Urology Services Inquiry

Oral Hearing

Day 6 – Tuesday, 8th 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 TUESDAY, 8TH NOVEMBER 2022 AS FOLLOWS:

CHAIR: Good morning, ladies and gentlemen, and welcome to the first public hearing of the Urology Services Inquiry. At the outset I would like to introduce myself and my colleagues who are here today. My name is Christine Smith KC. I am a senior counsel at the Bar of Northern Ireland where I have been in independent practice as a barrister since 1985. I am experienced in Inquiry work and in March 2021 I was appointed by the Minister for Health to lead this Inquiry. 10:29 10:30

My principal function is to ensure that the Inquiry fulfills its Terms of Reference which are set out on our website. I'm also the person who makes all the decisions about how the Inquiry is run and will rule on all applications and requests made to the Inquiry. 10:30

To my right is Dr. Sonia Swart who is my co-panelist. Dr. Swart is a former consultant in clinical haematology. She practised in her field as a consultant for over 25 years before moving into medical leadership and management roles. She became Medical Director and then Chief Executive officer of Northampton General Hospital. She is eminently qualified to advise the Inquiry on the issues of governance with which it is primarily concerned. 10:30

To my left is Mr. Damian Hanbury, assessor to the Inquiry. Mr. Hanbury is a consultant urologist at the Lister Hospital in Hertfordshire. He has many years experience of working as a consultant in clinical urology. He is currently Honorary Visiting Senior Lecturer at the University of Hertfordshire and is a college assessor for the Royal College of Surgeons. Mr. Hanbury advises the Inquiry on the clinical aspects of the cases we are looking at so that the Inquiry can better understand the issues it is tasked with considering. 10:31 10:31

Neither Dr. Swart nor Mr. Hanbury has worked in Northern Ireland previously and they have no connection to any of the Core Participants. 10:31

Also present today are Martin Wolfe KC, counsel to the Inquiry, who will deliver his formal opening statement shortly outlining the issues that the Inquiry is tasked with considering and indicating some of what the initial evidence appears to show. 10:31

Laura McMahon, junior counsel to the Inquiry, is also present and both Mr. Wolfe and Ms. McMahon will be questioning the witnesses who come to speak to us. 10:32

Ann Donnelly, solicitor to the Inquiry, who together with Mr. Wolfe heads up the legal team comprising Shauna Benson and Eoin Murphy, our deputy Inquiry

solicitors, Dr. Leah Treanor, Mr. Andrew Beech, Ms. Niamh Horscroft and Ms. Lara Smyth, our junior barristers.

Fiona Marshall, the Inquiry Secretary, heads up the secretariat team of six, three of whom, led by her deputy, Mrs. Eileen Casey, are engaged full-time on information management for the Inquiry. 10:32

Inquiries are set up to investigate matters of concern to the public. They are set up to examine the evidence, establish the facts, find out if things went wrong, if so, why they did go wrong and what lessons can be learned so that mistakes are not repeated. This Inquiry is no different. It was set up by Minister for Health Mr. Swann to examine the matters of concern that were raised regarding the treatment of patients within the Southern Trust that resulted in patients being harmed. 10:32 10:33

You will hear the Terms of Reference set out in full later by Mr. Wolfe but to put things in very simple terms, it is the task of the Inquiry to find out what happened in relation to the care of patients within the Urology Department of the Southern Health and Social Care Trust; what were the systems that allowed that to happen? Did the systems in place to prevent it happening work? If not, why not? And to make recommendations to try to avoid it happening again. 10:33

One of my first tasks as Inquiry Chair was to designate the Core Participants to the Inquiry. In considering who ought to be a Core Participant, I took several things into account and although not bound by the Inquiry Rules 2006, I had regard to Rule 5 of those rules in arriving at my decision. I determined that each of the three Core Participants before the Inquiry played or may have played a direct and significant role in relation to the matters to which the Inquiry relates, has a significant interest in an important aspect of the matters to which the Inquiry relates, or may be subject to explicit or significant criticism during the Inquiry proceedings or in the report or in any interim report. 10:34 10:34

Accordingly, the three Core Participants before the Inquiry are the Southern Health and Social Care Trust, the Department of Health, and Mr. Aidan O'Brien. The legal representatives of each Core Participant are here today and I invite them now to publicly announce their appearances and if I could bring first of all with the representatives for the Trust. 10:35

NO AUDIO COMING THROUGH

10:35

CHAIR: Thank you, Mr. Lunny. The representative for Mr. O'Brien please?

NO AUDIO COMING THROUGH

CHAIR: Finally the Department of Health.

NO CLEAR AUDIO COMING THROUGH

CHAIR: Thank you, Mr. Reid. 10:36

From the start of our work, the Inquiry has been conscious of the fact that it was due to issues concerning the care of patients that the Minister for Health announced this Inquiry on 24th November 2020. 10:37 Patients and families, some of whom sadly lost their lives, are at the heart of the work of this Inquiry and the Inquiry acknowledges the pain and suffering that they have sustained. 10:37

From my appointment in March '21 it was my intention to commence to hear from witnesses as soon as we could and to hear first from patients and families. Term D of the Inquiry's Terms of Reference tasks the Inquiry with affording patients and families an opportunity to tell 10:37 us of their experiences and about the impact of those experiences on them.

I have, to date, personally written to 75 former Trust patients or their immediate family members inviting 10:37 them to engage with the Inquiry, and I and my panel member and assessor are very grateful to those individuals and/or their legal representatives who took time to fill in questionnaires and provide us with

material.

In June and September the Inquiry held private hearings to allow some patients and families to relate their experiences to us. The public was not permitted access 10:38
to those hearings but I arranged that suitably redacted transcripts of those hearings were published on the Inquiry's website. I'm very grateful to those who did come and speak to us and relate their own experiences or those of their loved ones. We found hearing 10:38
directly from them about their experiences both moving and extremely helpful, and I would again encourage anyone who wishes us to know about their experiences to contact us. The Inquiry will continue to hold private hearings in the course of its work until we conclude 10:39
our hearings.

Today, however, marks a start of a different stage of our work --

MR. WOLFE KC: Chairman, I have been just passed a note 10:39
to indicate that there is no sound online streaming. It was suggested to me that we wait until the end but I think it is important that your opening statement should be heard.

CHAIR: Very well. If I can just check with our 10:39
communications staff if that can be rectified quickly? We can just then pause for a moment until we -- and if you could give me an indication as to when it is operational please.

SHORT PAUSE IN THE PROCEEDINGS

CHAIR: Okay, ladies and gentlemen, I think we're going to have to take a short break. The sound is not working just yet and I've been asked by the media if I will recommence my opening remarks. So I'm afraid that you're going to have sit and listen to it all over again but in the meantime we'll take a short break. 10:42

THE HEARING ADJOURNED BRIEFLY AND RESUMED AS FOLLOWS: 10:56

CHAIR: Good morning, ladies and gentlemen. Welcome to the first public hearing of the Urology Services Inquiry and at the outset I would like to introduce myself and my colleagues who are here today. My name is Christine Smith. I am a senior counsel of the Bar of Northern Ireland where I have been in practice as a barrister since 1985. I am experienced in Inquiry work and in March 2021 I was appointed by the Minister for Health to lead this Inquiry. 11:35 11:35

My principal function is to ensure that the Inquiry fulfills its Terms Reference which are set out on our website. I am also the person who makes all decisions about how the Inquiry is run and will rule on all applications and requests made to the Inquiry. 11:36

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Neither Dr. Swart nor Mr. Hanbury has worked in Northern Ireland and they have no connection to any of the Core Participants. 11:37

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Ann Donnelly, solicitor to the Inquiry, who together with Mr. Wolfe, heads up the Inquiry's legal team comprising Shauna Benson and Eoin Murphy, our deputy Inquiry solicitors, Dr. Leah Treanor, Mr. Andrew Beech, Ms. Niamh Horscroft and Ms. Lara Smyth, our junior barristers. 11:37 11:38

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Accordingly, the three Core Participants before the Inquiry are: The Southern Health and Social Care Trust, the Department of Health, and Mr. Aidan O'Brien. The legal representatives of each Core Participant are present here today and I invite them now to publicly announce their appearances and may I ask that each of

you speak as loudly and clearly as you can because there have been some sound issues today. So if I could call first upon the representative for the Southern Health and Social Care Trust.

MR. LUNNY KC: Chair, Dr. Swart, Mr. Hanbury, my name is Donal Lunny. I'm instructed on behalf of the Southern Health and Social Care Trust, I'm instructed along with fellow counsel, (inaudible) Elizabeth Ferguson and Sam Madden BL. We are instructed by the Directorate of Legal Services, Avril Frizell and Emmet Fox. With me here in the Chamber today I have Avril Frizell. I should also say that I have present in the chamber from the Southern Health and Social Care Trust, the Chief Executive, Dr. Maria O'Kane. Thank you, Chair.

CHAIR: Thank you, Mr. Lunny. Then if the representative for Mr. O'Brien would announce the appearance please.

MR. BOYLE KC: Good morning, Chair, Dr. Swart, Mr. Hanbury. My name is Gerry Boyle KC and together with my Friend, Mr. Robert Millar, Counsel, we appear on behalf of Mr. O'Brien. We are instructed by Tughans Solicitors, by Mr. Andrew Anthony, Kevin Hegarty, Aimee Crilly. Mr. O'Brien is present before you sitting in the Public Gallery.

CHAIR: Thank you, Mr. Boyle. Then for the Department of Health, please.

MR. REID: Good morning, Dr. Swart, Mr. Hanbury, my name is David Reid, Counsel. Sarah Wilson is present

from The Departmental Solicitors' Office. Mr. Robbie Davis from the Department of Health is also present.

CHAIR: Thank you, Mr. Reid.

From the start of our work, the Inquiry has been conscious of the fact that it was due to issues concerning the care of patients that the Minister for Health announced this Inquiry on 24th November 2020. Patients and families, some of whom sadly lost their lives are at the heart of the work that the Inquiry is undertaking and the Inquiry acknowledges their pain and suffering. 11:43 11:43

From my appointment in March 2021, it was my intention to commence to hear from witnesses as soon as we could and to hear first from patients and families. Term D of the Inquiry's Terms of Reference tasks the Inquiry with affording patients and families an opportunity to tell us of their experiences and about the impact those experiences had on them. 11:43 11:43

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to allow some patients and families to relate their experiences to us. The public were not permitted access to those hearings but I arranged that suitably redacted transcripts of the hearings were published on the Inquiry website. I'm very grateful for those who did come to speak to us and relate their own experiences or those of their loved ones.

We found hearing directly from them about their experiences was both moving and extremely helpful and I would, again, encourage anyone who wishes us to know about their experiences to contact us.

The Inquiry will continue to hold private hearings in the course of its work until we conclude our hearings.

Today, however, marks the start of a different stage of our work. Over the coming months, aside from those days when we sit again in private to hear from patients and families, the hearings will be live-streamed to the public from the Inquiry's website. All evidence will be recorded, transcribed and placed on the Inquiry's website as soon as practicable after it is heard to enable many of the people that are interested in our work to follow our proceedings without the need to attend in person. Our hearing chamber is small and provision for the public to attend and view the proceedings in person is limited. In total we can accommodate only 15 people in person in the public

gallery. I have made provision for an overflow room to accommodate members of the media. Proceedings in the chamber will be live-streamed to that room on a large screen.

As well as the transcripts of evidence, documents referred to in the course of the evidence will also be placed on the website, together with the response statements of the witnesses in full. Many of the documents called up in the chamber, statements and attachments will require redaction before they can be placed on the website. Redaction is a major exercise and there is likely to be a time lapse between a witness giving evidence and the statement appearing on the website. I would remind everyone that material shown in the chamber is subject to Restriction Order No. 2 of 2022, and any information displayed on the screens in the chamber which could identify people must not be disclosed.

11:46

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The Restriction Order can be found on the website and the Inquiry's website includes a number of documents relating to our procedures and protocols and I would refer you to those.

11:47

In June, when opening our private hearings, I made some comments about the nature of our work that bear repeating as we start our public hearings.

11:47

An inquiry is not a trial. The process is entirely

inquisitorial in nature. It is designed to uncover facts from which Dr. Swart and I can reach conclusions and then make recommendations to the Minister. The Inquiries Act 2005 under which we work expressly prevents us from making any finding of criminal or civil liability. That means that our findings will not have the legal effect of convicting any individual of a crime, nor will it have the legal effect of ordering any individual or body to pay compensation. 11:47

11:48

It is important to state clearly that Mr. O'Brien is one of the Core Participants before the Inquiry as it was cases involving his former patients that led to this Inquiry being set up. But I must stress that this is not an inquiry purely into the clinical practice of Mr. O'Brien; we are, however, looking at the clinical aspects of certain cases with a view to fulfilling paragraph (c) of our Terms of Reference. That Term of Reference tasks us with looking at the clinical aspects of cases for the purpose of providing a report about governance within the Trust. It is not the purpose of this Inquiry to re-examine patients to assess their treatment. The Trust is engaged in a lookback review of patients. The Royal College of Surgeons reported on a sample of Mr. O'Brien's cases and issues regarding his fitness to practise are matters for the General Medical Council. Any civil liability is a matter for the Courts. 11:48 11:48

While Mr. O'Brien's clinical practice has been a catalyst for this Inquiry, it is not the primary focus of our work, which relates to clinical and corporate governance within the Southern Health and Social Care Trust. 11:49

From when the Inquiry commenced its work in September 2001 (sic), in addition to contacting patients, I have issued a number of notices under Section 21 of the Inquiries Act 2005 seeking documents and witness statements. Questionnaires have been sent to staff and former staff who were involved in the Urology Department at the relevant time. Some of those staff members have also received Section 21 notices. Where I considered it appropriate to do so, I have granted extensions to the time permitted for responses to notices. 11:49

To date that work has generated substantial documentary material amounting to almost 400,000 pages of evidence, including 91 witness response statements, the shortest of which is ten pages and the lengthiest 9,555, including appendices. 11:50

In addition, we received 133 completed questionnaires from staff and 16 from patients or family members. There are still more responses to come in and more notices to issue. 11:50

Unfortunately I need to state publicly that the manner in which much of that material was provided to the Inquiry was far from satisfactory and caused much unnecessary work for the Inquiry's small, committed secretariat. Material was not properly ordered, indexed or accessible. Some material was not provided at all and some material was shared with the Inquiry that ought not to have been. I found it extremely surprising to have received material in such a poor state from a government department and Health Trust both of whom have dedicated legal teams and for this standard provision of material to have been allowed to continue when the Inquiry made it abundantly clear what was expected. 11:50 11:51

Once ordered and placed in the appropriate evidence bundles, the material has been scrutinised by the Inquiry legal team. Analysis of the material has frequently led the Inquiry to seek further material for clarification regarding which has been provided. The process of obtaining material and witness statements and the scrutiny of such material is labour-intensive, time-consuming and will continue throughout the duration of the Inquiry. 11:51 11:51

In order to ensure that the Inquiry's small team can properly prepare the evidence and in order to ensure that witnesses have access to the appropriate material, I have decided that, in general, the Inquiry will hold

hearings on three days each week, at least until Easter. This may increase after Easter. Normally hearings will be from Tuesday to Thursday and apart from our sittings in November and December, the pattern will be to sit on two weeks, followed by two weeks non-sitting. On some days we may hear from more than one witnesses and some witnesses may have to give evidence on more than one occasion. Hearings will continue throughout 2023. 11:52

I am conscious that many of the witnesses from whom the Inquiry has sought Section 21 responses have important work to do within our healthcare system and it is our intention only to call witnesses whom we consider we must hear from in person. Other witnesses who have provided evidence may not be called to speak to us in person but the Inquiry will formally read their evidence into the record and their responses to the Section 21 notices they received will be placed on the Inquiry website in due course. 11:53

In reaching any conclusions on the evidence, we will have regard to all that we hear and read. The timetable for witnesses can be found on the Inquiry's website. This will be updated regularly once attendance dates have been confirmed. It may be that changes will have to be made to the timetable at short notice and updates will be notified on the Inquiry website. So I would encourage everyone to check the 11:53

timetable regularly.

