



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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1 THE INQUIRY RESUMED AS FOLLOWS ON TUESDAY,
2 19TH SEPTEMBER 2023

3
4 CHAIR: Morning everyone. Good morning Ms. McMahon.

5 MS. McMAHON: Chair, this morning we're going to hear 10:01
6 evidence from Dr. Darren Mitchell, who is a Clinical
7 Oncologist at the City Hospital in the Belfast Trust.
8 Before that, I have a short opening statement to make
9 to introduce module four and set out aims and
10 objectives of the module and how it fits in with the 10:02
11 Terms of Reference. So I'll just read that and then a
12 copy will be available on the website.

13
14 OPENING BY MS. McMAHON

15 10:02
16 MS. McMAHON: Chair, we have now reached the fourth
17 module of the Inquiry's work. This will be an
18 opportunity for the Inquiry to engage with the work of
19 some of the clinicians who served within or who
20 interacted with the Southern Trust's Urology Service. 10:02

21
22 It will be recalled that during the scene setting phase
23 of the Inquiry's public hearings, which we commenced
24 last November, the Inquiry gained sight of, and
25 explored with witnesses, what the Southern Trust had 10:02
26 identified as shortcomings in the clinical practice of
27 Mr. Aidan O'Brien during 2020.

28
29 we were able to examine the nature and implications of

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

10:03

6
7 During the Inquiry's second module, which was directed
8 to Part E of the Inquiry's Terms of Reference, we
9 examined the operation of the MHPS framework. In doing
10 so, we also built upon the work of the first phase of
11 the Inquiry's public hearings by receiving from
12 witnesses their descriptions of a number of additional
13 concerns associated with Mr. O'Brien's practice,
14 including notably his failure to triage urgent and
15 routine referrals and his backlog of dictation
16 following clinical encounters. It was concerns such as
17 these and their implications for patient safety which
18 appear to have caused the Trust to instigate an MHPS
19 investigation in 2017.

10:03

10:03

20
21 Witnesses suggested that some of those concerns may
22 have been known to management and colleagues within the
23 Trust for many years.

10:04

24
25 In our last module, Governance in Action, which
26 completed last week, the Inquiry explored aspects of
27 the clinical governance arrangements which operated
28 within the Southern Trust. Against the backdrop of the
29 reported shortcomings and concerns, and having regard

10:04

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

10:04

5
6 Taken together, the evidence received by the Inquiry to
7 date will assist you, the panel, to gauge the
8 effectiveness and robustness of the Trust's frameworks
9 for identifying and challenging practice which may
10 depart from acceptable standards and its ability to
11 effectively provide for safe and reliable patient care
12 within the urology specialty.

10:04

13
14 The module which commences today and which we plan to
15 run until 4th December, will focus on the practice and
16 delivery of urology services within the Southern Trust.
17 Importantly, it will be possible, indeed necessary, to
18 scrutinise the practice and delivery of those services
19 by reference to the instruments of governance. Those
20 systems and structures, practices and procedures which
21 ought to be in place to underpin patient care and
22 safety.

10:05

10:05

23
24 The witnesses who are to be called during this module
25 are clinicians who have engaged with, or worked within
26 the Trust's urology service, and who will be able to
27 describe the practices of that specialty, how it
28 functioned and the difficulties which it faced. They
29 include a number of consultant urologists, as well as

10:05

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

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

17
18 The module is directed to a number of overlapping
19 requirements of the Inquiry's Terms of Reference. Part
20 A of the terms of reference encourages interest in 10:06
21 whether relevant complaints or concerns existed prior
22 to May 2020 which ought to have alerted the Trust to
23 commence an earlier investigation.

24
25 Part C of the terms of reference places the focus 10:07
26 squarely on the governance of patient care and safety
27 within the urology specialty using the vehicle of the
28 serious adverse incident cases and any other cases of
29 concern.

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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.

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.

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.

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

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

8
9 It will be necessary to investigate whether and how
10 patient safety was promoted by the clinicians who 10:09
11 worked within, or engaged with Southern Trust's urology
12 service. We will seek to explore what steps were taken
13 to address risk and to challenge the behaviour which
14 placed patients at risk.

15 10:09
16 The Southern Trust urology team had its own instruments
17 for communication, governance and learning. These
18 included departmental meetings, a patient safety
19 committee, and the urology cancer multidisciplinary
20 team meeting. The work of the team was performed 10:09
21 within a clinical governance framework which provided a
22 system to report practices or incidents which gave rise
23 to harm or risk of harm.

24
25 The Inquiry will wish to use the further evidence which 10:10
26 it will now receive to determine how well these
27 arrangements worked and to support its findings on the
28 governance of patient care and safety.
29

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

13
14 Towards the latter part of the Inquiry's programme for
15 this term, we will hear from a number of witnesses who 10:11
16 have contributed to the work of the Trust's Board,
17 notably its current Chair, Ms. Eileen Mullan, and its
18 former Chair, Mrs. Roberta Brownlee.

19
20 The Inquiry Terms of Reference at Part B require an 10:11
21 assessment to be made of the role of the Board,
22 particularly in the context of patient care and safety,
23 and we will turn our attention to that during the first
24 week of December.

25 10:11
26 Madam Chair, members of the panel, I hope that sets out
27 in broad terms the aims of this module which we are
28 formally opening today and which we will start by
29 hearing the evidence from Dr. Mitchell.

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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.

10:12

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.

10:12

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.

10:12

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

10:12

10:12

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

10:15

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

10:15

11 A. I'll try and speak up.

12 5 Q. That's fine. I might need to slow down, and you might
13 need to speak up, but we'll get there. So if I could
14 just ask you to do that, first of all, and then we'll
15 move through the issues in chronological order as best
16 we can. But just to give us a flavour of your
17 expertise?

10:15

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

10:15

10:16

1 prostate brachytherapy clinical fellow.

2

3 I had a brief few months of locuming in Limerick before
 4 obtaining a full substantive post in clinical oncology
 5 in Belfast, and that was June 2008, and I've been there 10:16
 6 since that time.

7 6 Q. So, 15 years you've been based in the Belfast Trust?

8 A. Yeah.

9 7 Q. And what is your particular area of specialty now?
 10 what is it that you do? what service do you provide? 10:17

11 A. So, I am a clinical oncologist with a special interest
 12 in urological cancers. As a clinical oncologist, that
 13 means I cover both chemotherapy treatments and
 14 radiotherapy treatments for prostate, bladder, some
 15 renal work, and some testicular radiotherapy work. As 10:17
 16 a special niche within that radiotherapy, I am one of
 17 two prostate brachytherapists working in Northern
 18 Ireland, and myself and my colleague would accept
 19 referrals across Northern Ireland for patients who are
 20 deemed suitable or want consultation on what prostate 10:17
 21 brachytherapy is.

22 8 Q. And who is your colleague in that specialty?

23 A. It's Prof. Suneil Jain.

24 9 Q. And the way in which people find their way to you, in
 25 particular with your prostate brachytherapy specialty 10:18
 26 is that either they're referred from other Trusts or
 27 through other consultants, is that how your process of
 28 people entering your particular area of care works?

29 A. So all patients will have been discussed at the multi

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

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

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

22 11 Q. Now, you mentioned that you've been in The City from
 23 2008?

24 A. (Witness Nods).

25 12 Q. And that seems to be, from your statement, the 10:19
 26 timeframe, the start of the timeframe of interest for
 27 matters that might be relevant for the purposes of the
 28 Inquiry, and so I want to look at that. I'll look at
 29 the period from which you identify as 2008 to 2014, we

1 call that the Bicalutamide 50 issue.

2 A. Yes.

3 13 Q. We'll move onto the 2014 e-mail to Mr. O'Brien. Then
 4 at 2015, you were involved in drafting, or you drafted
 5 the Regional Hormone Therapy Guidelines and just a 10:20
 6 little bit of context about that and the motivation for
 7 that.

8 A. Yeah.

9 14 Q. And then in 2016 there was an alleged delay in the
 10 muscle invasive bladder cancer case from Craigavon and 10:20
 11 you again wrote to Mr. O'Brien directly. So, there are
 12 three main highlights in relation to your evidence that
 13 touch upon the issues that we're interested in. So I
 14 want to go straight into the Bicalutamide prescribing
 15 issue. And I wonder if we could start off by going to 10:20
 16 WIT-96819? This is a record of your interview with
 17 Dr. Hughes and Patricia Kingsnorth on 23rd February
 18 2021. This is a document I think you're familiar with?

19 A. Yes.

20 15 Q. It was sent to you as well at the time. And this is 10:21
 21 the, as I said, the background is that they were
 22 speaking to you about the SAIs they were involved in
 23 looking at at the time. So, just the second paragraph
 24 there, the background to your involvement. So when you
 25 were speaking to Dr. Hughes you said this note: 10:21

26
 27 "Dr. Mitchell advised he was aware of issues going back
 28 a decade in relation to immunotherapy prescribing,
 29 prescribing outside guidelines and Bicalutamide.

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

4
5 -- "Mr. OB" it says there:

10:21

6
7 "...on his use of Bicalutamide. He escalated this to
8 his clinical lead, Chris Hagan, and the decision was
9 made to develop a guideline for the use of ADT in the
10 hope this would address the issues. This guideline was
11 presented when Mr. OB was Chair of the NCCN Urology
12 Group and he signed off on the guidelines."

10:22

13
14 That paragraph is a pithy explanation of the funneling
15 of the issues. So whenever you first started in 2008,
16 as I understand it, you were referred patients who had
17 been or were on Bicalutamide 50 as a monotherapy and
18 this drew your attention to this issue. Could you just
19 give us the context in your own words of how you first
20 became aware of this?

10:22

10:22

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

10:23

1 needed any hormone treatment, or if they weren't having
 2 brachytherapy, if they were having some other
 3 treatment, then I would have written back to the GP,
 4 copied the referring consultant to say that I was
 5 keeping them on Bicalutamide but at a correct dose of 10:23
 6 150mg. At least that's my memory of how I would have
 7 phrased the reply letter. I would have taken the
 8 patients then through their chosen treatment.

9 16 Q. So, in relation to sequencing, we'll go to the 2014
 10 e-mail just in a moment. The context that led to that 10:24
 11 was that you were getting referrals from patients who
 12 were on Bicalutamide 50. As you've said, you adjusted
 13 the dose to 150?

14 A. (Witness Nods).

15 17 Q. And we'll look at that in a moment. But that was an 10:24
 16 indication in 2014, when you thought about it you
 17 realised that this issue had been going back to 2008.
 18 Is that what your evidence is?

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

25 18 Q. Well, just as a baseline for your evidence, what's your 10:24
 26 understanding of the dosage that should be prescribed
 27 in relation to Bicalutamide?

28 A. So, the Bicalutamide falls into two doses; we have
 29 150mg once a day, which can be used as a monotherapy,

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

10:25

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

8 19 Q. And your concern at the time and on reflection was that
 9 some patients were being prescribed Bicalutamide 50 as
 10 a monotherapy and your understanding was that that was,
 11 was it suboptimal or unlicensed? what was your view on
 12 that?

10:25

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

14 20 Q. Now, if a patient is given an unlicensed dose, if
 15 they're given Bicalutamide 50 as a monotherapy, what's
 16 the impact of that? what's the issue for you as a
 17 clinician when you see that, if you don't think it's
 18 clinically mandated?

10:26

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

10:26

25 21 Q. How would delay come around because they're on
 26 Bicalutamide 50?

10:26

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

- 1 not referred, then you begin to worry at what point
 2 they're going to be referred, is that going to be at a
 3 point of resistance with rising PSA levels whilst on
 4 Bicalutamide 50? So, resistance and perhaps poor
 5 outcomes with subsequent treatment would be the 10:27
 6 concern.
- 7 22 Q. Now, you've mentioned resistance. As I understand it,
 8 that's almost a tolerance that builds up on long-term
 9 low dose monotherapy like Bicalutamide 50, the impact
 10 of which is that if the patient does need a higher dose 10:27
 11 or a greater impact of that at a later stage, that they
 12 may be resistant to that clinical regime?
- 13 A. Yeah, less likely to work.
- 14 23 Q. Now, just again to set the baseline of your
 15 recollection before I ask you some details about what, 10:28
 16 in particular, issues were. Do you recall any of the
 17 patients that you came across who were on this
 18 Bicalutamide 50mg monotherapy in what you consider to
 19 be an inappropriate drug regime?
- 20 A. No, I couldn't recall the patients between my - I 10:28
 21 started as consultant in 2014, and as I've been
 22 involved in the subsequent discussions it would be
 23 quite easily be mixed up with other cases that have
 24 been discussed and reflected on. But I couldn't recall
 25 patients between 2008 and 2014 specifically. 10:28
- 26 24 Q. What you're referring to there, just for the
 27 transcript, is your later involvement with Mr. Haynes?
- 28 A. Yes.
- 29 25 Q. In looking at patients who were on Bicalutamide 50 and

1 looking at whether that was appropriate treatment
 2 regime later on?

3 A. Yeah.

4 26 Q. But for the purposes of the period of 2008 to 2014,
 5 just in that period, do you recall names of patients? 10:29

6 A. No.

7 27 Q. For the record? Do you recall age groups of the
 8 patients? It probably lends itself to be older men,
 9 does it, or any trigger of any memory at all?

10 A. No. 10:29

11 28 Q. No. Do you understand there to be any circumstances in
 12 which Bicalutamide 50 is prescribed as monotherapy?

13 A. No, I'm not aware of any evidence base for Bicalutamide
 14 50 as a monotherapy in prostate cancer management.

15 29 Q. Now, Bicalutamide 50 can be used in what way? You tell 10:29
 16 me. What way is that prescribed?

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

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

5 10:31

6 The second scenario is for patients who are established
 7 on those hormone injections typically have advanced
 8 prostate cancer or prostate cancer that has spread, in
 9 other words metastatic prostate cancer. The hormone
 10 injections are beginning to fail, the PSA is rising, 10:31
 11 and the Bicalutamide 50 can be used as an add-on to
 12 those injections, and that's usually referred to as
 13 combined androgen blockade or maximum androgen
 14 blockade.

15 10:31

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

19 30 Q. And although you don't recall anything about the
 20 patients who you, on reflection, considered to be being 10:31
 21 prescribed inappropriately Bicalutamide 50 in
 22 monotherapy, they didn't fall within either of those
 23 two options that you've just describe?

24 A. No, they wouldn't have had a point where they were
 25 about to be commenced on a hormone injection, or where 10:32
 26 they've had failing disease whilst on hormone
 27 injections requiring additional treatment, they were
 28 coming de novo for discussion of radical therapy.

29 31 Q. Now, you've mentioned in your statement that there were

- 1 a few patients; do you have any better idea of numbers?
- 2 A. I suspect it was two or three cases over the period of
- 3 the five or six years. But it would have been that
- 4 small quantity of men within that time.
- 5 32 Q. Now, you've timed it to go back at 2008 when you first 10:32
- 6 started at the Trust. Did it go back that far or was
- 7 it just you thought, "well, I've moved here at that
- 8 time and perhaps it started then", but do you have a
- 9 recollection of a timeframe for us?
- 10 A. I don't remember anything prior to that in my training 10:33
- 11 as a registrar within the oncology system in Northern
- 12 Ireland. I'm aware that there would be other
- 13 consultants who were - who had a more formal role in
- 14 covering the urology service at the Southern Trust and
- 15 they may have had more experience. But I had no 10:33
- 16 experience prior to 2008.
- 17 33 Q. Now, you did mention in the very beginning with your
- 18 answer, you talked about the referrals of the GP and
- 19 the alteration of the prescription.
- 20 A. (Witness Nods). 10:33
- 21 34 Q. If you can recall, what was your view when you first
- 22 saw that prescribed in that way?
- 23 A. I think I saw it as a prescription error that simply
- 24 the wrong dose had been chosen and it should have been
- 25 correctly 150mg once a day rather than 50. 10:33
- 26 35 Q. And would this have been apparent to you by the
- 27 referral letter from the referring consultant?
- 28 A. Yeah, or the patient bringing their medication list
- 29 with them.

- 1 36 Q. And was there one consultant who you noticed a
 2 repetition on this issue?
- 3 A. Yeah, on reflection, I didn't see any Bicalutamide 50mg
 4 coming from other consultants, so, yes, Mr. O'Brien was
 5 the only consultant who appeared to be making this 10:34
 6 error.
- 7 37 Q. And when you saw the first one and you thought that,
 8 you know, "That's an error, I'll change that around",
 9 you've said the process was for you to send a letter to
 10 the GP, effectively ordering a new prescription for the 10:34
 11 correct dose.
- 12 A. (Witness Nods).
- 13 38 Q. And do you copy that letter to, copy that letter to the
 14 consultant, the referring consultant?
- 15 A. Yes, always. 10:34
- 16 39 Q. So if that was the first one that you saw, then when
 17 you saw the second one, whenever that was, because
 18 we're working in a six year timeframe, whenever you saw
 19 the second prescription for Bicalutamide 50, in
 20 circumstances in which you considered that that wasn't 10:35
 21 clinically appropriate, did you have an instinct then
 22 or did you have any sense that perhaps this isn't an
 23 error or there's another error? What was your
 24 response?
- 25 A. Again, it's a long time ago. The cases that I would 10:35
 26 have seen would have had a time period between them,
 27 and on reflection I should have picked it up as a
 28 systemic error. But I think I would have listed that
 29 as the same error again rather than a frequent

1 prescribing inaccuracy.

2 40 Q. Did Mr. O'Brien ever contact you after you changed the
3 treatment regime?

4 A. No.

5 41 Q. Did you ever contact him before 2014? 10:35

6 A. No.

7 42 Q. Did you ever have cause to follow-up with these
8 particular patients to find out if they had in fact
9 stayed on your new treatment regime?

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

18 43 Q. You've mentioned two of the possible adverse effects of
19 Bicalutamide 50 monotherapy being prescribed in an
20 inappropriate way, as you say; one is potential delay 10:36
21 and the other one is resistance. Is there also, given
22 that it is not licensed in that way, is there also the
23 potential that it is suboptimal treatment for people
24 and that they may actually, the disease may progress
25 more rapidly, not be effectively treated? Is this a 10:37
26 suboptimal, ineffective treatment regime in your view?

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

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

9 44 Q. Did you see it as representing any potential for
 10 patient harm or risk? 10:38

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

17 45 Q. Just to tease that out a little bit more. Just from a
 18 sort of a common sense point of view, would there be
 19 any potential that people who are not being treated
 20 appropriately for the diseases that they have are being 10:38
 21 placed on a drug regime which has not proven to be
 22 effective in the way that it needs to be for them, that
 23 that in itself is a patient safety concern?

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

26 46 Q. And should that have been picked up by you?

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

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

3 47 Q. Now, I know it's a 2008 to 2014 timeframe, things have
 4 changed and governance structures have changed, but at
 5 that time, what do you think would have been an 10:39
 6 appropriate response to what you had come across at
 7 that time? what do you think you might have done, or
 8 should have done, or could have done?

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

11 48 Q. And who was that?

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

17 49 Q. You've mentioned the GP letter; would the dosage of
 18 Bicalutamide 50 as a monotherapy, would that be widely
 19 known among GPs as perhaps an inappropriate drug regime
 20 on its own? 10:40

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

27 50 Q. Now, you were starting off your consultancy in 2008; do
 28 you recall at that time what the governance processes
 29 in place were? Now we have SAIs, IRIs, we've DATIXs.

- 1 Do you recall any of those? Are they familiar at that
2 time to you at all?
- 3 A. No, my knowledge of governance processes is poor, so I
4 wouldn't recall, and that's why I would speak to
5 someone who had more experience, such as the Clinical 10:41
6 Director.
- 7 51 Q. At the time when you were receiving referrals from
8 consultants, including Mr. O'Brien, what was the
9 process by which those referrals were divided up among
10 you and your fellow consultants? Were some of them 10:41
11 named to you, for example?
- 12 A. So these patients were coming through for a prostate
13 brachytherapy opinion, initially I would have been the
14 only consultant, so would have been named. I can't
15 quite remember when Prof. Jain returned from his time 10:41
16 in Canada doing brachytherapy, but I suspect there
17 would have been named referrals to him as well, but
18 they would have been direct named referrals to me for a
19 brachytherapy opinion.
- 20 52 Q. Do you recall if the ones that you remember being 10:42
21 Bicalutamide 50mg, do you remember if they were named
22 to you?
- 23 A. I would expect that they were, but I don't recall.
- 24 53 Q. So, there was just the two of you at that time in
25 brachytherapy, is that right? 10:42
- 26 A. I was a standalone practitioner for a couple of years,
27 and then laterally Prof. Jain completed training and
28 came back and started.
- 29 54 Q. What I'm trying to find out really is the potential for

- 1 other people to be receiving referrals with the same,
2 you say, clinical error on it. Are you saying that
3 that's a very limited possibility due to the fact that
4 you only got referrals for your specialism or were
5 there others who might have been receiving letters with 10:42
6 the same prescription on them?
- 7 A. So, I would have been seeing a fairly small group of
8 patients who fitted the correct criteria for
9 brachytherapy, and there would have been a number of
10 clinical oncologists who were job planned to provide 10:43
11 cover for urology in Craigavon, and they would have
12 seen a greater number of cases. By proportion, I would
13 have expected that they might have seen more cases of
14 Bicalutamide 50.
- 15 55 Q. Did you ever discuss what you had seen with others in 10:43
16 and around this timeframe?
- 17 A. Not that I remember. I think having decided it was a
18 prescription error, I didn't necessarily see a point of
19 asking them at that stage.
- 20 56 Q. Did anyone mention it to you, come to you and say "Is 10:43
21 this something you've noticed?"
- 22 A. So, the 2014 case which prompted the e-mail is the
23 first one that I can really look back and remember
24 discussions. If there were discussions before that,
25 they were informal. But I have no memory of that. 10:44
- 26 57 Q. Now, when you changed the treatment regime for these
27 patients to 150, did you explain to the patients that
28 there would be a change in their regime?
- 29 A. So, again, I can tell you what my believed practice

1 was. So, yes, I'd have said that the correct dose is
 2 150mg and it's for this period of time and here's the
 3 treatment we're offering. I don't necessarily believe
 4 I would have said to them that it was an error or a
 5 deliberate action, I would simply have said that it was 10:44
 6 the correct dose at 150.

7 58 Q. So, from their perspective, they were getting a new
 8 prescription?

9 A. Yes.

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

11 A. Increased. Yeah.

12 60 Q. And were there possible side effects in this increased
 13 dose that the patients were now being put on, or
 14 adverse effects of any type?

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

19 61 Q. Now, we'll come on to mention - you used the word
 20 "misled", I think? 10:45

21 A. Hmm.

22 62 Q. And you believe that the patients were misled. Can you
 23 give us a little bit more context to that statement?

24 A. I think this probably works more around the e-mail in
 25 2014. My subsequent involvement in the cases that were 10:45
 26 coming through the review process, it didn't appear
 27 that patients were informed that Bicalutamide 50mg
 28 monotherapy, that they were informed that that was an
 29 off licence prescription. So I saw that as the first

1 point where they were not informed correctly.

2 63 Q. Are you speaking about the review, the subsequent
3 review?

4 A. Yeah.

5 64 Q. You're not speaking about the 2014? 10:46

6 A. No.

7 65 Q. No.

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

12

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

23 66 Q. And was the delay because the commencement on that
24 treatment was considered a start of a treatment?

25 A. Yes. 10:47

26 67 Q. We'll just go to the e-mail of 2014, please.
27 WIT-96668, please. That's your statement. Sorry, my
28 apologies. The e-mail is at, sorry, AOB-71990. That's
29 the reference where you mention the e-mail in your

1 section 21.

2 A. Yeah.

3 68 Q. Hopefully this is the correct... Okay.

4 A. Yeah.

5 69 Q. So this is an e-mail that you -- you had received a 10:48
6 referral, you were now Regional MDT Chair in 2014. Had
7 you just taken up that post that year?

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

9 70 Q. And this e-mail is dated 20th November.

10 A. Yeah. 10:48

11 71 Q. It's from you to Mr. O'Brien. And we can see that
12 patient, the cipher at the top, Patient 126. And it
13 says:

14

15 "Ai dan, 10:48
16 Could I ask you to have a look at this case which was
17 passed to me as the Regional MDT Chair? It looks like
18 a young man with high grade organ confined disease from
19 2012. From my perspective, he would have been
20 considered... " 10:48

21

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

23 A. Neoadjuvant.

24 72 Q.

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

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-- adjuvant?

A. Adjuvant.

73 Q.

"...adjuvant hormonal therapy after EBRT, depending on 10:49
2008 or 2014 NICE Guidelines and patient tolerance.

I am not aware of his comorbidities or performance
status.

As hormonal therapy in this case we would use LHRHa or 10:49
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 10:50
protocol, and based on those studies we typically think
of 6 months neoadjuvantly in this kind of case.

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

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

1 the first year of his management.

2
 3 The NCCN hormone protocol (in process) would be useful
 4 in standardising our therapy across the region but
 5 Bicalutamide 50mg is not licensed for monotherapy use 10:50
 6 and will not be recommended in the protocol other than
 7 within the licensed context for the management of flare
 8 with LHRHa.

9
 10 The MHRA site provides information on off-label 10:51
 11 prescribing and our responsibilities within that."

12
 13 And then you've included, I presume it's a hyperlink to
 14 that?

15 A. Yes. 10:51

16 74 Q. "Happy to discuss this further."

17
 18
 19 And "DMM", that's you?

20 A. (Witness Nods). 10:51

21 75 Q. Now, just to - a lot of - just to translate this into
 22 English. But just in relation to MHRA site where you
 23 have provided the hyperlink, could you just explain
 24 what that is?

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

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

10:52

8
 9 So, it seemed like an appropriate thing to reference
 10 when I was sending this e-mail.

10:52

11 76 Q. So you've set out the history of the clinical
 12 presentation of the patient and, also, in relation to
 13 our purposes, the Bicalutamide 50, that the patient has
 14 been on it, that it is not licensed for monotherapy in
 15 the way in which this patient was on it?

10:52

16 A. (Witness Nods).

17 77 Q. That there has been - he's been on it for the first
 18 year of his management, and there has been - just move
 19 up, please:

20
 21 "...and the patient has just, only just been referred
 22 for radiotherapy at 2 years after initial MDT
 23 presentation."

10:53

24
 25 Is this an example of what you had talked about earlier
 26 in your evidence where commencing on a treatment regime
 27 such as this can result in what appears to be, is it a
 28 considerable delay?

10:53

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

- 1 longer than we would have wanted or have any evidence
2 base for when we're giving external beam radiotherapy.
3 So this doesn't fit with any of our protocols.
- 4 78 Q. Now, you've said at the top of the e-mail that it's
5 been passed to you, this particular case. Do you 10:53
6 remember who it was passed from?
- 7 A. Again, I believe this was Prof. Suneil Jain who had
8 reviewed this case, and as a colleague, a slightly more
9 senior colleague than him, he had brought the case,
10 we'd had a look at it, and I think it's badged as being 10:54
11 sent by me as the Regional Chair, but it may be more
12 correctly as a more senior colleague. So, I believe it
13 was Prof. Jain that saw this case initially.
- 14 79 Q. And when this was brought to you, you mentioned earlier
15 this morning that it was on reflection in 2014 that you 10:54
16 thought "I've seen this before". Is this the
17 crystallisation of that point?
- 18 A. It was, yeah.
- 19 80 Q. Now, in your role as Regional MDT Chair, does it fall
20 under your responsibility to undertake this sort of 10:54
21 task of having identified a clinical concern to contact
22 the consultant about that?
- 23 A. I think if there's clinical concern raised through the
24 MDM/MDT process, then we do have responsibility to
25 address those issues. I don't remember this case being 10:55
26 discussed through the regional meeting, so technically
27 I don't know that it was a regional share issue. There
28 was, however, potential that there would be other cases
29 which would become important for us as a regional MDT,

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

3 81 Q. Had you ever had to send an e-mail like this before to
 4 a consultant or since?

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

9 82 Q. In what way taken aback?

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

18 83 Q. And do you reflect on that as being evidence of the
 19 strength of your concern, or was it that you wanted to
 20 make sure that you were on a firm footing before you 10:56
 21 sent the e-mail off?

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

1 quite shocked at, at the forthrightness of the
 2 approach.

