group in 2015. He advised that they had challenged Mr. OB on his use of Bicalutamide. He escalated this to his clinical lead (Chris Hagan) and 11:34 the decision was made to develop a guideline for the use of ADT in the hope this would address the issues. This guideline was presented when Mr. OB was Chair of the NICaN Urology Group and he signed off on the guidelines." 11:35

Now, there's a reference there to you becoming Chair of the Cancer Group in 2015. And you've taken the opportunity in your statement to -- was it 2015?

A. No, I corrected this to Chair of the MDT in 2014.
120 Q. 2014. And the for the panel's note, that is at WIT-96666, that correction. So, just a couple of parts of this paragraph I just want to ask you about. You had mentioned earlier that there had been a hope that development of the guidelines would address the issues, and the issues being the Bicalutamide 50mg monotherapy. And the second issue is that you escalated the issue to your clinical lead, Chris Hagan. 11:35
A. (Witness Nods). 11:36
121 Q. Now, I just want to ask you a little bit about that. Do you recall having done that?
A. No, I don't remember the parenthesis. If it was clinical lead, I think that would have been Prof. O'Sullivan, but I don't think it was Chris Hagan. 11:36
122 Q. So, as far as these minutes are concerned, are they --
A. It would more correct to have Prof. O'Sullivan within the parenthesis.
123 Q. You wouldn't have said Chris Hagan, would you?
A. No. We have a discussion in terms of other issues that we did flag with Mr. Hagan, or Mr. Hagan flagged with us laterally, so I suspect those two have got mixed up within the time. 11:36
124 Q. I just wanted to check that.
A. Yeah. 11:36
125 Q. Obviously Chris Hagan is coming to give evidence this afternoon, and I just wanted to - it sort of jumped out slightly and I wasn't sure if it had been an error?
A. I think it was.

126 Q. So it more than likely is?
A. I think so.
127 Q. Now, you've said on that, in the last sentence of that paragraph, we'll go to the guidelines issue in a moment, but this guideline was presented when Mr. O'Brien was Chair of the NICaN Urology Group and he signed off on the guidelines. Is that your recollection, that once the guidelines had been presented that Mr. O'Brien did actually signed off on those? 11:37
A. So, I believed that the guidelines had been completed and that it was the responsibility of the NICaN Chair to then formally sign those off and adopt them. It wasn't until a number of years later that I was advised that actually there had been no action taken in signing off the guidelines, or my belief was that they had been signed off. 11:37
128 Q. So, there was no formal process by which those guidelines were adopted and signed off within the structures of the group? 11:38
A. Yes, I believe it would be a responsibility of the senior person requesting the guidelines to sign them off as part of that. But hence my statement to Dr. Hughes. So I believe that they had been signed off once complete. 11:38
129 Q. And I think you correct that in your statement. I don't need to go to this, but just for the panel's note, at paragraph 2.4, WIT-96670. Do you recall at the time that the guidelines were finalised, although

not -- well, it's unclear whether they were signed off - your recollection is you assumed they were. You subsequently think they weren't.

A. (Witness Nods).

130 Q. But do you recall that if, at that point, Mr. O'Brien was the Chair of NICaN Urology, or who was at that point? 11:39

A. So, the guidelines were discussed a number of times at the NICaN meeting. I think I sent those minutes through. So, Mr. O'Brien was Chair of NICaN during that period. 11:39

131 Q. We'll just go to one of the - an example of one of the minutes at WIT-96683. The minute of 18th September 2015. And we'll see those in attendance; Mr. O'Brien, you, Mark Haynes. Just names that might be familiar to the panel. And just when we go to "Welcome and introductions": 11:39

"Aidan O'Brien welcomed everyone to the meeting and apologies were recorded." 11:40

So that would indicate, would it, that Mr. O'Brien was the Chair?

A. Yes.

132 Q. There are other minutes of NICaN meetings at the following: The minutes of 30th January 2015 are at WIT-96687 to 96692, and the meeting of 17th April 2015 WIT-96693 to 96697. I will take you through the minutes of the meetings, but there doesn't seem to be 11:40

any challenge or any conversation around the Bicalutamide 50mg monotherapy recorded on any of those minutes. Would you accept that?

A. Not recorded on the minutes is correct.

133 Q. And it's your recollection that you took the opportunity in one of those meetings to raise that issue. Could you just tell us a little bit about that? 11:41

A. So, I believe, and consistent with my statement, that I had circulated the guidelines and had stated that the guidelines were the standardised practice within the guidelines in relation to hormone prescription and stop the off licence prescription of Bicalutamide 50mg once daily. My memory of that statement was an awkward pause, followed by Mr. O'Brien thanking myself and Prof. Jain for taking this forward, but that's not minuted within the minutes. 11:41

134 Q. We'll just go to where you say that in your statement at WIT-96669. Paragraph 1(ix). This is where you've mentioned the suggestion to Dr. Hughes that Mr. O'Brien had been challenged around the Bicalutamide 50, and we'd asked you a specific question in relation to that, and the question reads: 11:42

"Please provide further details in respect of the suggestion that MDM challenged Mr. O'Brien on his use of Bicalutamide in 2015. In particular, please set out : 11:42

The nature and form of the said challenge;

Who was present or otherwise involved in same and;

Mr. O'Brien's response.

Please provide the Inquiry with copies of any relevant contemporaneous documentation (record, note, e-mail, minute or otherwise) relating to this." 11:42

And you've answered by saying at 1(ix):

"I believe this to relate to the discussions at the NICaN Urology Group meeting on the Antigen Deprivation 11:43
Guidelines that had been circulated to the group.

I was Chair of the Regional Urology MDM at that stage and attended the NICaN meeting in that role.

11:43

I believe I raised the point at the NICaN urology meeting on 3/1/2015 that the Androgen Deprivation Guidelines were to standardise the prescription of hormone therapy and stop the use of off licence Bicalutamide 50mg monotherapy. However, the minutes of 11:43
NICaN meetings have not recorded this.

I remember there being a prolonged pause following my point, before Mr. O'Brien extended thanks to Darren Mitchell and Dr. Suneil Jain for their work in taking 11:43
this forward"."

So that's your recollection of that particular meeting on 3rd January 2015?

A. That's my memory.
135 Q. The guidelines had -- had they reached their final iteration at that point?
A. There were a few minor edits, as there were some evolution in other hormone therapies coming on-line, so there were a few things that were added in, but the bulk of the work was within that. 11:44
136 Q. If we just go back to the notes of the minute at WIT-96687. I just want to make sure I've got the date correct. So this was - would this have been the next meeting after that meeting on 3rd January 2015? How often did you meet? 11:44
A. Quarterly, if there was a quorum.
137 Q. We'll just go down to the next page, please. So, it might be that the date is wrong, is it 30th January as opposed to the 3rd? It says: "A meeting on 3/1/2015" in your statement. I'm just wondering if this is the meeting that you're -- it must be if you meet quarterly? 11:44
A. Yeah. 11:45
138 Q. There wouldn't have been another meeting so quickly afterwards. So we can --
A. I can't imagine a meeting on 3rd January --
139 Q. And then the 30th again?
A. Yeah. 11:45
140 Q. So just we'll note that. So that's to be corrected in the statement. And we'll see reference to the urology guidelines and pathways at paragraph 3, it's headed "Regional Hormone Therapy Guideline and Pathway", and I

just want to read this out:

"Mr. O'Brien extended thanks to Dr. Darren Mitchell and Dr. Suneil Jain for their work in taking this forward.

Dr. Mitchell advised that the draft guideline has been circulated to oncology colleagues for comment and to pharmacy to advise regarding licensing restrictions.

It was proposed that the guideline and pathway would also be circulated to the urology network group for consultation. A deadline date of end of February 2015 was agreed. Mr. O'Brien queried if bone..." 11:45

A. Densitometry. 11:46

141 Q.

"...densitometry testing should be considered within the guidance. Dr. Mitchell advised that he would review the guidance regarding this."

11:46

And the action point is:

"All members to forward comments on the draft guideline and pathway by the end of February 2015." 11:46

And patient care pathways point:

"Mr. O'Brien advised that he is currently reviewing and updating all pathways."

So that reflects the discussion at the meeting.
A. (Witness Nods).
142 Q. Your recollection is that you took things further and you've raised the point that these guidelines were going to standardise the approach? 11:46
A. That's my memory as a single sentence comment, yes.
143 Q. It's clear from that paragraph that Mr. O'Brien was engaged with the development of the guidelines.
A. There were a number of comments received from a number of colleagues, and I think as part of the NICaN meetings, as I say, there was an evolution of drugs coming through at that stage. So there were a few different edits until we finally got the document that we were happy with. I'm also aware that Mr. O'Brien had commented on some of my spelling errors as part of the initial draft. So I do believe he had read the guidelines. 11:47 11:47
144 Q. I think there was an e-mail - apologies to the panel, I don't have reference to it - an e-mail about the reference to license and licence, the difference between the two words, to indicate that you had perhaps made an error? 11:47
A. Yeah.
145 Q. So there was certainly some evidence to suggest that Mr. O'Brien had turned his attention to the guidelines and had looked at them in at least that detail? 11:47
A. Yes.
146 Q. To highlight to you possible spelling. Did Mr. O'Brien

ever raise the issue of the Bicalutamide 50mg monotherapy issue at these meetings? Did he reply at all or...

A. No.

147 Q. And when you -- your recollection is that you did verbalise it? 11:48

A. That's my memory.

148 Q. Did anyone in the room support you on that, or say "Yes, that's a good idea, I've seen that incorrectly prescribed, or I have experience of that"? 11:48

A. No, not that I remember.

149 Q. Now, if your view is that the guidelines are going to assist in standardising the practice around the appropriate dose of Bicalutamide, that was your intention in relation to the guidelines to allow that 11:48 pathway to become embedded, so that you had it recorded that there was an expectation that Bicalutamide 50mg would be prescribed within certain constrained ways as licensed?

A. Yes. So I -- 11:49

150 Q. And the guidelines were your gateway to do that, that you wanted to sort of codify an expectation of standards?

A. Yes, I think that's a good way to put it. This was a method by which all consultants who were reviewing the 11:49 guidelines would be aware of the appropriate dose, the appropriate prescription. So, if they were outside that guidance in the future, that would be reflected back that they hadn't then followed the guidelines that

they'd reviewed.

151 Q. And would the other clinicians on the group have been aware that that was the -- there was an intended target to at least an element of the guidelines?

A. No, I don't know that they would have been aware of that. I think again my discussion with Prof. Jain at this time, following the previous e-mail in 2014, was that I had intended to write these with that in mind, but I don't know that other clinical colleagues would have seen my intent within it. 11:49 11:50

152 Q. If we could go to WIT-96693. This should be the meeting of 17th April 2015 of the NICaN urology network and site specific group meeting. In attendance, Mr. O'Brien again, Prof. Jain, Darren Mitchell, Chris Hagan. So, this is the meeting after the one at which you said you'd mentioned the issue specifically verbally in front of others. There's an opportunity on this to correct or to record the minutes of the last meeting. Did you notice that your input, your oral input on the Bicalutamide 50 issue hadn't been recorded at that point? 11:50 11:51

A. Not at the time of the meeting. But on reflection, and pulling these documents out, then I realised that there was nothing on paper to confirm that.

153 Q. I suppose a wider point in relation to record keeping around governance is the absence of concerns documented. You can see that it's difficult then to follow the trail, should there be a trail? 11:51

A. Yes.

154 Q. And the opportunity to correct meetings is in itself a form of governance, not specific to you generally as a point in relation to NICaN and the minutes.

Now, we don't need to go to the guidelines themselves, because they do reflect what you intended that they would, that the Bicalutamide 50 issue would be dealt with in a standardised way, and there was an expectation that Mr. O'Brien would have to review those guidelines and accept them? 11:52 11:53

A. Yes.

155 Q. Was it your expectation, or potentially hope, that the standardisation of the guidelines in that way, and trying to deal with the issue in that way would allow Mr. O'Brien an opportunity to discuss his use of the drug and allow for an open discussion to perhaps further your understanding and perhaps his? 11:53

A. I think there were a number of opportunities, on review of the guidelines, to state individual practise and defend why that particular dose of drug was being used. 11:53 So, in addition to the e-mail regarding my spelling, there was an opportunity to state why Bicalutamide 50mg once daily as a monotherapy should be included within that, even though they're not licensed, and there was no e-mail to that regard. There would have been 11:54 opportunity within the NICaN meetings themselves to open discussion, and perhaps I should have done that more formally and asked him for comment. But, again, there was no comment on the practice of Bicalutamide

50mg once daily monotherapy.

156 Q. Now, there were other individuals involved in this, I think it's multi disciplinary?

A. Yes.

157 Q. Certainly from the names that we recognise, there's quite a broad range of individuals attend these meetings, and was it your experience that they were an opportunity to discuss issues among fellow professionals in a very safe way? 11:54

A. Yeah. Other issues would perhaps engender more discussion in terms of surgical techniques and where those techniques are best performed, so those kind of discussions happen very frequently within the NICaN meeting. We'd also then be developing service through that meeting, so looking for additional imaging resources, maybe a consensus of thought as to what best fits Northern Ireland's urology practice, compared with other standards. So, it is a forum for discussion. 11:55 11:55

158 Q. As a mode of trying to bring about clinical change when clinical concerned have been identified, in that specific context, how effective do you think guidelines are for that purpose? 11:55

A. I think for junior trainees, for non-medical representatives at the meeting, guidelines are great. You know, the vast majority of patients fit within guidance. When I read guidance, I look to see does my practise fit within that? And if it does, then I'm pleased. If my practise is outside that, then there's a questioning as to why it doesn't fit within the 11:56

standard of care guidelines. So I think guidelines are incredibly important. Was it the correct format for correcting an individual? Probably not. I should have followed more formal governance structures. But I saw it as a follow on to the e-mail. So having mentioned it in the e-mail, I think it was important to follow through with what could be looked back on and address as non standard practice. 11:56

159 Q. And the Bicalutamide 50mg monotherapy issue would be something, would it not, that you might expect Mr. O'Brien to be aware of, given his seniority and his experience, what was the licensed indication for that particular drug? 11:57

A. Yes, and by reading the guidelines that would encourage you to look and say "I prescribe within guidelines". 11:57

160 Q. Now, you've mentioned that, I can't remember exactly what you said, but would you disagree if I said that it's likely not the best governance tool to try and effect change when clinical care issues have been identified? 11:57

A. Yeah, I agree there are other avenues that I should have used rather than this, but it still felt the right thing to do to have our guidelines that we could then look back on and say "Are we following these appropriately?" 11:57

161 Q. Yes, I suppose there are two ways of use for the guidelines. The first is to standardise the way in which there was an attempt to bring about change?

A. Yeah.

162 Q. Which, my point was really in the abstract that could be done, but in the face of specific concerns, you had mentioned that there might have been other avenues that you could have pursued, other governance pathways you might have taken. 11:58

A. (Witness Nods).

163 Q. Could you just --

A. So, again, I think that's back to a discussion with Clinical Director and subsequent discussions with colleagues from the Southern Trust in terms of this non-standard practice, there were a number of other ways that I could have done it and, retrospectively, I wish I had. 11:58

164 Q. Well, you did send the e-mail in 2014, you did try to bring about change through the guidelines. Did you ask for, or access, or feel in any way supported in what you were doing to try and address your concerns? 11:58

A. I'm not sure how to answer that, to be honest. It was a responsibility as a clinician to ensure that patients are being looked after correctly, which is why I sent the e-mail, why I standardised guidelines. I'm not sure what I would have expected in terms of support from other colleagues. 11:59

165 Q. Did you feel like a lone voice?

A. Not particularly. I'm not aware of what other people were doing regarding this, but I didn't feel like I was alone, no. 11:59

166 Q. Given the issue of the guidelines, there must have been, arguably, still concerns in your mind that the

practice was continuing, that it needed to be formalised in the way that you had proposed through this. Is that correct?

A. So, it was a follow on from the e-mail, and as I've said previously, I did have a sense that I wasn't seeing patients or hearing about patients who were being prescribed this particular drug regime until the next set of discussions and e-mails in, I think, 2019. So, I think that really brought it back that actually the actions I'd taken hadn't resulted in any change. 12:00

167 Q. I just want to explore a little bit more with you. You pushed back when I perhaps suggested you didn't appear to be supported.

A. (Witness Nods).

168 Q. And certainly when we move forward to 2019 and you're involved in the review of the use of Bicalutamide with Mr. Haynes and you get to see the issue again through a different lens perhaps. In retrospect even, do you look back and think, well, there were other people who knew about this and maybe with a bit of a wind at our back and a bit of a collective push we may have collectively done a little bit more, or brought about a change in approach? 12:00 12:01

A. There were opportunities at that stage. And I think again your phrase is probably correct, that the right people at the right time to have the right conversations to bring this current episode to fruition. But that - it just didn't line up at the time of 2014/2015, regrettably. 12:01

169 Q. Was there anything about that period, or the processes in place, or the culture, or the way things were structured, that you considered to be a barrier to you following established governance processes?

A. I think it's my lack of knowledge of the established governance process as more than any real barrier. 12:02

170 Q. And what way do you think your knowledge might have been increased around governance? How might that have fed its way into your professional practice?

A. I think, you know, the governance training we would have, I believe would have been quite limited at time of starting a consultant's post, which was six/seven years prior to the e-mail and this episode. I think there's more robust teaching now in terms of governance measures, and I think junior colleagues coming through are more aware of those structures and more likely to speak out than we would have been in the years gone by. I think if that's what you're asking, I think -- 12:02 12:02

171 Q. I suppose do you know if there's a difference in the training or approach as you come up through the ranks as a clinician that increases your awareness and also highlights your responsibility? Is that system in place? 12:02

A. So, I think as clinical directors, people going into those posts are offered formal training in governance structures. But I didn't have that, that formal training in those structures, other than a brief two-day induction at the 2008 time. 12:03

172 Q. And do you think that that was perhaps at the root of

your attempts to sort this out without triggering a formal process?

A. I think, yeah, if I'd more knowledge of the processes, it would have been an easier pathway to follow.

173 Q. You've also mentioned in your statement that the guidelines were a way of effectively encouraging good practice, because they would be audited, and you thought that that would allow then perhaps any issues to rise up to the surface. 12:03

A. Yeah. 12:04

174 Q. That was one of your motivations as well.

A. Yeah, retrospectively, it would have been good to audit. There are many audits it would be good to do, and particularly from an MDM perspective, you know, there are a number of things we would like to look at. I think it would have taken probably precedence in moving the service forward more than Bicalutamide 50, but actually, yes, it would have been good to take it to a year time point after the guidelines to see were they being complied with. 12:04 12:04

175 Q. I'll just take you to that part of your statement where you encapsulate that as a potential system of oversight from a governance perspective. WIT-96670, paragraph 2(iii). You're asked the question by the Inquiry:

12:04

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

And you say:

"These guidelines could have been audited within each Trust. If my belief that Mr. O'Brien was the only person in the region using Bicalutamide 50mg monotherapy is correct, then it would in essence have been an audit of his hormone therapy prescriptions in the Southern Trust. The guidelines were written to encourage good practice and provide a point of reference if there were future cases identified with his off licence prescribing." 12:05 12:05

So, that was the potential possibility of an audit?

A. (Witness Nods).

176 Q. Rather than the knowledge that the guidelines would be audited? 12:05

A. Yes.

177 Q. They could provide a tool for that?

A. They could have, yeah.

178 Q. You've mentioned there about your belief that Mr. O'Brien was the only person in the region using Bicalutamide 50mg monotherapy. Did you ever form a belief that others were prescribing that way? 12:05

A. No, I wasn't aware of other consultants prescribing this. I believe in the lookback exercise there were two other prescriptions with this dose, but they were described as being errors, and so the 50mg dose had been offered rather than the 150 in error, rather than systemically. 12:06

179 Q. When you looked at the - when you undertook the process with Mr. Haynes, did you consider individual cases and look at their clinical presentation and their treatment regime in order to assess the appropriateness of Bicalutamide 50 as a monotherapy, did you look at that detail? 12:06

A. As part of the standard of care? Yes, we --

180 Q. In 2019.

A. Yes, we looked at the dose and, in essence, in my mind that exercise was a multi disciplinary meeting. I believe in part that's why I was asked to join it as the Regional Chair of the MDM in Belfast. So I had good working knowledge of processes. So when the questions were asked: "What would the standard of care have been for this patient?", we would have defined that, and if Bicalutamide 50 was listed, we would have said that was not a standard of care we'd have offered for that patient. 12:07 12:07

181 Q. So you looked at the clinical presentation of the patients? 12:07

A. Yes.

182 Q. Did you find that any of the urologists at the Southern Trust had been using the drug in that way off licence?

A. No. So I believe there was a mechanism used to identify Bicalutamide 50 prescriptions, and I stand to be corrected, I think there were 50 prescriptions, 48 of which were from Mr. O'Brien and two of which were not, and those two were looked at and found to be prescription errors. 12:07

183 Q. Now, I just want to read out two scenarios, I won't mention any names, just to see if they are familiar to you at all as scenarios you might have looked at with Mr. Haynes, and if you don't remember, please just say you don't remember, and if you do, obviously we can discuss it.

"Case of an 84-year-old man under the care of Mr. Young when it was reported at MDM that a clinical diagnosis of prostate cancer had been made years previously and that he had been on..."

-- is it Casodex?

A. Casodex is the other name for Bicalutamide.

184 Q. For Bicalutamide. So he had been on Casodex 50mg daily for some time.

"Apparently he was discussed at MDM as he then had an acute renal injury due to bilateral upper urinary tract obstruction secondary to advanced prostate cancer associated with a serum PSA level of 105, a bone scan confirming metastatic disease. He was prescribed LHRH antagonist."

Now, does that ring any bells with you, that particular scenario, that he had been on Bicalutamide 50mg daily for some time?

A. I don't remember the case, but it would be consistent with the case we flagged in 2014 where the patient had

been on Bicalutamide 50 and not referred for oncology opinion.

185 Q. Another example, just if you remember this case with Mr. Haynes:

12:09

"73-year-old found to have organ confined intermediate risk prostate cancer diagnosed in 2009. Allegedly this patient had been anxious concerning his serum PSA levels increasing prior to diagnosis. He was prescribed Bicalutamide 50mg daily and Tamoxifen 10mg daily..." 12:10

-- which he tolerated sufficiently well that he apparently was happy to have his cancer managed in this way. He was reviewed by Mr. Glackin, apparently, in 2016, and remained under his care thereafter. And he, the patient, was advised that he should remain on the same medication as his serum PSA was then 0.1. So that appears to be, from the example given, another potential prescribing of Bicalutamide 50mg daily, albeit with Tamoxifen 10mg. Do you recall that? 12:10 12:11

A. I don't recall that case, other than saying a short list of the summaries where patients had been on 50mg and the single line saying the patient had remained on 50mg. But I don't remember the case. The Tamoxifen relates to one of the side effects of Bicalutamide, so it's not a treatment for prostate cancer. 12:11

186 Q. I don't want to go into any more detail in relation to those patients because I know clinically I'm just

throwing information across at you, but they're examples that were provided where there may be others legitimately prescribing, in their view, Bicalutamide 50, in ways that perhaps don't fall within what would be considered the licensed recommendations. 12:12

A. So, this would have been the format of the lookback where clinical data was presented and we would have defined the standard of care and then looked to see did the patient fit within that standard of care.

