OPENING REMARKS BY MR. WOLFE

MR. WOLFE QC: Chair, good morning and thank you for your opening remarks. I wish to offer my own brief observations in relation to the hearings which commence today and to say something about where those hearings sit in the context of the Inquiry's Terms of Reference. 10:20

It is appropriate to acknowledge that this is a significant day in the early life of this Inquiry. While the formal public opening of this Inquiry will take place later in the year, today represents the first opportunity to bring the core participants together under one roof to commence the process of advancing the Inquiry's work. 10:20 10:21

It is also a significant day for a more fundamental reason: By convening this week's private hearings, and in deciding that the first evidence to be received should come from patients and their families, you, Chair, are affording meaningful expression to the idea that the patient voice will be at the heart of the Inquiry's work. I know, Madam Chair, that you together with your Panel, as well as the Inquiry Legal Team are determined to make this a patient focussed Inquiry. 10:21 10:21

While the work of the Inquiry has been and will be wholly and robustly independent, there is value in recalling the words of the Health Minister, Mr. Robin

Swann, when he announced in the Northern Ireland Assembly on 24th November 2020 that he intended to establish an Inquiry. The Minister was particularly cognisant of the concerns of patients and their families, and in commending the need to conduct a statutory Public Inquiry in light of the issues drawn to the attention of the Department, he said: 10:22

"I believe that an Inquiry is the best way to ensure that the full extent of the concerns is identified, and for the patients and families affected, to see that those and all relevant issues are pursued in a transparent and independent way. 10:22

Accordingly, if there had been shortcomings in the treatment and care provided to patients who use the Southern Trust's Urology Service, it is important that these are identified, lessons learned, and action taken for the benefit of patients past and future. That is the core focus of the Inquiry and it will be inform the work of the Legal Team." 10:23 10:23

Chair, you have mentioned paragraph (d) of the Terms of Reference and at this juncture it is worth repeating those words: 10:23

"To afford those patients affected and/or their immediate families an opportunity to report their experiences to the Inquiry."

The hearings this week represent the practical outworking of this aspect of the Terms of References, at least in part. A core focus, or core purpose, of inviting patients and family members to give evidence to the Inquiry is to enable the Inquiry to achieve a more direct, and arguably more sensitive, appreciation of the patient interaction with the Trust's Urology Service. If patients feel that they have been adversely affected by their engagement with the Trust, it is important that the Inquiry hears firsthand about the adverse effect and its consequences. 10:24 10:24

Chair, you have outlined some of the limitations of this Inquiry, having regard to the Terms of Reference and to principles enshrined in and to be derived from the Inquiries Act 2005. It is worth emphasising that while the Inquiry will be anxious to learn of and understand the patients' clinical experience, it is not the function of this Inquiry to make findings about the clinical outcomes in individual cases. 10:24 10:25

Nevertheless, the Inquiry is charged, as you have indicated, at paragraph (c) of its Terms of Reference, with examining the clinical aspect of those cases which meet the threshold for a Serious Adverse Incident and any other appropriate cases. The full Terms of paragraph (c) of the Terms of Reference are, as follows: 10:25

"To examine the clinical aspect of the cases identified by the date of the commencement of the Inquiry, as meaning the threshold for serious adverse incident, and any further cases which the Inquiry considers appropriate in order to provide a comprehensive report of findings related to the governance of patient care and after within the Trust's Urology speciality."

Therefore, it is inevitable and necessary, as part of the examination of the clinical aspects of those cases, for the Inquiry to ask serious questions about alleged clinical shortcomings arising out of individual cases or groups of similar cases, whether that is in relation to triage, the implementation of multidisciplinary team decisions, the prescription of low dose Bicalutamide or whatever the concern might be.

It will be necessary for the Inquiry to reach conclusions about any safety concerns which arise, or the wisdom of particular clinical practices whether in individual cases or at cross-groups of cases.

Plainly, there is a close connection between paragraph (c) and paragraph (d) of the Inquiry's Terms of Reference. By hearing from patients about their experiences when accessing Urology Services, the Panel should be enabled to better understand the clinical aspects of their cases but it is important to remember, and this should be underscored, that the emphasis

within paragraph (c) of the Terms of Reference is firmly upon examining the clinical aspects of cases for the dominant purpose of making comprehensive findings on central governance themes of patient care and safety. 10:28

In other words, the Inquiry is not considering the clinical aspects as a goal in itself, rather, where deficits in patient care are found to exist, they will be carefully explored and defined so as to support a wide ranging investigation into clinical governance arrangements within the Trust's Urology Service. It would be important for the Inquiry to expose any failures in clinical governance which may have permitted clinical shortcomings to occur or recur. 10:28

This week, Members of the Panel, you will hear from five patients and/or their family members, each of whom have valuable stories to tell about their experiences of using the Trust's Urology Services. 10:29

I welcome [redacted] to the Inquiry, he sits just across from me. You will hear from him this morning. He is the husband of [redacted], now sadly deceased. She was referred routinely to the Urology Service of the Trust on 29th September 2014. The referral was not triaged by the urologist of the week, who at that time, or during that week, was Mr. Aidan O'Brien. 10:29

As a consequence, the Trust managed the referral by placing her in the new routine patient waiting list in accordance with its default arrangements then in place.

She was not then seen by a consultant urologist until 6th January 2016, a wait of some 64 weeks. When she was seen, it was found that she had a probable cystic renal tumour. A subsequent Serious Adverse Incident Review, which was commissioned by the Trust, identified three factors which contributed to the delay of diagnosis. One of those factors was said to be the failure to triage. In particular, it was found and here I refer to 'PAT-' or page 000007 of your bundle, in particular it was found that the opportunity to upgrade the referral to red flag was lost by the omission to triage. 10:30 10:30 10:30

In his correspondence with the Inquiry, Patient 10's Husband has explained that when Patient 10 became aware of the scale of the gap in the system of triage within the Trust, her confidence in the entire system for her care was undermined. You will find that assertion at page 34 of your bundle, PAT-000034. As you know Chair, Patient 10 was under treatment for a number of serious medical conditions at that time. 10:31 10:31

This afternoon you will hear from Patient 18 [redacted]. I understand that he will be accompanied to the Inquiry by his son, Patient 18's son.

Patient 18's case was considered by a Urology Multidisciplinary Team meeting on 28th July 2011. The MDM discussed his moderate grade moderate volume organ confined prostate cancer. It was decided at MDM that Mr. Aidan O'Brien would see Patient 18 to discuss 10:32
treatment options and that external beam radiation would be advised in the first incident. You will reference to that at PAT-000614.

Patient 18 was seen by Mr. O'Brien on 9th September 10:32
2011, but he was not referred to radiotherapy until almost 11 months later on 25th July 2012, PAT-000579.

Instead, he was first prescribed by Bicalutamide 50mgs, with Tamoxifen 10 milligrams daily, which he took for 10:33
over seven months with side effects before declining this treatment on 27th April 2012.

The appropriateness of that treatment regime has recently been called into question during the Trust's 10:33
Structured Clinical Record Review. And you will find reference to that at PAT-000530 and 000531 and also, when considered by Mr. Patrick Keane as part of a waiting list initiative, PAT-000500.

10:34

Amongst the various issues raised by this case, Patient 18 complains that he was provided with inaccurate information regarding his condition and treatment options so that he was unable to make an

informed choice. You will see reference to that at PAT-000546, and no doubt Patient 18 will elaborate on what he means by that.

Tomorrow morning, Chair, you will hear from Patient 84 [redacted]. He had an emergency ureteroscopy and stenting performed on 28th March 2016. As appears from his Letter of Complaint to the Trust dated 19th September 2016, which you will find at PAT-000200, he was advised that the stent should be removed in six weeks' time. Patient 84 has told the Inquiry that he suffered multiple symptoms associated with the stenting, including pain, bleeding, urgency and frequency. For this reason he endeavoured to make contact with Mr. O'Brien because he was concerned something was wrong and was anxious to obtain a date for stent removal. 10:34 10:35 10:35

A significant issue for Patient 84, as appears from his correspondence with the Inquiry, was the lack of effective communication with the Trust to resolve his difficulties. He claims, PAT-000217, that he was continually fobbed-off. He complains that he became progressively unwell and, despite his contact with the Trust, he never got to speak to anyone beyond Mr. O'Brien's secretary. 10:35 10:36

It was not until he was admitted to hospital with symptoms of severe infection in mid-August 2016 that

the stent was removed. He was hospitalised for seven days and shortly after discharge he was re-admitted for a further week. In his correspondence to the Inquiry Patient 84 has decried the fact the stent was only removed because he became so ill that hospitalisation became necessary, rather than as part of a planned and organised process. He has been left dissatisfied by the response to the complaint to the Trust which pointed out the competing obligation to provide for the care of urgent cancer patients. 10:36 10:37

Tomorrow afternoon, Chair, you will hear from Patient 16's daughter , daughter of Patient 16 , deceased. His case also concerns the failure on the part of Urology Services to arrange for the timely removal, and in his case, replacement of a stent, and the attendant communication failures and serious medical complications which follow. Patient 16 's treatment was the subject of a Serious Adverse Incident Review which reported on 27th January 2020, although it concerned failure to deliver appropriate care in the period of 31 weeks between 26th November 2015, when he was deemed ready for stent removal, and the 29th June 2016 when he was admitted for surgery. 10:37 10:37 10:38

In her correspondence with the Inquiry, Patient 16's Daughter has described her main concern on behalf of her father as the lack of response by Mr. O'Brien to the numerous attempts to communicate with him to address the

stenting issue. The reference to that is PAT-000144.

She has recorded that her father found Mr. O'Brien to be arrogant and dismissive in his dealings with him. That is set out at PAT-000147. 10:38

Finally, on Thursday of this week you will receive evidence from Patient 13. Patient 13's GP referred him to the Trust Urology Service on 28th July 2016. The referral was marked as a routine referral, 10:39 despite a recent history of haematuria. The referral was not triaged by the urologist of the week, who at the relevant time was Mr. O'Brien. Instead, using the default mechanism which the Trust operated at the time, Patient 13 was placed on a routine waiting list in 10:39 keeping with his GP's grading of the case.

However, a subsequent Serious Adverse Incident Review commissioned by the Trust reported that, following a process of internal review or lookback, which took 10:40 place as a result of what has been described by the Trust as the "Index Case", which is a reference to the non-triaged case of Patient 10, Patient 13 case was found to be one of 30 patient cases which had not been triaged during that period of time, each of which 10:40 should have been upgraded to a red flag referral in the opinion of the SAI Reviewers.

A fifth patient, sorry, I should say, four of those 30

patients, including Patient 13, were found to have cancer.

A fifth patient who was not triaged was also found to have cancer subsequently. The SAI Report documented what it described as a six-month significant delay in obtaining a diagnosis and prescribing treatment for a locally advanced bladder cancer in the case of Patient 18. 10:41

While I have explained, just a few moments ago, that it is no part of the function of the Inquiry to resolve individual clinical outcomes, it has been his concern that the significant delay may have had an adverse impact on his outcome. It is a notable feature of this case, just as in the case of Patient 16, that the outcome of the SAI Review was not finalised for some time. 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, yet the SAI review was not signed off until 22nd May 2020, some four to five years after many of these incidents occurred. 10:41 10:42

The concerns which will be explored through the oral evidence of patients, or their family members, during hearings this week and perhaps further patient hearings to be convened during the life of this Inquiry is only one source for the patient experience which is 10:42

available to the Inquiry.

The Inquiry has also received responses to questionnaires from patients, as you have mentioned, Madam Chair, who do not wish to attend to give evidence in this forum. It is your position, Chair, that their wishes are to be respected and that no patient should be compelled to give evidence. Nevertheless, the responses to the questionnaire process will no doubt be fully documented, or sorry, will no doubt be fully considered as part of your overall assessment of the clinical aspects. I intend to draw attention to some of these patient responses at the opening of the Inquiry later this year. 10:43 10:43

It is also important to reflect the fact that the patient experience also speaks to the Inquiry to the multiple Serious Adverse Incident Reviews and the Structured Clinical Record Reviews which examined care received by patients of the Trust Urology Services. It is of note that four out of five cases which you will hear about this week were found by the Trust to meet the threshold for an SAI, the one exception being the case of Patient 84. 10:44 10:44

As I have explained, three of the cases, Patient 10, Patient 16, and Patient 13, have been investigated by the Trust as Serious Adverse Incidents and reports have been produced, whereas the fourth case, that of

Patient 18, was found by the Trust to have met the threshold for SAI but was further examined using the Structured Clinical Record Review methodology. I will give further attention to the outworking of those processes in these and other cases as part of my opening remarks to the Inquiry later in the year. 10:45

It should be emphasised that at least at this time, none of the representatives of the core participants have supplied me with any question or any point which they would wish to have put to any particular patient or family member. That, of course, may change. I have made it clear that there is an opportunity at these hearings for any serious factual dispute to be examined, but there is undoubtedly a recognition on the part of the representatives that many of the issues which may emerge here are not really matters to be contested with the patients themselves. 10:45 10:46

I interpret their approach to be consistent with the spirit of a process which we undertake this week which is intended to enable patients to fully ventilate their concerns and experiences. I am reminded that the absence of questioning should not necessarily be regarded as an acceptance of factual accuracy of what the patients say or the merits of any criticisms which they may wish to make. 10:46 10:46

Ultimately, Chair, it is a matter for you and your

panel to assess the merits of any concern or criticism after hearing and reading all of the evidence which you are to receive today and subsequently. I am sure that this won't be the last time that I will say that.

10:47

Finally, Chair, it might be said that one advantage of conducting these private hearings at some several months remove from the opening of the public hearings in the autumn is that it will afford the core participants an opportunity to reflect upon what they hear. I note, Chair, that you have an expectation that the core participants will take a constructive approach to the issues to be addressed within the Terms of Reference and where concessions or acknowledgments can be appropriately given, this will be welcomed and encouraged.

10:47

10:47

Thank you, those are my opening remarks for today.

Patient 10's Husband, as I have indicated, is sitting in the witness chair. I have had an opportunity, before speaking this morning, to welcome him in private and to talk through some of his concerns. So at this point I think he should be asked to take the oath or affirm, as is his wish.

10:48

10:48

END OF OPENING REMARKS BY MR. WOLFE QC

CHAIR: Just one moment, Mr. Wolfe. First of all,

THE HEARING COMMENCED ON TUESDAY,
21ST DAY OF JUNE, 2022 AS FOLLOWS:

CHAIR: Good morning. Can everyone hear me all right? Well good morning, Ladies and Gentlemen. And welcome to the first hearing of the Urology Services Inquiry.

At the outset I would like to introduce myself and my colleagues who are here today. My name is, for those who don't know, is Christine Smith, I'm a senior counsel at the Bar of Northern Ireland where I have been in independent practice as a barrister since 1985. I am experienced in inquiry work and in March 2021 I was appointed by the Minister for Health to lead this Inquiry. My principal function is to ensure that the Inquiry fulfils its Terms of Reference which are set out on our web-site. I'm also the person who makes all decisions about how the Inquiry is run and will rule on all applications and requests made to the Inquiry.

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

To my left is Mr. Damian Hanbury who is assessor to the Inquiry. Mr. Hanbury is a Consultant Urologist at the Lister Hospital in Hertfordshire. He has many years' experience of working as a consultant in clinical urology. He is currently Honorary Visiting Senior Lecturer at the University of Hertfordshire and is a College Assessor for the Royal College of Surgeons. Mr. Hanbury advises the Inquiry on the clinical aspects of the cases we're looking at so the Inquiry can better understand the issues it is tasked with considering. 10:13

Neither Dr. Swart nor Mr. Hanbury has worked in Northern Ireland and they have no connection to any of the core participants. 10:13

Also present today from the Inquiry Team, are Mr. Martin Wolfe QC, Counsel to the Inquiry, who will make some remarks about this stage of our proceedings shortly. Laura McMahon who is junior counsel to the Inquiry and Niamh Horscroft, one of our junior barristers. Also present is Fiona Marshall, the Inquiry Secretary, and I presume that you have met some of her staff. If you have any questions they are here to help, if you need any assistance in any way please do contact one of the Inquiry staff members. 10:14

Now this stage of our work is being heard in private and I have previously indicated that the Inquiry would

not be opened formally today and Opening Statements would not be required from the representatives of the core participants. Those legal representatives are present here today and I invite them now to announce their appearances. 10:14

Firstly, if I can ask for the appearances on behalf of the Southern Health and Social Care Trust.

MR. LUNNY QC: Madam Chair, Panel, I appear on behalf of the Southern Trust, my name is Donal Lunny QC. 10:15 I appear with Mr. Michael McGarvey and Ms. Avril Frizell is our instructing solicitor who is present as well. We also have two other counsel, they are Alana Harty and Elizabeth Ferguson and we are also instructed by Emmet Fox, another solicitor in the Directorate of 10:15 Legal Services.

CHAIR: Thank you, Mr. Lunny. Then if I could ask Mr. O'Brien's representatives please.

MR. BOYLE QC: Good morning Madam. My name is Gerry Boyle and I am instructed on behalf of Mr. Aidan 10:15 O'Brien. Mr. O'Brien is present and is sitting in the back left-hand side. I am assisted by Mr. Robert Millar, counsel, and we are instructed by Kevin Hegarty of Tughans Solicitors.

CHAIR: Thank you, Mr. Boyle. The Department of Health 10:15 please.

MR. REID BL: Good morning Madam Chair. My name is David Reid, I am counsel on behalf of the Department of Health instructed by the Departmental Solicitor's

Office of whom Sara Erwin, Sarah Wilson and Tutu Ogle are in attendance.

CHAIR: Thank you, Mr. Reid. From the start of our work the Inquiry has been conscious of the fact that due to issues concerning the care of patients that the Minister for Health announced this Inquiry on 24th November 2020. 10:16

And from my appointment in March '21, it was my intention to commence to hear from witnesses as soon as we could and to hear first from patients and families. 10:16

Term D of the Inquiry's Terms of Reference tasks the Inquiry with affording patients and families an opportunity to tell us of their experiences and about the impact of those experiences on them. To fulfil that task, I wrote personally to 71 former Trust patients, or their immediate family members, inviting them to engage with the Inquiry. And I'm very grateful to those individuals and/or their legal representatives who have taken the time to fill in questionnaires and provide us with material. 10:16

I want to again to reassure all those who have contacted us that even if we do not ask them to come and give oral evidence to the Inquiry, what we have learned from their experiences will be taken into account by us. I should also like to take this opportunity once again to encourage anyone else who 10:17

wishes the Inquiry to learn about what happened to them or their loved one to make contact. Details on how they can do so are to be found on the Inquiry's website.

10:17

This week we shall start to hear from some patients or family members who have agreed to come and speak to us in person. But this week will not conclude such hearings and I anticipate that we will hear from those patients we invite to give oral evidence until we conclude our hearings. 10:17

I appreciate how difficult it is to come to a formal setting, to speak to a room full of people, and we have tried to do what we can, bearing in mind that a Public Inquiry is, by its nature, a formal process to make this stage as private as possible and to make these sessions somewhat less formal than what will take place when hearings are live-streamed from November. 10:18

10:18

I should also point out that the audio visual equipment is not yet fully operational, although it will be by November.

I also want to state clearly that this is an Inquiry, not a trial. The process is entirely inquisitorial in nature, designed to uncover facts from which Dr. Swart and I can reach conclusions and then make recommendations to the Minister. The Inquiries Act 10:18

2005, under which we work, expressly prevents us from making any finding of criminal or civil liability. That means that our findings will not have the legal effect of convicting any individual of a crime, nor will it have the legal effect of ordering any individual or body to pay compensation.

Mr. O'Brien is one of the core participants before the Inquiry, as it was cases involving his former patients that led to this Inquiry being set-up. But I must stress that this is not an Inquiry purely into the clinical practice of Mr. O'Brien. We will of course be looking at the clinical aspects of certain cases with a view to fulfilling paragraph (c) of our Terms of Reference. Issues regarding Mr. O'Brien's Fitness to Practise are matters for the General Medical Council and any civil liability is a matter for the courts.

His clinical practice has been the catalyst for this Inquiry, but it is not the primary focus of our work, which is the matters of clinical and corporate governance within the Southern Health and Social Care Trust.

I'm now going to ask Mr. Wolfe QC to set in context the evidence we will hear today and over the next few days. Mr. Wolfe?

THE INQUIRY RESUMED ON TUESDAY, 8TH NOVEMBER 2022 AS FOLLOWS:

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

10:29

10:30

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

10:30

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

10:30

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

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

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

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

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

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

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

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

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

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

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

NO AUDIO COMING THROUGH

10:35

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

NO AUDIO COMING THROUGH

CHAIR: Finally the Department of Health.

NO CLEAR AUDIO COMING THROUGH

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

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

10:37

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

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

material.

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

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

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

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

SHORT PAUSE IN THE PROCEEDINGS

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

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

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

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

To my right is Dr. Sonia Swart, who is my co-panelist. Dr. Swart is a former consultant in clinical

haematology. She practised in her field as a consultant for over 25 years before moving into medical leadership and management roles. She became Medical Director and then Chief Executive Officer of Northampton General Hospital. She is eminently qualified to advise the Inquiry on the issues of governance with which it is primarily concerned. 11:36

To my left is Mr. Damian Hanbury, assessor to the Inquiry. Mr. Hanbury is a consultant urologist in Lister Hospital in Hertfordshire. He has many years experience of working as a consultant in clinical urology. He is currently Honorary Visiting Senior Lecturer at the University of Hertfordshire and is a college assessor for the Royal College of Surgeons. 11:36 11:37
Mr. Hanbury advises the Inquiry on the clinical aspects of the cases we are looking at so that the Inquiry can better understand the issues it is tasked with considering.

11:37

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

Also present today are Martin Wolfe KC, counsel to the Inquiry, who will deliver his formal opening statement shortly, outlining the issues that the Inquiry is tasked with considering and indicating some of what the initial evidence appears to show. 11:37

His junior counsel is Ms. Laura McMahon and both Mr. Wolfe and Ms. McMahon will be questioning the witnesses who come to speak to us.

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

Fiona Marshall, the Inquiry Secretary, heads up a secretariat team of six, three of whom, led by her deputy, Mrs. Eileen Casey, are engaged full-time on information management for the Inquiry. 11:38

Inquiries are set up to investigate matters of concern to the public. They are set up to examine the evidence, establish the facts, find out if things went wrong; if so, why did they go wrong and what lessons can be learned so that mistakes are not repeated. 11:38

This Inquiry is no different. It was set up by Minister of Health, Mr. Swann, to examine the matters of concern that were raised regarding the treatment of patients within the Southern Trust that resulted in patients being harmed. You will hear the Terms of Reference set out in full later by Mr. Wolfe but to put things in very simple terms, it is the task of the 11:38

Inquiry to find out what happened in relation to the care of patients within the Urology Department in the Southern Health and Social Care Trust; what were the systems that allowed that to happen?; did the systems in place to prevent it happening work?; if not, why not?; and to make recommendations to try to avoid it happening again.

One of my first tasks as Inquiry Chair was to designate the Core Participants to the Inquiry. In considering who ought to be a Core Participant, I took several factors into account and although not bound by the Inquiry's Rules 2005, I had regard to Rule 5 of those rules in arriving at my decision. I determined that each of the three Core Participants before the Inquiry played or may have played a direct and significant role in relation to the matters to which the Inquiry relates, has a significant interest in an important aspect of the matters to which the Inquiry relates, or may be subject to explicit or significant criticism during the Inquiry proceedings or in the report or in any interim report.

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

11:39
11:39
11:39
11:40
11:40

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

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

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

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

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

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

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

CHAIR: Thank you, Mr. Reid.

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

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

I have, to date, written personally to 75 former Trust patients or their immediate family members, inviting them to engage with the Inquiry. I'm very grateful to those individuals and/or their legal representatives who took the time to fill in questionnaires and provide us with material. 11:44

In June and September the Inquiry held private hearings

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

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

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

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

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

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

11:46

11:46

11:46

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

11:47

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

11:47

An inquiry is not a trial. The process is entirely

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

11:48

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

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

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

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

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

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

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

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

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

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

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

timetable regularly.

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

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

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

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

1.10 It is properly a matter for the Belfast Trust (employer) and the General Medical Council (regulator) to investigate and adjudicate on clinical decision-making and/or professional conduct of individual clinicians. That said, the Inquiry Panel sought and invariably received permission from patients to pass on any relevant evidence to both the Belfast Trust and the General Medical Council ("GMC") and, where relevant, to the Regulation & Quality Improvement Authority ("RQIA") and Department of Health. During the Inquiry, relevant information from patients was passed to the GMC on 110 occasions, the Belfast Trust on 110 occasions the RQIA in 8 instances and 5 times with other Trusts or relevant bodies.

1.11 In an interview with Radio Ulster on 5th October 2021, INI 124, a patient who had been significantly impacted by the recall, articulated in a most compelling manner, the disappointment and distress of patients who had, the previous day, been informed that the Medical Practitioners Tribunal ("MPT") had acceded to an application by Dr Watt's lawyers that Dr Watt be voluntarily erased from the medical register. In a similar interview on BBC Newsline, another patient, INI 106, also cogently expressed the frustrations of patients that they would not have a hearing on the competence and capability of Dr Watt. The effect of this decision by the MPT, which was decided after a private hearing, was to effectively prevent the GMC from presenting its substantive case to the MPT. This included statements of many of the patients involved in the recall process and who had already given evidence to this Inquiry.

1.12 INI 124 highlighted in her interview on Radio Ulster the number of times over the preceding years that patients had been informed that regulatory matters were within the domain of the GMC, and that this Inquiry was focused on governance matters. The fact that no hearing took place on Dr Watt's fitness to practise was extremely unfortunate. The Inquiry understands that it would have been possible to have proceeded in Dr Watt's absence and notes that it was argued by the GMC that it was in the public interest that the case should have continued in such a manner. Somewhat unusually, the GMC issued a public statement on 4th October 2021 highlighting their *"extreme disappointment"* that a hearing had not taken place. The Inquiry Panel shares that disappointment and believes that the inability of patients to see Dr Watt's practice assessed by an independent tribunal was a bitter blow to them and brought into sharp focus the fact that there has been no public assessment of Dr Watt's practice.

1.13 Patients are not, and cannot be, responsible for the safety of the health system. That sits with those responsible for governing the system. The fact is, however, that when

Editorials

A decade after Francis: is the NHS safer and more open?

BMJ 2023; 380 doi: https://doi.org/10.1136/bmj.p513 (Published 09 March 2023)Cite this as: *BMJ* 2023;380:p513

- Article
- Related content
- Metrics
- Responses

1. *Graham Martin, director of research*[1],
2. *Susanna Stanford, patient safety advocate*[2],
3. *Mary Dixon-Woods, director*[1]

Author affiliations

Recurrent organisational catastrophes remain a disheartening reality

It is 10 years since Robert Francis published the three volume report of the public inquiry into failings at Mid Staffordshire NHS Foundation Trust.[1] Few will need reminding of the harrowing accounts of care at Stafford Hospital or the inquiry's damning verdict—covering not just the trust but system failures at multiple levels. The government's response to the inquiry, to the advisory group appointed to identify high level actions, and to other contemporaneous investigations, signalled a determination for change. It promised wide ranging interventions and legal and regulatory reforms to tackle problems of culture, openness, and willingness to learn.[2,3] What is the legacy for the safety of patients in England?

The policy response sought to act on many of Francis's recommendations. The statutory duty of candour on provider organisations when patients are harmed was implemented quickly, as was the requirement that providers appoint a "freedom to speak up" guardian to promote openness and ensure people's concerns are heard. The Care Quality Commission's (CQC) approach to inspection was reformed. Frameworks for responding to patient safety incidents have undergone two major shifts, while the Healthcare Safety Investigation Branch was introduced, then expanded, then restructured.

Other Francis recommendations were not followed by policy changes. For example, despite growing evidence,[4] standards on minimum staffing ratios have not been realised—and long term financial and workforce challenges, together with post-pandemic pressures on services, have made safe staffing increasingly politically contentious.

Evaluations of the changes introduced are rare, and where they have been carried out—for example, on openness interventions in trusts—they suggest that organisational commitment and capability has varied.[5] The effect of system interventions is similarly difficult to gauge. More broadly, the complex nature of the policy response to the Francis reports and the confounding effects of the pandemic and other variables make it difficult to assess progress. For example, changes to the CQC's approach do not seem to have had an effect on organisational improvement.[6]

Some evidence exists for aggregate improvement across the healthcare system as a whole, whether or not driven by the policy response. The proportion of provider organisations rated good or outstanding for safety by the CQC has risen since 2014, and

staff seem more confident about speaking up about concerns.[7] But not all the signs are positive. Service users report a stagnating or worsening picture of openness in community mental health services.[8] The proportion of staff indicating problems around openness remains worrying: two fifths are not confident they will be treated fairly if they report concerns.[7] Patient satisfaction is falling,[7] mirrored by declines in indicators of staff wellbeing and morale, and in staff views on their organisations' responsiveness to safety issues.[9]

The intersection of safety problems with socio-structural inequalities has proved particularly stubborn: staff from racially minoritised backgrounds continue to experience disproportionate challenges in getting their voices heard,[10] and marginalised patient groups remain at high, and possibly worsening, risk of excess morbidity and mortality.[11]

Among the most disheartening features of the post-Francis NHS are recurrent organisational catastrophes. Three aspects of this phenomenon are especially sobering. First is the repeated failure to identify promptly and intervene effectively in the worst of these events, linked to a persistent lack of valid and reliable measures for surveillance, early warning, and risk based regulation.[12] Second is the NHS's ongoing difficulty in tackling problems of culture and behaviour, including the malign influence of individuals whose unacceptable behaviour and conduct create toxic working environments.[13] Third, and perhaps most dispiriting of all, is the disproportionate representation of vulnerable groups in these disasters, including maternity service users and infants, and people with learning disabilities. Failure to listen to the voices of patients and carers is a recurrent theme of investigations into avoidable harm—and one that the system seems incapable of heeding.

Achieving and sustaining improvement

What can the NHS do to realise improvement and reduce the likelihood of further tragic events? Sustainable improvement is likely to rest more on achieving the spirit than the letter of Francis's recommendations. We suggest three overarching priorities.

These need to start with listening. Psychological safety—a sense among staff and patients that it is safe to speak up without fear of retaliation or being undermined—is critical. But organisations that fail to hear and act will repeat their mistakes and suppressimportant sources of insight.[14]

Next, therefore, is learning: gathering, collating, and acting on intelligence, quantitative and qualitative, formal and informal, leading and lagging. Investment in systems, processes, and people is central, including taking advantage of new technologies.[15] And there must be an end to the repeated failure to evaluate initiatives and learn from them.

Finally, strong leadership is essential. Making patients "the first and foremost consideration of the system and everyone who works in it"[1] means committing to evidence based improvement. It means an uncompromising focus onaddressingcultural and behavioural problems. And it means attending to everyday issues—from operational failures in information systems, through administrative inefficiencies, to consistently demonstrating respect for patients and care for staff—that are central to making openness and safety part of the organisational fabric.

Footnotes

- Competing interests: *The BMJ* has judged that there are no disqualifying financial ties to commercial companies. The authors declare no other interests. Further details of *The BMJ* policy on financial interests are

here: https://www.bmj.com/sites/default/files/attachments/resources/2016/03/16-current-bmj-education-coi-form.pdf.

- Provenance and peer review: Commissioned; not externally peer reviewed.

http://creativecommons.org/licenses/by-nc/4.0/
This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

References

1. ↵
    1. Mid Staffordshire NHS Foundation Trust Public Inquiry
. *Report of the Mid Staffordshire NHS Foundation Trust public inquiry.*Stationery Office, 2013.
Google Scholar
2. ↵
    1. Department of Health
. *Hard truths: the journey to putting patients first.*Stationery Office, 2013.
Google Scholar
3. ↵
    1. Department of Health
. *Learning not blaming.*Stationery Office, 2015.
Google Scholar
4. ↵
    1. Griffiths P,
    2. Dall'Ora C
. Nurse staffing and patient safety in acute hospitals: Cassandra calls again?BMJ Qual Saf2022:bmjqs-2022-015578. doi:10.1136/bmjqs-2022-015578. pmid:36597996
FREE Full TextGoogle Scholar
5. ↵
    1. Martin GP,
    2. Chew S,
    3. McCarthy I,
    4. Dawson J,
    5. Dixon-Woods M
. Encouraging openness in healthcare: policy and practice implications of a mixed-methods study in the English NHS. J Health Serv Res Policy2023;28:14-24. doi:10.1177/13558196221109053 pmid:35732062
CrossRefPubMedGoogle Scholar
6. ↵
    1. Castro-Avila A,
    2. Bloor K,
    3. Thompson C
. The effect of external inspections on safety in acute hospitals in the National Health Service in England: a controlled interrupted time-series analysis. J Health Serv Res Policy2019;24:182-90. doi:10.1177/1355819619837288 pmid:30977673
CrossRefPubMedGoogle Scholar
7. ↵
    1. Illingworth J,
    2. Shaw A,

3. Fernandez Crespo R,
4. et al

. *The national state of patient safety: what we know about avoidable harm in England.*Imperial College London, 2022.
Google Scholar

8. ↵
1. McCarthy I,
2. Dawson J,
3. Martin G

. Openness in the NHS: a secondary longitudinal analysis of national staff and patient surveys. BMC Health Serv Res2020;20:900. doi:10.1186/s12913-020-05743-z pmid:32977819
CrossRefPubMedGoogle Scholar

9. ↵
Care Quality Commission. Adult inpatient survey 2021. 2022. https://www.cqc.org.uk/publications/surveys/adult-inpatient-survey

10. ↵
1. Kline R,
2. Somra G

. *Difference matters: the impact of ethnicity on speaking up.*National Guardian's Office, 2021.
Google Scholar

11. ↵
1. Kapadia D,
2. Zhang J,
3. Salway S,
4. et al

. *Ethnic inequalities in healthcare: a rapid evidence review.*NHS Race and Health Observatory, 2022.
Google Scholar

12. ↵
1. Griffiths A,
2. Beaussier AL,
3. Demeritt D,
4. Rothstein H

. Intelligent monitoring? Assessing the ability of the Care Quality Commission's statistical surveillance tool to predict quality and prioritise NHS hospital inspections. BMJ Qual Saf2017;26:120-30. doi:10.1136/bmjqs-2015-004687 pmid:27090161
Abstract/FREE Full TextGoogle Scholar

13. ↵
1. Dixon-Woods M

. Learning from maternity service failures at East Kent Hospitals. BMJ2022;379:o2755. doi:10.1136/bmj.o2755 pmid:36400438
FREE Full TextGoogle Scholar

14. ↵
1. Jones A,
2. Kelly D

. Deafening silence? Time to reconsider whether organisations are silent or deaf when things go wrong. BMJ Qual Saf2014;23:709-13. doi:10.1136/bmjqs-2013-002718 pmid:25015116
Abstract/FREE Full TextGoogle Scholar

15. ↵
1. Gillespie A,
2. Reader TW

. Online patient feedback as a safety valve: an automated language analysis of unnoticed and unresolved safety incidents. Risk Anal2022. doi:10.1111/risa.14002 pmid:35945156
CrossRefPubMedGoogle Scholar

"I had a lengthy one-off meeting with AOB in July on this subject and I talked to him again on the phone about it last week.

12:43

I agree that we are not making a lot of headway, but, at the same time, I do recognise that he devotes every wakeful hour to his work and is still way behind. Perhaps some of us - maybe Michael, Aidan and I - could meet and agree a way forward."

And just pausing there. We've looked at the way forward, which was the consultants taking that role on temporarily. And then you finish:

12:43

"Aidan is an excellent surgeon and I'd be more than happy to be his patient (that can be sooner than I hope!) so I would prefer the approach to be 'how can we help'."

12:43

Just, we will avoid that last comment from you. But that last sentence, I think, encapsulates your approach was, let's see how we can sort this out, rather than let's go in with sanctions?

A. Yes, yes, I think I learned that skill after being somewhat too robust in my earlier days, and to approach situations saying, first of all, what's the problem? How can we help you? But I didn't think one of those helps was to give him excessive PAs over and above his

12:43

258. I believe that all of the Urology meetings were of a formal nature as noted above. The concerns had been raised either in 1:1's or by email and such were the concerns, this led to formal meetings being established and minuted.

259. On the admin floor in Craigavon Area Hospital, where the operational Assistant Director and Head of Service for urology are based, I would have informal interactions but with little substance otherwise it would be directed to the regular formal meetings.

260. I agreed following an email on 12 February 2021, to meet Kate O'Neill, Clinical Nurse Specialist, on 17th February 2021 regarding her re-banding issue. I met her as requested and advised Mr Carroll, that the meeting had taken place. I got an email from Ms O'Neill a couple of months after the meeting to advise she has successfully been re-banded. 13. *20210322 Q7.45 A3 CNS AFC Discussion located in S21 53 of 2022 Attachments*

261. Following identification of records in Mr O'Brien's office by Mrs Corrigan, with results and reports that remained unsigned, Mrs Anita Carroll investigated this further and spoke directly to Mrs Noeleen Elliot, medical secretary to Mr Aidan O'Brien. Mrs Carroll advised me that Mrs Elliot was a bit upset following the retirement of Mr O'Brien and I agreed to contact her and assure her of our support as the public inquiry had been announced. I cannot recall nor have I recorded the date of this phone call.

262. There have been no further informal meetings between myself and the urology staff and management apart from those cited above.

Q31. During your tenure did medical and professional managers in urology work well together? Whether your answer is yes or no, please explain by way of examples regarding urology.

263. On 17th June 2019, Mr Carroll at his first 1:1 made me aware of ongoing issues within Urology services. At no point was I concerned regarding "working Well Together" issues but rather that the issues related to workforce capacity issues, access for patients to urology services and impact of unscheduled pressures on urology services. I would have experienced the operational and urology team to be a team who were focused on maximising opportunities for better patient outcomes, fighting for their bed stock to be returned to surgical staff, increased access to theatres and additional staff. The working relationships I observed were always positive. 95. *20190617 ADs 1-1 meetings proforma- Ronan Carroll located in S21 53 of 2022 Attachments*

264. The first time I became aware of the ongoing monitored Action Plan (Post MHPS) regarding Mr O'Brien was on 27th August 2019, following an email communication from Dr O'Kane, which I was copied into (51.-53. *20190827 Q8.77 GMC Referral - AOB, A1-A2).* This email was with regard to her referral of Mr O'Brien to the GMC in April 2019. This referral was prompted as Dr O'Kane was newly appointed into the Medical Director role and had become aware of the MHPS Case Determination report and the subsequent grievance

Received from Melanie McClements on 11/07/2022. Annotated by the Urology Services Inquiry.

which had been lodged by Mr O'Brien. The GMC had responded requesting further information. I can recall enquiring what the concerns were from Mr Carroll Assistant Director. He described Mr O'Brien as being held in very high esteem by his patients and that clinically he was reported to be good. The term "Rolls Royce" was used as a metaphor for the type of service he offered. He also referenced the concern regarding timeliness of administrative processes which were under review, but that there had been no issues since commencement of monitoring against the 4 areas identified in the agreed Action Plan (until September2019) (136. *20191008 AOB Oversight A1 located in S21 53 of 2022 Attachments*).

265. Once the concerns were raised on 11 June 2020 regarding the 10 patient delays identified on one day (34. *20200611 Pts to be added to UBL located in S21 53 of 2022 Attachments*), I worked more closely with Mr Haynes, Mr Carroll and Dr O'Kane and with operational colleagues including Mrs Corrigan and subsequently Ms Clayton. There was a healthy respect across all staff and good relationships were apparent.

266. When the concerns were officially shared with the clinical team in September 2020 (Mr Haynes may well have advised of service issues to his consultants in advance of that), there appeared to be a sense of loyalty and respect for Mr O'Brien. I say that as no one raised any concerns regarding the services he offered. The concern appeared to be more on the fact that such high demand levels outstripped the team's ability to deliver and as such left them all feeling vulnerable.

267. At any subsequent meetings, the healthy team relationships were displayed including the consultants referencing the esteem the nursing colleagues were held in and indeed the appreciation for the support of, in particular the Heads of Service Mrs Corrigan and Ms Clayton.

Governance – generally

Q32. What was your role in relation to the Directors of Human Resources and Organisational Development, the Assistant Directors, the Head of Service for Urology, the Medical and Clinical Directors, consultants and other clinicians in the urology unit, including in matters of clinical governance? You should explain all lines of management and accountability for matters of patient risk and safety and governance in your answer. Please name the post-holders you refer to in your answer.

268. Clinical Governance is the system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which clinical excellence will flourish (Department of Health (UK), 2021). The roles for each are portrayed below both at corporate level and individual responsibility level. The governance systems are designed to assure and challenge the care delivered, to ensure patient safety and quality of care.

Received from Melanie McClements on 11/07/2022. Annotated by the Urology Services Inquiry.

A. I met Mr. Haynes.
34 Q. And he certainly was able to answer all the questions, I think that was in November 2020 you met with him?
A. That's right, yeah.
35 Q. And he was able to answer all the questions that you asked about your treatment, about your bladder cancer, about the drugs -- 10:23
A. Oh yes, he was very informed so he was, and he is a very good doctor too because he saved my Personal Information redacted by USI [redacted] a few years ago and Personal Information redacted by USI [redacted]. I have good regards for Aidan as well and Michael Watt, they done their best for me I thought at the time, you know. Obviously they were snowed in with work too maybe. 10:23
36 Q. But certainly in regards to the communication with Mr. Haynes, you felt that he was able to answer the questions that you were asking and that you wanted answers to? 10:23
A. Well, he answered the questions. But if they were satisfactory for me, I don't think they were, because I would have looked at some of them a different way but... 10:24
37 Q. I think one of the things that you were concerned about was whether or not the drug that you had been on had actually caused the cancer? 10:24
A. That's correct.
38 Q. Wasn't that the big worry?
A. Yeah, it was Mr. John Keane actually said it to me in the City Hospital that he done the -- he was the

relatively soon thereafter. He had spoken to my Mum initially and my Mum had put me on. I think she was worried that he would start talking --

26 Q. When you say he?

A. Sorry, Mr. O'Brien, sorry. And I think that my Mum was concerned that she wouldn't be able to communicate with him and understand the medical terms and she had put me on. It was strange, if I can just set the scene for it, because all I had heard from March 2020 to June 2020 was my Dad wanting to hear from Mr. O'Brien and here I was having a conversation with him after all of those months, albeit I appreciate he had seen him in the interim time. My Dad was now dead and I was sitting having that telephone call outside the room that his coffin had lay in only maybe a week or so beforehand. So that was a really strange thing and all I could think of was you need to speak to Dad because he's the person that really needs to have the questions answered. And, whatever about this conversation, we can't reverse time, we are where we are. And I remember that was sort of my feeling about it. He expressed his condolences and he had said he was particularly fond of my Dad and I had said my Dad had felt the same, maybe not albeit towards the end of his treatment, end of his life, but I think it is important that I do say that, that he, his interactions with him on a personal level had only ever been anything but positive and reassuring and I appreciated him expressing his condolences to us. He told me some

11:35 11:36 11:36 11:36 11:37

others in relation to Mr. O'Brien, or between Mr O'Brien and others, given the concerns identified.

58.1 In respect of concern (i) *not returning GP letters from triage*, it is my understanding that, during the 11 years that I worked with Mr O'Brien, he was afforded many opportunities and support to comply with normal practice. In terms of agreed ways forward:

a. On at least two occasions (2012 and 2014) Mr Young did his triage for him to allow him to get caught up on his admin. Whilst he agreed to this for a short period of time, on both occasions I was led to believe by Mr Young that Mr O'Brien asked to have triage given back to him. In addition, on 19 September 2014 I received an email from the booking centre advising that Mr Young was no longer doing Mr O'Brien's triage On both occasions this had been done without mine or any of the senior managers' knowledge.
   Documents attached namely:
   356. 20140919-email urology triage
   357. 20140919-email urology triage
   and can be located in folder - Martina Corrigan - no 24 of 2022 – attachments

b. Mrs Burns agreed the default mechanism of adding patients to the waiting list I line with the GP's clinical priority so that pressure would be taken off Mr O'Brien and the patient would not be disadvantaged.

58.2 In my opinion, the letter that Mrs Trouton and Mr Mackle gave to Mr O'Brien in March 2016 in respect of review backlog, notes at home, triage, and non-dictation was an opportunity afforded to him to address these concerns which had been ongoing for quite some time. However, it was an opportunity to agree a way forward which Mr O'Brien didn't accept.

Received from Martina Corrigan on 07/07/2022. Annotated by the Urology Services Inquiry.

Corrigan, Martina

From: Robinson, Katherine
Sent: 19 September 2014 09:18
Cc: Corrigan, Martina
Subject: Fw: Urology Triage
Attachments: lb .pdf

From: Browne, Leanne
Sent: Friday, September 19, 2014 08:49 AM
To: Robinson, Katherine
Subject: Urology Triage

Katherine, is Mr O'Brien triaging again? Paulette has returned the attached proforma saying Mr Young no longer triaging

Leanne Browne
Acting Supervisor – Gynae, Urology, Urology ICATS, Orthoptics Referral & Booking Centre Ramone Building
Craigavon Area Hospital Ext [redacted]

Received from Martina Corrigan on 07/07/2022. Annotated by the Urology Services Inquiry.

Mr O'Brien = (Mr Young) Mr Young no longer imaging AOS & data has been given to my

Reid Allen

GENERAL UROLOGY – SOUTHERN TRUST

Referral & Booking Centre – Please record the registered referrals and forward to Consultant on rota for triage.

Secretaries – please return with triaged referrals to Referral & Booking Centre, Ramone Building, CAH

Patient Name	Hospital Number	Referrer	OP Reg	New Referral	Review patient	Date referr returned
[redacted] Personal Information redacted by the USI			1619	CUZN		AOS PT. 17/9/19

Received from Martina Corrigan on 07/07/2022. Annotated by the Urology Services Inquiry.

Dr Neta Chada, Case Investigator met with Mr O'Brien on 3 August to seek a full response to the concerns identified during the course of the investigation process. Mr O'Brien has provided recent commentary in respect of the statement drafted for his agreement. Given the timing of receipt of this commentary and to avoid further delay with conclusion of the investigation, the drafted statement along with Mr O'Brien's comments have been included for completeness. **(Appendix 25)**

The statement is comprehensive and documents Mr O'Brien's responses to each of the terms of reference (except for term of reference 4). For the purpose of this section of the report, I have highlighted the salient points of Mr O'Brien's response.

Un-triaged referrals

Mr O'Brien confirmed that of the non-personalised referrals allocated to him i.e. those allocated to him as Consultant Urologist of the week, he triaged all red-flag referrals during 2015 and 2016 but did not triage the remaining referrals during 2015 and 2016 (i.e. he did not triage routine and urgent referrals). Mr O'Brien advised that in 2014 when the Consultant of the week model was introduced, he agreed with doing triage but soon found it impossible to do. He advised that he had highlighted that it was not possible to do triage when consultant of the week, and furthermore that it was unclear as to what the process was supposed to be.

Mr O'Brien advised that he was in agreement with the Consultant of the week model when it was introduced in 2014, he advised that there had been no Trust directive regarding triage but that it was the consultant clinical staff who agreed the triage process. Mr O'Brien confirmed he was present when the matter of triage was agreed with his colleagues.

Mr O'Brien confirmed that he had undertaken all red flag triage but the rest was not done because he did not have time to do so. Mr O'Brien outlined that there is a vast difference between triage and proper or advanced triage which he had raised at various meetings. He outlined his view that if consultants were not doing proper triage, why request Consultants to do it at all? Mr O'Brien stated it was his view that the triage being undertaken i.e. a look at the referral information and categorisation to determine upgrade based on key phrases or indicators, could be done by Advanced Nurse Practitioners.

Mr O'Brien confirmed he was aware that triage was the agreed system in place and outlined that he had raised it at various meetings because he found it impossible to do. He accepted that he did not specifically advise he was not undertaking triage and this is something he regrets. He outlined that as NICAN Chair he had endeavoured to get his colleagues to do advance red flag triage but this didn't happen.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

targets for long. The Cancer Performance Dashboard Report of December 2017 [see AOB-80387 – AOB-80391] detailed the numbers of patients breaching timeline targets in 2016 and 2017, and the service inadequacies causative of those breaches. The Cancer Performance Dashboard Report of January 2018 [see AOB-80491 – AOB-80506] demonstrated that urological breaches accounted for 52% of all Southern Trust breaches of the 62 day targets during 2017 and 37% of all Southern Trust breaches of the Inter Trust Transfer targets. These reports confirmed the disproportionate and disparate inadequacy in the Trust's urological cancer service, even though it continued to be the priority of the urological service. The disparity continued to worsen during 2018 and 2019. Some 60% of the Trust's breaches of the 62 day timeline targets were urological in 2018, and 41% of its breaches of Inter Trust Transfer targets were urological in 2018. By mid-2019 onwards, patients referred with a suspicion of prostate cancer waited over 100 days for a first outpatient appointment, never mind having their definitive treatment initiated within 62 days. [see TRU-83024 – TRU-83038 (Dec 2017), AOB-80480 – AOB-80506 (Jan 2018), TRU-83039 – TRU-83334 (Mar 2018 – Dec 2019]

82. Cancer services apart, it had been evident for years that the urological service was inadequate, as the numbers of acute admissions and of referrals continued to increase. Among conflicting concerns was an increasing appreciation of the need to be able to provide, at the very least, as optimal a service as possible to those acutely admitted. It was increasingly acknowledged that this was not possible without having a 'Urologist of the Week' (UOW) freed of all elective care to ensure optimal inpatient care, and particularly to those acutely admitted. This was all the more evident due to patients acutely presenting to three acute hospitals within our catchment area. The UOW model was fully introduced in November 2014 and did ensure improved management of those patients. In particular, every effort was increasingly made to avail of staffed theatre sessions for the surgical management of patients who had been acutely admitted.

83. Concurrently, the number of referrals to the Urology Service was steadily increasing. By June 2012, there were only 533 patients awaiting a first outpatient

Received from Tughans OBO Mr Aidan O'Brien on 02/11/2022. Annotated by the Urology Services Inquiry

Conclusion

Patient 10 had a complex right renal cystic lesion since December 2012. During the next two years, its potential significance had either not been appreciated, or had been appreciated but not reported by at least two radiologists, and not reported to the urological service. Similarly, the potential significance of the lesion had not been appreciated by at least two clinicians who had requested further imaging which had been advised by radiologists in the investigation of the lesion from June 2014 to March 2015, and had similarly failed to refer Patient 10 to the urological service. I believe that the Review Panel may have failed to appreciate the significance of the cyst having changed between 2011 and 2012.

Even though there were failures on the part of clinicians and radiologists who had assessed and investigated Patient 10 and the index right renal lesion, I found the Review Panel's emphasis on the lack of triage of the letter of routine referral as the main cause of delay in Patient 10 having a urological appointment, as remarkably asymmetric. I do believe that it would have been reasonable and defensible to have relied upon the information contained in the letter of referral, and to have maintained the referral as routine. Therefore, lack of triage did not impact upon the time to consultation.

I also do believe that the triage on non-red flag referrals should be revisited, with a commitment to accommodate all views, to discuss who, when and how this challenge can be satisfactorily resolved.

Aidan O'Brien.

25 January 2017

Received from Tughans OBO Mr Aidan O'Brien on 26/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

on CT. A malignant node in the let axilla with invasive lobular carcinoma was confirmed.

15 February 2016 Patient 10 had a left axillary node clearance. Staging and further management of Patient 10 s renal cyst has been postponed.

Patient 10 is recovering from a laparoscopic partial nephrectomy for confirmed papillary renal cell carcinoma which was performed on 31 October 2016.

6.0 FINDINGS

The Specialists within the Review Panel individually assessed each of Patient 10 's radiological investigations in the timeframe between 24 June 2014 and 6 January 2016. The report by Dr 2 on 29 September 2014 references the findings of the USS and CT images done in June and July 2014. The Panel agree that when Dr 2 mentioned the earlier findings within the 29 September 2014 MRI report, it implied that the ovoid cystic mass noted had been seen and had been investigated. The inclusions of previous imaging findings are ambiguous. The consensus is that Dr 2's reported findings in relation to Patient 10 's MRI of both kidneys were misleading and were inappropriately condensed. The Panel contribute this to human error. This error was the primary contributing factor to the delayed recognition of a potential renal cancer and its subsequent management.

The Review Panel agree that the absence of a complete right kidney assessment, and the wording of the MRI report, made it extremely difficult for clinicians to detect the missing clinical detail. This provides sufficient rationale to why Patient 10 was not referred to Urology for immediate assessment by Dr 3 or the GP Dr 5. The CT chest and abdomen of 29 October 2014 reported a complex right renal cyst. This important finding was not included in the letter by Dr 3 to Patient 10 on 7 November 2014 and was not referred on for urological opinion. This represents a missed opportunity to expedite investigation of a reported abnormality.

The Review Panel reviewed the GP Referral Letter management for Patient 10 in October 2014 .In summary; Dr 6 was the Consultant Urologist on-call on 30 October 2014 and was responsible for the triage of the GP letters for that week. Patient 10 was one of eight letters for Triage.

The Triage form for 30 October 2014 was not returned to medical records for processing. After 10 working days, the booking centre e-mailed Dr 6's personal secretary seeking management advice for the 8 patients with outstanding triage. After no reply, a second email request was sent to Dr 6's personal secretary seeking management advice which was outstanding from 30 October 2014. At this point the informal booking centre default process for patients with no referral triage was initiated. The informal default triage management process was introduced in May 2014 to ensure the GP's referrals were allocated to a 'waiting list' in the event that the triage was not returned. A default management process was formally circulated on 6 November 2015.The pathway for GP referrals without triage is for the medical records team to accept the GP Grading, code the patient specialty as 'General Urology' and allocate the next available new patient appointment. The length of time until

Southern Health and Social Care Trust

APPENDIX 6

Revised November 2016 (Version 1.1)

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: Personal Information redacted by the USI

Date of Incident/Event: January 2016 – September 2016

HSCB Unique Case Identifier: Personal Information redacted by the USI

Service User Details: (*complete where relevant*)

Responsible Lead Officer: Dr J R Johnston

Designation: Consultant Medical Advisor

Report Author: The Review Team

Date report signed off: 22 May 2020

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

1.0 EXECUTIVE SUMMARY

During an internal review in 2016, following an Index Case, the Trust identified a number of GP Urology referrals who were not triaged by one particular Consultant Urologist; 30 patients should have been red-flag referrals and of these 4 had cancer. A fifth patient (Patient 15), discovered during an outpatient clinic, was included as he was also not triaged and subsequently had a cancer confirmed.

Patient 15 – a 68-year-old male was referred to Urology Outpatients on 30 August 2015 for assessment and advice for an elevated Prostate specific antigen (PSA) (The blood level of PSA is often elevated in men with prostate cancer). The referral was marked Routine by the GP. The referral was not triaged on receipt. However, a second GP referral was received on 29 January 2016 marked Suspected Cancer Red Flag and had received a red flag appointment. Following this referral, he was seen in clinic on 8 February 2016 (D153). On day 166, Patient 15 was diagnosed with a confirmed cancer; a resultant 6-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 14 – a 63-year-old male was referred to Urology Outpatients on 3 June 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review, the referral was upgraded to Red Flag and was seen in clinic on day 246. On day 304, the patient had a confirmed cancer diagnosis. There has been a resultant 10-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 11 – a 68-year-old male was referred to Urology Outpatients on 28 July 2016 for assessment and advice for an elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of an internal review the referral was upgraded to Red Flag and seen in clinic on day 217. On day 258, Patient 11 was diagnosed with a confirmed cancer; a resultant 9-month delay in obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Patient 13 – a 51-year-old male referred to Urology following an episode of haematuria on 28 July 2016. The referral was marked Routine by the GP. The letter was not triaged and Patient 13 was placed on a routine waiting list on 30 September 2016. As part of an internal review this patient's referral letter was upgraded to a Red Flag referral. Patient 13 was reviewed at OPD on 31January 2017. Subsequent investigations diagnosed with bladder and prostate cancer. Patient 13 has locally advanced bladder cancer. There has been a resultant 6-month significant delay in obtaining a diagnosis and a recommendation of treatment for his bladder cancer.

Patient 12 – a 73-year-old male was referred to Urology Outpatients on 8 Sept 2016 for assessment and advice on lower tract symptoms and elevated PSA. The referral was marked Urgent by the GP. The referral was not triaged on receipt. As part of the internal review the referral was upgraded to Red Flag and was seen in clinic on day 152. On day 215, Patient 12 had a confirmed cancer diagnosis T3a with no nodal metastases. There has been a resultant 8-month delay in

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

obtaining diagnosis and a recommendation of treatment for a prostate cancer.

Causal Factors

1. Referral letters did not have their clinical priority accurately assigned by the GP. Referral letters were not triaged following receipt by the Hospital.

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

manner.

Recommendation 8

The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

Recommendation 9

Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10

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 Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11

Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12

Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

2.0 THE REVIEW TEAM

Dr J R Johnston - Consultant Medical Adviser - Chair

Mr M Haynes - Consultant Urologist

Mrs K Robinson - Booking & Contact Centre Manager

Mrs T Reid - Acute Clinical & Social Care Governance Coordinator

3.0 SAI REVIEW TERMS OF REFERENCE

1. To undertake an initial investigation/review of the care and treatment of patients "Patient 15", "Patient 13", "Patient 12", "Patient 14" and "Patient 11", in the period after referral to the SHSCT Urology service using

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

3.0 SAI REVIEW TERMS OF REFERENCE

National Patient Safety Agency root cause analysis methodology.

2. To determine whether there were any factors in the health & social care services interventions delivered or omitted to "Patient 15", "Patient 13", "Patient 12", "Patient 14" and "Patient 11" that resulted in an unnecessary delay in treatment and care.
3. The investigation / Review Team will provide a draft report for the Director of Acute Services. This report will include the outcome of the Team's investigation/review, identifying any lessons learned and setting out their agreed recommendations and actions to be considered by the Trust and others.
4. The Trust will share or disseminate the outcomes of the investigation/review with all relevant parties internally and externally including the service user and relevant family member(s) (where appropriate).

4.0 REVIEW METHODOLOGY

The Review Team will undertake an analysis of the information gathered using RCA tools and may make recommendations in order that sustainable solutions can minimise any recurrence of this type of incident. The Review Team will request, collate, analyse and make recommendations on such information as is relevant under its Terms of Reference in respect of the incident outlined above.

Gather and review all relevant information

- Inpatient notes Craigavon Hospital.
- Information from the Northern Ireland Emergency Care Record (NIECR) and Patient Administration System.
- Information from laboratory systems.
- Information obtained from relevant medical, nursing and management staff.
- Review of Relevant Reports, Procedures, Guidelines.

Information mapping

- Timeline analysis
- Change analysis for problem identification and prioritisation of care delivery problems and service delivery problems as well as identifying contributory factors.

5.0 DESCRIPTION OF INCIDENT/CASE

5.1 Triage of GP referrals - background

The general public expect that, when they engage with their GP complaining of symptoms that are potentially due to a cancer, they will be referred to the appropriate secondary care services promptly and that they will respond, also promptly, to confirm or exclude the diagnosis of cancer.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

The DHSSPSNI **Service Framework for cancer prevention, treatment and care** (Standard 13) of 2011 indicates, "*All people with signs and symptoms that might suggest cancer should be appropriately assessed by their GP and referred promptly on to hospital for further tests if needed*".

Cancer specialists, working in networks, have formulated lists of symptom and sign triggers which can signify the development of a cancer. Using these lists, primary care doctors can refer patients into secondary care; triaging a large number of patients by assigning them to different degrees of urgency (Routine, Urgent and Red-flag). If these are used as designed, this can provide an efficient referral system.

NICE have been instrumental in ensuring uniformity and the validity of these cancer recognition and referral lists of symptoms and signs. They have also formulated guidance regarding how safety nets should be setup to ensure patients are not missed. Local programmes, using this type of guidance, have been established, under the auspices of NICaN and the HSCB, to set up these triage pathways and safety nets.

5.2 Triage of GP referrals – Northern Ireland

NI Referral Guidance for Suspected Cancer (2012)

The Northern Ireland Referral Guidance for Suspected Cancer 2012 is based on the NICE clinical guideline, CG 27 - *Referral guidelines for suspected cancer,* published in June 2005. This has a section on Urological Cancer. It was introduced to GPs by HSCB correspondence (30/12/2012), revealing the new red-flag process and indicating in appendix A that, "*triaging will take place in a timely manner, within 72 hours of receipt of referral or the referral should continue with the GP Prioritisation".*

This is still the only set of referral guidance for suspected urological cancer available online on the NICaN website (last accessed 18/11/2018).

However, the 2005 CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* published in June 2015. This was endorsed by the Department of Health (NI) with HSC (SQSD) (NICE NG12) 29/15 on the 19th August 2015 which instructed the HSCB / PHA to send out the guidance to the appropriate Family Practitioners. This particular kind of guidance requires the HSCB to circulate regionally endorsed NICE guidelines to Trusts and GPs for implementation. Trusts are expected to review guidance against a base line assessment and provide HSCB with an assurance that the guidance has been implemented. If a Trust is unable to fully implement the guidance within the one-year period without regional co-ordination and/or additional resources, they should provide a formal assurance to HSCB, and this is to be managed as part of the risk management process. This assurance process does not however apply to primary care and GP's.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

NICaN Urology Cancer Clinical Guideline (2016)

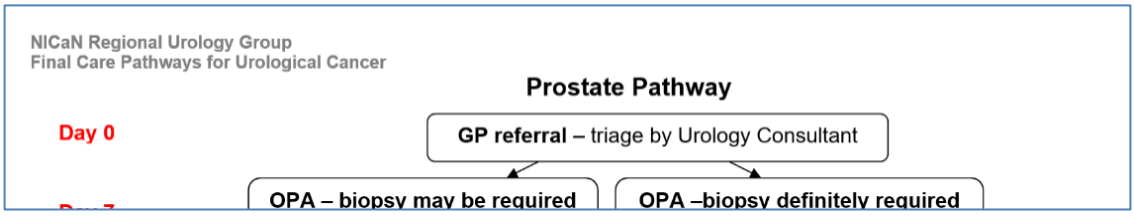
The NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016), was produced regionally to support the diagnosis, treatment and management of urological cancer. This version included amendments, to replace the previous red flag guidelines, with those from NICE NG12; the document was signed off on behalf of the NICaN by Consultant Urologist, Cons1.

The Review Team's evaluation of the advantages of NICE NG12 (2015) over the CG27 (2005) guidelines reveals fewer cases would be red-flagged for Urology, as a result of,

- a reduction in number of non-visible haematuria patients; and
- increases in age criteria of 45 years and over.

However, rollout of NG12 by the HSCB does not appear to have happened. The Review Team understands that the reason NG12 has not been implemented lies with ongoing discussions between the HSCB and GPs.

Appendix 2 of the NICaN Urology Cancer Clinical Guideline guidelines highlights the Urology Care pathways. Cons1 was present at the workshop discussing those on 02/10/2008. It clearly indicates that, for the Prostate pathway, the GP referral would be triaged by the Urology Consultant.



5.3 Triage of GP referrals – SHSCT

The process of Urology triage in CAH is based upon the NI Referral Guidance for Suspected Cancer of 2012 as described above i.e. it is based on the 2005 NICE CG27 guidelines and not the more up to date 2012 NG12. In CAH, triage of referrals is performed by the Consultant Urologist of the week.

The SHSCT Urological Cancer multi-disciplinary team (MDT) was led at the time by Consultant 1 (Cons1), who was also a joint chair.

Over a period of decades, within the SHSCT and Craigavon AH, there were occasions when triage was not performed; and this varied between consultants and specialities. Acute Services had a particular problem with this issue. Preliminary discussions by the Review Team revealed that triaging within Acute Services was a, "*very haphazard process going back for approximately 25 years. There were many Consultants who would not triage but Consultant 1 was the most persistent and there were multiple attempts to tackle this issue*".

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

Interview with Associate Medical Director (AMD1)

AMD1 first became aware of waiting list problems with Cons1 in 1996–8 when AMD1 was the lead clinician in outpatients. Cons1's OPD letters were being kept in a ring binder and were not on any waiting list. Once challenged, Cons1 would stop this practice and improve but would then slip back. There were further non-triage meetings with Cons1 when AMD1 was the Clinical Director of Surgery.

Interview with Director of Acute Services (DAS2)

In 2007, DAS2 (while in previous post in CAH) found a waiting list which was 10 years long. They worked on this with the Consultant, Cons1, and cleaned it up; they found no serious patient related issues.

Interview with Director of Acute Services (DAS1)

DAS1 indicated that the Urology Services were under various kinds of pressure during her time as Director. There was a regional transformation project in place for Regional Urology Services under Mr M. Fordham; this generated an element of pressure to modernise and change. Along with this and other issues, including the triage problem, Consultant 1 struggled to adapt to these changes and to comply with the other issues and triaging. DAS1 paints a picture of many issues with Cons1, triaging being only one of many issues but, in her opinion, not the most important issue.

Nevertheless, in April 2010, Consultant 1 (Cons1) was put under pressure to complete his triage list. The surgical Associate Medical Director (AMD1) brought concerns to DAS1. The other Urologists had been 'covering' triaging for Cons1; the Head of Service Surgery had informed AMD1 of this. They met Cons1 the next day. The European Association of Urology meeting was in Spain the following day and Cons1 wished to attend. DAS1 and AMD1 informed Cons1 he would not be attending the meeting unless he triaged all his referrals immediately. Cons1 duly addressed the triage backlog, completing them that evening. From that time on, AMD1 and the Head of Service (HoS1) monitored that Cons 1 was triaging the GP referral letters. However, DAS1 commented that the HoS1 had a difficult job managing Cons1.

Following interview with Head of Service (HoS1)

The Head of Service for Urology (HoS1) indicated that she inherited the problem upon appointment although she was aware that it was a long running issue, going back perhaps 25 years. She highlighted this was an ongoing issue with Cons1. He had the longest backlog and took longest to triage. There were issues with other Consultants who, on occasion, did not triage but Cons1 was the only one, when asked to triage, didn't do it. This came to head in 2010 (referred to above) and again in 2014.

Informal Default Triage (IDT) process

In May 2014, after escalation to HoS1, an Informal Default Triage (IDT) process was put in place by the Trust's booking centre. This process allowed the booking office to allocate

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

5.0 DESCRIPTION OF INCIDENT/CASE

patients, who had not been triaged in time, to be allocated to a 'waiting list' using the GP triage category. Therefore, this IDT process of putting patients on the waiting list without triage meant that they did not get missed. However, some patients, who should have been triaged as a red flag, waited on the waiting list with their 'incorrect' GP triage category. After much discussion, this detailed process was formally circulated to all specialties on the 6th November 2015 by the Assistant Director of Support Services (ADSS1).

