Urology Services Inquiry

Oral Hearing

Day 13 – Wednesday, 30th November 2022

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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Gwen Malone Stenography Services

THE INQUIRY RESUMED ON WEDNESDAY, 30TH DAY OF NOVEMBER, 2022 AS FOLLOWS:

CHAIR: Morning, everybody, welcome back, gentlemen. Mr. Wolfe.

MR. WOLFE KC: Good morning. Good morning, Mr. Gilbert and Dr. Hughes. We left off yesterday part way through the document relating to your meeting, Dr. Hughes, with the multidisciplinary team on 18th February 2021. I suppose a point I should make clear from the outset, as appears from all of these notes of the various meetings that they are not in the form of formal minutes; is that fair to say?

A. DR. HUGHES: They are not, yes, that would be fair. They are a note of the themes and discussions. They are not a word-for-word transcription.

Q. Yes. I think that's probably obvious. Could we go, please, to WIT-8350, just to finish this meeting off. Sorry, I should have said WIT-84350. That's it, yes.

A. DR. HUGHES: I should add that the notes were shared with the people we had the meetings with for amendments and corrections. I think there are probably one or two went through that process but they all were shared.

Q. Yes. I think I have seen that. I think the versions we are using are the final versions, I stand to be corrected on that, but I think that's the case. At the bottom of this page, just dealing with the nursing issue. Let's start with Jenny McMahon, she was a Nurse Specialist, you said:

"The role of the nurses was central and provides a fail safe process that is benchmarked with other Trusts." She asked if other Trusts have the same issues as the Southern Trust. 10:04

I assume that you agree with the first part of that, that the nurses are a fail-safe, or maybe a better description perhaps, is a safety net within the system.

A. DR. HUGHES: Yeah. We use the word fail-safe in the reports. That's not their primary role and I think people, I think they felt they were here to check on the work of others, and that's not the case. Their role is defined as holistic assessment, but also taking people through their investigations, scans, informing them, and as part of that role they would know then of the dates and times. They are a fail-safe if there are slips or misses or trips, or patients miss appointments, and that's part of the supportive role. 10:05

3 Q. You go on to comment that your understanding was that nurses meet patients with consultants, or, in the alternative, contact details are made available. 10:05

I understand it's a point that has come through some of the documentation, that the CNSs wouldn't be directly available, for example, when Mr. O'Brien, or any of the other Consultants for that matter, were at the clinic in the South-Western Area hospital? 10:06

A. DR. HUGHES: I believe that to be true, yes.

4 Q. That's where you make the point "or contact details can

be made available"?

A. DR. HUGHES: Yes. I probably should use the word "should be made available". It's pretty standard practice that best practice that the nurses are there at the time of breaking bad news, so they can hear what is being said and what the baseline understanding is. Then after that, the nurses would usually offer other opportunities for the patients to discuss further with them, and then obviously give them their name and telephone contact for other subsequent conversations. Usually this type of conversation takes place over many instances and a period of time. There clearly wasn't the ability to have nurses everywhere, but there should have been a process to have their contact details available everywhere. 10:06 10:07 10:07

5 Q. Yes.

A. DR. HUGHES: That's pretty standard practice across all of Northern Ireland.

6 Q. Just going over the page, the nursing theme continues. Jenny McMahon, it's a point she takes up again when you meet the nurses specifically at your next meeting, we will come to that in a moment. Jenny McMahon, she makes the point she doesn't think this is unique to one Consultant and suggests that it was a resource issue. Should I understand her as saying through this note that she didn't think it was just Mr. O'Brien who was not utilising the Nursing Specialists, but it was a broader issue, and it may be related to resources? 10:07 10:07

A. DR. HUGHES: Yeah. I explored that with the

Consultants, was it a geographic area, was it a resource issue? I was given assurance that every other Consultant used Clinical Nurse Specialists and all other practice had it embedded into their practice, and that then evolved into one of the assurance requirements in the action plan, but I did seek assurance because, obviously, we were very concerned about the effect on patients of having care that was unsupported and care in the community that they didn't join up with the many other needs within the community. 10:08

7 Q. Yes. Moving down to the middle of the page, please. Mr. Glackin makes the point that -- and maybe you will try to help us with the context for this. Mr. Glackin believes it is a criticism of the other Consultants or other consultants as it says here. Is that an intervention in the round dealing with your concerns about the MDM and how it functioned, or is that a specific remark in relation to the nursing issue? 10:09

A. DR. HUGHES: I think it's about the overall issues, and I think that the document we started with yesterday morning about the GMC, about other professionals' responsibilities when working in multidisciplinary teams was not really understood. When you work in a multidisciplinary team you share the care, but you also share the responsibility for the care to a degree, and if you are the MDM lead, you have additional responsibilities. I think at this stage the process had moved from what had happened to why it had happened, and a lot of professionals were reflecting on 10:09

their role on why things had happened and --

8 Q. Just pause there, because I think you touch upon this and I want to explore this a little with you. In your witness statement, if we go to WIT-84172, and if we look at the second bullet point, please. You say here: 10:10

"I believe the Professionals in the Trust found the SAI Review process concerning as the process involved review of patient pathways in a multidisciplinary setting. This moved governance questions from the 10:10 actions of a single professional to the responsibilities of the wider team. I believe some felt this unfair, but the SAI report was based on expected care and on standards of care evidenced by the Trust team to Cancer Peer Review of their service". 10:11

Is that germane to --

A. Yeah. It's my experience and my interpretation of how people responded to me. I think everybody understood there were care deficits. I don't think they fully 10:11 understood the deficits in the governance that, sort of, was responsible for the deficits being not exactly fully understood, not actioned, and some completely unknown. I think that moved possibly the spotlight of questioning from what happened with the care in the 10:12 immediate vicinity of Mr. O'Brien to what was the responsibility of the greater team overseeing the care that was delivered, because as a multidisciplinary team, when you are doing your Peer Review, it's not

a Consultant-specific response; it's what the team deliver. The team have to have ownership of the governance and have to have ownership of the deficits, and I think that was a bit of a hard journey.

9 Q. Yes. One of the things you reflect upon in your statement, was that the members -- I think at least two members of this multidisciplinary team had practised in Great Britain? 10:12

A. DR. HUGHES: Yes.

10 Q. Mr. Glackin and certainly Mr. Haynes. They had been exposed in the MDTs in their former practice which were better resourced for Governance purposes and better supported. I think your reflection was that they knew they could be done better. I think the point that you are making, and you've just made to us, is, but whoever it was, and we are not individualising this, amongst the group on that MDT, they didn't become proactive in chasing what could be done better? 10:12 10:13

A. DR. HUGHES: Yeah. I think there's a few things. There's experience of how it could be done better and there's additional resource. The third unspoken thing is culture. There clearly was not a culture of openness and the ability to discuss difficult things. We have heard from Mr. Haynes, when we raised the issue of Bicalutamide, there were very, very difficult conversations. I think we have heard from other people that there were very difficult conversations. I don't think resource is the only issue here; I think -- and it's a very hard thing to define -- I think the culture 10:13 10:13

was not one that would allow people to raise issues and success -- or feel comfortable in discussing difficult things in that environment. That's where I probably was critical of the senior cancer management, they seemed to know particularly little about the team. You know, that's where you need the senior management to step in to check the culture. Now there's ways of doing this and there's ways of ensuring, you know, functional MDT working, but that should have been on their radar and that should have been on their horizon, not simply we can't get a second radiologist and we can't meet all our 31/62 day targets, because it didn't take a lot of exploring to see that it was quite stressed MDT and not totally functional. I don't think it was a particularly happy Service and I think they would have required support. You could have started with the addressing the additionally. I mean, at times the MDT quorate levels were in 5%, and that clearly shows that the people could not be making fully informed decisions. I think they should have focused, if they had benchmarked all their MDTs across the Trust they probably would have seen this was the one in most difficulty and it needed the most support, and I don't think that support was being given. 10:14 10:14 10:15 10:15 10:15

11 Q. Let me move to the next meeting that you had. You had a meeting with Cancer Nurse Specialists on 22nd February 2021, and if we go to WIT-84357. The Nurse Specialists all attended. It's fair to say that during this meeting, a variety of views were expressed? 10:15

A. DR. HUGHES: Yes.

12 Q. If we go to the bottom of the next page, page 58, please, we can see that Kate O'Neill seemed to suggest that resources were an issue, but your response to that was that patients weren't even being given phone numbers? 10:16

A. DR. HUGHES: Yes.

13 Q. You had been assured elsewhere that adequate resources had been made available, and that's what the Peer Review seemed to suggest? 10:17

A. DR. HUGHES: Yeah. There was an increase from three nurses, which is a very poor level of nursing, to five. I'm not saying that was ideal but it was an increase and the response to Peer Review was a very positive one, and that they clearly said that Clinical Nurse 10:17 Specialists would be available to all patients. The experience from these nine patients, and it's my belief all other cancer patients who were cared for by Mr. O'Brien, did not get access to this, and that was confirmed by the Urology Manager of eleven years. 10:17

14 Q. At the top of the next page then you get a different perspective. Leanne McCourt claimed that he, that is Mr. O'Brien -- taking up the sentence in the previous page -- she felt that he didn't value the Nurse Specialists. She recalled him asking her in the 10:18 kitchen what the role of a Nurse Specialist was. He didn't understand the role of a Nurse Specialist, was her perception, whether that's fair or not.

A. DR. HUGHES: Yeah. I think that may be true. I think

there's a difference between somebody understanding a nurse who does urological procedures, but it was very clear in the Urology guidelines what their roles are and they step it out; holistic baseline, assessment of need, and assessment of need as that changes in the patient's pathway. Helping people to understand their investigative and diagnostic process, and critically, helping patients understand the MDT and their treatment options. I look at the cohort of patients, they are, by and large, elderly men who have gone through their first cancer pathway, you know, from a variety of backgrounds, but this is all new to them. A cancer pathway for the first time is incredibly complex and incredibly hard to understand, and the work that Clinical Nurse Specialists, and I have to say the work the Clinical Nurse Specialists do in the Southern Trust is exemplary. There's a cancer patient experience survey from 2018 I think, and it really shows high quality work. To have that resource and not made available to patients, I really can't understand it. To listen to patients describe a cancer journey that sounded completely bizarre and traumatic, unnecessarily traumatic is a difficult thing. These were people who were left, and I probably mentioned it yesterday, trying to access care through GPs. GPs were no longer used to providing this type of care because there was a network to do it, and then ending up in ED at the time of Covid trying to access care, and that's just not an appropriate place and not necessarily a place

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with the appropriate skills.

15 Q. Another perspective, more complementary or warmer to Mr. O'Brien perhaps is Jenny McMahon's, just down the page a little, she had a different experience. She wasn't sure why Mr. O'Brien didn't invite the CNS into the room, and that's a question for Mr. O'Brien, but she says that Mr. O'Brien spoke very highly of the CNS. She recalls Mr. O'Brien having Review Oncology on Friday, but she wasn't asked to attend. Her position seems to be, Mr. O'Brien did appreciate the role of the CNS, it was just on occasions he didn't invite them to participate. Is that the core of it for you? 10:20 10:21

A. DR. HUGHES: It's not a statement that makes sense to me. I think if you value somebody's skills and expertise, you ensure that your patients can access those skills and expertise. To say one thing but not actually put it into action is just pointless. I just don't understand it. It doesn't make sense. If you value their skills, experience and knowledge, then you make sure your patients have those, or indeed the Southern Trust makes sure their patients have access to those skills. 10:21 10:22

16 Q. Yes. At the bottom of the page -- I forget his name -- Jason, another CNS at the meeting. He advised he had worked with Mr. O'Brien, and his experience was again different from Kate's. He said he may not have been in the room, but would have been introduced after. I think he means with other Consultants, but with Mr. O'Brien he would not have had as much input. He 10:22

said Mr. O'Brien may have given contact details in the room, he doesn't know. Nevertheless, he said Mr. O'Brien was supportive in other ways and he made him aware of other patients. I'm not sure if you can help us with what that means, but, again, it appears to be a perspective that Mr. O'Brien didn't have him in the room and there wasn't an opportunity or there wasn't a situation where you'd be introduced to the patient after Mr. O'Brien had finished with the patient. 10:23

A. DR. HUGHES: Yeah. I mean, I think there's clear knowledge of at least potential patients weren't being seen, and I think that should have been escalated. I think Martina Corrigan did escalate it and appropriate action wasn't taken. I mean, again, the simple way around this is to have an Assurance Audit. There were audits of patient experience but they were only obviously the patients who had seen a Clinical Nurse Specialist, and a baseline part of that audit should have been how many patients are getting the opportunity talk to a Clinical Nurse Specialist. I think it's again a question about the Service that patients are receiving, despite the Service being present in that environment, and that's obviously a governance issue. I think it may be very difficult for nurses to deal with this in isolation, and I don't think that's appropriate; but I think that should have been part of the bi-yearly business meeting and addressed through normal business. 10:23 10:23 10:24

17 Q. Yes. I'm not going to open it just in the interests of some time, but you met with Heather Trouton on 23rd February. The reference for the Inquiry's note is WIT-84344. She, at that point, was the Director of Nursing, as I understand it? 10:24

A. DR. HUGHES: Mm-hmm.

18 Q. Having been, up to March 2016, Assistant Director for Surgery and Elective Care. One point she did make to you was that information, including leaflets and contact numbers, were visible in every consulting room 10:25 for the Clinicians, for the Consultants, but she accepted, and this goes back to the point you have just made, that there was no checking mechanism in place. This Inquiry's interest or main interest, I suppose, is that governance focus, the super intendance of what was 10:25 going on with patient care?

A. DR. HUGHES: Yes. I mean leaflets and booklets, classically when a patient is diagnosed with cancer, they are often overloaded with booklets. I was very conscious when I was Medical Director in the network 10:25 that 27% -- and we are not talking about these patients, but a lot -- 20% of Northern Ireland has a literary age of 12 so they needed supported information. When you are going through -- some of the MDT options for these patients would have been, for 10:26 example, curative intent treatment or surveillance. To a layperson they are totally different ends of the spectrum. That is a conversation that needs supported. That's a conversation that needs to be done in language

that they can understand. That's a conversation that probably needs to be taken over in an iterative way. While leaflets are available, these leaflets are normally given by a CNS and explained by a CNS, with the opportunity to go and read that and come back to me and a telephone number. That's a human dimension of the Service that these people did not get.

19 Q. We shouldn't lose sight of the fact that the MDT operational policy, which I opened to you yesterday, put an onus on the MDT Clinical Lead, and the core Nurse Practitioner, on at least on that piece of paper as I kept pointing out, to allocate the CNS. Is that a point that, for example, you raise with Mrs. Trouton or where did that point take you?

A. DR. HUGHES: I took that point to make sure that nurses were available, but my personal belief is that the Consultant responsible for the care is the person responsible for referring a patient to a CNS, in the same way they'd refer them to an AHP if they needed that Service, or a social worker if that was needed. I think that -- my discussion with Ms. Trouton was, there's a high focus on availability of nursing in various areas of enhanced care where there's nursing ratios, and this is part of the Service where we found there was a nursing resource available but not used. To my mind, that's a professional nursing issue. I was seeking to see if it had been raised at the governance issues to her and it clearly hadn't, and then she was unaware of it. There was an issue known locally, which

was attempted to be addressed through the Urology Service manager but it had gone nowhere, and then we were left with -- and the problem -- what we don't know is how long this problem existed. They have done lookback exercise on the basis of Bicalutamide prescribing, but I believe absence of CNS nurses has a significant issue as well, and it's specifically a significant issue when there is variation from MDT recommendations and about informed consent. 10:28

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I think also that the other issues we have picked up is that MDT recommendations where onward referral was asked to happen.

20 Q. Sorry, I missed that?

A. MDT recommendations, when there should have been onward referral to Oncology and it didn't happen. And if there's also a missing CNS in that process, I think that's an issue that needs to be addressed. 10:29

21 Q. Yes. Mr. Gilbert, I have been ignoring you for the past half day. Back to you. Are there circumstances in which the Consultant meeting the patient after the MDT can properly decide that, really, the patient seems content, is understanding of the advice I have given, and is exhibiting no worries or concerns, perhaps; I don't really need to trouble them with a CNS or perhaps mentioning the CNS the patient can say, no, thanks. How does a Consultant -- 10:29 10:30

A. MR. GILBERT: Clearly it's the right of any patient to decline treatment of any sort, but, in this

circumstance, we must understand that the Cancer Nurse Specialist's role is complementary to, not the same as the Medical Clinician's. A number of models for interacting with patients along the pathway for the CNS and for the Clinicians can be described. My experience 10:30
in Gloucestershire would be that all the CNSs would be at the MDT, the cases would be discussed. The Consultant would usually see the patient to describe the options available for treatment, but they would also have an appointment subsequently with a Cancer 10:31
Nurse Specialist in order to fulfil their particular role, which has already been described by Dr. Hughes. In addition, they could make sure that they understood what the doctor was saying, and put it in terms that might be more accessible to them. 10:31

In some models, the Clinical Nurse Specialist will sit in with the Consultant when the bad news is being given. That is a model that is perfectly reasonable. I'm less keen on it because it implies that the 10:31
Clinical Nurse Specialist is somehow the Consultant's assistant, and I would like to make sure the patients understand that the roles are quite different. The purpose of the Cancer Nurse Specialist isn't a fail-safe or a safety net; it is continuity. When 10:32
the patient presents from that moment, or from the time of diagnosis, the Cancer Nurse Specialist is there by the side of the patient, conducting them through their pathway, irrespective of who is delivering the

treatment, whether that's the original diagnostic Clinician or whether it's a Urologist or whether it's an Oncologist. As such, they are a point of access, and so the idea of fail-safe or safety net is simply because you've got somebody there for the patient, and every patient has a right to that sort of professional by their side. 10:32

22 Q. It is, however, a fail-safe or a safety net in circumstances where the nurse is fully aware of a recommendation, or an expected course of treatment, and exceptionally perhaps that isn't being delivered and it would be, in those circumstances, the nurse's role to highlight that? 10:32

A. Absolutely, by return to the MDT and to a receptive MDT that would understand, because, remember, all the resources that we have available for the management of patients come to the MDT. The Clinician, they should be there. The Clinicians, the Radiologists, the Pathologists, Cancer Nurse Specialists, some administrative staff who are key to the tracking practice, and the MDT becomes the focus for business. Why this patient not being referred? Why is the patient not being seen? Why has it become necessary to change treatment? All these questions can be resolved in this weekly meeting, and instead of having half-conversations in corridors we now have a formal process in which we can safely manage patients, and the key individual in that is the key worker and that, by and large, is the Cancer Nurse Specialist. 10:33 10:33 10:33

23 Q. Thank you. I am going to leave nursing for a moment. We might see it on the way back when we look at some of the specific cases. We can see through these meetings, Dr. Hughes, that you have explored managerial issues with their connection with governance, particularly the Clinical Lead for the MDT, Mr. Glackin, and the cancer management team, if I can put it in those terms. You have focused on nursing through the meeting with the MDT and with the nurses themselves and Ms. Trouton. You next, it appears, take up conversations specifically in relation to the issue of Bicalutamide. Obviously, that had arisen through Mr. Gilbert's work. You touched on it with Mr. Glackin and the MDT team and with Mr. Haynes as well. What brought you to meeting with Mr. O'Sullivan and Mr. Mitchell, who both practice outside of the Southern Trust? First of all, who directed you to them or what brought you to them? 10:34 10:35 10:35

A. DR. HUGHES: Professor Joe O'Sullivan at that time would have been the Clinical Lead for the Northern Ireland Cancer Centre, who supplied the Oncology Service to the Southern Trust. So while they are not part of the Southern Trust, they would have been part of the MDT, and part of that issue was about, actually, getting access to clinical Oncology and even more rarer, Medical Oncology. He was the Clinical Director for the Cancer Services which were part of that MDT, so while being separate, they did have particular responsibilities. The issue about Bicalutamide was a lot of these patients should have been going onward 10:35 10:36

to the Cancer Centre for treatment, and it was likely that the Cancer Centre would have a greater oversight of the issue around Bicalutamide because there wasn't a lot of clarity within the local MDT. The investigations were on the basis of the Bicalutamide issue and the really quite poor availability of staff.