187 Q. If you have a patient who has been on low dose and is tolerating it well, even though the clinical indicators or the usual prescription regime may be to increase the dose or to change to another regime altogether, and the patient is reluctant to do that and is tolerating the dose well, what would your approach generally be, as we are speaking in the abstract, but as a clinician, even if a patient was on an unlicensed but to them an effective regime? Would you switch them over or would you let them tolerate what they considered was beneficial and just wait and see what happened? 12:12 12:13

A. I would look at that case and either recommend stopping it, because it's not a licensed dose, or moving to the correct licensed dose, and I would give them those as the options that I'm offering. I don't believe I'd be happy to potentiate the 50mg once daily, but if that's being prescribed by another consultant and they take on that responsibility themselves, I'd be happy to flag that back on letter to them to say "Here's my recommendations", and let them make the decision with 12:13

their original consultant.

188 Q. And from a governance lens, if the consultant was to maintain the unlicensed but apparently tolerated drug regime, would you expect to see that recorded in the medical notes, that the patient had been advised that it is, if I can use the term, non traditional application of a licensed drug? 12:14

A. That would be good practice as per the MHRA guidelines that I had sent through previously.

189 Q. And would it be something that you would do in your practice if you were -- I don't you -- I think you said at the start that you haven't ever done that, but if you were to go off licence for whatever reason? 12:14

A. So, we do use off licence medication. But that off licence is backed up by evidence and backed up by guidelines, and we would explain to patients that this is an unlicensed or off licence medication and explain why it's being used or recommended in their case. So that that's not common, but it's not uncommon either. That's good practice. 12:14 12:15

190 Q. We'll look at the 2019 review shortly, but I want to look at the 2016 e-mail, when there's concern around a delay in muscle invasive bladder cancer, a case referred from Craigavon.

A. (Witness Nods). 12:15

191 Q. Now, there are e-mails between a variety of individuals which I think just set out the background and context, and we'll use those, I think, as the starting point. If we go to WIT-96703. Apologies, these e-mails always

appear, when they're printed it is difficult to find the first one when you're on the screen. Let me just... So a few of these e-mails you're not involved in and then you are copied in --

A. Laterally. 12:16

192 Q. Do you recall this? You've seen these as well. This is from Chris Hagan, sent on 21st June 2016 to Davinia Lee. Who is Davinia Lee? Do you know her?

A. So Davinia Lee would have been the - I'm not sure her formal title - Cancer Services Manager. So she would 12:17 have been -- my line manager as MDT Chair, and Jenna, I believe, was the surgical manager.

193 Q. Okay. The reason why we're looking at this, just to put it into broader governance context as opposed to individual details, is this appears to be an example of 12:17 e-mails among professionals trying to find a solution to a problem that someone has identified and the way in which that pans out or doesn't.

A. Yes.

194 Q. And then eventually there's an e-mail in 2016. But 12:17 this is the lead up to it. So, I just want to read this out.

"Davinia,
I am very concerned about delays in ITT." 12:17

Just tell what ITT is?

A. That's Inter Trust Transfer.

195 Q.

"...from Craigavon and how we raise this. Is it possible an interface SAI?"

-- and we'll come back to that in a moment.

Patient name redacted: 12:18

"Muscle invasive bladder cancer. Original resection 16/2/2016..."

- I think that should say: 12:18

"...with multiple local MDT discussions before a regional discussion 9/6/2016, and I see her today 21/6/2016.

12:18

In my view there are multiple avoidable delays which will potentially lead to an adverse outcome. She is not fit for cystectomy today.

Contrast this with an exemplar patient [name redacted] 12:18 ERBT on 25/5/2016 in Derry. Muscle invasive bladder cancer. Discussed region MDT on 9/6/2016 and seen today with radical surgery next week.

What do you think? 12:19

Happy to discuss."

Obviously just for the panel's note, when Chris Hagan

is here this afternoon, we don't need to discuss his input in this, but clearly he's setting out that there's a process problem from his perspective that has resulted in delayed treatment. Is that a fair summary?

A. Yes. 12:19

196 Q. If we just move up, please. He then comes back and says she can't find anything for patients on CaPPS or ECR:

"Is the health care number definitely correct? What is the patient's name?" 12:19

Then we move on. Mr. Hagan sends the patient's name, Patient 127. And then she replies again on 22nd June 2016, and she says: 12:19

"Hi Chris,

I've had a look at the patient's pathway from CaPPS (see attached). 12:19

I have compared it against the NICaN pathway (page 125 of the clinical guidelines) and the guidance is for muscle invasive bladder cancer to send to CT chest abdomen before MDT discussion. However in this case it 12:20 was discussed at MDT first.

There was then a delay to the bone scan and it took over a month for the CT after the first MDM and nearly

two months from the original report of the pathology. They then discussed at local MDT again on 28/4/16 and decided on a plain film of left shoulder and central MDM discussion.

12:20

The first discussion at the regional MDT was following this on 12/5 at which a CT was recommended of the shoulder. An MRI was carried out as recommended by the radiologist on 26/5 and then was discussed centrally again and transferred on 9/6/16. 12:20

Would you have a look at the pathway prior to the first central MDM discussion on 12/5 for me? It looks like a CT should have been requested following the original path on 29/2 in line with the pathway attached, which 12:21 would have saved at least a month, but would welcome your clinical view as to what should have happened post original resection and pre specialist MDT discussion before we decide on how to proceed."

12:21

I think the previous e-mail was the 21st, is that right? The 22nd. Just move back up again, please. So on the same day, the totality of information with the expected standard pathway is fed back to Mr. Hagan, and the concerns that he might have had are particularised 12:21 by date, diagnosis, treatment pathway, in order to establish that there was a delay. But, again, over you as the clinician to establish whether, from a clinical perspective, that causes concern. That seems to be the

flavour of this e-mail.

A. I believe within this e-mail Mr. Hagan quotes the evidence for the effect on outcomes, both surgical outcomes and survivor outcomes, for delayed treatment in muscle invasive bladder cancer. So I think that's within the body of this. 12:22

197 Q. And I think that this is as an example of clinicians working together and the head of cancer, in order to ascertain exactly what had happened?

A. (Witness Nods). 12:22

198 Q. It's an example of what could be said is good practice from a governance perspective, immediately on the issue?

A. With a different disease and a much greater importance on timeliness of investigation and referral. 12:22

199 Q. I should say this is - I'm just taking you through this, I'm not attributing any involvement on you in any of this, this is really just for the panel's purpose of showing how you come in later on and the background to the e-mail, but it also could be seen as an example of good governance practice within the Trust. 12:23

A. Yes.

200 Q. Then from Davinia Lee again to Chris Hagan and Jenna Crawford, Gillian Traub:

12:23

"Hi Chris,

Can I check if you've had an opportunity to review this patient's pathway and whether you still have concerns

we need to follow up on?."

So we've now moved to August. If we go back up, back up, please? Mr. Hagan replies again the next day:

12:23

"It may be more appropriate for the MDM lead to comment."

And he sets out what he considers to be the relevant parts of the guidance as they were applied to this person's pathway. I don't think we need to read through that medical detail.

12:23

Again, Darren Mitchell, this is you, came in to this one. Do you remember being asked to become involved in this particular issue?

12:24

A. Yes.

201 Q. And was that by Chris Hagan?

A. I think it was Davinia Lee who asked me to look at this, and perhaps it was Chris as well.

12:24

202 Q. In your role as?

A. As Regional MDM Chair, where this is now an MDM issue.

203 Q. Thank you. And you have said:

"Chris,

12:24

I agree there's no recommendation for isotope bone scan in the regional guidelines or NICE guidelines."

Then you've --

A. Copy and pasted the relevant guidelines from NICE.
204 Q. In order to show that there's no recommendation in those guidelines?
A. (Witness Nods).
205 Q. Then you say at the bottom: 12:24

"I think this should be flagged back to the Southern Trust and I would suggest to all non regional MDTs that any muscle invasive bladder cancer on pathology should be discussed at the regional meeting at the earliest 12:25 opportunity to allow early surgical assessment and guidance on role of neoadjuvant chemo or suitability for XRT/chemo..."

Chemo treatment is that, is it? XRT? 12:25
A. That's a combination of chemotherapy and radiotherapy at the same time.
206 Q. For chemo/radiotherapy.

"Scans as per guidance can occur in tandem. 12:25

The outcomes from muscle invasive bladder cancer are poor and as you have demonstrated early intervention is crucial. 12:25

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

SAI might be more appropriate if we see this as a consistent trend - so I also agree that a review of time lines for the last 30 to 50 muscle invasive cases coming to central MDT could be reviewed to identify trends." 12:26

Now, we've moved slightly away from the specifics of that case. Do you know what happened in particular to that individual who Chris Hagan had identified in the first place, the issue of delay, do you have any recollection? 12:26

A. I don't.

207 Q. You don't know of anybody who took that forward as an issue?

A. I'm sure it may even have been me, but I don't remember the next step for that particular case. 12:26

208 Q. If it may have been you, what might you have done in relation to that particular person?

A. So, the approach in this case, if they're not deemed suitably fit for surgery, would be to assess fitness for radiotherapy. If they're particularly fit with no sign of any comorbidities, from my perspective you can add in chemotherapy on top of the radiotherapy. If they're very unfit you would still likely give radiotherapy, but at a lower dose. The intention there is for disease control rather than cure. 12:26 12:27

209 Q. I suppose I mean more from the perspective of the impact of the delay that she had experienced. Would anyone have taken that forward as a potential SAI,

notwithstanding the suggestion of SAI as a process review in your e-mail? Would anyone have perhaps lifted that and thought perhaps "Let's have a look at this. This delay has impacted, potentially impacted on outcomes." 12:27

A. Yes, potentially. But I guess we were working through a process at that stage which was possibly going to lead to an SAI. So, the patient would have been informed as part of that. But I don't know for sure.

210 Q. This didn't ultimately lead to -- 12:27

A. No.

211 Q. An SAI?

A. No.

212 Q. And when you mention the SAI in this, was it an SAI to look at the potential breakdown in communication that 12:28 has impacted care pathways, or an individual SAI into that particular individual, or both? What might have been in your mind when you mentioned SAI?

A. So, I think knowing that the outcomes for bladder cancer are very time dependent, I saw this as an MDT 12:28 responsibility to see how we could improve processes for the wider group, as well as for this patient. So the review that I had recommended was part of a "How do we improve this for everyone?"

213 Q. Now, there was mention in the first e-mail, I think it 12:28 was the first or second e-mail, of an interface SAI.

A. (Witness Nods).

214 Q. Do you know what that is?

A. No, I presume it will be raised by the managers within

the e-mail. If so, I'd be expected to comment on that, and the SAI would then be passed through to the other Trusts to comment on. But I don't know the processes around that.

215 Q. Do you have experience or knowledge of cross-Trust SAIs? 12:29

A. I'm sure as MDT Chair, we would have had a number of SAIs that would have gone to other Trusts. But I couldn't give you a particular instance.

216 Q. So it was a process you were familiar with, even at this point? 12:29

A. 2016? I'd been Chair for a year and a half, two years. Possibly, yeah.

217 Q. You've mentioned that SAI might be more appropriate if we see this as a consistent trend, and the mention of review of timelines for the last 30 to 50 muscle invasive cases coming to central MDT could be reviewed. Was that ever followed up, that suggestion? 12:29

A. Yes. So we took a six-month period, I believe from January to July 2016, identified the muscle invasive bladder cancers being referred from the other Trusts. Actually there were delays within each of the Trusts coming in, and I'll come back to one more thing about this in a second or two, but I saw this as a time point that we could change. So the recommendation that muscle invasive bladder cancers were brought straight to the regional MDT as soon as pathology was available was put into practice, and scans could then happen in tandem. So we already knew about the case whilst scans 12:30 12:30

were pending. And we've continued to work on that over the last number of years, where surgeons have a concern there's a muscle invasive bladder cancer case at the time of pathology, we'll flag it to the pathologists and ask for an expedited report to try and shorten the timelines even more.

If we step back then to the issue around bone scans in bladder cancer cases, the only Trust that was doing bone scans was the Southern Trust. So there were four cases identified between June/July 2016, two of which had had bone scans. I believe there were three other cases who weren't being formally followed as a new muscle invasive, so I'm assuming they had non invasive disease, which progressed muscle invasive, and of those three cases I believe all three had had bone scans. So there was a trend for bone scans being performed in the Southern Trust that we didn't see in the other Trusts.

12:31

12:31

12:31

218 Q. And being performed when they weren't provided for in the guidelines?

12:31

A. That's correct.

219 Q. And who undertook that review? Were you part of that?

A. So, the Cancer Services Manager, Davinia Lee, took part in that with one of her staff. So the statistics were generated and circulated around, I believe, the recipients of this e-mail as well.

12:32

220 Q. Now, I just want to ask you about the two issues you've mentioned. The first was the once pathology is confirmed and then it's to regional?

A. That would be practice now, yes.
221 Q. That would be practice now. Just then how that comes about? If there's a decision taken that best practice would dictate that because of the significance of bladder cancer and the need to act quickly for optimised outcomes, if a decision is taken clinically within the Belfast Trust that that should be the best care pathway, how do you buy-in other Trusts to send people to you once pathology is confirmed? What's the process by which that happened? 12:32 12:33
A. So, I believe the guidelines would have been circulated, but at any subsequent MDT where cases were being presented we would have said to the referring Trust "Our practice is now to bring these straight to MDT with pathology rather than wait for scans to expedite the process." So we had a, and still do, have a number of points where we can tell clinicians linking remotely that that's what they need to do. 12:33
222 Q. And the guidelines are guidelines rather than mandatory, I assume, by the very nature of them. But do you have any difficulty getting buy-in and people coming on board with what's been established as being potentially the best patient outcome group? 12:33
A. No. So I think we felt that actually bypassing clinicians was maybe important for the Trust. So my understanding is that once a pathology is reported as muscle invasive, that comes through to the coordinator for the MDT, who will then put the case straight onto the meeting, and then the summary for the case is 12:33

generated. So, actually, as soon as pathology is available they go straight on, not waiting on someone else to do that for us.

223 Q. So that process, bypassing the clinicians once pathology is confirmed, actually takes out any possibility of an individual or any clinician reinterpreting or interpreting what they consider to be the best patient pathway? It happens -- 12:34

A. We felt that expedited the patient's journey.

224 Q. And does that system work efficiently in your view? 12:34

A. Yes. And we're still working on it.

225 Q. You mentioned about bone scans, they were identifying four cases from the Southern Trust.

A. So, we had four cases that were identified as part of that data pool with muscle invasive, and my memory is that two of those have had bone scans. There were three other cases who, I think they follow a slightly different pathway. So they weren't diagnosed with muscle -- my assumption is they weren't diagnosed with muscle invasive disease from the outset. They may have had superficial disease that progressed, and as they were being worked up for their radical treatment they were then given bone scans. So if I remember that e-mail correctly, two of the four we found and three of the non-tracked cases had all had bone scans and all from the Southern Trust. 12:34 12:35 12:35

226 Q. And the clinical significance of that is that it brings with it delay?

A. It's a delay, yeah.

227 Q. And is it also a factor that if the bone scan is not part of the NICE guidelines then it's arguably irrelevant to outcomes? Is there any purpose in doing the bone scan if NICE guidelines don't suggest it?

A. No. I think we had listed it as part of the highlighted section in this e-mail that for patients where there was concern of metastatic disease it was more appropriate to do a PET scan, and I think we had argued and have been able to access PET scans by the time this was going through. So this was more to highlight "Do a PET scan rather than do a bone scan if you really feel this is warranted for this" -- 12:36 12:36

228 Q. If a scan is necessary, this is the one you should be doing?

A. (Witness Nods). 12:36

229 Q. And what was the outcome of -- I heard you speak to the outcome of bypassing the clinicians in order to fast track appropriate treatment, I presume. In relation to this, the bone scans and your identification that a PET scan is probably -- 12:36

A. So we haven't seen bone scans in subsequent cases to this, and we feel the timelines are improving, but there's still work to do.

230 Q. So you adapt your guidelines, or you send out -- what way does it work in practice? If I am a clinician in the Southern or Northern Trust and I have been sending people for bone scans, not realising that a PET scan is probably a more optimal route, how do I find out that there's an expectation that I stop that practice and 12:36

start sending them for PET scans, if at all?

A. So, a couple of strands to that. So, these are NICE guidance documents, so clinicians who are involved in managing bladder cancer should be aware of this. Secondly, we write this into our Regional MDM policy, that this is what happens. And if other Trusts are bringing cases in for discussion, muscle invasive disease, when there may be factors within that discussion where we would say we are recommending this patient has a PET scan, a CT scan would be done as a matter of course, but we would then recommend to them, and I think there's learning within that. So all muscle invasive bladder cancer cases are discussed at the regional meeting. 12:37 12:37

231 Q. So the difficulties that were highlighted or became apparent as a result of this have resulted in changes in practice? 12:37

A. Yes.

232 Q. That have been sustained.

A. And improved on. 12:38

233 Q. And improved on. So, those are also examples of governance concerns being raised, being appropriately analysed, dissected, to use a medical term, and properly responded to, to bring about effective change?

A. (Witness Nods). 12:38

234 Q. I just want to make sure we don't miss any... So this is an e-mail just on the 17th, just before we get to the e-mail of 26th August. Davinia Lee, 17th August 2016, and it's to you, Chris Hagan, Gillian Traub and

Jenna Crawford, and she says:

"Thanks Darren.
I have chatted to Carol-Anne and she says there are two options to raise this with the Southern Trust. 12:38
1. Speak directly to the colleague in the Southern Health and Social Care Trust who transferred the patient (she advised discussion should be consultant to consultant) and advise of the concerns below and ask them to take forward an investigation locally. 12:39
2. Report this as an interface incident with HSCB. In this scenario we complete a one-page summary and submit to HSCB and they then contact SHSCT for investigation.

In either option we will need to have a discussion with 12:39
the Southern Trust referrer.

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

12:39

I will ask Tracey to pull the MDT data from January to June 2016 and pull out the muscle invasive bladder cancers. Do you want to look at all the Trusts or just the Southern?"

12:39

And we discussed that. So, Gillian Traub comes back with a following up and she wants to add two points. You're in this e-mail and Chris Hagan, for our purposes:

"Hi Davinia,
Thanks for following this up. I would add two points. There should be a consultant to consultant discussion as Carol-Anne says, but should this discussion be with the MDT Chair in SHSCT rather than with the individual consultant urologist, if the plan for this patient was agreed at MDT rather than being the patient's urologist own treatment plan?
B. In past experience with interface incidents (which must meet criteria for an SAI) they are not the most palatable route. We could do a 3 way - completion of a BHSCT incident report, which discussion with SHSCT clinician and then incident report shared with them and they are asked to investigate. It also gets shared between corporate governance teams so it is formally logged. If the SHSCT then investigate it and find that it meets SAI criteria, it would be incumbent on them to declare an SAI." 12:40 12:40 12:40

12:41

So the previous e-mail in this e-mail appeared to be ways of trying to tease out the best way to effect change, if I can put it that way, by using the governance routes available. It was mentioned in the previous e-mail with HSCB being involved. Did you ever have any involvement with the HSCB through any governance mechanism or complaint mechanism? 12:41

A. No.

235 Q. You're not sure, you don't know how that works, how

that interacts?
A. (Witness shakes head).
236 Q. There's mention there at point 1, or point A, of the MDT Chair in the Southern Health and Social Care Trust. Do you know who that was at the time? 12:41
A. Well, I know that I sent an e-mail based on this recommendation to Mr. O'Brien and copied in the cancer care coordinator, who I think was Shauna McVeigh at that time, asking for a review and shared learning.
237 Q. And you reply on 17th August to that e-mail, 17th August 2016, to say: 12:42

"Route 1 seems best. I think I would add weight to the discussion if we saw this as a trend and had evidence to that effect. 12:42

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

So that's in advance of your review. 12:42

And Chris Hagan replies on 18th August 2016 to say:

"The issue for me is the regional shared learning and clinician to clinician may not capture this. Raising 12:42 it as an IR1 and hoping ST..."

-- which presumably means Southern Trust?
A. (Witness Nods).

238 Q.

"...then escalate to SAI may not happen and therefore no regional learning will follow. I think we should ensure that this is shared regionally. I agree it would be useful to look back at referrals for MIBC and their timelines. The NICaN Urology Chair is part of the STMDT and NICaN should also be involved in this.

Chris." 12:43

Mr. Hagan appears to be trying to widen the issue out to others so that there's an awareness that, as he said, there needs to be regional learning around the issue. 12:43

A. (Witness Nods).

239 Q. Do you think that was an appropriate suggestion from Chris Hagan?

A. I think Mr. Hagan would have more experience of these things than I had, so I was happy to follow the guidance from the e-mail recipients. 12:43

240 Q. Is there any suggestion - I mean I'll ask Mr. Hagan about this - but just from our own understanding, there does seem to be, just reading between the lines at this remove, perhaps a little bit of reluctant to engage with formal governance processes, there's a bit of a, maybe not an SAI, what might happen, it has to reach a certain threshold, will it get lost in the system? Was there any sense of that feeling behind the e-mail 12:44

correspondence?

A. I get the sense of that from the e-mail context. And I'll say again I think, you know, I'm guided by people who have greater understanding of these things. It certainly reads that there was a reluctance to initiate something more formal. 12:44

241 Q. I mean it is difficult at this remove, but there's a hint of a suggestion maybe that people have had maybe experience of processes and are reluctant to consider that those processes effect real change. There does seem to be a genuine conversation around trying to find the best route to bring about learning. Would you agree with that? 12:44

A. I think that's what the e-mails would suggest.

242 Q. This is the e-mail then that was the out working of that that you sent to Mr. O'Brien, and as you say, you copied Shauna McVeigh in. It was sent on 26th August 2016. You've attached the Patient 127's details, and you say: 12:45

"Aidan,
This was one of the bladder cases flagged up from the review of timelines for muscle invasive bladder cancer - I think she has been seen by Chris Hagan and was deemed unfit for surgery. 12:45

We'll review it here and I suspect you'll want to do a case note review there and see if there is any shared learning from it either regionally or locally.

Thanks."

And then you sign off. So the suggestion of contacting the Urology MDT Chair has been taken up. It's fallen to you again to contact Mr. O'Brien, the third - well, at least the second correspondence, if not the third attempt at interaction with him around clinical care, and if I might be bold to say that the second paragraph is perhaps not incredibly robust in seeking to have the issues addressed. Would that be a fair assessment of it? 12:46 12:46

A. I think this was a more collegiate, you know, looking for buy-in and support for this patient group. And, yes, it could have been more robust in terms of our expectations. I'd have expected some response to this, which would then allow to have a further discussion, and in tandem we were looking at other ways to improve this group's outcomes anyway. So, yes, the e-mail could have been more robust in terms of what we expected from him. 12:46 12:47

243 Q. Or perhaps just a change in tack? You said you were surprised by the robustness of your e-mail in 2014 on review for the purposes of this Inquiry, and perhaps this was a - that didn't work, attaching guidelines, maybe this route will start conversations. Would that be also a possible interpretation? 12:47

A. Yeah, I think the difference for me in this is that, you know, I'd copied in the coordinator, I know when I

was Regional Chair, if my coordinator had received an e-mail to this, that they would have spoken to me and spoken to the line manager. So there was an opportunity for at least the line manager to be aware of something we were looking into. But I could find no replies from this e-mail.

244 Q. So, there were no replies. You've copied Shauna McVeigh in, who was the urology MDM coordinator. There was no action from her taken in relation to that, she's no record? 12:48

A. No.

245 Q. There's no records found in relation to that. But specifically as addressed back to you, there was no - nothing came of this?

A. No. 12:48

246 Q. Did you copy Shauna McVeigh in as -- well, why did you copy Shauna McVeigh in? Was it more etiquette as the MDM coordinator or was there an expectation that her being copied in might trigger some sort of wider involvement? 12:48

A. No, this was in the same way as if I was asking the coordinator at my MDT to look into something, you'd send the details and they would come back with the relevant information. So it was both a backup, but it was also to see if the relevant pathway information 12:49 from the Southern Trust could be generated and examined.

