Urology Services Inquiry

Oral Hearing

Day 7 – Wednesday, 9th 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.

_____

Gwen Malone Stenography Services

THE INQUIRY RESUMED ON WEDNESDAY 9TH NOVEMBER 2022 AS FOLLOWS:

CHAIR: Good morning everyone, welcome back to Day 2 of our public hearings. Mr. Wolfe, are you ready? 10:08

MR. WOLFE KC: I'm ready. Yes, good morning Mr. Hanbury, Dr. Swart, and Chair. This morning and part of today I am going to focus on those aspects of our investigation so far that touch upon Terms of Reference part (c). I understand that we are probably 10:09 aiming for a break to facilitate, in particular, the stenography team, at or about half eleven. I emphasise, I think, a relatively short break, it may be ten minutes or so.

10:09

Part (c) of your Terms of Reference, Chair, tasks the Inquiry with examining the clinical aspect of those cases which meet the threshold for Serious Adverse Incident and any other appropriate cases. While I have emphasised that it is not the role of this Inquiry to 10:09 make findings about clinical outcomes in individual cases, it will nevertheless remain necessary for the Inquiry to ask questions about clinical shortcomings arising from individual cases or groups of similar cases and, importantly, to reach conclusions about 10:10 patient safety concerns which arise.

I refer to the list of the SAI and SEA cases contained in your appendix A and otherwise set out in a cipher

list which has been communicated to the Core Participants.

The Inquiry's work in pursuance of Terms of Reference part (c) will necessarily include examination of each of those cases. As can be seen from the appendix, 19 cases or 19 patients are included in this cohort. The Inquiry has sought confirmation from the Trust that there are no other SAI cases which touch upon the care provided by Mr. O'Brien. One further SAI relating to a patient under the care of Mr. O'Brien has been identified. As I indicated earlier, that case -- I should say, as I indicated yesterday that case was identified very recently and is under consideration. 10:10 10:10 10:11

So, in addition to those 20 SAI cases, there are a large number of further cases which emerged from the look back exercise which the Trust considered met the criteria for SAI but which have not been progressed under the SAI procedures. Rather, those cases are the subject of a process called Structured Clinical Record Review or SCRR. 10:11

To set that decision in context, the Inquiry understands that at a meeting of the Urology Assurance Group on 30th October 2020 the Department and the Public Health Agency advised that the SAI process was not appropriate for investigating a potentially high number of patient cases as the SAI process was not 10:11

designed to meet the full requirements of a patient recall exercise of this nature. The decision to halt the SAI process and to instead progress any further cases identified as meeting the SAI threshold through a SCRR process was then made at a subsequent meeting of the UAG on 4th December 2020. The minutes of that meeting are available to us. They reflect the group's reasoning that a Structured Clinical Record Review process should be developed to ensure that patients are on the correct treatment pathway and that learning and areas for improvement can be captured, considered and implemented, importantly, without delay. 10:12 10:13

To date, the number of cases identified by the Trust and which are to be considered within the SCRR process stands at 53, although the Inquiry recognises that this figure may change as the Trust continues its work through the various stages of that process. At the time of drafting this opening statement only approximately half of those SCRR reviews had been completed through to report stage. 10:13 10:13

The Inquiry also recognises that, to date, the Trust has accepted the findings which have emerged from its SAI and SCRR processes which are, in the majority of cases, based on the opinion of independent external subject area experts. 10:13

whilst I understand that you, Chair, may permit space

for the ventilation of serious and significant disputes about the clinical aspects of cases, I anticipate that this will only be facilitated to the extent that it is considered necessary in furtherance of the Inquiry's Terms of Reference.

I should point out that I know that you have invited the Inquiry's Assessor, Mr. Hanbury, to consider the clinical aspects of those cases, including the SCRR cases and to provide advice. I understand that he will, in time, produce a report for the Inquiry's consideration based on his consideration of the SAI and SCRR materials. I know that in due course you will provide an indication of how that advice will inform the Inquiry's work and, if appropriate, you will make arrangements to disseminate the advice which you have received.

Let me now look at the SAIs concerning the 19 patients. Before looking at the conclusions to the SAI reviews in some detail let me briefly reflect upon the function of the SAI, its origin and purpose.

The first interim guidance on SAI reporting was introduced to Northern Ireland in 2004. It was introduced by way of circular. The circular advised that the process was developed to try and ensure that lessons are learned across the HPSS and that serious local incidents are not repeated. The overall

objective, therefore, is to strengthen organisational learning and minimise serious incidents through careful investigation. It is not in any sense a disciplinary process. Whilst the SAI process is not specifically provided for in statute, it can be observed that pursuant to the Health and Personal Social Services Quality Improvement Regulations (Northern Ireland) 2003, a statutory duty of quality is imposed on all Health and Social Care Trusts, of which SAI is a fundamental component. 10:16

The SAI process has undergone substantial development since its inception and most recently amendments were made in 2016. What began life as a brief template now involves a series of stages, membership requirements and timescales. The Inquiry notes that as recently as July of this year, the Health Minister announced plans to redesign the regional SAI procedure following publication of RQIA's review of the systems and processes for learning from SAI incidents in Northern Ireland. 10:17

In terms, then, of the current process for instigating an SAI review, the first step to be taken is at Trust level and it is to identify an adverse incident if one has occurred. Adverse incident is formally defined: 10:17

"Any event or circumstances that could have or did lead to harm, loss or damage to property, environment or

reputation arising during the course of the business of a HSC organisation, special agency or commissioned service."

This broad definition is then broken down into a number of criteria to be applied at Trust level. I won't rehearse them all, but so far as appears relevant to our work they include: 10:18

"Serious injury to or the unexplained death of a service user. 10:18
Unexpected or serious risk to a service user.
Serious harm or serious assault by a service user, member of staff or a member of the public within any healthcare facility providing a commissioned service. 10:19
Serious incidents of a public interest or concern relating to any of the criteria."

Where one or more criteria is met, the incident is considered to be an SAI. The procedure then, prior to the dissolution of the HSCB, required that Serious Adverse Incidents be reported to the HSCB, working in close partnership with the Public Health Agency using the notification form. Within the HSCB or the PHA, a Designated Review Officer attracted a key role. The role of the Designated Review Officer is to liaise with the reporting organisation, such as the Southern Trust, in determining the appropriate level of review to be undertaken, any immediate actions to be taken, setting 10:19 10:19

terms of reference for the review and seeking assurance that an associated action plan has been developed and implemented. In summary, the role of the HSCB or the PHA was that of providing oversight and assurance of the SAI process. However, the initiation and progression of SAIs remain largely the responsibility of the individual Trust as the reporting organisation.

Adverse incidents may come to be identified in a number of ways, but typically they will arise from a complaint by a service user or if they are highlighted by a member of staff. As I will touch on shortly, the Inquiry has seen examples of SAIs being raised via both of these avenues.

Members of staff who report an adverse incidents do so using an incident reporting form at local level on the Trust's Datex system. SAIs are to be conducted at a level appropriate and proportionate to the complexity of the incident under review.

There are three distinct levels of review:
Level 1 - these are referred to as significant event audits. It is the Inquiry's understanding that, in general, the majority of SAI reviews begin life at Level 1, at which stage they're referred to as an SEA. However, it is our understanding that only two of the cases which the Inquiry is to consider out of the 19 were developed as SEAs. The Trust has recently

suggested that a third case, the case of Patient 16, was handled as an SAE. On our view, this appears to be incorrect and the Inquiry will wish to take a closer look at that classification with the Trust to resolve this uncertainty. 10:22

In any event, the Level 1 approach has the following objectives: What has happened? Why it happened? What went wrong? Assess what has since been changed or needs to be changed and, above all, identify local and 10:22 regional learning.

Following an SAE, a case is either closed with no learning recommendations or closed with learning recommendations, or it can be escalated to a Level 2 or 10:23 Level 3 review.

Let me turn to the Level 2 form of review, root cause analysis reviews. The Inquiry understands that three of the cases for consideration out of the 19 were 10:23 developed as Level 2 reviews. For those SAIs which are considered serious or complex enough to escalate to Level 2, the reporting body, in this case a Trust, must submit draft terms of reference to the HSCB in addition to a proposed membership of the Review Team. This must 10:23 be done within four weeks of initiating a Level 2 review.

At Level 2 the review takes the form of a root cause

analysis investigating not only individual actions, but additionally what policies and organisational factors contributed to the incident. Upon completion of the RCA - the Root Cause Analysis - the final report should be submitted to the HSCB within 12 weeks from the date the incident was notified.

The Inquiry notes a number of occasions where this time limit was not observed by the Trust in the cases under consideration. For example, in the case of Patient 16 where an SAI was instigated following a complaint by the family, the final report was not signed off until 27th January 2020.

Let me turn to Level 3 SAIs, sometimes known as independent reviews. At Level 3 the SAI process takes the form of a full, independent review. This level of review is considered for cases which are particularly complex, often involving multiple organisations, if they involve a high degree of technical complexity that requires independent expert advice or are very high profile attracting public and media attention. The rule here appears to be that greater complexity requires greater investigatory independence. Level 3 reviews follow a similar format to Level 2 with a key distinction being that the team must be more fully independent of the organisation involved in the incident. The degree of independence of the Review Team will be dependent on the scale, complexity and

type of incident.

In light of the complex nature of review at this level there are no fixed timescales. Instead timelines for reporting, chair and membership of the Review Team will be agreed by the DRO at the HSCB at the outset when it is determined that a Level 3 review is required. 10:26

The majority, and we think it's a number of ten of the SAIs that the Inquiry will consider under part (c) of its Terms of Reference, fall under Level 3. Furthermore, the overarching review of the nine SAI cases which were actioned in 2020 were also conducted under a Level 3 format. 10:26

What happens at the completion of an SAI investigation? Upon completion of a review, a copy of the report is sent to both the HSCB and the service user or their family. Upon receiving the findings of the review, the HSCB, often in conjunction with the PHA, have responsibility for considering the report and ensuring that deems and learning are identified, including the dissemination of learning letters, newsletters and thematic reviews on a national or regional level, that there exists an assurance mechanism to ensure that learning from the SAI has been disseminated and appropriate action taken by all relevant organisations. And thirdly, that there has been a review and consideration given to learning from external or 10:27 10:27

independent reports relating to quality and safety.

Since 2016 all SAI reviews must be accompanied by a completed checklist for engagement with the service user or the patient. The purpose of this checklist is to confirm whether the patient or family has been made aware of the SAI review. 10:28

I pause here to remind the Inquiry of at least one occasion when it would appear, subject to any further evidence which may be received, on which such a checklist was erroneously completed. That was the case of Patient 15 which you heard about at the September patient hearings. 10:28

At this juncture, Chair, I will provide an overview of each of the SAI reviews, their findings and the recommendations which emerged. At this point it's helpful to keep one eye on the cipher sheet, or your appendix. You'll be familiar with the names of some of these patients, having heard from them or their families in June and September. That document otherwise provides the dates on which the incidents arose and when the SAI reviews were completed. 10:29 10:29

I start with SAI 1, as we call it, and that's the case of Patient 95 who initially presented electively to Craigavon Hospital for investigation of a visible haematuria. A cystoscopy on the 14th June 2009

revealed a large bladder tumour which was resected. Mr. O'Brien performed surgery on Patient 95 on 15th July 2009 during which a surgical swab was left in the cavity, an error which is known as a never event, it should not happen. Patient 95 subsequently attended the histology outpatient clinic in Craigavon Area Hospital on 5th August 2009 with a plan to have a surveillance CT in three months and an outpatient's review appointment in four months. That CT scan was undertaken promptly on 11th October 2009. The reporting consultant radiologist described a mass measuring 6.5 centimetres in the region of the right renal bed. While he did not diagnose a retained swab, his report clearly highlighted a pathological abnormality. 10:30 10:30 10:31

Mr. O'Brien did not read the report and no one took steps to further investigate this abnormality. It was Mr. O'Brien's practice, or so it is reported in the SAI report, to review radiological and laboratory reports when the patient returned for post-operative follow-up. In this case, to make matters worse, the planned four month follow-up review never took place due to the waiting times for review at outpatients. 10:31 10:31

Patient 95 next attended the Accident and Emergency Department on 6th July 2010, a full year after her surgery, with a two week history of abdominal pain. After some delay an emergency laparotomy was performed

on 21st July 2010 and a medium swab was identified and removed.

An SAI was commissioned by the Director of Acute Services. Understandably, perhaps, the Review Team determined that the primary issue was the retention of the swab. The secondary issue was the delay in diagnosis. 10:31

Nevertheless, Chair, it may appear to you, upon consideration of the report, that there was remarkably little attention given to this latter issue. 10:32

The recommendations made in the report focused on the need to improve process for counting and recording swabs and to generally improve that aspect of surgery. No doubt this was an important consideration. But the Review Team said nothing of the importance to be attached to reading radiology investigations in a timely fashion. They did make a recommendation in respect of the need to achieve a reduction of urological patient follow up waiting times. The Inquiry may consider that this was a well-intentioned recommendation, and no doubt a shorter waiting list would have allowed the problem associated with the retained swab to be discovered much sooner. But in the real world of longer waiting lists, should the Review Team not also have been drawing attention to the need for consultants to read their reports when they were 10:32 10:32 10:32

available, to mitigate the risks associated with the long waiting list?

Chair, I will shortly refer to a number of other cases which, with some variation, have in common a failure on 10:33
the part of Mr. O'Brien to promptly acknowledge or action the results of investigations. It may be that there are reasons, and perhaps good reasons, to explain this omission, but in all of these cases patients were endangered or potentially endangered. Consideration of 10:33
the case of Patient 95 with those of Patient 5, Patient 7, Patient 90 and Patient 92, which I'm going to come on to talk about, indicate an aspect of this critical shortcoming.

10:34

As I've said, the earliest indication of this issue was with respect to the case of Patient 95 and the retained swab. The case has been discussed in the Section 21 response of Mr. Eamon Mackle and he reinforces the concern that in 2009 a never event occurred where a 10:34
swab was post operatively left in a patient and only discovered a year later. He goes on to say:

"A CT scan had been reported as abnormal three months later but an investigation revealed that Mr. O'Brien 10:34
had a policy of not reviewing results until patients attended outpatients. Aidan O'Brien raised multiple objections when it was suggested that he should be reviewing all results. Therefore, an instruction was

issued to all consultants informing them that it was their responsibility to review all of the results of investigations on their patients once they are available."

In the absence of a recommendation or action plan in the report of the SAI review in respect of this issue, it was left to local management within the Urology Service to emphasise the importance of reviewing investigation results as soon as they are available. 10:35

After a Mrs. Corrigan drew the issue to the attention of the medical team, she was met with a challenge from Mr. O'Brien. His e-mail to Mrs. Corrigan of 25th August 2011 will be worthy of further consideration in evidence, but this prompted Mrs. Corrigan to seek help from Mr. Mackle and, in turn, he referred the issue to Mrs. Rankin on the 25th August 2011, identifying the matter as a governance issue which he appeared to expect her to resolve. 10:36

It is unclear how this matter was resolved, if at all, and it is the kind of governance consideration which the Inquiry will wish to explore at these hearings. It does not appear that the Trust implementing any form of monitoring of Mr. O'Brien's management of patient results. Whether he ever complied with the direction given by his management is currently unclear. The cases to be considered in the next short while suggest

that he may not have done so.

In general terms as the Inquiry processes its work it will be an important task to examine whether the lessons which were to be learnt from the process of 10:37
reviewing Serious Adverse Incidents was effective. The Inquiry is bound to ask questions about whether the Trust saw it as part of its governance business to lift the lessons out of Serious Adverse Incident reviews and
to use them to impose rigorous service-wide improvement 10:37
plans. The outcome of that investigation should not be prejudged, but the early evidence suggests that much more could have been done.

Let me turn to the second SAI which is under our 10:37
consideration. This concerns Patient 10. You'll be very familiar with the circumstances of that case, having heard from her husband in June.

A referral letter in connection with Patient 10 was 10:37
received into the booking centre of Craigavon Area Hospital on 29th September 2014 and given to Mr. O'Brien to triage on 30th September. He was fulfilling the duties of the urologist of the week at
that time, however, Patient 10 was not triaged by him. 10:38
This had the effect that Patient 10 was placed on the routine waiting list and was not seen by a consultant urologist until 6th January 2016, a wait of 64 weeks. When she was seen it was found that she had a probable

cystic renal tumour.

Mr. Haynes raised a Datex and the matter was screened for an SAI review. One of the factors indicated by the SAI review as giving rise to the delayed diagnosis was the failure to triage. It said in the review that the opportunity to upgrade the referral to red flag was lost by the omission to triage. The Review Team pointed up the absence of any communication from Mr. O'Brien or his secretary when, following his failure to triage this case and several others, efforts were made to seek management advice from him. The report suggests that those efforts to engage with him were simply ignored. In the recommendations section of the SAI report the Review Team pointed to an increased risk of harm to patients if the opportunity to secure early intervention via triage is lost. They made a number of recommendations. 10:39 10:39 10:40 10:40

In particular, they invited the Trust to review its default procedure which kicked in when triage was not performed. They also made specific reference to the circumstances in the Urology Department directing management to the urgent need to address the issue of untriaged referrals. 10:40

It will be recalled that this report and its recommendations were finalised at or about the time when Mr. O'Brien was made subject of a monitoring

arrangement in respect of his compliance with his obligation to triage. While in due course I will highlight certain concerns about the effectiveness of that monitoring arrangement, the Inquiry may wish to consider with the Trust's witnesses why it took so long for the Trust to impose a formal control, it being known that the failure to triage patients placed them at an increased risk of harm, how can the failure to intervene at an earlier stage be explained? Why did it take the intervention of Mr. Haynes in January 2016 to raise an incident report before anything was done? Even then, why did it take from January 2016 until January 2017 to formulate a monitoring plan? 10:41 10:41

For his part, Mr. O'Brien prepared a written response to the SAI back in 2017. That response is available on our papers. In his response, Mr. O'Brien makes the point that even if he had triaged, the referral letter which was received by him would not have allowed him to upgrade the case to Red Flag. Mr. O'Brien goes on to make the point that the inclusion of triage of all letters of referral within the duties and responsibilities of the urologist of the week was inappropriate. 10:41 10:42 10:42

While no doubt Mr. O'Brien will have carefully thought through this stance, and may still feel that it is justified, the Inquiry will wish to explore with him in due course how matters could have been better handled,

can he properly justify the abandonment of this duty and the failure to communicate when assistance was required? Ultimately the issue rests with the Trust and operational and medical management. They were working with a colleague whose actions they must have believed jeopardised patients and that was known. Why did they not act sooner? 10:43

The third of our SAIs is a group of five cases, all referring to the issue of triage. The case I have just referred to, that of Patient 10, was regarded by the Trust as the index case and. In light of that index case, an informal Lookback Review took place and it identified other cases where triage had not been performed. 10:43

It is a notable feature of this SAI that the outcome was not finalised for some time. As I have pointed out, this is not an isolated case of delay. The SAI concerned the care of five patients who were not triaged on various dates in 2015 and 2016 and was commissioned by the Trust in 2017. The SAI review was not signed off until 22nd May 2020, some four to five years after many of the incidents occurred. 10:44

Fundamentally, an SAI process is directed towards extracting learning from adversity in order to facilitate remedial action and to prevent future error. It may appear to the Inquiry that a process which 10:44

cannot be completed in a reasonable period of time cannot truly serve those objectives. The delay in this review, this particular review, remains unexplained and it is an issue which will be explored with the Trust's witnesses at the public hearings. 10:45