24 Q. Yes. Just to be clear, was it your decision to direct your investigation, if that's the right word --

A. DR. HUGHES: Yes.

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25 Q. -- towards these two practitioners? Let me just look then at your meeting. I was wrong to suggest, perhaps in my opening of this, that chronologically it came after the nurses. It was the first meeting, the meeting with Mr. O'Sullivan was 4th January. If we can open up that, please? It's WIT-84362. That was via Zoom, and you explained the process of your SAI review. You asked Mr. O'Sullivan was he aware of any issues regarding the practice of Mr. O'Brien. He told you that when he came into the post initially, about 17 years ago, he had concerns in relation to the use of Bicalutamide and he had frequently challenged Mr. O'Brien about, he made recommendations in clinic letters questioning the use of Bicalutamide instead of what he called the standard 150 milligrams LHRH agonist therapy. In the cases he had seen, the dose of Bicalutamide would not have resulted in a major detriment to the patient's therapy or outcome and, therefore, wasn't escalated further. He said he was aware that his colleague, and that's Darren Mitchell,

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is that right?

A. DR. HUGHES: Yes.

26 Q. As MDT Chair had raised "our concerns", is that the Belfast MDM's concerns?

A. DR. HUGHES: Yes. 10:39

27 Q. About AOB, Mr. O'Brien's Bicalutamide prescribing with the then Clinical Director from Pathology. Is that Mr. McAleer?

A. It's Seamus McAleer, yes.

28 Q. Probably in 2011. This conversation seemed to confirm, 10:39 to some extent, Mr. Gilbert's analysis that there was a reason to be concerned about Bicalutamide prescribing?

A. DR. HUGHES: I think we had a small number of cases and a variable degree of awareness within the local MDT, so 10:40 the rationale for asking the Northern Ireland Cancer Network Leads was to actually get their input, and it was very clear there had been concerns for a very long period of time where there was local attempts at resolution through clinic letters and one episode of 10:40 escalations but not 100% successful. The other discussions, I'm not sure if it's captured here, was around the quorate nature or lack of quorate or lack of staff locally.

29 Q. Just look at one particular issue. You can see there, 10:40 Mr. Gilbert, in the middle of that large paragraph, that the concern or the questioning was in respect of the use of 50mgs of Bicalutamide as opposed to what has been described here as standard 150mgs or LHRH. Does

that recall our conversation yesterday where you say in certain circumstances, 150mgs of Bicalutamide may be an appropriate treatment?

A. MR. GILBERT: Yes. As I said yesterday, it can, under certain circumstances, be an alternative to an LHRH analogue. I think, in this case, Professor O'Sullivan would have seen patients who had been started off on hormone therapy as a prelude to Radiotherapy. 10:41

A patient with localised prostate cancer disease confined to the prostate or its immediate vicinity would have been started on hormone therapy from the Southern MDM, with a referral up for Radiotherapy and, of course, that gives the opportunity to the Oncologist to amend the hormone therapy from what might have been an inappropriate dose of 50 milligrams up to a full dose. Whether that's an LHRH analogue or 150 milligrams of Bicalutamide is an individual decision. It just happens to be my practice, and most of the Oncologists I worked with would have preferred the LHRH analogue, but I maintain that 150 milligrams of Bicalutamide is an alternative. Okay? The patients that Professor O'Sullivan will have seen, he will have been able to change their treatment to an appropriate hormone regime prior to their Radiotherapy. Patients he won't have seen are those that were started off on hormone therapy, whatever that is, and then not referred on for an opinion from an Oncologist. It is those patients that I think form part of this cohort, and it's those patients who the Oncologists would not 10:42 10:42 10:42

have been aware of, because of the lack of referral on the suggestion of the MDT, or of the recommendation of the MDT that they go and have an opinion from a Radiation Oncologist. That didn't happen.

30 Q. Yes. Just going back to your choice of word on the 150, that is an individual decision, I think you said? 10:43

A. MR. GILBERT: Yes.

31 Q. But within parameters?

A. MR. GILBERT: The reasons I would recommend an LHRH analogue is that the trials that establish the current practice within giving external beam Radiotherapy for localised prostate cancer involved LHRH analogue, so why change? We know you get good results with that, stick with that. The other second reason is that the LHRH analogue is clearly licensed for locally advanced disease, which is a particular staging of prostate cancer. Staging, in its medical terms means how far has the cancer got? Where has it got to? Locally advanced means that the disease has spread just outside the capsule of the prostate and is clearly involving the surrounding tissues, but there is no evidence of any spread, either to lymph nodes or to bone, which are the two preferred sites for metastatic spread. It's that group of patients for which this drug is licensed. In essence, you could say that if somebody has generalised localised prostate cancer that is confined to the prostate itself, you shouldn't really be giving the 150 milligrams of Bicalutamide because it's outside the licence. Having said that, I think it's reasonably

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common practice for people to substitute one for the other.

32 Q. Yes. I just want to touch, Dr. Hughes, on the mode of communication here. Dr. O'Sullivan is saying that he has concerns about what he had come across, 50 milligrams being used when he didn't think that was appropriate. His approach is to write to Mr. O'Brien, it seems, repeatedly, with alternative therapeutic or prescribing recommendations, but not to escalate it on the basis that it doesn't appear to be causing significant harm. But if he is still seeing the cases coming back to him with Mr. O'Brien not listening, perhaps, is one inference from that, or taking a different view, to put it more neutrally; is that a satisfactory approach? 10:45 10:46 10:46

A. DR. HUGHES: No. I think part of the conversation was reflection on Professor O'Sullivan's part and Dr. Mitchell's part that perhaps they should have escalated it through normal practices. I think some of the issues, and this is obviously an issue for this Inquiry, is how governance is managed between institutions and between a Cancer Network and institutions, where there is knowledge and information. The normal pathway is to escalate that up through your own governance structures. It can be, you know, Medical Director to the Medical Director discussion. The understanding that they were the Cancer Network, or the Cancer Centre providing care for the patient in the Southern Trust, while they weren't directly related to 10:47 10:47

the governance in the Southern Trust, they actually had a governance responsibility for those patients. I think they know that and I think that they reflect on that as part of the discussions that we had. I hopefully reflected that in my statement, because I think they felt they should have done more.

33 Q. Yes. Indeed that is, I think, reflected in your statement. Just scroll down. I think Mr. O'Sullivan -- you also raised with him the issue of Oncology attendances, as you remembered. Part of the difficulty was that the MDM on lung cancers and the MDM on Urology clashed, it was the same day? 10:47 10:48

A. DR. HUGHES: It was actually more than that. A single-handed Oncologist was expected to staff the Urology clinics, the lung clinics, and two very high volume, complex MDMs. The jobs weren't attractive and the roles were very difficult to deliver. I slightly had more information than that because when I was the Medical Director we were sending professionals down to support on a locum basis, but it was actually a role that was not deliverable, and they needed to be picked apart and more resource put in. 10:48 10:49

34 Q. Mr. O'Sullivan did recognise, nevertheless, that there was a lot of good work going on at the MDT, and he wanted you to reflect that in your report? 10:49

A. DR. HUGHES: Yes.

35 Q. You next met with Dr. Mitchell. Was that at Mr. O'Sullivan's suggestion?

A. DR. HUGHES: Yes, he had mentioned that he had more

detailed information about that.

36 Q. Yes. Let's look at the record of that meeting. WIT-84363. Just scroll up, please. You explain to him that one of your concerns was nonadherence to MDT recommendations, including non-referral to Oncology Services. Dr. Mitchell apprised you of his concern about hormone therapy prescribing that had gone back a decade. He said that he took over as Chair of Regional Urology MDM in 2015 and had challenged Mr. O'Brien on his use of Bicalutamide as part of the development of clinical guidelines whilst Mr. O'Brien was Chair of NICaN. Dr. Mitchell said that his response was to write prescribing guidelines for hormone therapy. We touched on this yesterday. You explained that it was your understanding that the guidelines were as a direct response specifically to Mr. O'Brien's approach to prescribing? 10:50 10:50 10:51

A. DR. HUGHES: Yes. That was one of the major triggers because of the repeated variance from expected practice, and I think that's confirmed by the Bicalutamide Audit. 10:51

37 Q. He shared the guidelines with you. The penultimate paragraph there on 64. Dr. Mitchell advised that he had e-mailed the Consultant Mr. O'Brien in '16/'17, about his prescribing outside recommended guidelines, highlighting that it was his GMC duty to inform patients they were treated outside the recommended guidelines and the patients were misled -- presumably misled in the sense that they weren't informed their 10:52

treatment was outside of guideline. Did you ask for sight of that e-mail?

A. DR. HUGHES: He said he would try and find it. He didn't forward it to me so I'm not sure if he has found it. As part of the discussion, Dr. Mitchell clearly reflected that he should have escalated the issues. Despite the many actions that he had taken, he was still concerned about the persistent prescribing outside guidelines and felt that he should have done more. 10:53

38 Q. Yes. The note of your meeting with Dr. O'Sullivan is specific that the concern was prescribing at 50 milligrams, when the standard was 150 for the reasons explained by Mr. Gilbert, or, in the alternative, LHRH. I am not sure I have seen a specific diagnosis of the problem in what Mr. Mitchell was saying? 10:54

A. DR. HUGHES: We didn't delve into the details of the issue. The discussion was really about, did you know that this was a problem? How long did you know it was a problem? What actions did you take? Did you escalate? He obviously clearly did take actions in writing a regional hormone therapy guidelines, which was signed off at the NICaN Regional Clinical Reference Group, and he did take action on a personal basis by e-mailing and writing, but he didn't escalate it. That was the understanding at that meeting, so, again, we had knowledge of a problem in part of the wider system in Northern Ireland, not appropriate escalation of the governance, and a problem not being necessarily passed 10:54 10:54

back to the Southern Trust and the right actions not being taken, and both professionals did reflect on that.

39 Q. Yes. Was Dr. Mitchell still involved in the role as Chair of MDT or in Oncological Services at the point when you were speaking to him? 10:55

A. DR. HUGHES: I don't think so. That's the Chair -- the names sound the name. The Regional MDT is the MDT that all the Southern Trusts and the Northwest Trust would feed into on a regular basis, so it's a regular regional meeting. The NICaN Regional Reference Group is a very separate group that oversees production of guidelines and consistent delivery of guidelines, interfaces with the Commissioners, and does that type of work. Dr. Mitchell was the Chair of the Regional Urology MDT for specialist cases, and cases that would be passed on from the three cancer unit MDTs. 10:55 10:56

40 Q. Yes. Nevertheless, cases relating to Mr. O'Brien's patients would make it to Cancer Services in Belfast, presumably you were finding the problems in cases in 2019/2020? 10:56

A. DR. HUGHES: Yes.

41 Q. Some cases, as you point out, don't get the referral, notwithstanding the MDM recommendation, but the issue of prescribing outside of the guidelines, as you put it in your report, must, nevertheless, have been known outside of the Southern Trust, not just in the time of O'Sullivan and Mitchell, but beyond that? 10:57

A. DR. HUGHES: I think it was known outside of the

Southern Trust, and obviously it was known in the Northern Ireland Cancer Network. I mean, it wasn't something I had to -- it was very clear as soon as we had the discussion, they were well-apprised of the issue.

42 Q. I think, as you have said a moment or two ago, that it does raise across institution, across site governance issues that need to be addressed by the Inquiry, perhaps?

A. DR. HUGHES: Yes. 10:57

43 Q. You have explained that you met with families on three occasions?

A. DR. HUGHES: Yeah.

44 Q. Not all together as a group, but individual meetings. You have reflected in your statement that you were met with, on many occasions, upset and anger, and my words, not yours, presumably a sense of bewilderment as to how these things had happened? 10:58

A. DR. HUGHES: Yeah. The family were very stoic. I think the first three people in Patient 1's family, Patient 9's family and I think, yeah, probably maybe patient -- I want to get these numbers right, I don't want to -- Patient 2. 10:58

45 Q. Just repeat that?

A. Patient 1, Patient 9 and Patient 2. The first two patients had prostate cancer. Patient 1 had, sadly, deceased. They had found the process very troubling and a lot of that was about having a coherent care plan about understanding what was happening about accessing 10:59

basic services, difficulties with catheters, and it seemed -- this is evolving as we discussed, it seemed that the point of contact was the Consultant's secretary for care. I literally couldn't understand that because that was not my understanding how any Cancer Services work because, in essence, we would be seeking access through Services, probably through a very business secretary who had no clinical background. I was immediately asking what about your Clinical Nurse Specialists? They didn't have access to that and didn't really know about that. Patient 9 was somebody who had delayed diagnosis of cancer and eventually presented with GI symptoms and presented to the GI MDT with presumed rectal cancer but had actually had locally advanced prostate cancer. Even at that stage he was referred back out but he wasn't given a Clinical Nurse Specialist at that stage. Obviously because of the locally advanced cancer, he had specific needs and specific nursing needs. I think the conversations, to tell somebody things did not need to be this way, it was quite difficult for them, and depending on the amount of insight, it probably took a while for that to sink in. Initially we met with families and patients with support, usually of a spouse. That's always a very difficult conversation, to say you've come to harm, and possibly come to harm because of Services that you haven't received or Services that you haven't received in a timely way. We did that with all the patients. Some had to be by Zoom

10:59 11:00 11:00 11:00 11:01

because of the time of Covid, which was not ideal, because these conversations are always better in the room. We then met at a midpoint, after we stepped through a lot of the information, and then we met finally before issue of final report. I think when we met the second time, the families had time to digest what happened, and the conversations had moved from the specific professional that was delivering the care to the, how did this happen? I mean, they all knew about the MDT and multidisciplinary input, they had different ways of describing, but they all expected that cancer care was delivered to a higher standard with greater oversight and greater governance. A lot of them thought the reason they didn't have Specialist Nursing was because of Covid or because services were stressed, and I think it was really, really difficult for them to understand that other patients -- and they did ask about the standard of the Service for everybody else and the support they got. It was very difficult to find that people were somewhat unique in not having a basic standard Service, and I think the focus did move from their care to how that care was delivered, seemingly in a multidisciplinary governance supported environment, that their care would have been different.

11:01 11:02 11:02 11:02

46 Q. This question would probably be better targeted at the patients and families themselves. From your perspective, taking into account your experience working through these nine SAIs, and indeed your wider experience, how does, and how did in this case, the SAI

11:03

process work for the patients? Do you believe that, in general terms, patients and families get a degree of understanding and perhaps satisfaction from the process, or are there other shortfalls in the process that might be improved upon? I suppose finally to reflect in your answer, sorry, a long question, is there anything that you would suggest by way of recommendation in this area?

A. DR. HUGHES: I think, I'm careful, I don't really want to be presumptive and speak on the part of the families. My reflections from this, when I benchmark it to other work I have done, I have done work where people had concerns about their care and maybe had to lobby for quite a while until that care was appropriately reviewed. If they go through that process and they are vindicated that's a very positive thing, and then people can take something of that. This cohort of families, and four of the patients have sadly died. They just thought their parent or relative had really bad disease, and to be told, actually, you should have been referred to Oncologists at an earlier stage on many occasions, or you should have a different type of therapy and your care should have been supported in a different way, was a very difficult story to tell. No matter what we found, we are not going to be able to fix that. I think the process, I know you met the daughter of family 1. She shared many of the things that impacted on her life, and we can never redress that. So, I'm left thinking the SAI

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process is meant to be patient and family focused in an attempt to show redress and improve the services. It may help for some, but I think it was quite traumatic for many.