I am shortly going to ask Mr. Wolfe KC to deliver counsel's opening statement. I understand that that will conclude on Thursday. After he has finished, each of the legal representatives of the Core Participants will have the opportunity to make a short opening statement on behalf of their clients. Next week we will start to hear from non-patient witnesses. A schedule for next week's witnesses is on the Inquiry website and will be updated the week before each sitting week with the names of the witnesses who are coming the following week. 11:54

We recognise that the Inquiry process is challenging for everyone involved but hope that those who are involved see the Inquiry process in itself as an opportunity for reflection on what has occurred and an opportunity to correct mistakes that might have been made. 11:54

It is our hope that all who are asked to help the Inquiry in fulfilling its Terms of Reference do so frankly and openly and in a spirit of collaboration, remembering that the entire raison d'être for the Inquiry is to help secure patient safety. 11:55

I'll now ask Mr. Wolfe to give more details of the scope and work of the Inquiry. Mr. Wolfe.

SUBMISSION BY MR. WOLFE KC:

MR. WOLFE KC: Madam Chair, Dr. Swart, Mr. Hanbury, good morning, just about good morning! I propose speaking for just about an hour this morning, what remains of the morning and then we'll break for lunch. 11:55

Today marks an important landmark in the life of the Urology Services Inquiry. For approximately the past 12 months the Inquiry's legal team has worked assiduously behind closed doors to begin the process of investigating the issues described in the Terms of Reference. We now formally commence the public phase of the Inquiry's work. 11:55 11:56

Thank you, Chair, for introducing the members of the hard-working legal team, they'll thank me for saying that no doubt, and for referring to the work of the industrious secretariat. I am indebted to each member of the legal team and to the secretariat for their contribution to the work of the Inquiry to date and for their assistance in the production of this opening statement. Of course all errors and inaccuracies reside with me. 11:56 11:56

Despite what you've just said, Madam Chair, I must also extend my appreciation to the legal teams for the three Core Participants. It has not always been plain

sailing. As you have pointed out, Chair, the manner of disclosure has caused real difficulties and was eminently avoidable. I do not demur from your criticism. However, more generally, I am happy to report that the legal teams have acknowledged their obligation to assist the Inquiry and certainly in their dealings with me and my legal team have recognised the obligation to work collegiately and to assist the work of the Inquiry so that we may proceed efficiently. 11:57

Let me say a few words about the purpose of this opening. It is beyond the scope of this opening statement to reflect upon every facet of the information which has been gathered as part of the Inquiry's initial investigations. Rather, we have set ourselves the rather more modest objective of outlining the key issues which have emerged from the investigations to date and to provide an indication of our working map for the road ahead. It will be possible to use that map to point to some of the places of interest and the key destinations and to identify the kinds of questions which will be asked at each location as part of these public hearings. 11:58 11:58

In the nature of things, there is undoubtedly much that is yet to be revealed about the key issues, even to the legal team which has worked at a pace to provide an intelligible explanation of the areas of concern. Therefore, while I am satisfied that our compass is 11:58

pointing in the right direction, I fully anticipate that we will have to take the occasional detour into other areas of interest as the Inquiry progresses.

I now wish to say something about the immediate background to the Inquiry. 11:59

This Inquiry was ordered by Mr. Robin Swann, MLA, Health Minister, in an oral statement which he made to the Northern Ireland Assembly on 24th November 2020. 11:59 The Minister considered that a public inquiry was the best way to ensure "that the concerns which had been drawn to the Department's attention would be fully identified so that the patients and families affected would see all issues pursued in a transparent and 11:59 independent way."

What were those concerns and how did they come to the Department's attention?

12:00

On 31st July 2020, the Trust's Medical Director communicated to the Department using the Early Alert Mechanism. This alert was given the code 182-20. The alert advised the Department that on 7th June 2020 the Trust became aware of potential concerns regarding 12:00 delays of treatment of surgery patients who were under the care of an unnamed consultant urologist employed by the Trust. That consultant urologist was known to be Mr. Aidan O'Brien, although he was not named in the

alert. The Department was further advised that arising out of those concerns, a lookback exercise had been conducted which had examined the consultant's work for the period 1st January 2019 to 31st May 2020 with the following results: 12:01

Concerns had been identified in 46 out of 147 patients taken to theatre during the lookback period. Those concerns were not further explained. 12:01

Of the 334 elective inpatient cases which had been reviewed, 120 cases showed a delay in dictation of outcomes ranging from two to 41 weeks and in the case of a further 36 patients, there was no record of care noted on their regional NIECR system. In one of the 12:01 elective inpatient cases the concerns were such that the case had been identified for screening for Serious Adverse Incident Review. It was indicated that a further two cases involving prostatic cancer which were under the management of this consultant were being 12:02 screened for Serious Adverse Incident Review or as I will call it SAI because there were indications of potential deficiencies in care provided by the consultant and that these deficiencies potentially had an impact on patient prognosis. 12:02

The early alert also advised the Department that the Trust had taken a number of steps to follow up on what had been discovered. Discussions had been held with

the General Medical Council Employer Liaison Service. The case had also been discussed with NHS Resolutions which had recommended restrictions to clinical practice, including a restriction on private practice pending further exploration. The Trust had put that request to the consultant.

Additionally, the Trust had placed its own restrictions so that the consultant would no longer undertake clinical work or access patient information. 12:03

A preliminary discussion had been held with the Royal College of Surgeons regarding the consultant's practice and the ambit of any necessary lookback exercise.

12:03

Mr. Ryan Wilson, acting Director of Secretary Care for the Department of Health has explained that until the early alert was received from the Trust, the Department had no awareness whatsoever of any concerns relating to Mr. O'Brien or the issues described in the early alert. 12:03

The Health Minister was notified of the early alert by way of a submission from his officials on 6th August 2020. The submission asked the Minister to note the latest Trust advice that at that time the number of 12:04 patients who may have received suboptimal care comprised a cohort of approximately 230 patients and that the full scope of the consultant's practice was not currently known.

On 18th August 2020, the Trust submitted an update to the Chief Medical Officer advising that the consultant had now retired, had agreed not to see private patients and, to the Trust's knowledge, was not working for any other Trust. 12:04

The update advised that the Trust was liaising with the GMC, continuing to consider other potential quality of care issues and liaising with the Royal College of Surgeons to consider the import and the extent of the findings to date. It explained that the Trust was minded to make a decision on the requirement for a formal lookback exercise and was preparing to contact service users impacted as part of the SAI process. 12:05 12:05

On 24th August 2020, the Trust further updated the Department that decisions were required in relation to requesting the Royal College of Surgeons to carry out a lookback exercise, an appropriate process for investigating the conduct of the consultant, involvement of an expert patient to sit on the panel reviewing what at that time was three SAIs and the timing of external communications concluding with SAI patients and families. 12:05 12:06

From 3rd September 2020, that's a little over two months following the early alert, sorry, I should say a little over a month following the early alert, the

Trust hosted weekly meetings with the Department of Health, the Health and Social Care Board and the Public Health Agency in order for the Trust to provide an update regarding its ongoing scoping work in relation to Mr. O'Brien's patients and plans regarding communications with patients and families. This was to lead to the formal establishment of the Urology Assurance Group.

12:06

On 22nd October 2020, the Department notified the Trust that it wished to establish such a group and would lead on that initiative. Draft Terms of Reference and ultimately final Terms of Reference were provided.

12:07

The group - that is the Urology Assurance Group - is comprised of officials from the Department, the HSEB, the Public Health Agency and the Trust and sits under the Chairmanship of the Department's permanent Secretary. It provides external oversight of the work streams undertaken by the Trust to address the concerns identified in its Urology Services Department.

12:07

12:07

On 15th October 2020, the Trust sent a full background report to the Department containing a history of events relating to Mr. O'Brien, a summary of clinical concerns and an outline of the plans being put in place to respond to primary care colleagues and to establish a patient helpline.

12:08

On 15th October 2020, due to issues which were emerging in relation to the consultant's prescribing practices, the early alert was updated by the Trust. By this date, the Trust had appointed an SAI review team under the external and independent leadership of Dr. Dermot Hughes to begin to review what would eventually become nine Serious Adverse Incidents. The updated alert reported to the Department that following a meeting of the review team, additional concerns had been brought to Trust's attention regarding prescribing of the medication Bicalutamide. Those concerned were described as involving the use of unlicensed sub-therapeutic doses of the drug, which the Trust considered as a significant and potentially wide patient-safety risk requiring immediate reaction. The updated alert pointed to the fact that the urgent regional action which was required, that patients and clients would need to be contacted about possible harm and that there was a potential for regional media interest. 12:08 12:09 12:09 12:09

On 16th October 2020, due to a concern that there was inadequate assurance that Mr. O'Brien would not desist from further medical practice, the Chief Medical Officer issued a series of alert letters advising healthcare providers throughout the United Kingdom to contact the Southern Trust if Mr. O'Brien was to seek employment with their organisation. 12:10

The letters were cancelled on 24th November 2020 after satisfactory undertakings were provided by Mr. O'Brien that he had no intention of seeking further employment.

On 26th October 2020, the Health Minister received a submission from his officials advising him of these further developments and recommending that he make a brief written statement to the Assembly with a view to making a more detailed oral statement later. The Minister accepted that advice and a written statement was lodged that day with the Assembly in which he indicated that an early alert had been sent to the Department on 31st July, that the concerns referred to in the alert were being examined and that a Urology Assurance Group had been established. 12:10 12:11 12:11

So, Madam Chair, that was the first articulation in the public sphere by the Health Minister as to the developments which he was then aware of.

The Minister received a further submission from his officials on 20th November 2020. This submission recommended that due to the seriousness and extent of the concerns identified with the practice of Mr. O'Brien, a public inquiry should be established under the Inquiries Act. 12:11 12:12

As I mentioned a short time ago, the Minister made a detailed oral statement to the Assembly on 24th

November to indicate that he had accepted that recommendation and identifying Mr. O'Brien as the consultant whose practices had given rise to the immediate concerns.

12:12

Chair, it is worthy of note that this healthcare-related public inquiry takes its place and commences its hearings in the wake of the publication of the report of the Independent Urology Inquiry and only some four years after the publication of the report of the Inquiry into Hyponatremia-related Deaths in Northern Ireland. Another public Inquiry, the Muckamore Abbey Hospital Public Inquiry, has recently commenced its work.

12:12

12:13

It will be for others to comment on what these public Inquiries may have in common, beyond their connection with healthcare settings in Northern Ireland. It is notable, however, that the reports of both the neurology Inquiry and the Hyponatraemia Inquiry point to significant governance concerns and the report for each inquiry contains recommendations for governance improvement and reform.

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The need for these inquiries and their proliferation is undoubtedly a matter of public concern. The Neurology Inquiry was announced by the Permanent Secretary to the Department of Health in May 2018 and was converted to a statutory Inquiry by the Health Minister in December

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2020. The Inquiry was established after Northern Ireland's largest ever patient recall. The recall revealed that a considerable number of patients had been misdiagnosed and/or mistreated. The report was published on 21st June of this year and made 76 recommendations. A number of those recommendations related to the MHPS policy, which is an area of concern for this Inquiry also. 12:14

I will address those recommendations later in this opening statement during what will be a detailed consideration of the MHPS framework. 12:14

The Hyponatraemia Inquiry considered the deaths of five children amid concerns that their deaths were caused by fluid mismanagement. The Inquiry's report was published in January 2018. It made 96 recommendations to the Department and we understand that these have been transferred into 120 actions. The Inquiry has been told that 45 of the recommendations have been implemented and that the Minister of Health will soon be updating the Assembly in respect of same, assuming the Assembly returns of course. 12:15 12:15

Many of the recommendations have centred around concerns about candour and openness and the use that was made of Serious Adverse Incident Reviews. Mr. Peter May, the current Permanent Secretary of the Department of Health, has indicated to the Inquiry that 12:15

when these recommendations are fully implemented, they will have implications for the medical profession in relation to candour and being open, death certification, the Trust's duty of quality, paediatric care, Serious Adverse Incidents, education and training, and professional regulation.

The Inquiry will wish to learn more about the package of reforms which are being implemented following those Inquiries and will have an opportunity to examine this issue with departmental witnesses when they attend with us next week. 12:16

I want to say something more about the context for this particular Inquiry. 12:16

What is the Urology Services Inquiry about?

In specific terms, this is an inquiry which is focused on patient safety. The reports emanating from the Trust acknowledge that patients of its Urology Department have suffered harm or been placed at risk of harm because of clinical and governance shortcomings. It is the Inquiry's most basic function to investigate how that situation has occurred and to determine how it wasn't prevented; to make findings and to report. 12:16 12:17

It is regularly reported that the Health Service in Northern Ireland is the subject of the most tremendous

pressures and strains. Nevertheless, all patients of our publicly-funded Health Service have a right to expect that despite the challenges, that the care that they receive will be safe and of the highest standard. We all have experience of the talented and resourceful healthcare professionals who staff our hospitals and healthcare settings and who every day go beyond the call of duty in an effort to achieve this goal. But sometimes shortcomings occur which place patients at risk and cause substantial harm, and when this happens, repeatedly or in large numbers, as is reportedly the case here, it is important that challenging questions are asked, learning points are extracted and appropriate recommendations made. 12:18 12:18 12:19

The immediate context for this Inquiry can be summarised in the following terms:

Mr. Aidan O'Brien was an experienced consultant urologist whose practice gave cause for concern in 2017 that he was temporarily excluded from the workplace, allowed to return to work under a monitoring arrangement, and subjected to an investigation under the MHPS framework. That investigation took place in 2017 and 2018 at the same time as, or overlapping with, the conduct of a number of Serious Adverse Incident Reviews which concerned, at least in part, his role in the triage and/or the care of seven patients. Two further SAI Reviews were triggered in 2018, which were 12:19 12:19

again concerned with his role, at least in part, in the care of patients. The SAI Reviews found significant deficits in the management or care of all nine patients, leading to harm or the risk of harm, although only one SAI report was finalised before 2020. 12:20
The MHPS investigation reported in 2018 and upheld the concerns which had been raised. Those concerns related to the failure to triage large numbers of referrals; the failure to dictate clinical correspondence following outpatients clinics for large numbers of 12:21
patients; the retention of large numbers of patients' notes at home or in his office; and the advantaging of some private patients. It was determined, following this investigation, that Mr. O'Brien should appear before a conduct hearing and that a further action plan 12:21
with monitoring and a job plan should be formulated. It was also determined that there should be an independent review of administrative arrangements because of systemic management failings.