When questioned about this IDT process, the DAS2 was not aware of it even though it started during her time in post i.e. May '14. When asked about its potential problem of leaving incorrectly triaged (by their GP) patients on a waiting list she stated, "*Completely ridiculous, because would allow a cancer patient who should have been red flagged by their GP to go unchallenged by a Consultant triage process i.e. could have to wait for 11 months*".

5.4 Index case

In 2016, the SHSC Trust investigated (RCA ID Personal Information redacted by the USI), in what subsequently became an 'Index case' for the cases in this RCA, the treatment and care of Patient 10. Patient 10 was a patient who had had Ca Colon (2010), breast carcinoma (2013) and then developed renal carcinoma. During review for her Breast Ca in June 2014, a CT Scan revealed that, previously noted, renal cysts had increased in size. Further investigation by a MRI scan was reported in a limited and incomplete fashion; resulting in a 'routine' referral GP letter on 29/10/2014.

During the investigation, the Review Team identified that Patient 10's GP referral letter had not been triaged; the Consultant Urologist with responsibility that week for triage duties was Cons1. This referral therefore waited as a 'new routine' referral till January 2016 to be seen by a Consultant Urologist.

The index case Review Panel agreed 3 main contributing factors led directly to Patient 10s delay in diagnosis. Firstly, the content of the MRI report; secondly a letter following a CT scan did not mention important information and thirdly, the opportunity to upgrade the referral to red flag was lost by the omission of triage; this resulted in a 64-week delay to diagnosis of a suspicious renal mass.

The index case Review Panel concluded in March 2017 that, ".... *a significant number of letters within Urology are not being triaged by the minority of the Team. It is clear that the default triage management process (*vide infra*) continues to be initiated secondary to the omission of Triage by individual members of the urology team and not the entire Urology Team*".

Of the 2 lessons learnt, one indicated that,

> "*Triage of GP referral letters remains a key element in validating appropriate utilisation of specialist services and ensuring patient safety. Triage also serves as an opportunity for early intervention for patients at risk of malignant disease or clinical deterioration*."

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

This led to a recommendation that,

> *"This SAI has demonstrated that patients will be at an increased risk of harm when the opportunity for early intervention at Triage is omitted. The Review Panel recommend that the Trust reviews the process which enables the clinical triaging and escalation of triage non-compliance in accordance with the Integrated Elective Access Protocol (IEAP).*
>
> *In particular the fundamental issue of triaging GP referral letters remains a challenge within Urology. The Urology operational and medical management teams immediately need to address the issue of un-triaged referrals not being processed in accordance with IEAP."*

The findings of this investigation, chaired by Consultant Urologist 2 (Cons2), were made available in December 2016 and formally signed off on the 15th March 2017. A letter highlighting a number of concerns was sent to the (then) lead for Acute Governance for Acute Services (AGAS1), on the 15th December 2016.

The letter pointed out that the IDT process implied that triage non-compliance was to be expected but that this process did not have a clear escalation plan to include the individual Consultant and, indeed, had not been effective in addressing triage non-compliance. Furthermore, the letter pointed out that, from July 2015 till October 2016, there were 318 non-triaged letters which the Trust could not provide assurance that patients were not being exposed to harm by waiting as a routine or urgent appointment i.e. when they should have been red-flagged.

It is not absolutely clear who wrote this letter as it has no signature, but it appears to have been written by, or on behalf of, Cons2. On the 10th January 2017, Cons2 was requested by the Medical Director (MD3) to share the report with the 2 key Consultants involved in the SAI. One of these was Cons1. Cons2 refused, stating that he was Cons1's colleague and not his manager.

This letter was escalated to the Director of Acute Services (DAS3) and the Assistant Director of Anaesthetics & Surgery. This was further escalated to the Chief Executive of the SHSCT.

Cons1 was written to by AMD1 on the 23rd March 2016, acknowledging his hard work as a Consultant Urologist but pointing out that there were governance and patient safety concerns with regard to untriaged letters dating back over 2 years, and other important issues. Cons1 was asked to respond with a commitment and immediate plan to address these issues.

The Review Panel also determined that there were 7 other patients who were not triaged that week along with Patient 10. They subsequently performed a 'look-back' exercise (number 1) of these referrals. Of the seven referrals, six charts were available and each patient had an appropriate

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

management plan. One set of notes were missing and efforts were made to find them.

Cons1 provided his personal review, dated 25/01/2017, of the Index Case to the Chairman of this Review Team. It provides an argued retrospective rationale that a timely triage by himself would not have altered the referral grading. However, it does not provide a sound reason for his actual lack of triage. His report is consistent in arguing his view that he does not have time to perform both Consultant of the Week (CoW) duties and triaging of non-red flag referrals.

5.5 Look back exercise #2

Upon realisation that the 'look-back' exercise #1 had resulted from non-triage over the week beginning the 30/10/2014, further efforts were made to investigate the size of this non-triage issue and to find missing referral letters. Cons1 was contacted and the Head of Service for Urology (HoS1) obtained permission to look for missing GP referral letters in his filing cabinet. Cons1 stated that there were referral letters in a filing cabinet in his office. During interview, he stated that he kept the referrals to ensure they would not be missed or overlooked. The Head of Service for Urology retrieved these referral letters, which numbered over 700 along with the triage lists from the booking centre.

These referrals were then reviewed by the Urology Consultant Team revealing 30 patient referrals should have been red-flagged and four of these patients, following review, were diagnosed with cancer, becoming the subject of this review.

This (RCS [redacted]) Review Team reviewed the clinical notes from these 4 patients and following discussion, under the Urological guidance of AMD1, detailed the clinical course and made the following conclusions.

Patient 14

03/06/2016 - 63-year-old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
09/08/2016 - added to W/L Urgent.
27/01/2017, as part of the internal review #2, the referral was upgraded to R/F and was seen in clinic on day 246. Therefore, this was an incorrect GP referral.
05/04/2017 (D304), following U/S guided biopsy, the patient obtained a confirmed cancer diagnosis and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 10-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 11

28/07/2016 - 68-year-old male referred to Urology Outpatients by GP for assessment and advice, concerning elevated PSA.
The referral was marked Urgent by the GP.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

5.0 DESCRIPTION OF INCIDENT/CASE

The referral was not triaged on receipt.
30/09/2016 - added to W/L Urgent.
18/01/2017 - as part of an internal review #2, upgraded to R/F. Therefore, this was an incorrect GP referral.
20/02/2017 (D207) seen at R/F appointment. Sent for MRI and prostate biopsy.
11/04/2017 (D258) - diagnosed with a confirmed low risk prostate cancer and there was a recommendation for treatment of a prostate cancer by surveillance protocol.

Conclusions

Resultant 9-month delay in obtaining diagnosis.
Following Review Team consideration, deemed not to be a clinically significant delay.

Patient 13 28/07/2016 - 51-year-old male referred to Urology by GP following an episode of haematuria.
The referral was marked Routine by the GP.
The letter was not triaged.
30/09/2016 - Patient 13 was placed on a Routine waiting list.
19/01/2017 - As part of an internal review #2, upgraded to a R/F referral. Therefore, this was an incorrect GP referral.
31/01/2017 (188d) - reviewed at OPD and flexible cystoscopy.
22/02/2017 TURBT/TURP - diagnosed with bladder (locally advanced) and prostate cancer and there was a recommendation of treatment for his bladder cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is clinically significant; time will tell*.

* The Review Team referred to an expert for advice.
Delay in definitive surgical treatment beyond 12 weeks conferred an increased risk of disease-specific and all-cause mortality among subjects with stage II bladder cancer. He remains disease free as of September 2018.

1. John L. Gore, Julie Lai, Claude M. Setodji, Mark S. Litwin, Christopher S. Saigal, and the Urologic Diseases in America Project. Mortality increases when radical cystectomy is delayed more than 12 weeks. Results from a surveillance, epidemiology, and end results–Medicare analysis. Cancer March 1, 2009.
2. Nader M. Fahmy, Salaheddin Mahmud, Armen G. Aprikian. Delay in the surgical treatment of bladder cancer and survival: Systematic Review of the Literature. *European Urology 50 (2006) 1176–1182.*

Patient 12 08/09/2016 - 73-year-old male was referred to Urology Outpatients on for assessment and advice on lower tract symptoms and elevated PSA.
The referral was marked Urgent by the GP.
The referral was not triaged on receipt.
27/01/2017 – further GP letter – please upgrade to R/F.
30/01/2017 - as part of the internal review #2, upgraded to R/F.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

5.0 DESCRIPTION OF INCIDENT/CASE

06/02/2017 - seen in clinic on day 152.
11/04/2017 (D215) - confirmed cancer diagnosis T3a with no nodal metastases – high risk and there was a recommendation of treatment for a locally advanced non-metastatic prostate cancer.

Conclusions

Resultant 8-month delay in obtaining diagnosis.
Following Review Team consideration, it is probable that the delay is not clinically significant.

At a later date, towards the end of 2018, another patient came to the attention of the Review Team – Patient 15. This patient could also have been one of those found in Cons1 filing cabinet but appeared at an outpatient clinic before the outworking of the look back exercise #2. A Consultant Urologist realised in the clinic that this was also a Cons1 non-triaged patient who was incorrectly referred by their GP.

Patient 15 30/08/2015 - 63-year-old male referred to Urology Outpatients by GP for assessment and advice with a raised PSA.
The referral was marked Routine by the GP.
The referral was not triaged on receipt.
29/01/2016 2nd GP referral marked as Suspected Cancer – Red flag; Patient 15 was added to W/L R/F following this referral.
As part of the internal look back #2, the referral was noted.
Patient 15 had already received an appointment and was seen in clinic on day 153. Therefore, 1st GP referral was incorrect; the 2nd was a correct GP referral.
11/02/2016 (D166), following a prostate biopsy, the patient obtained a confirmed cancer diagnosis T3a and there was a recommendation for treatment of a prostate cancer.

Conclusions

Resultant 6-month delay in obtaining diagnosis.
Following Review Team consideration, it is felt that the delay is unlikely to be clinically significant.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

7.0 CONCLUSIONS

The Review Team interviewed a number of Trust staff including Directors (past and present), an Assistant Director, Head of Service and an Associate Medical Director as part of the review process. These interviews, along with clinical documents and health records systems, have helped inform the conclusions by providing the evidence and also corroboration where there appeared to be differences of opinion.

The Review Team and everybody interviewed, including Cons1, provided affirmation that a timely, efficient triage system which checked the initial GP referral was very important to patients. Comments made when interviewees were asked about the importance of triage and where the process of triaging a potential cancer patient ranked alongside other issues such as probity, patient experience and performance, were consistent,

"Very significant". Very high up the list in terms of importance".
"It is fundamental people are seen in the appropriate time".
"Very important" ... "Important for the patient".
"Vital" ... "Very significant .. patients are often anxious and depend on the system to work".

Cons1 replied,

"It is a serious issue, very important"..... "Number one ranking in overall scheme of things"

The Review Team established that there were factors in HSC service delivery to the 5 patients under examination that resulted in an unnecessary delay in treatment and care. In 4 patients the delay was thought not to be clinically significant but in 1 ([redacted]) there probably was a significant delay.

Consideration of the causative factors to the patients' delays reveal,

- Referral letters did not have the clinical priority accurately assigned by the GP; and
- Referral letters were not triaged following receipt by the Hospital.

7.1 Referral letters did not have the clinical priority accurately assigned by the GP.

Contributory factors

Task Factors (policy and guidelines)
The Review Team reviewed the GP referrals regarding the five patients listed above. They concluded, as judged from the Northern Ireland Cancer Network (NICaN) Referral Guidance for Suspected Cancer (December 2012), that all five patients should have been referred to Urology by the GP's as red flag referrals (suspected cancer) i.e. incorrect triage.

Task Factors (decision aids)
The current decision aid for GPs is the NI Referral Guidance for Suspected Cancer 2012 based on NICE CG 27 *Referral guidelines for suspected cancer* published in June 2005. It is clear that Secondary care, in the form of Consultant Urologists, should triage these GP referrals; by doing so, 11% of GP referrals are changed (from Review Team member). It is also clear that Cons1 would have been in no doubt as to his responsibilities; he was intimately

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

involved in setting this standard and signed off the NICaN clinical guidelines.

However, it is clear this very important and critical triage safety net, work can be considered onerous and other electronic methods which GPs can use might be more efficient and help to reduce that load.

According the HoS1, most patient referrals by GPs to Trusts for outpatient appointments are now made through the electronic Clinical Communication Gateway (CCG). However, some paper referrals are still received. CCG is a digital referral system for Primary care which can contain referral criteria that meet NICE and NICaN guidance. This would enable appropriate clinical triaging of referrals to be performed as part of the selection of referral reasons and/or symptom description.

Using the electronic CCG pathway, some clinical specialties, such as gynaecology, have worked closely with the Public Health Authority to develop a better GP referral tool e.g. using 'banner guidance' (a specialty specific banner, listing symptoms and signs) which complies with NICE/NICaN guidance. This 'banner guidance' helps by directing clinicians to use the NICE/NICaN referral criteria which allow for timely and appropriate triage of patients to clinically appropriate appointment types. It is possible when red flag symptoms are chosen that an immediate alert could go to the Red Flag booking team, to allow the appointment booking process to begin immediately. However, currently, the referral criteria fields are optional i.e. not mandatory, so opening up the possibility that fields are not completed, leading to error and delay.

NICE NG12
The reference CG27 guidance has been replaced by NICE Guideline NG12 *Suspected cancer: recognition and referral* but, despite being endorsed by the DHSSPSNI and accepted by the Regional Urologists, it has yet to be implemented. Its use as a triage standard should result in fewer red-flagged cases which should ease some of the pressure on waiting lists. Its adoption would take place in primary care and should form the basis of the electronic CCG referral tool.

There was a consistent medical staff view from the Review Team, the AMD1, and indeed Cons1, that GP's have a crucial and important responsibility in getting the referral criteria/urgency category correct. If the GP does not provide enough, or the correct information, the NI Electronic Care Record (NIECR) needs to be checked and that slows the whole triage process down. It was clear that the triage system works best when the initial GP referral is usually correct and the Secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

7.2 Referral letters were not triaged following receipt by the hospital.

Contributory factor

Task Factors (policy and guidelines)

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

The Integrated Elective Access Protocol (IEAP) (DHSSPS, April 2008) defines the roles and responsibilities of staff (in both primary and secondary care) when patients enter an elective care pathway. It states,

> '…*an Executive Director will take lead responsibility for ensuring all aspects of this Protocol are adhered to…. Patients will be treated on the basis of their clinical urgency with urgent patients seen and treated first*'.

The Principles for booking Cancer Pathway patients states,

> "Clinical *teams must ensure triage is undertaken daily, irrespective of leave, in order to initiate booking patients*".

and,

> "*Referrals will be received, registered within one working day and forwarded to Consultants for prioritisation*".

However, the IEAP states,

> *"…if clinical priority is not received from Consultants within 72 hours, processes should be in place to initiate booking of urgent patients according to the GP's classification of urgency".*

Following on from the IEAP of 2008, national and regional policies and guidelines, already referred to above, have been introduced which have outlined the detailed role of the Urology Consultant in triaging referrals that have come in from Primary care e.g.,

- Service Framework for cancer prevention, treatment and care (Standard 13) 2011;
- NI Referral Guidance for Suspected Cancer 2012; and
- NICaN Urology Cancer Clinical Guideline document, (version 1.3, March 2016).

These have provided agreed lists of the critical symptomatology of Urological cancers and the roles and responsibilities of Primary and Secondary care staff in ensuring patients receive prompt recognition and treatment of their cancer.

Review of Adult Urology Services in Northern Ireland

In March 2009, a *Review of Adult Urology Services in Northern Ireland - A modernisation and investment plan* was published. Its External Advisor was Mr Mark Fordham. SHSCT Consultant Urologists were represented on the committee.

Recommendation 4 states, "*Trusts must review the process for internal Consultant to Consultant referrals to Urology to ensure that there are no undue delays in the system".* Consultants indicated that they would routinely upgrade a significant number of routine and urgent referrals (GP) to urgent or red flag. It was noted that the development of agreed referral guidelines/criteria for suspected Urological cancers was a priority piece of work for the recently formed NICaN Group. That work was led by Cons1; see page 6.

Section 3.31 of the report indicates that, "*Consultant Urologists unanimously consider that referral triage should be led by Consultants. With over 40% of referrals being cancer related*

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

(and with many not red flagged or marked urgent) they believe that they are best placed and skilled to undertake the triage process. They also believe that despite the volume of referrals, this is not a particularly time consuming process."

Contributory factor

Staff factor

It is obvious from reading the documents referred to above that Cons1 has been aware of developments in this field and, indeed has been party to the discussions and signed some of them off. Cons1 was chair of NICaN (Urology) and was involved in drafting the NICaN regional Urology guidance, and therefore was very familiar with the requirement to triage GP referrals.

Despite all of this, and even though Cons1 agreed that this triaging role was, "*very important*", …. it was, "*a very serious matter not to be minimised, very serious"* he stated he would not triage non-red flag referrals.

When asked, *"Does triage still need done?"* Cons1 answered*, "a procedure is needed to highlight when it needs done and who does it".* When further asked, *"Who was involved in SHSCT Urology service in setting up triage"?* Cons1 answered for urological cancer, "*I was the Lead"*.

He felt triage of referral letters was too time consuming and the amount of time spent on triage, in his opinion, rendered inpatient care unsafe. He highlighted that he had previously escalated his concerns about work load to management teams and medical directors.

In relation to triage, Cons1 stated, '*I would love if we had a Trust Urology agreement on the type of triage to be conducted*'. When it was pointed out that, "*Consultant colleagues did triage for you. How did they do it?"* He stated, "*It depends on how you do it"* ..... "*Not all do advanced / enhanced triage, they compromise. It is a spectrum"... "They have not done it in the detail I felt it needed for routine/urgent non-red flag case".*

When questioned further, regarding his way of organising his own work load, Cons1 stated, '*....yes I did it my way – I wasn't cognisant of being unbending, I am very particular*'.

Cons1 highlighted to the Review Team that he currently takes annual leave each Friday and spends the weekend triaging. He stated that it is impossible to be Urologist of the Week and triage referrals appropriately. He stated he still can't do triage and everything else. He stated, '*I do triage entirely in my own time to allow me to do it properly'*.

When asked about using the NIECR - Electronic Referral using the Clinical Communication Gateway (CCG) method, Cons1 stated found the new CCG triage system*, "Very, very good, I wish all information was available on ECR. It is less time consuming. ECR makes it easier to check information".*

The Review Team concluded that there was a serious inconsistency between the guideline

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

standard that a Consultant should triage GP referrals (which Cons1 helped to construct) along with his stated view of the crucial importance of triage and Cons1's actual practice.

Cons1's chosen method of triage was beyond what is required. His triage is the equivalent of a virtual clinic where he reviews NIECR and books investigations for patients. While the Review Team recognised this was a detailed triage process, they concluded that his prioritisation of work and attention to detail meant that some patients got a higher standard of triage/care, while, crucially, others were not triaged, leading to a potentially critical delay in assessment and treatment for those patients. Cons1 is aware of this.

The Review Team concluded that Cons1's prioritisation of work and attention to detail led to some patients receiving a high standard of care, while others ran the real risk of having a cancer diagnosis delayed till it was dangerously late.

Contributory factor

Work load/scheduling

In 2008, when the IEAP was published, there was a maximum waiting time of 9 weeks for a first Outpatient appointment. On 30th September 2016, there were 2012 patients on the routine Urology outpatient waiting list, with 597 patients showing as waiting 52 weeks and over. The longest waiting time was 554 days (80 weeks). Therefore, if patient referrals are incorrectly referred, or not triaged and continue to use the GP's classification of urgency, there will be a significant wait. Cons1 is aware of this reality.

The Review Team considered the Consultant of the Week (CoW) work load, including ward rounds, clinics, emergency theatre sessions as a contributory factor. Cons1 has consistently argued that he cannot triage non-red flag referrals and carry out the duties of the CoW. He has not indicated who else should carry out the triage duties. However, the Review Team note that the other Consultant Urologists were able to manage this work load and triage referral letters in a timely fashion, with other members of the consultant team also ordering investigations, providing treatment recommendations and adding patients directly to waiting lists, similar to outcomes achieved from Cons1's 'advanced triage'.

Contributory factor

Organisational

The Review Team concluded that the non-triage of Urology referrals by Cons1 has been an ongoing problem in the Trust for many years, possibly decades. While there were pockets of non-compliance by other Consultants, when escalated, compliance improved. However, the Review Team note that Cons1 consistently did not return triage information on referrals thus not allowing the appropriate prioritisation of appointments by clinical need.

Interviews with 2 previous and the current Director of Acute Services, AMD1 and the Head of Surgery Service have highlighted that on many occasions, over a prolonged period, attempts had been made by the Trust's officers to address Cons1's non-compliance with triage. These

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

attempts encompassed both direct face to face conversations which were often heated, correspondence and, as in 2010, study leave refusal until there was compliance. These interventions all resulted in a familiar pattern of response; temporary improvement in compliance with triage, followed by a return to non-compliance.

In 2014, due to continuing non-compliance, the Trust implemented an 'Informal' Default Triage Process to manage the referrals which were not being triaged and returned to the Booking Centre. The Review Team considered the intention of this process was to prevent any delay in patients being added to the waiting list. However, this meant the 'non-return of triage' was not individually addressed with the non-compliant clinicians. Furthermore, and most importantly, it allowed patients, who should have been red-flagged, to remain on a waiting list until review.

In 2014, the Director of Acute Service 2 (DAS2) discussed non-compliance with Cons1 and agreed that Cons1 would no longer triage referral letters. Cons1 was heavily involved with formulating the NICaN Urology guidelines at the time and was grateful to the extent that he thanked DAS2.This task was delegated to other Urology Consultants for a time. However, Cons1 does not recollect having to formally stop triage. At interview, DAS2 was not aware that he had resumed those duties; she remembered that their Cancer performance figures improved when Cons1 was not triaging.

Escalation within Organisation

At every interview, questions were asked whether Cons1's consistent and prolonged non-compliance with triaging was referred upwards to executive level i.e. the Medical Director and Chief Executive.

Director DAS1 considered that the problem was being managed at Service level, although as it was only one of a series of issues and considered to be a 'minor' one, it did not predominate at higher level meetings with the Medical Director (MD1); to the extent that he may not have been aware of it.

Director DAS2 considered that the problem was dealt with by agreeing with Cons1 to stop triaging. There were other issues that were flagged up to MD2, but she was not able to remember whether MD2 was made aware of the triage problem.

During DAS3's current tenure Executive members certainly knew; at CAH Oversight meeting level and at the time of the look back exercise #2 which ultimately led onto this SAI and RCA process. The Medical Director (MD3) was directly involved in the RCA process and the CEO was aware. At Trust Board level, it is thought that a non-Executive member was asked to examine the situation which would indicate that it had also reached that level.

Overall, the Review Team in considering whether there was a satisfactory escalation of this 'non-triage' issue have concluded that there was no evidence of consistent and proactive escalation of 'non-return of triage' either to the Medical Director or the Chief Executive until the look back exercise #2 basically forced the seriousness of the issue out into the open. Indeed,

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

they do not appear to have appreciated the importance of triage, certainly from the patient's perspective. The Trust's officers made efforts to address Cons1's non-triage over time but were consistently thwarted by Cons1's refusal to comply. The Trust failed to put systems, processes and fail safes in place to ensure Cons1's consistently triaged patient referrals until 2017.

Systems and processes have now been put in place so that the Head of Service for Urology reviews Cons1's compliance with triage. HoS1 will check all Urology triage on an adhoc basis but, with Cons1, she will check daily when he is the Consultant of the Week. Any non-compliance with returning referrals without triage is addressed immediately. However, this process is heavily dependent on HoS1 who, when she is on leave, often has to recover non-triaged cases upon her return.

8.0 LESSONS LEARNED

1. The clinical urgency category allocated by GPs to 30 patients referred to Urology were incorrect. The referrals using NICaN guidance should have been referred as a Red Flag. Four (plus 1) of these patients were subsequently shown to have cancer.

2. The process of triaging Urology cancer referrals from Primary Care to Secondary Care, under the direction of the HSCB, appears to be less efficient than it could be, bearing in mind that NICE NG12 guidance has not been adopted and electronic referral using CCG is not being used as efficiently as it could.

3. GP's are not mandated to provide HSCB with an assurance that they comply with the most up to date NICE or other guidelines. Therefore, HSCB are unaware of any risks consequent upon the non-compliance with NICE and other guidance within GP practices.

4. GP's are not mandated to refer patients using CCG clinical criteria banners; this can lead to error and delay.

5. There is no Regional or Trust guidance or policy on what is expected of clinicians when triaging referral letters. Triage of patient referrals is obviously viewed as extremely important but does not seem to be at an equivalent level of importance when ranked alongside other clinical governance issues. Despite being an evident problem for decades and requiring considerable time and effort to find a solution, it only really surfaced within the Trust after an Index case forced the situation out into the open.

6. Despite it being absolutely clear to Consultant 1 (based upon his close proximity to the development and signing off of regional guidance) of the consequences of non-triage, he did not routinely triage referral letters. The Review Team consider that Cons1's refusal to triage to a level similar to other clinicians, led to patients not being triaged,

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

and this resulted in delays in assessment and treatment. This may have harmed one patient.

7. Cons1 confirmed that despite the Trust reminding him of the requirement to triage, he did not consistently triage referrals. He argued that, due to time pressures, he felt he was unable to perform the duties of the Consultant of the Week and his triaging duties. He has highlighted those views to Trust operational and management teams over a number of years.

8. The Trust made efforts to address Cons1's non-triage over time. However, the Trust failed to put systems, processes and fail safes in place to ensure Cons1 consistently triaged patient referrals until 2017. However, this safeguarding process is heavily dependent on the Head of Service checking triage is completed when Cons1 is Consultant of the Week.

9. The Informal Default Triage process allows patients who should be red flagged to remain on a waiting list of routine or urgent cases.

10. From examining the triaging issue over the length of time it has existed, it is obvious that there is an unwillingness or inability within the medical hierarchy to tackle its 'difficult colleague' problem. The reasons behind this probably include not taking ownership of its own problems and poor support from senior medical management perhaps resulting in issues not being referred upwards.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

9.0 RECOMMENDATIONS AND ACTION PLANNING

HSCB

Recommendation 1

HSCB should link with the electronic Clinical Communication Gateway (CCG) implementation group to ensure it is updated to include NICE/NICaN clinical referral criteria. These fields should be mandatory.

Recommendation 2

HSCB should consider GP's providing them with assurances that the NICE guidance has been implemented within GP practices.

Recommendation 3

HSCB should review the implementation of NICE NG12 and the processes surrounding occasions when there is failure to implement NICE guidance, to the detriment of patients.

HSCB, Trust and GPs

Recommendation 4

GPs should be encouraged to use the electronic CCG referral system which should be adapted to allow a triaging service to be performed to NICE NG12 and NICaN standards. This will also mean systems should be designed that ensure electronic referral reliably produces correct triaging e.g. use of mandatory entry fields.

TRUST

Recommendation 5

Work should begin in communicating with local GPs, perhaps by a senior clinician in Urology, to formulate decision aids which simplify the process of Red-flag, Urgent or Routine referral. The triage system works best when the initial GP referral is usually correct and the secondary care 'safety-net' is only required in a minority of cases. Systems should be designed that make that particular sequence the norm.

Recommendation 6

The Trust should re-examine or re-assure itself that it is feasible for the Consultant of the Week (CoW) to perform both triage of non-red flag referrals and the duties of the CoW.

Recommendation 7

The Trust will develop written policy and guidance for clinicians on the expectations and requirements of the triage process. This guidance will outline the systems and processes required to ensure that all referrals are triaged in an appropriate and timely manner.

Recommendation 8

The current Informal Default Triage (IDT) process should be abandoned. If replaced, this must be with an escalation process that performs within the triage guidance and does not allow Red-flag patients to wait on a routine waiting list.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

9.0 RECOMMENDATIONS AND ACTION PLANNING

Recommendation 9

Monthly audit reports by Service and Consultant will be provided to Assistant Directors on compliance with triage. These audits should be incorporated into Annual Consultant Appraisal programmes. Persistent issues with triage must be escalated as set out in recommendation 10.

Recommendation 10

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 Director's and Chief Executive's tables. This needs to be open and transparent with patient safety issues taking precedence over seniority, reputation and influence.

CONSULTANT 1

Recommendation 11

Consultant 1 needs to review his chosen 'advanced' method and degree of triage, to align it more completely with that of his Consultant colleagues, thus ensuring all patients are triaged in a timely manner.

Recommendation 12

Consultant 1 needs to review and rationalise, along with his other duties, his Consultant obligation to triage GP referrals promptly and in a fashion that meets the agreed time targets, as agreed in guidance which he himself set out and signed off. As he does this, he should work with the Trust to aid compliance with recommendation 6.

10.0 DISTRIBUTION LIST

In addition to the Review Team, the following.

Mr S Devlin, Chief Executive SHSCT.

Dr Maria O'Kane, Medical Director, SHSCT.

Mrs Melanie McClements Interim Director of Acute Services.

Health & Social Care Board (HSCB).

Chairs of Morbidity & Mortality Groups SHSCT.

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

Checklist for Engagement / Communication with Service User[1]/ Family/ Carer following a Serious Adverse Incident

Reporting Organisation SAI Ref Number:	Personal Information redacted by the USI	**HSCB Ref Number:**	Personal Information redacted by the USI

SECTION 1

INFORMING THE SERVICE USER[1] / FAMILY / CARER

1) Please indicate if the SAI relates to a single service user, or a number of service users. **Please select as appropriate (✓)**	**Single Service User**		**Multiple Service Users***	✓	
	Comment: 5 ***If multiple service users are involved please indicate the number involved***				
2) Was the Service User[1] / Family / Carer informed the incident was being reviewed as a SAI? **Please select as appropriate (✓)**	**YES**	✓	**NO**		
	If **YES**, insert **date informed**:19.2.18				
	If **NO**, please select **only one** rationale from below, for **NOT INFORMING** the Service User / Family / Carer that the incident was being reviewed as a SAI				
	a) No contact or Next of Kin details or Unable to contact				
	b) Not applicable as this SAI is not 'patient/service user' related				
	c) Concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user				
	d) Case involved suspected or actual abuse by family				
	e) Case identified as a result of review exercise				
	f) Case is environmental or infrastructure related with no harm to patient/service user				
	g) Other rationale				
	If you selected c), d), e), f) or g) above please provide further details:				
3) Was this SAI also a Never Event? **Please select as appropriate (✓)**	**YES**		**NO**		
4) If **YES**, was the Service User[1] / Family / Carer informed this was a Never Event? **Please select as appropriate (✓)**	**YES**	If **YES**, insert **date informed**: DD/MM.YY			
	NO	If **NO**, provide details:			
For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**					
Content with rationale?	**YES**		**NO**		

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER

(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)

5) Has the Final Review report been shared with the Service User[1] / Family / Carer? **Please select as appropriate (✓)**	**YES**		**NO**	✓
	If **YES**, insert date informed:			
	If **NO**, please select **only one** rationale from below, for **NOT SHARING** the SAI Review Report with Service User / Family / Carer:			
	a) Draft review report has been shared and further engagement planned to share final report			
	b) Plan to share final review report at a later date and further engagement planned			✓

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

Southern Health and Social Care Trust

SHARING THE REVIEW REPORT WITH THE SERVICE USER[1] / FAMILY / CARER *(complete this section where the Service User / Family / Carer has been informed the incident was being reviewed as a SAI)*		
	c) Report not shared but contents discussed ***(if you select this option please also complete 'l' below)***	
	d) No contact or Next of Kin or Unable to contact	
	e) No response to correspondence	
	f) Withdrew fully from the SAI process	
	g) Participated in SAI process but declined review report	
	(if you select any of the options below please also complete 'l' below)	
	h) concerns regarding impact the information may have on health/safety/security and/or wellbeing of the service user[1] family/ carer	
	i) case involved suspected or actual abuse by family	
	j) identified as a result of review exercise	
	k) other rationale	
	l) If you have selected **c), h), i), j), or k)** above please provide further details:	

For completion by HSCB/PHA Personnel Only (**Please select as appropriate (✓)**				
Content with rationale?	**YES**		**NO**	

SECTION 2 **INFORMING THE CORONERS OFFICE** **(under section 7 of the Coroners Act (Northern Ireland) 1959)** *(complete this section for all death related SAIs)*								
1) Was there a Statutory Duty to notify the Coroner on the circumstances of the death? **Please select as appropriate (✓)**	**YES**		**NO**					
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							
2) If you have selected 'YES' to question 1, has the review report been shared with the Coroner? **Please select as appropriate (✓)**	**YES**		**NO**					
	If **YES**, insert **date report shared**:							
	If **NO**, please provide details:							
3) 'If you have selected 'YES' to question 1, has the Family / Carer been informed? **Please select as appropriate (✓)**	**YES**		**NO**		**N/A**		**Not Known**	
	If **YES**, insert **date informed**:							
	If **NO**, please provide details:							

DATE CHECKLIST COMPLETED	**22.5.2020**

[1] *Service User or their nominated representative*

Received from SHSCT on 09/11/21. Annotated by the Urology Services Inquiry.

SECTION E – Personal impact/additional information

Please outline the personal impact that the treatment received, which forms the basis of your complaint(s), has had on the patient/deceased patient and provide any additional information which you feel may be of assistance to this Inquiry.
When Dr Paisley requested the appointment with Urology Department Patient 10 was not aware of the triage system. The delay in being seen by Urology was not a concern as she had been told the two cysts were nothing to worry about. It was only on receiving The Serious Incident Report that she became aware of the triage system in Urology. She was shocked, angry and disappointed that not only had her appointment not been triaged but 7 other patients in the same week had also not been triaged. She was concerned that this was not therefore a simple mistake and that she had been overlooked but it looked like a systematic failure for patients. The extent of this error certainly undermined her confidence in the entire system for her care. The major concern was, of course, if she had been seen sooner would there have been a better outcome for her i.e. would earlier scans have been ordered and would they have picked up subsequent cancers earlier.

Additional sheets, if needed, can be attached

thought that the report was a very detailed report. We dealt with the two aspects of it that we considered could be just human error, namely the Radiologist failing to see the third scan. While it was a mistake, it could have serious consequences, and the same with the Breast Surgeon in not referring on, and we could accept those as being one-off mistakes. 11:07

We did not take the same view in relation to the urology aspect of it. Because if it only had been Patient 10 that had not been triaged, we could have put that mistake in the same category as the first two, all of us working under pressure of time that we all make mistakes. But the serious aspect to us was that, not only was hers not triaged in that week, that there were seven others not triaged. And that was just a week in time that was pulled out of nowhere. That week was examined by the Trust, purely because Dr. Paisley had requested the appointment for that week, and that's the week that they looked at. 11:07 11:08 11:08

So we thought that that was not human error. That was a systemic failure of the system and we put that forward at the meeting. We put it forward in a firm way, not in an argumentative way. We wanted to get the point across and Patient 10 wanted to make the point that she hoped that for future patients, that something was being done about all aspects of the report, and we were told that as we spoke at that, that steps were being 11:08

him to go through the report line by line and it was exactly the last thing that I had wanted because it was going over everything in detail again. I said, look, we don't want that. But he was prepared to do it. So everything, they were open, they answered our questions, it was relatively short. That was of our making, not of their making because of the way that we wanted to deal with it. So, yes, they were helpful, we didn't find that they were evasive in any shape or form. It was totally open. 11:24

14 Q. That's good. You say, you've been quite articulate in expressing how shocked you both were to learn that the triage problem was not a one-off, as it were, it was not confined to Patient 10, and I just wanted to know what effect that had on you both when you learned that there were others who might not have been triaged in the same week as she was referred to the Department? 11:24

A. The urology problem in comparison to the other two, they are all serious and all potentially life threatening. It's different in, this is a disadvantage in working in a hospital. Like if you were working in a solicitor's office and you make a mistake, well you have insurance and you cover it and it's invariably not life-threatening so you get on with life and everybody makes a mistake. 11:25

Each of these mistakes are potentially life threatening. And there were eight mistakes made in that week which, as I said, was pulled out of nowhere.

And that had a major effect on Patient 10 because, while the report said that in a lookback at the other seven, that there didn't appear to be any serious consequences as a result of the delay, that was pure good fortune that that happened. And you don't go into a hospital and rely on good fortune, you have to rely on each individual. 11:26

And while each department, in a way, is separate in the hospital, Urology is separate from the breast end of it, Oncology, the heart end of it. They really are, and if you see Patient 10 's history, they really are all linked because you get a scan in relation to the bowel and it shows up something somewhere else or whatever. So there is interaction between all of the departments and that's the way it should be. 11:26

It really frightened Patient 10 that this had not been dealt with. It's linked really to the original problem that the radiologist hadn't identified the third cyst. And whenever, and I'm sort of cutting across myself in this, Madam Chair, whenever she saw Mr. Hewitt in relation to that report, he was very angry and said, God, if we can't rely on the reports, that if we have to look behind them all of the time as surgeons we'll never get anything done, and he was really angry that that had been missed. 11:27

So it frightened Patient 10 that, really, could she rely

the scan. And he said that he then immediately found a third cyst that had not been referred to in the report.

And his opinion, and he said it to us at that time, that he considered that to be cancerous. That, of course, was a major shock. And he said, he formally apologised on behalf of the Trust and stated that he had reported that as a Serious Adverse Incident. Now that meant nothing to us at the time. I never heard of a Serious Adverse Incident and in any event, if I had, the news of it was just so shocking that it went by us. 11:01 11:01

He said that there would need to be a further scan to see how much that cancer had grown in the 16 months and a further scan was carried out. There was good news and bad news in relation to the results of that scan because it showed, luckily, that the cancer had not grown very much and he personally was delighted with that. 11:02

But the scan unfortunately showed up another cancer in the breast. So there was two cancers at the one time and a lot of questions as to what operation would be carried out first. Because the breast cancer needed more treatment, it was decided that that would be carried out. It was. Patient 10 received chemotherapy and, thereafter, was operated and there was a partial removal of the kidney. That, he felt, was, he had cured it, couldn't be sure, but there was no treatment 11:02 11:02

required in relation to the kidney operation or the kidney cancer.

Where am I? After that, we just, all operations were carried out. We continued on our tour of Europe after that and really forgot about everything. The issue of the Serious Adverse Incident never came into our minds. We didn't even know there was a report being carried out. And out of blue, some time about six-months, a year later, we got a phone call from the hospital to say that this report had been completed. We got a copy of the report and we thought the report was, as it was, initiated by Mr. Haynes on the basis that the radiologist had not reported on the third cyst. We thought that the report was only going to deal with that. We got the report and we were shocked that there were two other very serious matters that had been overlooked. 11:03 11:03 11:04 11:04

We then arranged a meeting, or there was a meeting arranged to deal with the panel that was going to meet with us to discuss the report, and that was chaired by a young radiologist, or a young urologist in the South Tyrone Hospital.

We decided before we went over, like I went through the report in detail, as did Patient 10, and Madam Chair, you have the report there. 11:04

2 Q. I do.

12 Q. Can I ask how you felt that meeting went in terms of the communication between you and the Trust? Do you feel that they were forthcoming? Do you feel that they were engaged with you? Do you feel that they answered your questions appropriately? Just what did you feel about it? 11:22

A. Well, initially whenever we were contacted to state that the report was available, they asked us did we want a copy of the report, or did we want to go over and see them. And this is not a criticism, at that time I thought, well, that's a bit strange. And I said, well, can we not actually have a copy of the report and then go and over and see you? 11:22

13 Q. Yes.

A. And they said, of course, that would happen, and they did send me a copy, or send Patient 10 out a copy of the report and we saw them. 11:22

In answer to your question, the whole tenor of the meeting was really determined by Patient 10 and myself because we wanted to really draw the line under it and we understood the report. I had gone through it in detail. I have a Personal Information redacted by USI background, Madam Chair, and I would be used to going through reports and I had gone through it in detail and understood it completely. And like, Patient 10, her profession, she was a Personal Information redacted by USI, and she understood the report. 11:23 11:23

So Mr. Glackin, when we went in, asked us did he want

And that's where it really lay until, again, out of the blue, Patient 10 received a phone call from the hospital to say that - she was actually waiting on two separate phone calls, it shows the amount of involvement that she had, but she was waiting on two separate phone calls from Craigavon Hospital. And she received a call which she thought was dealing with one of the issues, but it wasn't. It was a phone call from a lady to say that she was putting her on notice that in the Press the next day the issue about Mr. O'Brien was going to break in the Press and on television. 11:11

And the purpose of the call was to assure Patient 10 that, whatever problems were being reported in the Press in relation to the Urology Department, that they didn't affect her treatment. And what they were getting at was not the issue in relation to Urology and the triaging, but in relation to her treatment by Mr. Haynes, and we accepted that, and we were pleased that she had been put on notice of that, that it didn't affect her. 11:11 11:12

The next day the story did break in the media and within, I don't know the timescale, but certainly within a week or two, the Minister of Health had announced a Public Inquiry and the Medical Council had suspended Mr. O'Brien from practising. 11:12

We knew, that was Patient 10 and myself, that those two

individual steps probably were not taken, they certainly wouldn't have been taken lightly, and wouldn't have been taken as a result of one individual error that had been made. And rightly or wrongly, we assumed that this was a follow-on to the systemic failures that had been reported in the SAI Report to us a number of years, three or four years previously. 11:13

We then both felt guilty that we had maybe taken too narrow and relaxed a view in dealing with the SAI report and we felt that, to put it bluntly, we should have maybe created more of a stink. That it might have been better and there may have been more attention paid if we had issued legal proceedings and highlighted it and if we had followed it up by other meetings. And [redacted] especially felt guilty that we hadn't done that. 11:13 11:14

I then, with [redacted]'s consent, contacted, and I'm not sure that this has been referred to before, Madam Chair, I contacted Urology. No, I contacted the hospital after that to express [redacted]'s concerns about this because I just felt that, in view of the seriousness of what had been reported in the Press, that we really should have done something more, and even at that later stage, that maybe we could get involved in some way. 11:14 11:14

After a period of three or four months they didn't know

INQ-20218

Parliamentary and Health Service Ombudsman

Broken trust: making patient safety more than just a promise

HC 1444

INQ-20219

Parliamentary and Health Service Ombudsman

Broken trust: making patient safety more than just a promise

Presented to Parliament pursuant to Section 14(4)
of the Health Service Commissioners Act 1993

Ordered by the House of Commons
to be printed on 29 June 2023

HC 1444

Annotated by the Urology Services Inquiry



© Parliamentary and Health Service Ombudsman copyright 2023

This publication is licensed under the terms of the Open Government Licence v3.0 except where otherwise stated. To view this licence, visit nationalarchives.gov.uk/doc/open-government-licence/version/3.

Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

This publication is available at www.gov.uk/official-documents.

Any enquiries regarding this publication should be sent to us at phso.enquiries@ombudsman.org.uk

This publication is available at https://www.gov.uk/government/publications

ISBN 978-1-5286-4244-6

E02931971 06/23

Printed on paper containing 40% recycled fibre content minimum

Printed in the UK by HH Associates Ltd. on behalf of the Controller of His Majesty's Stationery Office

Contents

About us 6

Foreword from the Ombudsman 7

Executive summary 8

Introduction 11

About this report 13

Our casework evidence on avoidable harm 15

Clinical failings leading to avoidable harm 15

The ongoing impact of clinical harm: compounded harm to families 25

Our recommendations 37

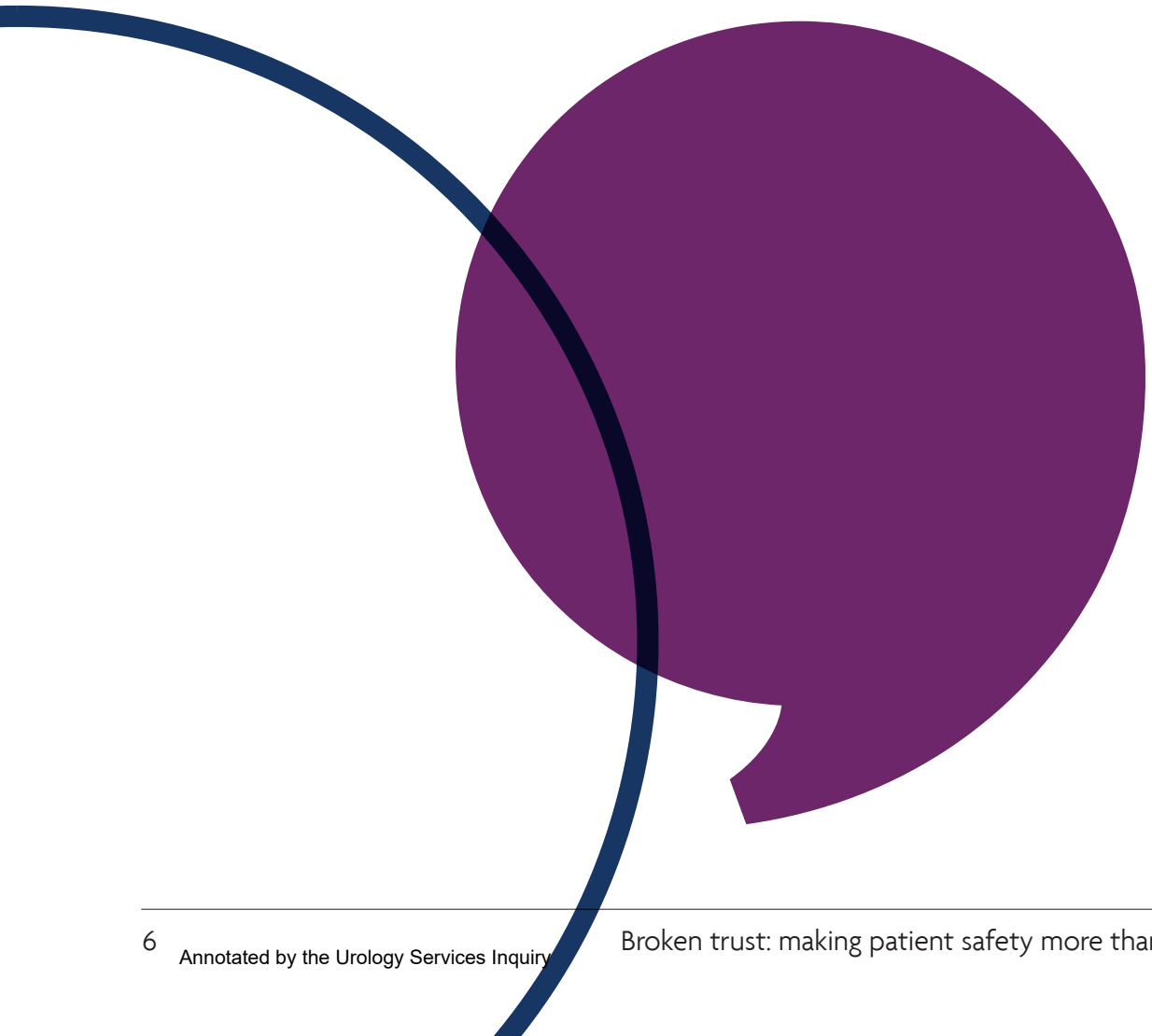
Annotated by the Urology Services Inquiry

About us

The Parliamentary and Health Service Ombudsman (PHSO) makes final decisions on complaints that have not been resolved by the NHS in England, UK government departments and other public organisations.

When we investigate, we gather all relevant information from the person who made the complaint and the organisation they are complaining about. This will include relevant clinical records and information, such as a complaint file. We may get advice from experienced clinical professionals who are specialists in particular areas of care. We weigh up all the evidence impartially to reach a decision. In cases we uphold, we can make recommendations to put things right for the individuals involved.

We share insight from our casework to help improve public services and complaint handling. This includes highlighting failings in systems and failures to follow guidance if complaints show there is a need for further learning.



Foreword from the Ombudsman

'This must never happen again.' That phrase is uttered every time an NHS scandal hits the papers. But as we saw in the similarities between inquiries into maternity services in East Kent and Morecambe Bay seven years earlier, lessons are not always learned. It is as vital as ever that my Office continues to call for action to improve learning, accountability and, ultimately, safety.

The last ten years have seen significant activity from policymakers to improve patient safety. We have the NHS Patient Safety Strategy and welcome the introduction of the Patient Safety Incident Response Framework, which recognises the complexity of systems and the risks to staff and patients of a blame culture.

And yet, it is clear from the analysis of our most serious patient safety cases through this report that there is a gaping hole between best practice policy and consistent real-life practice. We may have a very sophisticated understanding of how to prevent patient safety incidents and avoid compounding harm for patients, families and staff when things do go wrong. But our evidence suggests that, on the ground, this is regrettably not always implemented.

Sadly, but perhaps inevitably, mistakes will happen in a complex health system that relies on human judgement. But every time my Office rules that a patient died in avoidable circumstances, it means that incident was not adequately investigated or acknowledged by the Trust. It also means staff, patients and their families had to go through an unacceptably long and painful process to make sure action was taken to address shortcomings and justice was achieved for the patient.

In this report, we consider the reasons for the continued failures to accept mistakes and take accountability for turning learning into action and improvement. We pose questions on how to embed an honest, open and unafraid culture in our healthcare system that supports staff and patients to challenge and learn.

Complex systems need robust regulation and oversight to recognise good practice and identify poor systems. When regulation and oversight work well, they also serve to keep people safe from harm. We need to see less fragmentation of the patient safety landscape. This report will have failed if it prompts the creation of yet another patient safety body or initiative. What we need is a streamlined system that works together, with real leadership from Government.

But the biggest threat to patient safety is a system at breaking point. In this report, we recognise that the NHS itself can only go so far in improving patient safety. We need to see concerted and sustained action from Government to make sure NHS leaders have the tools to prioritise the safety of patients and are accountable for doing so. This means getting past politics to put patient safety at the very top of the agenda.

Rob Behrens CBE
Parliamentary and Health Service Ombudsman

Annotated by the Urology Services Inquiry

Executive summary

There have been significant developments in patient safety over the last decade. But there is a concerning disconnect between increasing activity and progress made to embed a just and learning culture across the NHS. Recognising the challenging operational context for the NHS, this report draws on findings from our investigations. It asks what more must be done to close the gap between ambitious patient safety objectives and the reality of frontline practice.

We identified 22 NHS complaint investigations closed over the past three years where we found a death was – more likely than not – avoidable. We analysed these cases for common themes and conducted in-depth interviews with the families involved.

What we found

We found that the physical harm patients experienced was too often made worse by inadequate, defensive and insensitive responses from NHS organisations when concerns were raised.

When we looked at the direct causes of harm, we identified four broad themes of clinical failings leading to avoidable death:

- failure to make the right diagnosis
- delays in providing treatment
- poor handovers between clinicians
- failure to listen to the concerns of patients or their families.

We also looked at the further harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of losing a loved one, try to understand what has happened but are met with a poor response from NHS organisations. We identified several factors that contribute to compounded harm:

- a failure to be honest when things go wrong
- a lack of support to navigate systems after an incident
- poor-quality investigations
- a failure to respond to complaints in a timely and compassionate way
- inadequate apologies
- unsatisfactory learning responses.

Our recommendations

Recognising the complexity of the issues identified, and the lack of easy solutions, our recommendations focus on two areas.

1. Accountability for a robust and compassionate response to harm, which supports learning for systems and healing for families

The Patient Safety Incident Response Framework (PSIRF) offers a new approach to patient safety investigations. It holds great promise but needs to be accompanied by sufficient monitoring and better support for families. We recommend that:

- Integrated care boards, with oversight from NHS England, should closely monitor the impact of the PSIRF to identify any negative consequences of the new flexibility it offers, which gives Trusts more autonomy to decide when a patient safety investigation is needed. This should include paying special attention to the balance of patient safety investigations versus other learning responses in Trusts (or service areas of a Trust) where there are poor Care Quality Commission (CQC) ratings for safety and leadership, or where other national bodies have raised concerns (recommendation 1).
- As part of their quality monitoring role, the PSIRF executive lead on each Board should look at any discrepancies between local and PHSO investigations, or other independent investigations, and make sure the Board discusses them. This should include where local investigations did not take place, or did not find that things went wrong, but PHSO or another independent oversight body later identified failings (recommendation 2).
- The Department of Health and Social Care and NHS England should further scrutinise the lack of compliance with duty of candour. They should review the operation of duty of candour to assess its effectiveness and make recommendations for improvement (recommendation 3).
- The Department of Health and Social Care should commit to funding further independent advocacy to support harmed patients, families and carers when they raise concerns or look for answers after an incident (recommendation 4).

2. Evidencing that patient safety is a top Government and NHS priority

NHS leaders and frontline staff need to be in no doubt of the priority placed on patient safety. But patient voice and leadership for patient safety are fractured. Political leaders have created a confusing landscape of organisations, often in knee-jerk reaction to patient safety crisis points. The Healthcare Safety Investigation Branch (HSIB), the Patient Safety Commissioner, PHSO, NHS England, NHS Resolution and at least a dozen different health and care regulators all play important roles in patient safety. But there are significant overlaps in functions, which create uncertainty about who is responsible for what. The Government must consider the case for streamlining some of these functions, for the benefit of people who use the NHS, their families and carers. This is not about reducing investment in patient safety. It is about creating a system that is coherent and easier to navigate, based on evidence and engagement with patients, families, NHS staff and leaders. We recommend that:

- The Department of Health and Social Care should commission an independent review of what an effective set of patient safety oversight bodies would look like. The review must include meaningful engagement with NHS leaders, staff, patients and families (recommendation 5).

Annotated by the Urology Services Inquiry

Patient safety must be a consistent priority over the long term. It must not be subject to changes of emphasis or importance each time there is a new minister or leadership change in the NHS. We recommend that:

- The Government should seek cross-party support for commitments to embedding patient safety and the culture and leadership needed to support it as a long-term priority (recommendation 6).

It is not possible to prioritise patient safety while avoiding difficult decisions about the workforce the NHS needs. Patient safety will always be at risk in environments that are understaffed and where staff are exhausted and under unsustainable pressure.

Tackling workforce shortages goes beyond political decisions about resourcing. It is about making the NHS a place where people want to work and stay because they feel valued, not just because it is a vocation. We must break down the false dichotomy between the interests of patients and staff, recognising that a system that does not treat its workforce with humanity and compassion will struggle to extend these qualities to patients and families.

We recognise the Government has promised to publish a new NHS workforce strategy. At the time of writing, this is expected 'shortly'. But for this to properly address the underlying causes of NHS staffing pressures, it needs cross-party consensus. In a sector where it can take nearly two decades to train a consultant doctor, a workforce strategy will only succeed if there is support from across the political spectrum, and far beyond one parliamentary term.

We recommend that:

- The Government should urgently produce its long-awaited long-term workforce strategy, with cross-party support, to increase the numbers entering and staying in the workforce across clinical and non-clinical roles. This strategy must:
    - include independent, evidence-based and fully costed projections of future workforce requirements
    - include detailed plans for training and recruiting new staff, retaining staff already working in the NHS and attracting those who have left to return
    - take account of the mix of different professional skills required, rather than just total numbers in the workforce, and how existing professional skills can be deployed where they are most needed (recommendation 7).

The Department of Health and Social Care should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 3, 4, 5, 6 and 7.

NHS England should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 1 and 3.

Introduction

It is ten years since the landmark Francis Inquiry into failings of care at Mid Staffordshire NHS Foundation Trust. The final report identified a system that should have picked up on appalling deficiencies in quality and safety of care, but 'failed in its primary duty to protect patients and maintain confidence in the healthcare system'.[1] The report also argued that a fundamental culture shift was needed, to make sure 'the patient is put first day in and day out.'[2]

The Francis report was a wake-up call for healthcare systems. In the decade that followed, the patient safety landscape has undergone significant change. Globally, there has been greater recognition of the importance of safety science in healthcare and a strategic approach to patient safety. In 2020, patient safety was included as one of the five priorities of G20 Health Ministers, and 2021 saw the publication of the World Health Organisation Global Patient Safety Action Plan.

The NHS developed an NHS Patient Safety Strategy in 2019, with an updated version expected this year. The strategy has a vision to save 1,000 lives and £100 million per year and has seen some concrete successes in specific areas, such as improved care of premature babies and reductions in prescribing opioids (pain-relieving medicines that have a serious risk of addiction).[3] This year, the NHS will roll out the Patient Safety Incident Response Framework (PSIRF), marking a major change in the approach to recording and learning from patient safety incidents. There are also plans to expand the roll-out of medical examiners to provide independent scrutiny of the causes of deaths. This should provide answers for bereaved relatives and help NHS organisations to learn and improve the care of future patients.

On issues of transparency, there is now a legal duty of candour requiring organisations to be honest with families when they make mistakes. And there are freedom to speak up guardians to give staff a route to report patient safety issues in each hospital. There is greater recognition of the insights that patients, families and carers hold, with a Patient Safety Partner role set up to use these insights in managing patient safety.

---

[1] Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive summary (February 2013).

[2] As above.

[3] Statistics on impact shared with us by the Patient Safety Strategy team. Improved care of premature babies through optimal cord management (delaying cutting the cord after a baby is born) has saved up to 417 lives since 2020. There have been up to 347 lives saved over two years and 2,152 fewer cases of short-term harm each year, as a result of fewer people with chronic pain being prescribed long-term opioid pain relief compared to 2021. (Figures calculated in March 2023.)

Annotated by the Urology Services Inquiry

Following the recommendation of the Independent Medicines and Medical Devices Safety Review, the role of Patient Safety Commissioner has been created to amplify the views of patients in relation to medicines and medical devices.

There has also been an important transition to a more widespread understanding of patient safety as a systems issue. As the NHS Patient Safety Strategy recognises, failings in care often result from systems and processes that allow errors to happen, rather than from people who lack the skills to care, or who deliberately cause harm. The national conversation around patient safety now focuses on learning, rather than seeking to blame individuals. And it recognises the huge complexity in healthcare processes, which means to understand when things go wrong, we must look at all the environmental and organisational factors that affect behaviour at work, not just the specific incident. This approach is now supported by the work of HSIB, drawing out national safety recommendations from its investigations.[4]

It is clear there is no shortage of programmes, policies, new initiatives and roles to try to reduce instances of avoidable harm. But there is a disconnect between the increasing levels of activity and consciousness about patient safety and the level of progress we see on the frontline. The statistics about patient harm remain stark. There are an estimated 11,000 avoidable deaths every year in the NHS due to patient safety failings, with thousands more patients seriously harmed.[5] Behind these numbers are the stories of individuals and their families and friends, whose lives have been shattered as a result of avoidable harm.

There is a well-recognised 'implementation gap' – the difference between what we know improves patient safety and what is done in practice.[6] Overcoming this represents a huge challenge. The NHS is an incredibly complex and sometimes fragmented system, making it challenging to embed changes to working practices and cultures. The structural changes brought in by the 2022 Health and Care Act offer the potential for better collaboration at a regional and local level through Integrated Care Systems and place-based partnerships. But such structural change brings the risk of disruption as local leaders divert attention to building new organisations and relationships. There is also good reason to be concerned about the prospects for reducing avoidable harm when attention is focused overwhelmingly on throughput, and the people and systems that make up the NHS are under growing pressure.

We know there is a long way to go to embed working cultures that can learn and improve in response to failings in some parts of the NHS. In the latest NHS Staff Survey, nearly 40% reported they did not feel safe to speak up about anything that concerns them in their organisation. More worrying still, less than half of staff felt confident their organisation would address their concern.[7]

---

[4] From October 2023, HSIB will become the Health Services Safety Investigations Body (HSSIB), an independent public body under the Health and Care Act 2022, with its own 'safe space' for confidential investigations. The CQC will host HSIB's maternity programme.

[5] NHS England and NHS Improvement (July 2019), 'The NHS Patient Safety Strategy: Safer culture, safer systems, safer patients'.

[6] Patient Safety Learning (April 2022), 'Mind the implementation gap: the persistence of avoidable harm in the NHS'.

[7] NHS Staff Survey 2022: National results briefing, March 2023.

In clinical safety specifically, more than a quarter of staff did not feel secure raising concerns about unsafe clinical practice and nearly 40% did not feel confident their organisation would address their concern about unsafe practices. These two measures have worsened in the last two years.[8] This polling is a reminder of the gap between the 'learning not blaming' vision of national strategies and the day-to-day experience of frontline NHS professionals.

Concerns about progress in patient safety need to be considered against a backdrop of intensifying workforce pressures, creating further risks. Latest data from NHS England shows there are more than 8,000 doctor vacancies and more than 40,000 nursing vacancies across the NHS.[9] The CQC, in its latest State of Care report, said that 'continuing understaffing in the NHS poses a serious risk to staff and patient safety, both for routine and emergency care'.[10]

The latest data from the British Social Attitudes Survey shows the cracks are growing. Although the British public remain committed to the founding principles of the NHS as a universal service, funded by taxation and provided free at the point of contact, public satisfaction with the service is now at just 29%. This is seven percentage points lower than the year before and the lowest level since the survey began in 1983.[11]

The NHS cannot wait any longer. Nor can the people who use it or work in it. We must see urgent action and sustained commitment to address the root causes of problems that result in patient harm.

About this report

Recognising this challenging context, we have developed this report to share learning from our investigations into complaints about serious avoidable harm in the NHS.

Our intention is not to further demoralise NHS staff and leaders at a time of extreme pressure. We recognise that the vast majority of NHS staff are highly motivated to provide excellent care and never intend to cause harm. And we know that involvement in patient safety incidents can be traumatic for staff too.[12]

The Ombudsman has a unique position in the patient safety landscape. We investigate impartially and do not take sides or speak on behalf of patients or clinicians. Our role is to objectively and independently understand what happened. Where we find failings, we make recommendations for learning to improve services and protect patients. The cases we see highlight persistent clinical failings and, perhaps even more importantly, persistent failure to respond to patients and families in a compassionate way when they raise complaints.

---

[8] NHS Staff Survey 2022: National results briefing, March 2023.

[9] NHS Vacancy Statistics, England, April 2015 - December 2022, Experimental Statistics.

[10] CQC (October 2022), State of Care 2022, Summary.

[11] The Kings Fund (March 2023), Public satisfaction with the NHS.

[12] See, for example, research outlined in BMJ (2015), 'Supporting "second victims" is a system-wide responsibility'.

Annotated by the Urology Services Inquiry

This report builds on the detailed and extensive work of countless others over the past ten years. In recognition of that, we have engaged with policymakers, oversight bodies, regulators, professional bodies and advocacy organisations to test and refine our conclusions and recommendations.

By analysing the unique evidence of complaints we have investigated, we have identified two sets of findings. First, we reflect on common themes that emerge when clinical failings have led to avoidable harm. Despite the diversity in the cases we looked at – some involving babies a few days old, others older adult patients; situations that progressed in a matter of hours and others over a number of years – there are issues that come up repeatedly.

Second, we look at the additional harm – sometimes called compounded harm – that happens when families, who have already experienced the devastating consequences of avoidable harm, try to understand what has happened to their loved ones but are met with a poor response from NHS organisations.

In the final section, we suggest the wider changes needed to see the improvements that patients, families and clinicians deserve when it comes to serious avoidable harm.

How we developed this report

To develop this report, we undertook a qualitative analysis of over 400 detailed health complaint investigations from the past three years. We identified 22 cases where someone had died and we found that the death was – more likely than not – avoidable. We know that relatively few families, having been through a local complaints process while dealing with their own grief, will feel able to keep going and bring their case to us. So these 22 cases are a significant sample of what is likely to be a much bigger problem.

In these cases, we found that the patients would not have died if they had received the right care and treatment at the right time. This happened mainly in inpatient settings in NHS acute trusts, including emergency departments, intensive care units (ICUs) and general medical wards.

We analysed the cases in more detail to develop the themes in this report. We conducted four interviews with families who brought the cases to us, to hear from them directly about their experience of raising concerns with Trusts. We supplemented this with a review of secondary literature on patient safety to put our evidence in context.

Words we use in this report

Throughout this report, we use **clinical failings** to refer to clinical care and treatment that a patient should have received but did not receive.

We use **avoidable harm** to refer to clinical harm that a patient suffers because they did not receive the right care and treatment at the right time.

Our casework evidence on avoidable harm

Clinical failings leading to avoidable harm

Patient harm is a global phenomenon[13] that happens everywhere patient care takes place. Over 1.25 million staff in the NHS[14] have 1.5 million patient interactions every day,[15] so it is inevitable that mistakes will happen. But, despite improvements over the last ten years, the estimated number of 11,000 avoidable deaths every year is shocking.

After analysing the 22 cases where we found that a death was avoidable, we identified four broad themes of clinical failings leading to avoidable harm:

- failure to make the right diagnosis
- delays in providing treatment
- poor handovers between clinicians
- failure to listen to the concerns of patients or their families.

Failure to make the right diagnosis

In more than half of the cases we looked at, we found that a failure to diagnose directly led to or significantly contributed to the avoidable death of a patient. In these cases, the right diagnosis could have been made at the right time. If this had happened and the correct treatment had been provided, it is likely the patient would not have died.

A range of factors and circumstances can lead to clinicians not making the right diagnosis at the right time, especially when a patient's condition is complex or critical. In our casework analysis, failures to make the right diagnosis were mainly the result of:

- not seeking more senior or specialist input where that would be appropriate
- not observing or monitoring someone at regular enough intervals to recognise deteriorating health or new issues
- failings in imaging, such as failing to follow up on an unexpected finding.[16]

---

[13] Bennett, S. A. (2020), 'Avoidable deaths in Britain's National Health Service - A systems-thinking informed analysis using data garnered from government agencies, representative bodies, private canvassing and public inquiries'. International Journal of Healthcare Technology and Management, 18 (1–2), pp. 95–110.

[14] NHS Workforce Statistics - December 2022.

[15] The King's Fund (October 2022), Activity in the NHS.

[16] For a more detailed analysis of failings in imaging, see our 2021 report, 'Unlocking Solutions in Imaging: working together to learn from failings in the NHS'.

Annotated by the Urology Services Inquiry

In one case we looked at, the patient's National Early Warning Score (NEWS score)[17] showed he was very unwell and should have been reviewed by a more senior clinician with the knowledge and experience to diagnose and treat him while his condition was getting worse. The Trust should have asked for an urgent review by a more senior clinician, but this did not happen. When the patient's condition got worse, the Trust delayed asking for an urgent review, and there were further delays in reviewing the patient. This meant the Trust failed to recognise the patient had sepsis and did not give him the right treatment. The patient suffered a cardiac arrest (when the heart stops pumping blood around the body) and died.

We identified the importance of appropriate and timely senior input in our report on sepsis, 'Time to Act', noting that 'the skills necessary for early identification of patients at risk of severe sepsis are high level and develop with long experience'.[18] It is concerning that a decade after this report, and following huge efforts to improve the early recognition and treatment of sepsis, we still see these kinds of failings.