47 Q. Is there anything you could suggest that might improve the process or is it a case, in your view, maybe it's not always done in SAIs, but to they involve the families as much as possible, and you have pointed out I am not sure if you can improve upon three meetings, it's specific stages? 11:06

A. DR. HUGHES: Yeah, I thought what had happened to these families was that they had a very poor understanding of their care, very poor information, simply because one of the major tenets of how you inform patients and how you support patients was not made available to them, and their care package was very complex and very difficult. I was as honest and forthright as I could be, but I think Patient 1 obviously found that quite blunt and I'll need to reflect on that. I think these patients would require a wider piece of work done. I think they would be very concerned if they weren't referred to Oncologists, they would want to know how many people did that also happen to? There needs to be an audit to review non-action on MDT specifically around referral. I know there's a lookback in terms of Bicalutamide, which is something that may be easier to do, but an MDT recommendation that says please refer on to Oncologist, not actioned, is a significant deficit and they would be very concerned about that. We can

easily find out how many people weren't supported by Clinical Nurse Specialists. I think when you know the breadth and depth of the problem you can make an honest statement about fixing it, but unless you know those details, I think the families -- I am speaking on behalf of the families and I shouldn't do that -- I think they would want to know the depth and breadth of the problem and the extent of the remedy. One family and it's Patient 9, the last meeting was with their extended family and they had lots of insight and they were clearly saying, we want to know why, we want to know how. I think that's the role of this Inquiry. 11:08 11:08

48 Q. Yes. One point you make in your statement at WIT-84173, the first bullet point. If I can skip to the second sentence: 11:09

"The major issue throughout the reviews was the finding of care deficits that were professional-specific but happened within a multidisciplinary setting. An SAI is ultimately a learning and improvement tool - the weakness of this process was that those responsible for managing care and service did not have the opportunity to meet the patients and families and contextualize the deficits. The families had offered to be part of the assurance process which considering the trauma suffered was brave and constructive". 11:09 11:09

You ensured this was included in the recommendations, and I understand that that is being taken forward.

Your observations about a weakness of the process being that the families and patients on one side never get to engage with the treating Clinicians or the MDT on the other, and vice versa, I'm not sure you are suggesting that that is something that could be put into a process. Is that reflection contained in your statement, does that derive from a concern on your part that those responsible for managing care didn't seem to get the Patient Safety issues that arose from the work that they were supposed to be doing? 11:10 11:10

A. DR. HUGHES: No, I think they understood the Patient Safety issues, I think they heard the deficits. I don't think they understood the experience of the families and patients. I think part of the problem was, these deficits were parked with a named individual, and the wider ownership and the wider responsibility was not fully understood because it's easier to park it with an individual. The families had moved past that, several of the families said, this is not about Mr. O'Brien, this is about the Southern Trust and indeed the wider network. The families clearly had insight because it's not what happened, it's why it happened and how it happened. 11:10 11:11

49 Q. One person who you didn't hear from as part of the process, and who you wished to hear from, was Mr. O'Brien. I want to explore that in the next 10 or 15 minutes or so before our break. Can I bring you to your witness statement, please, at WIT-84154: You say 11:11

in the last couple of lines of that paragraph:

"The review team considered the clinical care and pathways for all 9 patients. The investigation team wrote to Mr. O'Brien with specific questions for clarification. These questions were not responded to despite extension of deadlines."

Can we just look at another aspect of your statement in similar context? If we go to WIT-84172. You say: 11:12

"The major deficit within the review was the inability to engage with the professional who was the named consultant for all the patients. This would have allowed some insight into variations from expected practice, as defined by the regional and national guidelines. Despite repeated communications and extended timelines responses to the questions regarding patient care were not received." 11:13

Paragraph 19, and you are asked:

"Having regard to any difficulty identified above" -- the difficulty being Mr. O'Brien's non-response, as you put it -- "are you of the opinion that it undermined or impacted upon the quality of the SAI Review process?" 11:14

You say: "I do not believe that non-engagement by the named Consultant hindered the 'finding of fact' aspect

of the SAI process - this was a process of benchmarking patient timelines, patient stories and patient outcomes against regional and national guidelines common to all urology cancer care. It is not unusual for an SAI process to be carried out independent of the professional delivering the care. We were however unable to ascertain why therapeutic choices were made, often at variance with regional guidelines and recommendations of the Urology Cancer MDM." 11:14 11:15

I want to ask you, Dr. Hughes, the purpose in making contact with Mr. O'Brien was, as I understand it from your answer here, to understand why the therapeutic choices were reached outside of the guidelines?

A. DR. HUGHES: Yeah. We wrote in December to meet and to explain the process. It was a Level 3 SAI where an independent component and the clinical -- 11:15

50 Q. Let's just have that on the screen. You wrote in December. It was 11th December. TRU-162602. A short letter: 11:16

"As part of the normal SAI process we have been carrying out interviews with all relevant members of staff who have been involved in these patients' care. These interviews are based on the patients' journey and are aimed at identifying learning and making recommendations. We are seeking to complete the staff interviews before Christmas in order to keep the time frames of the review. We would be keen to have your 11:16

input into this process."

By this stage you had met patients. By this stage Mr. Gilbert had delivered his first draft. Was there any thought given to engaging with Mr. O'Brien at an earlier stage before Mr. Gilbert had finalised his first draft, which I suppose, by definition, had come to specific conclusions about shortcomings? 11:17

A. DR. HUGHES: Yeah. It's a Level 3 SAI with an independent component, and part of the independent component is an independent external clinical opinion, and that's the structure of how I chose to do the Level 3 SAI. It's similar to a similar process I did for another Trust involving nine thoracic cancers where the Royal College of Surgeons provided an independent clinical opinion of the work done by professionals. Then you have seen the learning from that and our questions from that. There are questions for a range of professionals, and we would have had the same process for Mr. O'Brien. It's not litigation where you have one professional counter-arguing against another clinical opinion. We took a road to get an independent external appointed clinical adviser, Mr. Gilbert, and it was his role to give an external independent opinion. The variance from accepted best practice would be the themes, then we would that variance, be it Clinical Nurse Specialist, be it Oncology or be it the work of Mr. O'Brien, so while the input on was on that basis it was not necessary to argue the clinical 11:17 11:17 11:18 11:18

opinion with Mr. O'Brien as part of the process. That is how I have done other Level 3 SAIs where the clinical opinion is given separate to the people who would have been involved in care, because we are looking for, has harm or potential harm occurred? There's an obvious conflict of interest if you are involved in delivering that care. I think that may not be fully understood, so that was one part of the reason for our initial meeting. We themed the questions that we would liked answered and bring forward for discussion through Mr. O'Brien's legal team. I should say this is what we explained to the families, that the clinical opinion given would be independent of Northern Ireland and of the Southern Trust, and that was part of the engagement process. Without that I don't think we would have got truly proper engagement. 11:19 11:19 11:19

51 Q. Implicit in your answer, Dr. Hughes -- sorry to cut across you -- is that Mr. Gilbert's opinion is not something that is open to debate within the process, as you imagine it, but is it not, nevertheless, important in matters which occasionally can give rise to clinical judgment, where two practitioners might have room for legitimate debate, where the clinician has access to the patient, whereas Mr. Gilbert doesn't; given those kinds of factors, is it not, nevertheless, appropriate, even within an SAI process, to want to hear the clinician's views so that Mr. Gilbert, he may not change his mind, but would have a more rounded understanding of what was going on in any individual 11:20 11:20

patient's case?

A. DR. HUGHES: Yeah, I think that's reasonable. We formed our questions on the basis of not general themes but on the basis of individual patients, and we asked about the Bicalutamide, we asked about non-inclusion of nurses, non-referral, so we did ask and gave him the opportunity respond to questions on each individual patient. 11:21

52 Q. Let me just work through some of the stages in this. That letter that you wrote, which is up in front of us on the screen, was met with a response from Mr. O'Brien's legal representatives on 23rd December. Just to pull that up, please. It is at AOB-03095. They, I think, apologise for the delay in responding. Mr. O'Brien has been unwell. They, as a legal firm, were tied up with the medical practitioners tribunal on related issues. It's not mentioned here, I don't think. I think there had been a bereavement in Mr. O'Brien's family and there was to be a subsequent illness and bereavement in early January. That's the context in which they are responding. I think, as it appears from that, they are anxious to get across the point that Mr. O'Brien has received your correspondence and wishes to assist. 11:21 11:22 11:22

A. DR. HUGHES: Yeah. 11:22

53 Q. They ask for some information, if you scroll down to the bottom of the page. In the context where you, in your earlier correspondence, haven't been entirely specific about why you wished to meet Mr. O'Brien, they

are trying to tease that out, and they ask for materials relevant to the cases. The Terms of Reference, the review methodology, a description of the incident case, the timeline drafted by the SAI group, the threshold criteria for each SAI engaged, the specific issues which you are inviting Mr. O'Brien to address, and complete copies of patient records and complete data available from the NICaN system. You had no difficulty in agreeing to provide that? 11:23

A. DR. HUGHES: No, no. 11:23

54 Q. We know in your response, if we look at AOB-03112, you have attached the various documents. You emphasise that:

"As we are facing time constraints from the HSCB", you would ask that answers to the questions posed would be received within two weeks, by 29th January. 11:24

If we just look at the specific questions that you were raising. The questions were identified following a meeting or at a meeting of the team; is that right? 11:24

A. DR. HUGHES: Yes.

55 Q. Of the Review Team. You ask three or four questions on each case, which were primarily focused on -- well, they cover the broad range of concerns, but fairly narrow questions. Was that deliberate? 11:25

A. DR. HUGHES: Yes. It's the same process that we would have had for everybody else who had contributed to the team. We had the core team and then we took advice and

information and input from all the other professionals in the care. We had an independent note review already in place, and we were asking clarification of items that we could not form an opinion on. Incidentally, the involvement of clinical specialists is the MDT, and it's an independent process with access from those delivering care.

56 Q. Yes. Throughout this period there's a flurry of correspondence. On 19th January, in answer to this correspondence. Mr. O'Brien's solicitors are advising that there's been a bereavement in the family, they were unable to take instructions until the following week. Then on 22nd January -- if we can just put up on the screen, please, TRU-162611. This is a request for further information coming your way. The solicitors on Mr. O'Brien's behalf wish to see the Datix forms. Ask questions about whether the draft Terms of Reference are finalised. Asking questions about family engagement. Asking questions about the review methodology. I'm not going to go through this in any greater detail. But scrolling down we can see that in relation to the questions document that you had sent the week before, they ask a series of questions in relation to that. Again, Mr. O'Brien's facing into a GMC process? 11:26 11:26 11:27 11:27 11:28

A. DR. HUGHES: Yes.

57 Q. The Inquiry has been announced, and you are asking questions, quite appropriately, I'm sure nobody doubts that, about the nine patients. It's understandable

that a cautiously cooperative approach is being adopted here?

A. DR. HUGHES: Yeah, I can understand that. An SAI is not a legal process. It's a family and patient-centred process. I can understand how we ended up going through documents and iteration of documents, but we did get involvement from everybody else we asked, and at times those people were in equally difficult circumstances, who will probably be giving evidence here, and questioning their roles. We tried to make the burden as little as possible because the independent clinical opinion had been given by Mr. Gilbert and we needed input from the professionals delivering care. It was the same ask of the Specialist Nurses. I can understand the legal process but I think, I know there's a timeline from the Department of Health to have this done and to get a greater understanding of the depth and breadth of the problems, but there was a human dimension to this that two family members had already died and two further members had died earlier that year, I think not quite at that stage but by the time the document was submitted four members had -- four patients had died. 11:28 11:29 11:29 11:29

58 Q. Yes. If we jump ahead a month to mid-February, if we can go to AOB-3225. By this stage, this is Mr. Anthony, who is Mr. O'Brien's legal representative. He's writing to Mrs. Kingsnorth and he is telling, I suppose, your review process that Mr. O'Brien is working through the voluminous documentation provided. 11:30

Incidentally, he had only received some of the last documents requested as recently as 16th February?

A. DR. HUGHES: Yeah, I was not aware of that fact.

59 Q. Yes. I needn't open up the document to you, but it's recorded that he received the Datix material he had requested on 8th February and the full NICAR records on 16th February. Do you understand it took some seven weeks, I suppose, if you take the timeline from the 23rd December when he first started making requests for material, through to mid-February? 11:31 11:32

A. DR. HUGHES: I do understand. I should say the Datix reports were not part of our review. We received post triage, so we were not retrospectively reviewing how it came to be in our review process, so I am not quite sure why -- I can understand why some people would want to know that, but we certainly weren't asking questions about how a case was triaged into the process so I don't think that should have delayed the issue. 11:32

60 Q. It's recorded here:

"We are progressing well with comments in Service users A and B. Mr. Anthony is on leave next week and hopes to have comments to you on these two cases by the end of next week or the following week." 11:32

It's clear from this correspondence that Mr. O'Brien is intending to cooperate with you and is cooperating with you; is that fair?

A. DR. HUGHES: To that point, yeah.

61 Q. Yes. There then followed some correspondence between the lawyers, Tughans for Mr. O'Brien and the Directorate of Legal Service on behalf of the Trust. If we can bring up on the screen, please, AOB-03349. This is Business Service Organisation Directorate of Legal Services on behalf of the Trust. This is 5th March and the lawyers on behalf of the Trust say they intend sending the draft patient report and draft overarching report with recommendations to each patient and family on 8th March. So three days later. That's, I suppose, on the back of the correspondence of the 19th February saying Mr. O'Brien is mindfully working through these. 11:33 11:34

In that period of two weeks between those pieces of correspondence, had you or anybody else on your team, perhaps Mrs. Kingsnorth, chased to see what was happening or are we going to have a response to the questions? 11:34

A. DR. HUGHES: I believe Mrs. Kingsnorth did. 11:35

62 Q. Okay.

A. I did not.

63 Q. Okay. In any event, somebody had made a decision that these were going to be disseminated and published by this date, even implicitly even if we don't have a response from Mr. O'Brien? 11:35

A. DR. HUGHES: I think that's the case, yes.

64 Q. Yes. Can you help us, what was the pressure for that?

A. DR. HUGHES: I think the pressure was three-fold. The

Southern Trust were required to get clarity for the overarching supervision, I can't remember the name of the group, but the Department of Health. I think the other pressure was the families wanted access to these, especially those who had been recently bereaved. 11:36

65 Q. Yes. I started this sequence by pointing out the sections of your statement which, in terms, said Mr. O'Brien had been asked questions and, despite extended time limits or deadlines, he never responded. The suggestion there is that Mr. O'Brien wasn't 11:36 cooperating?

A. DR. HUGHES: We didn't receive responses in the timelines I would have expected to relatively simple questions and perhaps that, on reflection, is wrong. When I was writing my witness statement I probably 11:36 reflected part of that in that it would have been better to wait, so I think you do have a point.

66 Q. Just to be clear, in light of what we have seen from the correspondence, Mr. O'Brien was showing cooperation. Quite plainly he didn't dismiss your 11:37 questions. It's been said on his behalf he is working through them. You are facing the competing pressure, threefold pressure of having to publish and, with the benefit of some hindsight perhaps, it might have been better to wait? 11:37

A. DR. HUGHES: Yes, I think that's fair.

67 Q. It might have been better to wait because, if you had received responses from Mr. O'Brien, you would have obtained an understanding and Mr. Gilbert would have

obtained an understanding of his thinking around treatments?

A. DR. HUGHES: Yes. I think some of the issues that are clearly benchmarked against international standards probably wouldn't have changed because we were benchmarking against known best practice, and I don't think those views would have changed. I think the underlying question is why some of this happened? You know, why referrals weren't made? Why nurses weren't involved? I think that would have been appropriate, yeah. 11:38

MR. WOLFE KC: Would this be a convenient time, Chair, for a short break?

CHAIR: Five to 12.

MR. WOLFE KC: Thank you. 11:38

THE INQUIRY ADJOURNED BRIEFLY AND RESUMED AS FOLLOWS:

CHAIR: Mr. Wolfe.

MR. WOLFE KC: As appears from Mr. O'Brien's witness statement to the Inquiry, he has had opportunity to review three of the cases that were the subject of an SAI Review, and he has provided comments, which, to some extent, put a challenge up to some of the findings contained within the reviews and I wish to go through some of that now with you, primarily, Mr. Gilbert. The Inquiry's Term of Reference C is primarily driven and focused upon the governance aspects of these cases, but, clearly, where there is a challenge being 11:55 11:56

expressed to some of the clinical aspects of the cases, it's important to take a look. The first case I wish to explore with you, Mr. Gilbert, concerns Service User A or Patient 1. Let me just start by looking at the MDM recommendation in that case. If I could have up on the screen, please, PAT-001481. You are familiar with this case, Mr. Gilbert, I'm sure? It can be seen that he was first discussed at an MDM on 29th August 2019. It was recommended that various investigations would be conducted, bone scans, CT chest, abdomen, pelvis and for further discussion at a future MDM. 11:56 11:57

The primary issue in this case, Mr. Gilbert, in terms of your review, was the prescribing of Bicalutamide and, in addition, the failure, as you saw it, to refer to Oncology; is that right? 11:58

A. MR. GILBERT: Yes. I report the second before the first.

68 Q. Okay. I'll bear that in mind. Let's pick up on something of the prescribing history here. We can see it recorded that the patient had been prescribed Bicalutamide 150 milligrams daily and Tamoxifen 10 milligrams daily while awaiting completion of imaging. The medication however was accompanied by intolerable adverse toxicity, and that was mainly in the form of light-headedness, to the extent that the patient lost the confidence to drive. He was asked, by Mr. O'Brien assumedly, to discontinue taking both and to resume taking Bicalutamide at only 50 milligrams daily from 11:58 11:59

1st November. A bone scan, et cetera, was requested, and he was for review on the November.

The CT scan reports here on 28th October, no evidence of metastatic disease, and then into the MDM, I think a couple of days later. Discussed at the MDM on 31st October, where it was found that Patient 1 has intermediate risk of prostate cancer and he is to start ADT and refer to ERBT. That's a form of Radiology, is that right? Radiotherapy? 12:00

A. MR. GILBERT: External beam radiotherapy.

69 Q. Yes. The next stage is for Mr. O'Brien to see the patient. He sees him in November. If we could just have up on the screen, please, the note of that review. PAT-001453. Would you anticipate, Mr. Gilbert, that this is the opportunity to discuss the recommendation of the MDM, the next review between treating clinician and patient? 12:01

A. MR. GILBERT: No, I would have thought the opportunity had come before then. The patient was referred -- I'm sorry, the dates are not clear. The histology was obtained. He had had an MRI scan which showed he had localised prostate cancer, that is disease within the gland itself. The MDM had recommended that he attend a specialist MDT, that is the one based in Belfast that can offer radical therapy, to discuss whether or not this disease should be managed by so-called active surveillance or by active treatment. That didn't happen. It was recommended also that he should have 12:01

staging scans at that stage.