I do not propose to outline the facts of each of the five patient cases. They all share the common feature of being a referral received by the Urology Department when Mr. O'Brien was urologist of the week. They were 10:45 each inappropriately marked as routine or urgent when they should have been red flagged upon receipt at the hospital. His failure to triage led to a situation in which the cases were placed on the Trust's routine waiting list by operation of the default arrangement, 10:45 whereas effective triage by him would, or at least could have led to an upgrade to Red Flag. This group of patients suffered delays to diagnosis and treatment of between six and ten months. Let me illustrate the point by reference to one example. 10:46

Chair, you are familiar with the case of Patient 13, he gave evidence before you in June. His GP referred him to the Trust's Urology Service on 28th July 2016. The referral was marked as a routine referral, despite a 10:46 recent history of haematuria. The referral was not triaged by the urologist of the week who at that relevant time was Mr. O'Brien. Instead, using the default mechanism, Patient 13 was placed on a routine

waiting list in keeping with the general practitioner's erroneous grading of the case. As part of an internal review Patient 13's referral was upgraded to a Red Flag referral. Patient 13 was reviewed at clinic on 31st January 2017. Following a further investigation, he was diagnosed with prostate cancer and locally advanced bladder cancer. The SAI report concluded that there had been a resultant six month significant delay in obtaining a diagnosis and a recommendation of treatment for his bladder cancer. 10:47

The SAI report covering the five cases made a number of pertinent recommendations. Having regard to the shortcomings associated with the referrals which had come in from general practitioners of the patients concerned, some of those recommendations were directed to the HSCB and the primary care sector. Six specific recommendations were directed to the Trust. The recommendations appear to have been well considered. Chief amongst them was a recommendation to abandon the informal default triage process and, if replaced, a strong suggestion that it should take the form of an escalation process that performs within the triage guidance and does not allow Red Flag patients to wait on a routine waiting list. 10:48

Additionally, the recommendations invited the Trust to think through what it was asking its consultants to do. The Trust was told to review the model for urologist of

the week to assure itself that it was feasible for the consultant to conduct triage in addition to the other duties of that role. The Trust was encouraged to formulate written policy and guidance to better inform their consultants as to what they were expected as part of triage. And thirdly, having achieved that clarity, the Trust was invited to audit compliance with triage and to link those audits to the annual appraisal framework and to escalate non-compliance to the senior management team. 10:49

The recommendation at 10 of the report is particularly pointed. It appears to have been motivated by a determination to confront what the Review Team appears to have seen as an organisation and a culture which did not have an appetite to challenge difficult staff and difficult issues. It said: 10:49

"The Trust must set in place a robust system within its medical management hierarchy for highlighting and dealing with difficult colleagues and difficult issues, ensuring that patient safety problems uncovered anywhere in the organisation can make their way upwards to the Medical Directors and Chief Executives' tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputational and influence." 10:50 10:50

In many respects this recommendation is a remarkable

message to emerge from an SAI review. As I have highlighted, it is a view which was being expressed many years after Mr. O'Brien had decided that he could not or would not comply with the arrangements for triage, and yet the report was signed off less than two months before his retirement. The Inquiry will have an early opportunity to ask one of the members of the Review Team, Mr. Haynes, about this delay, and to explain more fully what it was that informed this particular recommendation. Equally, Dr. O'Kane will be asked to help the Inquiry to understand whether, on the basis of her experience within both the Medical Director's office and now the Chief Executive's office, this recommendation resonates with her and, if so, what action has been taken as a result. 10:51 10:51 10:51

Mr. O'Brien prepared a lengthy written response to this SAI report. This is available to the Inquiry. In his response Mr. O'Brien is critical of the SAI report. He says that the SAI review investigated the failure to triage urgent and routine referrals in isolation of other pressures in clinical priorities which he indicates in his view are more important. 10:52

The Inquiry will note that, in essence, the Review Team told Mr. O'Brien, through their recommendations, that they thought he was wrong. In essence he was told to desist from his chosen method of advanced triage and to review his approach so that he could comply with the 10:52

obligation to triage all GP referrals in a fashion which complies with the guidelines.

The Inquiry may consider that, regardless of the substance of this recommendation, and regardless even of the merits of the respective sides of the triage debate, the more important message is that it is for operational and medical management to intervene at the earliest possible opportunity to ensure that where a practise problem is known to exist, it is investigated, solutions found and the matter resolved. It should not take an SAI review reporting five years after the event to formulate the correct management approach or a possibly correct management approach, particularly where patient safety is at the heart of the matter.

The HSCB had been advised of these cases on the 21st September 2017, some months after it was determined to initiate an SAI review. It is not entirely clear whether the HSCB made the connection with the earlier SAI concerning Patient 10. Upon notification of the five cases, the HSCB immediately asked the Trust whether it had assured itself that no other referrals had slipped through. HSCB was advised that the Trust had performed a lookback exercise and that this lookback exercise was complete. The Inquiry may consider that this response, concise though it was, does not candidly explain that there was a widespread failure of triage associated with this consultant and

that there were many more cases left untriaged than the five selected for SAI review.

It does not appear that the HSCB sought a specific explanation for the delay in production of the SAI report. It is indicated that generic letters were sent to the Trust to point out that the review was overdue, but no specific follow-up action was taken. The Inquiry will be anxious to explore with the former HSCB why a more proactive approach was not taken to pushing for the production of the report. The report was finally received by the HSCB in May 2020 and was closed the following year with no regional learning identified. 10:54 10:55

The fourth SAI, that concerns Patient 16. Patient 16's case concerns the failure on the part of Urology Services to arrange for the timely removal and replacement of a stent and the attendant communication failures and serious medical complications which followed. Again, members of the Inquiry, you'll be familiar with this case, having heard from the daughter of Patient 16 in June of this year. 10:55

The SAI review found that there was a delay associated with the changing of Patient 16's ureteric stents due to the lack of effective communication systems and processes and long waiting lists. The Review Team considered that the delay was probably significant in 10:56

that it rendered more difficult the process of removing and replacing the stents and had an adverse impact on Patient 16's level of pain and comfort towards the end of his life.

10:56

Mr. O'Brien prepared a written response to this SAI report. Again that response is available to the Inquiry. In his response Mr. O'Brien makes the point that one of the letters, whilst received, was not addressed to him but, rather, to another consultant. 10:57 He explains that he has no memory of ever having received that letter. With regard to his failure to respond to requests for admission of this patient, Mr. O'Brien refers broadly to a lack of time available to do so. 10:57

Nevertheless, it is clear that several items of correspondence are likely to have arrived with Mr. O'Brien or his secretary during the relevant period from 26th November 2015. However, the Inquiry may 10:57 consider that in light of its Terms of Reference the real issue to be confronted here is the absence of an effective Trust system to manage and track the administrative working of clinical decision-making. Patient 16 was well supported by an active and 10:57 energetic family who were willing advocates on his behalf. Yet, despite even their efforts, they could not penetrate the system to secure appropriate and timely treatment for him. The frustration and worry

experienced by the daughter of Patient 16 has been well and fully articulated to you.

The six recommendations set out in the SAI report, two of which were directed to the HSCB, seek to grapple with the shortcomings revealed by this case. Perhaps the central recommendation was the call for the Trust to develop written guidance for clinicians and administrative staff to address the management of clinical correspondence for the purposes of ensuring that such correspondence is actioned in an appropriate and timely manner. The Review Team identified the need for a process of audit to assist with securing compliance and the importance of linking this issue into consultant appraisal programmes and for an escalation process to be developed to target non-compliance. 10:58 10:58 10:59

Again, the Inquiry will no doubt recognise these recommendations as commendably thoughtful and well focused. A familiar set of questions emerge, however. Any clinician at any time may be capable of an administrative slip, and important clinical correspondence may be missed. The potential risks to the wellbeing of the patient are, of course, obvious. In circumstances where it was known that Mr. O'Brien was often, to put it at its most neutral, less than efficient in addressing his obligations in respect of clinical correspondence, a concern that was known at 10:59 10:59

least as far back as the commencement of the MHPS process four years earlier, why did it require the report of an SAI review to make recommendations to formulate a system of governance?

11:00

The Inquiry will ask, since this issue was widely known, why was the organisation - that is the Trust - dilatory in addressing it and has anything changed today?

11:00

The fifth SAI was conducted as an SAE, a Level 1 SAI, and it concerned Patient 90 who was admitted to Craigavon Area Hospital on 9th May 2018 for surgery that day, including cystoscopy, replacement of ureteric stents and bilateral ureterolysis. Following the 11:01
procedure, Patient 90's condition deteriorated and he was admitted to the Intensive Care Unit critically ill. Patient 90 suffered cardiac arrest and died on the same day.

11:01

The SAI or the SAE Review Team noted that ureterolysis was a high risk surgical procedure which was rarely performed in the Trust. Patient 90 was a man with significant comorbidities. He had been added to
Mr. O'Brien's surgical waiting list a year before the 11:01
surgery took place. The results of a CT scan dated December 2016 were available at the time he went on to the list, which showed that Patient 90 had an enlarged heart and that he awaited an outpatient echocardiogram.

This remained outstanding at the time of surgery. Importantly, the Review Team found that despite the comorbidities, he did not receive the benefit of a formal preadmission, preoperative assessment with optimisation of his clinical condition prior to surgery in contravention of Trust and NICE guidance. 11:02

Mr. O'Brien had consented Patient 90 for surgery. Amongst the concerns expressed by the SAE Review Team they noted that they were unable to find documentation of any detailed discussion of Patient 90's individual risks based on the comorbidities described in his notes. 11:02

In his response to the review, Mr. O'Brien expressed regret for failing to send Patient 90 for a cardiac work up, including echo and coronary angiography, although he insisted that he did not regret the surgery since the patient's quality of life was poor. However the anaesthetist for the surgery indicated to the Review Team that in his view there was no pressure to get the surgery done. 11:03

It was clear to the SAE Review Team that this surgery ought not to have proceeded in the circumstances. It is notable that in this case, just as in the case of Patient 95 - that is the retained swab case of eight years earlier - that the Trust continued to have a problem with clinicians failing to take the basic step of considering the results of investigations for their 11:03

patients in a timely fashion. The Review Team directed the Trust to the need to develop and implement guidance for clinical results sign-off and to audit compliance.

Additionally, it told the Trust of the need to focus on ensuring that all patients having formal preoperative assessment completed prior to surgery and to enable formal consent, the risks and benefits of surgery should be discussed with the patient. The Inquiry will be anxious to scrutinise what progress has been made with these kinds of recommendations. 11:04 11:04

The sixth SAI was also conducted as an SAE. Patient 92 was admitted to a ward for treatment in November 2017 and prior to her discharge a follow-up outpatient urology review appointment was arranged for six weeks and a repeat CT abdominal scan for three months' time. Patient 92 did not receive the follow-up urology outpatient appointment, however she did have a repeat CT scan on 13th March 2018, and the report was finalised on 20th March of that year. It referred to a solid nodule, suspicious of renal cell carcinoma. There was no follow up after the CT scan was reported. The results of Patient 92's CT scan sat unread, just like the results for Patient 90 and Patient 95 before her, despite the fact that communication had been e-mailed to the referring consultant, Mr. O'Brien, to his secretary, and to an additional secretary on 20th March 2018. 11:05 11:05 11:06

Patient 92 attended her GP on 10th July 2018 complaining of right sided abdominal pain, that is four or five months after the CT report was available. Fortuitously her GP noted the overlooked CT report and 11:06
immediately forwarded a Red Flag referral to Craigavon Area Hospital. Patient 92 was ultimately found to have a tumour demonstrating features in keeping with papillary renal cell carcinoma. The Level 1 Review Team concluded that had Mr. O'Brien acknowledged and 11:07
responded to the e-mail from the Radiology Department and had the Radiology Department escalated the to the Cancer Tracker Team, Patient 92 would have received treatment for her cancer at an earlier stage. The Review Team highlighted that the Trust had no single 11:07
formal process for following up test results and no formal process for tracking letters or e-mails to ensure that they had been received, acknowledged, reviewed, or actioned.

11:07

The Review Team made a number of recommendations. Again, the principal concern was to direct the Trust to consider a single system and process by which results can be communicated to referring consultants and electronically signed off by the consultant. However, 11:07
as will be seen shortly, still further cases were to emerge from the failure on the part of Mr. O'Brien to read and action test results and the failure on the part of the Trust to devise and enforce compliance with

the safer approach.

The Inquiry will wish to consider the remarks of Mr. Mark Haynes in connection with this particular SAE which are also of more general significance. He has told the Inquiry: 11:08

"I am of the view that while SAI investigations and reports may identify individual clinician failings within the reports, the subsequent recommendations often do not address any action plan to address these individual failings or monitor subsequent performance." 11:08

He has added that the Trust is aware of the risk relating to the length of time an SAI process can take to investigate. He has also indicated, referring particularly to the case of Patient 10, which is one of the triage cases, that another weakness of the process is that a number of SAI recommendations over many years have taken significant periods to implement. Despite this level of awareness, it is not clear what steps the Trust, the former HSCB, or the PHA have taken to speed up the process. The Inquiry might be inclined to the view that if the goal is to learn valuable lessons from clinical and/or governance failure, a premium should be placed on an expedited investigation and a streamlined process for implementing recommendations and action planning. Mr. Haynes has explained that many action plans sit uncompleted, including that arising out of 11:08 11:09 11:09

the case of Patient 92, because they are not fed back or escalated through the acute governance meeting.

So, members of the Inquiry, those are the SAIs in the timeframe up to 2020. There were nine SAIs, as you know, triggered in 2020. Before considering those nine SAIs I'm going to take two preliminary steps. First, I think it will be helpful to provide you with an overview of the Trust's use of the Multidisciplinary Team process in its Urology Service since shortcomings in that process were found to occur repeatedly in consideration of those nine SAIs. 11:10

And Secondly, albeit more briefly, I'm going to go back to a ground I touched on yesterday, which is the circumstances which led to the commencement of those nine SAI reviews. So, in the 20 minutes or so leading up to the break I'm going to refer to the Multidisciplinary Team approach to patient care. 11:11

The objective of the Multidisciplinary Team, or the MDT as I will call it, is to ensure that all patients with a new diagnosis of urological cancer are discussed by Multidisciplinary Team members who agree treatment plans for patients prior to treatment commencing. 11:11

The purpose of an MDT is to recognise survival and quality of life, providing holistic patient-centred care to explore all options of treatment available, to

offer these options through clear communication and to appreciate the impact of these options on patients' lives. The MDT brings together staff with the necessary knowledge, skills and experience to ensure high quality diagnosis, treatment and care for patients 11:12
with cancer. MDT working has been advocated in each of the NICE Improving Outcomes Guidance and is strongly supported by clinicians. The aim is to provide a high standard of care for all patients, including efficient and accurate diagnosis, treatment and ensuring 11:13
continuity of care. The MDT should ensure a formal mechanism for multidisciplinary input into treatment planning and ongoing management. Amongst its key functions, it should provide an opportunity for multidisciplinary discussion of all new cases of 11:13
urological cancer presented to them, assess newly diagnosed cancers and determine, in light of all available information and evidence, the most appropriate treatment and care plan for each individual patient, ensure care is delivered according to 11:13
recognised guidelines, ensure that the MDT work effectively together as a team regarding all aspects of diagnosis, treatment and care, and to facilitate communication with other professional groups within the hospital and between the MDT and other agencies, such 11:14
as primary care and palliative care.

Let me touch upon MDT within the Southern Trust. An MDT for urological cancer at the Southern Trust was

formally established in April 2010. Mr. Akhtar, consultant urologist, was its lead clinician and the Chair of its MDM from April 2010 until March 2012. From April 2012 until October 2016 the lead was Mr. Aidan O'Brien. With increasing numbers of consultant urologists joining the team in Southern Trust, the functions of lead clinician and of Chair of the MDM were separated to enhance active participation in and responsibility for the MDM. The lead clinician from late 2016 has been Mr. Anthony Glacken. The responsibilities of the lead clinician are set out in a document to which I will refer, TRU-99642. The lead clinician is joined on the Multidisciplinary Team by core members and extended members in accordance with the Manual For Cancer Services, Urology Measures. The Urology Cancer MDT is made up of the following core members or their cover: Urology surgeon is the clinical lead, clinical oncologist with responsibility for chemotherapy, imaging specialist, histopathologist, clinical nurse specialist and the MDT coordinator. It is not feasible in the context of this opening statement to address the functions of the core members in any particular detail.

11:14 11:15 11:15 11:15

As I discussed, the typical work of an MDM, it will be noted that the role of the coordinator is pivotal and he has a number of influential responsibilities, including tracking patients, data collection and working closely with the MDM Chair.

11:15

The urology MDT in the Southern Trust meets each Thursday afternoon with the number of patients to be discussed generally capped at 40. The meeting takes place in a room with video conferencing facilities 11:16
enabling communication by video to Daisy Hill Hospital in Newry and with the specialist MDM in Belfast. It is the policy of the Southern MDT that all MDMs should finish by 5:00 p.m. at the latest. It has been the experience of the MDT that the number of cases to be 11:16
discussed has had to be limited to 40 in order to enable the MDM to finish by that time.

In the five years between 2015 and 2020 there were 308 Multidisciplinary Team meetings leading to a discussion 11:17
of 8,710 cases. During the past decade there has been a 40% increase in the number of red flag referrals throughout Northern Ireland. The greatest rise occurred within the Southern Trust area with an increase of 84% from 410 in 2013 to 753 in 2014. The 11:17
increase continued throughout that decade and in 2015/16 there were some 1,878 red flag referrals. More recent figures are not yet available to the Inquiry, but the increasing reportage of cancer symptoms brings with it additional demands and pressures for the MDT 11:17
arrangements within the Trust.

All new cases of urological cancer in those following urological biopsy will be reviewed. Patients with

disease progression or treatment related complications will also be discussed and a treatment plan agreed. Patients' holistic needs will be taken into account as part of the multidisciplinary discussion. The clinician who has dealt with the patient will represent 11:18
the patient and family concerns at the meeting and ensure the discussion is patient centred. The MDT coordinator is responsible for collating the information on all patients being discussed and ensuring that all necessary information is available to 11:18
enable clinical decisions to be made. In all instances it is the responsibility of the presenting clinician to ensure all appropriate clinical results are available for the meeting.

11:18

Investigation plans and treatment recommendations are formulated during the meeting and recorded in narrative format by the coordinator. The Chair should articulate a summary of the recommendations arising from the discussion before proceeding to the next case. 11:19

It has been agreed by MDT core members that it is the responsibility of urological surgeons to provide a clinical summary regarding each patient to be discussed at MDM for the first time and an update when patients 11:19
are to be discussed again at a later juncture in their clinical course. The clinical summaries and updates are provided to the coordinator and they are provided in a textual format suitable for uploading on to the

CaPPS database as a permanent record. It is also the responsibility of the coordinator to request provision of a clinical summary adequate to enable MDM discussion.

11:19

The decisions which emerge at an MDT are in the form of recommendations. These recommendations can only be as good as the information available to the MDT at the meeting. The final decision on the way forward needs to be made by the patient in discussion with the clinician. MDTs should be alerted if there are significant changes to their recommendations and the reason for this so that they have the opportunity to review and learn from these cases.

11:20

11:20

Attendance at the core MDT meetings must be sufficient to make a clinical decision. It has been the policy of the Southern Trust MDT to have a minimum of two consultant urological surgeons present at each MDM. In the event of an MDM not being quorate it is Trust policy that the discussion of patients who definitely do not require the input of the absent member should proceed. In the absence of a core member, management plans are agreed with the deputy and communicated to the absent member by the chairperson or his nominee. Otherwise discussion will be deferred to the next MDM and it will be the responsibility of the coordinator to reschedule the patient and notify the absent member of the deferment.