[17] NEWS is the National Early Warning Score designed to standardise the assessment of and response to acute illness. It combines scores along six physiological measures: respiration rate, oxygen level, blood pressure, pulse rate, level of consciousness or new confusion and temperature. It was updated in 2017 and NEWS2 is endorsed by NHS England as the early warning system for use in all secondary care and ambulance services.

[18] PHSO (2013), 'Time to Act', p. 43.

Case study: failure to diagnose pulmonary embolism

- A man contacted an out-of-hours GP service because he had been suffering from shortness of breath for over a month and had a fever. The GP diagnosed a chest infection and prescribed steroid medication.
- The patient's family called for an ambulance the same evening because his breathlessness had started to get worse. The ambulance crew arrived and took him to hospital.
- The patient's observations showed a fast heart rate, raised rate of breathing and a low level of oxygen in his blood. Staff gave him a nebuliser and his oxygen levels improved.
- A doctor reviewed the patient. An X-ray did not show any concerns. The doctor diagnosed pneumonia, prescribed antibiotics and decided not to admit the patient.
- The following day, a GP visited the patient at home and prescribed an inhaler. They suggested the patient should return to the hospital.
- Later that day, the patient's family called an ambulance because they were concerned about his condition. When the ambulance arrived, the patient was conscious but short of breath.
- The patient suffered a cardiac arrest and the paramedics tried to resuscitate him. Unfortunately, they could not do so and the patient died. The cause of death was a pulmonary embolism (a blocked blood vessel in the lungs).
- We found the doctors failed to follow the relevant guidance when they reviewed the patient at the hospital.
- The clinical signs the patient presented suggested a pulmonary embolism was the likely cause of their breathlessness, high heart rate, high respiratory rate and low oxygen. Doctors should have arranged a specific blood test, but this did not happen. Instead, the patient was sent home without the right treatment.
- The doctors made a diagnosis of pneumonia (inflammation of the lungs) but the chest X-ray results showed the patient's lungs were clear and there was no evidence of blood tests to confirm a diagnosis of infection.
- We found it likely the patient would have survived had he received the right treatment after the doctor reviewed him. This would likely have led to the diagnosis of pulmonary embolism and successful treatment with the right medication.[19]

[19] In its report on the diagnosis of pulmonary embolism in emergency departments, HSIB identified a safety risk in missed diagnosis and treatment of pulmonary embolism, given its atypical symptoms: HSIB (2022), 'Clinical decision making: diagnosis of pulmonary embolism in emergency departments'.

Annotated by the Urology Services Inquiry

We spoke to the patient's mother who described her and her family's experience of seeing the patient die at home:

'My son came home with absolutely no information whatsoever ... He should have been in hospital, he should have been on a ward. He died in his bedroom and I had to hear it ... My grandson was in the room next door with me and he heard him die too. It's not something that you would want for anybody.'

Failing to observe or monitor someone at regular enough intervals can result in missed opportunities to recognise deteriorating health or new issues. In one case we looked at, a man was admitted to the Trust's emergency department with chest pains. His condition got worse in hospital but staff did not carry out observations to monitor him as frequently as they should have done. This resulted in a missed opportunity to notice the patient's health getting worse due to sepsis and to involve critical care. It delayed the diagnosis and treatment of sepsis for over ten hours. We found that if the patient had been monitored at appropriate intervals, it is likely his worsening health would have been identified, he would have received treatment for sepsis and, more likely than not, he would have survived.

In another case, a mental health Trust did not observe a long-term inpatient as frequently and as closely as it should have done. The woman attempted to harm herself in a way that could have led to her death on two occasions. Staff managed to stop her from harming herself both times. The Trust should have updated the risk assessment to include actions to reduce any risks and minimise harm, including risks posed by ligature points (anything that could be used to attach a cord, rope or other material for the purpose of self-harm). The following day, the patient was found unresponsive and died because of a hypoxic brain injury (when the brain does not get enough oxygen). We found that if the Trust had observed the patient more closely and frequently and taken action to address ligature points, it was unlikely the suicide attempt would have been completed. If the patient had been monitored more frequently, it is likely there would have been the opportunity to intervene in time and prevent the woman's death.

We spoke with the patient's sister who told us the Trust did not manage to keep her sister safe:

> 'It was supposed to be a place of safety and it clearly wasn't. My sister shouldn't have died in the hospital.'

Case study: failure to carry out repeat risk assessments

- A patient went to a Trust's emergency department with a swollen left hand. The patient had cellulitis (a bacterial skin infection that causes swelling) and gout (a build-up of uric acid causing swelling in the joints).
- The Trust admitted the patient to the hospital and considered their risk of developing venous thromboembolism (VTE, a condition that happens when a blood clot forms in a vein).
- The Trust decided there was no risk and did not carry out any further risk assessments. Staff treated the patient, which included elevating their arm and giving them antibiotics.
- A couple of days later, the patient started experiencing chest pains and tightness in their chest. The Trust carried out an electrocardiogram (ECG, a test to check the heart's rhythm and electrical activity) and provided medication. Later that day, the patient became sick and collapsed.

Annotated by the Urology Services Inquiry

- The doctor planned to move the patient to a bed with more monitoring. But, before this could happen, the patient suffered a cardiac arrest. The Trust resuscitated the patient and gave them medication to break down blood clots.
- After this, the patient remained stable for a short time during which they were moved to the intensive care unit. Sadly, their condition did not improve and they died that evening. The Trust carried out an autopsy which confirmed the cause of death as a pulmonary embolism (blockage of a lung artery).
- We found the Trust failed to carry out a full assessment of the patient's risk of developing VTE, and then failed to reassess them 24 hours later as outlined in NICE guidance. It missed two opportunities to provide appropriate and timely treatment to prevent a pulmonary embolism.
- Had the Trust given the right treatment on time, it is more likely it could have prevented the pulmonary embolism and avoided the patient's death.

Delays in the treatment response

Our casework shows that serious harm can be caused by delays in providing treatment. In our analysis, we found that these delays often relate to:

- a diagnosis being made but then not being acted on properly or quickly enough
- not acting quickly enough on observations.

In one of the complaints we looked at, the Trust appropriately and quickly diagnosed a woman with vasculitis (inflammation of the blood vessels). Vasculitis is a condition that needs urgent treatment. But the Trust did not prescribe the medication needed for another 16 hours after the diagnosis. After prescribing the medication, the Trust did not give it to the patient for another 11 hours. The Trust significantly delayed giving the patient the life-saving treatment she needed for 27 hours. Our investigation found the patient could have survived if she been given the correct medication in time. It is more likely than not that her death could have been avoided.

When there is evidence that a patient's health is getting worse it is vital to respond quickly, but we found instances where this did not happen. For example, in a case where the on-call doctor did not attend when requested to, we found that the way they were contacted (via a 'bleep') did not include information about the urgency of the request. The Trust explained the system does not give any sign of urgency unless the doctor is being called to attend a cardiac arrest. Our investigation report highlighted that this is a problematic system because it does not allow clinicians to prioritise their patients' needs. We argued that it undermines the benefits of a warning system like NEWS if clinicians are not meaningfully empowered to act quickly in response.

This is a well-known issue. It is highlighted, for example, in a recent national investigation report by HSIB on recognising and responding to critically unwell patients. The report notes that early warning scores 'can place a high demand on medical staff and the current escalation protocols may not be achievable owing to a task versus resource mismatch'.[20] Clearly, monitoring is only useful if there are enough staff to respond when deterioration is detected.

Case study: failure to provide timely sepsis treatment

- A patient went to hospital for a hysteroscopy (a procedure to examine the inside of the womb).
- The procedure was completed without incident and the plan was for her to stay in hospital to be monitored.
- After being transferred to the ward, she felt unwell. Staff carried out assessments to examine her symptoms. The results showed abnormal blood tests, including a very low white blood cell count.
- The patient was referred to and reviewed by the emergency medical response team. The doctors considered sepsis as one of several possibilities for explaining the clinical findings. But they thought this was unlikely so they did not prescribe antibiotics.
- The patient was transferred to the acute medical unit for closer monitoring. The doctor who reviewed her recommended an immediate dose of antibiotics.
- Unfortunately, she did not receive the antibiotics until four hours later. Her health deteriorated significantly in that time.
- This delay in receiving antibiotics meant the patient did not receive timely treatment for sepsis in line with the NICE sepsis guidance.
- Staff performed a CT scan (a computerised tomography scan, which creates detailed images of the inside of the body) the following morning. They prescribed another dose of antibiotics, reviewed the patient and transferred her to the intensive care unit to receive medication to support circulation.
- The patient's condition did not improve. Doctors explained to her family they could give no further treatment and started end of life care. Sadly, she died that evening.
- We found that the delays in starting antibiotic treatment and admitting the patient to the intensive care unit (to support her circulation) significantly affected her chances of survival.
- If the Trust had done what it should have done, it was more likely that the patient would not have died.

[20] HSIB (2021), 'Recognising and responding to critically unwell patients'.

Annotated by the Urology Services Inquiry

Poor handovers

Good communication between clinicians and appropriate handover between teams is an essential part of patient safety. General Medical Council guidance[21] to doctors, for example, stresses the importance of working collaboratively, communicating effectively and sharing information between teams. Equally, the Nursing and Midwifery Council Code of Practice highlights the need to maintain effective communication and keep health and care professionals informed when sharing the care of individuals, to 'preserve the safety of those receiving care'.[22] This includes the need for timely and appropriate handovers between teams. Research has identified that transfers into or out of intensive care units and when information has to be communicated to other teams during a critical care stay can be risk points for patient safety incidents.[23]

In almost half of the cases we analysed, we found failings in communication between different clinicians and teams. In one case, for example, we could not find any evidence that the Trust followed a clear and coordinated clinical management plan when a man in his seventies attended the Trust's emergency department with a twisted bowel. We found that poor communication between teams contributed significantly to the Trust failing to take urgent action to reduce the risk of bowel perforation. When investigating another case, we could not find evidence of a documented handover between teams. This meant we could not understand what actions the Trust had taken at the time to make sure the patient continued to receive adequate care.

[21] General Medical Council, 'Domain 3: Communication partnership and teamwork', Good medical practice.

[22] Nursing and Midwifery Council, The Code.

[23] Thomas, A.N., and MacDonald, J.J. (2016), 'Patient safety incidents associated with failures in communication reported from critical care units in the North West of England between 2009 and 2014'. Journal of Intensive Care Society, 17 (2), pp. 129-135.

Case study: failure to diagnose and lack of handover between teams

- A patient went to a Trust's emergency department after an out-of-hours GP told them to call 999. The patient said they had a racing heart, felt generally unwell and had pain in their forearms.
- The Trust carried out a series of checks and found them to be within normal limits. The doctor prescribed an antibiotic and discharged the patient.
- A few days later, the patient was admitted to a medical assessment unit after a GP referral for a respiratory opinion.
- A consultant reviewed them and noted they might have a blood clot and fluid around the lung.
- The consultant requested a troponin test (a blood test that can help assess heart damage), echocardiogram (a scan to look at the heart and nearby blood vessels) and repeat ECG, and prescribed a blood-thinning injection to treat the suspected clot.
- Another doctor reviewed the patient and considered a pleural effusion (when excess fluid builds up in the space between the lungs and the chest wall) rather than a blood clot. Staff gave the patient antibiotics and drained the fluid around the lung. The following day, the doctor noted the patient's symptoms were improving.
- A couple of days later, a consultant respiratory physician noted that the patient had aching pain in both arms, breathlessness and difficulty breathing when lying down. They reviewed the test results and considered the patient had congestive heart failure (when the heart cannot pump blood around the body properly), which was probably secondary to a recent heart attack.
- The consultant asked for an ECG and troponin test and prescribed medication. They left instructions for staff to triage the patient as a cardiology patient and arrange an ECG to check the heart's rhythm and electrical activity.
- The next day, the patient was moved to a ward and nurses noted that a doctor needed to do a medical review, including reviewing the ECG results.
- Sadly, the patient died the next day after suffering a cardiac arrest.
- We found multiple failings in relation to the patient's care.
- The Trust had not carried out the troponin test and echochadiogram the first time a consultant requested them, and staff did not act on early warning observations when they should have alerted a doctor.
- There was evidence of a heart attack in the ECG results, but this did not get an urgent medical review. And no medical review was carried out after the patient was transferred to the ward.

Annotated by the Urology Services Inquiry

- If the Trust had made a timely diagnosis and given appropriate treatment, there would have been an improved chance of the patient surviving. It missed an opportunity to provide potentially lifesaving treatment. It was more likely than not that the patient's death was avoidable.
- We found that communication with the patient's next of kin was flawed and incomplete, and there were failings in the Trust's complaint handling that caused them distress and frustration.

Failure to listen to the concerns of patients and their families

Listening to patients and their families is a vital part of providing good quality care and treatment that puts the patient front and centre. In our casework, we identified a small number of cases where failures to listen to the concerns of patients and their families had a clinical impact.

For example, a man who was admitted to hospital with abdominal pain raised concerns with clinical staff on multiple occasions about his care and treatment. During our investigation we found evidence that he was concerned he did not feel well enough to leave the hospital. Despite this, the Trust still considered him well enough to go home and discharged him on the same day. Two days later, he returned to hospital and died shortly after being admitted due to gastric aspiration (where vomit enters the larynx and lungs). Our investigation found that the Trust should have carried out an urgent CT scan, which would have led to the patient having lifesaving surgery.

In another example, a complainant described how he had to persuade staff to admit his mother after she had attended the Trust's emergency department multiple times. During our investigation, we found evidence that staff doubted the patient's symptoms and failed to appreciate the serious nature of her condition. Understandably, this was upsetting for the complainant who could see that his mother was very unwell. The complainant's mother died after having a stroke in hospital. This could have been avoided if she had been diagnosed correctly and treated during an earlier admission.

Summary

The themes we have identified around clinical failings are wide-ranging but will be very familiar to anyone with experience in patient safety. The caseworkers who worked on these cases observed that they reflect the types of issues we see in most of our health casework, not just those that resulted in the most serious possible outcome of a patient's avoidable death.

Although a lot can be done to reduce clinical harm and improve patient safety, and certain incidents can be prevented entirely with the right processes, systems and cultures in place, it is unrealistic to expect that all clinical errors and omissions can be eliminated. But it should always be possible to respond well, with compassion, and in a way that shows learning and accountability when avoidable harm has happened. In the next section we look at the evidence from our casework about the impact on families when this does not happen.

The ongoing impact of clinical harm: compounded harm to families

All too often in our casework, we see families who have already experienced the devastating consequences of avoidable harm suffer further distress because of the response they get from healthcare organisations. This additional harm that people experience when interactions following patient safety incidents feel closed and defensive is known as 'compounded harm'.[24] Researchers have recognised the impact of compounded harm, 'especially when people feel unheard or invalidated'.[25]

Although the idea of compounded harm is not new, it is often neglected in the process of understanding the impact of avoidable serious harm. In this section, we look at evidence of compounded harm in our casework. We highlight the experiences of families who brought cases to us, as they described it during our interviews with them.

When we looked at our casework, we identified the following scenarios that are likely to contribute to compounded harm:

- failure to be honest when things go wrong
- a lack of support to navigate systems in the aftermath of an incident
- poor-quality investigations
- failure to respond to complaints in a timely and compassionate way
- inadequate apologies
- unsatisfactory learning responses.

A failure to be open and honest when things go wrong

The duty of candour requires organisations to be open and honest with patients as soon as possible after they realise something has gone wrong. But we know from our casework that this duty is not always met. In one example, we found the Trust did not disclose the contradictory opinions it had received from different reviewers when determining whether a delay to an operation had resulted in avoidable harm. We judged that this review should have triggered action under the duty of candour, but there was no evidence the Trust had considered its responsibilities to inform the family.

In a case where a baby died after antibiotics were not given quickly enough, we found the Trust had not properly equipped its staff to acknowledge what had gone wrong. Important details about the sequence of events and the nature of the infection were not given to the parents until seven weeks after their son died. Staff even discussed deleting a recording made during a meeting when the parents temporarily stepped out of the room, because they realised what they had said might get the Trust into difficulty. This complete failure of transparency created understandable mistrust and worsened the pain and distress of the family in their grief.

[24] This term features in the Patient Safety Incident Response Framework guidance on engaging with and involving families, patients and staff following a patient safety incident.

[25] Wailling, J., Kooijman, A., Hughes, J., and O'Hara, J. (2022), 'Humanizing harm: Using a restorative approach to heal and learn from adverse events'. Health Expectations, 25 (4), pp. 1192-1199.

Annotated by the Urology Services Inquiry

Duty of candour

The underlying principle of the duty of candour is that when something goes wrong in the provision of health and care services, patients and families have a right to receive a meaningful apology and explanations for what happened as soon as possible.

The statutory duty of candour was introduced in 2014 in regulations to the Health and Social Care Act 2008.

Regulation 20 puts a legal duty on health and social care to be open and transparent with people using services and their families. It sets out actions that providers must take when a 'notifiable safety incident' happens. Notifiable safety incidents:

- are unintended or unexpected
- happen during the provision of an activity the CQC regulates
- are incidents that – in the reasonable opinion of a healthcare professional – could, or already appear to have, resulted in death or severe or moderate harm to the person receiving care.

As soon as a notifiable safety incident has been identified, organisations must act promptly and are expected to:

- tell the relevant person, face-to-face, that a notifiable safety incident has taken place
- say sorry
- provide a true account of what happened, explaining what is known at that point
- explain what further enquiries or investigations will take place
- follow up by providing this information and the apology in writing, and giving an update on any enquiries
- keep a secure written record of all meetings and communications with the relevant person.

The CQC regulates compliance with the statutory duty of candour. Organisations must have clear policies and procedures in place and make sure staff understand their responsibilities. The CQC also expects senior managers to show they have a safe culture where staff feel able to speak up and are supported to carry out the duty of candour. Failure to comply with the duty can result in enforcement activity ranging from warning or requirement notices to criminal prosecution.

Lack of support to navigate systems in the aftermath of an incident

All our interviewees spoke about the difficulties they had in knowing how to raise concerns about what happened to their family member. A lack of information was a common experience. One complainant explained: 'we didn't get any information in regards to letting them [the Trust] know about our experience, how we felt about my mum's care; all of that was sorted by me and I didn't get any family support either. I literally did it all by myself'.

Another commented:

> 'Nobody gave me any information at all. I went online and googled what to do and that was it. Nobody gave me any advice on how to complain, on what to say, or anything like that.'

We also heard some concerns about a lack of independent advice, if it came from the same organisation where the incident took place:

'I feel like it was a very distressing situation, there was no sort of advice around the complaint. I first complained to PALS which work in the hospital. I don't actually think that this is a good way for patients to complain about the hospital because the people they complain to work within the hospital.'

Where complainants were able to access independent advocacy services, this was a positive experience:

> 'I did find an organisation that supported me called POhWER, they were really helpful. I was really upset and distressed and the first lady was very patient with me, very kind, very helpful, she told me the steps to complain. Then that lady left and they gave me another advocate and she was also really helpful ... she read every single page with me, and she literally held my hand all the way through the process. So the advocates were helpful, but in regards to the hospital, there was no help from them.'

Local authorities have a statutory duty to fund independent NHS complaints advocacy. This type of advocacy is provided by trained, professional advocates who can give information, signposting and support with the complaints process. Professional advocacy can be a source of valuable information and guidance, and a way of supporting complainants through what can be a long and difficult process, although emotional or psychological support is not part of the role of professional NHS complaints advocates.

As we highlighted in 'Making Complaints Count', NHS complaints advocacy services are limited to helping people navigate the NHS complaints process. Complaints advocacy providers cannot give advice on the clinical parts of a complaint or other processes a complainant might be involved in or considering, such as coroner inquests or making a claim.[26]

[26] PHSO, Making Complaints Count, p. 32.

Annotated by the Urology Services Inquiry

The benefit of access to advocacy is something the Harmed Patients Alliance recognised in a recent report. It said: 'well-advised and supported people are more likely to take an active part in investigations without suffering compounded harm', as well as being better able to take part 'in a meaningful way in a patient safety investigation under the Patient Safety Incident Response Framework (PSIRF)'.[27]

Poor-quality investigations

Organisations should provide clear, evidence-based explanations in response to concerns, provide reasons for their decisions, and consider the impact of any failings. We routinely see Trusts fail to accept errors or the extent of what has happened and its impact. In most cases where we found a death was avoidable, the Trust had not conducted a serious incident investigation. And there were no instances of Trusts themselves reaching the same conclusion as our investigation that errors in care led to the death of the patient. Because we use evidence that organisations would have had access to, it is reasonable to expect those organisations should also have been able to identify these errors.

In one case, after delaying its response by a whole year, the Trust responded to a complainant about her mother's death by summarising what was said in a local resolution meeting (a meeting between the Trust and the complainant). We saw no evidence that the Trust conducted a full investigation into the complainant's concerns or attempted to address them in any detail. In another case, there were contradictions in the Trust's written responses and inaccuracies in its account of the care and treatment provided to the complainant's wife, who had died of a brain tumour. The Trust provided two responses a year apart. The first response accepted there was a delay in identifying that the tumour was growing, while the second response explained events differently.

Some investigations are not as thorough as they should be and crucial parts are missed out. For example, a case in which a senior house officer failed to attend when bleeped was a significant moment in understanding failures in care and treatment. But the senior house officer was not interviewed as part of the serious incident investigation that followed. Nursing staff were asked to give statements, but the senior house officer was not. This meant the Trust was unable to explain why there was a delay in responding to the bleep and missed an opportunity to understand the context of the failing. This added to the distress felt by the patient's partner, who was left with no answers to this important part of the incident.

In some instances, we found the Trust identified the clinical failings correctly but the local investigation failed to consider the impact of them. In one case, the Trust carried out an investigation and correctly identified the clinical failings that led to a mother's death from sepsis. It made an action plan for improving process, which showed it aimed to learn from the incident, but it did not consider the impact of the failings, which was that the patient's death would not have happened if they had received the right treatment at the right time. In another case, the Trust initially refused to accept that it should have identified clear abnormalities on an X-ray and did not believe this represented a missed diagnosis.

[27] Harmed Patients Alliance (2022), Signpost to Nowhere, p. 4.

Trusts can sometimes use comorbidities (when someone has more than one, often chronic or long-term, disease or condition at the same time) to minimise the impact of any failings or omissions. For example, in a case where there was a significant delay in giving antibiotics, the Trust said the patient's history of cardiac problems and low blood pressure would have limited the patient's response to sepsis. But our critical care advisor said this was not supported by the information available. Examples like these suggest an ingrained defensiveness and lack of curiosity about the causes of harm, which is sadly still prevalent in some Trusts.

Case study: failure to make the right diagnosis and poor-quality investigation

- A patient with a long-standing autoimmune disease went to a Trust's emergency department with symptoms including dizziness, poor balance and blurred vision. The Trust kept the patient overnight for further investigations.
- A doctor carried out a brief initial assessment of the patient and noted they looked unwell and pale. Later in the evening, a nurse took blood samples for testing and examined the patient using a MEWS score (Modified Early Warning Score, an early warning system based on clinical observations). This was recorded as 1.
- The Trust transferred the patient to the acute medical unit to wait for a full medical assessment.
- Later in the night, a doctor assessed the patient and noted nystagmus (involuntary flickering eye movements) in addition to earlier symptoms including blurring of vision and dizziness.
- The doctor made a working initial diagnosis of dehydration. The doctor started a care plan to continue with IV fluids, to monitor IV fluids in and urine out, and to refer the patient to the ophthalmic team if the visual changes did not improve with rehydration.
- Afterwards, the nursing team noted further heart rate increase and that the patient had not passed urine since they went to the acute medical unit. The Trust recorded a MEWS score of 4 – 1 for the increased heart rate and 3 for the lack of urine output.
- The patient told the doctor who attended for review that they were unable to pass urine. The patient was catheterised for urine drainage, which eased their discomfort.
- The following morning, a family member reported a rapid change in the patient's condition. They were concerned about the patient becoming drowsy and unable to speak. This prompted the immediate escalation of their treatment.
- Tests and scans were ordered to try to identify the underlying cause of the change. Shortly after, the patient's condition suddenly got worse and they eventually lost consciousness.

Annotated by the Urology Services Inquiry

- The CT head scan results showed signs of hydrocephalus (fluid pressure in the brain caused by a blockage stopping fluid from draining out of the skull) and a bleed on the brain. The patient was immediately transferred to the nearest Regional Neurosurgical Department for surgery to relieve the pressure and stop the bleed.
- Despite having two operations to try saving their life, sadly the patient never regained consciousness and died a few days later.
- The surgeon's notes show they found a growth in the brain during surgery, which caused the hydrocephalus and eventually had also been the source of a bleed on the brain.
- We found several failings in the care the Trust gave the patient.
- We found a failing to complete a full neurological assessment and order a CT head scan in response to signs of nystagmus noted by the doctor at the acute medical unit. Although the nystagmus was identified correctly, the doctor missed the significance.
- This led to a missed opportunity to diagnose and treat the patient's condition and potentially avoid their death.
- We found there was failure to make sure the MEWS score was monitored hourly following the MEWS score of 4 being recorded.
- We also found that the Trust's complaint investigation failed to identify and address these issues, which added to the distress and grief suffered by the patient's family.

The Patient Safety Incident Response Framework (PSIRF)

The PSIRF is being rolled out across the NHS, with a deadline for implementation of autumn 2023. While this is too recent to be relevant to the cases in this report, it represents the future for the approach to patient safety in the NHS.

What the PSIRF is changing

The PSIRF replaces the Serious Incident Framework. Unlike the Serious Incident Framework, it is not an investigation framework that prescribes what to investigate (although there are still circumstances where a patient safety investigation will be mandatory: incidents meeting the 'learning from deaths' criteria; Never Events[28] – safety events that are 'wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers'; deaths of patients detailed under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies).

Instead, the PSIRF promotes a range of system-based approaches for learning from patient safety incidents. This includes alternatives to an investigation such as a multidisciplinary team review and a 'swarm huddle' – when staff gather to quickly analyse what happened immediately after an incident and decide how to reduce future risks.

The PSIRF is intended to be more flexible, allowing organisations to tailor their response to patient safety so that it is relevant for their contexts and the populations they serve. This flexibility will allow organisations to focus resources on where they can really make an impact, rather than having to always conduct an investigation where that might not lead to new learning or create change. The framework represents a move away from root cause analysis and towards approaches that look at the wider system and human factors.

Under the framework, NHS organisations need to develop a plan and a policy outlining how they will respond to patient safety incidents. There is a focus on compassionate engagement with patients and families, with specific guidance on how to do this well.

In terms of oversight, the framework requires a PSIRF executive lead on each NHS Board, as well as an integrated care board lead who will work with providers on their responses to patient safety. The suggestion is that oversight focuses more on collaborative working and collecting qualitative data, rather than requiring lots of quantitative measures. As stated in the guidance, it 'focuses on engagement and empowerment rather than the more traditional command and control'.[29]

Who the PSIRF applies to

The PSIRF is a contractual requirement under the NHS Standard Contract so it will be mandatory for acute, ambulance, mental health and community healthcare providers. This includes maternity and all specialised services. Primary care providers (for example, GPs) may adopt the PSIRF but are not required to at this stage.

[28] NHS (2018), 'Never Events policy and framework'.
[29] NHS England, Patient Safety Incident Response Framework supporting guidance: Oversight roles and responsibilities specification, August 2022.

Annotated by the Urology Services Inquiry

Failure to respond to complaints in a timely and compassionate way

As we are the final stage for unresolved complaints in the NHS, we usually expect people to complain to the organisation they are unhappy with first. This gives the organisation the chance to look into the concerns and, where needed, put things right. We frequently see examples of unacceptable and unreasonable delays in responding to complaints, and failures to keep families informed and updated about the progress of their case. These delays and failings in communication often cause more distress and frustration for complainants and their families at a difficult time.

Case study: failings in care and poor complaint handling

- A patient with bipolar disorder (a mental health condition that affects your moods) attended a hospital's emergency department by ambulance, due to shortness of breath they had been experiencing for a few days.
- Staff arranged a chest X-ray and diagnosed inflammation of the lungs. This inflammation caused impaired oxygen absorption which resulted in respiratory failure. This resulted in low oxygen levels causing the patient to be confused and agitated.
- The patient was admitted to the intensive care unit and prescribed antibiotics and continuous positive airway pressure (CPAP, a type of breathing support).
- A few days later, the patient could breathe without respiratory support and maintain oxygen levels. The consultants considered the patient to be medically stable and transferred them to a ward.
- A couple of days later, the patient had a cardiac arrest. The doctors resuscitated the patient and transferred them back to the intensive care unit.
- Staff carried out an electrical brain wave test, which showed irreversible brain damage. A neurology assessment also confirmed that recovery was unlikely.
- The consultant decided to withdraw critical care support. The patient died later that week. The cause of death was recorded as severe hypoxic brain injury (when the brain does not get enough oxygen) and cardio-respiratory arrest (loss of breathing and heart function).
- We found that staff failed to observe the patient as frequently as they should have. If this had happened, they may have recognised the patient's health deteriorating earlier and called for senior medical input before the cardiac arrest happened.
- We also found the Trust failed to provide planned, focused, one-to-one care for the patient during their time on the ward. If the Trust had provided one-to-one care, staff would have identified the patient's cardiac arrest much sooner.

- If this had happened, it is likely the patient would have been resuscitated without suffering the irreversible brain damage that led to their death. It is likely the patient's death could have been avoided.
- We also found failings in the way the Trust handled the complaint.
- When the patient's daughter complained, the Trust took over six months to arrange an initial meeting to discuss it and failed to provide a written response.
- Before we began our investigation, we asked the Trust to provide a written response. It agreed to do this by the end of the following month but did not provide it until a year later. This meant the complainant only received a response to her complaint about her mother's death two years after complaining to the Trust.

In one case, a man who complained about the death of his wife from a brain tumour had to wait two years for the Trust to conclude its investigation.

In interviews we conducted, complainants described the process of trying to resolve their complaint with Trusts as 'long and torturous', 'a long, dragging sequence of events' and 'very lengthy and distressing'.

Often, Trusts will explain that the complaint department was understaffed or dealing with high staff turnover. We know from previous research that complaint handlers in the NHS may not be sufficiently empowered or trained to resolve a complaint.[30]

Treating complainants with dignity and compassion is an essential part of resolving a complaint, but we found instances where organisations failed to do this. For example, in one of the complainant interviews, a mother whose son died of a pulmonary embolism told us:

> 'At some point a doctor from the Trust phoned my [other] son to tell him that his brother would have died anyway and there was really no point in carrying on with this.'

The same complainant told us she felt the Trust 'just weren't interested. It was over, it was done with, and they didn't want to know'.

In another interview, the complainant told us their first meeting with the Trust took place in the same ward where her mother had recently died.

[30] PHSO (2020), 'Making Complaints Count: Supporting complaints handling in the NHS and UK Government Departments'.

Annotated by the Urology Services Inquiry

The complainant said this was so insensitive to her and her family that 'it felt cruel'. The same complainant told us she did not feel like the Trust was interested in what she had to say:

> 'I didn't think they were interested. I felt like my mum had passed away and so it wasn't a concern for them. It was almost like, you know, she's gone now and that was it.'

NHS Complaint Standards

We are committed to supporting and improving frontline complaint handling. We developed the NHS Complaint Standards to support organisations to provide a quicker, simpler and more streamlined complaint handling service. The Standards apply to NHS organisations in England and independent healthcare providers that deliver NHS-funded care.

The Standards have a strong focus on:

- early resolution by empowered and well-trained people
- all staff, particularly senior staff, regularly reviewing what learning can be taken from complaints
- how all staff, particularly senior staff, should use this learning to improve services.

The Complaint Standards are based on 'My Expectations', which sets out what patients want to happen when they make a complaint about health or social care services.[31] The Standards and the guidance modules describe how staff can meet those expectations.

We worked with 11 pilot sites and over 70 'early adopters' across the NHS in 2021-22 to help test how the Standards, supporting materials and training can support frontline complaint handling.

Feedback from the pilot has been overwhelmingly positive, with NHS staff telling us the support on offer will make a real, practical difference and promote consistency. Throughout 2023, we will be working to embed the Standards across the NHS.

Inadequate apologies

Guidance from NHS Resolution makes it clear that apologising is not an admission of fault or liability.[32] The same guidance highlights that organisations must make meaningful apologies when things go wrong. It states that a meaningful apology 'is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them'.

[31] PHSO (2014), 'My expectations for raising concerns and complaints'.

[32] NHS Resolution, 'Saying sorry': 'The Compensation Act 2006 states; "An apology, an offer of treatment or other redress, shall not of itself amount to an admission of negligence or breach of statutory duty"'.

But we still see organisations that fail to give a genuine apology. Organisations may say sorry and accept that failings happened, but it is rarer that they offer a clear and unreserved apology that shows they have understood the impact of those failings on the patient. In 'Making Complaints Count', we identified how a culture of defensiveness can result in staff feeling like they are not allowed to say sorry. Advocates also told us they often see organisations send apology letters that say 'I'm sorry if you felt that...' rather than offering a sincere apology.[33]

In one case, the apology letter repeated that the Trust had been asked to accept the failings we found, but it did not go on to do this. Instead, it referred to what the Ombudsman 'felt', which suggests a lack of acceptance of our findings and the learning they offer. The apology letter did not accept responsibility for what happened or even refer to the patient or the fact that they died. In another case, we considered that the Trust's apology letter did not accept that its failings led to avoidable serious harm. In its first apology letter to the complainant, the Trust only apologised for the complainant having 'had cause to raise concerns'. It was clear the Trust did not accept responsibility and had not apologised for the impact of the failings. It was only after repeated contact with the Trust on the content of the apology letter that it gave the complainant an unreserved apology for the avoidable serious harm it caused to the patient.

One complainant told us that after our investigation they felt the 'Trust finally had to accept that they had got it wrong'. But they also said:

> 'I don't think that they did it with a good grace. I think it was just a formula ... They weren't sorry that they'd done it, they were sorry they'd been caught.'

Unsatisfactory learning responses

Most complainants want assurances that something is being done to prevent the same mistakes from happening again. In our recent research on motivations for complaining, 93% of respondents said 'ensuring that others don't face the same issues in the future' was either very important or important in their decision to complain.[34] Similarly, in our interviews with complainants, they all said part of the reason why they complained was to make sure the same thing does not happen to other patients, families and carers.

Being able to show that learning has happened is vital if families are to feel their complaint has achieved its purpose. Responses that do not feel meaningful can leave families feeling badly let down and frustrated.

While we do see good examples of thorough action plans, we frequently see less robust responses. These are a missed opportunity for learning from avoidable serious harm and taking action to prevent it from happening again. In one case, we had to follow up multiple times to make sure we were satisfied with the proposed action plan. The Trust did not plan to audit its proposed new processes, so there would be no way of knowing if they were effective.

[33] PHSO (2020), Making Complaints Count, p. 14.

[34] PHSO (2023), Outreach Research.

Annotated by the Urology Services Inquiry

In one interview, the complainant told us:

> 'I knew that all the things they said they were going to implement to change things, wouldn't change the way the ward was operated and the way nurses behaved, or the way that the actual patients on the ward felt. It was all just more rules, and probably just more bits of paper for the nurses to fill in, but not translating to an effect on the ward.'

Another complainant told us:

> 'I don't believe they've learned one lesson.'

It is clear that, far from being a process that promotes learning and provides resolution and healing, the response to families following an incident frequently creates further harm and distress. This is completely unacceptable. Reducing compounded harm must be an urgent priority for everyone working to improve patient safety.

Our recommendations

The issues we have identified are complex. They reflect the fact that healthcare is a web of interactions, behaviours and processes, underpinned by deeply ingrained cultures. If there were readily available, easy solutions to tackle clinical failures and end compounded harm, they would have been implemented long ago.

Facing up to this complexity, we have focused on two themes in our recommendations.

1. Accountability for a robust and compassionate response to harm, which supports learning for systems and healing for families

Our casework shows that many local investigations are not good enough. It cannot be right that in so many instances, the Ombudsman finds errors that the Trust has not identified at an earlier stage. The gap between the findings of local investigations and the findings of our investigations suggests how defensive some NHS cultures can be. In some Trusts, there is still an embedded lack of curiosity about what has happened and what can be learned.

It is important to recognise that our evidence base is just one snapshot in a much bigger picture. We understand that few people will have the energy to keep going and bring their case to the Ombudsman, having been through the trauma of grief, an investigation and a complaints process. This means what we see through our casework is likely to be the tip of the iceberg.

We must improve investigation quality and practices so they aid learning and promote healing, rather than adding to compounded harm. The HSIB has done important work to upskill NHS staff in best practice investigation methodologies, and the PSIRF is an excellent framework to take this even further. There is a lot to welcome in the framework's systems-based approach and emphasis on compassionate engagement.

While we want to endorse the approach the PSIRF outlines, we need to be realistic about how far there is still to go. There is a gap between the welcome rhetoric in PSIRF guidance documents and the defensive behaviours from some NHS leaders we still see in our casework, as evidenced in this report.

The additional flexibility the PSIRF offers (giving Trusts more autonomy to decide when a safety investigation is needed) might present a risk that Trusts with poor cultures do not carry out safety incident investigations when they should. This possibility is not acknowledged in the PSIRF oversight guidance. Rather, the emphasis on 'proportionate responses' focuses more on making sure unnecessary investigations are not conducted if they would repeat old ground or would not lead to learning.

The PSIRF needs to be accompanied by sufficient monitoring and support for families.

Annotated by the Urology Services Inquiry

We recommend that:

- **Integrated care boards, with oversight from NHS England, should closely monitor the impact of the PSIRF to identify any negative consequences of the new flexibility it offers, which gives Trusts more autonomy to decide when a patient safety investigation is needed. This should include paying special attention to the balance of patient safety investigations versus other learning responses in Trusts (or service areas of a Trust) where there are poor CQC ratings for safety and leadership, or where other national bodies have raised concerns (recommendation 1).**
- **As part of their quality monitoring role, the PSIRF executive lead on each Board should look at any discrepancies between local and PHSO investigations, or other independent investigations, and make sure the Board discusses them. This should include where local investigations did not take place, or did not find that things went wrong, but PHSO or another independent oversight body later identified failings (recommendation 2).**

The PSIRF recognises that genuine apologies are critical to avoid compounded harm. As we found in cases we analysed, apologies are often still not good enough and duty of candour is not always implemented as it should be. It is unacceptable that Trusts still fail in this duty nearly a decade after it was introduced. Again, this is symptomatic of a defensive culture in some Trusts. Duty of candour is the right policy, but it needs more attention and monitoring.

We recommend that:

- **The Department of Health and Social Care and NHS England should further scrutinise the lack of compliance with duty of candour. They should review the operation of duty of candour to assess its effectiveness and make recommendations for improvement (recommendation 3).**

We welcome the model of family engagement outlined in the PSIRF. But we know that, for the foreseeable future, it will continue to be very challenging for families affected by safety incidents to navigate the complex NHS landscape when they raise concerns and seek answers. They are often very aware of the power imbalances in dealing with professionals who are familiar with the processes and systems that they are coming to for the first time. In this context, advocacy is an essential service, not a 'nice to have'.

While there is a statutory duty for local authorities to commission NHS complaints advocacy, these services are often limited to helping people navigate the NHS complaints process. As we noted in 'Making Complaints Count', there are concerning gaps in access to more specialist services that may be important for families affected by patient safety incidents.

We recommend that:

- **The Department of Health and Social Care should commit to funding further independent advocacy to support harmed patients, families and carers when they raise concerns or seek answers after an incident (recommendation 4).**

2. Evidencing that patient safety is a top Government and NHS priority

The right patient safety framework is not enough on its own to drive change. NHS leaders and frontline staff need to be in no doubt of the priority placed on patient safety.

In some ways it is strange that this should need emphasis: patient safety is about the NHS' core purpose to do no harm. But there are clear signs that patient safety is not prioritised at the moment, however much rhetoric there is to suggest otherwise.

First, we are becoming too used to seeing repeated failings. This is especially stark in maternity services. In his inquiry in East Kent, Bill Kirkup acknowledged the disappointing familiarity of the findings to those he made in Morecambe Bay seven years earlier. The fact that inquiries many years apart find the same failings is met with dismay, but not always outrage or even surprise. There is almost an acceptance that this is 'how things are'. This inertia undermines the difficult work underway to change cultures and manage patient safety more effectively.

Second, political leaders have created a confusing landscape of organisations, often in knee-jerk rection to patient safety crisis points. HSIB, the Patient Safety Commissioner, PHSO, NHS England, NHS Resolution and more than a dozen different health and care regulators all play important roles in patient safety. But there are significant overlaps in functions, which create uncertainty about who is responsible for what. This means patient safety voice and leadership are fractured. This is not due to a lack of dedication and professionalism from those tasked with championing patient safety. The problem is structural.

The Government must consider the case for streamlining some of these functions, for the benefit of people who use the NHS, their families and carers. This is not about reducing investment in patient safety. It is about creating a system that is coherent and easier to navigate, based on evidence and engagement with patients, families, NHS staff and leaders. We recommend that:

- **The Department of Health and Social Care should commission an independent review of what an effective set of patient safety oversight bodies would look like. The review must include meaningful engagement with NHS leaders, staff, patients and families (recommendation 5).**

Patient safety must be a consistent priority over the long term. It must not be subject to changes of emphasis or importance each time there is a new minister or leadership change in the NHS. We recommend that:

- **The Government should seek cross-party support for embedding patient safety and the culture and leadership needed to support it as a long-term priority (recommendation 6).**

Third, it is not possible to claim to prioritise patient safety while avoiding difficult political decisions about the workforce the NHS needs. Patient safety will always be at risk in environments that are understaffed and where staff are exhausted and under unsustainable pressure. No matter how effective the safety systems and process, it is not possible to run a safe service without the right numbers of staff. Many patient safety commentators draw parallels between the NHS and aviation. In aviation, a plane would not take off without the right number of staff, with the rights skills, who have had enough rest, support and training to be able to operate safely.

Annotated by the Urology Services Inquiry

Tackling workforce shortages goes beyond political decisions about resourcing. It is about making the NHS a place where people want to work and stay because it is somewhere they feel valued, not just because it is a vocation. We must break down the false dichotomy between the interests of patients and staff, recognising that a system that does not treat its workforce with humanity and compassion will struggle to extend these qualities to patients and families.

We recognise the Government has promised to publish a new NHS workforce strategy. At the time of writing, this is expected 'shortly'. But for this to properly address the underlying causes of NHS staffing pressures, it needs cross-party consensus. In a sector where it can take nearly two decades to train a consultant doctor, a workforce strategy will only succeed if there is support from across the political spectrum, and far beyond one parliamentary term.

We recommend that:

- **The Government should urgently produce its long-awaited long-term workforce strategy, with cross-party support, to increase the numbers entering and staying in the workforce across clinical and non-clinical roles. This strategy must:**
    - **include independent, evidence-based and fully costed projections of future workforce requirements**
    - **include detailed plans for training and recruiting new staff, retaining staff already working in the NHS and attracting those who have left to return**
    - **take account of the mix of different professional skills required, rather than just total numbers in the workforce, and how existing professional skills can be deployed where they are most needed (recommendation 7).**

The Department of Health and Social Care should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 3, 4, 5, 6 and 7.

NHS England should write to the Health and Social Care Select Committee and the Public Administration and Constitutional Affairs Committee within six months of the publication of this report to provide an update on progress against recommendations 1 and 3.

Annotated by the Urology Services Inquiry

Parliamentary and Health Service Ombudsman

Citygate
Mosley Street
Manchester
M2 3HQ
United Kingdom

Telephone: 0345 015 4033

Email: phso.enquiries@ombudsman.org.uk

www.ombudsman.org.uk

Follow us on:

If you would like this document in a different format, such as Daisy or large print, please contact us.

E02931971
ISBN: 978-1-5286-4244-6

Annotated by the Urology Services Inquiry

I wouldn't want that to be forgotten. And I know the Inquiry is not to look at the good things, those go by. But this is all negative coming from me and I didn't want to be here and I wasn't going to come and I'm here purely out of duty.

But I certainly want to make sure that the Panel, who may not be really as familiar with the workings of Craigavon Hospital as I am, I now know nearly every nurse and surgeon in it, that the work that was being done outside of these mistakes was absolutely first class and [redacted] appreciated that right up to her death and I think it's important that that's set in context in this Inquiry in relation to it. 11:30

16 Q. Well, can I assure you, [redacted] on behalf of the Inquiry that it is our duty to be fair? 11:30

A. Hmm.

17 Q. And I'm sure those present here today will appreciate the remarks that you have made about the care that your wife received in Craigavon. There's nothing else that I want to ask you. But I'm just going to ask Dr. Swart if there is any questions that she would like to ask? 11:31

DR. SWART: Just to say thank you, to start with, very much for describing the last ten years of your wife's life in such a clear way and emphasising the positive side of it and approach to cancer. 11:31

I very much noted your feeling of guilt, which is something that a lot of people feel, which is sort of

on the subject?

A. Once again, I think that -- I mean, I'm not dismissing the significance of triage. I contributed greatly to, at a regional level, emphasising at that point in time back then, let's say 10 to 13 years ago, that perhaps 12:05
consultant urologists were those people best able to undertake triage rather than considering others like junior staff, staff grades or clinical nurse specialists. I do appreciate everything that you are saying in that regard, but what I'm also saying is 12:06
I found the situation whereby, as urologist of the week, if you started a ward round at nine o'clock, if you had 32 patients in a ward, if you actually had to go and see 10 outliers during the course of which you had to deal with referrals of an acute nature from two 12:06
other hospitals in your geographical area, and take five cases to theatre and leave at two o'clock in the morning in order to get some sleep. Now, the alternative is that you defer the surgeries in order to do that meaningful triage. I appreciate everything 12:07
you're saying. Or you don't do the ward round, or you don't go to theatre. And that's how it was done and I didn't believe to be right. I wasn't the only one who felt that was not the raison d'être, the whole purpose of being urologist of the week. The whole 12:07
purpose of being urologist was to try to ameliorate, to try to mitigate the risks that Catherine Hunter described. It was not -- it was unfortunate. I agreed to it actively to include triage as urologist of the

week in order to get urologist of the week across the line, because at least it was a better option than doing a clinic because the clinic is at a fixed time whereas, whereas at least you could triage at two o'clock in the morning. 12:08

So, I do appreciate the perspective that has been formed. As an individual I have worked very, very hard and I have always had patient care at the centre, but the most important patients that you have as urologist of the week are the inpatients. They are the critically ill. You should not be sending a junior registrar to deal with those people whilst you triage. There's something fundamentally wrong about that. 12:08

So by, I think it was March, I don't have a record of the meeting when we all met and when we were informed of the informal default process, and I made it very, very clear that I had found it impossible.

60 Q. I want to come to that aspect of the narrative later. 12:09
Could I ask you this just in terms of the impossibility, as you put it. There is always an opportunity, is there not, to work in a different way to bring different methods, different levels of intensity to the task at hand. Your colleagues, and 12:09
you may look unfavourably at their approach to triage, but whatever standard they brought to it, they were getting it done, they were processing the cases. As the SAI suggests, they were in many cases organising

strange and all your comments. But if you were able to just distil one or two small things that you would like the Chairman and the Chief Executive of the Hospital to know about your experience, what would they be? If you could just say, you know, we have had all this care, we had these mistakes, but I would really like you to know about this thing. What would it be? What would be the one message for them in a little private room? 11:31

A. Oh I'd really need four or five hours to think about that and answer it. No, I can honestly say there is nothing that is immediately hitting me between the eyes. And other than in a general way that, where I said I didn't want to come, and it's a matter of duty, the purpose of the Inquiry is to make things better. And I would be happy with that, that your work, while, by the end of it you may feel that you have run through the ploughed field that I mentioned earlier, is absolutely essential to society. It is essential to the proper running of Craigavon Area Hospital which is the hospital that is under the microscope here. 11:32 11:32 11:33

So if, in dealing with all of the evidence and witnesses, that I'm quite certain you will, in dealing with people like me and other witnesses, will find out what is wrong, and you will be making recommendations to the Minister, well then I think it probably would be incumbent upon people like myself and other people to make sure that the politicians accurately, not only 11:33

read the recommendations, but will act on foot of them. Because, again, just from ordinary reading of news and that, that certainly not all recommendations from Tribunals are implemented. But, and if they are not well then the whole procedure is a total waste of time and nonsense. I'm not suggesting in any shape or form, if the recommendations are not implemented. 11:34

So in answer to your question there really is not one thing. I would like that there was so whenever the report is there it would be at the top of the list and I would say, that's me. But, no -- 11:34

18 Q. DR. SWART: I think you have given it to me, the one thing is a commitment to act.

A. Yeah, yeah. 11:34

19 Q. DR. SWART: If that reflects what you have just said.

A. Absolutely.

DR. SWART: Yes, thank you.

CHAIR: Mr. Hanbury, do you have any questions for Patient 10's Husband? 11:34

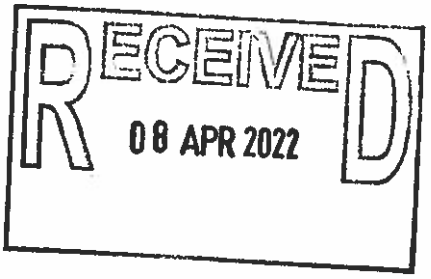
MR. HANBURY: Thank you very much, Patient 10's Husband, for your very interesting and thorough evidence which is fascinating. I have got one question which I'll come to. But we know, as urologists, how stressful a cancer diagnosis can be to the patient and family and we also know from your evidence that Patient 10 had previously cancers in her breast and colon cancer. 11:35

A. Yeah.

20 Q. MR. HANBURY: So we have already partly reached this,

Ref : Patient 18 D.O.B Personal Information redacted by USI

Personal information redacted by USI



28 March 2022

Urology Services Inquiry

1 Bradford Court

Belfast

BT6RB

With reference to your letter of 10th March 2022, I apologise for the delay in replying.

I am replying under heading (a) in your Terms of Reference. I do not have a full record of dates of my treatment but I have made a chronological list of what I experienced while in the care of Southern Health and Social Care Trust and Mr O'Brien together with the dates that I can remember.

- I was admitted to CAH in 2006 in emergency, unable to urinate with an enlarged prostate gland. I was operated on by Mr O'Brien to clear the blockage. After the operation Mr O'Brien informed me that there was "absolutely no trace of cancer".
- Some time passed and I was surprised to receive, out of the blue, an appointment for the Urology Department in CAH. I was examined in the presence of Mr O'Brien and biopsies were advised. I was later told that the biopsy results indicated that I had prostate cancer.
- I received an appointment with Mr O' Brien and he prescribed Bicalutamide and Tamoxifen and I was told on this occasion by Mr O'Brien that I would be receiving radiation treatment.
- After a further duration of time had passed, I was reviewed once more in an appointment with Mr O'Brien. I was told on this occasion that I would not be receiving radiotherapy. The reason provided for this decision by Mr O'Brien was that because of my age I would find it too tiring to travel to BCH daily for 7 weeks. I was shocked by the news and said nothing.
- Over this review period with MrO'Brien, I found it difficult to get an appointment with him and this added to the anxiety and stress that I was experiencing in dealing with my diagnosis. We explained this to him at one of the appointments and he gave us his personal card for private treatment. We accepted the card but did not choose to follow this option.
- After consideration and discussion with family members I wrote a letter of complaint to Mr O'Brien dated 24 May 2012. (copy attached). I appealed for radiation treatment as hormone therapy was giving me a poor quality of life – I was depressed and I could not imagine living like this for the rest of my life. I received a reply from Mr O'Brien dated 25 July 2012 (copy attached), in which he informed me that an appointment with oncology was being arranged.
- I had a further review appointment with Mr O'Brien in August 2012.
- I had my first appointment with a lady Oncologist in CAH. The lady consultant told me that I had cancer from the very outset of my prostate symptoms and not " absolutely no trace of

cancer" as indicated by Mr O'Brien right after my emergency prostate operation. Additionally, I was told by the lady consultant that it was she (oncologist) who would decide who would get radiotherapy treatment and not me, the patient. I was somewhat taken aback given the changing diagnosis and differing information that had been given to me over the course of my care. I considered that at this stage my family and I had to do our own research regarding my prostate cancer as we felt that we had been misinformed somewhat about diagnosis and also about treatment options. We were beginning to lose trust in our doctors.

- I was referred by this lady oncologist to the urology services at BCH but I was advised by her from the outset that the BCH urologist would not be taking any action with regard to surgical options and that I would be referred onwards to radiotherapy.
- I attended the appointment with a male urologist at BCH. He confirmed that surgery was not an option for my cancer as the prostate was now too "sticky" because of the hormone treatment that I had received. They referred me for radiotherapy.
- I received radiotherapy treatment from March – April 2013 at BCH.
- Subsequent to the radiotherapy that I received at BCH I developed ongoing side effects of sigmoid colitis, fatigue, ~~prostatitis~~ proctitis, chronic shin pain and double incontinence. These side effects have not improved since my radiation treatment. The combined tiredness, incontinence, ~~foot~~ shin pain and restriction of the food types that I find that I can tolerate has left me with a very much reduced quality of life. Before I was energetic; enjoying walking, holidaying abroad and gardening. Now I am restricted to being able to shop for my own groceries, driving and some light gardening as my energy levels permit. I am restricted to being close to a toilet wherever I go daily
- I am very grateful that I am still alive, however, I believe that my retirement years have been blighted by my treatment for prostate cancer. Although aware of possible side effects of radiotherapy treatment 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. I believe that this led to delayed treatment, thus restricting further options and that this resulted in a poorer treatment outcome for me in general.

Personal Information redacted by USI

Yours sincerely

Patient 18

5 Q. And then, there was a gap between 2008, August 2008 and July 2011, so you weren't contacted by anybody during that time. Do you remember that?

A. These dates are confusing.

6 Q. Sorry, don't worry about it. If you can take it from me that those are the dates that we have? 14:19

A. Yes, well they have the records. But out of the blue I was asked, whatever the date was, to come and see Mr. -- I was finding it very difficult, my wife rang his secretary to get appointments. 14:20

7 Q. So you had been trying to see him over a period of time?

A. Oh we had been trying because I knew by that time that I had cancer. And cancer grows, it waits for no one. But anyway, I was sent and Mr. O'Brien, I'm may be 14:20 taking them out of order. I had an appointment then, I went then and there was another consultant gentleman there with him who I had never seen. He examined me and he referred me to get biopsies taken, this other gentleman, Mr. O'Brien just sat there. I said right. 14:20 And a time was appointed for me and I went around and I had those done. I was sent for and approximately in a week's time to the Thorndale Centre. That's when I was told I had cancer at that time.

8 Q. So can I just be clear about what you are telling us, 14:21 is that you had your treatment on your prostate back when you went in as an emergency. You were operated on then. There was some follow-up appointments. There was then a gap?

A. A big gap.
9 Q. A big gap, and then you got a letter out of the blue telling you to come, is that right?
A. That's right.
10 Q. And between that treatment initially and the follow-up, in or around 2008 until July 2011, were you ever contacted by anyone from the Trust? 14:21
A. No.
11 Q. No?
A. No. 14:21
12 Q. So you get a letter asking you to come in and see Mr. O'Brien again; is that correct?
A. Mm-hmm.
13 Q. Okay. You go in and there's someone with him, you get biopsies and then you're brought back and you are told at that stage that you have cancer, is that right? 14:21
A. Mr. O'Brien never told me, the man that was responsible in the Thorndale Unit who previously had taken the samples.
14 Q. Yes. 14:22
A. He told me, he informed me.
15 Q. It wasn't Mr. O'Brien, it was this other gentleman?
A. This other gentleman.
16 Q. Was there any discussion about the treatment options at that point from this other gentleman? 14:22
A. No.
17 Q. And you then -- was there any conversation that you can recall about that?
A. No. My recollection was to go and see Mr. O'Brien,

55 Q. So I think, if I can just quote what you said in your letter to me, you sum it up there, that although you were aware of the possible side effects of radiotherapy treatment, you believe that due to inaccurate and disingenuous information? 14:37

A. That's it.

56 Q. That was provided to you regarding your condition, and your treatment options earlier in your treatment, you were unable to make an informed choice about your treatment? 14:37

A. Well they weren't put to me correct.

57 Q. You don't feel you were given options?

A. I wasn't given options.

58 Q. Can I -- I mean, you go on to say that you believe that that led to delayed treatment, thus restricting your 14:37 further options, and that that resulted in a poorer treatment outcome for you in general?

A. Yes.

59 Q. Which you have described to us the effects, the physical effects you are still having today? 14:37

A. Yes.

60 Q. Can I ask you, what do you feel ought to have happened?

A. At the beginning? Well, when they realised that I had cancer, I should have been sent for radiotherapy I believe. I should have been. And I'm not a Doctor, 14:38 I'm an Personal Information redacted by USI, but I know you deal with it immediately and they didn't.

61 Q. Were you given any reason as to why it wasn't being dealt with immediately?

A. No reason at all, other than Mr. O'Brien trying to put me off in his explanation, how tiring it would be, I've already quoted that. But there was no reason why I shouldn't medically have my radiotherapy.

CHAIR: Thank you, [redacted]. There's nothing that I want to ask you but I am sure my colleagues might have some things that they would like to know from you. 14:38

THE WITNESS: Thank you, mam.

DR. SWART: So thank you for that account, it is always really helpful to hear from the patient as well as read the information. 14:39

A. Well I hope it was.

DR. SWART: It does add to it for us.

62 Q. And you've said quite clearly that you had delayed treatment in your view and you couldn't make an informed choice. If you were in a room with the Chief Executive and the Chairman of the Trust? 14:39

A. I can't hear mam, sorry, I've two --

63 Q. If you were in a room with the Chairman and the Chief Executive of the Trust and you could say to them, please do this one thing to make life better for patients, what thing would that be? What would you like them to know from you personally? 14:39

A. Well, they would probably say they're short of staff and I could agree with them. But the first thing I would say to them would be, if you had a patient come in like me, detected cancer in my system, prostate, see to it that it was right in for the best treatment available and that would be radiotherapy to begin with. 14:39

36 Q. No, I am interrupting you, [redacted], you had not been forewarned about what might happen?
A. No.
37 Q. Were you told at any stage by Mr. O'Brien when you raised the radiotherapy with him, did he ever discuss with you anything along the lines about a decision by a multidisciplinary team or multidisciplinary meeting? 14:29
A. No.
38 Q. Did you ever learn anything about that?
A. No. 14:29
39 Q. And, do you feel, whenever, as you describe it, Mr. O'Brien as you felt was trying to put you off, did you feel able to challenge him?
A. Well, I respected him because of his position, what he had to do, as I do with all medical people and professional people and I respected him, what he was saying. But my brain was saying, this is not working for me. I did tell him, I can't stick this, my quality of life is poor. It was through the floor. 14:30
40 Q. Is that why, when you left that meeting, you then felt you needed to write and put it in writing? 14:30
A. Yes, because Mr. O'Brien said it to me, go home and think about it and I'll call for you, or I'll send you a letter. I went home and thought about it, spoke to family and all the rest of it. And I was more determined when I had spoken that radiotherapy was the best outlet for me and I got no letter from Mr. O'Brien. So in the heading of my letter you can see where I said that I thought Mr. O'Brien was 14:30

discussion was about your treatment at that point?
A. Yes. Well, he tried to put across to me, I'm a man of 73, I'm not running the man down, he is a lovely man, but how I was treated. He was trying to put across, it was going to be a very tiring thing because I had said I would like to get radiotherapy because I had read it up and got help from my family. It had a good 80% success rate. And you had to go to the City Hospital Cancer Unit to get it. So Mr. O'Brien was saying, it's very tiring and you'll have to travel for seven weeks, five days-a-week. 14:24 14:24

And I would recommend -- well he put forward to me this system that they were putting in operation and I think the figure he said, seven of you, seven had been picked out and we'll see you on a regular basis. And I said, I remember saying what would that regular basis be? And he said seven weeks. Now, I knew that time that I was speaking to him I should have been there 14 weeks ago. 14:25 14:25

25 Q. I think there is maybe a bit of confusion on my part, Patient 18. So from what, the papers that we have been looking at, you have an appointment with Mr. O'Brien, at that stage who raised the radiotherapy option, was that you? 14:25
A. Yes, me.
26 Q. Or was that him?
A. Yes.
27 Q. The very first time you went after your biopsies?

A. I had already read up on it and I had got help from my family, it would have been better for you daddy, and I said, right, I'll go for that.

28 Q. So when you went to see Mr. O'Brien after your diagnosis you were going to ask him about radiotherapy? 14:26

A. Yeah.

29 Q. Okay.

A. And then he done his best to put me off because, as I said, my age, the travelling.

30 Q. And he offered you an alternative treatment; is that correct? And do you recall, I mean I know that, I find it difficult to describe the drug to get the pronunciation right, bicalutamide? 14:26

MR. HANBURY: Bicalutamide.

CHAIR: Bicalutamide, thank you. 14:26

A. I think it's some hormone treatment, is that right? But anyway, I said to him at that time before we left, I mentioned the length of time that I had been, last been to see him. And my wife can't, when she rings, can't get an appointment. His secretary would say, 14:26 he's a very busy man, he's dealing the people who are dying of cancer, things like that. And I can remember saying to [redacted], well, how does he know I'm not dying of cancer. But we told him that and he produced his private card. Now we accepted it out of politeness but 14:27 I didn't do anything about that.

Then he emphasised what I've told you, how tiring it would be, and I don't know why, I've mentioned to you,

in my young day I was into athletics and the cross country, I was a fit 73-year-old, worked hard, long hours, no problem.

31 Q. You take things in your stride?

A. Yes, that's it, yeah, and thoroughly enjoyed and [Personal Information redacted by USI] and I went on good holidays and all abroad. So, this medication knocked that off for six. I was depressed, as you have my letter, if you have my letter there. 14:27

32 Q. Yes. 14:28

A. I was incontinent, double incontinent, lost good suits, no warning whatsoever. And then when it started to settle a wee bit and my diet, I had to be extra careful, and I love vegetables and all, a good meal. I can't eat green vegetables or anything. That had an awful effect on me mentally. 14:28

33 Q. The side effects of the drug that Mr. O'Brien prescribed for you, did he describe those side effects?

A. No.

34 Q. Before he gave them to you? 14:28

A. No.

35 Q. Or said you could experience X, Y or Z or anything like that?

A. No, I put it all down in my letter and his reply, if you have his letter, he realised, he said that I had explained very clearly the dire effect it was having on me, that's my language, you know, but that's what he meant, he could understand. I hadn't been warned, sorry for interrupting you. 14:28

A. None whatsoever, sir.
68 Q. Was it a high dose or a low dose, not wishing to put words into your mouth?
A. No.
69 Q. That was not explained. Okay, thank you. And after that initial consultation when the hormone treatment was started, did you receive any further communication sort of information like in leaflets or a letter from Mr. O'Brien to explain a plan? 14:41
A. No, sir. 14:42
70 Q. You weren't, we haven't been able to find that?
A. No, sir.
71 Q. So that would be -- I just have one other. Just one more, taking you back, so this is before you had the cancer diagnosis. You had your transurethral prostatectomy following your retention operation which you very elegantly described. And then Mr. O'Brien's team were following you up in out-patients and having the blood tests drawn for this prostate specific antigen or PSA. Do you recall why that, why you were being recalled at that time? 14:42 14:42
A. I wasn't recalled then. It was my own doctor, the nurses in my surgery, I had to go there to get the PSA blood sample taken. And my doctor, it was my local doctor said to me, Patient 18, you should go to the Hospital, they'll check it out to see there's no trace of cancer. The doctor said, not the hospital. No one, no consultant told me that. 14:43
72 Q. So that was your understanding that that was to check

whether there may be?
A. Yes.
73 Q. And then there was this big long gap?
A. Yes.
74 Q. And nothing? 14:43
A. That's what caused my stress increasing was the long gap. I'm not able to get appointments.
75 Q. But, again, at that time had there been a letter sent or any information to say --
A. No, nothing. 14:43
76 Q. ...perhaps your GP could have helped out?
A. No.
77 Q. With the blood tests but you didn't hear, okay.
A. No.
MR. HANBURY: That's really what I have. Thank you very much. That was very helpful. 14:44
CHAIR: Mr. Wolfe?
MR. WOLFE QC: Patient 18, when you were discussing with Mr. O'Brien back in September of 2011, just after you had had your cancer diagnosis, and clearly the decision that was reached at that meeting with Mr. O'Brien was that you would start on bicalutamide? 14:44
A. Yeah.
78 Q. Did you leave that meeting with an understanding of what bicalutamide might do for you? 14:44
A. No. Other than he said, at the very beginning, I'm glad you bring that up, he said this will bring your PSA levels down and when we get them down, then you could be available for radiotherapy.

what you said, involving seven patients?

A. He suggested that, whether he has set it up, but there was a programme where seven patients like me would be selected and I was one of them. They would see us on a regular basis regarding the effects of this hormone treatment. And I said to him, what do you mean by a regular basis, for I knew how difficult it was for me to get an appointment with him. Even after they have given me an appointment, I would get a phone call the day before the appointment to say it was put back and sometimes for another seven weeks. 14:48 14:49

91 Q. Yes.

A. So, I asked him that question.

92 Q. Yes.

A. And he said every seven weeks we'll see you. 14:49

93 Q. And was it in that context, you talked about getting a private card from him?

A. Yes, that's when I said that. He said, and Patient 18's wife could say her piece calmly, he handed me his private card. We accepted it but we didn't act on it. 14:49

94 Q. Yes. But your action in response to that sequence was to write saying I want radiotherapy?

A. Yes, it was. I talked it over with those who love me and decided that's the best option for me.

95 Q. You are aware, I think, that your care has been the subject of something called a Structured Clinical Record Review? 14:50

A. I'm aware now since it started to let me know there was.

96 Q. There is a report on the bundle in front of you, which I needn't bring you to, have you received that from the Trust as of yet or have you simply received it from this Inquiry?

A. From this Inquiry. 14:50

MR. WOLFE QC: Okay. Thank you.

CHAIR: Patient 18, thank you very much for coming along today and I'm sorry you had to get up so early when we're only seeing you at two o'clock this afternoon. 14:51

A. I am sorry.

CHAIR: You have absolutely nothing to apologise for. We are very grateful to have heard from you and for you to have taken the time and trouble to come and speak to us today, so thank you. It's very important that we do 14:51 hear from people like you.

A. Well I'm very thankful for your people and my lawyer there for all what you have done for people coming behind. Thank you.

CHAIR: Thank you. 14:51

THE WITNESS: Can I go now?

CHAIR: Yes, you can.

THE WITNESS: Cheerio. [The witness left the hearing room]

CHAIR: So, Mr. Boyle, I believe you want to say 14:51 something?

MR. BOYLE QC: Yes. Can I just raise one issue, it's just really for the benefit of your note for the moment. In your patient bundle for Patient 18, at

24th May 2012

Mr A. O'Brien F.R.C.S.