3 84 Q. I just want to look at the governance issues around
 4 this from two different perspectives. The first one
 5 really is the way in which it got to you, the way it 10:57
 6 was brought to you as the Regional MDT Chair. As a
 7 governance process, when another clinician identifies a
 8 concern, do you think coming to you as the Regional MDT
 9 Chair to deal with that is an appropriate response in
 10 this scenario? 10:57

11 A. If it's a non MDT issue then I think it goes to
 12 Clinical Director rather than MDT. If it's a problem
 13 with an MDT decision, or something that the MDT should
 14 have had action on, then we would follow the
 15 appropriate channels. And during my tenure as MDM 10:57
 16 Chair, we had a number of cases that we had to take
 17 through the appropriate governance processes. Again,
 18 my knowledge of governance is poor, so for those
 19 particular cases I'd have gone to the service manager,
 20 who was my line manager within the MDM, raised it, and 10:58
 21 followed the appropriate avenues.

22 85 Q. I suppose the two examples you've provided, this
 23 doesn't fit in either of those. It's not an MDT
 24 decision-making issue and it's not one that falls
 25 outside the regional MDT framework. This is a 10:58
 26 clinician having concerns about the clinical package of
 27 care, and various aspects of that --

28 A. Yes.

29 86 Q. Which we don't need to go into. But certainly the

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

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

18 87 Q. We can just look at that, where you forwarded that,
 19 just for the panel. WIT-96678. So you sent this
 20 e-mail just to Mr. O'Brien, didn't copy anyone, but you 11:00
 21 then let your colleagues know that "This is what I've
 22 done"?

23 A. I had acted, yeah.

24 88 Q. And this is the retrieved e-mail that shows on 20th
 25 November. You sent it, as you say, to Lucy Jellett, 11:00
 26 Joe O'Sullivan, and Dr. Jain, and you say:
 27
 28 "Lucy, Joe, Suneil,
 29 I have e-mailed Aidan to open a discussion on this

1 case, copy below for your information."

2

3 And just for completeness, if we just go to the e-mail
 4 below the panel will see that that's the e-mail to
 5 Mr. O'Brien. If you just go back up, please. Now, who 11:00
 6 was your Clinical Director at that point in November
 7 2014, do you recall?

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

13 89 Q. And so your Clinical Director is aware then, you've
 14 copied him in to show him what you have done?

15 A. (Witness Nods). 11:01

16 90 Q. Did you have discussions with him or any of the other
 17 cc'd individuals prior to sending the e-mail to inform
 18 the contents of it or the tone?

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

27 91 Q. But he factually was your Clinical Director?

28 A. I believe so.

29 92 Q. And we'll hear from him tomorrow. And I think the

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

3 A. (Witness Nods).

4 93 Q. Did he ever come to you after and say "Did you get a
5 reply to that e-mail, or if you haven't received a
6 reply I maybe need to speak to my counterpart in the
7 trust, the Southern Trust"? Did those conversations
8 ever take place?

11:02

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

11:02

14 94 Q. Well, you've said to your colleagues that you wanted to
15 open discussion on this case. Was it your view that
16 you anticipated either an e-mail in reply, or perhaps a
17 phone call or some communication from Mr. O'Brien to
18 explore some of the suggestions you had made in your
19 e-mail?

11:02

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

11:03

11:03

29 95 Q. And in some respects, the protocol and the guidelines

1 that were anticipated through NICAⁿ were more in the
2 abstract; what was here was a specific patient clinical
3 concern.

4 A. (Witness Nods).

5 96 Q. Was there any suggestion from you or any of your 11:03
6 colleagues or your Clinical Director, Prof. O'Sullivan,
7 that this needed followed up in the absence of a reply?
8 Did you ever receive a reply?

9 A. No.

10 97 Q. Mr. O'Brien didn't contact you at all about this? 11:04

11 A. No.

12 98 Q. In that -- given that, was there any movement at all
13 from you or your colleagues, or did you have a
14 conversation and think, you know, we need to maybe
15 pursue this, or perhaps we need to speak to other 11:04
16 consultants and see what's happening?

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

23 99 Q. Can we take from your answer that you've just given
24 that the referrals to you after this e-mail reduced, or
25 -- 11:05

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

28 100 Q. Do you recall after this e-mail ever receiving a
29 referral from Mr. O'Brien?

- 1 A. I suspect that I did. But the brachytherapy practice,
 2 we tend not to use hormone treatments, so the
 3 particular prescription issue that we're discussing may
 4 not have come through those referrals.
- 5 101 Q. So you didn't see another patient with Bicalutamide 50 11:05
 6 as a monotherapy post this e-mail?
- 7 A. Not that I remember. And I think it was then the
 8 subsequent cases that again were being flagged up by
 9 Prof. Jain that then prompted the different avenue of
 10 approach. 11:05
- 11 102 Q. When you didn't get any more referrals around this
 12 issue, is there a possibility that it perhaps
 13 engendered a false sense of security that the issue had
 14 been dealt with and had simply gone away?
- 15 A. I think the answer is yes, in truth, with a busy 11:06
 16 clinical practice, and this wasn't top of the things
 17 that I was doing, and as time went on and not seeing
 18 the issue again, it simply moved to the bottom of the
 19 list, until the subsequent cases were raised.
- 20 103 Q. Now, if this issue was to materialise as it is now, 11:06
 21 what would you expect the governance processes, how
 22 would you expect it to operate to deal with this?
- 23 A. I think I'm a bit older, a bit wiser, I'd have a bit
 24 more of an expectation that this really needs to go
 25 further, be more direct, likely have a face-to-face 11:06
 26 discussion or phone call regarding the prescription
 27 error, seeing it as a systemic error and take it to the
 28 Clinical Director. So, I would have a different
 29 approach now as to what I did ten years ago.

1 104 Q. Now, Prof. O'Sullivan does mention a conversation with
2 you in his statement, and if we just go to that at
3 WIT-96650. And just to round off the point about the
4 Thursday morning clinic, at paragraph (ix). So he's
5 asked: 11:07
6
7 "Please give details of any discussions you had with
8 Dr. Mitchell regarding shared concerns."
9
10 And he says: 11:07
11
12 "Dr. Mitchell, as Chair of the Urology MDT, raised
13 concerns in 2014 to Mr. O'Brien in relation to a
14 particular case which had been referred to the MDT and
15 was receiving Bicalutamide 50mg daily as monotherapy 11:07
16 for prostate cancer. At that time, I mentioned to
17 Dr. Mitchell about the historical cases I had
18 remembered from my early years as a consultant in
19 Belfast. This discussion would have taken place at one
20 of our Thursday morning pre clinic meetings at the 11:08
21 Northern Ireland Cancer Centre."
22
23 Now, we take from that evidence that Prof. O'Sullivan
24 also had historical cases which he remembered, and is
25 it your recollection that they were around the 11:08
26 Bicalutamide 50 monotherapy issue?
27 A. I would suspect so, and I think that's why the e-mail
28 in 2014 were formulated, because it became more
29 apparent as a widespread issue, and that particular

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

3 105 Q. Did you ever discuss it with him at all after, that
 4 there might be a possibility that the suboptimal
 5 prescribing of Bicalutamide 50 as a monotherapy was 11:09
 6 continuing, given the silence, the absence of a reply
 7 to the e-mail, and no indication that a discussion was
 8 willing to be started from Mr. O'Brien?

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

12 106 Q. Just before we move onto the guidelines, you've
 13 indicated the guidelines, I think were almost in the
 14 back of your mind as a potential route to try and
 15 address this in another way; would that be a fair 11:09
 16 reflection on your thinking at the time?

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

22 107 Q. Well, we'll move on to those just in one second. I
 23 don't mean to interrupt you, but just to finish off
 24 this point and then we'll look at those, the
 25 guidelines, in a bit of detail. It's the patients 11:10
 26 misled point that I mentioned earlier, I just want to
 27 make sure the panel have a reference to that.
 28 WIT-96671, and paragraph 4(iii). You're asked the
 29 question, this is a comment to Dr. Hughes:

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"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?"

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.

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

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

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

1 sentence:

2

3 "This outlines our responsibilities as prescribers to
4 use medication within licence and if a decision is made
5 to use medication outside its licensed indication or 11:12
6 dose then good practice may inform the patient of
7 that."

8

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

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

19 108 Q. And that's the latter part of your involvement?

20 A. Yes. 11:13

21 109 Q. 2019/2020.

22 A. Yes.

23 110 Q. If we go back to your earlier involvement, when you saw
24 the patients that you did in the early years...

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

26 111 Q. Did you form a view at that point of any of those
27 patients that you saw prior to 2014, whether these
28 patients had come to harm due to being prescribed
29 Bicalutamide 50mg daily for a period of time, in your

- 1 view?
- 2 A. So from the limited memory I have of those cases, I
 3 don't remember there being a particular delay in their
 4 referral, and I would see the delay as the greater
 5 issue than the dose prescription, because we would have 11:13
 6 had opportunity there because there wasn't delay to
 7 make a correction to the dose.
- 8 112 Q. Just come back to your point about what can be given if
 9 you step outside the licensed indication for
 10 medication. I just want to ask you, do you accept that 11:14
 11 it is acknowledged that Bicalutamide 150mg daily may be
 12 prescribed for patients with metastatic disease and who
 13 wish to maintain physical and sexual function but that
 14 this is not a licensed indication?
- 15 A. Yes. 11:14
- 16 113 Q. You may not be aware of this reference, but I'm going
 17 to read the question to you and you can comment. If
 18 you don't know then please just say. Do you
 19 acknowledge that the section of oncology of the British
 20 Association of Urological Surgeons recommended in March 11:14
 21 2020 that patients with localised low and intermediate
 22 risk prostate cancer could be prescribed Bicalutamide
 23 50mg daily while awaiting definitive management that
 24 had been deferred because of the Covid-19 pandemic,
 25 even though it was not a licensed indication? 11:15
- 26 A. I'm aware of that and not aware of the evidence on
 27 which it was based. And it was during a particularly
 28 difficult time period for us as a service.
- 29 114 Q. And it doesn't fall within the period that we're

1 discussing for the purposes of your evidence?

2 A. No.

3 115 Q. So, you would accept, therefore, given your answers,
4 that there may be circumstances when it is acceptable
5 to prescribe Bicalutamide for unlicensed conditions? 11:15

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

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

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

19 117 Q. And that's evidenced by the fact that you changed it?

20 A. (Witness Nods). 11:16

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

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

25 11:16

26 SHORT ADJOURNMENT

27

28 CHAIR: Thank you everyone.

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

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

4 A. Yes.

5 118 Q. And we're at 2015 at this point. 11:33

6 A. (Witness Nods).

7 119 Q. So you've seen a few cases, you've sent the e-mail of
8 2014, we've now moved on to the Regional Guidelines.
9 And just to put some background in context on this, I
10 just want to go to a couple of extracts from your 11:33
11 interview with Dr. Hughes in February 2021. The first
12 one is at WIT-96819. Just these paragraphs aren't
13 numbered, so it's a bit more difficult to find. I
14 think we're just at the top of the screen on the second
15 sentence: 11:34

16
17 "Dr. Mitchell advised he took over as Chair of the
18 Cancer Group in 2015. He advised that they had
19 challenged Mr. OB on his use of Bicalutamide. He
20 escalated this to his clinical lead (Chris Hagan) and 11:34
21 the decision was made to develop a guideline for the
22 use of ADT in the hope this would address the issues.
23 This guideline was presented when Mr. OB was Chair of
24 the NCCN Urology Group and he signed off on the
25 guidelines." 11:35

26
27 Now, there's a reference there to you becoming Chair of
28 the Cancer Group in 2015. And you've taken the
29 opportunity in your statement to -- was it 2015?

1 A. No, I corrected this to Chair of the MDT in 2014.

2 120 Q. 2014. And the for the panel's note, that is at
3 WIT-96666, that correction. So, just a couple of parts
4 of this paragraph I just want to ask you about. You
5 had mentioned earlier that there had been a hope that 11:35
6 development of the guidelines would address the issues,
7 and the issues being the Bicalutamide 50mg monotherapy.
8 And the second issue is that you escalated the issue to
9 your clinical lead, Chris Hagan.

10 A. (Witness Nods). 11:36

11 121 Q. Now, I just want to ask you a little bit about that.
12 Do you recall having done that?

13 A. No, I don't remember the parenthesis. If it was
14 clinical lead, I think that would have been
15 Prof. O'Sullivan, but I don't think it was Chris Hagan. 11:36

16 122 Q. So, as far as these minutes are concerned, are they --

17 A. It would more correct to have Prof. O'Sullivan within
18 the parenthesis.

19 123 Q. You wouldn't have said Chris Hagan, would you?

20 A. No. We have a discussion in terms of other issues that 11:36
21 we did flag with Mr. Hagan, or Mr. Hagan flagged with
22 us laterally, so I suspect those two have got mixed up
23 within the time.

24 124 Q. I just wanted to check that.

25 A. Yeah. 11:36

26 125 Q. Obviously Chris Hagan is coming to give evidence this
27 afternoon, and I just wanted to - it sort of jumped out
28 slightly and I wasn't sure if it had been an error?

29 A. I think it was.

1 126 Q. So it more than likely is?

2 A. I think so.

3 127 Q. Now, you've said on that, in the last sentence of that
 4 paragraph, we'll go to the guidelines issue in a
 5 moment, but this guideline was presented when 11:37
 6 Mr. O'Brien was Chair of the NICaN Urology Group and he
 7 signed off on the guidelines. Is that your
 8 recollection, that once the guidelines had been
 9 presented that Mr. O'Brien did actually signed off on
 10 those? 11:37

11 A. So, I believed that the guidelines had been completed
 12 and that it was the responsibility of the NICaN Chair
 13 to then formally sign those off and adopt them. It
 14 wasn't until a number of years later that I was advised
 15 that actually there had been no action taken in signing 11:37
 16 off the guidelines, or my belief was that they had been
 17 signed off.

18 128 Q. So, there was no formal process by which those
 19 guidelines were adopted and signed off within the
 20 structures of the group? 11:38

21 A. Yes, I believe it would be a responsibility of the
 22 senior person requesting the guidelines to sign them
 23 off as part of that. But hence my statement to
 24 Dr. Hughes. So I believe that they had been signed off
 25 once complete. 11:38

26 129 Q. And I think you correct that in your statement. I
 27 don't need to go to this, but just for the panel's
 28 note, at paragraph 2.4, WIT-96670. Do you recall at
 29 the time that the guidelines were finalised, although

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

4 A. (Witness Nods).

5 130 Q. But do you recall that if, at that point, Mr. O'Brien 11:39
 6 was the Chair of NICaN Urology, or who was at that
 7 point?

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

12 131 Q. We'll just go to one of the - an example of one of the
 13 minutes at WIT-96683. The minute of 18th September
 14 2015. And we'll see those in attendance; Mr. O'Brien,
 15 you, Mark Haynes. Just names that might be familiar to 11:39
 16 the panel. And just when we go to "welcome and
 17 introductions":

18

19 "Aidan O'Brien welcomed everyone to the meeting and
 20 apologies were recorded." 11:40
 21

22 So that would indicate, would it, that Mr. O'Brien was
 23 the chair?

24 A. Yes.

25 132 Q. There are other minutes of NICaN meetings at the 11:40
 26 following: The minutes of 30th January 2015 are at
 27 WIT-96687 to 96692, and the meeting of 17th April 2015
 28 WIT-96693 to 96697. I will take you through the
 29 minutes of the meetings, but there doesn't seem to be

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

4 A. Not recorded on the minutes is correct.

5 133 Q. And it's your recollection that you took the 11:41
 6 opportunity in one of those meetings to raise that
 7 issue. Could you just tell us a little bit about that?

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

17 134 Q. We'll just go to where you say that in your statement
 18 at WIT-96669. Paragraph 1(ix). This is where you've
 19 mentioned the suggestion to Dr. Hughes that Mr. O'Brien
 20 had been challenged around the Bicalutamide 50, and 11:42
 21 we'd asked you a specific question in relation to that,
 22 and the question reads:

23
 24 "Please provide further details in respect of the
 25 suggestion that MDM challenged Mr. O'Brien on his use 11:42
 26 of Bicalutamide in 2015. In particular, please set out
 27 :

28 The nature and form of the said challenge;
 29 Who was present or otherwise involved in same and;

1 Mr. O'Brien's response.

2

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

6

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

8

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

12

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

15

11:43

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

22

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

27

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

1 A. That's my memory.

2 135 Q. The guidelines had -- had they reached their final
3 iteration at that point?

4 A. There were a few minor edits, as there were some
5 evolution in other hormone therapies coming on-line, so 11:44
6 there were a few things that were added in, but the
7 bulk of the work was within that.

8 136 Q. If we just go back to the notes of the minute at
9 WIT-96687. I just want to make sure I've got the date
10 correct. So this was - would this have been the next 11:44
11 meeting after that meeting on 3rd January 2015? How
12 often did you meet?

13 A. Quarterly, if there was a quorum.

14 137 Q. We'll just go down to the next page, please. So, it
15 might be that the date is wrong, is it 30th January as 11:44
16 opposed to the 3rd? It says: "A meeting on 3/1/2015"
17 in your statement. I'm just wondering if this is the
18 meeting that you're -- it must be if you meet
19 quarterly?

20 A. Yeah. 11:45

21 138 Q. There wouldn't have been another meeting so quickly
22 afterwards. So we can --

23 A. I can't imagine a meeting on 3rd January --

24 139 Q. And then the 30th again?

25 A. Yeah. 11:45

26 140 Q. So just we'll note that. So that's to be corrected in
27 the statement. And we'll see reference to the urology
28 guidelines and pathways at paragraph 3, it's headed
29 "Regional Hormone Therapy Guideline and Pathway", and I

1 just want to read this out:

2

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

5

11:45

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

9

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

11:45

14

15 A. Densitometry.

11:46

16 141 Q.

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

20

11:46

21 And the action point is:

22

23 "All members to forward comments on the draft guideline
24 and pathway by the end of February 2015."

25

11:46

26 And patient care pathways point:

27

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

1

2 So that reflects the discussion at the meeting.

3 A. (Witness Nods).

4 142 Q. Your recollection is that you took things further and
5 you've raised the point that these guidelines were
6 going to standardise the approach?

11:46

7 A. That's my memory as a single sentence comment, yes.

8 143 Q. It's clear from that paragraph that Mr. O'Brien was
9 engaged with the development of the guidelines.

10 A. There were a number of comments received from a number
11 of colleagues, and I think as part of the NICaN
12 meetings, as I say, there was an evolution of drugs
13 coming through at that stage. So there were a few
14 different edits until we finally got the document that
15 we were happy with. I'm also aware that Mr. O'Brien
16 had commented on some of my spelling errors as part of
17 the initial draft. So I do believe he had read the
18 guidelines.

11:47

11:47

19 144 Q. I think there was an e-mail - apologies to the panel, I
20 don't have reference to it - an e-mail about the
21 reference to license and licence, the difference
22 between the two words, to indicate that you had perhaps
23 made an error?

11:47

24 A. Yeah.

25 145 Q. So there was certainly some evidence to suggest that
26 Mr. O'Brien had turned his attention to the guidelines
27 and had looked at them in at least that detail?

11:47

28 A. Yes.

29 146 Q. To highlight to you possible spelling. Did Mr. O'Brien

- 1 ever raise the issue of the Bicalutamide 50mg
2 monotherapy issue at these meetings? Did he reply at
3 all or...
- 4 A. No.
- 5 147 Q. And when you -- your recollection is that you did 11:48
6 verbalise it?
- 7 A. That's my memory.
- 8 148 Q. Did anyone in the room support you on that, or say
9 "Yes, that's a good idea, I've seen that incorrectly
10 prescribed, or I have experience of that"? 11:48
- 11 A. No, not that I remember.
- 12 149 Q. Now, if your view is that the guidelines are going to
13 assist in standardising the practice around the
14 appropriate dose of Bicalutamide, that was your
15 intention in relation to the guidelines to allow that 11:48
16 pathway to become embedded, so that you had it recorded
17 that there was an expectation that Bicalutamide 50mg
18 would be prescribed within certain constrained ways as
19 licensed?
- 20 A. Yes. So I -- 11:49
- 21 150 Q. And the guidelines were your gateway to do that, that
22 you wanted to sort of codify an expectation of
23 standards?
- 24 A. Yes, I think that's a good way to put it. This was a
25 method by which all consultants who were reviewing the 11:49
26 guidelines would be aware of the appropriate dose, the
27 appropriate prescription. So, if they were outside
28 that guidance in the future, that would be reflected
29 back that they hadn't then followed the guidelines that

- 1 they'd reviewed.
- 2 151 Q. And would the other clinicians on the group have been
3 aware that that was the -- there was an intended target
4 to at least an element of the guidelines?
- 5 A. No, I don't know that they would have been aware of 11:49
6 that. I think again my discussion with Prof. Jain at
7 this time, following the previous e-mail in 2014, was
8 that I had intended to write these with that in mind,
9 but I don't know that other clinical colleagues would
10 have seen my intent within it. 11:50
- 11 152 Q. If we could go to WIT-96693. This should be the
12 meeting of 17th April 2015 of the NICaN urology network
13 and site specific group meeting. In attendance,
14 Mr. O'Brien again, Prof. Jain, Darren Mitchell, Chris
15 Hagan. So, this is the meeting after the one at which 11:50
16 you said you'd mentioned the issue specifically
17 verbally in front of others. There's an opportunity on
18 this to correct or to record the minutes of the last
19 meeting. Did you notice that your input, your oral
20 input on the Bicalutamide 50 issue hadn't been recorded 11:51
21 at that point?
- 22 A. Not at the time of the meeting. But on reflection, and
23 pulling these documents out, then I realised that there
24 was nothing on paper to confirm that.
- 25 153 Q. I suppose a wider point in relation to record keeping 11:51
26 around governance is the absence of concerns
27 documented. You can see that it's difficult then to
28 follow the trail, should there be a trail?
- 29 A. Yes.

1 154 Q. And the opportunity to correct meetings is in itself a
 2 form of governance, not specific to you generally as a
 3 point in relation to NICaN and the minutes.

4
 5 Now, we don't need to go to the guidelines themselves, 11:52
 6 because they do reflect what you intended that they
 7 would, that the Bicalutamide 50 issue would be dealt
 8 with in a standardised way, and there was an
 9 expectation that Mr. O'Brien would have to review those
 10 guidelines and accept them? 11:53

11 A. Yes.

12 155 Q. Was it your expectation, or potentially hope, that the
 13 standardisation of the guidelines in that way, and
 14 trying to deal with the issue in that way would allow
 15 Mr. O'Brien an opportunity to discuss his use of the 11:53
 16 drug and allow for an open discussion to perhaps
 17 further your understanding and perhaps his?

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

- 1 50mg once daily monotherapy.
- 2 156 Q. Now, there were other individuals involved in this, I
3 think it's multi disciplinary?
- 4 A. Yes.
- 5 157 Q. Certainly from the names that we recognise, there's 11:54
6 quite a broad range of individuals attend these
7 meetings, and was it your experience that they were an
8 opportunity to discuss issues among fellow
9 professionals in a very safe way?
- 10 A. Yeah. Other issues would perhaps engender more 11:55
11 discussion in terms of surgical techniques and where
12 those techniques are best performed, so those kind of
13 discussions happen very frequently within the NICaN
14 meeting. We'd also then be developing service through
15 that meeting, so looking for additional imaging 11:55
16 resources, maybe a consensus of thought as to what best
17 fits Northern Ireland's urology practice, compared with
18 other standards. So, it is a forum for discussion.
- 19 158 Q. As a mode of trying to bring about clinical change when
20 clinical concerns have been identified, in that 11:55
21 specific context, how effective do you think guidelines
22 are for that purpose?
- 23 A. I think for junior trainees, for non-medical
24 representatives at the meeting, guidelines are great.
25 You know, the vast majority of patients fit within 11:56
26 guidance. When I read guidance, I look to see does my
27 practise fit within that? And if it does, then I'm
28 pleased. If my practise is outside that, then there's
29 a questioning as to why it doesn't fit within the

- 1 standard of care guidelines. So I think guidelines are
 2 incredibly important. Was it the correct format for
 3 correcting an individual? Probably not. I should have
 4 followed more formal governance structures. But I saw
 5 it as a follow on to the e-mail. So having mentioned 11:56
 6 it in the e-mail, I think it was important to follow
 7 through with what could be looked back on and address
 8 as non standard practice.
- 9 159 Q. And the Bicalutamide 50mg monotherapy issue would be
 10 something, would it not, that you might expect 11:57
 11 Mr. O'Brien to be aware of, given his seniority and his
 12 experience, what was the licensed indication for that
 13 particular drug?
- 14 A. Yes, and by reading the guidelines that would encourage
 15 you to look and say "I prescribe within guidelines". 11:57
- 16 160 Q. Now, you've mentioned that, I can't remember exactly
 17 what you said, but would you disagree if I said that
 18 it's likely not the best governance tool to try and
 19 effect change when clinical care issues have been
 20 identified? 11:57
- 21 A. Yeah, I agree there are other avenues that I should
 22 have used rather than this, but it still felt the right
 23 thing to do to have our guidelines that we could then
 24 look back on and say "Are we following these
 25 appropriately?" 11:57
- 26 161 Q. Yes, I suppose there are two ways of use for the
 27 guidelines. The first is to standardise the way in
 28 which there was an attempt to bring about change?
- 29 A. Yeah.

1 162 Q. which, my point was really in the abstract that could
 2 be done, but in the face of specific concerns, you had
 3 mentioned that there might have been other avenues that
 4 you could have pursued, other governance pathways you
 5 might have taken. 11:58

6 A. (Witness Nods).

7 163 Q. Could you just --

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

14 164 Q. Well, you did send the e-mail in 2014, you did try to
 15 bring about change through the guidelines. Did you ask 11:58
 16 for, or access, or feel in any way supported in what
 17 you were doing to try and address your concerns?

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

24 165 Q. Did you feel like a lone voice?

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

28 166 Q. Given the issue of the guidelines, there must have
 29 been, arguably, still concerns in your mind that the

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

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

11 167 Q. I just want to explore a little bit more with you. You
 12 pushed back when I perhaps suggested you didn't appear
 13 to be supported.

14 A. (Witness Nods).

15 168 Q. And certainly when we move forward to 2019 and you're 12:00
 16 involved in the review of the use of Bicalutamide with
 17 Mr. Haynes and you get to see the issue again through a
 18 different lens perhaps. In retrospect even, do you
 19 look back and think, well, there were other people who
 20 knew about this and maybe with a bit of a wind at our 12:01
 21 back and a bit of a collective push we may have
 22 collectively done a little bit more, or brought about a
 23 change in approach?

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

- 1 169 Q. Was there anything about that period, or the processes
2 in place, or the culture, or the way things were
3 structured, that you considered to be a barrier to you
4 following established governance processes?
- 5 A. I think it's my lack of knowledge of the established 12:02
6 governance process as more than any real barrier.
- 7 170 Q. And what way do you think your knowledge might have
8 been increased around governance? How might that have
9 fed its way into your professional practice?
- 10 A. I think, you know, the governance training we would 12:02
11 have, I believe would have been quite limited at time
12 of starting a consultant's post, which was six/seven
13 years prior to the e-mail and this episode. I think
14 there's more robust teaching now in terms of governance
15 measures, and I think junior colleagues coming through 12:02
16 are more aware of those structures and more likely to
17 speak out than we would have been in the years gone by.
18 I think if that's what you're asking, I think --
- 19 171 Q. I suppose do you know if there's a difference in the
20 training or approach as you come up through the ranks 12:02
21 as a clinician that increases your awareness and also
22 highlights your responsibility? Is that system in
23 place?
- 24 A. So, I think as clinical directors, people going into
25 those posts are offered formal training in governance 12:03
26 structures. But I didn't have that, that formal
27 training in those structures, other than a brief
28 two-day induction at the 2008 time.
- 29 172 Q. And do you think that that was perhaps at the root of

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

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

5 173 Q. You've also mentioned in your statement that the 12:03
 6 guidelines were a way of effectively encouraging good
 7 practice, because they would be audited, and you
 8 thought that that would allow then perhaps any issues
 9 to rise up to the surface.

10 A. Yeah. 12:04

11 174 Q. That was one of your motivations as well.