11:20

11:20

The quorum for the Urology Cancer MDT is made up of the following core members or their cover: Urology surgeon, clinical oncologist, imaging specialist, histopathologist, clinical nurse specialist and the MDT coordinator. In the cases which we will consider shortly, the nine SAIs that followed in 2020 and which were considered by Dr. Hughes and his team, he reported that quorate meetings were rarely achieved for Urology Cancer MDMs in the Trust. 11:21

Patient Pathways

NICaN created and circulated the standard working policy for Urology Cancer MDT in October 2009. This became the initial template for MDTs. Importantly it indicated those patients who should be treated locally and those patients which should be sent to the specialist MDM in Belfast. The policy indicated that patients with small renal mass, penile and testicular cancer, amongst others, should be referred to be discussed at the regional specialist MDM. In four of the SAI cases considered by Dr. Hughes, which I will refer to shortly, the failure to refer or in one case the delay in referral to regional specialist MDM was identified with concern. 11:22

The Inquiry may be interested to consider the care pathways for the main urological cancers which have been described in the NICaN Regional Urology Group

charts as follows:

Prostate - and I provided you with a reference for that. Castration resistant prostate cancer, renal, penile cancer and there's a Trust document called the Protocol Care For Urology Cancer MDT circulated in January '20 which reiterates the need for certain cancers to be referred to specialists in Belfast. 11:23

Outcome Reports From MDT 11:23

MDT outcome reports are generated from the CaPPS database for each patient. The outcome reports would be signed by the individual chairing the MDT that day and are then communicated to a number of stakeholders. Those reports are communicated to the referring or treating clinician if he or she is not a member of the specialist MDT. A summary of all MDT outcomes is circulated electronically to the Urology MDT and these outcomes are also available on the ECR, the Electronic Care Record. They are also circulated to the patient's GP. Any referrals required should be generated by the MDT coordinator as each case is discussed, and e-mailed to the relevant service following the MDT meeting and a printed record of the outcome is filed in the patient notes. 11:23 11:24 11:24

It is the responsibility of the clinician to ensure the treatment plan agreed at the MDT meeting is followed. If a change of plan is required the clinician

responsible for the patient care should represent the case at the next scheduled MDT meeting and provide the reason for the change. In several of the cases which were considered by Dr. Hughes and his Review Team, and in a number of the SCRR reports produced to date, there was indication of evidence of deviation from the treatment plan which had been agreed at the MDT meeting, but no indication that these cases were revisited by the MDT to discuss the change in plan. 11:24

Following the MDM it is the policy of the Trust's MDT that all patients are reviewed by the end of the first week following their MDM discussion. If that is not possible the Chair of the MDM may decide to allocate the review of any patient to that of another consultant. It is also the policy of the MDT that patients should be offered the opportunity of referral to consultant specialists relating to each management modality, such as oncologists, for their further advice so that the patient may arrive at an optimally informed choice. 11:25 11:25

I want to briefly summarise some of the concerns that are apparent from the Inquiry's investigations to date arising out of the Southern Trust MDT. 11:26

The first concern relates to what Mr. Glacken has said in his Section 21 response in terms of the understanding of the role of lead clinician. Within

his response he indicates that he has never been presented with a job description for the role and has been presently working with other medical staff to create one. It is unclear whether hes has been able to access the responsibilities document which sets out the duties of the lead clinician which I have referred to above. The Inquiry will wish to explore with Mr. Glacken whether, if he had any uncertainty about his responsibilities as lead clinician, or if there was any ambiguity at all, this could have caused or contributed to the kinds of concerns which the SAI reviews have identified. 11:26 11:27

A further issue of concern which emerges from the papers to date is the difficulty which the Trust has encountered in recruiting sufficient clinical oncologists and radiology expertise to support the MDM. It appears that there has been a chronic inability to recruit adequate numbers of clinical oncologists and radiologists. 11:27 11:27

Another issue relates to the Cancer Tracker Coordinator. It is clear that the Urology MDM has been underresourced for appropriate patient pathway tracking. As I will shortly indicate, the SAI Review Team under Dr. Hughes found that the patient tracking related only to diagnosis and first treatment. Within the MDM there has not been the facility to enable tracking to function as a whole system and whole 11:28

pathway process which resulted in preventable delays and deficits in care.

Another concern relates to the Cancer Nurse Specialist and key worker. The MDT Guidelines indicate that all 11:28
newly diagnosed patients should have a key worker appointed. If a specialist nurse is excluded from the cancer pathway it can create a clinical risk. The Inquiry will wish to consider whether this was adequately understood by the senior service managers 11:29
and the professional leads within the Trust. In none of the nine cases considered by Dr. Hughes and his team did patients have access to a key worker or a Cancer Nurse Specialist.

11:29

Another issue that has emerged as a concern associated with the Southern Trust MDT is inadequacy of the job plan. The Inquiry has observed that in 2016 many MDT members raised concerns about the inadequate allocation of hours within their job plans for preparation and 11:29
effective participation within the Urology MDM. Some steps to resolve that were taken but it is unclear currently whether all the requisite job plans were amended to reflect the required preparation time and to fully resolve this issue. 11:30

Having regard to the problems which have been identified with the operation of the MDT, the Inquiry will wish to further assess whether members of the MDM

are adequately resourced for their preparatory work and attendance.

Other issues briefly, members of the Inquiry, that have emerged in association with the MDT is the absence of audit, the regular failure to achieve quoracy, and I would draw your particular attention to the problems identified in the NICaN peer review of the Southern Trust's Urology MDM following a visit in June 2015. The review highlighted four concerns: The absence of cover arrangements for the urologist supporting the MDT. The low attendance by oncology and radiology. Nephron sparing surgery was being undertaken locally when it should have been referred to the specialist MDT. A fourth concern relating to the fact that at that time routine referrals were waiting up to 52 weeks for their initial clinical appointment. Some assurance was provided to the peer review. The reviewers were told that consultants triaged all referrals so that even routine referrals were looked at and could be upgraded, if appropriate, hence avoiding some of the problems associated with the waiting list. It is now clear that this assurance was not factually correct. It is the case that Mr. O'Brien did not triage routine or urgent referrals and, as I've explained above, the omission to do so in combination with the extensive waits created the kind of risk which the peer review was evidently concerned about.

11:30 11:31 11:31 11:31 11:32

The peer review report which emerged placed a 35% rating on its assessment of the quality of the review, whereas -- I'll say that again. It produced a peer review assessment of only 35% which is indicative of its view of the quality of the MDM, whereas the clinical leads on the ground in that MDT produced a self-assessment which was recorded as 70%. It would appear that members of the MDT believed there was greater compliance with the requirements of a properly functioning MDT than was actually the case. 11:32 11:33

I think that would probably be a suitable time for a break.

CHAIR: I would suggest that. Ladies and gentlemen, if we could be back promptly at quarter to twelve please and we'll finish in or around one o'clock for lunch. 11:33

THE INQUIRY ADJOURNED BRIEFLY AND RESUMED AS FOLLOWS:

CHAIR: Mr. Wolfe. 11:46

MR. WOLFE KC: Thank you, Chair. By way of brief background to the nine Serious Adverse Incident reviews that were conducted from 2020, you'll recall, as I said yesterday, that a number of concerns arose in respect of the practise of Mr. O'Brien from June of that year, leading to the early alert, a formal lookback and nine SAI reviews. 11:46

The starting point, or so it appears, was an e-mail

sent by Mr. O'Brien to Mr. Haynes on 7th June 2020 wherein Mr. O'Brien explained that he had added ten patients to the existing list of patients for urgent treatment. Mr. Haynes has told the Inquiry that the e-mail caused him concern. It caused him to be suspicious that Mr. O'Brien may not have been completing his dictation following outpatient clinics and that he may not be completing the patient related administrative follow-up. He escalated his concern to the Medical Director on 11th June. Due to the potential safety, patient safety concerns, the Trust conducted an administrative or informal lookback exercise considering Mr. O'Brien's theatre activity for both emergency and elective care between January 2019 and May 2020. I told you about the results of that lookback yesterday. 11:47 11:47 11:47

The Inquiry has been told that the administrative lookback highlighted a number of concerns in both emergency and elective procedures. A little later on 7th July 2020 Mr. Haynes raised concerns about the care provided to Patient 1 and Patient 9. In his Section 21 response to the Inquiry, Mr. Haynes explains that the deeper Lookback Review of Mr. O'Brien's care at that time revealed additional patients who had significant findings on imaging which had not been actioned, such as Patient 5. Pathology showing cancer, which had not been put through MDM, and the patient was unaware, such as Patient 8. Delayed oncology referral in the case of 11:48 11:48

Patient 3, and issues with prostate cancer management. Mr. Haynes also recalls having noted that Patient 4 had been prescribed low dose Bicalutamide in January 2020. He describes having made an assumption at that time that this was perhaps an error. However, when referring Patient 4's care in October 2020, Mr. Haynes describes having recognised that the treatment he received fitted the same pattern as other patients and raised this as an incident report, an IR1. 11:49

Other incident reports were at that time raised by Mrs. Corrigan and by Mr. Glacken. Ultimately a total of nine cases were screened for SAI review. The Review Team in each of the nine was led by Dr. Dermot Hughes and included Mr. Hugh Gilbert, an expert external clinical advisor from the British Association of Urological Surgeons. This review, as you know, was conducted as a Level 3. 11:50

Let me deal briefly with the nine cases which were separately the subject of an SAI review and the results ultimately captured in an overarching review. 11:50

Patient 1 was diagnosed with Gleason 4 + 3 prostate cancer on 28th August 2019. His case was discussed at MDM on 31st October 2019, at which time the recommendation of the MDM was to commence LHRH or hormone therapy and to refer Patient 1 for an opinion from a clinical oncologist regarding external beam 11:50

radiation therapy. The recommendation of the MDM was not implemented. Instead, Patient 1 was continued on low dose Bicalutamide, 50 milligrams daily, a regime he had been on from in or about mid October 2019.

11:51

Patient 1 was commenced on LHRH on 1st June 2020 and was referred to oncology by Mark Haynes on 22nd June 2020. His disease progressed and he died on 18th August 2020, and you can recall hearing from his daughter at the September hearings.

11:52

The SAI was critical of the treatment afforded to Patient 1 and of the failure to comply with the recommendation of the MDM. It concluded that the prescription of Bicalutamide did not conform to the

11:52

relevant Northern Ireland Cancer Network Guidelines and that Patient 1 developed metastases while being inadequately treated for high rate prostate cancer. The Review Team observed that as time passed the disease progressed and the inadequate treatment

11:52

continued. The opportunity to offer him radical treatment was lost.

The second of the nine we refer to as Patient 9. Patient 9 was referred to urology services in the

11:52

Southern Trust via the Emergency Department following an episode of urinary retention in May 2019. He was reviewed by Mr. O'Brien who noted an elevated PSA. Suspicious of prostate cancer, Mr. O'Brien commenced

Patient 9 on Bicalutamide 50 milligrams, whilst awaiting prostatic resection. A TURP was performed and the pathology of the TURP was benign, however Mr. O'Brien documented in the GP letter that he suspected that there may be cancer in the unresected prostate gland and therefore arranged a repeat PSA level, an ultrasound of the urinary tract and an MRI scan of the prostate. Depending on the PSA result, Mr. O'Brien indicated in the letter that he was considering performing a prostatic biopsy of the gland remnant but delayed this until a planned review in September 2019. That review did not happen. Patient 9 was not seen again until he presented in the Emergency Department in May 2020 with urinary retension and a fistula and was diagnosed with advanced prostate cancer. 11:53 11:53 11:54

The SAI review was concerned with the shortcomings which this case exposed. It concluded that Patient 9 is likely to have suffered an unnecessary outcome owing to delays in the investigation of his symptoms and signs, the unconventional treatment of prostate cancer and failures in follow up procedures. They added: 11:54

"Had the appropriate investigations and treatment been intuited in a timely fashion, there is likelihood that Patient 9 would have enjoyed a good quality of life for an extended period." 11:54

Patient 5.

Patient 5 was an 88 year old man under the care of the urologist following successful nephrectomy for cancer. He had a follow-up scan which unexpectedly showed a probable metastatic prostate cancer in the spine. 11:55
Unfortunately the result was not acted upon which the consequence that the patient was not recalled for discussion and further treatment until some eight months after the result was available. I have already referred to the concerns expressed by Mr. Haynes in 11:55
respect of this kind of shortcoming. From his perspective the Trust was aware that this kind of thing was happening, but it was not learning the lessons quickly enough. The SAI report concluded that the abnormal findings on the postoperative review scan 11:55
should have been noted and acted upon. The Review Team observed that it would be unusual for a renal cell carcinoma to produce a sclerotic metastatic bone deposit and other options should have been considered.
11:56

Patient 8

Patient 8 was placed on the waiting list for TURP in October 2014. At that time his PSA level was measured which indicated a low risk of prostate cancer. Having been on the waiting list for over five years, Patient 8 11:56
was finally admitted for the procedure on 29th January 2020. The histology report on the resected specimen confirmed incidental prostate cancer. On the operation note, Mr. O'Brien documented a plan to review Patient 8

in April 2020 but this didn't happen until August 2020 with the result that Patient 8 was not informed of his diagnosis for eight months following surgery.

The SAI Review Team met with Patient 8 on two occasions and established that the delay in being reviewed caused him considerable anxiety and described his shock at being informed of his diagnosis eight months after the surgery. The SAI report concluded that no material harm was caused to Patient 8's health other than that of an unacceptably long wait to resolve his significant symptoms. 11:56 11:57

Patient 7

Patient 7 had a small renal mass since 2016 which was under surveillance by urology. At an outpatient review clinic on 29th March 2019, Patient 7 was advised that his renal mass was stable and he was for surveillance. This is despite the Urology MDM outcome of the previous day advising that he should be informed of the option of laparoscopic radical nephrectomy as opposed to continued surveillance with its attendant risk discussed. On 13th November 2019 Patient 7 had a follow-up renal CT scan. The report identified an enhancing lesion which had increased in size. This scan was not signed off and there was no record of action taken recorded on the NIECR. No urological follow-up or review took place at that time and Patient 7 was not seen until August 2020. We have already seen 11:57 11:57 11:58

how this failing has impacted on the safety of patients in a number of cases. It is by now becoming a familiar shortcoming.

The SAI noted that Patient 7 was seen by Mr. O'Brien and two different locum consultants over the surveillance period which led to somewhat fragmented care, inconsistency in investigations and a poor experience. The Review Team added that locum staff did not attend MDM and so did not feed back on the patient reviewed at outpatients. The Review Team believe that Mr. O'Brien had ample opportunities to refer Patient 7 for a specialist opinion and questioned why he decided to vary from established guidelines, practice and MDM recommendations. 11:58 11:59 11:59

Patient 6

Patient 6 was referred to urology by his GP with elevated PSA. On 30th July 2019 an ultrasound-guided biopsy confirmed prostate cancer Gleason 7. Patient 6 was identified at the MDM on 8th August 2019. It was agreed that Mr. O'Brien would review patient 6 in outpatients and discuss management with surative intent or surveillance. Patient 6 was advised of his diagnosis at review with Mr. O'Brien on 3rd September 2019. Rather than implement the recommendation of the MDM, it appears that Patient 6 was continued on a subtherapeutic dose of Bicalutamide. There was no evidence available to the SAI Review Team of any 11:59 12:00

discussion of the radical treatment options for prostate cancer recommended by the MDM at its meeting on 8th August. More than 12 months later, on 2nd October 2020, Patient 6 was reviewed by another consultant urologist following Mr. O'Brien's retirement. The consultant discussed his prostate cancer diagnosis and the available treatment options. Patient 6 reported that he did not recall any prior discussion about EBRT as a radical treatment, or discussion of surveillance as an option when he was under the care of Mr. O'Brien. 12:00 12:01

The SAI review found that the failure to refer Patient 6 to a urology Cancer Nurse Specialist and the failure to follow MDM recommendations were contributory factors to the failings in Patient 6's case. 12:01

Patient 2

Patient 2 was a 47 year old man who was referred by his GP to Urology Services in November 2018 for assessment and management of left scrotal pain which had been attributed to chronic left -- you will have to help with that, Mr. Hanbury, epididymitis which he had experienced for some years. A subsequent request was made for his appointment to be expedited. This took place in June 2019 when it was confirmed that he had a testicular tumour which was removed in July 2019. 12:01 12:02

Patient 2 was subsequently referred to the Cancer

Centre at Belfast City Hospital with a view of consideration of adjuvant chemotherapy. He was made aware at that time as the treatment would be delivered outside the recommended 12 week mark from surgery, the exact benefit in terms of reduction and relapse was uncertain. The SAI review report concluded that Patient 2 had received suboptimal treatment for testicular cancer as a consequence of a delay in onward referral. While the Review Team concluded that care was appropriate up to surgery, there was a failure to provide adequate adjuvant treatment thereafter. Mr. O'Brien had delayed in making a referral to a medical oncologist despite the recommendation which was made by the MDT at their meeting on 25th July 2019. 12:02 12:02 12:03

Patient 3

Patient 3 was referred to Urology Services by his GP on 20th February 2019 in view of a growth on his foreskin. He was referred for urgent circumcision which was performed on 10th April 2019. Histology confirmed squamous cell carcinoma. There was both lymphovascular invasion and perineural infiltration, both of which were associated with an increased risk of metastatic disease at presentation or subsequently. Patient 3's case was discussed at the MDM on 18th April 2019. This MDM was a virtual meeting conducted by a single urologist and it recommended that arrangements would be made for a CT scan of the patient's chest, abdomen and pelvis to complete staging. At a further MDM on 12th 12:03 12:04

September 2019 it was agreed that Patient 3 should undergo a left inguinal lymphoidectomy. There was no referral of Patient 3 to a super regional penile cancer MDT. Patient 3 was later referred to the regional penile cancer service in February 2020. Sadly, Patient 3 was admitted to hospital in December 2020 for unrelated reasons. By that time his disease had progressed and he died in January 2021. 12:04

The SAI Review Team found that the MDM recommendations did not follow NICE Guidance for the management of penile cancer, despite the fact that there were opportunities at each meeting to intervene and question Patient 3's management. The Review Team concluded that the MDM should have recommended an urgent staging CT scan and simultaneous referral onward to the Super Regional Penile Cancer Specialist Network for all subsequent management. The treatment provided to the patient was also said to be contrary to the NICaN Urology Cancer Clinical Guidelines. 12:04 12:05 12:05

There was significant delay in obtaining a CT scan of ten weeks and a further delay of seven weeks before outcome was reported to the patient. When scan results were available it showed clinical stage G2pT1 and this should have led to a consideration of surgical staging with either a bilateral inguinal lymph node dissection or sentinel node biopsy. This omission reduced the likelihood of his five-year survival from 90% to less 12:05

than 4%.

It is said that penile cancer is an unpredictable disease, but in this case appropriate management could have provided a 90% five-year survival. The patient, 12:06
the review concluded, was deprived of that opportunity.

Patient 4
Patient 4 attended the Emergency Department at Craigavon Hospital on 24th December 2018. Urinary 12:06
retention was diagnosed and treatment with the insertion of a urinary catheter. On 3rd June 2019 Patient 4 attended his GP complaining of haematuria. A red flag referral was made to urology. Patient 4 was diagnosed with prostate cancer approximately seven 12:07
months following his initial presentation with urinary retention. The SAI Review Team noted a number of shortcomings in Patient 4's care, including an absence of a record of a digital rectal examination having been performed, delay in commencing ADT, failure of the MDM 12:07
to recommend urgent referral to an oncologist, an inappropriate prescription of Bicalutamide. The SAI review concludes that through inadequate treatment this gentleman's poorly differentiated prostate cancer was allowed to progress and cause him severe and 12:07
unnecessary distress. There is a chance that despite this, the clinical course might not have been any different, but he should have been given every opportunity to consider proper and adequate treatment

options.