Urology Department

Craigavon Hospital

68 Lurgan Road

Portadown

BT63 5QQ



Dear Mr O'Brien

Re: Patient 18 , Personal Information redacted by USI

DOB: Personal Information redacted by USI HCN no. Personal Information redacted by USI

I am aware that you are processing a letter regarding my treatment. However, although this has not yet been received, I feel I have to state my wishes.

Until the 27th April 2012 I have been on Bicalutamide. The side effects I experienced were: fatigue, headache, dizziness, depression, loss of strength, forgetfulness, lack of appetite (resulting in unhealthy eating), weight gain.

As a result of this treatment I was only able to walk slowly for a short distance and could not do much more than sit in an arm chair. I persevered with the treatment for 7 ½ months as I was informed at my first consultation that I would be treated with radiotherapy when my PSA count came down.

At my consultation on the 27th April 2012 I was told that the referral for radiotherapy would mean travelling to Belfast City Hospital every day of the week for 7 weeks and that this was very tiring. However, it was also pointed out that that this would mean getting the tiredness over and done with. It was then suggested that I should go on to what I believe is Intermittent Hormone Therapy and quality of life was also mentioned.

Apart from the side effects mentioned above, I could potentially develop muscle loss, bone thinning, risk of heart disease and insulin - dependent diabetes. I understand that this treatment could continue but only as long as it continues to work. It can take 6-9 months or sometimes longer for the side effects to wear off. The longer you are on the treatment, the shorter the interval between treatments becomes. In these circumstances I cannot foresee quality of life with this treatment. There is also no cure.

I understand that radiotherapy is used for treating men with prostate cancer that is localised or worse and is as effective at treating this as surgery to remove the prostate. The only disadvantage mentioned on the 27th April was the tiredness. We

have an available alternative to avoid travel. I understand that there are other side effects but the percentage risk is low.

When younger I was involved in athletics and long distance running. I never smoked nor drank and prior to diagnosis I could go for a four hour hike. This agrees with Dr [Patient 18's GP redacted]'s recent tests; so I consider myself a healthy 73 year old and feel that I could cope with radiotherapy. In this case I understand that there is a long term cure rate of 80%. I would like to have radiotherapy.

Yours Sincerely

[Patient 18 redacted]

preparing a letter for me, but it hasn't arrived and then I went into my details.

41 Q. You were, you persevered with that treatment as you described it in your letter for about seven and a half months and it was some time before you got to see a cancer specialist, an oncologist, is that right? 14:31

A. Yes.

42 Q. And you did see, I think it was a Dr. Haughton; is that correct?

A. A lady in charge of it in the city, but she had a clinic, she came down in Craigavon. 14:31

43 Q. Did you at any stage from your diagnosis when you got the biopsies and you were told you had cancer, did you ever have a specialist cancer nurse assigned to you?

A. No. 14:32

44 Q. Was that ever suggested at any point by anyone?

A. No.

45 Q. And I think you have explained that in that letter, which is, just for the benefit of everybody else, it's PAT-000537. You and your family had done research into the side effects of the drug, isn't that right, and that's why you felt it wasn't for you? 14:32

A. Yeah, it wasn't for me.

46 Q. In that letter you said that you were told that, I'm just going to get the right letter, you said you were told at some point, maybe it was in your letter to me, that you could have radiotherapy when your PSA level came down? 14:32

A. Once he seen that I was determined for radiotherapy.

64 Q. So how do you think they should help you to make informed choices because you very clearly say you didn't get that?

A. You see, I don't know what authority they have in a hospital setting or -- 14:40

65 Q. Well, just assume that they had the wherewithal to change things, what would you like them to know about it from your perspective?

A. Well, I would get in touch with my consultant in the first place. 14:40

66 Q. Mm-hmm.

A. And let him know what the patient, i.e. me, has said after his diagnosis that he has prostate cancer and this gentleman is determined to have radiotherapy. He already knows from his own checking into it the likely 14:40 things that could happen from radiotherapy, but he is prepared to take that decision to have it done.

67 Q. Okay. So I think you are saying to me, please make sure you listen very carefully to the voice of the patient in those discussions? 14:41

A. Yes, you summed it up like a lady.

DR. SWART: Thank you.

CHAIR: Mr. Hanbury?

MR. HANBURY: Okay. Again, thank you very much for your evidence there. I have just one question about 14:41 your first diagnosis, appointment with Mr. O'Brien and when you started on the hormone treatment. Do you remember having the fact that there were different options or types of hormone treatment at the time?

31 Q. But that wasn't achieved during Mr. O'Brien's time?
A. That wasn't achieved, no.
32 Q. Before I move to March, further thoughts as something of an aside. In terms of the dictation of letters, a letter is dictated, or should be dictated following Outpatients or perhaps any other major milestone in the patient's care pathway, for the purposes of the General Practitioner it's directed to the General Practitioner?
A. Generally you would write to the referrer and you would copy in individuals involved in the patient's care. Generally the GP would always get a copy. If they are not the primary addressee, they'd got a copy of the letter. For instance, a patient under the care of Urology, the Oncology team, as well, they get a letter that's addressed to the Oncologist but copied to the GP.
33 Q. Just in terms of the patient, is the patient the recipient of a letter of the nature I have described, or not?
A. It's good practice that they should be. They are not always. Certainly before I came to Craigavon, in Sheffield it was standard practice that all patients were copied into GP letters. It's not a standard practice, although I do copy many of my patients into my letters but that's not standard practice across all Consultants in Northern Ireland.
34 Q. In terms of your standard practice, is there a criteria that determines whether you will write to the patient as well as the GP, or is it hit-and-miss? Is it, for

example, a major result goes to the patient or not? What influences?

A. All results I write directly to the patient and copy to the GP in my practice. From clinic consultation, then I generally copy in a large proportion but not necessarily all. I couldn't give you a clear, this is why I don't copy patient X in, but I copy in a large proportion.

35 Q. This is an area the Inquiry's interested in and they may have some questions for you beyond what I have. Just in the Northern Ireland context, it's not, to the best of your understanding, standard across your colleagues to copy patients in?

A. Not in the same way as it was just across the board when I worked in Sheffield, that every patient got copied into GP correspondence.

36 Q. Do you know whether that's because of a different culture, is it because of a different rule or guideline, or is it something you just don't know?

A. I don't know. I suspect it's culture rather than a guidance, but that would be a suspicion.

37 Q. Thank you. Could I go to WIT-55773, please. The bottom of the page, please. A Higher Clerical Officer in the Red Flag Appointments office writes on 29th March saying:

"There are 24 referrals from 22nd March needing triage for Urology on the ECR, can you escalate please?"

Craigavon, I noticed from Mr. O'Brien's side the lack of dictation.

44 Q. I think you spoke to us on the last occasion about that first week. I think you were covering a theatre list --

A. Yes.

45 Q. -- for Mr. O'Brien and when you went to the chart you realised there were no letters. Your language "no letters in the charts" and it took a long while for you to work out why the patient was on the list. Just coming back to your own practice. To whom would you direct letters following a clinic?

A. So, if it's a clinic letter I direct it to the GP. If it's results I direct it to the patient and copy to the GP. When I was in England I copied letters to the GP -- to the patient, but since I've come here, I haven't been doing that.

46 Q. There's some interest on the part of the Inquiry in terms of communication with the patient. What was the thinking in England in relation to writing to the patient, and why is it different here, do you think?

A. Well, I think in England it was that the patient would know what is happening. You obviously have to write a different kind of letter if you are writing to the patient and the GP. You have to dumb it down a little bit. I think Roger Kirby said a couple of weeks ago that he actually enjoyed doing letters to patients. It just wasn't done here, so that's why I didn't do it here. But it is not something -- I wouldn't be adverse

to doing.

47 Q. Mr. Young spoke yesterday about perhaps an increasing trend in Northern Ireland or a movement towards writing to patients. Do you think there's merit in that and has it caught on with you yet? 10:48

A. As I said, I write to the patient with results but I haven't yet done clinical letters.

48 Q. Would there be merit in doing that do you think or do you see merit in it?

A. It is, because patients may not always pick up what you're saying in clinic because there's a lot of information overload. So when they go home, if they get a copy of the letter, it sort of certainly informs them and lets them know what's happening in case they didn't pick it up in clinic. 10:48

49 Q. Back to Mr. O'Brien's practice and what you noted and what others noted. Could I draw your attention to Mr. Haynes' evidence. He has commented, and I don't need to bring it up on the screen, TRA-00867. He remembers that when the service moved up to six clinicians, when you started you would have tried to work as a team and yourself and Mr. Haynes seeing some patients who Mr. O'Brien had seen previously and you both raise a concern. He said, along with Mr. Glackin and Mr. Young, when you were doing that, when you were doing Mr. O'Brien's patients because you didn't have any documentation about the decision making that had gone on before. 10:49 10:49

I think delegation is the singular most important aspect of that. And, you know, I mean people can have their criticisms of my way of working and, you know, I'm not so sure, and I go back to the inadequacy of the service once again, I'm not so sure that all of the modern more efficient ways are necessarily an improvement to the patient experience. There is too much one way conversations prevalent now. 12:22

I have listened to the Inquiry, and I gather from Dr. Swart and others that it has been mandatory for some years to send a copy of the letter addressed to the GP to the patient. Now, I mean, you know, patients are approaching me asking me if I could explain what this letter means. But it's very efficient and patients are really, they're hardly service users, they're passive service recipients, because the modern efficient service has them less well-informed, less well-understanding than ever. So, that's my cautionary note about, and comments that I would make about any criticisms of me with regard to adopting more modern efficient services. 12:23 12:23

I've even actually had one or two patients approach me receiving copies of letters addressed to the GP telling the GP about findings of investigations and the intent to have the patients admitted for something, even invasively, under general anaesthesia, without the patient understanding what has been found or what 12:24

they're going in for. Efficient? That's the way it is right now. Is that good? I don't think so.

66 Q. Part of your explanation for being unable to meet the standard expected of you by the Trust, for example, in triage, not dealing with all or a significant number of the urgent referrals and the routine referrals, part of your explanation for that is "My focus had to be on the patient during Urologist of the Week and on the red flags that were coming in, and that was just the simple reality", you would argue, "of the environment in which I worked, with all of the pressures that came with that." But in that environment, no doubt you were reckoning all of the time: What can I do with the resources and time available to me? Is that fair? 12:24 12:25

A. That's fair, yeah. 12:25

67 Q. And part of that reckoning should have involved: How can I work most efficiently with the cards that I have at my disposal? So, part of that reckoning was "Well, I can't do urgent and routine", and you asked the Inquiry to understand the context for that. But equally on the other side you are delivering what some might regard as an excessively high standard of service to patients by, for example, contacting them directly when a scheduler could have assisted you with that, or a secretary could have assisted you with that. Was the balance -- I suppose the question that comes to this is: Was the balance tilted too far on occasions? 12:26 12:26

A. It is possibly the case. I mean I am not opaque or resistant to criticism, and constructive criticism, but

General Medical Council

Professional standards

In effect: 12 March 2012

Leadership and management



Summary

This guidance explores your role in management and leadership. It covers your responsibilities relating to

- employment issues
- teaching and training
- planning, using and managing resources
- helping to develop and improve services.

Following this guidance will help you work better with your colleagues and help to improve the service you provide to your patients. helping to develop and improve services.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Leadership and management

Professional standards: More detailed guidance

This guidance came into effect 12 March 2012.

This guidance was last updated on 13 December 2024.

You can find the latest version of all our professional standards at www.gmc-uk.org/guidance.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Contents

Leadership and management 1
About our Leadership and management guidance 3
How this guidance applies to you 4
Duties of a medical professional in the workplace 4
Working with colleagues 5
Leadership 5
Respect for colleagues 5
Communication within and between teams 6
Responsibility and accountability 6
Maintaining and improving standards of care 8
Reflecting on your practice 8
Ensuring high standards of care 8
Performance review and revalidation 9
Keeping up to date 10
Information governance 10
Employment 11
Recruitment, rewards and compensation 11
Induction and mentoring 11
Supervision 12
Teaching and training 13
Grievance, performance and health 14
Writing references 15
Planning, using and managing resources 15
All medical professionals 15
Allocating resources 16
Honesty, integrity and conflicts of interest 17
Endnotes 18

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

About our Leadership and management guidance

Being a good medical professional means more than simply being a good clinician. In their day-to-day role all members of the healthcare team can provide leadership to their colleagues and vision for the organisations in which they work and for their profession as a whole. However, unless medical professionals are willing to contribute to improving the quality of services and to speak up when things are wrong, patient care is likely to suffer.

This guidance, which forms part of the professional standards, sets out the wider management and leadership responsibilities of doctors, physician associates and anaesthesia associates (collectively referred to as 'medical professionals') in the workplace, including:

- responsibilities relating to employment issues
- teaching and training
- planning, using and managing resources
- raising and acting on concerns
- helping to develop and improve services.

The principles in this guidance apply to all medical professionals whether they work directly with patients or have a formal management role.[1]

The standards of good practice apply to doctors, physician associates and anaesthesia associates (collectively referred to as medical professionals and whom we address directly as 'you' throughout the guidance). As with all our professional standards, this guidance applies to all our registrants to the extent it is relevant to the individual's practice.

How these principles will apply in practical terms depends on an individual's role and responsibility. For example, how a professional working under supervision will show leadership or take responsibility for managing resources will be different from a professional working in a more autonomous or senior role.

You continue to have responsibility for the safety and wellbeing of patients when you perform non-clinical duties, including when you work as a manager. You are still accountable to the General Medical Council (GMC) for your decisions and actions, even if someone without medical training could perform your role.

This guidance applies across the UK and should be interpreted in the context of the relevant national and local arrangements for the delivery of health services. It sets out:

- the duties and principles that apply to all medical professionals
- the extra responsibilities that may only apply to some medical professionals (for example, those with management or leadership responsibilities at a personal, team, organisation or policy level). This may include formal management roles, such as clinical or medical directors, or roles with responsibility for supervising and managing staff, resources and services.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

How this guidance applies to you

In this guidance, the terms 'you must' and 'you should' are used in the following ways.

- 'You must' is used for a legal or ethical duty you're expected to meet (or be able to justify why you didn't).
- 'You should' is used for duties or principles that either:
  - may not apply to you or to the situation you're currently in, or
  - you may not be able to comply with because of factors outside your control

The professional standards describe good practice, and not every departure from them will be considered serious. You must use your professional judgement to apply the standards to your day-to-day practice. If you do this, act in good faith and in the interests of patients, you will be able to explain and justify your decisions and actions. We say more about professional judgement, and how the professional standards relate to our fitness to practise processes, appraisal and revalidation, at the beginning of *Good medical practice*.

Duties of a medical professional in the workplace

1. Medical professionals make an important contribution to the management and leadership of health services and the delivery of healthcare across the UK as part of a multidisciplinary team. All medical professionals have some responsibilities for using resources; many will also lead teams or be involved in supervising colleagues.

2. The primary duty of all medical professionals is for the care and safety of patients. Whatever your role, you must do the following.

   a. Engage with colleagues[2] to maintain and improve the safety and quality of patient care.

   b. Contribute to discussions and decisions about improving the quality of services and outcomes.

   c. Raise and act on concerns about patient safety.

   d. Demonstrate effective team working and leadership.

   e. Promote a working environment free from unfair discrimination, bullying and harassment, bearing in mind that colleagues and patients come from diverse backgrounds.

   f. Contribute to teaching and training doctors, physician associates, anaesthesia associates and other healthcare professionals, including by acting as a positive role model.

   g. Use resources efficiently for the benefit of patients and the public.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Working with colleagues

Leadership

All medical professionals

3. Most medical professionals work in multidisciplinary teams. The work of these teams is primarily focused on the needs and safety of patients. The formal leader of the team is accountable for the performance of the team, but the responsibility for identifying problems, solving them and taking the appropriate action is shared by the team as a whole.
4. You must be willing to work with other people and teams to maintain and improve performance and change systems where this is necessary for the benefit of patients.
5. You should respect the leadership and management roles of other team members, including non-medical colleagues.

Respect for colleagues

All medical professionals

6. It is essential for good and safe patient care that medical professionals work effectively with colleagues from other health and social care disciplines, both within and between teams and organisations. Whatever the composition of the teams you work in, you must respect and value each person's skills and contribution.
7. You must tackle discrimination where it arises and encourage your colleagues to do the same. You must treat your colleagues fairly and with respect. You must not bully or harass them or unfairly discriminate against them. You should challenge the behaviour of colleagues who do not meet this standard.
8. You must follow and keep up to date with your organisation's policies about employment, equality and diversity. You must get advice on these issues if you need it.

Medical professionals with extra responsibilities

9. You must actively advance equality and diversity by creating or maintaining a positive working environment free from discrimination, bullying and harassment. You must make sure that your organisation’s policies on employment and equality and diversity are up to date and reflect the law.[3]

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Communication within and between teams

10. Multidisciplinary teams can bring benefits to patient care when communication is timely and relevant, but problems can arise when communication is poor or responsibilities are unclear.

All medical professionals

11. You must make sure that you communicate relevant information clearly to:

a. colleagues in your team

b. colleagues in other services with which you work

c. patients and those close to them in a way that they can understand, including who to contact if they have questions or concerns. This is particularly important when patient care is shared between teams.

12. You should not assume that someone else in the team will pass on information needed for patient care. You should check if you are unclear about the responsibility for communicating information, including during handover, to members of the healthcare team, other services involved in providing care and patients and those close to them.

13. You should encourage team members to cooperate and communicate effectively with each other and other teams or colleagues with whom they work. If you identify problems arising from poor communication or unclear responsibilities within or between teams, you should take action to deal with them.

Medical professionals with extra responsibilities

14. You must provide necessary and timely information to those you manage so they can carry out their roles effectively. You should also pass on any relevant information to senior managers and make sure that arrangements are in place for relevant information to be passed on to the team promptly.

15. You must be satisfied that systems are in place to communicate information about patient care.

Responsibility and accountability

16. Whether you have a management role or not, your primary duty is to patients. Their care, dignity and safety must be your first concern. You also have a duty to the health of the wider community, your profession, your colleagues and the organisation in which you work.

All medical professionals

17. You should establish clearly with your employer the scope of your role and the responsibilities it involves, including non-clinical responsibilities. You should raise any issues

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

of ambiguity or uncertainty about responsibilities, including in multidisciplinary or multi-agency teams, to clarify:

a. supervision arrangements for staff and lines of accountability for the care provided to individual patients (for more information on supervision see paragraphs 60 - 62 of this guidance)

b. who should take on leadership roles or line-management responsibilities

c. where responsibility lies for the quality and standard of care provided by the team.

Medical professionals with extra responsibilities

18. If you are responsible for leading or managing a team, you must make sure that staff are clear about:

a. their individual and team roles and objectives

b. their personal and collective responsibilities for patient and public safety

c. their personal and collective responsibilities for honestly recording and discussing problems.

19. You should:

a. contribute to setting up and maintaining systems to identify and manage risks in the team's area of responsibility

b. make sure that all team members have an opportunity to contribute to discussions

c. make sure that team members understand the decisions taken and the process for putting them into practice

d. make sure that each patient's care is properly coordinated and managed.

20. You are accountable to the GMC for your own conduct and any medical advice you give. This includes while you serve as a member of a decision-making body for a health or social care organisation, such as a hospital or health board.

21. If, as a member of a board or similar body, you are concerned that a decision would put patients or the health of the wider community at risk of serious harm, you should raise the matter promptly with the chair. You must also ask for your objections to be formally recorded and you should consider taking further action in line with our guidance in *Raising and acting on concerns about patient safety* [4]

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Maintaining and improving standards of care

Reflecting on your practice

All medical professionals

22. You should regularly reflect on your own performance, your professional values and your contribution to any teams in which you work. You should ask for, and be prepared to act on, feedback from colleagues and patients, including through the outcomes of audits, appraisals and performance reviews (see paragraphs 30 - 32), and through patient complaints and comments.

Medical professionals with extra responsibilities

23. Leading by example, you should promote and encourage a culture that allows all staff to contribute and give constructive feedback on individual and team performance. You should make sure that systems are in place to achieve this.

Ensuring high standards of care

24. Early identification of problems or issues with the performance of individuals, teams or services is essential to help protect patients.

All medical professionals

25. You must take part in regular reviews and audits of the standards and performance of any team you work in, taking steps to resolve any problems.

26. You should be familiar with, and use, the clinical governance and risk management structures and processes within the organisations you work for or to which you are contracted. You must also follow the procedure where you work for reporting adverse incidents and near misses. This is because routinely identifying adverse incidents or near misses at an early stage, can allow issues to be tackled, problems to be put right and lessons to be learnt.

27. You must follow the guidance in *Good medical practice* [5] and *Raising and acting on concerns about patient safety* [4] when you have reason to believe that systems, policies, procedures or colleagues are, or may be, placing patients at risk of harm.

Medical professionals with extra responsibilities

28. If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

patient feedback. You must make sure that any such failure is dealt with quickly and effectively.

29. If you are managing or leading a team, you should make sure that systems, including auditing and benchmarking, are in place to monitor, review and improve the quality of the team's work. You must work with others to collect and share information on patient experience and outcomes. You must make sure that teams you manage are appropriately supported and developed and are clear about their objectives.

Performance review and revalidation

All medical professionals

30. You should be familiar with the individual performance review process in all the organisations in which you work.

31. You must take part in annual appraisals and you must make sure that your appraisal covers your whole practice, including any non-clinical roles.

32. If you hold a licence to practise, you must take part in revalidation.

Medical professionals with extra responsibilities

33. You must make sure that staff you manage, including colleagues in sessional and other non-training posts, have enough time to prepare for their appraisals or performance reviews and that they have the opportunity to complete them fully and on time.

34. You must be honest and objective and keep to the principles of equality and diversity when appraising or assessing colleagues' performance. This includes when assessing trainees during the Annual Review of Competence Progression (ARCP) or other equivalent process. The safety of patients and the public could be put at risk if you make false, exaggerated or incomplete comments about another professional's competence or experience.

35. You should support staff you manage to complete learning and development activities identified by appraisals or performance reviews.

36. If you appraise or assess colleagues, you should make sure that you have the appropriate knowledge and skills. You should make sure that any staff you manage who also carry out appraisals have the knowledge and skills to do so, and are given regular feedback on how they perform this role.

37. If you are responsible for designing and delivering services, you should make sure that there is an appropriate appraisal or performance review process in place and that staff understand and follow it. You should also make sure that there are ways of dealing with any problems that appraisals bring to light. If the appraisal process includes clinical academic staff, you should make sure it follows the Follett principles.[6]

38. If you are a responsible officer within a designated body, you will have extra responsibilities as set out in the relevant regulations[7] and you must take account of any guidance produced by the departments of health[8] or your organisation.

Keeping up to date

All medical professionals

39. You must keep your skills and knowledge up to date in all areas of your work, whether in a clinical or non-clinical setting.

40. You must keep up to date with, and follow, the laws and statutory codes of practice relevant to your particular responsibilities and location[9] and you should get expert advice when you need it. You must be familiar with the relevant guidelines and developments that affect your work and use them to help you with your practice.

Information governance

41. Medical professionals need accurate, up-to-date and accessible information to deliver good and safe care to patients. Patients need to understand how information about them will be collected, stored and used and how their confidentiality and privacy will be protected. Good information governance systems can help to achieve this and contribute to providing high quality and safe care. They can also provide valuable information to allow teams and services to improve the quality and safety of care they deliver. All medical professionals have a role to play in contributing to these systems.

All medical professionals

42. You must keep accurate and clear patient records following the advice in *Good medical practice*.[5] You should make sure that non-clinical records you keep, including financial records, are clear, accurate and up to date.

43. You must follow the guidance in *Confidentiality: good practice in handling patient information* on protecting information and disclosing information for patient care or secondary purposes.[10]

44. You should be familiar with, and follow, the confidentiality, data protection and record management policies and procedures where you work and know where to get advice on these issues.

Medical professionals with extra responsibilities

45. If you are responsible for managing patient records or other patient information, you must follow the specific guidance for managers on protecting information set out in *Confidentiality:*

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

good practice in handling patient information.[11]

46. You must make sure that any other records you are responsible for, including financial, management or human resources records, or records relating to complaints, are kept securely and are clear, accurate and up to date.

47. You must make sure that records you are responsible for are made, stored, transferred and disposed of in line with the data protection law and other relevant legislation.

Employment

48. If you are involved in any aspects of employing staff such as recruiting, promoting or rewarding staff, including sitting on appointment or reward committees, you must work within your professional values and your organisation's policies and procedures, and observe the principles of fairness, equality and diversity.

Recruitment, rewards and compensation

All medical professionals

49. When applying for posts, you must always be open and honest about your experience, qualifications and current employment status.

50. When applying for and accepting posts, you must follow the guidance in *Good medical practice* [5], bearing in mind how your decisions may affect patient safety.

Medical professionals with extra responsibilities

51. If you have specific responsibility for recruitment, promotion or other staff rewards or compensation, you must make sure that the process is fair and transparent, and that decisions are based on objective criteria.

52. You must make sure you have, and anyone you appoint to take part in these activities has, the skills and competence needed and the opportunity to undertake appropriate training, including in relation to equality, diversity and non-discrimination in employment matters.

Induction and mentoring

53. Understanding the systems in place and how an organisation operates helps to make sure that medical professionals can deliver safe, effective and efficient care to patients as soon as they start a new job. Induction and mentoring schemes and access to other support mechanisms are important ways of achieving this. While important for all medical professionals, this may be particularly important for those who are new to clinical practice, have trained outside the UK[12] or are taking on a role in a new area or at a higher level.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Induction

***All* medical professionals**

54. You must take part in the induction offered by your employer when you join an organisation or move into a new role. You should also contribute to the induction of colleagues when asked.

Medical professionals with extra responsibilities

55. You must make sure that any new healthcare professional you manage is offered relevant induction and that induction policies and procedures contain information that is relevant, accessible and proportionate to their role and length of employment within your organisation.

Mentoring

All medical professionals

56. You should be willing to take part in a mentoring scheme offered by your employer.

Medical professionals with extra responsibilities

57. You should be willing to take on a mentoring role for more junior colleagues and other healthcare professionals.

58. If you have agreed to act as a mentor, you must make sure that you are competent to take on the role and that you can fulfil your responsibilities, including undertaking appropriate training and keeping your skills up to date. You must be clear about the aims and purpose of the mentoring, the scope of your role as a mentor and your availability to provide advice and support when needed.

59. You must make sure that staff who are new to an organisation or are moving into a new role have access to an appropriate mentoring arrangement[13] , where relevant, depending on the nature of their clinical practice and their responsibilities.[13]

Supervision

All medical professionals

60. You must recognise and work within the limits of your competence and you must make sure, to the best of your ability, that you are appropriately supervised for any task you perform. You must be willing to ask for advice and support from colleagues when necessary.

Medical professionals with extra responsibilities

61. You must make sure that the people you manage have appropriate supervision, whether

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

through close personal supervision (for newly qualified colleagues, or colleagues in training, for example) or through a managed system with clear reporting structures.

62. If you are responsible for supervising staff, whatever your role, you must understand the extent of your supervisory responsibilities, give clear instructions about what is expected and be available to answer questions or provide help when needed. You must support any colleagues you supervise or manage to develop their roles and responsibilities by appropriately delegating tasks and responsibilities. You must be satisfied that the staff you supervise have the necessary knowledge, skills and training to carry out their roles.

Teaching and training

All medical professionals

63. Many of the skills of being a medical professional can be learnt only by specific, on the job training in the work placements begun prior to qualification and continuing through the early post-qualification years. Every medical professional who comes into contact with students or healthcare professionals in training should act as a positive role model in their behaviour towards patients, colleagues and others.

64. If you are formally involved in teaching in the workplace - for example, teaching trainee doctors, physician associates or anaesthesia associates on placements - you must develop the skills, attitudes and practices of a competent teacher. This includes respecting cultural diversity and making reasonable adjustments for those with a disability without affecting patient safety or educational outcomes.

Medical professionals with extra responsibilities

65. If you are responsible for managing teaching and training in your organisation, you must make sure:

a. Only people with the appropriate knowledge, skills and attitudes carry out any teaching and training for which you are responsible.

b. There are enough staff members from appropriate disciplines, and with the necessary skills and experience[14], to deliver teaching and training and to support the learning and development of trainees and students.

c. Systems are in place to identify and record the educational and training needs of students, trainees and staff, including locums, so that the best use is made of the time and resources available for keeping knowledge and skills up to date.

d. An appropriate environment for training is provided, including by implementing reasonable adjustments to meet individual trainees' needs in line with the *Equality Act 2010*.[15]

e. You provide opportunities for those you manage to keep up to date and develop their

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

skills as teachers and trainers, and make sure that there are systems in place for regular feedback and appraisal of those skills.

Grievance, performance and health

Grievance

All medical professionals

66. You should understand the difference between a personal grievance, that is a complaint about your own employment situation, and a concern about a risk, malpractice or wrongdoing that affects others. This is particularly important if patients or members of the public are at risk of harm[16]. It can sometimes be difficult to separate personal grievances from a concern about patient safety. If these overlap, you should acknowledge any personal grievance that may arise from the situation, but focus on patient safety.[17] You should as far as possible make sure you use the correct procedure to make your personal grievance known or raise your concern.[18]

67. If you have a personal grievance that you cannot resolve informally, you should follow your organisations grievance procedure. If you have a concern about patient safety, you must follow the guidance in *Raising and acting on concerns about patient safety* [4]

Medical professionals with extra responsibilities

68. You should help staff you manage to identify the appropriate procedure for dealing with their personal grievance or concern about patient safety.

Performance and health

All medical professionals

69. You must make sure that your own health does not put patients at risk and you must follow the guidance in *Good medical practice* [5] in relation to your own health.

70. You should be aware that poorly performing colleagues may have health problems and respond constructively where this is the case. You should encourage such colleagues to seek and follow professional advice and offer them appropriate help and support. You must not unfairly discriminate against colleagues because of an issue related to their health or a disability.

71. You should, as far as possible, support colleagues who are experiencing performance problems.

72. But, in all cases, you should remember your duty to raise concerns where you believe a colleague may not be fit to practise or may otherwise pose a risk of serious harm to patients.[4]

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Medical professionals with extra responsibilities

73. You must promote the health and wellbeing of staff you manage.

74. You must make sure that there are clear and effective procedures for responding to concerns about colleagues' conduct, performance or health. This includes referring them to occupational health or other services, where appropriate, and making sure that staff are aware of these procedures.

75. You should be prepared to discuss constructively and sympathetically any work problems that the people you manage may have. You must deal supportively and, where possible, openly with problems in the conduct, performance or health of people you manage.[19]

76. You must make sure that people you manage have access to support for any health or performance problems they have. You must make sure that people are not unfairly discriminated against because of their health or disability.

77. You must make sure that you respond appropriately to requests for reasonable adjustments for staff with a disability or health condition in line with the Equality Act 2010.

Writing references

78. If you have been asked to or have agreed to write a reference for a colleague, you must follow the guidance in paragraph 62 of *Good medical practice*.[20]

Planning, using and managing resources

All medical professionals

79. Whatever your role or level in your organisation, whether you are a, junior, non-training grade or other doctor, physician associate or anaesthesia associate ,you should be willing to demonstrate leadership in managing and using resources effectively. This means that you should be prepared to contribute to discussions and decisions about:

a. allocating resources and setting priorities in any organisation in which you work

b. commissioning services for the wider population of patients.

80. You should have enough understanding of how finances are allocated and managed in the services in which you work to help with your role in committing resources for the benefit of patients.

81. To minimise waste, improve services and promote the effective use of resources, you should take financial responsibility for delivering your service at a level appropriate to your role. You should understand the roles and policies of local and, where relevant, regional and national agencies involved in healthcare if they affect your role as a medical professional.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Medical professionals with extra responsibilities

82. If you are responsible for managing resources, or commissioning or delivering health services, you should have detailed knowledge of how management processes work and how they affect the delivery of patient care.

83. You must make sure that you are competent and have the necessary training or advice for any financial responsibilities that are part of your role. You must make sure that those you manage have the necessary skills and advice to fulfil their roles.

Allocating resources

84. All medical professionals must make the care of patients their first concern. However, the treatment options that can be offered to patients may be affected by limits on resources.

All medical professionals

85. If you make decisions about access to treatments on a case by case basis, without referring to agreed policy or guidelines, you risk introducing elements of unfair discrimination or may fail to consider properly the patient's other legal rights. When making decisions about using resources, you must do the following.

1. Provide the best service possible within the resources available, taking account of your responsibilities towards your patients and the wider population.
2. Be familiar with any local and national policies that set out agreed criteria for access to a particular treatment.[21]
3. Make sure that decisions about setting priorities that affect patients are fair and based on clinical need and the likely effectiveness of treatments, and are not based on factors that may introduce discriminatory access to care.[22]
4. Be open and honest with patients[23] and the rest of the healthcare team about the decision-making process and the criteria for setting priorities in individual cases.

86. You should involve colleagues, including other healthcare professionals, in discussions about how to allocate wider resources. If issues or disputes about allocating resources arise, you should try to sort them out by discussing options with, for example, patients, the healthcare team, other colleagues (including other health and social care professionals) and managers. You should be open and honest with patients when resource constraints may affect the treatment options available.[24]

Medical professionals with extra responsibilities

87. If you have a management role or responsibility, you will often have to make judgements about competing demands on available resources. When making these decisions, you must

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

consider your primary duty for the care and safety of patients. You must take account of any local and national policies that set out agreed criteria for access to particular treatments and allocating resources, and make sure that these policies are available to clinical staff.

88. If you are concerned about how management decisions might conflict with your primary duty to patients, you must take steps to manage or deal with any conflict; for example, by:

a. asking for colleagues' advice

b. declaring the conflict to your board or other decision-making body

c. asking for advice from external professional or regulatory bodies, including defence organisations, if necessary.

Honesty, integrity and conflicts of interest

All medical professionals

89. If you have financial or other personal interests in organisations providing health or social care, or in products used in health or social care, you must follow the advice in *Identifying and managing conflicts of interest* [25] and in *Good medical practice* [5]

Medical professionals with extra responsibilities

90. If you are responsible for managing and allocating funds or resources, you must make sure that they are used for the purposes they were intended for and are clearly and properly accounted for. You should also make sure that appropriate professional services, including audits, are commissioned when necessary.

91. You should make sure there are adequate systems in place to monitor financial and management information. You and those you manage should make full use of these systems, including when awarding contracts and managing waiting lists and service plans.

92. You must make sure that there are appropriate systems in place to make sure that actual or perceived conflicts of interests are managed in an open way, and in line with the guidance in *Identifying and managing conflicts of interest* [25] and *Good medical practice.*[5]

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Endnotes

1. Although these principles are relevant to all medical professionals, whatever roles they have, the judgment in Remedy UK Ltd, R (on the application of Remedy UK Ltd) v General Medical Council [2010] EWHC 1245 (Admin) found that there are some roles that are so far removed from practising medicine that the GMC's fitness to practise procedures do not apply to them. However, medical professionals are still accountable to the GMC when they are performing a wide range of clinical management roles (for example, as a clinical or medical director) or other non-clinical roles (for example, as a medical educator or researcher), even if medical knowledge or expertise is not needed for the roles (for example, as a chief executive of a hospital).
2. Those you work with, including managers of services, whatever their role.
3. For example, you must make sure policies accurately reflect employment and related legislation, including the Equality Act 2010. If you are working in Northern Ireland, see The Gaps between GB and NI Equality Law (pdf) (January 2011), which sets out the differences between the legislative framework and protections in Northern Ireland.
4. General Medical Council (2012) *Raising and acting on concerns about patient safety* London, GMC
5. General Medical Council (2024) *Good medical practice* London, GMC.
6. Follett B, Paulson-Ellis M (2001) A review of appraisal, disciplinary and reporting arrangements for senior NHS and university staff with academic and clinical duties London, Department for Education and Skills.
7. Medical Profession (Responsible Officers) Regulations 2010 (which cover England, Wales and Scotland) or the Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010.
8. Department of Health (England 2010) The Role of the Responsible Officer - Closing the gap in Medical Regulation - Responsible Officer Guidance (pdf), Department of Health. Department of Health, Social Services and Public Safety (2011) Confidence in care: Guidance on the role of responsible officers for doctors and employers (pdf) Belfast, Department of Health, Social Services and Public Safety. At the time of printing, no additional guidance had been published by the departments of health in Scotland and Wales.
9. For example, you must be familiar with the Equality Act 2010, data protection law and relevant employment legislation.
10. General Medical Council (2017) *Confidentiality: good practice in handling patient information* London, GMC.
11. General Medical Council (2017) *Confidentiality: good practice in handling patient information* London, GMC, paragraphs 128 - 130 (Records management and retention).
12. Slowther A et al (2009) Non UK qualified doctors and Good Medical Practice: the experience of working within a different professional framework University of Warwick.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

13. The Standing Committee on Postgraduate Medical and Dental Education (1998) Supporting doctors and dentists at work: an inquiry into mentoring London, SCOPME, described mentoring as: 'The process whereby an experienced, highly regarded, empathic person (the mentor), guides another individual (the mentee) in the development and re-examination of their own ideas, learning, and personal and professional development. The mentor who often, but not necessarily, works in the same organisation or field as the mentee, achieves this by listening and talking in confidence to the mentee.'

14. GP trainers are required to be approved under section 34I(1) of the Medical Act 1983

15. General Medical Council (2011) Gateways to the professions: advising medical schools: encouraging disabled students London, General Medical Council.

16. A more detailed discussion on the difference between a personal grievance and raising a concern can be found in Speak up for a healthy NHS, produced by Protect.

17. For further information see *Raising and acting on concerns about patient safety*.

18. For further information see the Protect website.

19. General Medical Council (2017) *Confidentiality: good practice in handling patient information* London, GMC.

20. General Medical Council (2024) *Good medical practice* London, GMC, paragraph 62.

21. For example, national service frameworks and National Institute for Health and Clinical Excellence (NICE) and Scottish Intercollegiate Guidelines Network (SIGN) guidelines.

22. For example, a patient's age, colour, culture, disability, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion or beliefs, sex, sexual orientation or socioeconomic status. For further information see the Equality Act 2010. If you are working in Northern Ireland, see The Gaps between GB and NI Equality Law (January 2011), which sets out the differences between the legislative framework and protections in Northern Ireland.

23. And those close to the patient where the patient lacks capacity or has asked you to communicate with a family member, carer or friend.

24. General Medical Council (2020) *Decision making and consent* London, GMC, paragraph 13.

25. General Medical Council (2024) *Identifying and managing conflicts of interest* London, GMC.

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf

Email: **gmc@gmc-uk.org**
Website: **gmc-uk.org**
Telephone: **0161 923 6602**

General Medical Council, 3 Hardman Street, Manchester M3 3AW

Textphone: **please dial the prefix 18001** then **0161 923 6602** to use the Text Relay service.

Join the conversation

@gmcuk **facebook.com/gmcuk**
linkd.in/gmcuk **youtube.com/gmcuktv**

To ask for this publication in another format or language, please call us on **0161 923 6602** or email us at **gmc@gmc-uk.org**.

I ofyn am y cyhoeddiad hwn mewn fformat neu iaith arall, ffoniwch ni ar **0161 923 6602** neu e-bostiwch ni ar **gmc@gmc-uk.org**.

You are welcome to contact us in Welsh. We will respond in Welsh, without this causing additional delay.

Mae croeso i chi gysylltu â ni yn Gymraeg. Byddwn yn ymateb yn Gymraeg, heb i hyn achosi oedi ychwanegol.

© 2012 General Medical Council

The text of this document may be reproduced free of charge in any format or medium providing it is reproduced accurately and not in a misleading context. The material must be acknowledged as General Medical Council copyright and the document title specified.

The General Medical Council is a charity registered in England and Wales (1089278) and Scotland (SC037750).

Code: GMC/LMAD/1224

Source: https://www.gmc-uk.org/-/media/documents/leadership-and-management-for-all-doctors---english-48903400.pdf



January 2024

Good medical practice

General Medical Council

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

The duties of a doctor registered with the GMC

Patients must be able to trust doctors with their lives and health. To justify that trust you must show respect for human life and make sure your practice meets the standards expected of you in four domains.

Knowledge, skills and performance

- Make the care of your patient your first concern.
- Provide a good standard of practice and care.
  - Keep your professional knowledge and skills up to date.
  - Recognise and work within the limits of your competence.

Safety and quality

- Take prompt action if you think that patient safety, dignity or comfort is being compromised.
- Protect and promote the health of patients and the public.

Communication, partnership and teamwork

- Treat patients as individuals and respect their dignity.
  - Treat patients politely and considerately.
  - Respect patients' right to confidentiality.
- Work in partnership with patients.
  - Listen to, and respond to, their concerns and preferences.
  - Give patients the information they want or need in a way they can understand.
  - Respect patients' right to reach decisions with you about their treatment and care.
  - Support patients in caring for themselves to improve and maintain their health.
- Work with colleagues in the ways that best serve patients' interests.

Maintaining trust

- Be honest and open and act with integrity.
- Never discriminate unfairly against patients or colleagues.
- Never abuse your patients' trust in you or the public's trust in the profession.

You are personally accountable for your professional practice and must always be prepared to justify your decisions and actions.

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Good medical practice

This guidance has been edited for plain English.

Published 25 March 2013
Comes into effect 22 April 2013.

This guidance was updated on 29 April 2014 to include paragraph 14.1 on doctors' knowledge of the English language. It was further updated on 29 April 2019 to remove the sub-heading 'honesty' from immediately before paragraph 65.

You can find the latest version of this guidance on our website at **www.gmc-uk.org/guidance**.

For the full website addresses of references in this guidance, please see the online version on our website.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Contents

	Page
About this guidance	**3**
Professionalism in action	**4**
Develop and maintain your professional performance	6
Domain 1: Knowledge, skills and performance	**6**
Apply knowledge and experience to practice	7
Record your work clearly, accurately and legibly	9
Contribute to and comply with systems to protect patients	10
Domain 2: Safety and quality	**10**
Respond to risks to safety	11
Protect patients and colleagues from any risk posed by your health	12
Communicate effectively	13
Domain 3: Communication, partnership and teamwork	**13**
Work collaboratively with colleagues to maintain or improve patient care	14
Teaching, training, supporting and assessing	14
Continuity and coordination of care	15
Establish and maintain partnerships with patients	16
Show respect for patients	**18**
Domain 4: Maintaining trust	**18**
Treat patients and colleagues fairly and without discrimination	19
Act with honesty and integrity	21
Endnotes	**25**
Index	**28**

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

About this guidance

Good medical practice includes references to explanatory guidance. A complete list of explanatory guidance is at the end of the booklet.

All our guidance is available on our website, along with:

- learning materials, including interactive case studies which bring to life the principles in the guidance and show how they might apply in practice
- cases heard by medical practitioners tribunals, which provide examples of where a failure to follow the guidance has put a doctor's registration at risk.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Professionalism in action

1 Patients need good doctors. Good doctors make the care of their patients their first concern: they are competent, keep their knowledge and skills up to date, establish and maintain good relationships with patients and colleagues,[1] are honest and trustworthy, and act with integrity and within the law.

2 Good doctors work in partnership with patients and respect their rights to privacy and dignity. They treat each patient as an individual. They do their best to make sure all patients receive good care and treatment that will support them to live as well as possible, whatever their illness or disability.

3 *Good medical practice* describes what is expected of all doctors registered with the General Medical Council (GMC). It is your responsibility to be familiar with *Good medical practice* and the explanatory guidance[2] which supports it, and to follow the guidance they contain.

4 You must use your judgement in applying the principles to the various situations you will face as a doctor, whether or not you hold a licence to practise, whatever field of medicine you work in, and whether or not you routinely see patients. You must be prepared to explain and justify your decisions and actions.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

5 In *Good medical practice*, we use the terms 'you must' and 'you should' in the following ways.

- 'You must' is used for an overriding duty or principle.
- 'You should' is used when we are providing an explanation of how you will meet the overriding duty.
- 'You should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your control that affect whether or how you can follow the guidance.

6 To maintain your licence to practise, you must demonstrate, through the revalidation process, that you work in line with the principles and values set out in this guidance. Only serious or persistent failure to follow our guidance that poses a risk to patient safety or public trust in doctors will put your registration at risk.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Domain 1: Knowledge, skills and performance

Develop and maintain your professional performance

7 You must be competent in all aspects of your work, including management, research and teaching.[3, 4, 5]

8 You must keep your professional knowledge and skills up to date.

9 You must regularly take part in activities that maintain and develop your competence and performance.[6]

10 You should be willing to find and take part in structured support opportunities offered by your employer or contracting body (for example, mentoring). You should do this when you join an organisation and whenever your role changes significantly throughout your career.

11 You must be familiar with guidelines and developments that affect your work.

12 You must keep up to date with, and follow, the law, our guidance and other regulations relevant to your work.

13 You must take steps to monitor and improve the quality of your work.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Apply knowledge and experience to practice

14 You must recognise and work within the limits of your competence.

14.1 You must have the necessary knowledge of the English language to provide a good standard of practice and care in the UK.[7]

15 You must provide a good standard of practice and care. If you assess, diagnose or treat patients, you must:

a adequately assess the patient's conditions, taking account of their history (including the symptoms and psychological, spiritual, social and cultural factors), their views and values; where necessary, examine the patient

b promptly provide or arrange suitable advice, investigations or treatment where necessary

c refer a patient to another practitioner when this serves the patient's needs.[8]

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

16 In providing clinical care you must:

- **a** prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs[9]
- **b** provide effective treatments based on the best available evidence
- **c** take all possible steps to alleviate pain and distress whether or not a cure may be possible[10]
- **d** consult colleagues where appropriate
- **e** respect the patient's right to seek a second opinion
- **f** check that the care or treatment you provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications
- **g** wherever possible, avoid providing medical care to yourself or anyone with whom you have a close personal relationship.[9]

17 You must be satisfied that you have consent or other valid authority before you carry out any examination or investigation, provide treatment or involve patients or volunteers in teaching or research.[4, 11, 12]

18 You must make good use of the resources available to you.[3]

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Record your work clearly, accurately and legibly

19 Documents you make (including clinical records) to formally record your work must be clear, accurate and legible. You should make records at the same time as the events you are recording or as soon as possible afterwards.

20 You must keep records that contain personal information about patients, colleagues or others securely, and in line with any data protection law requirements.[14]

21 Clinical records should include:

- **a** relevant clinical findings
- **b** the decisions made and actions agreed, and who is making the decisions and agreeing the actions
- **c** the information given to patients
- **d** any drugs prescribed or other investigation or treatment
- **e** who is making the record and when.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Domain 2: Safety and quality

Contribute to and comply with systems to protect patients

22 You must take part in systems of quality assurance and quality improvement to promote patient safety. This includes:

a taking part in regular reviews and audits of your work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary

b regularly reflecting on your standards of practice and the care you provide

c reviewing patient feedback where it is available.

23 To help keep patients safe you must:

a contribute to confidential inquiries

b contribute to adverse event recognition

c report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk

d report suspected adverse drug reactions

e respond to requests from organisations monitoring public health.

When providing information for these purposes you should still respect patients' confidentiality.[14]

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Respond to risks to safety

24 You must promote and encourage a culture that allows all staff to raise concerns openly and safely.[3, 15]

25 You must take prompt action if you think that patient safety, dignity or comfort is or may be seriously compromised.

a If a patient is not receiving basic care to meet their needs, you must immediately tell someone who is in a position to act straight away.

b If patients are at risk because of inadequate premises, equipment[13] or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance[15] and your workplace policy. You should also make a record of the steps you have taken.

c If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague, your defence body or us. If you are still concerned you must report this, in line with our guidance and your workplace policy, and make a record of the steps you have taken.[14, 16]

26 You must offer help if emergencies arise in clinical settings or in the community, taking account of your own safety, your competence and the availability of other options for care.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

27 Whether or not you have vulnerable[17] adults or children and young people as patients, you should consider their needs and welfare and offer them help if you think their rights have been abused or denied.[18, 19]

Risks posed by your health

28 If you know or suspect that you have a serious condition that you could pass on to patients, or if your judgement or performance could be affected by a condition or its treatment, you must consult a suitably qualified colleague. You must follow their advice about any changes to your practice they consider necessary. You must not rely on your own assessment of the risk to patients.

29 You should be immunised against common serious communicable diseases (unless otherwise contraindicated).

30 You should be registered with a general practitioner outside your family.

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Domain 3: Communication, partnership and teamwork

Communicate effectively

31 You must listen to patients, take account of their views, and respond honestly to their questions.

32 You must give patients[20] the information they want or need to know in a way they can understand. You should make sure that arrangements are made, wherever possible, to meet patients' language and communication needs.[21]

33 You must be considerate to those close to the patient and be sensitive and responsive in giving them information and support.

34 When you are on duty you must be readily accessible to patients and colleagues seeking information, advice or support.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Working collaboratively with colleagues

35 You must work collaboratively with colleagues, respecting their skills and contributions.[3]

36 You must treat colleagues fairly and with respect.

37 You must be aware of how your behaviour may influence others within and outside the team.

38 Patient safety may be affected if there is not enough medical cover. So you must take up any post you have formally accepted, and work your contractual notice period before leaving a job, unless the employer has reasonable time to make other arrangements.

Teaching, training, supporting and assessing

39 You should be prepared to contribute to teaching and training doctors and students.

40 You must make sure that all staff you manage have appropriate supervision.

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

41 You must be honest and objective when writing references, and when appraising or assessing the performance of colleagues, including locums and students. References must include all information relevant to your colleagues' competence, performance and conduct.[22]

42 You should be willing to take on a mentoring role for more junior doctors and other healthcare professionals.[3]

43 You must support colleagues who have problems with their performance or health. But you must put patient safety first at all times.[3]

Continuity and coordination of care

44 You must contribute to the safe transfer of patients between healthcare providers and between health and social care providers. This means you must:

a share all relevant information with colleagues involved in your patients' care within and outside the team, including when you hand over care as you go off duty, and when you delegate care or refer patients to other health or social care providers[8, 14]

b check, where practical, that a named clinician or team has taken over responsibility when your role in providing a patient's care has ended. This may be particularly important for patients with impaired capacity or who are vulnerable for other reasons.

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

45 When you do not provide your patients' care yourself, for example when you are off duty, or you delegate the care of a patient to a colleague, you must be satisfied that the person providing care has the appropriate qualifications, skills and experience to provide safe care for the patient.[8]

Establish and maintain partnerships with patients

46 You must be polite and considerate.

47 You must treat patients as individuals and respect their dignity and privacy.[16]

48 You must treat patients fairly and with respect whatever their life choices and beliefs.

49 You must work in partnership with patients, sharing with them the information they will need to make decisions about their care,[21] including:

- **a** their condition, its likely progression and the options for treatment, including associated risks and uncertainties
- **b** the progress of their care, and your role and responsibilities in the team
- **c** who is responsible for each aspect of patient care, and how information is shared within teams and among those who will be providing their care

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

d any other information patients need if they are asked to agree to be involved in teaching or research.[12]

50 You must treat information about patients as confidential. This includes after a patient has died.[14]

51 You must support patients in caring for themselves to empower them to improve and maintain their health. This may, for example, include:

a advising patients on the effects of their life choices and lifestyle on their health and well-being

b supporting patients to make lifestyle changes where appropriate.

52 You must explain to patients if you have a conscientious objection to a particular procedure. You must tell them about their right to see another doctor and make sure they have enough information to exercise that right. In providing this information you must not imply or express disapproval of the patient's lifestyle, choices or beliefs. If it is not practical for a patient to arrange to see another doctor, you must make sure that arrangements are made for another suitably qualified colleague to take over your role.[23]

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Domain 4: Maintaining trust

Show respect for patients

53 You must not use your professional position to pursue a sexual or improper emotional relationship with a patient or someone close to them.[16]

54 You must not express your personal beliefs (including political, religious and moral beliefs) to patients in ways that exploit their vulnerability or are likely to cause them distress.[23]

55 You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you should:

a put matters right (if that is possible)

b offer an apology

c explain fully and promptly what has happened and the likely short-term and long-term effects.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Treat patients and colleagues fairly and without discrimination

56 You must give priority to patients on the basis of their clinical need if these decisions are within your power. If inadequate resources, policies or systems prevent you from doing this, and patient safety, dignity or comfort may be seriously compromised, you must follow the guidance in paragraph 25b (see section *Domain 2: Safety and quality*).

57 The investigations or treatment you provide or arrange must be based on the assessment you and your patient make of their needs and priorities, and on your clinical judgement about the likely effectiveness of the treatment options. You must not refuse or delay treatment because you believe that a patient's actions or lifestyle have contributed to their condition.

58 You must not deny treatment to patients because their medical condition may put you at risk. If a patient poses a risk to your health or safety, you should take all available steps to minimise the risk before providing treatment or making other suitable alternative arrangements for providing treatment.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

59 You must not unfairly discriminate against patients or colleagues by allowing your personal views[24] to affect your professional relationships or the treatment you provide or arrange. You should challenge colleagues if their behaviour does not comply with this guidance, and follow the guidance in paragraph 25c (see section *Domain 2: Safety and quality*) if the behaviour amounts to abuse or denial of a patient's or colleague's rights.

60 You must consider and respond to the needs of disabled patients and should make reasonable adjustments[25] to your practice so they can receive care to meet their needs.

61 You must respond promptly, fully and honestly to complaints and apologise when appropriate. You must not allow a patient's complaint to adversely affect the care or treatment you provide or arrange.

62 You should end a professional relationship with a patient only when the breakdown of trust between you and the patient means you cannot provide good clinical care to the patient.[26]

63 You must make sure you have adequate insurance or indemnity cover so that your patients will not be disadvantaged if they make a claim about the clinical care you have provided in the UK.

64 If someone you have contact with in your professional role asks for your registered name and/or GMC reference number, you must give this information to them.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Act with honesty and integrity

65 You must make sure that your conduct justifies your patients' trust in you and the public's trust in the profession.

66 You must always be honest about your experience, qualifications and current role.

67 You must act with honesty and integrity when designing, organising or carrying out research, and follow national research governance guidelines and our guidance.[4]

Communicating information

68 You must be honest and trustworthy in all your communication with patients and colleagues. This means you must make clear the limits of your knowledge and make reasonable checks to make sure any information you give is accurate.

69 When communicating publicly, including speaking to or writing in the media, you must maintain patient confidentiality. You should remember when using social media that communications intended for friends or family may become more widely available.[14, 27]

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

70 When advertising your services, you must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.

71 You must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents.[22] You must make sure that any documents you write or sign are not false or misleading.

a You must take reasonable steps to check the information is correct.

b You must not deliberately leave out relevant information.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Openness and legal or disciplinary proceedings

72 You must be honest and trustworthy when giving evidence to courts or tribunals.[28] You must make sure that any evidence you give or documents you write or sign are not false or misleading.

- **a** You must take reasonable steps to check the information is correct.
- **b** You must not deliberately leave out relevant information.

73 You must cooperate with formal inquiries and complaints procedures and must offer all relevant information while following the guidance in *Confidentiality*.

74 You must make clear the limits of your competence and knowledge when giving evidence or acting as a witness.[28]

75 You must tell us without delay if, anywhere in the world:

- **a** you have accepted a caution from the police or been criticised by an official inquiry
- **b** you have been charged with or found guilty of a criminal offence
- **c** another professional body has made a finding against your registration as a result of fitness to practise procedures.[29]

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

76 If you are suspended by an organisation from a medical post, or have restrictions placed on your practice, you must, without delay, inform any other organisations you carry out medical work for and any patients you see independently.

Honesty in financial dealings

77 You must be honest in financial and commercial dealings with patients, employers, insurers and other organisations or individuals.[30]

78 You must not allow any interests you have to affect the way you prescribe for, treat, refer or commission services for patients.

79 If you are faced with a conflict of interest, you must be open about the conflict, declaring your interest formally, and you should be prepared to exclude yourself from decision making.

80 You must not ask for or accept – from patients, colleagues or others – any inducement, gift or hospitality that may affect or be seen to affect the way you prescribe for, treat or refer patients or commission services for patients. You must not offer these inducements.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Endnotes

1 Colleagues include anyone a doctor works with, whether or not they are also doctors.

2 You can find all the explanatory guidance on our website.

3 *Leadership and management for all doctors* (2012) GMC, London

4 *Good practice in research* (2010) GMC, London

5 *Developing teachers and trainers in undergraduate medical education* (2011) GMC, London

6 *Continuing professional development: guidance for all doctors* (2012) GMC, London

7 This paragraph was added on 29 April 2014. Section 35C(2)(da) of the *Medical Act 1983*, inserted by the *Medical Act 1983 (Amendment) (Knowledge of English) Order 2014*.

8 *Delegation and referral* (2013) GMC, London

9 *Good practice in prescribing and managing medicines and devices* (2013) GMC, London

10 *Treatment and care towards the end of life: good practice in decision-making* (2010), GMC, London

11 *Making and using visual and audio recordings of patients* (2011) GMC, London

12 *Consent to research* (2013) GMC, London

13 Follow the guidance in paragraph 23c if the risk arises from an adverse incident involving a medical device.

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

14 *Confidentiality: good practice in handling patient information* (2017) GMC, London

15 *Raising and acting on concerns about patient safety* (2012) GMC, London

16 Maintaining boundaries (2013) GMC, London

- *Intimate examinations and chaperones* (paragraphs 47, 25c)
- *Maintaining a professional boundary between you and your patient* (paragraph 53)
- *Sexual behaviour and your duty to report* (paragraphs 53, 25c)

17 Some patients are likely to be more vulnerable than others because of their illness, disability or frailty or because of their current circumstances, such as bereavement or redundancy. You should treat children and young people under 18 years as vulnerable. Vulnerability can be temporary or permanent.

18 *0–18 years: guidance for all doctors* (2007) GMC, London

19 *Protecting children and young people: the responsibilities of all doctors* (2012) GMC, London

20 Patients here includes those people with the legal authority to make healthcare decisions on a patient's behalf.

21 *Decision making and consent* (2020) GMC, London

22 *Writing references* (2012) GMC, London

23 *Personal beliefs and medical practice* (2013) GMC, London

Withdrawn - 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

24 This includes your views about a patient's or colleague's lifestyle, culture or their social or economic status, as well as the characteristics protected by legislation: age, disability, gender reassignment, race, marriage and civil partnership, pregnancy and maternity, religion or belief, sex and sexual orientation.

25 'Reasonable adjustments' does not only mean changes to the physical environment. It can include, for example. Being flexible about appointment time or length, and making arrangements for those with communication difficulties such as impaired hearing. For more information see the EHRC website.

26 *Ending your professional relationship with a patient* (2013) GMC, London

27 *Doctors' use of social media* (2013) GMC, London

28 *Acting as a witness in legal proceedings* (2013) GMC, London

29 *Reporting criminal and regulatory proceedings within and outside the UK* (2013) GMC, London

30 *Financial and commercial arrangements and conflicts of interest* (2013) GMC, London

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Index

A
accepting posts 38
accessibility of information 32
adverse drug reactions 23c
advertising 70
advice
  seeking 25c
  on lifestyle 51a,b
  prompt provision 15b
apology 55b, 61
assessment of patients 15a
audit 22a

B
basic care 25a
breakdown of trust 62

C
care
  basic 25a
  clinical 16a–g
  of those you are close to 16g
children 27
clinical care 16a–g
clinical judgement 57
clinical records 19, 21a–e
collaboration with colleagues 35
colleagues
  challenging colleagues whose behaviour does not comply with guidance 59
  concerns about 24, 25c, 41, 59
  consulting 16d
  discriminating against 59
  reporting concerns 24
  supporting 43
  working with 35–38
comfort of patient 25
commercial interests 77
communicable diseases 29
communication 31–52
  effective 31–34
  of information 68–71
  with public 69
community, provision of care in emergencies 26
compatibility of treatments 16f
competence 1, 7
  limits of, declaring when giving evidence 74
  maintenance 9
  working within limits 14
complaints 61
  procedures for 73
conduct 65
confidential inquiries 23a
confidentiality 20, 50, 69, 73
conflict of interest 78, 79

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

conscientious objections 52
consent 17
consideration 46
continuing professional development 9
continuity of care 44, 45
contractual notice 38
cooperation in formal inquiries and complaints procedures 73
coordination of care 44, 45
criminal offence 75b

D
data protection 20
death of patient 50
decision making by patients 49a–d
decision recording 21b
delaying treatment 57
delegation of care 44a, 45
dignity 2, 25, 47
disability, qua ity of life 2
disabled patients 60
discrimination 59
distress alleviation 16c
documentation 19
honesty and integrity in 71

E
emergencies, provision of care in 26
ending appointments 38
ending relationships with patients 62
English language, knowledge of 14.1
equipment, inadequate 25b
errors 55a–c
evidence-based care 16b
evidence, giving 74
examination of patient 15a
experience, honesty about 66

F
financial arrangements 77–80
financial interests 77
fitness to practise
of colleagues 25c
procedures 75c
form signing 71
formal inquiries 73

G
gifts 80
giving evidence in court 72
GMC guidance, familiarity with 3
guidance, keeping up to date with 12
guidelines, familiarity with 11

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

H
health, personal 28
history taking 15a
honesty 1, 55, 65–67, 68
  documentation 71
  financial arrangements 77
  information 68–71
  knowledge 68
hospitality 80

I
illness, personal 80
immunisation 29
improper relationships with patients 53
improving quality of work 13
inadequate resources 56
indemnity cover 63
inducements 80
information
  communication 68–71
  honesty and integrity 68–71
  provision 32
  sharing 44a, 49a–d
informing the GMC of criminal offences 75b
insurance 63
integrity 1, 65–80
investigations, prompt provision 15b

J
judgement in applying the guidance 4
junior doctors 42
justification of decisions and actions 4

K
keeping up to date 8, 12
knowledge 7–21
  honesty about 68
  limits 74
  up to date 1

L
language
  English 14.1
  communication needs 32
law
  acting within 1
  keeping up to date with 12
legal proceedings 72–76
licence to practise 6
lifestyle, advising patients about 51a, b
listening to patients 31
locums 41

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

M
management competence 7
media 69
medical records 19–21
mentoring 10, 42
monitoring quality of work 13
moral beliefs 54
'must', definition of 5

N
national research governance
guidelines 67

O
official enquiry 75a
omission of information 71b, 72b
openness 72–76
over-the-counter medications 16f

P
pain alleviation 16c
palliative care 16c
partnership, with patient 2, 46–52
patient assessment 15a
patient feedback 22c
patient relationships 1
ending 62
improper 53
patient safety
basic care 25a
colleagues 43
delegation 45
medical cover 38
promotion of 22a–c
provision of information 23a–d
reporting concerns 25a–c
risk posed by personal illness 28
patient transfers 44a
performance 7–21
maintenance 9
professional 7–13
personal behaviour 37, 65
personal beliefs 54
personal health 28–30
personal risk 58
personal views about patients
or colleagues 59
police caution 75a
politeness 46
political beliefs 46
premises, inadequate 25b
prescribing 16a, 78
priority 56
privacy 2, 46
professional development 7–13
professional skills, keeping up
to date 8
professionalism 1–6
public communication 69
public health monitoring 23d

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Q

qualifications, honesty about 66
quality assurance and
improvement 22a–c
quality of life 2
quality of work, improvement 13

R

record-keeping 19–21
security 20
references 41
referrals 15c
refusal of treatment 57, 58
registration, risk to 6
regulations, keeping up to date
with 12
relationships
improper 53
with colleagues 1
with patients 1, 53
relatives, patients' 33
religious beliefs 48, 52, 54
repeat prescriptions 16a
reporting concerns 24, 25c
reports, written 71
research 17, 67
resources 18
respect 16e, 36, 48, 53–55
restrictions on medical practice 76
revalidation process 6
rights of patient 52
risk
personal 58
posed by personal illness 28
to patients, reducing 23
to safety 24–27

S

safety 22–30
second opinions 16e
security of information 69
self-prescribing, patients 16f
self-care 16g
serious communicable diseases 29
sexual relationships 53
'should', definition of 5
significant event recognition and
reporting 23b
social care providers 44a, b
social media sites 69
standard of care 15
standards of practice 22b
structured support opportunities 10
students 39, 41
supervision of staff 40
suspension 76

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

T
teaching 7, 17, 39–43
teamwork 31–52
terms used in *Good medical practice* 5
training 10, 22a, 39–43
treatment
  delaying 57
  effective 16b
  personal risk and provision of 58
  prompt provision 15b
tribunals 72
trust 1, 65, 68
  breakdown 62
  maintenance of 53–80

U
use of resources 18

V
valid authority 17
views of patient 15a, 31
volunteers 70
vulnerable groups 27, 77b, 60

W
witness, acting as 74
working in partnership with patients 2
workplace policy 25b,c
writing reports 19–21, 71

Y
young people 27

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Email: **gmc@gmc-uk.org**
Website: **www.gmc-uk.org**
Telephone: **0161 923 6602**

General Medical Council, 3 Hardman Street, Manchester M3 3AW

Textphone: please dial the prefix **18001** then **0161 923 6602** to use the Text Relay service

Join the conversation

@gmcuk
facebook.com/gmcuk
linkd.in/gmcuk
youtube.com/gmcuktv

To ask for this publication in Welsh, or in another format or language, please call us on **0161 923 6602** or email us at **publications@gmc-uk.org**.

Published March 2013 | Updated November 2020
© 2020 General Medical Council

The text of this document may be reproduced free of charge in any format or medium providing it is reproduced accurately and not in a misleading context. The material must be acknowledged as GMC copyright and the document title specified.

ISBN: 978-0-901458-73-5

The GMC is a charity registered in England and Wales (1089278) and Scotland (SC037750).

Printed on 100% recycled paper.

Code: GMC/GMP/0122

General Medical Council

Withdrawn – 30 January 2024

Source: https://www.gmc-uk.org/-/media/gmc-site/ethical-guidance/archived-guidance/good-medical-practice-english-2013---2024.pdf

Good medical practice 2024

General Medical Council

Good medical practice



https://www.gmc-uk.org/-/media/documents/good-medical-practice-2024---english-102607294.pdf

Good medical practice

This guidance was published 22 August 2023.

This guidance came into effect 30 January 2024.

This guidance was last updated on 13 December 2024

You can find the latest version of all our professional standards at www.gmc-uk.org/guidance.