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Only the latter recommendation was carried out; that is the review of the systemic management failings. Only that was carried out and even this took almost two years to commence. The actions in relation to Mr. O'Brien were not addressed at all. 12:22

In 2020 further concerns emerged shortly before and shortly after Mr. O'Brien's retirement. Those concerns gave rise to a further nine Serious Adverse Incident

Reviews as well as a formal lookback Review which considered the care of 2,112 patients who were under the management of Mr. O'Brien in the period between January 2019 and June 2020. The SAI Reviews have reported additional significant shortcomings in the management and care of all nine patients and instances of harm or risk of harm to those patients. In particular, the SAI report authored by Dr. Hughes, documented that four of the nine patients reported on suffered serious and significant deficits in their care. They also found the systems of governance were in effective. 12:23 12:23

Arising out of the formal lookback Review, the Trust has reported the following: 12:23

In addition to the nine SAI patients which I have just mentioned, a further 53 patient cases have met the threshold for a Serious Adverse Incident and are being examined under a separate process called Structured Clinical Record Review. An additional 583 patient cases revealed 777 instances of suboptimal care in areas such as diagnostics, medication, treatment, communication (including recording-keeping and referral), although they did not meet the threshold for a Serious Adverse Incident Review. 12:24 12:24

The RQIA has recently recommended that urgent consideration should be given to expanding the temporal

parameters of the lookback process.

Chair, that is a broad overview of the clinical context which has prompted this Inquiry. Based on these reports, a significant number of patients have been adversely affected. This overview doesn't, however, describe the scope of the Inquiry's work. To answer that question, it is necessary to reach for the Inquiry's Terms of Reference. 12:25

The Terms of Reference, Madam Chair, can be found at INQ-50001. I'm going to ask James to put it up on the screen for us, if only to prove that I know how to use this system! The Terms of Reference are contained over two pages and I will begin this section of my statement by highlighting key aspects of the Terms. 12:26

As the Health Minister explained in his statement to the Assembly on 31st August 2021, the process of developing the Terms of Reference for this Inquiry included stakeholder engagement with patients and families affected, and the Assembly's Healthcare Committee, as well as consultation with you, Chair. The Inquiry is bound by the Terms of Reference and is required to apply them fully. The Terms of Reference provide the formal boundaries within which the Inquiry must conduct its work. They inform the nature and extent of the investigations which the legal team is to perform on the Inquiry's behalf. Over the next two 12:26

days or so I will begin to sketch out how we have set out the task of implementing the Terms of Reference, what has been discovered to date, what issues remain to be explored and how this is to be done. I'll refer to aspects of the Terms frequently throughout the statement but it is important you obtain a sense of the key aspects of those terms at the outset so that we are clear as to the direction of travel. 12:27

There are a number of prominent features of the Terms of Reference which are immediately obvious and which should be emphasised and explained. It can be seen that this is a statutory Inquiry. This Inquiry has been established pursuant to and operates within the terms of the Inquiries Act 2005. It can use and has used the powers contained within that legislation. The fact that this Inquiry has been afforded the status of a statutory public inquiry speaks to the gravity of the issues which are to be explored as part of its remit and the implication of those issues for the public. 12:27 12:28

Importantly, this is also an independent Inquiry. Since the activities which are to be scrutinised by the Inquiry fall within the ambit of the Department of Health, it is normal that it is department which sponsors the Inquiry. That means that the Inquiry is funded from the budget of the Department and it is to the Health Minister that the Inquiry shall report and make recommendations. But the Inquiry stands apart 12:28

from the Minister and its officials and conducts its affairs in a manner which is wholly independent of the Department. The Inquiry's investigation is not the subject of oversight by the Department and nor has there been any attempt to direct the Inquiry's work or its interpretation or application of the Terms of Reference.

I speak for the legal team when I say that we value and jealously guard the independence of our work and we hold in the highest regard the fact that this empowers us to thoroughly investigate all of the issues and all of the persons and bodies identified within the Terms of Reference without fear or favour.

I will shortly describe the bodies which are the subject of the Inquiry's interest. It can be seen, if we just focus in on Part (b) of our Terms of Reference, that the Terms of Reference -- sorry, it can be seen from Part (b) of the Terms of Reference that the Inquiry must evaluate the clinical and governance arrangements within the Trust which gave rise to the need to conduct a lookback review. As part of that work, the Inquiry has been specifically charged with examining the communication and escalation of the reporting of issues related to patient care and safety within and between the Trust and the following public bodies: The Health and Social Care Board, as it was then called; the Public Health Agency; and the

Department. It will also be necessary to make an assessment of the role of the Trust's Board. In the course of this opening statement I will further explain the role of these public bodies and I will explore, in some detail, the role of the Trust Board in association with Trust's governance arrangements. 12:30

Let me now say a little more about the issues contained in the Terms which must be investigated. Necessarily the Terms have been formulated in a concise manner without detailed elaboration. I will attempt to further explain what is contemplated by these terms. 12:31

First and foremost this is patient-centred. You have made that remark already, Chair, and I would underscore it. 12:31

Part (d) of the Terms of Reference enjoins the Inquiry to afford patients and/or their families an opportunity to report their experiences. The Inquiry prioritised the need to receive evidence from patients and their families and convened private hearings in June and September for that purpose. 12:31

The second point of note is that this Inquiry concerns matters arising out of the provision of urology services at the Southern Trust. I will shortly tell you something about that Trust and where it sits within the Northern Ireland healthcare structures. I will 12:31

also tell you about the arrangements and the delivery of urology services provided by the Trust, their origin and development, the work that it is performed and the difficulties that are faced.

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Another significant feature of the Terms of Reference is the name Mr. Aidan O'Brien. He is the only medical practitioner named within the Terms. Mr. O'Brien was a consultant urologist who was employed by the Trust from in or about 1992 through to his retirement in July 2020, a period of some 28 years. In a short while I will tell you some more about him and what he has told the Inquiry about the issues under consideration.

12:32

It is clear from the Terms of Reference that the concerns which have been expressed about the performance of Mr. O'Brien during his employment at the Trust are a significant aspect of the Inquiry's work. Nevertheless, I wish to emphasise the basic fact that this is not the Aidan O'Brien Inquiry, despite what is sometimes reported. The Inquiry must examine aspects of Mr. O'Brien's work, especially those cases which it met the threshold for a Serious Adverse Incident. We will use the available evidence to search for, describe and catalogue shortcomings in clinical practice but it is not the function of this Inquiry to make findings in individual cases or reach conclusions on causation issues, for example. That is more properly the domain of civil proceedings.

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As you have already emphasised, Chair, the Inquiry's examination of the clinical aspects of the identified cases serves a specific objective. That objective does not involve inquiry into Mr. O'Brien's clinical practice as such. Instead, the key focus of the Inquiry's work is to scrutinise the Trust's governance arrangements. That much is clear from paragraphs (b), (c) and (f) of the Terms of Reference in particular. The Trust's framework for clinical and social care governance shall be examined to determine whether and to what extent it permitted clinical shortcomings to a care, whether those shortcomings were known and unremedied or unchallenged, or whether they remained undetected during the course of Mr. O'Brien's employment, and whether this undermined patient care and placed patient safety in jeopardy. 12:34 12:34 12:35

So, the critical mainstay of the Inquiry's work is not to investigate Mr. O'Brien per se, but it will be to examine the systems of clinical governance to expose any weaknesses or gaps in those systems and, if appropriate, to hold to account those systems and those who operated them. This is not the expression of a pedantic detail, it is an important point of substance. I say this, not only in fairness to Mr. O'Brien, but also in order to direct particular attention to the focus of the Inquiry's work as it is defined in the Terms of Reference. 12:35 12:35

Mr. O'Brien's name appears prominently in the Terms of Reference because it has been reported that he failed to practise his profession safely or in accordance with accepted norms so that some of his patients were the subject of substandard treatment. It is his practices or primarily has practices which will be used as the vehicle to test the effectiveness and reliability of the governance arrangements. Some of those practices have attracted the attention of the General Medical Council. It is the responsibility of the GMC to investigate allegations that a doctor's fitness to practise is impaired. The GMC exercises this function in order to protect the public. It will investigate where there is a concern that a doctor's actions fall seriously or persistently below the standards the GMC expect. Following an investigation, if the GMC's case examiners decide that there is a realistic prospect of establishing that a practitioner's fitness to practise is impaired, they may decide to refer the matter to the Medical Practitioners Tribunal Service which will independently adjudicate on the matter and make findings. 12:36 12:36 12:37 12:37

The nature and scope of the GMC's investigations are generally confidential to the practitioner, the complainant or referrer and the Council. However, it is a matter of public record that the GMC is actively investigating the fitness to practise of Mr. O'Brien. 12:37

The Inquiry understands that this investigation continues. The GMC has not finalised allegations against Mr. O'Brien and a hearing before the Medical Practitioners Tribunal has not been arranged at this time. If there are any developments in that respect, I will update the Inquiry accordingly. 12:38

Mr. O'Brien is currently registered with the GMC with a licence to practise medicine. However, he has been the subject of an interim order since 2020, which means that there are conditions attached to that registration. That order was initially imposed for a period of 18 months but was the subject of extension by the High Court in Northern Ireland on 13th June of this year and will expire on 14th June 2023. The conditions provide, inter alia, that Mr. O'Brien will only practise in non-clinical roles or in medicolegal work. They provide for a range of notification and disclosure obligations in the event that employment is obtained and they permit the GMC to exchange information with any employer or contracting body. It is the Inquiry's understanding that Mr. O'Brien is not currently employed in any capacity. 12:38 12:38 12:39

Chair, the Terms of Reference are explicit in emphasising that this Inquiry shall not encroach upon the jurisdiction of the GMC, and I understand and expect that that is a line that we will thoroughly respect in the work that we conduct. 12:39

The alleged clinical shortcomings of Mr. O'Brien which have been reported to the Inquiry are not isolated cases. We are instead dealing with a significant number of cases over a prolonged period of time and across a range of clinical issues and administrative issues associated with the safe practice of medicine. It has been acknowledged by the Trust that some patients have suffered significant harm as a result of these shortcomings and it has apologised for the harm that has been suffered. 12:40 12:40

For example, in the overarching Serious Adverse Incident Review report published on 1st March 2021 in respect of the nine patients I have previously mentioned, the Trust offered the following words: 12:40

"The Southern Trust recognise the life-changing and devastating consequences to the nine families. It wishes to offer an unequivocal apology to all the patients and their families involved in this review. This was not the cancer care they expected and should not have been the cancer care that they received." 12:40

That can be found referenced at DOH-00113. 12:41

As appears from Part (c) of your Terms of Reference, the Inquiry has been charged with the responsibility of examining the clinical aspects of those cases which

have met the threshold for a Serious Adverse Incident with the dominant purpose of investigating the governance aspects. The Inquiry's primary interest will be in the cases of patients for whom Mr. O'Brien provided care and was responsible as consultant urologist. That is the direction in which the Terms of Reference point and based on our investigations to date, the vast majority of Serious Adverse Incident Reviews which have emerged from the Trust's urology service in recent years have involved the work of Mr. O'Brien, at least in part. 12:41 12:42

The Inquiry has discovered that there have been 16 Serious Adverse Incident Reviews relating to care provided by Mr. O'Brien, at least in part, to 20 patients in the period since 2010. The Inquiry has just been made aware of the 16th SAI which we are currently in the process of reviewing. 12:42

Furthermore, the Inquiry will wish to examine whether other cases which may have met the threshold for SAI -- sorry, I'll commence that sentence again. Furthermore, the Inquiry will wish to examine whether other cases which may have met the threshold for SAI were wrongly or inappropriately screened out of the process. 12:42 12:43

Additionally, as I have mentioned already, the Trust has indicated that as part of its lookback review, 53 other cases relating to Mr. O'Brien's practice have

also met the threshold for SAI but it has been decided to examine those cases under that other process called Structured Clinical Record Review.

I will outline in greater detail what has been reported 12:43
to the Inquiry in these respects in a short time.

I would wish to emphasise that Part (c) of our Terms of Reference empowers the Inquiry to examine the clinical aspects of any case of concern for the purposes of 12:44
providing a comprehensive report into the governance of patient care and safety within the Trust's urology speciality. This means that the Inquiry is not restricted to looking at the work of Mr. O'Brien for these purposes. The Inquiry will determine for itself 12:44
whether any case, regardless of the clinician involved, should be scrutinised for the purposes of making determinations in relation to the governance aspect.

Part (a) of the Terms of Reference poses a question: 12:44
Is there anything which should have alerted the Southern Trust to instigate an earlier and more thorough investigation? I'll just focus on Part (a) of the Terms. Thank you, James.

12:45

The Inquiry will wish to consider the information which has been presented, where it indicates that concerns relating to how Mr. O'Brien practised were known to his colleagues and to medical and operational management

within the Trust for some years before the events in 2020 which triggered this public inquiry. Some of those practice issues were the subject of informal discussion and challenge as part of day-to-day management. Other issues were formally considered through the SAI process. Additionally, I have indicated that Mr. O'Brien was temporarily excluded from the workplace at the start of 2017 and that a formal investigation took place under the MHPS Framework. The Inquiry will no doubt wish to ask very specific questions about the quality and effectiveness of the steps which were taken both before and after the MHPS process was used. 12:45 12:45

It can be seen from paragraph (e) of the Terms of Reference that the implementation of the MHPS policy in the context of the investigation into Mr. O'Brien is to be a central component of the Inquiry's work. Therefore, I will say something more about that MHPS investigation and its output in the course of this opening statement so that the Inquiry may begin the task of considering, for the purposes of both Part (a) and Part (e), whether that process was effective and whether there was a missed opportunity to get to grips with the problems before further significant issues came to light from June 2020. Part of that consideration will involve an examination of whether the pressures on clinicians such as Mr. O'Brien were such that it became difficult to practise safely in all 12:46 12:46

respects; was there a need to reevaluate his role or the role of others in the delivery of certain services or to provide greater support to him? And was that support forthcoming?

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Furthermore, building upon its understanding of how MHPS was applied in this case, the Inquiry will give consideration to whether this policy is broadly effective or whether it requires strengthening.

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Ultimately, it will be for the Inquiry to bring these various strands together, to identify learning points, to make appropriate recommendations, and to report, as required, by Parts (f) and (g) of the Terms. The conduct of a public inquiry such as this can act as a watershed moment. If those who are to participate are prepared to engage cooperatively, authentically, and in a spirit of openness, and if they actively reflect upon what they, as well as their colleagues, could have done differently, or better, there will be a genuine opportunity to change healthcare provision in Northern Ireland for the better.

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Let me briefly set out the work of this Inquiry to date. I know, Chair, that you have touched on some of the vital statistics. They may bear repeating and emphasis.

12:48

We're able to open the public hearings of this Inquiry

today because for the past 12 months the legal team has engaged with the Core Participants and other bodies and persons as part of an intensive evidence-gathering phase. We have drafted and issued separate staff and patient questionnaires and received an excellent response. To date, the Inquiry has received 14 patient or family questionnaire responses, and eight patients have gone on to give oral evidence to the Inquiry at our hearings in June and September. 12:49

The Inquiry has identified 16 medical registrars and 200 qualified nursing staff to be of interest and questionnaires have been issued to them. The Inquiry has received questionnaire responses from nine registrars and 116 nursing staff. At an appropriate point, the results from those questionnaires will be reviewed and the results disseminated. 12:50

Chair, an important point of the Inquiry's work has been to use your powers under Section 21 of the Inquiries Act to issue notices to compel witnesses to produce documents and to provide a witness statement. Each of the Core Participants have answered notices and the responses are normally authored by the senior employee in the organisation. For example, the Chief Executive of the Trust has answered notices, as has the Permanent Secretary of the Department of Health. Mr. O'Brien has very recently provided a detailed response which is currently being reviewed. The 12:50 12:50

process of issuing notices is an ongoing one and it is anticipated that further notices will be issued throughout the life of the Inquiry.