Chair, that's a summary of the clinical aspects of the nine cases.

12:08

In addition to preparing individual reports in respect of the nine cases -- I will just go back on a point that I made for the record.

I was discussing Patient 14 and I may have said that this omission reduced the likelihood of his five-year survival from 90% to 4%. I should have said to less than 40%. So the sentence should read: 12:08

"This omission reduced the likelihood of his five-year survival from 90% to less than 40%." 12:08

Apologies for that.

So the SAI Review Team under the leadership of Dr. Hughes produced an overarching SAI review to identify themes and learning across the nine cases. Dr. Hughes, as well as Mr. Gilbert, will attend the Inquiry to give evidence on 29th November 2022. The overarching SAI report identified findings under six significant headings and those findings gave rise to a number of recommendations. 12:09 12:09

First of all the six findings. Under diagnosis and

staging the review found that five of the nine patients experienced significant delay in diagnosis of their cancer. One patient had a delay of over 15 months from presentation to diagnosis. Two patients experienced delay due to investigations not being followed up. 12:10
Another patient had a 17-week wait for a staging scan and in another patient's case the MDM recommendation to discuss its case with the Regional Small Renal Lesion Team was not actioned.

12:10

A second finding came under the heading of targets. The Review Team concluded that just three out of the nine patients had met one of their 31 or 62 day targets.

12:10

The third finding considered the broad issue of multidisciplinary meeting. The Review Team found a number of concerns arising out of the operation of the MDM. It made the following findings: That the MDM made appropriate recommendations for eight of the nine 12:11
patients under consideration, but the Trust had no mechanism in place to check that actions were actually being implemented. The kinds of actions which had been recommended at MDM included further investigation, staging, treatment and appropriate onward referral. 12:11
They also found that NICaN Regional Hormone Therapy Guidelines were not followed. They found that the MDM failed in its primary purpose to ensure patients receive best care. It found that the Urology MDM was

underresourced and frequently non-quorate due to the lack of professionals.

Radiology had only one urology cancer specialist radiologist, that impacted on attendance, and critically this meant that there was no independent quality assurance of images by a second radiologist prior to discussion. And, of course, it drew attention to the regular absence of attendance by clinical oncology and medical oncology. 12:12

A further finding concerned multidisciplinary working and referral. The Review Team noted the repeated failure to refer patients appropriately, whether to oncology, palliative care or specialist MDTs. Further, the Review Team noted that none of the nine patients under the management of Mr. O'Brien were referred to urology cancer nurse specialists, despite this resource being increased and made available by the Trust. As patients were not rediscussed at MDM, and urology cancer nurse specialists were not involved in care, the failure to refer was an unknown to others within the MDM. 12:13

The Review Team found under the heading "patient support and experience" that whilst all of the patients reported a generally positive experience with their treating consultant, Mr. O'Brien, none of them were aware of the additional support available to other 12:13

patients. The report records that all of the patients and families were shocked to discover that their care was not supported and that the care did not follow MDM recommendations.

12:13

Under the heading "governance and leadership" the review found that the treatment provided to eight of the nine patients was contrary to the NICaN Urology Cancer Clinical Guidelines. The report notes that the Urology MDM made recommendations which were deemed 12:14
appropriate in eight out of those nine cases and that those recommendations were made with the contribution and knowledge of Mr. O'Brien. However, many of the recommendations were not actioned by him or alternative therapies were given. The Review Team reflected that 12:14
there was no system to track if recommendations were appropriately completed.

Another governance and leadership concern arose from the Cancer Nurse Specialist issue. The Review Team 12:14
noted that the use of a CNS, Cancer Nurse Specialist, was common for all other urologists in the Trust. The Review Team regarded the absence of a specialist nurse from care to be a clinical risk which was not fully understood by senior service managers and the 12:14
professional leads and they added that they were clear that patients suffered significant deficit because of the non-inclusion of nurses in their care. The report emphasised that while this is the primary

responsibility of the referring consultant, there is a responsibility on the Trust to know about the issue and address it.

Furthermore, the review found that assurance audits of patient pathways within the Urology Cancer Services were limited between the years 2017 and 2020 and, as such, could not have provided assurance about the care delivered. The Review Team concluded by pointing up the absence of adequate safety nets. It found the tracking of patients was flawed by limitations within the MDM systems and that the lack of specialist urology nurses from their key worker role meant that two of the three normal safety nets for patient pathway completion were, in essence, absent. They further noted that a collaborative approach did not appear to be actively encouraged within the MDT and in that sense they considered that the nine patients who formed part of this review received uni-professional care despite a multidisciplinary resource being available to all others. 12:15 12:15 12:16 12:16

As regards Mr. O'Brien's practices, the review found that the cancer care given by him did not follow agreed MDM recommendations and nor did it comply with regional or national best practice guidelines. The care which he provided was given without the input of the CSN and, in particular cases, without referral to oncology or palliative care. In summary, the Review Team concluded 12:16

that the approach adopted by Mr. O'Brien was inappropriate, did not meet patient need, and was the antithesis of quality multidisciplinary cancer care.

Arising out of those findings, the Review Team made a number of recommendations which speak to the shortcomings or gaps in clinical practise and the failures of governance which existed. The Inquiry will no doubt wish to examine the recommendations inserted into the individual SAI reports. The overarching report made a number of apposite recommendations, joined together the learning and recommendations to be found in each of the individual cases. It will be convenient to focus on the recommendations set out in this report which may be said to centre on four main concerns. 12:17 12:17 12:18

Firstly, quality and assurance. The Review Team advised that the Trust must strive to provide high quality urological cancer care for all of its patients and that all patients should receive cancer care based on accepted best care guidelines. The Review Team emphasised that the roles of the Clinical Lead Cancer Services and associated Medical Director for Cancer Services should be reviewed and the Trust must consider how these roles can redress governance and quality assurance deficits identified within the report. 12:18 12:18

The second recommendation comes under the heading of

the MDM. The Trust was told that it must ensure that patients are discussed appropriately at MDM and by the appropriate professionals and that MDM meetings are resourced to provide appropriate tracking of patients and to confirm agreed recommendations and actions are completed. The report recommends that an MDM Chair should be appointed and that they should have an enhanced role in multidisciplinary care governance to ensure a common and collaborative approach. 12:19

The third area of recommendations comes under the heading "patient support". The Review Team emphasised that all patients receiving care from the Trust's urological cancer services should be appropriately supported and informed about their cancer care. It should meet the standards set out in the regional and national guidance and meet the expectation of cancer peer review, for instance, with regard to the allocation of a key worker or a Cancer Nurse Specialist. 12:19 12:20

Fourthly, as regards culture, the Review Team indicated that the recommendations speak of a need for the Trust to promote and encourage a culture that allows all staff to raise concerns openly and safely. 12:20

More positively, the Inquiry is aware of steps taken by the Trust to design new roles and new processes arising out of the recommendations. The Inquiry, however, will

be anxious to consider why it was that the systems and standards identified in the recommendations did not already form part of the Trust's approach to urological services when Mr. O'Brien was employed. The Inquiry will also wish to examine what steps the Trust has now taken to progress the recommendations and to assess whether those steps go far enough. 12:21

It can be reported that following completion of these SAI reviews the Trust established a steering group to address the recommendations of the SAIs. After the initial meeting in June 2021, Mr. Ronan Carroll and Dr. Shahid Tariq were appointed joint chairs. The work of the steering group is not restricted to urology but will explore the need for improvement across all the multidisciplinary tumour sites. The Trust promptly acknowledged that further investment was required to address the recommendations, such as the need for additional support for MDTs, additional specialty input to MDT and greater benchmarking with national standards. The Trust has co-produced an investment plan and submitted it to the HSCB and the Department of Health to seek funding so that improvement can be delivered. More recently, perhaps in recognition of the gaps within the system, new roles have emerged to support the cancer MDTs. As indicated earlier, perhaps I didn't raise this earlier -- yes, it can be said that the Trust has now appointed a Cancer MDT Administrator, Mrs. Angela Muldrew. She has taken up post from 12:21 12:22 12:22 12:22

January 2022. It is said this is the first post of the kind in Northern Ireland and she, it is intended, will be an active support to the work of the MDTs.

Furthermore, the Inquiry has been told that over the past one to two years the Trust has secured permission from the Commissioner to veer the funding for a seventh urologist post to other elements of the service, including additional clinics, extended attendances at multidisciplinary meetings, including pathology, radiology, oncology and a band 5 post to serve as an administrative officer to support the MDT chairs. 12:23 12:23

Additionally, the Trust was aware that a peer reviewed format was not in place to use the clinical experience available within MDTs to review their working model. This has now been embedded across all tumour specialties to ensure evidence based guidance from the National Cancer Action Team is used to assess the practices within the Southern Trust MDT and to enable learning to be applied to facilitate more effective multidisciplinary team working. 12:24 12:24

That's all I want to say for the moment on the SAI process and what emerged from it. 12:24

I now turn to look at the Lookback Review and the Structured Clinical Record Review which is at the subset of lookback.

At a meeting on 23rd October 2020, Dr. Hughes advised Trust managers of the initial findings of the overarching SAI. This instigated the Trust to further consider other cohorts of patients centred on the emerging themes. That exercise came to be known as the Lookback Review and formally commenced in March 2021. 12:25

I have previously explained the circumstances in which the Trust in conjunction with its partners in the Urology Assurance Group decided to close the SAI process to further cases associated with the care provided by Mr. O'Brien. I explained that it was determined that any further cases which met the threshold for SAI would be examined through the SCRR process. But there was a stage before that, it was first necessary to conduct a formal lookback to ensure that all patients who had been under the care of Mr. O'Brien were reviewed to assess whether they were on the correct management plan, to identify any patients who may not have received optimal care, and to advise patients of the issues. 12:25 12:26

All patients under Mr. O'Brien's care from January 2019 to June 2021 have been included in the Lookback Review, except for those new outpatients referrals that were sent into the Urology Service that were directly named to him but who were never seen by him. The Inquiry has been advised that the Lookback Review comprises four 12:26

broad stages in line with the Department's Regional Guidance for Implementing a Lookback Review. The Inquiry understands that the process should operate as follows:

12:27

Stage 1 is a preliminary investigation. At this stage the Trust identified the need for Lookback Review and undertook a scoping exercise to identify an initial cohort. It was determined that the lookback should focus on all of the patients between the dates that I've just mentioned. 2,112 patients were identified as being under Mr. O'Brien's care in that period. This figure of 2,112 is said to have included the following cohorts of patients:

12:27

Those seen at outpatient clinics, both new and review. Those admitted under his care as an emergency or elective patient. Those who had been seen by him either whilst on the ward or at an outpatient clinic and had been added to his inpatient and day case lists. And finally those patients who were on a review outpatient waiting list and were past their client appointment date.

12:27

12:28

The second stage of the process was a review. Having identified a cohort of relevant patients, the Trust then set about reviewing those patients. At this stage of the process a number of things were happening. 68 cancer patients were reviewed by an independent sector provider. The remaining patients were reviewed using a

12:28

Structured Patient Review Form or a PRF, about which I will say something further a little later. Those patients were reviewed in one of two ways, either by a Trust consultant in a face-to-face or telephone appointment, or virtually by an independent urologist using the patient's clinical records contained in the NICaN, to complete the Patient Review Form. Those Patient Review Forms which were completed virtually and returned to the Trust were then triaged by the Head of Lookback Review. The outcomes were noted and actions to be taken were recorded and followed up. Those outcomes fell into a number of categories: No concerns, secondly no concerns but issues with care or cases that were undetermined. Those cases that were undetermined went to a second level triage undertaken by Urology Clinical Nurse Specialists to determine next steps. If required, a third level triage could be undertaken by consultants. An example of this is when the PRF - that is the Patient Review Form - where that Patient Review Form notes an investigation is recommended but had not been ordered, the consultant will review the patient's case to establish if the investigation is still required and, if so, he will order this. If there is possible harm experienced by the patient or if there is learning, these cases go to a screening meeting to identify if new learning exists.

12:28 12:29 12:29 12:30 12:30

A third stage is recall and screening for SCRR. At the time third stage of the lookback there were two

distinct elements which fall to be considered, first of all the recall. Patients identified with concerns are recalled and reviewed by a urologist in an outpatient setting, either in person or by telephone, according to the patient's preference. If it is clear that the concerns identified reflect the issues found in the overarching SAI, the patient's case is put on a list for SCRR screening. If the concern raised is not one of the SAI themes, but there is suspicion of a patient experiencing possible harm, the patient's case is also added to the SCRR screening list. 12:30 12:31

Screening for SCRR

At an SCRR screening meeting the case is discussed by senior consultants to determine whether the case meets the threshold for SCRR. On occasion there is insufficient information to finalise an outcome and in that situation the individual case may be discussed at a second or third screening meeting before a final conclusion is reached. For those patients who have been screened into the SCRR process, the rationale for this is recorded on a template and forwarded to the identified external reviewer, together with patient notes and records for the purposes of conducting the review and preparing a report. 12:31 12:31 12:32

Stage 4 then, there are two broad stages falling within this, an SCRR reporting stage and an analysis stage. Once completed, the independent reviewers return their

report to the Trust. At the time of preparing this opening statement 24 SCRR reports had been returned to the Trust, 20 of which have so far been disclosed to the Inquiry. Thereafter correspondence sharing the outcomes of the report with the patient or their family will issue and, in some cases, meetings take place. The Inquiry has heard about such a meeting when the son of Patient 35 gave evidence to the Inquiry in September. 12:32

It has been indicated to the Inquiry that when the SCRR reporting exercise is completed the Trust intends to conduct the analysis stage retaining Mr. Gilbert to produce a thematic report which will be drafted to reflect emerging learning and to identify aspects of practice that require attention. Additionally, the Inquiry understands that the Lookback Review Team, as distinct from the SCRR arrangements, has appointed five recently retired senior nurses to conduct a review of completed Patient Review Forms. The Inquiry has been told that all Patient Review Forms returned will be scrutinised by a senior nurse and cross-checked by a second senior nurse and any reference to suboptimal care is reported. 12:33 12:33

Whilst the Inquiry is fully cognisant that this Lookback Review process remains a work in progress, it is nevertheless useful to summarise the findings which have so far emerged. I will commence a description of 12:34

the findings by addressing a decision to conduct an audit of the prescription of the drug, Bicalutamide. It will recalled in some of the SAI reviews, which had been led by Dr. Hughes, the conclusion had been reached that some patients were prescribed low dose Bicalutamide outside of licensed indications or standard practice in the treatment of prostate cancer. The audit enabled the Trust to obtain a baseline to measure the extent of that concern as an adjunct to the Lookback Review. 12:34 12:35

The Bicalutamide Audit

As a result of the concerns identified, contact was made with the Trust's Director of Pharmacy, Dr. Tracy Boyce, with a view to identifying patients who were then receiving a prescription for Bicalutamide to allow the Trust to audit Bicalutamide prescribing. That data was provided on 22nd October 2020 and the audit took place in November 2020 prior to the formal commencement of the Lookback Review. The objectives of the audit were as follows: 12:35 12:35

To ensure that where Bicalutamide has been prescribed, this was only where indicated and as per licensed usage in accordance with the NICE Guidance.

Secondly, to ensure that where Bicalutamide had been prescribed, this was prescribed in the correct therapeutic dosages. 12:36

Thirdly, to ensure that all patients prescribed Bicalutamide were appropriately reviewed as part of

ongoing care.
Fourthly to ensure that any deviation from prescribing guidance was based on sound guidance or based on clinical rationale.

12:36

The Bicalutamide database was compiled by HSCB and comprised a list of 1,265 patients on primary care prescriptions of Bicalutamide. The data provided identified all patients of the HSC Trusts who received a prescription for Bicalutamide at any time between March and August 2020. The overall data pool was then narrowed to the 764 persons who were Southern Trust patients. Following identification of Southern Trust patients the audit proceeded by way of a consultant-led review of prescribing to identify prescribing of Bicalutamide which was outside of that prescription guidance contained in the NICE Guideline.

12:36

12:37

12:37

The Audit Findings
In respect of low dose Bicalutamide, that is 50 milligrams daily, the Inquiry has been provided with a breakdown of the audit findings in that respect. The following picture has emerged:
A total of 466 patients were identified within the Southern, Northern and Western Trust Local Commissioning Group as having received a prescription of low dose Bicalutamide. 34 of the 466 were identified as being on the incorrect treatment. Two of those 34 had been commenced on medication by services

12:38

outside of Northern Ireland Urology. Of the remaining 32 patients, 31 had been commenced on low dose Bicalutamide by Mr. O'Brien. Of the 53 patients that were ultimately screened for SCRR by 15th April 2022, those 31 and the one other were on low dose Bicalutamide. 12:38

Let me tell you then about the results for the audit relating to high dose Bicalutamide, 150 milligrams. The Trust has advised that a review was also undertaken of patients' medication to determine if additional patients receiving at the time of the audit a prescription of the higher dose had previously been treated with low dose Bicalutamide. This practice had been identified in some patients and the Trust sought to establish whether the prescribing had been in line with recognised indications. In addition, for those patients receiving monotherapy alone, patient records were examined for the purposes of determining whether MDM recommendations in respect of curative treatment options had been discussed with the patient. 12:39 12:39 12:39

The findings of the high dose audit are as follows: A total of 298 patients were receiving high dose Bicalutamide during the audit period. 26 patients, all of whom had their prostate cancer treatment initiated by Mr. O'Brien, were identified with concerns. No concerns were identified with the remaining 272. Of the 26, one patient had already been identified and his 12:40

care had been the subject of an SAI. One patient was prescribed Bicalutamide monotherapy for metastatic disease with no evidence of discussion of reduced efficacy of the treatment. Nine patients had initially been treated with low dose Bicalutamide which had then been increased to 150 milligrams by Mr. O'Brien. 21 patients had no evidence of discussion of MDM recommendations of radical treatment or evidence of discussion of watchful waiting as an alternative to hormone manipulation. 12:41

I will now discuss the Trust's follow-up to the audit. The Bicalutamide audit undertaken in November 2020 resulted in 38 patients requiring a face-to-face appointment to adjust their prescribed medications. 12:41 These patients were reviewed during November and December 2020. The Inquiry has asked the Trust to clarify whether these issues highlighted through the Bicalutamide audit are to give rise to any further exploration or investigation of the issue. The Inquiry 12:42 asked the Trust whether it had considered retrospectively reviewing Bicalutamide over a greater period of time. The Trust, we are told, is currently preparing an options paper which will be discussed with and agreed on by the Urology Assurance Group to inform 12:42 the decision on a second phase of the Lookback Review. Each of the options in that paper, we are advised, will include patients with prostate cancer, therefore a review of Bicalutamide prescribing during a time period

further back will take place as part of that phase of the Lookback Review.

The Trust has conceded that robust medication audits had not been carried out during the period of interest to the Inquiry and has confirmed that it is not aware of any previous audits concerning Bicalutamide prescribing. Reflecting on this in her response to a Section 21 notice, Dr. O'Kane has indicated that there was no rigorous process, audit or otherwise, for following up on MDM recommendations that would flag incorrect medication doses and she has opined that, had a longitudinal audit been carried out on prescribing practices, this trend would likely to have been identified. The Inquiry has been told that this is currently being addressed with a new MDM audit process being implemented across all tumour groups and the Inquiry will undoubtedly be keen to learn more about those new best processes as her work continues. 12:42 12:43 12:43

Madam Chair, I pause here to indicate that issues around Bicalutamide prescribing, having emerged from those processes, gave rise to following overall findings. 12:44

Of all of the Patient Record Forms returned, 27.6% were identified as having suboptimal care. 21.8% of those instances of suboptimal care related to medication alone. In terms of those cases identified under the

medication header, 35.4% related to the incorrect or potentially incorrect dose of Bicalutamide, that is approximately 5.8% of all suboptimal care instances identified to date.