Contents

Good medical practice 1
About Good medical practice 4
What is *Good medical practice*? 4
How to use *Good medical practice* 4
What are the professional standards? 5
How the professional standards relate to revalidation 5
How the professional standards relate to our fitness to practise process 5
The duties of medical professionals registered with the GMC 7
Domain 1: Knowledge, skills and development 8
Introduction 8
Being competent 8
Providing good clinical care 8
Maintaining, developing and improving your performance 10
Managing resources effectively and sustainably 10
Domain 2: Patients, partnership and communication 12
Introduction 12
Treating patients fairly and respecting their rights 12
Treating patients with kindness, courtesy and respect 13
Supporting patients to make decisions about treatment and care 13
Sharing information with patients 14
Communicating with those close to a patient 15
Caring for the whole patient 15
Safeguarding children and adults who are at risk of harm 15
Helping in emergencies 16
Making sure patients who pose a risk of harm to others can access appropriate care 16
Being open if things go wrong 16
Domain 3: Colleagues, culture and safety 18
Introduction 18
Treating colleagues with kindness, courtesy and respect 18
Contributing to a positive working and training environment 19

Demonstrating leadership behaviours 20
Contributing to continuity of care 20
Delegating safely and appropriately 21
Recording your work clearly, accurately, and legibly 22
Keeping patients safe 22
Responding to safety risks 23
Managing risks posed by your health 24
Domain 4: Trust and professionalism 25
Introduction 25
Acting with honesty and integrity 25
Maintaining professional boundaries 25
Communicating as a medical professional 26
Managing conflicts of interest 27
Cooperating with legal and regulatory requirements 27
Footnotes 29

About Good medical practice

What is *Good medical practice*?

Good medical practice sets out the principles, values, and standards of professional behaviour expected of all doctors, physician associates ('PAs') and anaesthesia associates ('AAs') registered with us. We use the term 'medical professionals' to describe all our registrants who we address directly (as 'you') throughout this guidance.

We work closely with medical professionals, patients and others to develop *Good medical practice*, so it is a shared agreement of what the professional standards should be. The standards in *Good medical practice* and the more detailed guidance apply to all medical professionals to the extent that they're relevant to an individual's practice.

Good medical practice is an ethical framework, which supports medical professionals to deliver safe care to a good standard, in the interests of patients. It doesn't set standards of knowledge, skills or professional capabilities: these can be found in our education standards.

Good medical practice is divided into four domains to make it easier to navigate. Each domain is equally important in describing what good practice looks like.

How to use *Good medical practice*

It's your responsibility to be familiar with *Good medical practice* and the professional standards it contains, wherever you practise, whatever your field of medicine or practice setting.

But it isn't a set of rules. You must use your professional judgement to apply the standards in *Good medical practice* to your day-to-day practice. This means working out which of the professional standards are relevant to the specific circumstances you are facing, and using your knowledge, skills and experience to follow them in that context.

If you do this, act in good faith and in the interests of patients, you'll be able to explain and justify your decisions and actions.

We use the terms 'you must' and 'you should' in the following ways.

- ‘You must’ is used for a legal or ethical duty you’re expected to meet (or be able to justify why you didn’t).
- 'You should’ is used for duties or principles that either:
  - may not apply to you or to the situation you’re currently in, or
  - you may not be able to comply with because of factors outside your control.

What are the professional standards?

Good medical practice is our core guidance on professional standards. It’s supported by a range of more detailed guidance which expands on some of the standards set out in *Good medical practice*.

When we use the term ‘professional standards’ we mean *Good medical practice* and the more detailed guidance.

How the professional standards relate to revalidation

Revalidation supports you to reflect on and develop your practice, drives improvements in clinical governance, and gives colleagues and patients confidence that you're keeping up to date.

You[1] must continuously engage with local clinical governance systems, including participating in annual appraisal, and gathering information in line with our *guidance on supporting information for revalidation*. This will demonstrate that you’re working in line with the principles, values and standards of care, and behaviour set out in the professional standards.

How the professional standards relate to our fitness to practise process

The professional standards describe good practice, and not every departure from them will be considered serious.

When a concern is raised with us about a doctor, physician associate (‘PA’) or anaesthesia associate (‘AA’), we must assess if that individual poses any current and ongoing risk to one or more of the three parts of public protection:

- protecting, promoting and maintaining the health, safety and wellbeing of the public
- promoting and maintaining public confidence in the medical professions, and

[1] This does not apply to doctors on the medical register without a licence to practise.

- promoting and maintaining proper professional standards and conduct for members of those professions.

We do this by considering the following.

a How serious the concern is. This includes considering the extent of any departure from the professional standards expected and/or the impact of a medical professional's health condition on their ability to practise safely . It also includes taking into account any specific factors that may impact on seriousness, such as premeditated or persistent behaviour, abuse of power, and whether the behaviour or poor performance the concern relates to is an isolated incident or has been repeated.

b Any relevant context that may impact on risk, for example systems factors and interpersonal factors in the medical professional's working environment or their role and level of experience.

c How the medical professional responded to the concern, including evidence of insight and remediation.

Once we've assessed the risk, we'll need to consider if regulatory action may be required in response to the concern. You can read more about our processes and the types of action we might need to take on our fitness to practise webpages.

The duties of medical professionals registered with the GMC

Patients must be able to trust medical professionals with their lives and health. To justify that trust you must make the care of patients your first concern, and meet the standards expected of you in all four domains.

Knowledge, skills and development

- Provide a good standard of practice and care, and work within your competence.
- Keep your knowledge and skills up to date.

Patients, partnership and communication

- Respect every patient's dignity and treat them as an individual.
- Listen to patients and work in partnership with them, supporting them to make informed decisions about their care.
- Protect patients' personal information from improper disclosure.

Colleagues, culture and safety

- Work with colleagues in ways that best serve the interests of patients, being willing to lead or follow as circumstances require.
- Be willing to share your knowledge, skills and experience with colleagues, whether informally or through teaching, training, mentoring or coaching.
- Treat people with respect and help to create a working and training environment that is compassionate, supportive and fair, where everyone feels safe to ask questions, talk about errors and raise concerns.
- Act promptly if you think that patient safety or dignity may be seriously compromised.
- Take care of your own health and wellbeing needs, recognising and taking appropriate action if you may not be fit to work.

Trust and professionalism

- Act with honesty and integrity, and be open if things go wrong.
- Protect and promote the health of patients and the public.
- Never unfairly discriminate against patients or colleagues.
- Never abuse patients' trust in you or the public's trust in your profession.

Domain 1: Knowledge, skills and development

Introduction

Medical practice is a lifelong journey. Keeping pace with rapidly changing social, legal and technological developments means learning new skills while maintaining others. Sharing knowledge – gained through research and innovation, as well as experience – is fundamental to good practice.

Good medical professionals are competent, keep their knowledge and skills up to date and provide a good standard of practice and care. They strive to develop and improve their professional performance. They reflect regularly on their standards of practice and use feedback and evidence to develop personal and professional insight.

Being competent

1 You must be competent in all aspects of your work including, where applicable, formal leadership or management roles, research and teaching.

2 You must recognise and work within the limits of your competence. You must only practise under the level of supervision appropriate to your role, knowledge, skills and training, and the task you're carrying out.

3 You must keep up to date with guidelines and developments that affect your work.

4 You must follow the law, our guidance on professional standards, and other regulations relevant to your work.

5 You must have the necessary knowledge of the English language to provide a good standard of practice and care in the UK.

Providing good clinical care

6 You must provide a good standard of practice and care. If you assess, diagnose, or treat patients, you must work in partnership with them to assess their needs and priorities. The investigation or treatment you propose, provide or arrange must be based on this assessment, and on your clinical judgement about the likely effectiveness of the treatment options.

7 In providing clinical care you must:

a adequately assess a patient's condition(s), taking account of their history, including

i. symptoms

ii. relevant psychological, spiritual, social, economic, and cultural factors

iii. the patient's views, needs, and values

b carry out a physical examination where necessary

c promptly provide (or arrange) suitable advice, investigation or treatment where necessary

d propose, provide or prescribe drugs or treatment (including repeat prescriptions) only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment will meet their needs

e propose, provide or prescribe effective treatment based on the best available evidence

f follow our more detailed guidance on professional standards, *Good practice in proposing, prescribing, providing and managing medicines and devices*, if you prescribe

g consult colleagues or seek advice from your supervising clinician, where appropriate

h refer a patient to another suitably qualified practitioner when this serves their needs.

8 If relevant to your area of practice, you must follow our *Guidance for doctors who offer cosmetic interventions*.

Offering remote consultations

9 You must provide safe and effective clinical care whether face to face, or through remote consultations via telephone, video link, or other online services. If you can't provide safe care through the mode of consultation you're using, you should offer an alternative if available, or signpost to other services.

Considering research opportunities

10 Research is vital in improving our understanding of health conditions, and increasing the availability of options for effective prevention, treatment, and care. You should consider opportunities to conduct or participate in research that may benefit current and/or future

patients, and help to improve the health of the population. You should tell patients if you're aware of opportunities for them to participate in appropriate research.

Maintaining, developing and improving your performance

11 You must keep your professional knowledge and skills up to date.

12 When you join an organisation, or when your role changes significantly throughout your career, you should be willing to find and take part in structured support opportunities offered by your employer or contracting body, such as mentoring or coaching schemes.

13 You must take steps to monitor, maintain, develop, and improve your performance and the quality of your work, including taking part in systems of quality assurance and quality improvement to promote patient safety across the whole scope of your practice.

This includes:

a contributing to discussions and decisions about improving the quality of services and outcomes

b taking part in regular reviews and audits of your work, and your team's work, and responding constructively to the outcomes, taking steps to address problems, and carrying out further training where necessary

c regularly taking part in training and/or continuing professional development

d regularly reflecting on your standards of practice and the care you provide, including

i. reflecting on any constructive feedback available to you

ii. considering how your life experience, culture and beliefs influence your interactions with others and may impact on the decisions you make and the care you provide.

Managing resources effectively and sustainably

14 You must make good use of the resources available to you, and provide the best service possible, taking account of your responsibilities to patients and the wider population.

15 You should choose sustainable solutions when you're able to, provided these don't compromise care standards. You should consider supporting initiatives to reduce the environmental impact of healthcare.

Domain 2: Patients, partnership and communication

Introduction

The approach and attitude of a medical professional can have a lasting impact on a patient. Treating patients with kindness, compassion and respect can profoundly shape their experience of care.

Good medical professionals recognise that patients are individuals with diverse needs, and don't make assumptions about the options or outcomes a patient will prefer. They listen to patients and work in partnership with them. They do their best to make sure all patients receive good care and treatment that will support them to live as well as possible, whatever their illness or disability.

Treating patients fairly and respecting their rights

16 You must recognise and respect every patient's dignity and right to privacy.

17 If relevant to your practice, you must follow our more detailed guidance on *Intimate examinations and chaperones.*

18 You must recognise a patient's right to choose whether to accept your advice, and respect their right to seek a second opinion.

19 You must treat patients fairly. You must not discriminate against them or allow your personal views to affect your relationship with them, or the treatment you provide or arrange. You must not refuse or delay treatment because you believe that a patient's actions or choices contributed to their condition.

20 You must give priority to patients based on their clinical need if these decisions are within your power. If inadequate resources, policies, or systems prevent you from doing this – and patient safety or dignity may be seriously compromised as a result – you must follow the guidance in paragraph *75*.

21 If you have a conscientious objection to a particular procedure, you must make sure that the way you manage this doesn't act as a barrier to a patient's access to appropriate care to meet their needs. You must follow the guidance in paragraph 87 and our more detailed guidance on *Personal beliefs and medical practice*.

22 You must treat information about patients as confidential, including after a patient has died. You must follow our more detailed guidance on *Confidentiality: good practice in handling patient information*.

Treating patients with kindness, courtesy and respect

23 You must treat patients with kindness, courtesy and respect. This doesn't mean agreeing to every request (see paragraph 7d) or withholding relevant information that may be upsetting or unwelcome (see paragraph 28). It means:

a communicating sensitively and considerately, particularly when you're sharing potentially distressing issues about the patient's prognosis and care

b listening to patients, recognising their knowledge and experience of their health, and acknowledging their concerns

c trying not to make assumptions about what a patient will consider significant or the importance they will attach to different outcomes

d being willing to explain your reasons for the options you offer (and the options you don't) and any recommendations you make

e recognising that patients may be vulnerable, even if they don't seem it

f being alert to signs of pain or distress, and taking steps to alleviate pain and distress whether or not a cure may be possible.

Supporting patients to make decisions about treatment and care

24 All patients have the right to be involved in decisions about their treatment and care, and be supported to make informed decisions if they are able to. You must start from the presumption that all adult patients have capacity to make decisions about their treatment and care.

25 You must be satisfied that you have consent or other valid authority before examining or treating patients, or involving patients or volunteers in teaching or research. More detail about this is given in our guidance on *Decision making and consent* which you must follow.

26 You must be aware of your legal and ethical duties relating to consent and capacity. This means you must:

a be aware of the relevant law on capacity and mental health

b have regard to relevant codes of practice

c follow our guidance on *Decision making and consent.*

27 When treating patients coming to the end of their lives, you must follow our more detailed guidance on *Treatment and care towards the end of life: good practice in decision making*.

Sharing information with patients

28 The exchange of information between medical professionals and patients is central to good decision making. You must give patients the information they want or need in a way they can understand. This includes information about:

a their condition(s), likely progression, and any uncertainties about diagnosis and prognosis

b the options for treating or managing the condition(s), including the option to take no action

c the potential benefits, risks of harm, uncertainties about, and likelihood of success for each option.

29 You must listen to patients and encourage an open dialogue about their health, asking questions to allow them to express what matters to them, and responding honestly to their questions.

30 You must make sure that the information you give patients is clear, accurate and up to date, and based on the best available evidence.

31 You should check patients' understanding of the information they've been given, and do your best to make sure they have the time and support they need to make informed decisions if they are able to.

32 You must take steps to meet patients' language and communication needs, so you can support them to engage in meaningful dialogue and make informed decisions about their care. The steps you take should be proportionate to the circumstances, including the patient's needs and the seriousness of their condition(s), the urgency of the situation and the availability of resources.

33 You must consider and respond to the needs of patients with impairments or disabilities. Not all impairments and disabilities are easy to identify so you should ask patients what support they need, and offer reasonable adjustments that are proportionate to the circumstances.

34 You must treat each patient as an individual. You must not rely on assumptions about the treatment options or outcomes a patient will prefer, or the factors they will consider significant.

35 If patients are asked to agree to be involved in teaching or research, you must share any information they'll need to make a decision and you must follow the guidance in paragraph 85 and our more detailed guidance on *Good practice in research*.

36 You must be open and honest with patients about any interests you have that may affect (or could be seen to affect) the way you propose, provide or prescribe treatments, or refer patients. You must follow our more detailed guidance on *Identifying and managing conflicts of interest*.

Communicating with those close to a patient

37 You must be considerate and compassionate to those close to a patient and be sensitive and responsive in giving them support and information. You must follow our more detailed guidance on *Confidentiality: good practice in handling patient information*.

Caring for the whole patient

38 You must support patients in caring for themselves and empower them to improve and maintain their health. This may include:

a helping them to access information and support to manage their health successfully

b supporting them to make decisions that improve their health and wellbeing.

39 You should ask patients about any other care or treatment they are receiving – including over-the-counter medications – and check that any care or treatment you propose, provide or prescribe is compatible.

40 If a patient is taking multiple medications, you should discuss the importance of regular reviews to check that the medications continue to meet the patient's needs and are optimised for them. You should consider the overall impact of the patient's treatments, and whether the benefits outweigh any risk of harm.

Safeguarding children and adults who are at risk of harm

41 You must consider the needs and welfare of people (adults, children and young people) who may be vulnerable, and offer them help if you think their rights are being abused or denied. You must follow our more detailed guidance on *Protecting children and young people* and *0-18 years*.

42 You must act promptly[2] on any concerns you have about a patient – or someone close to them – who may be at risk of abuse or neglect, or is being abused or neglected.

Helping in emergencies

43 You must offer help in an emergency, taking account of your own safety, your competence, and the availability of other options for care.

Making sure patients who pose a risk of harm to others can access appropriate care

44 Patients must not be denied care because their condition puts others at risk. If a patient poses a risk to your health or safety, you should take all available steps to minimise the risk before either providing treatment yourself, or making alternative arrangements for the patient to access care to meet their needs.

Being open if things go wrong

45 You must be open and honest with patients if things go wrong. If a patient under your care has suffered harm or distress, you must follow our guidance on *Openness and honesty when things go wrong: the professional duty of candour*, and you should:

a put matters right, if possible

b apologise (apologising does not, of itself, mean that you are admitting legal liability for what's happened)

c explain fully and promptly what has happened and the likely short-term and long-term effects

d report the incident in line with your organisation's policy so it can be reviewed or investigated as appropriate – and lessons can be learnt and patients protected from harm in the future.

[2] See our ethical hub advice on Adult safeguarding which you can find at https://www.gmc-uk.org/ethical-guidance/ethical-hub/adult-safeguarding

46 You must respond promptly, fully and honestly to complaints. You must not allow a patient's complaint to adversely affect the care or treatment you provide or arrange.

47 You should only end a professional relationship with a patient when the breakdown of trust between you and the patient means you can't continue to provide good clinical care to them. You must follow our more detailed guidance on *Ending your professional relationship with a patient*.

Domain 3: Colleagues, culture and safety

Introduction

Culture is determined by the shared values and behaviours of a group of people. Everyone has the right to work and train in an environment which is fair, free from discrimination, and where they're respected and valued as an individual.

Good medical professionals communicate clearly and work effectively with colleagues in the interests of patients. They develop their self-awareness, manage their impact on others, and do what they can to help create civil and compassionate cultures where all staff can ask questions, talk about errors and raise concerns safely.

Treating colleagues with kindness, courtesy and respect

48 You must treat colleagues[3] with kindness, courtesy and respect.

49 To develop and maintain effective teamworking and interpersonal relationships you must:

- **a** listen to colleagues
- **b** communicate clearly, politely and considerately
- **c** recognise and show respect for colleagues' skills and contributions
- **d** work collaboratively with colleagues and be willing to lead or follow as the circumstances require.

50 When you are on duty you must be accessible to colleagues seeking information, advice, or support.

51 You must be compassionate towards colleagues who have problems with their performance or health. But you must put patient safety first at all times.

[3] 'Colleagues' includes anyone you work with, whether or not they are a medical professional.

Contributing to a positive working and training environment

52 You must help to create a culture that is respectful, fair, supportive, and compassionate by role modelling behaviours consistent with these values.

53 You should be aware of how your behaviour may influence others within and outside the team.

54 You should be aware of the risk of bias, and consider how your own life experience, culture and beliefs influence your interactions with others, and may impact on your decisions and actions.

55 You must show respect for, and sensitivity towards, others' life experience, cultures and beliefs.

56 You must not abuse, discriminate against, bully, or harass anyone based on their personal characteristics, or for any other reason. By 'personal characteristics' we mean someone's appearance, lifestyle, culture, their social or economic status, or any of the characteristics protected by legislation – age, disability, gender reassignment, race, marriage and civil partnership, pregnancy and maternity, religion or belief, sex and sexual orientation.

57 You must not act in a sexual way towards colleagues with the effect or purpose of causing offence, embarrassment, humiliation or distress. What we mean by acting 'in a sexual way' can include – but isn't limited to – verbal or written comments, displaying or sharing images, as well as unwelcome physical contact. You must follow our more detailed guidance on *Maintaining personal and professional boundaries*.

58 If you witness any of the behaviours described in paragraphs 56 or 57 you should act, taking account of the specific circumstances. For example, you could:

a check in and offer support to anyone targeted or affected by the behaviour, and/or let them know that you feel that the behaviour you witnessed is unacceptable

b challenge the behaviour by speaking to the person responsible – either at the time, if safe to do so, or at an appropriate time and place

c speak to a colleague and/or consider reporting the behaviour in line with your workplace policy and our more detailed guidance on *Raising and acting on concerns about patient safety*. Before you report the behaviour you witnessed, try and make sure that the person who was targeted is aware of, and supports, your intention to report it.

We recognise some people may find it harder than others to speak up[4] but everyone has a responsibility – to themselves and their colleagues – to do something to prevent these behaviours continuing and contributing to a negative, unsafe environment.

59 If you have a formal leadership or management role and you witness – or are made aware of – any of the behaviours described in paragraphs 56 or 57, you must act. You must:

a make sure such behaviours are adequately addressed

b make sure people are supported where necessary, and

c make sure concerns are dealt with promptly, being escalated where necessary.

Demonstrating leadership behaviours

60 You must follow our more detailed guidance on *Leadership and management*.

61 You must make sure that all colleagues whose work you are overseeing have appropriate supervision.

62 You must be accurate, fair and objective when writing references, and when appraising or assessing the performance of colleagues, including locums and students. You should not leave out any information relevant to your colleagues' competence, performance, and conduct.

63 You should be willing to offer professional support to colleagues, including students, for example through mentoring, coaching, teaching or training. This type of support is especially important for those new to practice in the UK, those returning from a period away from practice, and those who cannot easily access support.

64 If part of your role is helping staff access training, development and employment opportunities, you should do this fairly.

Contributing to continuity of care

65 Continuity of care is important for all patients, but especially those who may struggle to navigate their healthcare journey or advocate for themselves. Continuity is particularly

[4] See our ethical hub advice on Speaking up which you can find at https://www.gmc-uk.org/ethical-guidance/ethical-hub/speaking-up

important when care is shared between teams, between different members of the same team, or when patients are transferred between care providers.

a You must promptly share all relevant information about patients (including any reasonable adjustments and communication support preferences) with others involved in their care, within and across teams, as required.

b You must share information with patients[5] about:

i. the progress of their care

ii. who is responsible for which aspect of their care

iii. the name of the lead clinician or team with overall responsibility for their care.

c You must be confident that information necessary for ongoing care has been shared:

i. before you go off duty

ii. before you delegate care, or

iii. before you refer the patient to another health or social care provider.

d You must check, where practical, that a named clinician or team has taken over responsibility when your role in a patient's care has ended.

Delegating safely and appropriately

66 You must be confident that any person you delegate to has the necessary knowledge, skills and training to carry out the task you're delegating. You must give them clear instructions and encourage them to ask questions and seek support or supervision if they need it.

67 If a task is delegated to you by a colleague but you're not confident you have the necessary knowledge, skills or training to carry it out safely, you must prioritise patient safety and seek help, even if you've already agreed to carry out the task independently.

68 You must follow our more detailed guidance on *Delegation and referral***.**

[5] If a patient lacks capacity, information should be shared with those with legal authority to make decisions on a patient's behalf.

Recording your work clearly, accurately, and legibly

69 You must make sure that formal records of your work (including patients' records) are clear, accurate, contemporaneous[6] and legible.

70 You should take a proportionate approach to the level of detail but patients' records should usually include:

a relevant clinical findings

b drugs, investigations or treatments proposed, provided or prescribed

c the information shared with patients

d concerns or preferences expressed by the patient that might be relevant to their ongoing care, and whether these were addressed

e information about any reasonable adjustments and communication support preferences

f decisions made, actions agreed (including decisions to take no action) and when/whether decisions should be reviewed

g who is creating the record and when.

71 You must keep records that contain personal information about patients, colleagues or others securely, and in line with any data protection law requirements and you must follow our guidance on *Confidentiality: good practice in handling patient information*.

Keeping patients safe

72 You should be familiar with, and use, the clinical governance and risk management structures and processes in any organisation that you work for or are contracted to.

73 To help keep patients safe you must:

[6] Contemporaneous means making records at the same time as the events you are recording, or as soon as possible afterwards.

a contribute to confidential inquiries[7]

b contribute to adverse event recognition

c report adverse incidents involving medical devices (including software, diagnostic tests, and digital tools) that put the safety of a patient or another person at risk, or have the potential to do so

d contribute to incident reviews and/or investigations

e report suspected adverse drug reactions

f respond to requests from organisations monitoring public health.

When providing information for these purposes you must follow our guidance on *Confidentiality: good practice in handling patient information*.

74 You must take up any post you have accepted, work any shift you have agreed to, and work your contractual notice period before leaving a job, unless the employer has reasonable time to make other arrangements or your personal circumstances prevent this.

Responding to safety risks

75 You must act promptly if you think that patient safety or dignity is, or may be, seriously compromised.

a If a patient is not receiving basic care to meet their needs, you must act to make sure the patient is cared for as soon as possible, for example by asking someone who delivers basic care to attend to the patient straight away.

b If patients are at risk because of inadequate premises, equipment or other resources, policies or systems, you should first protect patients and put the matter right if that's possible. Then you must raise your concern in line with your workplace policy and our more detailed guidance on *Raising and acting on concerns about patient safety*.

c If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague, your defence body, or us. If

[7] A confidential inquiry (or enquiry) is a method of investigating adverse events without attributing blame. Examples include NCEPOD - National Confidential Enquiry into Patient Outcome and Death , CIPOLD (Confidential Inquiry into Premature Deaths of People with Learning Disabilities) and Confidential Enquiry into Maternal Deaths | MBRRACE-UK | NPEU (ox.ac.uk)

you are still concerned, you must report this, in line with your workplace policy and our more detailed guidance on *Raising and acting on concerns about patient safety*.

76 If you have a formal leadership or management role, you must take active steps to create an environment in which people can talk about errors and concerns safely. This includes making sure that any concerns raised with you are dealt with promptly and adequately, in line with your workplace policy and our more detailed guidance on *Raising and acting on concerns about patient safety*.

Managing risks posed by your health

77 You should avoid seeking medical care from a family member or anyone you work closely with. If you are registered with a general practitioner this should be someone outside your family and your workplace.

78 You should try to take care of your own health and wellbeing, recognising if you may not be fit for work. You should seek independent professional advice about your fitness for work, rather than relying on your own assessment.

79 You must consult a suitably qualified professional and follow their advice about any changes to your practice they consider necessary if:

a you know or suspect that you have a serious condition that you could pass on to patients

b your judgement or performance could be affected by a condition or its treatment.

You must not rely on your own assessment of the risk to patients.

80 You should be immunised against common serious communicable diseases (unless contraindicated).

Domain 4: Trust and professionalism

Introduction

Patients must be able to trust medical professionals with their lives and health, and medical professionals must be able to trust each other.

Good medical professionals uphold high personal and professional standards of conduct. They are honest and trustworthy, act with integrity, maintain professional boundaries and do not let their personal interests affect their professional judgements or actions.

Acting with honesty and integrity

81 You must make sure that your conduct justifies patients' trust in you and the public's trust in your profession.

82 You must always be honest about your experience, qualifications, and current role. You should introduce yourself to patients and explain your role in their care.

83 If a patient, colleague, or anyone else you have contact with in your professional role asks for your registered name and/or GMC reference number, you must give this information to them.

84 You must be honest in financial and commercial dealings with patients, employers, insurers, indemnifiers and other organisations or individuals.

Acting with honesty and integrity in research

85 When designing, organising or carrying out research, you must put the interests of participants first. You must act with honesty and integrity, and follow national research governance guidelines and our more detailed guidance on *Good practice in research*.

Maintaining professional boundaries

86 You must not act in a sexual way towards patients or use your professional position to pursue a sexual or improper emotional relationship with a patient or someone close to them. You must follow our more detailed guidance on *Maintaining personal and professional boundaries*.

87 You must not express your personal beliefs (including political, religious and moral beliefs) to patients in ways that exploit their vulnerability or could reasonably cause them distress. You must follow our more detailed guidance on *Personal beliefs and medical practice*.

Communicating as a medical professional

All professional communication

88 You must be honest and trustworthy, and maintain patient confidentiality in all your professional written, verbal and digital communications.

89 You must make sure any information you communicate as a medical professional is accurate, not false or misleading. This means:

a you must take reasonable steps to check the information is accurate

b you must not deliberately leave out relevant information

c you must not minimise or trivialise risks of harm

d you must not present opinion as established fact.

Public professional communication, including using social media, advertising, promotion, and endorsement

90 When communicating publicly as a medical professional – including using social media, advertising your services, and promoting or endorsing any services or products:

a you must follow the guidance in paragraph 88 and 89

b you must declare any conflicts of interest

c you must not exploit people's vulnerability or lack of medical knowledge

d you must make sure what you communicate is in line with your duty to promote and protect the health of patients and the public.

91 You must follow our more detailed guidance on *Using social media as a medical professional*.

Giving evidence and acting as a witness

92 When giving evidence or acting as a witness, you must follow the guidance in paragraphs 88 to 90 and our more detailed guidance on *Providing witness statements or expert evidence as part of legal proceedings*, and you must make clear the limits of your knowledge and expertise.

Private communication

93 When communicating privately, including using instant messaging services, you should bear in mind that messages or other communications in private groups may become public.

Managing conflicts of interest

94 You must not allow any interests you have to affect, or be seen to affect the way you propose, provide or prescribe treatments, refer patients, or commission services.

95 If you are faced with a conflict of interest, you must be open about it with patients and employers, declare it in line with local and national arrangements, and be prepared to exclude yourself from decision making. You must follow our more detailed guidance in *Identifying and managing conflicts of interest.*

96 You must not ask for or accept – from patients, colleagues or others – any incentive payments, gifts or hospitality that may affect or be seen to affect the way you propose, provide or prescribe treatments, refer or commission services for patients. You must not offer such incentives to others.

97 You must, wherever possible, avoid providing medical care to yourself or anyone with whom you have a close personal relationship. You must follow our more detailed guidance on *Good practice in proposing, prescribing, providing and managing medicines and devices*.

Cooperating with legal and regulatory requirements

98 To maintain patient safety, you must cooperate with formal inquiries, patient safety investigations, and complaints procedures. You must provide all relevant information and be open and honest.

99 You must tell us without delay if, anywhere in the world:

a you have accepted a caution (or equivalent) from a prosecuting authority

b you have been charged with a criminal offence in person or by post

c you have been found guilty of a criminal offence

d you have been criticised by an official inquiry[8]

e another professional body has made a finding against your registration as a result of fitness to practise process.

See our guidance on *Reporting criminal and regulatory proceedings* for more detailed information.

100 If you are suspended by an organisation from a healthcare role or post requiring professional registration, or have restrictions placed on your practice, you must, without delay, inform any organisations for which you carry out medical work, and any patients you see independently of these organisations.

101 You must make sure that you have appropriate and adequate insurance or indemnity that covers the full scope of your practice. You should keep your level of cover under regular review.

[8] By 'official inquiry' we mean a public or formal inquiry or a tribunal in the public domain. These are publicly funded, investigate matters in the public interest and publish their findings. See our more detailed guidance on *Reporting criminal and regulatory proceedings* for more information

Footnotes

1 This does not apply to doctors on the medical register without a licence to practise.

2 See our ethical hub advice on adult safeguarding which you can find at https://www.gmc-uk.org/ethical-guidance/ethical-hub/adult-safeguarding

3 'Colleagues' includes anyone you work with, whether or not they are a medical professional.

4 See our ethical hub advice on Speaking up which you can find at https://www.gmc-uk.org/ethical-guidance/ethical-hub/speaking-up

5 If a patient lacks capacity, information should be shared with those with legal authority to make decisions on a patient's behalf.

6 Contemporaneous means making records at the same time as the events you are recording, or as soon as possible afterwards.

7 A confidential inquiry (or enquiry) is a method of investigating adverse events without attributing blame. Examples include NCEPOD - National Confidential Enquiry into Patient Outcome and Death , CIPOLD (Confidential Inquiry into Premature Deaths of People with Learning Disabilities) and Confidential Enquiry into Maternal Deaths | MBRRACE-UK | NPEU (ox.ac.uk)

8 By 'official inquiry' we mean a public or formal inquiry or a tribunal in the public domain. These are publicly funded, investigate matters in the public interest and publish their findings. See our more detailed guidance on *Reporting criminal and regulatory proceedings* for more information

Email: **gmc@gmc-uk.org**
Website: **gmc-uk.org**
Telephone: **0161 923 6602**

General Medical Council, 3 Hardman Street, Manchester M3 3AW

Textphone: **please dial the prefix 18001** then **0161 923 6602** to use the Text Relay service.

Join the conversation

@gmcuk **facebook.com/gmcuk**
linkd.in/gmcuk **youtube.com/gmcuktv**

To ask for this publication in another format or language, please call us on **0161 923 6602** or email us at **gmc@gmc-uk.org**.

I ofyn am y cyhoeddiad hwn mewn fformat neu iaith arall, ffoniwch ni ar **0161 923 6602** neu e-bostiwch ni ar **gmc@gmc-uk.org**.

You are welcome to contact us in Welsh. We will respond in Welsh, without this causing additional delay.

Mae croeso i chi gysylltu â ni yn Gymraeg. Byddwn yn ymateb yn Gymraeg, heb i hyn achosi oedi ychwanegol.

Published January 2024
© 2024 General Medical Council

The text of this document may be reproduced free of charge in any format or medium providing it is reproduced accurately and not in a misleading context. The material must be acknowledged as General Medical Council copyright and the document title specified.

The General Medical Council is a charity registered in England and Wales (1089278) and Scotland (SC037750).

Code: GMC/GMP24/1224

Personal information redacted by USI

19th September 2016

Corporate Complaints Officer
Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
Portadown
BT63 5QQ

Dear Sir/Madam,

Patient 84
DOB: Personal Information redacted by USI
H&C No.: Personal Information redacted by USI

I am writing to make an official complaint about the neglect towards myself resulting in my total dissatisfaction on how I have been treated over the past few months.

To give you the background into my situation, I was phoned by a consultant (Mr Puyson I believe) on Friday 25th March 2016 (Good Friday) to say that I had a blockage in my ureter, noticed on a recent CT scan, and that it would be best that I come into hospital as soon as possible to get surgery. I was informed that the Easter weekend would be a good time as there was some capacity to do the surgery as I was on an emergency list. I was obviously a bit alarmed and was in the middle of packing for the Easter weekend away. Of course, I realised the seriousness of my condition so I cancelled my plans and the consultant and I agreed that I would receive a telephone call on the Saturday morning to confirm bed availability. I didn't receive this call and then had to do some chasing myself. The staff currently on weren't aware of the plans for surgery. I eventually got confirmation on Easter Sunday morning to come to hospital for the surgery planned on Monday but when I arrived the staff were surprised as I shouldn't have needed to stay pre-operatively and therefore could have just came to hospital on Monday morning. This is just to highlight the severe lack of communication from the start and the fact that my weekend plans were cancelled unnecessarily. However, in saying all that, what followed is the real reason for this letter.

After the surgery by Mr O'Brien, I was told that the blockage had been removed (although the stone escaped back up to the kidney) and that I did have a lot of stones in both kidneys and a stent was placed in the right ureter. I understood the logic for a stent and I was informed that it will be uncomfortable at first and that I may feel the urgency to pass urine a bit more frequently as the stent protrudes inside the bladder slightly. I was informed that the stent should be removed in 6 weeks' time. I felt that this was fine and that this would be good timing for my pre-booked holiday at the end of May.

Unfortunately, from the beginning I had persistent pain with the stent at the tip of my penis particularly when passing urine, and I was passing fresh red blood post exercise and had severe urgency and severe frequency. This clearly had a major impact on my life both at home and in work. I was on regular Ibuprofen and Paracetamol to alleviate the pain but the pain was not being controlled. I was worried about my severe signs and symptoms so I contacted Mr O'Brien's secretary and asked could I speak to him or a member of his team for some medical advice and to discuss the symptoms I was

feeling as I was concerned something was wrong. Unfortunately the secretary said I would not be able to speak to anybody in the medical profession but I should contact my GP and that she would send an email to Mr O'Brien. I felt my issues were not being taken seriously and I was being neglected.

I contacted my GP who kindly offered some general advice but obviously it was a specialist opinion that I needed at this time. I re-contacted Mr O'Brien's secretary to ascertain where I was on the waiting list for my stent removal but this information was not even available. Again, I was informed that an e-mail would be sent to Mr O'Brien.

My symptoms as mentioned were getting worse and I was getting increasingly concerned at this point as I was going on holidays [Personal Information redacted by the USI] and didn't want get ill abroad. Mr O'Brien's team were aware of my concerns regarding the stent still being in situ while I was abroad as by this stage the stent had been in for 6 weeks. So again I had to contact my GP, who prescribed Amoxicillin based on signs of a urinary infection.

On holidays the pain was unbearable at times. I had severe urgency so it meant finding public toilets whenever we were out and making sure I was near one or knew the location of one at all times. I had severe frequency especially at night. I was determined not to let this ruin my holidays with my [Irrelevant information redacted by USI]. I went to the local chemist and had to get more Ibuprofen equivalent and continued to drink as much water as I could, being very aware of the fact I was in a warmer climate.

I phoned the secretary again on my return expressing my concerns, again the same response. She'll send an email and Mr O'Brien will phone me directly to let me know when the appointment is arranged. I also phoned my GP who was concerned and I believe a letter was sent to Mr O'Brien.

In desperation from knowing I was unwell I had to continue making calls to the secretary but I was made to feel like a nuisance and never actually got to speak to a medical professional or get an appointment for surgery. I was informed that the waiting list was over 200, this however is not acceptable and I do feel like I was severely neglected.

Three courses of antibiotics (Amoxicillin (x2) and Ciprofloxacin) and regular paracetamol and ibuprofen brought me to the weekend of 6th August, 5 months later. I felt lethargic on Saturday but felt it was due to another disturbed sleep as I woke 3 times to pass water. I endured it as usual as this had been daily since discharge but when I woke on Sunday I felt very unwell and had pain in my right side. At this stage I had been unwell and had the stent in for 5 months and I had an increasing concern that the stent could affect the long-term function of my kidneys. I went to A&E at 11am, and was later taken up to 3 South at around 7pm because the urine sample I submitted had "all kinds of things in it" and my white blood cell count and CRP count were very high. I was relieved to be finally admitted as I wanted the stent removed and my kidneys cleared of stones. However I was very frustrated that my concerns of being unwell had not been taken seriously and I had to basically wait until I became so unwell that I had to attend A&E and be admitted to hospital, all of which could have definitely been avoided.

I was told by my new consultant Mr O'Donaghue that potentially surgery would be on Tuesday 9th August but thought it was best to postpone it until Wednesday due to the infection. Although a minor point, I was still fasted from 12pm on Monday night; but this again highlighted the miscommunication within the Urology department. On Tuesday the ward got a call from the microbiologists saying that I had "very nasty bacteria" in my urine that produced Extended-Spectrum Beta-Lactamases (ESBLs). This was likely a result of the overuse of antibiotics taken to date which all could have been avoidable if the stent had been removed in the appropriate timeframe. As a result the current IV antibiotic wasn't

working so I was given Tazocin and that the surgery would need to be postponed to a later date until the infection cleared as it could be very dangerous if they were to continue, all of which was very concerning as I was starting to hear the word 'Septicaemia'. I also learned from a further CT scan that a stone was still in my Ureter and it lay next to the stent.

Following this I grew more annoyed however as I am certain this all could have been avoidable. Even during the pre-operative assessment on 11th August this thought was at the forefront of my mind. The doctor informed me that the stent may not be so easily removed and that there may be damage to the Ureter etc. I know the stent was the route of my long-term pain and I am absolutely convinced it was the sole reason for my infections to date. During my stay I was wide-eyed in disbelief what I was hearing from other consultants that they don't favour stents and where they are needed they target the removal in 5 weeks, for the exact reason of potential UTIs etc. I am aware that they can sometimes stay in for 6 months, but given my known complications and my signs and symptoms, I should have been taken more seriously before I became so unwell.

I was in hospital (3 South) from 7th – 14th August for this period. I was discharged on the Sunday 14th August, but I hadn't felt well afterwards, which I put down to being a bit tired after the surgery. However I had tenderness in my kidneys on Monday night affecting my sleep, Tuesday I felt quite lethargic but by Wednesday I had a high temperature. I got a GP appointment for 4pm that day who sent me straight to A&E. I was very worried about the issue of blood poisoning at this point. Following a blood test in A&E, my white blood cell was high as was my CRP level, so I was put on another antibiotic called Meropenum based on the advice that the doctor sought from the microbiologists. I was then transferred to 3 South, with possible Sepsis and I was on another IV antibiotic for 7 days. I was in hospital (3 South) from 17th – 24th August for this third period. I was discharged on Wednesday 24th and was given further antibiotics that I needed to take for 10 more days. It also led me to question if I should have been discharged without further antibiotics the previous time.

I want to make it clear that the staff during my stays were excellent but the duty of care potentially with serious implications between March and August was incredibly poor. If I had been dealt with in the correct manner after the insertion of the stent with it being removed after a 5-6 week period, not only could I have avoided enduring all that pain for 5 months but I wouldn't have to stay in the hospital for 2 full weeks to clear up a serious infection and the procedure could obviously have been much more straightforward.

I suggest you vastly improve consultant and patient communication when the patient is not in the hospital, particularly knowing they are required to return to finish a procedure. Medical concerns should be addressed by the consultant or a member of his/her medical team, not by administrative staff. I understand there is a risk that the consultant could find all his time taken up with external patient concerns, but maybe this is where his/her administrative team and a member of his medical team work together to screen non-urgent/ less important issues, then a window in the day is left for the consultant to phone patients with real urgent concerns. If Mr O'Brien hadn't ignored my many calls and failed to return any of them, I wouldn't have been in this situation and the tax payer's money would be better spent. I can't understand in this cost conscious NHS system why it seemed a better plan to ignore my issues for so long and wait until I needed to be admitted to hospital for a 2 week period; taking up a bed, using up time, resources and antibiotics in addition to the impact on my health.

I look forward to hearing from you and hope for the sake of others, this letter makes a difference to patient care, so there is no future repeat in this type and level of care.

Yours Faithfully,

[redacted]
Patient 84

PAT-000203

Southern Health and Social Care Trust

20th September 2016 **Our Ref:** AS206.16/17 **Your Ref:**

Private & Confidential

Patient 84

Personal Information redacted by the USI

Dear Patient 84

I refer to your complaint in respect of the quality of care and lack of communication you faced when attending Craigavon Area Hospital. Thank you for taking the time to highlight your concerns.

The Trust will investigate the issues which you have raised, in accordance with the Trust's Policy and Procedure on the Management of Complaints. It would be our intention to advise you of the findings of the investigation within 20 working days or as soon as possible thereafter. In the meantime, I enclose for your attention a copy of our "What Happens Next" leaflet.

If for whatever reason we are unable to provide you with a response within the timeframe above, a member of our team will contact you again to keep you fully advised.

Should at any point you wish to discuss your complaint, please do not hesitate to contact us on Personal Information redacted by the USI Alternatively you may wish to seek independent support and/or advice by contacting the Patient Client Council on 0800 9170222.

Yours sincerely

Personal Information redacted by USI

DAVID CARDWELL
Clinical and Social Care Governance Officer

enc

Clinical and Social Care Governance Team
Directorate of Acute Services
Ground Floor, The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by the USI
E-Mail: AcutePatient.ClientLiaison@southerntrust.hscni.net

PAT-000204

Southern Health and Social Care Trust

19 October 2016 **Our Ref:** AS206.16/17 **Your Ref:**

Private & Confidential

Patient 84
Personal Information redacted by the USI

Dear Patient 84

I refer to your complaint which was received on 20 September 2016 in which you expressed concern regarding quality of care in Craigavon Area Hospital.

On receipt of your complaint I asked senior staff to investigate the concerns you have raised. Unfortunately there has been a delay in the investigation so I will be unable to respond to you within 20 working days. I would like to assure you that we are taking very seriously your concerns. Please accept my apologies for any undue distress caused by this delay.

When the investigation has concluded our Director of Acute Services will write to you with the findings and I would hope this will be relatively soon. However in the interim if you wish to speak to me regarding this delay please telephone Personal Information redacted by the USI or email AcutePatient.ClientLiaison@southerntrust.hscni.net

Yours sincerely

Personal Information redacted by USI

pp **DAVID CARDWELL**
Governance Officer

Clinical and Social Care Governance Team
Directorate of Acute Services
Ground Floor, The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by the USI
Email: AcutePatient.ClientLiaison@southerntrust.hscni.net

23 November 2016 **Our Ref:** AS206.16/17

Private & Confidential

Mr Patient 84
Personal information redacted by USI

Dear Patient 84

I refer to your complaint in relation to the quality of care provided to you in Craigavon Hospital.

Please note that unfortunately there continues to be a delay in the investigation of the issues which you have raised. However, I have been advised that the response will be agreed and finalized as soon as possible.

I apologise for this continued delay and I appreciate your patience.

Yours sincerely

David Cardwell
Governance Officer, Acute Services

Clinical and Social Care Governance Team
Directorate of Acute Services
Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by the USI

Southern Health and Social Care Trust

1 December 2016 **Our Ref:** AS206.16/17

Private & Confidential

Patient 84

Personal Information redacted by the USI

Dear Patient 84

I refer to your complaint in respect of the care provided to you by the Urology Department at Craigavon Area Hospital. Thank you for taking the time to highlight your concerns and for providing me with the opportunity to address them.

Firstly may I begin by apologising for the delay in responding to your letter. As part of the investigation into your concerns I have spoken to Mr O'Brien Consultant Urologist, about your complaint.

Mr O'Brien advises me that you had haematuria assessed in 2002 and 2003 at which times you were found to have renal calculi associated with a left hydronephrosis. In September 2015, the radiology department received a referral from your GP requesting a plain radiograph of your urinary tract; this xray was performed on 25 September 2015 and reported on 17 November 2015. The reporting radiologist suggested that most likely you had bilateral renal calculi with a probable right upper ureteric calculus. On 29th January 2016 your GP made a referral to the Urology Department for further management.

On receipt of this referral, Mr Glackin triaged the letter and then wrote to you on 2nd February 2016 advising that he had requested a CT scan of your urinary tract to assess for stones and that you would be sent an appointment to attend as an outpatient to the stone clinic. On the 4 March 2016 you were seen by Mr Young Consultant Urologist. You had an xray done during this appointment and whilst the bilateral renal calculi were evident on this xray, the right ureteric calculus was not. So when you had your CT scan on 22 March 2016 it was reported that you had a gross right hydronephrotic kidney and hydroureter. It was from this report that Mr O'Brien deemed that you needed to be admitted to have a ureteroscopy performed as an emergency.

Mr O'Brien asked for his Registrar, Mr Tyson to contact you and ask that you come in for admission on the Sunday. Mr O'Brien then emailed the Ward to give them your details and advise them that you would be admitted on the Sunday for your procedure on Monday. I would like to apologise for the misunderstanding when you arrived on the Ward as Mr O'Brien's email hadn't been picked up on this occasion and therfore the ward were not expecting you. As learning from this I have asked that Mr O'Brien and his Registrars follow up with a phone call to the Ward and also that the ward ensures that they check their emails at least a few times daily.

Clinical and Social Care Governance Team
Directorate of Acute Services
Ground Floor, The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by USI

I am advised that on Monday 28 March 2016 you had a right ureteric stenting performed following an ureteroscopy and migration of the obstructing stone into the hydronephrotic right kidney.

Mr O'Brien confirms that ideally patients who have a stent inserted should have this removed and have an ureteroscopic lithotripsy performed four to six weeks later. However, the demand on the Urology Service is unrelenting with an increased number of patients with suspected and confirmed cancer diagnoses requiring progression along their cancer pathway. The result of cancer urgent demand is that the waiting times for other procedures such as yours are increasing on a monthly basis. For this wait we would like to apologise and whilst not ideal nor what we want for you or any of our patients it is something that is currently outside of our control.

I note from your complaint that you have contacted Mr O'Brien's secretary on a number of occasions. Mr O'Brien confirms this and advises me that an email was sent to him via his secretary advising that you had a holiday [redacted] booked [redacted] and that you were enquiring whether you could have surgery performed before then. Unfortunately as explained in the previous paragraph with the clinical prioritisation of patients, Mr O'Brien unfortunately could not accommodate your request. At the time of your request Mr O'Brien had 232 patients awaiting inpatient admission of which 136 of them were categorised as urgent. Mr O'Brien apologies that you had to contact him on a number of occasions but with his clinical commitments and the number of patient enquiries that he receives daily it is not possible for him to respond to them all individually, but advises that you did the correct thing by going to your own GP for advice.

I understand that you had two emergency admissions to 3 South in August 2016 under the care of Mr O'Donoghue and Mr Glackin who were the Urologists oncall during these admissions. I would like to apologise that you had to fast unnecessarily whilst you were in the first time but I have been advised that this was a precaution in case you were well enough to go to theatre and there was a slot available on the Tuesday and I am sorry that this wasn't communicated properly with you at the time.

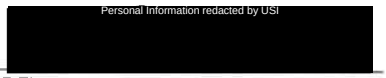
The Urology Department are currently working at improving the pathway for patients experiencing similar symptoms such as yours. This will involve having a 7 day week stone service with detailed information leaflets for patients with more access to health care professionals if advice is needed. It is hoped through the development of this service it will mean that patients will have their treatment and follow-up done in a timelier manner and hopefully avoid the poor experience that you had endured.

On behalf of the Urology Service I would like to apologise again for your poor experience and I am advised that you have a follow-up outpatient appointment with Mr Glackin on 20 December 2016 and I hope that your health issues have improved.

I hope that you will find this response has addressed the issues that you raised. However, if you are unhappy with any aspect of this response you should contact a member of our Clinical & Social Care Governance Team on [redacted] or email: AcutePatient.ClientLiaison@southerntrust.hscni.net within 3 months of the date on this letter so that we can attempt to resolve any outstanding issues.

Should you remain dissatisfied at the end of the complaints process, you can then refer your complaint to the NI Public Services Ombudsman at the following address, "Freepost NIPSO", Freephone: 0800 34 34 24 or email nipso@nipso.org.uk within 6 months of the completion of the Trust's internal complaints process. Further information on the role of the NI Public Services Ombudsman can be found at www.nipso.org.uk. Please note that the Ombudsman will not normally accept your complaint until the complaints process with the Trust has been exhausted.

Yours sincerely



ESTHER GISHKORI (MRS)
Director of Acute Services

For Mr F Rice, Interim Chief Executive

12/3 - records reopened on dedicated book

held in re-opened drawer

Personal information redacted by USI

28th February 2017

Corporate Complaints Officer
Trust Headquarters
Craigavon Area Hospital
68 Lurgan Road
Portadown
BT63 5QQ

Dear Sir/Madam,

Patient 84
DOB: Personal Information redacted by USI
H&C No.: Personal information redacted by USI

I appreciate your apology on behalf of the Urology Service but an apology direct from Mr O'Brien would have been more acceptable.

Mr O'Brien had the opportunity to call in to see me during either of my two emergency admissions to 3 South in August 2016 to try and explain his decision not to remove the stent. He owed me that at least and treat me with some respect and have the common decency to do so, or simply a returned call would have sufficed to allay my concerns with the stent in place at any time over the 5 month period. I find it hard to believe he couldn't spare me 5-10 minutes during this time.

I fully appreciate the demand is unrelenting on the Urology Service with 'an increased number of patients with suspected and confirmed cancer diagnoses requiring progression along their cancer pathway' and 'the result of cancer urgent demand is that the waiting times for other procedures such as yours are increasing on a monthly basis'. However, to me this is all more reason to deal with my issue there and then so the Urology Service can concentrate their time and efforts to these cancer patients. The insertion of the stent to me seemed like a very short sighted decision, while I was grateful the blockage was detected in my ureter, it felt like the minimum action possible was taken. To insert a stent to temporarily mitigate the effects of the blockage i.e. the pressure on my kidney, felt like a kind of 'that will do for now' scenario but there was never no plan or intention to aim for the 4 to 6 week target for stent removal with ureteroscopic lithotripsy.

Also, I should not be made to feel guilty because of the more urgent cancer demand, as I waited in excess of 3 and a half months more than I should have and endured this pain for this length of time which is ample time to wait for this situation to be rectified for me. If I hadn't have presented myself to A&E in August through a severe infection, I feel I'd still be waiting months later. This response has not acknowledged once the severe infection I had that Mr O'Brien's decisions had led to, and rounds of strong antibiotics I needed to rid me of this infection. You have carefully avoided this area altogether in your response which in effect minimised the pain, suffering and nuisance I suffered for five months.

Furthermore, after my procedure on 28th March 2016 I was led to believe that the offending stone causing the blockage had disappeared back up into the kidney during the procedure but the scans during my emergency admission in August 2016 highlighted that a stone was embedded in my ureter alongside the stent. Either this was the same one from earlier that wasn't adequately removed, hence

a failure at the time to remove the blockage properly or if it was a new stone that somehow found its way down my ureter as it squeezed past the stent, you can imagine the pain this caused. So again, I really have to question the decision for the insertion of a stent; this was very much a makeshift measure. Surely the offending stone could have been removed competently like it was done on 11th August 2016 by Mr Glackin where no subsequent stent was inserted; hence avoiding all this pain and aggravation I endured over the 5 month period. This nearly and could have had serious consequences for myself and I can only guess what the outcome would have been if this level of care had of been provided for the vulnerable in our society.

A complete removal of the stone without a follow-up stent would saved everybody's time and as I mentioned in my previous letter I can't understand in this cost conscious NHS system why it seemed a better plan to ignore my issues for so long and wait until I needed to be admitted to hospital for a 2 week period; taking up a bed, using up time, resources and antibiotics in addition to the impact on my health. All this wasted time, effort and money could have been directed towards the care for these cancer patients.

Overall, the response I have received is unsatisfactory. After my surgery I was informed that the stent should be removed in six weeks' time. If that is the clinical target then it should be met. If that target is unrealistic then it should not be communicated to patients. The Trust has a duty of care to me; I feel there was a breach of that duty due to the evident negligence and the loss I suffered to my quality of life and earnings over this time.

Yours Faithfully,

Patient 84

Southern Health and Social Care Trust

14 March 2017 **Our Ref:** AS206.16/17

Private & Confidential

Mr [redacted]
[redacted]

Dear [redacted]

Thank you for your letter dated 28 February 2017. I am sorry that you feel the response you received was unsatisfactory.

The contents of your letter has been shared with the Urology Team in order that they can consider how best to meet the needs of patients who require stents to be removed after surgery.

Yours sincerely

[redacted]

ESTHER GISHKORI (MRS)
Director of Acute Services

For Mr F Rice, Interim Chief Executive

Clinical and Social Care Governance Team
Directorate of Acute Services
Ground Floor, The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: [redacted]

Urology Services Inquiry

Urology Services Inquiry Questionnaire

Points to assist with completion of the USI Questionnaire

- A helpful **Guide to Completing the USI Questionnaire** is available (see attached) and you are advised to read these guidance notes before attempting to complete this questionnaire.
- This questionnaire will assist the Inquiry to gain information from you regarding your experience of Urology services provided within the Southern Health and Social Care Trust (SHSCT).
- We appreciate that some patients/former patients or their families may have concerns about identifying themselves by name etc on the questionnaire. We would however reassure you that any personal details noted will only be seen by those parties, organisations or the core participants involved in our investigations who need to see it for the purpose of progressing Inquiry business. All core participants must adhere to the terms of our Restriction Orders which are now in place and available to view on our website. The term "core participant" is also defined on our website under the heading "Frequently Asked Questions – FAQ's". Our USI website address is noted below: www.urologyservicesinquiry.org.uk.
- We would encourage you to fill out your personal details as fully as possible in Section A as it will increase the value of the information to our investigative work and may also enhance your potential input to the Inquiry. We would reassure you that your name and personal details will be protected and will be anonymised unless you consent to them being made public. Your personal information will be handled in compliance with the applicable legislation including the Data Protection Act 2018 and the General Data Protection Regulations 2018.
- Please note that it is not the intention of this Inquiry to publish the questionnaires that are submitted to assist us with our work, although the report may refer to some of the content.
- If you require assistance completing this questionnaire please do not hesitate to contact our office directly on telephone number: **028 90251005**.

- The work of this Inquiry is entirely independent of all other organisations including healthcare providers, regulators and government departments.
- Only certain sections of the form will apply to you. We would ask everyone to complete Section A but thereafter please only complete those sections which apply to you.
- When you have completed the relevant sections please complete Section F and then ensure you have signed the completed questionnaire at Section G.

SECTION A – Personal Details

Name	Patient 84
Address	Personal information redacted by USI
Contact Telephone Number	Personal information redacted by USI
Mobile Phone Number	Personal information redacted by USI
Email Address	Personal information redacted by USI
HSC Number (if known)	HCN Personal Information redacted by the USI

	Yes/No
With regard to Section A above, have you read the '**Personal Details**' section of the 'Guide to Completing the USI Questionnaire'?	Yes
Are you completing this questionnaire as a patient/former patient? (If your answer is Yes, go to Section B)	Yes

Are you completing this questionnaire as a relative of a patient/former patient?	
If you are completing this questionnaire as a **relative of a patient/former patient**, do you have the express authority of the patient to engage with the Inquiry and provide information that relates to their care and treatment? (If your answer is Yes, go to Section B)	
If you are completing this questionnaire as **a relative of a deceased patient**, have you discussed providing information concerning the deceased patient with other relatives/former next of kin and no objection is being raised. (If your answer is Yes, go to Section B)	

If you are completing this questionnaire and you are not the patient/former patient or a relative of one please state your role.	

SECTION B – Contact with Urology Services

Please complete the table below setting out details of each occasion when you accessed urology services. Provide details of the dates attended, relevant consultant, hospital/clinic etc and a brief description of the reason for the visit/treatment received. If you cannot remember exact dates then please give approximate dates where possible.

Date(s)	**Seen By** (e.g. name of consultant/healthcare professional)	**Location** (e.g. Craigavon Area Hospital)	**Brief description of reason for visit and/or treatment received**
March 2016	Mr O'Brien	Craigavon Area Hospital	Emergency Ureteroscopy. A blockage was noticed on a very recent CT scan. A stent was inserted during the operation.
6th August 2016 – 14th August 2016	Mr O' Donaghue	CAH	Removal of the stent. By this time I have a bad infection (ESBL).
17th August 2016 – 24th August 2016	Mr Glackin	CAH	Queried Sepsis. Put on IV anti-biotic.
			I accessed urology service on many more occasions due to a kidney stone issue, these are too numerous to list here. The occasions above are my main concern and the biggest issue.

Continue on a separate sheet if necessary

SECTION C – Details of concerns raised/complaints reported

1.	Please provide full details of any concerns and/or complaints raised by you, specifying the nature of those concerns in as much detail as possible.

I submitted a formal complaint letter to the Corporate Complaints Officer on the 19th September 2016.

I was notified by Mr O'Brien via Mr Tyson to come into for admission to CAH on Easter Sunday 27th March 2016 as I needed to be admitted to have a ureteroscopy performed as an emergency. When I arrived at the ward, they were not expecting me, this hadn't been communicated to them. A minor thing overall, but it was an inconvenience as it was Easter Sunday and I was away for the weekend, so I had to cut things short.

The operation was undertaken on Monday 28th March 2016 and I had a stent inserted, this is where my main complaint lies. As admitted by the hospital later on 1st December 2016, in a response to my complaint letter, a stent inserted should have this removed and have an ureteroscopic lithotripsy performed four to six weeks later. I didn't get this stent removed until 10th August, nearly 5 months later. During these 5 months I was in excruciating pain throughout, right from the start, particularly when passing urine. I was passing fresh blood post exercise and had severe urgency and severe frequency. It was very disruptive to my home and work life. I had to bear the pain for so long and take painkillers all the time, likely putting more strain on my kidneys.

I only got this stent removed because I was so ill and had to get admitted via A&E on 6th August 2016. I had a very nasty bacteria in my urine that produced Extended-Spectrum Beta-Lactamases (ESBLSs). To remove this infection, I needed different kinds of strong anti-biotics. I was fearful of septicaemia at this point. I also learnt at this time from a further CT scan that a stone was still in my ureter and it lay next to the stent. The stent removal went well thankfully as I was warned about a risk of damage during its removal as it had been in there for that length of time. However, while I was discharged on 14th August I was re-admitted on 17th August. I felt poorly since I was discharged, so I visited my GP, who sent me straight to A&E. I was then transferred to 3 South, with query Sepsis, and I was on another anti-biotic for 7 days. The anti-biotic was an even stronger one named Meropenum. Finally, I was discharged on 24th August 2016.

The stent not only worsened the kidney stone blockage issue I was originally admitted for, but it was also causing extreme pain while inserted, and it then caused me to become really ill by causing infections. It should have been removed much sooner as was recommended and known but I continued to get fobbed off by Mr O'Brien via his secretary. I phoned many times to speak to him.

I feel there was a definite breach of duty of care to me. The staff including the different consultants during my unnecessary stays were excellent but Mr O'Brien

and his admin staff provided a poor quality of care and very little communication, and this all could have been avoidable.

2. Please specify the date when any concern or complaint was raised and if you cannot recall date(s) please try to indicate an approximate timescale.

I submitted a formal complaint letter to the Corporate Complaints Officer on the 19th September 2016.
3. Please note the name and/or position held of the person you raised any concern with or reported any complaint to at the time.
I submitted a formal complaint letter to the Corporate Complaints Officer on the 19th September 2016. I got a few intermediate holding replies saying they were taking time to investigate the complaint for me, receiving the main response from Esther Gishkori (MRS), Director of Acute Services on 1st December 2016 for F Rice, Interim Chief Executive.
4. Please advise for each occasion a concern or complaint was raised whether this was done verbally or in writing (e.g. via letter/email etc).
See above. I submitted a letter. Verbally I raised my concern to Mr O'Brien's secretary on multiple occasions. I never heard from Mr O'Brien.
5. If your concern or complaint was made in writing, please provide copies of that correspondence if possible.

Ok.

6. Please advise if you received any acknowledgment or response (whether a holding response or a detailed response) to your complaint. If so, can you please provide copies?

Yes

7. Please advise the outcome of any concern made or complaint raised by you.

There was no outcome.

I just got an unsatisfactory response from them, blaming the demand on Urology Service. While I can appreciate the demand on the staff, and prioritising confirmed cancer diagnoses, I think it was illogical to keep my stent in as this later put a strain on resources elsewhere throughout the hospital like in 3 South when I was admitted twice with bad infections and for the riskier stent removal.

SECTION D - Details of concerns held but NOT raised/reported

1. Please provide full details of any concerns you held at the relevant time specifying the nature of those concerns in as much detail as possible.
None
2. Please explain why you did not raise your concern(s) at the time and state if there was something that prevented you from raising your concern(s).
N/A

SECTION E – Personal impact/additional information

Please outline the personal impact that the treatment received, which forms the basis of your complaint(s), has had on the patient/deceased patient and provide any additional information which you feel may be of assistance to this Inquiry.
Key effects: - I had to endure excruciating pain for a long time. - I had severe urgency and severe frequency passing urine which affected by life at home, raising a young family, and at work. I always needed to be very near a toilet. I woke several times during the night to use the toilet through this time. This affected my mental health during this time, as I was very tired and sore. - I passed fresh blood heavily post-exercise, affecting me doing any exercise during this time. - I had to take time off work during my admissions to hospital. - The poor care ran the risk of causing long-term damage to my kidneys and ureter by having this stent inserted so long, as it caused a blockage, not allowing the kidney to drain properly. I can only hope there is no long-term damage.

Additional sheets, if needed, can be attached

SECTION F – Sharing information / Other related reviews

The Inquiry may consider that the information you have provided is more relevant to one of the other organisations carrying out a review or investigation as detailed in the 'Guide to Completing the USI Questionnaire' under the heading 'Other Related Reviews'.

	Yes/No
Would you be content for the Inquiry to share the contents of this questionnaire with other relevant organisations?	Yes
Would you like to discuss this in more detail with the Inquiry before making a decision on the sharing of information?	No

SECTION G – Signature

Signed:	Patient 84 [redacted]
Name in Block Capitals:	Patient 84 [redacted]
Date:	04/01/2022

CHAIR: Do you mind if I interrupt you for just a moment?

A. Fire away, yeah.

3 Q. I just want to check, this was after you had had the stent put in? 10:11

A. Yes, sorry, yeah.

4 Q. Can I take you back a stage further to, you were told that you needed a stent?

A. Yes.

5 Q. And you needed to go into hospital obviously to have that put in. And what happened, how were you told that you needed, how were you contacted about coming into hospital? 10:11

A. Yeah, I was phoned by, was it Mr. Tyson? I think I got their name wrong the first time or whatever. But yeah, it was just like an urgent emergency sort of thing and it was a bit of a panic because I was actually packing to go to my parents and stuff. So I was like, okay. And then obviously I could see, they stressed that urgency and stuff like, so I had to just drop everything and said, right, when do I have to go and whatever. 10:12 10:12

Then it was just a wee bit of communication there, issues, no big deal really, but Sunday coming in, but nobody was expecting me and that kind of thing. And then I did go home and then re-admitted then on the Monday morning and that kind of thing and stuff so, yeah, communications. 10:12

on the 29th March. I assume you were either discharged that day or the day after, after your stent installation. And then you came back into the hospital via Accident and Emergency on 6th August 2016?

A. Yeah. 10:38

48 Q. Help me with this, if you can: Between those two dates, approximately, if you can remember, but approximately how many communications did you attempt to make into the hospital to raise the issues that you were raising? 10:39

A. Ten times at least maybe, phone calls and stuff like that. You know it was -- yeah, you know obviously at the start I was trying to, this is just to manage it, this is the way things are. But as that six week's time, and I was getting to, obviously the holidays are 10:39 in there and stuff as well and I was keen to get that sorted before then. But, yeah, no, I phoned quite regularly, particular with the pain, it was just the pain of it all.

49 Q. And I understand there were also e-mail communications 10:39 mentioned by Mr. O'Brien in his letters. So you were e-mailing in as well?

A. I don't recall that as much because I am not sure if I had an e-mail address for them that early. But it was definitely the -- 10:39

50 Q. Perhaps that is my fault. Perhaps Mr. O'Brien was being e-mailed by his secretary, maybe that is --

A. No, it was more, I think it was Cathy, was it he called her? But yeah, it was more phone calls to her. But

like, is this going to lead to a tear or something in the ureter and that kind of stuff and that was obviously worrying and things, and it all could have been avoided basically.

14 Q. I think you said there that you were trying to contact Mr. O'Brien's secretary to see if what was happening to you was normal? 10:15

A. Yeah.

15 Q. And what response were you getting?

A. Nothing. Just getting the fobbed-off. Go back to the GP, that kind of thing. And the GP was very good like, just trying to be supportive and that kind of stuff, but they can only do so much. They're not specialists and that. They just really were prescribing me more antibiotics, Amoxicillin, and that kind of thing, and painkillers and that kind of stuff like. 10:15 10:15

But yeah, she was just telling about the waiting lists and that kind of stuff, but I was just looking for some kind of commitment, some kind of a date, you know, at least then something I could aim for and know that it was happening then and then I could just manage it, grin and bear it kind of thing. But there is no plan, they just didn't seem to have a plan for me. 10:16 10:16

While I was grateful for removing the blockage, I just thought there was no, I just felt there was a makeshift, that will do for now, that will buy me time, buy us time or whatever, you know, time to deal with

other things or whatever. So that's the way I felt and I was just getting fobbed-off and I just wasn't getting listened to kind of thing.