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

21 175 Q. I'll just take you to that part of your statement where
 22 you encapsulate that as a potential system of oversight
 23 from a governance perspective. WIT-96670, paragraph
 24 2(iii). You're asked the question by the Inquiry:

25 12:04
 26 "In your view, ought these guidelines have been subject
 27 to audit within individual Trusts? Please explain your
 28 answer."
 29

1 And you say:

2

3 "These guidelines could have been audited within each

4 Trust. In my belief that Mr. O'Brien was the only

5 person in the region using Bicalutamide 50mg 12:05

6 monotherapy is correct, then it would in essence have

7 been an audit of his hormone therapy prescriptions in

8 the Southern Trust. The guidelines were written to

9 encourage good practice and provide a point of

10 reference if there were future cases identified with 12:05

11 his off licence prescribing."

12

13 So, that was the potential possibility of an audit?

14 A. (Witness Nods).

15 176 Q. Rather than the knowledge that the guidelines would be 12:05

16 audited?

17 A. Yes.

18 177 Q. They could provide a tool for that?

19 A. They could have, yeah.

20 178 Q. You've mentioned there about your belief that 12:05

21 Mr. O'Brien was the only person in the region using

22 Bicalutamide 50mg monotherapy. Did you ever form a

23 belief that others were prescribing that way?

24 A. No, I wasn't aware of other consultants prescribing

25 this. I believe in the lookback exercise there were 12:06

26 two other prescriptions with this dose, but they were

27 described as being errors, and so the 50mg dose had

28 been offered rather than the 150 in error, rather than

29 systemically.

1 179 Q. When you looked at the - when you undertook the process
 2 with Mr. Haynes, did you consider individual cases and
 3 look at their clinical presentation and their treatment
 4 regime in order to assess the appropriateness of
 5 Bicalutamide 50 as a monotherapy, did you look at that 12:06
 6 detail?

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

8 180 Q. In 2019.

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

19 181 Q. So you looked at the clinical presentation of the
 20 patients? 12:07

21 A. Yes.

22 182 Q. Did you find that any of the urologists at the Southern
 23 Trust had been using the drug in that way off licence?

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

1 183 Q. Now, I just want to read out two scenarios, I won't
 2 mention any names, just to see if they are familiar to
 3 you at all as scenarios you might have looked at with
 4 Mr. Haynes, and if you don't remember, please just say
 5 you don't remember, and if you do, obviously we can 12:08
 6 discuss it.

7
 8 "Case of an 84-year-old man under the care of Mr. Young
 9 when it was reported at MDM that a clinical diagnosis
 10 of prostate cancer had been made years previously and 12:08
 11 that he had been on..."

12
 13 -- is it Casodex?

14 A. Casodex is the other name for Bicalutamide.

15 184 Q. For Bicalutamide. So he had been on Casodex 50mg daily 12:08
 16 for some time.

17
 18 "Apparently he was discussed at MDM as he then had an
 19 acute renal injury due to bilateral upper urinary
 20 tract obstruction secondary to advanced prostate cancer 12:09
 21 associated with a serum PSA level of 105, a bone scan
 22 confirming metastatic disease. He was prescribed LHRH
 23 antagonist."

24
 25 Now, does that ring any bells with you, that particular 12:09
 26 scenario, that he had been on Bicalutamide 50mg daily
 27 for some time?

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

1 throwing information across at you, but they're
 2 examples that were provided where there may be others
 3 legitimately prescribing, in their view, Bicalutamide
 4 50, in ways that perhaps don't fall within what would
 5 be considered the licensed recommendations. 12:12

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

10 187 Q. If you have a patient who has been on low dose and is 12:12
 11 tolerating it well, even though the clinical indicators
 12 or the usual prescription regime may be to increase the
 13 dose or to change to another regime altogether, and the
 14 patient is reluctant to do that and is tolerating the
 15 dose well, what would your approach generally be, as we 12:12
 16 are speaking in the abstract, but as a clinician, even
 17 if a patient was on an unlicensed but to them an
 18 effective regime? Would you switch them over or would
 19 you let them tolerate what they considered was
 20 beneficial and just wait and see what happened? 12:13

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

- 1 their original consultant.
- 2 188 Q. And from a governance lens, if the consultant was to
3 maintain the unlicensed but apparently tolerated drug
4 regime, would you expect to see that recorded in the
5 medical notes, that the patient had been advised that 12:14
6 it is, if I can use the term, non traditional
7 application of a licensed drug?
- 8 A. That would be good practice as per the MHRA guidelines
9 that I had sent through previously.
- 10 189 Q. And would it be something that you would do in your 12:14
11 practice if you were -- I don't you -- I think you said
12 at the start that you haven't ever done that, but if
13 you were to go off licence for whatever reason?
- 14 A. So, we do use off licence medication. But that off
15 licence is backed up by evidence and backed up by 12:14
16 guidelines, and we would explain to patients that this
17 is an unlicensed or off licence medication and explain
18 why it's being used or recommended in their case. So
19 that that's not common, but it's not uncommon either.
20 That's good practice. 12:15
- 21 190 Q. We'll look at the 2019 review shortly, but I want to
22 look at the 2016 e-mail, when there's concern around a
23 delay in muscle invasive bladder cancer, a case
24 referred from Craigavon.
- 25 A. (Witness Nods). 12:15
- 26 191 Q. Now, there are e-mails between a variety of individuals
27 which I think just set out the background and context,
28 and we'll use those, I think, as the starting point.
29 If we go to WIT-96703. Apologies, these e-mails always

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

5 A. Laterally. 12:16

6 192 Q. Do you recall this? You've seen these as well. This
 7 is from Chris Hagan, sent on 21st June 2016 to Davinia
 8 Lee. Who is Davinia Lee? Do you know her?

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

13 193 Q. Okay. The reason why we're looking at this, just to
 14 put it into broader governance context as opposed to
 15 individual details, is this appears to be an example of 12:17
 16 e-mails among professionals trying to find a solution
 17 to a problem that someone has identified and the way in
 18 which that pans out or doesn't.

19 A. Yes.

20 194 Q. And then eventually there's an e-mail in 2016. But 12:17
 21 this is the lead up to it. So, I just want to read
 22 this out.

23
 24 "Davi ni a,
 25 I am very concerned about del ays in ITT. " 12:17

26
 27 Just tell what ITT is?

28 A. That's Inter Trust Transfer.

29 195 Q.

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

3
4 -- and we'll come back to that in a moment.

5 Patient name redacted: 12:18

6
7 "Muscle invasive bladder cancer. Original resection
8 16/2/2016..."

9
10 - I think that should say: 12:18

11
12 "... with multiple local MDT discussions before a
13 regional discussion 9/6/2016, and I see her today
14 21/6/2016.

15 12:18
16 In my view there are multiple avoidable delays which
17 will potentially lead to an adverse outcome. She is
18 not fit for cystectomy today.

19
20 Contrast this with an exemplar patient [name redacted] 12:18
21 ERBT on 25/5/2016 in Derry. Muscle invasive bladder
22 cancer. Discussed region MDT on 9/6/2016 and seen
23 today with radical surgery next week.

24
25 What do you think? 12:19

26
27 Happy to discuss."

28
29 Obviously just for the panel's note, when Chris Hagan

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

5 A. Yes. 12:19

6 196 Q. If we just move up, please. He then comes back and
7 says she can't find anything for patients on CaPPS or
8 ECR:

9
10 "Is the health care number definitely correct? What is 12:19
11 the patient's name?"

12
13 Then we move on. Mr. Hagan sends the patient's name,
14 Patient 127. And then she replies again on 22nd June
15 2016, and she says: 12:19

16
17 "Hi Chris,

18
19 I've had a look at the patient's pathway from CaPPS
20 (see attached). 12:19

21
22 I have compared it against the NICA pathway (page 125
23 of the clinical guidelines) and the guidance is for
24 muscle invasive bladder cancer to send to CT chest
25 abdomen before MDT discussion. However in this case it 12:20
26 was discussed at MDT first.

27
28 There was then a delay to the bone scan and it took
29 over a month for the CT after the first MDM and nearly

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

12:20

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

12:20

11
12 Would you have a look at the pathway prior to the first
13 central MDM discussion on 12/5 for me? It looks like a
14 CT should have been requested following the original
15 path on 29/2 in line with the pathway attached, which
16 would have saved at least a month, but would welcome
17 your clinical view as to what should have happened post
18 original resection and pre specialist MDT discussion
19 before we decide on how to proceed."

12:21

20
21 I think the previous e-mail was the 21st, is that
22 right? The 22nd. Just move back up again, please. So
23 on the same day, the totality of information with the
24 expected standard pathway is fed back to Mr. Hagan, and
25 the concerns that he might have had are particularised
26 by date, diagnosis, treatment pathway, in order to
27 establish that there was a delay. But, again, over you
28 as the clinician to establish whether, from a clinical
29 perspective, that causes concern. That seems to be the

12:21

12:21

1 flavour of this e-mail.

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

7 197 Q. And I think that this is as an example of clinicians
8 working together and the head of cancer, in order to
9 ascertain exactly what had happened?

10 A. (Witness Nods). 12:22

11 198 Q. It's an example of what could be said is good practice
12 from a governance perspective, immediately on the
13 issue?

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

16 199 Q. I should say this is - I'm just taking you through
17 this, I'm not attributing any involvement on you in any
18 of this, this is really just for the panel's purpose of
19 showing how you come in later on and the background to
20 the e-mail, but it also could be seen as an example of 12:23
21 good governance practice within the Trust.

22 A. Yes.

23 200 Q. Then from Davinia Lee again to Chris Hagan and Jenna
24 Crawford, Gillian Traub:

25 12:23

26 "Hi Chris,

27

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

1 we need to follow up on?."

2

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

5

12:23

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

8

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

12:23

13

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

12:24

17 A. Yes.

18 201 Q. And was that by Chris Hagan?

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

12:24

21 202 Q. In your role as?

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

23 203 Q. Thank you. And you have said:

24

25 "Chris,

12:24

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

28

29 Then you've --

1 A. Copy and pasted the relevant guidelines from NICE.

2 204 Q. In order to show that there's no recommendation in
3 those guidelines?

4 A. (Witness Nods).

5 205 Q. Then you say at the bottom:

12:24

6

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

12:25

14

15 Chemo treatment is that, is it? XRT?

12:25

16 A. That's a combination of chemotherapy and radiotherapy
17 at the same time.

18 206 Q. For chemo/radiotherapy.

19

20 "Scans as per guidance can occur in tandem.

12:25

21

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

25

12:25

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

29

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

12:26

6
 7 Now, we've moved slightly away from the specifics of
 8 that case. Do you know what happened in particular to
 9 that individual who Chris Hagan had identified in the
 10 first place, the issue of delay, do you have any
 11 recollection?

12:26

12 A. I don't.

13 207 Q. You don't know of anybody who took that forward as an
 14 issue?

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

12:26

17 208 Q. If it may have been you, what might you have done in
 18 relation to that particular person?

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

12:26

12:27

27 209 Q. I suppose I mean more from the perspective of the
 28 impact of the delay that she had experienced. Would
 29 anyone have taken that forward as a potential SAI,

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

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

10 210 Q. This didn't ultimately lead to -- 12:27

11 A. No.

12 211 Q. An SAI?

13 A. No.

14 212 Q. And when you mention the SAI in this, was it an SAI to
 15 look at the potential breakdown in communication that 12:28
 16 has impacted care pathways, or an individual SAI into
 17 that particular individual, or both? what might have
 18 been in your mind when you mentioned SAI?

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

25 213 Q. Now, there was mention in the first e-mail, I think it 12:28
 26 was the first or second e-mail, of an interface SAI.

27 A. (Witness Nods).

28 214 Q. Do you know what that is?

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

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

5 215 Q. Do you have experience or knowledge of cross-Trust 12:29
 6 SAIs?

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

10 216 Q. So it was a process you were familiar with, even at 12:29
 11 this point?

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

14 217 Q. You've mentioned that SAI might be more appropriate if 12:29
 15 we see this as a consistent trend, and the mention of
 16 review of timelines for the last 30 to 50 muscle
 17 invasive cases coming to central MDT could be reviewed.
 18 Was that ever followed up, that suggestion?

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

1 were pending. And we've continued to work on that over
 2 the last number of years, where surgeons have a concern
 3 there's a muscle invasive bladder cancer case at the
 4 time of pathology, we'll flag it to the pathologists
 5 and ask for an expedited report to try and shorten the 12:31
 6 timelines even more.

7
 8 If we step back then to the issue around bone scans in
 9 bladder cancer cases, the only Trust that was doing
 10 bone scans was the Southern Trust. So there were four 12:31
 11 cases identified between June/July 2016, two of which
 12 had had bone scans. I believe there were three other
 13 cases who weren't being formally followed as a new
 14 muscle invasive, so I'm assuming they had non invasive
 15 disease, which progressed muscle invasive, and of those 12:31
 16 three cases I believe all three had had bone scans. So
 17 there was a trend for bone scans being performed in the
 18 Southern Trust that we didn't see in the other Trusts.

19 218 Q. And being performed when they weren't provided for in
 20 the guidelines? 12:31

21 A. That's correct.

22 219 Q. And who undertook that review? Were you part of that?

23 A. So, the Cancer Services Manager, Davinia Lee, took part
 24 in that with one of her staff. So the statistics were
 25 generated and circulated around, I believe, the 12:32
 26 recipients of this e-mail as well.

27 220 Q. Now, I just want to ask you about the two issues you've
 28 mentioned. The first was the once pathology is
 29 confirmed and then it's to regional?

1 A. That would be practice now, yes.

2 221 Q. That would be practice now. Just then how that comes
3 about? If there's a decision taken that best practice
4 would dictate that because of the significance of
5 bladder cancer and the need to act quickly for 12:32
6 optimised outcomes, if a decision is taken clinically
7 within the Belfast Trust that that should be the best
8 care pathway, how do you buy-in other Trusts to send
9 people to you once pathology is confirmed? what's the
10 process by which that happened? 12:33

11 A. So, I believe the guidelines would have been
12 circulated, but at any subsequent MDT where cases were
13 being presented we would have said to the referring
14 Trust "Our practice is now to bring these straight to
15 MDT with pathology rather than wait for scans to 12:33
16 expedite the process." So we had a, and still do, have
17 a number of points where we can tell clinicians linking
18 remotely that that's what they need to do.

19 222 Q. And the guidelines are guidelines rather than
20 mandatory, I assume, by the very nature of them. But 12:33
21 do you have any difficulty getting buy-in and people
22 coming on board with what's been established as being
23 potentially the best patient outcome group?

24 A. No. So I think we felt that actually bypassing
25 clinicians was maybe important for the Trust. So my 12:33
26 understanding is that once a pathology is reported as
27 muscle invasive, that comes through to the coordinator
28 for the MDT, who will then put the case straight onto
29 the meeting, and then the summary for the case is

- 1 generated. So, actually, as soon as pathology is
 2 available they go straight on, not waiting on someone
 3 else to do that for us.
- 4 223 Q. So that process, bypassing the clinicians once
 5 pathology is confirmed, actually takes out any 12:34
 6 possibility of an individual or any clinician
 7 reinterpreting or interpreting what they consider to be
 8 the best patient pathway? It happens --
- 9 A. We felt that expedited the patient's journey.
- 10 224 Q. And does that system work efficiently in your view? 12:34
- 11 A. Yes. And we're still working on it.
- 12 225 Q. You mentioned about bone scans, they were identifying
 13 four cases from the Southern Trust.
- 14 A. So, we had four cases that were identified as part of
 15 that data pool with muscle invasive, and my memory is 12:34
 16 that two of those have had bone scans. There were
 17 three other cases who, I think they follow a slightly
 18 different pathway. So they weren't diagnosed with
 19 muscle -- my assumption is they weren't diagnosed with
 20 muscle invasive disease from the outset. They may have 12:35
 21 had superficial disease that progressed, and as they
 22 were being worked up for their radical treatment they
 23 were then given bone scans. So if I remember that
 24 e-mail correctly, two of the four we found and three of
 25 the non-tracked cases had all had bone scans and all 12:35
 26 from the Southern Trust.
- 27 226 Q. And the clinical significance of that is that it brings
 28 with it delay?
- 29 A. It's a delay, yeah.

- 1 227 Q. And is it also a factor that if the bone scan is not
2 part of the NICE guidelines then it's arguably
3 irrelevant to outcomes? Is there any purpose in doing
4 the bone scan if NICE guidelines don't suggest it?
- 5 A. No. I think we had listed it as part of the 12:36
6 highlighted section in this e-mail that for patients
7 where there was concern of metastatic disease it was
8 more appropriate to do a PET scan, and I think we had
9 argued and have been able to access PET scans by the
10 time this was going through. So this was more to 12:36
11 highlight "Do a PET scan rather than do a bone scan if
12 you really feel this is warranted for this" --
- 13 228 Q. If a scan is necessary, this is the one you should be
14 doing?
- 15 A. (Witness Nods). 12:36
- 16 229 Q. And what was the outcome of -- I heard you speak to the
17 outcome of bypassing the clinicians in order to fast
18 track appropriate treatment, I presume. In relation to
19 this, the bone scans and your identification that a PET
20 scan is probably -- 12:36
- 21 A. So we haven't seen bone scans in subsequent cases to
22 this, and we feel the timelines are improving, but
23 there's still work to do.
- 24 230 Q. So you adapt your guidelines, or you send out -- what
25 way does it work in practice? If I am a clinician in 12:36
26 the Southern or Northern Trust and I have been sending
27 people for bone scans, not realising that a PET scan is
28 probably a more optimal route, how do I find out that
29 there's an expectation that I stop that practice and

1 start sending them for PET scans, if at all?

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

15 231 Q. So the difficulties that were highlighted or became 12:37
16 apparent as a result of this have resulted in changes
17 in practice?

18 A. Yes.

19 232 Q. That have been sustained.

20 A. And improved on. 12:38

21 233 Q. And improved on. So, those are also examples of
22 governance concerns being raised, being appropriately
23 analysed, dissected, to use a medical term, and
24 properly responded to, to bring about effective change?

25 A. (Witness Nods). 12:38

26 234 Q. I just want to make sure we don't miss any... So this
27 is an e-mail just on the 17th, just before we get to
28 the e-mail of 26th August. Davinia Lee, 17th August
29 2016, and it's to you, Chris Hagan, Gillian Traub and

1 Jenna Crawford, and she says:

2

3 "Thanks Darren.

4 I have chatted to Carol -Anne and she says there are two
5 options to raise this with the Southern Trust. 12:38

6 1. Speak directly to the colleague in the Southern
7 Health and Social Care Trust who transferred the
8 patient (she advised discussion should be consultant to
9 consultant) and advise of the concerns below and ask
10 them to take forward an investigation locally. 12:39

11 2. Report this as an interface incident with HSCB. In
12 this scenario we complete a one-page summary and submit
13 to HSCB and they then contact SHSCT for investigation.

14

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

17

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

20

12:39

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

25

12:39

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

1
 2 "Hi Davinia,
 3 Thanks for following this up. I would add two points.
 4 There should be a consultant to consultant discussion
 5 as Carol-Anne says, but should this discussion be with 12:40
 6 the MDT Chair in SHSCT rather than with the individual
 7 consultant urologist, if the plan for this patient was
 8 agreed at MDT rather than being the patient's urologist
 9 own treatment plan?
 10 B. In past experience with interface incidents (which 12:40
 11 must meet criteria for an SAI) they are not the most
 12 palatable route. We could do a 3 way - completion of a
 13 BHSCT incident report, which discussion with SHSCT
 14 clinician and then incident report shared with them and
 15 they are asked to investigate. It also gets shared 12:40
 16 between corporate governance teams so it is formally
 17 logged. If the SHSCT then investigate it and find that
 18 it meets SAI criteria, it would be incumbent on them to
 19 declare an SAI."
 20 12:41
 21 So the previous e-mail in this e-mail appeared to be
 22 ways of trying to tease out the best way to effect
 23 change, if I can put it that way, by using the
 24 governance routes available. It was mentioned in the
 25 previous e-mail with HSCB being involved. Did you ever 12:41
 26 have any involvement with the HSCB through any
 27 governance mechanism or complaint mechanism?
 28 A. No.
 29 235 Q. You're not sure, you don't know how that works, how

1 that interacts?

2 A. (Witness shakes head).

3 236 Q. There's mention there at point 1, or point A, of the
4 MDT Chair in the Southern Health and Social Care Trust.
5 Do you know who that was at the time? 12:41

6 A. Well, I know that I sent an e-mail based on this
7 recommendation to Mr. O'Brien and copied in the cancer
8 care coordinator, who I think was Shauna McVeigh at
9 that time, asking for a review and shared learning.

10 237 Q. And you reply on 17th August to that e-mail, 17th 12:42
11 August 2016, to say:

12

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

16

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

19

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

21

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

23

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

27

28 -- which presumably means Southern Trust?

29 A. (Witness Nods).

1 238 Q.

2

3

"...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 NlCaN Urology Chair is part of the STMDT and NlCaN should also be involved in this.

12:43

9

10 Chris."

12:43

11

12

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

16

A. (Witness Nods).

17

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

18

19

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

22

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

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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

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

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

1 was Regional Chair, if my coordinator had received an
 2 e-mail to this, that they would have spoken to me and
 3 spoken to the line manager. So there was an
 4 opportunity for at least the line manager to be aware
 5 of something we were looking into. But I could find no 12:48
 6 replies from this e-mail.

7 244 Q. So, there were no replies. You've copied Shauna
 8 McVeigh in, who was the urology MDM coordinator. There
 9 was no action from her taken in relation to that, she's
 10 no record? 12:48

11 A. No.

12 245 Q. There's no records found in relation to that. But
 13 specifically as addressed back to you, there was no -
 14 nothing came of this?

15 A. No. 12:48

16 246 Q. Did you copy Shauna McVeigh in as -- well, why did you
 17 copy Shauna McVeigh in? Was it more etiquette as the
 18 MDM coordinator or was there an expectation that her
 19 being copied in might trigger some sort of wider
 20 involvement? 12:48

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

28 247 Q. Now, the review that you discussed that happened with
 29 the bone scan outcome and the pathology triggering

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

3 A. Yeah. And we --

4 248 Q. It wasn't dependent on the involvement of Mr. O'Brien?

5 A. No. 12:49

6 249 Q. I have asked you the questions before around was there
7 another possible way that this could have been
8 escalated from a governance perspective? I know there
9 were a lot of discussions in the e-mails and this
10 option was taken as ostensibly the most likely to 12:50
11 perhaps get some buy-in or be the most effective, and
12 it seemed to be a collective, or at least a
13 collectively aware decision to take this particular
14 route. In hindsight, do you think this was the way to
15 deal with this particular issue? 12:50

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

21 250 Q. And again this is 2016. Was there any particular
22 context in place from either the SAI processes or from
23 a cultural perspective that meant that you still were
24 reluctant, or others might have been reluctant to
25 engage in more established or potentially effective 12:51
26 governance processes?

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

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

4 251 Q. Were they senior to you or were they the same --

5 A. Mr. Hagan would have --

12:51

6 252 Q. Grade.

7 A. would have more experience than I would. And I would
 8 expect with the more senior managers that they would
 9 have had much more experience in terms of generating
 10 and dealing with DATIX as IR1s SAIs than I have.

12:52

11 253 Q. Now, I just want to move on from that period of time
 12 and just talk generally about the knowledge and
 13 escalation within the Belfast Trust to non escalation
 14 among individuals, and I just want to just run through
 15 a couple of points just to highlight them from your
 16 section 21. I will bring this one up, it's WIT-96669.
 17 Paragraph 1(viii). And you're asked the question by
 18 the Inquiry:

12:52

19
 20 "Were you aware of others who had knowledge of these
 21 issues or who may have shared similar concerns? Please
 22 give full details."

12:53

23
 24 And you reply and say:

25
 26 "I believe the oncologists providing support as part of
 27 their job plan to the Craigavon Urology Service would
 28 have routinely been referred cases from Mr. O'Brien and
 29 may have come across this off licence prescribing.

12:53

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

4
 5 Can we take it from that that you're naming other 12:53
 6 individuals who may have come across the same issue but
 7 didn't specifically discuss that with you.

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

18 254 Q. But they didn't discuss them with you?

19 A. No.

20 255 Q. And you didn't have conversations with them. They 12:54
 21 never mentioned to you, "Oh, I have a few of those as
 22 well"?

23 A. No.

24 256 Q. That's not your evidence?

25 A. No. 12:54

26 257 Q. Now, you mentioned in your statement, just the point
 27 above that, we've asked you to identify each and every
 28 individual with whom you discussed issues, concerns,
 29 and provide full details to include dates and means of

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

6 A. Dr. McAleer.

7 258 Q. Seamus McAleer?

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

9 259 Q. In the Belfast Trust?

10 A. Yes. 12:55

11 260 Q. And:

12

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

17

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

24

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

28

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

1 spoken to Mr. McAleer in 2011?

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

4 261 Q. If we go to 96672, paragraph 5(ii). And we've asked
5 you specifically about Mr. McAleer:

12:56

6
7 "How and when did you raise these concerns with the
8 Clinical Director, Dr. McAleer? Please provide full
9 details together with copies of any relevant
10 contemporaneous documentation."

12:57

11
12 And you say:

13
14 "I believe my first discussion with Dr. McAleer
15 occurred at the time of the informal discussions with
16 Mr. Haynes in 2019 outlined above.

12:57

17
18 I advised Dr. McAleer that I was contributing to a
19 process of investigation of Mr. O'Brien's practice and
20 that I anticipated that as it evolved that it was
21 likely I would have to provide evidence to any
22 subsequent investigation within the Southern Trust.
23 When I was invited to a case review meeting with the
24 Southern Trust on 1/10/2020 I also advised Dr. McAleer
25 of my role in this at that time. I have no
26 documentation from these discussions."

12:57

12:57

27
28 So from the -- you never advised Dr. McAleer of your
29 2014 e-mail, 2015 motivation around the guidelines, or

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

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

4 262 Q. But he was - I mean at this point when you did speak to
 5 him, you didn't say "Actually, I've had engagement with 12:58
 6 Mr. O'Brien". You didn't tell him? It's just for the
 7 record, I need to know the time line?

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

18 263 Q. And it was through Mr. Haynes that you became involved
 19 in the 2019/2020 lookback process?

20 A. Yes. 12:58

21 264 Q. Now, you said that Dr. Hughes, you acknowledged that
 22 you'd written to Mr. O'Brien about his practice, but
 23 you didn't escalate the issue to the Southern Health
 24 and Social Care Trust.

25 12:59

26 "This is something both individuals..."

27

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

29

1 "...regretted and reflected upon."

2

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

5

12:59

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

12:59

12

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

13:00

18 A. Yeah.

19 265 Q. Paragraph 7(ii):

20

13:00

21 "Please explain why the issue was never escalated to
22 SHSCT, providing details of any real or perceived
23 obstacles to such escalation?"

24

25 And you say:

13:00

26

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

28

29 Now, at this point issues had become apparent and there

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

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

13 266 Q. At no time did anyone from the Southern Trust raise any
 14 concerns with you? There were no concerns came from
 15 that direction to you around care that was being given 13:01
 16 --

17 A. Prior to Mr. Haynes?

18 267 Q. Yes.

19 A. No.

20 268 Q. Now, the panel have heard evidence before around the 13:01
 21 quoracy about MDM meetings and you've set those out.
 22 Just for the panel's note: The problems with staffing,
 23 particularly for oncologists and radiologists, and this
 24 is a theme. For reference it's at WIT-96673 and
 25 paragraph 9. We don't need to go to this. You also 13:02
 26 flagged the issue about the MDM quoracy at a NICaN
 27 meeting on 18th September 2015 at WIT-96686. There's
 28 also reference again in 2018, e-mail chain at WIT-42353
 29 to WIT-42350, just working backwards in order on those

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

5
 6 "With the usual query from our core radiology team to
 7 see if Southern Health and Social Care Trust had
 8 radiology cover to present cases at MDT."
 9

13:03

10 And that's the e-mail chain at TRU-285231.

13:03

11
 12 And Anthony Glackin responds to you, saying:

13
 14 "Unfortunately we are struggling for adequate cover and
 15 quoracy."
 16

13:03

17 Now, you worked with Mark Haynes on the lookback and
 18 you were set three questions which you applied to each
 19 one of the cases, and you were involved in that, and
 20 that did involve you looking, as we said earlier, at
 21 some of the Bicalutamide 50 monotherapy, and your
 22 understanding, just to summarise that, was that there
 23 were no other consultants involved in prescribing
 24 Bicalutamide 50mg monotherapy when it wasn't clinically
 25 indicated under licence?
 26

13:04

13:04

26 A. That's correct.

27 269 Q. I was going to ask you about learning, I think we've
 28 worked through that, and I'm conscious that the panel
 29 may have some questions and I'm conscious of the time.