12:44

Let me turn now to the more general findings of the Lookback Review. As of 25th October of this year, 82.2% of the Patient Record Forms have been returned and triaged by the Trust. Of those PRFs which had been triaged, 78.8% are said to have no concerns or correct management had been applied. 10.5% of the forms returned are identified with concerns. Of all of the PRFs returned, a significant 27.6%, as I have just indicated, were identified as having some form of suboptimal care. A breakdown of themes in this group is approximately as follows:

12:45

12:45

28.5% of the concerns relate to diagnostics. 21.8% to medication, 28.6% to treatment, 35.3% to communication issues, and 19% to referral issues.

12:46

I don't propose Chair, in the interests of brevity, to go through the finer details of those statistical outcomes. The information is available to the Inquiry and the Core Participants through the Section 21 responses and no doubt we will look at that as the public hearings continue.

12:46

I want to turn briefly to the Patient Review Form, I've

sometimes been calling it the patient record form, it's the Patient Review Form or PRF. This formed the centrepiece of stage 2 of the Trust's Lookback Review and is utilised in the SCRR process.

12:47

The Trust initially developed a ten-question PRF. The form had been designed so that the focus of the first four questions was on current care being received or provided to the patient with the remaining six questions looking backwards at the patients' past care. 12:47
At the outset of the Lookback Review, the Trust began to review the case notes of all patients in the 2019/2020 cohort against the ten-question PRF in order to review both current and previous care. However, from 25th November 2021 the format of the PRF and the 12:48
process was fundamentally changed to remove the questions that referred to previous care, therefore, meaning that only the patients' current care as at the time of the review was considered.

12:48

Dr. O'Kane has addressed this issue in a Section 21 response. She has explained that the decision to adjust the approach was taken to support the Trust in being able to review more case records more quickly to allow the Trust to assure as many patients as possible 12:48
that their current management and treatment is appropriate. Following that decision, two Southern Trust urologists, Mr. O'Donoghue and Mr. Young proceeded in that vein which resulted in 126 patients

being reviewed using the four-question model. Professor Sethia and Mr. Haynes, who had already started their work reviewing patients before the 1st November decision, continued to review patients using the ten-question approach as, based on their experience to that date, they were concerned that patients may have had historical issues with care received, even if their current care was correct.

12:49

In light of those concerns, and in an attempt to promote the consistent methodology across all cases, the Trust decided to revert to the ten-question PRF model and they did this in March 2022. This meant that the 126 patients whose care had been reviewed using the four-question method had to be reviewed once again for the purposes of assessing historical care. This work commenced in June 2022 under Professor Sethia, the Trust's external reviewer.

12:49

12:50

Turning back then to the SCRR process.

12:50

As I indicated earlier, this process is ongoing and the independent subject area experts appointed by the Trust continue to work their way through those cases which, following review, have been screened into the SCRR process. Progress appears to have been slow. At the last count, as I have just mentioned, 24 completed SCRR reports have been received back into the trust which represents just under half of the total 53 SCRR cases

12:50

which have identified. Nevertheless it is possible to offer some insight into the themes which appear to be emerging from SCRR. The first point to make is that the emerging themes are in many cases little different from what was found in the SAI cases which we have just considered. This is perhaps unsurprising. Amongst the themes reflected in the SCRR reports are the concerns that Mr. O'Brien disregarded MDM decision-making in which he had participated, of failing to engage properly with his patients on the available treatment options, failing to follow standard practice for prostate cancer management, including a departure from guidelines, delaying or denying referral for radical radiotherapy and showing an unexplained preference for the prescription of low dose Bicalutamide to the detriment of his patients. 12:51 12:52 12:52

The inappropriate use of Bicalutamide features prominently in a number of the cases considered and the reviewers frequently make reference to the unnecessary side effects suffered by patients affecting quality of life. 12:52

In some cases the concern about the impact of substandard care may have been more far-reaching with it being suggested by reviewers that shortcomings in the treatment provided may have impact on life expectancy in some cases. As noted already, in the case of Patient 35 it has been said that the delay in 12:52

providing radical treatment reduced the chance of curative radiotherapy being successful, although it was understandably difficult to quantify the exact impact of prognosis. Additionally, in that case it was said that the side effects of inappropriate Bicalutamide monotherapy could have been avoided with appropriate treatment. The Inquiry will recognise the similarities between the case of Patient 1, whose daughter gave evidence to the Inquiry in September, and the case of Patient 37 which was recently reported by an SCRR reviewer. The issues in Patient 37's case were summarised as follows: 12:53 12:53

MDT discussion in January 2020 recommended either radical treatment with radiotherapy or surveillance. This advice was ignored and the patient started on Bicalutamide, 150 milligrams monotherapy. This does not represent standard of care and the patient was not treated according to evidence, guidelines or MDT recommendation. The lack of radical treatment could have an adverse outcome on prognosis in terms of cancer-specific survival. When offered radiotherapy in what appears to be 2021 - I think there's a date error in the reporting form - patient went forward with treatment. Standard prostate cancer guidelines were not followed. Both Patient 1 and Patient 37 were under the care of Mr. O'Brien at the same time in early 2020. On the face of the evidence to date, they were each deprived of the treatment pathway recommended by MDM. 12:54 12:54 12:54

In the opinion of the reviewer in Patient 37's case, the advice of the MDM was ignored. Both patients, that is 10 and 37, were started on 150 milligrams of Bicalutamide monotherapy and in the opinion of those who have looked at these cases through the SCRR and SAI processes that treatment did not represent standard practice. There is a real concern in both cases that the failure to provide timely radical treatment had an adverse impact on outcome. 12:55

Patient 46 was also diagnosed with prostate cancer. His care followed a similar pattern. When asked to comment on the standard of care overall the reviewer in Patient 46's case described it as poor care in terms of prostate cancer management. Elaborating on the point he explained: 12:55 12:56

"If he had poor performance status then surveillance would have been a good option and if good performance status, radiotherapy with a short course of androgen ablation would have been appropriate. The MDT advice was ignored and the patient started on an unlicensed dose of androgen ablation medication. The patient does not appear to have had an opportunity to discuss treatment options with explanations of their pros and cons. In this respect the level of care fell below the standard I would expect." 12:56 12:56

The reviewer opined that Patient 46 may have suffered

harm in the following respects:
Potential worsened prognosis in terms of cancer specific survival with no opportunity for radical treatment. Potential prolonged side effects from androgen ablation therapy which could have been reduced or avoided. Psychological impact of knowledge that treatment was not appropriate.

Madam Chair, I wanted to provide you with this overview of what is beginning to emerge from the SCRR process. There will no doubt be an opportunity to provide you with a more comprehensive series of findings as that process reaches its conclusion and the Trust obtains the overarching thematic report which has been promised. But by this stage, at least according to the opinions expressed by a number of independent subject area experts, the conclusions are as clear as they are disturbing. Multiple patients have been harmed or have been placed at risk of harm because Mr. O'Brien failed to comply with standard treatment guidelines and often provided the wrong treatment or the inappropriate treatment. Mr. O'Brien complains that he has been excluded from this process but there is a developing consensus amongst the independent experts who have examined the cases, both SCRR and SAI, that patients were not well treated.

You will consider the conclusions reached across the processes. It may follow from those conclusions and

you will have to take a view, that as we saw with the SAI cases the Trust did not have in place any or any adequate system for identifying such shortcomings so that Mr. O'Brien wasn't challenged and his shortcomings were not escalated. If clinical colleagues knew of the 12:59
treatment provided and recognised it as a shortcoming, did they do their best to address it with him? We know that some colleagues raised formal incident reports or made informal reports, but was that effective? The net result, so it would appear, is that time and again 12:59
patients were left without safeguards and were placed at risk. Ultimately, Chair, that is a matter for you to take a view on in light of all of the evidence to be received.

12:59

I see, Chair, it's coming up to one o'clock. I think it's a convenient place to park.

CHAIR: Certainly, Mr. Wolfe. Thank you for that. And we'll sit again at two o'clock, ladies and gentlemen.

13:00

<u>THE INQUIRY ADJOURNED FOR LUNCH AND RESUMED AS FOLLOWS:</u>

CHAIR: Good afternoon, everyone. Mr. Wolfe, are you ready?

MR. WOLFE KC: Yes. The plan this afternoon is that I 14:01
will speak for an hour, just over an hour and then we'll break for ten minutes and continue maybe through to quarter past/half four.

CHAIR: That's fine.

MR. WOLFE KC: I want to begin this afternoon by looking at an issue of underreporting or possible underreporting. What I mean, briefly, by that is whether there were bases of clinical shortcoming that ought to have been directed into the SAI or SCRR process for that matter because they met the threshold but weren't, they didn't go into that process. That will be something that on consideration of the evidence that the Inquiry will have to work out. 14:02

Let me set out some of the pieces around that.

The Trust has disclosed to the Inquiry an e-mail from Professor Sethia to Patricia Kingsnorth dated 23rd February 2021 which can be found at TRU-252392 and in that e-mail he advises on a number of cases which are to be regarded as serious incidents. This correspondence appears to form part of a screening exercise for the purposes of the SCRR process. Professor Sethia expresses the view that: 14:03

"Whilst the management of the cases was not always conventional or correct, I do not think that there's any definite evidence of harm having been done." 14:03

The indication would appear to be that those cases should not be examined within the SCRR process. The cases he considered involved two cases of delays in management, Patient 96 and Patient 97, two cases of

failure to discuss at the MDM, 98 and Patient 100, and three cases of the unconventional use of Bicalutamide, Patients 58, 100 and 101. Elaborating, Professor Sethia acknowledges that the instances of delays in management and failure to discuss at MDM represents substandard care. As regards the patients prescribed Bicalutamide he comments: 14:04

"Those cases raise the question as to whether Mr. O'Brien should have offered earlier radiotherapy." 14:04

Professor Sethia indicates that this would certainly have been better practise and concludes that the patients were denied the chance of discussing the options properly. 14:05

So far as the Inquiry has been able to determine of the seven patients mentioned in this correspondence the only patient that eventually found their way into the SCRR process was Patient 58. The other six cases appear to have been screened out on the basis of a finding of no clear evidence of harm. Yet other cases with similar shortcomings have entered the SCRR process. 14:05

Madam Chair, you will recall, just to draw this comparison out, the cases of Patient 35 and Patient 18, to take two examples. Those were cases that were considered under SCRR. Patient 35 had been treated

with low dose Bicalutamide. There was no evidence that Mr. O'Brien offered a range of treatment options including radiotherapy and his treatment was delayed. The reviewer noted in that case that he had finally had radical radiotherapy in 2014 after further MDM review but could have had it earlier in 2009. Again drawing the analysis out, Patient 18 also commenced on low dose Bicalutamide. You will recall that he gave evidence to the effect that he was dissuaded from radiotherapy by Mr. O'Brien and it was only when he wrote into Mr. O'Brien requesting radiotherapy that he received that treatment. Interestingly, in his response to the Inquiry questionnaire, Patient 18 makes the following point:

14:06

14:06

14:06

"Although aware of possible side effects of radiotherapy I believe that due to inaccurate and disingenuous information provided to me regarding my condition and treatment options earlier in my treatment pathway I was unable to make an informed choice."

On the face of it the comparison of these cases raises a question about the consistency of the approach adopted by the Trust to SCRR screening. As I explained earlier, it is our understanding that the trigger for SAI review does not require proof of harm to the patient. Rather one aspect of the threshold is set at unexpected or serious risk to the patient. If that is, or ought to have been the test, can it be said that the

14:07

patients concerned here were not exposed to unexpected or serious risk if their access to appropriate cancer treatment was delayed?

Professor Sethia appeared to form the view that Patient 58 may have been a candidate for radiotherapy four years before he came forward for treatment. He thought that Patient 100 may have been a candidate for radiotherapy eight years earlier. Is it really anything to the point that both patients fortunately appeared to Professor Sethia to be doing well. 14:07 14:07

There is other evidence of apparent inconsistency. Chair, you will recall Patient 15, a case involving a failure to triage a referral resulting in a six month delay in treatment and diagnosis of prostate cancer. Patient 15's case was investigated by way of SAI despite involving a delay of a much shorter duration than in the cases of Patient 58 and 100. 14:08

The SAI report on Patient 15's case noted that following Review Team consideration it is felt that the delay is unlikely to be clinically significant. The Inquiry will also wish to consider whether there is any meaningful distinction between the cases of patient 15, an SAI case, and Patient 101, since both appear to involve a six-month delay in treatment with an absence of evidence of harm. Similar questions arise in respect of the decision making around the cases of 14:08

Patient 93 and 102.

The Inquiry also needs to consider whether any underreporting of adverse incidents might not be a recent development affecting only the SCRR process. During Mr. O'Brien's period of employment and in cases relating to his care, was there a failure to apply the SAI criteria so as to accurately determine whether an adverse incident constituted an SAI? 14:09

The Inquiry is aware that an incident report was raised by Mr. Haynes relating to Patient 102. This was a case where the recommendation of an MDM in late 2014 was that Patient 102 should be referred for radiotherapy directly. This was not actioned. Mr. O'Brien did review the patient in outpatients on 28th November 2014, but the incident report indicates that no referral was made. Fortuitously patient's 102's GP wrote in October 2015 to indicate that no oncology appointment had been made, but this was nearly 12 months after the MDM decision. 14:09 14:10

The Inquiry has seen an e-mail from Heather Trouton, Marina Corrigan and Eamon Mackle dated 22nd October 2015 asking whether the case needed to be screened for SAI. The Inquiry could not see an answer to that question in the material disclosed by the Trust so clarification was sought. 14:10

In correspondence dated 28th October 2022, the Inquiry has been advised on behalf of the Trust that Mr. Mackle and Ms. Trouton have no recollection of discussing the case. There is no record of a screening decision and the Trust has concluded that the case was never screened. We can see that the incident report form records that a David Cardwell sent a message in December 2015 that it was for Martina Corrigan to speak to the consultant concerned, Mr. O'Brien. This suggests that a decision had been made at some level that an SAI was not required and that the matter could be addressed by the head of service. However the decision-making around this is rather opaque. Justification for declining to conduct a SAI review or failing to screen the case is not known. The clinician who reported the incident, Mr. Haynes, has indicated to the Inquiry that he remains unaware how his concern was investigated or what, if any, action was taken to resolve the issue. The Inquiry has been advised in the recent correspondence that Ms. Corrigan has no recollection of ever being asked to speak to Mr. O'Brien about this particular patient. 14:11 14:11 14:11 14:11

There's another example of this underreporting which concerns Patient 103. I won't descend into the detail of that but again it raises questions about the process being followed by medical management within the Urology Unit when faced with a report of an adverse incident. In that case, in summary, there was a failure to bring 14:12

it within a screening process. The matter was dealt with informally and ultimately no SAI was ordered, despite a delay of some several months following a failure of triage.

14:13

So, at a time when Mr. O'Brien remained in employment it is quite clear that some of his colleagues in management were concerned about poor practise, but it would appear that in some cases there was sufficient evidence to merit further consideration within the SAI process. It will be necessary to examine, with Trust witnesses, whether the SAI process was used in all appropriate cases or whether there was sometimes a tendency to turn a blind eye to underreport and to fail to subject the concerns to the necessary scrutiny.

14:13

14:13

Regardless of the view to be taken on those questions, Chair, it can be seen that the SAI and SCRR cases should not be relied upon as necessarily a reliable statistical count. The degree of underreporting, if that's what it is, is unclear, but it is certainly an issue which the Inquiry will wish to address.

14:14

Finally in this section, Part 2 of my opening looking at clinical aspects, I want to touch upon two ancillary processes; that is two reports that have emerged in recent months concerning the whole issue of lookback.

14:14

The first report comes from the RQIA. It was published

in September and the second report published by the Royal College of Surgeons a short time later.

The RQIA report is a review of the Southern Trust's SCRR process. The RQIA is an independent statutory body which is responsible for regulating and reviewing the quality of health and social care services in Northern Ireland. At the invitation of the Trust the RQIA conducted a review of the Trust's SCRR processes deploying its core staff and an expert Review Team. 14:15
Its report can be found at TRU-157737. The Terms of Reference for the review were agreed as follows:

To assess the suitability of the structured judgment review method, as they call it, and which was the basis for the SCRR process. 14:15
To assess the specific Trust SCRR methodology in relation to its effectiveness in identifying learning;
Thirdly to assess the overall Trust process or framework for conduct of its record review. 14:16
Finally, to make recommendations in relation to the overall process and if the SCRR process is not considered to be appropriate, to suggest an alternative approach.

14:16

In its report published in September 2022, the RQIA has commended the Trust for its commitment to ensuring that the work of SCRR is undertaken in a manner that is robust and effective in deriving learning and informing

improvements and it endorsed the Trust's decision to apply the SCRR framework to those cases which were found during the Lookback Review to have met the threshold for SAI.

Nevertheless, the outcome of the review pointed to a number of concerns and the expert Review Team of RQIA saw fit to make 18 recommendations straddling both the SCRR process and the Lookback Review itself. The most significant of those concerns I will summarise. 14:17

At a most basic level, the RQIA found that the Trust had failed to articulate a clear set of objectives for the SCRR process and it recommended that steps be taken to explicitly define its purpose. It also highlights 14:17 that the SCRR structure does not reflect the current regional guidance for implementing a Lookback Review process. The Inquiry may consider it surprising that these key coordinates were not formulated at the outset and it may wish to question whether such shortcomings 14:18 have affected the quality and output of the process.

More significantly, RQIA has drawn attention to the fact that the current phase of the Lookback Review and the attendant SCRR process is only concerned with those 14:18 patients who were under the care of Mr. O'Brien in the period between 1st January 2019 and 30th June 2020. Recognising that commencing with a review of those patients identified as being most at risk was sensible,

justified and consistent with the regional guidance, RQIA nevertheless considered that since the Trust has established, through its patient case note process, the patients who were under the care of Mr. O'Brien prior to 2019 may also have received substandard care, it is now necessary to press ahead with an expansion of the review.

At the time of the publication of the RQIA Review, the Trust was still awaiting a report from the Royal College of Surgeons which the Inquiry understands was intended to assist the Trust in determining whether it is necessary to look back at the treatment and care received by patients prior to 2019. In its review RQIA stated explicitly "do not wait any longer." And note the language here: 14:19 14:19

"There is already enough evidence to inform a risk assessment that patient groups receiving treatment prior to 2019 are at risk of harm and, therefore, Southern Trust should not wait for the Royal College's work to conclude and should proceed as a matter of urgency to extend the Lookback Review to identify and recall at-risk patients under the care of Mr. O'Brien prior to 2019." 14:20 14:20

They round off by saying:

"Given the risk posed to live patients, it is

imperative that a further phase of the lookback is commenced as a matter of priority."

Recognising that any expansion of the Lookback Review is a considerable undertaking, RQIA emphasised that it is important that the Trust is adequately supported by its partners within the health and social care system, including the Department, the SPPG, the UAG and PHA. It also sets out the merits of engaging an external body to complete the work. This would mean that the SCRR is conducted by an independent organisation, but it considers that there is value in this. 14:20 14:21

The Inquiry will have an early opportunity to hear from both the Department and the Trust about whether plans are now in place to facilitate the urgent expansion of the Lookback Review process in line with these recommendations. I know, Chair, that this Inquiry will take seriously the need to address the needs of those live patients who may be at risk. 14:21 14:21

The Report also pointed to shortcomings in the level of personal public involvement with the SCRR process. According to the RQIA, the absence of a consistent mechanism to proactively seek the concerns of patients and families for consideration as part of the individual SCRR represents a considerable deficit in the information available to formulate findings. It also suggested that the personal public involvement, 14:21

expertise residing within the Public Health Authority and the Patient Client Council has been underutilised to date.