247 Q. Now, the review that you discussed that happened with the bone scan outcome and the pathology triggering

automatic referral, that took place anyway, that was a review that was ongoing?

A. Yeah. And we --

248 Q. It wasn't dependent on the involvement of Mr. O'Brien?

A. No. 12:49

249 Q. I have asked you the questions before around was there another possible way that this could have been escalated from a governance perspective? I know there were a lot of discussions in the e-mails and this option was taken as ostensibly the most likely to 12:50 perhaps get some buy-in or be the most effective, and it seemed to be a collective, or at least a collectively aware decision to take this particular route. In hindsight, do you think this was the way to deal with this particular issue? 12:50

A. I think it was one of the ways to deal with it. And with limited knowledge of those other processes, I was happy to take that guidance. Similarly, if there'd been a recommendation to raise it as an interface SAI then I would have done that. 12:50

250 Q. And again this is 2016. Was there any particular context in place from either the SAI processes or from a cultural perspective that meant that you still were reluctant, or others might have been reluctant to engage in more established or potentially effective 12:51 governance processes?

A. I don't think I would have been aware of barriers. I was happy to take the recommendations that I was given, and should perhaps have had more understanding of those

processes, but these were a group of people who have had previous experience of these and if that's what they recommended, that's what they did.

251 Q. Were they senior to you or were they the same --

A. Mr. Hagan would have -- 12:51

252 Q. Grade.

A. Would have more experience than I would. And I would expect with the more senior managers that they would have had much more experience in terms of generating and dealing with DATIX as IR1s SAIs than I have. 12:52

253 Q. Now, I just want to move on from that period of time and just talk generally about the knowledge and escalation within the Belfast Trust to non escalation among individuals, and I just want to just run through a couple of points just to highlight them from your 12:52 section 21. I will bring this one up, it's WIT-96669. Paragraph 1(viii). And you're asked the question by the Inquiry:

"Were you aware of others who had knowledge of these 12:53 issues or who may have shared similar concerns? Please give full details."

And you reply and say:

12:53

"I believe the oncologists providing support as part of their job plan to the Craigavon Urology Service would have routinely been referred cases from Mr. O'Brien and may have come across this off licence prescribing.

This would include Dr. Jonathan McAleese, Prof. David Stewart, and Dr. Fionnuala Houghton. I am not aware of any discussions they had if they had concerns."

Can we take it from that that you're naming other individuals who may have come across the same issue but didn't specifically discuss that with you. 12:53

A. So, these are the three consultants that I can remember who were job planned to provide an oncology service to the Southern Trust. And purely based on proportion, if I had seen a few cases of which a handful had prescribed Bicalutamide 50 monotherapy, if they had seen more cases there was a greater chance that they would have seen proportionally the same number but a greater number of cases with the same prescription error. So, I was listing these as people who were job planned and may have seen more cases. 12:54 12:54

254 Q. But they didn't discuss them with you?

A. No.

255 Q. And you didn't have conversations with them. They never mentioned to you, "Oh, I have a few of those as well"? 12:54

A. No.

256 Q. That's not your evidence?

A. No. 12:54

257 Q. Now, you mentioned in your statement, just the point above that, we've asked you to identify each and every individual with whom you discussed issues, concerns, and provide full details to include dates and means of

communication. And we've discussed most of the relevant issues. We'll talk about the 2019 period in a moment, but if we just go down to the top of the next page. You say you spoke to Mr. McAleer. Just for the transcript, can you tell us who Mr. McAleer is? 12:55

A. Dr. McAleer.

258 Q. Seamus McAleer?

A. Seamus McAleer. He was the Clinical Director in 2019.

259 Q. In the Belfast Trust?

A. Yes. 12:55

260 Q. And:

"I spoke to Mr. McAleer, I believe, in 2019, at the point of initial discussion with Mr. Haynes, and then again in 2020 at the point of being asked to contribute 12:55 to the lookback exercise."

I just want to correct perhaps an error from Prof. O'Sullivan. He says in his statement that he was aware -- I beg your pardon, he doesn't say in his 12:55 statement, it's in Dr. Hughes' note, that Prof. O'Sullivan said he was aware that his colleague, DM - this is you -

"...as MDT Chair, had raised our concerns about AOB's 12:56 Bicalutamide prescribing with then the Clinical Director for oncology SMcA probably in 2011."

Now, I'm not sure if that's an error or if you had also

spoken to Mr. McAleer in 2011?

A. No, the only two points I remember speaking to Dr. McAleer were the two I've listed; 2019/2020.

261 Q. If we go to 96672, paragraph 5(ii). And we've asked you specifically about Mr. McAleer: 12:56

"How and when did you raise these concerns with the Clinical Director, Dr. McAleer? Please provide full details together with copies of any relevant contemporaneous documentation." 12:57

And you say:

"I believe my first discussion with Dr. McAleer occurred at the time of the informal discussions with 12:57 Mr. Haynes in 2019 outlined above.

I advised Dr. McAleer that I was contributing to a process of investigation of Mr. O'Brien's practice and that I anticipated that as it evolved that it was 12:57 likely I would have to provide evidence to any subsequent investigation within the Southern Trust. When I was invited to a case review meeting with the Southern Trust on 1/10/2020 I also advised Dr. McAleer of my role in this at that time. I have no 12:57 documentation from these discussions."

So from the -- you never advised Dr. McAleer of your 2014 e-mail, 2015 motivation around the guidelines, or

the e-mail of 2016, it never came up with him at any point as your Clinical Director?

A. So Dr. McAleer wasn't the Clinical Director in 2014.

262 Q. But he was - I mean at this point when you did speak to him, you didn't say "Actually, I've had engagement with Mr. O'Brien". You didn't tell him? It's just for the record, I need to know the time line? 12:58

A. I don't think I could give an answer that I could stand over. I suspect that there was some discussion around why I was being asked, but actually I couldn't recall that easily. From memory, it was that we were discussing a case and I'd highlighted to Mr. Haynes, and there was likely to be some follow on, but I don't remember anything else other than that. So, yeah, it's possible what you've said could have happened, I could have referenced the previous 2014 incident, but I don't remember that. 12:58

263 Q. And it was through Mr. Haynes that you became involved in the 2019/2020 lookback process?

A. Yes. 12:58

264 Q. Now, you said that Dr. Hughes, you acknowledged that you'd written to Mr. O'Brien about his practice, but you didn't escalate the issue to the Southern Health and Social Care Trust.

12:59

"This is something both individuals..."

He's referring to Prof. O'Sullivan as well:

"...regretted and reflected upon."

And that was something that you said to him at the 2021 interview.

"In evidence, Dr. Hughes also said that Dr. Mitchell clearly reflected he should have escalated the issues, despite the many actions that he had taken, he was still concerned about the persistent prescribing outside guidelines and felt that he should have done more." 12:59

And I think we've dealt with that. That's at TRA-01178, for the panel's note. Now you do mention in your statement when you're asked about escalation, you say you escalated it to Mr. Haynes in 2020, in answer to your question. That's at WIT-96673. 13:00

A. Yeah.

265 Q. Paragraph 7(ii):

"Please explain why the issue was never escalated to SHSCT, providing details of any real or perceived obstacles to such escalation?" 13:00

And you say:

"This was escalated to Mr. Haynes in 2020."

Now, at this point issues had become apparent and there

was much more intense focus. So it would be fair to say that it was a conversation with Mr. Haynes rather than your escalation of issues?

A. Yeah, it was both. So there had been informal conversations as part of Mr. Haynes attending the regional urology meeting, we'd come across a few more cases about Bicalutamide 50 and we'd discussed that with him. So I believe Mr. Haynes asked me to document that and formally let him know the case numbers, as part of his work. So, I agree both. I did escalate to Mr. Haynes, but actually there was really a pressure of movement towards an investigation. 13:01 13:01

266 Q. At no time did anyone from the Southern Trust raise any concerns with you? There were no concerns came from that direction to you around care that was being given -- 13:01

A. Prior to Mr. Haynes?

267 Q. Yes.

A. No.

268 Q. Now, the panel have heard evidence before around the quoracy about MDM meetings and you've set those out. Just for the panel's note: The problems with staffing, particularly for oncologists and radiologists, and this is a theme. For reference it's at WIT-96673 and paragraph 9. We don't need to go to this. You also flagged the issue about the MDM quoracy at a NICaN meeting on 18th September 2015 at WIT-96686. There's also reference again in 2018, e-mail chain at WIT-42353 to WIT-42350, just working backwards in order on those 13:01 13:02

e-mails. And that's concerns about the radiology cover for the Craigavon neurology MDT. And as recently as August 2021 you were also sending an e-mail and you've used the phrase:

"With the usual query from our core radiology team to see if Southern Health and Social Care Trust had radiology cover to present cases at MDT."

And that's the e-mail chain at TRU-285231. 13:03

And Anthony Glackin responds to you, saying:

"Unfortunately we are struggling for adequate cover and quoracy." 13:03

Now, you worked with Mark Haynes on the lookback and you were set three questions which you applied to each one of the cases, and you were involved in that, and that did involve you looking, as we said earlier, at some of the Bicalutamide 50 monotherapy, and your understanding, just to summarise that, was that there were no other consultants involved in prescribing Bicalutamide 50mg monotherapy when it wasn't clinically indicated under licence? 13:04

A. That's correct.

269 Q. I was going to ask you about learning, I think we've worked through that, and I'm conscious that the panel may have some questions and I'm conscious of the time.

So, in the hope that they'll sit on a little bit longer and complete the evidence, I'll hand you over.

CHAIR: I think we'll definitely sit on and let you get away eventually, Mr. Mitchell.

13:04

QUESTIONS BY THE PANEL

CHAIR: I'm going to ask Mr. Hanbury, I'm sure he has several questions for you, as a fellow urologist.

MR. HANBURY: Thank you very much. As a urologist we have a lot to do with clinical oncology. So fortunately you've answered quite a lot of my questions, but there are just a couple of things. 13:04

Looking at the sort of general issue of delays to referral from Southern Trust to yourselves, as Mr. O'Brien says, as part of his justification for some of the delays that he was seeing the effect of hormone treatment on the PSA before he referred to you, what's your thoughts on that? 13:05

A. So, Bicalutamide is an antiandrogen. It would be expected to have an impact on testosterone interaction with the receptor, so you would expect some degree of PSA response. But I would reflect back on the work done by AstraZeneca in developing the drug, and if Bicalutamide 50mg as a monotherapy was appropriate, then they would have worked to licence that. So, I still don't see the justification for Bicalutamide 50 for that reason, because of a PSA response. 13:05

270 Q. So that wouldn't have been a good reason not to refer after MDM, in your view?
A. No. No.
271 Q. Just to sort of -- okay. Thank you. The issue of patients with lower urinary tract symptoms and needing radiotherapy is a real one which we jointly address between yourselves and us as urologists. Do you have a view on whether LHRH inhibitors are better than antiandrogens in the form of Bicalutamide or -- in managing lower tract symptoms? 13:06
A. So, not necessarily from a lower urinary tract symptom perspective, but as a brachytherapist if we're sent a patient whose prostate is too large for implant, we know that LHRH agonists will get a greater degree of site reduction in the prostate gland than Bicalutamide. 13:07
So, for patients who are in that scenario, we will have a discussion about downsizing, and then the discussion on the impact on sexual function, comparing both those options. But I would view LHRH agonists as being better at site reduction than Bicalutamide. I suspect 13:07
that probably also has a greater impact on their urinary function as well.
272 Q. Okay. Thank you. And in the same way, if you have someone with relatively severe symptoms, from a urology point of view if a patient may need bladder outflow 13:07
surgery...
A. Mmm.
273 Q. We've noticed that under Mr. O'Brien's service that would seem to preclude the referral to yourselves,

whereas many urologists, I think, would refer to oncology but say, "Listen, this patient's got severe symptoms. Let's see how, if we can manage them medically and have a joint discussion with oncology colleagues." How do you play that with perhaps other urologists? 13:08

A. So, I think that's a fairly common conundrum that we all face. I tend to like to see the patients and to have the discussion on the impact of treatment. The key feature is, if they are having bladder outflow surgery, when is that going to be? If it's going to be timely and not have a significant impact on their radical treatment, then do it early. If it's likely that they're going to wait for surgery for a long time, then get on with radiotherapy and deal with the consequence of that subsequently. So in fact I look at the intervention as the trigger. 13:08

274 Q. But, again, you would expect to be involved in that discussion with the referral -- sorry, referring urologist, rather than just not knowing about the case? 13:09

A. Yes.

275 Q. Okay. Thank you. We mentioned Tamoxifen very briefly.

A. Mmm.

276 Q. I mean hormone treatment can have side effects. And had you come across this routine prescription Tamoxifen alongside Bicalutamide or other hormone treatments -- 13:09

A. Yes.

277 Q. From other clinicians, or was this specific to Mr. O'Brien's practice?

A. No, I think that's a universal practice. And from my memory of the Chip clinical study, I think Tamoxifen was listed as a method of reducing the gynecomastia that Bicalutamide can sometimes cause. So I think it's a standard practice to offer Tamoxifen along with Bicalutamide. 13:09

278 Q. Okay. Thank you. Just to go back to your -- there's been lots of debate about the non quoracy at the Southern Trust MDM, and obviously having a clinical oncologist present has lots of advantages. Would you like to elaborate those? I mean you've mentioned muscle invasive disease? 13:10

A. Yeah.

279 Q. And testicular cancer I'll talk about, as well as prostate? 13:10

A. So the muscle invasive cancers, I don't see that as necessarily a quoracy issues, because they should be coming through to the regional meeting where the surgeons who do the cystectomies are present. So that is what our practice is. But I agree that having an oncologist present at an MDT is an important group of people to have. 13:10

I also then am aware of the lack of radiology consistent cover and the e-mails which have been referenced within the regional meeting, we had two radiologists who were struggling to keep on top of our cases then being asked to comment on cases from another meeting, and my memory is that they would refer to 13:10

guidelines in terms of the inappropriateness of commenting on cases ad hoc on a brief presentation and the appropriateness for preparation time prior to meeting. So, I think they were quite robust in their saying that they could not provide radiology cover for a separate MDT on top of their already job planned work.

280 Q. And I suppose just to push you a little bit more, were you ever asked as a group, "Okay, listen, Southern Trust are really struggling for cover, are there any free sessions that anybody in the department could offer either remotely or personally to assist?" 13:11

A. I think I was excluded from those conversations because I already had a clinical commitment doing the regional meeting on a Thursday afternoon. So, the discussions would have been with the clinical directors to see who else was available to provide cover for that meeting. But I think I was excluded from those because I was already busy. 13:12

MR. HANBURY: That's all. Thank you very much. Thank you. 13:12

CHAIR: Dr. Swart.

DR. SWART: Thank you. I'd just like to go back to the 2014 e-mail, which seems to have been an important e-mail about a particular patient, and I know you would have put quite a lot of thought into that e-mail. What did you say to that patient when he was in front of you and subsequently, and how did you deal with that aspect of it? 13:12

A. So, I didn't see that patient, the patient was passed through to me by Prof. Suneil Jain. So I'm not aware of the consultation he has had with the patient.

281 Q. What would you have said to the patient? Because I'm just interested in the general topic of how patients can share their treatment decisions and what happens in the event of something like this. 13:13

A. So, I'd look at the cases that were reviewed subsequent to the lookback exercise, and I would have said to them that we would have liked to have seen them at an earlier stage and were they aware of the treatments that we were offering and had they any concerns? But I don't remember any of the patients expressing concerns or a feeling that they had not been referred in a timely manner. 13:13

282 Q. Were patients at that time routinely given a summary of all the treatment decisions and a summary of all letters? This is 2014.

A. If they were -- 2014? I think if there was a clinical nurse specialist within the consultation, they would routinely have been given a record of consultation. However, we have struggled with our number of CNSs in the region, so it wasn't always possible for a CNS to be in the consultation meeting. 13:13

283 Q. And at that time, this eventually led to the new guidelines being written, but you agree that perhaps dealing with an individual clinician by writing a guideline for everyone might not be the whole best way of doing it, but anyway, that's the way it was dealt 13:14

with.

What was the mechanism at that time for knowing whether people were adhering to guidelines anyway? Because there's loads of guidelines everywhere. Was there an established culture of audit for NICaN guidance that was recommended for the region? 13:14

A. So, there was a process of audit, but we were auditing things like the use of neoadjuvant chemotherapy and bladder cancer and the uptake of that. I don't think we would have looked at -- 13:15

284 Q. You wouldn't generally recommend a --

A. -- at a Bicalutamide 50mg audit.

285 Q. I mean, you know, if I asked you the question "How do you know people are adhering to all the guidelines?", how would you know? 13:15

A. I think when they come for their opinion and you're seeing a trend of non adherence, that's the flag for concern.

286 Q. But there's no systematic look at that, you don't think? 13:15

A. No.

287 Q. No. You mentioned at the time that you dealt with this you didn't have any support, this was under questioning. But what does it say about the culture if you felt, or you didn't feel the need to ask people about this issue, do you think, looking back on it? I mean, I've spent a lot of time in various roles and I know that the commonest conversation would have been 13:15

"How do we deal with something of this nature?" It's not necessarily by e-mail, it's with the wisdom of colleagues and with the complexity of medicine in mind, because it's not a simple thing to do. But what do you think that tells you and us about what was going on at that time? Why didn't you think, "Gosh, I need to go and talk to somebody and see how to do this"? 13:16

A. So, this was the 2014?

288 Q. 2014.

A. Yes. 13:16

289 Q. I mean the e-mail was, you know, it's a perfectly apt e-mail and so on, but I'm thinking of you being a little bit isolated here, when this is a tricky issue, actually.

A. Yes. So I think I saw it as the delay being the greater issue and perhaps opportunity to work through that as -- 13:16

290 Q. No, I'm talking about the whole thing: The delay, the prescription causing the delay, a patient who's had two years who needs an explanation, the knowledge that there are other cases, the clinician involved is in another Trust. None of this is entirely straightforward. 13:16

A. Yeah, I --

291 Q. So why didn't you? It's not just about knowledge. Why did you feel you should have all the answers and not go and talk to somebody more senior about how to do this? 13:17

A. I don't know.

292 Q. You don't know? Okay.

A. You know, I felt I had discussed it with my clinical colleagues. They had been included in the e-mail. I had an intention to write guidelines as a follow-up. But these actions didn't actually result in change. So. 13:17

293 Q. And the culture at the time, you have clinical directors and medical management culture in place. You will not have had formal clinical governance training during your time as a medical student and in your, probably in your training generally. You arrive as a consultant, you're supposed to know everything. What efforts did the clinical directors make to get people together to improve the clinical governance structure, do you think, or was there just not enough time to do all of this? 13:17 13:18

A. Probably the latter. There were other concentrated issues other than governance.

294 Q. Because you can't have -- - you can have as many policies as you like, but it's really the way they're used and the way people feel about using them that matters. And clinical medicine is the best illustration of that, because it's so complicated. 13:18

A. Yeah.

295 Q. Do you think that's changed over the last decade or do you think this is still a problem in terms of being able to give it the attention it deserves? 13:18

A. So, I still think the vast majority of patients, that within guidelines I think they're incredibly important.

296 Q. Mm-hmm.

A. Increasingly when I see my trainees coming through, they'll be looking at guidelines and following guidelines, and probably quicker to flag when something's outside guidelines and ask why that's happening. So I think that process is still important. 13:19
I think we need to be clear in terms of where we work outside guidelines as to how we document that. And within our specialty we now have robust peer review where cases that sit outside guidelines for radiotherapy treatments will be discussed with your 13:19
peers and signed off as having been peer reviewed and accepted. So having that kind of approach is helpful and supportive.

297 Q. Mm-hmm. Coming onto the bladder cancer one, where there are clearly very serious delays and you've 13:19
improved things now, but do you think the understanding of the need to perhaps trigger these as serious incident investigations and learn from that was embedded at that time? Is it getting more embedded? Is it not working properly? Or what's your feeling 13:19
about that? Because that must have been a difficult, another very difficult thing to deal with because of the time problem.

A. I think years later it's more likely we would raise this as an SAI straightaway rather than go through the 13:20
e-mail process.

298 Q. And looking back on all of that, what is your personal reflection on what would have made a big difference in terms of dealing with these various issues differently

over the time. I mean there's a bit more than learning. What do you think would have assisted you and the Trust in terms of picking the issues up quicker, dealing with it quicker, not doing it from the approach of blame, but from the approach of learning for patients?

A. I think increasingly people are more open and that duty of candour has become much more important if we do make an error. So that's good. I think there's less of a blame culture. So, if there's an error, we look at how to improve that rather than look at who caused it. So all those things are improving. 13:20 13:21

299 Q. Do you look back on this and worry about it?

A. I look back and wish that I'd taken different steps at the time and reflect on what I could have done, and whilst I did some things, I don't think they were adequate in dealing with this particular situation. 13:21

300 Q. But what one thing would you have done differently if there was just one thing?

A. I think I would have been more robust in going to a Clinical Director and saying "What form do I need to fill out to make this work?" 13:21

301 Q. I don't think there is one probably!

A. No.

DR. SWART: Thank you. 13:21

CHAIR: Just one thing that I'm not entirely clear on. Your involvement in the lookback review. And I think your evidence was that you identified two issues, or two cases of the 50mg of Bicalutamide being prescribed

by someone other than Mr. O'Brien, is that correct?
A. Yeah, I'd have to go back to the e-mails and review, but I believe Mr. Haynes had asked one of the pharmacists within the Southern Trust, and perhaps regionally, to look at Bicalutamide 50mg prescription. 13:22
I believe there were 50 cases identified, 48 of which were Mr. O'Brien's, and I believe --
302 Q. I think you said two were identified as errors?
A. Yes.
303 Q. And I just was keen to know is how you knew they were 13:22
errors?
A. I didn't look at them. I believe Mr. Haynes has looked at those.
304 Q. Okay. So we'll ask Mr. Haynes about that. The only reason I ask is that your evidence was that when you 13:22
first saw this come across your desk, you assumed it was an error, that it should have been 150 rather than 50?
A. Yes.
305 Q. So I'm keen to tease out whether or not these were 13:22
actual errors or not. Do you see where I'm coming from?
A. Yes.
306 Q. So Mr. Haynes should be able to answer that?
A. I think he probably has got more access to the data 13:22
than I have.
307 Q. Okay. Thank you. And one of the other things, just in terms of SAIs and reporting and the learning from SAIs, the process seems to take, or can take, depending on

the complexity of the case, quite a long time before you get to the learning. And I'm wondering is that one of the reasons why you go down this more informal e-mail approach to try to get the learning quicker, or am I incorrect in that? 13:23

A. No, I think looking back at those cases it should have been a tandem approach, we should have both flagged it formally and informally. And you are correct, you know, the hope would be that someone gets an e-mail like the 2014 e-mail and changes their practice 13:23 immediately before there's a subsequent review ten years later.

308 Q. And as far as you were concerned, you believed Mr. O'Brien had changed his practice as a result of your steps, because you weren't seeing them? 13:24

A. I had a sense of that. But I couldn't stand over that.

309 Q. Certainly not with hindsight probably?

A. No.

CHAIR: Okay. Thank you very much, Dr. Mitchell, for coming along. It's been a little bit later than we 13:24 anticipated, but...

MS. McMAHON: It has. Could I just tidy up the last point?

CHAIR: Sure.

MS. McMAHON: On the two patients, just while we're on 13:24 that. At Dr. O'Kane's section 21 reply, WIT-20089, she refers to, at the bottom:

"A total of 466 patients was identified from the

western, northern and southern local commissioning group areas as having received a prescription for Bicalutamide 50."

And then:

"34 of these patients were identified as being on incorrect treatment, as determined by the clinical indications above, and two patients had been commenced on the medication by services outside of NI urology: One by GP, one in South Africa in 2005, and that had continued following the move to Northern Ireland."