70 Q. Just in terms of the dates, sorry. The MDT was at the end of October, 31st October. This is the review on 11th November immediately following --

A. MR. GILBERT: Okay. 12:02

71 Q. -- the MDT. Just so I understand the process. The clinician, in this case Mr. O'Brien, has the recommendation of the MDM. He takes that with him to meet the patient as soon as may be and, for whatever reason, the review takes place eleven days -- 12:03

A. MR. GILBERT: Sorry, yes. That was the opportunity for him to request the staging scans, a CT scan and a bone scan.

72 Q. Sorry, no, just to be clear. They have been done --

A. MR. GILBERT: Yeah. 12:03

73 Q. -- for the MDM on 31st October?

A. MR. GILBERT: Yes.

74 Q. You have seen the recommendation?

A. MR. GILBERT: Yes.

75 Q. This is the meeting between patient and clinician immediately after that? 12:03

A. MR. GILBERT: Okay, right. Sorry, I got the dates mixed up.

76 Q. Yes. The recommendation, as you know, is to start ADT and to refer for EBRT? 12:03

A. MR. GILBERT: Yes.

77 Q. What we see in this note is that there's a lower urinary tract issue, it's unchanged, and the plan is query EBRT and review.

A. MR. GILBERT: Yes.

78 Q. Let me take you to your SAI findings in this context. If we start at PAT-001304. All the way down to the next page. The Executive summary reminds us that he's been discussed on 31st October at MDM and it says: 12:04

"A recommendation to commence LHRH analogue and refer for an opinion was agreed."

The specific recommendation, Mr. Gilbert, was to start ADT? 12:05

A. MR. GILBERT: Specifically as neoantigen treatment for external beam radiotherapy. It wasn't started as the definitive treatment. This patient would normally have been treated in most MDTs by being referred to the 12:05 specialist MDT, following the staging scans, for consideration of external beam radiotherapy, and the effects of external beam radiotherapy are improved if they are proceeded by a four to six month period of hormone therapy with ADT. 12:05

79 Q. Yes.

A. MR. GILBERT: This ADT was specifically given as a prelude to external beam radiotherapy. Under these circumstances where you have localised prostate cancer, ADT is specifically not included in the recommended 12:06 treatments. Okay?

80 Q. Sorry, I need to go over that again. Just factually and specifically, the recommendation --

A. MR. GILBERT: Yes.

81 Q. -- it doesn't say we recommend LHRH; it says we recommend ADT. The specific question, I suppose, is: Mr. O'Brien had started this patient on 150 milligrams per day seven months prior to the MDM. The patient ran into difficulty with side effects and it was to be reduced to 50 milligrams going forward. The MDM intervenes and says, radiotherapy and start ADT. 12:06

A. MR. GILBERT: Okay.

82 Q. Is it fair to say that Bicalutamide, at 150 milligrams, would be a form of ADT? 12:07

A. MR. GILBERT: It is a form of ADT. Some people would use it, yes.

83 Q. Yes.

A. MR. GILBERT: It is as a prelude to external beam radiotherapy. Think of that treatment as one treatment modality; hormones for four months and then the radiotherapy. 12:07

84 Q. Yes.

A. MR. GILBERT: That is how you treat localised prostate cancer with radiotherapy. Okay? 12:07

85 Q. Yes.

A. MR. GILBERT: To treat localised prostate cancer with ADT is against guidelines. The treatment options for the continuing treatment of localised prostate cancer are either to maintain active surveillance, which is essentially just monitoring the disease, not on any hormones, or to seek external beam radiotherapy as an alternative. Okay? For this patient, who had localised prostate cancer, what should have happened at 12:08

the outset is that as soon as he was known not to have metastasise he could start hormone therapy pending his immediate referral to the specialist MDT which is capable of delivering radiotherapy and they would make the definitive decision about treatment, which, in my mind, is pretty obvious that that is the path the patient should have taken.

86 Q. To summarise: In your view, this patient should have immediately after the MDM, it should have been recommended to him that he recommences on Bicalutamide 50 milligrams as an anti-flare moving to LHRH and referral to Oncology? 12:08 12:09

A. MR. GILBERT: Yes. You could have started an anti-flare treatment for a period of three weeks, is what they say in NICaN. It could be anything between two and four but there it is, three weeks. He would start his LHRH analogue, he would have a month's dose initially to make sure he tolerated it, and if he tolerated it, 19 out of 20 men do, then he would have a dose that would last him for three months. During that period of time, the sooner the better so the patient is informed about what their best options are, he should have met or been discussed within the specialist MDT to decide whether it was reasonable to continue on active surveillance, but because he had intermediate disease that would have been not in his best interest, or whether he should have active treatment. The option that had been steered by the local MDT in the Southern Trust was that he should have external beam radiotherapy. 12:09 12:09 12:09

87 Q. Yes.
A. MR. GILBERT: As opposed to radical surgery.
88 Q. Just turning to the SAI report. Just scroll down to the key findings at PAT-001309. The Review Team's finding that initial assessment was satisfactory. You go on to say: 12:10

"The initial treatment should have been reversible ADT, most commonly LHRH analogue, pending the results of the scans." 12:10

As we know, Mr. Gilbert, the patient was started on 150 Bicalutamide. Mr. O'Brien's rationale for that was that this patient had a history of, I believe, cardio -- 12:11
A. MR. GILBERT: Miocardial infarction.
89 Q. Yes, cardiovascular disease. We discussed this earlier. In the circumstances where you've, I think, acknowledged that 150 milligrams Bicalutamide is a call that can be made by clinicians -- 12:11
A. MR. GILBERT: Certainly a proportion of Urologists may offer that as treatment, but the majority would offer an LHRH analogue in the first instance.
90 Q. Yes. Is there any great criticism to be made that he elected to start with 150? 12:12
A. MR. GILBERT: No.
91 Q. You go on to say that the prescribing didn't conform with the 2016 NICaN guidelines, or the hormone therapy guidelines. Is that a reference to the 150 at the

start, or is that a reference to the 50 milligrams which the patient commenced after the MDM in November?

A. MR. GILBERT: Specifically the 50 milligram dose.

92 Q. Just scrolling down. You say:

12:12

"The subsequent management" -- again that's the 50 milligrams -- "with unlicensed anti-androgenic treatment at best delayed definitive treatment. It's only currently indicated as a preliminary anti-flare."

12:13

The thinking of Mr. O'Brien at that point is set out in a letter which, no doubt, was available to you, to the General Practitioner. I want to bring that up on the screen. PAT-001487. This is the period after the MDT. The patient hadn't tolerated well the 150, had come off it for a short time before the MDT and was recommenced on 50. This is a letter written after the 11th November clinic, which I had just opened to you. It says:

12:14

12:14

"It would be ideal for the patient to have an optimal biochemical response to the androgen blockade or androgen deprivation prior to consideration of radical radiotherapy. If his PSA level has not decreased further it may be necessary to take an incremental approach to increased androgen blockade by increasing the dose of Bicalutamide to 50 milligrams twice daily and hopefully subsequently to take the higher dose of 150 milligrams once again, as I suspect that the

12:15

addition of LHRH agonist may be more intolerable."

Therefore you have the thinking, the patient, his case is considered at MDM, the Clinician knows that the patient has a history of intolerance towards 150 Bicalutamide, and he wants to get an effective biochemical response prior to referral to Radiotherapy. That's a perfectly acceptable way of thinking, is it? 12:15

A. MR. GILBERT: I would question it. The aim of the hormone therapy is to render the patient castrate. Sorry to use that term but that's the term that is used. Indeed, under certain circumstances, it's possible to do so, it's not appropriate in this case because you want a reversible situation, but you could take the testicles off to achieve exactly the same effect. In fact, that was the first treatment for metastatic prostate cancer. 12:16

93 Q. Yes.

A. MR. GILBERT: The fact that this gentleman had side effects to 150 milligrams is peculiar and particular to that agent. Reducing it may well have alleviated his symptoms, but under normal practice I think most clinicians would have said he wasn't suitable for Bicalutamide. The 50 milligram dose would be ineffective in achieving the castrate level, and, therefore, he should go on to an LHRH analogue, and that to me is the logical sequence of decision-making. 12:16 12:17

94 Q. You say ineffective. Are you saying that, on the face of it, 50 milligrams was simply under-treating the

patient if the desired objective is to reduce the size of the prostate and the tumour with a view to radiotherapy?

A. MR. GILBERT: Yes, in effect.

95 Q. If we go to PAT-001311, just into the conclusions section. What you say is, after explaining your view, that this should have been handled with at least four months' ADT, with a referral to Oncology, that: 12:17

"The opportunity to offer the patient radical treatment with curative intent was recommended by the MDM but not actioned by those responsible for his care. The local progression of the disease should have been considered in the light of both the symptomatic deterioration and PSA changes." 12:18 12:19

That was your view essentially, accepted by the team?

A. MR. GILBERT: Yes.

96 Q. You plainly thought that this was inadequate treatment, and that allowed for disease progression? 12:19

A. MR. GILBERT: That was my conclusion, yes.

97 Q. Yes. Can I ask you this -- let's just pull up PAT-001310. That's the wrong reference. Allow me a moment. If we could have WIT-82635, please. Sorry about that. 12:20

This is Mr. O'Brien's statement. He's picking up on your conclusion, and sets out the reference there, that he developed metastasis while being inadequately

treated for high risk prostate cancer. Mr O'Brien argues that risks the inference that to develop the metastasis because he was inadequately treated. His position is that what caused the difficulty here was not inadequacy of treatment, but because the patient 12:21
suffered adverse side effects from adequate hormonal treatment, which -- that was the obstacle that caused the difficulty, that there was no other adequate treatment, in his view. He was on the right treatment path, but it was slowed up because of the patient's 12:22
inability, at various stages, to cope with it. The goal was always, inferring from this, the goal was always to get him back on to 150 milligrams of Bicalutamide, and that would have addressed the issue.

A. MR. GILBERT: There's quite a lot to comment on in that. 12:22
It feels slightly knotted. We've discussed what I felt the treatment should be. An impressive PSA response would be 4 to 0.1 or less, that would be an impressive response, and indeed expected response. For it to have fallen down to 2 and 3 -- sorry I can't remember the 12:23
precise figures -- is not impressive, it is inadequate. They need to be suppressed. The prostate and the prostate cancer needs to start shrinking. Okay? The Bicalutamide is essentially a competitive antagonist. What that means it's like a key that locks into a lock 12:23
and blocks the real key from going into cause its damage. Okay? If that's reasonable way of describing it.

98 Q. Yes.

A. MR. GILBERT: There are lots of these locks on the cancer cell and so what you do is you give a dose of these inactive keys to block up all the locks. If you give insufficient keys to block up all the locks, you leave some of them open which allows the processes that allow progression of prostate cancer to happen. I have tried to explain something that even I find difficult to understand, that's a terrible thing to say. Anyway, he was clearly on inadequate treatment. Okay? That's the first thing to say. Next thing to say is, okay, he developed symptoms as a consequence of the treatment. Those symptoms may be due to the effect of the treatment, that is the reduction in testosterone, that may be why he was having those, or they may be a direct consequence of the drug itself. No one can tell you what that is. Experience might give you a feel for it, but no one will tell you which of those is applying, and indeed they may both be applying. The answer is not to move to an inadequate treatment, the answer is to use a reasonable alternative. In this case, the reasonable alternative is the more commonly used treatment by Urologists across the spectrum, and that would have been an LHRH analogue. My difficulty with this is that that was not the step that was taken.

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The second difficulty I have with this case specifically around this, was that the diagnostic clinician, Mr. O'Brien, should have, at the time of the MDM discussion, for referral, and knowing that there is

no metastatic disease, have referred the patient immediately to a specialist MDT, where his treatment could be continued definitively. Because that didn't happen, I think there was potential opportunity for the disease to have progressed when it may not have needed to. However, I would put a big caveat on that by saying that's speculation. I don't know that even if he had done what I think most Urologists would have done that the same events would not have happened and the disease would have progressed, for whatever reason. All I'm saying is that he didn't take the steps, the fair and reasonable steps to ensure that this gentleman had the best chance of avoiding that happening. 12:26 12:26

99 Q. The history of ischaemic heart disease would appear to be prominent in Mr. O'Brien's reasoning for placing a reliance on Bicalutamide initially, and it seemed a determination to get back up to 150 milligrams, notwithstanding the earlier side effects. Is that thinking or that rationale a justification, an adequate justification for the approach adopted? 12:26 12:27

A. MR. GILBERT: The hormone treatment was going to be given for four months. Any evidence for the deleterious effect of low testosterone on men's health, particularly their cardiac health, relates to men who are on the drug for longer periods of time, essentially men who are being treated for metastatic disease for which hormone therapy is the definitive treatment. Under these circumstances, I can see no reason to consider that. Most of the decisions about whether or 12:27

not you treat somebody for prostate cancer are based on their performance status, that's how active they are, and there are a number of schemes, the most commonly used is the WHO and if somebody is fit and active WHO zero, even if they have had a myocardial infraction, you are going to treat them the same way. This is the difficulty I have in reviewing these notes is I don't actually see the patient. 12:28

100 Q. Yes.

A. MR. GILBERT: Okay? I would clearly admit that is a substantial deficiency in being able to make a judgment about individual patients, so I'd rather stick to the principles here of treatment rather than the specific events. To me, the theme that needs to be explored is the non-referral or the lack of referral for specialist, advice regarding specialist treatment. The non-referral to the support of a Cancer Nurse Specialist, who would have been helpful under these circumstances as things turned out, and a prescribing practice which is readily questionable. Those are the three themes. 12:28 12:28 12:29

101 Q. Yes. Is there a fourth theme? If the recommendation of the MDT is not capable of being implemented in the eyes of the clinician, does that go back, in your view, to the local MDM? 12:29

A. MR. GILBERT: It would certainly do so in my practice and, I think, in the practice of most Urologists.

102 Q. I opened the correspondence to the General Practitioner written by Mr. O'Brien in late January, eight weeks or

so after the MDM, and he is explaining to the General Practitioner that I want to see a sufficient biochemical response prior to referral or prior to possible referral. Bearing in mind that the MDM set out its recommendation at the end of October, as a matter of practice, is the Clinician to make that referral after consultation with the patient immediately or is he to deliver a satisfactory biochemical response prior to putting it in the hands of the specialists? 12:30

A. MR. GILBERT: The difficulty with answering these questions is that you are asking me to take a journey I wouldn't have taken and to comment how would I have reversed my tracks if I had gone down them inadvertently. 12:31

103 Q. Put it in simpler terms. If the recommendation is to start ADT and to refer for EBRT, or an opinion as to whether EBRT is to be done, what is the sequencing for that? When do you make the EBRT referral, assuming your patient is amenable to that? 12:31

A. MR. GILBERT: As soon as you've fully staged the disease and it's been discussed in the MDM, there should be an action. Before other mechanisms were in place, I would go and sit down in my office and write letters to a specialist as matters of referral and make sure they were sent off urgently. 12:31

104 Q. We know in this case the referral on to Oncology doesn't take place until June 2020, some seven or eight months after the MDM recommendation. I think

Mr. Haynes makes that referral when he, coincidentally, sees the patient when Mr. O'Brien was off duty, for whatever reason. Just to be clear, the Clinician waiting for an adequate biochemical response, that's not the time to make the referral; you make it -- 12:32

A. MR. GILBERT: No, you make the referral immediately. 19 out of 20 patients, probably more, are going to respond. What's the point in delaying to see a non-response in one patient? Anyway, if there's a non-response in a patient, then a specialist MDT 12:32 should have been informed because they are going to look at alternative treatments, which would not be provided locally. All patients for consideration of radical treatment, and this is plainly given in all the guidelines, all patients for consideration of 12:33 specialist MDT must be referred to the specialist MDT as soon as possible so that they can be considered for the appropriate radical treatment.

105 Q. Yes. Let me move on to a second case that Mr. O'Brien helpfully deals with in his statement. It concerns 12:33 Service User B, who is Patient 9. If we can bring up the SAI report at DOH-00026. On the next page we will see the Executive summary.

This is a case, Mr. Gilbert, you will remember, where 12:34 the patient came into the emergency Department at the Southern Trust with severe pain and urinary retention on or about 1st May 2019. He saw Mr. O'Brien on 24th May 2019, and it was a suspicion of cancer of the

prostate. Mr. O'Brien commenced on 50 milligrams of Bicalutamide, arranged for a TURP on 12th June, and that took place. He reviewed the patient on 2nd July and advised the General Practitioner that he planned to see the patient, there was some doubt as to whether it was August or September but I think Mr. O'Brien says it was to be August, when he planned for an ultrasound and an MRI for diagnostic purposes. 12:35

Within the Executive summary, you've set some of that history out. What ultimately happened was that the review, it says here, that was planned for September -- as I say, Mr. O'Brien thinks it was planned for August and he made that clear in a letter to the General Practitioner -- that didn't happen and the patient wasn't seen again until a year later, or a year from his original presentation, May 2020, by which stage he was found to have a large rectal mass and a fistula. 12:35

Let me address some of Mr. O'Brien's concerns about your findings. He makes four broad points. If we could open WIT-82636. As I say, his first point, Mr. Gilbert, is that he specifically deferred the prostatic biopsy until a planned review in August. That is a response, I suppose, to the concern expressed in the SAI Review, presumably by you, that there was a failure to get on with diagnostics quickly enough? 12:36 12:37

A. MR. GILBERT: Yes. There was a suspicion of prostate cancer that was expressed at the time of his initial

presentation. There was a wait until he had a TURP, a short wait. That didn't prove the diagnosis, as I try and recall.