On methodology, the RQIA acknowledges that the SCRR framework adopted by the Trust generally appears reasonable and commends the structured judgment review methodology developed by the Royal College of Physicians. In theory that methodology the RQIA notes produces a rich set of information about the case in a form that can be aggregated to produce knowledge about clinical services and systems. But the RQIA has highlighted that in contrast to the approach to be taken in a formal structured judgment review, the adapted methodology applied by the Trust is not comprehensive and does not seek to address the following: 14:22 14:22 14:23 14:23

Quality of documentation in the records, Communication between consultant and patient and Communication between colleagues, Multidisciplinary Team and primary care.

This is perhaps the most significant concern identified by the RQIA in terms of the Trust's SCRR Framework and it is recommended that the Trust give accurate consideration to adjusting the SCRR tool to include such matters. 14:23

The RQIA was advised by the Trust that the production of, at that time, 20 SCRR reports had led to a broadly similar learning across the Board. In turn RQIA concluded that a point of saturation might be reached and there may be limited benefit to reviewing all cases, as was initially intended. Additionally the RQIA pointed to the fact that SCRR has become a prolonged process in a context where Trust is keen to establish the full extent of learning in relation to these cases. 14:24

Certainly the production of 20 SCRR reports - it's now 24 as I noted earlier - by four clinical reviewers over a period of approximately six months appeared unsatisfactory to the RQIA and may be of concern to this Inquiry. At the current rate the SCRR process may not be completed for up to another 12 months even if no further cases are added to the workload. The Inquiry may consider that if the main objects are to produce learning points and to implement changes to systems and practise as soon as possible and to provide valuable feedback to patients, this has to improve. 14:24 14:25

In the circumstances, RQIA suggested that it might be valid for the Trust to approach the Department to make a case for a sampling approach for the purposes of expedited learning and making arrangements for the earlier implementation of improvements. I know, Chair, that you're concerned with this proposal. The Inquiry 14:25

will wish to explore with Trust witnesses whether a departure from the original plan is being considered and, if so, whether it can be justified. As has been identified, a sampling approach risks disenfranchising patients and families who may have a reasonable expectation that shortcomings in their care will be subject to specific individualised scrutiny.

The RQIA has further suggested that if a case or cases is removed from the SCRR process, the patient or family member who is impacted by this may submit a concern to this Inquiry. That suggestion appears to hold out the false promise that this Inquiry will operate as a safety net and be in a position to pick up the task of investigating the clinical shortcomings of a patient's case if the Trust decides that it will not do so. This is not the function of this Inquiry. And I know, Chair, that you have informed the RQIA that this is the position in a letter of 4th October 2022.

I know that you have received some preliminary correspondence from the RQIA which have acknowledged your concerns.

The RQIA has also recognised that at the conclusion of the lookback and SCRR processes there is a requirement to effectively disseminate the outcomes. The RQIA has called upon the Trust to work with its partners to develop a strategy to ensure that learning is shared

regionally with all appropriate stakeholders so that the public is adequately informed. I'm sure that this Inquiry shares that aspiration.

Finally, the RQIA report comments on the Trust's plan 14:27
to deploy a single independent consultant urologist to develop a thematic report on the SCRR findings at the conclusion of the process. I previously indicated that the Trust have invited Mr. Gilbert to fulfil this role. The RQIA have proposed that instead of a single expert 14:28
practitioner approach, a review panel should be established, including an expert on governance, for the purposes of identifying learning and determining recommendations arising from consideration of the individualised SCRR reports. 14:28

As I've said earlier, the Royal College of Surgeons has now reported. Its report was fashioned around 96 clinical records related to the Urology Service on behalf of the Southern Health and Social Care Trust. 14:28
It issued the report on 29th September 2022. It is necessary to say something about the background to this work, the nature and scope of the work and the findings which the Review Team has reached.
14:29

Something of the background: On 9th November 2020, the Trust applied to the Chair of the Royal College of Surgeons Invited Review Mechanism to ask for an invited clinical record review to be conducted of 100 urology

cases. Making this application the Trust referred the RCS to the concerns which were then emerging in respect of Mr. O'Brien's treatment of some patients and which had prompted a Lookback Review.

14:29

The Trust's application was considered and approved by the Chair of the Invited Review Mechanism and a representative of the British Association of Urological Surgeons. A four-person Review Team was invited to conduct the review and their work commenced in June 2021. Before examining the work of the review, let me address the delay in the production of the review report.

14:30

It is quite clear that the Trust was awaiting the report of the Royal College of Surgeons to inform its decision-making around whether there was a need to extend its lookback exercise. In a document, Southern Trust's Frequently Asked Questions, Urology. November 2022, it is indicated that the scope and scale of any further Lookback Review beyond an initial 18 months would be based on the Trust's internal review of patient records, concerns which may now be raised by patients and families and advice from the Royal College of Surgeons.

14:30

14:31

It is quite clear that the report has been substantially delayed. The delivery date was put back several times and, as I have said, was only released at

the end of September. This was just a little under two years after Dr. O'Kane recognised that a review was necessary and set about approaching the Royal College. As I will explain, the report of the invited review has produced some findings which point to a specific need to provide follow up to a number of patients. It has also produced conclusions which may support the Trust with its process of introducing governance reforms and improvements in service delivery. But a critical issue which emerges is whether the Trust ought to have tied itself to such a lengthy review process to determine a question around the parameters of its Lookback Review exercise when, as the RQIA have suggested, the answer may have been more readily accessible. 14:31 14:31 14:32

The Inquiry may take the view that the Trust cannot be blamed for the delays on the part of the Royal College. The Trust was diligent in seeking regular updates from the Royal College in relation to the production of the report, sometimes in response to expressions of concern from this Inquiry. I should also emphasise that my remarks make no criticism of the Royal College and its invited Review Team. It has produced a report in answer to its Terms of Reference and often thorough and comprehensive work is beset by unavoidable and unanticipated delays. The issue, rather, is whether the invited review process was the appropriate route to take. 14:32 14:32

Let me return to the substance of the review itself. The Review Team was supplied with clinical records and supporting documentation and the process has been described as a clinical record review, emphasising the fact that the core source of evidence was the clinical records. The report emphasises that the conclusions reached by the Review Team are based on those records. There was no opportunity, for example, to meet with or discuss the cases with any clinician involved in the provision of care, or the patients. 14:33

The Terms of Reference for the invited review were agreed between the Royal College, the Trust and the Review Team on 12th April 2021. They are set out at TRU-157786. They required the Review Team to consider the standard of care across a number of clinical issues including, for example, assessment, treatment, communication, and record keeping. It was agreed that as part of the process of assessing the standard of care across these themes or issues, the Review Team would, where appropriate, take the following steps: Raise any immediate patient safety issues, form conclusions as to the standard of care provided and make recommendations for the consideration of the Southern Trust's Medical Director. 14:33 14:34 14:34

It should be noted that while it appears that the Trust's intention had been to supply the Review Team with clinical records for 100 patients who had received

some form of care or treatment from Mr. O'Brien, the Review Team established that he was not involved in any part of the clinical journey of four of the patients for whom records were supplied. Hence my earlier indication that the review was fashioned around consideration of the clinical records of some 96 patients and not 100, as was the original intention.

The Review Team approached its work by reviewing each of the 96 cases by reference to the factors outlined within its Terms of Reference. The conclusions section of the report at Chapter 3 is structured so as to helpfully provide a summary of the principal findings in respect of each of those factors and it provides abbreviated observations in relation to those cases where particular shortcomings had been identified. Each case is then afforded a much more detailed treatment at appendix A of the report.

Let me now outline what the Review Team found in respect of some of the principal issues. As I proceed, I will highlight some examples of cases which caused the Review Team concern. These are for illustrative purposes only. I will use the patient cipher used by the Royal College and the Inquiry will no doubt review the report in detail to obtain a comprehensive understanding of each of the cases which have emerged as a concern.

14:34 14:35 14:35 14:35 14:36

Under the theme "assessment including history taking, examination and diagnosis" the Review Team found that in 80 of the 96 cases considered, appropriate assessment checks had been undertaken but it concluded that there was room for improvement in four cases and in a further six cases patients' assessment was unacceptable so that the patients' standard of care was of significant concern.

14:36

When describing the patient cases which caused the Review Team concern -- as I said earlier, I will use the patient descriptors to avoid confusion. Amongst the cases which caused the Review Team concern was patient A63. It was noted that at the initial assessment that he was not suitable for radiotherapy as his prostate was considered to be too large, was not the correct decision, unless the patient had been considered for brachytherapy alone. In the case of A83, the absence of any record of any prostate assessment by DRE and the failure to record his PSA in the clinical record was found to be unacceptable.

14:36

14:37

14:37

Under the theme of investigations and imaging undertaken, the Review Team found that six cases exhibited concerns in respect of investigations in imaging. In those cases the care provided was either unacceptable or required improvement. In the case of Patient A72, for example, the Review Team expressed concern and that there were delays in undertaking scans

14:37

and that there were no reasons set out in the record to account for the delays.

Under the heading "treatment including clinical decision-making, case selection, operation or procedures and prescribing practices", while the Review Team considered that in 69 of the cases reviewed the treatment provided was of an acceptable standard, significant concern was expressed in respect of clinical decision-making, surgical procedures and prescribing practices in five cases and in 17 other cases the Review Team noted that there was scope for improvement. 14:38 14:38

Amongst the cases in respect of which significant concern has been expressed, I draw attention to the following: In the case of A28 there was an unexplained delay of over 2 months before a planned cystoscopy was conducted. The Review Team considered that it was possible that this delay had contributed to the poor clinical outcome in the case. 14:38 14:39

In the case of A29 the Review Team noted that there was a delay of 10 to 11 months before planned surgery was conducted, during which time there had been disease progression from superficial to muscle invasive cancer. It was noted that the patient subsequently died and it was the Review Team's view that the patient had suffered significant harm. 14:39

Under the heading "communication with the patient, their family and general practitioners and patient consent" the Review Team found that communication with patients, families or carers was acceptable in 54 of the cases considered but they found grounds for concern in 22 cases considered against these factors. The Review Team studied the consent process under this factor and expressed significant concern in respect of the consenting of patients. In particular the Review Team pointed to a failure in a number of cases to discuss all reasonable treatment options with patients, to explain the implications of treatment or to document relevant consent information to an acceptable standard. The Review Team also identified failures in terms of communication with patients under this factor. 14:39 14:40 14:40

Patient A95, for example, attended a consultation in September 2015 but the follow up letter was not written until December 2016, some 15 months later, thereby depriving the patient's GP of information regarding her condition and care. 14:40

The Inquiry will note that these failures of communication are of the same kind as those which were the subject of investigation by the Trust during the MHPS process which I will look at later this afternoon. 14:41

Team working, including communication with other

members of the care team, MDT discussions and working with colleagues, was another theme explored by the Royal College Review Team. They found that team working was of an acceptable standard in 76 of the cases considered. However, it found grounds for concern in nine cases, whether because of an absence of adequate documentation or because there was a clear need for improvement or evidence of unacceptable practice.

14:41

In the case of A63, for example, the Review Team pointed to the fact that Mr. O'Brien had prescribed Bicalutamide monotherapy in the absence, or in the apparent absence, of any MDT discussion and where there was no evidence that the medication was discussed with the patient. The Inquiry will note that this is a concern which emerged in a significant number of the cases which were considered by the Trust under SAI and SCRR.

14:42

In a further failure of team working, the Royal College highlighted that since this patient had significant comorbidities they should have been referred to clinical oncology or discussed at specialist urology MDT.

14:42

A further heading considered by the Royal College was the issue of "follow up on the patient care". Here under follow up the Review Team highlighted five cases

where there was a need for some improvement. For example in the case of A54, the team pointed to a significant delay in the patient's follow-up care from June '15 to 2017. There were seven other cases which caused the Review Team even greater worry. Here they found evidence of unacceptable practice giving rise to concern for the standard of treatment received by the patients. For example, A13 was a patient who had TURP and had a diagnosis of both prostate cancer and bladder cancer. He had TURP as well as TURBT, another procedure related to the bladder. The Review Team found that there was no clear evidence that he received follow up at any of the three different stages of his clinical journey. In other cases there were large and unexplained gaps between follow ups. 14:43

A29 suffered a delay to his planned surgery and received what the Review Team described as poor follow up care. A55 experienced a two-year delay between diagnosis and surgery. In the case of A82, the Review Team expressed concern that for reasons unknown there were large gaps in follow up. 14:44

The Review Team also looked at the completeness of patient records in connection to the patient's episodes of care. 14:44

The Review Team pointed to significant dissatisfaction with the adequacy of patient records generally. In

particular, it found that record keeping in some clinical records were substandard, referring to records that lacked detailed information of the examinations undertaken, the impact of treatment and aftercare requirements. In respect of some preoperative correspondence and documentation, the Review Team expressed the concern that the inadequacies which were exhibited could indicate that insufficient time had been spent preparing patients for major and sometimes life-changing operations. 14:44 14:45

As regards operation notes, the Review Team made a number of criticisms, including excessive brevity and illegibility.

14:45

All told, the Review Team identified 37 cases in which there was some measure of concern under this heading. Of those 37 cases, it pointed to nine cases where the record keeping was unacceptable to the extent that the patient's standard of care was a concern. 14:45

As I've indicated, Chair, the Royal College was asked to tell the Trust whether there were cases where harm may have occurred and, if so, whether this was serious or moderate harm. 14:46

The Review Team expressed itself satisfied that the clinical management in 90 of the cases reviewed was acceptable in the sense that it had not led to harm.

But it is noteworthy that across a relatively small sample of less than 100 cases, the Review Team pointed to a suspicion that inappropriate care could have caused harm or may have contributed to a poor clinical outcome in four cases. Although in one of those four cases they did observe that it was possible that other urological surgeons would have managed the care in the same manner.

In three other cases the Review Team was more confident in deciding that the quality and safety of the patients' care was unacceptable and that as a consequence the standard of care was of concern. The following observations were made in respect of those three cases: 14:46 14:47

A13. It was unclear to the Review Team whether the patient's Bicalutamide medication was the cause of the interstitial lung disease that the patient developed. Furthermore, it was of serious concern to the Review Team that the patient appeared not to have had any follow up of care following his procedures being undertaken, as well as specific follow up for their prostate cancer for several months prior to the patient's death. 14:47

A29. It was of significant concern to the Review Team that there was a delay in undertaking the planned surgery between February and December 2014, by which time the patient's disease had progressed from 14:47

superficial to muscle-invasive cancer, of which the patient subsequently died. It was the Review Team's opinion that this patient had experienced significant harm due to this delay.

14:48

A55. The Review Team concluded that moderate harm occurred in this case due to the prolonged patient's symptoms for some two years. The Review Team were deeply concerned that there was a two-year delay between the Plaintiff's diagnosis to their surgery being undertaken.

14:48

In turn, the Royal College identified patients that may require further follow up by the Trust. The Review Team pointed to seven cases where there was a need for follow-up care by the Trust to ensure patient safety. Additionally, the Inquiry will note that the Royal College Panel concluded their report by setting out a series of urgent recommendations to address patient safety risks and formulated recommendations for service improvement.

14:48

14:49

The Review Panel did not deal with and were not asked to deal with the adequacy of the Trust's currently Lookback Review or whether the Trust should commence the task of expanding that Lookback Review or of finding some other mechanism to examine the care provided to patients by Mr. O'Brien prior to 2019. The Inquiry will wish to explore with the Trust and its

14:49

witnesses how it proposes to address that question now that it has the report of the Royal College and in light of the concerns which have been expressed so resoundingly by the RQIA. This is clearly a sensitive patient safety issue. No doubt the Trust will want to provide the public with appropriate assurance that the RQIA's concern that a further phase of the Lookback Review should be prioritised and commenced is being given due consideration. 14:50

All of the recommendations which have been made by the Royal College Review Team will no doubt be considered by the Inquiry. Some of those recommendations are specific and relate to the need for the Trust to consider and disseminate this report to its staff and to review its records to ensure that adequate follow-up work is carried out in relation to individual patient cases. Some of the report's recommendations relate to the systems of governance which should be operated by the Trust, are overarching in nature and point to the need for the Trust to adopt better processes to ensure that its interaction with patients and delivery of care is safe. 14:50 14:50

The Inquiry will observe that many of the recommendations resemble the kinds of conclusions to have emerged from the processes initiated by the Trust itself, including as a result of the SAI processes across a number of cases. The Inquiry may judge that 14:51

the repetition of similar concerns and suggestions for reform which have now been registered by the participants in separate review and investigative processes serves to pinpoint where the real issues are, provides a reliable basis upon which the Trust can direct improvement initiatives. 14:51

Let me conclude this part of this opening statement by recapping on what I have discussed.

Madam Chair, as I have demonstrated, there are many issues which have already emerged from a preliminary consideration of the evidence made available by the Core Participants and others which are relevant to part (c) of the Terms of Reference. Our core material is the output from the SAI and SCRR processes, but as you will have observed, there is much of value to be extracted from the evidence provided and to be provided by patients and families and employees of the Trust in particular. It may not yet be possible to exhaustively identify the matters of interest which arise from the cases which have met the threshold for SAI. Further probing and consideration will be necessary, but the main issues are becoming clear. 14:51 14:52 14:52

You will have noted that there is evidence from the SAI and SCRR processes, the Royal College report, and anecdotally, to strongly suggest that patients have suffered harm or have been placed at risk of harm

because of shortcomings in the provision of care or because of failures in the systems of administration, communication, and decision-making which ought combine to enable the safe and timely delivery of appropriate care. 14:53

In summary, the following themes have emerged from the clinical aspects of the cases and will merit further examination, further governance implications. Failures of triage, delays to diagnosis other than as a result 14:53
of failures of triage, failures to secure MDM quorum and appropriate professional attendance, failures to refer patients to specialist MDM, oncology or specialist surgery, failures to implement MDM decisions, whether on time or sometimes at all. 14:54
Shortcomings in the prescription of hormone therapy, primarily relating to what has been reported to the Inquiry as the improper use of Bicalutamide. Failure to utilise or allocate Specialist Cancer Nurses in the care pathway. Failure to access, read and respond to 14:54
reports including histopathology and radiological investigation reports problems with surgical waiting lists. Delays in providing outpatient appointments. Poor secretarial performance and poor communications. The identification of these themes, and there may be 14:54
others, gives rise to many questions. Leaving aside the specific governance-related questions which attach to each incident and each species of clinical shortcoming, there is a general point of particular

significance. The evidence so far assembled appears to show, and this is ultimately a matter for you, Dr. Swart and Chairman, that long before Mr. O'Brien's retirement in July 2020, and the discovery of what has been reported to the Inquiry as multiple findings, and which gave rise to the early alert, the nine further SAIs and a substantial Lookback Review exercise, the Trust had available to it multiple insights into a practice of urological medicine which the Trust admits was at variance with the standards which the Trust set for its consultants and which was placing patients at risk. Those insights were gained or were available to be gained from the events which led to the triggering of the SAI or the SEA reviews and which were initiated between 2010 and 2018. 14:55 14:55 14:56

When these matters are further considered at our public hearings important questions have to be addressed with the witnesses. What lessons were learned from those SAIs? Were appropriate recommendations formulated and were they followed up and enforced? What action plans were put in place? Was there any system of monitoring or follow up? Should Mr. O'Brien's practise have been the subject of particular supervision and scrutiny if there was evidence of repeated transgressions? Was there an underreporting of poor performance? Importantly, why did it take until 2020, after his retirement, for further concerns to come to light? 14:56 14:56

When hospitals and doctors get it wrong there's sometimes a tendency to advance the suggestion that the prevailing institutional culture was one of turning a blind eye. Whether or not there was such a culture in this Trust is a matter for the Inquiry to consider and 14:57
determine. What we do know, and what I will now move on to consider, is that the Trust did not ignore what it judged to be shortcomings. There were the SAI reviews and it did take steps to investigate the performance of Mr. O'Brien using the Managing High 14:57
Performance Standards Framework. That investigation and its effectiveness will now be considered after a short break, I think.