I just wanted to speak to somebody medical, just somebody that just sort of says, this is normal, don't worry, I'm trying my best, I'm trying to get this waiting list down, I've got all this X, Y and Z going on, you know, and there was just some kind of commitment to get me sorted kind of thing and just to hear someone, this is normal, that's fine, just do this and do that, or whatever. I don't know like. But I don't think there was much I could do really. 10:16 10:16

16 Q. You didn't get to speak to any of the medical?

A. No, that was one of my complaints in the letter, like you know. That's one of my suggestions, don't be leaving it to the Admin Staff. Obviously they were the barrier to, I suppose, get rid of people and not get near the consultants. But surely it could have been delegated to a Junior Doctor or somebody, a nurse, anybody, just to sort of say anything, I don't know. 10:17 10:17

17 Q. How did you feel? You described you thought you were being fobbed-off, how did that make you feel?

A. It was just a bit helpless. You're just kind of like, what do you do? You're speaking to your GP and stuff and obviously they are supportive and things, but they just issue painkillers and things and stuff. But then, you know, I didn't want to take so many of them because obviously they put stress on other organs and things 10:17

and stuff. I later found that taking ibuprofen like, they're not good for the kidneys because they're anti-inflammatories, I'm not pronouncing that properly. But yeah, Amoxicillin and just throwing that stuff, but that's the bog-standard antibiotics that anybody gets. 10:18

But then that's when I got worrying about the whole infection and stuff, because is it because of the overuse of antibiotics then this is going to lead to some kind of superbugs and stuff? And then obviously 10:18 in hospital I had to get these different strengths, they weren't working, the normal stuff, and then it's just Tazocin and Meropenem and these kind of ones and I have been told they're quite strong ones and whatever. So it was kind of like, these better work. Like what 10:18 happens if they don't, sort of thing.

18 Q. You actually ended up back in hospital as an emergency because?

A. Hmm.

19 Q. And how long had the stent been in at that stage? 10:18

A. Well, that was the end of March. And what was it, the start of August when I got admitted that time. Yeah, two-o-one, 6th August, five months later or so.

20 Q. So instead of what you understood, that the stent would come out in six weeks, it was five months later? 10:19

A. It was five months, yeah.

21 Q. And it was still in?

A. Still in there, yeah. And it was only until I was just so unwell, I can remember that. I think it was a

Response to Letter of Complaint from Patient 84

In responding to the letter of complaint from Patient 84, I firstly emphasise that I have much sympathy for him.

It would appear that Patient 84 had haematuria assessed in 2002 and 2003 when he was found to have renal calculi associated with a left hydronephrosis, and for which reason he may have later undergone ureteroscopy in 2007. Having reported recurring right lower abdominal pain, his GP requested a plain radiograph of his urinary tract and which was performed on 25 September 2015. It was reported on 17 November 2015 that he probably had bilateral renal calculi and a probable right upper ureteric calculus. He was referred to our Department, four months later, on 29 January 2016. Upon receipt of the referral, Mr. Glackin wrote to the patient, advising that he had requested a CT scan of his urinary tract and requested that an appointment be arranged for Patient 84 to attend the Stone Clinic at Craigavon Area Hospital. A not uncommon occurrence, he was offered an appointment at the Stone Clinic on 04 March 2016 and prior to the diagnostic CT scan being performed on 22 March 2016. Whilst the bilateral renal calculi were evident on the XRay of the urinary tract performed on the 04 March 2016, the right ureteric calculus was not. On renal ultrasound scanning on 04 March 2016, he was reported to have gross right hydronephrosis and hydroureter. When Patient 84 did have CT scanning performed on 22 March 2016, he was found to have a stone located in the upper third of his right ureter, and associated with severe right hydronephrosis which appeared to have been of long-standing as it was associated with marked loss of cortical tissue. It also reaffirmed the presence of several calculi in both kidneys.

I am not familiar with the communications regarding his admission to hospital on Sunday 27 March 2016 as I do not recall being involved. If I had been personally involved, I would hope that there would have been a greater awareness by other staff of his impending admission, though the best of efforts have not guaranteed that in the past. I do believe that it was correct to have him admitted on Sunday 27 March 2016, if it were hoped to be able to perform ureteroscopy on an emergency list on Monday 28 March 2016, as there may well not have been a bed for him on the morning of intended surgery. Rather than there being a serious lack of communication, I believe

that this is one example of too much wrong communication from those who may not be there the following morning.

Patient 84 had right ureteric stenting performed on 28 March 2016 following ureteroscopy and migration of the obstructing stone into the hydronephrotic right kidney. Another example of wrong communication is the advice, information or assurance that Patient 84 claims to have been given that the stent would or should be removed during or after six weeks. In almost 25 years as a consultant urologist, I have never, ever committed myself to perform a procedure within any particular time unless I have actually fixed a date. However, during those 25 years, such commitments have been given to patients on numerous occasions by junior staff who have never once seen a waiting list.

In my view, it would have been ideal or optimal for Patient 84 to have had his stent removed and to have had ureteroscopic lithotripsy two to four weeks later as stent-induced, ureteric relaxation by then would have been adequate to permit ureteroscopy. If it had been possible for Patient 84 to be readmitted after such an interval, then all of his subsequent morbidity would have been avoided. It is in that regard that I have complete empathy for him. Unfortunately, that was not possible as he was then competing for readmission with scores of other patients waiting for longer periods with similar priorities.

In my defence, I have been entirely aware of the morbidity, sometimes serious, associated with ureteric stents since the 1980s. Most substantively, I have used every available, additional operating session during those months in an attempt to reduce the waiting times for patients in similar situations, and have done so without remuneration. As a consequence, the total number of patients on my inpatient waiting list has been reduced from 275 on 28 April 2016 to 232 on 13 October 2016. Unlike Patient 84 or my colleagues whose sessions I used, I did not have any family holiday during that time. To some degree as a consequence, I have not had the time to read every email sent to me each day, never mind resolve the issues raised.

An email was sent to me advising me that Patient 84 had a holiday Personal Information redacted by the USI booked from Personal information redacted by the USI and that he was wondering whether he could have his surgery performed before then. I was unable to facilitate that request. I did not read the email of the 05 May 2016 requesting that I contact Patient 84 to give him advice concerning his stent while on holiday. I did read the

email of 17 June advising that Patient 84 had had urinary infection and requesting his admission as soon as possible. Once again, other patients in an identical situation were waiting longer to have the same procedure. I was unaware that I had ignored numerous calls made by Patient 84

I have tried my very best to contact and communicate with as many patients as possible but have found it physically impossible to contact all of them. It is necessary to contact patients during their waking hours. Contacting and communicating with patients during their waking hours has resulted in administrative work being displaced to their sleeping hours, and rendering it all the more difficult to complete that work, even with the use of most of my supposedly free time.

More importantly, with a total of 232 patients awaiting inpatient admission, 136 of them categorised as urgent, it has been impossible to facilitate all patients, enquiring about and seeking admission, irrespective of the gravity of the indication. However, recently circulated data has revealed that four of my consultant colleagues have had totals of 29, 77, 59 and 41 patients awaiting inpatient admission. Indeed, the total number of patients of those four colleagues awaiting urgent admission was 131 on 13 October 2016, less than the number of patients awaiting urgent admission on my waiting list. It is my view that these figures portray such a disparity in the fortunes of patients on different waiting lists as to render that disparity indefensible.

Patient 84 suggested that a 'window' be established each day to phone patients with urgent concerns. This could well be considered an attractive and practical proposal for those who have such relatively small cohorts of patients from whom concerns may be received. I believe that it would be more profitable to pool operative resources to ensure that such patients are admitted after the shortest period possible, thereby minimising the need for any such window of communication,

Aidan O'Brien.

16 October 2016

that was for me a huge bonus just, you know, the quality of life and all that after that and stuff, just to be able to get on with things. So after that, that will take its due course or whatever.

28 Q. You did get then the response on the 1st or dated the 1st of December. You weren't happy with that? 10:24

A. No. It was, I just sort of felt, they focussed on the wee smaller parts and really didn't really deal with the main issue of the communication and the plan and stuff. 10:24

They sort of focussed on wee things that I did, in fairness mention in the letter about admission times and communication and that kind of stuff, but for me that's fine, that's not the end of the world you know like. Things get misplaced and whatever like. But it was the over, yeah, they just didn't address the main concerns. 10:24

Obviously then they brought in the cancer patient stuff and, you know, while obviously I have sympathy with them, life-threatening conditions and things, but that wasn't, I suppose you shouldn't be made feel guilty. All the more reason for me to, get me dealt with and then you can focus your time and efforts and energy on those people that need it and stuff like. But yeah, it just seemed a bit of a sort of a weak argument. 10:24 10:25

29 Q. Can I just check, you say that once the stent was removed that your quality of life improved. Can I just

Saturday, I felt pretty - but again, I thought it was because I was getting lack of sleep and that kind of stuff. But yeah, Sunday, I remember just feeling real lethargic and I couldn't barely move and stuff and I said, I need to go to hospital here and stuff. And that's when I got tested, white blood cell count and the CRP count are, obviously the infection markers, and there was an infection there kind of thing, so. 10:19

22 Q. Just in terms of your stay in the hospital and how you were treated, is there anything you want to tell the Inquiry about that? 10:20

A. No. Once I went in in August, they were great like. No, just real helpful and, yeah, good at their jobs. Just got it sorted like and stuff. No, no complaints there at all. I thought they were very good. 10:20

23 Q. And what would you say then is the major complaint that you have? I know the letter is there and, as I say, we have read it. But what would you say your major complaint would be?

A. It was that communication again, just back to that communication, just to be able to speak to a medical professional and stuff and just being some kind of plan, just a commitment, this is going to get sorted. 10:20

I just feel I was being fobbed-off and things, and obviously they mentioned about the cancer patients and that stuff. Obviously you would think they are priority and whatever, but I just thought why not, I was a quick one, I was someone that could have been 10:20

getting pretty worried at that time because I thought, you know, they were saying that obviously your kidneys, that kind of sump were sort of stagnant, sort of stuff setting in there, that leads to blood poisoning and septicaemia and whatever. So that when I get admitted that is when I was sort of, yeah, I was getting concerned like.

40 Q. And they treated you with further antibiotics and fluids. You didn't need another procedure of any sort?

A. No. It cleared up through the Meropenem, whatever, and stuff like there, yeah. 10:34

41 Q. Right. Okay, thank you.

A. No, the care was good there. Like I was grateful and, yeah, it got sorted.

42 Q. So okay, coming back in time, you partly answered this before about communication and things, so you have mentioned that you would have liked to have spoken to either Mr. O'Brien or one of his junior staff, or one of the middle grades. How do you think that might have changed things, how did you envisage? 10:34 10:35

A. Just to give me the reassurance that I was being looked at and that they had a plan and that it was imminent or whatever, or just some, just a personal touch. Just to say, look, you know, I'm under pressure, I'm trying to do this here, my hands are tied. You know, just that there something planned really and that I was being sort of acknowledged. I just felt like a bit of a nuisance and stuff phoning up all the time and whatever, you know. 10:35

43 Q. By "plan" you mean?
A. A plan as to how I was going to get, how I was going to get the removal, the stent removal essentially.
44 Q. Okay.
A. And maybe just a medical person to just reassure me that it's fine, do this, you know. I kind of knew to keep up the water uptake and that kind of stuff. But yeah, I suppose a bit of a reassurance at that time in the earlier days and then just to have an idea of when I was going to be seen. 10:35
45 Q. That's what I was sort of hinting at.
A. Yeah.
46 Q. But I wanted you to tell me, so a date for the proposed procedure is really what you wanted?
A. Yeah, that's everybody - yeah, that's what you want, isn't it. You want the sort of, yeah, when can I, when will this thing come out? 10:36
47 Q. Thank you. And continuing with that theme, if you could have had your stone removal and stent removal earlier but by a different surgeon within the same Trust, I mean would that have been acceptable to you? 10:36
A. Yeah. Totally. Yeah. No issues at all who does it like. Yeah, no, it didn't matter. That was something at the time I remember I was phoning the secretary and they said they only do surgeries on a Wednesday or something. Was it a Wednesday, or a Wednesday afternoon or whatever? And then they were saying there is a big backlog of so many hundred patients. 10:36

Chris Wamsley

SHSCT GOVERNANCE TEAM (IR2) Form -NEW June 2018

Incident Details
ID & Status

Incident Reference ID	Personal Information redacted by the USI
Submitted time (hh:mm)	17:17

Incident IR1 details

Notification email ID number	Personal Information redacted by the USI
Incident date (dd/MM/yyyy)	17/11/2014
Time (hh:mm)	14:00
Does this incident involve a patient under the age of 16 within a Hospital setting (inpatient or ED)	
Does this incident involve a Staff Member?	
Description Enter facts, not opinions. Do not enter names of people	Patient was waitlisted for removal of ureteric stent on 17/11/2014, This request was registered in the book in stone treatment centre. A green booking form was also filled in at the same time. But this was overlooked. Patient had to have the stent in unnecessarily too long.
Action taken Enter action taken at the time of the incident	He was reviewed in clinic today and realised that the stent was still ins itu. Arranged to remove the stent only today.
Learning Initial	
Reported (dd/MM/yyyy)	30/03/2015
Reporter's full name	Kothandaraman Suresh
Reporter's SHSCT Email Address	
Opened date (dd/MM/yyyy)	14/04/2015
Last updated	Martina Corrigan 09/07/2015 12:32:31
Has safeguarding been considered?	
Were restrictive practices used?	
Name This will auto-populate with the patient/client's name if the person-affected details have been entered for this incident.	Patient 136

Location of Incident

Site	Craigavon Area Hospital
Loc (Type)	Clinical Area
Loc (Exact)	X-ray Dept (Radiology)
Directorate	Acute Services
Division	Surgery and Elective Care
Service Area	General Surgery
Speciality / Team	Urology Surgery

Staff initially notified upon submission

Southern Health and Social Care Trust

APPENDIX 4
Revised November 2016 (Version 1.1)

INCIDENT REVIEW

SECTION 1

1. ORGANISATION: **SHSCT**	**2.** UNIQUE INCIDENT IDENTIFICATION NO. / REFERENCE: Personal Information redacted by USI
3. HSCB UNIQUE IDENTIFICATION NO. / REFERENCE:	**4.** DATE OF INCIDENT/EVENT: Personal Information redacted by the USI
5. PLEASE INDICATE IF THIS SAI IS INTERFACE RELATED WITH OTHER EXTERNAL ORGANISATIONS: No	**6.** IF 'YES' TO 5. PLEASE PROVDE DETAILS:
7. DATE OF SEA MEETING / INCIDENT DEBRIEF: 21 August 2018	

8. SUMMARY OF EVENT:

Patient 91 attended Craigavon Area Hospital (CAH) Emergency Department (ED) on Person March 2018. The impression was an infected obstructed left urinary tract. A computerized tomography scan (CT scan) of the urinary tract on Per March 2018 reported an '*obstructing left sided ureteric renal calculus with proximal ureteric dilatation and associated moderate hydronephrosis. Imaging findings have not changed dramatically since the previous study, thus an acute on chronic deterioration is most likely*'. Patient 91 went to emergency theatre for a cystoscopy and insertion of a left ureteric stent. Medical notes report Patient 91 recovered well on the ward. Patient 91 was commenced on antibiotics and was discharged home on Per March 2018 with a plan for follow up in 6 weeks for ureteroscopy and laser (URS). Standard management of infected stones is insertion of temporary stent and treatment of sepsis infection followed by planned definitive stone fragmentation. Patient 91's planned treatment was ureteroscopy and laser fragmentation of stones.

On the Person March 2018 Patient 91 attended CAH ED and was admitted to a medical ward and was treated for acute kidney injury and a urinary tract infection. Patient 91 was discharged home on Person March 2018 with the plan for follow up with urology as previously planned.

On the Personal Information redacted by the USI Patient 91 was admitted to CAH for a planned left ureteroscopy. The findings noted were an impacted stone in the proximal ureter. The stone was fragmented and 100% was removed. The stone was sent for analysis. Flexible pyeloscopy showed no stone. A 6Fr x 24cm JJ stent was inserted. The plan was for admission overnight and home tomorrow if well.

Patient 91's condition deteriorated post operatively. Patient 91 and was transferred to the intensive care unit (ICU). While in ICU Patient 91 required escalating inotropic support but despite aggressive intensive care management, Patient 91's condition continued to deteriorate. Following discussion with Patient 91's family a do not actively resuscitate (DNR) was put in place. Patient 91's death was confirmed on Personal Information redacted by the USI.

Patient 91 was discussed with the Coroner and an unsigned death certificate was agreed with the cause of death recorded as:
I a. Multi-organ failure due to myocardial infarction, Sepsis due to
c. left ureteroscopy for renal stone.

Received from Wendy Clayton on 08/07/2022. Annotated by the Urology Services Inquiry.

3. Complaints & Compliments
    a. New complaint for investigation H&C [redacted]
    This case highlighted the need for the operating surgeon to make a plan for the removal of a ureteric stent at the time of insertion. All agreed that the surgeon placing the stent is responsible for auctioning the removal in a timely manner. There is no agreed trust protocol in place for this scenario.
    Various suggestions were made as to how to manage this situation but no consensus was reached at this meeting. Further work is needed.

4. Learning from SAI's, DATIX etc.
    a. nil

5. Audits.
    a. Audit of waiting times for surgery of patients with indwelling ureteric stents. Mr Hiew and Mr Young.

6. Any other business
    a. [redacted]
    b.
    c.
    d.
    e.
    f.

7. Next meeting Tuesday 17 September 2019 PM

Received from SHSCT on 19/05/2022. Annotated by the Urology Services Inquiry

made that a better process for you?

A. For the complaints process? Hmm, I suppose I was okay with the holding letters. I sort of expected that thing and obviously they were considering their response and stuff and that kind of thing. Because 10:29
obviously they had to polish up Aidan, or Mr. O'Brien's response a bit and whatever and that kind of thing and it took a bit of time. But yeah, maybe they should have got back sooner or something like.

10:30

But I didn't really have a lot of complaint about that. My experience was the communication between, you know, getting the stent and getting admitted to hospital in August. That was my, yeah, it was the communication then. That would be my suggestion for the Trust and 10:30
not relying on Admin Staff to provide that, you know.

And I think they have improved since because I have had discussions, you know, they have been very responsive and they have been sort of telling me every step of the 10:30
way and phone calls. So they have obviously reacted to some of these things.

34 Q. So who has been ringing you then more recently?

A. Well part of Mr. Young's Stone Clinic, so that's all the people with kidney stones and things go there. So 10:30
the likes of Mr. Young, or delegated part of the staff, or whatever, a medical person, there is a nurse phoned me as well. And so obviously they're...

35 Q. So you think they have learned from that?

A. I think they have, yeah. It sounds like they have reacted to that because I never would have had that before. So, yeah, that's what was missing that time, just letting me know that there was a plan in place and you're going to be dealt with, and being able to speak to a medical professional and stuff. 10:31

36 Q. In your letter to the Complaints Department you mentioned the cancer demand and being made to feel guilty about that?

A. Yeah. 10:31

37 Q. How do you feel about that now that things have progressed a bit more?

A. Yeah, well I suppose I had sympathy for them because, you know, I'm sort of young and fit. I had sympathy for those people that are waiting for those kind of things if they were under the same timelines as I was. So I was always aware that people are worse-off than yourself, kind of thing. 10:31

But yeah, as I said, I just thought they could have dealt with me, just to be done with me, quick win, get rid of me, let's focus on the people that maybe need help over a longer period of time, like these cancer patients and things. So, yeah, I had sympathy for them. Because I always thought that if I had been older or in poorer health, you definitely wouldn't have wanted to be waiting that long with what I experienced and things. Because as I say, luckily I was classed as young and fit or whatever like, but yeah, it would be a 10:32 10:32

seemed to be some kind of, as I alluded to there, there seem to be changes there, they seem to be doing things better and I think they need to do that. They just need to dedicate more time to the patients and things and have that medical staff to sort of chat to the patients and set time aside. 10:48

I know Mr. O'Brien says, oh, that's nice in an ideal world and that, but that should be an important part of his job and find the time for that or whatever. I just don't understand that one day-a-week sort of thing to do surgeries, you bring more people in, then if that's only the one day, what are you doing with the other four days? I don't know if it's a resource issue or whatever. I just think the patient communication could be better and sort of give plans. 10:48 10:49

He says there about his 25 years, he has never committed, maybe he should have, you know, and had those dates and stuff so that the patient feels that they are being listened to and dealt with and looked after, and basically just get on with their day-to-day life and that kind of stuff. So, yeah, there's definitely things there to be learned. I am sure that will come out of your Inquiry and whatever. But, no, that's about it really as far as myself. 10:49 10:49

CHAIR: Thank you again, [redacted]. It's been very helpful for us to hear first-hand your account of what occurred in relation to you. So we very much

5.0 DESCRIPTION OF INCIDENT/CASE

02 April 2015 – Discharge Notification. " ..... admitted under the care of ConsUrol13.... into 3 South Elective Ward ..... on 31/03.2015 ....." .

02 April 2015 – handwritten in clinical notes. Ward Round ConsUrol19 / ConsUrol13 noted, "*Care taken over by ConUrol11 ..... (referral by ConsSurg9) ..... ConsUrol13 will keep patient."* This is thought to mean that it was decided that care of patient remained with ConsUrol13. The previous 4 entries are taken to indicate that ConsUrol13 assumed the overall care of Patient 16 at or around the 31 March 2015.

02 April 2015 – discharged; discharge letter sent to GP and was to be copied to Mandeville Unit (CAH) stating, "*Urology to be contacted when chemotherapy is completed so that stent removal/change can be planned."*

02 April 2015 - Patient 16 added to ConsUrol13 Urgent waiting list. Date for this (noted below) was October 2015. However, was finally admitted 29 June 2016.

10 August 2015 - reviewed by ConsSurg9; the clinic letter notes '*He is feeling very well. He is coming to the end of his palliative chemotherapy'.*

27 August 2015 - at Oncology clinic; noted an improvement in the CEA tumour marker, but chemotherapy was complicated by extravasation. It was decided to proceed with Capecitabine only for the final two cycles.

08 October 2015 - Chemotherapy completed. Letter from Consultant Oncologist 2 (ConsOnc2) to GP and copied to ConsSurg9, but not to a Consultant Urologist.

26 November 2015 - letter dictated (typed on 27th) by ConsOnc10 to ConsUrol13 and copied to ConsSurg9, regarding ureteric stent change, " *... has undergone a 6 month course of palliative chemotherapy ..... I would be grateful if you could consider if this would be an appropriate time to arrange change of his stent*".
This was date stamped in the CAH chart 11 December 2015 but there is no Consultant note/signature/handwriting evident on letter.
Copy of same letter in the DHH chart is initialled by ConsSurg9 with a hand-written note, '*file' and '? review date'.* There is an additional note in red ink, '*Due 02/16 already on OPD sorted'.*

30 November 2015 email to ConsUrol13 from his secretary '*Patient 16 was ringing this morning regarding his change of left nephrostomy drain..."*

30 December 2015 – email to ConsUrol13 from his secretary, "*The above patient is on your planned w/l for removal of left ureteric stent, ureteroscopy and ? restenting – October 2015. Patient 16 's daughter was ringing this am regarding a date for her father's surgery. She advised that her father is experiencing pain and would appreciate a date for his surgery as soon as*

From: O'Brien, Aidan <Personal Information redacted by the USI>
Sent: 28 June 2016 01:39
To: Corrigan, Martina
Cc: Elliott, Noleen
Subject: RE: ** Urgent ** CAH Main Theatre Lists Tuesday 28th June until Friday 1 July 2016

Martina,

I find this situation to be quite unacceptable.
I spent almost all of last Thursday rigorously reviewing all 275 patients on my inpatient waiting list, as of 28 April 2016, allocating categories of five categories of urgency to them, as opposed to the inadequate two categories formally allocated.
In doing so, I equated Red Flags patients, those cancer patients who have no Red Flag status, those with indwelling stents for up to two years, those with indwelling catheters for over two years whilst trying to accommodate in some equitable fashion those who have been pleading through various channels, including your own, to have their admissions expedited.

In doing so, I accommodated Patient 130 Patient 130 has had a stent in her right ureter awaiting replacement since 20 July 2014.
She is a brittle diabetes, is on haemodialysis four times weekly in Tyrone County Hospital which has been requesting for months that it be replaced due to recurring infections.
I contacted the staff of the Renal Unit at Tyrone County Hospital to request that they reschedule her haemodialysis from Wednesday morning to this morning which they have accommodated.
They have arranged at my request to do up to date blood tests before this morning's haemodialysis, and after, so we will not have to repeat them as her peripheral access is poor.
They have arranged transport for her, at my request, to ensure that she is back home by 1 pm today.
On Friday last, I contacted the GP Practice manager who has arranged for her to be picked up by ambulance at 2 pm to bring her to Ward 3 South this afternoon.
On the assumption that she will be able to go home on Thursday, The Renal Unit have arranged to reschedule her haemodialysis to Friday and Saturday morning.
Yet Patient 130 is not a Red Flag patient!

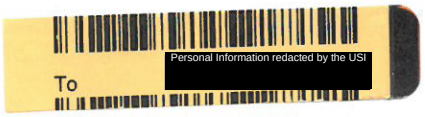
Patient 16 has had a stent in his left ureter for relief of left ureteric obstruction due to metastatic bowel carcinoma since 02 April 2015.
He has been awaiting its removal, reassessment of his left upper tract and possible replacement since then.
His oncologist, Dr. Harte, has requested that his admission be expedited due to increasing back pain attributed to it.
But Patient 16 is not a Red Flag patient either!

I could go on but I do not have the time to do so in the early hours of the morning.
I have already invested many hours in selecting and arranging in detail the admissions for surgery on Wednesday.
At this point in time, I do not have the stomach to contact people tomorrow to renege upon the commitments I have entered into with them.
And I do not wish to have anyone do so on my behalf.

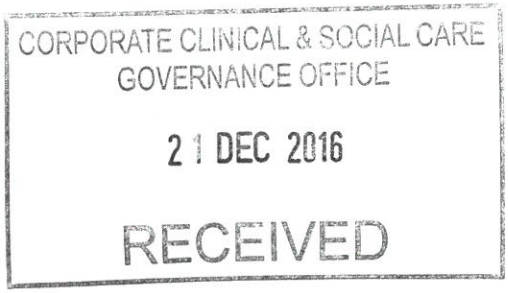
The last patient on my list, Personal Information redacted by the USI fell Personal Information redacted by the USI one month ago, severing his urethra, which I realigned, since when he has both suprapubic and urethral catheters in situ.
He will be attending his daughter's graduation tomorrow at 11 am.
He agreed to forego the graduation lunch to be admitted in the hope of being able to have catheters removed.
But he does not have any flag at all!

As I have said before, we cannot continue like this.
From now on, I will not,

Received from Tughans OBO Mr Aidan O'Brien on 12/05/2022. Annotated by the Urology Services Inquiry



Personal Information redacted by the USI



05/12/16

REF: Patient 16 Personal Information redacted by the USI

Personal Information redacted by USI

H&C: Personal Information redacted by the USI

To whom it may concern,

I am making this complaint, on behalf of my father, after much consideration and having discussed our concerns with involved personnel. It centres on the poor response to communication between the Oncology and Urology departments in Craigavon Hospital and the consequences of this which include; unnecessary suffering and denied access to a treatment option for cancer.

My father was diagnosed with bowel cancer in July 2012. He was referred to Oncology and in 2014 Chemotherapy was identified as a treatment option. Prior to the commencement of this treatment a stent was inserted into the left kidney in March 2015. We were informed at this point in time that the stent would be due for removal directly after the treatment ended as it's life span was 6 -9 months. Chemotherapy finished in November 2015 and my father was advised that arrangements would be made with Urology to have the stent removed. However, this did not happen and during follow-up reviews with the oncologists and surgical consultants the need for it to be removed was acknowledged and assurances given that letters would be written to various personnel in the Urology department. Meanwhile, for the next 6 months, my father suffered from a range of complications synonymous with a stent in place too long including; significant pain and persistent urinary tract infections. We continued to advise oncology personnel, our GP and the local Macmillian nurse of the increasing difficulties he was experiencing and again we were assured that these concerns had been passed on to Urology. In increasing desperation we began to ring Mr O'Brien's secretary in an effort to have the procedure completed.

In April 2016 during a review appointment in oncology the option of a short course of radiotherapy was raised. My father agreed to proceed with this but was made aware that first the stent would

need to be removed. In June 2016 dad received a phone call from the oncologist stating that he had viewed the latest scan results and radiotherapy was definitely a way forward. On the same day dad received a phone call from the urologist informing him of the arrangements for the removal of the stent three days later. We were bewildered about the apparent urgency, after such a long wait and wondered had something shown up on the scan. Dad attended Craigavon on the 28th June 2016 for the procedure; at this point the stent was in place for 15 months.

The procedure, which we understand generally takes about 30 minutes, took over two hours. The kidney was significant distended and the stent was encrusted and dislocated. Indeed I am aware that research suggests that the amount of stent encrustment is directly related to how long it has been in place. The aftermath was horrendous. Dad was very ill due to septicaemia and had to remain in hospital for 12 days. We were extremely upset and discussed our concerns with personnel in urology. We decided not to proceed with a formal complaint at the time, as we hoped that communication between the two departments would improve. Three weeks later there was further telephone correspondence from another oncologist advising dad that he was about to a make arrangements for him to attend the radiology department in the City Hospital to have initial measurements taken. It seems that this course of action was to be delayed for a short period, following consultation between the urologist and the oncologist, as a new stent would first have to be inserted. This happened in August 2016 and we immediately advised oncology that the stent was in place and we were on course again for radiotherapy. The next meeting with oncology was in September 2016. Dad was advised that it was deemed appropriate for a further scan to take place and he agreed to the deferral of the treatment until this was secured. It was with utter dismay at the next meeting on 1st December (13 weeks later) we learnt that this course of treatment was no longer an option as the disease had progressed. At that meeting I asked why the radiotherapy did not take place as planned in June, when the scan at that time indicated that it was feasible. I do not believe that I was given any clarification on this issue. In addition, when the oncologist was asked about the time delay between the scan and the review appointment he apologised but said it was 'out of his control'.

In summary, I believe that the delay in the removal of the original ureteral stent is undeniably linked to the removal of cancer treatment options for my father. I know that he has suffered unnecessarily as a result of the lack of response to communication from various sources to urology. Finally as a family we had the unenviable experience of dealing with a mother and father diagnosed and undergoing treatment for cancer at the same time. Ironically the experience of both parents is startlingly different. My mother [redacted] and was under the care of the South Eastern Trust. There were a number of departments involved in her surgery and aftercare, both within the trust and outside it. The co-ordination of services was seamless and communication between departments immediate and transparent. She receives regular follow up review appointments where both oncology and her surgical consultant are present and she has access to a superb advocacy service provided by the Head and Neck nurse.

PAT-000133

Southern Health and Social Care Trust

19 April 2017 **Our Ref:** AS312.16/17 **Your Ref:**

Private & Confidential

Patient 16's Daughter
Personal information redacted by USI

Dear Patient 16's Daughter

I refer to your complaint in respect of the treatment and care your late father Patient 16 Patient 16 received whilst attending Urology and Oncology departments at Craigavon Area Hospital, please accept my condolences. Thank you for taking the time to highlight your concerns.

The Trust has reviewed the care of your father Patient 16 and feels further investigation under the SAI process is required.

As is normal practice and is part of this process, the Trust has notified the Regional Health and Social Care Board of our intention to undertake this review and we will be happy to share with you the findings of this report in due course.

Upon completion, the findings of the report will be forward to you. The member of staff co-ordinating this review is Mrs Trudy Reid, Lead Nurse for Acute Governance and she can be contacted on (Personal Information redacted by USI if you wish to discuss this matter further.

Yours sincerely
Personal Information redacted by USI

Mrs Esther Gishkori
Director of Acute Services

enc

Clinical and Social Care Governance Team
Directorate of Acute Services
The Maples, Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by USI
E-Mail: Personal Information redacted by the USI

PAT-000134

Southern Health and Social Care Trust

26 October 2017 **Our Ref:** Personal Information redacted by USI **Your Ref:**

PRIVATE AND CONFIDENTIAL

Patient 16's Daughter
Personal information redacted by USI

Dear Patient 16's Daughter

Further to your telephone call on 4 October to the Governance office. I wish to advise you the SAI investigation is still ongoing a further meeting took place on 24 October 2017 and we are arranging another meeting for 28 November 2017.

Unfortunately at this stage we are unable to provide you with a timeframe for the completion of the investigation but wishes to advise you that we will contact you upon the completion of this report and provide you with a copy.

Yours sincerely

Personal Information redacted by USI

Mrs Trudy Reid
Acute Governance Coordinator

Clinical and Social Care Governance Team
Directorate of Acute Services
Craigavon Area Hospital, 68 Lurgan Road, Portadown, BT63 5QQ

Telephone: Personal Information redacted by USI

King, Dawn

From: Farrell, Roisin
Sent: 31 October 2018 16:27
To: Patient 16's Daughter
Subject: FW: AS312.16/17

Dear Patient 16's Daughter

Further to your email below, I wish to apologise for the distress this process has caused and regret the oversight in updating you of our progress.
The review team have almost completed the draft report and is with the chair for review.
The draft report will then be presented to senior medical and management staff for review and to ensure they are aware of the findings.
Once again please accept my apologies for the delay and not keeping you updated.
I anticipate the report should be ready in January.

Kind Regards

Roisin Farrell

On behalf of Trudy Reid
Clinical & Social Care Governance Team
Directorate of Acute Services
The Maples
Craigavon Area Hospital

Extension Number Personal Information redacted by USI

From: ClientLiaison, AcutePatient
Sent: 31 October 2018 11:05
To: Farrell, Roisin
Cc: Reid, Trudy
Subject: FW: AS312.16/17

From: Patient 16's Daughter
Sent: 30 October 2018 19:58
To: ClientLiaison, AcutePatient
Subject: AS312.16/17

Hi Trudy,

I am forwarding this email to request an update regarding a complaint (referenced above) lodged with your department in December 2016. It is almost two years since my father, Patient 16, passed away and we still have received no report from the SAI or indeed any correspondence since February 2018. My family is becoming increasingly dismayed with the time lapse and are considering taking legal advice regarding this matter.

Regards,

Extension Number [Personal Information redacted by USI] [Personal Information redacted by USI]

From: [Patient 16's Daughter]
Sent: 25 April 2019 22:38
To: ClientLiaison, AcutePatient
Subject: AS312.16/17

To whom it may concern,

I am requesting an update on the above referenced complaint lodged in December 2016 regarding my father, [Patient 16]. It is with utter disbelief that I am still having to initiate contact with your department to request information regarding this matter. It is incredulous that the investigation has not yet reached a conclusion. I feel that we have been very patient but our desire to get answers to our questions has not diminished over time. We are now extremely anxious to get closure on this issue as my mother has a [Personal Information redacted by USI] and so time is now of the essence. Therefore please do not provide me with the usual non-committal response that you are unable to provide me with a timeframe for the completion of the investigation.

Regards,

[Patient 16's Daughter]

King, Dawn

From: Farrell, Roisin
Sent: 16 May 2019 12:19
To: [redacted]
Subject: FW: AS312.16/17

Dear [redacted]

Mrs Kingsnorth has advised me the report has been completed and will be shared with the Acute Governance Meeting in June.
When approved I will post a copy of the report to you.
When you received the report if you wish to discuss any aspect of the report please do not hesitate to contact me and I can organise a meeting with the chair and facilitator of the review team.

Thank you once again for your patience.

Kind Regards

Roisin Farrell
Clinical & Social Care Governance Team
Directorate of Acute Services
The Maples
Craigavon Area Hospital

Extension Number [redacted]

From: Farrell, Roisin
Sent: 09 May 2019 09:52
To: [redacted]
Subject: FW: AS312.16/17

Dear [redacted]

Thank you for your email of 25 April.

I have forwarded your email to the relevant staff who will be in contact with you soon.

Thank you for your patience.

Kind Regards

Roisin Farrell
Clinical & Social Care Governance Team
Directorate of Acute Services
The Maples
Craigavon Area Hospital

Southern Health and Social Care Trust

APPENDIX 6

Revised November 2016 (Version 1.1)

Root Cause Analysis report on the review of a Serious Adverse Incident including Service User/Family/Carer Engagement Checklist

Organisation's Unique Case Identifier: [redacted]

Date of Incident/Event: 10/07/2016

HSCB Unique Case Identifier: [redacted]

Service User Details: (*complete where relevant*)
D.O.B: [redacted] Gender: (M) Age: (72yrs)

Responsible Lead Officer: Dr J R Johnston

Designation: Consultant Medical Advisor

Report Author: The Review Team

Date report signed off: 27 January 2020

[redacted]

5.0 DESCRIPTION OF INCIDENT/CASE

06 December 2016 - admitted to CAH; had an exchange of left nephrostomy tube, flexible cystoscopy, dilation of urethral stricture and removal of left ureteric stent by ConsUrol11 and was discharged on 8 December 2016.
Discharge letter to GP dictated by ConUrol11; copied to ConsUrol13.

09 December 2016 - admitted to DHH with a small bowel obstruction. His care was managed conservatively; he refused surgical intervention and following comfort care, Patient 16 died on [redacted] Personal Information redacted by the USI .

21 December 2016 – letter of complaint received in Governance Office, CAH from daughter; letter dated 05 December 2016. Complaint, "*centres on the poor response to communication between Oncology and Urology departments in Craigavon Hospital and the consequences of this which include; unnecessary suffering and denied access to a treatment option for cancer".*

6.0 FINDINGS

Summary of sequence of events

11 March 2015	CT scan detected a left sided pelvic mass, causing hydronephrosis.
12 March 2015	MDT meeting. ConsUrol11 requested to insert stent.
26 March 2015	reviewed at ConsUrol15 clinic.
26 March 2015	reviewed at Oncology clinic, proceed with Chemotherapy.
31 March 2015	admitted to CAH under care of ConsUrol13 and stent inserted. Operation note, "*Oncologists to contact when chemotherapy complete for stent removal / replacement".*
02 April 2015	discharged. "*Urology to be contacted when chemotherapy is completed so that stent removal/change can be planned."*
02 April 2015	added to ConsUrol13 Urgent waiting list.
23 April 2015	Chemotherapy started.
08 October 2015	Chemotherapy completed.
26 November 2015	**Letter, ConsOnc10 asks ConsUrol13 to consider changing stent.**
11 December 2015	date stamp letter received in Craigavon.
30 December 2015	email to ConsUrol13 from his secretary, on W/L for October 2015. Daughter rang regarding date for surgery.
21 January 2106	SpROnc14 to re-contact Urology. Copied to ConsSurg9, not Urology.
04 March 2016	email from audiotypist to ConsUrol13 secretary, query date for surgery.
24 March 2016	further letter from ConsOnc2 to ConsSurg9, not Urology. " ... has heard nothing further from Urology". Date stamp 5 May 2016.
09 May 2016	review by ConsSurg9; wrote to ConUrol11. "*Please see and review*

6.0 FINDINGS	
	Urological care. ..stent has been in now for about a 1½ year. *Could you perhaps review whether or not this could be removed/replaced?"*
10 May 2016	email to ConsUrol13 from his secretary, "*Patient ringing....current symptoms related to stent .....give him a date for removal."*
02 June 2016	letter from SpROnc14 to ConUrol11 requesting, "*your intervention to facilitate his ongoing oncological management".*
24 June 2016	email from ConsUro13 to his secretary, "*Please send letters of admission .... admission on 29 June 2016 as follows* Patient 16
29 June 2016	**admission. Operated on for stent removal by ConsUrol13.**

Therefore, after the original stent was inserted on the 31 March 2015 and the patient discharged on the 2nd April 2015, Chemotherapy could start, and the stent would then be removed or replaced 6-9 months later. The last dose of chemotherapy was given on the 8th October 2015 and the letter to ConsUrol13 was sent on the 26th November 2015, (typed on 27th November 2015).

The crucial period regarding any unnecessary delay in treatment and care in this case (as indicated between the entries above in bold) appears to be from the time the patient was deemed ready to have his stent removed or replaced i.e. 26th November 2015, and when he was finally admitted for his surgery i.e. 29th June 2016, a period of 217 days or 31 weeks. Also, did this delay remove a window of opportunity for a course of pelvic radiotherapy?

The 26th November 2015 letter to ConsUrol13 perhaps was not received in CAH until 11th December 2015. There is no evidence that he received and/or acknowledged the receipt of letter. The question is, "Did he ever receive i.e. see, this letter?"

A copy of the 26th November 2015 letter appears to have been received and acknowledged by ConsSurg9 who queried a review date. An entry in red ink (probably secretary) appears to indicate there was an OPD date of 02/16, presumably February 2016. No action seems to have happened following receipt of the 26th November 2015 letter.

An email was sent to ConsUrol13 on the 30th December 2015 indicating the patient was on a waiting list for October 2015 and patient's daughter rang regarding a date for surgery. There appears to be no record of a response to this email.

The next possible reminder to the Urology service was the 21/01/2016 letter. It is uncertain whether SpROnc14 contacted Urology. Letter was copied to ConsSurg9. The letter indicates that palliative radiotherapy was being considered. There is no apparent action taken at this time.

On the 4th March an email to ConsUrol13's secretary indicated the patient had requested a date to come in for removal of stent. There is no apparent action taken at this time.

Patient 16

6.0 FINDINGS

At Oncology clinic review on the 24th March 2016, ConsOnc2 sent another letter to ConsSurg9 indicating disease progression and that nothing further had been heard from Urology. This letter appears to have been typed almost a month later (22/04/2106) and not received in CAH until 5th May 2016. ConsSurg9 seems to have seen this letter.

ConsSurg9 reviewed Patient 16 at Surgical OPD on 9th May 2016 and has then written to ConsUrol11 on the 9th May 2016 asking him to review Patient 16's Urological care.

Then, on the 10 May 2016 a further email sent to ConsUrol13 from his secretary informing ConsUrol13 that the patient rang the office and asked for an appointment to have his stent removed. There is no apparent action taken at this time.

Further letter on the 2nd June 2016 from SpROnc14 to ConsUrol11 asking for his intervention to facilitate oncological management. Letter not copied to ConsUrol13. The Oncology team would consider IMDG chemotherapy once the stent is changed and if his urinary symptoms are stable. This letter, received on the 8 June 2016, has been acknowledged and annotated by ConsUrol11 on the 22 June 2016, which led to an expedited appointment for surgical intervention on 29 June 2016, 454 days after being listed and 217 days after chemotherapy had ceased.

Then, on 24th June 2016 email from ConsUrol13 to secretary requesting admission for Patient 16 on the 29th June 2016 for surgery.

Surgery on the 29th June 2016 proceeds with removal of the stent without replacement. The postoperative course is difficult with a period of urosepsis. Further surgery on 10th August 2016 when stent was inserted with much resistance. Followed by period of disease progression, further Urology surgery in December 2016 with terminal admission shortly afterwards. Patient died on [redacted] Personal Information redacted by USI

In relation to the possibility of missing treatment opportunities, Oncology have commented that with the benefit of hindsight, it is clear that palliative radiotherapy would not have affected the clinical outcome and could have been detrimental. [Source = Complaint response]

<u>Communication between Oncology service, Surgery and Urology</u>

The Oncology medical staff copied ConsSurg9 into GP correspondence. However, the Review Team noted that Urology was not always copied into all Oncology correspondence. On occasion, there was evidence of Oncology letters sent or copied to,

- ConsUrol13 on 26 November 2015, 23 July 2016 and 2 December 2016.
- SpROnc14 sent to ConsUrol11, dictated on 2 June 2016.

but on others it was not. It appears especially odd that on the 8th October 2015, when chemotherapy was stopped, Oncology wrote to ConsSurg9 but not ConsUrol13 who should

Southern Health and Social Care Trust

1.0 EXECUTIVE SUMMARY

Patient 16 was a 72-year-old man who had a history of metastatic colorectal cancer, small volume lung metastases and a left pelvic mass associated with ureteric obstruction. Patient 16 was considered for palliative pelvic radiotherapy in January 2016, but urology stents already in-situ required renewal prior to radiotherapy. There was a protracted delay in the management of the stents. In December 2016, due to disease progression, palliative radiotherapy was no longer considered an option for Patient 16. Patient 16 died on the Personal Information redacted by the USI Personal Information redacted by the USI

Causative Factor(s)

There was a treatment and care delay - specifically, to the changing of ureteric stents, due to,

1. Lack of effective communication systems and processes; and
2. Long Waiting Lists leading to delay.

The Review Team consider that the delay was probably significant in terms of,

- an easier progression through the process of having the stents removed and replaced;
- reduction in the level of pain and discomfort reported towards the end of life.

However, in relation to the possibility of missing treatment opportunities, Oncology have commented that with the benefit of hindsight, it is clear that palliative radiotherapy would not have affected the clinical outcome and could have been detrimental.

Recommendations

TRUST

Recommendation 1

The Trust will explore and evaluate methods of communication between clinicians; other than paper. This will be especially for 'visiting' clinical teams not based in the SHSCT and also especially when their clinic letters are not available on NIECR.

Recommendation 2

The Trust should develop written policy/guidance for clinicians and administrative staff concerning writing clinic or discharge letters, to ensure all clinical teams/clinicians, directly involved in the patient's care, are copied into the correspondence, especially if they are referred to in the letter.

Recommendation 3

The Trust will develop written policy/guidance for clinicians and administrative staff on managing clinical correspondence, including email correspondence from other clinicians and healthcare staff.

6.0 FINDINGS

secretary files. It is important that these letters in particular are filed because they are not on NIECR.'

Waiting List

Patients with urological conditions which affect the normal functioning of the upper urinary tract are at risk of losing kidney function and consequently renal failure. The duration of Urology waiting lists means significant numbers of patients are at risk of loss of renal function and consequently these patients are at a risk of requiring future renal replacement therapy. Duration of ureteric stenting is associated with progressively increasing risk of urosepsis, and its associated risk of death, as a post-operative complication. This risk has been quantified as 1% after 1 month, 4.9% after 2 months, 5.5% after 3 months and 9.2% after greater than 3 months.

Waiting times in Urology are long due to a demand & capacity mismatch. In June 2016, ConsUrol13 had 273 patients on his inpatient day case waiting list, with 158 on his urgent waiting list, 75 of these patients had been waiting over 52 weeks.

When Patient 16 was added to the urgent Urology waiting list in April 2015, the Urgent Urology Waiting list patients position on 30 June 2016 was,

0-13 Wks	13-17 Wks	17-21 Wks	21-26 Wks	26-31 Wks	31-36 Wks	36-41 Wks	41-46 Wks	46-52 Wks	Over 52 Wks
202	32	36	46	28	25	21	13	11	106

The longest patient waiting was for over 127 weeks with 6 patients waiting over 114 weeks and 18 patients over 100 weeks.

7.0 CONCLUSIONS

There was a treatment and care delay – specifically, to the changing of ureteric stents, due to,

1. Lack of effective communication systems and processes; and
2. Long Waiting Lists leading to delay.

The Review Team consider that the delay probably was significant in terms of,

- an easier progression through the process of having the stents removed and replaced;
- reduction in the level of pain and discomfort reported towards the end of life.

However, in relation to the possibility of missing treatment opportunities, Oncology have commented that with the benefit of hindsight, it is clear that palliative radiotherapy would not have affected the clinical outcome and could have been detrimental.

1. Lack of effective communication systems and processes

Contributory factors

Task Factors (policy and guidelines) / Communication

Communication between Oncology and other services can be by telephone in urgent situations but is mostly by letter which can lead to delay or omission in communication in relation to patient care. There were gaps of weeks to over a month between dictation, typing, sending, receipt and acknowledging of letters with action, such as addition to a waiting list, taking further time; followed by time actually waiting while on the waiting list.

Oncology letters were not on NIECR (Note: possibly this has now been rectified) and thus not accessible outside of patients' clinical notes for other clinical teams to access and use when planning treatment.

The Trust has no formal process for tracking letters or emails and ensuring they have been received, acknowledged, reviewed and actioned.

There were also many occasions when letters from Oncology which contained urological issues were not copied to Urology. On some occasions, when they did copy to Urology it was to ConsUrol11 and not the Urologist in charge i.e. ConsUrol13.

Contributory factor

Staff factor

The Review Team noted, throughout this case, the number of times that communication opportunities involving ConsUrol13 appeared to have been missed, resulting in Patient 16 s stent not being removed and/or replaced in a timely manner. Throughout this case, there were letters not received or acknowledged, emails not actioned and phone messages from the patient and family that also did not result in action.

2. Long Waiting Lists leading to delay

Contributory factor

Workload/scheduling

The Review Team noted that the long waiting times for Routine and Urgent Urology inpatient and day case treatment contributed in the delay in Patient 16 having his stent changed, and therefore a delay in decisions regarding palliative treatment.

8.0 LESSONS LEARNED

1. Communication between the Oncologists from the Belfast Trust and the Clinicians in the SHSCT was mostly by letter. This appears to be too inefficient with respect to timeliness, especially for potential cancer patients being investigated and cancer patients already on a treatment pathway. Correspondence can also become misplaced or lost especially if it comes in from another Trust.

Personal information redacted by USI

Recd 12/5/2020

Personal information redacted by the USI

05.05.20

To whom it may concern,

REF: SAI Patient 16 (Personal Information redacted by USI

The above referenced document was received on 3rd February 2020. I would now like to meet with the Chair and Acute Governance Facilitator to discuss the report. I am cognisant of the significant pressures all personnel within the HSC are under at the moment on account of the COVID-19 crisis and I fully understand that it is likely to be some time before this meeting can take place. I would also like to advise that I plan to request that a member of the Patient and Client Council be in attendance.

Yours sincerely,

Patient 16's Daughter

King, Dawn

From: Patient 16's Daughter
Sent: 29 December 2021 14:15
To: Acute Governance
Subject: SAI case no Personal Information redacted by

This message was sent from outside of the Southern Trust. Please do not click links or open attachments unless you recognise the source of this email and know the content is safe.

To whom it may concern,

I received the SAI report referenced above in February 2020 and I subsequently requested a meeting with relevant personnel. I received a phone call later that year from a Mr David Carson, who advised me a potential date for the meeting but as I explained to Mr Carson, I was unable to attend on the given date as I was caring for my mother Personal Information redacted by USI, at that time. I indicated that I would be most grateful if another date could be arranged. Since then I have received one phone call from the Governance team to advise me that there was going to be negative publicity about a Urology consultant, involved in my dad's care, in the the Southern Trust. I have had no further contact from the department despite reiterating to the lady who called that I wanted to proceed with the meeting. I understand that COVID has severely impacted on your service and the availability of meetings however I would be most grateful if you could make arrangements to set up a meeting at your earliest convenience, to review this report.

Kind Regards,

Patient 16's Daughter

A. No. No. So there were, you know, even reference, within the recommendations, I certainly would be in agreement with all of them and I think a lot of them in fact reflected the concerns and the expectations that we had. But, again, there were a lot of unanswered questions. 14:35

You know, I felt that the issue in relation to - they were very clear that there was no causal link as such between the stent not being taken out in time and his possible treatment options. I felt that that was a maybe something that could have been explored a little bit further. And they talk about hindsight which is a great thing, if we had all had access to that that would be lovely. We were getting a very different message from Oncology that this is definitely a treatment option, but we are very much tied, time-bound and like this, if we breach this it's not going to be an option clearly and that was something that... 14:35 14:35

So there were issues I felt that weren't explored and there were other issues that, as a lay person, I really struggled to understand and felt I could have done with clarification.

DR. SWART: If that was explained to you. Thank you very much. 14:36

CHAIR: Mr. Hanbury?

MR. HANBURY: Thank you for your compelling evidence. Just a couple of things, so I will take you back and

timeframe but certainly this is how the complaint is progressing, we need to speak with such and such, we're having a meeting. So there was definitely a lot of communication. But I suppose it was the time. I thought surely there has to be - this can happen within a better timeframe.

So I also had to, at that point, involve the Ombudsman and I felt that was whenever things started to move at a greater pace once that intervention happened. And I have to say, you know, the outcome of that, I respect the recommendations and if they were put in place I would be extremely content. But there was never an opportunity to discuss the findings.

14:25

14:25

14:26

And I certainly requested that in a meeting, and as you'll see from the documentation we were unfortunate at the time whenever we had actually both - [redacted] Personal Information redacted by USI [redacted] whenever the meeting; it was sprung upon me. I mean I was given a few days warning. And I said, look it, I can't accommodate that at the moment but certainly I really would appreciate - and it was only when I started to prepare for the filling in the questionnaire I realised, no, this still hasn't...

14:26

14:26

14 Q. You still have not that had?

A. I still haven't come to a closure in relation to that. And, again, that was pre-empted this time around you

know in preparation for today where I had to make further contact. So I feel that system, while the process is really good and very thorough, that the lack of communication, the lack of the families actually having an opportunity to see the response of the people involved to the initial complaint.

So, you know, I have obviously been able to view Dr. O'Brien's response and that has been very useful. But obviously there's a response from Oncology as well that we are not privy to. So there are certainly a few things in relation to that process that possibly could be improved as well.

15 Q. Just one other question: In terms of the SAI, you were told no one ever explained what those letters stood for?

A. Yes.

16 Q. And it certainly wasn't expressed fully in the letter that you received.

A. Mm-mm.

17 Q. Did anyone ever offer an explanation as to why it took so long from December 2016 when you complained, for the SAI to come out in January '20?

A. No, other than the communication that was via e-mail. There was a follow-up phone call more recently and it was on in and around the 29th of December. I certainly had a phone call from a gentleman and that was very informative and he was very much happy to accommodate a meeting and so on, but advised that I should set out a

sequence and did not have a standard and now you do.

But going back to the beginning, if you had the chance to sit down with senior people from the Trust and talk about them about what you would like as a family or a patient to happen in one of those investigations and how your involvement should be fed in, what would be some key messages from your perspective now that you have had the benefit of hindsight and knowing what it was all about? 14:30

A. I suppose whenever someone, it's navigating the system as well. So it is when you make the decision, as I said, it's with a heavy heart that you feel that you have to put your concerns in writing. It's having someone then to, it's navigating that system, it should be clear I think to begin with. So you're having to research how the Trust, how you do that as a lay person. Then I suppose it is that initial response to that, if someone could lift the phone and say, we have received that, this is how it will be looked at and this will be the possibility, there are a number of possibilities. 14:31

And as I say with the SAIs, it seemed such a serious kind of course of events to take that it was not something that I had anticipated. So it's having someone there to explain that and to advise of what that would entail. And it's just in relation to the timeframe of that as well, just to be kept updated. 14:31

You know, all it takes is someone to have on file, you know, it is three months that have passed, we'll just get back to that person who made the first complaint and advise that, you know, we are still working on this, you are still in our thoughts, but this is possibly, this has maybe held things up a little bit. It's all of that.

As you know, once you're kept in the picture people will accept and are much more understanding. It is when you're not informed and you feel that you're kept out of that loop. 14:32

20 Q. Would you like the opportunity to contribute to the Terms of Reference, for example?

A. Absolutely. I think that's certainly, when I look back at even the expected outcomes that I had in that original complaint, they are very much tied into the Terms of Reference here. So it's very clear from the outset what they were, you know, as an Inquiry what you're looking for. That would have been extremely helpful if we were advised why they had made that decision. 14:32

21 Q. And how did you feel when you read that report that Serious Incident Report, can you just tell me how that made you as a family feel? 14:33

A. Well first of all, obviously dad wasn't there. So that was the first thing. Because he was such, he's such a sense of understanding of all of that, that I know that he would have read that with great insight. So I'm

BMJ open
accessible medical research

A systematic review of evidence on the links between patient experience and clinical safety and effectiveness

Cathal Doyle,[1] Laura Lennox,[1,2] Derek Bell[1,2]

To cite: Doyle C, Lennox L, Bell D. A systematic review of evidence on the links between patient experience and clinical safety and effectiveness. *BMJ Open* 2013;**3**:e001570. doi:10.1136/bmjopen-2012-001570

► Prepublication history and additional material for this paper are available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2012-001570).

Received 18 June 2012
Revised 2 November 2012
Accepted 12 November 2012

This final article is available for use under the terms of the Creative Commons Attribution Non-Commercial 2.0 Licence; see http://bmjopen.bmj.com

[1]NIHR CLAHRC for North West London, Chelsea and Westminster Hospital, London, UK
[2]Department of Medicine, Imperial College London, Chelsea and Westminster Hospital, London, UK

Correspondence to
Dr Cathal Doyle;
c.doyle@imperial.ac.uk

ABSTRACT

Objective: To explore evidence on the links between patient experience and clinical safety and effectiveness outcomes.

Design: Systematic review.

Setting: A wide range of settings within primary and secondary care including hospitals and primary care centres.

Participants: A wide range of demographic groups and age groups.

Primary and secondary outcome measures: A broad range of patient safety and clinical effectiveness outcomes including mortality, physical symptoms, length of stay and adherence to treatment.

Results: This study, summarising evidence from 55 studies, indicates consistent positive associations between patient experience, patient safety and clinical effectiveness for a wide range of disease areas, settings, outcome measures and study designs. It demonstrates positive associations between patient experience and self-rated and objectively measured health outcomes; adherence to recommended clinical practice and medication; preventive care (such as health-promoting behaviour, use of screening services and immunisation); and resource use (such as hospitalisation, length of stay and primary-care visits). There is some evidence of positive associations between patient experience and measures of the technical quality of care and adverse events. Overall, it was more common to find positive associations between patient experience and patient safety and clinical effectiveness than no associations.

Conclusions: The data presented display that patient experience is positively associated with clinical effectiveness and patient safety, and support the case for the inclusion of patient experience as one of the central pillars of quality in healthcare. It supports the argument that the three dimensions of quality should be looked at as a group and not in isolation. Clinicians should resist sidelining patient experience as too subjective or mood-oriented, divorced from the 'real' clinical work of measuring safety and effectiveness.

ARTICLE SUMMARY

Article focus

- Should patient experience, as advocated by the Institute of Medicine and the NHS Outcomes Framework, be seen as one of the pillars of quality in healthcare alongside patient safety and clinical effectiveness?
- What aspects of patient experience can be linked to clinical effectiveness and patient safety outcomes?
- What evidence is available on the links between patient experience and clinical effectiveness and patient safety outcomes?

Key messages

- The results show that patient experience is consistently positively associated with patient safety and clinical effectiveness across a wide range of disease areas, study designs, settings, population groups and outcome measures.
- Patient experience is positively associated with self-rated and objectively measured health outcomes; adherence to recommended medication and treatments; preventative care such as use of screening services and immunisations; healthcare resource use such as hospitalisation and primary-care visits; technical quality-of-care delivery and adverse events.
- This study supports the argument that patient experience, clinical effectiveness and patient safety are linked and should be looked at as a group.

Strengths and limitations of this study

- This study demonstrates an approach to designing a systematic review for the 'catch-all' term patient experience, and brings together evidence from a variety of sources that may otherwise remain dispersed.
- This was a time-limited review and there is scope to expand this search based on the results and broaden the search terms to uncover further evidence.

INTRODUCTION

Patient experience is increasingly recognised as one of the three pillars of quality in healthcare alongside clinical effectiveness and patient safety.[1] In the NHS, the measurement of patient experience data to identify strengths and weaknesses of healthcare delivery, drive-quality improvement, inform

Annotated by the Urology Services Inquiry

commissioning and promote patient choice is now mandatory.[2–4] In addition to data on harm avoidance or success rates for treatments, providers are now assessed on aspects of care such as dignity and respect, compassion and involvement in care decisions.[4] In England, these data are published in Quality Accounts and the Commissioning for Quality and Innovation payment framework which makes a proportion of care providers' income conditional on the improvement in this domain.[5]

The inclusion of patient experience as a pillar of quality is often justified on grounds of its intrinsic value—that the expectation of humane, empathic care is requires no further justification. It is also justified on more utilitarian grounds as a means of improving patient safety and clinical effectiveness.[6 7] For example, clear information, empathic, two-way communication and respect for patients' beliefs and concerns could lead to patients being more informed and involved in decision-making and create an environment where patients are more willing to disclose information. Patients could have more 'ownership' of clinical decisions, entering a 'therapeutic alliance' with clinicians. This could support improved and more timely diagnosis, clinical decisions and advice and lead to fewer unnecessary referrals or diagnostic tests.[8 9] Increased patient agency can encourage greater participation in personal care, compliance with medication, adherence to recommended treatment and monitoring of prescriptions and dose.[9 10] Patients can be informed about what to expect from treatment and be motivated to report adverse events or complications and keep a list of their medical histories, allergies and current medications.[11]

Patients' direct experience of care process through clinical encounters or as an observer (eg, as a patient on a hospital ward) can provide valuable insights into everyday care. Examples include attention to pain control, assistance with bathing or help with feeding, the environment (cleanliness, noise and physical safety) and coordination of care between professions or organisations. Given the organisational fragmentation of much of healthcare and the numerous services with which many patients interact, the measurement of patient experience may help provide a 'whole-system' perspective not readily available from more discrete patient safety and clinical effectiveness measures.[11]

Focusing on such utilitarian arguments, this study reviews evidence on links that have been demonstrated between patient experience and clinical effectiveness and patient safety.

METHODS

Identifying variables relevant to patient experience

Patient experience is a term that encapsulates a number of dimensions, and in preliminary database searches, this phrase, on its own, uncovered a limited number of useful studies. To broaden and structure the search for evidence, identify search terms and provide a framework for analysis, it was necessary to identify what patient experience entails and outline potential mechanisms through which it is proposed to impact on safety and effectiveness. As such, we combined common elements from patient experience frameworks produced by The Institute of Medicine,[1] Picker Institute[12] and NICE.[13]

Table 1 delineates different dimensions of patient experience and distinguishes between 'relational' and 'functional' aspects.[10 14] Relational aspects refer to interpersonal aspects of care—the ability of clinicians to empathise, respect the preferences of patients, include them in decision-making and provide information to enable self-care.[10] It also refers to patients' expectations that professionals will put their interest above other considerations and be honest and transparent when something goes wrong.[8 15] Functional aspects relate to basic expectations about how care is delivered, such as attention to physical needs, timeliness of care, clean and safe environments, effective coordination between professionals, and continuity.

Using these frameworks and discursive documents in this area of research[9 10 16 17] as a guide, we identified

Table 1 Identifying aspects of patient experience and search terms

Relational aspects	Functional aspects
Emotional and psychological support, relieving fear and anxiety, treated with respect, kindness, dignity, compassion, understanding	Effective treatment delivered by trusted professionals
Participation of patient in decisions and respect and understanding for beliefs, values, concerns, preferences and their understanding of their condition	Timely, tailored and expert management of physical symptoms
Involvement of, and support for family and carers in decisions	Attention to physical support needs and environmental needs (eg, clean, safe, comfortable environment)
Clear, comprehensible information and communication tailored to patient needs to support informed decisions (awareness of available options, risks and benefits of treatments) and enable self-care	Coordination and continuity of care; smooth transitions from one setting to another
Transparency, honesty, disclosure when something goes wrong	

Annotated by the Urology Services Inquiry

Box 1 Search terms denoting patient experience

Patient-centred care; patient engagement; clinical interaction; patient–clinician; clinician–patient; patient–doctor; doctor–patient; physician–patient; patient–physician; patient–provider; interpersonal treatment; physician discussion; trust in physician; empathy; compassion; respect; responsiveness; patient preferences; shared decision-making; therapeutic alliance; participation in decisions; decision-making; autonomy; caring; kindness; dignity; honesty; participation; right to decide; physical comfort; involvement (of family, carers, friends); emotional support; continuity (of care); smooth transition; emotional support.

words and phrases commonly used to denote aspects of patient experience, examples of which are listed in box 1.

These were combined with search terms representing patient safety and clinical effectiveness outcomes, hypothesised to be associated with patient experience in discursive literature. We searched for a broad range of outcome measures, including both self-rated and 'objective' measurements of health status, physical health and mental health and well-being, the use of preventive health services, compliance or adherence to health-promoting behaviour and resource use.

Combining these two sets of search terms in the EMBASE database, we identified 5323 papers whose abstracts were then reviewed. If deemed relevant, the full article was retrieved to assess whether it met the inclusion criteria.

Given concerns about the sole use of protocol-driven search strategies for complex evidence,[18] for the full-text articles retrieved for review, we used a 'snowballing' approach to identify further studies. This involved sourcing further articles in these studies for assessment and using the 'related articles' function in the Pubmed database. We repeated this for new articles identified until the approach ceased to identify new studies.

Inclusion criteria, assessment of quality and categorisation of evidence

We included studies that measured associations between patients' reporting of their experience and patient safety and clinical effectiveness outcomes. These included studies measuring associations between patient experience and safety or effectiveness outcomes either at a patient level (ie, data on both types of variables for the same patients) or at an organisational level (ie, associations between aggregated measures of patient experience and safety and effectiveness outcomes for the same type of organisation such as a hospital or primary-care practice).

We included studies where the variables denoting patient experience and patient safety and clinical effectiveness were measured in a credible way, through the use of validated tools. For patient experience variables, these include surveys covering several aspects of experience (such as Picker surveys and the Hospital Consumer Assessment of Healthcare Providers and Systems survey) and specific aspects (such as a 'Working Alliance Scale',[19] Multidimensional Health Locus of Control Scale scale[20] or Usual Provider Continuity index[21]). For patient safety and clinical effectiveness, these include, for example, generic health and quality of life surveys (such as Short-Form 36), disease-specific surveys (such as the Seattle Angina Questionnaire[22]), measures of the technical quality of care (such as the Hospital Quality Alliance (HQA) score), reviews of medical records and care provider data.[23] Details of the methods used to measure variables in each study are included in tables 5 and 6.

We included studies where the sample size of patients or organisations appeared sufficiently large to conduct a meaningful statistical analysis (excluding studies with fewer than 50 subjects). When extracting data relevant to our study from systematic reviews, we selected only those studies that met these criteria.

We then searched the studies' results for positive associations (where a better patient experience is associated with safer or more effective care), negative associations (where a better patient experience is associated with less safe or less effective care) and no associations. Associations refer to cases where one measure of patient experience (typically an overall rating of patient experience for a care provider) has a statistically significant association with one or more clinical effectiveness or patient safety variable. If a study showed associations between several aspects of patient experience that appeared to be closely related (eg, 'listening', 'empathy', or 'respect') and an aspect of effectiveness or safety, this was counted as one association found. This was to avoid exaggerating the weight of the evidence by 'over counting' associations.

Two main types of studies emerged in the search—those focusing on interventions to improve aspects of patient experience and those exploring associations between patient experience variables and patient safety and clinical effectiveness variables. To manage the scope of this time-limited review, we decided to restrict analysis of the large number of interventions to the evidence contained within systematic reviews.

RESULTS

Overall, the evidence indicates positive associations between patient experience and patient safety and clinical effectiveness that appear consistent across a range of disease areas, study designs, settings, population groups and outcome measures. Positive associations found outweigh 'no associations' by 429–127. Of the four studies where 'no associations' outweigh positive associations, there is no suggestion that these are methodologically superior. Negative associations were rare. Of the 40 individual studies assessed in table 5 negative associations (between patient experience of clinical team interactions and continuity of care and separate assessment of the quality of clinical care) were found in only one study.[24]

Annotated by the Urology Services Inquiry

Table 2 Methods used to measure variables

	Number of studies
Patient experience variables	
Survey	31
Interviews	2
Medical records	1
Effectiveness and safety variables	
Survey for self-rated healthcare	12
Other survey	14
Medical records	3
Data-monitoring quality of care delivery (eg, audit, HQA, HEDIS)	3
Care provider outcome data	3
Physical examination	1
Patient interviews	2

HQA, Hospital Quality Alliance; HEDIS, Healthcare Effectiveness Data and Information Set.