That may be the two patients that you're referring to, just to close that off.

A. Sorry, I hadn't seen that paper. Yeah.

MS. McMAHON: You hadn't seen that. I am very grateful to Ms. Treanor for identifying it for the Inquiry.

CHAIR: And I had forgotten. I had seen it! So thank you, Ms. Treanor. That's helpful. Thank you very much.

MS. McMAHON: Thank you.

CHAIR: Ladies and gentlemen, it's almost half past one. Could we manage with 45-minute break for lunch and see you back then at, say, a quarter past two?

LUNCHEON ADJOURNMENT

THE INQUIRY RESUMED AS FOLLOWS AFTER THE LUNCHEON ADJOURNMENT

CHAIR: Good afternoon everyone. Ms. McMahon, I think we have a familiar if somewhat new face. 14:21

MS. McMAHON: Perhaps we'll go straight to that issue. Now that we have representation from the Belfast Trust, if I could ask Mr. Aiken to introduce himself and his team.

MR. AIKEN KC: Thank you, Ms. McMahon. Chair, I am Joseph Aiken KC. I appear on behalf of the Belfast Trust and I am assisting Mr. Hagan, who has come to give evidence to you today. I am accompanied by Ms. O'Neill from the Directorate of Legal Services, who instructs me. 14:22

CHAIR: Thank you, Mr. Aiken. Welcome.

MS. McMAHON: Thank you. The witness this afternoon is Mr. Chris Hagan, Consultant Urologist, and also the Executive Medical Director of the Belfast Trust in his current post, and I understand he wishes to affirm. 14:22

MR. CHRIS HAGAN, HAVING AFFIRMED, WAS EXAMINED BY MS. MCMAHON AS FOLLOWS:

MS. McMAHON: Mr. Hagan, thank you for coming along to give evidence today. I know you're quite softly spoken, so I'll just make sure that the microphone is close enough to pick you up on the transcript and we can hear your answers. 14:23

You have already helpfully provided a section 21 response to the Inquiry, and I just want to look at that first of all and then I'll take you through the context and the layout for your evidence. 14:23

If we go to WIT-98839, you'll see that's section 21 number 11 of 2023, and the date of the notice is 6th June 2023, and it is signed at WIT-98867. The signature on the bottom dated 9th August 2023, do you 14:24 recognise that as your signature?

A. Yes, that's correct.

310 Q. And do you wish to adopt that as your evidence to the Inquiry?

A. Yes, please. 14:24

311 Q. Any amendments that you can think of at the moment? Is there anything in particular that you want to address at this point?

A. The only thing was the typo on WIT-98843, which was my 2000 rotational training at Craigavon. 14:24

312 Q. Can you get that up, 98843, just make sure we're changing the correct date. So the highlighted part that we can see has already been annotated by Inquiry staff, so it should read 2000 and not 2010?

A. That's correct, yeah. 14:25

313 Q. Thank you. Now, the context of why you're here to give evidence is that in your response to the Inquiry you have provided information on some issues that may arguably fall within the terms of reference and may be

of relevance to them in their considerations. Now, the section 21 was sent to you, as you were mentioned by Dr. Colin Fitzpatrick in his statement earlier this year, and that was the reason why we reached out and asked you some questions, and you've very helpfully provided us with a fulsome section 21 reply. 14:25

The purpose of today is to look into some aspects of that in a little more detail. The panel have your written evidence. The core participants have your evidence and it will be up on the website as well. But it's just to get an opportunity to explore some of the issues that you raise in a little bit more detail so that the panel can consider the governance issues that arise from those concerns and examples that you provide that may inform recommendations that they may take a view on. So, that's the context. 14:25 14:26

Just given the route by which we found you, as it were, when you heard the public Inquiry announcement at that time, did you think it might have been appropriate to contact the Inquiry in order to let them know that you had some knowledge or experience that might be of interest? 14:26

A. I don't think that occurred to me at the time. I think my assumption was that the Inquiry -- I mean, my experience of dealing with Inquiries before was that the Inquiry approached people that might have worked with individuals or worked in that department, and 14:26

Maria O'Kane had written to me at some point, at one point, about the 2010 bladder cancer cases. So I took it from that that the Inquiry was also aware that I had raised concerns, and I expected then, because of that, that you might have wanted to talk to me. But it hadn't -- I suppose it's just my reflection having dealt with Inquiries before, that usually Inquiries approached individuals who had worked there.

314 Q. Thank you. Now, I want to look at your statement in the order, in the chronological order of some of the events that you describe, and I will be covering the following topics - we only have this afternoon, we hope to finish with you this afternoon, so I've tried to tease out what might be the most relevant aspects. And if there's anything else that you feel that you need to say, we can do that towards the end, if that's okay? 14:27 14:27 14:28

I will start shortly just with your employment and career history, so the Inquiry gets a flavour of your experience. Then we'll look at your time in 2000, your six-month period of time in Craigavon Area Hospital in urology, look at some of the areas of concern that you raised or observed and in which you give evidence that you spoke to some people about. Then we'll look at the review of the adult urology services in 2010 and the movement of some of the services to the Regional Unit in Belfast and some of the issues that arose then. 14:28 14:28

In 2016 there were delays in referral from Craigavon

Area Hospital, and in 2017/2019 the issue around the endoscopic resection and the use of glycine and the TUR syndrome. So they're the sort of highlights.

Now, the panel heard this morning from Darren Mitchell. 14:29
We looked at some e-mails that you were mentioned in and were the author of in relation to the 2016 referrals from Craigavon, and they've looked at that in some detail. So I will, when we come to that, I may short circuit some of that, but I can still find out 14:29
your views and any concerns that you had around that and we can take it that way, rather than opening all of the documents again.

But if we just start off, if you could outline, I know 14:29
you have in your statement, but if you could give us a run through your employment history and how you ended up in the Belfast Trust?

A. So, briefly, I trained in Manchester Medical School and then moved to Scotland and got some urological 14:30
experience there, a middle grade rota, or middle grade job, and then came back to Belfast in 1998, when I was a trainee in the Northern Ireland Urology Rotational Scheme, and got my CCT in 2003 and was appointed a consultant urologist and transplant surgeon in Belfast 14:30
in 2003.

Then from 2005 I was the clinical lead for urology and then became the Clinical Director for Urology in 2009,

and that included transplantation.

Around the time of 2010, there's a reconfiguration in Northern Ireland and we were joined with the urology team in the Ulster, and I became the Clinical Director for both services. 14:30

Then in 2015 I was appointed the Associate Medical Director in Belfast Trust, and that covered children's, maternity, and orthopaedic services. 14:31

Then in 2016 I took on a role as Chair of division for children's services.

Then in 2018 to 2020 I was the Deputy Medical Director, primarily for risk and governance. 14:31

Then 2020 I became Executive Medical Director.

315 Q. Thank you. So there have been roles involving, in particular governance, as part of your responsibility as you have moved up the clinical professional ladder, you have gained more experience and more knowledge of governance issues. Would that be fair? 14:31

A. So I think the clinical leadership role has a responsibility primarily for patient safety and clinical governance is at the heart of patient safety. So, as I progressed through, I took more responsibility for clinical governance systems within Belfast. 14:31

316 Q. Now, if we go straight to the time when you went to

Craigavon Area Hospital, that was February 2000 to August 2000, and at that time there were two consultants in the Urology Department; Mr. O'Brien and Mr. Young.

A. (Witness Nods).

317 Q. And you say in your statement that you had met both of them before at educational events, but you hadn't worked with them previously.

A. (Witness Nods).

318 Q. Now, at that time those two consultants had their own set of urology patients, but you say they did a joint Thursday morning ward round together which you attended? 14:32

A. (Witness Nods).

319 Q. Can you give us a flavour of what that was like on a Thursday morning? Was that, was it a grand ward round or was that what they called it or... 14:32

A. So they called it a grand ward round where the two consultants, with the trainees and some nurses, would have gone round all the patients on the ward and discussed them. And I believe that had been happening for some time before I was in Craigavon. So it was a way, I think, of working together more as a team, I suspect. 14:33

320 Q. So both consultants walked around and discussed patients together? 14:33

A. That's correct, yes.

321 Q. And this was before the team obviously increased in numbers. It was a small team at that time?

A. Yes, there was just the two of them.
322 Q. And for the purposes of your rotation for your surgical experience to fulfil your rotational requirements, did you work in particular with one of the consultants or both of them equally? What was the structure like for you? 14:33
A. So I was the only higher surgical trainee, so I would have worked with both of them to try -- the focus is on getting surgical experience, so attending as much of their theatre lists as possible and then joining them in outpatient clinics. 14:34
323 Q. And just prior to this move, you had spent almost a year and a half at the urology department in the City Hospital?
A. That's correct. 14:34
324 Q. And what would be your view on the breadth of your experience at that point? It's quite early on in your surgical rotation, but having been in the Belfast City Hospital in this specialty.
A. Well, I think, you know, prior to that I'd worked in Glasgow in a big unit and a sort of middle grade role, so I'd had a fair amount of surgical experience at that stage, and particularly in my second year in Belfast, like that's when I decided I was going to do surgical oncology, I spent a lot of time doing that, that six months. 14:34 14:35
325 Q. And just so we understand it, when you say you had a bit of surgical experience, was it at that stage that you were able to do any operations alone or were you

always supervised? What was the fit in your surgical training?

A. So at that point I had done a lot of TURP surgery, so I was competent to do TURP. In Glasgow I'd done a lot of nephrectomy, removal of the kidney surgery, under supervision. So I was reasonably competent to do straightforward nephrectomy under supervision, and I was learning how to do cystectomy during that second year in Belfast. 14:35

326 Q. And you'd been to Glasgow, as you say, and you'd been to Belfast. Did you feel that you had seen quite a breadth of urological surgical experience even at that stage? 14:35

A. So, both those units were not only - they had DGH functions, they were district general hospital functions for the local population, but they were also tertiary units, so they would have taken referrals. So the unit in Glasgow would have taken referrals from outside Glasgow for pelvic cancer surgery and retroperineal lymph node dissection surgery, and then the unit in Belfast would have taken the complex cases that, you know, they did the majority of cystectomy operations, for instance, or the complex kidney cancer surgery with involvement of the major vessels up to the heart. 14:36 14:36

327 Q. And in 2000 was there already a movement towards referring the more complex perhaps higher risk surgery to the Belfast City Hospital, given their ancillary support structures, like intensive care and such?

A. So at that time the district general hospitals, like the Mater Hospital and the Ulster Hospital, would have referred complex major surgery like cystectomy to Belfast. In Derry they were still doing the majority of the major surgery, but as we progressed towards 2008/2009, they stopped doing the cystectomies but kept doing the prostatectomies.

328 Q. And had you experience of either observing or participating in cystectomies at this point by the time you arrived in Craigavon? 14:37

A. So, in my second year in Belfast I worked almost exclusively with Patrick Keane, whose main surgical practice was cystectomy and complex kidney cancer surgery. So he was an excellent trainer and mentor, and consultant colleague laterally, and he and I worked very closely together and he was a really good trainer. So by the time I went to Craigavon, I was able to do a considerable part of cystectomy. 14:38

329 Q. There's perhaps sometimes a misperception that city hospitals in general get to see a much greater range of complex surgeries and perhaps a greater turnover. Was that your experience, having been to two major city hospitals? 14:38

A. So, if you take yourself back to that time in surgery, there was a growing realisation that you got better outcomes for complex surgery if you concentrated it in big centres where they were doing higher volumes with a smaller number of surgeons. And the IOG guidance from 2002, which I have attached to my statement, lays that 14:38

out very clearly about how you're going to get better outcomes with less surgeons doing bigger volumes. And it also sets out the roles and responsibilities of DGHs in terms of rapid investigation and referral. So, that was a very live conversation at that time about centralisation of complex cases, because that's how you're going to get the best outcomes. And if you put patients at the centre, which we always should do, then you organise your services around how you're going to get the best outcome for patients. And it's important to put aside personal preference, shall we say. 14:39 14:39

330 Q. So at the start of your urological career and your surgical rotation, it was the time of parallel movement towards centralisation of some areas of expertise so that patients who needed particularly complex or high risk operations or treatments would be attended by people who had the most experience in those procedures? 14:40

A. That's correct. And the unit in Belfast had started to organise itself in that way as well. So you've some surgeons specialising in stones, some surgeons specialising in reconstruction, and others specialising in oncology. And that was reflected across the UK at that time of that transition. 14:40

331 Q. And when you arrived in Craigavon in February 2000, what was the flavour of the, or the profile of the urology patients at that point? What sort of stuff did you see there? 14:40

A. So it was a unit, and the majority of work would have been core DGH urology work - you know, stone -- the

commonest reason for being admitted to a urology unit acutely is urinary retention or stone disease. So that makes up predominantly what was happening. And then, you know, investigation of haematuria and UTIs and what have you. So it was busy in that respect. And then there would have been a smaller number, I suppose, of more complex procedures being done.

332 Q. And what level of autonomy did you have in the unit at that time on your surgical rotation? Were you operating again as you had been before? Were you stepping up? What was the expectation? 14:41

A. So, as a trainee, there should always be somebody available to supervise. Now, as you get more experienced that supervision becomes less hands-on. So, you know, when you're teaching somebody to operate, you will be scrubbed in with them and you will demonstrate things to them and ask them to repeat. As that person gets more competent, the consultant may not actually scrub in, they may watch in the theatre room. And as they get even better, the consultant may sit in the coffee room and then be available should there be a problem. 14:41 14:42

So, you know, I transitioned through my training in that way. I was competent, as I said, to do the endoscopic resections with a consultant in the coffee room and could be called if there was a problem. But if I was doing a major open operation, you know, then I would have wanted a consultant standing beside me, 14:42

because that is the level of training. Because I wouldn't have been able to do all of it at that point in time.

333 Q. And what was your feeling about the level of support you received and education and mentorship while you were there for the six months? What was your general view of that? 14:42

A. Well, as I've said in my statement, it was a busy unit, and I think there was opportunities to operate. My view when I had gone there would be that it was predominantly to gain more experience of core urology. So, you know, because you had to attain, as I think I said in the statement, about 100 TURPs, that was the attainment, so I was really focused on that. I hadn't really gone expecting to get a lot of experience in major complex cancer surgery, because, you know, I was very much of the view you need to work in a busy oncology unit to get that type of experience. 14:43 14:43

334 Q. Now, I'll just go to your statement at WIT-98844, paragraph 28, please. I just want to read this in. This is your section 21 response at paragraph 28 and you say: 14:43

"I have reflected over time arising from the questions posed by the USI in the section 21 notice, about the six months I spent in CAH. 14:44

As I have done so, I have recalled that there were a number of situations that arose that caused me to feel

concerned about some of the practices of Mr. O'Brien. With the passage of time it is not now possible to me to recall all the details. I did not keep a formal record at the time. I am afraid it would not have occurred to me to do so. I did raise issues that concerned me with Mr. O'Brien himself, and also with Mr. Young about Mr. O'Brien, during my six 6 months rotation. 14:44

In 2000 that would have seemed like a brave or courageous step from a higher surgical trainee. I am sure I probably saw it that way at the time. Whereas, with all the more recent and ongoing changes in medical culture (transparency, openness and the many mechanisms for raising concerns) and the development of clinical governance (introduced into health and social care around 2003), it hardly seems sufficient by today's standards when the opportunity for trainees to raise concerns are much more organised and available, and their use encouraged. Trainees are now heard and listened to in a way they would not have been in 2000." 14:44 14:45 14:45

Before we move on to this, can we just go back up to the beginning of that paragraph, please? So, you say that given the questions asked by USI, was it a case that it triggered in you recollections of events that caused you concern at the time, continued to cause you concern, or just matters that were always on your mind and this was the opportunity to put it in writing? 14:45

A. No, I think it was being asked the questions made me reflect back and think about things that had happened, and I thought that was important to share.

335 Q. You say at paragraph 29, I just want to read this line: 14:46

"I responded to all the matters that concerned me in 2000 would be different from how I would respond to them today, if I was still a trainee, including because the available mechanisms for responding are slightly different." 14:46

Now, I appreciate that we're 23 years away from 2000 and that's the context we need to try and keep in our minds when we're looking at some of these issues that you raise. If I could just ask you today, first of all 14:46 in relation to trainee surgical -- surgical trainees who may have issues, just to put it in context before we look back in time. If a surgical trainee has an issue that they wish to raise, and we'll look at some of the issues you raise so they might be in your mind 14:47 when you answer this question, what are the governance routes that they could trigger in order to have those concerns, first of all listened to and perhaps properly addressed?

A. So, all trainees now would have a clinical supervisor 14:47 and then an educational supervisor. So the Northern Ireland Medical Dental Training Association will always encourage trainees to raise concerns through their clinical supervisor or educational supervisor. They're

also given teaching and incident reporting, DATIX, raising concerns through standard governance methodology, but then also every year the GMC carry out an anonymous survey of trainees, called the National Training Survey, which also gives trainees an opportunity to reflect on the unit that they work in, if they don't feel safe, to raise those concerns to their clinical supervisor or educational supervisor. And then in Belfast we also survey the trainees ourselves on a regular basis. Because trainees are often the eyes and ears of what goes on in units and I think their voice is really important, and we need to facilitate them to be able to express any concerns they have, and feel safe to do so, and it's very much the culture of being open and a system that is open and welcome people raising concerns is a much safer system. So, openness is actually at the heart of patient safety. 14:48 14:48 14:48

336 Q. And you've mentioned the clinical and educational supervisor; what sort of timeframe were those roles introduced? Can you recall even just a ballpark? 14:48

A. I'm sorry, I can't remember.

337 Q. Now, you've mentioned also the GMC. Would they anonymously seek information from trainees in order to inform, presumably, best practice? 14:49

A. Hmm.

338 Q. How does that work in a, for example, the Trust that you're now the Executive Medical Director in, how does that operate if the trainee is anonymous and perhaps

the issue that they're complaining about is anonymous? How does that feed itself into the system?

A. So, in the first instance, the training unit gets a RAG rating, a red, amber, green rating, and if the unit gets reds or ambers, that's a sort of flag for my team to be curious about what's happening there, first of all. And then there's an opportunity for free text where trainees can raise a concern. Now, when that has happened, I would usually have a conversation with NIMTIDA (sic) and are they able to identify where the trainee works, perhaps who it is, can we support the trainee, first of all, and then also investigate the concerns. 14:49 14:50

So, I think the key, you know, the key to this is if a concern is raised that you are brave and you investigate it and find out what's actually happening, and it's acting on the concern is the important thing. 14:50

339 Q. And in your view, what is the effectiveness of, in particular, that GMC process around trainees? Do you consider that to be something that is successful for both the trainee and for the Trust? 14:50

A. Absolutely. I mean, I think I welcome things like this. I think that it can only improve our services and it can only improve the experience for trainees. They also survey trainers for their feedback. But ultimately what it does is create safer services. 14:51

340 Q. And is it used much? Is it triggered much within - I know you only can speak to your Trust - but is it

something that you say, "Well, that's working because people are actually using it"?

A. Oh, no, absolutely. Because, you know, it's an annual survey and it gives you -- and if you have areas that have been highlighted as pink or red, you work with the team and with the trainees, to identify what the issues are in order that you can then improve that. But if there aren't improvements in a training environment, the GMC can actually put trust into enhanced monitoring, because of the trainee experience, and the ultimate sanction is to remove trainees if the trainee experience is poor. 14:51 14:51

341 Q. And it's also a way in which they can identify their concerns about others, is it, this system? Some of the concerns that you raise, some of the examples we're going to come to, that's the way in which they can -- if this system existed in 2000, the system you've just described, would that be the route that you would have gone down? 14:52

A. So it's a way of -- I mean you can raise patient safety concerns through this. Now what we try and do is encourage trainees to raise patient safety concerns through incident reporting, because then it will be captured in normal Trust processes and allows you then to review and determine if it's a serious adverse incident, for instance, or there's any professional concerns in respect of what's being raised. 14:52 14:52

342 Q. So the route in which someone chooses to trigger their concern will dictate the actions after IR1 would allow

it to go into the process for the Trust and perhaps if patient safety be dealt with more effectively, the GMC way is a trainee overview almost of identifying systemic issues?

A. I think both ways are effective. I think that it's important that we use the full range of processes that are available to us. I think when trainees raise patient safety concerns this way, I worry that they maybe don't feel safe to raise it locally. And, again, that comes back to culture. 14:53

343 Q. So if the systems you describe were available in 2000, when you were having some of your concerns, what would you have done with the processes you have now before we look at what the processes were then?

A. Well, obviously you can raise the issue, as I did, with a consultant in charge, or his colleague, or you can complete a DATIX, or you can raise it through your clinical supervisor or educational supervisor, or go through the GMC NTS route. So there's lots of things that would have been open to me -- or, sorry, in the same situation if I were a trainee, would be open to me to raise those issues. 14:53 14:54

344 Q. And you've mentioned in your statement that governance has evolved over the years and become more structured and codified and perhaps of greater awareness around it from staff. But when we look back at 2000, do you recall what governance was like then? Are you able to look back and think, "Well, we didn't have DATIX, we didn't have this and that." What do you recall having 14:54

as a potential remedy for concerns?

A. It's a long time ago. I suppose the main one would have been the M&M type meeting, and I can't recall what processes there were in Craigavon at that time. I know that in Belfast we had an M&M meeting where we could review, you know, complications in respect of surgery. 14:55

345 Q. So it was still very much, sometimes it was local approach dictated what the processes were?

A. Yeah, I mean, there wasn't the structure that there is now. Absolutely not. 14:55

346 Q. There was no standardised governance structures across the Trusts at that time?

A. Not to my recollection. I mean, I think you have to remember that I was a trainee then. I think also trainees may not have been as aware of those systems as well. Because part of the thing about training is learning about those types of things. I think you spend a lot of time training trainees about how to raise concerns. Now, probably -- well, I know that we didn't do 23 years ago. 14:55 14:55

347 Q. I suppose the background to the questions is establishing a baseline then, if at all possible from this remove, so that the panel can look at what might have been done, what could have been done, what should have been done, and not unfairly assess that against systems that simply weren't in place. So, it's more trying to explore what was open to you. 14:56

A. Well, I mean clinical governance wasn't adopted in Northern Ireland until 2003/2004, and it has massively

evolved over the past 20 years. And I think for me, the main things have been around how we triangulate information. So, you know, bringing in information from complaints, incidents, SAIs, coroners, NIPSO, clinical negligence, and how we pool that together into a system that makes sense and is focused on patient safety, and I think pulling all those strands together is how you make clinical governance work really effectively. 14:56

348 Q. And a lot of the things you mention are the outworking of clinical governance, the end product, coroners and medical negligence, civil claims, learning from perhaps the wrong end of the telescope. Do you consider that there is -- well, what part do you think that culture in a place has to play in both the triggering of governance and the effectiveness of any action taken? 14:57

A. I'm going to answer the -- in answering the question it's quite complicated, but in 2018/19 in Belfast, I brought in a system based around the measurement and monitoring of safety, and it was based on a document written by the Health Foundation in 2013 by Charles Vincent. And basically, it turns your organisation into a problem sensing organisation, where you ask really profound questions, like: Are you safe today? Are your systems reliable? Are you learning from past harm? Are you looking forward to see where there's going to be issues? And we've adopted that in Belfast as a way of thinking and about how we problem sense, and I think that you're right, you have to learn it 14:57 14:58

from harm, but it is - it tends to be reactive. What we try to do is shift that thinking into how can we make sure we're safe today?

So the out-workings of that are daily safety huddles, right the way up to executive team, ehm, weekly huddles where divisional teams come together and they review all their safety data from the previous week and look to, you know, is there any immediate learning? Is there anything that needs to be raised as a concern? 14:58

We also created a system in Belfast called the Professional Governance Information System which, you'll see is a recommendation of the Independent Urology Inquiry, about how we collate information in respect of doctors, so that if a concern is raised about a doctor, I will have information in relation to incidents, complaints, SAIs, coroner's cases, clinical negligence, that let's me build a picture. So it's building a safer system. 14:59

So, I think that answers what you were...