To date, the Inquiry has issued 111 notices and has received 87 responses with 24 responses outstanding. Some witnesses have been called upon to address more than one notice. The Inquiry has received responses from a total of 66 witnesses to date. It has not yet been necessary to take enforcement action to compel compliance with a notice but the Inquiry reserves the right to do so, if necessary, in an appropriate case. 12:51

The Inquiry has accumulated a significant volume of documents and materials using this process. Some of those documents are still in the process of being sorted and referenced. At a conservative estimate, the Inquiry has received in the region of 400,000 individual pages of material from the Core Participants and their staff members, the vast majority of which at 200,000 pages has been disclosed by the Southern Trust. The Inquiry has received materials from individual witnesses, and a separate witness bundle has been compiled. It currently stands at more than 80,000 pages of documentation. The volume of material assembled speaks to the significance and complexity of the Inquiry's work. 12:51 12:52 12:52

I want to finish this opening section of the opening

statement by setting out the areas I intend to look at over the next couple of days.

Chair, having regard to the major thematic issues which emerge from the Terms of Reference, I intend to work through the remainder of this opening statement in four parts. 12:52

Part 1: 12:53

Part 1 is an introduction to the Core Participants and the other persons or bodies named in our Terms of Reference. So we'll be looking at the Department of Health, the Southern Trust and within the Southern Trust we'll be looking at the Urology Services Unit, the Trust Board. I will then move on to say something further about Mr. O'Brien. We will look at the Health and Social Care Board and the Public Health Authority. 12:53

Part 2 of this opening statement primarily engages Parts (c) and (d) of the Terms of Reference, what in short form I can call the clinical aspects. Here I will document what the Inquiry has established so far in relation to the recorded concern that patients have been harmed or placed at risk of harm by shortcomings in the clinical activities of Mr. O'Brien. 12:53 12:54

I will refer to the patient and family evidence which the Inquiry has received. I will describe the Serious

Adverse Incident Reviews, the SDRR process, and the lookback process, including an audit of the prescription of the drug Bicalutamide, and I will refer to the findings which have so far emerged from each of these processes. 12:54

I will spend some time explaining the significance of the multidisciplinary team approach to patient care. I will refer to the conclusions reached in a recent report by the Royal College of Surgeons which considered a random sample of patients who were under 12:55
the care of Mr. O'Brien in 2015 and which suggests that there may be a need to expand the Trust's lookback review. I will also detail the concerns expressed by the RQIA about the conduct of the current lookback review. 12:55

Part 3 of my opening statement will specifically focus on Part (e) of the Terms of Reference; that is the MHPS policy or to give it its full time, Managing High Professional Standards. Here I will explain the 12:55
function and purpose of the MHPS framework and explain some of its cardinal operating principles.

I will outline the steps which were taken by the Trust and which led to the use of that framework in order to 12:55
investigate concerns regarding Mr. O'Brien in 2017 to '18, the findings of that investigation, and what followed thereafter.

Chair, it will become clear that the MHPS process will be an important area of consideration for the Inquiry. Taken together, parts 2 and 3 of this opening statement will touch upon issues and material which will be relevant to paragraph (a) of the Terms of Reference and the question of whether an earlier and more thorough investigation was indicated. 12:56

Finally, part 4 of my opening statement will touch upon Parts (b), (c) and (f) of your Terms of Reference. Here I will sketch out the key components of the corporate and clinical governance arrangements and examine, in summary fashion, how the governance framework responded to the circumstances which ultimately gave rise to the lookback review. I will also place before you some material which will allow the Inquiry to begin to consider the vulnerabilities of that framework and whether it was fit for purpose. 12:56 12:57

At this point, coming up to one o'clock, I think I've reached a convenient point in the opening to invite you to rise and maybe sit again at two o'clock? 12:57

CHAIR: Certainly, Mr. Wolfe. The Inquiry will sit again at two o'clock. Thank you.

12:57

THE HEARING ADJOURNED FOR LUNCH AND CONTINUED AS FOLLOWS:

CHAIR: Good afternoon, everyone. Mr. Wolfe.

MR. WOLFE KC: Good afternoon, Madam Chair. I think it's our intention, all being well, to sit all the way through to at least four o'clock, but maybe a little after four o'clock and I'll stop at a convenient point in my speaking note. 14:07

I'm about to commence now with the first part, first formal part of the opening in relation to the Core Participants and others. I'll spend some time introducing the bodies and persons referred to in the Terms of Reference. It's really in the form of a pen 14:07 picture. There'll be other opportunities, during the course of this statement, to look at detailed aspects of these persons and bodies.

So, commencing with the three Core Participants and 14:07 initially the Department of Health.

The Department of Health is one of nine devolved departments provided for by the Northern Ireland Act 1998 and the Fresh Start Stormont House Agreement and 14:08 implementation plan. The Department has described its public task as to help the Northern Ireland Executive secure the most appropriate and effective use of resources and services for the benefit of the community. In pursuing this aim, the key objective of 14:08 the Department is to deliver quality, cost-effective and an efficient public Health Service throughout Northern Ireland with its core functions carried out within a legislative framework. The Department is

responsible for three main areas:

Health and social care, including family practitioner services, personal social services, community health policy and legislation; public health; and thirdly public safety to include legislation and policy for the Fire and Rescue Service.

The Department has referred to its mission as being to improve health and social wellbeing of the people of Northern Ireland. It endeavours to do so by leading a major programme of cross government action to improve the health and wellbeing of the population, and reduce health inequalities including by using interventions involving health promotion and education to encourage people to adopt activities, behaviours and attitudes which will lead to better health and wellbeing. The aim is to develop a population which is much more engaged in ensuring its own health and wellbeing. The Department has set itself the objective of ensuring the provision of appropriate health and social care services both in clinical settings such as hospitals and GP services and in the community through nursing, social work and professional services.

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Within the Department there are a number of key business groups. These are the Resources and Performance Management Group, the Healthcare Policy Group, the Social Services Policy Group, the Office of

the Chief Medical Officer.

The Permanent Secretary of the Department is currently Peter May. At the time when this Inquiry was announced, the Permanent Secretary was Mr. Richard Pengelly. The Permanent Secretary is principal adviser to the departmental minister for all departmental activities and principal accounting officer responsible to the Northern Ireland Assembly through the Public Accounts Committee for the sound management of public funds. The Permanent Secretary is required to ensure that the Department and its subsidiaries operate effectively. 14:10 14:10

The Health and Social Care (Reform) Act (Northern Ireland) 2009 established a number of arm's length bodies. They include the six Health and Social Care Trusts, the Health and Social Care Board, the Health Promotion Agency as well as the Regulation and Quality Improvement Authority, the RQIA, the Patient and Client Care Council and the Regional Business Services Organisation. 14:11 14:11

Mr. May explains that the Department delegates its operational responsibilities to its arm's length bodies. The arm's length bodies in turn operate independently of the Department and are governed by specific statutory provisions. Each body is nevertheless accountable to the Department and subject 14:11

to its direction.

The Minister then is accountable to the Northern Ireland Assembly when sitting for the activities and performance of all arm's length bodies, including the Southern Trust. 14:11

The Permanent Secretary is responsible for the overall organisation, management and staffing of the sponsor department. As departmental accounting officer, the Permanent Secretary also designates the Chief Executive of each Trust as its accounting officer. 14:12

The departmental accounting officer shall ensure that the Trust's strategic aims and objectives support the sponsor department's wider strategic aims and is also responsible for ensuring the arrangements are in place to continuously monitor the Trust activities to measure progress against approved targets, standards and actions and to assess compliance with safety and quality, governance, risk management and other relevant requirements. 14:12

The departmental accounting officer shall assess risks through objectives and activities, address significant problems in the Trust and bring concerns about the activities of the Trust to the attention of the Trust Board. 14:12

The Department sets the framework, budget, priorities and targets for each Trust. The Chief Executive of the Trust, as its accounting officer, is accountable through the Permanent Secretary to the Minister and Assembly in terms of performance and expenditure of resources. 14:13

In addition to statutory requirements, the Minister of Health issues directions and guidance which are incorporated into Standing Orders or other corporate governance documentation, including notably codes of practice and accountability and the HPSS code of practice on openness. The Trust must comply with all existing legislation, Department of Health Framework document, management statement, financial memorandum, codes of conduct and accountability and relevant circulars. 14:13

The code of conduct and accountability for board members of, for example, Trusts, are to be found, members of the Inquiry, at TRU-113436. The issue of the code of conduct and accountability for board members is something we will turn to directly when discussing the Board. 14:14

The strategic control framework within which the Southern Health and Social Care Trust is required to operate is set out in a financial memorandum between the Department and the Trust. The performance 14:14

Framework for the Trust is determined by the Department including key targets, standards and actions.

The Inquiry will note that Mr. Wilson of the Department, who I referred to earlier, occupies a role within the secondary care directorate which is a directorate within the Healthcare Policy Group. His role is as a senior adviser to the Minister on matters related to secondary healthcare policy. He has referred the Inquiry to the standard policy brief for Urology which was last reviewed by the Department in 2019 and provides the Department's officials with accessible, factual, high-level information concerning the location of services, legislation, clinical guidelines and waiting lists.

He has also explained that as required by Section 5 of the 2009 Act - that's the Reform Act - the Department produced the Health and Social Care Framework document in 2011 which describes the roles and function of the various health and social care bodies, the systems that govern their relationships with each other, so, for example, the PHA and HSCB or the HSCB and the Trusts, as well as the Department and the service commissioning process.

Mr. Wilson acknowledges that the Department has a direct responsibility for the concerns that have arisen within urology at Southern Trust at a policy and

oversight level. He has highlighted the work which is already underway to identify a number of areas where revised policies and processes are necessary to mitigate or prevent a further recurrence of similar issues and risks and he explains the Department's commitment to bringing forward a number of reviews. However, he has acknowledged that the ability of the Department to address similar issues arising out of the Hyponatraemia and Neurology Inquiries has been constrained by budgetary consideration despite being Departmental priorities. 14:16 14:17

The Southern Health and Social Care Trust:

The Trust is an arm's length body of the Department. It is a statutory body which came into existence on 1st April 2007 under the Southern Health and Social Care Trust (Establishment) Order (Northern Ireland) 2006. The Trust is established for the purposes specified in Article 10(1) of the Health and Personal Services (Northern Ireland) Order 1991. These include any functions of the Department with respect to administration of health and social care that the Department may direct. 14:17 14:17

Additionally, Section 21 of the Reform Act - that's the 2009 Act - provides that it is the duty of a Health and Social Care Trust to exercise its functions with the aim of improving the health and social wellbeing of and

reducing health inequalities between those for whom it provides or may provide health and social care.

The Trust headquarters are based at the Southern College of Nursing, Craigavon Hospital in Portadown, County Armagh. The Trust provides health and social care services to the Armagh, Banbridge and Craigavon Council area, the Mid Ulster Council area, and the Newry, Mourne and Down Council area. The population served by the Trust is approximately 380,700 at the time of the last publication of population estimates in June 2021. 14:18 14:18

The Trust is an integrated Health and Social Care Trust providing acute and community hospital services together with a range of community health and social services. The Trust's Management Statement from 2017 and the Trust's Standing Orders can be found at TRU-01864 and TRU-01966 respectively. 14:19

The Management Statement sets out the broad framework within which the Trust will operate, in particular, the Trust's overall aims, objectives and targets; the rules and guidance relevant to the exercise of the Trust's functions, duties and powers; the conditions under which any public funds are paid to the Trust and how the Trust is to be held to account for its performance. Its vision is to deliver safe, high-quality health and social care services respecting the dignity and 14:19

individuality of all who use them. It lists its core values as working together, excellence, openness, honesty and compassion.

I will now provide a brief account of the Trust's budgetary and financial position. 14:20

The following information has been drawn from the Draft Trust Annual Report and Accounts for the last financial year, 2021-2022, year ending 31st March. 14:20

At the beginning of each financial year, the Trust prepares a detailed financial strategy which is approved by the Trust Board. This strategy forms the basis of how budgets are to be allocated across all directorates within the Trust. Financial performance is monitored and reviewed monthly with all directors and detailed financial reports and year-end forecasts are produced monthly for both the Trust Board and the Trust's senior management team. 14:20 14:21

The Trust receives the vast majority of its income - that's some 88% - from the Department through the commissioning body - that's the HSCB for the purposes of our Terms of Reference, now called the SPPG. In addition, the Trust is provided with a funding allocation for medical education. The largest single remaining funding stream is the income derived from clients in residential and nursing homes. 14:21

The Trust's total revenue expenditure in the year I've just referred to was 993 million and that was directed as follows:

The vast majority, 389 million, going towards acute hospital services; 192 million to older people services; 180 million directed to mental health and disability services; and 107 million directed to children's services. Additionally, some 53 million was allocated to a range of supporting services. 14:21 14:22

Unsurprisingly, staff costs are consistently the largest component of expenditure accounting for 60% of operating expenditure. At the end of March 2022 the Trust employed 15,653 including staff with more than one post. 14:22

I should indicate, panel members, there is hopefully helpfully an appendix at C of your bundle behind my speaking note, which contains a list of the key post holders within the Trust which are relevant to the work of this Inquiry, and I thank Mr. Murphy for preparing that at late notice yesterday. 14:22

CHAIR: Thank you. 14:23

MR. WOLFE KC: Urology services within the Trust:

The Trust has been providing a urology service for patients living in the southern part of Northern

Ireland since 1992. Prior to 1992, fully-trained urologists were based at the Belfast City Hospital and the Royal Victoria Hospital here in Belfast. In 1992 urologists were appointed to Craigavon, the Mater Hospital and Altnagelvin Hospitals. By 1999 there were ten full-time urologists in posts providing services on the above sites along with Lagan Valley and Coleraine Hospitals. In addition to these ten urologists, there were two consultant general surgeons, one based in the Mater and one based in the Ulster Hospital at Dundonald who were accredited as urologists and whose workload was increasingly in the field of urology. 14:23 14:23

A review of adult urology services was published by the Health and Social Care Board in March 2009. You'll find that at WIT-50807. 14:24

The aim of the review was to develop a modern, fit-for-purpose-in-21st-century reformed service model for adult urology services which takes account of relevant guidelines, including NICE, good practice, Royal College, BAUS and BAUN. 14:24

The future model should ensure quality services are provided in the right place at the right time by the most appropriate clinician through the entire pathway from primary care to intermediate to secondary and tertiary care. 14:24

This review was to mark a significant change in the delivery of urology services in Northern Ireland. From 1st January 2013 those services were built around a three-team model: Team East, Team North and a Team South based in the Southern Trust. 14:25
As part of this remodelling the Southern Trust or Team South took on responsibility for the provision of urology services to the population of County Fermanagh. The review report argued that this reorganisation was necessary to achieve long-term stability and viability. 14:25
The statement of Mr. Wilson, amongst others, provides a high-level account of the review of urology services. Some witnesses have commented in detail in relation to the impact of this review and there will be an opportunity to engage with this evidence, where 14:25
necessary, in the public hearings.

Concerns have been expressed to this Inquiry regarding resources which have been devoted to servicing this model. I note in reading Mr. O'Brien's statement 14:26
recently that he spends a lot of time dealing with that aspect of this issue and I touch on aspects of it when I come to say something about him.

Mr. Mark Haynes, a consultant urologist in the Southern 14:26
Trust who joined urology team in May 2014 after the three-team model had been implemented contends that the service was effectively commissioned at a level where it would fail to meet the population need from its

inception and this gap would widen given the absence of projections related to increasing demand resulting from population and demographic changes. He claims that this is the pattern across urology in Northern Ireland and remains the case. 14:27

Mr. Haynes explains that the Trust's urology output does not exist as a separate self-contained entity. Rather, it is a service which sits within the Trust's acute directorate, and patient care is delivered across multiple sites, including Craigavon, Daisy Hill 14:27 Hospital, South Tyrone Hospital, South West Acute Hospital and Banbridge Poly Clinic.