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

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

13:04

5
6 QUESTIONS BY THE PANEL

7
8 CHAIR: I'm going to ask Mr. Hanbury, I'm sure he has
9 several questions for you, as a fellow urologist.

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

13:04

14
15 Looking at the sort of general issue of delays to
16 referral from Southern Trust to yourselves, as
17 Mr. O'Brien says, as part of his justification for some
18 of the delays that he was seeing the effect of hormone
19 treatment on the PSA before he referred to you, what's
20 your thoughts on that?

13:05

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

13:05

13:05

- 1 270 Q. So that wouldn't have been a good reason not to refer
 2 after MDM, in your view?
- 3 A. No. No.
- 4 271 Q. Just to sort of -- okay. Thank you. The issue of
 5 patients with lower urinary tract symptoms and needing 13:06
 6 radiotherapy is a real one which we jointly address
 7 between yourselves and us as urologists. Do you have a
 8 view on whether LHRH inhibitors are better than
 9 antiandrogens in the form of Bicalutamide or -- in
 10 managing lower tract symptoms? 13:06
- 11 A. So, not necessarily from a lower urinary tract symptom
 12 perspective, but as a brachytherapist if we're sent a
 13 patient whose prostate is too large for implant, we
 14 know that LHRH agonists will get a greater degree of
 15 site reduction in the prostate gland than Bicalutamide. 13:07
 16 So, for patients who are in that scenario, we will have
 17 a discussion about downsizing, and then the discussion
 18 on the impact on sexual function, comparing both those
 19 options. But I would view LHRH agonists as being
 20 better at site reduction than Bicalutamide. I suspect 13:07
 21 that probably also has a greater impact on their
 22 urinary function as well.
- 23 272 Q. Okay. Thank you. And in the same way, if you have
 24 someone with relatively severe symptoms, from a urology
 25 point of view if a patient may need bladder outflow 13:07
 26 surgery...
- 27 A. Mmm.
- 28 273 Q. We've noticed that under Mr. O'Brien's service that
 29 would seem to preclude the referral to yourselves,

- 1 whereas many urologists, I think, would refer to
 2 oncology but say, "Listen, this patient's got severe
 3 symptoms. Let's see how, if we can manage them
 4 medically and have a joint discussion with oncology
 5 colleagues." How do you play that with perhaps other 13:08
 6 urologists?
- 7 A. So, I think that's a fairly common conundrum that we
 8 all face. I tend to like to see the patients and to
 9 have the discussion on the impact of treatment. The
 10 key feature is, if they are having bladder outflow 13:08
 11 surgery, when is that going to be? If it's going to be
 12 timely and not have a significant impact on their
 13 radical treatment, then do it early. If it's likely
 14 that they're going to wait for surgery for a long time,
 15 then get on with radiotherapy and deal with the 13:08
 16 consequence of that subsequently. So in fact I look at
 17 the intervention as the trigger.
- 18 274 Q. But, again, you would expect to be involved in that
 19 discussion with the referral -- sorry, referring
 20 urologist, rather than just not knowing about the case? 13:09
- 21 A. Yes.
- 22 275 Q. Okay. Thank you. We mentioned Tamoxifen very briefly.
- 23 A. Mmm.
- 24 276 Q. I mean hormone treatment can have side effects. And
 25 had you come across this routine prescription Tamoxifen 13:09
 26 alongside Bicalutamide or other hormone treatments --
- 27 A. Yes.
- 28 277 Q. From other clinicians, or was this specific to
 29 Mr. O'Brien's practice?

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

7 278 Q. Okay. Thank you. Just to go back to your -- there's
 8 been lots of debate about the non quoracy at the
 9 Southern Trust MDM, and obviously having a clinical
 10 oncologist present has lots of advantages. Would you 13:10
 11 like to elaborate those? I mean you've mentioned
 12 muscle invasive disease?

13 A. Yeah.

14 279 Q. And testicular cancer I'll talk about, as well as
 15 prostate? 13:10

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

23
 24 I also then am aware of the lack of radiology
 25 consistent cover and the e-mails which have been 13:10
 26 referenced within the regional meeting, we had two
 27 radiologists who were struggling to keep on top of our
 28 cases then being asked to comment on cases from another
 29 meeting, and my memory is that they would refer to

1 guidelines in terms of the inappropriateness of
 2 commenting on cases ad hoc on a brief presentation and
 3 the appropriateness for preparation time prior to
 4 meeting. So, I think they were quite robust in their
 5 saying that they could not provide radiology cover for 13:11
 6 a separate MDT on top of their already job planned
 7 work.

8 280 Q. And I suppose just to push you a little bit more, were
 9 you ever asked as a group, "Okay, listen, Southern
 10 Trust are really struggling for cover, are there any 13:11
 11 free sessions that anybody in the department could
 12 offer either remotely or personally to assist?"

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

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

22 CHAIR: Dr. Swart.

23 DR. SWART: Thank you. I'd just like to go back to the
 24 2014 e-mail, which seems to have been an important
 25 e-mail about a particular patient, and I know you would 13:12
 26 have put quite a lot of thought into that e-mail. What
 27 did you say to that patient when he was in front of you
 28 and subsequently, and how did you deal with that aspect
 29 of it?

- 1 A. So, I didn't see that patient, the patient was passed
 2 through to me by Prof. Suneil Jain. So I'm not aware
 3 of the consultation he has had with the patient.
- 4 281 Q. What would you have said to the patient? Because I'm
 5 just interested in the general topic of how patients 13:13
 6 can share their treatment decisions and what happens in
 7 the event of something like this.
- 8 A. So, I'd look at the cases that were reviewed subsequent
 9 to the lookback exercise, and I would have said to them
 10 that we would have liked to have seen them at an 13:13
 11 earlier stage and were they aware of the treatments
 12 that we were offering and had they any concerns? But I
 13 don't remember any of the patients expressing concerns
 14 or a feeling that they had not been referred in a
 15 timely manner. 13:13
- 16 282 Q. Were patients at that time routinely given a summary of
 17 all the treatment decisions and a summary of all
 18 letters? This is 2014.
- 19 A. If they were -- 2014? I think if there was a clinical
 20 nurse specialist within the consultation, they would 13:13
 21 routinely have been given a record of consultation.
 22 However, we have struggled with our number of CNSs in
 23 the region, so it wasn't always possible for a CNS to
 24 be in the consultation meeting.
- 25 283 Q. And at that time, this eventually led to the new 13:14
 26 guidelines being written, but you agree that perhaps
 27 dealing with an individual clinician by writing a
 28 guideline for everyone might not be the whole best way
 29 of doing it, but anyway, that's the way it was dealt

1 with.

2

3 what was the mechanism at that time for knowing whether

4 people were adhering to guidelines anyway? Because

5 there's loads of guidelines everywhere. Was there an 13:14

6 established culture of audit for NICaN guidance that

7 was recommended for the region?

8 A. So, there was a process of audit, but we were auditing

9 things like the use of neoadjuvant chemotherapy and

10 bladder cancer and the uptake of that. I don't think 13:15

11 we would have looked at --

12 284 Q. You wouldn't generally recommend a --

13 A. -- at a Bicalutamide 50mg audit.

14 285 Q. I mean, you know, if I asked you the question "How do

15 you know people are adhering to all the guidelines?", 13:15

16 how would you know?

17 A. I think when they come for their opinion and you're

18 seeing a trend of non adherence, that's the flag for

19 concern.

20 286 Q. But there's no systematic look at that, you don't 13:15

21 think?

22 A. No.

23 287 Q. No. You mentioned at the time that you dealt with this

24 you didn't have any support, this was under

25 questioning. But what does it say about the culture if 13:15

26 you felt, or you didn't feel the need to ask people

27 about this issue, do you think, looking back on it? I

28 mean, I've spent a lot of time in various roles and I

29 know that the commonest conversation would have been

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

8 A. So, this was the 2014?

9 288 Q. 2014.

10 A. Yes. 13:16

11 289 Q. I mean the e-mail was, you know, it's a perfectly apt
 12 e-mail and so on, but I'm thinking of you being a
 13 little bit isolated here, when this is a tricky issue,
 14 actually.

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

18 290 Q. No, I'm talking about the whole thing: The delay, the
 19 prescription causing the delay, a patient who's had two
 20 years who needs an explanation, the knowledge that 13:16
 21 there are other cases, the clinician involved is in
 22 another Trust. None of this is entirely
 23 straightforward.

24 A. Yeah, I --

25 291 Q. So why didn't you? It's not just about knowledge. why 13:17
 26 did you feel you should have all the answers and not go
 27 and talk to somebody more senior about how to do this?

28 A. I don't know.

29 292 Q. You don't know? Okay.

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

13:17

6 293 Q. And the culture at the time, you have clinical
 7 directors and medical management culture in place. You
 8 will not have had formal clinical governance training
 9 during your time as a medical student and in your,
 10 probably in your training generally. You arrive as a
 11 consultant, you're supposed to know everything. What
 12 efforts did the clinical directors make to get people
 13 together to improve the clinical governance structure,
 14 do you think, or was there just not enough time to do
 15 all of this?

13:17

13:18

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

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

13:18

23 A. Yeah.

24 295 Q. Do you think that's changed over the last decade or do
 25 you think this is still a problem in terms of being
 26 able to give it the attention it deserves?

13:18

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

29 296 Q. Mm-hmm.

- 1 A. Increasingly when I see my trainees coming through,
 2 they'll be looking at guidelines and following
 3 guidelines, and probably quicker to flag when
 4 something's outside guidelines and ask why that's
 5 happening. So I think that process is still important. 13:19
 6 I think we need to be clear in terms of where we work
 7 outside guidelines as to how we document that. And
 8 within our specialty we now have robust peer review
 9 where cases that sit outside guidelines for
 10 radiotherapy treatments will be discussed with your 13:19
 11 peers and signed off as having been peer reviewed and
 12 accepted. So having that kind of approach is helpful
 13 and supportive.
- 14 297 Q. Mm-hmm. Coming onto the bladder cancer one, where
 15 there are clearly very serious delays and you've 13:19
 16 improved things now, but do you think the understanding
 17 of the need to perhaps trigger these as serious
 18 incident investigations and learn from that was
 19 embedded at that time? Is it getting more embedded?
 20 Is it not working properly? Or what's your feeling 13:19
 21 about that? Because that must have been a difficult,
 22 another very difficult thing to deal with because of
 23 the time problem.
- 24 A. I think years later it's more likely we would raise
 25 this as an SAI straightaway rather than go through the 13:20
 26 e-mail process.
- 27 298 Q. And looking back on all of that, what is your personal
 28 reflection on what would have made a big difference in
 29 terms of dealing with these various issues differently

1 over the time. I mean there's a bit more than
 2 learning. What do you think would have assisted you
 3 and the Trust in terms of picking the issues up
 4 quicker, dealing with it quicker, not doing it from the
 5 approach of blame, but from the approach of learning 13:20
 6 for patients?

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

13 299 Q. Do you look back on this and worry about it?

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

18 300 Q. But what one thing would you have done differently if
 19 there was just one thing?

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

23 301 Q. I don't think there is one probably!

24 A. No.

25 DR. SWART: Thank you. 13:21

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

- 1 by someone other than Mr. O'Brien, is that correct?
- 2 A. Yeah, I'd have to go back to the e-mails and review,
3 but I believe Mr. Haynes had asked one of the
4 pharmacists within the Southern Trust, and perhaps
5 regionally, to look at Bicalutamide 50mg prescription. 13:22
6 I believe there were 50 cases identified, 48 of which
7 were Mr. O'Brien's, and I believe --
- 8 302 Q. I think you said two were identified as errors?
- 9 A. Yes.
- 10 303 Q. And I just was keen to know is how you knew they were 13:22
11 errors?
- 12 A. I didn't look at them. I believe Mr. Haynes has looked
13 at those.
- 14 304 Q. Okay. So we'll ask Mr. Haynes about that. The only
15 reason I ask is that your evidence was that when you 13:22
16 first saw this come across your desk, you assumed it
17 was an error, that it should have been 150 rather than
18 50?
- 19 A. Yes.
- 20 305 Q. So I'm keen to tease out whether or not these were 13:22
21 actual errors or not. Do you see where I'm coming
22 from?
- 23 A. Yes.
- 24 306 Q. So Mr. Haynes should be able to answer that?
- 25 A. I think he probably has got more access to the data 13:22
26 than I have.
- 27 307 Q. Okay. Thank you. And one of the other things, just in
28 terms of SAIs and reporting and the learning from SAIs,
29 the process seems to take, or can take, depending on

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

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

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

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

17 309 Q. Certainly not with hindsight probably?

18 A. No.

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

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

24 CHAIR: Sure.

25 MS. McMAHON: On the two patients, just while we're on 13:24
 26 that. At Dr. O'Kane's section 21 reply, WIT-20089, she
 27 refers to, at the bottom:
 28
 29 "A total of 466 patients was identified from the

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

4
5 And then:

13:24

6
7 "34 of these patients were identified as being on
8 incorrect treatment, as determined by the clinical
9 indications above, and two patients had been commenced
10 on the medication by services outside of Neurology:
11 One by GP, one in South Africa in 2005, and that had
12 continued following the move to Northern Ireland."

13:24

13
14 That may be the two patients that you're referring to,
15 just to close that off.

13:25

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

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

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

13:25

22 MS. McMAHON: Thank you.

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

13:25

26
27 LUNCHEON ADJOURNMENT

28

29

1 THE INQUIRY RESUMED AS FOLLOWS AFTER THE LUNCHEON
2 ADJOURNMENT

3
4 CHAIR: Good afternoon everyone. Ms. McMahon, I think
5 we have a familiar if somewhat new face. 14:21

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

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

16 CHAIR: Thank you, Mr. Aiken. welcome.

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

21
22 MR. CHRIS HAGAN, HAVING AFFIRMED, WAS EXAMINED BY
23 MS. McMAHON AS FOLLOWS:

24
25 MS. McMAHON: Mr. Hagan, thank you for coming along to 14:23
26 give evidence today. I know you're quite softly
27 spoken, so I'll just make sure that the microphone is
28 close enough to pick you up on the transcript and we
29 can hear your answers.

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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 recognise that as your signature?

14:24

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

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

7
8 The purpose of today is to look into some aspects of
9 that in a little more detail. The panel have your
10 written evidence. The core participants have your 14:25
11 evidence and it will be up on the website as well. But
12 it's just to get an opportunity to explore some of the
13 issues that you raise in a little bit more detail so
14 that the panel can consider the governance issues that
15 arise from those concerns and examples that you provide 14:26
16 that may inform recommendations that they may take a
17 view on. So, that's the context.

18
19 Just given the route by which we found you, as it were,
20 when you heard the public Inquiry announcement at that 14:26
21 time, did you think it might have been appropriate to
22 contact the Inquiry in order to let them know that you
23 had some knowledge or experience that might be of
24 interest?

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

1 Maria O'Kane had written to me at some point, at one
 2 point, about the 2010 bladder cancer cases. So I took
 3 it from that that the Inquiry was also aware that I had
 4 raised concerns, and I expected then, because of that,
 5 that you might have wanted to talk to me. But it 14:27
 6 hadn't -- I suppose it's just my reflection having
 7 dealt with Inquiries before, that usually Inquiries
 8 approached individuals who had worked there.

9 314 Q. Thank you. Now, I want to look at your statement in
 10 the order, in the chronological order of some of the 14:27
 11 events that you describe, and I will be covering the
 12 following topics - we only have this afternoon, we hope
 13 to finish with you this afternoon, so I've tried to
 14 tease out what might be the most relevant aspects. And
 15 if there's anything else that you feel that you need to 14:28
 16 say, we can do that towards the end, if that's okay?

17
 18 I will start shortly just with your employment and
 19 career history, so the Inquiry gets a flavour of your
 20 experience. Then we'll look at your time in 2000, your 14:28
 21 six-month period of time in Craigavon Area Hospital in
 22 urology, look at some of the areas of concern that you
 23 raised or observed and in which you give evidence that
 24 you spoke to some people about. Then we'll look at the
 25 review of the adult urology services in 2010 and the 14:28
 26 movement of some of the services to the Regional Unit
 27 in Belfast and some of the issues that arose then.

28
 29 In 2016 there were delays in referral from Craigavon

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

4
 5 Now, the panel heard this morning from Darren Mitchell. 14:29
 6 We looked at some e-mails that you were mentioned in
 7 and were the author of in relation to the 2016
 8 referrals from Craigavon, and they've looked at that in
 9 some detail. So I will, when we come to that, I may
 10 short circuit some of that, but I can still find out 14:29
 11 your views and any concerns that you had around that
 12 and we can take it that way, rather than opening all of
 13 the documents again.

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

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

27
 28 Then from 2005 I was the clinical lead for urology and
 29 then became the Clinical Director for Urology in 2009,

1 and that included transplantation.

2
 3 Around the time of 2010, there's a reconfiguration in
 4 Northern Ireland and we were joined with the urology
 5 team in the Ulster, and I became the Clinical Director 14:30
 6 for both services.

7
 8 Then in 2015 I was appointed the Associate Medical
 9 Director in Belfast Trust, and that covered children's,
 10 maternity, and orthopaedic services. 14:31

11
 12 Then in 2016 I took on a role as Chair of division for
 13 children's services.

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

17
 18 Then 2020 I became Executive Medical Director.

19 315 Q. Thank you. So there have been roles involving, in
 20 particular governance, as part of your responsibility 14:31
 21 as you have moved up the clinical professional ladder,
 22 you have gained more experience and more knowledge of
 23 governance issues. Would that be fair?

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

29 316 Q. Now, if we go straight to the time when you went to

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

5 A. (Witness Nods). 14:32

6 317 Q. And you say in your statement that you had met both of
 7 them before at educational events, but you hadn't
 8 worked with them previously.

9 A. (Witness Nods).

10 318 Q. Now, at that time those two consultants had their own 14:32
 11 set of urology patients, but you say they did a joint
 12 Thursday morning ward round together which you
 13 attended?

14 A. (Witness Nods).

15 319 Q. Can you give us a flavour of what that was like on a 14:32
 16 Thursday morning? Was that, was it a grand ward round
 17 or was that what they called it or...

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

25 320 Q. So both consultants walked around and discussed 14:33
 26 patients together?

27 A. That's correct, yes.

28 321 Q. And this was before the team obviously increased in
 29 numbers. It was a small team at that time?

- 1 A. Yes, there was just the two of them.
- 2 322 Q. And for the purposes of your rotation for your surgical
3 experience to fulfil your rotational requirements, did
4 you work in particular with one of the consultants or
5 both of them equally? what was the structure like for 14:33
6 you?
- 7 A. So I was the only higher surgical trainee, so I would
8 have worked with both of them to try -- the focus is on
9 getting surgical experience, so attending as much of
10 their theatre lists as possible and then joining them 14:34
11 in outpatient clinics.
- 12 323 Q. And just prior to this move, you had spent almost a
13 year and a half at the urology department in the City
14 Hospital?
- 15 A. That's correct. 14:34
- 16 324 Q. And what would be your view on the breadth of your
17 experience at that point? It's quite early on in your
18 surgical rotation, but having been in the Belfast City
19 Hospital in this specialty.
- 20 A. Well, I think, you know, prior to that I'd worked in 14:34
21 Glasgow in a big unit and a sort of middle grade role,
22 so I'd had a fair amount of surgical experience at that
23 stage, and particularly in my second year in Belfast,
24 like that's when I decided I was going to do surgical
25 oncology, I spent a lot of time doing that, that six 14:35
26 months.
- 27 325 Q. And just so we understand it, when you say you had a
28 bit of surgical experience, was it at that stage that
29 you were able to do any operations alone or were you

1 always supervised? what was the fit in your surgical
2 training?

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

10 326 Q. And you'd been to Glasgow, as you say, and you'd been 14:35
11 to Belfast. Did you feel that you had seen quite a
12 breadth of urological surgical experience even at that
13 stage?

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

26 327 Q. And in 2000 was there already a movement towards
27 referring the more complex perhaps higher risk surgery
28 to the Belfast City Hospital, given their ancillary
29 support structures, like intensive care and such?

- 1 A. So at that time the district general hospitals, like
2 the Mater Hospital and the Ulster Hospital, would have
3 referred complex major surgery like cystectomy to
4 Belfast. In Derry they were still doing the majority
5 of the major surgery, but as we progressed towards 14:37
6 2008/2009, they stopped doing the cystectomies but kept
7 doing the prostatectomies.
- 8 328 Q. And had you experience of either observing or
9 participating in cystectomies at this point by the time
10 you arrived in Craigavon? 14:37
- 11 A. So, in my second year in Belfast I worked almost
12 exclusively with Patrick Keane, whose main surgical
13 practice was cystectomy and complex kidney cancer
14 surgery. So he was an excellent trainer and mentor,
15 and consultant colleague laterally, and he and I worked 14:38
16 very closely together and he was a really good trainer.
17 So by the time I went to Craigavon, I was able to do a
18 considerable part of cystectomy.
- 19 329 Q. There's perhaps sometimes a misperception that city
20 hospitals in general get to see a much greater range of 14:38
21 complex surgeries and perhaps a greater turnover. Was
22 that your experience, having been to two major city
23 hospitals?
- 24 A. So, if you take yourself back to that time in surgery,
25 there was a growing realisation that you got better 14:38
26 outcomes for complex surgery if you concentrated it in
27 big centres where they were doing higher volumes with a
28 smaller number of surgeons. And the IOG guidance from
29 2002, which I have attached to my statement, lays that

- 1 out very clearly about how you're going to get better
2 outcomes with less surgeons doing bigger volumes. And
3 it also sets out the roles and responsibilities of DGHS
4 in terms of rapid investigation and referral. So, that
5 was a very live conversation at that time about 14:39
6 centralisation of complex cases, because that's how
7 you're going to get the best outcomes. And if you put
8 patients at the centre, which we always should do, then
9 you organise your services around how you're going to
10 get the best outcome for patients. And it's important 14:39
11 to put aside personal preference, shall we say.
- 12 330 Q. So at the start of your urological career and your
13 surgical rotation, it was the time of parallel movement
14 towards centralisation of some areas of expertise so
15 that patients who needed particularly complex or high 14:40
16 risk operations or treatments would be attended by
17 people who had the most experience in those procedures?
- 18 A. That's correct. And the unit in Belfast had started to
19 organise itself in that way as well. So you've some
20 surgeons specialising in stones, some surgeons 14:40
21 specialising in reconstruction, and others specialising
22 in oncology. And that was reflected across the UK at
23 that time of that transition.
- 24 331 Q. And when you arrived in Craigavon in February 2000,
25 what was the flavour of the, or the profile of the 14:40
26 urology patients at that point? what sort of stuff did
27 you see there?
- 28 A. So it was a unit, and the majority of work would have
29 been core DGH urology work - you know, stone -- the

1 commonest reason for being admitted to a urology unit
2 acutely is urinary retention or stone disease. So that
3 makes up predominantly what was happening. And then,
4 you know, investigation of haematuria and UTIs and what
5 have you. So it was busy in that respect. And then 14:41
6 there would have been a smaller number, I suppose, of
7 more complex procedures being done.

8 332 Q. And what level of autonomy did you have in the unit at
9 that time on your surgical rotation? Were you
10 operating again as you had been before? Were you 14:41
11 stepping up? What was the expectation?

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

23
24 So, you know, I transitioned through my training in
25 that way. I was competent, as I said, to do the 14:42
26 endoscopic resections with a consultant in the coffee
27 room and could be called if there was a problem. But
28 if I was doing a major open operation, you know, then I
29 would have wanted a consultant standing beside me,

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

4 333 Q. And what was your feeling about the level of support
 5 you received and education and mentorship while you 14:42
 6 were there for the six months? What was your general
 7 view of that?

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

19 334 Q. Now, I'll just go to your statement at WIT-98844,
 20 paragraph 28, please. I just want to read this in. 14:43
 21 This is your section 21 response at paragraph 28 and
 22 you say:

23
 24 "I have reflected over time arising from the questions
 25 posed by the USI in the section 21 notice, about the 14:44
 26 six months I spent in CAH.

27
 28 As I have done so, I have recalled that there were a
 29 number of situations that arose that caused me to feel

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

9
10 In 2000 that would have seemed like a brave or 14:44
11 courageous step from a higher surgical trainee. I am
12 sure I probably saw it that way at the time. Whereas,
13 with all the more recent and ongoing changes in medical
14 culture (transparency, openness and the many mechanisms
15 for raising concerns) and the development of clinical 14:45
16 governance (introduced into health and social care
17 around 2003), it hardly seems sufficient by today's
18 standards when the opportunity for trainees to raise
19 concerns are much more organised and available, and
20 their use encouraged. Trainees are now heard and 14:45
21 listened to in a way they would not have been in 2000."
22

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

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

4 335 Q. You say at paragraph 29, I just want to read this line:
 5
 6
 7 "I responded to all the matters that concerned me in
 8 2000 would be different from how I would respond to
 9 them today, if I was still a trainee, including because
 10 the available mechanisms for responding are slightly
 11 different." 14:46

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

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

- 1 also given teaching and incident reporting, DATIX,
2 raising concerns through standard governance
3 methodology, but then also every year the GMC carry out
4 an anonymous survey of trainees, called the National
5 Training Survey, which also gives trainees an 14:48
6 opportunity to reflect on the unit that they work in,
7 if they don't feel safe, to raise those concerns to
8 their clinical supervisor or educational supervisor.
9 And then in Belfast we also survey the trainees
10 ourselves on a regular basis. Because trainees are 14:48
11 often the eyes and ears of what goes on in units and I
12 think their voice is really important, and we need to
13 facilitate them to be able to express any concerns they
14 have, and feel safe to do so, and it's very much the
15 culture of being open and a system that is open and 14:48
16 welcome people raising concerns is a much safer system.
17 So, openness is actually at the heart of patient
18 safety.
- 19 336 Q. And you've mentioned the clinical and educational
20 supervisor; what sort of timeframe were those roles 14:48
21 introduced? Can you recall even just a ballpark?
- 22 A. I'm sorry, I can't remember.
- 23 337 Q. Now, you've mentioned also the GMC. Would they
24 anonymously seek information from trainees in order to
25 inform, presumably, best practice? 14:49
- 26 A. Hmm.
- 27 338 Q. How does that work in a, for example, the Trust that
28 you're now the Executive Medical Director in, how does
29 that operate if the trainee is anonymous and perhaps

- 1 the issue that they're complaining about is anonymous?
2 How does that feed itself into the system?
- 3 A. So, in the first instance, the training unit gets a RAG
4 rating, a red, amber, green rating, and if the unit
5 gets reds or ambers, that's a sort of flag for my team 14:49
6 to be curious about what's happening there, first of
7 all. And then there's an opportunity for free text
8 where trainees can raise a concern. Now, when that has
9 happened, I would usually have a conversation with
10 NIMTIDA (sic) and are they able to identify where the 14:50
11 trainee works, perhaps who it is, can we support the
12 trainee, first of all, and then also investigate the
13 concerns.
- 14
- 15 So, I think the key, you know, the key to this is if a 14:50
16 concern is raised that you are brave and you
17 investigate it and find out what's actually happening,
18 and it's acting on the concern is the important thing.
- 19 339 Q. And in your view, what is the effectiveness of, in
20 particular, that GMC process around trainees? Do you 14:50
21 consider that to be something that is successful for
22 both the trainee and for the Trust?
- 23 A. Absolutely. I mean, I think I welcome things like
24 this. I think that it can only improve our services
25 and it can only improve the experience for trainees. 14:51
26 They also survey trainers for their feedback. But
27 ultimately what it does is create safer services.
- 28 340 Q. And is it used much? Is it triggered much within - I
29 know you only can speak to your Trust - but is it

- 1 something that you say, "well, that's working because
2 people are actually using it"?
- 3 A. Oh, no, absolutely. Because, you know, it's an annual
4 survey and it gives you -- and if you have areas that
5 have been highlighted as pink or red, you work with the 14:51
6 team and with the trainees, to identify what the issues
7 are in order that you can then improve that. But if
8 there aren't improvements in a training environment,
9 the GMC can actually put trust into enhanced
10 monitoring, because of the trainee experience, and the 14:51
11 ultimate sanction is to remove trainees if the trainee
12 experience is poor.
- 13 341 Q. And it's also a way in which they can identify their
14 concerns about others, is it, this system? Some of the
15 concerns that you raise, some of the examples we're 14:52
16 going to come to, that's the way in which they can --
17 if this system existed in 2000, the system you've just
18 described, would that be the route that you would have
19 gone down?
- 20 A. So it's a way of -- I mean you can raise patient safety 14:52
21 concerns through this. Now what we try and do is
22 encourage trainees to raise patient safety concerns
23 through incident reporting, because then it will be
24 captured in normal Trust processes and allows you then
25 to review and determine if it's a serious adverse 14:52
26 incident, for instance, or there's any professional
27 concerns in respect of what's being raised.
- 28 342 Q. So the route in which someone chooses to trigger their
29 concern will dictate the actions after IR1 would allow

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

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

11 343 Q. So if the systems you describe were available in 2000,
 12 when you were having some of your concerns, what would
 13 you have done with the processes you have now before we
 14 look at what the processes were then?