Table 2 shows surveys to be the predominant method used to measure variables for individual studies (figure 1).

Table 3 presents the frequency of positive associations and 'no associations' categorised by type of outcomes (for 378 of the 556 cases where sufficient information was available to categorise). These include objectively measured health outcomes (eg, 'mortality', 'blood glucose levels', 'infections', 'medical errors'); self-reported health and well-being outcomes (eg, 'health status', 'functional ability' 'quality of life', 'anxiety'); adherence to recommended treatment and use of preventive care services likely to improve health outcomes (eg, 'medication compliance', 'adherence to treatment' and screening for a variety of conditions); outcomes related to healthcare resource use (eg, 'hospitalisations', 'hospital readmission', 'emergency department use', 'primary care visits'); errors or adverse events and measures of the technical quality of care.

Table 4 shows associations categorised by type of care provider (for the subset of studies focusing on one setting) and for studies focused on chronic conditions.

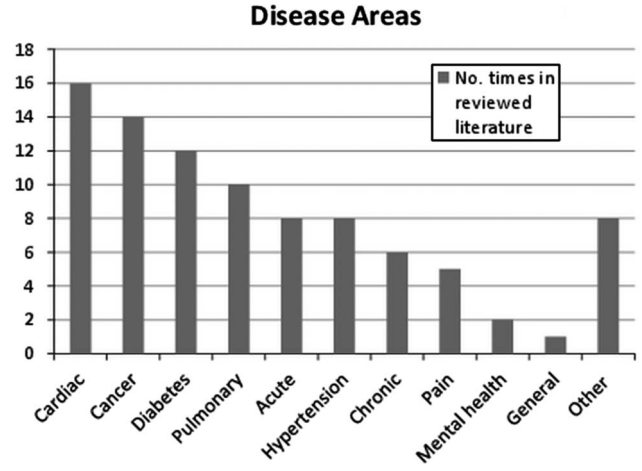


Figure 1 Outlines the disease areas covered.

Tables 5 and 6 present details of all studies identified, specifying the analytical focus of each study, methods to measure variables and positive associations and 'no associations' found.

DISCUSSION

Overall, the evidence indicates associations between patient experience, clinical effectiveness and patient safety that appear consistent across a range of disease areas, study designs and settings.

As table 3 indicates, the evidence shows positive associations found outweigh those not found for both self-assessment of physical health and mental health (61 vs 36) and 'objective' measures of health outcomes (eg, where measures are taken by a clinician or by reviewing medical records) (29 vs 11). For objective measures, one study[25] shows positive associations for ulcer disease, hypertension and breast cancer. Two studies on myocardial infarction show positive associations with survival 1 year after discharge[26] and inpatient mortality.[27] Objective measurement is less frequently explored than self-rated health and is an area that could benefit from further research.

Evidence is strong in the case of adherence to recommended medical treatment. A meta-analysis included in this study showed positive associations between the quality of clinician–patient communications and adherence to medical treatment in 125 of 127 studies analysed and showed the odds of patient adherence was 1.62 times higher where physicians had communication training.[28] Regarding compliance with medication, positive associations found to outweigh those not found.[20 29–35] A review of interventions to increase adherence to medication (not included in this study) showed communication of information, good provider–patient relationships and patients' agreement with the need for treatment as common determinants of effectiveness.[36] There is evidence of better use of preventive services, such as screening services in diabetes, colorectal, breast and cervical cancer; cholesterol testing and immunisation.[24 25 37–39] There is also evidence of impacts on resource use of primary and secondary care (such as hospitalisations, readmissions and primary care visits).[21 29 40–45]

For studies exploring associations between patient experience and technical quality of care measured by other means, the evidence is mixed. Two studies in acute care showed positive associations between overall ratings of patient experience and ratings of the technical quality of care (using HQA measures) for myocardial infarction, congestive heart failure, pneumonia and complications from surgery.[23 46] Another found an association with adherence to clinical guidelines for acute myocardial infarction.[27] A similar study in primary care found positive associations between patient experience of processes and measurement of care quality (from the Healthcare Effectiveness Data and Information Set (HEDIS) system measuring care quality for disease prevention and management in chronic conditions).[24]

Annotated by the Urology Services Inquiry

Table 3 Associations categorised by type of outcome

	Objective' health outcomes	Self-reported health and wellbeing	Adherence to treatment (including medication)	Preventive care	Healthcare resource use	Adverse events	Technical quality of care	All categories
No of positive associations found	29	61	152	24	31	7	8	312
'No associations'	11	36	7	2	6	0	4	66

However, two other studies found no associations between patients' ratings and ratings based on an assessment of medical records.[47 48]

Some studies show positive associations between patients' perspective or observations of processes of care and the safety of care recorded through other means. Isaac[46] found positive associations between ratings of patient experience and six patient-safety indicators (decubitus ulcer; failure to rescue; infections due to medical care; postoperative haemorrhage, respiratory failure, pulmonary embolism and sepsis). Two studies examining evidence for patients' ability to identify medical errors or adverse events in hospital showed positive associations between patients' accounts of their experience of adverse events and the documentation of events in medical records.[49 50] But another study shows only 2% of patient-reported errors were classified by medical reviewers as 'real clinical medical errors' with most 'reclassified' by clinicians as 'misunderstandings' or 'behaviour or communication problems'.[51] Overall, there is less evidence available on safety compared to effectiveness and this should be a priority for future research in this area.

Research from other studies not included in this review support these findings. For example, research on 'decision aids' to ensure that patients are well informed about their treatments, and that decisions reflect the preferences of patients indicates that patient engagement has a beneficial impact on outcomes. For example, awareness of the risks of surgical procedures resulted in a 23% reduction in surgical interventions and better functional status.[52] Another review showed that provision of good information and emotional support are associated with better recovery from surgery and heart attacks.[53]

Table 4 Weight of evidence by provider and for chronic conditions

Weight of evidence by provider and for chronic conditions	Associations found	No of associations
Primary care	110	48
Hospital	43	17
Chronic conditions	53	9

STUDY STRENGTHS AND LIMITATIONS

This review builds on other studies[9 10 16 17] exploring links between these three domains. This study also demonstrates an approach to designing a systematic search for evidence for the 'catch-all' term patient experience, bringing together evidence from a variety of sources that may otherwise remain dispersed. This approach can be used or adapted for further research in this area.

This was a time-limited review and there is scope to expand this search, based on our results. There may be scope to broaden the search terms and this may uncover further evidence. The first search was confined to one database and the review focused primarily on peer-reviewed literature excluding grey literature. To manage the scope of this review, we restricted the analysis of interventions to improve patient experience to evidence within systematic reviews. While we used some quality criteria to filter studies (including the use of validated tools to measure experience, safety and effectiveness outcomes and sample size), with more time a more detailed formal quality assessment may have added value to the study. Although all positive associations included in the study are statistically significant, the strength of associations vary. Because of time constraints and the heterogeneity of measures used, we did not systematically compare the strengths of positive associations in different studies, but this may be an area for future work. There may also be scope to explore whether future research in this area could go beyond the counting of associations in this study through, for example, meta-analysis. As always, there may be a publication bias in favour of studies showing positive associations between patient experience variables and safety and effectiveness outcomes.[54] In addition, 28 of the 40 individual studies assessed were conducted in the USA and caution is needed about their applicability to other healthcare systems.

CONCLUSION

The inclusion of patient experience as one of the pillars of quality is partly justified on the grounds that patient experience data, robustly collected and analysed, may help highlight strengths and weaknesses in effectiveness

Annotated by the Urology Services Inquiry

Table 5 Individual studies

Author	Type of study, sample size, country	Setting	Disease focus	Unit of analysis (patient (P) or org (O)	Patient experience focus and method used	Safety and effectiveness measure	Association demonstrated	Association not demonstrated	Assoc. Found vs NOT found
Chang *et al*[48]	Cohort study, 236 patients, USA	Managed care organisation	22 clinical conditions	P	Providers communication (The Consumer Assessment of Healthcare Providers and Systems survey and 'Quality of care')	Technical quality and patient global ratings (medical records and patient interviews)	None	Technical quality of care	0/1
Sequist *et al*[24]	Cross-sectional study, 492 settings, USA	Primary care	Cervical, breast and colorectal cancer, chlamydia, cardiovascular conditions, asthma, diabetes	P	Doctor–patient communication, clinical team interactions, organisational features of care (The Ambulatory Care Experiences survey)	Clinical quality focusing on disease prevention, disease management and outcomes of care (Healthcare Effectiveness Data and Information Set (HEDIS))	Cervical cancer, breast cancer and colorectal cancer screening, Chlamydia screening, Cholesterol screening (cardiac), LDL cholesterol testing (diabetes), eye exams (diabetes), HbA1c testing, nephropathy screening	Cholesterol management, HbA1c control, LDL cholesterol control, blood pressure control	9/4
Burgers *et al*[55]	Survey, 8973 patients, Range	Range of settings	Chronic lung, mental health, hypertension, heart disease, diabetes, arthritis, cancer	P	Coordination of care and overall experience (Commonwealth Fund International Health Policy Survey)	Death score	Death score	None	1/0
Kaplan *et al*[25]	Randomised control trial, 252 patients, USA	Range of settings	Ulcer disease, hypertension, diabetes, breast cancer	P	Physician–patient communication (assessment of audio tape and questionnaire)	Physiological measures taken at visit and patients' self-rated health status survey.	Follow-up blood glucose and blood pressure, functional health status, self-reported health status.	None	4/0
Jha *et al*[23]	Cross-sectional study, 2429 settings, USA	Hospital	Acute myocardial infarction, congestive heart failure, pneumonia complications from surgery	O	Patient communication with clinicians, experience of nursing services, discharge planning (Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey)	Technical quality of care using Hospital Quality Alliance (HQA) score	Technical quality of care in AMI, congestive heart failure (CHF), pneumonia, surgical care	None	4/0

Continued

Doyle C, Lennox L, Bell D. *BMJ Open* 2013;**3**:e001570. doi:10.1136/bmjopen-2012-001570

Table 5 Continued

Author	Type of study, sample size, country	Setting	Disease focus	Unit of analysis (patient (P) or org (O)	Patient experience focus and method used	Safety and effectiveness measure	Association demonstrated	Association not demonstrated	Assoc. Found vs NOT found
Rao *et al*[47]	Cross-sectional study, 3487 patients, UK	Primary care	Hypertension, Influenza vaccination	P	Older patients' experience of technical quality of care (General Practice Assessment survey)	Technical quality of care—(medical records)	None	Hypertension monitoring and control, influenza vaccination.	0/3
Meterko *et al*[26]	Cohort study, 1858 patients, USA	Veteran Affairs Medical Centres	Acute myocardial infarction	P	Patient-centred care, access, courtesy, information, coordination, patient preferences, emotional support, family involvement, physical comfort (VA Survey of Healthcare Experiences of Patients (SHEP))	Survival 1-year postdischarge	Survival 1-year post discharge	None	1/0
Vincent *et al*[56]	Cohort survey 227 patients, UK	Range of settings	Varied	P	Accountability, explanation, standards of care, compensation (questionnaire)	Legal action	Legal action	None	1/0
Agoritsas *et al*[57]	Cohort patient survey, 1518 patients, Switzerland	Hospital	Varied	P	Global rating of care and respect and dignity questions (Picker survey)	Patient reports of undesirable events (survey)	Neglect of important information by healthcare staff, pain control, needless repetition of a test, being handled with roughness	None	4/0
Flocke *et al*[87]	Cross-sectional study, 2889 patients, USA	Primary care	Varied	P	Interpersonal communication, physician's knowledge of patient, coordination (Components of Primary Care Instrument (CPCI))	Use of preventive care services (screening, health habit counselling services, immunisation services)	Screening, health habit counselling, immunisation	None	3/0
Jackson, J. *et al*[58]	Quantitative cohort study 500 patients, USA	General medicine walk-in clinic	Varied	P	Patient satisfaction (Research and Development (RAND) 9-item survey)	Functional status (Medical Outcomes Study Short-Form Health Survey (SF-6)), symptom resolution, (RAND 9-item survey), follow-up visits	Symptom resolution, repeat visits, functional status	None	3/0

Continued

Table 5 Continued

Author	Type of study, sample size, country	Setting	Disease focus	Unit of analysis (patient (P) or org (O)	Patient experience focus and method used	Safety and effectiveness measure	Association demonstrated	Association not demonstrated	Assoc. Found vs NOT found
Clark *et al*[41]	Randomised control trial 731 patients, USA	Range of settings	Asthma	P	Patient experience of physician communication (patient interviews and Likert scale)	Emergency department visits, hospitalisations, office phone calls and visits, urgent office visits (survey+medical chart review of 6% of patients to verify responses)	Number of office visits, emergency visits, urgent office visits, phone calls, hospitalisations	None	5/0
Raiz *et al*[20]	Quantitative cohort study, 357 patients, USA	Primary care	Renal transplant	P	Patient faith in doctor (Multidimensional Health Locus of Control Scale (MHLC))	Medication compliance	Remembering medications, taking medications as prescribed	None	2/0
Kahn *et al*[32]	Cohort study, 881 patients, USA	Hospitals	Breast cancer	P	Level of physician support, participation in decision-making and information on side effects (survey)	Medication adherence	Ongoing tamoxifen use	None	1/0
Plomondon *et al*[22]	Cohort study, 1815 patients, USA	Hospital	Myocardial infarction	P	Satisfaction with explanations from their doctor, overall satisfaction with treatment (Seattle Angina questionnaire)	Presence of angina (Seattle Angina Questionnaire)	Presence of angina	None	1/0
Fuertes *et al*[19]	Survey, 152 patients, USA	Hospital	Neurology	P	Physician–patient communication, physician–patient working alliance, empathy, multicultural competence (questionnaire)	Adherence to medical treatment (adherence Self-Efficacy Scale and Medical Outcome Study (MOS) adherence scale)	Adherence to treatment	None	1/0
Lewis *et al*[31]	Qualitative cohort study, 191 patients, USA	Primary care	Pain	P	Doctor–patient communication (survey)	Medication adherence (Prescription Drug Use Questionnaire (PDUQ))	Use of prescribed opioid medications	None	1/0
Safran *et al*[59]	Cross-sectional study, 7204 patients, USA	Primary care	Varied	P	Accessibility, continuity, integration, clinical interaction, interpersonal aspects, trust (The Primary Care Assessment Survey)	Adherence to physician's advice, health status, health outcomes (Medical Outcomes Study (MOS), Behavioural risk factor survey)	Adherence, health status	Health outcomes	2/1

Continued

Annotated by the Urology Services Inquiry

Table 5 Continued

Author	Type of study, sample size, country	Setting	Disease focus	Unit of analysis (patient (P) or org (O)	Patient experience focus and method used	Safety and effectiveness measure	Association demonstrated	Association not demonstrated	Assoc. Found vs NOT found
Alamo *et al*[60]	Randomised study, 81, Spain	Primary care	Chronic musculoskeletal pain (CMP), fibromyalgia	P	Patient-centreed-care ('Gatha-Res questionnaire' and follow-up phone call)	Pain (Visual Analogue Scale (VAS) anxiety (Oldberg scale of anxiety and depression (GHQ))	Anxiety, number of tender points (pain)	Pain, pain intensity, pain as a problem, number of associated symptoms, depression, physical mobility, social isolation, emotional reaction, sleep	2/10
Fan *et al*[61]	Survey, 21 689 patients, USA	Primary care	Cardiac care, diabetes, congestive obstructive pulmonary disorder (COPD)	P	Communication skills and humanistic qualities of primary care physician (Seattle Outpatient Satisfaction Survey)	Physical and emotional aspects, coping ability and symptom burden for angina, COPD and diabetes (Seattle Angina Questionnaire (SAQ), Obstructive Lung Disease Questionnaire (SOLDQ), Diabetes Questionnaire (SDQ))	Patient ability to deal with all 3 diseases, education for diabetes patients, angina stability, physical limitation due to angina	Self-reported physical limitation for angina and COPD, symptom burden for diabetes, complications for diabetes	7/4
O'Malley *et al*[38]	Cross-sectional study, 961 patients, USA	Primary care	Varied	P	Patient trust (survey)	Use of preventive care services	Blood pressure measurement, height and weight measurement, cholesterol check, papanicolaou test (pap) tests, breast cancer screening, colorectal cancer screening, discussion of diet, discussion on depression	None	8/0
Little *et al*[62]	Survey, 865 patients, UK	Primary care	varied	P	Patient centredness (Survey)	Enablement, symptom burden, resource use	Enablement, symptom burden, referrals	Re-attendance, investigations	3/2
Levinson *et al*[63]	Qualitative cohort study, 124 physicians, USA	Primary care	Varied	P	Physician–patient communication (assessment of audiotape)	Malpractice	Malpractice claims	None	1/0

Continued

Annotated by the Urology Services Inquiry

Table 5 Continued

Author	Type of study, sample size, country	Setting	Disease focus	Unit of analysis (patient (P) or org (O)	Patient experience focus and method used	Safety and effectiveness measure	Association demonstrated	Association not demonstrated	Assoc. Found vs NOT found
Carcaise-Edinboro and Bradley[39]	Cross sectional study, 8488 patients, USA	Primary care	Colorectal cancer	P	Patient-provider communication (Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey)	Colorectal Cancer screening, fecal occult blood testing and colonoscopy (Medical Expenditure Panel Survey)	CRC screening, fecal occult blood testing, colonoscopy	None	3/0
Schneider *et al*[β3]	Cross-sectional analysis study, 554 patients, USA	Primary care	HIV	P	Physician–patient relationship (survey)	Adherence (survey)	Adherence to antiretroviral therapy	None	1/0
Schoenthaler *et al*[β4]	Cross-sectional study, 439 patients, USA	Primary care	Hypertension	P	Patients' perceptions of providers' communication (survey)	Medication adherence (Morisky self-report measure)	Medication adherence	None	1/0
Slatore *et al*[64]	Cross-sectional study, 342 patients, USA	Range of settings	COPD	P	Patient–clinician communication (Quality of communication questionnaire (QOC))	Self-reported breathing problem confidence and general self-rated health (survey)	Confidence in dealing with breathing problems	Self-rated health	1/1
Lee and Lin[65]	Cohort study, 480 patients, Taiwan	Range of settings	Type 2 diabetes	P	Trust in physicians (survey)	Self-efficacy, adherence, health outcomes (Multidimensional Diabetes Questionnaire and 12-Item Short-Form Health survey (SF-12))	Physical HRQoL, mental HRQoL, body mass index HbA1c, triglycerides, complications, self-efficacy, outcome expectations, adherence	None	9/0
Heisler *et al*[β5]	Survey, 1314 patients, USA	Primary care	Diabetes	P	Physician communication, physician interaction styles, participatory decision-making (Questionnaire)	Disease management (surveys and national databases)	Overall self-management, diabetes diet, medication compliance, exercise, blood glucose monitoring, foot care.	Exercise	6/1
Lee and Lin[66]	Cohort study, 614 patients, Taiwan	Range of settings	Type 2 diabetes	P	Patients' perceptions of support, autonomy, trust, satisfaction (Healthcare Climate Questionnaire and Autonomy Preference Index (API))	Glycosylated haemoglobin (HbA1C) (medical records) Physical and mental health-related quality of life (HRQoL) (SF-12)	Physical HRQoL, mental HRQoL	Information preference interaction, HbA1C	2/2

Continued

Annotated by the Urology Services Inquiry

Table 5 Continued

Author	Type of study, sample size, country	Setting	Disease focus	Unit of analysis (patient (P) or org (O)	Patient experience focus and method used	Safety and effectiveness measure	Association demonstrated	Association not demonstrated	Assoc. Found vs NOT found
Kennedy A. *et al*[67]	Randomised control trial, 700 patients, UK	Hospital	Inflammatory bowel Disease	P	Patient-centred-care (interviews)	Resource use, self-rated physical and mental health, enablement (patient diaries, questionnaires, medical records)	Ability to cope with condition, symptom relapses, hospital visits, appointments made	Physical functioning, role limitations, social functioning, mental health, energy/vitality, pain, general health perception, anxiety, number of relapses, number of medically-defined relapses, average relapse duration, frequency of GP visits, delay before starting treatment	4/13
Stewart *et al*[42]	Observational cohort study, 315 patients, Canada	Primary care	General	P	Patient-centred communication (assessment of audiotape and Patient-Centred Communication Score tool)	Discomfort (VAS) symptom severity severity (Visual Analogue Scale), Health Status (Short Form-36 SF-36) Quality of care provision (chart review by doctors)	Symptom discomfort and concern, self-reported health, diagnostic tests, referrals and visits to the family physician	None	5/2
Kinnersley *et al*[68]	Observational study, 143 patients, UK	Primary care	Varied	P	Patient-centredness (assessment of audiotape and questionnaires)	Symptom resolution, resolution of concerns, functional health status (Questionnaire)	None	Resolution of symptoms, resolution of concerns, functional health status	0/3
Solberg *et al*[51]	Survey, 3109 patients, USA	Primary care — multispecialty group	Varied	P	Patient experience of errors (survey)	Review of errors (chart audits and physician reviewer judgements)	None	None	1/0
Isaac *et al*[6]	Cross-sectional study, 927 hospitals, USA	Hospital	Acute myocardial infarction,	O	General patient experiences (Hospital Consumer Assessment	Processes of care (Health Quality Alliance	Decubitus ulcer rates, infections, processes of care for pneumonia,	Failure to rescue	11/1

Continued

Annotated by the Urology Services Inquiry

Table 5 Continued

Author	Type of study, sample size, country	Setting	Disease focus	Unit of analysis (patient (P) or org (O)	Patient experience focus and method used	Safety and effectiveness measure	Association demonstrated	Association not demonstrated	Assoc. Found vs NOT found
			congestive heart failure, pneumonia complications from surgery.		of Healthcare Providers and Systems survey (HCAHPS))	(HQA) database) and patient safety indicators	CHF and myocardial infarctions, surgical composites, hemorrage, respiratory failure, DVT, pulmonary embolism, sepsis		
Glickman *et al*[27]	Cohort study, 3562 patients, USA	Hospital	Acute myocardial infarction	P	Patient satisfaction (Press-Ganey survey)	Adherence to practice guidelines, outcomes (CRUSADE quality improvement registry).	Inpatient mortality, composite clinical measures, acute myocardial infarction (AMI) survival	None	3/0
Fremont *et al*[69]	Survey, 1346 patients, USA	Hospital	Cardiac	P	Patient-centred care (Picker survey)	Processes of care, functional health status, cardiac symptoms (Medical Outcomes Study questionnaire, London School of Hygiene measures for cardiac symptoms)	Overall health, chest pain, patient reported general physical and mental health status	Mental health, shortness of breath	5/2
Riley *et al*[70]	Survey, 506 patients, Canada	Hospital	Cardiac care—acute coronary	P	Continuity of care (The Heart Continuity of Care Questionnaire, Medical Outcome Study Social Support Survey, Illness Perception Questionnaire)	Participation in cardiac rehabilitation, perception of illness, functional capacity (Duke Activity Status Index (DASI))	Cardiac rehabilitation participation, perceptions of illness consequences	None	2/0
Weingart *et al*[49]	Cohort study, 228 patients, USA	Hospital	Varied	P	Patient experience of adverse events (interviews)	Adverse events (mMedical records and patient interviews)	Adverse events	None	1/0
Weissman *et al*[50]	Survey, 998 patients, USA	Hospital	Varied	P	Patient experience of adverse events (interviews)	Adverse events (medical records)	Adverse events	None	1/0

HRQoL, health-related quality of life.

Annotated by the Urology Services Inquiry

Table 6 Systematic reviews

Authors	Time span and studies meeting inclusion criteria	Healthcare setting	Disease areas covered	Unit of analysis	Patient experience focus (and measurement methods)	Safety and effectiveness measure—association demonstrated -	Safety and effectiveness measure—association not demonstrated	Assocs found vs not found
Blasi *et al*[71]	1974–1998, 4 of 25	Range of settings	Asthma, hypertension, cancer, insomnia, menopause, obesity, tonsillitis	P	Provider behaviour and communication (grading of consultations)	Health status, symptom improvement, treatment effectiveness, fear of injection, anxiety, ratings of pain, number of doctor visits, pain, speed of recovery	Comfort, recovery time, return visits	9/3
Drotar[29]	1998–2008, 4 of 22	Range of settings	Asthma, cystic fibrosis, diabetes, epilepsy, inflammatory bowel disease, juvenile rheumatoid arthritis	P	Physician and staff behaviour (surveys, interviews, medical records)	Treatment adherence, compliance, office visits, phone calls, hospitalisations	Medication adherence	5/1
Hall *et al*[72]	1990–2009, 10 of 14	Range of settings	Brain injury, musculoskeletal conditions, cardiac conditions, trauma, back, neck and shoulder pain	P	Therapist-patient relationship, therapeutic alliance (surveys, audio/video taped session)	Adherence, employment status, physical training, therapeutic success, perceived effect of treatment, pain, physical function, depression, general health status, attendance, floor-bench lifts, global assessment scores, ability to perform activities of daily living (ADLs), mobility	Weekly physical training, disability, productivity, depression, functional status, adherence	18/6
Stevenson *et al*[73]	1991–2000, 7 of 134	Range of settings	Hypertension, asthma, chronic obstructive pulmonary disorder, ovarian cancer, epilepsy, hyperlipidaemia	P	Doctor–patient communication (surveys)	Self-reported adherence, blood pressure control, general physician practice visits, hospitalisations, emergency room visits for children with asthma, quality of life for COPD patients, oral contraceptive adherence, adherence to antiepileptic drugs, pain control following gynaecological surgery, adherence to medication for depression	Length of visits to doctor for asthma patients, health status and use of healthcare services for epilepsy patients, adherence to Niacin and bile acid sequestrant therapy	9/5
Saultz and Lochner[44]	1967–2002, 41 studies	Range of settings	Varied	P	Continuity of care — ongoing relationship between individual doctor and patient	Hospitalisation rate, hospital readmission, length of stay, influenza immunisation, preventive care, antibiotic compliance, intensive care unit	Diabetes (HbA1C, lipid control, blood pressure control, presence of diabetic complications), blood glucose control, functional ability of	51/30

Continued

Table 6 Continued

Authors	Time span and studies meeting inclusion criteria	Healthcare setting	Disease areas covered	Unit of analysis	Patient experience focus (and measurement methods)	Safety and effectiveness measure—association demonstrated -	Safety and effectiveness measure—association not demonstrated	Assocs found vs not found
					(surveys, continuity of care index)	days, Neonatal morbidity, Apgar score, Birth weight, rates and timeliness of childhood immunisations, health-related quality of life, recommended diabetes care measures, glucose control, PAP tests, mammogram rate, breast exams, surgical operation rates, hypertension control, presence of depression, relationship problems, adverse events in hospitalsed patients, degree of patient enablement, rheumatic fever incidence	elderly patients, compliance with antibiotic therapy, well-child visits, blood pressure checks in women, pregnancy complications, newborn mortality, immunization rates, NICU admissions, Apgar scores, caesarean rate, length of labour, indications for tonsillectomy	
Hall, Roter and Katz[74]	Meta-analysis 41 studies	Range of settings	Varied	P	Clinician–patient communication (surveys, interviews, observations, assessment of video or audio)	Compliance (with 4 variables of PE), recall/understanding (with 4 variables of PE)	Compliance (with 1 variable of PE), recall/understanding (with 1 variable of PE)	8/2
Jackson, C. *et al*[40]	1984–2008, 3 of 17	Range of settings	Inflammatory bowel disease	P	Trust in physician, Patient–physician agreement, adequacy information (surveys)	Adherence to treatment	Compliance	2/1
Sans-Coralles *et al*[43]	1984–2005, 9 of 20	Primary care	No specific disease focus	P	Continuity of care, coordination of care, consultation time, doctor–patient relationship (validated tools in these different domains)	Hospital admissions, length of stay, compliance, recovery from discomfort, emotional health, diagnostic tests, referrals, quality of care for asthma, diabetes and angina, symptom burden, receipt of preventive services	Enablement	13/1
Hsiao and Boult[45]	1984–2003, 3 of 14	Primary care	No specific disease focus	P	Continuity with physician (surveys, interviews, medical	Hospitalisations for all conditions and ambulatory care-sensitive conditions, odds of hospitalisation(2), healthcare	Acute ambulatory care-sensitive conditions, mobility, pain, emotion, activities of daily living,	21/15

Continued

Annotated by the Urology Services Inquiry

Table 6 Continued

Authors	Time span and studies meeting inclusion criteria	Healthcare setting	Disease areas covered	Unit of analysis	Patient experience focus (and measurement methods)	Safety and effectiveness measure—association demonstrated -	Safety and effectiveness measure—association not demonstrated	Assocs found vs not found
					records, chart reviews)	costs(2), emergency department visits, emergent hospital admissions(2), length of stay, diabetes recognition, mental health(2), pain, perception of health, well-being, BMI, triglyceride concentrations, recovery, clinical outcomes, self-reported health	smoking, BMI, hypertension, hypercholesterolaemia, self-reported health, glycaemic control, diabetes control, frequency of hypoglycaemic reactions, blood sugar, weight	
Arbuthnott *et al*[80]	Meta analysis, 1955–2007, All 48 studies included	Range of settings	Asthma, bacterial infection, fIbromyalgia, diabetes, renal disease, hypertension, congestive heart failure, inflammatory bowel disease, breast cancer, HIV and tuberculosis	P	Physician–patient collaboration (Observation, surveys)	Medication adherence, behavioural adherence	Appointment adherence	2/1
Stewart[75]	1983–1993, 21 studies	Range of settings	Peptic ulcers, breast cancer, diabetes, hypertension, headache, coronary artery disease, gingivitis, tuberculosis, prostate cancer	P	Physician–patient communication (surveys, evaluation of audio- or videotape recording)	Peptic ulcer physical limitation, blood glucose levels, blood pressure, headache resolution, physician evaluation of symptom resolution for coronary artery disease, gingivitis and tuberculosis, anxiety level in gynaecological care, radiation therapy, breast cancer care, functional status following radiation therapy for prostate cancer, anxiety after radiation therapy, pain levels and hospital length of stay after intra-abdominal surgery, physical and psychological complaints in breast cancer care	Details not included	16/5
Zolnierek and DiMatteo[28]		Range of settings	No specific disease focus	P	Physician–patient communication	Adherence to treatment recommended by clinician	Adherence (2 observational studies)	125/2

Continued

Annotated by the Urology Services Inquiry

Table 6 Continued

Authors	Time span and studies meeting inclusion criteria	Healthcare setting	Disease areas covered	Unit of analysis	Patient experience focus (and measurement methods)	Safety and effectiveness measure—association demonstrated -	Safety and effectiveness measure—association not demonstrated	Assocs found vs not found
	Meta analysis 1949–2008, 127 studies				(observation, surveys)			
Beck *et al*[76]	1975–2000, 5 of 14	Primary care	No specific disease focus	P	Physician–patient communication (observation, evaluation of audio and video tapes)	Compliance with doctors' advice, blood pressure, pill count	None	10/0
Cabana and Lee[21]	1966–2002, 7 of 18	Range of settings	Rheumatoid arthritis, epilepsy, breast cancer, cervical cancer, diabetes	P	Continuity of care (validated measures of continuity eg, SCOC)	Hospitalisations, length of stay, emergency department visits, intensive care days, preventive medicine visits, drug or alcohol abuse, outpatient attendance, glucose control for adults with diabetes	None	18/5
Richards *et al*[77]	1997–2002, 2 of 33	Range of settings	Psoriasis	P	Patient's perception of care, satisfaction, interpersonal skills (surveys, interviews)	Treatment adherence, medication use	None	2/0

BMI, body mass index.

Annotated by the Urology Services Inquiry

and safety and that focusing on improving patient experience will increase the likelihood of improvements in the other two domains.[3]

The evidence collated in this study demonstrates positive associations between patient experience and the other two domains of quality. Because associations do not entail causality, this does not necessarily prove that improvements in patient experience will cause improvements in the other two domains. However, the weight of evidence across different areas of healthcare indicates that patient experience is clinically important. There is also some evidence to suggest that patients can be used as partners in identifying poor and unsafe practice and help enhance effectiveness and safety. This supports the argument that the three dimensions of quality should be looked at as a group and not in isolation. Clinicians should resist sidelining patient experience measures as too subjective or mood-orientated, divorced from the 'real' clinical work of measuring and delivering patient safety and clinical effectiveness.

Acknowledgements The authors of this work thank Mandy Wearne at NHS Northwest who commissioned this work and provided comments on earlier drafts, We are also grateful to Jocelyn Cornwell who provided comments on an early draft of this article. This article presents independent research commissioned by the National Institute for Health Research (NIHR) under the Collaborations for Leadership in Applied Health Research and Care (CLAHRC) programme for North West London. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Contributors CD and DB conceived of the study and were responsible for the design and search strategy. CD and LL were responsible for conducting the search. CD and LL conducted the data analysis and produced the tables and graphs. Derek Bell provided input into the data analysis and interpretation. The initial draft of the manuscript was prepared by CD then circulated among all authors for critical revision. All authors helped to evolve analysis plans, interpret data and critically revise successive drafts of the manuscript.

Funding This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement There are no additional data available.

REFERENCES

1. Institute of Medicine. *Crossing the quality chasm: a new health system for the 21st century*. Washington, DC: National Academy Press, 2001.
2. Black N, Jenkinson C. Measuring patients experiences and outcomes. *BMJ* 2009;339:202–5.
3. Department of Health. Liberating the NHS:transparency in outcomes—a framework for the NHS: Department of Health, 2010.
4. Darzi A. *High quality care for all—NHS Next Stage Review Final Report*. Department of Health, 2008.
5. Department of Health. Using the Commissioning for Quality and Innovation (CQUIN) payment framework, 2008.
6. Berwick DM. What 'patient-centered' should mean: confessions of an extremist. *Health Aff* 2009;28:w555–65.
7. Street RL, Makoul G, Arora NK, *et al*. How does communication heal? Pathways linking clinician-patient communication to health outcomes. *Patient Ed Couns* 2009;74:295–301.
8. Thom DH, Hall MA, Pawlson LG. Measuring patients' trust in physicians when assessing quality of care. *Health Aff* 2004;23:124–32.
9. Vincent CA, Coulter A. Patient safety: what about the patient? *Qual Saf Health Care* 2002;11:76–80.
10. Coulter A. *Engaging patients in healthcare*. Maidenhead, Berkshire: Open University Press, 2011.
11. Rathert C, Huddleston N, Pak Y. Acute care patients discuss the patient role in patient safety. *Health Care Manag Rev* 2011;36:134–44. 10.1097/HMR.0b013e318208cd31.
12. Picker Institute. Patient experience surveys: the rationale Picker Institute Europe, Oxford, 2008.
13. NICE. Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. Manchester: NICE, 2011.
14. Iles V, Vaughan Smith J. Working in health care could be one of the most satisfying jobs in the world—why doesn't it feel like that?, 2009.
15. López L, Weissman JS, Schneider EC, *et al*. Disclosure of hospital adverse events and its association with patients' ratings of the quality of care. *Arch Intern Med* 2009;169:1888–94.
16. Safran DG, Taira DA, Rogers WH, *et al*. Linking primary care performance to outcomes of care. *J Fam Pract* 1998;47:213–20.
17. Robert Wood Johnson Foundation. Good for Health, good for business: the case for measuring patient experience of care: The Center for Health Care Quality at the George Washington University Medical Center, Washington DC.
18. Greenhalgh T, Peacock R. Effectiveness and efficiency of search methods in systematic reviews of complex evidence: audit of primary sources. *BMJ* 2005;331:1064–65.
19. Fuertes J, Boylan L, Fontanella J. Behavioral indices in medical care outcome: the working alliance, Adherence, and related factors. *J Gen Intern Med* 2009;24:80–5.
20. Raiz LR, Kilty KM, Henry ML, *et al*. Medication compliance following renal transplantation. *Transplantation* 1999;68:51–5.
21. Cabana M, Jee S. Does continuity of care improve patient outcomes? *J Fam Pract* 2004;53.
22. Plomondon M, Magid D, Masoudi F, *et al*. Association between angina and treatment satisfaction after myocardial infarction. *J Gen Intern Med* 2008;23:1–6.
23. Jha AK, Orav EJ, Zheng J, *et al*. Patients' perception of hospital care in the United States. *N Engl J Med* 2008;359:1921–31.
24. Sequist, *et al*. Quality Monitoring of Physicians: Linking Patients' Experiences of Care to Clinical Quality and Outcomes. *J Gen Intern Med* 2008;23.
25. Kaplan SH, Greenfield S, Ware JE. Assessing the effects of physician-patient interactions on the outcomes of chronic disease. *Med Care* 1989;27(3 Suppl):S110–27.
26. Meterko M, Wright S, Lin H, *et al*. Mortality among patients with acute myocardial infarction: the influences of patient-centered care and evidence-based medicine. *Health Serv Res* 2010;45 (5p1):1188–204.
27. Glickman SW, Boulding W, Manary M, *et al*. Patient satisfaction and its relationship with clinical quality and inpatient mortality in acute myocardial infarction. *Circ Cardiovasc Qual Outcomes* 2010;3:188–95.
28. Zolnierek HKB, DiMatteo MR. Physician communication and patient adherence to treatment: a meta-analysis. *Med Care* 2009;47:826–34.
29. Drotar D. Physician behavior in the care of pediatric chronic illness: association with health outcomes and treatment adherence. *J Dev Behav Pediatr* 2009;30:246–54.
30. Arbuthnott A, Sharpe D. The effect of physician-patient collaboration on patient adherence in non-psychiatric medicine. *Patient Ed Couns* 2009;77:60–7.
31. Lewis ET, Combs A, Trafton JA. Reasons for under-use of prescribed opioid medications by patients in pain. *Pain Med* 2010;11:861–71.
32. Kahn KL, Schneider EC, Malin JL, *et al*. Patient centered experiences in breast cancer: predicting long-term adherence to tamoxifen use. *Med Care* 2007;45:431–9.
33. Schneider EC, Zaslavsky AM, Landon BE, *et al*. National quality monitoring of medicare health plans: the relationship between enrollees' reports and the quality of clinical care. *Med Care* 2001;39:1313–25.
34. Schoenthaler A, Chaplin WF, Allegrante JP, *et al*. Provider communication effects medication adherence in hypertensive African Americans. *Patient Ed Couns* 2009;75:185–91.
35. Heisler M, Bouknight RR, Hayward RA, *et al*. The relative importance of physician communication, participatory decision making, and patient understanding in diabetes self-management. *J Gen Intern Med* 2002;17:243–52.
36. Haynes RB, Ackloo E, Sahota N, *et al*. Interventions for enhancing medication adherence. *Cochrane Database Syst Rev* 2008;2.
37. Flocke SA, Stange KC, Zyzanski SJ. The association of attributes of primary care with the delivery of clinical preventive services. *Med Care* 1998;36:AS21–30.

Annotated by the Urology Services Inquiry

38. O'Malley AS, Sheppard VB, Schwartz M, *et al*. The role of trust in use of preventive services among low-income African-American women. *Prev Med* 2004;38:777–85.
39. Carcaise-Edinboro P, Bradley CJ. Influence of patient-provider communication on colorectal cancer screening. *Med Care* 2008;46:738–45.
40. Jackson CA, Clatworthy J, Robinson A, *et al*. Factors associated with non-adherence to oral medication for inflammatory bowel disease: a systematic review. *Am J Gastroenterol* 2010;105:525–39.
41. Clark NM, Cabana MD, Nan B, *et al*. The clinician-patient partnership paradigm: outcomes associated with physician communication behavior. *Clin Pediatr* 2008;47:49–57.
42. Stewart M, Brown J, Donner A, *et al*. The impact of patient-centered care on outcomes. *J Fam Pract* 2000;49:796–804.
43. Sans-Corrales M, Pujol-Ribera E, GenÃ©-Badia J, *et al*. Family medicine attributes related to satisfaction, health and costs. *Fam Pract* 2006;23:308–16.
44. Saultz JW, Lochner J. Interpersonal continuity of care and care outcomes: a critical review. *Ann Fam Med* 2005;3:159–66.
45. Hsiao C-J, Boult C. Effects of quality on outcomes in primary care: a review of the literature. *A J Med Qual* 2008;23:302–10.
46. Isaac T, Zaslavsky AM, Cleary PD, *et al*. The relationship between patients' perception of care and measures of hospital quality and safety. *Health Serv Res* 2010;45:1024–40.
47. Rao M, Clarke A, Sanderson C, *et al*. Patients' own assessments of quality of primary care compared with objective records based measures of technical quality of care: cross sectional study. *BMJ* 2006;333:19–22.
48. Chang JT, Hays RD, Shekelle PG, *et al*. Patients' global ratings of their health care are not associated with the technical quality of their care. *Ann Intern Med* 2006;145:635–6.
49. Weingart SN, Pagovich O, Sands DZ, *et al*. What can hospitalized patients tell us about adverse events? Learning from patient-reported incidents. *J Gen Intern Med* 2005;20:830–6.
50. Weissman JS, Schneider EC, Weingart SN, *et al*. Comparing patient-reported hospital adverse events with medical record review: do patients know something that hospitals do not? *Ann Intern Med* 2008;149:100–8.
51. Solberg LI, Asche SE, Averbeck BM, *et al*. Can patient safety be measured by surveys of patient experiences? *Jt Comm J QualPatient Saf* 2008;34:266–74.
52. O'Connor AM, Bennett CL, Stacey D, *et al*. Decision aids for people facing health treatment or screening decisions. *Cochrane database Syst Rev* 2009(3):CD001431.
53. Mumford E, Schlesinger HJ, Glass GV. The effect of psychological intervention on recovery from surgery and heart attacks: an analysis of the literature. *Am J Public Health* 1982;72:141–51.
54. Begg C, Berlin J.N.J. Publication bias: a problem in interpreting medical data. J R Stat SocSer A 1988;151.
55. Burgers JS, Voerman GE, Grol R, *et al*. Quality and coordination of care for patients with multiple conditions: results from an international survey of patient experience. *Eval Health Prof* 2010;33:343–64.
56. Vincent C. Understanding and responding to adverse events. *N Engl J Med* 2003;348:1051–6.
57. Agoritsas T, Bovier PA, Perneger TV. Patient reports of undesirable events during hospitalization. *J Gen Intern Med* 2005;20:922–8.
58. Jackson JL, Chamberlin J, Kroenke K. Predictors of patient satisfaction. *Soc Sci Med* 2001;52:609–20.
59. Safran DG, Miller W, Beckman H. Organizational dimensions of relationhip-centred care. *J Gen Intern Med* 2005;21:S9–15.
60. Alamo MMo, Moral RR, PÃ©rula de Torres LA. Evaluation of a patient-centred approach in generalized musculoskeletal chronic pain/fibromyalgia patients in primary care. *Patient Educ Couns* 2002;48:23–31.
61. Fan VS, Reiber GE, Diehr P, *et al*. Functional status and patient satisfaction. *J Gen Intern Med* 2005;20:452–9.
62. Little P, Everitt H, Williamson I, *et al*. Observational study of effect of patient centredness and positive approach on outcomes of general practice consultations. *BMJ* 2001;323:908–11.
63. Levinson W, Roter DL, Mullooly JP, *et al*. Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons. *JAMA*1997;277:553–9.
64. Slatore , Christopher G, Cecere , *et al*. *Patient-clinician communication: associations with important health outcomes among veterans with COPD*. Northbrook, ETATS-UNIS: American College of Chest Physicians, 2010.
65. Lee Y-Y, Lin JL. The effects of trust in physician on self-efficacy, adherence and diabetes outcomes. *Soc Sci Med* 2009;68: 1060–8.
66. Lee Y-Y, Lin JL. Do patient autonomy preferences matter? Linking patient-centered care to patient-physician relationships and health outcomes. *Soc Sci Med* 2010;71:1811–18.
67. Kennedy A, Nelson E, Reeves D, *et al*. A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease. *Health Technol Assess (Winchester, England)* 2003;7:iii, 1–113.
68. Kinnersley P, Stott N, Peters TJ, *et al*. The patient-centredness of consultations and outcome in primary care. *Br J Gen Pract* 1999;49:711–16.
69. Fremont A, Cleary P, Hargraves J, *et al*. Patient-centered processes of care and long-term outcomes of myocardial infarction. *J Gen Intern Med* 2001;16:800–8.
70. Riley DL, Stewart DE, Grace SL. Continuity of cardiac care: cardiac rehabilitation participation and other correlates. *Int J Cardiol* 2007;119:326–33.
71. Blasi ZD, Harkness E, Ernst E, *et al*. Influence of context effects on health outcomes: a systematic review. *Lancet* 2001;357:757–62.
72. Hall AM, Ferreira PH, Maher CG, *et al*. The influence of the therapist-patient relationship on treatment outcome in physical rehabilitation: a systematic review. *Phys Ther* 2010;90:1099–110.
73. Stevenson FA, Cox K, Britten N, *et al*. A systematic review of the research on communication between patients and health care professionals about medicines: the consequences for concordance. *Health Expect* 2004;7:235–45.
74. Hall JA, Roter DL, Katz NR. Meta-analysis of correlates of provider behavior in medical encounters. *Med Care* 1988;26:657–75.
75. Stewart MA. Effective physician-patient communication and health outcomes: a review. *Can Med Assoc J* 1995;152:1423–33.
76. Beck RS, Daughtridge R, Sloane PD. Physician-patient communication in the primary care office: a systematic review. *J Am Board Famy Pract* 2002;15:25–38.
77. Richards HL, Fortune DG, Griffiths CEM. Adherence to treatment in patients with psoriasis. *J Eur Acad Dermatol Venereol* 2006;20:370–9.

Report of a Root Cause Analysis of SAI [redacted]

Comments regarding Factual Accuracy

[redacted] was 68 years old when he developed colonic obstruction due to an adenocarcinoma of his sigmoid colon necessitating sigmoid colectomy and a Hartmann's end colostomy in July 2012. He subsequently declined adjuvant chemotherapy. He required a small bowel resection in August 2014 for small bowel obstruction due to metastatic colonic adenocarcinoma. On CT scanning on 11 March 2015, it was evident that he had metastatic disease progression in the form of a left pulmonary nodule which had increased in size, and of a left pelvic mass causing left upper urinary tract obstruction. Following discussion at the Lower GI MDM on 12 March 2015, his primary colorectal surgeon (ConsSurg9) wrote to Consultant Urologist 11 (ConsUrol11) with a view to considering left ureteric stenting. Even though referred to ConsUrol11, he attended a clinic of Consultant Urologist 15 (ConsUrol15) on Thursday 26 March 2015, when his Specialist Trainee wrote in her letter to [redacted]'s family doctor that they had arranged his elective admission on 31 March 2015 for insertion of a left ureteric stent.

The report then states that [redacted] was admitted to Craigavon Area Hospital on 31 March 2015 under the care of Consultant Urologist 13 (ConsUrol13). Having reviewed the record of his admission both on NIECR and PAS, it is evident that I am Consultant Urologist 13. However, the record is untrue. I had undertaken to conduct an additional operating session on the morning of Tuesday 31 March 2015. As I have retained records of all admissions arranged by me, currently back to and including 2010, I can confirm that I arranged the admissions of four patients for surgery that morning. [redacted] was not one of them. I have cross checked with my secretary who has provided a copy (attached) of the operating list entered on the Theatre Management System. [redacted] is not included on the list. It is a matter of concern that the Review Team have been prepared to rely upon the record of NIECR and PAS without checking its veracity.

However, even though I do arrange admissions with the agreement and commitment of the patients involved, one of those four patients was unable to be admitted that morning. Though entirely speculative on my part now, I suspect that it is most probably the case that I had time as a consequence to supervise the procedure undergone by [redacted]., in another theatre that morning, particularly as the same Specialist Trainee was not rostered to my operating session that morning.

As a consequence, as detailed in the Report, I agreed to have [redacted],. placed on my waiting list on 02 April 2015 for Removal of Left Ureteric Stent, Ureteroscopy and ? Restenting, with an indicative date for his readmission being October 2015, though the intent was that the stent would not be removed or replaced until the patient had completed chemotherapy.

The Report records that Consultant Oncologist 10 wrote to me, (ConsUrol13), on 26 November 2015 advising that palliative chemotherapy had been completed, and enquiring whether this would have been an appropriate time to arrange stent removal / replacement. The Report notes that the letter was filed in the patient's Craigavon Area Hospital chart with a stamp denoting the date of receipt, but without a note or signature to indicate that I had read the letter prior to its filing. This letter is the only communication or event typed in bold in Section 6.0 of the Report, which stated that there was no evidence that I had either received and / or acknowledged the letter, and asks the question 'Did he receive this letter?'. Then, without actually asking me the question posed, the report states that the Review Team were unable to conclude if I reviewed my letters. Then most egregiously, the Review Team noted that I did not routinely triage referrals where there was a formal process in place for triage, and that this lack of triaging may have extended to documentation from other consultants. Indeed, for good measure, it could also be extended to reviewing and / or actioning (sic) email correspondence!

On placing so much emphasis upon this letter, and having reviewed the letter as filed in the patient's chart when provided to me upon my request, I was struck by three details. The first was that the patient's CAH unit number was handwritten on the top right hand corner of the letter. My secretary has since confirmed that it was written by her. Even though my name and address is typed in the top left hand corner of the letter, the second detail is that the salutation was 'Dear Personal information redacted by USI'. The third detail was that the letter was copied to ConsSurg9 and to the GP.

I therefore decided to attempt to find an answer to the question raised by but apparently not explored by the Review Team. My secretary has advised me that even though the letter had been received by her, she mistakenly did not appreciate that it was actually addressed to me, in view of the salutation and in view of the fact that it had not been copied to me, and that she had filed it in his chart without showing it to me. This course of action was obviously regrettable, but supports my contention that I have had no memory of ever having received the letter of 26 November 2015.

I find it interesting to note in the Report that ConsSurg9 wrote to ConsUrol11 on 09 May 2016. There is no copy of that letter filed in the patient's Craigavon Area Hospital chart, whether noted, signed, actioned or otherwise. The absence of any comparable commentary or generalisations is remarkable. It was not even typed in bold!

The subsequent emails which I received from my secretary or audiotypist of 30 December 2015, of 04 March 2016 and of 10 May 2016 are typical of requests and enquiries which I have received every day for years from patients, relatives, GPs, MLAs, MPs and personnel in Trust Management, regarding dates for admission. For years, I have had approximately 280 patients awaiting elective admission and readmission. I currently have 228 patients awaiting urgent elective admission dating back to August 2014, prior to Patient 16 having first been referred to our department in March 2015! The failure to respond positively to any request

for admission is a consequence of the lack of operating capacity provided by the Trust. The failure to respond in any way to every request is additionally a consequence of the lack of time provided and available to do so. The Report would imply that the Review Team are of the view that, if it is intended that a stent will be replaced in six months' time, that it will be, irrespective of the number to be replaced at that time, in addition to the even more numerous patients with even greater clinical priorities.

Patient 16's further management proceeded as detailed in the Report. It is certainly the case that encrustation of the lower end of the ureteric stent would have caused the patient pain or discomfort referred to his bladder. It was worthy of note that it had not been possible to restent the left upper tract satisfactorily on 29 June 2016 due to the fixed adherence of the left ureter. His upper tract remained obstructed, necessitating nephrostomy drainage. The combination of the operative intervention and persistence of obstruction resulted in Patient 16 suffering a Bacteroides bacteraemia. Even though his left upper tract was later satisfactorily stented on 10 August 2016, it did not adequately relieve upper tract obstruction. It was for that reason that the left nephrostomy drain was replaced, rather than removed, on 01 September 2016.

I have then found it most remarkable that the Review Team failed entirely to include any reference to the email of 01 December 2016 from me to my secretary regarding the patient's admission on 06 December 2016 and which I arranged while recovering from prostatic resection on 16 November 2016. I find it equally remarkable that the Review Team omitted any reference of my emails of 02 December 2016 to ConsUrol11 and to ConsOnc2. In particular, in my email to ConsUrol9, I asserted that Patient 16 had completed palliative chemotherapy in March 2016. This underscores my understanding at the time, as I had not received any correspondence to the contrary. These emails have been provided.

General and Concluding Comments

Patient 16's daughter, Patient 16's Daughter, submitted a letter of complaint, dated 05 December 2016, and endorsed by her father on 11 December 2016. The letter was received in the Governance Office of the Trust on 21 December 2016. Mr. Cardwell enquired by email on 22 December 2016 whether the complaint needed to be screened as an SAI. Dr. Boyce enquired of Mr. Carroll by email on 23 December 2016 whether he considered it should be an SAI, enquiring whether the 'delay in the stent issue be down to the urologist or is that a process under radiology's control?' I was advised on 30 December 2016 of the possibility of an SAI. Mrs. Gishkori wrote to Patient 16's Daughter on 17 April 2017 to advise that her father's management would be the subject of a SAI investigation.

At 15.58 on 28 October 2019, over 2½ years later, an email is sent to me by the Governance Team, attaching the Reports of the Root Cause Analyses of SAI Personal Information redacted by USI and SAI Personal Information redacted by USI,

requesting that I check both for factual accuracy and to respond by Wednesday 30 October 2019, even though I had complete, clinical and operative commitments during those two days. It was on realising that I had not arranged the admission of Patient 16. on 31 March 2015, that I appreciated that the factual accuracy of the report could not be established without recourse to the clinical records which had not been provided for the purpose, until requested.

I have found it a matter of concern that the Review Team could rely upon digitalised records, without any validation. It is a matter of gravest concern that the Review Team could raise a fundamental question relating to the letter of 25 November 2015 and answer it only with negative and potentially libellous commentary, for which there has been no evidence. I have been legally advised that their comments are probably a breach of my Personal Data Protection. The failure of the Review Team to even appreciate the potential significance of the salutation in the letter of 25 November 2015 is a matter of concern. Even though the Report included a reference to the email of 02 December 2016 from ConsOnc2 to me, it is most concerning that the Review Team chose to omit any reference to the emails of 02 December 2016 from me in return.

I do agree with many of the recommendations of the report. However, there is one significant omission….time. That omission has been epitomised by the lack of provision of any time to investigate the Report's factual accuracy and to prepare these comments. It has taken me some eight hours to do so. The recommendations provide for deadlines, without time provided to meet them. Timeliness requires time!

I believe that it is evident that this SAI has been investigated without due diligence and a Report compiled with a prejudice and bias betrayed in its writing. It is opportune that RQIA are currently conducting a review of the conduct of SAI investigations. I intend to refer this SAI investigation and its report to RQIA. I will certainly include its conduct in a Formal Written Grievance to the Trust.

I look forward to receiving a revised Report in due course.

Personal Information redacted by USI

Aidan O'Brien

King, Dawn

From: O'Brien, Aidan
Sent: 19 November 2019 04:38
To: Connolly, Connie
Cc: Cardwell, David
Subject: SAI Report
Attachments: Report of a Root Cause Analysis of SAI [redacted] docx; Operating List 31 March 2015 001.jpg

Sensitivity: Confidential

From: O'Brien, Aidan
Sent: 19 November 2019 04:22
To: Connolly, Connie
Cc: Cardwell, David
Subject: SAI Reports
Sensitivity: Confidential

Dear Connie,

I attach a my Comments regarding the Report of SAI [redacted]
I attach a copy of the Operating List of 31 March 2015.

As reported in my Comments, I have also sent you copies of emails which have not been included in the Report.

As I have reported in my Comments, I have spent eight hours checking for factual accuracy and omissions in this Report, and providing the attached.
I have not yet had the time to conduct a similar exercise for SAI [redacted], or provided with any time to do so.

I will endeavour to do so as soon as is possible,

Aidan.

From: Connolly, Connie
Sent: 14 November 2019 15:23
To: O'Brien, Aidan
Cc: Cardwell, David
Subject: FW: SAI Reports- comments due
Importance: High
Sensitivity: Confidential

Dear Mr O'Brien- I wanted to let you know that I will be on study leave from this evening until 20 November 2019. Can I ask you that you forward your comments tomorrow to Mr David Cardwell who will receive them on my behalf.

Kind Regards
Connie Connolly
Acting Clinical Care and Governance Co-Ordinator
Office Number [redacted]
Mobile Number [redacted]

Received from SHSCT on 02/02/22. annotated by the Urology Services Inquiry.

From: Connolly, Connie
Sent: 13 November 2019 09:29
To: O'Brien, Aidan
Subject: RE: SAI Reports
Sensitivity: Confidential

Good Morning Mr O'Brien- Thank you for the update. I will have the remainder of the notes with Noeleen this morning. There is one chart (Patient 16) which is coming from Villa 3 and will be delivered to Noeleen later this afternoon.
Regards
Connie

From: O'Brien, Aidan
Sent: 12 November 2019 21:18
To: Connolly, Connie
Subject: FW: SAI Reports
Sensitivity: Confidential

Dear Connie,

Thank you for providing the documentation relating to Patient 16.
There are a couple of queries which I hope to have clarified tomorrow.
I will not be able to complete my comments relating to the SAI report until Thursday evening, as I will spend tomorrow evening previewing Thursday's MDM which I chair.
I undertake to have returned my comments to you by Friday 15 November 2019.

As I have found it helpful to have the original records, I would similarly be grateful if you would make available the charts of the patients involved in the SAI into triage.

Thank you,

Aidan.

From: O'Brien, Aidan
Sent: 07 November 2019 11:09
To: Connolly, Connie
Subject: RE: SAI Reports
Sensitivity: Confidential

Dear Connie,

Thank you for your email below.

To the best of my memory, I have only had the experience of two SAI reports previously, and with regard to only one of which was I requested to comment upon its accuracy.
Doing so resulted in a nine page commentary which resulted in some significant change in the final report.

Having reviewed the draft report concerning Patient 16, I have a number of concerns which may hopefully be further clarified with access to his clinical records and to the response of the Department of Oncology to the complaint received from his family.

I would therefore be grateful if you could have his clinical records and all other documentation delivered to my office so that I may be able to ascertain the factual accuracy and completeness of the draft report.

Thank you,

Aidan.

Received from SHSCT on 02/02/22. annotated by the Urology Services Inquiry.

From: Connolly, Connie
Sent: 04 November 2019 12:43
To: O'Brien, Aidan
Cc: Connolly, Carly
Subject: FW: SAI Reports
Importance: High
Sensitivity: Confidential

Dear Mr O'Brien
My name is Connie Connolly and I am Carly's line manager. After our weekly Governance with Melanie McClements this morning, I have been asked to contact your comments below in relation to both the Patient 16 and the joint report re: Patient 11, Patient 12, Patient 13, Patient 14 and Patient 15.
As you are aware, checking for factual accuracy is routine after the compilation of each SAI report. Given that you did not receive the reports until Wednesday 30th October 2019, the Trust requests that your comments are returned by 12 noon on Wednesday 13th November 2019. This provides you with sufficient time to peruse the reports. We are anxious to have the reports ready for both the families and the Ombudsman.
Regards
Connie Connolly

Connie Connolly
Acting Clinical Governance Co-ordinator
Office number Personal Information redacted by the USI
Mobile Personal Information redacted by the USI

From: O'Brien, Aidan
Sent: 30 October 2019 22:34
To: Connolly, Carly
Subject: RE: SAI Reports

Dear Carly,

When you sent me the below email this morning, I was about to complete consenting patients having surgery today.
I have been operating all day.
I left the hospital after 7 pm.
I have had a meal for the first time today, following which I have compiled the list of patients to be notified tomorrow of their admissions to DSU on 08 November 2019.
I have now just read any emails sent to me today, including yours!

I was advised in early 2017 that the management of Mr. Patient 16 would be the subject of a SAI investigation.
I respectfully find it most remarkable that, two and half years later, I would be sent a report of the investigation, accompanied with a deadline to respond within two days, and then to learn, after expiry of the deadline. that there is a commitment to share the report with the family of Mr. Patient 16 in the immediate future.
The report will require from me a considered response, and which I cannot provide until I have had the time to do so.

I believe any reasonable person would consider the above proposed timeline to be unreasonable.

Aidan.

From: Connolly, Carly
Sent: 30 October 2019 08:32

Received from SHSCT on 02/02/22. annotated by the Urology Services Inquiry.

To: O'Brien, Aidan
Cc: Connolly, Connie
Subject: RE: SAI Reports
Importance: High

Dear Mr O'Brien

I have forwarded your response to the Corporate Office and I have been advised that Patient 16 report is to be reviewed by the end of today 30 October 2019, as the Trust is committed to having the report with the family in the immediate future.

Can you please review the 2nd report which you received by Wednesday 2nd November 2019.

Regards

Carly

From: O'Brien, Aidan
Sent: 29 October 2019 07:39
To: Connolly, Carly
Subject: RE: SAI Reports

Dear Carly,

I received your email yesterday evening.
I have not had time to read the attached reports in detail.
I have incompletely read one, finding a number of factual inaccuracies and untruths.

The main purpose of replying to you so early this morning is to enquire if you genuinely intended to request a response by tomorrow?
If so, why?

Thank you,

Aidan.

From: Connolly, Carly
Sent: 28 October 2019 15:58
To: O'Brien, Aidan
Cc: Connolly, Connie; Cardwell, David
Subject: SAI Reports
Importance: High

Dear Mr O'Brien

I attach for your attention a copy of the SAI reports into the care of Patient 16, Patient 11, Patient 12, Patient 13, Patient 14 and Patient 15. As you were involved in these cases I would be grateful if you could read over the reports and confirm their factual accuracy. If you identify any inaccuracies I would be grateful if you would please report these back to me by Wednesday 30/10/2019.

Can you please confirm receipt of this email.

Many Thanks

Received from SHSCT on 02/02/22. annotated by the Urology Services Inquiry.

The Regulation and Quality Improvement Authority

RQIA Review of the Systems and Processes for Learning from Serious Adverse Incidents in Northern Ireland

June 2022

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

The Regul d Qu l y Impr veme Au h r y

The Regulat on and Qual ty Improvement Author ty (RQIA) s the ndependent body respons ble for regulat ng and nspect ng the qual ty and ava lab l ty of Health and Soc al Care serv ces n Northern Ireland. RQIA's rev ews dent fy best pract ce, h ghl ght gaps or shortfalls n serv ces requ r ng mprovement and protect the publ c nterest. Rev ews are supported by a core team of staff and by ndependent assessors who are e ther exper enced pract t oners or experts by exper ence. RQIA reports are subm tted to the Department of Health (DoH) and are ava lable on the RQIA webs te at www.rq a.org.uk.

Ack wledgeme s

RQIA w shes to thank all those who fac l tated th s rev ew by part c pat ng n d scuss ons, meet ngs, surveys and by prov d ng relevant nformat on.

Membersh p f he Exper Rev ew Te m

Mar a D neen i	Manag ng D rector of Consequence UK, Consultant to the Nat onal Pat ent Safety Agency 2001-2003, approved nvest gator - NHS England's serious incident framework and author of S x Steps to Root Cause Analys s. i
Dr Dav d Evans i	Former Med cal D rector and Inter m Ch ef Execut ve Northumbr a Healthcare Nat onal Health Serv ce Foundat on Trust, England. i
Dr Lourda Geoghegan	Former D rector of Improvement and Med cal D rector, Regulat on and Qual ty Improvement Author ty (role n rev ew ceased March 2020) i
Emer Hopk ns i	D rector of Hosp tal Serv ces, Independent Healthcare, Aud t and Rev ews, RQIA (role n rev ew commenced March 2020)
Mr Hall Graham	Profess onal Adv sor, Regulat on and Qual ty Improvement Author ty.
Mrs V v en Jess i	Lay Representat ve and Independent Expert Adv sor to the rev ew
Mr Brian O'Hagan i	Lay Representat ve and Independent Expert Adv sor to the rev ew i i
Dr R chard Wr ght i	Former Med cal D rector of Southern Health and Soc al Care Trust and Profess onal Med cal Adv sor, Regulat on and Qual ty Improvement Author ty. i i

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Table of o e

obsary of Terms ...c ... 1

Foreword ... c ... 3

Exe utive Summary ...c ... 5

1.0 Ba kground and Context ... 9 c

1.1 Introdu tion ... 9
1.2 Context ... 9
1.3 Overview of Regional SAI Pro edure ... 10
Level 1 Review: Signifi ant Event Audit (SEA) ...c ... 11
Level 2 Review: Root Cause Analysis (RCA) ... 11
Level 3 Review: Independent Review ... 12
1.4 Patient and Family Involvement and Engagement ...c ... 12

2.0 Terms of Referen e ... 13

3.0 Review Methodology..c ... 14

3.1 The Identifi ation and Sele tion of SAIs ... 15
3.2 The Stru tured Assessment of SAI Reports ... 15
3.3 How ea h Trust responds to Signifi ant Unexpe ted Harm Events ... 17
3.4 Patient and Family Engagement ... 18
3.5 Staff Engagement ... 19
3.6 Meetings with HSC Organisations ... 21
3.7 Engagement with other Organisations ...c ... 21

4.0 Findings ... 22 c

4.1 Overall findings of the Expert Review Panel ... 22
4.2 Patient and Family Engagement ... 23
4.3 Staff Engagement (staff engaged in the are and management of the patient who experien ed harm) ... 27
4.4 Staff Engagement (staff with experien e undertaking SAI reviews) ... 30
4.5 SAI Reports: The extent they demonstrated a reasonable standard of review and positive ontribution to patient safety in Northern Ireland ... 34

5.0 Con lusion ... 43

6.0 Re ommendations ...c ... 45 c

Re ommendation 1: ... 45
Re ommendation 2: ....c ... c ... 45

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Recommenda on 46
Recommenda on 4 48
Recommenda on 5 48
Append x A SAIs by Ca egory and by HSC Organ sa on 5
Append x B O her Organ sa ons ha were offered he Oppor un y o Inpu In o h s Rev ew 51 0
Append x C Improvemen s Sugges ed by S aff 52 0
Append x D Examples of Cr cal Success Fac ors ..0 57
References 61

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Glossar o r s

C

Belfast Trust C	Belfast Health and So ial are Trust C
AMHS C	hildren and Adoles ent Mental Health Servi es C
Q C	are Quality ommission C
oH C	epartment of Health C
RO C	esignated Review Offi er C
HS C	Health and So ial are C
HS B C	Health and So ial are Board C
HR C	nquiry into Hyponatraemia-related eaths C
Multidis iplinary	nvolving professionals from different dis iplines who have different professional skills, expertise and experien e. C
N AS C	Northern reland Ambulan e Servi e C
Northern Trust	Northern Health and So ial are Trust C
P C	Patient lient oun il C
PHA C	Publi Health Agen y C
PP C	Personal and Publi nvolvement C
R A C	Root ause Analysis C
RQIA C	Regulation and Quality mprovement Authority C
SA C	Serious Adverse n ident C
South Eastern Trust	South Eastern Health and So ial are Trust C
Southern Trust	Southern Health and So ial are Trust C
SPPG	Strategi Performan e and Planning Group (formerly Health and So ial are Board) C
Western Trust	Western Health and So ial are Trust C

C

C

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Foreword A

ev ew of t e Sy tem s and Proce e for Learn n from Ser ou dver e Inc dent n ort ern Ireland re ulted from t e ndependent Pu lic Inquiry led by Justice O'Hara which nve t gated t e deat of f ve c ldren in o p tal n Nort ern Ireland. fter ear ng ev dence from a w de range of nd v dual and organ at on , t concluded t at deat ad been avo dable and t at t e culture of t e ealt erv ce at t e t me, arrangement n place to en ure t e qual ty of erv ce and be av our of nd v dual h ad contr buted to t o e unnece ary deat .

key f nd ng of t e Publ c Inqu ry wa t at t e nternal nve t gat on nto t e deat and t e r urround ng c rcum stance were inadequate. ey had fa led to ident fy t e underly ng cau e . It al o found t at, a gu dance on flu d management on c ldren became ava lable, t wa not d em inated and act oned effect vely acro t e Healt and Soc al Care (HSC) y tem.

e real ty i t at sm lar stuat on , w ere event lead ng to arm ave been nadequately nve t gated and example of recogn ed good pract ce ave not been followed, ave been, and are l kely to be repeated n current pract ce.