106 Q. Yes.

A. MR. GILBERT: That is a pit fall into which Urologists can fall. 12:38

107 Q. Yes. Another point you make in the report is that there was no digital rectal examination, and that was a concern you expressed. Just scrolling down to number 4, we will come on to 2 and 3 in a moment, Mr. O'Brien says, just to be clear: 12:38

"The report found there was no record in the medical notes of DRE. This is incorrect as a DRE was performed and it's written into his consultation note" 12:38

I am sorry, I don't have that consultation note to show you. But those findings, T3, query T4?

A. MR. GILBERT: The first thing I would like to say is I apologise for missing that. I put my hands up. However, there are levels of suspicion for prostate cancer. If the PSA had been marginally raised and the prostate was a little bit hard on one side, then I might accept that it would be reasonable to defer things. If, however, the PSA was significantly raised and the prostate felt obviously cancerous, which is what is being alluded to here, T3/T4, the finger is telling you the diagnosis, then I think that puts even more urgency than I actually implied in my report. 12:39 12:39

108 Q. Yes.
A. MR GILBERT: The biopsy should have been done in May.
109 Q. Yes. Sorry to jump a little bit about here, I just want to put your conclusions in front of us so we have them absolutely clear. It's DOH-00028, and second paragraph down. What you say is:

"The patient was seen on 24th May. Dr. O'Brien noted a history of lower urinary tract symptoms and a failed trial removal of catheter. A serum prostate specific antigen was elevated. Following an examination Mr. O'Brien was suspicious of the presence of significant prostate cancer. He initiated partial androgen blockade by prescribing Bicalutamide while awaiting a TURP which was arranged for 12th June." 12:40 12:40 12:41

Just going down to DOH-00030, down to the bottom of the page, please. What you are saying is that:

"the patient presented with urinary retention and demonstrated features of possible prostate cancer. This possibility should have been pursued by the request of an MRI of the prostate and pelvis and ultrasound guided needle biopsy. Alternatively an urgent TURP and the needle biopsies could have been performed simultaneously after the MRI scan. This would have established the diagnosis and following staging with a bone scan, the patient could have been referred for special opinion on radical therapy." 12:41 12:42

The Review Team believe that Mr. O'Brien suspected prostate cancer based on clinical examination and, in essence, shouldn't have planned to wait until August or September to carry out appropriate diagnostics. That's the position you reached?

A. MR. GILBERT: In the light of the digital rectal examination, I think reinforced, yes, absolutely.

110 Q. Yes.

A. MR. GILBERT: There was a suspicion in May when he presented that he had locally advanced prostate cancer, the digital rectal T refers to the stage, before how far the cancer has got in the organ itself, how far it has spread within the body. T refers to tumour, which is the primary tumour and tells you the relationship of the cancer to the original organ itself. T3 means that the cancer has grown outside the capsule of the prostate. T4 means it has become attached to adjacent structures. This is locally advanced disease. This is a dangerous disease. It is my practice, and I didn't put this in because it's slightly unconventional, most people would send the patient off to have a formal biopsy, but I would have given the patient antibiotics in the clinic and taken a biopsy there and then, and the diagnosis would have been available four days later, the staging scans could have been done within a couple of weeks, and this patient could have been discussed at the MDT, although -- should have been discussed at the MDT and then referred on for

12:42 12:42 12:43 12:43 12:43

specialist treatment.

111 Q. Yes. The point, though, from Mr. O'Brien's perspective, set out in his statement, and we will turn to the detail of it in a moment. He didn't pursue the diagnostics in June. He consciously, intentionally was waiting to see the patient again in August. He was planning to MRI at that point, and the rest of the diagnostics. A short wait was inconsequential but for the fact that the Trust, he argues, failed to deliver that patient for review in August. He wasn't given an appointment and was lost until the following year when he presents in May 2020 with these great difficulties, including a fistula. That's reasonable, isn't it, to wait until a few months, maybe not even two months, until August, to see the patient for diagnostics. What was the rush to pursue it in June? 12:44 12:45 12:45

A. MR. GILBERT: The rush was to obtain a diagnosis, proper staging of the disease, and to allow him to enjoy treatment as soon as possible. You are dealing with cancer. 12:46

112 Q. Is it the position that as soon as you have a suspicion, whether it's DRE or through other investigations, once you had that suspicion you should move as quickly as possible?

A. MR. GILBERT: Within the constraints of any particular system you work within, yes. There are waiting lists for, say, biopsies, and so on and so forth. I don't see the point of putting a wait into a wait, if you see what I mean. A wait to start a wait for your MRI scan, 12:46

why not just get the MRI scan done?

113 Q. If you have the patient in for a TURP on, I think it's 12th June, is there any obstacle, when you have him there, to carrying out, for example, the biopsy at that point? 12:47

A. MR. GILBERT: That was an absolute and clear opportunity TO perform a biopsy. The problem with prostate cancer is it tends to affect the peripheral outer part of the gland, so it's easy to feel sometimes. It's not if it's at the front of the gland. Most cancers are at 12:47 the back of the grand at the periphery, at the outside. When you are doing a TURP what you are doing is you are actually coring out the prostate. If you imagine an apple, the TURP is taking out the core to allow the urine to flow properly, but the cancers tend to be 12:47 located in the flesh of the apple, not in the core. So, taking out the core does not necessarily lead to a histological diagnosis, and this is a pit fall that most Urologists would acknowledge. If you put your finger inside the tail-end and you can feel the clear 12:47 cancer then, for the sake of two minutes, you could obtain two pieces of issue that would have given you the diagnosis there and then.

114 Q. In general, Dr. Hughes, and Mr. Gilbert, there is no particular focus within your reports on the 12:48 circumstances of the Trust and, in this particular case, on Mr. O'Brien's account, the fact that this patient didn't get the appointment which Mr. O'Brien had planned for him, which may be worthy of further

investigation; we may look at it. Plainly there were significant waiting lists, pressures, maybe this is a mere clerical or administrative error and he dropped out of the system with any possible number of reasons, perhaps. This context of the Trust not delivering, not being in a position, perhaps, to deliver an adequate Service more widely as a contextual factor, is that something you were conscious of? 12:48

A. DR. HUGHES: We certainly were conscious of the pressures on the Trust and the fact that the Trust has expanded its catchment area and the volume of work was increasing. In this case, with a positive T3/T4 on DRE, I mean that would be an indication to immediately start the re-diagnostic pathway. The diagnostic pathway includes a transrectal ultrasound services provided by the Specialist Nurses, and there would have been no reason why that could not have been instigated on 23rd May. 12:49

115 Q. Yes.

A. DR. HUGHES: But it wasn't. They will have their waiting lists, but as long as you make that referral into the system, people will not be lost. This is not a classical pathway. This is addressing a urological TURP issue and then, at a later stage, addressing a T3/T4 significant cancer issue. I would question that. Obviously, the primary focus should have been at what was considered clinically at T3/T4 cancer, and there are expedient challenges to do that. 12:49 12:50

116 Q. Just from a Governance perspective on this case, is

there anything that could have been done from a tracking monitoring perspective in the particular circumstances of this case?

A. DR. HUGHES: Tracking traditionally kicks in when somebody has an appropriate -- a formal tissue diagnosis of a cancer, which is a failing in many types of cancer, and two other patients had, radiologically, renal cancer, but because they didn't have a tissue diagnosis, didn't have a clinical nurse. I think, in this instance, and one of the reasons I reflected on a previous SAI, the clinical administration in Mr. O'Brien's practice was known to be under stress, was known to be replete with problems, so there's a delay or a loss of a patient in this case, but it's not the only one in this cohort of nine patients. The Trust already knew this and possibly should have put steps in place to address this, because if there's an issue with, and some of the work was with the front end of the pathway, the triage in cases, but you would have to make this assumption there may be clerical and administration processes elsewhere in the pathway. When I look at this, the clinical thought process should be if you detect, query T3/T4 locally advanced cancer, that should be your primary focus, and the focus seemed to be on doing further PSAs, then do your TURP and then perhaps doing -- which could have been possibly an aggressive cancer, as it turned out to be.

12:50 12:51 12:51 12:51 12:52

117 Q. Yes. Just one final point on this case, Mr. Gilbert, if I could trouble you for your comment. If we go to

WIT-82637 at number 3, please. I am conscious that you won't have the opportunity to review any notes, so I ask this question with a degree of hesitation:

"Mr. O'Brien says when Service User B was reviewed by the Cancer Centre in Belfast City Hospital on 5th November 2020" -- that was after he had come back into the system obviously and had been referred from the Southern Trust's MDT to the regional centre -- "he was prescribed Bicalutamide 50 milligrams daily". 12:53

This is contrary to the assertion from the Review Team, primarily you, Mr. Gilbert, that Bicalutamide 50 milligrams is only indicated for the prevention of tumour flare associated with the first injection. 12:53

Do you understand that --

A. MR. GILBERT: I understand precisely what's being said but I maintain my position. I don't know why anyone in Belfast City Hospital, on 5th November 2020, would have 12:54 prescribed 50 milligrams of Bicalutamide for this patient. Unless it was a preliminary to starting an LHRH analogue if he hadn't started it at that stage.

118 Q. We will maybe have an opportunity to look at that further. Can I move then to the case of service F, who 12:54 is Patient 6. The SAI report for that case can be found at DOH-00073. You are familiar with that case, Mr. Gilbert?

A. MR. GILBERT: Yeah.

119 Q. Just down to the next page, please. The Executive summary tells us that:

"The patient was commenced on a low dose, described as sub-therapeutic dose of Bicalutamide for prostate cancer. There was no documentary evidence of any discussion of the radical treatment options for the prostate cancer recommended by the multidisciplinary meeting."

12:55

Mr. O'Brien in his witness statement makes the following points. He says that the so-called multidisciplinary meeting on the August, I think it should say 2019, was not an MDM at all. It was a review by Mr. Haynes because the MDM didn't happen that day. It wasn't possible to arrange because of attendance issues. Prior to that consideration of the case by Mr. Haynes, the patient had been started on 50 milligrams of Bicalutamide by Mr. O'Brien, and he sets out the reasons for that. Just before looking at the reasons, let's examine the conclusions reached by your review. If we can scroll down, please, to the conclusions section. Sorry I don't have a reference for it. It says:

12:55 12:56 12:56

"A standard pathway for this man was followed up to and including the first MDM"

12:57

I will put a caveat against MDM and ask for your comments in a moment.

"At that point acceptable practice should have been to discuss the options available as recommended by the MDT. Most urological centres would have requested a bone scan to complete staging, and should the patient have chosen to pursue radical therapy it would have been reasonable to start ADT."

A number of points, Mr. Gilbert. Could we have up on the screen, please, WIT-82637. Number 1. He comments, in response to your opinion expressed in the report, Mr. Gilbert, that your view that the commencement on a low dose of Bicalutamide was sub-therapeutic is incorrect, in his view. He was commenced on 50 milligrams of Bicalutamide to relieve the patient's concern regarding the risk of progression of any presumed prostate cancer while awaiting confirmation of its presence by biopsy. 12:57 12:58 12:58

I think that's a view or that's a fact that is acknowledged within the SAI. You pick up on that and report on that. Is it appropriate, in your view, to commence on 50 milligrams of Bicalutamide while awaiting full diagnosis as a reassurance approach? 12:59

A. MR. GILBERT: No. 12:59

120 Q. Is it appropriate to start it prior to a full diagnostic investigation on the basis of a suspicion that we will eventually see a confirmed diagnosis?

A. MR. GILBERT: No, and I will give a specific reason on

this occasion. Certainly, in my hospitals, I have been encouraged to obtain histology prior to any commencement of hormone therapy. Starting hormone therapy can affect the histological interpretation of prostate cancer. We haven't even touched on this, but how you manage prostate cancer is determined by what's called the grade of the disease or differentiation of the disease. Differentiation refers to, in lay terms, the aggressiveness of the cancer. The more aggressive the cancer various treatment options are given. Scores for this, Gleason score which measures the aggressiveness of the cancer runs from, for technical reasons, from 6 to 10. 6 is a very quiescent disease, indolent disease, and is usually managed by observation. 10 is a very, very aggressive disease, rarely seen it has to be said. This gentleman's cancer I think was Gleason 7, but our Pathologist would have sent me a fairly smart and tetchy e-mail if I had started hormone therapy beforehand because the distinctions that can be made, which are critical to the allocation to the treatment options for the patient, may be obscured by pretreating the patient with hormones.

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121 Q. The rationale here is to commence him on the Bicalutamide to relieve concern because there's a fear on the part of the patient that disease will progress in the meantime. Does that make sense as an assurance mechanism on any level?

13:02

A. MR. GILBERT: No, not on any. As it transpired, this

man had localised prostate cancer, and sorry to use technical terms again, to re-iterate this is a disease confined to the prostate, this was going to be amenable either being managed by active surveillance or to radical therapy, which, as an aside, is dependent on the Gleason score that I just alluded to. The one treatment option that is not indicated under these circumstances is hormone treatment, ADT. Even less, a lower dose of ADT than is conventional. If the patient needed to be reassured, there were two possible things. Mr. O'Brien himself could have exercised his professional expertise and reassured the patient that this did not happen, and it is a common concern of patients that things will progress but the correct words will assuage that. Secondly, there could have been a Cancer Nurse Specialist available so that any of his immediate concerns could have been addressed immediately. He would have had access to support and advice that would have ameliorated his concerns. 13:02 13:03 13:03

122 Q. Yes. 13:03

A. MR. GILBERT: I think actually giving a sub-optimal dose of ADT for all those reasons was inappropriate.

MR. WOLFE KC: Chair, there's a few more points that might me take to take probably ten minutes to complete on this particular case, probably wise I think just to break for lunch, unless you want me to? 13:04

CHAIR: If you are going to take ten minutes we will continue on and come back later after lunch.

MR. WOLFE KC: Very well.

123 Q. So just moving over to the next page, please. The second point which is raised is that the MDM on 8th August, as I alluded to earlier, was, in fact, an online review conducted by Mr. Haynes, as it not been possible to hold MDM due to the lack of availability of other Consultants. There was no discussion of Patient F or agreement concerning his diagnosis, there was nothing multidisciplinary about this MDM. 13:04

I am quite sure that the paperwork that you received for the purposes of your review, correct me if I'm wrong, would have indicated that it was the minute of an MDM? 13:05

A. MR. GILBERT: It appeared to me to be a minute of an MDM. Whether it was a triaged session or not, I'm not clear about. 13:05

124 Q. Yes. So does this --

A. MR. GILBERT: I would have no issue with this at all.

125 Q. It takes you by surprise but you have no issue with it?

A. MR. GILBERT: It doesn't take me by surprise because I would point to many other of the so-called MDMs that the Southern Trust has held and they were not quorate. What makes this one in particular not an MDM when others are not quorate because, in my view, those are not MDMs either. 13:05 13:06

126 Q. The surprise I am alluding to is that you didn't know, when writing your report, that this case had only been looked at by Mr. Haynes?

A. MR. GILBERT: I knew that on several occasions the MDMs

included what might be termed a skeleton crew. I wasn't aware that it was him on his own without anybody else being present.

127 Q. What emerged from Mr. Haynes' consideration of the case was that the recommendation -- just allow me a moment, please. Sorry, I have just lost my note. 13:06

CHAIR: Do you want us to rise give you some time to locate the note? Do you want us to rise and we can come back then?

MR. WOLFE KC: Sorry, if you go on to the bottom of the page, paragraph 8. Yes, maybe we should rise, it's not working for me. Apologies for that. 13:07

CHAIR: Ten past two.

MR. WOLFE KC: Thank you.

13:08

THE INQUIRY ADJOURNED FOR LUNCH

THE INQUIRY CONTINUED AFTER LUNCH AS FOLLOWS:

CHAIR: Afternoon, everyone.
MR. WOLFE KC: Two brief matters of housekeeping, if I may, before we start. I have mentioned to the witnesses over lunchtime that it's unlikely that I will get them through their evidence today, and I know the Panel may need some time to ask questions, so I propose working through to 4 o'clock, hopefully without a need for a break, and then I have spoken to the witnesses about their availability to come back, subject to the Secretariat. Both of them are available for 25th January so we are having a patient day on the 24th. 14:10 14:10
CHAIR: The 25th, then, if you could, gentlemen, please put that into your diaries. We will have some questions to ask you, and we have discussed it and we think it would be better to have our questions until we have had all of your evidence delivered to us, and then we will ask you some questions at the very end, on the 25th hopefully. 14:10 14:11
MR. WOLFE KC: I am happy to correct something I dealt with yesterday, and I will mention it now. The transcript for yesterday at page 130 commencing at line 5, reads, and this is a preface to a question from me: 14:11

"Mr. Carroll, we know has worked in the Trust for some years and has worked closely with Mr. O'Brien over those years and he provides quite a personal response to it".

You will recall the remarks that Mr. Carroll made to Dr. Hughes about Mr. O'Brien. It appears to be the case, certainly from Mr. Carroll's written evidence to the Inquiry, that he never met with Mr. O'Brien. So, 14:11
my emphasis on him working closely with Mr. O'Brien is in that sort of personal context sense, incorrect, or so it appears from Mr. Carroll's statement, albeit he did mention in the area in which Mr. O'Brien worked, the Acute Directorate in which Mr. O'Brien worked for 14:12
some years. I am happy to provide that clarification

CHAIR: Thank you, Mr. Wolfe.

MR. WOLFE KC: Just before the break, I was stumbling over my note, and the point I wanted to get to, Mr. Gilbert, was this: As regards Patient 6, Service 14:12
User F, as you know, he was, as it appeared to you, discussed at a multidisciplinary meeting on 8th August 2019. Mr. O'Brien says that wasn't a multidisciplinary meeting, that was Mr. Haynes dealing with the matter remotely by himself. What emerged from that -- and 14:13
this is the point where I got lost, but just to be clear. What emerged from that was a recommendation that Mr. O'Brien would review the patient in Outpatients and that he would discuss management with curative intent or surveillance. You make the point in 14:13
the SAI that, at that point, post-MDM, as you took it to be, acceptable practice should have been to discuss the options recommended by the MDT.