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

23 344 Q. And you've mentioned in your statement that governance
 24 has evolved over the years and become more structured
 25 and codified and perhaps of greater awareness around it 14:54
 26 from staff. But when we look back at 2000, do you
 27 recall what governance was like then? Are you able to
 28 look back and think, "Well, we didn't have DATIX, we
 29 didn't have this and that." What do you recall having

- 1 as a potential remedy for concerns?
- 2 A. It's a long time ago. I suppose the main one would
3 have been the M&M type meeting, and I can't recall what
4 processes there were in Craigavon at that time. I know
5 that in Belfast we had an M&M meeting where we could 14:55
6 review, you know, complications in respect of surgery.
- 7 345 Q. So it was still very much, sometimes it was local
8 approach dictated what the processes were?
- 9 A. Yeah, I mean, there wasn't the structure that there is
10 now. Absolutely not. 14:55
- 11 346 Q. There was no standardised governance structures across
12 the Trusts at that time?
- 13 A. Not to my recollection. I mean, I think you have to
14 remember that I was a trainee then. I think also
15 trainees may not have been as aware of those systems as 14:55
16 well. Because part of the thing about training is
17 learning about those types of things. I think you
18 spend a lot of time training trainees about how to
19 raise concerns. Now, probably -- well, I know that we
20 didn't do 23 years ago. 14:55
- 21 347 Q. I suppose the background to the questions is
22 establishing a baseline then, if at all possible from
23 this remove, so that the panel can look at what might
24 have been done, what could have been done, what should
25 have been done, and not unfairly assess that against 14:56
26 systems that simply weren't in place. So, it's more
27 trying to explore what was open to you.
- 28 A. Well, I mean clinical governance wasn't adopted in
29 Northern Ireland until 2003/2004, and it has massively

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

10 348 Q. And a lot of the things you mention are the outworking 14:57
11 of clinical governance, the end product, coroners and
12 medical negligence, civil claims, learning from perhaps
13 the wrong end of the telescope. Do you consider that
14 there is -- well, what part do you think that culture
15 in a place has to play in both the triggering of 14:57
16 governance and the effectiveness of any action taken?

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

1 from harm, but it is - it tends to be reactive. What
2 we try to do is shift that thinking into how can we
3 make sure we're safe today?
4

5 So the out-workings of that are daily safety huddles, 14:58
6 right the way up to executive team, ehm, weekly huddles
7 where divisional teams come together and they review
8 all their safety data from the previous week and look
9 to, you know, is there any immediate learning? Is
10 there anything that needs to be raised as a concern? 14:58
11

12 We also created a system in Belfast called the
13 Professional Governance Information System which,
14 you'll see is a recommendation of the Independent
15 Urology Inquiry, about how we collate information in 14:59
16 respect of doctors, so that if a concern is raised
17 about a doctor, I will have information in relation to
18 incidents, complaints, SAIs, coroner's cases, clinical
19 negligence, that let's me build a picture. So it's
20 building a safer system. 14:59
21

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

23 349 Q. I think it partly did --

24 A. But then the cultural bit was then about being open.
25 So, we've done a lot of work around being open and 14:59
26 encouraging staff to come forward, to feel safe to do
27 so. Because I think I said earlier on, at the heart of
28 any safe system is staff feeling safe to raise concerns
29 and be open, and be open when things go wrong, and when

1 things do go wrong, that they will feel safe and that
 2 they won't feel that they're going to be blamed.
 3 Because we're all human, we all make mistakes, and it's
 4 important that we accept and acknowledge that we will
 5 make mistakes. But it's how we learn from it. And I 15:00
 6 think how we make our clinical governance even better
 7 is how we focus on how we learn, because that can be
 8 difficult sometimes to make sure that you put systems
 9 in place that engineer a change.

10 350 Q. Well, we'll look now at the areas of concern that you 15:00
 11 experienced in Craigavon in 2000. And for the panel's
 12 note they will be at - we can bring it up, but I'll be
 13 summarising the issues. WIT-98845 will be the start of
 14 them. And you'll see at paragraph 31 you're working
 15 your way through... I'm going to read from the 15:00
 16 statement and then I'll ask you some questions about
 17 each of these individually from a governance
 18 perspective. So you say:

19

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

1 "Mr. O'Brien's regime".

2

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

12

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

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

28 351 Q. And did you speak to Mr. O'Brien about that?

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

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

10 352 Q. Did you know if they were private patients? 15:03
 11 A. I honestly don't know.

12 353 Q. When they were brought into the ward, were they brought
 13 in on certain days, or certain times, or to stay
 14 overnight? what was the regime that's described?

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

22 354 Q. Did they present as being clinically unwell?
 23 A. Not in my experience. Because I think if they had been
 24 unwell then there may well have been justification for
 25 the treatment. 15:04

26 355 Q. I'm not sure in 2000 if they still had notes at the end
 27 of beds, but did you have access to notes to have a
 28 look and see, 'I wonder what these patients are in for,
 29 I'll have a look'?

- 1 A. So, on the ward round you would - if I was leading the
 2 ward round, would have written in the notes every
 3 morning. So I would have had access to notes. But
 4 often the patient was, as I have said, was admitted, it
 5 wasn't clear why they were admitted, but they were to 15:05
 6 have this regime.
- 7 356 Q. And you've said they stay in over a couple of days.
 8 You've mentioned Mr. O'Brien. Had you any awareness of
 9 Michael Young also bringing patients in or being part
 10 of IV fluid or IV antibiotic therapy? Was he part of 15:05
 11 this regime?
- 12 A. Not to my recollection. But I mean he would have been
 13 aware of these patients from the Thursday grand round.
- 14 357 Q. And did you discuss it with him and say "I'm not sure
 15 what's happening here? Do you know why these people 15:05
 16 are in hospital?"
- 17 A. So, as I've said in my statement, I know that I raised
 18 concerns both with Mr. O'Brien and Mr. Young. I can't
 19 recall about which specific patients, but I know that I
 20 spoke to them about what I thought was some unusual 15:06
 21 practice.
- 22 358 Q. Do you recall what sort of numbers of people were
 23 brought in? Were there cohorts of several patients?
 24 Was it individuals?
- 25 A. I can't remember, to be honest with you. I just 15:06
 26 remember it was a relatively frequent occurrence.
- 27 359 Q. Given that you can't recall and you weren't able to get
 28 to the bottom of what might have been clinically wrong
 29 with these individuals, do you think now that it's

1 something that you might report - I use "report" in an
 2 informal way; maybe draw to the attention of someone?
 3 would that be something you would expect a trainee to
 4 say "I see people coming in, I'm not getting any
 5 rationale why. I need to speak to someone clinically
 6 senior." 15:07

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

27 360 Q. Yes, and they will be coming to give evidence.

28 A. Yeah.

29 361 Q. I suppose what my questions are aimed at is

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

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

16
17 Now, I've described to you earlier all the mechanisms
18 available for trainees to raise concerns, but they
19 didn't exist then.

20 362 Q. Yes, and we appreciate that. And that's why I started 15:09
21 your evidence as an Executive Medical Director and
22 allowing you to set the landscape as it is - no
23 expectation from the Inquiry that you would be judging
24 yourself from this remove. But there is an expectation
25 that when you were in this scenario, was this 15:10
26 sufficiently concerning that something else might have
27 been done?

28
29 Now, I phrase that in the sense that this is the first

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

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

12 363 Q. If we look at the next example, cystectomy and
 13 orthotopic, is that correct?

14 A. That's correct.

15 364 Q. Orthotopic neobladder formation: 15:11

16
 17 "Amongst the patients coming in for antibiotic therapy
 18 and IV fluids was a patient who had had a cystectomy (a
 19 major operation to remove the bladder that would
 20 generally take between 4 and 5 hours) and neobladder 15:11
 21 (creation of a new bladder) to treat recurrent urinary
 22 tract infections (UTIs).

23
 24 There was a young woman in her early 20s who had this
 25 procedure before I arrived to do my rotation at CAH, 15:11
 26 but who then had subsequent admissions for fluids and
 27 antibiotics during the time I was in CAH."
 28
 29 Just stopping there. Is she a patient then that falls

1 within the previous cohort of patients?

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

3 365 Q.

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

8
9 And you have done so.

10 15:12

11 "The USI may wish to look at the particular case.

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

17
18 The predominant indication for cystectomy and
19 neobladder is for treatment of bladder cancer and I was
20 disturbed that this major procedure had been undertaken 15:12
21 for recurrent UTIs in a young woman. I could find no
22 evidence base in the literature for this.

23
24 At the end of a ward round where I accompanied
25 Mr. O'Brien, I challenged him as to why he had carried 15:12
26 out such a radical and life changing operation on this
27 young woman in the context of recurrent UTIs. He
28 remarked that someone else had said that to him and he
29 justified it to me by telling me he had specifically

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

8
9 I think this was the only case of this type that I
10 myself saw during my rotation, but I cannot say if 15:13
11 there were others with whom this approach was taken.

12
13 I did speak to Mr. Young during my rotation about
14 various concerns I had about Mr. O'Brien, but I cannot
15 now say whether this was one of the matters that I 15:13
16 spoke to Mr. Young about. I may have, but I cannot say
17 that I did.

18
19 Looking back on this now with 17 years experience as a
20 consultant urological cancer surgeon, I can see no 15:13
21 justification for the operation."

22
23 Just your last sentence indicates where we have to
24 straddle two worlds in many ways in trying to look at
25 some of your concerns through the lens of a second year 15:14
26 trainee, but also in hindsight you're still able to
27 provide some opinion on the appropriateness of what you
28 saw, perhaps more so now given the breadth of evidence
29 that you have had since your time in Craigavon.

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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).

15:14

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?

15:14

A. Mm-hmm.

15:15

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.

15:15

15:15

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

- 1 through a major operation for what's a common condition
 2 in young women, was very unusual.
- 3 368 Q. So, what you did know about this lady at the time was
 4 that it was a benign presentation?
- 5 A. Correct. 15:16
- 6 369 Q. whatever the underlying clinical condition was, which I
 7 think was recurrent - was it recurrent UTIs was the
 8 fundamental dominant presentation?
- 9 A. Yes. Yes.
- 10 370 Q. And what you're saying is that even since then, there's 15:16
 11 nothing you've seen or learned in your career that
 12 makes you look back on that set of circumstances that
 13 would make you think that a cystectomy and neobladder
 14 was an appropriate clinical response?
- 15 A. I don't think so. I mean, I've spent 17 years doing 15:16
 16 cystectomy for patients with bladder cancer and that's
 17 the main indication for doing that operation.
- 18 371 Q. Have you ever performed a cystectomy/neobladder on
 19 someone who is presenting with benign symptoms?
- 20 A. I haven't, no. 15:17
- 21 372 Q. would it be something that you would be familiar with
 22 others doing in your field?
- 23 A. There's a small proportion of patients who maybe had a
 24 neurological disorder who may benefit from cystectomy
 25 if they have small contracted bladders. And, again, 15:17
 26 the numbers of patients having that are extremely
 27 small, and they predominantly would have been done in
 28 Belfast with the reconstruction team and we might have
 29 helped them as the bladder cancer team, but the

1 indications are it's very rare, to be honest with you.
 2 And cystectomy and orthotopic neobladder is primarily
 3 an operation for people with bladder cancer.

4 373 Q. And is it ever indicated for people with recurrent
 5 UTIs?

15:18

6 A. Not in my experience, no.

7 374 Q. As you've said, it's a major operation. Does it have
 8 any other potential fallout for young women? You say
 9 this lady was in her early 20s - is there any other
 10 potential impact or complication that you would expect
 11 or see?

15:18

12 A. I'm not sure how technically it was carried out - I
 13 mean there's a lot of different types of orthotopic
 14 neobladder that you can perform, but I suppose the risk
 15 is to fertility, in terms of adhesions affecting the
 16 fallopian tubes and what have you. So there is a risk
 17 in that.

15:18

18 375 Q. You don't know if any of that applies in this case?

19 A. I don't know that. I mean, you're just asking me the
 20 potential risks, and that would be one of them.

15:19

21 376 Q. Do you recall how long this, after a major operation
 22 like that, was she in the hospital for a while, do you
 23 remember that?

24 A. So I wasn't there when she had the surgery, but she --

25 377 Q. She came back in?

15:19

26 A. She kept - she was in fairly -- on several occasions
 27 she was admitted with recurrent infections and pelvic
 28 pain.

29 378 Q. would that of itself be an indication that the reason

1 for doing the operation hadn't actually eradicated the
 2 problem?

3 A. I suppose my reflection and why it stuck in my mind was
 4 that she was very unhappy, and I used the word
 5 "miserable". 15:19

6 379 Q. And still having recurrent UTIs?

7 A. Yeah.

8 380 Q. We can't be sure, but you think the possibility was
 9 that that was the reason for why she was operated on in
 10 the first place? 15:20

11 A. That would be my recollection. I think it would be
 12 important if you want, you know, to look more closely
 13 at that case.

14 381 Q. Now, you spoke to Mr. O'Brien and he mentioned that he
 15 had discussed this case with a urologist in the United 15:20
 16 States of America. I don't suppose you remember the
 17 name of the urologist?

18 A. No, but his response stuck in my mind. Because, you
 19 know, I remember asking him and I remember him saying
 20 somebody else had raised this as an issue and he had 15:20
 21 spoken to somebody in the United States of America who
 22 said in the circumstances it was a reasonable course of
 23 action.

24 382 Q. And he didn't say who the other person was who had also
 25 perhaps shared your views, who had expressed the same 15:20
 26 view?

27 A. No. I mean, I think that, I suppose I felt brave
 28 challenging him and I got an explanation back which
 29 was, it was difficult to argue with.

- 1 383 Q. And you don't recall - you can't say whether you spoke
2 to Mr. Young about this issue or not? You just don't
3 recall?
- 4 A. So, undoubtedly, you know, because of the joint ward
5 rounds, I would have expected that Mr. Young would have 15:21
6 been aware of some of these patients. And when I did
7 raise concerns with Mr. Young, as I've said in my
8 statement, his response was "That's just Aidan".
- 9 384 Q. And what did you take that to mean when he said that?
- 10 A. It's hard to know how to interpret it. But I felt I 15:21
11 was speaking to another consultant and raising an issue
12 and that was the response. And, again, you look back
13 and you think 'I'm a second year trainee, I don't know
14 everything about urology, I'm working with senior
15 consultants, maybe they think this is acceptable'. 15:22
- 16 385 Q. Is cystectomy and neobladder, are those procedures that
17 are fairly unusual today or are they routinely done for
18 bladder cancer?
- 19 A. So, I was appointed in 2003 and I had got training in
20 neobladder. So I started a cystectomy and neobladder 15:22
21 service in Belfast and working with another colleague.
22 It's a really good operation for the right person,
23 particularly young people with bladder cancer who are
24 highly motivated to manage the neobladder and you get
25 really good outcomes. It's less good an operation in 15:22
26 older, less fit people, because they have to learn how
27 to use their new bladder. And traditionally the
28 standard in Northern Ireland had been to create a bag,
29 so this was a new type of procedure being offered for

1 people with bladder cancer.

2
3 My experience of it was really good, but it was really
4 important to select patients carefully and
5 appropriately. And, as I say, I had good outcomes with 15:23
6 that operation. But predominantly in Northern Ireland
7 people would still tend to get a bag as a way of
8 diverting the urine after cystectomy.

9 386 Q. So in 2000, when you were in Craigavon, on one view you
10 could read that and see that as a potentially good 15:23
11 learning experience for somebody who's on a surgical
12 rotation for someone to say "Let me talk you through
13 this, why we ended up making the decision to do this."
14 Do you think that that was an opportunity that could
15 have been used to explain to you exactly what was going 15:24
16 on?

17 A. So that's sort of an interesting slant on something.
18 Surgery is a craft specialty, but the actual thing that
19 makes you a good surgeon is not whether you're good in
20 theatre, it's your decision-making before and 15:24
21 afterwards, in terms of operating on the right people
22 and making sure you look after them if there's a
23 complication. Most people going through a surgical
24 training scheme can be got to a level where they're
25 safe in theatre. What differentiates good from really 15:24
26 good surgeons is their decision-making about when they
27 take people to theatre and, as I say, how they look
28 after them when they've got complications. And that's
29 what tests surgeons, is complications.

- 1 387 Q. Well, if I ever end up in the Belfast Trust I'd like
 2 someone who's good in theatre as well, so if you could
 3 arrange all of that!
- 4 A. I don't want to minimise it, but you can train people
 5 to be safe in theatre, okay, and they have competencies 15:25
 6 to attain, but the really hard bit about surgery is
 7 actually deciding who to operate on.
- 8 388 Q. So the whole journey is learning and the --
- 9 A. It is.
- 10 389 Q. And the decision-making is key? 15:25
- 11 A. So to come back to your point, I think that it's a
 12 really bad of example of when to do cystectomy and
 13 neobladder, so I didn't think it was a good learning
 14 experience, other than to say I can't understand why
 15 you would do that operation. 15:25
- 16 390 Q. Thank you. I'd just like to move on to the next
 17 example, which is the transurethral resection as a
 18 prostate procedure.
- 19
- 20 "TURP is a core urological procedure for the treatment 15:25
 21 of benign prostatic hypertrophy to remove symptoms of
 22 bladder outlet obstruction.
- 23
- 24 In 2000 it was performed using monopolar diathermy, a
 25 form of electric current, to re-set, cut and remove 15:25
 26 tissue from the prostate via an endoscopic sheath.
- 27 Glycine (a potent neurotoxin), 1.5% fluid was used as a
 28 non-ionic irrigation fluid in order to maintain vision
 29 during the procedure.

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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 cardiac neurological and respiratory side effects and even occasionally death.

15:26

The key risk factors for TUR syndrome include resection time (greater than one hour), height of the fluid bag, (greater than 70cm) and large blood loss.

15:26

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 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.

15:27

One of the key mantras of the training which I 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

15:27

1 for another 10 minutes to control any bleeding. I was
2 therefore disturbed as a trainee in CAH when a TURP
3 that Mr. O'Brien was carrying out involved a resection
4 that lasted significantly greater than 1 hour.

15:27

5
6 The case I recall involved resection time approaching 2
7 hours, and the anaesthetist and nursing staff
8 expressing concerns to Mr. O'Brien about the length of
9 operating time, but Mr. O'Brien continued. I thought
10 this was a patient safety issue because it was putting
11 the patient at what I considered to be unnecessary
12 risk. I expressed that view to Mr. O'Brien.

15:28

13 Mr. O'Brien's view, as far as I recall it, was that
14 resection time was not the significant issue I

15 considered it to be. I believe I did speak to

15:28

16 Mr. Young about this issue (I did speak to him a number
17 of times during my rotation about different issues) and
18 my recollection is of him saying "That's just Aidan".

19
20 I cannot say for certain that the remark from Mr. Young
21 that I recall was definitely in connection with this
22 issue, but it is definitely a phrase that Mr. Young
23 used to me when I raised an issue about Mr. O'Brien
24 during my time in CAH."

15:28

25
26 So this is -- a couple of issues in this particular;
27 it's the length of time taken. There seems to be a
28 professionally accepted cutoff point of no more than an
29 hour, and we established at the outset of your evidence

15:28

1 that you had been involved in these operations prior to
 2 coming to Craigavon, so you knew what to expect. This
 3 wasn't a new procedure for you to observe and form a
 4 view that might be misinformed, you were familiar with
 5 this? 15:29

6 A. Oh, yeah, I mean I'd had a lot of exposure and
 7 experience of TURP in Glasgow and Belfast before going
 8 to Craigavon, and I've trained lots of urologists as
 9 well about safe TURP, and a core part of that is that
 10 you should cease within an hour to reduce the risks. 15:29

11 391 Q. And the risks, as you have set out, are quite
 12 clinically significant, including possible death?

13 A. Well, TUR syndrome is something you wanted to avoid,
 14 and I mean as you know later in my evidence I talk
 15 about how we moved away from Glycine in 2013, because 15:30
 16 Glycine is actually a relatively dangerous fluid,
 17 particularly if it's absorbed into the circulation.

18 392 Q. And was it not until 2013 that they found a safe
 19 alternative that was able to be rolled out for Glycine?
 20 Is that why there was a change in practice, or what was 15:30
 21 it?

22 A. So, there had been earlier equipment using bipolar,
 23 which was not as good, and a company brought out a
 24 really good set of resection equipment that used
 25 bipolar, and it became very clear that that was at 15:30
 26 least as good as the standard monopolar, but much
 27 safer.

28 393 Q. And did that involve people learning to do this
 29 procedure in a different way?

- 1 A. Do you know, if you're experienced at TURP, it would be
2 really straightforward to slightly -- you just had to
3 slightly adapt your technique in terms of controlling
4 bleeding. It's not difficult.
- 5 394 Q. Did it affect your ability to see what you were doing, 15:31
6 to have a good clear vision? Was there any argument
7 around that?
- 8 A. I think that's spurious.
- 9 395 Q. Spurious because you didn't experience it or because it
10 doesn't actually happen in reality? 15:31
- 11 A. I don't think it happens. I mean we introduced bipolar
12 in Belfast in 2013, we took all the monopolar sets out
13 and the whole team moved over to bipolar without any
14 real issue.
- 15 396 Q. So you were the Clinical Director then, were you? 15:31
- 16 A. That's right.
- 17 397 Q. So you identified a better way and a safer way of doing
18 something, and presumably your colleagues were on board
19 and you just said "This is what we're doing from now
20 on"? 15:31
- 21 A. Well, it was the tragic death of a woman having a
22 gynae, gynaecological procedure. But it's very similar
23 in terms of the fluid used. And there was a clear
24 patient safety issue to me, and if we have good
25 technology that makes surgery safer then we should 15:32
26 adopt it. And the other thing that was coming down was
27 obviously laser prostatectomy, but we don't need to get
28 into that here, because this is --
- 29 398 Q. Just in relation to, that's one of the examples we

1 referred to earlier where an inquest or something
 2 tragically happens and the learning comes backwards in
 3 the hope that --

4 A. Yeah.

5 399 Q. And it wasn't your field, it was gynae, the death of 15:32
 6 that lady. But it was something obviously that
 7 informed your view on what good practice would be, so
 8 it was the next logical step for you to get rid of the
 9 Glycine?

10 A. I felt very strongly about it. I felt, you know, we 15:32
 11 want to make surgery as -- I mean you talked, we talked
 12 about good surgery, and this is about good surgery,
 13 it's making it as safe as possible and reducing risks
 14 for patients.

15 400 Q. I'm just interested in the procedure from a governance 15:32
 16 perspective of how you go about buying-in everyone's --
 17 maybe it's just a matter of "This is the equipment
 18 that's available, so this is what you have to use", or
 19 did people still try to hold on to previous ways of
 20 doing things because that's what they were comfortable 15:33
 21 with?

22 A. So, I didn't find it difficult introducing it in
 23 Belfast, because all the team that I work with focus on
 24 patient safety and they put patient safety before their
 25 own personal preferences. And the data was compelling 15:33
 26 on this. And I think it's really important to use data
 27 to inform your decisions. And if you have a technique
 28 that's demonstrably safer, I don't understand why you
 29 wouldn't adopt it.

- 1 401 Q. within your role you might have a little bit more
2 insight into the answer to this, but if there is a
3 technique that's safer and it's demonstrably so, is
4 there a Trust appetite for spending money on equipment
5 that's needed? You're in the Belfast Trust; is there 15:34
6 generally -- the mindset is to make the best equipment
7 available or you still face problems with budgetary
8 constraints?
- 9 A. I mean, do you have a specific example?
- 10 402 Q. Well, I'm thinking if this was to be the case now and 15:34
11 Glycine was an alternative that was safer, had been
12 established and was available - I know it came as a
13 result of tragic circumstances and that might have
14 focused minds a bit more - but just on a day-to-day
15 decision-making from a cost benefit analysis, is there 15:34
16 a good appetite in the Trust for advancing equipment so
17 that patient safety is still at the fore?
- 18 A. So, patient safety has to be at the heart of everything
19 we do. And there was clear data to support this was a
20 much safer way to do the operation. And, you know, 15:34
21 good care costs, but poor care costs even more, either
22 in terms of complications or negligence. So I think
23 it's really important that you do invest in equipment,
24 if you can do the operation more safely.
- 25 403 Q. In relation to the TURP issue that you've identified, 15:35
26 you've mentioned that the resection time approached two
27 hours, and it appears at this remove to be quite
28 significantly past one hour, it doesn't seem to be just
29 over, there does seem to be moving into twice what the

- 1 operation would be clinically expected to be. Was
 2 there something in particular about that operation that
 3 you remember, "well, I can see why it lasted more than
 4 an hour, but two hours really was a bit much." Was
 5 there something happened, do you recall? 15:36
- 6 A. No. I mean, I think it's exceptional to go to that. I
 7 mean, my approach for doing TURP surgery is that if
 8 it's a big prostate, you still stop at 50 minutes to an
 9 hour and you can always come back another day, you
 10 don't keep going. And that's - I've witnessed that 15:36
 11 with other consultants and it's how I train trainees,
 12 because it's all about being safe. Once you go beyond
 13 an hour, the risks of a complication increase
 14 significantly.
- 15 404 Q. Do they increase exponentially? 15:36
- 16 A. I don't think anybody has ever measured it in term --
 17 but there is that -- I mean it is a mantra in terms of
 18 any experience I've had, anywhere I've worked, where
 19 people stop within 50 minutes to an hour. And
 20 generally speaking the reason you run into problems 15:36
 21 with TURP is bleeding, and that becomes manifest quite
 22 quickly. So if you do run into problems with bleeding,
 23 it happens early and you try and get on top of that and
 24 then stop.
- 25 405 Q. So there wasn't anything that you recall that justified 15:37
 26 this being a longer operation, irrespective of it being
 27 two hours?
- 28 A. Not that I can recall, no.
- 29 406 Q. And you mention that the anaesthetist and the nursing

1 staff expressed concerns to Mr. O'Brien. Do you recall
2 his reply in that context?

3 A. I can't remember specifically, but he obviously was
4 dismissive. Because the nursing staff and
5 anaesthetists are very clued in to the section time 15:37
6 lasting more than an hour and they will, you know, they
7 will tell surgeons "You've been resecting for 30
8 minutes, 45 minutes", do you know? So they keep on top
9 of the clock. Because you can sometimes lose sense of
10 time. So the theatre staff will be very aware of that. 15:37

11 407 Q. And did you get the sense from either the anaesthetists
12 or the nursing staff, as far as you can remember, that
13 this was an unusual event?

14 A. I don't know.

15 408 Q. You don't remember. Even with the knowledge now, the 15:38
16 knowledge that you've gained all of these years later,
17 do you look back on that and still have the same view
18 about the appropriateness of what happened?

19 A. Well, I think it's not appropriate, you know? And I
20 think working in a team in Belfast where patient safety 15:38
21 was paramount, this is something that, you know, we
22 wouldn't have thought was acceptable within our team.