349 Q. I think it partly did --

A. But then the cultural bit was then about being open. So, we've done a lot of work around being open and encouraging staff to come forward, to feel safe to do so. Because I think I said earlier on, at the heart of any safe system is staff feeling safe to raise concerns and be open, and be open when things go wrong, and when

things do go wrong, that they will feel safe and that they won't feel that they're going to be blamed. Because we're all human, we all make mistakes, and it's important that we accept and acknowledge that we will make mistakes. But it's how we learn from it. And I think how we make our clinical governance even better is how we focus on how we learn, because that can be difficult sometimes to make sure that you put systems in place that engineer a change.

350 Q. Well, we'll look now at the areas of concern that you experienced in Craigavon in 2000. And for the panel's note they will be at - we can bring it up, but I'll be summarising the issues. WIT-98845 will be the start of them. And you'll see at paragraph 31 you're working your way through... I'm going to read from the statement and then I'll ask you some questions about each of these individually from a governance perspective. So you say: 15:00 15:00

"The concerns were as follows:
1. Patients being admitted to the ward for prolonged intravenous fluids and antibiotic therapy.
There was a group of patients that seemed to me to be being regularly admitted to the ward for antibiotics and IV fluids by Mr. O'Brien. My recollection is that these patients would make contact with Mr. O'Brien in some way and be admitted directly to the ward as an in-patient for treatment. When I asked about this practice the ward nurses referred to this treatment as 15:01 15:01

"Mr. O'Brien's regime".

I would do an unaccompanied ward round every morning during my 6 months rotation when I would come across these patients. It was often not clear to me the reason for this approach or the evidence base for the treatment. I considered patients who fell into this category could have been managed as outpatients, as they could eat and drink. I did not encounter this approach in any other urological unit I worked in before or since." 15:01 15:02

Just in relation to that particular issue of the patients admitted for the purpose of IV fluids and antibiotic therapy, just set out why that caused you, as a clinician, concern at that time. 15:02

A. Well, there was no clear rationale for the treatment. The reason for bringing somebody in for IV fluids and antibiotics is usually for sepsis, and my recollection is that these patients often weren't septic and could easily have managed oral fluids and oral antibiotics and could have been managed at home, if at all they needed antibiotics, and you will note in WIT-99131, Gillian Rankin, in a letter that she wrote, raised the issue of that ten years later around IV fluids and antibiotics. So, I wasn't alone in thinking that this was an unusual practice. 15:02 15:03

351 Q. And did you speak to Mr. O'Brien about that?

A. So, I will have asked him to understand, you know, "Why

is this patient having this?", but it was very clear to me that this was - that there was a group of patients that he was in -- I don't know how they -- I mean, I have said in my statement, it was never clear how they got admitted. They didn't come through the emergency department, they were direct admissions, and I don't know who they contacted or who they spoke to, but they came in and there was a set regime that the nursing staff adhered to. 15:03

352 Q. Did you know if they were private patients? 15:03

A. I honestly don't know.

353 Q. When they were brought into the ward, were they brought in on certain days, or certain times, or to stay overnight? What was the regime that's described?

A. So, my recollection is that they would have been in for several days. I don't recall if they came in on set days, but they would have been in for several days on this regime of IV fluids and antibiotics. And it wasn't quite clear to me, I suppose, what the goals or treatment were, and it was something I'd not - I had never encountered it before or since. 15:04

354 Q. Did they present as being clinically unwell?

A. Not in my experience. Because I think if they had been unwell then there may well have been justification for the treatment. 15:04

355 Q. I'm not sure in 2000 if they still had notes at the end of beds, but did you have access to notes to have a look and see, 'I wonder what these patients are in for, I'll have a look'?

A. So, on the ward round you would - if I was leading the ward round, would have written in the notes every morning. So I would have had access to notes. But often the patient was, as I have said, was admitted, it wasn't clear why they were admitted, but they were to have this regime.

356 Q. And you've said they stay in over a couple of days. You've mentioned Mr. O'Brien. Had you any awareness of Michael Young also bringing patients in or being part of IV fluid or IV antibiotic therapy? Was he part of this regime? 15:05

A. Not to my recollection. But I mean he would have been aware of these patients from the Thursday grand round.

357 Q. And did you discuss it with him and say "I'm not sure what's happening here? Do you know why these people are in hospital?" 15:05

A. So, as I've said in my statement, I know that I raised concerns both with Mr. O'Brien and Mr. Young. I can't recall about which specific patients, but I know that I spoke to them about what I thought was some unusual practice. 15:06

358 Q. Do you recall what sort of numbers of people were brought in? Were there cohorts of several patients? Was it individuals?

A. I can't remember, to be honest with you. I just remember it was a relatively frequent occurrence. 15:06

359 Q. Given that you can't recall and you weren't able to get to the bottom of what might have been clinically wrong with these individuals, do you think now that it's

something that you might report - I use "report" in an informal way; maybe draw to the attention of someone? Would that be something you would expect a trainee to say "I see people coming in, I'm not getting any rationale why. I need to speak to someone clinically senior."

A. I think you need to take this back to the context of you're a trainee and you're working in a unit where there's established consultants and there's a practice going on that you don't quite understand, but you're still a junior trainee, and the consultants who are managing the ward and the nurses who are managing the ward seem to think this is okay, and you've spoken to the consultants and said "I don't quite understand this", and they have given some form of explanation or shrugged their shoulders. I think at that point in time as a trainee, raising a concern directly with a consultant and his colleague was actually, as I've said, a brave thing to do. Northern Ireland's a small place and I think you -- I think it takes bravery -- given the context of what surgical training would have been like then, it takes bravery to actually raise a concern. So, I think I had done that. I don't know what action they took after I had raised it, you would need to talk to them, I suppose, in that respect. But I know I'd raised it. 15:07 15:07 15:07 15:07 15:08

360 Q. Yes, and they will be coming to give evidence.

A. Yeah.

361 Q. I suppose what my questions are aimed at is

establishing your sense of when you pull the trigger for a governance concern. Ostensibly these people are getting IV fluids - I'm just trying to get a sense of it, because we're going to obviously move on to other issues - did you think that they were coming to harm at that point? 15:08

A. I suppose you're asking me to look back through a lens of me as a medical director now and what I would expect to happen. But I have to put myself in the shoes of a youngish man in his 30s, and as a trainee I felt that I had done what I should have done, I raised it with the consultants, and it was up to them as consultants, because they were in charge of the ward. It wouldn't have occurred to me to go beyond them, because I had raised it with them. 15:09

Now, I've described to you earlier all the mechanisms available for trainees to raise concerns, but they didn't exist then.

362 Q. Yes, and we appreciate that. And that's why I started your evidence as an Executive Medical Director and allowing you to set the landscape as it is - no expectation from the Inquiry that you would be judging yourself from this remove. But there is an expectation that when you were in this scenario, was this sufficiently concerning that something else might have been done? 15:09 15:10

Now, I phrase that in the sense that this is the first

example we've come to - we will come to other examples - and it was really just to elicit from you: Did you consider that the patient safety issue or risk of harm was such that you felt that you might have brought it to someone else's attention when you didn't get any response or any, perhaps, credence from Mr. O'Brien or Mr. Young, if indeed it was raised with them, because you're unable to remember? 15:10

A. Look, we're looking back 23 years, but I don't think I would have known who to go to beyond the two consultants directly running that ward. 15:10

363 Q. If we look at the next example, cystectomy and orthotopic, is that correct?

A. That's correct.

364 Q. Orthotopic neobladder formation: 15:11

"Amongst the patients coming in for antibiotic therapy and IV fluids was a patient who had had a cystectomy (a major operation to remove the bladder that would generally take between 4 and 5 hours) and neobladder (creation of a new bladder) to treat recurrent urinary tract infections (UTIs). 15:11

There was a young woman in her early 20s who had this procedure before I arrived to do my rotation at CAH, but who then had subsequent admissions for fluids and antibiotics during the time I was in CAH." 15:11

Just stopping there. Is she a patient then that falls

within the previous cohort of patients?

A. That's how I came across her, yes.

365 Q. "I am not absolutely certain of the correct name of the patient at this remove, but my legal representative will provide the USI with the name that is in my memory." 15:11

And you have done so.

"The USI may wish to look at the particular case. 15:12

The young woman made a lasting impression on me as she was really miserable, especially as she was continuing to have UTIs notwithstanding the major operation she had been put through. 15:12

The predominant indication for cystectomy and neobladder is for treatment of bladder cancer and I was disturbed that this major procedure had been undertaken for recurrent UTIs in a young woman. I could find no evidence base in the literature for this. 15:12

At the end of a ward round where I accompanied Mr. O'Brien, I challenged him as to why he had carried out such a radical and life changing operation on this young woman in the context of recurrent UTIs. He remarked that someone else had said that to him and he justified it to me by telling me he had specifically 15:12

discussed this case with a urologist in the United States of America who agreed it had been a reasonable course of action. I felt, as a second year surgical trainee, inevitably anxious about challenging an experienced consultant, that I had expressed my view and Mr. O'Brien had provided an explanation that was hard to dispute at the time. 15:13

I think this was the only case of this type that I myself saw during my rotation, but I cannot say if there were others with whom this approach was taken. 15:13

I did speak to Mr. Young during my rotation about various concerns I had about Mr. O'Brien, but I cannot now say whether this was one of the matters that I spoke to Mr. Young about. I may have, but I cannot say that I did. 15:13

Looking back on this now with 17 years experience as a consultant urological cancer surgeon, I can see no justification for the operation." 15:13

Just your last sentence indicates where we have to straddle two worlds in many ways in trying to look at some of your concerns through the lens of a second year trainee, but also in hindsight you're still able to provide some opinion on the appropriateness of what you saw, perhaps more so now given the breadth of evidence that you have had since your time in Craigavon. 15:14

So, in relation to this, in summary form, I think the key points is this was a cystectomy and neobladder carried out for benign disease, presumably?

A. (Witness Nods).

366 Q. No suggestion of cancer that might have necessitated the operation. You don't seem to have, and we don't have details of the underlying clinical presentation that might have suggested that it was the right decision and it was the right thing to do. And just given that context, what was it about this lady, I think it mentioned that it stayed with you, I can't remember the sentence, but you recall it quite clearly, it seems?

A. Mm-hmm.

367 Q. What was it about this that raised concerns with you?

A. So, it's highly unusual to remove the bladder in young people unless there's some very unusual congenital abnormality. The main indication for bladder removal is bladder cancer, and my understanding at the time was that she'd had this performed for recurrent urinary tract infections, and I couldn't -- I remember searching the literature at the time and when I prepared the statement looked at the literature and couldn't find any series of patients who had had cystectomy, neobladder formation for a recurrent urinary tract infection.

So I felt, and I still feel, that to put somebody

through a major operation for what's a common condition in young women, was very unusual.

368 Q. So, what you did know about this lady at the time was that it was a benign presentation?

A. Correct. 15:16

369 Q. Whatever the underlying clinical condition was, which I think was recurrent - was it recurrent UTIs was the fundamental dominant presentation?

A. Yes. Yes.

370 Q. And what you're saying is that even since then, there's nothing you've seen or learned in your career that makes you look back on that set of circumstances that would make you think that a cystectomy and neobladder was an appropriate clinical response? 15:16

A. I don't think so. I mean, I've spent 17 years doing cystectomy for patients with bladder cancer and that's the main indication for doing that operation. 15:16

371 Q. Have you ever performed a cystectomy/neobladder on someone who is presenting with benign symptoms?

A. I haven't, no. 15:17

372 Q. Would it be something that you would be familiar with others doing in your field?

A. There's a small proportion of patients who maybe had a neurological disorder who may benefit from cystectomy if they have small contracted bladders. And, again, the numbers of patients having that are extremely small, and they predominantly would have been done in Belfast with the reconstruction team and we might have helped them as the bladder cancer team, but the 15:17

indications are it's very rare, to be honest with you. And cystectomy and orthotopic neobladder is primarily an operation for people with bladder cancer.

373 Q. And is it ever indicated for people with recurrent UTIs? 15:18

A. Not in my experience, no.

374 Q. As you've said, it's a major operation. Does it have any other potential fallout for young women? You say this lady was in her early 20s - is there any other potential impact or complication that you would expect 15:18 or see?

A. I'm not sure how technically it was carried out - I mean there's a lot of different types of orthotopic neobladder that you can perform, but I suppose the risk is to fertility, in terms of adhesions affecting the 15:18 fallopian tubes and what have you. So there is a risk in that.

375 Q. You don't know if any of that applies in this case?

A. I don't know that. I mean, you're just asking me the potential risks, and that would be one of them. 15:19

376 Q. Do you recall how long this, after a major operation like that, was she in the hospital for a while, do you remember that?

A. So I wasn't there when she had the surgery, but she --

377 Q. She came back in? 15:19

A. She kept - she was in fairly -- on several occasions she was admitted with recurrent infections and pelvic pain.

378 Q. Would that of itself be an indication that the reason

for doing the operation hadn't actually eradicated the problem?

A. I suppose my reflection and why it stuck in my mind was that she was very unhappy, and I used the word "miserable". 15:19

379 Q. And still having recurrent UTIs?

A. Yeah.

380 Q. We can't be sure, but you think the possibility was that that was the reason for why she was operated on in the first place? 15:20

A. That would be my recollection. I think it would be important if you want, you know, to look more closely at that case.

381 Q. Now, you spoke to Mr. O'Brien and he mentioned that he had discussed this case with a urologist in the United States of America. I don't suppose you remember the name of the urologist? 15:20

A. No, but his response stuck in my mind. Because, you know, I remember asking him and I remember him saying somebody else had raised this as an issue and he had spoken to somebody in the United States of America who said in the circumstances it was a reasonable course of action. 15:20

382 Q. And he didn't say who the other person was who had also perhaps shared your views, who had expressed the same view? 15:20

A. No. I mean, I think that, I suppose I felt brave challenging him and I got an explanation back which was, it was difficult to argue with.

383 Q. And you don't recall - you can't say whether you spoke to Mr. Young about this issue or not? You just don't recall?

A. So, undoubtedly, you know, because of the joint ward rounds, I would have expected that Mr. Young would have been aware of some of these patients. And when I did raise concerns with Mr. Young, as I've said in my statement, his response was "That's just Aidan". 15:21

384 Q. And what did you take that to mean when he said that?

A. It's hard to know how to interpret it. But I felt I was speaking to another consultant and raising an issue and that was the response. And, again, you look back and you think 'I'm a second year trainee, I don't know everything about urology, I'm working with senior consultants, maybe they think this is acceptable'. 15:21 15:22

385 Q. Is cystectomy and neobladder, are those procedures that are fairly unusual today or are they routinely done for bladder cancer?

A. So, I was appointed in 2003 and I had got training in neobladder. So I started a cystectomy and neobladder service in Belfast and working with another colleague. It's a really good operation for the right person, particularly young people with bladder cancer who are highly motivated to manage the neobladder and you get really good outcomes. It's less good an operation in older, less fit people, because they have to learn how to use their new bladder. And traditionally the standard in Northern Ireland had been to create a bag, so this was a new type of procedure being offered for 15:22 15:22

people with bladder cancer.

My experience of it was really good, but it was really important to select patients carefully and appropriately. And, as I say, I had good outcomes with that operation. But predominantly in Northern Ireland people would still tend to get a bag as a way of diverting the urine after cystectomy.

386 Q. So in 2000, when you were in Craigavon, on one view you could read that and see that as a potentially good learning experience for somebody who's on a surgical rotation for someone to say "Let me talk you through this, why we ended up making the decision to do this." Do you think that that was an opportunity that could have been used to explain to you exactly what was going on? 15:23 15:23 15:24

A. So that's sort of an interesting slant on something. Surgery is a craft specialty, but the actual thing that makes you a good surgeon is not whether you're good in theatre, it's your decision-making before and afterwards, in terms of operating on the right people and making sure you look after them if there's a complication. Most people going through a surgical training scheme can be got to a level where they're safe in theatre. What differentiates good from really good surgeons is their decision-making about when they take people to theatre and, as I say, how they look after them when they've got complications. And that's what tests surgeons, is complications. 15:24 15:24

387 Q. Well, if I ever end up in the Belfast Trust I'd like someone who's good in theatre as well, so if you could arrange all of that!

A. I don't want to minimise it, but you can train people to be safe in theatre, okay, and they have competencies to attain, but the really hard bit about surgery is actually deciding who to operate on. 15:25

388 Q. So the whole journey is learning and the --

A. It is.

389 Q. And the decision-making is key? 15:25

A. So to come back to your point, I think that it's a really bad of example of when to do cystectomy and neobladder, so I didn't think it was a good learning experience, other than to say I can't understand why you would do that operation. 15:25

390 Q. Thank you. I'd just like to move on to the next example, which is the transurethral resection as a prostate procedure.

"TURP is a core urological procedure for the treatment of benign prosthetic hypertrophy to remove symptoms of bladder outlet obstruction. 15:25

In 2000 it was performed using monopolar diathermy, a form of electric current, to re-set, cut and remove tissue from the prostate via an endoscopic sheath. Glycine (a potent neurotoxin), 1.5% fluid was used as a non-ionic irrigation fluid in order to maintain vision during the procedure. 15:25

TURP is generally a safe procedure but carries risks including bleeding (requiring transfusion), incontinence, impotence, sepsis, and a rare but life-threatening condition called TUR syndrome. 15:26

TUR syndrome is caused by absorption of Glycine fluid leading to Glycine related side effects in the central nervous system, increased plasma and ammonia levels and dilatational hyponatraemia. This can lead to serious 15:26 cardiac neurological and respiratory side effects and even occasionally death.

The key risk factors for TUR syndrome include resection time (greater than one hour), height of the fluid bag, 15:26 (greater than 70cm) and large blood loss.

TURP is a key surgical procedure for trainees to gain competency. At the time of completing my training in urology trainees were expected to have completed at 15:27 least 100 TURPs. Consequently, I would have undertaken most of the TURPs at CAH during my six month rotation, which is generally one or two a week.

One of the key mantras of the training which I 15:27 experienced in Glasgow, Belfast, and later Dublin, where I also worked during my five years as a surgical trainee, was that resection must stop no later than an hour and ideally cease by around 50 minutes to allow

for another 10 minutes to control any bleeding. I was therefore disturbed as a trainee in CAH when a TURP that Mr. O'Brien was carrying out involved a resection that lasted significantly greater than 1 hour.

15:27

The case I recall involved resection time approaching 2 hours, and the anaesthetist and nursing staff expressing concerns to Mr. O'Brien about the length of operating time, but Mr. O'Brien continued. I thought this was a patient safety issue because it was putting 15:28
the patient at what I considered to be unnecessary risk. I expressed that view to Mr. O'Brien. Mr. O'Brien's view, as far as I recall it, was that resection time was not the significant issue I considered it to be. I believe I did speak to 15:28
Mr. Young about this issue (I did speak to him a number of times during my rotation about different issues) and my recollection is of him saying "That's just Aidan".

I cannot say for certain that the remark from Mr. Young 15:28
that I recall was definitely in connection with this issue, but it is definitely a phrase that Mr. Young used to me when I raised an issue about Mr. O'Brien during my time in CAH."

15:28

So this is -- a couple of issues in this particular; it's the length of time taken. There seems to be a professionally accepted cutoff point of no more than an hour, and we established at the outset of your evidence

that you had been involved in these operations prior to coming to Craigavon, so you knew what to expect. This wasn't a new procedure for you to observe and form a view that might be misinformed, you were familiar with this? 15:29

A. Oh, yeah, I mean I'd had a lot of exposure and experience of TURP in Glasgow and Belfast before going to Craigavon, and I've trained lots of urologists as well about safe TURP, and a core part of that is that you should cease within an hour to reduce the risks. 15:29

391 Q. And the risks, as you have set out, are quite clinically significant, including possible death?

A. Well, TUR syndrome is something you wanted to avoid, and I mean as you know later in my evidence I talk about how we moved away from Glycine in 2013, because 15:30 Glycine is actually a relatively dangerous fluid, particularly if it's absorbed into the circulation.

392 Q. And was it not until 2013 that they found a safe alternative that was able to be rolled out for Glycine? Is that why there was a change in practice, or what was 15:30 it?

A. So, there had been earlier equipment using bipolar, which was not as good, and a company brought out a really good set of resection equipment that used bipolar, and it became very clear that that was at 15:30 least as good as the standard monopolar, but much safer.

393 Q. And did that involve people learning to do this procedure in a different way?

A. Do you know, if you're experienced at TURP, it would be really straightforward to slightly -- you just had to slightly adapt your technique in terms of controlling bleeding. It's not difficult.

394 Q. Did it affect your ability to see what you were doing, to have a good clear vision? Was there any argument around that? 15:31

A. I think that's spurious.

395 Q. Spurious because you didn't experience it or because it doesn't actually happen in reality? 15:31

A. I don't think it happens. I mean we introduced bipolar in Belfast in 2013, we took all the monopolar sets out and the whole team moved over to bipolar without any real issue.

396 Q. So you were the Clinical Director then, were you? 15:31

A. That's right.

397 Q. So you identified a better way and a safer way of doing something, and presumably your colleagues were on board and you just said "This is what we're doing from now on"? 15:31

A. Well, it was the tragic death of a woman having a gynae, gynaecological procedure. But it's very similar in terms of the fluid used. And there was a clear patient safety issue to me, and if we have good technology that makes surgery safer then we should 15:32 adopt it. And the other thing that was coming down was obviously laser prostatectomy, but we don't need to get into that here, because this is --

398 Q. Just in relation to, that's one of the examples we

referred to earlier where an inquest or something tragically happens and the learning comes backwards in the hope that --

A. Yeah.

399 Q. And it wasn't your field, it was gynae, the death of that lady. But it was something obviously that informed your view on what good practice would be, so it was the next logical step for you to get rid of the Glycine? 15:32

A. I felt very strongly about it. I felt, you know, we want to make surgery as -- I mean you talked, we talked about good surgery, and this is about good surgery, it's making it as safe as possible and reducing risks for patients. 15:32

400 Q. I'm just interested in the procedure from a governance perspective of how you go about buying-in everyone's -- maybe it's just a matter of "This is the equipment that's available, so this is what you have to use", or did people still try to hold on to previous ways of doing things because that's what they were comfortable with? 15:32 15:33

A. So, I didn't find it difficult introducing it in Belfast, because all the team that I work with focus on patient safety and they put patient safety before their own personal preferences. And the data was compelling on this. And I think it's really important to use data to inform your decisions. And if you have a technique that's demonstrably safer, I don't understand why you wouldn't adopt it. 15:33

401 Q. Within your role you might have a little bit more insight into the answer to this, but if there is a technique that's safer and it's demonstrably so, is there a Trust appetite for spending money on equipment that's needed? You're in the Belfast Trust; is there generally -- the mindset is to make the best equipment available or you still face problems with budgetary constraints? 15:34

A. I mean, do you have a specific example?

402 Q. Well, I'm thinking if this was to be the case now and Glycine was an alternative that was safer, had been established and was available - I know it came as a result of tragic circumstances and that might have focused minds a bit more - but just on a day-to-day decision-making from a cost benefit analysis, is there a good appetite in the Trust for advancing equipment so that patient safety is still at the fore? 15:34

A. So, patient safety has to be at the heart of everything we do. And there was clear data to support this was a much safer way to do the operation. And, you know, good care costs, but poor care costs even more, either in terms of complications or negligence. So I think it's really important that you do invest in equipment, if you can do the operation more safely. 15:34

403 Q. In relation to the TURP issue that you've identified, you've mentioned that the resection time approached two hours, and it appears at this remove to be quite significantly past one hour, it doesn't seem to be just over, there does seem to be moving into twice what the 15:35

operation would be clinically expected to be. Was there something in particular about that operation that you remember, "Well, I can see why it lasted more than an hour, but two hours really was a bit much." Was there something happened, do you recall? 15:36

A. No. I mean, I think it's exceptional to go to that. I mean, my approach for doing TURP surgery is that if it's a big prostate, you still stop at 50 minutes to an hour and you can always come back another day, you don't keep going. And that's - I've witnessed that 15:36 with other consultants and it's how I train trainees, because it's all about being safe. Once you go beyond an hour, the risks of a complication increase significantly.