If you can pull up on the screen WIT-82639, paragraph 9, please. Back up slightly to paragraph 8. Mr. O'Brien takes the point, quite properly, that notwithstanding this wasn't an MDM:

14:14

"I would have discussed both options recommended by Mr. Haynes, though advising Service User F that all of the features of his confirmed prostate cancer indicated that would be best served by proceeding with management with curative intent. I would not have recommended active surveillance and did not recommend it. I recommended androgen deprivation prior to radical radiotherapy as indicated in my letter to the patient's general practitioner dated 27th October 2019."

14:15

There you have it, MDM, or a version of the MDM, put it in those terms, make its recommendation. Mr. O'Brien says he did discuss it and, indeed, he refers to the letter that went to the General Practitioner setting out his view that ADT, leading into radical radiotherapy, was his view of the way to go. I think the point that you make in the SAI report is that there was no documentary evidence of any discussion of the radical treatment options. Certainly Mr. O'Brien sees the patient on 27th September, and there is no note of a discussion of those options, albeit a month or so later he writes to the General Practitioner, 27th October, to refer to his view of a curative approach. In terms of medical practice, in discussing options

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arising from an MDM, is the expectation that there they would be recorded into the clinical note?

A. MR. GILBERT: Yes.

128 Q. Is that provided for maybe, Dr Hughes, in GMC provisions about record-keeping? 14:17

A. DR. HUGHES: Yes, you'd take a note of all pertinent information given to the patient.

129 Q. Is the governance assumption that if you don't make the note you haven't had the conversation, or was that the assumption you made, Mr. Gilbert? 14:17

A. MR. GILBERT: No, it wasn't an assumption I made. I was simply pointing out that it hadn't been recorded, and it would have been normal practice to have dictated a letter immediately after the clinic, or during the clinic indeed, indicating that conversation had taken 14:17 place at that time; the options included, the reasons for them being dismissed as inappropriate, or the reasons given as to which is the preferred treatment. Then that letter should also form part of a referral to somebody who can provide that treatment. 14:18

There is one sort of caveat that I'd like to expand on, and that is the notion of what might be termed local MDTs and regional MDTs or specialist MDTs. Local MDTs tend to be those that are in district general 14:18 hospitals, deal with a lot of diagnostic work, and it is clear from Outcomes guidance that was published in 2001/2002, that any patient considered for radical therapy should be referred up to the centre, not for

the treatment but for discussion of the options available to them. There's a critical difference in there between saying, I'm deciding that you are going to have external beam radiotherapy at the local level, and somebody with specialist expertise talking to the patient as well.

130 Q. Thank you.

A. MR. GILBERT: That's the main point of the referral, to get the patient to the appropriate expertise.

131 Q. Is that a point which, in your experience, has to be made? The immediate clinician can tell the patient about the recommendation, but are you saying the advice should be you really need to put yourself in front of the Oncologist? 14:19

A. MR. GILBERT: A patient in this position should have (1), a cancer Nurse Specialist would be helpful in order to explain the options available. There is no reason why a local clinician shouldn't have the expertise to explain the options to a patient and point out the advantages of, say, Radiotherapy over surgery. The patient probably should have the opportunity to have a discussion with those who deliver that treatment, so the idea of a joint Oncology clinic is prevalent in other parts of the United Kingdom, where the patient will go to find out about Radiotherapy, its process and its complications and its outcomes and the same for surgery, and the Cancer Nurse Specialist, because remember about that continuity, is the very person who the patient could go back to and say look, 14:19 14:20 14:20

I have just been given this huge amount of information, I can't make up my mind, that's what the Cancer Nurse Specialist is for. Because I haven't worked in the Southern Trust, I'm not exactly familiar with their processes and how things work, but there seemed to be some leeway in the timing of getting those experts' opinions for patients so that they could make appropriate decisions about their own management.

132 Q. Yes. As the SAI report highlights at DOH-00078, there was no Oncology referral, and Mr. O'Brien deals with that and he puts forward a clear explanation as to why there was none. 14:21

If we could have up on the screen, please, WIT-82639, paragraph 6. The report, which I have just read out, the report finds there's no Oncology referral. 14:22

"This is correct as I considered it inappropriate to refer Patient F for radical radiotherapy until he had undergone assessment and management of his severe lower urinary tract symptoms in compliance with NICE guideline NG131, paragraph 1.3.4". 14:22

You have just indicated that the patient should have the benefit of the oncological advice, the referral, but the treating Clinician, who knows the patient very well, in this case knows that he, as we can see from the GP notes and records -- sorry, not in the GP notes and records, from Mr. O'Brien's note keeping, that the 14:22

lower urinary tract issue is something that is a frequent reference point within the notes. Mr. O'Brien is entitled to judge the timing of the referral based on other comorbidities?

A. MR. GILBERT: Clearly. However, what I would say is that there is no reason why the information and education of the patient should not happen in parallel; that is to say, the referral should have gone immediately. Do remember that even the patient was going to be on hormones for a period of a minimum of four months prior to the radiotherapy, and it is my practice in this not uncommon situation, this happens frequently, remember we are dealing with old men who have enlarged prostates and therefore have lower urinary tract symptoms, who have concomitant cancer that those two aspects are dealt with in parallel. I would normally say to them get them started on hormone therapy. I would personally review them some weeks, maybe even three months later, to see whether the hormone therapy had improved matters, and that allows time for assessment of the lower urinary tract symptoms to ascertain whether or not a surgical procedure is going to improve for the patient. Those things happen in parallel. There is no reason to wait with a patient in ignorance of their future to sort out the waterworks; you do that, you know, that's your own duty to get on with things. Meanwhile the patient can go on, plan their treatment, plan their lives around their treatment whilst you are sorting out their

14:23 14:23 14:24 14:24 14:24

waterworks.

133 Q. Yes. As you say, this kind of development, or perhaps comorbidity, is not uncommon. If the thinking is this man has this difficulty, he may not be at the moment suitable for radiotherapy; is that the kind of thing that generally should go back to the MDM to have it out there, or is that something that the clinician really, as your last answer suggested, should get on with and refer to the oncologist? 14:25

A. MR. GILBERT: If the clinician thinks that the lower urinary tract symptoms should exclude the patient from radiotherapy then, yes, it should go back to the MDT. However, I don't think that would be a common scenario. The job is to sort out the cancer by referring to the specialist MDT, period. You have a period of time to sort out the urinary tract symptoms, and that is the job of a general Urologist. In my own practice, with this patient, I would have referred at the time of the decision-making. In the meantime I would have arranged urodynamics to ensure or ascertain exactly what sort of treatment might alleviate his lower urinary tract symptoms, and if that involved a TURP, then he could come in and have it done because you have got a window of opportunity. 14:25 14:26 14:26

134 Q. Dr. Hughes it's a nuance I think in my question to date that was somewhat lost on me. Mr. O'Brien makes the perfectly reasonable point that this wasn't an MDM, and I have looked at the MDM record and while it's in the usual stationery for the MDM with the title of MDM and 14:26

all, it's not distinctive from any of the other MDM records. You, as the author of this report with Mr. Gilbert, might be forgiven for thinking this was a standard MDM, but just for clarity, in this one in particular or in any others that you were looking at, was it your assumption, based on the paperwork, that this was a fully functioning MDM, multidisciplinary meeting that looked at this case? 14:27

A. DR. HUGHES: We didn't make that assumption for any of the MDMs. 14:27

135 Q. Sorry, you didn't?

A. DR. HUGHES: We didn't make that assumption for any of the MDMs in the Southern Trust, because when you actually look at the attendance and the reports are peppered with the annual quorate rates, very, very few of the MDMs were appropriately quorate. We did drill down at times by year. We didn't drill down into every individual MDM to see if it was quorate, but the overall figures were so low that the assumption that it was not a quorate MDM. There were some virtual MDMs because at the time of Covid and the attendances did vary. The recommendation in this case, as in many cases at MDMs, is through standardised regional protocols and the output, although it wasn't a quorate meeting, is not an unusual recommendation. 14:28 14:28

A. MR. GILBERT: No. If I may, this is what I would call, without being disparaging to the patient, a straightforward case. The actions required for this patient are clear and obvious. The patient should be

referred to discuss the options available to him for treatment of their prostate cancer at the specialist centre.

136 Q. I just want to put up on the screen DOH-00079, Dr. Hughes. The predominance of the recommendations in this case were around MDMs. That might give an indicator of your suspicion that it possibly wasn't an MDM, whether or not you drilled down into the fine detail of this one, you make the point at recommendation 2 that the MDMs should be quorate, and you make the point that the Chair's responsibilities must include regular quality assurance activity, which is a broader point that runs across all of the cases, I think? 14:29 14:29

A. DR. HUGHES: Yes. Those are recommendations that apply across quite a lot of the reviews, if not all. The MDM quorate levels were at 0.or 5%, which was largely due to absence of Oncology. 14:29

137 Q. Moving away from the individual cases. I want to ask you about the issue of assurances that you were anxious to seek during your review process and apparently received. Could I bring up on the screen, please, WIT-84155. Just go down to (iii), please. The question at (iii) is: 14:30 14:31

"What was the purpose of speaking to these individuals?"

The individuals being the core members of the MDT,

meetings with management and those with managerial roles followed. You say the purpose, possibly one of several purposes, was to gain a detailed understanding of how cancer patient pathways were delivered.

14:31

"The meetings also sought assurance regarding how others delivered care within the Urology Service given the clinical deficits identified. This was critical to provide assurance regarding ongoing care quality. This would be a requirement of any SAI Review. Discussions with Managers and Clinicians with managerial responsibility focused on governance of care and governance of those who provided care. Lastly, the meetings were to discuss how the care experienced by the patients under review varied from best practice.", et cetera.

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I want to go back to this issue of assurance. You said it's important to ask for and to receive it. How was the assurance given to you?

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A. DR. HUGHES: This was during the process of SAI when we'd learned the initial themes. The themes were failure to refer on to specialist care, failure to have a Clinical Nurse Specialist supporting patients, off guidance use of medication, and failure to bring cases back to MDT and re-discuss patients. I would call this early learning, early action, and we had to provide assurance to the Southern Trust that the services they currently provided were fit for purpose and did meet

14:32

the expectations. We asked about did everybody use a Clinical Nurse Specialist? Did everybody adhere to MDT guidance? Did people re-refer patients back to MDM as the disease progressed? Did everybody adhere to regional guidance around prescriptions? On a professional level we got verbal assurance around that, but that's not an assurance that would stand up to families or public, so the assurance required was written into the action plan, so the action plan really detailed the expectations of a functioning MDT. It then detailed how they would provide assurance to the public and to the rest of the healthcare community. It gives them dates by when they would do that. This was what I would call an immediacy that was required to seek assurances around the Services. At that stage we needed to know was it endemic? Did everybody use Clinical Nurse Specialists? Was the prescribing problem beyond a single individual? We got assurances based on proof as the professionals gave that commitment, but we had to follow that up with a robust action plan that would give detailed audited assurance. 14:33 14:33 14:34 14:34

138 Q. Yes. I asked the question, and let me pose it in this way. Yesterday we saw the 2017 Peer Review document, signed off by Mr. Glackin. It assured the Peer Review that they, that is the MDT, followed the regional guidelines. That must mean the MDT, for example, follows the regional guidelines as regards prescribing. Secondly, we could see in that assurance document, if I can call it that, Mr. Glackin telling the Peer Review 14:35

people that all first diagnosed cancer patients within Urology receive the services of a Cancer Nurse Specialist. Against that background, you had discovered those assurances to the Peer Review, for whatever reason, didn't stand up. Is it fair to say that you weren't able to check? It wasn't your job to check the assurances that you were being given by these professionals? 14:36

A. DR. HUGHES: Yeah. I think it was my job to point out what you have just pointed out, and I think it was my job to say this is what you said to an external accrediting body and this is what we have found; are you aware of a deficit and your responsibility for that? Everybody I talked to I referenced the Peer Review document, because sometimes, you know, people have a slightly optimistic view or over-optimistic view of how functioning their service is, but these are clear and different deficits. This is saying everybody got something, when clearly everybody didn't, and everybody was adhering to guidance. The underlying end point of that discussion was that these things were being said without data, without audit, without proper assurance, and then that fed into the action plan, which was very prescriptive and people probably found it a bit difficult. It was explained to them that to provide the public, patients and other professionals with assurances about the Service they would have to do this. Part of the deficit was they have already said one thing and that was not proven to be true. 14:36 14:37 14:37

139 Q. Yes. Just so that I can fully understand it, you recognised, I suppose, the deficits of the assurances that had been given to the Peer Review?

A. DR. HUGHES: Yes.

140 Q. You needed to obtain some assurance from the professionals that they worked in accordance with what the Peer Review had been told? 14:37

A. DR. HUGHES: Yeah.

141 Q. You weren't able to test that assurance, but what you did was write in to your recommendations and action plan a series of methodologies or mechanisms by which those assurances could be tested going forward? 14:38

A. DR. HUGHES: Yeah. The discussions probably would have happened around December/January, and the final report and action plan probably would have been available in April, but they would have been shared a draft to know their expectations. Some of the issues around the action plan and dates were people saying oh, we can't do that, we don't have the resources, they are unreasonable timelines, but I had to push back on that. 14:38

142 Q. I want to move on for the rest of this afternoon to look at some of the key findings that emerged from your series of reviews and ultimately integrated into an overarching report, and just to focus on those. 14:39

Can I turn, first of all, to your witness statement at WIT-84166. Just scroll up so we can see 15. What the Inquiry asked you was to outline in broad terms the key themes, trends, findings or conclusions which the

Review Team reached across the nine reviews. Let me just set them out because they follow down in your statement. The first thing you say is professional delivering care without a multidisciplinary input was a finding. A failure of onward referral to Oncology or palliative care was a key finding. You've said that prolonged treatment pathways was a key thing. Care varying from regional/national best practice; and separately, departures from MDT recommendations; a failure to action the results; the Bicalutamide issue; no input from the CNS; quorum; and an absence of assurance, audits or a coherent escalation in governance structures. 14:40 14:40

I want to work through those with you between the rest of this afternoon and the next occasion. Looking at what you have said here as a kind of high level introduction to some of these issues, you have said: 14:41

"International best practice indicates that cancer care is best delivered on an agreed evidence base by teams of professionals with differing but complementary skill sets. This should ensure patients are partners in care, informed about their care and supported throughout their journey - including the palliative phase of disease. Cancer care in Northern Ireland has been resourced to a considerable degree to achieve these outcomes. Each cancer type has a regional group which includes patients, to determine best treatment 14:41 14:42

pathways for each aspect of care - this is founded on research and international, national, and regional guidelines. The guidelines explain best care and how it should be delivered. Adherence to such guidelines is delivered at Trusts / Hospital levels through patient discussion at the multidisciplinary team meeting."

That is the context, I think, you are saying within which the Southern Trust Urology Multidisciplinary Team was expected to work. The knowledge, based on international research and experience, should have been well known? 14:42

A. DR. HUGHES: Yes, yes.

143 Q. The system was funded? 14:43

A. DR. HUGHES: It was funded and it obviously could be better, but when I was Medical Director everybody complained that cancer got most of the money, so it was funded.

144 Q. In essence, this multidisciplinary team, supported by the Cancer Service Management, should have known how to do it, and do it well? 14:43

A. DR. HUGHES: Yes.

145 Q. You go on at 84174, a few pages further on, at the last bullet point, you say: 14:44

"Much of the SAI Reviews are framed in terms of what care and support patients did or did not receive. Patients with urological cancers often fall within the

older age group and may be more often be passive recipients of decisions and advice."

Sorry, I think -- I was at the right place. The piece I want to focus, on, Dr. Hughes was: 14:44

"Individual decisions of a single professional took precedence over patients' rights to best care based on evidence and best supported care." 14:45

You've set out the context, and this is one of your key findings?

A. DR. HUGHES: Yes.

146 Q. That one professional didn't work within a multidisciplinary environment, or didn't comply with 14:45 the working principles of that multidisciplinary team?

A. DR. HUGHES: Yes.

147 Q. But the bigger focus, I think, at least so far as the Inquiry is concerned, is how and why that was allowed to happen in governance terms? 14:45

A. DR. HUGHES: Yes. To be fair, that's what the families reflected back to me after meetings 2 and 3, that it's not what happened, it's why and how.

148 Q. I suppose, in a nutshell, the answer to that question across a number of themes is that this could have been 14:46 prevented with appropriate tracking and audit, and quality assurance?

A. DR. HUGHES: And culture. I think it's important to say, an SAI is not the way to pick up deficits in

a service because, by definition, something bad has happened. The patients have suffered or potentially suffered a deficit. The culture should be that you can raise any concern at any time, preferably when it's a minor concern, and the MDT is ready and willing and in acceptance of that approach. If you leave things to dwell, they may become too difficult to deal with, and with poor consequences. I think culture needs to be called out as well.

149 Q. The first of the main themes then is professional delivering without multidisciplinary input. If we go to 84167, please, WIT-84167. There you set out the key guideline that we are by now familiar with, and that's the benchmark that you use to assess the patient experience. You found that the use of a CNS was common for all other Urologists? 14:47 14:47

A. DR HUGHES: Yes.

150 Q. Were you entirely satisfied about that, even in the absence of audit or assurance documents?

A. DR. HUGHES: I cannot say that I had complete certainty, but the reason we put in the strict assurance processes within the recommendations and action plan was to address that. As part of early learning and early action, I had discussions with the Medical Director about the deficits, and the team were informed by their line managers and their professional officers what was expected, so I think that helped as well. 14:48 14:48

151 Q. Just to be clear, your finding, as set out in the

overarching SAI -- I needn't bring it up on the screen, but it's DOH-00128 -- your finding was that all nine of the patients that you were looking at were deprived of access to a CNS and, as a result, used what you describe as uni-professional care, despite the availability of a multidisciplinary resource?