23 409 Q. We took the opportunity to feed back some of your
24 statement to Mr. Young, as relevant in relation to what
25 he recalls. I just want to deal with the -- sorry, I 15:38
26 should have dealt with this at the time, the benign
27 cystectomy:

28
29 "Mr. Young has confirmed that he does not recall this

1 being raised as a concern with him by Mr. Hagan."

2

3 The TURP issue with the risk of tear that we're just
4 discussing:

5

15:39

6 "Mr. Young does not recall this concern being raised
7 with him. He has also provided instructions more
8 broadly on this issue."

9

10 And I'm just going to summarise them. This is just
11 feedback for the purposes of you coming to give
12 evidence. It has to be formalised in a reply, but just
13 so that you can have an opportunity to reply rather
14 than come back. His instructions are:

15:39

15

15:39

16 "It is the aim to finish a TURP within an hour.
17 Sometimes it may be necessary to go beyond this point,
18 for instance if there is bleeding that requires
19 addressing.

20

15:39

21 Urologists have for a long time been very aware of TUR
22 syndrome (hyponatraemia) and monitoring of the fluid
23 balance arising during surgery is critical. An
24 imbalance in fluids after only a short operative time
25 is an indication to stop the procedure.

15:39

26

27 Mr. Young has no recollection of this operation being
28 discussed with him by Mr. Hagan. However, if it was
29 discussed, he believes he would have asked if

1 hyponatraemia had occurred."

2

3 Do you recall if hyponatraemia had occurred in this
4 particular example?

5 A. I can't recall.

15:40

6 410 Q. So it's a possibility?

7 A. It is possible. I mean, TUR syndrome will cause a low
8 sodium.

9 411 Q. And did you stay for the duration of the procedure?

10 A. No.

15:40

11 412 Q. And if hyponatraemia had occurred it would require
12 medical intervention at some point, in theatre
13 presumably?

14 A. Or in intensive care.

15 413 Q. In intensive care. And you don't know whether that
16 happened?

15:40

17 A. No.

18 414 Q. I'll just move on to the next issue, which is ureteric
19 stone treatment. This is your fourth concern.

20 Ureteric stone treatment:

15:40

21

22 "There are two different issues in this area.

23 First, emergency admission to urology units for stones
24 in the ureter (the tube connecting the kidney to the
25 bladder) is common. Most stones are less than 1cm in
26 size and around 90% should pass spontaneously without
27 surgical intervention.

15:41

28

29 There was emerging evidence in and around 2000 that

1 prescribing alpha blocking medication, such as..."

2

3 A. Tamsulosin.

4 415 Q. Thank you:

5

15:41

6 "...could assist stone passage. This conservative
7 management of stones was my experience from working in
8 Glasgow and Belfast. Mr. O'Brien's approach to
9 ureteric stone management was very different and his
10 preference was to intervene surgically at a very early
11 stage.

15:41

12

13 When discussing patient management with Mr. O'Brien, I
14 challenged him in relation to this approach, as I felt
15 that suitable stones should be allowed to pass
16 naturally. This is because intervention carries risks,
17 including sepsis and ureteric perforation.

15:41

18 Mr. O'Brien, however, referred to his training in
19 Tallaght Hospital in Dublin and that this was how he
20 managed stones.

15:42

21

22 Generally, I found Mr. O'Brien to be dismissive of me
23 when I raised concerns. He was clear that it was an
24 appropriate course of treatment."

15:42

25

26 The second aspect of this concern is:

27

28 "The second issue related to the energy source used in
29 the destruction of stones.

1 Destruction of ureteric stones requires an energy
2 source. In 2000 there were a number of sources
3 commonly used when operating on the ureter, such as
4 laser and pneumatic devices, such as the Swiss
5 Lithoclast. Both these types of energy sources had 15:42
6 good safety profiles. Mr. O'Brien's preference,
7 however, was to use an electrohydraulic EHL energy
8 source. It was powerful and unpredictable. EHL has
9 uses for large bladder stones and kidney stones where
10 its use is safe, but in the ureter it carries a very 15:43
11 high risk of ureteric perforation.

12
13 I discussed this risk with Mr. O'Brien as I felt this
14 was a high risk energy source to use in the ureter with
15 real safety risks. I described my experience with the 15:43
16 Lithoclast (which has a zero risk of ureteric
17 perforation) and questioned why he would not use it as
18 it was very cheap technology. Again, I found
19 Mr. O'Brien to be dismissive of my concerns.
20 Mr. O'Brien did not accept my view. 15:43

21
22 Unfortunately, when carrying out a left ureteric stone
23 case with Mr. O'Brien directly supervising me, he told
24 me to use the EHL probe to break up the stone. As
25 instructed, I did this, and the discharge of the energy 15:43
26 source caused a very large perforation in the upper
27 third of the ureter. Mr. O'Brien took over the case
28 and was unable to negotiate a ureteric stent into the
29 kidney due to the size of the defect. This then

1 required the patient to have an open surgical repair of
 2 his ureter. I was very distressed by this
 3 complication, as I felt very much to blame for it, even
 4 though I had carried out the instructions of the
 5 supervising consultant. 15:44

6
 7 Mr. O'Brien spoke to the patient afterwards as he was
 8 ultimately responsible for the operation. I was not
 9 present. I don't know what Mr. O'Brien said to the
 10 patient. With hindsight, it is clear to me that the 15:44
 11 direction I received from the supervising consultant to
 12 use the EHL was not appropriate in the situation and
 13 this was an entirely avoidable complication."

14
 15 So, the first, there are two different issues. The 15:44
 16 first one was the issue around the stones. Now, you
 17 have had experience of this particular -- I presume
 18 that is quite a common issue in urology, stones?

19 A. So, it's one of the commonest reasons for admission to
 20 a urological unit is with a ureteric stone due to pain, 15:44
 21 and a substantial portion of ureteric stones will pass
 22 themselves, with appropriate pain relief and use of
 23 alpha blockers. So, my experience, as I say, in
 24 Belfast and Glasgow was generally conservative
 25 treatment and only intervening in situations where 15:45
 26 patients were septic or there was a very large stone
 27 that wasn't going to pass.

28 416 Q. And what was it about this particular issue? You were
 29 discussing the patient management with Mr. O'Brien and

1 you challenged him in relation to this approach. Was
 2 it because your experience to date was different or did
 3 you think his approach just, you couldn't understand
 4 it? What was it?

5 A. So, it's in respect of intervening in stones that I 15:45
 6 thought would be able to pass themselves and you would
 7 avoid the risk of surgery. The instrument you use to
 8 get into the ureter is a rigid steel rod and it can
 9 cause damage to the tube coming from the kidney, called
 10 the ureter. And it's also about avoiding unnecessary 15:46
 11 surgery.

12 417 Q. So it's wait and see if the stone passes and, if
 13 necessary, intervene?

14 A. Yes.

15 418 Q. So, Mr. O'Brien took a view that he was going to 15:46
 16 intervene, and your view was that it was inappropriate
 17 because you needed to give the non-intervention time?

18 A. So, again, you know, I am coming as a second year
 19 trainee and this has not been my experience elsewhere.
 20 I'm trying to understand why we would intervene in 15:46
 21 stones that should pass themselves. But he was very
 22 clear this was his approach to managing ureteric stones
 23 and justified it with this is how he had been trained.
 24 And, you know, he's a senior consultant and this is
 25 what he felt was the appropriate course of treatment. 15:47

26 419 Q. Was it your experience at the time, or has it been your
 27 experience since, that perhaps consultants who are more
 28 senior, who are more used to their own way of doing
 29 things, find it difficult either to be challenged or to

1 adjust their practice to reflect advances?

2 A. So, I think that at the heart of safe consultant
3 practice is good team working, and that working in a
4 functioning team where there's a built-in peer review,
5 essentially. I think when you work in isolation, 15:47
6 there's a risk that you develop practice that maybe
7 doesn't follow best practice or best guidance or, you
8 know, keep up to date with current best thinking.

9 420 Q. And is it still your view at this remove that your view
10 would be the same in relation to hands off and see if 15:48
11 the stone passes, or would you say now, "well, I can
12 see maybe where he was coming from, because that
13 patient presented in a certain way"?

14 A. No.

15 421 Q. I know you don't remember -- 15:48

16 A. I think for small ureteric stones the appropriate
17 course of treatment is to see if they'll pass
18 themselves. I think if the patient is septic or it's a
19 very large stone, then you obviously need to intervene.

20 422 Q. Now the second issue where you were being supervised in 15:48
21 your -- in the use of EHL. Had you been using EHL in
22 your previous posts?

23 A. So, in Belfast there's a procedure called a
24 percutaneous nephrolithotomy. So it's basically where
25 you put a tube into the kidney to remove stones and you 15:49
26 can use EHL there or you can use EHL to break up big
27 bladder stones, because it's safe, there's a much
28 bigger space, you're less likely to cause damage to
29 surrounding structures. EHL's quite an unpredictable

1 energy source and there was -- there's fairly good
 2 evidence that it's use in the ureter carries a much
 3 higher risk of ureteric perforation by a factor of up
 4 maybe up to a couple of hundred potentially risk of
 5 ureteric perforation.

15:49

6
 7 So, it wasn't something I had ever encountered. And
 8 there was reasonably good literature about its risk,
 9 about its safety profile.

10 423 Q. And that was in advance, you knew that information in
 11 advance of this procedure, or was that something...

15:49

12 A. So, I was surprised, I think, that the EHL was being
 13 used to treat ureteric stones, when there's other safer
 14 technology; laser, if used correctly, is extremely
 15 safe, and the lithoclast carries a zero risk of
 16 ureteric perforation.

15:50

17 424 Q. And you've mentioned that you discussed the risk with
 18 Mr. O'Brien. This was in advance of you carrying out
 19 the procedure, I take it?

20 A. So, I recall having a conversation about the use of EHL
 21 and its safety profile, and he was dismissive of it
 22 being an issue.

15:50

23 425 Q. And when you say "dismissive", did you get to explain
 24 your concerns before they weren't listened to, or were
 25 you not listened to?

15:50

26 A. I wasn't listened to.

27 426 Q. And you say he did not accept your view?

28 A. Well, no. Because I think that if you had kept up to
 29 date with the literature, you would have known that it

1 was a high risk energy source to use in the ureter.

2 427 Q. Was it with a degree of reluctance then that you used
3 this equipment on this occasion?

4 A. So I was doing the case on the left ureter and was --
5 he said "No, use the EHL for that", and I was 15:51
6 concerned, but he said "No, it'll be fine", type, you
7 know, that type of conversation. But I -- there's a
8 trigger to activate it, and with one activation it
9 caused a huge perforation of the ureter. And something
10 like that, you don't forget, because I'd never seen it 15:51
11 before and felt directly responsible for a complication
12 which, when you know that something's avoidable, you
13 don't forget.

14 428 Q. On your evidence, it was a bit more than avoidable,
15 because you'd actually spoken about it just prior to 15:52
16 the event?

17 A. Yeah. Absolutely.

18 429 Q. So you had expressed the risk and then the risk
19 manifested?

20 A. Yes. 15:52

21 430 Q. And do you recall what Mr. O'Brien might have said or
22 if he said anything? Your recollection of his reaction
23 to this?

24 A. From what I can recall, he took over the case and tried
25 to get a stent into the ureter, and he wasn't able to. 15:52
26 And then there was a decision to perform an open repair
27 of the ureter.

28 431 Q. And were you involved with the patient afterwards? I
29 know you said Mr. O'Brien spoke to the patient, but

- 1 were you involved in their care?
- 2 A. well, he was on the ward. I don't know what he said to
3 the patient in respect of the complication.
- 4 432 Q. And what are outcomes from that ureteric rupture?
- 5 A. well, the risk is that the repair narrows and then 15:52
6 obstructs the kidney and the kidney doesn't drain
7 properly and then will stop working. I don't know what
8 the long-term outcome was of this patient.
- 9 433 Q. When you talk about there being other opportunities to
10 use equipment that was more clinically appropriate, was 15:53
11 that equipment available in Craigavon at that time?
- 12 A. I don't know if they had a laser. They didn't have a
13 lithoclast. But I talked about how we had got -- I'd
14 used a lithoclast in Glasgow and they bought one in
15 Belfast, because I described my experience and I said, 15:53
16 you know, that this is cheap, safe technology that
17 anybody can use safely to try and break up stones with
18 much less risk. Now, I think laser's better, but there
19 is a cost with laser and the laser technology wasn't as
20 good then as it is now. 15:53
- 21 434 Q. This example, I suppose, is slightly different than the
22 previous examples with the TUR; you weren't there for
23 the whole of the operation, you don't know if there
24 were complications, you aren't able to say -- you
25 weren't there for the cystectomy in the old bladder 15:54
26 operation, you saw the admission of the lady in the
27 hospital after. In this example you identified a risk,
28 the risk materialised, and I think from what you've
29 described it would be fair to say there was patient

1 harm?

2 A. Yes.

3 435 Q. And perhaps significant harm?

4 A. Yes.

5 436 Q. Now, I know that we can get the impression when I read 15:54
6 these out that they all happened in sequential order;
7 it may be that this was the first thing that happened
8 in Craigavon, it may be the last, I'm not quite sure if
9 you remember, if you've tried to recall them in any
10 particular order? 15:54

11 A. Sorry, I can't remember.

12 437 Q. And given that there was patient harm, was this
13 something that you - did you go and speak to anyone
14 about this and say, "Look, I might have messed up", or
15 "I said that might happen and it did and I'm just 15:54
16 training", so was there anyone you could speak to?

17 A. As I say, I raised issues with Mr. O'Brien and
18 Mr. Young. I didn't speak to anybody else about this.

19 438 Q. And just Mr. Young, ureteric stone treatment, again
20 just replying at this stage: 15:55
21
22 "Mr. Young has confirmed that he does not recall
23 Mr. Hagan ever having spoken to him about this issue."
24
25 And he more broadly instructs as follows: 15:55
26
27 "By way of general background, EHL (electrohydraulic
28 lithotripsy), was a method used to fragment stones.
29 There were different electrode probe sizes to be used

1 depending upon which part of the urinary tract they
2 were used in.

3
4 Mr. Hagan fairly comments that his
5 experience/observation was its use in bladder stone 15:55
6 endoscopy. There are accepted probes designed for use
7 in the ureter. This was the instrument used in the
8 department at the time. It was the equipment that
9 Mr. O'Brien had been using, and it is assumed upon
10 which he had been trained in Dublin during his 15:56
11 registrar time.

12
13 Mr. Young found it a device that had to be handled with
14 particular care and he would instruct registrars very
15 precisely on its use and techniques. He also 15:56
16 instructed the registrars to use what is known as a
17 safety guide wire before performing a ureteroscopy "in
18 case".

19
20 Mr. O'Brien did not regularly use this technique and 15:56
21 Mr. Young raised this with him. Mr. Young also
22 continued to instruct the registrars to do so to "to
23 keep them right".

24
25 It is accepted that a guide wire does hinder the 15:56
26 optical view but has its advantages.

27
28 In respect of Mr. Hagan's point about the use of the
29 Lithoclast with a zero risk of perforation, Mr. Young

1 agrees that it has a better safety history and is
 2 economically viable and he observes that the lithoclast
 3 is a straight instruction and can only be used in the
 4 ureter and not the kidney, whereas the EHL system could
 5 be used anywhere in the urinary tract." 15:57

6
 7 I don't think he mentions that they didn't have an
 8 alternative in that, he doesn't seem to indicate that
 9 that was the only equipment that they had. The last
 10 sentence seems to suggest that the EHL was more dual 15:57
 11 function, possibly. I'm not sure if that's right, but
 12 that seems to be the suggestion.

13
 14 It's clear from that feedback from Mr. Young that he
 15 had identified concerns about the equipment and the use 15:57
 16 of it. And I read this out to give you an opportunity
 17 to comment, if you want, rather than find this out
 18 after you've given evidence. But he seems to have been
 19 actively involved with registrars, who were more senior
 20 than you at that point - you were a third year surgical 15:58
 21 rotation, were you?

22 A. Second.

23 439 Q. Second year. So he gives them:

24
 25 "He instructs them to use a safety guide wire in case 15:58
 26 and continues to instruct registrars to do so "to keep
 27 them right". "

28
 29 So, he seems to be, from what he has said, alert to the

1 possibilities of the complications that appear. Did
 2 Mr. O'Brien give you any such instructions?

3 A. Not that I can remember.

4 440 Q. Had you ever seen the EHL used with a guide wire
 5 before? 15:58

6 A. I'd never seen EHL used in the ureter.

7 441 Q. I don't think there's much point in asking you then if
 8 that might have assisted if you'd never seen it used
 9 where you were going to use it anyway, if a safety
 10 guide wire might have helped? 15:58

11 A. They had EHL in Belfast and Glasgow and they didn't use
 12 it in the ureter.

13 442 Q. So it's more the part of the anatomy rather than the
 14 technique?

15 A. I don't think it's a strong argument to say that it's 15:59
 16 because of the dual energy source then we should use
 17 something that is very unsafe in the ureter. That
 18 would be my view on that.

19 443 Q. Is there anything else you'd like to comment on in
 20 relation to what Mr. Young has said? I mean, I think 15:59
 21 he's speaking in the abstract because we don't have the
 22 patient details, you can't recall anything about the
 23 particular patient.

24 A. No, I don't think so.

25 444 Q. So he's just replying to what you have said. 15:59

26 CHAIR: Ms. McMahon, are we about to move on?

27 MS. McMAHON: Yes, we are.

28 CHAIR: I've just realised it's four o'clock and I'm
 29 sure we could all do with a short break. So if we come

1 back at a quarter past four.

2 MS. McMAHON: Yes. Sorry. Thank you.

3

4 SHORT ADJOURNMENT

5

16:10

6 CHAIR: welcome back everyone. Ms. McMahon.

7 MS. McMAHON: Mr. Hagan, I just want to move on to --
8 you've given another couple of examples in relation to

9 paediatric urology and radical prostatectomy and high
10 PSA, and the panel have your experience on those

16:15

11 issues. Just there was one other issue at page
12 WIT-98850, paragraph (vii). And this one you are able
13 to date to the last week in your traineeship in
14 Craigavon:

15

16:15

16 "Priapism and penile disassembly."

17

18 And I'll just read out this paragraph:

19

20 "In my last week as a trainee in CAH in 2000 a patient
21 was admitted with a longstanding priapism (an erection

16:15

22 of the penis that does not go away). Once a priapism
23 has been established for more than 24 to 48 hours
24 surgical decompression or hematoma evacuation will not
25 be successful as the hematoma will have organised and
26 erectile function will be lost.

16:15

27

28 Andrologists (physicians who specialise in treating
29 men's reproductive related issues) in Great Britain

1 were recommending early referral to London for
 2 insertion of artificial penile prosthesis for
 3 management of this rare condition. However, in the
 4 case I remember, Mr. O'Brien took the patient to
 5 theatre and performed what I can only describe as a 16:16
 6 penile disassembly by separating the corpus... "

7
 8 A. Cavernosum.
 9 445 Q. Cavernosum:
 10
 11 "... and..." 16:16

12
 13 A. Spongiosum.
 14 446 Q.
 15 "... spongiosum tissues. I was not myself scrubbed in 16:16
 16 for the procedure along with Mr. O'Brien, and whoever
 17 was assisting him, but I just remember being present in
 18 the theatre at some point and wondering what
 19 Mr. O'Brien was trying to achieve.

20
 21 I remember being concerned that the procedure could 16:16
 22 risk compromising the vascular supply to the penis. I
 23 remember leaving the theatre as I did not want to watch
 24 what was happening.

25
 26 I never found a description of the procedure in any 16:17
 27 text. My recollection is that when the patient
 28 returned to the ward there was concern in respect of
 29 the ischaemia of parts of the penis. I do not know the

1 final outcome for this patient as I left CAH to return
 2 to BCH as part of the urology rotation. This patient
 3 will have been on the urology ward for a period of time
 4 post his operation, so it may well be Mr. Young or
 5 others will recall the case because of its unusual
 6 features."

16:17

7
 8 This sounds like something that would be pretty rare to
 9 see generally?

10 A. I mean, priapism in Northern Ireland is relatively
 11 rare. It is usually associated with drugs that men
 12 would use to get erection. It's more common in Great
 13 Britain with sickle cell and thalassemia and things
 14 like that. But the key point in this is once you go
 15 beyond four hours with a priapism, if you're going to
 16 try and do something surgically you need to do it then.
 17 And once you get to 36 to 48 hours, surgery -- there's
 18 a procedure where you can create shunts -- is of no
 19 value. The shunting procedures that are available,
 20 this is not what is described in books, so I had never
 21 seen anything like this before. But there was emerging
 22 evidence from a urologist in GB called David Ralph that
 23 inserting an artificial penile prosthesis was actually
 24 the best way to manage a priapism greater than sort of
 25 48 hours. And he actually came over to Belfast and
 26 gave a lecture to us as trainees. And actually, for
 27 the purpose of today I read -- he had published a
 28 recent article on that - I mean obviously that article
 29 is recent, but it's a good way to manage unusual

16:17

16:18

16:18

16:18

1 priapism of longstanding duration.

2 447 Q. In relation to the knowledge in 2000, you've said that
3 once a priapism has been established for more than 24
4 to 48 hours, surgical decompression or hematoma
5 evacuation will not be successful. I mean was that 16:19
6 established medical knowledge at that time?

7 A. Yeah. Absolutely.

8 448 Q. Had you seen anything like this in your previous
9 rotations or work experience as a clinician in other
10 hospitals? 16:19

11 A. So, any priapisms I'd had to deal with would have
12 presented within the sort of four to 24-hour window
13 where you would usually aspirate blood from the penis
14 and use alpha -- or adrenergic drugs or alpha agonists
15 to try and bring it down. And that -- I had never seen 16:20
16 that not working. But I hadn't -- this is a very
17 different scenario, this is a long established priapism
18 of a man, I think it was possibly 72-hours, I can't
19 remember exactly.

20 449 Q. You mentioned an expert effectively in London who has a 16:20
21 specialty in cases presenting such as this. Was that
22 something that was known at the time as well, that if
23 there was -- time is of the essence, if you're moving
24 into danger zone then either advice or referral to
25 London was the appropriate route, in your view? 16:20

26 A. So, that was certainly my view as a consultant
27 urologist, that if I was in this situation that's what
28 I would have done. I can't recall exactly when David
29 Ralph came over to give us the lecture, whether it was

- 1 before I went to Craigavon or after, but I know that
2 that was an emerging theme of how to manage this.
3 Because the penile prosthesis was a good way to manage
4 refractory erectile dysfunction. And, you know, we had
5 some experience of inserting them in Belfast, but we 16:21
6 also had good links with David Ralph in London.
- 7 450 Q. And in this case you can't remember anything about
8 this, the patient, their name, their age, how long they
9 were in for?
- 10 A. No, I can't. As I say, it was my last week. I wasn't 16:21
11 involved in the decision-making of going to theatre,
12 but I came to watch and thought -- as I say, I left,
13 because I didn't really know what was happening, to be
14 quite honest with you.
- 15 451 Q. So you didn't know the lead up, you didn't know the 16:21
16 clinical buildup to --
- 17 A. No, I knew the patient was in, but I wasn't involved in
18 the decision-making process to take the patient to
19 theatre. Mr. O'Brien had that decision.
- 20 452 Q. And did you speak to Mr. O'Brien about it and why he 16:21
21 had chosen that particular course of action?
- 22 A. Not that I can specifically remember. I think that by
23 that time I had challenged Mr. O'Brien on quite a lot
24 of things, and I suppose the response had always been
25 dismissive. And, you know, I think you also have to 16:22
26 take into account, and I've said it lots of times
27 already, I'm a second year trainee, I have never seen
28 anything like this before. That doesn't mean to say
29 that he mightn't have had a good reason. But, you

1 know, as part of the training, you learn different ways
 2 to manage priapism, and I could not find any textbook
 3 description of this procedure that he undertook.

4 453 Q. And, again, I don't think you spoke to anyone about
 5 this, it was your last week, as you say. 16:22

6 A. No.

7 454 Q. Just in relation to the stone issue that we mentioned
 8 just before the break as well when the ureter ruptured,
 9 I just want to bottom out if you actually did speak to
 10 anyone about that because of the patient harm involved. 16:23
 11 Did you speak to anyone senior to you or even a peer
 12 around that?

13 A. So, I know I discussed issues with Michael Young, and
 14 stone treatment was one of them, and the use of EHL in
 15 the ureter, you know, would have been part of that 16:23
 16 conversation, because it wasn't something that I had
 17 ever encountered before. And I know that I had
 18 discussions about purchasing a lithoclast and safer
 19 ureteric surgery.

20 455 Q. I know Mr. Young doesn't -- I think his wording is he 16:23
 21 doesn't recall you having spoken to him about any of
 22 the issues that you raise. If you're right and that
 23 you did speak to Mr. Young about the issues, some of
 24 the issues we have discussed in your evidence - and
 25 I've just used some examples to illustrate some of your 16:24
 26 concerns at the time - if you're right and you did
 27 express your concern to Mr. Young, given what you know
 28 now and your experience, could he or should he have
 29 considered this indisputably a clinical concern?

- 1 A. So, I think the key to managing patient safety concerns
2 is appropriate escalation. So, I think if a trainee
3 was raising a concern with a clinical supervisor or
4 educational supervisor about a patient safety concern,
5 I would expect the CS or AES to raise that with the 16:24
6 Clinical Director of the service and then escalation as
7 appropriate. So, to me, it comes back to the heart of
8 how you manage clinical performance concerns and about
9 early -- you know, if there is escalation, that it's
10 dealt with appropriately, people in senior positions 16:25
11 respond to that appropriately and investigate it
12 appropriately.
- 13 456 Q. And in these particular examples, rather than
14 generically, what would be best practice to happen,
15 given the information that I've read out, the 16:25
16 information you've provided to the Inquiry? If this
17 were the case and you had spoken to Mr. Young, do you
18 consider that these are cases that should trigger an
19 approach by him to act accordingly to perhaps explore
20 your concerns to speak to Mr. O'Brien, to speak to a 16:25
21 colleague? Do you think these pass the threshold for
22 necessitating some governance action?
- 23 A. So, I would have expected him to have a conversation
24 with his Clinical Director. And, you know, these were
25 patients who were on the ward, these were patients that 16:26
26 he would have been aware of, you know, on the joint
27 ward rounds. So, irrespective of whether or not he
28 remembers me talking to him about it, he would have had
29 sight and visibility of these patients.

1 457 Q. And also would it be right to say irrespective of
 2 whether you're right or not in your concerns, there's
 3 an obligation?

4 A. Absolutely.

5 458 Q. Those examples we have used to tease out some of the 16:26
 6 governance issues around what might have been expected
 7 to happen or what could have or should have happened.
 8 And you've identified some other issues around
 9 administrative delays that are outpatient practice,
 10 people coming in for review, things that the panel may 16:26
 11 consider are familiar in some respects. But I think
 12 we'll move on from those examples. We've talked about
 13 you, the difficulty of raising concerns as a trainee.
 14 Now I want to sort of fast forward to 2010. You've now
 15 -- you're a consultant in the City and there is the 16:27
 16 review of adult urology services and there was some
 17 issues with patients in 2010 being referred.

18 A. Hmm.

19 459 Q. And we touched a bit on this at the beginning of your 16:27
 20 evidence where there was perhaps a following of
 21 expertise and the relevant patients to a location that
 22 would enable them to get the most appropriate clinical
 23 assessment and treatment by the people who were most
 24 commonly doing those operations or procedures, and that
 25 was the City Hospital for urology at that time? 16:27

26 A. That's right.

27 460 Q. And the Inquiry has heard evidence of the background to
 28 the review and perhaps some pushback, reluctance,
 29 difficulty with letting go perhaps of areas of

1 expertise that some consultants wanted to hold on to,
 2 and that's just a brief overview, because we've heard
 3 evidence, and I know that you were part of the
 4 scenario, so hopefully what I'm saying to you is
 5 familiar. That's the background to an incident you 16:28
 6 recount in your statement in relation to patients who
 7 were referred up to Belfast. We can go to this,
 8 WIT-98857. Now, three of these patients - I don't
 9 intend to read all of this in, we have it available,
 10 but the context - three of these patients ultimately 16:28
 11 fell to you.