404 Q. Do they increase exponentially? 15:36

A. I don't think anybody has ever measured it in term -- but there is that -- I mean it is a mantra in terms of any experience I've had, anywhere I've worked, where people stop within 50 minutes to an hour. And generally speaking the reason you run into problems 15:36 with TURP is bleeding, and that becomes manifest quite quickly. So if you do run into problems with bleeding, it happens early and you try and get on top of that and then stop.

405 Q. So there wasn't anything that you recall that justified 15:37 this being a longer operation, irrespective of it being two hours?

A. Not that I can recall, no.

406 Q. And you mention that the anaesthetist and the nursing

staff expressed concerns to Mr. O'Brien. Do you recall his reply in that context?

A. I can't remember specifically, but he obviously was dismissive. Because the nursing staff and anaesthetists are very clued in to the section time lasting more than an hour and they will, you know, they will tell surgeons "You've been resecting for 30 minutes, 45 minutes", do you know? So they keep on top of the clock. Because you can sometimes lose sense of time. So the theatre staff will be very aware of that. 15:37

407 Q. And did you get the sense from either the anaesthetists or the nursing staff, as far as you can remember, that this was an unusual event?

A. I don't know.

408 Q. You don't remember. Even with the knowledge now, the knowledge that you've gained all of these years later, do you look back on that and still have the same view about the appropriateness of what happened? 15:38

A. Well, I think it's not appropriate, you know? And I think working in a team in Belfast where patient safety was paramount, this is something that, you know, we wouldn't have thought was acceptable within our team. 15:38

409 Q. We took the opportunity to feed back some of your statement to Mr. Young, as relevant in relation to what he recalls. I just want to deal with the -- sorry, I should have dealt with this at the time, the benign cystectomy: 15:38

"Mr. Young has confirmed that he does not recall this

being raised as a concern with him by Mr. Hagan."

The TURP issue with the risk of tear that we're just discussing:

15:39

"Mr. Young does not recall this concern being raised with him. He has also provided instructions more broadly on this issue."

And I'm just going to summarise them. This is just feedback for the purposes of you coming to give evidence. It has to be formalised in a reply, but just so that you can have an opportunity to reply rather than come back. His instructions are: 15:39

15:39

"It is the aim to finish a TURP within an hour. Sometimes it may be necessary to go beyond this point, for instance if there is bleeding that requires addressing.

15:39

Urologists have for a long time been very aware of TUR syndrome (hyponatraemia) and monitoring of the fluid balance arising during surgery is critical. An imbalance in fluids after only a short operative time is an indication to stop the procedure. 15:39

Mr. Young has no recollection of this operation being discussed with him by Mr. Hagan. However, if it was discussed, he believes he would have asked if

hyponatraemia had occurred."

Do you recall if hyponatraemia had occurred in this particular example?

A. I can't recall. 15:40

410 Q. So it's a possibility?

A. It is possible. I mean, TUR syndrome will cause a low sodium.

411 Q. And did you stay for the duration of the procedure?

A. No. 15:40

412 Q. And if hyponatraemia had occurred it would require medical intervention at some point, in theatre presumably?

A. Or in intensive care.

413 Q. In intensive care. And you don't know whether that happened? 15:40

A. No.

414 Q. I'll just move on to the next issue, which is ureteric stone treatment. This is your fourth concern.

Ureteric stone treatment: 15:40

"There are two different issues in this area.

First, emergency admission to urology units for stones in the ureter (the tube connecting the kidney to the bladder) is common. Most stones are less than 1cm in 15:41 size and around 90% should pass spontaneously without surgical intervention.

There was emerging evidence in and around 2000 that

prescribing alpha blocking medication, such as..."

A. Tamsulosin.

415 Q. Thank you:

15:41

"...could assist stone passage. This conservative management of stones was my experience from working in Glasgow and Belfast. Mr. O'Brien's approach to ureteric stone management was very different and his preference was to intervene surgically at a very early stage. 15:41

When discussing patient management with Mr. O'Brien, I challenged him in relation to this approach, as I felt that suitable stones should be allowed to pass naturally. This is because intervention carries risks, including sepsis and ureteric perforation. 15:41
Mr. O'Brien, however, referred to his training in Tallaght Hospital in Dublin and that this was how he managed stones. 15:42

Generally, I found Mr. O'Brien to be dismissive of me when I raised concerns. He was clear that it was an appropriate course of treatment."

15:42

The second aspect of this concern is:

"The second issue related to the energy source used in the destruction of stones.

Destruction of ureteric stones requires an energy source. In 2000 there were a number of sources commonly used when operating on the ureter, such as laser and pneumatic devices, such as the Swiss lithoclast. Both these types of energy sources had good safety profiles. Mr. O'Brien's preference, however, was to use an electrohydraulic EHL energy source. It was powerful and unpredictable. EHL has uses for large bladder stones and kidney stones where its use is safe, but in the ureter it carries a very high risk of ureteric perforation. 15:42 15:43

I discussed this risk with Mr. O'Brien as I felt this was a high risk energy source to use in the ureter with real safety risks. I described my experience with the lithoclast (which has a zero risk of ureteric perforation) and questioned why he would not use it as it was very cheap technology. Again, I found Mr. O'Brien to be dismissive of my concerns. Mr. O'Brien did not accept my view. 15:43 15:43

Unfortunately, when carrying out a left ureteric stone case with Mr. O'Brien directly supervising me, he told me to use the EHL probe to break up the stone. As instructed, I did this, and the discharge of the energy source caused a very large perforation in the upper third of the ureter. Mr. O'Brien took over the case and was unable to negotiate a ureteric stent into the kidney due to the size of the defect. This then 15:43

required the patient to have an open surgical repair of his ureter. I was very distressed by this complication, as I felt very much to blame for it, even though I had carried out the instructions of the supervising consultant.

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

So, the first, there are two different issues. The first one was the issue around the stones. Now, you have had experience of this particular -- I presume that is quite a common issue in urology, stones?

A. So, it's one of the commonest reasons for admission to a urological unit is with a ureteric stone due to pain, and a substantial portion of ureteric stones will pass themselves, with appropriate pain relief and use of alpha blockers. So, my experience, as I say, in Belfast and Glasgow was generally conservative treatment and only intervening in situations where patients were septic or there was a very large stone that wasn't going to pass.

416 Q. And what was it about this particular issue? You were discussing the patient management with Mr. O'Brien and

you challenged him in relation to this approach. Was it because your experience to date was different or did you think his approach just, you couldn't understand it? What was it?

A. So, it's in respect of intervening in stones that I thought would be able to pass themselves and you would avoid the risk of surgery. The instrument you use to get into the ureter is a rigid steel rod and it can cause damage to the tube coming from the kidney, called the ureter. And it's also about avoiding unnecessary surgery. 15:45 15:46

417 Q. So it's wait and see if the stone passes and, if necessary, intervene?

A. Yes.

418 Q. So, Mr. O'Brien took a view that he was going to intervene, and your view was that it was inappropriate because you needed to give the non-intervention time? 15:46

A. So, again, you know, I am coming as a second year trainee and this has not been my experience elsewhere. I'm trying to understand why we would intervene in stones that should pass themselves. But he was very clear this was his approach to managing ureteric stones and justified it with this is how he had been trained. And, you know, he's a senior consultant and this is what he felt was the appropriate course of treatment. 15:46 15:47

419 Q. Was it your experience at the time, or has it been your experience since, that perhaps consultants who are more senior, who are more used to their own way of doing things, find it difficult either to be challenged or to

adjust their practice to reflect advances?

A. So, I think that at the heart of safe consultant practice is good team working, and that working in a functioning team where there's a built-in peer review, essentially. I think when you work in isolation, there's a risk that you develop practice that maybe doesn't follow best practice or best guidance or, you know, keep up to date with current best thinking. 15:47

420 Q. And is it still your view at this remove that your view would be the same in relation to hands off and see if the stone passes, or would you say now, "Well, I can see maybe where he was coming from, because that patient presented in a certain way"? 15:48

A. No.

421 Q. I know you don't remember -- 15:48

A. I think for small ureteric stones the appropriate course of treatment is to see if they'll pass themselves. I think if the patient is septic or it's a very large stone, then you obviously need to intervene.

422 Q. Now the second issue where you were being supervised in your -- in the use of EHL. Had you been using EHL in your previous posts? 15:48

A. So, in Belfast there's a procedure called a percutaneous nephrolithotomy. So it's basically where you put a tube into the kidney to remove stones and you can use EHL there or you can use EHL to break up big bladder stones, because it's safe, there's a much bigger space, you're less likely to cause damage to surrounding structures. EHL's quite an unpredictable 15:49

energy source and there was -- there's fairly good evidence that it's use in the ureter carries a much higher risk of ureteric perforation by a factor of up maybe up to a couple of hundred potentially risk of ureteric perforation. 15:49

So, it wasn't something I had ever encountered. And there was reasonably good literature about its risk, about its safety profile.

423 Q. And that was in advance, you knew that information in advance of this procedure, or was that something... 15:49

A. So, I was surprised, I think, that the EHL was being used to treat ureteric stones, when there's other safer technology; laser, if used correctly, is extremely safe, and the lithoclast carries a zero risk of ureteric perforation. 15:50

424 Q. And you've mentioned that you discussed the risk with Mr. O'Brien. This was in advance of you carrying out the procedure, I take it?

A. So, I recall having a conversation about the use of EHL and its safety profile, and he was dismissive of it being an issue. 15:50

425 Q. And when you say "dismissive", did you get to explain your concerns before they weren't listened to, or were you not listened to? 15:50

A. I wasn't listed to.

426 Q. And you say he did not accept your view?

A. Well, no. Because I think that if you had kept up to date with the literature, you would have known that it

was a high risk energy source to use in the ureter.

427 Q. Was it with a degree of reluctance then that you used this equipment on this occasion?

A. So I was doing the case on the left ureter and was -- he said "No, use the EHL for that", and I was concerned, but he said "No, it'll be fine", type, you know, that type of conversation. But I -- there's a trigger to activate it, and with one activation it caused a huge perforation of the ureter. And something like that, you don't forget, because I'd never seen it before and felt directly responsible for a complication which, when you know that something's avoidable, you don't forget. 15:51 15:51

428 Q. On your evidence, it was a bit more than avoidable, because you'd actually spoken about it just prior to the event? 15:52

A. Yeah. Absolutely.

429 Q. So you had expressed the risk and then the risk manifested?

A. Yes. 15:52

430 Q. And do you recall what Mr. O'Brien might have said or if he said anything? Your recollection of his reaction to this?

A. From what I can recall, he took over the case and tried to get a stent into the ureter, and he wasn't able to. And then there was a decision to perform an open repair of the ureter. 15:52

431 Q. And were you involved with the patient afterwards? I know you said Mr. O'Brien spoke to the patient, but

were you involved in their care?

A. Well, he was on the ward. I don't know what he said to the patient in respect of the complication.

432 Q. And what are outcomes from that ureteric rupture?

A. Well, the risk is that the repair narrows and then obstructs the kidney and the kidney doesn't drain properly and then will stop working. I don't know what the long-term outcome was of this patient. 15:52

433 Q. When you talk about there being other opportunities to use equipment that was more clinically appropriate, was that equipment available in Craigavon at that time? 15:53

A. I don't know if they had a laser. They didn't have a lithoclast. But I talked about how we had got -- I'd used a lithoclast in Glasgow and they bought one in Belfast, because I described my experience and I said, you know, that this is cheap, safe technology that anybody can use safely to try and break up stones with much less risk. Now, I think laser's better, but there is a cost with laser and the laser technology wasn't as good then as it is now. 15:53 15:53

434 Q. This example, I suppose, is slightly different than the previous examples with the TUR; you weren't there for the whole of the operation, you don't know if there were complications, you aren't able to say -- you weren't there for the cystectomy in the old bladder operation, you saw the admission of the lady in the hospital after. In this example you identified a risk, the risk materialised, and I think from what you've described it would be fair to say there was patient 15:54

harm?

A. Yes.

435 Q. And perhaps significant harm?

A. Yes.

436 Q. Now, I know that we can get the impression when I read these out that they all happened in sequential order; it may be that this was the first thing that happened in Craigavon, it may be the last, I'm not quite sure if you remember, if you've tried to recall them in any particular order? 15:54

A. Sorry, I can't remember.

437 Q. And given that there was patient harm, was this something that you - did you go and speak to anyone about this and say, "Look, I might have messed up", or "I said that might happen and it did and I'm just training", so was there anyone you could speak to? 15:54

A. As I say, I raised issues with Mr. O'Brien and Mr. Young. I didn't speak to anybody else about this.

438 Q. And just Mr. Young, ureteric stone treatment, again just replying at this stage: 15:55

"Mr. Young has confirmed that he does not recall Mr. Hagan ever having spoken to him about this issue."

And he more broadly instructs as follows: 15:55

"By way of general background, EHL (electrohydraulic lithotripsy), was a method used to fragment stones. There were different electrode probe sizes to be used

depending upon which part of the urinary tract they were used in.

Mr. Hagan fairly comments that his experience/observation was its use in bladder stone endoscopy. There are accepted probes designed for use in the ureter. This was the instrument used in the department at the time. It was the equipment that Mr. O'Brien had been using, and it is assumed upon which he had been trained in Dublin during his registrar time. 15:55 15:56

Mr. Young found it a device that had to be handled with particular care and he would instruct registrars very precisely on its use and techniques. He also instructed the registrars to use what is known as a safety guide wire before performing a ureteroscopy "in case". 15:56

Mr. O'Brien did not regularly use this technique and Mr. Young raised this with him. Mr. Young also continued to instruct the registrars to do so to "to keep them right". 15:56

It is accepted that a guide wire does hinder the optical view but has its advantages. 15:56

In respect of Mr. Hagan's point about the use of the lithoclast with a zero risk of perforation, Mr. Young

agrees that it has a better safety history and is economically viable and he observes that the lithoclast is a straight instruction and can only be used in the ureter and not the kidney, whereas the EHL system could be used anywhere in the urinary tract." 15:57

I don't think he mentions that they didn't have an alternative in that, he doesn't seem to indicate that that was the only equipment that they had. The last sentence seems to suggest that the EHL was more dual function, possibly. I'm not sure if that's right, but that seems to be the suggestion. 15:57

It's clear from that feedback from Mr. Young that he had identified concerns about the equipment and the use of it. And I read this out to give you an opportunity to comment, if you want, rather than find this out after you've given evidence. But he seems to have been actively involved with registrars, who were more senior than you at that point - you were a third year surgical rotation, were you? 15:57 15:58

A. Second.

439 Q. Second year. So he gives them:

"He instructs them to use a safety guide wire in case and continues to instruct registrars to do so "to keep them right"." 15:58

So, he seems to be, from what he has said, alert to the

possibilities of the complications that appear. Did Mr. O'Brien give you any such instructions?

A. Not that I can remember.

440 Q. Had you ever seen the EHL used with a guide wire before? 15:58

A. I'd never seen EHL used in the ureter.

441 Q. I don't think there's much point in asking you then if that might have assisted if you'd never seen it used where you were going to use it anyway, if a safety guide wire might have helped? 15:58

A. They had EHL in Belfast and Glasgow and they didn't use it in the ureter.

442 Q. So it's more the part of the anatomy rather than the technique?

A. I don't think it's a strong argument to say that it's because of the dual energy source then we should use something that is very unsafe in the ureter. That would be my view on that. 15:59

443 Q. Is there anything else you'd like to comment on in relation to what Mr. Young has said? I mean, I think he's speaking in the abstract because we don't have the patient details, you can't recall anything about the particular patient. 15:59

A. No, I don't think so.

444 Q. So he's just replying to what you have said. 15:59

CHAIR: Ms. McMahon, are we about to move on?

MS. McMAHON: Yes, we are.

CHAIR: I've just realised it's four o'clock and I'm sure we could all do with a short break. So if we come

back at a quarter past four.
MS. McMAHON: Yes. Sorry. Thank you.

SHORT ADJOURNMENT

16:10

CHAIR: Welcome back everyone. Ms. McMahon.
MS. McMAHON: Mr. Hagan, I just want to move on to -- you've given another couple of examples in relation to paediatric urology and radical prostatectomy and high PSA, and the panel have your experience on those issues. Just there was one other issue at page WIT-98850, paragraph (vii). And this one you are able to date to the last week in your traineeship in Craigavon:

16:15

16:15

"Priapism and penile disassembly."

And I'll just read out this paragraph:

"In my last week as a trainee in CAH in 2000 a patient was admitted with a longstanding priapism (an erection of the penis that does not go away). Once a priapism has been established for more than 24 to 48 hours surgical decompression or hematoma evacuation will not be successful as the hematoma will have organised and erectile function will be lost.

16:15

16:15

Andrologists (physicians who specialise in treating men's reproductive related issues) in Great Britain

were recommending early referral to London for insertion of artificial penile prosthesis for management of this rare condition. However, in the case I remember, Mr. O'Brien took the patient to theatre and performed what I can only describe as a penile disassembly by separating the corpus..." 16:16

A. Cavernosum.

445 Q. Cavernosum: 16:16

"...and..."

A. Spongiosum.

446 Q.

"...spongiosum tissues. I was not myself scrubbed in for the procedure along with Mr. O'Brien, and whoever was assisting him, but I just remember being present in the theatre at some point and wondering what Mr. O'Brien was trying to achieve. 16:16

I remember being concerned that the procedure could risk compromising the vascular supply to the penis. I remember leaving the theatre as I did not want to watch what was happening. 16:17

I never found a description of the procedure in any text. My recollection is that when the patient returned to the ward there was concern in respect of the ischaemia of parts of the penis. I do not know the

final outcome for this patient as I left CAH to return to BCH as part of the urology rotation. This patient will have been on the urology ward for a period of time post his operation, so it may well be Mr. Young or others will recall the case because of its unusual features."

This sounds like something that would be pretty rare to see generally?

A. I mean, priapism in Northern Ireland is relatively rare. It is usually associated with drugs that men would use to get erection. It's more common in Great Britain with sickle cell and thalassemia and things like that. But the key point in this is once you go beyond four hours with a priapism, if you're going to try and do something surgically you need to do it then. And once you get to 36 to 48 hours, surgery -- there's a procedure where you can create shunts -- is of no value. The shunting procedures that are available, this is not what is described in books, so I had never seen anything like this before. But there was emerging evidence from a urologist in GB called David Ralph that inserting an artificial penile prosthesis was actually the best way to manage a priapism greater than sort of 48 hours. And he actually came over to Belfast and gave a lecture to us as trainees. And actually, for the purpose of today I read -- he had published a recent article on that - I mean obviously that article is recent, but it's a good way to manage unusual

priapism of longstanding duration.

447 Q. In relation to the knowledge in 2000, you've said that once a priapism has been established for more than 24 to 48 hours, surgical decompression or hematoma evacuation will not be successful. I mean was that established medical knowledge at that time? 16:19

A. Yeah. Absolutely.

448 Q. Had you seen anything like this in your previous rotations or work experience as a clinician in other hospitals? 16:19

A. So, any priapisms I'd had to deal with would have presented within the sort of four to 24-hour window where you would usually aspirate blood from the penis and use alpha -- or adrenergic drugs or alpha agonists to try and bring it down. And that -- I had never seen that not working. But I hadn't -- this is a very different scenario, this is a long established priapism of a man, I think it was possibly 72-hours, I can't remember exactly. 16:20

449 Q. You mentioned an expert effectively in London who has a specialty in cases presenting such as this. Was that something that was known at the time as well, that if there was -- time is of the essence, if you're moving into danger zone then either advice or referral to London was the appropriate route, in your view? 16:20

A. So, that was certainly my view as a consultant urologist, that if I was in this situation that's what I would have done. I can't recall exactly when David Ralph came over to give us the lecture, whether it was

before I went to Craigavon or after, but I know that that was an emerging theme of how to manage this. Because the penile prosthesis was a good way to manage refractory erectile disfunction. And, you know, we had some experience of inserting them in Belfast, but we also had good links with David Ralph in London.

450 Q. And in this case you can't remember anything about this, the patient, their name, their age, how long they were in for?

A. No, I can't. As I say, it was my last week. I wasn't involved in the decision-making of going to theatre, but I came to watch and thought -- as I say, I left, because I didn't really know what was happening, to be quite honest with you. 16:21

451 Q. So you didn't know the lead up, you didn't know the clinical buildup to -- 16:21

A. No, I knew the patient was in, but I wasn't involved in the decision-making process to take the patient to theatre. Mr. O'Brien had that decision.

452 Q. And did you speak to Mr. O'Brien about it and why he had chosen that particular course of action? 16:21

A. Not that I can specifically remember. I think that by that time I had challenged Mr. O'Brien on quite a lot of things, and I suppose the response had always been dismissive. And, you know, I think you also have to take into account, and I've said it lots of times already, I'm a second year trainee, I have never seen anything like this before. That doesn't mean to say that he mightn't have had a good reason. But, you 16:22

know, as part of the training, you learn different ways to manage priapism, and I could not find any textbook description of this procedure that he undertook.

453 Q. And, again, I don't think you spoke to anyone about this, it was your last week, as you say. 16:22

A. No.

454 Q. Just in relation to the stone issue that we mentioned just before the break as well when the ureter ruptured, I just want to bottom out if you actually did speak to anyone about that because of the patient harm involved. 16:23 Did you speak to anyone senior to you or even a peer around that?

A. So, I know I discussed issues with Michael Young, and stone treatment was one of them, and the use of EHL in the ureter, you know, would have been part of that 16:23 conversation, because it wasn't something that I had ever encountered before. And I know that I had discussions about purchasing a lithoclast and safer ureteric surgery.

455 Q. I know Mr. Young doesn't -- I think his wording is he 16:23 doesn't recall you having spoken to him about any of the issues that you raise. If you're right and that you did speak to Mr. Young about the issues, some of the issues we have discussed in your evidence - and I've just used some examples to illustrate some of your 16:24 concerns at the time - if you're right and you did express your concern to Mr. Young, given what you know now and your experience, could he or should he have considered this indisputably a clinical concern?

A. So, I think the key to managing patient safety concerns is appropriate escalation. So, I think if a trainee was raising a concern with a clinical supervisor or educational supervisor about a patient safety concern, I would expect the CS or AES to raise that with the Clinical Director of the service and then escalation as appropriate. So, to me, it comes back to the heart of how you manage clinical performance concerns and about early -- you know, if there is escalation, that it's dealt with appropriately, people in senior positions respond to that appropriately and investigate it appropriately. 16:24 16:25

456 Q. And in these particular examples, rather than generically, what would be best practice to happen, given the information that I've read out, the information you've provided to the Inquiry? If this were the case and you had spoken to Mr. Young, do you consider that these are cases that should trigger an approach by him to act accordingly to perhaps explore your concerns to speak to Mr. O'Brien, to speak to a colleague? Do you think these pass the threshold for necessitating some governance action? 16:25 16:25

A. So, I would have expected him to have a conversation with his Clinical Director. And, you know, these were patients who were on the ward, these were patients that he would have been aware of, you know, on the joint ward rounds. So, irrespective of whether or not he remembers me talking to him about it, he would have had sight and visibility of these patients. 16:26

457 Q. And also would it be right to say irrespective of whether you're right or not in your concerns, there's an obligation?