The main setting for the provision of services is the Craigavon Hospital where services are provided by a 14:27 team of consultants, urologists, clinical nurse specialists, staff nurses and allied health professionals, in addition to visiting radiographers and radiologists.

14:28

The urology service provided at Craigavon encompasses the main facets of urological investigation and management with some notable exceptions including radical pelvic surgery, renal transplantation and associated vascular access surgery which are provided 14:28 by the Regional Transplantation Service based in Belfast. Additionally, neonatal and infant urological surgery is provided by the Regional Paediatric Surgical Service in Belfast.

The Trust has a purpose-built urology outpatient facility located in the Thorndale Unit. It is run by five clinical nurse specialists. Outpatients services at Craigavon include urodynamics, ultrasound, 14:28
intravesical therapy, prostate biopsy and flexible cystoscopy. Craigavon Hospital has been designated as a cancer unit with its urological department being designated the urological cancer unit for the area's population. A wide spectrum of urological cancer 14:28
management has been provided for some time. Outreach clinics are currently provided in a number of locations in the Southern Trust area.

Later in this opening statement I will explain the 14:29
managerial structures within the urology service of the Trust. At this point it suffices to note that structurally the urology service is managed within the acute services directorate. On the operational side there's a head of service who acts as the direct link 14:29
between the urology service and the staff members who manage individual areas and departments within the Trust where urological clinical activity is delivered.

She - and it has tended to be a she through recent 14:29
appointments - provides operational day-to-day management with regards to the activities delivered by the urology team with support from the clinical lead for the service. The head of service is in turn

accountable to the Assistant Director for Surgery and Elective Care.

The urology service has long been troubled by an inability to fill all available posts. As of September 2022 there was a 2.2 person vacancy at consultant level, for example. The current interim Head of Service is Ms. Wendy Clayton. She has explained that these vacancies - and they're not just at the level of consultant - these vacancies have impacted on the provision, management and governance of urology services. She has highlighted, for example, that the inability of the Trust to fill its consultancy vacancies in urology which has resulted in a reduction in clinical activity which has in turn been a factor in the increased waiting times. 14:30 14:30 14:31

Additionally, the pressures on the current group of consultants, and perhaps for some time before, has increased so that, for example, they're required to cover the urologist of the weak service more frequently and that in turn has an adverse impact on the time spent in theatre and in clinic. 14:31

Understandably, the inability to meet demands leads to ongoing patient complaints and challenges which have to be managed. The waiting list statistics for urology in the Trust provide us with a striking demonstration of the pressures faced by the urology service. 14:31

The commissioning plan directions score care shows that as of 31st January of this year, 5,530 people were on the Trust urology outpatient waiting list. Integrated elective access protocol, which you will hear frequent 14:32
mention of during the life of this Inquiry, the IEAP, provides an outline of the approved procedures, including a time limit, target time limit I should say, for managing elective referrals to first definitive
treatment or discharge. It was first introduced on 9th 14:32
May 2008 and has been updated as recently as June 2020.

The IEAP target for outpatient appointments is nine weeks but as of January 2022, 4,869 patients had been
waiting for longer with the vast majority, 3,763, 14:32
waiting for more than a year. The longest wait was staggeringly 313 weeks or six years.

The situation has rapidly deteriorated over the past several years. In 2016 some 2,040 were waiting more 14:33
than the nine-week target but most patients were seen inside a year. But by March 2019, that had jumped to almost 2,000 patients waiting for more than a year and has continued to climb ever since.
14:33

The position is little better when considering the prospects for patients on the inpatient day case waiting list for urology. Here, the IEAP target is 13 weeks but as of 31st January 2022, 2,086 patients were

on the waiting list with more than 80% - that is 1,737 - not treated by that target date and many - 1,263 - waiting for more than 12 months.

Again, the trend of waiting times for surgery has followed that for outpatient appointments and has been one of exponential increases since 2016. In that year, 2016, more than 50% of patients were treated inside the 13-week target, although 301 were waiting for more than 52 weeks. But by March 2020, those waiting in excess of a year had more than trebled to 934 and, as I say, it's much worse today. 14:34 14:34

There has been and there remains a very significant capacity demand mismatch. The figures made available to the Inquiry show that commissioned output activity has remained stationary at 299 cases per month for several years, but that the population demand far outstrips this sitting at an average of more than 400 cases per month in every year, bar the Covid-affected year of 2021. Therefore, the variance of capacity gap for the Trust has sat at an average of 159 cases per month over a six-year period. 14:35 14:35

A number of initiatives have been pursued by the Trust in an effort to mitigate these waiting list pressures. Ms. Clayton has referred to the use of independent sector providers who address new outpatient referrals and to perform a small number of TURP procedures. On 14:35

occasion it has been possible to transfer patients to neighbouring Trusts with shorter waiting times. Mr. Haynes has explained that the Trust has tried to grapple with incoming demand by engaging with the HSCB to reach agreement for new referrals from some population centres to be treated, for example, in the Western Trust area where waiting times are shorter. Nevertheless, he has explained that his urology colleagues so frequently see patients come to harm while awaiting surgery, that it is almost normalised. He makes the point that patients languishing on routine waiting lists simply do not get treatment while urgent, non-cancer cases often wait many years. 14:36 14:36

It is clear that resources have had to be targeted as prioritising the treatment of cancer patients but even cancer patients have been adversely affected by resources issues. Ms. Clayton has highlighted that IEAP target for a red flag outpatient first appointment is 14 days. However, Trust performance measured against that target in April 2016 was 3.5 weeks and has rapidly deteriorated; five to seven weeks by April 2019 and 11 weeks as of 1st April this year. 14:37 14:37

The problem is not limited to the Southern Trust and it is of note that in his role as Chair of the NICaN Clinical Reference Group, Mr. Haynes wrote to the HSCB in October 2019 to set out that group's concern that urological cancer surgeons could not consistently offer 14:37

surgery within expected timescales for cancer treatment and that increasingly difficult choices were having to be made when prioritising cancer treatments. In practice this means inevitably delaying some patients' cancer treatment in order to expedite another patient's treatment. If treatment is delayed, Mr. Haynes indicates there is a risk of progression and complication and a need for additional interventions, thereby placing a greater demand on the healthcare system. Clearly a vicious circle. 14:38

The Inquiry is, therefore, acutely aware that the context in which dedicated clinicians, nursing staff, allied health professionals and managers seek to deliver a urology service in the Southern Trust is very far from optimal. As I have already indicated, the Inquiry will wish to evaluate to what extent the impact of working under great pressure to meet demand impacts upon service delivery. 14:39

Mr. Haynes, for example, has suggested at the very least the workload pressures which exist in attempting to deliver a service in the absence of adequate resources impacts on the likelihood of individuals working within the service to identify and raise concerns. This is a significant intervention. It is one which the Inquiry will wish to explore with him when he gives evidence next week. 14:39

The Trust Board, the Southern Trust Board:

The Southern Trust Board has corporate responsibility for ensuring that the Trust fulfills the aims and objectives set by the Department. The Board establishes the overall strategic direction of the Trust and should constructively challenge the Trust's Executives team in their planning, target-setting and delivery of performance, ensure the Department is kept informed of any change likely to impact the strategic direction of the Trust, and should demonstrate high standards of corporate governance at all times. 14:40 14:40

The Board is comprised of a non-executive Chair, seven non-executive members made up of six lay persons and a layperson with a financial experience and up to five executive members, usually comprising the Chief Executive, Director of Finance, Medical Director, Director of Nursing and Director of Social Work. Members are expected to consider the key strategic and managerial issues facing the Trust in carrying out its statutory and other functions. 14:40 14:41

The Chair of the Board is responsible for leading the Board, for working closely with the Chief Executive and is accountable to the Minister. The Chair ensures that the Trust's policies support the strategic policies of the Minister. The Chair and Trust board members share corporate responsibility and ensure the Trust fulfills 14:41

the aims and objectives set by the Department and Minister. The Chair ensures risk management is considered regularly and formally at board meetings and ensures the Board meets regularly throughout the year and has minutes recorded, including, where appropriate, the views of individual board members.

Mrs. Roberta Brownlee was the Chair throughout most of the period with which we are concerned. She was succeeded by Ms. Eileen Mullen at the start of 2021. 14:42

The Board appoints a Chief Executive to the Trust. As I have noted already, the Chief Executive is the Trust's accounting officer. The Chief Executive is responsible for the overall performance of the executive functions of the Trust and is directly accountable to the Chair and non-executive members of the Board for ensuring Board decisions are implemented. 14:42

The Chief Executive deals with the operational delivery of the Trust, advises the Trust Board on the discharge of its responsibilities, the Trust's performance against its aims and objectives and ensures risk management is maintained and ensures that effective procedures for handling complaints about the Trust are well established and widely disseminated. 14:42

The Trust has experienced a high degree of turnover in the Chief Executive's office. The Chief Executive at

present is Dr. Maria O'Kane and she succeeded Mr. Shane Devlin at the start of this year. The Inquiry will wish to consider the turnover of Chief Executives within the Trust and to consider whether the impact that this may have had on the continuity and effectiveness of governance systems.

The Trust has professional executive directors for medical, nursing and allied health professionals and social work who are each responsible for professional standards of practice within their respective fields. Each directors reports to the Trust Board on professional governance issues. Executive members or senior members of Trust staff are appointed to lead each of its major professional and corporate functions. The Medical Director, for example, has executive responsibility for all professional medical issues.

The management statement between the Department and the Trust sets out the broad framework within which the Trust will operate, including the Trust's aims, objectives and targets in support of the Department's wider strategic aims; the rules and guidelines relevant to the exercise of the Trust's functions; duties and powers; conditions for public funds; and how the Trust is held to account for its performance.

The Board holds approximately seven meetings per year. The majority of meetings involve a public and a

confidential session. The confidential session is held at the beginning of the meeting and is closed to the public. Mr. Devlin, who I've explained is the former Chief Executive of the Trust, has indicated that this private session or confidential session allows for the sharing of information on concerns or performance issues that are identified to be raised and discussed directly with Trust board members. He further explains that these confidential meetings are minuted to ensure an accurate record but they're not held in public session so that issues of policy and development are confidential in terms of identifiable information can be shared. 14:44 14:45

A separate agenda is prepared for the public and confidential sections of the meeting and separate meeting packs of documentation are prepared for members. There are packs of documentation provided to the Trust Board for each meeting. The Inquiry has considered these packs which contain a variety of different papers prepared by various members of the Board, committees, or external individual agencies. 14:45 14:45

It is difficult to ascertain the intensity of the discussion which takes place at board meetings. The Trust Board minutes are not detailed in nature. It is unclear if the Trust Board minutes accurately reflect the full extent of discussion and challenge at meetings and this is a matter which the Inquiry may wish to 14:45

explore in evidence.

The volume of documentation provided in these packs may be a relevant fact to consider in exploring the extent of engaged engagement with the issues raised at Trust board meetings. It appears from our consideration of the packs that it would not be unusual for the meeting packs to extend to more than 800 pages of material. It is unclear how far in advance of the meeting these packs are provided to the Trust Board members. 14:46

Mr. Devlin has explained that the public Trust Board agenda is structured under three key domains: Strategy, accountability and culture. It is not apparent from the Trust Board minutes how much time is spent on each part of the agenda. Mr. Devlin suggested the Board agenda is regularly 60% discussion of clinical governance issues. If this is accurate, it would indicate that clinical governance was a prominent feature of the Board's discussions. Regardless of the time spent by the Board on discussing clinical governance matters, however, the Inquiry will be interested to explore whether those discussions adequately focused on addressing issues of concern and whether the overall site of clinical governance was effective. 14:47

The Board minutes and agendas disclose that at the commencement of Trust board meetings an opportunity is

provided for those present to declare any conflict of interest.

Furthermore, the Inquiry is aware of occasions when board members have been reminded of their obligations under the codes of conduct and accountability. For example, on 24th March 2017, the Department wrote to all of the Health and Social Care Boards and arm's length bodies to remind their members of their obligations under the codes and their requirement to identify and manage any conflict of interest in order to maintain the integrity of the Board and public confidence within it. 14:48 14:48

One issue of particular concern to the Inquiry relates to whether the former Chair of the Trust Board, Mrs. Roberta Brownlee, properly discharged her duties under the codes. At the meetings on 24th September 2020 and 12th November 2020, Mrs. Brownlee declared an interest in an agenda item involving Mr. O'Brien and left the room when the item was discussed. The nature of the conflict is not otherwise elaborated upon in the minutes. However, the minutes of board meetings indicate that she did not always disclose a conflict of interest when issues relating to Mr. O'Brien were discussed. She attended meetings on 27th August 2020 and 22nd October 2020 when issues of concern relating to Mr. O'Brien were reported. The minutes of the latter meeting show that she actively engaged in the 14:48 14:49

discussion regarding the update on clinical concerns within urology which related to Mr. O'Brien. It is unclear why the declaration of a conflict was not made at the August and October meetings when it was made at the September and November meetings. 14:49

Mr. Devlin has told the Inquiry that he had concerns about Mrs. Brownlee's approach and has questioned her "total commitment to be totally open with regards to her willingness to criticise urology and specifically Mr. O'Brien." Mr. Devlin contends that at the meeting 14:50 of 22nd October 2020, Mrs. Brownlee advocated on Mr. O'Brien's behalf. Concerns about the role of Mrs. Brownlee have been expressed by other witnesses, including, for example, Mrs. Corrigan.

14:50

Mrs. Brownlee has been served with a Section 21 notice by the Inquiry but in fairness to her I must point out that the deadline for compliance with that notice has not yet expired. In the circumstances, it was thought appropriate to alert her legal representative to the 14:50 fact that this issue would be ventilated as part of this opening statement and to offer Mrs. Brownlee the opportunity to respond. In doing so, it was explained to the legal representative that it was necessary to raise this matter publicly since it is an issue which 14:51 the Inquiry is bound to consider but that of course no finding has been made by the Inquiry at this time.

It is important to state that Mrs. Brownlee has now

responded, through her legal representative, and it has been indicated to the Inquiry that she refutes any suggestion of impropriety and she has asserted that she exercised her duties as Chair of the Southern Trust in an appropriate manner for the entirety of her tenure. She is currently gathering evidence to support her position and this will be provided for the consideration of the Inquiry in due course. 14:51

These are serious and significant allegations and the Inquiry will want to carefully consider whether the claims that had been made about Mrs. Brownlee are well founded. The Inquiry itself directs no allegation against Mrs. Brownlee and no criticism is made of her. These are issues to be explored through the evidence. Hypothetically, if the Inquiry was to find that there's some merit in the claims which have been made about her, then - and only then - will it become important to consider what impact, if any, this had on the approach adopted by the Trust to issues involving Mr. O'Brien. 14:52 14:52

The Inquiry will note that notwithstanding his concerns in relation to Mrs. Brownlee, Mr. Devlin does not believe that this has any impact on the path that was followed with Mr. O'Brien's case or with urology. 14:52

The Board of the Trust appoints committees to support it in fulfilling its functions effectively. The minutes and reports of all Board committee meetings

shall be brought to the public board meeting for information immediately following committee approval, except where confidentiality needs to be expressly protected. The senior management team is represented on each such committee. The Trust Board packs contain 14:53
minutes and reports of the meetings of the following committees: The Audit Committee, the Endowments Committee, the Governance Committee, the Patient and Client Experience Committee and the Performance Committee. In general, there is limited evidence 14:53
within the minutes of the Board meetings to suggest that the work of the committees is discussed in detail or that further information is sought by the Trust Board about matters raised at committee. The time set aside to discuss the work of the committees does not 14:54
appear to be extensive. Indeed, the minutes for the Board meeting on 24th October 2019 show that a new standardised format for dealing with sub-committee business was introduced so that each committee report would be taken as read and not further discussed unless 14:54
an urgent issue arises.