A. DR. HUGHES: Yes. Most of a cancer patient's journey is actually in the community, and that's where they often need resource and support. You really do need that link between secondary care and primary care, and that's provided by the Clinical Nurse Specialist who can address these issues, and none of the nine patients had a Clinical Nurse Specialist. 14:49

152 Q. Was it of any interest to you to establish not so much how that's happened, I think that was your primary, but why it happened? Why, in the sense of, why had the clinician taken this route? 14:49

A. DR. HUGHES: Yeah, and that formed some of the questions that we sent to Mr. O'Brien. I should say part of me didn't not care, it was a standard of care. It was a standard of best cancer care recognised everywhere, and I don't think there would be a logical reason to give to say that nurses should not be there to provide their skills and support. While it may be a useful discussion to have, I'm not sure if I could actually internalise any reason to exclude nurses from care. 14:50 14:50

153 Q. We know, Mr. Gilbert, that the MDT operating policy, that I referred to yesterday, puts an onus, one might

say, on the Clinical Lead in the MDT, on the core nurse member, to ensure that an allocation has been made. It's Mr. O'Brien's earnest belief that that's how it should have been done. Let's follow that along. If that's how it should be done and you are the Clinician treating the patient realising that it hasn't been done, that your patient is without a Nurse Specialist at his or her side; is that something, (a) that you would realise or you would see it, would it be visible to you, and if so, is it something you would be inquiring about? 14:51 14:51

A. MR. GILBERT: Yes, it would be visible, mainly because you'd simply ask who the Nurse Specialist was whenever you saw the patient so he or she could be copied into the correspondence that might be generated. 14:52

154 Q. It's something you would make an inquiry about?

A. MR. GILBERT: Yes. If there was clearly no Cancer Nurse Specialist allocated, then I would either directly approach or e-mail the Cancer Nurse Specialist team and say, come on, whose patient is this, or please can you allocate somebody? That would probably be followed up with a conversation. It's a slightly uncomfortable position for me to describe because if you're working within a functional MDT it all just happens. There's no question of the Lead having to do things, it's the question of the nursing team present at the MDT putting up their hands or talking amongst themselves saying oh, that chap lives in this particular geographical area, he is one of yours, can you get in touch? I really 14:52 14:52

need to impress on you the collegiate, collaborative nature of well functioning MDTs, and it is that function that benefits patients. If somebody has fallen through the net and they haven't got them, then it's clear they haven't got a Cancer Nurse Specialist and it would be incumbent upon the clinician, whether that's a Consultant or a Registrar, to make sure that they were teamed up, for whatever reason. 14:53

155 Q. Does the specialist nurse add value to your work? Or to put it a slightly different way, does it assist the Clinician's work in that complementary sense that you have described? 14:53

A. MR. GILBERT: I will turn your question on its head, I would ask whether my work contributes anything to the Cancer Nurse Specialist's work. My job has become increasingly technical, in the sense of I go through a diagnostic process, which is well described, well-documented, well-evidenced, and, to a certain extent, I may have less involvement with the patient. The person who is looking after the person, the patient, is the Cancer Nurse Specialist; she knows, he knows, about the everyday worries and concerns of somebody living with cancer, and that used to be, to a degree, a clinician's role, but in the way in which our responsibilities have shifted, doctors have become much more technical in their approach and it's the Cancer Nurse Specialist. If I had cancer and you asked me would I rather have a Consultant or a Nurse Specialist, dead easy, Cancer Nurse Specialist, because 14:54 14:54 14:54

they are going to address your whole life.

156 Q. Another aspect of the role I just want to touch on one example because I think we have been over the ground here quite a bit, but just one example of a patient that you have made a recommendation in respect of. 14:55
It's, by way of example only, Patient 5 or C. We can find this at WIT-00041. It should have been DOH. Thank you. If we scroll down to the recommendations, and what you say here, recommendation 1 is that:

14:57

"All patients receiving in the Trust Urology Cancer Services should be appropriately supported and informed about their cancer care. This should meet the standards set out in the regional national and national guidance and meet the expectation of cancer Peer 14:57
Review. This must be supported by a Urology Cancer Nurse Specialist at an early point in their surveillance journey."

Is the early point usually after the diagnosis has been 14:57
made and the MDM's recommendations are known?

A. DR. HUGHES: This was a renal cell tumour, a kidney cancer. It's slightly different. The first offer of a Urology Cancer Nurse Specialist came after tissue diagnosis, whereas somebody who was undergoing 14:58
surveillance with a radiologically known or potential cancer and was being reviewed on a regular basis, and most of them found that very concerning, and really quite unsupported, so the recommendation was to have

a Clinical Nurse Specialist at the early part of their stage, which would have helped regularise the rather sporadic way the patient was being reviewed, and it would have supported people because, in essence, they are living with a 90% knowledge or certainty of cancer, and that issue was the point in that case.

157 Q. Just going back to the findings in this case. If we can go back to page 41 in this series DOH-00041. At the middle of the page what you say is: 14:58 14:59

"The patient was not referred to a cancer nurse nor any contact details given."

You set out the recommendations of Peer Review and make the point in the next bullet point: 14:59

"The Review Team are of the opinion that a specialist nurse would also have been a fail-safe for identifying the delayed scan report and bringing it to the MDM sooner." 14:59

That was the case where there had been a CT scan ordered and it sat un-actioned for some time, leading to delay in the care pathway. To what extent, Dr. Hughes, or Mr. Gilbert, would a Nurse Specialist be of practical assistance in that kind of scenario? 15:00 Would he or she be expected to know, for example, that the scan had been ordered and be alive to the need to follow up, or does it work in a different way?

A. MR. GILBERT: It depends on the way in which the Cancer Nurse Specialists operate within a particular Trust, but the short answer to your question is yes, because of that continuity of care they would be aware of the follow-up appointments, and they would be aware of 15:00
somebody falling through, or they would be a point of access for somebody who said, I haven't heard about my CT scan. This case was managed perfectly well in an exemplary fashion by Mr. O'Brien, period. The follow-up CT scan discovered a coincidental problem. 15:01
It just happens that it was a coincidental cancer within the same subspeciality but remember we are dealing with five different cancers, none of which are connected biologically, they are separate diseases. The only criticism here that can be levelled is that 15:01
that result wasn't picked up. The source of who should have picked it up is for other people to deliberate on. I would suggest there should have been some sort of alerting system so if a Radiologist saw a result that was unusual, and this was what the CT scan was looking 15:01
for was chest deposits, which is the common case for metastases after kidney cancer but coincidentally another finding which happened to be related to prostate cancer, and there should have been a mechanism in place to allow direct contact between a Radiologist 15:02
and the Clinician in question. That system, if not in place, would have been helped, but who is to say why the result didn't come through? That would have been helped had there been a Cancer Nurse Specialist in

place. I'm not saying that it would be an absolute safety net but it would certainly be a great assistance.

158 Q. Yes. The next broad theme that you depict in your statement, Dr. Hughes, is let's move to WIT-84167. This is a failure of onward referral of patients to oncological or palliative care. You identify seven patients who had this problem or this obstacle in their care pathway. It wasn't only a problem of Mr. O'Brien, as you point out in your overarching report. There was one case out of the seven, where the problem of referral was a decision of the multidisciplinary team itself. I think that was the case of Patient 3 or Patient H, which was a penile cancer case; is that right? 15:02 15:03 15:04

A. DR. HUGHES: Yes, that's correct.

159 Q. If we look at that one, if we go to some of the findings in the report, DOH-00095. Just before we look at it; in context, where a regional Cancer Centre, such as the Southern Trust, has a case of penile cancer coming through its doors, what are you saying within the report was the appropriate response? 15:04

A. DR. HUGHES: Penile cancer is very rare. Northern Ireland would have about 20 cases a year. So there's very limited experience. Penile cancer is arranged in supra-regional groupings Northern Ireland links with the Christie in Manchester. This work is not normally done in a district general hospital. It's normally referred to a large centre or supra-regional centre 15:05

where there is high volume care and better outcomes. It's a basic standard of practising within your field of competence and suggesting it should have been referred on. The local MDT didn't seem to make that connection until very late in the pathway.

160 Q. Yes. We can see, I think, if we go to the conclusions on the next page, please, this patient ultimately succumbed to his illness; isn't that right?

A. DR. HUGHES: Yes, indeed.

161 Q. You say: 15:06

"Although there was a five-week delay in initial referral and appointment, the management of the case was appropriate up to the MDM on 18th April. At this point the MDM should have recommended an urgent CT scan and simultaneous referral on to the regional centre specialist group", which you say is in Manchester for Northern Ireland cases? 15:06

A. DR. HUGHES: Yes.

162 Q. "For all subsequent management. Penile cancer is an unpredictable disease. In this case appropriate management could have provided a 90% five year survival. The patient wasn't offered this opportunity." 15:07

15:07

Were you able to establish why, because as I think we looked at yesterday, the 2016 NICaN document provide chapter and verse, in its penile cancer section, of the need to avoid local treatment beyond the initial

management and make the referral. Were you able to establish what had gone wrong here?

A. DR. HUGHES: Yes. Commissioning of a service in Northern Ireland would have been appropriate but they did need to have a regional link that linked to Manchester and that seemed to take at least three years. They eventually set up a Northern Ireland hub of the Christie system in the Western Trust. 15:07

163 Q. In Altnagelvin?

A. DR. HUGHES: Yes. So that said, I think Mr. Gilbert will say from 2008 professionals would have been self-selecting to send their cases on to a regional centre. 15:08

A. MR. GILBERT: Yes. Certainly my personal experience, and those of my peers, would have been at the instigation of supra-regional networks which initially covered four million population. For the southwest of England, Bristol is the centre and it covers Gloucestershire out to Wiltshire and right down to Cornwall, so a very large geographical area. Certainly we would refer all suspected penile cancer cases for, initially advice. That was the first function for the MDT. They would write back and say, go on and do a circumcision, because sometimes that's all you need to do, or they will write back and say no, we need to see this patient, we will take over management. As time has gone by, that relationship has become less fluid and the referrals are much, much stricter, and that has been probably the case for at least the last 15:08 15:08 15:09

ten years, if not longer. There's no room for somebody to try their hand at a rare operation.

164 Q. As I have said, there's seven examples of inappropriate behaviour in association with onward referral. We touched on one this morning, the failure to refer Patient 1, Patient A, until June 2020, some eight months after the MDM had made its recommendation. We will touch in some detail as we go on, on the overarching recommendations but in governance terms can you give us a taster on how you saw this as being preventible? What precisely are the mechanisms of governance that need to be embedded in order to pick up on this kind of shortcoming? 15:10 15:10

A. DR. HUGHES: Past experience that we would have. People have called it enhanced tracking, but it's just what I would call normal tracking. The tracking team would actually check that a referral has been done and sent and received, and that was designed to, you know, pick up misses or forgetfulness. It's not initially designed as a governance pathway to check that the right thing has been done. It's to check that somebody hasn't forgotten to do something and that things have happened in a timely fashion. In fact, if the tracking team is empowered they would often have a very good relationship with the receivers, or if it's particular scans, they will be able to schedule them and they are invaluable to good functioning cancer care. The positive added value to that is you have immediate feedback when things aren't being done and when things 15:11 15:11 15:11

are being done differently. But the initial reasoning for having that tracking system is to ensure everybody gets the best care delivered along the agreed lines and at the best time.

165 Q. You make it sound as if it's commonplace and not rocket science. 15:12

A. DR. HUGHES: It's commonplace where I work. As well as having a function in MDT, the clinical community would have been very respectful of the tracking team, because very often the tracking team are, have you done this, have you done that, and are pestering Radiology to get scans done. They were the engine that drove the system forward. You do need that mutual respect for all professionals delivering cancer care, because this is very much the engine in the background, the unrecognised team. I regard it as normal practice and I found this quite strange because, in essence, it was very focused on the 31 and 62-day targets. 15:12 15:13

166 Q. Yes. Mr. Gilbert, you go to an MDM in north Bristol and you have four or five of your patients being discussed and you leave the meeting that late afternoon with five recommendations for, let's stick with prostate cancer, ADT and onward referral for oncological opinion, but you forget to do two of those, or it's been a busy week and two aren't referred. How does the tracker practically, on the ground, spot that? Is it an electronic system or do they rap your door every couple of days? 15:13 15:13

A. MR. GILBERT: Each patient has a formal e-mail pro forma

sent to me and, in that, the outcome of the MDT is described and the actions required and the response from the person responsible for those actions will be given as well. For example, if a patient has a recent diagnosis of prostate cancer and they need to have the 15:14
options treated, it will say at the bottom, I don't need to do anything because the patient is going to see a Cancer Nurse Specialist in three days' time. Or it might say, this patient has no cancer on their biopsy, and then it becomes my responsibility to arrange some 15:14
form of follow-up to inform them of that, although the MDT will also generate a standard letter to let them know. I think that's a little bit formulaic. They need somebody to speak to so I will arrange to speak to them during the course of the following week to say the 15:14
biopsies are fine, and this is what we are going to do as future management. It's all done by people, it's always very easy to disguise these tracking things behind electronics, but ultimately the people who are running this are the coordinators we call them, 15:15
coordinators because they are responsible for guiding the patients into the MDT process, watching them go through it, coming out the other end and making sure that there's good communication with the patients, and each stage is confirmed to have happened. For example, 15:15
if I forget to request an MRI scan during the course of a busy clinic, they will be on to me the following day and saying you haven't requested this, get on with it. It's incredibly reassuring.

167 Q. Yes.
A. MR GILBERT: Incredibly reassuring.
168 Q. Yes. Dr. Hughes, is it your sense that this is a wider Northern Ireland Trust problem, or is it your experience that THE Southern Trust was an outlier when it comes to this kind of apparently straightforward tracking arrangement, or do you not know? 15:16
A. DR. HUGHES: Perhaps my assumption was that this is how everybody worked. The only one I would have detailed knowledge of now is the Southern Trust because of this case. That doesn't reflect my normal, but I couldn't comment on the other three Trusts because I generally have not had an opportunity to look at them. 15:16
169 Q. Yes. Your experience was of the Western Trust, I think did you say in an earlier answer in my place we tracked, no? 15:16
A. DR. HUGHES: Yeah, I was employed in the Western Trust.
170 Q. Yes. When you gave that answer, do they track for this kind of thing when you were in the Western Trust?
A. DR. HUGHES: Yes. Part of the process, as Mr. Gilbert says, it's about empowering the coordinators to do that, and when they are doing their job they are respected for doing their job. People are grateful to be reminded because ultimately Clinicians are incredibly busy and it's not unknown for things to be forgotten or misplaced, and you have this supporting infrastructure, which is not available in many or clinical specialties, making sure the right thing is done within the right short time frames. 15:17 15:17

171 Q. I don't want to get into healthcare funding this afternoon, but in commissioning terms and resources terms, if you are commissioned, and thereby funded to provide a cancer service or urological cancer service within your Trust, and given that resources has been identified by some of these managers and practitioners as being an issue around some of these shortcomings, is it a resources issue in that sense? 15:17

A. DR. HUGHES: Yes.

172 Q. When you as a Trust are commissioned, should you only accept the commission if you are funded for the process of providing it safely? 15:18

A. DR. HUGHES: Yeah. I think it's how we explain the role of these professionals. Classically, they are banded within the clerical administration group, but the role is about getting patient care done in a timely fashion and about keeping patients safe. I think if you explain that role the commissioners would be more responsive. I think if it's imagined there is some sort of administration, I think that really undersells and doesn't really describe their role. They are really essential to good patient care. Are the Commissioners is always responsive to that? Possibly not due the other pressures of direct clinical care. 15:18 15:19

173 Q. In practical terms I think you are accepting of the view that if you are going to provide prostate cancer care to a patient, it should be part of the care package -- 15:19

A. DR. HUGHES: Yes.

174 Q. -- to, as much as putting an injection in the man's arm, it's also part of the care package to ensure that when he needs the referral to Oncology, you are to refer is known, that's part of the care, and yet, part of the explanation given to you is oh, we are not funded to do that, that's why we didn't do it? 15:20

A. DR. HUGHES: Yes. That was rehearsed repeatedly. Part of it may be that their understanding, back to yesterday morning when we discussed the responsibilities of people with leadership, that their role is to sort of promote their services in the Trusts and lobby for additional resources, albeit from within Trust funds. These organisations are billion pound organisations, you are looking for relatively small sums of money to keep patients safe, and I think a leadership role is also about ensuring that your service is appropriately resourced, and clinicians have lots of power to do that. 15:20 15:20

175 Q. Just in conducting this conversation, you are really at a relatively high level, but did you reflect on whether it really and truly was a resources issue or whether, in fact, more particularly, it could have been an insight, understanding, cultural issue, because there was a coordinator for this MDT? 15:21

A. DR. HUGHES: Mm-hmm. 15:21

176 Q. Mr. Gilbert explains that it's the coordinator's role to do the follow-up, the tracking, it's a human interaction and it's done, you know, rapping the door, telephoning, chasing them up, so it should fall within

that kind of job description, no doubt the coordinator in the Southern Trust was a busy person. Part of what was reflected to you, particularly from the cancer management people that we will see in a moment, seemed to portray a lack of understanding that these things were important? 15:22

A. DR. HUGHES: I think that is fair to say. I think the mechanisms of how things worked weren't completely clear to them. I think the statement about we are not funded to do that was somewhat defensive, because it explains how the systems were at the time. I am not sure if they had explored, could it have been done better. I should say Urology MDT is an incredibly busy service and it certainly needs more than one person to deliver on that, not least for continuity but just the sheer volume of cases. 15:22

A. MR. GILBERT: I think it would be worth remembering at this juncture one of the comments made by the oncologists in their conversation, which was that actually two of the Consultant Urologists interacted extremely well, so somehow the resources were working for some of the people within the Trust. A lot of the times clinicians, we find that we have to fill in gaps for roles that we would like other people to have alongside, like the coordinator, like tracking results and so on and so forth. Clearly in Southern Trust, irrespective of whether they were in full complement or not, at least two of the clinicians responsible for cancer seemed, on the basis of the reports of the 15:23 15:23

oncologists, that they were performing well.