A. Absolutely.

458 Q. Those examples we have used to tease out some of the governance issues around what might have been expected to happen or what could have or should have happened. And you've identified some other issues around administrative delays that are outpatient practice, people coming in for review, things that the panel may consider are familiar in some respects. But I think we'll move on from those examples. We've talked about you, the difficulty of raising concerns as a trainee. Now I want to sort of fast forward to 2010. You've now -- you're a consultant in the City and there is the review of adult urology services and there was some issues with patients in 2010 being referred. 16:26 16:26 16:27

A. Hmm.

459 Q. And we touched a bit on this at the beginning of your evidence where there was perhaps a following of expertise and the relevant patients to a location that would enable them to get the most appropriate clinical assessment and treatment by the people who were most commonly doing those operations or procedures, and that was the City Hospital for urology at that time? 16:27 16:27

A. That's right.

460 Q. And the Inquiry has heard evidence of the background to the review and perhaps some pushback, reluctance, difficulty with letting go perhaps of areas of

expertise that some consultants wanted to hold on to, and that's just a brief overview, because we've heard evidence, and I know that you were part of the scenario, so hopefully what I'm saying to you is familiar. That's the background to an incident you recount in your statement in relation to patients who were referred up to Belfast. We can go to this, WIT-98857. Now, three of these patients - I don't intend to read all of this in, we have it available, but the context - three of these patients ultimately fell to you. 16:28 16:28

A. (Witness Nods).

461 Q. They became your patients. And if you could just give us a background as to how the patients found their way to the City Hospital and what the issue was? 16:29

A. So, this goes back to September 2010. Heather Trouton, who is the Acting Director of Acute Services in Craigavon, had contacted Beth Molloy, who's sadly deceased, of Health and Social Care Board, and Diane Corrigan, who was the Commissioner, and they were involved in the review of urology and the clear recommendations that pelvic cancer should be centralised in Belfast by, I think, March 2010, and that Mr. O'Brien had been planning to perform two or three cystectomy procedures, and that Diane Corrigan had instructed that these patients be referred to Belfast. So there was correspondence between the two Trusts, and I arranged to see the three patients who were for cystectomy procedure, but we arranged to 16:29 16:29

discuss them at the, our regional MDT beforehand, because I felt that it was important that there was, the MDT functioned appropriately, reviewed the cases, as you would expect, and came to the determination about the best way to manage patients. 16:30

462 Q. So, in particular in one of the patients, you were concerned about the care they'd received at Craigavon and the delays, as you say, in one patient with aggressive bladder cancer receiving definitive treatment that may have affected their outcome, in 16:30 Patient 1. Is that after reviewing the paperwork or seeing the patient?

A. I was very concerned about the management of all three. But the patient with sarcomatoid bladder cancer, that's a very rare pathology, and the patient had a re 16:30 resection when they should have had an immediate cystectomy. Now, thankfully that patient's still alive today, but I think that their outcome could have adversely been affected by the re resection and the unnecessary investigations that were performed before 16:31 -- including bone scan, for instance. So that, I think that was a really significant patient safety issue for that individual. And then the other two patients had unfortunately metastatic disease. And in my experience of 17 years of doing cystectomy for bladder cancer, 16:31 there's very few indications for palliative cystectomy, and generally speaking it takes three months to get over a cystectomy operation, and that's in very fit, healthy people. Patients that are compromised by

metastatic diseases, they don't get back, they won't get back to their baseline. And one of those patients died several months later, unfortunately, and the other died the following year.

16:32

So, I remember feeling quite upset about the proposed management for these patients, and you'll see the letter that I wrote to my medical director at that time about my concerns about patient safety in respect of these three patients.

16:32

463 Q. That will be one of the e-mails we looked at this morning. Just bear with me. I have a reference for where the five patients are mentioned and the three relevant --

A. I can give you the references. WIT-99135.

16:32

464 Q. Yeah. And I've got 99136. So they must go over the page. We'll just go to that. So this is the e-mail that you have -- this is the first one. Could we just move it down just to make sure I've got my dates. Friday, 8th September. Yeah. Okay. So this is from

16:33

Jennifer Welsh on 28th September 2010 to Tony Stevens, Ray Hannon, and you're copied in, and Brian Armstrong. And this is the discussion around the urology patients, the group of five:

16:34

"Update re urology patients we discussed yesterday.

I spoke to Chris yesterday evening and he has had detailed discussion with the patient involved. All

were discussed thoroughly at last week's regional urology MDT and while treatment decision may now be different than had been agreed at SHSCT, all seem to understand why this is the case. Therefore, I don't think we need a second opinion. 16:34

In addition, Brian Armstrong has spoken to Gillian Rankin and explained about the tone/inference of the letters which were received by Chris and the patients' GPs. 16:34

Gillian has apologised on behalf of the SHSCT and has advised that Dr. Loughran will be writing formally to the consultant in question. 16:35

The only action remaining are:
1. Operational discussion re swap of minor or benign procedures to facilitate the fact that we have taken in additional complex patients - Brian will lead on this.
2. Response to Minister's office re one of these patients - Karen McClanahan is leading on this. 16:35

And that's from Jennifer Welsh, Director of Cancer and Specialist Service. 16:35

Now, the last part of that e-mail refers to e-mail correspondence back and forth about capacity, and that if five patients are coming up from Craigavon we perhaps need a greater level of intervention. Then

there's a suggestion, and I think it attempts to follow through, that five patients who are maybe benign or require minor surgery should go to Craigavon and have that done. So that's the backdrop.

16:35

If we move up to the main body of the e-mail, the backdrop to this, rather than read all of that out, is that you assessed the patients, as you say. One of them had received what you considered to be inappropriate treatment that had resulted not only in delay but could have impacted prognosis, and the other two patients had been communicated with in a way about their care that didn't reflect what you thought should happen?

16:36

A. (Witness nods).

16:36

465 Q. And you were in the invidious position, perhaps, of having to tell them that their care wouldn't be as they planned. Mr. O'Brien had written to the patients, written to you as well and to the patients, indicating what he thought the care should be. And you, I won't say took exception to this, but this did upset you, as you've indicated in your statement.

16:36

A. I need to clarify. What upset me is not the fact that he wrote to me.

466 Q. No, I didn't mean to imply that.

16:37

A. No. What upset me was the poor management decisions in relation to patients with complex bladder cancer. And, you know, if you take the time to read IOG2002 NICE Guidance around management of complex cancer, it's

clear what should happen, you know, and the Northern Ireland Review of Urology also made that clear what should happen. And the benefit of appropriate and proper multi disciplinary team working, so you have oncologists, surgeons, radiologists, pathologists, specialist nurses all contributing to the conversation to get the best outcome for patients, offering patients with metastatic bladder cancer cystectomy as opposed to good palliative care is unfair to those patients. It gives them false hope and false expectation. But more importantly puts them through a major operation that is never going to benefit them. 16:37 16:37

467 Q. So did you have to tell them that what had been suggested was not the optimal course of treatment and in fact that wasn't going to happen? Was that the position you were in? 16:38

A. Yes.

468 Q. Now, that was in relation to Patient 2.

A. And Patient 3.

469 Q. And Patient 3. But Mr. O'Brien, in relation to Patient 3, wrote to the GP and to you? 16:38

A. But, you know, shockingly, the oncologist that saw Patient 3 didn't feel she was even fit for chemotherapy. Now, if a patient is not fit for chemotherapy, they're definitely not fit for a major operation. And there was a misinterpretation of Dr. McAleese's clinical interpretation by Mr. O'Brien, and I think that's detailed in my statement, about what Dr. McAleese actually said. 16:38

470 Q. In relation to Patient 1, Mr. O'Brien did write to the patient's GP and to the patient themselves, indicating his displeasure that they were being referred to Belfast and the cancellation of the admission to Craigavon. And again in Patient 3, Mr. O'Brien wrote to the GP and to you around the prearranged cystectomy. Now, there was some suggestion from the contents of the correspondence to you that you felt, or could have felt some pressure to carry out what Mr. O'Brien had indicated to the patient would be the proper course of treatment, when in fact your clinical assessment was that that wasn't the way to go. 16:39 16:39

A. Well, it wasn't just my clinical assessment, it was the clinical assessment of the Regional MDT. I wouldn't have made that decision in isolation, because that's why we've formed MDTs, was to make collective decisions in the best interests of patients and to reduce the risk or prevent single handed practitioners making poor management decisions about patients. And I think, to me, it demonstrated a poor insight and knowledge of management of bladder cancer and what was appropriate treatment, and using, you know -- and using -- the regional resource was there, the expertise was there even to -- all the other urology units in the region were dialling in to the Regional MDT, apart from Craigavon, and there would have been opportunities to discuss these cases. 16:39 16:40 16:40

471 Q. Now, you do reference that, and I'll give the panel's reference in your statement, WIT-98862, that your view,

supported by the Regional MDM. So that would appear to be an example of governance oversight where collectively you took a view that was completely different from the referring clinician's view initially? 16:41

A. Absolutely.

472 Q. You mentioned a letter that Gillian Rankin had written earlier in 27th September 2010, and this letter touches on two issues that we've spoken about; one is the transfer and the appropriateness of Mr. O'Brien's actions in relation to those patients and the IV fluids. Just have a look at that at WIT-99131. It's dated 27th September 2010 to Mr. O'Brien: 16:41

"Dear Mr. O'Brien, 16:41

I am in receipt of correspondence in relation to 3 patients. In each case you have written to the patient, the general practitioner, and Mr. Hagan consultant urologist in Belfast City Hospital. 16:42

Each of these patients has been transferred to the City Hospital for further management by Mr. Hagan.

I understand that you expected and wished to carry out this surgery yourself in Craigavon Area Hospital, but 16:42 following contact from our Commissioner, the Trust was obliged to refer the patients to Belfast.

It is of great concern that you have indicated to a

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

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

Please acknowledge your agreement by return."

16:42
16:42
16:43

So, two issues there: A bit of a suggestion in the letter that they were sent to Belfast because they were obliged to send them, which might have taken the sting possibly out of it being a rebuke in some respects. But certainly there's a suggestion there that the behaviour was inappropriate. Do you know if any other action was taken against Mr. O'Brien on this issue or did you ever hear back in relation to it?

16:43
16:43

A. All I know is that Tony Stevens wrote to Paddy Loughran, who was the Medical Director in Southern

Trust at that time. But I don't know if any further action happened to that.

But I think Gillian Rankin's letter sort of misses the point, in that, okay, the communication was inappropriate, but the management decisions in the three bladder cancer patients were all incorrect, and there was two patients who were for radical prostatectomy who also had a different change in their management. If you read the letter that I sent to Tony Stevens. 16:44

473 Q. Tony Stevens. WIT-99146. So, this is the e-mail that you sent. We just need to read some parts of it. And you make the point here that you've just made to us in evidence: 16:44

"Tony and Ray,
Whilst the letters sent about these patients were unhelpful I think it misses the point that these patients and the governance issue that have been raised." 16:44

Then you go on to explain why clinically the decisions were, in your view, erroneous. I don't think there's any suggestion, it's just your view, as you say, the MDT reached a decision that there should be different pathways for each of them, and so you set out clearly what your concerns are. 16:45

Then on 29th September there should be a reply from Tony Stevens. Tony Stevens, at the time was the?

A. He was the Medical Director in the Belfast Trust.

474 Q. Your current role?

A. Yeah. 16:45

475 Q. Did you take over from him?

A. No, Cathy Jack.

476 Q. There's an e-mail... yes, from Tony Stevens, 29th September, to you and Ray Hannon: 16:45

"Chris,
Thanks for this. If you are comfortable, I will write to the medical director in southern copying this e-mail. I understand that the situations is further complicated by advice given by one consultant to 16:45
patient. If you have detail on this it would be helpful. I am prepared to take strong line on this if continues, to extent of considering need for GMC referral. Happy to discuss.
Tony." 16:46

When he says "I am prepared to take strong line on this if continues", your letter was very clinically based; you set out your concerns. What did you take this to mean in that sentence,"if this continues", "on this if 16:46
continues"?

A. So, I'm assuming that if they didn't start referring patients appropriately.

477 Q. So, was there a suggestion here that Mr. Stevens also

jumped over the clinical concerns issue and was concentrating on the process for referral?

A. No, my understanding is he wrote, he shared the correspondence with, or spoke to Dr. Loughran. I mean, you'll need to talk to Dr. Loughran about what he received, but my understanding is he raised the concerns with Dr. Loughran appropriately. 16:47

478 Q. Did anyone come to you and say, "Well, never mind the procedure, there's patient harm here"? Did anyone say, you know, there are a couple of different ways of looking at what happened; the patient should have been referred perhaps sooner, in particular in one of them, they had treatment plans that were perhaps suboptimal, there was resistance in their referral which delayed their treatment when they did get to Belfast, the clinician had tried to perhaps, on one view, dictate the course of action that you would take as an MDT, the patients had been told this and their expectations had been raised, but there's also the fact that people were arguably harmed? 16:47

A. Hmm.

479 Q. Did no one carve those out as governance concerns and say, "Well, we'll deal with the process, but my goodness, what's happening? What's happening in Craigavon?" 16:48

A. So, I think that -- I think I did the right thing and I raised it to my medical director, who then raised it to the responsible officer for Mr. O'Brien. So, the actions that you describe, whilst all correct, should

have been taken by the medical director in Southern Trust, you know.

480 Q. So you would expect somebody to do something about all of those issues now? If that scenario happened now, you would say "Okay, let's break this down. There's quite a few links have broken in this chain. Let's deal with the patient harm one first and then we'll work backwards to the least harmful"? 16:48

A. Yes. So I mean there's lots of issues arising. You know, I think that there's obviously an adverse, there are adverse incidents that should have been recorded as such, but there are professional issues that should have been dealt with as well. 16:48

481 Q. And who should have recorded it as an adverse incident?

A. So this should have been recorded, to my mind in Craigavon, because the issues were raised in Craigavon. 16:49

482 Q. And your way of getting that information back to Craigavon, or not just your way, but Tony Stevens' way, was to contact Paddy Loughran and inform him? That was the procedure in place. I'm just trying to understand how you would cross contact another Trust? 16:49

A. So that - it's actually a good example of communication between organisations where responsible officers have spoken to each other about a concern in respect of a doctor, and it's up to the responsible officer for the doctor to take action as appropriate, that the concerns have been raised with them, so they have been -- I think managed well in that respect in terms of raising the issues. 16:49

483 Q. If we just go to WIT-99145. This is your reply then, whenever Mr. Stevens replied to you, you reply on 4th October 2010:

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

Now, this is a point at which patients have been told either their expectations are not being to be met or the news is perhaps not as positive as they have been led to believe. Do you think that response to Tony Stevens, given your view that an SAI should have been triggered, that that response tends to dampen everything down a bit?

A. Look, I don't think it dampened it down in terms of the concerns were raised and I know they were shared, and I know that Tony had a conversation with Paddy Loughran and he wrote to him to say that he was going to address

the issues. So I think it was, in that respect it was managed. I think that there are no such things as off the record conversations, and I accept now, looking back 13 years, that that's not what I would say now in terms of off the record, because it definitely needed to be on the record. 16:51

484 Q. Off the record would almost be antithesis to good governance, wouldn't it?

A. Look, I've learned a lot in the past.

485 Q. I'm just asking you to share that learning. 16:52

A. Yeah. No, no, I mean I fully accept that concerns were raised appropriately and they were acted on. I think that asking -- I think it reflects a different time, when -- and I think we've advanced considerably since then. 16:52

486 Q. Would you do the same thing now if the situation arose?

A. In terms of raising the concerns? Absolutely. But I'm in a different role now.

487 Q. You would do -- would you have the same reaction? Would you say have an off the record -- 16:52

A. No, no, I would -- in terms of raising the concerns to my medical director, absolutely. I think at the end of the day it's the medical director's decision what to do with the concerns.

488 Q. We can follow that, we can follow his line of what he did then. So I think you were the only -- the next e-mail, and I think it's the last one that you're involved in in this particular trail, but we'll close this loop. The 4th October, Tony Stevens replied to 16:52

you and said:

"Chris,
I will be content to chat to Paddy Loughran informally.
If that does it, fine. If not, and if your concern 16:53
persists, then you will need to consider next steps.
Tony."

Clearly, without any governance structure, the
oversight of whether this happens again and who's 16:53
responsible for keeping an eye on it or reporting it,
all falls away. And as you've said, things have
changed. But I just want to make the point that it's
inherently an effective way of dealing with a multitude
of governance concerns, from just that one example of 16:53
those patients.

A. I think -- well, I'm not sure I quite agree. But I think the concerns were raised appropriately and highlighted, and I know that they were shared with Craigavon, and the responsibility of dealing with that 16:53
lay within Craigavon. They were raised with Craigavon. I didn't work for Craigavon, I worked for Belfast Trust.

489 Q. Is it your evidence to the Inquiry that because the concerns were shared with Craigavon, the responsibility 16:54
for raising them as a governance issue rests solely with Craigavon?

A. So, you asked me about the concerns about Mr. O'Brien, and Dr. Loughran was his responsible officer and the

concerns were raised with them, in the same way that if concerns are raised with me as a responsible officer by a doctor, I see it as my role to deal with and manage those.

490 Q. So it's the -- just so I'm clear on your evidence. So it's superior clinician of the individual who's been complained about where responsibility lies for triggering, for pressing the governance button? 16:54

A. The responsible officer is the decision maker in terms of management of concerns about doctors. 16:54

491 Q. I don't know whether you're right or not. I just want to make sure that that's what your evidence is, that once you say the problem is Craigavon, it's an issue for them, then you can turn away and they have to deal with it or not? 16:55

A. Hold on, we didn't turn away. Because what we did was effect a change, in that from that date onwards, all patients with bladder cancer who required surgery were referred into Belfast. So we effected a change in terms of patient safety. So that was a really important thing to achieve. 16:55

492 Q. Is that under the terms of the review, the urology review, that the patients with bladder cancer had to come to Belfast?

A. Sorry, what? 16:55

493 Q. Under the urology review, was that one of the requirements, that bladder cancer patients had to come to Belfast?

A. No, patients who required a radical cystectomy should

be done in Belfast. So, those with muscle invasive bladder cancer.

494 Q. We just heard from Darren Mitchell this morning who indicated that once pathology is triggered for bladder cancer they bypass the clinicians and they get straight -- referral straight to Belfast. So we just maybe need to unpick that a bit to make sure we understand the process. You're saying that this brought about referral of bladder cancer patients to Belfast from Craigavon and they started to refer patients. 16:55 16:56

A. So, they started -- after I raised the concerns, they then started to tele-link in to the Belfast MDM in order to present patients that had muscle invasive bladder cancer that may require cystectomy, and patients with prostate cancer that may require radical prostatectomy. So the raising of the concerns effected a change to improve safety for patients. 16:56

I think as the MDT has evolved to improve the pathway, I think what Darren's referring to is that if somebody is diagnosed with muscle invasive bladder cancer, that immediately triggers discussion. But we weren't at that place 2010, it has evolved over time. 16:56

495 Q. That's correct. And what you're describing as having solved is, with respect, one aspect of governance concern that arose here. That's the point. Governance has been carved up in some way that you can deal with the referral and get that sorted out and Craigavon can look after its issues. Is that right? Maybe that's 16:56

right. I just need to know what your evidence is.

A. So, I think it would have been important for Craigavon to examine the patient pathways of those patients that were referred to Belfast that required change in management. Because I would have seen that as my responsibility in Belfast as a medical director if that was presented to me, because the decision-making happened in Craigavon. So they would need to understand why they came to that decision and, you know, what was the process around that, etc., etc. 16:57

496 Q. I think we got there eventually. I think we got there eventually. And the fault was probably mine. So, I just need to understand what your evidence is around who is responsible for governance. Obviously that's our key. So I think the final part of your answer has made it clear. 16:58

There's a letter of 21st October 2010 from Paddy Loughran to Tony Stevens, WIT-100350. And this has been sent to us by the Trust. 21st October 2010: 16:58

"Dear Tony,

Further to our discussion about one of your urologists, in private at the conclusion of the medical directors meeting I have done the following: 16:58

The urologist concerned had witnessed the transfer of a number of patients who required major pelvic surgery as a result of cancer. He wrote to the patients and their general practitioner and expressed concern with the

transfer, and a very clear view that he would have preferred one particular surgical procedure. I believe that these patients were not subject to a multi disciplinary discussion between the Belfast and the Southern Trust. 16:59

I was shown the correspondence and given a message that a senior member of the receiving urology team in your Trust was very upset. 16:59

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

I have been advised that our AMD in surgery has been given an undertaking that there will be not be a repeat of the above. Any multi disciplinary decision that is made between the Belfast and the southern urologists will be respected by all of our urologists. 16:59

The director of acute services has also written to the urologist concerned, having drafted the letter with my advice and support. The letter includes the following..." 16:59

And that's the letter that Gillian Rankin sent that we've already looked at. 16:59

"I would be grateful if you would accept my apologies for the distress and difficulty that has been caused by

your receiving team. I hope that you will accept on the reassurances of last week and this letter that there will not be a repeat.

I would be very happy to discuss this with you, if you wish by telephone or in person. 17:00

Yours sincerely.
Patrick Loughran."

17:00

I think there's one more e-mail, just to close that off. I think we have this e-mail Bates numbered, but I'll read out the end of the reply:

"Paddy, 17:00
Many thanks for dealing with this quickly and sensitively. I am happy with this approach. Are you content for me to share the letter with the CD for urology in Belfast? "

17:00

And Mr. Loughran replies, saying:

"Tony,
Thanks for the reply. Fine to share the letter, but I would ask for no other copies, as things with our 17:00 clinicians are very delicate."

So, that's the outcome of the Patients 1, 2, 3 issue. And given the concerns, the myriad of concerns, in your

view now as medical director, if that's the end of the line of the high point of what has happened after all of that, do you think that that's an appropriate governance response to all of the patient harm and other issues that emerged with those three patients? 17:01

A. So, I suppose -- well I don't know if anything else happened.

497 Q. Well, we've asked and this is the last document we have been given. This seems to be the closing of the loop, subject to anything else might emerge? 17:01

A. So, there was no review took place of the individual patients in Craigavon then?

498 Q. Well, we haven't received any documentation in relation to that. Would that be something that you think that would have been an appropriate thing to do, review the 17:01 patients at the originating hospital?

A. So, I don't want to get into speculation, because I'm in a very different position in terms of my role. Are you asking me what I would do now if I was presented --

499 Q. I'm asking you, given that you know intimately the 17:02 facts of the journey of those three patients from they were referred to you right through, what do you think was an appropriate response? Would this have been an appropriate outcome for you?

A. So, I think that it focused more on the distress around 17:02 the letters to GPs and patients rather than actually the misdiagnosis. The misdiagnosis is the key here, and I think that this was probably a signal, you know, to have a look. And the way I approached these types

of things is probably ask the college, perhaps, to come and review the cases and give an external view on the management.