12 A. (Witness Nods).

13 461 Q. They became your patients. And if you could just give
 14 us a background as to how the patients found their way
 15 to the City Hospital and what the issue was? 16:29

16 A. So, this goes back to September 2010. Heather Trouton,
 17 who is the Acting Director of Acute Services in
 18 Craigavon, had contacted Beth Molloy, who's sadly
 19 deceased, of Health and Social Care Board, and Diane
 20 Corrigan, who was the Commissioner, and they were 16:29
 21 involved in the review of urology and the clear
 22 recommendations that pelvic cancer should be
 23 centralised in Belfast by, I think, March 2010, and
 24 that Mr. O'Brien had been planning to perform two or
 25 three cystectomy procedures, and that Diane Corrigan 16:29
 26 had instructed that these patients be referred to
 27 Belfast. So there was correspondence between the two
 28 Trusts, and I arranged to see the three patients who
 29 were for cystectomy procedure, but we arranged to

1 discuss them at the, our regional MDT beforehand,
2 because I felt that it was important that there was,
3 the MDT functioned appropriately, reviewed the cases,
4 as you would expect, and came to the determination
5 about the best way to manage patients. 16:30

6 462 Q. So, in particular in one of the patients, you were
7 concerned about the care they'd received at Craigavon
8 and the delays, as you say, in one patient with
9 aggressive bladder cancer receiving definitive
10 treatment that may have affected their outcome, in 16:30
11 Patient 1. Is that after reviewing the paperwork or
12 seeing the patient?

13 A. I was very concerned about the management of all three.
14 But the patient with sarcomatoid bladder cancer, that's
15 a very rare pathology, and the patient had a re 16:30
16 resection when they should have had an immediate
17 cystectomy. Now, thankfully that patient's still alive
18 today, but I think that their outcome could have
19 adversely been affected by the re resection and the
20 unnecessary investigations that were performed before 16:31
21 -- including bone scan, for instance. So that, I think
22 that was a really significant patient safety issue for
23 that individual. And then the other two patients had
24 unfortunately metastatic disease. And in my experience
25 of 17 years of doing cystectomy for bladder cancer, 16:31
26 there's very few indications for palliative cystectomy,
27 and generally speaking it takes three months to get
28 over a cystectomy operation, and that's in very fit,
29 healthy people. Patients that are compromised by

1 metastatic diseases, they don't get back, they won't
 2 get back to their baseline. And one of those patients
 3 died several months later, unfortunately, and the other
 4 died the following year.

5
 6 So, I remember feeling quite upset about the proposed
 7 management for these patients, and you'll see the
 8 letter that I wrote to my medical director at that time
 9 about my concerns about patient safety in respect of
 10 these three patients. 16:32

11 463 Q. That will be one of the e-mails we looked at this
 12 morning. Just bear with me. I have a reference for
 13 where the five patients are mentioned and the three
 14 relevant --

15 A. I can give you the references. WIT-99135. 16:32

16 464 Q. Yeah. And I've got 99136. So they must go over the
 17 page. We'll just go to that. So this is the e-mail
 18 that you have -- this is the first one. Could we just
 19 move it down just to make sure I've got my dates.

20 Friday, 8th September. Yeah. Okay. So this is from 16:33
 21 Jennifer Welsh on 28th September 2010 to Tony Stevens,
 22 Ray Hannon, and you're copied in, and Brian Armstrong.
 23 And this is the discussion around the urology patients,
 24 the group of five:

25
 26 "Update re urology patients we discussed yesterday. 16:34

27
 28 I spoke to Chris yesterday evening and he has had
 29 detailed discussion with the patient involved. All

1 were discussed thoroughly at last week's regional
2 urology MDT and while treatment decision may now be
3 different than had been agreed at SHSCT, all seem to
4 understand why this is the case. Therefore, I don't
5 think we need a second opinion. 16:34

6
7 In addition, Brian Armstrong has spoken to Gillian
8 Rankin and explained about the tone/inference of the
9 letters which were received by Chris and the patients'
10 GPs. 16:34

11
12 Gillian has apologised on behalf of the SHSCT and has
13 advised that Dr. Loughran will be writing formally to
14 the consultant in question. 16:35

15 The only action remaining are:

- 16 1. Operational discussion re swap of minor or benign
17 procedures to facilitate the fact that we have taken in
18 additional complex patients - Brian will lead on this.
- 19 2. Response to Minister's office re one of these
20 patients - Karen McClanahan is leading on this. 16:35

21
22
23 And that's from Jennifer Welsh, Director of Cancer and
24 Specialist Service. 16:35

25
26 Now, the last part of that e-mail refers to e-mail
27 correspondence back and forth about capacity, and that
28 if five patients are coming up from Craigavon we
29 perhaps need a greater level of intervention. Then

1 there's a suggestion, and I think it attempts to follow
 2 through, that five patients who are maybe benign or
 3 require minor surgery should go to Craigavon and have
 4 that done. So that's the backdrop.

16:35

5
 6 If we move up to the main body of the e-mail, the
 7 backdrop to this, rather than read all of that out, is
 8 that you assessed the patients, as you say. One of
 9 them had received what you considered to be
 10 inappropriate treatment that had resulted not only in
 11 delay but could have impacted prognosis, and the other
 12 two patients had been communicated with in a way about
 13 their care that didn't reflect what you thought should
 14 happen?

16:36

15 A. (Witness nods).

16:36

16 465 Q. And you were in the invidious position, perhaps, of
 17 having to tell them that their care wouldn't be as they
 18 planned. Mr. O'Brien had written to the patients,
 19 written to you as well and to the patients, indicating
 20 what he thought the care should be. And you, I won't
 21 say took exception to this, but this did upset you, as
 22 you've indicated in your statement.

16:36

23 A. I need to clarify. What upset me is not the fact that
 24 he wrote to me.

25 466 Q. No, I didn't mean to imply that.

16:37

26 A. No. What upset me was the poor management decisions in
 27 relation to patients with complex bladder cancer. And,
 28 you know, if you take the time to read IOG2002 NICE
 29 Guidance around management of complex cancer, it's

1 clear what should happen, you know, and the Northern
 2 Ireland Review of Urology also made that clear what
 3 should happen. And the benefit of appropriate and
 4 proper multi disciplinary team working, so you have
 5 oncologists, surgeons, radiologists, pathologists, 16:37
 6 specialist nurses all contributing to the conversation
 7 to get the best outcome for patients, offering patients
 8 with metastatic bladder cancer cystectomy as opposed to
 9 good palliative care is unfair to those patients. It
 10 gives them false hope and false expectation. But more 16:37
 11 importantly puts them through a major operation that is
 12 never going to benefit them.

13 467 Q. So did you have to tell them that what had been
 14 suggested was not the optimal course of treatment and
 15 in fact that wasn't going to happen? Was that the 16:38
 16 position you were in?

17 A. Yes.

18 468 Q. Now, that was in relation to Patient 2.
 19 A. And Patient 3.

20 469 Q. And Patient 3. But Mr. O'Brien, in relation to Patient 16:38
 21 3, wrote to the GP and to you?

22 A. But, you know, shockingly, the oncologist that saw
 23 Patient 3 didn't feel she was even fit for
 24 chemotherapy. Now, if a patient is not fit for
 25 chemotherapy, they're definitely not fit for a major 16:38
 26 operation. And there was a misinterpretation of
 27 Dr. McAleese's clinical interpretation by Mr. O'Brien,
 28 and I think that's detailed in my statement, about what
 29 Dr. McAleese actually said.

- 1 470 Q. In relation to Patient 1, Mr. O'Brien did write to the
2 patient's GP and to the patient themselves, indicating
3 his displeasure that they were being referred to
4 Belfast and the cancellation of the admission to
5 Craigavon. And again in Patient 3, Mr. O'Brien wrote 16:39
6 to the GP and to you around the prearranged cystectomy.
7 Now, there was some suggestion from the contents of the
8 correspondence to you that you felt, or could have felt
9 some pressure to carry out what Mr. O'Brien had
10 indicated to the patient would be the proper course of 16:39
11 treatment, when in fact your clinical assessment was
12 that that wasn't the way to go.
- 13 A. Well, it wasn't just my clinical assessment, it was the
14 clinical assessment of the Regional MDT. I wouldn't
15 have made that decision in isolation, because that's 16:39
16 why we've formed MDTs, was to make collective decisions
17 in the best interests of patients and to reduce the
18 risk or prevent single handed practitioners making poor
19 management decisions about patients. And I think, to
20 me, it demonstrated a poor insight and knowledge of 16:40
21 management of bladder cancer and what was appropriate
22 treatment, and using, you know -- and using -- the
23 regional resource was there, the expertise was there
24 even to -- all the other urology units in the region
25 were dialling in to the Regional MDT, apart from 16:40
26 Craigavon, and there would have been opportunities to
27 discuss these cases.
- 28 471 Q. Now, you do reference that, and I'll give the panel's
29 reference in your statement, WIT-98862, that your view,

1 supported by the Regional MDM. So that would appear to
 2 be an example of governance oversight where
 3 collectively you took a view that was completely
 4 different from the referring clinician's view
 5 initially?

16:41

6 A. Absolutely.

7 472 Q. You mentioned a letter that Gillian Rankin had written
 8 earlier in 27th September 2010, and this letter touches
 9 on two issues that we've spoken about; one is the
 10 transfer and the appropriateness of Mr. O'Brien's
 11 actions in relation to those patients and the IV
 12 fluids. Just have a look at that at WIT-99131. It's
 13 dated 27th September 2010 to Mr. O'Brien:

16:41

14
 15 "Dear Mr. O'Brien,
 16 I am in receipt of correspondence in relation to 3
 17 patients. In each case you have written to the
 18 patient, the general practitioner, and Mr. Hagan
 19 consultant urologist in Belfast City Hospital.

16:41

20
 21 Each of these patients has been transferred to the City
 22 Hospital for further management by Mr. Hagan.

16:42

23
 24 I understand that you expected and wished to carry out
 25 this surgery yourself in Craigavon Area Hospital, but
 26 following contact from our Commissioner, the Trust was
 27 obliged to refer the patients to Belfast.

16:42

28
 29 It is of great concern that you have indicated to a

1 patient (in advance of a care pathway being agreed)
2 your preferred management of the case. I believe this
3 puts inappropriate pressure on the receiving team and
4 is regrettable. I understand that the transfer of
5 these patients with whom you may have already formed a 16:42
6 good therapeutic relationship was somewhat unexpected.

7
8 There is another difficult area which we are currently
9 examining, the intravenous therapy IVT cohort. Since
10 we have internal agreement that the future care pathway 16:42
11 of these patients will be subject to a multi
12 disciplinary decision, I do not want you to write to
13 any of these patients individually. Any outcome of the
14 multi disciplinary team should be "signed off" by that
15 team and only an agreed communication sent/provided to 16:43
16 each patient.

17
18 Please acknowledge your agreement by return."

19
20 So, two issues there: A bit of a suggestion in the 16:43
21 letter that they were sent to Belfast because they were
22 obliged to send them, which might have taken the sting
23 possibly out of it being a rebuke in some respects.
24 But certainly there's a suggestion there that the
25 behaviour was inappropriate. Do you know if any other 16:43
26 action was taken against Mr. O'Brien on this issue or
27 did you ever hear back in relation to it?

28 A. All I know is that Tony Stevens wrote to Paddy
29 Loughran, who was the Medical Director in Southern

1 Trust at that time. But I don't know if any further
2 action happened to that.

3
4 But I think Gillian Rankin's letter sort of misses the
5 point, in that, okay, the communication was 16:44
6 inappropriate, but the management decisions in the
7 three bladder cancer patients were all incorrect, and
8 there was two patients who were for radical
9 prostatectomy who also had a different change in their
10 management. If you read the letter that I sent to Tony 16:44
11 Stevens.

12 473 Q. Tony Stevens. WIT-99146. So, this is the e-mail that
13 you sent. We just need to read some parts of it. And
14 you make the point here that you've just made to us in
15 evidence: 16:44

16
17 "Tony and Ray,
18 Whilst the letters sent about these patients were
19 unhelpful I think it misses the point that these
20 patients and the governance issue that have been 16:44
21 raised. "

22
23 Then you go on to explain why clinically the decisions
24 were, in your view, erroneous. I don't think there's
25 any suggestion, it's just your view, as you say, the 16:45
26 MDT reached a decision that there should be different
27 pathways for each of them, and so you set out clearly
28 what your concerns are.

29

1 Then on 29th September there should be a reply from
 2 Tony Stevens. Tony Stevens, at the time was the?

3 A. He was the Medical Director in the Belfast Trust.

4 474 Q. Your current role?

5 A. Yeah.

16:45

6 475 Q. Did you take over from him?

7 A. No, Cathy Jack.

8 476 Q. There's an e-mail... yes, from Tony Stevens, 29th
 9 September, to you and Ray Hannon:

10

16:45

11 "Chris,

12 Thanks for this. If you are comfortable, I will write
 13 to the medical director in southern copying this
 14 e-mail. I understand that the situation is further
 15 complicated by advice given by one consultant to
 16 patient. If you have detail on this it would be
 17 helpful. I am prepared to take strong line on this if
 18 continues, to extent of considering need for GMC
 19 referral. Happy to discuss.

16:45

20 Tony."

16:46

21

22 when he says "I am prepared to take strong line on this
 23 if continues", your letter was very clinically based;
 24 you set out your concerns. what did you take this to
 25 mean in that sentence,"if this continues", "on this if
 26 continues"?

16:46

27 A. So, I'm assuming that if they didn't start referring
 28 patients appropriately.

29 477 Q. So, was there a suggestion here that Mr. Stevens also

- 1 jumped over the clinical concerns issue and was
2 concentrating on the process for referral?
- 3 A. No, my understanding is he wrote, he shared the
4 correspondence with, or spoke to Dr. Loughran. I mean,
5 you'll need to talk to Dr. Loughran about what he 16:47
6 received, but my understanding is he raised the
7 concerns with Dr. Loughran appropriately.
- 8 478 Q. Did anyone come to you and say, "well, never mind the
9 procedure, there's patient harm here"? Did anyone say,
10 you know, there are a couple of different ways of 16:47
11 looking at what happened; the patient should have been
12 referred perhaps sooner, in particular in one of them,
13 they had treatment plans that were perhaps suboptimal,
14 there was resistance in their referral which delayed
15 their treatment when they did get to Belfast, the 16:47
16 clinician had tried to perhaps, on one view, dictate
17 the course of action that you would take as an MDT, the
18 patients had been told this and their expectations had
19 been raised, but there's also the fact that people were
20 arguably harmed? 16:47
- 21 A. Hmm.
- 22 479 Q. Did no one carve those out as governance concerns and
23 say, "well, we'll deal with the process, but my
24 goodness, what's happening? what's happening in
25 Craigavon?" 16:48
- 26 A. So, I think that -- I think I did the right thing and I
27 raised it to my medical director, who then raised it to
28 the responsible officer for Mr. O'Brien. So, the
29 actions that you describe, whilst all correct, should

1 have been taken by the medical director in Southern
2 Trust, you know.

3 480 Q. So you would expect somebody to do something about all
4 of those issues now? If that scenario happened now,
5 you would say "Okay, let's break this down. There's 16:48
6 quite a few links have broken in this chain. Let's
7 deal with the patient harm one first and then we'll
8 work backwards to the least harmful"?

9 A. Yes. So I mean there's lots of issues arising. You
10 know, I think that there's obviously an adverse, there 16:48
11 are adverse incidents that should have been recorded as
12 such, but there are professional issues that should
13 have been dealt with as well.

14 481 Q. And who should have recorded it as an adverse incident?

15 A. So this should have been recorded, to my mind in 16:49
16 Craigavon, because the issues were raised in Craigavon.

17 482 Q. And your way of getting that information back to
18 Craigavon, or not just your way, but Tony Stevens' way,
19 was to contact Paddy Loughran and inform him? That was
20 the procedure in place. I'm just trying to understand 16:49
21 how you would cross contact another Trust?

22 A. So that - it's actually a good example of communication
23 between organisations where responsible officers have
24 spoken to each other about a concern in respect of a
25 doctor, and it's up to the responsible officer for the 16:49
26 doctor to take action as appropriate, that the concerns
27 have been raised with them, so they have been -- I
28 think managed well in that respect in terms of raising
29 the issues.

1 483 Q. If we just go to WIT-99145. This is your reply then,
 2 whenever Mr. Stevens replied to you, you reply on 4th
 3 October 2010:

4
 5 "Tony, 16:50
 6 This is obviously very awkward for me, urology is a
 7 small specialty and 2 of the CAH urologists were my
 8 trainers. I think if the surgeons concerned fully
 9 engage in the Regional MDM then hopefully a lot of
 10 these issues can be avoided in the future. This would 16:50
 11 certainly be my hope. Thankfully, on Thursday, 2 of
 12 the 3 CAH urologists tele-linked with the Regional MDM
 13 and referred two patients to Belfast. However, a
 14 private perhaps "off the record" discussion with CAH MD
 15 about some of these issues probably needs to happen, 16:50
 16 even if just to make him aware, as it is highly likely
 17 there will be patient/relative complaints."

18
 19 Now, this is a point at which patients have been told
 20 either their expectations are not being to be met or 16:51
 21 the news is perhaps not as positive as they have been
 22 led to believe. Do you think that response to Tony
 23 Stevens, given your view that an SAI should have been
 24 triggered, that that response tends to dampen
 25 everything down a bit? 16:51

26 A. Look, I don't think it dampened it down in terms of the
 27 concerns were raised and I know they were shared, and I
 28 know that Tony had a conversation with Paddy Loughran
 29 and he wrote to him to say that he was going to address

1 the issues. So I think it was, in that respect it was
 2 managed. I think that there are no such things as off
 3 the record conversations, and I accept now, looking
 4 back 13 years, that that's not what I would say now in
 5 terms of off the record, because it definitely needed 16:51
 6 to be on the record.

7 484 Q. Off the record would almost be antithesis to good
 8 governance, wouldn't it?

9 A. Look, I've learned a lot in the past.

10 485 Q. I'm just asking you to share that learning. 16:52

11 A. Yeah. No, no, I mean I fully accept that concerns were
 12 raised appropriately and they were acted on. I think
 13 that asking -- I think it reflects a different time,
 14 when -- and I think we've advanced considerably since
 15 then. 16:52

16 486 Q. Would you do the same thing now if the situation arose?

17 A. In terms of raising the concerns? Absolutely. But I'm
 18 in a different role now.

19 487 Q. You would do -- would you have the same reaction?
 20 would you say have an off the record -- 16:52

21 A. No, no, I would -- in terms of raising the concerns to
 22 my medical director, absolutely. I think at the end of
 23 the day it's the medical director's decision what to do
 24 with the concerns.

25 488 Q. We can follow that, we can follow his line of what he 16:52
 26 did then. So I think you were the only -- the next
 27 e-mail, and I think it's the last one that you're
 28 involved in in this particular trail, but we'll close
 29 this loop. The 4th October, Tony Stevens replied to

1 you and said:

2

3

"Chris,

4

I will be content to chat to Paddy Loughran informally.

5

If that does it, fine. If not, and if your concern

16:53

6

persists, then you will need to consider next steps.

7

Tony."

8

9

Clearly, without any governance structure, the

10

oversight of whether this happens again and who's

16:53

11

responsible for keeping an eye on it or reporting it,

12

all falls away. And as you've said, things have

13

changed. But I just want to make the point that it's

14

inherently an effective way of dealing with a multitude

15

of governance concerns, from just that one example of

16:53

16

those patients.

17

A. I think -- well, I'm not sure I quite agree. But I

18

think the concerns were raised appropriately and

19

highlighted, and I know that they were shared with

20

Craigavon, and the responsibility of dealing with that

16:53

21

lay within Craigavon. They were raised with Craigavon.

22

I didn't work for Craigavon, I worked for Belfast

23

Trust.

24

489 Q. Is it your evidence to the Inquiry that because the

25

concerns were shared with Craigavon, the responsibility

16:54

26

for raising them as a governance issue rests solely

27

with Craigavon?

28

A. So, you asked me about the concerns about Mr. O'Brien,

29

and Dr. Loughran was his responsible officer and the

1 concerns were raised with them, in the same way that if
 2 concerns are raised with me as a responsible officer by
 3 a doctor, I see it as my role to deal with and manage
 4 those.

5 490 Q. So it's the -- just so I'm clear on your evidence. So 16:54
 6 it's superior clinician of the individual who's been
 7 complained about where responsibility lies for
 8 triggering, for pressing the governance button?

9 A. The responsible officer is the decision maker in terms
 10 of management of concerns about doctors. 16:54

11 491 Q. I don't know whether you're right or not. I just want
 12 to make sure that that's what your evidence is, that
 13 once you say the problem is Craigavon, it's an issue
 14 for them, then you can turn away and they have to deal
 15 with it or not? 16:55

16 A. Hold on, we didn't turn away. Because what we did was
 17 effect a change, in that from that date onwards, all
 18 patients with bladder cancer who required surgery were
 19 referred into Belfast. So we effected a change in
 20 terms of patient safety. So that was a really 16:55
 21 important thing to achieve.

22 492 Q. Is that under the terms of the review, the urology
 23 review, that the patients with bladder cancer had to
 24 come to Belfast?

25 A. Sorry, what? 16:55

26 493 Q. Under the urology review, was that one of the
 27 requirements, that bladder cancer patients had to come
 28 to Belfast?

29 A. No, patients who required a radical cystectomy should

- 1 be done in Belfast. So, those with muscle invasive
2 bladder cancer.
- 3 494 Q. We just heard from Darren Mitchell this morning who
4 indicated that once pathology is triggered for bladder
5 cancer they bypass the clinicians and they get straight 16:55
6 -- referral straight to Belfast. So we just maybe need
7 to unpick that a bit to make sure we understand the
8 process. You're saying that this brought about
9 referral of bladder cancer patients to Belfast from
10 Craigavon and they started to refer patients. 16:56
- 11 A. So, they started -- after I raised the concerns, they
12 then started to tele-link in to the Belfast MDM in
13 order to present patients that had muscle invasive
14 bladder cancer that may require cystectomy, and
15 patients with prostate cancer that may require radical 16:56
16 prostatectomy. So the raising of the concerns effected
17 a change to improve safety for patients.
- 18
19 I think as the MDT has evolved to improve the pathway,
20 I think what Darren's referring to is that if somebody 16:56
21 is diagnosed with muscle invasive bladder cancer, that
22 immediately triggers discussion. But we weren't at
23 that place 2010, it has evolved over time.
- 24 495 Q. That's correct. And what you're describing as having
25 solved is, with respect, one aspect of governance 16:56
26 concern that arose here. That's the point. Governance
27 has been carved up in some way that you can deal with
28 the referral and get that sorted out and Craigavon can
29 look after its issues. Is that right? Maybe that's

1 right. I just need to know what your evidence is.

2 A. So, I think it would have been important for Craigavon
3 to examine the patient pathways of those patients that
4 were referred to Belfast that required change in
5 management. Because I would have seen that as my 16:57
6 responsibility in Belfast as a medical director if that
7 was presented to me, because the decision-making
8 happened in Craigavon. So they would need to
9 understand why they came to that decision and, you
10 know, what was the process around that, etc., etc. 16:57

11 496 Q. I think we got there eventually. I think we got there
12 eventually. And the fault was probably mine. So, I
13 just need to understand what your evidence is around
14 who is responsible for governance. Obviously that's
15 our key. So I think the final part of your answer has 16:58
16 made it clear.

17

18 There's a letter of 21st October 2010 from Paddy
19 Loughran to Tony Stevens, WIT-100350. And this has
20 been sent to us by the Trust. 21st October 2010: 16:58

21

22 "Dear Tony,
23 Further to our discussion about one of your urologists,
24 in private at the conclusion of the medical directors
25 meeting I have done the following: 16:58
26 The urologist concerned had witnessed the transfer of a
27 number of patients who required major pelvic surgery as
28 a result of cancer. He wrote to the patients and their
29 general practitioner and expressed concern with the

1 transfer, and a very clear view that he would have
2 preferred one particular surgical procedure. I believe
3 that these patients were not subject to a multi
4 disciplinary discussion between the Belfast and the
5 Southern Trust. 16:59

6
7 I was shown the correspondence and given a message that
8 a senior member of the receiving urology team in your
9 Trust was very upset.

10 16:59
11 I agree that our urologist should not have written to
12 the patients in the manner that he did.

13
14 I have been advised that our AMD in surgery has been
15 given an undertaking that there will be not be a repeat 16:59
16 of the above. Any multi disciplinary decision that is
17 made between the Belfast and the southern urologists
18 will be respected by all of our urologists.

19
20 The director of acute services has also written to the 16:59
21 urologist concerned, having drafted the letter with my
22 advice and support. The letter includes the
23 following... "

24
25 And that's the letter that Gillian Rankin sent that 16:59
26 we've already looked at.

27
28 "I would be grateful if you would accept my apologies
29 for the distress and difficulty that has been caused by

1 your receiving team. I hope that you will accept on
2 the reassurances of last week and this letter that
3 there will not be a repeat.

4
5 I would be very happy to discuss this with you, if you 17:00
6 wish by telephone or in person.

7
8 Yours sincerely.
9 Patrick Loughran. "

10 17:00
11 I think there's one more e-mail, just to close that
12 off. I think we have this e-mail Bates numbered, but
13 I'll read out the end of the reply:

14
15 "Paddy, 17:00
16 Many thanks for dealing with this quickly and
17 sensitively. I am happy with this approach. Are you
18 content for me to share the letter with the CD for
19 urology in Belfast? "

20 17:00
21 And Mr. Loughran replies, saying:

22
23 "Tony,
24 Thanks for the reply. Fine to share the letter, but I
25 would ask for no other copies, as things with our 17:00
26 clinicians are very delicate. "

27
28 So, that's the outcome of the Patients 1, 2, 3 issue.
29 And given the concerns, the myriad of concerns, in your

1 view now as medical director, if that's the end of the
 2 line of the high point of what has happened after all
 3 of that, do you think that that's an appropriate
 4 governance response to all of the patient harm and
 5 other issues that emerged with those three patients? 17:01

6 A. So, I suppose -- well I don't know if anything else
 7 happened.

8 497 Q. Well, we've asked and this is the last document we have
 9 been given. This seems to be the closing of the loop,
 10 subject to anything else might emerge? 17:01

11 A. So, there was no review took place of the individual
 12 patients in Craigavon then?

13 498 Q. Well, we haven't received any documentation in relation
 14 to that. Would that be something that you think that
 15 would have been an appropriate thing to do, review the 17:01
 16 patients at the originating hospital?

17 A. So, I don't want to get into speculation, because I'm
 18 in a very different position in terms of my role. Are
 19 you asking me what I would do now if I was presented --

20 499 Q. I'm asking you, given that you know intimately the 17:02
 21 facts of the journey of those three patients from they
 22 were referred to you right through, what do you think
 23 was an appropriate response? Would this have been an
 24 appropriate outcome for you?

25 A. So, I think that it focused more on the distress around 17:02
 26 the letters to GPs and patients rather than actually
 27 the misdiagnosis. The misdiagnosis is the key here,
 28 and I think that this was probably a signal, you know,
 29 to have a look. And the way I approached these types

1 of things is probably ask the college, perhaps, to come
 2 and review the cases and give an external view on the
 3 management.
 4

5 So, if you're -- as I say, I didn't know that nothing 17:03
 6 further had happened in this.

7 500 Q. No, I appreciate that. It's just really to look at...
 8 A. Hmm.

9 501 Q. Seemed to have dropped off the patients somewhere along
 10 the journey. 17:03

11 A. And then, you know, there's also any concerns around
 12 the doctor should be managed within what's called
 13 Maintaining High Professional standards. And, you
 14 know, any concerns in respect of conduct health or
 15 performance should also be managed within that 17:03
 16 framework.

17 502 Q. And at that time there were processes available for
 18 that?

19 A. Yeah. Well, MHPS existed in 2010. So, there's
 20 potentially conduct and performance concerns within 17:03
 21 this.

22 503 Q. Thank you. I think we've jumped back and forward a bit
 23 with some of the topics, and I think I've covered
 24 everything I wanted to highlight. I know the panel
 25 have some questions for you and it may be the time now 17:04
 26 that they, given the time it is, that they get their
 27 opportunity to ask them. Thank you very much. Thank
 28 you.
 29

1 QUESTIONS BY THE PANEL

2
3 CHAIR: Thank you, Ms. McMahon. Sorry we can't let you
4 go, I know it's quite late in the day, but we do have
5 some questions and I'm going to ask Mr. Hanbury first 17:04
6 of all to ask you some questions.