The Inquiry may consider that these committees are central to the effective operation of the governance framework at board level and that, therefore, it might 14:54
be expected that the full board would take an active interest in discussing what they're producing. If there was this active interest, it might be expected that the Board minutes would reflect back to the

committee some areas of concern, requests for clarification or assurance, questions to be addressed for the next meeting, specific issues to be further examined or investigated by a committee.

14:55

The Inquiry will explore the approach taken by the Trust Board to the work of governance-related committees in the reports or minutes and whether, in particular, there's evidence of the Board engaging in a meaningful discussion, intervention or debate about the issues considered by the committees.

14:55

The Trust Board was familiar with the challenges faced by its urology service. This can be discerned from consideration of the Trust minutes. The material disclosed to the Inquiry by the Trust indicates that the service was considered to present the greatest or certainly one of the greatest risks to the operational performance of the Trust. Capacity issues were discussed very frequently at board meetings or were otherwise documented in committee reports, and I refer in my speaking note to a number of examples of that.

14:55

14:56

At a meeting in March 2016, for example, the Trust Board was advised that the longest Trust waits are in urology with 34 patients waiting from 2012-13; in January 2017 the Trust Board was told that the majority of breaches of the 62-day waiting target are within urology; in January 2019 the Trust Board was advised

14:56

that the longest wait in terms of inpatient and day-case waits are within urology.

These are just some indications that the Board was anxious to discuss these challenges. Sorry, I'll repeat that sentence. There are some indications that the Trust Board was anxious to discuss these challenges. 14:57

By way of further example, the minutes of the Board meeting for 30th August 2012 indicate that the Chair informed members that at the request of the non-executive directors more time will be devoted to discussion on the performance report at Trust board meetings going forward. At the meeting seven years later, on 24th January 2019, by way of further example, board members discussed urology waiting times and sought assurance that controls were in place. Nevertheless, the degree of intervention may have been piecemeal and intermittent. 14:57

I have already raised a question concerning the degree to which the Board exhibited interest in the work of its committees? One example of a committee discussion concerning urology can be found within the Trust Board pack for the meeting of 24th October 2019. A report prepared by the Chair of the Patient and Client Experience Committee disclosed that the committee had considered a presentation highlighting work in urology. 14:58

It noted the challenges to the service and the real impact of performance figures on service users. The minutes of the Board meeting indicate that one of the non-executive directors, Mr. John Wilkinson, presented the committee report but the same minutes do not suggest that any substantive discussion took place. There's no indication that the issues raised in the committee report were interrogated or challenged or that further clarification or assurance was sought. 14:58

The Inquiry is unaware of any Board sub-committee discussion relating to the particular issues concerning the performance of Mr. O'Brien. Generally speaking, while committee minutes and reports contain references to concerns about operational capacity and delivery within urology services, it is the Inquiry's current understanding that concerns relating to Mr. O'Brien, which were known and discussed operationally, were not drawn to the attention of any committee until after matters were brought to the attention of the Department by the early alert in July 2020 when they were then discussed at a governance committee meeting of the Board in November of that year. 14:59 14:59

It is also the Inquiry's understanding that the first occasion on which the Trust Board was informed of an issue relating to Mr. O'Brien's clinical practice was on 30th September 2010. At that time, Dr. Rankin, who I understand was the Medical Director - we maybe need 14:59

to check that - advised the Board by reference to a briefing note that the Health and Social Care Board had raised concerns relating to the use of IV fluids and antibiotics in the treatment of patients with urinary tract infections and at the higher level than usual rate of benign cystectomy was being carried out in the Trust. The briefing note referred to the involvement of two surgeons, one of whom was Mr. O'Brien, although neither clinician was identified. The meeting was told that a review had commenced. 15:00

At the next meeting on 25th November 2010, the Trust Board was advised that the review had been completed with 13 patients but that it had been decided to undertake a review of the whole original cohort of patients which would take several more weeks to complete. The minutes of the Board meeting do not suggest that members raised any questions or sought any further information. The minutes do not suggest that board members asked about any possible wider ramifications or about any other compliance or management issues within the Urology Department involving these clinicians. No further update appears to have been given to the Board following the meeting of 25th November 2010 and there's no indication that any board member asked for an update. 15:01

The Inquiry is unaware of any further board discussion of the practices of Mr. O'Brien until a meeting of 27th

January 2017, just under seven years later. The minutes for that meeting referred to an unnamed consultant urologist who had been excluded from practice for a four-week period who could now return to work subject to a number of controls and who would now be investigated using the MHPS Framework. Given the seriousness of the facts conveyed to the Trust Board, the Inquiry may be concerned to understand why the Trust Board was not provided with any form of documentation which set out the detail of the circumstances that had led to Mr. O'Brien's exclusion, the decision to instigate the MHPS process, or the decision to permit him to return to work. 15:02 15:02

Furthermore, the Inquiry will be concerned that the Trust Board does not appear to have been provided with any information about the nature of the concerns raised in respect of Mr. O'Brien nor any detail about the controls that had been put in place. 15:02

It is appropriate to observe at that time that Mr. John Wilkinson had been assigned to the MHPS process in accordance with the framework and will have been in a position to ask further questions of those involved. You'll recall Mr. Wilkinson was a non-executive director of the Board, so he was the Board person attached to the MHPS process. 15:03 15:03

In that role he was familiar with at least some of the

significant developments. Furthermore, as Chief Executive, Mr. Devlin was also a board member.

The MHPS case manager met with Mr. Devlin on a number of occasions and made him aware of the conclusions reached by the MHPS process. So far as the Inquiry is aware, there is no indication that Mr. Devlin or Mr. Wilkinson or indeed the Medical Director took steps at any time to update the Board in connection with the MHPS process. 15:03 15:04

For that matter there's no indication, either, that the Board took any steps of its motion to follow up on the information provided in early 2017 in order to chart the progress of the MHPS investigation and its outcome, the continued performance of the clinician involved or patient safety issues. The Inquiry will wish to consider why further information on such matters, including information concerning the referral of Mr. O'Brien to the GMC in 2019, information on Serious Adverse Incidents and departures from his work plan were not brought to the Board, and whether the Board's lack of pro-activity around these issues raises any concerns. 15:04 15:04 15:05

Mr. Devlin has provided the Inquiry with three examples of matters that were escalated to the Trust Board where there have been patient quality and safety concerns. I won't deal with the detail of those examples now but

what he says of those details is as follows:

They reveal clear engagement, challenge, planning and improvement on the part of the Board. The Inquiry may be interested to explore these examples in greater detail and to consider whether they do in fact reveal a willingness on the part of the Board to engage, challenge, plan and improve and whether a similar approach was or ought to have been applied in connection with Mr. O'Brien after January 2017. 15:05 15:06

The next Board discussion in connection with Mr. O'Brien after the January 2017 discussion did not occur until 27th August 2020, more than three years later, when the minutes record that Dr. O'Kane brought to the Board's attention the fact that Serious Adverse Incident investigations were taking place into concerns involving "a recently retired consultant urologist". The minutes do not reflect the fact that the Trust had issued by that stage an early alert to the Department a month earlier. The Inquiry may be concerned to understand the rationale for the extremely limited terms in which the issues were reported to the Trust Board at that stage. 15:06 15:06 15:07

It can be said, however, that a detailed report setting out both the history of issues in relation to Mr. O'Brien and the more recent concerns which had emerged was prepared by Dr. O'Kane for the Board

meeting on 24th September 2020. Within this report, Dr. O'Kane refers to the fact that an early alert had been made to the Department but the date of the early alert was not mentioned. The minutes of the meeting disclosed that a Trust member requested this information but the Chief Executive, for whatever reason, Mr. Devlin, was not in a position to provide the information but undertook to provide it. It may appear surprising that the early alert had not been provided to the Board at its previous meeting. 15:07

Further board meetings took place on 22nd October 2020 and 12th November 2020 at which the fallout from the early alert was again discussed. Mrs. Brownlee attended her last meeting as Chair on 12th November. Shortly thereafter, the Minister announced his decision to instigate this public inquiry. 15:08

I want to move on now and discuss Mr. O'Brien.

Mr. Aidan O'Brien graduated from Queens University Belfast in 1978. After undertaking postgraduate surgical training in Northern Ireland, he was appointed as a registrar in urology in Belfast City Hospital in 1984; St. James's Hospital, Dublin, in 1985; in 1986 he was appointed research fellow with Meath Hospital; a senior registrar in 1988 and he went on to complete higher surgical training in urology on 30th June 1991. He was then appointed senior registrar in paediatric 15:08

urology at the Royal Hospital for Sick Children in Bristol on 1st September 1991. In a two-month interval prior to taking up this post in Bristol, Mr. O'Brien served as a locum consultant at Craigavon Area Hospital for some seven weeks primarily performing TURP procedures. After competitive interview, Mr. O'Brien returned to Craigavon to take up post as consultant urologist on 6th July 1992. He worked in that capacity until July 2020 when he retired. 15:09

In his detailed response to the MHPS investigation, which I will examine later in this opening, Mr. O'Brien provides a helpful description of the developments in the urology services in Craigavon from when he took up his post. At the time of his appointment the only specialist urology service in Northern Ireland was provided by Belfast City Hospital and urology provision was minimal at Craigavon. He explains that it focused mainly on carrying out TURP procedures. In the view of Mrs. Gishkori, that is G-i-s-h-k-o-r-i, in the view of Mrs. Gishkori, former Director of Acute Services, Mr. O'Brien built up urology services in the Trust "single handedly". Mr. O'Brien was a sole consultant for four years, a period which he has described as difficult when he was responsible for providing 24/7 emergency urological services 48 weeks a year until the appointment of a Mr. Baluch in 1996 who was replaced by Mr. Young in 1998. 15:09 15:10 15:10

Mr. O'Brien has reflected that the appointment of a second consultant was a necessity at that time as it had otherwise become impossible for a single consultant urologist to provide an adequate service to meet the increasing urological needs of the population. 15:11
Mr. O'Brien suggests that the urological department at Craigavon Hospital had been remarkably successful in its first decade and was widely recognised throughout Northern Ireland for being so.

15:11

He has expressed the view that this led to some envious resentment from other departments which has subsequently led to a long delay in further desperately-needed development of the service, the loss of the single urology inpatient department in Ward 2 15:11
South and radical pelvic surgery being centralised in Belfast City Hospital.

Mr. O'Brien has explained that despite the expansion in the number of consultants employed at what had become 15:11
the Southern Trust, there were enormous difficulties in meeting demand. He explains that the operating capacity allocated to the urological service had not been correspondingly increased in response to the number of referrals which accumulated annually, leading 15:12
to increased waiting times for surgery.

In light of concerns over waiting times, Mr. O'Brien undertook extended operation days, operating until

8:00 p.m. each Wednesday which he says was usually followed by a minimum of four hours further work preparing for MDM meetings ahead of the next day.

In a submission made for the purposes of the formal grievance which he raised at the conclusion of the MHPS process in December 2018, Mr. O'Brien outlines that the demands on his time became more acute owing to additional pressures that built up between 2012 and 2016. Here he points to a reduction in his patient-related administration time to two hours per week by 2016, his appointment as a lead clinician of the Southern Trust Urology NDT and Chair of the Urology MDM in April 2012. He indicates that his duties in the latter role, that is as Chair of the MDM, required him to chair 137 meetings which necessitated a conservatively estimated 480 hours additional work or additional administration work undertaken in his own time, in addition to the need to take steps to prepare the urological oncology service for national peer review in June 2015. 15:12 15:13 15:13 15:13

Mr. O'Brien outlines that despite raising these pressures with the Head of Service, Mrs. Corrigan, on more than one occasion, no remedial or supportive plan or action was put in place to alleviate him of this overwhelming burden which gave rise to an administrative backlog in terms of dictation of letters and which became a subject of concern. 15:14

In the material disclosed to the Inquiry by Mr. O'Brien, he provides a perspective on some of the arrangements which were implemented in the Trust to support the delivery of urology services. Mr. O'Brien outlines that the urologist of the week system was introduced in 2014 and that it was agreed that the duty consultant would be responsible for the triage of referrals. He recounts how shortly after the introduction of this arrangement, he realised that there simply was not enough time to do triage effectively and optimally whilst also delivering optimal, definitive and timely management to those patients who had been acutely admitted. Mr. O'Brien believed that the primary purpose of the urologist of the week is to optimally care for those patients acutely admitted and it was not possible to accommodate the triage of an average 160 referrals a week without compromising the standard of care provided as urologist of the week, or compromising the standard of triage, or both. 15:14 15:15 15:15 15:15

As I will explain in the course of this opening statement, what the Trust regarded as Mr. O'Brien's failure to perform triage on urgent and routine referrals, and the implications of this for the safe management of patients was to be the trigger for a number of Serious Adverse Incident reviews and in substantial part the MHPS investigation. At the point 15:16

when the Trust decided to initiate this investigation, Mr. O'Brien was formally excluded from the workplace for four weeks.

Upon his return to work in February 2017 a monitoring arrangement was put in place by the Trust to seek to ensure compliance with, for example, his duty to triage. 15:16

Mr. O'Brien has outlined in his grievance submission that from that time he was only able to triage in a timely manner by taking a day of annual leave after completing each period as urologist of the week. He describes this commitment as amounting to up to 65 virtual consultations with patients, advising them of investigations requested and treatment to be initiated, in addition to dictating letters to referrers, GPs and patients. He adds that this has been equivalent to conducting up to nine additional new patient clinics while urologist of the week and during his role as urologist of the week. 15:16 15:17 15:17

It is Mr. O'Brien's perspective that the inclusion of this requirement to triage within this role has compromised patient management and that it was therefore unsafe. Mr. O'Brien is on record as having described the triage performed by some of his consultant colleagues as unsafe and inadequate and that those undertaking triage, while being urologist of the 15:17

week, has resulted in triage being conducted instead of patient management leading to suboptimal outcomes.

Mr. O'Brien was a supporter of advanced triage, a position he would contend which was necessitated by the waiting times for first appointment for routine and urgent referrals. He considered that these waiting times were so lengthy that to allow that time to elapse, without having directed some further investigation, can lead to a compromised outcome. 15:18

As outlined in an interview conducted with him during the MHPS investigation, Mr. O'Brien was unable to secure agreement of his colleagues to adopt an advance system of triage and, in his view, the Trust failed to supply appropriate time to ensure that this crucial task was completed. 15:18

Mr. O'Brien has described 2016 as a difficult year for several reasons, most notably his increasing concern about the morbidity and mortality of patients waiting ever-longer periods of time. His refusal or inability to take leave in an endeavour to mitigate, so far as possible, the risk of harm to patients, his own deteriorating health necessitating surgery in the latter part of that year, and the need to provide support to a colleague. 15:19 15:19

Mr. O'Brien has indicated that while recuperating from

surgery, he was able to use his time to reduce significantly the backlog of undictated clinical correspondence which had built up associated with his outpatient clinics.

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During this period, on 30th December 2016 Mr. O'Brien was informed of concerns about his practice by the then Medical Director, Dr. Wright. He has described this development, which was to precipitate his temporary exclusion from practice and the launch of the MHPS investigation, as shocking and devastating and he has recalled that it initiated the worst month of his life with serious consequences for his health.