CHAIR: I was going to suggest the same, Mr. Wolfe.

MR. WOLFE KC: I think it's a convenient point. 14:57

CHAIR: So if we reconvene no later than quarter past three and then we can continue.

THE INQUIRY ADJOURNED BRIEFLY AND RESUMED AS FOLLOWS: 15:04

CHAIR: Mr. Wolfe.

MR. WOLFE KC: Thank you. Good afternoon and now for something completely different.

This is Part 3 of the Inquiry's opening statement. 15:14
We're now going to consider managing, let me correct that, I called it managing high professional standards earlier, we'll amend the record to reflect its proper title, Maintaining High Professional Standards or MHPS

which is probably the safer way to express it.

This is the standard or framework or procedure which part (e) of the Inquiry's Terms of Reference requires the Inquiry to examine. There are three constituent parts to this part of the Terms of Reference; namely a need to review the implementation of MHPS with regards to Mr. O'Brien. This will involve an examination of the actions of the Trust leading to a decision to initiate a formal MHPS process, a review of the steps taken within that process to include any follow up action. As part of this examination, it will be necessary to assess whether it was appropriate to initiate a formal process under MHPS at that time and to consider whether the process could or should have been used at an earlier stage or at all. 15:15

The Inquiry is further asked to determine whether the application of the framework was effective. That's the second element of our work. This will require an assessment of the aims of the framework to understand why it was put in place and what factors may have impacted on its effectiveness. In considering the effectiveness of the framework it is important for the Inquiry to bear in mind that additional concerns regarding Mr. O'Brien's clinical practise emerged in 2020 less than two years after the investigation under MHPS concluded and which had not been identified during that investigation. 15:16

As appropriate, I will indicate the kinds of questions which arise for the Inquiry in terms of the Trust's use of the MHPS Framework and its response to what emerged.

15:16

Thirdly, under this part of the Terms of Reference, the Inquiry is required to make recommendations, recommendations to strengthen the framework if required. In order to assist you with that task, Chair, I will briefly draw attention to the reviews 15:17 which have been commenced by the Department, although left unfinished, and some reflections from those who have worked at the coal face of MHPS in recent times.

Let me start with the MHPS Framework and the related 15:17 guidelines. A copy of the MHPS Framework can be found at WIT-18490. It was published by the Department of Health, Social Services and Public Safety (as it then was) in November 2005. It is important to note that paragraph 1 of the introduction to MHPS establishes 15:17 that the document introduces a new framework for handling concerns about the conduct, clinical performance and health of medical and dental employees. It covers any action to be taken when a concern first arises about a doctor or dentist and any subsequent 15:18 action when deciding whether there needs to be any restriction or suspension placed on a doctor's or dentist's practise.

A circular attaching the framework was sent by the Department on 30th November 2005 explaining that MHPS superseded specified pre-existing guidance. Stakeholders were directed to notify the Department of the action they had taken to comply with the framework by 31st January 2006. Both the Trust and the Department have been unable to provide the Inquiry with copies of this notification, although there is no doubt that the Trust sought to embed the framework across its workforce. 15:18 15:19

Disputes have arisen from time to time concerning the contractual status of the framework. In the case of M.A. -v- the Belfast Health and Social Care Trust which was a 2008 Northern Ireland case reported at Northern Ireland Queen's Bench 142, the High Court held at paragraph 50: 15:19

"The MHPS Framework had been incorporated into the contract of employment of a HSE employee in the particular circumstances of that case." 15:19

The Court held:

"By virtue of the statutory provisions, the Department is empowered to give directions to Trusts and Trusts are obliged to comply with such directions. By a duly made instrument of subordinate legislation dated 29th November 2005, the Department directed the Trust and 15:19

others to comply with the MHPS."

From 1st December 2005 or at the very latest 31st January 2006, the Court held:

15:20

"The Departmental MHPS was incorporated into the Plaintiff's contract of employment in that case."

The 2005 directions had the effect of imposing an absolute obligation of compliance with the Framework 15:20
Code on all agencies to whom they were addressed.

The MHPS Framework is clear that health and social care bodies must have their own internal procedures for handling concerns which, in accordance with 15:20
paragraph 11 of the introduction to the framework, must reflect the framework in this document and allow for informal resolutions of problems where deemed appropriate.

15:20

The Trust developed its own guidelines - that is the 2010 guidelines - a copy of which appears at TRU-83985. These were issued on 23rd September 2010.

Chair, you may wish to note that at various points, 15:21
most notably in submissions to Dr. Khan, who was the MHPS case manager in the investigation relating to Mr. O'Brien, and in a grievance raised by Mr. O'Brien on 27th November 2018, Mr. O'Brien argued that it was

only the 2010 Trust guidelines which were incorporated through his contract and not the MHPS Framework. The Stage 1 Grievance Panel, in a detailed response, rejected that submission.

Vivienne Toal, Director of HR and Organisational Development within the Trust who was intimately involved in the production of the guidelines is clear in her view that the Trust Guidelines 2010 were intended to sit alongside and to be read in conjunction with MHPS and the NCAS 2010 guide. 15:21 15:22

I refer to this legal controversy, not in the expectation that the Inquiry should seek to resolve it, rather, you may wish to comment on the fact that a controversy exists at all, almost 20 years into the operation of the Framework and you will wish to consider whether these kinds of legal tensions impact on the effectiveness and efficiency of the process. Of course, regardless of the controversy, the Inquiry may wish to note that Mr. O'Brien did not take legal action to prevent the application of the MHPS Framework in his case. 15:22 15:22

The MHPS Framework includes detailed provisions for dealing with concerns around the conduct, clinical performance and health of practitioners. It is set out in six sections. As should become clear, Chair, you will wish to focus most of your attention on the underlying purpose of the MHPS Framework and the 15:22

provisions contained in Sections 1 and 2 relating to the actions to be taken when concerns first arise, exclusions and restrictions from practise.

Before immersing yourselves in the substance of the Framework, it is important to note paragraph 8 of the introduction sets out the Framework's place as part of a broader apparatus directed to setting and maintaining high standards of practice within the health and social care sector in Northern Ireland. It states: 15:23

"The new approach set out in the Framework builds on four key elements, appraisal and revalidation, the advisory and assessment services of NCAS, tackling the blame culture and new arrangements for handling exclusion from work as set out in Sections 1 and 2 of this Framework." 15:24

I know that many of these elements, including appraisal, revalidation and medical culture are on the Inquiry's radar. I will touch upon aspects of this later in this opening statement. 15:24

Paragraph 9 of the introduction to the MHPS Framework sets out an important objective. It explains that the Framework seeks to address clinical performance issues through remedial action, including retraining rather than solely through disciplinary action while, at the same time, not intending to weaken accountability or 15:24

avoid disciplinary action where the situation warrants that approach. As the Inquiry explores the evidence relevant to this part of its Terms of Reference you will wish to consider and assess whether the appropriate balance has been struck within the Framework and its application between protecting patients from aberrant practise on the one hand and seeking to support practitioners through remedial action on the other. Further, you may wish to assess whether the correct balance is struck in practice between supporting practitioners with remedial intervention and the perhaps competing need on occasion to initiate disciplinary or regulatory action. 15:25 15:25

Paragraph 10 of the introduction to the Framework is also worthy of note. It states that: 15:25

"At the heart of the new arrangements is a co-ordinated process for handling concerns about the safety of patients posed by the performance of doctors and dentists when this comes to the attention of the HPSS." 15:25

It emphasises that when information comes to light the response must be to:

"Ascertain quickly what happened and establish the facts. To determine whether there is an immediate risk. To decide whether immediate action is needed to ensure the protection of patients and to put in place action to address any underlying problem. 15:26

Under these mechanisms it was envisaged that exclusion from work was to be used only in the most exceptional circumstances".

The Inquiry will ultimately have to assess whether in practice those seeking to apply the MHPS Framework in the Southern Trust were able to fulfil these five objectives. If they were unable to do so, the Inquiry will wish to understand why that was the case. As I have already indicated, the Inquiry has the benefit of knowing that the issues touching on patient safety, which were exposed in 2020 and subsequently and which led to multiple SAIs and a significant lookback exercise, did not register during the MHPS investigation. Consideration will need to be given to whether the failure to identify those issues was due, in whole or in part, to the actions of those charged with implementing the MHPS Framework, the complexity of the issues or more fundamental structural issues within the Framework itself. 15:26 15:26 15:27 15:27

The primary focus, I suggest, of the Inquiry's work will be on Section 1 of MHPS relating to the action to be taken when a concern first arises. Part 1 of this section emphasises that the management of performance is a continuous process and this is underscored with the guidance that remedial and supporting actions can be quickly taken before problems become serious or patients harmed. Having regard to this emphasis, the 15:27

Inquiry will wish to explore whether and to what extent remedial action or support was offered to Mr. O'Brien and whether it was effective in dealing with the underlying cause of any concerns.

15:28

Paragraph 3 places an onus on the Trust to ensure that all concerns are properly investigated to establish the facts and the substance of any allegations. That appears to be the key focus of Section 1 of the Framework.

15:28

Paragraph 6 again emphasises the need to consider a remedial or supportive approach, what the Framework labels an informal approach. It is only in cases where informal resolution cannot be found should an employer commence a formal investigation with the potential for exclusion of the clinician to ensure patient safety.

15:28

Chair, you will note that the Framework imports a formal/informal dichotomy. You may wish to consider whether the use of this language is altogether helpful. It is the case that just because the action is informal in the sense that it does not result in a formal MHPS investigation, does not mean that the process cannot be robust and set clear expectations. The language of the Framework may not make this entirely clear. The Inquiry will wish to examine whether the Trust adequately understood what could be achieved using an informal approach, assess any informal steps that were

15:29

15:29

taken and reach a view on whether it was appropriate to instigate a formal investigation in December 2016 or whether this should have been initiated at all or at an earlier or later stage.

15:30

Paragraphs 8 to 14 of Section 1 of the Framework defines the responsibilities of those who may have a role in the MHPS process. They include the Chair, and you will note the particular roles assigned to the designated board member, the Chief Executive, the case manager, the case investigator, the HR director and an organisation called NCAS. I will refer at the end of this section in some greater detail to the important role of NCAS.

15:30

Evidence received by the Inquiry would appear to suggest that some uncertainty existed in relation to the duties attached to some of these functions and interrelationship between them, particularly with regard to the roles of the designated board member, case manager and case investigator. The Inquiry will wish to assess how clearly the Framework defines the relevant functions and whether any uncertainty caused difficulty in the application of the Framework before or after a formal investigation was commenced.

15:30

15:31

As noted above, as noted earlier, great weight is placed within the Framework on the need to quickly establish the facts and on informal approaches.

However, there is relatively little guidance contained within the Framework as to how this should be achieved. Paragraph 15 provides some assistance, although this highlights the objective and purpose of prompt identification of issues rather than describe the method. At paragraph 15 it says:

"The first task of the Clinical Manager is to identify the nature of the problem or concern and assess the seriousness of the issue on the information available. As a first step, preliminary inquiries are essential to verify or refute the substance and accuracy of any concerns or complaints. In addition, it is necessary to decide whether an informal approach can address the problem or whether a formal investigation is needed. This is a difficult decision and should not be taken alone but in consultation with the Medical Director and the Director of Human Resources taking advice from NCAS or Occupational Health Service where necessary."

Further limited assistance is provided at paragraph 16 emphasising that it would be wrong to jump to the conclusion that an individual clinician is to blame for the adverse events, as well as paragraph 17 which highlights that consideration should be given to whether a local action plan to resolve the problem can be agreed with the practitioner. The 2010 Trust Guidelines endeavor to be more specific in relation to the requirement to promptly establish the facts. There

is reference at paragraph 2(1) of the Guidelines to the need to go through a screening process when concerns are first identified, although this is not further explained. This gives way at paragraph 2(4) to the need for the Clinical Manager to immediately undertake 15:33
an initial verification of the issues raised. The Guidelines themselves provide no further substantive guidance on steps which a Clinical Manager should take in conducting this verification exercise, although it is indicated that any actions or decisions taken should 15:33
be reached by that Clinical Manager in conjunction with the nominated HR Manager. Possible action could include no further action, informal remedial action with the assistance of NCAS or formal investigation and/or to include exclusion or restriction of practise. 15:34

The guidelines then introduce the idea of an oversight group comprising of the Medical Director, Director of Human Resources and the relevant Operational Director. Under 2.8 of the guidelines the Clinical Manager and HR 15:34
Case Manager will come to a view and notify their informal assessment and decision to the group which will then quality assure the decision and recommendations regarding the invocation of the MHPS Framework following informal assessment by the Clinical 15:34
Manager and the HR Case Manager and, if necessary, ask for further clarification.

The oversight group's role, therefore, appears to be to

quality assure the decision of the Clinical Manager and to ensure consistency of approach in respect of the Trust's handling of concerns as opposed to being a decision-making body itself. Concept of an oversight group is not one recognised in the MHPS Framework itself, although consultation with the Medical Director and Human Resources is envisaged.

The Inquiry Panel will be concerned to assess how this relationship between the Clinical Manager and the Oversight Group played out in practice, in particular during the critical period between September 2016 and January '17 when a screening report was produced by a Non-Clinical Assistant Director from the Medical Director's office. During that time, Mr. O'Brien was without a Clinical Manager and it appeared to some, including the Case Manager appointed for the MHPS investigation, that the Oversight Group was actively making decisions as opposed to simply quality assuring decisions of clinical managers. 15:35 15:35 15:36

Paragraph 2.8 of the Guidelines suggests that the Oversight Group will promote fairness, transparency, and consistency of approach to the process of handling concerns. The Inquiry will wish to consider whether in fact the personnel who convened to consider concerns in respect of Mr. O'Brien were as familiar as they ought to have been with the Guidelines and what was required from them. The Framework places a great deal of 15:36

emphasis on the importance of the preliminary stages of the process and consideration will be given as to whether the available guidance provided sufficient direction to those holding the key roles.

15:36

Paragraph 18 of Part 1 of the Framework addresses the issue of exclusion and restrictions. This option or these options may be considered when significant issues relating to performance are identified which may affect patient safety. The importance of consulting with NCAS prior to any decision is highlighted. Any such exclusion is limited to a maximum of four weeks before the provisions of Section 2 of the Framework come into effect.

15:37

15:37

Paragraph 20 adds that the four-week period should be used to carry out a preliminary situation analysis and at the end of the period a case conference involving the Clinical Manager, the Medical Director and appropriate representation from Human Resources should be convened.

15:37

Paragraph 10 of Section 2 of the Framework provides additional guidance on the functioning of a case conference, including reference to the need, where a case investigator, if appointed, to provide a report and for the Case Manager to determine if there is a case to answer before considering whether an extended formal exclusion is necessary.

Once a decision to initiate a formal investigation has been reached, the Chief Executive, following a discussion with the Medical Director and Director of Human Resources should appoint a Case Manager, Case Investigator and Designated Board Member. 15:38

Paragraph 29 of Part 1 of the Framework stipulates that all concerns should be investigated quickly and appropriately. A clear audit route must be established for initiating and tracking progress of the investigation, its costs and resulting action. Despite this, the Trust have advised the Inquiry that no formalised audit process was adopted. As I will shortly demonstrate, the MHPS process in respect of Mr. O'Brien became unnecessarily long and protracted and the Trust failed to implement the Case Manager's determination. Would the use of a clear audit route with a purpose of tracking progress and resulting action have prevented these shortcomings? 15:38 15:39 15:39

The precise mechanics of how to conduct a formal investigation are not included in the Framework. The Guidelines are of some better assistance in providing practical teaching and here I refer you to TRU-83692. The same onerous timetable for the completion of the MHPS investigation and related processes is described at Section 1, paragraph 7 of the Framework as is contained in the Guidelines, including a requirement 15:39

for the case investigator to complete the investigation within a period of four weeks from date of appointment, save for provision in the Framework for exceptional circumstances with a further five days to submit a report to the Case Manager. 15:40

The evidence received to date suggests that such frameworks are only rarely complied with. Yet it is quite clear that one of the underlying aims of the time frames is to conduct thorough but urgent investigations. The Inquiry may note with some concern that the process in Mr. O'Brien's case from investigation to determination lasted for longer than 18 months and even then the determination was not implemented. The Inquiry will wish to consider whether this is acceptable in a healthcare setting with patient safety potentially at risk. Can such a process be fit for purpose? The Inquiry will also wish to consider and assess the precise factors which contributed to this delay. 15:40 15:40 15:41

Having considered the investigation report, a Case Manager is required to reach a determination. The options available at that stage are several and they include a decision that no further action is needed, restrictions on practice or exclusion from work, an occupational health intervention, referral to a conduct panel in cases of misconduct, referral to NCAS in cases of concern about clinical performance, referral to the 15:41

General Medical Council where there are serious fitness to practise concerns, and referral to a clinical performance panel where there are intractable problems. The Inquiry will examine the determination which was made following the investigation in Mr. O'Brien's case and question whether all appropriate options were considered having regard to the findings which were made in the investigation. Importantly, it will assess why it appears that no aspect of the determination was implemented during the period of more than 18 months when Mr. O'Brien remained in the employment of the Trust. 15:42 15:42

Let me turn now to introduce the application of the MHPS Framework in the case of Mr. O'Brien. I do that in several stages. I will first of all examine the period, the timeframe I should say, between January and November 2016. 15:42

The material assembled by the Inquiry indicates that management was aware of performance issues and raised those issues with Mr. O'Brien on an ad hoc basis over a number of years. The issues raised with him included triaging, record keeping and storage of notes. So far as the Inquiry can establish, the management of those issues was not escalated, in the words of Mr. Eamon Mackle, for a period of time Associate Medical Director, as a serious governance concern and the MHPS arrangements were not engaged. This was to change in 15:43 15:43

2016. It appears that this was at least partly due to issues being raised by some of Mr. O'Brien's more recently appointed consultant colleagues, Mr. Haynes and Mr. O'Donoghue. Ms. Corrigan, then Head of Service, has recalled that both clinicians drew her attention to cases in which clinical letters had not been dictated and patient records could not be found. Their concerns were shared with Ms. Trouton, then Assistant Director and escalated to Mr. Mackle and on to the Director of Acute Services Ms. Gishkori. The evidence shows that the Medical Director, Dr. Richard Wright, was approached about the issues and that an informal and unminuted meeting took place on 11th January 2016. Dr. Wright has indicated that he cannot recall the details of this meeting. The Inquiry may consider that these events mark the start of a process which was to evolve into a formal MHPS investigation by the end of that year and which only reached a conclusion nearly three years later, albeit not a particularly satisfactory conclusion. 15:44 15:44 15:44 15:45

Let me turn to the March meeting. Ms. Corrigan and Mr. Mackle met with Mr. O'Brien on 30th March 2016 and presented him with a letter. That letter is to be found at AOB-00979. This letter identified four areas of his practise which were regarded as causing clinical governance and patient safety concerns. They were untriaged referral letters, a review backlog, patient centre letters and Mr. O'Brien storing patient notes at 15:45

home.