177 Q. Thank you. Let's move on to the third of the themes picked up in your witness statement, Dr. Hughes. Prolonged treatment pathways, if you go to WIT-84167. You say, Dr. Hughes: 15:24

"5 of the 9 patients in this review experienced significant delay in diagnosis of their cancer -- We looked at one this morning -- "this was related to patients with prostate cancer and reflected variable 15:24 adherence to regionally agreed diagnostic pathways". Service User B was the case we looked at this morning.

Again, were you able to establish why that was a feature of this MDT and this one practitioner? 15:25

A. DR. HUGHES: Yes. Service User B is the case we looked at this morning where there was a clinical diagnosis of prostate cancer T3/T4 based on digital examination, yet the thought processes then went down the pathway of TURP and a range of additional things. Clearly, if 15:25 that was your first clinical impression from the first appointment you should click into the well-defined diagnostic pathways for prostate cancer. I don't believe the working patterns were systematized and focused the way normal cancer diagnostic pathways are. 15:26 It is a bit industrialised, and it is high volume, but to do things in very tight timelines is best practice is that you adhere to the regional and national guidelines, and I think there was regular variance from

that and, in a more disjointed way.

178 Q. Again, is this a matter of adequately tracking or, I suppose, with the patient we looked at this morning, the tracking wouldn't have kicked in to post diagnosis?

A. DR. HUGHES: The tracking wouldn't have kicked into diagnosis, although, that being said, 60% of patients come in through the red flag referral route, give or take. There would be a range of people coming through that pathway for their diagnostic process, and that should be managed. It may not be the tracker but it should be managed in another way. In the Southern system for prostate cancer the Trust biopsy service is actually provided by the Clinical Nurse Specialist, so there is a systemised process way of doing that. 15:26 15:27

179 Q. One of the cases that you identify as having a prolonged pathway is Patient 4 or Patient D. If you go to the conclusions in that report at DOH-000107. This was a patient that presented with urinary retention, a little like Patient B we saw this morning. Again, you say the initial assessment should have included a DRE. 15:27 15:28

"The TURP was expedited by a significant development of haematuria rather than as a result of clinical judgment. The histology was an indicator of prognosis disease and urgent staging, including a CT chest, abdomen and pelvis, together with a bone scan, should have been reported within four weeks. The investigations from those investigations should have 15:28

been presented at MDM whose recommendations should have included, even if not present, an urgent referral onwards to the oncology service for expert consideration."

15:29

You go on to say over the page:

"Through inadequate treatment this gentleman's poorly differentiated prostate cancer is allowed to progress and cause him severe and unnecessary distress. There's a chance that despite this, the clinical course might not have been any different but he should have been given every opportunity to consider proper and adequate treatment options."

15:29

15:29

Mr. Gilbert, this, as we will see across a collection of five out of the nine cases, delayed or prolonged the diagnostic pathway. In the context of prostate cancer, urgent intervention is sometimes, perhaps mostly important?

15:29

A. MR. GILBERT: Prostate cancer is a wide spectrum of disease from very indolent disease that doesn't need to be treated and just needs to be observed, through to extremely aggressive disease which defies treatment. This was an elderly gentleman, as I recall. He's presenting with the, if you remember I described the Gleason scale running from 6, which is relatively inert or indolent disease, through to Gleason 10. This is Gleason 10, which is very poorly differentiated, very

15:30

aggressive, was not producing much PSA, which is the blood test for the discussion, that prostate cancer produces, but this is so bizarre tissue, so distant from prostate disease that it's not even producing the normal chemicals that the prostate produces. It's undergone very, very severe transformation into cancer, and it's likely that any treatment option might have been difficult, or might not have had any difference on the pathway, the prognosis, and the outcome. However, it would have been appropriate to consider giving hormone therapy. It may not have worked under these circumstances, but it could have been tried. In fact, this might be the sort of case in which you might consider 150 milligrams of Bicalutamide as the preferred treatment. It's an elderly man whom you don't want to generate too many side effects, but that's another point for discussion. It could have been tried. Equally, the disease itself could, in part, at least, be controlled with either palliative radiotherapy, that is radiotherapy designed to hold the disease in check, as opposed to radical radiotherapy which would be intended to cure. I don't think that would have been an appropriate option for this man. But certainly the consideration of other modalities, hormones, maybe palliative radiotherapy, should have been considered. The sooner it's done the better, for two reasons. One, biologically, and, secondly, because the patient feels something has been done.

15:30 15:31 15:31 15:31 15:32

A. DR. HUGHES: I think this gentleman should have also

been referred to the palliative care team because he was presenting with an aggressive disease. He was elderly and he would have a time limited disease, so a plan would be in place and coordinated. Unfortunately that wasn't and the family had to keep going back, I think through a Consultant's secretary, to try and get access to the appropriate services.

180 Q. Yes. Certainly in your findings in this one, at DOH-00107, we see that point being made. He wasn't even given so much as a phone number. You say: 15:32 15:33

"Absence of the Cancer Nurse Specialist resulted in uncoordinated care and difficulty accessing this support in the community".

15:33

Just take a look at the key lessons in that case. Yes, thank you. What you found was that the effective management of urological cancer requires a cooperative multidisciplinary team working collectively and interdependently. 15:34

"A single member of the team should not choose to be expected to manage all the clinical supportive and administrative steps of a patient's care."

15:34

Just on that, what is the dynamic within the MDT that should pick up on the fact that a Consultant is taking it all on himself for whatever reason? Is there something that should --

A. DR. HUGHES: Normal course of action, when a patient's disease progresses, their case is brought back to the MDT for discussion because the MDT will have palliative Nurse Specialists and palliative physicians, and that's the focus for discussion. I think there should have been an awareness that cases weren't being brought back to palliative care team. Palliative care teams usually audit their ongoing work, and it would be unusual that the single professional wasn't having that cohort of patients coming back to the MDT. The MDT needs to be functioning to provide all care needs, just not simply new diagnosis and 62 day targets. It needs to be there to consider and determine the care needs of those whose disease is progressing. 15:34 15:35

181 Q. You again refer in the findings, the lessons learned -- sorry, I should say, the importance of the key worker and a Nurse Specialist, that the clinical record should include the reasons for any delay in management. The record didn't make any mention of the reasons. Prompt communication with the general practitioner following interaction with the patient; why is that important? 15:35 15:35

A. DR. HUGHES: Patients spend most of their time in the community and somebody who is in a care role will need community care, coordinated care, and the GP will be providing oversight for that care. The GP needs to be closely embedded in the discussions and understanding of the discussions as to opposed to maybe a family member having to go up and explain it secondhand to a GP that that's not coordinated care or appropriate 15:36

care.

182 Q. Is another feature of the importance of communicating well with the GP so that the GP can pick up any unexplained delay and advocate for the patient, because we have seen cases, for example, earlier in the evidence where the fact that a scan had been performed was reported to the GP, the fact that the scan hadn't been actioned became obvious to the GP eventually, and then he was able to red flag the patient into the system. Is that knowledge of what's going on on the part of the GP important from that perspective? 15:36 15:37

A. DR. HUGHES: I think it would be inappropriate to expect GPs to be a safety net for missed examinations. The reason GPs are copied into all the work was that these are their patients and they will have possibly lots, multiple comorbidities and other issues, but the GP will be involved in the care, and the GP wider team, and we have lots of multidisciplinary teams in GP practices now, will be part of that. This rather complex sort of inter disciplinary team which involves secondary care and primary care, and that's usually managed by palliative care nurses or Clinical Nurse Specialists. It's about providing what a patient needs in their home and community, as well as in secondary care. 15:37 15:37 15:38

183 Q. Mr. Gilbert, in the England or where you work, is there a feature of the system which involves writing to the patient, him or herself, following each important stage in the pathway, or does that not exist?

A. MR. GILBERT: Every letter I write is copied to the patient. I still, because I am a little old-fashioned, write to the GP and copy the patient, but a lot of my colleagues will write to the patient and copy the GP. So, yes, every interaction is covered with correspondence to the patient.

184 Q. That's not generally a feature of practice here, is it, Dr. Hughes?

A. DR. HUGHES: Yes, it is.

185 Q. It is? 15:39

A. DR. HUGHES: Yes. That has been. Patients get a copy of the right patient letter and that should happen. That has been evolving for the past decade. The first cohort to do this was cancer care but it's quite common practice in a range of other care, and it's about 15:39 having patients as partners in care.

186 Q. We don't always see that as a feature of care in these cases?

A. DR. HUGHES: It should be in cancer care.

187 Q. Maybe we will look at that. It's certainly not 15:39 a deficit you picked up on?

A. DR. HUGHES: No, no.

188 Q. Going down the page to WIT-84168. Here we pick up, Dr. Hughes, on another theme you extract from the nine, ten reports, and that's care varying from regional and 15:40 national best, and you found that in eight of the nine cases. Do you recall what was the one case that was consistent with best practice? Can you recall?

A. DR. HUGHES: I think it's [name redacted], we are

working without notes here.

MR. WOLFE KC: Call that Patient 5.

CHAIR: We will pause. It's easily done.

A. DR. HUGHES: Can I apologise for that.

CHAIR: We will stop the recording, we have built in a delay so that we can just make sure that the name doesn't go in. 15:41

A. DR. HUGHES: Thanks very much for that. I am just very conscious that I shouldn't have done that.

CHAIR: As I say, it's easily done. We have built in a system to ensure that these things don't happen. So the IT will tell me when we are ready to resume again. We can return to that, but to make absolutely clear the name did not come on the live-stream. 15:41

MR. WOLFE KC: Yes. We were wondering which was the case. That sounds rather like an exam question. 15:42

A. DR. HUGHES: Patient 5, a gentleman with a kidney tumour, and the care was exemplary, but then had a late diagnosis of prostate.

189 Q. That is the case where the result from the CT scan was missed and delayed the process, but the recommendation emerging from the MDT was appropriate in that case? 15:43

A. DR. HUGHES: Yes.

190 Q. Whereas as you have said, eight out of the nine, when they were to be implemented didn't make the mark, and that's where you get to with the next theme. If we scroll down. Departures from MDT recommendations were eight out of the nine cases. 15:43

If we can go to your overarching report at DOH-00123. Here you have fully summarised -- it's a useful note for the Panel -- each of the derogations from the recommendations; is that right?

A. DR. HUGHES: Yes, yes. 15:44

191 Q. The most significant number were the prostate cases obviously?

A. DR. HUGHES: Yes.

192 Q. The derogations were primarily around the Bicalutamide and the failure of onward referral, either at all or in a timely fashion? 15:45

A. DR. HUGHES: Yes.

A. MR. GILBERT: Yes. Sorry.

193 Q. We obviously had the penile case and there was also a testicular case that notably failed to comply with the guidelines as well. Again, Dr. Hughes, all of these derogations, regardless of type or classification, should all of them be amenable to some kind of tracking mechanism to ensure compliance with the guidelines and to quality-assure the care process? 15:45 15:46

A. DR. HUGHES: Yes, the tracking mechanism is set up to ensure that actions are taken. It isn't really set up as a governance tool, as an oversight tool because there's a professional responsibility to refer back to the MDT if there's a change in plan, or if a plan does not happen, and there should be a governance tool around that. I think, as a by-product of a tracking procedure you would get that knowledge, but we have to say it's the professional's responsibility to reinform 15:46

his colleagues or the colleagues of the MDT that a plan has changed and the rationale for that plan and that you plan, and the MDT would have the opportunity to re-discuss, agree or disagree or seek a third opinion. But the process of treatment plan and an expectation for a patient and then something else happening and hearing about it is not governance.

194 Q. I think we discussed yesterday the proposition that a recommendation properly made by an MDM, in accordance with the guidelines, may not be implementable for a variety of reasons. Mr. O'Brien, helpfully in his Section 21 response, sets out some of that, just by way of an example, the patient won't buy into the recommendation or the patient's circumstances or clinical condition has changed. They are all perfectly acceptable reasons to depart from the recommendation or to pause the recommendation.

A. DR. HUGHES: Yes.

195 Q. But what -- sorry. Answer.

A. DR. HUGHES: My experience is if that happens, professionals always bring it back to the MDT for a couple of reasons, to inform the MDT there's an appropriate record of the patient's care and not the outstanding information, which would be on the cancer patient pathway system, so you have information. But the other way professionals bring it back is to ensure they have got governance and power and support for their diagnosis. We don't want to portray this as big procedure looking over your shoulder. This is your MDT

15:47 15:47 15:48 15:48 15:48

supporting you through your decisions, and if decisions change that could be for very good reasons but you need support and you need the MDT to agree to that.

196 Q. Let's just look at the testicular case, by way of a specific example. That was Patient 2 or Patient E on your list. 15:49

A. DR. HUGHES: Yes.

197 Q. If we go to DOH-00086. We can see that the MDT took place on 25th July 2019, second paragraph, with the recommendation that Mr. O'Brien would review the patient in Outpatients and refer him to the Regional Testicular Cancer Oncology Service. Scrolling down, this referral was not made until 25th September. Scrolling over the page, I think, if we just go to DOH-00088, Mr. Gilbert. Is the management of testicular cancer particularly time-critical? 15:49 15:50

A. MR. GILBERT: Yes. It's been clearly demonstrated that the shorter the period between diagnosis and treatment in any of its stages, the better the outcomes.

198 Q. We see in the recommendations, just scrolling down, some very specific recommendations. There should be an audit of all aspects of the MDT's primary function, which includes the timing of access to definitive treatment, and that a Chair should be appointed to oversee the quality assurance of this. Just to break that down for us, Dr. Hughes. What does the audit of the timings of access to definitive treatment mean? What would that look like? 15:50 15:51

A. DR. HUGHES: Classically, the timings have been divided

into 31 and 62 days, but that's based on ministerial targets, so you what need to do is audit all times and all outcomes. Where cases are particularly long, you run an exception report and you review each case and you pick up, at your business meeting, the causes for that. It might be bottlenecks at Radiology, it might be bottlenecks to PET scans or whatever, and you address those individual problems. So timeliness of service is often seen as a ministerial or a departmental return, but timeliness of service is a patient quality issue and, in this case, a Patient Safety issue. It's to make sure they have ownership of that and a responsibility for that, and those recommendations go into the overarching plan as part of the assurance process. 15:51 15:52 15:52

199 Q. The next recommendation is what we have just been talking about a moment or two ago:

"Any divergence from an MDT recommendation should be justified about further discussion and informed consent of the patient." 15:52

In this context, I want to ask you about observations that you made, Dr. Hughes, in the context of a particular patient. If I can go to PAT-001323. This was the meeting which took place between yourself and Patient 1's family back in November 2020. Just scroll down, please. Yes. You conceptualise the MDT here as a contract between the medical team and the patient, 15:53

and it's based on international best practice guidelines. You say:

"Individuals do not have the right to deviate from that." 15:54

Just on that, is that intended to suggest that the MDT and the patient are in a bargain with each other; the MDT makes a recommendation and the patient and treating Clinician must follow it? 15:55

A. DR. HUGHES: Yeah. I suppose the language isn't the best of language. It was an attempt to explain that we practice Cancer Services in a multidisciplinary way based on guidance and based on guidelines, and that the determination of the MDT is the recommendation that 15:55 should be offered to the patients, and that you cannot have unilateral deviation from that without re-discussing it with your MDT colleagues. That is best practice. It's best practice for patients. It's also best practice for professionals because then they 15:55 have the governance. It is not suggested that it is contracting as you would probably understand it, but it is an expectation from your employers that if these are the best -- if an MDT is the internationally agreed way of delivering best cancer care and it makes 15:56 a recommendation, that should be the recommendation offered to the patient. If you vary from that recommendation it should be described, noted and explained. I don't believe that can be explained

without the input of a Clinical Nurse Specialist who can -- in essence, you are going into a conversation that is quite difficult, where you say this has been recommended against international best practice and agreed by my colleagues, but we are offering you or I am going to offer you something different. That's an incredibly complex conversation and I don't believe that conversation could have happened in an appropriate way without being supported by a Clinical Nurse Specialist, so that other supporting mechanism to have that conversation wasn't present. I believe if there was an agreement to change the treatment plan, that should have gone back to the MDT. 15:56 15:56

200 Q. Yes. For the avoidance of doubt, across the nine cases you are not saying contractually, or otherwise, that Mr. O'Brien was obliged to deliver that outcome through the patient; what you are saying is that he ought to have advised the patient of the MDT recommendation and noted that, and if there was any dissent from that, whether from the patient or from Mr. O'Brien, perhaps because of the discovery of a fresh circumstance, that should also be noted -- 15:57 15:57

A. DR. HUGHES: Yes.

201 Q. -- and best practice would be that a fresh decision shouldn't be made unilaterally by Mr. O'Brien with the patient unless it's extremely urgent, I suppose, but generally speaking, it should go back to the following week's MDM for further discussion? 15:58

A. DR. HUGHES: Yes.

202 Q. I suppose -- sorry.
A. DR. HUGHES: If it was an extreme emergency and action had to be taken, the action should have been brought back so at least the MDT would know about it.
203 Q. Yes, yes. 15:58
A. MR. GILBERT: It's also possible to have emergency MDMs, which means essentially finding one of your colleagues, discussing the case, saying this is what I'm going to do, agreeing that will be brought to the next MDT, but the action will be pursued before the formal ratification. 15:59
MR WOLFE KC: I think, just in terms of my note this afternoon, I realise that we are facing into at least the best part of a day to finish off, maybe half a day from my perspective, but I know that the Panel has questions. Would this be a convenient point? 15:59
CHAIR: Yes, I think so. Thank you, Mr. Wolfe. Thank you both, gentlemen, for coming along and giving us so much of your time already. We are very grateful that you have indicated you are willing to come back and speaking to us again in January. We look forward to seeing you both again then, and in the meantime, I hope you have a happy Christmas. 15:59

I think tomorrow we have Mr. Haynes again, Mr. Wolfe; isn't that correct? 15:59
MR. WOLFE KC: Yes, starting with Mr. Haynes, to finish him tomorrow --
CHAIR: At 10:00.

MR. WOLFE KC: -- from the first day of his evidence. Tomorrow at 10:00.

CHAIR: Thank you.

THE INQUIRY WAS THEN ADJOURNED TO THURSDAY, 1ST DECEMBER 2022 AT 10AM