7 A. Okay.

8 MR. HANBURY: Thanks very much for your evidence, it's
9 been a bit of a marathon for you. I just want to dot
10 around a little bit, starting about your time at 17:04
11 Craigavon and just a couple of things on a few of your
12 nine concerns.

13
14 The extended TURP, you can probably remember as though
15 it was yesterday. So there you are in theatre and the 17:04
16 anaesthetist is not happy and the scrub nurse is not
17 happy. What was the dynamic then? Did the surgeon
18 just carry on or try to speed up the end or...

19 A. My recollection is the surgeon just carried on.

20 504 Q. Was there -- what happened then? I mean, was there 17:05
21 instability with the patient or...

22 A. I can't remember the outcome of the patient. It was
23 more the fact that the resection time was going on too
24 long and the anaesthetist and nurses becoming anxious
25 about the resection time, and either a sense that they 17:05
26 were being ignored I think is probably the best way to
27 describe it.

28 505 Q. Okay. And was critical care alerted after that? Do
29 you remember those sort of details or -- it's a long

1 time ago I know.

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

3 506 Q. Yeah. Yeah. Okay. It can be a lonely place up the
4 upper third of the ureter with a stone and someone
5 breathing over your neck, it can be quite difficult; 17:05
6 many of my trainers, I'm sure you have always told your
7 registrars that you can always abort, stay safe, stent
8 and send away. I mean, did this sort of thing happen
9 when the case that you were describing was going
10 forward? 17:06

11 A. So, I completely agree with you, upper third stones, I
12 would -- I mean, I didn't practise as a stone surgeon
13 once I became a consultant, other than doing emergency
14 work on-call. But in the upper third I would generally
15 have always advised to stop and put a stent in. I 17:06
16 think stone surgeons, with flexible ureteroscopes,
17 etc., might have been braver, but that wasn't the
18 technology that was available then.

19 507 Q. The input from Mr. Young is interesting there. I mean,
20 were you trained up until -- I mean, you had good sound 17:06
21 training in Glasgow, and before you went to Craigavon
22 were you always taught to have a safety wire up before
23 or was this something that was a variable feast?

24 A. So, I was lucky in Belfast that we had some excellent
25 stone surgeons who basically, in the same way that I 17:07
26 changed practice in our team for bipolar TURP, they
27 also introduced a lot of safety mechanisms around
28 ureteric stone treatment and one of them would have
29 been a safety wire, that if you're doing any ureteric

1 stone procedure, make sure you have a safety wire in,
 2 because you can always put a stent in. I think it was
 3 less common practice then amongst older urologists,
 4 but, you know, in Belfast we had a young consultant
 5 team who were very focused on safety, and the stone 17:07
 6 surgeons led on making sure we had the best and safest
 7 stone practice. So it's not relevant the names of the
 8 individuals, but they certainly led on that.

9 508 Q. And the lithoclast technology was available then in
 10 Belfast? 17:08

11 A. So, we had it in Glasgow and as a trainee in Belfast I
 12 suggested that we purchase a lithoclast, because I
 13 thought it was a really safe way to manage stones. So
 14 we got one in Belfast. And, you know, it's cheap
 15 technology and very safe. 17:08

16 509 Q. Yeah. So, you knew that it was the safer way, although
 17 it wasn't available in Craigavon?

18 A. I suppose it's one of those things where you feel
 19 surprised that people are using technology that's
 20 inherently unsafe. And when there are better 17:08
 21 alternatives and the alternative is cheap. So, I felt
 22 very uncomfortable about using it and I suppose I was
 23 in this situation being supervised and told to use it.
 24 And that's why it stuck with me, because I had never
 25 seen that complication before, I'd never seen an open 17:08
 26 pair of a ureteric injury before.

27 510 Q. Okay. And that happened straightaway on the table?

28 A. No, no. No, no. The patient was woken up, and my
 29 understanding is Mr. O'Brien spoke to the patient and

- 1 then they were booked for an open repair.
- 2 511 Q. Okay. Thank you. Just a more general terms about
3 discussion of complications and emergencies and things
4 that happen. A week is a long time in a big urology
5 department. Did you have, on your Thursday morning 17:09
6 grand round, did you have time to discuss emergencies,
7 complications, things of common interest that perhaps
8 didn't go so well?
- 9 A. Ehm...
- 10 512 Q. Between yourself and the department, not just you, but 17:09
11 the department?
- 12 A. It was designed as an opportunity to have a longer
13 discussion about patients on the wards, and I can't
14 recall specific discussion. I mean all of those things
15 that I have highlighted about unusual patients, the -- 17:10
16 I guess.... sorry, I can't remember.
- 17 513 Q. I suppose not just talking about that particular case,
18 but in urology there's lots of complicated stuff and
19 it's good to share thoughts and ideas and people to
20 refer to perhaps. 17:10
- 21 A. I don't think grand rounds are necessarily a good way
22 to do that, in my experience. I think that they can be
23 quite intimidating for trainees. We have had
24 experience in other services in Northern Ireland where
25 grand rounds don't work particularly well. I think 17:10
26 structured M&M discussions is a much better way to
27 learn from patient safety incidents and to -- because
28 you can't really have that conversation in the time
29 allowed at the end of a patient's bed, it's not

1 appropriate. So I think that's a much better way to
 2 manage patient safety concerns.

3 514 Q. Okay. I take your point. At that time were you having
 4 the weekly X-ray meeting on a Thursday morning at eight
 5 o'clock? 17:11

6 A. I can't remember...

7 515 Q. Perhaps another opportunity to have those discussions.
 8 Just one question on the priapism issue. Presumably
 9 were you involved with the patient all the way along?
 10 Did you know whether they had had the drugs and the 17:11
 11 aspiration?

12 A. No. The patient came in with a late -- they were
 13 admitted with a late priapism. I know it was more than
 14 48 hours. So there was no point in trying to -- I
 15 wasn't directly involved when they were admitted, but I 17:11
 16 know that if there had been any aspiration, it hadn't
 17 been successful. I was not involved in that.

18 516 Q. Okay.

19 A. And I wasn't involved in the decision-making to go to
 20 theatre. But I was in the theatre area and, as you do, 17:11
 21 you go in when you're curious as a trainee and you,
 22 because you hope to learn, and you see something and
 23 you think, "Oh, gosh, I'm not really sure what's going
 24 on here."

25 517 Q. Just to pin down a bit then, was the procedure, do you 17:11
 26 think on reflection it might have been an attempted
 27 shunt procedure or...

28 A. I wondered about that. I think if you're going to
 29 attempt a shunt, I think you're much better to go

- 1 through the glans straight into the corpora rather than
2 take the glans off, which is what had happened.
- 3 518 Q. Step 2. Yeah. Okay. Thank you. Right. I see what
4 you mean. Was Mr. O'Brien operating on his own or did
5 he call for assistance then? 17:12
- 6 A. He may have had, he probably had somebody --
- 7 519 Q. At consultant level I mean.
- 8 A. No, no. No, no, no. No.
- 9 520 Q. I see. He was --
- 10 A. No, I don't believe there was another consultant 17:12
11 urologist there.
- 12 521 Q. Okay. Thank you. You mentioned children's surgery and
13 referring. Do you have any examples of that, that
14 perhaps things were done at Craigavon that perhaps
15 should have been referred, or is that a general 17:12
16 comment?
- 17 A. I suppose what made me surprised was that they had
18 acquired a set of paediatric cystoscopes, and in 17
19 years of consulting practice I've never had a single
20 indication to use a paediatric cystoscope. We have a 17:13
21 children's hospital very close to Craigavon with two
22 trained paediatric urologists. I think that district
23 general urologists are safe to do torsion and
24 circumcision, and possibly hernia repair, but beyond
25 that, I can't think of any surgical procedure that an 17:13
26 adult urologist should be performing on a child. You
27 may be able to think of something. But certainly
28 cystoscopy in children is not commonly performed unless
29 there is a congenital abnormality.

1 522 Q. You didn't see that happening?

2 A. No.

3 523 Q. -- difficult orchidopexy or anything like that?

4 A. No.

5 524 Q. Okay. I take your point. So the patients having 17:13
6 intravenous antibiotics and fluids, just there you are
7 at the end of the bed, and it was the time that there
8 were the charts. Do you recall what drugs they were
9 on? What type of antibiotics?

10 A. I can't remember. 17:14

11 525 Q. Because we had evidence from Tracey Boyce and they were
12 all on low dose gentamicin?

13 A. Right.

14 526 Q. Did that stick in your mind?

15 A. No. Sorry. 17:14

16 527 Q. No. Okay.

17 A. It was more the philosophy of fluids and antibiotics
18 for patients that were quite capable of taking oral
19 medication.

20 528 Q. Yeah. 17:14

21 A. There was no reason why they needed to be fasted and
22 not drink. It didn't make sense.

23 529 Q. Okay. So maybe on the same theme, the benign
24 cystectomy in the young lady who you described in great
25 detail. You mentioned Mr. O'Brien sort of had phoned a 17:14
26 friend in the States. Did he say he'd phoned a friend,
27 one of his trainers, Belfast, Dublin, London, an expert
28 in urinary tract infections, physicians, anybody else?

29 A. No, he just -- and I know it's 20 odd years ago, but

1 conversations sometimes stick in your head, and that "I
2 spoke to somebody in America who said it was not an
3 unreasonable course of action". And, you know, I
4 suppose I accepted that at face value. But in
5 preparing for this Inquiry, I looked again is there any 17:15
6 literature to support this, and I can't find any
7 literature to support cystectomy and orthotopic
8 neobladder formation for a urinary tract infection in
9 young females.

10 530 Q. I agree. We skipped over a few of your other concerns, 17:15
11 and I've just got some short questions. The
12 administration side, Mr. O'Brien, you commented on
13 heaps of charts and letters and results. Would you
14 have any more comments on reflection there? I don't
15 want to get into too many details? 17:15

16 A. His office was chaotic, with charts everywhere, and his
17 secretary was frustrated that it took time for letters
18 and results to be dealt with. And then his letters
19 were extraordinarily long. So, it seemed to me if
20 there's an issue with keeping on top of things, write 17:16
21 shorter, more succinct, to the point correspondence.

22 531 Q. Thank you. I mean, did he ask you to get involved and
23 help out?

24 A. No.

25 532 Q. Thank you. You mentioned comment about the outpatient 17:16
26 practice and trying to discharge people who don't need
27 to be there, which is commendable. And then someone
28 mysteriously coming back that you thought you
29 discharged.

- 1 A. Yes. I thought that was really unusual. I mean, as a
 2 trainee in that team, you were mainly seeing review
 3 patients and not new patients, and I was conscious that
 4 there was a lot, there seemed to be a lot of patients
 5 who were on the routine review for no good reason. So, 17:17
 6 I started trying to discharge patients. But then when
 7 an individual reappeared, I thought this is really odd.
 8 And he said that he had phoned Mr. O'Brien's wife, who
 9 had put him onto the next clinic.
- 10 533 Q. An unusual way back. 17:17
- 11 A. Perhaps.
- 12 534 Q. Did you, did you -- to change the subject, but still on
 13 outpatients. Did you notice any other sort of trends,
 14 sort of cancer follow-up, benign follow-up that struck
 15 you as unusual, compared to other urologists I mean? 17:17
- 16 A. There seemed to be a lot of review patients. But I
 17 can't recall specifics in terms of trends.
- 18 535 Q. Okay. Thank you. You made some comment about
 19 Mr. O'Brien's practice with radical prostatectomy and
 20 patients with quite high PSAs. Could you just 17:17
 21 summarise that in a few short sentences?
- 22 A. So I think there was really good evidence then, and
 23 there's a good publication from 2002, you know, stating
 24 that radical - hormone treatment for radical
 25 prostatectomy has no place. Now, hormone treatment 17:18
 26 will reduce your positive margin rates, but it doesn't
 27 improve outcomes. And I think offering it to men with
 28 high PSAs is actually wrong, because it's highly likely
 29 they have micro metastatic disease and you're putting

1 them through a major operation that can affect
 2 incontinence, potency and other issues, when they're
 3 not going to get any benefit from it. And I think, you
 4 know, it was PR07 at that time was recruiting patients
 5 with higher PSAs and intermediate high risk prostate 17:18
 6 cancer for radiotherapy in hormones, and I think Balls
 7 study, et al., showed the benefit of that approach. So
 8 it was an unusual approach to the management of
 9 prostate cancer. I know that there were individuals
 10 around the world who may have single centre series 17:19
 11 around that. So I'm aware that there are others that
 12 were practising that, but there's really good evidence,
 13 I think, that it's not indicated.

14 536 Q. Did you see any cases being done by Mr. O'Brien with
 15 that? 17:19

16 A. He did a small number of radical prostatectomies when I
 17 was there, but I cannot - I would have put it in my
 18 statement if I could remember the specifics.

19 537 Q. You didn't think of offering to write them up? It
 20 would have been an interesting project. No? 17:19

21 A. No, I didn't.

22 538 Q. Just one more thing. Just going, rowing forward to the
 23 sort of 2016 -- sorry, 2011 problems with the
 24 cystectomy patients which you alluded to. So, what
 25 would have happened if it hadn't have been for the IOG 17:19
 26 Directive? Do you think those cases that were sent to
 27 you with Metastatic Disease 1 and -- in the lymph nodes
 28 would have ended up with a cystectomy?

29 A. In Belfast or with Mr. O'Brien?

1 539 Q. No, with Mr. O'Brien, had he not been --

2 A. Well, I think he had dates set aside for those

3 patients. I think from memory reading that he had

4 dates later on in September for those patients.

5 MR. HANBURY: Right. Thank you very much. 17:20

6 CHAIR: Thank you, Mr. Hanbury. Dr. Swart?

7 DR. SWART: So, thank you for your evidence. It's

8 interesting what you can remember after all this time.

9 And I suspect some of these cases stick in your mind

10 for specific reasons. You were a registrar in other 17:20

11 places. Did you see anything like the scale of this in

12 any of your other registrar roles?

13 A. No. No, I mean I worked in really good units in

14 Glasgow, Belfast and Dublin.

15 540 Q. Yes. 17:20

16 A. The unit I worked in in Dublin was excellent, it was a

17 really good transplant unit with a major oncological

18 focus as well.

19 541 Q. Did you have cause to ask any similar questions, like

20 "why are you doing this?", or anything like that? Can 17:21

21 you tell us how that atmosphere might have been

22 different in the other units?

23 A. I've always been curious and asked questions.

24 542 Q. Mm-hmm.

25 A. But usually questions in a sort of, in a supportive 17:21

26 discussion.

27 543 Q. Yeah.

28 A. But not like this, and not repeatedly and feeling that

29 this feels unusual practice.

- 1 544 Q. And when you asked questions in other units, did you
2 get satisfactory explanations, when it was something
3 perhaps you weren't familiar with? How was that dealt
4 with?
- 5 A. So my experience of working in really good units is 17:21
6 people welcome questions, they welcome challenge, they
7 welcome people asking you is this -- you know, have you
8 thought of doing something different? What about this?
9 Because often trainees are really well read because
10 they're preparing for exams. 17:22
- 11 545 Q. Yes. Exactly.
- 12 A. And they will maybe be more up to date than some
13 consultants will be. And that's not to say something
14 negative about consultants, but in preparing for FRCS
15 urol you needed to be really on top of your game at 17:22
16 that point.
- 17 546 Q. You do, yeah. I'm going to ask you to speculate a bit.
18 The coroner's rulings issue, we have sight of the
19 letter that medical directors got in 2013, I think, and
20 we also have sight of the - because it's an appendix to 17:22
21 your statement actually - the regional guidance in
22 2015. So if you were a medical director today and you
23 got a letter like that, and medical directors do get
24 copies of letters like that as a result of coroner's
25 rulings, what would you do with it exactly? 17:22
- 26 A. So, my approach -- I mean, what the coroner is doing is
27 raising a significant patient safety concern.
- 28 547 Q. Yeah.
- 29 A. And generally my approach is to meet teams that are

- 1 involved in these things and get an understanding of is
2 this something that is applicable and can we introduce
3 it here?
- 4 548 Q. Yeah. 17:23
- 5 A. Because I sort of straddle various positions in this,
6 because I knew that we could do something to really
7 improve patient safety with this. So I think as a
8 medical director you need to support teams to do the
9 right thing, even if that sometimes comes with some
10 additional cost. And, you know, this was a young woman 17:23
11 that died of a TCRE and my sense was we should try and
12 make sure something like this never happens again, and
13 that's when I --
- 14 549 Q. And how would you place it in your governance
15 structures? Where would you put that so that assurance 17:23
16 was sought and tracked and followed up and all that
17 stuff?
- 18 A. Okay. So, I would have done something like this in my
19 deputy medical director role for risk and governance.
- 20 550 Q. Yeah. 17:23
- 21 A. We have a group that monitors new procedures and we put
22 in audit to measure outcomes and to ensure that we are
23 - we were safe, I suppose. We've also introduced a new
24 system in Belfast, a quality management system, which
25 will pick up issues in terms of outcomes, etc., and 17:24
26 then we have things like outcome review group which
27 looks at mortality across, and we can get mortality
28 down into teams, so we will know if there's an increase
29 in mortality in that area. So we have lots of ways of

- 1 picking up data in terms of outcomes.
- 2 551 Q. But you would be seeking assurance, would you?
- 3 A. Absolutely.
- 4 552 Q. That this had been dealt with, appropriate action had
5 been taken at the relevant part, place in the Trust? 17:24
- 6 A. Yes. Yes.
- 7 553 Q. So, there was another crack at this then in 2015 when
8 there was a regional document produced which suggested
9 that Trusts should adopt this with, I think they put
10 your own logo in, and it also mentions the need to take 17:24
11 various methodologies forward in terms of long times
12 for surgery and all of that. What did you do with that
13 in the Belfast Trust? How did you deal with that then?
- 14 A. So, we were ahead of that in a way, because we'd
15 introduced bipolar resection in 2013. We had 17:25
16 completely eliminated Glycine, we'd taken it out of
17 theatre, so the surgeons couldn't actually use it. We
18 used it for bladder tumours as well as TURPs.
- 19 554 Q. So did you just adopt the regional guidelines and say
20 "Yes, we do this"? 17:25
- 21 A. Absolutely.
- 22 555 Q. And you continued to audit it?
- 23 A. Yeah. And I mean, we do the -- in theatre they do the,
24 there's a specific protocol for monitoring fluids.
- 25 556 Q. There is, yeah. 17:25
- 26 A. So we adopted that, even though for bipolar it's
27 probably not necessary, but we still adopted it.
- 28 557 Q. And the operation time issue as well?
- 29 A. Oh, yes. And I talked about how the nurses would call

- 1 out where you are in the operation and how long you've
2 been operating for. So, the whole thing was adopted
3 and...
- 4 558 Q. Yeah. So it's a bit more speculation; you've adopted,
5 you know, a specific approach to patient safety, which 17:26
6 you have described. There's quite a lot of experience
7 of this in English hospitals, which I'm sure you know
8 about, but what has been the impact in Belfast on, for
9 example, the medical leadership and management culture
10 and the way teams approach safety? Have you been able 17:26
11 to develop any sort of sense of a measurable impact of
12 that?
- 13 A. So, one of the things -- I mean we learned a lot from
14 the Independent Neurology Inquiry.
- 15 559 Q. Yeah. 17:26
- 16 A. But even prior to that, we had done a lot around our
17 safety culture. So I talked a little bit about that
18 earlier on.
- 19 560 Q. You did. That's why I'm picking you up on it.
- 20 A. But we used framework called "The measurement and 17:26
21 monitoring of safety", written by Charles Vincent,
22 which is probably the best document I've ever read on
23 patient safety, because it gives you measurables for
24 it.
- 25 561 Q. Yeah. 17:27
- 26 A. And we got our teams to start focusing on the five
27 elements of that.
- 28 562 Q. You've managed to embed that and continue with it?
- 29 A. So it's completely embedded across the Trust. So it's

1 used as the framework for our safety huddles. So our
2 safety huddle framework is that there's a huddle, and
3 it's based on -- like Philadelphia, where it was
4 described where there's a safety huddle in the morning
5 at very local level, and then there's a higher level 17:27
6 huddle, and then at eleven o'clock the entire executive
7 team meet with the chief executive and we do a safety
8 huddle, and any issues that can't be resolved at the
9 local level are brought to the safety huddle. So it's
10 made us very conscious of being: Are we safe today? 17:27
11 But it also let's us focus on the reliability of our
12 systems, and it has brought in a new way of talking and
13 thinking.

14
15 But then I also brought in another thing called 17:27
16 divisional live governance. So we have a structure in
17 Belfast where we have the executive team and then
18 there's 13 divisions underneath. So in a division
19 there's a doctor, a nurse, and a manager, and they meet
20 every once a week and they go through all their 17:28
21 incidents, their high risk complaints, their mortality,
22 any coroner's cases upcoming, and ensure that if
23 there's anything that needs to be escalated then it can
24 go to the relevant professional lead. So that's a
25 really good way of picking stuff up. 17:28
26

27 And we've also created, tried to flatten our structures
28 as well. So in the past few weeks I've, you know, CDs
29 are quite comfortable to phone me directly and say "I

1 have a concern, can I talk to you about it?".

2 563 Q. Yes.

3 A. And it is about -- because they know that they will, if

4 they raise a concern, somebody will listen and they

5 will act appropriately. And it's the acting 17:28

6 appropriately is the absolute key to this. You can put

7 all the safety systems you want in place, but when the

8 concern is raised, you have to act.

9 564 Q. So this only works if the Board embraces this --

10 A. Sure. 17:28

11 565 Q. Fairly comprehensively. And for me that would be all

12 the members of the Board, it can't just be the medical

13 director and the nursing director, it's got to be

14 everyone. Has that happened as part of this and does

15 the Board ask you what the measurable improvements in 17:29

16 safety metrics are?

17 A. So, we have a quality management system now which has

18 measurables.

19 566 Q. Yeah.

20 A. And we bring that to Trust Board, to every Trust Board, 17:29

21 where we share that data, and that will include

22 mortality data, and adverse incident data, high risk

23 complaints, and then we have committee structures

24 beneath that where we have non executive directors.

25 So, for example, one of the committees I Chair is 17:29

26 around complaints and patient experience, so there's a

27 a non executive director co-Chairs that with me. We've

28 an SAI review group that I Chair and the report goes to

29 Trust Board on that. So Trust Board are fully sighted.

- 1 And that is part of the key to really good assurance
2 framework.
- 3 567 Q. And in your view this has been partly learning from the
4 Neurology Inquiry or was it something that was already
5 in train at that time? 17:30
- 6 A. I think it was in train. There was also the IHRD as
7 well, which I think shone a light on openness and that,
8 the importance of openness as a cultural... .
- 9 568 Q. And you've got the information systems to support this?
10 A. Yeah. But I think overriding this is a curiosity. You 17:30
11 have to be curious. You have to go and ask difficult
12 questions. You have to look at your data and say "That
13 doesn't make sense, tell me what's going on here".
- 14 569 Q. So on that, just a bit more conjecture, it's my last
15 thing. The cystectomy issue is fairly, it's a big 17:30
16 issue when one reads it altogether. Clearly, a change
17 was made which is actually to follow IOG and follow the
18 centralisation, and in a way it illustrates the need
19 for this very well. If you were -- if that came to you
20 as medical director and responsible officer, you've 17:31
21 talked a little bit about what you might do, but
22 outline your total approach to that if that happened
23 today. How would you deal with this? Because this is
24 a multi faceted issue actually when you look at all the
25 different things. Certainly from a patient perspective 17:31
26 there are massive issues, there's cultural issues in
27 the Trust and so on. What would you do with it, apart
28 from have a little moment?
- 29 A. So, are you asking me that in my current role?

- 1 570 Q. Yes. I'm not asking you what they should have done
2 then, because you were a registrar, you reported
3 something, you don't know really what governance was in
4 the Southern Health Trust. But since we're learning
5 about governance and since you're here and you've seen 17:31
6 all of this, I'm just asking you to have a little
7 think.
- 8 A. Okay. So you're right, it's multi-stranded. But being
9 quite technical, any concern about a doctor in terms of
10 conduct, health or performance, should be managed 17:32
11 within the MHPS framework. And there are concerns in
12 this for me about conduct and performance. So, I think
13 that that's how I would approach it in terms of the
14 individual doctor. But there's also patient safety
15 issues. 17:32
- 16
17 Adverse incident, it should be reported as an adverse
18 incident. And whether you would chose to do then an
19 SAI, which probably meets that threshold, but in a case
20 like this where you have several cases, I have often 17:32
21 found asking the college to become involved and review
22 the cases and do a sense check on what's happening and
23 maybe actually expand that into other cases. And I
24 think that's probably the approach, having been put on
25 the spot. And you need thinking time and you need to 17:32
26 discuss how you manage these things with other
27 individuals and you will take advice from practitioner
28 performance, for instance.
- 29 571 Q. What would you do in terms of talking to the individual

1 doctor?

2 A. So, it's important that you meet the doctor and share
3 the concerns and seek a response and explain what
4 you're going to do. And to my mind, you couldn't not
5 carry out some form of investigation. And the college 17:33
6 is often very useful in these cases where there's
7 several cases, in my experience.

8 DR. SWART: Thank you. That's all from me.

9 CHAIR: Just one thing. The move towards
10 centralisation of complex cases, is that continuing in 17:33
11 Northern Ireland? Is that part of our transformation
12 process or not?

13 A. Certainly in urology, it is. We have several regional
14 specialties in Belfast like compatibility surgery,
15 upper GI surgery, haematology, transplantation. So, a 17:34
16 lot of regional services have been centralised in
17 Belfast. We're a small population and there's huge
18 benefits to it, because you can concentrate skills and
19 that's how you get the best patient outcomes. And
20 there's lots of really good evidence to support that. 17:34

21 572 Q. So, I'm maybe putting you on the spot somewhat, but
22 would you be supportive of a hub and spoke type
23 approach to urology, first of all, but more generally
24 in your role as medical director?

25 A. So, we developed a really good model with urology where 17:34
26 one of the urologists in Craigavon, who is an excellent
27 pelvic cancer surgeon and kidney cancer surgeon, in a
28 practice very close to my own, because we both did a
29 lot of laparoscopic urology, so he came to Belfast to

1 do his complex cases, we had a really good working
2 relationship and we were quite comfortable looking
3 after each others' patients. And that can work really
4 well. But at the end of the day, it's about
5 individuals wanting to work collectively in teams. And 17:35
6 one of the biggest risks I think you have in terms of
7 consultant practice is lone working, and the
8 consultants that work in an isolated way, because they
9 are the ones that carry the biggest risk. So one of
10 the things that I've been working on in Belfast is 17:35
11 around effective high performing teams. And the
12 central thing about that is to avoid lone working and
13 to get doctors working collaboratively and collectively
14 looking after the same patients, so that you basically
15 keep people safe, so you keep patients safe, but you 17:35
16 keep doctors safe.

17 573 Q. And that would be a direct learning of INI?

18 A. Oh, absolutely. And, you know, we learned about
19 complaints with INI, we brought in a new process how to
20 manage complaints, in that they are now all -- any 17:36
21 complaint about a doctor is reviewed by another
22 clinician, where you get them to do, there's a
23 technique called structured judgment review developed
24 by the Royal College of Physicians, so if there is a
25 complaint, a patient makes a complaint about their care 17:36
26 and treatment in relation to a doctor, we do a
27 structured judgment review to assess whether the care
28 was satisfactory, room for improvement, or
29 unsatisfactory. And if there's unsatisfactory then we

1 will pick that up with the doctor.
2 CHAIR: Okay. Thank you very much. You'll be
3 delighted to know that at twenty to six you have
4 concluded your evidence for this Inquiry. I'm sure
5 you're very relieved. And it's been a long day for all 17:36
6 of us present here today, so I'm sure we'll all be glad
7 to get home. See you all tomorrow, ladies and
8 gentlemen. Ten o'clock.

9
10 THE INQUIRY WAS THEN ADJOURNED UNTIL WEDNESDAY, 20TH 17:36
11 SEPTEMBER 2023 AT 10:00 A.M.

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