The letter directed Mr. O'Brien to respond with a commitment and immediate plan to address the above as soon as possible. The formality of a letter and a meeting would appear to have marked a step change in the approach to managing Mr. O'Brien, but the Inquiry will wish to consider whether it was particularly well conceived. The letter to Mr. O'Brien mentioned a plan but it did not prescribe any specific objective target or timeframe. It did not refer to any form of oversight process or reporting mechanism. The MHPS arrangements were not referred to. No deadline was set. What was this plan to look like? And was he to be assisted in its production? Ms. Corrigan states that support was offered to Mr. O'Brien but not taken up. While Mr. O'Brien contends that when he asked about what was expected he was met with a shrug of the shoulder. There was no follow-up to this meeting. Mr. O'Brien did not produce a plan and no one approached him to ask why or to force the issue. This may be explained, at least in part, by the significant personnel change which occurred at or about that time. Mr. Mackle stepped down as Associate Medical Director in April 2016, a month after the meeting and was replaced by Dr. Charles McAllister, while Mr. Colin Weir also came into the post of Clinical Director in June 2016.

On the operational side, Mr. Ronan Carroll replaced Ms. Trouton as the Assistant Director in April 2016. Ms. Corrigan remained in her post, however, and she has explained that the change in personnel meant that the letter of March 2016 was now followed up as it should have been. She acknowledged that this was a failing on the part of herself and others. 15:47

The extent to which those newly in post were briefed or were otherwise aware of the issues will be explored. It is clear, however, that no further steps were taken until 9th August 2016 when Dr. Wright sought an update from Ms. Corrigan before instructing Simon Gibson, who was the Assistant Director in the Medical Director's office, to commence a discrete piece of work on issues of concern and actions taken to date. 15:48 15:48

Mr. Gibson established that no one in the management team had received any proposals from Mr. O'Brien to address the issues raised in the March letter. He produced a screening investigation report for Dr. Wright on 5th September 2016 which indicated that the issues which had been raised in March were all still present and remained unresolved. The report concludes that: 15:48 15:49

"Previous informal attempts to alter Dr. O'Brien's behaviour have been unsuccessful."

And went on to recommend consideration of an NCAS supported external assessment of Mr. O'Brien's organisational practice. It will be recalled, Chair, that paragraph 15 of Section 1 of the MHPS Framework envisages that the task of completing screening or preliminary inquiries should be performed by the Clinical Manager. Mr. Gibson was not that person, yet the task was allocated to him by Dr. Wright. Mr. Gibson has acknowledged that his actions at that point were outside the agreed guidelines, a view shared by Ms. Toal, the Human Resources lead. 15:49 15:49

The significance of the initial screening exercise would appear to be that from that point forward the die was effectively cast and those issues identified in the March 2016 letter and Mr. Gibson's report were largely the focus of the investigation under MHPS which was to follow, although an issue relating to the treatment of private patients was added as an later stage. 15:50

The Inquiry will wish to examine whether steps were taken to try to identify to the fullest extent possible all of the issues of potential concern or whether this was a missed opportunity. A specific question arises in terms of whether it would have required the specific insight and experience of a Clinical Manager to carry out effective screening enquiries and whether Mr. Gibson was capable of that insight. 15:50

Mr. Gibson discussed the concerns with NCAS on 7th September of that year, 2016. In a follow-up letter from NCAS on 13th September it was suggested that disciplinary action could be initiated regarding the storage of patient notes, that poor note taking should be the subject of an audit and that problems with the review of patients and triage could best be addressed by meeting with the doctor and agreeing a way forward. 15:51

An Oversight Group meeting was convened on 13th September 2016 attended by Dr. Wright, Ms. Toal, Mrs. Gishkori, Mr. Gibson and Malcolm Clegg who was the Medical Staffing Manager. The minutes of the meeting which can be found at TRU-00025 are scant. They contain no reference to any discussion with NCAS and simply record the actions agreed, namely that Mr. Gibson was to draft a letter which Mr. Weir and Mr. Carroll were to present to Mr. O'Brien the following week. This letter was to inform Mr. O'Brien that an informal investigation under MHPS was being initiated and Mr. O'Brien had four weeks to address the four areas of concern. A Clinical Manager was not in attendance at that meeting. 15:51 15:52 15:52

Later that same day Mr. Gibson drafted the correspondence. It stipulated that Mr. O'Brien was required to complete triage within 72 hours, reduce the review backlog by 70 patients per month. He was not to store notes at home and it included a requirement to 15:52

make contemporaneous notes in patient records with clinical note reviews to be introduced to ensure that this was occurring.

This letter never issued and the agreed actions which had been discussed at the Oversight Group were never implemented. Mr. Gibson has indicated that he regards this as a missed opportunity to manage Mr. O'Brien at that time. The decision not to issue the letter and implement the steps referred to within it would appear to have been as a result of an intervention by Ms. Gishkori. Having discussed the issues with Dr. McAllister on 14th September, she issued the following new strategy overturning the decisions reached at the oversight meeting of the previous day, a meeting that she had attended. She said: 15:53 15:53 15:53

"I am clear that I wish..."

this is directed to Dr. McAllister: 15:54

"That I wish you [Dr. McAllister] and Colin [Weir] to take this forward and explore the options and potential solutions before anyone else gets involved. We owe this to a well respected and competent colleague. I can confirm you will have communication in relation to this before the end of the week." 15:54

The Medical Director, Dr. Wright, who chaired the

Oversight Group, was consulted on this. Ms. Gishkori told him that the clinical managers had plenty of ideas to try out and she requested three months to deal with this. Dr. Wright indicated that he required sight of an action plan which was to be put in place before consenting to this change of approach. Mr. Weir, Dr. McAllister and Mr. Carroll agreed a further action plan but there is no evidence that it was implemented or shared with the Medical Director. Shortly thereafter, Dr. McAllister ceased to be Associate Medical Director and was not replaced until September 2017. The Inquiry may consider that this created a significant gap in the medical management structure at an important time. 15:54 15:55

A further meeting of the Oversight Group took place on 12th October 2016. At this meeting it was noted that Mr. O'Brien was to be off work in November for planned surgery. It was recorded that Mr. O'Brien had not been told of the concerns raised, however a plan was in place to deal with the range of backlogs with Mr. O'Brien's practise during his absence. 15:55 15:55

An assurance was offered by Ms. Gishkori that when Mr. O'Brien returned the administrative practices would formally be discussed with him. The Inquiry will note that this was now more than six months after issues had been raised with Mr. O'Brien at the March meeting and the process was no further forward. 15:56

In November and December concerns began to emerge about the full implications of an SAI review which was nearing completion in respect of Patient 10. The worry, apparently, was not limited to the issue of triage. In a letter sent to Ms. Gishkori on 15th December by the SAI Review Team, there was reference to grave concerns that urology patient letters were not being dictated. On 20th December Catherine Robinson, Booking and Contact Centre Manager, reported to Anita Carroll, Assistant Director, which was then shared with members of the Oversight Group, that there were 60 clinics going back to 24th November 2014 for which Mr. O'Brien had not provided dictation and she pointed to a risk that something could be missed. Therefore, the Oversight Group met on 22nd December, chaired by Dr. Wright. Again, no Clinical Manager was in attendance, although it has been indicated that both Dr. McAllister and Mr. Weir were on sick leave at the time.

15:56 15:57 15:57

Prior to the meeting, various documents were circulated, a spreadsheet of outstanding triage, the final draft of the Patient 10 SAI report and a summary of the letter of 15th December 2016.

15:58

This was to be a pivotal meeting in the context of the MHPS Framework. Three issues were discussed. Triage: The Patient 10 SAI was said to have highlighted other delays in the triage of referrals.

Mr. Carroll provided an update that between July 2015 and October 2016 there were 318 referrals not triaged.

The second issue discussed was notes. Concern was expressed that patient notes were being stored at Mr. O'Brien's home with a concern that clinical management plans for these patients is unclear and may be delayed. 15:58

The third issue to be discussed was dictation. A backlog of over 60 undictated clinics was reported going back over 18 months and concerning approximately 600 patients. It was said that the Trust is unclear what the clinical management plan is for these patients. 15:59 15:59

The meeting decided that action plans were required by 10th January 2017 to address the issues identified. Concern was expressed that Mr. O'Brien's administrative practices may have caused harm to patients and that there would be a risk of further harm should he return to work. Therefore, it was decided to exclude him from work for the duration of a formal investigation to be conducted under the MHPS Framework. It was agreed that Dr. Wright would arrange to make contact with NCAS to seek confirmation of the approach and that the intention would be to meet with Mr. O'Brien on Friday, 30th December to inform him of this decision. 15:59 16:00

Mr. Weir was to be appointed Case Investigator and Dr. Khan the Case Manager.

An interesting perspective on the activity of the Oversight Group was articulated by the panel which reviewed Mr. O'Brien's Stage 1 Grievance Decision in June 2021. The panel appeared critical of the group, concluding that the "failure to follow up on the March 2016 meeting and letter and the decision to defer any activity on the action plan which had been agreed in September suggests that if the SAI concerning Patient 10 had not arisen, that the question of an MHPS investigation may have been delayed even further or not have arisen at all. The plans to work around Mr. O'Brien are likely to have continued as they had for years previously". 16:00 16:00 16:01

The Inquiry will appreciate that 2016 was a formative period in the context of the MHPS process in this case. It may consider that while the issues of concern were known and relatively well understood, insufficient progress was made towards tackling them until the last hours of the year. The Inquiry Panel will wish to assess the events of 2016 to determine whether management should have more quickly grappled with the concerns and taken appropriate steps to more fully understand all of the facets of Mr. O'Brien's practise where patients were potentially at risk. 16:01 16:02

I now wish to look at the short period between 23rd December 2016 and January 2017.

Between the meeting of the Oversight Group on 22nd December 2016 and the case conference on 26th January 2017, attempts were made by managers within the Acute Services Directorate, most notably Mr. Carroll and Mrs. Corrigan, to ascertain the precise extent of the concerns. The Inquiry Panel will wish to understand who was involved in this process, the sources of information and what, if any, additional concerns or trends were or should have been identified and escalated. 16:02 16:03

Advice was sought from NCAS and this was provided in writing on 29th December 2016. The Trust was told that the investigation should not be an unfocused trawl of Mr. O'Brien's work and that if there were concerns that harm had been caused to patients, or inadequate records, this could be scrutinised in a separate audit or lookback. The Inquiry is conscious that a range of issues came to light in 2020 as a result of a lookback process and further SAI reviews, which were not identified in 2016 and 2017 and had not been flagged by the extant governance systems. 16:03 16:03

Could more have been done in preparation for the commencement of the MHPS investigation to ensure that all potential concerns were exposed and placed within

the Terms of Reference? Or is it the case that the MHPS arrangements would not have permitted such approach? Would this have amounted to an unfocused trawl?

16:04

An additional issue was brought into play at or about that time which hadn't featured in the discussions of the Oversight Group before.

On 23rd December 2016, Mr. Haynes suggested that a concern regarding Mr. O'Brien's management of private patients should be examined. An example of a private patient seen by Mr. O'Brien on 5th September 2016 and placed on the NHS theatre list on Wednesday 21st September was cited. Mr. Haynes flagged his belief that if the theatre lists were scrutinised over the past year, a significant number of similar patients are patient admissions would be identified. Mr. Haynes had previously raised this issue with Mr. Young, who was a consultant urologist and clinical lead and colleague of Mr. O'Brien, and Ms. Corrigan, and this was raised by Mr. Haynes on 27th May 2015 and again on 26th November 2015.

16:04

16:04

16:05

On 28th November 2016, Mr. Carroll flagged this private patient issue with Dr. Boyce, Dr. Wright and Mr. Gibson and Mr. Carroll asked for a report on Mr. O'Brien's TURP procedures for the year 2016.

16:05

While the process of ascertaining the extent of the concerns to be investigated was ongoing, the Trust set about communicating their decision to Mr. O'Brien. Dr. Wright convened a meeting with Mr. O'Brien on 30th December. An agenda explained that the purpose of the meeting was to "discuss an investigation into alleged irregularities of patient note keeping and review triage under the Framework of Maintaining High Professional Standards". At the meeting Mr. O'Brien was informed of concerns with triage, storage of notes and undictated outcomes. The private patients issue, which had been raised by Mr. Haynes, was not discussed at that time. He was also advised of the exclusion. 16:06 16:06

Mr. O'Brien received written confirmation of his immediate exclusion on 6th January 2016. This correspondence noted that exclusion would last for no more than four weeks and that the Case Manager would make contact as soon as possible to progress the formal investigation. The letter also outlined that a meeting would be arranged during the four-week exclusion to allow Mr. O'Brien to propose alternatives to exclusion. 16:06 16:07

On 17th January, Mr. O'Brien wrote to the Trust to outline his concerns noting that he had not been informed of the identity of the non-executive director who was to be attached to the MHPS process. No meeting had been arranged for him to state his case on the immediate exclusion, and raising his concern regarding 16:07

the slow pace of proceedings, having regard to the four-week target set out in the Framework. This subsequently led to correspondence from Mr. Weir dated 20th January 2016 advising that the identity of the Designated Board Member was Mr. John Wilkinson and 16:08
inviting Mr. O'Brien to a meeting on 24th January 2017.

I think that must have been a typo. Let me read that again. This subsequently led to correspondence from Mr. Weir dated 20th January 2017 advising that the 16:08
identity of the Designated Board Member was John Wilkinson and inviting Mr. O'Brien to a meeting on 24th January 2017 to state his case.

Dr. Wright also wrote to Mr. O'Brien at that time. 16:08
Within that correspondence he advised Mr. O'Brien that investigations are rarely completed within four weeks.

A number of other important developments took place during this period, including on 2nd January, 16:09
Mr. O'Brien, as requested, returned patient notes to Ms. Corrigan from his home. The documentation reviewed to date indicates that there were 307 sets of patient notes returned, including 94 Trust patients who had been seen privately by Mr. O'Brien. Ms. Corrigan also 16:09
identified a further 88 sets of records in Mr. O'Brien's office and on cross-referencing PAS found that 27 sets of notes were not available.

On 9th January 2017, Ms. Corrigan met with Mr. O'Brien and was provided with copies of outcome sheets for 571 patients who had been seen at clinic but not dictated. That same day, having been aware of the presence of records in his filing cabinet, Ms. Corrigan went to Mr. O'Brien's office and removed 783 untriaged letters going back to June 2015. The consultant urology team, Mr. Young, Mr. Glacken, Mr. Haynes and Mr. O'Donoghue, worked throughout January to triage these letters, completing this task by the end of the month. 16:10

This period culminated in a case conference which was held on 26th January 2017, attended by members of the Oversight Group, a Case Manager and the Case Investigator. By that date resources had been focused on addressing the triage problem rather than the undictated clinics. The consultant urologist had returned 330 letters triaged, of which nine patients were upgraded to red flag. Seven patients had seen a consultant and met the red flag criteria but were never triaged, and 28 patients had been upgraded from routine to urgent. The remaining 363 untriaged letters were to have been completed by the end of January. 16:10 16:11

The case conference received a report authored by Mr. Colin Weir and Ms. Hynds, Head of Employee Relations. The report highlighted that attempts had been made to resolve the issues informally but noted that no response had been received from Mr. O'Brien when 16:11

matters were raised with him in the previous March. Mr. Weir pointed out that he was aware of some initial indications that suggested patients may have been adversely affected or harmed as a result of Mr. O'Brien's failings, but he was awaiting the outcome of the review then being conducted by the four consultant urologists before going able to determine the full implications.

The responses offered by Mr. O'Brien at his meeting with Mr. Weir on 24th January were also outlined.

The notes of the case conference record that Mr. Weir provided what is described as advocacy for Mr. O'Brien in his capacity as Clinical Director making the point that he was a good, precise and caring surgeon. That he adopted this advocacy role while also acting in the role of Case Investigator appears to be acknowledged by him in his response to the Inquiry. The Inquiry may wish to consider whether it was appropriate for Mr. Weir to be wearing two hats. While he ultimately vacated the role of Case Investigator and was replaced by Dr. Chadha, the fact that he sought to advance the position for Mr. O'Brien, based on his knowledge of his abilities as a surgeon may betray a failure to properly understand his role and the purpose of the MHPS process.

The minutes of the case conference record that the Case

Manager, Dr. Khan, considered that there was a case to answer following the preliminary investigation. It is further recorded that the members agreed with this decision that a formal investigation would now commence. There is some cause for concern that the minutes may not reflect an entirely authentic position. This is because Dr. Khan has since explained to the Inquiry, in his Section 21 response, that he was not clear at the outset what his role involved and that there was some blurring of roles and responsibilities. He has highlighted that the Oversight Group or the Oversight Committee had already made decisions prior to his involvement and the Inquiry is aware that a decision to proceed with informal investigation had been taken by the Oversight Group in December 2016, yet Dr. Khan insists that the decision to proceed with a formal investigation was made by him but that the decision was reached having received advice from the Oversight Committee members. 16:13 16:13 16:14 16:14

The extent to which Dr. Khan had actual ownership of the decision in his role as Case Manager, rather than simply adopting a decision already made by the Oversight Group, is an area of interest for the Inquiry. 16:14

The case conference on 26th January 2017 also determined that Mr. O'Brien would return to work subject to monitoring, hence lifting the exclusion.

The expectation was that any concerns which might be identified during this monitoring arrangement would be brought back before the Oversight Group. It was also agreed that there should be an urgent review of Mr. O'Brien's job plan. 16:15

Ms. Corrigan has indicated that in her view, Mr. O'Brien should not have been allowed back to work so soon. She has called this a mistake. The Inquiry will wish to consider whether the Trust had any option 16:15 other than to permit his return. Ms. Corrigan considers that there were so many issues which weren't considered and that his return to work was not accompanied by a proper plan to manage him. She points out that the monitoring arrangements focused on the 16:15 gaps in his outpatient dictation and outcomes but they completely ignored his administrative responsibilities towards patients who came in as emergencies or as a day case. The monitoring did not attach to that cadre of patients so that the full scale of Mr. O'Brien's 16:16 administrative shortcomings was, in her view, not appreciated or monitored. She points out that this was only identified as a consequence of the investigations which took place from June or July 2020.

16:16

The Chief Medical Officer had been advised on 30th December 2016 that the Trust was engaging in what Dr. Wright described as a four-week period to scope out the scale of the potential problems in relation to

Mr. O'Brien's administrative practise. His scoping exercise was to help to establish the parameters for the Terms of Reference of that investigation.
Ms. Corrigan's contribution would tend to suggest that what was absolutely required, as a matter of urgency, 16:17
was a thorough stripping down of the engine of Mr. O'Brien's practise to see what additional problems were hiding away. If extensive problems of an administrative nature are occurring in one area of his practise affecting several hundred patients and placing 16:17
them at risk of harm, should the Trust have been curious and should it have looked to see what was happening elsewhere? It would appear that this was not done. The Inquiry will wish to consider why it wasn't done and what the implications of that failure were. 16:17

I think, Chair, at twenty past four it might be a convenient period to break. I will finish the Inquiry's opening statement by no later than one o'clock tomorrow. You can hold me to that. And I 16:18
understand that you then intend to hear from the Core Participants from two o'clock with a view to wrapping up hopefully around 4:30/five o'clock tomorrow, perhaps sitting a little later
CHAIR: Gentlemen, those of you who are delivering your 16:18
opening statements on behalf of your clients have been given a one-hour slot, as it were, and we will take a short break to allow movement around in between each of those statements. While you have been given an hour,

please feel free to take less time, if you can. But I have given you an hour and I'll certainly allow that amount of time.

We hopefully will finish at a reasonable hour tomorrow afternoon but I intend to sit on until all three Core Participants have delivered their statements. So ten o'clock tomorrow morning. 16:18

16:19

THE INQUIRY WAS THEN ADJOURNED UNTIL THURSDAY, 10TH NOVEMBER 2022 AT 10:00 A.M.