So, if you're -- as I say, I didn't know that nothing further had happened in this. 17:03

500 Q. No, I appreciate that. It's just really to look at...

A. Hmm.

501 Q. Seemed to have dropped off the patients somewhere along the journey. 17:03

A. And then, you know, there's also any concerns around the doctor should be managed within what's called Maintaining High Professional standards. And, you know, any concerns in respect of conduct health or performance should also be managed within that framework. 17:03

502 Q. And at that time there were processes available for that?

A. Yeah. Well, MHPS existed in 2010. So, there's potentially conduct and performance concerns within this. 17:03

503 Q. Thank you. I think we've jumped back and forward a bit with some of the topics, and I think I've covered everything I wanted to highlight. I know the panel have some questions for you and it may be the time now that they, given the time it is, that they get their opportunity to ask them. Thank you very much. Thank you. 17:04

QUESTIONS BY THE PANEL

CHAIR: Thank you, Ms. McMahon. Sorry we can't let you go, I know it's quite late in the day, but we do have some questions and I'm going to ask Mr. Hanbury first of all to ask you some questions. 17:04

A. Okay.

MR. HANBURY: Thanks very much for your evidence, it's been a bit of a marathon for you. I just want to dot around a little bit, starting about your time at Craigavon and just a couple of things on a few of your nine concerns. 17:04

The extended TURP, you can probably remember as though it was yesterday. So there you are in theatre and the anaesthetist is not happy and the scrub nurse is not happy. What was the dynamic then? Did the surgeon just carry on or try to speed up the end or... 17:04

A. My recollection is the surgeon just carried on.

504 Q. Was there -- what happened then? I mean, was there instability with the patient or... 17:05

A. I can't remember the outcome of the patient. It was more the fact that the resection time was going on too long and the anaesthetist and nurses becoming anxious about the resection time, and either a sense that they were being ignored I think is probably the best way to describe it. 17:05

505 Q. Okay. And was critical care alerted after that? Do you remember those sort of details or -- it's a long

time ago I know.

A. I can't. I'm really sorry, I can't remember.

506 Q. Yeah. Yeah. Okay. It can be a lonely place up the upper third of the ureter with a stone and someone breathing over your neck, it can be quite difficult; many of my trainers, I'm sure you have always told your registrars that you can always abort, stay safe, stent and send away. I mean, did this sort of thing happen when the case that you were describing was going forward? 17:05 17:06

A. So, I completely agree with you, upper third stones, I would -- I mean, I didn't practise as a stone surgeon once I became a consultant, other than doing emergency work on-call. But in the upper third I would generally have always advised to stop and put a stent in. I think stone surgeons, with flexible ureteroscopes, etc., might have been braver, but that wasn't the technology that was available then. 17:06

507 Q. The input from Mr. Young is interesting there. I mean, were you trained up until -- I mean, you had good sound training in Glasgow, and before you went to Craigavon were you always taught to have a safety wire up before or was this something that was a variable feast? 17:06

A. So, I was lucky in Belfast that we had some excellent stone surgeons who basically, in the same way that I changed practice in our team for bipolar TURP, they also introduced a lot of safety mechanisms around ureteric stone treatment and one of them would have been a safety wire, that if you're doing any ureteric 17:07

stone procedure, make sure you have a safety wire in, because you can always put a stent in. I think it was less common practice then amongst older urologists, but, you know, in Belfast we had a young consultant team who were very focused on safety, and the stone surgeons led on making sure we had the best and safest stone practice. So it's not relevant the names of the individuals, but they certainly led on that.

508 Q. And the lithoclast technology was available then in Belfast? 17:08

A. So, we had it in Glasgow and as a trainee in Belfast I suggested that we purchase a lithoclast, because I thought it was a really safe way to manage stones. So we got one in Belfast. And, you know, it's cheap technology and very safe. 17:08

509 Q. Yeah. So, you knew that it was the safer way, although it wasn't available in Craigavon?

A. I suppose it's one of those things where you feel surprised that people are using technology that's inherently unsafe. And when there are better alternatives and the alternative is cheap. So, I felt very uncomfortable about using it and I suppose I was in this situation being supervised and told to use it. And that's why it stuck with me, because I had never seen that complication before, I'd never seen an open pair of a ureteric injury before. 17:08

510 Q. Okay. And that happened straightaway on the table?

A. No, no. No, no. The patient was woken up, and my understanding is Mr. O'Brien spoke to the patient and

then they were booked for an open repair.

511 Q. Okay. Thank you. Just a more general terms about discussion of complications and emergencies and things that happen. A week is a long time in a big urology department. Did you have, on your Thursday morning grand round, did you have time to discuss emergencies, complications, things of common interest that perhaps didn't go so well? 17:09

A. Ehm...

512 Q. Between yourself and the department, not just you, but the department? 17:09

A. It was designed as an opportunity to have a longer discussion about patients on the wards, and I can't recall specific discussion. I mean all of those things that I have highlighted about unusual patients, the -- I guess.... sorry, I can't remember. 17:10

513 Q. I suppose not just talking about that particular case, but in urology there's lots of complicated stuff and it's good to share thoughts and ideas and people to refer to perhaps. 17:10

A. I don't think grand rounds are necessarily a good way to do that, in my experience. I think that they can be quite intimidating for trainees. We have had experience in other services in Northern Ireland where grand rounds don't work particularly well. I think structured M&M discussions is a much better way to learn from patient safety incidents and to -- because you can't really have that conversation in the time allowed at the end of a patient's bed, it's not 17:10

appropriate. So I think that's a much better way to manage patient safety concerns.

514 Q. Okay. I take your point. At that time were you having the weekly X-ray meeting on a Thursday morning at eight o'clock? 17:11

A. I can't remember...

515 Q. Perhaps another opportunity to have those discussions. Just one question on the priapism issue. Presumably were you involved with the patient all the way along? Did you know whether they had had the drugs and the 17:11 aspiration?

A. No. The patient came in with a late -- they were admitted with a late priapism. I know it was more than 48 hours. So there was no point in trying to -- I wasn't directly involved when they were admitted, but I 17:11 know that if there had been any aspiration, it hadn't been successful. I was not involved in that.

516 Q. Okay.

A. And I wasn't involved in the decision-making to go to theatre. But I was in the theatre area and, as you do, 17:11 you go in when you're curious as a trainee and you, because you hope to learn, and you see something and you think, "Oh, gosh, I'm not really sure what's going on here."

517 Q. Just to pin down a bit then, was the procedure, do you 17:11 think on reflection it might have been an attempted shunt procedure or...

A. I wondered about that. I think if you're going to attempt a shunt, I think you're much better to go

through the glans straight into the corpora rather than take the glans off, which is what had happened.

518 Q. Step 2. Yeah. Okay. Thank you. Right. I see what you mean. Was Mr. O'Brien operating on his own or did he call for assistance then? 17:12

A. He may have had, he probably had somebody --

519 Q. At consultant level I mean.

A. No, no. No, no, no. No.

520 Q. I see. He was --

A. No, I don't believe there was another consultant urologist there. 17:12

521 Q. Okay. Thank you. You mentioned children's surgery and referring. Do you have any examples of that, that perhaps things were done at Craigavon that perhaps should have been referred, or is that a general comment? 17:12

A. I suppose what made me surprised was that they had acquired a set of paediatric cystoscopes, and in 17 years of consulting practice I've never had a single indication to use a paediatric cystoscope. We have a children's hospital very close to Craigavon with two trained paediatric urologists. I think that district general urologists are safe to do torsion and circumcision, and possibly hernia repair, but beyond that, I can't think of any surgical procedure that an adult urologist should be performing on a child. You may be able to think of something. But certainly cystoscopy in children is not commonly performed unless there is a congenital abnormality. 17:13 17:13

522 Q. You didn't see that happening?
A. No.
523 Q. -- difficult orchidopexy or anything like that?
A. No.
524 Q. Okay. I take your point. So the patients having intravenous antibiotics and fluids, just there you are at the end of the bed, and it was the time that there were the charts. Do you recall what drugs they were on? What type of antibiotics? 17:13
A. I can't remember. 17:14
525 Q. Because we had evidence from Tracey Boyce and they were all on low dose gentamicin?
A. Right.
526 Q. Did that stick in your mind?
A. No. Sorry. 17:14
527 Q. No. Okay.
A. It was more the philosophy of fluids and antibiotics for patients that were quite capable of taking oral medication.
528 Q. Yeah. 17:14
A. There was no reason why they needed to be fasted and not drink. It didn't make sense.
529 Q. Okay. So maybe on the same theme, the benign cystectomy in the young lady who you described in great detail. You mentioned Mr. O'Brien sort of had phoned a friend in the States. Did he say he'd phoned a friend, one of his trainers, Belfast, Dublin, London, an expert in urinary tract infections, physicians, anybody else? 17:14
A. No, he just -- and I know it's 20 odd years ago, but

conversations sometimes stick in your head, and that "I spoke to somebody in America who said it was not an unreasonable course of action". And, you know, I suppose I accepted that at face value. But in preparing for this Inquiry, I looked again is there any literature to support this, and I can't find any literature to support cystectomy and orthotopic neobladder formation for a urinary tract infection in young females. 17:15

530 Q. I agree. We skipped over a few of your other concerns, and I've just got some short questions. The administration side, Mr. O'Brien, you commented on heaps of charts and letters and results. Would you have any more comments on reflection there? I don't want to get into too many details? 17:15

A. His office was chaotic, with charts everywhere, and his secretary was frustrated that it took time for letters and results to be dealt with. And then his letters were extraordinarily long. So, it seemed to me if there's an issue with keeping on top of things, write shorter, more succinct, to the point correspondence. 17:16

531 Q. Thank you. I mean, did he ask you to get involved and help out?

A. No.

532 Q. Thank you. You mentioned comment about the outpatient practice and trying to discharge people who don't need to be there, which is commendable. And then someone mysteriously coming back that you thought you discharged. 17:16

A. Yes. I thought that was really unusual. I mean, as a trainee in that team, you were mainly seeing review patients and not new patients, and I was conscious that there was a lot, there seemed to be a lot of patients who were on the routine review for no good reason. So, I started trying to discharge patients. But then when an individual reappeared, I thought this is really odd. And he said that he had phoned Mr. O'Brien's wife, who had put him onto the next clinic. 17:17

533 Q. An unusual way back. 17:17

A. Perhaps.

534 Q. Did you, did you -- to change the subject, but still on outpatients. Did you notice any other sort of trends, sort of cancer follow-up, benign follow-up that struck you as unusual, compared to other urologists I mean? 17:17

A. There seemed to be a lot of review patients. But I can't recall specifics in terms of trends.

535 Q. Okay. Thank you. You made some comment about Mr. O'Brien's practice with radical prostatectomy and patients with quite high PSAs. Could you just summarise that in a few short sentences? 17:17

A. So I think there was really good evidence then, and there's a good publication from 2002, you know, stating that radical - hormone treatment for radical prostatectomy has no place. Now, hormone treatment will reduce your positive margin rates, but it doesn't improve outcomes. And I think offering it to men with high PSAs is actually wrong, because it's highly likely they have micro metastatic disease and you're putting 17:18

them through a major operation that can affect incontinence, potency and other issues, when they're not going to get any benefit from it. And I think, you know, it was PR07 at that time was recruiting patients with higher PSAs and intermediate high risk prostate cancer for radiotherapy in hormones, and I think Balls study, et al., showed the benefit of that approach. So it was an unusual approach to the management of prostate cancer. I know that there were individuals around the world who may have single centre series around that. So I'm aware that there are others that were practising that, but there's really good evidence, I think, that it's not indicated. 17:18 17:19

536 Q. Did you see any cases being done by Mr. O'Brien with that? 17:19

A. He did a small number of radical prostatectomies when I was there, but I cannot - I would have put it in my statement if I could remember the specifics.

537 Q. You didn't think of offering to write them up? It would have been an interesting project. No? 17:19

A. No, I didn't.

538 Q. Just one more thing. Just going, rowing forward to the sort of 2016 -- sorry, 2011 problems with the cystectomy patients which you alluded to. So, what would have happened if it hadn't have been for the IOG Directive? Do you think those cases that were sent to you with Metastatic Disease 1 and -- in the lymph nodes would have ended up with a cystectomy? 17:19

A. In Belfast or with Mr. O'Brien?

539 Q. No, with Mr. O'Brien, had he not been --
A. Well, I think he had dates set aside for those patients. I think from memory reading that he had dates later on in September for those patients.
MR. HANBURY: Right. Thank you very much. 17:20
CHAIR: Thank you, Mr. Hanbury. Dr. Swart?
DR. SWART: So, thank you for your evidence. It's interesting what you can remember after all this time. And I suspect some of these cases stick in your mind for specific reasons. You were a registrar in other 17:20
places. Did you see anything like the scale of this in any of your other registrar roles?
A. No. No, I mean I worked in really good units in Glasgow, Belfast and Dublin.
540 Q. Yes. 17:20
A. The unit I worked in in Dublin was excellent, it was a really good transplant unit with a major oncological focus as well.
541 Q. Did you have cause to ask any similar questions, like "why are you doing this?", or anything like that? Can 17:21
you tell us how that atmosphere might have been different in the other units?
A. I've always been curious and asked questions.
542 Q. Mm-hmm.
A. But usually questions in a sort of, in a supportive 17:21
discussion.
543 Q. Yeah.
A. But not like this, and not repeatedly and feeling that this feels unusual practice.

544 Q. And when you asked questions in other units, did you get satisfactory explanations, when it was something perhaps you weren't familiar with? How was that dealt with?

A. So my experience of working in really good units is people welcome questions, they welcome challenge, they welcome people asking you is this -- you know, have you thought of doing something different? What about this? Because often trainees are really well read because they're preparing for exams. 17:21 17:22

545 Q. Yes. Exactly.

A. And they will maybe be more up to date than some consultants will be. And that's not to say something negative about consultants, but in preparing for FRCS urol you needed to be really on top of your game at that point. 17:22

546 Q. You do, yeah. I'm going to ask you to speculate a bit. The coroner's rulings issue, we have sight of the letter that medical directors got in 2013, I think, and we also have sight of the - because it's an appendix to your statement actually - the regional guidance in 2015. So if you were a medical director today and you got a letter like that, and medical directors do get copies of letters like that as a result of coroner's rulings, what would you do with it exactly? 17:22 17:22

A. So, my approach -- I mean, what the coroner is doing is raising a significant patient safety concern.

547 Q. Yeah.

A. And generally my approach is to meet teams that are

involved in these things and get an understanding of is this something that is applicable and can we introduce it here?

548 Q. Yeah.

A. Because I sort of straddle various positions in this, because I knew that we could do something to really improve patient safety with this. So I think as a medical director you need to support teams to do the right thing, even if that sometimes comes with some additional cost. And, you know, this was a young woman that died of a TCRE and my sense was we should try and make sure something like this never happens again, and that's when I -- 17:23 17:23

549 Q. And how would you place it in your governance structures? Where would you put that so that assurance was sought and tracked and followed up and all that stuff? 17:23

A. Okay. So, I would have done something like this in my deputy medical director role for risk and governance.

550 Q. Yeah. 17:23

A. We have a group that monitors new procedures and we put in audit to measure outcomes and to ensure that we are - we were safe, I suppose. We've also introduced a new system in Belfast, a quality management system, which will pick up issues in terms of outcomes, etc., and then we have things like outcome review group which looks at mortality across, and we can get mortality down into teams, so we will know if there's an increase in mortality in that area. So we have lots of ways of 17:24

picking up data in terms of outcomes.

551 Q. But you would be seeking assurance, would you?

A. Absolutely.

552 Q. That this had been dealt with, appropriate action had been taken at the relevant part, place in the Trust? 17:24

A. Yes. Yes.

553 Q. So, there was another crack at this then in 2015 when there was a regional document produced which suggested that Trusts should adopt this with, I think they put your own logo in, and it also mentions the need to take 17:24 various methodologies forward in terms of long times for surgery and all of that. What did you do with that in the Belfast Trust? How did you deal with that then?

A. So, we were ahead of that in a way, because we'd introduced bipolar resection in 2013. We had 17:25 completely eliminated Glycine, we'd taken it out of theatre, so the surgeons couldn't actually use it. We used it for bladder tumours as well as TURPs.

554 Q. So did you just adopt the regional guidelines and say "Yes, we do this"? 17:25

A. Absolutely.

555 Q. And you continued to audit it?

A. Yeah. And I mean, we do the -- in theatre they do the, there's a specific protocol for monitoring fluids.

556 Q. There is, yeah. 17:25

A. So we adopted that, even though for bipolar it's probably not necessary, but we still adopted it.

557 Q. And the operation time issue as well?

A. Oh, yes. And I talked about how the nurses would call

out where you are in the operation and how long you've been operating for. So, the whole thing was adopted and...

558 Q. Yeah. So it's a bit more speculation; you've adopted, you know, a specific approach to patient safety, which you have described. There's quite a lot of experience of this in English hospitals, which I'm sure you know about, but what has been the impact in Belfast on, for example, the medical leadership and management culture and the way teams approach safety? Have you been able to develop any sort of sense of a measurable impact of that? 17:26

A. So, one of the things -- I mean we learned a lot from the Independent Neurology Inquiry.

559 Q. Yeah. 17:26

A. But even prior to that, we had done a lot around our safety culture. So I talked a little bit about that earlier on.

560 Q. You did. That's why I'm picking you up on it.

A. But we used framework called "The measurement and monitoring of safety", written by Charles Vincent, which is probably the best document I've ever read on patient safety, because it gives you measurables for it. 17:26

561 Q. Yeah. 17:27

A. And we got our teams to start focusing on the five elements of that.

562 Q. You've managed to embed that and continue with it?

A. So it's completely embedded across the Trust. So it's

used as the framework for our safety huddles. So our safety huddle framework is that there's a huddle, and it's based on -- like Philadelphia, where it was described where there's a safety huddle in the morning at very local level, and then there's a higher level huddle, and then at eleven o'clock the entire executive team meet with the chief executive and we do a safety huddle, and any issues that can't be resolved at the local level are brought to the safety huddle. So it's made us very conscious of being: Are we safe today? But it also let's us focus on the reliability of our systems, and it has brought in a new way of talking and thinking. 17:27 17:27

But then I also brought in another thing called divisional live governance. So we have a structure in Belfast where we have the executive team and then there's 13 divisions underneath. So in a division there's a doctor, a nurse, and a manager, and they meet every once a week and they go through all their incidents, their high risk complaints, their mortality, any coroner's cases upcoming, and ensure that if there's anything that needs to be escalated then it can go to the relevant professional lead. So that's a really good way of picking stuff up. 17:27 17:28 17:28

And we've also created, tried to flatten our structures as well. So in the past few weeks I've, you know, CDs are quite comfortable to phone me directly and say "I

have a concern, can I talk to you about it?".

563 Q. Yes.

A. And it is about -- because they know that they will, if they raise a concern, somebody will listen and they will act appropriately. And it's the acting appropriately is the absolute key to this. You can put all the safety systems you want in place, but when the concern is raised, you have to act. 17:28

564 Q. So this only works if the Board embraces this --

A. Sure. 17:28

565 Q. Fairly comprehensively. And for me that would be all the members of the Board, it can't just be the medical director and the nursing director, it's got to be everyone. Has that happened as part of this and does the Board ask you what the measurable improvements in safety metrics are? 17:29

A. So, we have a quality management system now which has measurables.

566 Q. Yeah.

A. And we bring that to Trust Board, to every Trust Board, where we share that data, and that will include mortality data, and adverse incident data, high risk complaints, and then we have committee structures beneath that where we have non executive directors. So, for example, one of the committees I Chair is around complaints and patient experience, so there's a a non executive director co-Chairs that with me. We've an SAI review group that I Chair and the report goes to Trust Board on that. So Trust Board are fully sighted. 17:29 17:29

And that is part of the key to really good assurance framework.

567 Q. And in your view this has been partly learning from the Neurology Inquiry or was it something that was already in train at that time? 17:30

A. I think it was in train. There was also the IHRD as well, which I think shone a light on openness and that, the importance of openness as a cultural... .

568 Q. And you've got the information systems to support this?

A. Yeah. But I think overriding this is a curiosity. You have to be curious. You have to go and ask difficult questions. You have to look at your data and say "That doesn't make sense, tell me what's going on here". 17:30

569 Q. So on that, just a bit more conjecture, it's my last thing. The cystectomy issue is fairly, it's a big issue when one reads it altogether. Clearly, a change was made which is actually to follow IOG and follow the centralisation, and in a way it illustrates the need for this very well. If you were -- if that came to you as medical director and responsible officer, you've talked a little bit about what you might do, but outline your total approach to that if that happened today. How would you deal with this? Because this is a multi faceted issue actually when you look at all the different things. Certainly from a patient perspective there are massive issues, there's cultural issues in the Trust and so on. What would you do with it, apart from have a little moment? 17:30 17:31 17:31

A. So, are you asking me that in my current role?

570 Q. Yes. I'm not asking you what they should have done then, because you were a registrar, you reported something, you don't know really what governance was in the Southern Health Trust. But since we're learning about governance and since you're here and you've seen all of this, I'm just asking you to have a little think. 17:31

A. Okay. So you're right, it's multi-stranded. But being quite technical, any concern about a doctor in terms of conduct, health or performance, should be managed within the MHPS framework. And there are concerns in this for me about conduct and performance. So, I think that that's how I would approach it in terms of the individual doctor. But there's also patient safety issues. 17:32

Adverse incident, it should be reported as an adverse incident. And whether you would chose to do then an SAI, which probably meets that threshold, but in a case like this where you have several cases, I have often found asking the college to become involved and review the cases and do a sense check on what's happening and maybe actually expand that into other cases. And I think that's probably the approach, having been put on the spot. And you need thinking time and you need to discuss how you manage these things with other individuals and you will take advice from practitioner performance, for instance. 17:32

571 Q. What would you do in terms of talking to the individual

doctor?

A. So, it's important that you meet the doctor and share the concerns and seek a response and explain what you're going to do. And to my mind, you couldn't not carry out some form of investigation. And the college is often very useful in these cases where there's several cases, in my experience. 17:33

DR. SWART: Thank you. That's all from me.

CHAIR: Just one thing. The move towards centralisation of complex cases, is that continuing in Northern Ireland? Is that part of our transformation process or not? 17:33

A. Certainly in urology, it is. We have several regional specialties in Belfast like compatibility surgery, upper GI surgery, haematology, transplantation. So, a lot of regional services have been centralised in Belfast. We're a small population and there's huge benefits to it, because you can concentrate skills and that's how you get the best patient outcomes. And there's lots of really good evidence to support that. 17:34

572 Q. So, I'm maybe putting you on the spot somewhat, but would you be supportive of a hub and spoke type approach to urology, first of all, but more generally in your role as medical director? 17:34

A. So, we developed a really good model with urology where one of the urologists in Craigavon, who is an excellent pelvic cancer surgeon and kidney cancer surgeon, in a practice very close to my own, because we both did a lot of laparoscopic urology, so he came to Belfast to 17:34

do his complex cases, we had a really good working relationship and we were quite comfortable looking after each others' patients. And that can work really well. But at the end of the day, it's about individuals wanting to work collectively in teams. And one of the biggest risks I think you have in terms of consultant practice is lone working, and the consultants that work in an isolated way, because they are the ones that carry the biggest risk. So one of the things that I've been working on in Belfast is around effective high performing teams. And the central thing about that is to avoid lone working and to get doctors working collaboratively and collectively looking after the same patients, so that you basically keep people safe, so you keep patients safe, but you keep doctors safe. 17:35 17:35

573 Q. And that would be a direct learning of INI?

A. Oh, absolutely. And, you know, we learned about complaints with INI, we brought in a new process how to manage complaints, in that they are now all -- any complaint about a doctor is reviewed by another clinician, where you get them to do, there's a technique called structured judgment review developed by the Royal College of Physicians, so if there is a complaint, a patient makes a complaint about their care and treatment in relation to a doctor, we do a structured judgment review to assess whether the care was satisfactory, room for improvement, or unsatisfactory. And if there's unsatisfactory then we 17:36 17:36

will pick that up with the doctor.

CHAIR: Okay. Thank you very much. You'll be delighted to know that at twenty to six you have concluded your evidence for this Inquiry. I'm sure you're very relieved. And it's been a long day for all of us present here today, so I'm sure we'll all be glad to get home. See you all tomorrow, ladies and gentlemen. Ten o'clock. 17:36

THE INQUIRY WAS THEN ADJOURNED UNTIL WEDNESDAY, 20TH SEPTEMBER 2023 AT 10:00 A.M. 17:36