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In his response to the Inquiry's Section 21 notice, Mr. O'Brien has further reflected his concern and disappointment on what led up to these developments and he has argued that what has happened since then has lacked candour and honesty with regard to the treatment of him. He says:

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"I had always felt that the urological, medical and nursing staff had worked well together, enjoyed good relations with each other and were supportive of each other in endeavouring to provide the best care that they could provide to those in most of it, even though a severely inadequate service had been commissioned and resourced as described throughout his response."

15:21

However, he says, that he found it disappointing to learn that a colleague could initiate a Serious Adverse Incident investigation concerning Patient 10 in 2006, that should read 2016, without ever being informed of it and having it chaired by another colleague, without ever having been consulted about it. Since then, Mr. O'Brien says, he has increasingly listened to criticisms of colleagues without these colleagues being aware of the criticisms and since then he has found the absence of candour, honesty and integrity to be disappointing and most concerning. 15:21 15:22

It is clear, Chair, that Mr. O'Brien considers that his commitment, dedication and hours of hard work in an effort to deliver optimal, definitive and timely management of patients was undermined by a system where delivery was compromised by the lack of adequate sources and prioritisation. He contends that he was left without support to deal with the issues which arose. He has recalled the time when he met with Mr. Mackle, who was then Associate Medical Director, and Mrs. Corrigan, the Head of Service, on 30th March 2016. He recalls asking what he was supposed to do to address issues such as triage and dictation. He claims that he was, yet again, left to deal with the problems alone and without any input, assistance, intervention, monitoring or supervision by line management or by the Trust. 15:22 15:22 15:23

He also contends that when the MHPS process was being instigated, his then clinical manager, Mr. Weir, was disconnected from the process and did not become involved in the decision-making. Mr. O'Brien has a number of concerns about the MHPS process and contends 15:23
that the early communication with NCAS - and I'll turn to their role presently - was seriously misleading and that the case investigator failed to take account of the evidence which he provided to her. He was particularly aggrieved at what he regarded as her 15:24
failure to ensure that a comparative analysis of NHS patients was conducted when she considered the allegation that he was responsible for advantaging private patients.

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Mr. O'Brien has expressed great unhappiness in relation to how his retirement from practice as a consultant urologist in the Southern Trust was forced upon him. He has recalled that while he had reached a decision in early 2020 to come out of full-time employment, he 15:24
considered that he had the support of the clinical lead, Associate Medical Director and Head of Service to return to a part-time role with the Trust after a short break. He recalls that on 8th June 2020 he was told by Mr. Haynes and Mr. Carroll that he could not return on 15:24
a part-time basis as the Trust had a practice of not reengaging people with ongoing HR processes. This, he said, came as a complete shock to him since he was committed to returning to work in order to positively

contribute to mitigating the risks associated with a beleaguered urology service.

On 11th July 2020, Mr. O'Brien was made aware of concerns which had recently been identified with regards to his practice. Those concerns formed part of the early alert which was sent to the Department at the end of that month. In his statement to the Inquiry, Mr. O'Brien has expressed significant concern in relation to the information that was provided to the Minister and/or the Department of Health prior to the announcement of the Inquiry on 24th November 2020. He complains that the very trigger for what was an informal lookback exercise at first of all his patients to January 2019 was the totally untrue assertion - and that's his claim - in a letter of 11th July 2020 about two patients who had been placed on the patient administration system in the ordinary way and which he says any competent and impartial consideration of the medical records and correspondence held by the Trust would have revealed. 15:25 15:25 15:26 15:26

The concerns relating to the administration of those two patients formed part of a number of concerns which the Trust considered from July 2020 and which were to lead to the identification of nine patients who met the threshold for SAI review and the establishment of an SCRR process. I will look at this in further detail shortly. 15:26

Mr. O'Brien, however, has expressed his concern that he has not been afforded the opportunity to meaningfully contribute to either of these processes and with his legal representatives he has argued that this lack of engagement with him is grossly unfair and is likely to produce outcomes from both processes which are unreliable and inaccurate. 15:27

Mr. O'Brien has frequently voiced his deep concern with the urology service provided by the Trust. This has been reiterated most recently in his witness statement to the Inquiry where he argues that throughout his tenure, the greatest threat to the safety of urological patients was the inadequacy of the services provided by the Trust. He claims that this inadequacy has resulted in an unsafe service which resulted in increasing risks of serious harm to multiples of these patients. He contends that the Trust has failed to provide a urological service equitable to other specialist services which it has provided and that not only has it failed to address and resolve the concerns that its consultant urologists had for years, but has instead avoided and evaded sharing the responsibility for the clinical consequences, transferring that responsibility to the inadequate numbers of clinicians who have overworked beyond their contractual obligations to mitigate the risks of patients coming to harm. 15:27 15:28 15:28

Reflecting upon the impact on him personally, Mr. O'Brien maintains that these failures resulted in a relentless burden carried by him and his two few colleagues to maximally mitigate the risk of patients coming to harm due to that inadequacy. He says that he has worked far beyond any contractual obligations and that this has been acknowledged. He has worked when on leave and even when on sick leave. He says that he's tried to do the impossible but the impossible proved not to be possible, and he invites the Inquiry the consider that any failings on his part would be viewed in this light. 15:29 15:29

I'm going to move on now to look at the Health and Social Care Board. 15:29

Chair, as I have explained, part (b) of your Terms of Reference requires the Inquiry to consider the communication and escalation of the reporting of issues between the Trust and the Health and Social Care Board, the PHA and the Department of Health. 15:30

The Inquiry is also empowered to consider any other areas which directly bear on patient care and safety. 15:30

The Health and Social Care Board was established under Section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009. It was dissolved with effect from 1st April this year. Absolutely no connection to

this Inquiry but it's dissolution occurred earlier this year and its functions transferred to the Department of Health's Strategic Planning and Performance Group, the SPPG, pursuant to Section 1 and Schedule 1 of the Health and Social Care Act (Northern Ireland) 2022. 15:31
The closure of the HSCB followed what Sharon Gallagher has described as a review of commissioning which concluded that the system was overly bureaucratic and complex. In anticipation of that closure, Mrs. Gallagher took up a dual post as Chief Executive 15:31
of the HSCB and Deputy Secretary of the Health Service Operations Group on 28th September 2020. She now leads the SPPG in her role as Deputy Secretary, and in that role she oversees the commissioning arrangements for health and social care for the Northern Ireland 15:31
population. She works closely with the Chief Executive of the PHA to ensure the delivery of an integrated health and social care commissioning plan for Northern Ireland. She has been a member of the Department-led Urology Assurance Group since its inception in late 15:32
2020.

Mrs. Gallagher has explained the functions and activity of the HSCB and now the SPPG and its relationship with the Department, the Trusts and the PHA in particular. 15:32
The brief overview which I'm about to provide does not do justice to the detail and complexity of the account which she has provided. It is anticipated that the Inquiry will hear from Mrs. Gallagher in due course.

She has explained that the HSCB was established to perform the following broad functions:

To arrange or commission a comprehensive range of modern and effective healthy and social services for the population of Northern Ireland, and to performance manage Health and Social Care Trusts that directly provide services to people to ensure that these achieve optimal quality and value for money in line with relevant government targets and within the budget envelope available. 15:33 15:33

Pursuant to Section 8 of the 2009 Act, the HSCB was required to produce an annual commissioning plan in response to the Department's commissioning plan direction and in full consultation and agreement with the PHA. Mrs. Gallagher has explained that this requirement is at the core of the key working relationship that translates the strategic objectives, priorities and standards set by the Department into a range of high-quality, accessible health and social care services and general improvement in public health and wellbeing. 15:33 15:33

Employees of the Health and Social Care Board and the PHA work in fully integrated, multidisciplinary teams to advance the commissioning process at regional and local levels. 15:34

Mrs. Gallagher's response to the Inquiry acknowledges that the HSCB was for some time aware of service capacity issues within urology services generally and was focused on a strategic regional solution to those issues. She does not comment on or engage with the severity of those capacity issues and the impact on the Southern Trust, its staff or the population it serves, nor has she expressed a view on whether sufficient steps have been taken to mitigate these issues even allowing for resourcing constraints. She has explained, in some detail, the outworking of the 2009 regional review on urology services and has referred to the role of the Regional Urology Planning and Implementation Group which monitors demand and available capacity to help reduce variation in waiting times across the region. She has explained that work continues to be undertaken to expand urology services across the region within the resources available. 15:34 15:34 15:35 15:35

As well as commissioning services, the HSCB's role was to engage with all of the Trusts in respect of performance management and service improvement. In order to discharge its performance management role, the HSCB scrutinised management reports and raised challenges where necessary. The HSCB's Director of Performance and Director of Commissioning met regularly with the Trusts at director level. The HSCB had available to it a range of escalation measures if 15:35

monitoring of performance identified concerns about a Trust performance or a serious risk to the achievement of targets. There is no suggestion that any escalation measure was applied to the Trust's urology service.

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The HSCB has, since 2009, monitored complaints, processes, outcomes and service improvements. Furthermore, pursuant to a departmental circular, 8/2010, issued on 30th April 2010, Trusts were obliged routinely to report SAIs to the HSCB and now to the SPPG. The PHA work closely with the HSCB in this sphere. The previous arrangement had been for Trusts to make these reports on Serious Adverse Incidents to the Department.

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At Section 7 of her response, Mrs. Gallagher has helpfully described the SAI process, its importance generally and the role of the HSCB in that context. As part of its performance management function, the HSCB engaged with the Trusts to assess final SAI reports to ensure that any review had been sufficiently robust and gave consideration to regional learning. The HSCB was not involved in SAI investigations per se.

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Mrs. Gallagher has observed that delays in compliance with SAIs have been prevalent for some time and an improvement plan was introduced by the HSCB as recently as February 2021. She has also explained the engagement between the HSCB and the Southern Trust in

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relation to the three Serious Adverse Incident reviews involving urology services in the Trust which emerged in or about 2016 when nine SAI reviews involving urology services in the Trust which emerged in 2020 were the subject of a paper which was discussed by the HSCB senior management team in June 2021. 15:38

As I have just explained, the Inquiry must explore the communication and escalation of the reporting of issues between the Trust and the HSCB, the HPA and the Department. Mrs. Gallagher has emphasised that the SAI review process is not designed to identify errant practice at the level of the individual practitioner. Therefore, the HSCB was not alerted to the Trust's concerns regarding Mr. O'Brien's practice until they were specifically notified by the Trust through the early alert process in 2020. 15:38 15:39

Mrs. Gallagher has expressly commented that there is no record within the HSCB to indicate any awareness of the issues relating to Mr. O'Brien prior to 31st July 2020 and its focus prior to that date was not on the specific practice of any individual consultant team or hospital. She has added that no pattern/trends of concern or clusters of complaint were identified to the HSCB with regards to the urology services at the Trust or the practice of Mr. O'Brien. 15:39 15:39

The Inquiry is interested in the capacity issues which

were a constant presence during the relevant timeframe and will wish to explore with the former HSCB whether there was any concern that those issues and the pressures they created could have impacted on the safe delivery of care, even if that concern was not formally communicated and escalated. The quality of the communication between the HSCB and the Trust and the sensitivity of the former's performance management function will fall to be considered as the Inquiry progresses. 15:40

Finally in this section looking at the Core Participants and the other bodies and people named in our Terms of Reference, I look at the PHA, the Public Health Agency. 15:41

As I have mentioned, the Inquiry's Terms of Reference in part (b) engage looking at the communication between the Public Health Agency and the Trust. 15:41

I will introduce the Inquiry to the role of the PHA by providing a brief overview of its functions and its relationship with the other public bodies that the Inquiry is concerned with. 15:41

Like the HSCB and now the SPPG, the PHA is a statutory body. It came into existence on 1st April 2009. As a statutory body, the agency has specific powers to act as a regulator to contract in its own name and to act

as a corporate trustee. The PHA's senior leadership team is structured around the Chief Executive and four directors who are supported by 13 assistant directors. The current Chief Executive is Mr. Aidan Dawson who has kindly assisted the Inquiry by providing a witness statement. In his statement, Mr. Dawson has explained that the PHA has three primary functions: Improvement in health and social wellbeing, health protection and service development. He has indicated that working with the HSCB, the PHA has an important role to play in providing professional leadership to the HSCB sector. More generally, in discharging these functions, the PHA has a responsibility for promoting improved partnership between the health and social care sector and local government, other public sector organisations and the voluntary and community sectors to bring about improvements in public health and social wellbeing and for anticipating the new opportunities offered by community planning.

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Quite apart from the statutory descriptions of its functions, the PHA is also the recipient of instructions and guidance from the Department. Mr. Dawson has drawn the Inquiry's attention to an important example of such instruction, namely the Department's framework document which you have heard something about already. Mr. Dawson has addressed the relationship between the PHA and the other bodies that the Inquiry is particularly concerned about within part

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(b). I will briefly summarise the position but the detail is to be found in Mr. Dawson's response.

Firstly, the Department. The PHA is required to report regularly to its departmental sponsor branch to provide assurance on a range of governance areas, including roles and responsibilities, business planning and risk management, governance and internal audit. I have already touched upon aspects of the dual approach necessarily adopted by the PHA and the HSCB given the overlapping nature of their interests and functions. Not only does the HSCB and PHA work together to provide professional leadership to the health and social care sector, but they also work closely on commissioning matters. For example, HSCB is required to prepare and publish a commissioning plan in full consultation with and with the approval of the PHA each financial year.

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Mr. Dawson explains that the HSCB and PHA also collaborate in supporting providers to improve performance and achieve desired outcomes.

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The HSCB is the lead organisation for supporting providers in relation to the delivery of a wide range of health and social care services and outcomes but this work is supported using the professional staff of the PHA.

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PHA, in turn, is the lead organisation for supporting

providers in the areas of health improvement, screening, and health protection within the support provided by the performance commissioning, finance, primary and social care staff of the HSCB. The resolution of any provider performance issues is a matter for the HSCB in close cooperation with the PHA escalating to the Department only if required.

Mr. Dawson's description you may think helpfully illustrates the close relationship between those two public bodies. 15:45

Mr. Dawson has indicated that from 2009 the role of staff who were previously employed in the Southern Health and Social Services Board and who moved to the PHA with the formation of the new organisation was to change. Since 2009 there has been a much greater emphasis on regional commissioning issues with the result, he says, that there has been more limited opportunity for direct engagement with clinicians or service managers at Trust level in respect of individual specialities or performance management. 15:46

The Inquiry may wish to consider whether that has created any sense of disconnect in relation to the problems that might be felt in terms of service delivery on the ground. 15:46

Mr. Dawson has explained the PHA's involvement with the

regional urology service issues. He has advised that PHA staff participate, as required, in regional working groups. For example, its staff were involved in the working group concerning the regional review of urology services. Moreover, PHA staff are members of the Northern Ireland Cancer Network or NICaN. PHA staff members are not members of the urology clinical reference group of NICaN but as with other clinical reference groups, they may attend by invitation to discuss particular topics of concern. 15:47

One of the Inquiry's particular interest is the process for reviewing Serious Adverse Incidents. Mr. Dawson has addressed this area in considerable detail in his Section 21 response to the Inquiry. He has indicated that the process which is generally followed is for the Trust to notify the HSCB governance team of the incident. Once received, these notifications are allocated, as appropriate, to either a professional group in the case of a Level 1 SAI, or a designated review officer in the case of a Level 2 or Level 3 SAI. These professionals may be medical, nursing or allied health professionals from the PHA or social care or primary care professionals from HSCB. Mr. Dawson indicates that the PHA does not have a governance lead for SAI. That role is provided by the HSCB. 15:47 15:48 15:48

Mr. Dawson has outlined the activity which the PHA has engaged in concerning specific SAIs which are of

interest to this Inquiry. He has explained that in the case of Patient 95 - and I should pause at this point to remind the Core Participants and indeed yourself, Chair, that there's an appendix setting out a cipher list for all of the patients that we are concerned with. So he has explained that in the case of Patient 95, for example, which I will examine in somewhat greater detail later, the designated review officer, Dr. Corrigan, was dissatisfied with the recommendations which emerged from the Trust's SAI Review. The SAI recommendations failed to engage with the fact that the consultant concerned, Mr. O'Brien, had failed to review the results of a CT scan as soon as those results were available in the case of a retained swab. Dr. Corrigan expressed her concerns to the Trust and asked for this issue to be addressed. Whether the issue was satisfactorily addressed is an issue of concern or interest for the Inquiry.

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Incidentally, it is of note that at or about that time in 2010/11, Dr. Corrigan was also engaged in discussions with the Trust about the use of intravenous antibiotic therapy in benign cystectomy procedures. Both issues also involve Mr. O'Brien, however the SAI report concerning Patient 95 did not identify the clinicians involved and it may be that she did not appreciate that Mr. O'Brien was involved in both issues.

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Mr. Dawson has also referred the Inquiry to particular engagement between the PHA and the Trust in order to discuss what he has called a cluster of three SAIs relating to urology services and mainly related to triage issues. The designated review officer for those cases was a Dr. McLean. She made contact with the Trust's Medical Director, Dr. Richard Wright, on 27th September 2017. She invited Dr. Wright to explain whether the issue in these triage cases had arisen because of a problem with an individual's practice or whether it was a systems issue in urology. She was advised by Dr. Wright that the problem was with an individual doctor, whom he named as Mr. O'Brien, who was the subject of restrictions and was being managed under the MHPS process. Dr. McLean e-mailed the Director of Public Health and other senior staff to summarise the conversation with Dr. Wright but did not name the doctor involved as the identity was not relevant to the PHA. 15:51 15:51 15:51

Mr. Dawson highlights that the SAI process anonymises clinicians. He also places emphasis on that part of the SAI procedure which addresses the reporting and follow-up of SAI review and which directs the SAI review team to be aware of the distinction between SAI reviews which are solely for identification and reporting learning points and disciplinary, regulatory or criminal processes. He also highlights that the PHA do not have a role in the management of individual 15:52 15:52

doctors employed by the Trust and nor does it have a role in the MHPS process.

Dr. Dawson has explained that as a result of Covid, changes have been made to the SAI process which will remain in situ as they have been found to provide a better oversight and allow for improved detection of themes or trends. However, he argues that the process of SAI review is not intended to detect individual clinical shortcomings. He says: 15:53

"The aim of the SAI process is to provide a mechanism to effectively share learning in a meaningful way with a focus on safety and quality, ultimately leading to service improvement for service users. It was not designed as a measure to address the types of patient safety and clinical issues and clinical issues identified within the urology service in the Southern Trust. It follows that the PHA does not regard the SAI process as an effective measure to address concerns relating to errant practice on the part of individual practitioners."

Mr. Dawson has indicated that the other matters of concern relating to Mr. O'Brien which were examined as part of the MHPS process, and here he refers to patients notes tracked out to Mr. O'Brien and not returned, undictated patient outcomes from outpatient clinics, and the alleged preferential scheduling of

private patients were not brought to the attention of the PHA until the early alert was received in the summer of 2020.

The nature and extent of the communication between the PHA and the Trust is of interest to the Inquiry. It is clear that at various points the PHA engaged with the Trust on issues of concern arising out of the practice of Mr. O'Brien but that it may not have linked those issues together and did not in any event contemplate for itself a role in managing the performance of an individual clinician. The Inquiry will wish to consider the soundness of that position. 15:54 15:55

I'm going to move, Chair, to spend just ten minutes opening Part 2 of the opening statement just to introduce it. We've lost some time earlier today and I want to make hay while the sun is shining in my eyes. So I will aim to finish by about five or ten past. 15:55

CHAIR: So if anybody has any difficulty with that, if they need to leave sooner than, please feel free but just to be clear, my intention will be to sit certainly until about half past four each day. 15:55

MR. WOLFE KC: Part 2 of this opening statement concerns clinical aspects and patient impact. 15:56

Madam Chair, I will now turn to consider aspects of the issues which fall within paragraphs (c) and (d) of the Inquiry's Terms of Reference and what the Inquiry's

work to date has revealed about the clinical shortcomings which have been reported in respect of Mr. O'Brien's practice. I will commence by recapping on the evidence received by the Inquiry from patients of the Trust urology service. I then propose to 15:56
highlight the findings of the SAI and the SEA reviews which have been conducted within the Trust in respect of care provided to 19 patients of Mr. O'Brien. As I indicated earlier, the SAI review in respect of the 20th patient is still under consideration as it was 15:57
only drawn to our attention yesterday and so I will not address it here.

These reviews were important exercises in which various review teams documented significant and repeated 15:57
clinical and governance failings over a prolonged period of time. I will also refer to the recommendations that flowed from those reviews and while it might be suggested that those recommendations were not always comprehensive, the Inquiry may consider 15:57
that they at least provided an opportunity to stimulate improvement and reform.

I will point out the kinds of governance concerns which arise from those reviews for the Inquiry's 15:57
consideration. I will also refer to the emerging findings of the Trust's lookback review and SCRR exercises which have been initiated since Mr. O'Brien's retirement in 2020. Those processes have enabled the

Trust to identify those patients whose care was suboptimal or was of concern and in some cases different care treatments options have been proposed and implemented.

15:58

Those preliminary findings will be examined alongside the conclusions which have been reached following two recent reviews. The first of those reviews carried out by the RQIA identifies a number of shortcomings in the SCRR process to date. The second review conducted by 15:58
the Royal College of Surgeons examined a small sample of Mr. O'Brien's patients from 2015 and identifies concerns in the delivery of urological services across a range of issues. On the basis of both reviews, it is understood that the Trust is considering whether to 15:58
extend the scope of its lookback review.

I will examine other indications of concern about clinical issues arising out of cases which have not been considered in any SAI or SCRR process. 15:59

It appears on the basis of the evidence received to date that mere consideration of the SCRR or SAI cases in an effort to achieve an accurate count of the number of Serious Adverse Incidents is unlikely to prove 15:59
reliable. It is quite possible that there has been a degree of underreporting. If we simply focus on the official count, it can be said that the Trust has so far identified 73 patients, that is 20 patients who

have had an SAI or a sub species of SAI called SEA, in the period since 2010; 53 who are being considered in the SCRR process, whose care or an aspect of whose care under Mr. O'Brien has met the threshold for Serious Adverse Incident.

As you know, Chair, the Inquiry is obliged to examine the clinical aspects of those cases for the purposes set out in part (c) of your Terms of Reference.

Taking the paragraphs of your Terms of Reference out of their natural order, I will start with part (d) which provides that the Inquiry is to afford those patients affected, and/or their immediate families, an opportunity to report their experiences to the Inquiry.

If patients feel that they have been adversely affected by their engagement with the Trust, it is important that this Inquiry hears about that adverse affect and its consequences. In seeking to give effect to part (d), the Inquiry has undertaken a process of patient engagement and that patient engagement has involved the use of the patient questionnaire and I've referred earlier to the fact that to date 14 completed questionnaires have been received from affected patients and families. In addition to those completed questionnaires, the Inquiry has also received correspondence from other patients.

In those communications with the Inquiry, patients have

shared their experiences of using and accessing urology services in the Trust. A number of themes can be discerned from those questionnaires to date: Two patients experienced delays in the removal of urinary stents; several patients raised issues about poor communication; a number of patients described issues with delay; and one referred to the inappropriate prescription of low-dose Bicalutamide.

Madam Chair, it is important I think that I should reflect that the positive reports from patients in respect of their treatment by Mr. O'Brien in particular have been provided to the Inquiry. In the words of some of those former patients, "Mr. O'Brien has been attentive, totally professional" and some have expressed to the Inquiry that the care and treatment that they have received from him was "of a high standard" and "second to none".

A further aspect of engagement with patient and/or their families has involved contact with the Patient and Client Council or the PCC, another arm's length body established under the 2009 Reform Act. The Inquiry has explained to that organisation the role of the Inquiry and invited it to promote awareness of the Inquiry's work with patients and their families and the public generally.

At this juncture I would emphasise for the benefit of

any members of the public following along today that the Inquiry continues to actively invite and welcome engagement from any patients or immediate family members who wish to report their experiences. As I have mentioned, the questionnaire is available on the Inquiry's website or, in the alternative, can be requested from the Inquiry by telephone. 16:03

I want to recap, members of the Inquiry, albeit briefly, on the information or evidence you received during the private patient hearings. 16:03

Chair, you made the point correctly this morning that a full record of those hearings is available by transcript but I think given that this is the first opportunity to reflect publicly the experiences of those patients, I will briefly set out what you were told. 16:03

The purpose of those hearings which took place in June and September of this year was to give effect to part (d) of the Inquiry's Terms of Reference. The Inquiry heard from eight patients and families. The names of those patients cannot be given publicly, although each of the Core Participants are aware of their identities. Instead I will refer to them using the Inquiry's cipher, and the media is required to use these cipher in any reportage of these matters and must not under any circumstances identify the patients or their family 16:04 16:04

members.

The patient evidence:
For the purposes of this opening statement, I will provide a brief summary of the issues raised by the patient or family member when they came to give evidence to the Inquiry as follows: 16:04

Patient 18 gave evidence to the effect that there had been no discussion of treatment options with him and that Mr. O'Brien had effectively dissuaded him from pursuing radiotherapy, instead prescribing low-dose Bicalutamide. Patient 18 was only offered radiotherapy after he had written to Mr. O'Brien requesting same in very clear terms. Patient 18 explained that he had not been assigned a cancer nurse specialist and felt he was unable to make an informed decision about his treatment. The care afforded to Patient 18 has been the subject of an SCRR report which pointed to a failure to comply with the multidisciplinary meeting consensus resulting in delayed referral for radiotherapy and criticised the use of Bicalutamide. 16:05 16:05 16:05

Patient 16's daughter described the significant difficulties with communication which she and her family experienced when dealing with urology. Ultimately this prompted a complaint to the Trust as well as to the Public Service Ombudsman such was the level of frustration and concern. The delay in 16:06

removing her father's stent meant that radiotherapy was no longer an option in treating his prostate cancer. This patient's case was the subject of an SAI review which I will discuss later. Patient 16's daughter told the Inquiry that the SAI process had never been explained to the family and that they had to rely on the Patient Client Council for support. 16:06

Patient 10's husband explained that there had been a 64-week delay in his wife's case "because of a failure to triage her referral". He described his and his wife's shock and concern at discovering that her case was not the only case where Mr. O'Brien had failed to triage whilst he was urologist of the week. This case was the subject of a SAI review. Patient 10's husband raised issues around the adequacy of the Trust's communication in respect of the SAI process telling the Inquiry that there had been no communication from the Trust until the report had been finished. He told the Inquiry that neither here nor his wife were aware that an SAI report was being compiled before then. 16:06 16:07 16:07

Patient 84 told the Inquiry about the difficulty he experienced when trying to contact Mr. O'Brien with regard to delay in removing his urinary stent. He felt he had been, in his words, "fobbed off" by administrative staff and despite trying ten times, he never managed to get speaking to Mr. O'Brien. He was left disappointed and annoyed with the outcome. 16:07

Patient 13 explained to the Inquiry that he felt that he had not been given much information. Patient 13 explained that he first became aware that there been a delay in processing his GP referral in February 2018 despite that referral having been made in July 2016. He recalled receiving a telephone call to inform him that a newspaper article was due to be published in the Irish News and to reassure him that his care had been appropriate. His care was one of the five cases considered together as part of a single SAI review which in common with the SAI review of Patient 10's care focused on the failures of triaging within urology services. 16:08 16:08

Patient 15's son conveyed his frustration at the lack of communication and information forthcoming from the Trust to his family in respect of his father's care. He recounted to the Inquiry the impact of the six-month delay in receiving treatment had on his father's health. He described having first been informed that there were potential issues with his father's care in May 2021 during a telephone call from Mr. Haynes. Patient 15's son was very clear in his evidence that the purpose of that phone call was to advise the family that there would be an article published in the Irish News. It was his evidence that the family did not come away from that phone call with an understanding that there had been an SAI review of his father's care. 16:09 16:09

Indeed Patient 15's son indicated that the SAI review report was first shared with the family by this Inquiry.

Patient 35's son described how his father had been prescribed low-dose Bicalutamide and managed by way of active surveillance as opposed to having been offered radical treatment. He explained to the Inquiry that when his father suffered a recurrence of cancer, the seriousness of his illness had been downplayed by Mr. O'Brien and described the family's shock in learning that his father was to be managed palliatively. The care afforded to Patient 35 has also been the subject of an SCRR and Patient 35 and his mother have met with the Trust to discuss the review's findings. Those findings showed that the management of Patient 35's cancer treatment fell well below what was expected and that while it was difficult to quantify the precise impact on prognosis, the delay reduced the chance of curative radiotherapy being successful.

Finally, Patient 1's daughter also gave evidence suggesting that the seriousness of Patient 1's illness had not been fully explained to Patient 1 or his family. She described the side effects her father had experienced as a result of taking Bicalutamide. She explained that her father had never been allocated a cancer nurse specialist and described the significant challenges the family faced in caring for Patient 1 without support during the Covid-19 pandemic. Patient

1's daughter also described having received a telephone call from the Trust in advance of the publication of an article in the Irish News relating to urology. Patient 1's daughter also gave evidence that following her father's death, Mr. O'Brien made a telephone call in which he sought to assure with the family that all appropriate care had been given. In the questionnaire submitted to the Inquiry by Patient 1's family, they described the impact of the shortcomings in his care explaining that Patient 1 felt that he had been thrown under a bus by the healthcare system. The care afforded to Patient 1 was the subject of an SAI review and the Trust met with the family to discuss its findings. 16:11 16:12

16:12

So, Chair, eight families or eight patients, a small number of patient testimonies perhaps, but each one tells a story about how the urology service has let them down. Each of those patients or their family members have provided valuable evidence about their experiences which has helped to contextualise the impact of clinical shortcomings and to provide an insight into their often traumatic experiences. 16:12

There is a close connection between part (d) and part (c) of the Inquiry's Terms of Reference. By hearing from patients about their experiences when accessing urology services, the Inquiry is enabled to better understand the clinical aspects of their cases. 16:13

Further patient hearings, as you've said, are planned for early next year. It is anticipated that the Inquiry will continue to convene such hearings periodically at convenient points in the Inquiry's process if the need arises. 16:13

Tomorrow morning, if this is a convenient time, I will take up what is perhaps the longest section of the opening, thanks to Ms. Treanor, who contributed significantly to it, and I imagine that will take us through the large part of the morning and perhaps into the afternoon. 16:13

CHAIR: Thank you very much, Mr. Wolfe. Well, ladies and gentlemen, that concludes the first public sitting of the Inquiry. We will resume again tomorrow morning at 10:00 a.m. so if everyone can convene for that time please. 16:14

THE INQUIRY WAS THEN ADJOURNED UNTIL WEDNESDAY, 9TH NOVEMBER 2022 AT 10:00 A.M. 16:14