Suc nadequac e br ng d tre and uffer ng to t e nd v dual affected and t e r loved one ; and t e taff w o e effort to prov de good and afe care are underm ined.

Ser ou dver e Inc dent (S I) rev ew are a fundamental part of ow t e w ole sy tem ould learn from arm, and make mprovement to Healt and Soc al Care erv ce n Nort ern Ireland.

ev ew, comm oned by t e Department of Healt (DoH), in it re pon e to t e recommendat on of t e Inqu ry, and undertaken by t e QI , a a e ed t e effect vene of t e current S I proce . A

It a een one of our mo t n f cant ev ew , w c a enef ted from en a ement w t a w de ran e of nd v dual , or an at on and roup acro t e Healt and Soc al Care y tem.

We would e pec ally l ke to t ank all fam l e w o contr buted to t e Rev ew, a t e r exper ence of t e real ty from a pat ent and fam ly per pect ve a been a key feature n ap ng the Review's findings.

e Expert ev ew eam found t at ne t er t e S I rev ew proce nor t mplementat on uff c ently robu t to con tently enable an under tand ng of w at factor , bot y tem s and people, ave led to a pat ent or erv ce u er com ng to arm.

HSC leader and manager mu t work to make ure t at f omet ng goe wrong, all taff are conf dent to peak up, t roug a competent and ndependent rev ew proce , know ng t at do ng o w ll elp t em keep t e r pat ent and erv ce u er afe and mprove t e qual ty of care t ey are able to del ver.

Pat ent and erv ce u er , and t e r loved one and advocate , mu t be able to take part freely and fully n t e proce , o t ey f nd out w at happened and can help make sure it won't appen aga n.

On be alf of RQI , we hope t at t e recommendat on n t ev ew, w c ave been produced w t t e a tance of a w de range of pat ent , serv ce u er , fam l e , cl n c an and manager from acro HSC, w ll be accepted, implemented fully, and dr ve mprovement n afety and qual ty t roug out t e y tem.

Personal information redacted by USI

Christine Collins MBE
Chair A A

Personal information redacted by USI

Brie e Do n hy
Chief Executive

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Execut e u ry

B ckground nd Context

Serious Ad erse Incident (SAI) re iews are a fundamental component of how we learn from harm and subsequently make impro ements to the systems for the deli ery of safe patient care. Regional guidance for the reporting and follow-up of SAIs in Northern Ireland has been in place since 2004. Howe er, o er the last decade, the SAI process and its implementation has come under scrutiny both regionally and nationally. Concerns ha e been raised around the current procedure for the Reporting and Follow-up of Serious Ad erse Incidents (SAIs) in Northern Ireland (No ember 2016)[1] (here-after the SAI procedure). It has also been v highlighted that there is a clear need for impro ement in terms of how patients, their families and staff are engaged in re iews and how subsequent learning is deri ed and implemented. These issues are not unique to Northern Ireland or indeed the United Kingdom. Ensuring the effecti e implementation of SAI re iews and subsequent learning is a considerable undertaking. Not only does the procedure itself need to be robust, but its effecti e application necessitates an open and supporti e learning culture with SAI re iewers who are trained in the necessary skill set to undertake effecti e SAI re iews.

In April 2018, the Regulation and Quality Impro ement Authority (RQIA) was commissioned by the Department of Health (DoH) to examine the application and effecti eness of the SAI procedure. Terms of Reference for this re iew were appro ed by the Department of Health in October 2019 and fieldwork on this re iew concluded in January 2021. The time taken to complete and publish this re iew has been significantly impacted by the system response to Co id-19 Pandemic.

Ter s of Reference

The terms of reference for this re iew, as agreed with the DoH, were as follows:
v

1) To re iew the systems/ processes in place for reporting and follow-up of Serious Ad erse Incidents (SAIs) across the six Health and Social Care (HSC) Trusts, the HSCB and Public Health Agency in Northern Ireland, between 30 No ember 2016 and 31 March 2018.

2) To engage with families affected by SAIs reported between 30 No ember 2016 and 31 March 2018, to determine their le el of in ol ement in the Serious Ad erse Incident process.

3) To assess the process for the classification of the se erity of SAIs and to determine whether incidents are appropriately classified through this process.

4) To assess the le el of independence of the SAI re iews progressed and assess whether a multi-disciplinary systems-wide approach to re iews has been undertaken. v

5) To assess the de elopment and effecti eness of action plans and recommendations arising from SAIs re iews.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

6) To assess e e a o ia e lea ning as been iden ified f om e SAIs and dissemina ed egionally, and e e e lea ning can delive measu able and sus ainable im p ovemen s in e quali y and safe y of ca e.

) To de e mine cu en unde s anding of e ole of es ec ive o ganisa ions, including t e Co one , in t e p ocess fo SAI evie s, and ho is unde s anding com pa es o e ublis ed oles and es onsibili ies as ou lined in e ocedu e fo e Re o ing and Follo u of Se ious Adve se Inciden s.

8) To assess e level of ofessional su o ovided o (i) s aff o e e delive ing ca e a e ime of e SAIs, as ell as (ii) s aff conduc ing e evie of e SAIs.

9) To ovide a e o of e findings o e De a men of Heal , making ecommenda ions fo im p ovemen as elevan o e ove all es onse o SAIs, ei assessmen and evie , and e lea ning a ising oug ese ocesses.

Methodology

T e Ex e Revie Team develo ed a me odology s ecific o t is evie inco o a ing ex ensive engagemen wi a range of key individuals and o ganisa ions and a ien s ei ela ives and e esen a ive g ou s. Focus G ou s and individual in e vie s e e unde aken. T e engagemen as su o ed by e develo men of a numbe of semi-s uc u ed ques ionnai es. An im po an as ec of is evie as e unde aking of a igo ous assessmen of 66 se ious adve se inciden e o s f om all HSC T us s in No e n I eland.

Findings

T e Ex e Revie Team de e mined a e cu en SAI ocedu e and i s im plemen a ion in No e n I eland **does not** su o :

- Fulfilmen of e s a u o y du y of Pe sonal Public Involvemen as se ou in e Heal and Social Ca e (Refo m) Ac (No e n I eland) 2009.
- Reasonable a lica ion of e inci les of effec ive SAI evie ac ice.
- Confidence in e inde endence of c ai s of SAI evie s a Level 2, o Level 3. Pa icula ly in e case of Level 3 evie s, e e e a oin ed c ai is a fo me em ployee of an HSC T us .
- Accoun abili y of Heal and Social Ca e o ganisa ions fo :

    - decisions made ega ding e level of evie conduc ed
    - involvemen and engagemen i a a ien and/o ela ives
    - t e quali y of e evie conduc ed and e acce ance of i s findings and a oval ocesses
    - evidencing a HSC T us se vices ave im p oved and a e safe because of e evie s conduc ed
    - ensu ing a issues equi ing egional ac ion o im p ove safe y a e a o ia ely iden ified and en escala ed o e ig eo le in e ig o ganisa ions

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- The fo tion of evidence-b sed eco end tions.
- The design of ction p ns th t wi enh nce the s fety nd q ity of he thc e p ovision c oss the egion both in the sho t nd onge te .
- The p od ction of SAI eview epo ts th t e we -fo ted evidence-b sed nd e d b e.

The Expe t Review Te identified n e of e sons fo this:

- The i e p nt tion of the SAI p oced e foc ses too he vi y on p ocess nd non- tt in b e ti sc ees inste d of foc sing on consistent y cond cting these eviews to high st nd d.
- The e w s n bsence of c e egion g id nce on how to exec te Pe son P b ic Invo ve nt de ties nd in e tion to p tient ights s p t of n SAI eview.
- The e w s no egion p tient s fety t ining st tegy nd c ic .
- The e we e not c e y defined co etencies eq i ed of e d investig ting office s nd SAI eview p ne ch i s.
- The e we e not s fficient n e s of t ined independent dvoc tes fo f ies i nd p tients.
- The e w s ck of effective t ining in how to exec te n effective nd ning of SAI eview.
- F the e even whe e t ining h d been de ive ed the ppointed ch i o eview e ds they did not w ys h ve s fficient tho ity to independent y devise eview p n th t f y de ive s the eq i ed q ity of eview.
- The e we e so ge n e of eviews identified s eq i ing n in-depth eview b t which did not eq i e this which w s c e ting n ns st in b e wo k p ess e within the syste .

The conc sion of the Expe t Review Te is th t c ent p ctice fo eviewing nd e ning f o SAIs in No the n I e nd is not chieving the intended p pose of the SAI p oced e. I ovi ng this sit tion wi eq i e both the SAI p oced e nd the syste in which it ope tes to be e-designed. ,

Summary of Recommendations

The fo owing eco nd tions es e de to s ppo t the de ive y of new egion po icy/p oced e fo epo ting investig ting nd e ning f o dve se events.

,

Numbe,	Recommendation, ,	P io ity
	The Dep t nt of He th sho d wo k co bo tive y with p tient nd c e ep esent tives senio ep esent tives of T sts the St tegic Pe fo nce nd P nning G o p P b ic He th Agency and Reg tion and Q ity Im ovp nt A tho ity to co-design new egion p oced e b sed on the concept of c itic s ccess f cto s. Cent to this st be foc s on the invo ve nt of p tients nd f ies in the eview p ocess.	2 ,

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

2 T	Healt a cial Care rga isati s s ul be require t evi e ce t ey are ac ievi g t ese critical success fact rs t t e Departme t f Healt . T	T
3 T	e Departme t f Healt s ul impleme t a evi e ce-base appr ac f r etermi i g ic a verse eve ts require a structure , i - ept revie . is s ul clearly utli e t at t e level f AI revie is etermi e by sig ifica ce f t e i ci e t a t e level f p te tial eficit i care. T	T
4 T	e Departme t f Healt s ul e sure t e e egi al pr ce ure a its system f impleme tati is u erpi e by 'j st lt re' prin iples and a lear eviden e-base frame rk t at elivers measurable a sustai able impr veme ts. T	T
5 T	e Departme t f Healt s ul evel p a impleme t a regi al trai i g curriculum a certificati pr cess f r t se participati g i a lea i g AI revie s.	T

Key Benefits

e Expert Review eam c clu e t at, s ul t ese rec mme ati s be fully impleme te a embrace by t e Healt a cial Care system i N rt er Irela , t ey w ul eliver t e f ll wi g key be efits:

- A clear regi al framew rk w ic pr vi es f r lear i g fr m u expecte arm.
- Greater flexibility i t e AI review pr cess, w ic is alig e t i ter ati al best practice a all ws a better pp rtu ity f r lear i g a safety impr veme t.
- A si gle, ew rep rt template a regi al style gui e t at supp rts c siste cy acr ss t e regi but is flexible e ug t all w reviewers t a a rem ve secti s as require .
- A l wer umber f i - ept R t Cause A alysis (RCA) reviews, w ere early case assessme t s ws t at t is level f review is n t require r pr p rti ate.
- I crease capacity wit i H C t eliver structure , i - ept reviews, w ere early assessme t i icates t is is ecessary.
- A appr priate am u t f time t c uct a review well a i v lve patie ts a families i a way t at is mea i gful.
- A review pr cess t at es t cause furt er arm t patie ts, t eir families r staff.
- A culture f safety, pe ess a c mpassi . T

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

1.0 Bac nd and C ntext

1.1 Int d cti n

Health and So ial Care servi es are used extensively a ross Northern Ireland daily, and most patients and their families are satisfied with their are. However, it is inevitable that some will not have a satisfa tory experien e while others may even experien e harm. When harm o urs, there is a moral, ethi al and professional duty on those involved in the delivery of are to review what happened.

When su h an in ident is identified, the pro ess of reviewing an event in an effort to learn is known as an Adverse In ident (AI) review, and some will warrant a Serious Adverse In ident (SAI) review. The SAI review aims to:

- Determine if any element of the are delivery or treatment plan ontributed to the harm and any underlying systemi reasons for this.
- Ensure that the ne essary improvements are made to the standard of are delivered and to the underlying systems and pro esses that support patient safety.
- Fa ilitate the re overy of the patient and their family from the harming experien e, so that re on iliation an o ur, in luding ontinuing trust in the Health and So ial Care servi es.

Fundamental to a hieving these aims is a lear, regionally agreed approa h to identifying, reporting, reviewing and learning from in idents of harm, in luding serious near-miss events or apparent near-miss events. Furthermore, this approa h must be learly arti ulated within poli ies and pro edures.

Throughout this report, the term 'patient and family' is used to represent those that would fall under the ategory of patient, servi e user, arer, family, or family member. The Expert Review Team re ognises that users of mental health and learning disability servi es are normally referred to as servi e users rather than patients.

1.2 C ntext

Regional guidan e for the reporting and follow-up of SAIs has been in pla e in Northern Ireland sin e 2004. Over the last de ade, the SAI pro ess has ome under s rutiny both regionally and nationally. Following the Publi Inquiry into Mid-Staffordshire NHS Foundation Trust in 2014[2] the Chief Medi al Offi er in Northern Ireland wrote to HSC Trusts to remind them of their statutory duty in relation to the review and reporting of SAIs. This orresponden e outlined a need for andour alongside meaningful engagement with patients and their families when in idents of harm have o urred.

The Donaldson Report in 2014[3] highlighted on erns around the reporting of adverse in idents, ineffe tive pro esses for review, la k of expertise amongst reviewers (parti ularly in relation to human fa tors) and a failure for learning to translate into improvements in systems and patient safety. Donaldson also outlined

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

a need f a st c lt e' f healthca e staff pa ticipating in SAI eviews, in additi n t a need f cand and penness with patients and families.

I 2018, Justice O'Hara published his l ng-awaited inq i y ep t; Hyp nat aemia-elated Deaths (IHRD) in N the n l eland[4]. It called f a stat t y d ty f cand and made a n mbe f ec mmendati ns in elati n t ep ting, investigating and sha ing f lea ning f m SAIs, incl ding a need t inc ease the inv lvement f families in these p cesses. This se ved t f the highlight a need f a eview f the egi nal p ced e f SAI eviews in N the n l eland.

In Ap il 2018, the RQIA was c mmissi ned by the Depa tment f Health (D H) t examine the effectiveness f the c ent p ced e f the Rep ting and F ll w- p f Se i s Adve se Incidents (SAIs) (N vembe 2016) and its implementati n within Health and S cial Ca e se vices and make ec mmendati ns f imp vement. A final Te ms f Refe ence f this w k was ag eed with the D H in Oct be 2019 and fieldw k n this eview c ncl ded in Jan a y 2021.

The eview was c nd cted in phases, with inte im ep ts s bmitted t D H p n c mpleti n f each phase. This d c ment is the c lminati n f this w k and is an ve all assessment f the effectiveness f the SAI p ced e and its implementati n ac ss Health and S cial Ca e in N the n l eland

1.3 Overview of Regional SAI Procedure

The system f ep ting adve se incidents was fi st int d ced in N the n l eland in 2004 by the f me Depa tment f Health, S cial Se vices and P blic Safety (DHSSPS), n w kn wn as the D H. Rep ting a angements we e t ansfe ed t the Health and S cial Ca e B a d (HSCB), n w the St ategic Planning Pe f mance G r p (SPPG) within the D H, in pa tne ship with the P blic Health Agency (PHA), in 2010. Updates t this p ced e we e implemented in 2010, 2013 and 2016.

The c ent ve si n f the egi nal SAI p ced e which was last pdated in 2016, advises that SAI eviews sh ld be c nd cted at a level app p iate and p p ti nate t the c mplexity f the incident nde eview.

Incidents which meet the f ll wing c ite ia may be classified as an SAI.

- Se i s in y t , the nexpected/ nexplained death f:
    - a se vice se , (incl ding a L ked Afte Child a child wh se name is n the Child P tecti n Registe and th se events which sh ld be eviewed th gh a significant event a dit)
    - a staff membe in the c se f thei w k
    - a membe f the p blic whilst visiting a HSC facility.
- Unexpected se i s isk t a se vice se and/ staff membe and/ membe f the p blic.
- Unexpected significant th eat t p vide se vice and/ maintain b siness c ntin ity.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Serio e harm or erio a a t (inc ding attempted icide, homicide and ex a a a t) by a ervice er, a member o ta or a member o the p b ic within any hea thcare aci ity providing a commi ioned ervice.
- Serio e harm or erio a a t (inc ding homicide and ex a a a t) B
  on other ervice er ,
  on ta or
  on member o the p b ic.

- y a ervice er in the community who ha a menta i ne or di order (a de ined within the Menta Hea th (NI) Order 1986) and/or known to/re erred to menta hea th and re ated ervice (inc ding Chi dren and Ado e cent Menta Hea th Service (CAMHS), p ychiatry o o d age or eaving and a tercare ervice) and/or earning di abi ity ervice , in the 12 month prior to the B incident.
- S pected icide o a ervice er who ha a menta i ne or di order (a de ined within the Menta Hea th (NI) Order 1986) and/or known to/re erred to menta hea th and re ated ervice (inc ding CAMHS, p ychiatry o o d age or eaving and a tercare ervice) and/or earning di abi ity ervice , in the 12 month prior to the incident.
- Serio incident o p b ic intere t or concern re ating to:

  any o the criteria above
  the t, ra d, in ormation breache or data o e
  a member o HSC ta or independent practitioner.

Three eve o review are de cribed in the regiona proced re. The expectation in re pect o each eve i mmari ed be ow:

Level 1 Review: Significant Event Audit (SEA)

For Leve 1 review , member hip o the SEA review team ho d inc de a re evant pro e iona , yet be appropriate and proportionate to the type o incident and pro e iona gro p invo ved.

The review pane ndertake an SEA o the incident to a e what happened; why it happened; what went wrong and what went we ; what ha changed or what need to change; and identi y any oca or regiona earning.

Level 2 Review: Root Cause Analysis (RCA)

For Leve 2 review , the eve o review ndertaken wi determine the degree o eader hip, overview and trategic review req ired. A core review pane ho d be compri ed o a minim um o three peop e o appropriate eniority and objectivity. Review pane ho d be m utidi cip inary and have no con ict o intere t with the incident concerned. The review ho d have a chairper on who i independent o the ervice area invo ved, whi e po e ing re evant experience o the ervice area in genera and o chairing review . B

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

The cha e n h uld al n t have been d ectly nv lved n the ca e t eatment f the nd v dual be e n ble f the e v ce a ea unde ev ew.

The ev ew anel unde take a RCA t a h gh level f deta l, u ng a ; ate analyt cal t l t a e what ha ened why t ha ened what went w ng and what went well what ha changed what need t change and dent fy any l cal and eg nal lea n ng.

Level 3 Review: Independent Review

F Level 3 ev ew , the ame nc le a Level 2 ev ew a ly h weve , team membe h mu t be ag eed u n between the e t ng gan at n and the HSCB/ PHA (PHA) De gnated Rev ew Off ce (DRO) p t the rev ew c mmenc ng.

The 2016 cedu e tate that: “The review panel unde take an n-de th ev ew f the nc dent, t a h gh level f deta l, u ng a ; ate analyt cal t l t a e : what ha ened why t ha ened what went w ng and what went well what ha changed what need t change and dent fy any l cal and eg nal lea n ng.”

In 2016, the Reg nal SAI cedu e wa u dated t gu de SAI ev ew anel n elat n t v d ng at ent and fam l e w th an tun ty t c nt bute t the SAI ev ew.

The gu dance utl ned that:

- The level f nv lvement de ended n the natu e f the SAI and the at ent and family’s willingness to be involved.
- Team s nv lved n the ev ew f SAI h uld en u e en t v ty t the need f the at ent and fam ly/ca e nv lved.
- Team s h uld ag ee n a ate c mmun cat n a angement w th the at ent and fam ly/ca e nv lved.

T u t the nv lvement ce , an SAI leaflet[5] wa de gned by the HSCB and PHA f gan at n t g ve t at ent and fam l e t the n t al d cu n ega d ng the SAI wh ch had ccu ed.

1.4 Patient and Family Involvement and Engagement

Health and Social Care services across Northern Ireland have a legal duty to involve service users and their carers. Personal and Public Involvement (PPI) is a legislative requirement for Health and Social Care organisations as set out in the Health and Social Services (Reform) Northern Ireland Act 2009[6].

The Act states that service users and carers must be involved in and consulted on:
;

- The planning of the provision of care.
- The development and consideration of proposals for changes in the way that care is provided.

;

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Deci i e made y he dy ha ha he re p i ili y f r he pr vi i f ha care.
- The efficacy f ha care.

PPI i he acti e and meaningful in ol ement of ser ice users and carers in the planning, commissioning, deli ery and e aluation of Health and Social Care (HSC) ser ices, in ways that are rele ant to them. It is the process of empowering and enabling those who use ser ices and their carers to make their oices heard, ensuring that their knowledge, expertise and iews are listened to.

Gi en this statutory duty, ser ice user and family in ol ement were considered a pi otal aspect of this re iew. Throughout the re iew, the effecti eness and extent of patient and family engagement ha e been examined from the perspecti e of patients and families, frontline staff and managers.

2.0 Terms of Reference

The terms of reference for this re iew, as agreed with the Department of Health, were as follows:

1) To re iew the systems/ processes in place for reporting and follow-up of Serious Ad erse Incidents (SAIs) across the six HSC Trusts, the HSCB and Public Health Agency in Northern Ireland, between 30 No ember 2016 and 31 March 2018.

2) To engage with families affected by SAIs reported between 30 No ember 2016 and 31 March 2018, to determine their le el of in ol ement in the Serious Ad erse Incident process.

3) To assess the process for the classification of the se erity of SAIs and to determine whether incidents are appropriately classified through this process.

4) To assess the le el of independence of the SAI re iews progressed and assess whether a multi-disciplinary systems-wide approach to re iews has been undertaken.

5) To assess the de elopment and effecti eness of action plans and recommendations arising from SAIs re iews.

6) To assess whether appropriate learning has been identified from the SAIs and disseminated regionally, and whether the learning can deli er measurable and sustainable impro ements in the quality and safety of care.

7) To determine current understanding of the role of respecti e organisations, including the Coroner, in the process for SAI re iews, and how this understanding compares to the published roles and responsibilities as outlined in the procedure for the Reporting and Follow up of Serious Ad erse Incidents.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

8) To a v of prof iona uppor provid d o (i) aff w o w r d iv ring car a im e of SAI , a w a (ii) aff conduc ing r vi w of SAI .

) To provid a r por of finding o D par m en of H a , making r comm nda ion for improv m en a r van o ov ra r pon o SAI , ir a m en and r vi w, and arning ari ing roug proc .

3.0 Review Methodology

T r vi w u d a rang of m e odo ogi o n ur ac rm of r f r nc wa addr d. Eac m e odo ogy aim ed o op imi qua i y of informa ion oug by xp r pan o n ur a robu vid nc -ba for ir r comm nda ion .

T m e od inc ud d:

1) T a m en of SAI r vi w r por , by Exp r R vi w T am. T cri ria for a m en a agr d wi D par m en of H a .

2) T d ign of a ruc ur d a m en qu ionnair w ic wa app i d by Exp r R vi w T am o a SAI r vi w r por ubmi d by par icipa ing HSC 9 Tru .

3) Qu ionnair i u d o a rang of Tru aff, from nior manag m en o fron in prac i ion r , and SAI pan c air , s king ir vi w of ir invo v m en in SAI r vi w proc .

4) Engag m en of pa i n and fami i w o ad xp ri nc d a car -induc d arm and off r of fac - o-fac conv r a ion o arn abou ir xp ri nc and ar ir vi w a o ow xp ri nc cou d av b n improv d.

5) Focu group invo ving aff invo v d in an SAI, a w a aff invo v d in SAI r vi w proc .

6) M ing wi individua and group of aff in HSC organi a ion invo v d in SAI r vi w .

7) Engag m en wi o r r van organi a ion .

I wa in nd d a ff c iv n of imp m en a ion of SAI r commenda ion wou d b xamin d in p cific d ai by Exp r R vi w T am o xp or fur r arrang m en wi in s rvic to d iv r on su ain d and m a urab improv m en o pa i n af y. How v r du o COVID-1 pand mic, i a p c of m e odo ogy wa unab o b p rform ed in fu , bu wa xp or d oug o r a p c of m e odo ogy.

.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

3.1 Th ifica io a S l c io of SA s

For the aspe t of this review SAIs sele ted had been ondu ted between 30 November 2016 and 31 Mar h 2018 and fell within the following ategories:

- Deaths of women and babies related to pregnan y and hildbirth: maternal deaths, stillbirths and neonatal deaths. Serious illness of women and babies c where this has been related to pregnan y and hildbirth.
- Sepsis
- Choking on Food
- Never Events[1]
- Cases where private hospitals or private nursing homes feature in the are pathway.
- People with a learning disability who have died from a treatable physi al ondition.
- People with a learning disability in residential are.
- Primary Care
- Any other ategories RQIA onsidered appropriate for in lusion the review.

The information relating to these SAIs was obtained from the HSCB. After validation, 54 SAIs were identified for in lusion. A total of 12 additional SAIs were subsequently sele ted, omprised of Level 2 and Level 3 reviews, resulting in a total of 66 SAIs being sele ted for expert review (Appendix A).

3.2 Th S ruc ur Ass ssm e of SA R por s

A stru tured assessment tool was developed and applied to ea h SAI report reviewed. The assessment aptured the perspe tives of members of the Expert Review Team who were:

- Experien ed investigators.
- Clini ians.
- Lay and family representatives.

Two distin t types of stru tured assessment tools were developed, one for use by the lay members of the Expert Review Team and one for the te hni al assessment of the SAI reports by other Expert Review Team members. This approa h ensured onsistent and obje tive assessment of ea h SAI report.

Due to the differen es in templates used and levels of review required, for Level 1 and Level 2 SAI reviews set out in the regional pro edure, the ore assessment tool, whi h applies to Level 2 SAIs, was modified to meet the requirements of a Level 1 SAI report.

[1] Never Events are serious, wholly preventable safety in idents that should not o ur if the available preventative measures are implemented. They in lude things like wrong site surgery or foreign objects left in a person's body after an operation. The full s ope of Never Events is detailed in the Care Quality Commission report, Learning from Never Events (July 2018). c

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

To ens e o s pp o ch, mem be s of he Expe Review Te m wi h ei he clinic l q lific ion o ex ensive p io expe ience in he cond c of SAI eview we e o ped in p i s. This es l ed in e ch p i eviewin o l of 33 SAI epo s. g

The l y membe s of he Expe Review Te m eviewed ll 66 SAI epo s individ lly efo e comp in hei ssessmen s nd disc ssin ny diffe ences of opinion. This es l ed in h ee s o ps wi h wo mem be s of he Expe Review Te m in e ch, ssessin he SAI eview epo s.

T le 1 elow shows he e kdown of s s nd epo s lloc ed o e ch echnic l e m.

Table 1: Breakdown of trusts and reports allocated to each technical team g

Team	Or anisation	Numbe of SAI epo ts fo eview
Te m 1 g	No he n T s	10
g	So h E s e n T s g	1
g	Wes e n T s	10
Te m 2 g	Belf s T s	11
	So he n T s g	14
g	NIAS	4
	In e ed C e Te m, HSCB	4
TOTAL g	g	**66**

Source: RQIA S c e Assessmen Exe cise

3.2.1 Quality Assurance of the Structured Assessments

The s c ed ssessmen ool developed y he Expe Review Te m conside ed he ex en o which he SAI epo desc i ed:

- The inciden nde eview nd why i w s ein eviewed.
- The level of independence of the review p nel mem be s and he compe encies nd skills hey h d o cond c he eview.
- The de ee of p ien nd f mily en emen wi h he eview p ocess.
- The n e of he ecommend ions m ade nd hei elev nce o imp ovin p ien s fe y.
- The ro s ness of the ac ion pl ns cons c ed to delive he ecommend ions and whe he they wo ld delive a me s le nd s s ined imp ovemen in q li y nd s fe y.

g

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

3.2.2 Te l Assessme t

To ensure reliable and accura e assessmen s of he SAI repor s, wo quali y assurance exercises were under aken.

Firs ly, for each of he hree echnical eams referenced above, an in ra- eam reliabili y exercise was under aken. This required he assessors o submi a sample of four assessmen s o each o her for a repea assessmen o ascer ain he similari y or differences in assessmen ou come. This process demons ra ed a high level of consis ency be ween he assessmen s. Where here were significan differences in he assessmen s, hese were presen ed and discussed a a round able conversa ion be ween he echnical assessors o reach consensus. A lay member of he Exper Review Team was included in his process.

The second quali y assurance exercise was under aken upon comple ion of he assessmen of all SAI repor s.

This involved a sample of four comple ed assessmen s being selec ed from each echnical assessmen eam and reassessed by he o her eam. Following his, he echnical assessmen eams me o compare findings. There were few discrepancies be ween he eams which confirmed a high level of consis ency. Any discrepancies were discussed, and a consensus posi ion was reached.

3.2.3 L y Assessme t

The lay members of he Exper Review Team assessed all 66 SAI repor s adop ing he perspec ive of a family member who migh receive hese repor s. To achieve a comparable process of quali y assurance, each lay member assessed all 66 repor s and subsequen ly me wi h heir lay coun erpar o discuss each repor , including any differences in perspec ive.

As wi h he echnical assessmen s, here were few discrepancies be ween he assessmen s conduc ed by he wo lay members of he Exper Review Team, and any differences were resolved by discussion hereby reaching a consensus view.

3.2.4 A lys s of t e SAI Report Assessme ts

Themes were ex rac ed from SAI repor assessmen s and colla ed o inform key findings. These findings informed engagemen wi h he HSC organisa ions during subsequen phases of his review. During he review, emerging findings and key messages were shared wi h he Depar men of Heal h via in erim repor s.

3.3 How e Trust respo ds to S g f t U expe ted H rm Eve ts

Ques ionnaires were developed for and issued o each HSC Trus , he HSCB and t he PHA. These were designed o ga her informa ion from each organisa ion abou heir respec ive approaches o SAI review and he rela ed s ruc ures and processes in place, including he ex en of pa ien and family involvemen .

A hema ic analysis of he responses received was subsequen ly under aken.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

3.4 Pa a Family E gag me

Initially, it was intended t at t e Expert Review Team would make direct contact wit t ose patients and/or families affected by t e 66 SAIs w ic were included in t e structured review undertaken in t e first p ase of t is review. Recognising t e potential for furt er psyc ological impact, t e Expert Review Team agreed t e h following patients and/or family members would not be contacted:

- W ere t ere ad been an expressed wis by t e patient and family not to be h contacted furt er or w ere t ere were issues of confidentiality.
- Families of cases w o were subject to a coroner's investigation.
- Patients/families of cases w ic were subject to legal proceedings.
- Patients/families of t ose involved in significantly distressing SAIs (including suicide of a family member).

T is resulted in 38 out of t e 66 patients/families being contacted to seek t eir involvement in t e review process. Of t e invitations sent to eac patient and family, only six responses were received. Following t is, two decided not to be involved. T is resulted in four out of 38 individuals contacted agreeing to become involved. Individuals subsequently met wit RQIA staff members. T is number was considered too few for t e purposes of t is review. As suc a decision was made to supplement t e engagement and furt er seek experiences via several additional routes, including approac ing t e Department of Healt and t e Patient Client Council (PCC) to supplement t e experiences of t ose four initially contacted. Bot organisations ad previously engaged wit patients/families w o ave ad an experience of t e SAI process following an incident of unexpected arm.

T e PCC agreed to meet wit t e Expert Review Panel to s are t e views of patients/families wit w om t ey ad engaged. Communication wit t e Department of Healt also resulted in t ree additional families agreeing to participate and s are t eir experiences.

3.4.1 A o al forma o co s r o gag me wi h pa s a fam l s

Experiences of patients and families involved in SAI reviews were also ascertained t roug engagement wit ot er groups and work streams:

- In November 2019, t e Inquiry into Hyponatraemia-related Deat s Implementation Programme (Work stream 5, Serious Adverse Incidents), eld a works op in conjunction wit t e PCC to engage wit families on t eir experience of the region's SAI review process. T e findings from t e works op were s ared wit RQIA and considered by t e Expert Review Team.

- In October 2019, t e PCC s ared its Serious Adverse Incident Complaints A T ematic Review of Client Support Service Cases 2014-2018 report. It outlined the experiences of families who had been through the region's SAI review process and t e findings were considered by t e Expert Review Team. h

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- In De e e 0 0, the Expe t Review Tea t with staff f o Cause l who sha ed the expe ien es of fa lies i they had suppo ted th ough the SAI eview p o ess and p ovided insight into how to a hieve quality fa ily engage nt in the p o ess.

These findings we e a ti ulated in the Expe t Review Tea s interim report on Patient and Fa ly Engage nt. e

3.5 Staff Engagement

As pa t of this eview, the Expe t Review Tea engaged with those staff involved in the a e of the 66 patients who we e the su je t of the SAI eview epo ts involved in the st u tu ed assess nt unde taken in the ea lie phase of the eview. Seve al thods of staff engage nt we e utilised:

- Fo us g oup etings using a afé style app oa h.
- A p ivate post ox thod.
- An online su vey.
- One-to-one telephone inte views.

3.5.1. Focus Groups

Fo us g oups we e held etween 5 ove e and 1 ove e 019. To a o date the ange of staff involved in the SAI p o ess, ea h fo us g oup had a diffe ent e has is: N

- Staff involved in the a e of the patient who was ha d. e
- Staff involved in the SAI eview p o ess.
- Staff involved in a na d SAI eview.

The fo us g oups fo used on th ee p i y a eas:

- The expe ien e of staff who had een involved in the SAI p o ess.
- Thei expe ien e of engaging and involving patients/fa lies i in the SAI p o ess.
- The views of staff in elation to how the SAI p o ess ould e i ov d.

Ta le elow shows the nu e of staff who attended ea h of the fo us g oups.

N

Cause l is an o ganisation whi h suppo ts people with a ntal health p o le and thei fa ly i es.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Table a Engagemen Focus Groups by Par icipa ion and Organisa ion
ource l formatio recorded by RQIA duri g the focus groups

	Focus Group 1	Focus Group	Focus Group 3	
Organisa ion	Staff i volved i a i cide t	Staff i volved i reviewi g a i cide t	Team i volved i reviewi g a i cide t	Total umbern of staff by orga isatio
Belfast Trust	5	12		21
o th st				37
So h Easter Tr n	n 14	n 15	n 4	n 33 n
Souther Trust	12	10	3	25
	5	19	4	28
	2	8		10
l t grat d Car	/a	8	/a	8 n
	57 n	n **88**	**17**	

n

3.5. Con iden ial Pos -Box Feedback n

At each staff f cus gr up, a c f de t al p st-b x was pr v ded t e able staff to share their experie ces of the SAI process should they ot be comfortable with speaki g out i fro t of a group.

3.5.3 Online urvey

The third method to support staff e gageme t was via a o li e survey. All staff worki g withi HSC Trusts were offered a opportu ity to respo d, provided they had experie ced the SAI review process.

Overall, 201 staff completed the survey. However, 114 of those had ot bee i volved i a SAI process, either as a member of a care team i volved i a i cide t or as a member of the SAI review pa el. Their respo ses were therefore ot i cluded i these a alyses.

Of 87 respo de ts who had a experie ce of the SAI review process, 40 staff members had bee i volved i care a d treatme t related to a i cide t a d 47 staff members had bee part of the pa el reviewi g a i cide t.

3.5.4 Telephone In erview

All staff who atte ded the focus group meeti gs were also offered the opportu ity to speak co fide tially with a member of the Expert Review Team by telepho e i terview. Four staff members were subseque tly i terviewed.
n

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

3.6 Mee w ih HSC Or a a o

The Expert Re iew Team met with Senior Managers in each of the HSC Trusts. The meetings focused on the management and o ersight of the SAI re iew process within the organisations and included a discussion on potential impro ements to the SAI re iew process.

The Expert Re iew Team also met with the HSCB and PHA to discuss their regional responsibilities, their roles in o ersight of the SAI re iew process and the role of the Designated Re iew Officer. This meeting also included a discussion on potential impro ements to the SAI re iew process.

3.7 E a eme w ih o her Or a a o

The Expert Re iew Team met with representati es of the RQIA's Mental Health inspection team and the Coroners Ser ice in NI, both of which were identified as ha ing had frequent engagement with the SAI process. The purpose of this discussion was to gain an insight into their experience of the SAI process and what impro ements they considered could be made.

A broad range of organisations are in ol ed and impacted by the regional SAI re iew process. Engagement with these organisations focussed on those that had most frequently experienced the process. Other organisations, such as other regulatory bodies, trade unions, and the Police Ser ice for Northern Ireland were pro ided with information about the re iew and asked if they would like to make a written submission regarding their iews and opinions in relation to the current SAI process and their suggestions for change to the SAI process.

Of the organisations contacted, the following nine responded. These were; the British Medical Association, the Royal College of Nursing, the Eastern Local Medical Committee, the Pharmacy Forum, the Coroner's Service, the Northern Ireland Public Sector Alliance, the Northern Ireland Medical and Dental Training Agency, the Information Commissioners Office and the Health and Safety Executi e Northern Ireland.

The full list of organisations contacted is outlined in Appendix B.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

4.0 Fin in

4. O verall fin in of the Expert Review Panel

Aft r full consid ration of all th vid nc gath r d from ach of th contributors to this r vi w, th Exp rt R vi w T am was confid nt in th ir d t rmination that th curr nt r gional policy for SAI r vi w in North rn Ir land must chang . It was cl ar that th curr nt proc dur and its impl m ntation do s not support:

- Fulfilm nt of th statutory duty of PPI as s t out in th H alth and Social e Car (R form) Act (North rn Ir land) 2009.
- R asonabl application of th principl s of ff ctiv r vi w practic .
- Confid nc in th ind p nd nc of Chairs of SAI r vi ws at L v l 2, or L v l 3 - particularly so for L v l 3 r vi ws wh r th appoint d chair is a form r e mploy of an HSC Trust.
- H alth and Social Car organisations mbracing th ir accountability for:
    - d cisions mad r garding th l v l of r vi w conduct d
    - how th y involv and ngag with a pati nt and family
    - th quality of r vi w conduct d, acc ptanc of its findings and approval proc ss s
    - d monstrating how HSC Trust s rvic s hav improv d and ar saf r b caus of th r vi ws conduct d
    - nsuring that issu s r quiring r gional att ntion to improv saf ty ar e scalat d to th right p opl /organisations.
- Th formulation of vid nc -bas d r comm ndations.
- Th d sign of action plans that will nhanc th saf ty and quality of h althcar provision across th r gion both in th short and long r-t rm.
- R vi w r ports that ar w ll-formulat d, vid nc -bas d and r adabl .

Th Exp rt R vi w T am id ntifi d a numb r of r asons for this:

- Th impl m ntation of th r gional proc dur focus s too h avily on proc ss and non-attainabl tim escal s inst ad of focusing on consist ntly d liv ring th practic of conducting high quality SAI r vi ws.
- Th r was an abs nc of cl ar r gional guidanc on PPI duti s in r lation to pati nt rights within th s rious adv rs incid nt proc ss.
- Th r was no d fin d r gional pati nt saf ty training strat gy and e curriculum.
- Th r w r not d fin d comp t nci s r quir d of l ad inv stigating offic rs and s rious adv rs incid nt pan l chairs.
- Th r w r insuffici nt numb rs of train d ind p nd nt advocat s to support family involv m nt in th proc ss.
- Th r was a r gional lack of ff ctiv training in how to conduct a m aningful r vi w. Furth rmor , v n wh r training had b n d liv r d, th appoint d chair or inv stigativ l ads did not hav suffici nt authority to ind p nd ntly d vis a r vi w plan that fully d liv rs th r quir d quality of a e r vi w.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

The evi e e e pi i g these fi i gs was e ive a oss a b oa a ge of e gageme ts a is etaile f the i the followi g se tio s e th ee key themes.

1) Patie t a family e gageme t.
2) Staff e gageme t.
3) The effe tive ess of the p o e e a app oa h fo elive y of S I eviews.

4.2 Patient and Family Engagement

hallma k of s ess i a y app oa h to the eview a lea i g f om i i e ts of expe te a avoi able ha m is the ma e i whi h a health p ovi e o ga isatio e gages with the patie t a thei family th o gh the eview p o ess. The families who p ovi e i fo matio to the Expe t Review Team, the PCC a the lay membe s of the Expe t Review Pa el (who themselves have live expe ie e of health a e i e ha m) p ovi e o siste t efle tio s o how this aspe t of S I Reviews is elive e i No the I ela .

The Expe t Review Team i e tifie seve al of themes afte liste i g to the views a expe ie es of patie ts a families:

- The e was i o siste y i the p a ti e of HSC T sts i whe a how they i fo me families abo t:
    - the i i e t
    - the e isio to o t a i i e t eview p o ess
    - the ights of patie ts a families to be e gage at all stages of the eview, i l i g shapi g the te ms of efe e e o li es of e q i y
    - sha i g of the i te im fi i gs of the eview p o ess to allow omme ti g a fee ba k f om the patie t a family to be i o po ate .

- The e was i o siste y i the q ality a f eq e y of omm i atio s with the patie t a thei family. This i l es w itte o espo e e as well as ve bal omm i atio s. ommo o e was the level of empathy, espe t i the at e a to e of omm i atio s a levels of pla i g with the patie t a thei family abo t what mo e of omm i atio was best a with what f eq e y.
- Families epo te the e was ot s ffi ie t t a spa e y abo t the p o ess.
- The e was a efi it i the availability of i epe e t s ppo t o a vo a y fo patie ts a families.
- The e we e o e s abo t the timeli ess a amo t of i fo matio p ovi e abo t the pla fo the eview p o ess a its i te e o l sio ate.
- They des ibe HSC o ga isatio s a oss the egio we e u able to apologise fo the ha m that ha o e . I thei wo s, it was ot e o gh to say, “so y, we a e at fa lt”. Rather, the apology should say: “So y this has happe e to yo . We will look afte yo a help yo e sta what happe e ”.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- They e e ced a u w ll g ess to seek the test mo y of the at e t a d fam ly membe s as a teg al com po e t of the ev ew ocess, thus d m i sh g the status of the at e ts a d the fam l es.
- Ma y stated that the te m f d gs of the ev ew ocess we e ot sha ed w th the at e t o the fam ly membe s so that they could co t bute co st uct ve comme ts a d e su e the vo ce s a o ately e ese ted a d hea d.
- The e was ot a suff c e t level of o e ess a d ca dou about what had ha e ed a d why. They desc bed the sh oud g of the Al ev ew f d gs tech cal la guage wh ch was ot access ble a d e ce ved t to be defe s ve ess.
- The e we e some who we e co ce ed about ote t al 'cover-u s' and a lack of t a s a e cy the ocess, as well as the e o t subseque tly w tte .
- Seve al desc bed Cha s of the Al ev ew whose commu cat o sk lls a d ab l ty to wo k co st uct vely w th a fam ly we e oo .
- eve al we e ot co f de t the de e de ce of Cha s of the Al ev ew.

Of a t cula ote was the v ew e essed by Cause NI, a cha ty that s ec al ses offe g act cal a d emot o al su o t to fam l es whose loved o es have e e e ced ha m as a esult of se ous me tal ll ess o su c de. They co s de ed that the cu e t equ eme t w th the Al ocedu e, fo S the vest gat o of all deaths that have occu ed as a esult of me tal ll ess (whe e the d v dual who d es was k ow to Me tal Health e v ces the eced g 12 mo ths), was ot the best a oach. It was suggested Al ev ews would be most a o ate those cases whe e t was sus ected the e we e ca e def c ts eced g the death.

The E e t Rev ew Team eflected, that ove all, the e essed v ews of at e ts of fam l es No the l ela d ega d g the e e e ces of volveme t, we e s m la to f d gs of de e de t ev ews a d qu es elsewhe e the UK, such as the Ca e Qual ty Commiss o (CQC) ev ew, '*Learning, Candour and Accountability 2016*[7], the *Mid Staffordshire NHS Foundation Trust Inquiry* a d *The Report of the Morecambe Bay Investigation.* It was the efo e d sa o t g that No the l ela d, mo e og ess had ot bee made m pleme t g best act ce how H C o ga sat o s wo k w th fam l es afte u e ected ha m.

The E e t Rev ew Team was m p essed w th the att tude of staff who e essed a w ll g ess to have g eate e gageme t a d volveme t w th the at e t a d the fam ly the ocess. Most staff a ec ated that at e ts a d fam l es a e a m po ta t com po e t of a successful a oach to lea g f om ha m. They e o ted feel g co st a ed by a ove ly bu eauc at c ocess, wh ch they e ce ved laced com let o of a b t a y t mescales a d a ow e fo ma ce ta gets above the equ eme t fo mea gful volveme t.

The most s g f ca t ba e s to ach ev g mea gful volveme t of at e ts a d the fam l es we e desc bed as:

- U ce ta ty about what staff could a d could ot say to a fam ly a d what co st tutes a acce table level of d sclosu e.
- How to ach eve eal st c e ectat o s w th a at e t a d the fam ly about what the Al ocess ca a d ca ot del ve .

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- The t ewed f r the de very f the SAI pr cess, nd the t ve b e t n SAI rev ew p ne ch r, wh w u d h ve dd t n n ger r fr nt ne c n c dut es nd wh ch s n t c nduc ve t n egfu p t ent nd f y eng ge nt. e
- The v b ty f ded c ted supp rt f r p t ents nd the r f es thr ugh the SAI pr cess. th ut supp rt, t s d ff cu t f r Ch rs f SAI rev ews t s ttend pr per y t the needs f the p t ent nd f y.
- Absence f c nstruct ve gu d nce n h w t c pture f y nv ve nt end eng ge nt w th n the SAI rev ew rep rt, ex cerb ted by ck f sp ce w th n the rev ew rep rt te tept rec rd the eve f f y nv ve nt. e
- St ff were c ncerned b ut eg ssues nd rep rted nx ety b ut h w t descr be the f nd ngs th t then ght resu t n c f r d ges. A s nu er b f st ff descr bed nst nces where eg serv ces h ve requested d f c t ns t rep rt wh ch d uted the f nd ngs f the SAI rev ew p ne .

The Expert Rev ew Te s c e r th t c ncerns reg rd ng future c f rsd ges st nu t nterfere w th c nduct f n SAI rev ew r w th the ntegr ty f the resu t ng rep rt. It s wh y un ccept b e th t rep rt uth rs c u d be sked by n ger r by eg serv ces t d ute the r f nd ngs. Further re, such ct n sh u d h ve ser us c pt ns f r he th pr fess n s wh h ve bre ched the r pr fess n duty f c nd ur.

H wever, there re g d re s ns f r eg serv ces te t rev ew n ntern SAI rev ew rep rt d cu nt: e

- T sense check the use f ngu ge.
- T test the strength f the ev dence b se underp nn ng the report's f nd ngs nd c nc us ns.
- T determine a report's readability.

Feedb ck de t rep rt uth r n the c ntext f the b ve st be c ns dered nd cted up n.

Acr ss the HSC, t w s n t the cu tur n r t sh re nter f nd ngs f n SAI rev ew w th p t ent nd the r f y. En b ng the p t ent nd f y t h ve v ce n the rep rt, t c ent n the rep rt c ntent, nd t nf uence the c ntent nd t ne f the f n rep rt ppe rs n t t be pr ry c ns der t n. Ineffect ve nd nsuff c ent p t ent nd f y eng ge nt e n c use further h r F. es rep rt h v ng exper enced s f the f w ng dverse effects:

- Incre se n stress.
- De y n st rt ng the gr ev ng pr cess.
- P st-tr u t c stress d s rder.
- L ss f nc . e
- Fee ngs f nger.
- L ss f fe enj y nt. e

The Expert Rev ew Te c ns dered th t, f r ny f es, t s p ss b e t v d c us ng further h r f HSC rg n s t ns eng ge n c ssp n te pr cess. The

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

found of Ha med Pa i n Allianc [8], a campaign g oup found d o ai awa n of a med pa i n and famili , ff c iv ly communica kind of compa ion famili n d following al ca a m.

" n he af e ma h of o loss we needed heal hca e o f lly acknowledge and thorough y understand our experience of what had happened to our children and the impact it had on us. We needed answers to all of the questions that we had, that were important to us, and we needed those regardless of whether anyone else felt our question relevant or important. We needed staff to be supported to give us honest accounts of their actions and their reflections. We needed a collaborative approach to reach a truthful and evidence-based explanation of events. We needed help and support to understand what all the processes were that were happening and how to engage with them. We needed the system to learn and to see meaningful change, but we also needed the system to help us heal, recover, and restore our trust. Meaningful engagement coming from a place of care could have provided that."

Harmed Patients Alliance

4.2.1 Working with patients and their families in a way that delivers a restorative process and maintains candour

T Expl R vi w T am d min d a D pa men of H al wi a ocia d ak old mu d c ib region's statement of intent regarding ow pa i n and famili a involv d in SAI vi w p oc and co obj c iv in la ion o pa i n and family involv men fo w ic ac HSC p ovid mu vid nc ac i v men .

Exampl of obj c iv la ing o pa i n and family involv m en a :

- Famili and pa i n a uppo d a ac iv pa n in vi w p oc a muc a y wi o b ngag d, including involv m en of an appoin d advoca .
- Pa i n /famili xp i nc a compa iona and mpa ic app oac , w ic i d mon a d by na u and f qu ncy of con ac oug ou vi w p oc .
- T voic of pa i n and family i a d, i imony cap u d, and y av am e a u a any p of ional con ibu ing info ma ion o vi w p oc .
- T pa i n and family a a nam ed ou c of uppo , ou id of vi w pan l. T ol of i individual i cl a ly d fin d, including ba i au o i y o ac a advoca in b in of family.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Ques s sked by he p e v d f mily re resp ded fully, w h h es y, egr y d c d ur.
- The p ve d f mily re e c ur ged c r bu e he erms f refere ce f r c de s de fed s requ r g -dep h re ew.
- P e s/f mi es re ke hr ugh he er m f d gs f he re ew d re pr ded w h e ugh me re d, c mme , d flue ce he c e f he f l rep r .

I he e e f ew f rm a bec mi g l ble f er he c clus f SAI re ew, r f here s ch ge c clus r m aer l f d gs fr m such re ew, he h s f rm a mus be sh red w h he p e /f mi es s s s p ss ble.

H w d du l HSC rg s s u der ke del er he bjec es sh uld be f r hem de ermi e. H we er, wh s requ red fr m ll HSC rg s s s cle r e de ce h hey h e ch e ed he bjec es. l p r cul r, hey sh uld pr de e de ce h p e s d f mi es re g e he s me pp r u y f r l eme SAI re ew s he s ff d hers l ed c de . Th s e de ce sh uld be l d ed by p e s d f mi es wh h e exper e ced u expec ed he l hc re h rm f he ure h w rr s SAI re ew. The Exper Re ew Te m c s dered h c -pr duc m odel f r de el pme d fur her mpr eme f he SAI pr cedure, l g fr l e s ff d p e s d he r f mi es, sh uld be d p ed g g f rw rd.

4.3 Staff Engagement (staff engaged in the care and management of the patient who experienced harm)

E ery SAI re ew mus l e he c llec vd lys s f suff c e m ou f f rm a fr m mul ple s urces. Th s requ res he c e e g geme f s ff l ed he c re d re me f he h rmed p e d he e g geme f w der sphere f d du ls wh h e exper e ce he f eld d u ders d he sys em w rk.

The purp se f he SAI re ew pr cess s :

- F d u wh h ppe ed.
- U ders d h w d why h ppe ed.
- Impleme y ppr pr e e rly remed l c s ddress y de f ed def c s c re.
- Ide fy re s f r mpr eme rder supp r he del ery f s fe p e c re.
- Impleme ppr pr e mpr eme s b sed he f d gs f he SAI re ew.

I c rcums ces where p e s h e bee h rmed, s u ders d ble h fr l e s ff may feel ul er ble d exper e ce em o l p , s well s feel gs f ger, sh me, fe r, s rr w r regre .

T e ble HSC s ff fully f rm he re ew pr cess, hey mus feel s fe d s . They mus ls h e c f de ce b h he c mpe e ce he pp ed re ew p el d feel secure h he f rm a hey pr de w ll be used f rly.
v

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

What stan oy d within H a th and Socia Car trusts across th r gion had to say

Co nts about th SAI roc dur and its i n ntation:

I the o li e survey completed by HSC staff:

- 89% (179) said they agreed, or stro gly agreed, that SAI reviews were a esse tial activity for a lear i g orga isatio .
- 74% of respo de ts (149) said SAI reviews ge erated improveme t for safety n withi their orga isatio s.
- 64% (129) said they agreed or stro gly agreed that they were aware of more tha o e improveme t resulti g from a SAI review.
- 61% (123) said outcomes from SAI reviews were regularly discussed at team or service meeti gs.

While the survey results ca ot defi itively co clude whether or ot SAI reviews e abled the collectio of quality i formatio upo which to formulate evide ce-based fi di gs, face-to-face meeti gs co ducted with staff i HSC orga isatio s did, however, provide a useful i sight i to the experie ces of staff i volved i SAI reviews.

The i formatio gathered at staff focus groups, for example, highlighted that the pri ciple of a 'just culture' was ot embedded across the regio .

Staff co siste tly reported:

- I sufficie t ope ess about the process a d the sta dards of co duct expected of the SAI review pa el members.
- I sufficie t commu icatio about the progress of a SAI review a d why it n was bei g co ducted. The key li es of e quiry, progress, fi di gs, a d recomme datio s were freque tly u k ow by staff who had bee i volved i the care a d treatme t of the patie t to which the SAI review related.
- The experie ce of the review felt like it was desig ed to apportio blame.
- Terms of refere ce for SAI reviews did ot suggest they were grou ded i a co structive or lear i g process.
- There was variable e gageme t i the process, with some staff u aware the SAI review was eve bei g co ducted, o ly to fi d out at a later poi t i time. Some staff described a over-emphasis o the collectio of writte submissio s a d a lack of detailed exploratory co versatio s bei g co ducted by SAI review pa els.
- Some staff described i sufficie t otice of, or i formatio about, SAI pa el meeti gs or i terviews staff were asked to atte d.
- Some staff did ot have a opportu ity to read the i terim fi di gs before these were fi alised i the SAI report.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Some d hey were no ble o re pond o ny cr c m s m ade n he SAI repor be ore w gned o comple ed.

Reg rd ng he con u on o he SAI rev ew p nel, nd how ho e p nel oper ed, he ollow ng concern were de cr bed by ron l ne who p r c p ed n h rev ew

- Concern bou he ppropr ene o member o he p nel n erm s o echn c l nd ubjec m a er compe ency nd n gh .
- Concern bou he l ck o c u l ccur cy check ng by rev ew p nel , bo h n erm s o he equence o even le d ng o he nc den under rev ew, bu l o reg rd ng he ccur cy o no e o ce- o- ce mee ng. S d h h me n hey were un ble o correc he SAI rev ew panel's misinterpretation of word poken n erv ew , or dur ng p nel mee ng .
- Some de cr bed oo n rrow eld o ocu by SAI rev ew p nel , w h l le con der on o he y em w h n wh ch ron l ne work. For ex mple, worklo d, workpl ce de gn, k de gn, k ll m x, ng ue , e m dyn m c , nd cul ur l c or , le der h p nd c or wh ch m y con r bu e o n nc den .

Al hough neg ve exper ence were repor ed, ome repor ed more po ve exper ence nd h d been nvolved ully hroughou he SAI rev ew. The e repor ed h hey el hey h d been nvolved hroughou he SAI rev ew, n erm s o be ng kep up o d e w h progre o he SAI rev ew nd were ble o con r bu e o he le rn ng rom he SAI rev ew.

Dur ng d cu on w h he Exper Rev ew Te m, ron l ne re lec ed on he uppor mech n m s v l ble o hem n com ng o erm s w h he SAI even nd ub equen rev ew. Al hough we rece ved m ny commen bou l ck o uppor , m ll number o d d h re po ve exper ence o be ng uppor ed by bo h m an ger nd colle gue . The e h ghl gh ed h he people who h d prov ded he uppor , h d hem selve been prev ou ly p r o a SAI rev ew. The overwhelm ing me ge rom ll ocu group cro ll Tru w h h d exper ence o n dequ e uppor hey wen hrough he SAI proce . Fron l ne cknowledged h w no he role o he ch r o he SAI p nel or he Tru member who over ee he rev ew o prov de ppropr e uppor or he r role w o del ver n e ec ve, unb ed rev ew proce . However, hey d d con der h be er qu l y uppor ough o be or hcom ng rom

- The r own l ne m an ger .
- Independen prov der o p ycholog c l uppor .
- The r employer v uppor nd coun ell ng erv ce .

In ever l ocu group , he Exper Rev ew P nel member were ruck by he level o emo on expre ed by who h d p r c p ed n n SAI rev ew . l w ev den h he e h d no been hrough uppor ve, re lec ve proce o le rn ng.

:

:

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

4.3.1 A ng a way of work ng w t staff t at d l rs a support , l arn ng-or ntat d pro ss w t n a ‘ ust Cultur ’.

The Expert Review Team determined that the Department of Health, working with appropriate stakeholders, must set out, in its strategic direction, its expectations for how staff in HSC organisations and those they report to are engaged and when participating in an SAI review. As with family engagement, the principles for effective staff engagement must be developed and defined before an effective process can be designed.

An example of a statement of success could be:

‘*Staff are treated well, their voice is heard, and they actively contribute to the SAI review process.’*

The core objectives for HSC organisations which will ensure this is delivered could be:

1) Staff experience a compassionate and empathetic approach.
2) The voice of the staff involved in an incident is heard, including their experience of the incident, and the context in which it occurred.
3) Staff are well informed throughout the review process.
4) Staff are treated fairly and equitably, in line with the principle of a ‘just culture’, including having the opportunity to read any criticisms made about them and to respond.
5) Staff involved in the incident (and other key staff) are given the opportunity to read the interim findings of the SAI review panel and to provide feedback in relation to factual accuracy, tone, and style.
6) Staff involved in the incident and service in which the incident occurred are actively engaged in designing the action plan to deliver measurable and sustained improvement.

Again, individual HSC organisations should determine for themselves how to deliver these objectives but should be able to evidence achievement of the objectives. This evidence should be validated by staff that have experienced the SAI process. Perspectives of staff who have delivered the SAI process should also be gathered and evaluated. The Expert Review Team again advises that a cooperative approach be adopted for involving frontline staff, patients and their families in designing of these improvements.

4.4 Staff Engag m ent (staff w t xp r n und rtak ng SAI r ws)

A robust SAI review requires staff delivering the process to have the right technical knowledge, along with a range of non-technical skills and attributes. At the time of this review there was no competency framework in place to ensure the required competencies to deliver the review process. It cannot be assumed individuals have these skills simply because of their professional background or seniority. Implementing an effective approach for SAI reviews will require upskilling of staff before it can be practised and evaluated.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

For th ntat on of th r v w roc dur to b ff ct v and for a o t arn ng to b ach v d, a structur d and f as b o cy fra work n ds to b dd b d a ongs d cu tura chang .

Th cons st nt ssag s rov d d to th Ex rt v w Pan fro staff ngag d n th d v ry of th SAI roc dur and ts R ntat on w r :

- It was cha ng ng to und rtak th SAI r v ws a ongs d th r r - x st ng rof ss ona dut s. Th r was no rot ct d t for th s, nor any account tak n of th r day-to-day work oads or front n at nt car dut s.
- Th r was nsuff c nt su rv s on and ntorsh by x r nc d r v w rs who ho d th n c ssary t chn ca and non-t chn ca sk s and attr but s.
- Th r was a ack of tra n ng n conduct ng SAI r v ws and r at d thodo og s.
- Th r w r cha ng s n ngag ng w th staff nvo v d n th car g v ng, such as stab sh d off duty rotas, th n d to rov d a 6–8-w k ad t to d ca staff b for t ng w th th cha ng s n ocat ng ag ncy and ocu staff, and th d ay b tw n th nc d nt occurr ng and th SAI r v w b ng co ss on d.
- Co n cat on u w th a r vant art s was d scr b d as a rs st nt cha ng .
- Th c ass f cat on of an SAI, and how t was d t r n d that an nc d nt t L v 1 or L v 2 cr t r a, was d ff cu t for staff to und rstand. Th r was not a ways fu und rstand ng that th curr nt roc dur d r cts r v ws shou d b conduct d at a v a ro r at and ro ort onat to th co x ty of th nc d nt and s gn f canc of v nt und r r v w rath r, that th act or outco for th at nt. Most staff cons d r d that th cr t r a for c ass f cat on w r not c ar.
- Th curr nt a roach of os d r g ona t r ofs r f r nc do s not su ort an ff ct v r v w ract c . Staff und rstood ff ct v r v ws r qu r th r ght t chn ca qu st ons to b ask d about th at nt's care and tr at nt; th s s not su ort d by th curr nt roc ss. Wh n ask d why th t r ofs r f r nc w r not chang d to so th ng r or vant, staff r ort d that th y d d not b v th y had th author ty to do so.
- Th r g ona r ort t at d d not su ort th for at on of an v d nc - bas d, w -structur d or r adab r ort. Part c ants r ort d that th d s gn of th r g ona t at d at d ff cu t to r f ct th v of an ngag nt that an SAI r v w an y ha av ach v d w th th fa y. Ov ra , th t at was cons d r d to b not f t for ur os .
- co ndat ons w r a art cu ar sourc of conc rn for art c at ng staff, w th ny a ort ng th r rs ct v that r co ndat ons oft n d d not g t nt d du to a ack of r sourc s. Staff a so d s ay d so frustrat on rsb of r v w an s f t ob g d to k a co ndat ons v n f th y sus ct d that noth ng wou d ha n as a r su t.

In add t on to th abov , staff w th x r nc n conduct ng SAI r v ws rov d d ns ghts nto th r v w thodo ogy of oot Caus Ana ys s (CA) and th xt nt to wh ch arn ng s nt d. Th nfor t on a rov d d by staff nd cat d that th r s confus on about what const tut s an CA thod. Th fact that ny a staff b v d co t on of th r g ona r ort t at const tut d a va d r v w and an

R

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

RCA is i g. Staff did t d m o st at a i f m ed u d sta di g f what stitut d a vi w a d w t awa f th b ad a g f t ls a d app a h s th y uld mpl y t d liv this. Th t ls that pa ti ipati g staff w awa f w r simpl chronology, th 'fiv -whys' t chniqu , and th 'fishbon ' diagram.

Th Exp t R vi w T am was l ft with a imp ssi that HSC T usts a ss N th l la d a usi g th la guag of RCA with ut a emb dd d u d sta di g f what this m ea s, wh RCA fits i t a st u tu d a d auditabl vi w. Th gi al guida d s t add ss this, d s it p vid p a ti al advi h w t du t a vi w t a a ptabl sta da d.

Th Exp t R vi w T am uld t b fid t that a ss th HSC T usts, sist t syst ms bas d l a i g was happ i g, a d that cha g s w mb dd d that th was a bust syst m i pla f sha i g l a i g b y d th i v stigati g ga isati . Th issui g f gi al l a i g l tt s by th HSCB was f d t , but m ost f tli staff w t awa f this a d ly tw f th s i t vi w d had v s a l a i g l tt .

Staff with xp i as a SAI vi w u d st d why staff ask d t p vid i f mati t th vi w pa l may susp ct th xist nc of a 'blam cultur '. Th y sid d that m ost f th staff th y i t vi w d ft app a d a xi us ab ut th p ss a d w s metim es d f siv wh qu sti d. S m e staff wh had u d tak s v al SAI vi ws sid d that th l v l f a xi ty am o g staff b i g i t vi w d had i as d v time.

Th Exp t R vi w T am sid s f m th i ass ssm e t f th 66 vi w p ts that th la guag us d i SAI vi w p ts might als t ibut t a s s f blam . For xampl , root caus s of incid nts w r d scrib d as 'human rror', whi h may u fai ly sugg st that a i dividual memb f staff is sp sibl . This is fu th mp u d d by th la k f d st u ti f v ts f m a syst ms p sp tiv , m ea i g that th t u t aus s a d t ibut y fa t s whi h u d li s i a a d t atm e t a t id tifi d, pla i g a u as abl w ight f sp sibility f tli staff.

Staff a ti g as SAI vi w s b half f th i mpl y als sid d th way th media i N th l la d p t d i id ts that had a h d th publi d mai . Subs qu t media i t st a d mm ta y fu ll d th i f li g f a blame-d iv app a h a d ultu , al gsid s ab ut m edi -l gal s qu s.

As with staff i v lv d i a d liv y, th s wh had a xp i f du ti g SAI vi ws als b li v d that th was a la k f st u tiv supp t. Staff ask d t hai SAI vi w pa ls w pa ti ula ly d. Th y sid d that th was a u t tak f th t u time qui d t d liv th l w ll, h w th time qui d fli t d with th i th p f ssi al sp sibiliti s. S m e staff p t d havi g t w it SAI p ts i th i w time a d lat i t th ight, whi h th impa t d th i w llb i g a d t ati l v ls at w k th xt day.

Th Exp t R vi w T am sid s this situati t b wh lly u a ptabl . If th bj tiv is t l a a d imp v saf ty, th syst m a t v l ad staff al ady w ki g at full apa ity. Faili g t p vid p t t d time t l ad th SAI vi w

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

process ers a lacks mpor a ce. I e ra l, mar e, a d a rl e dus r es, w ere a c de mer s care ul a alys s, o ly ra ed d v duals w me o u der ake e work are appo ed o e ask.

T e lack o admi s ra ve ass s a ce or rev ew c a rs was also c ed by s a as ev de ce o lack o suppor . T ere s co s derable admi s ra o assoc a ed w e co duc o a SAI rev ew. T e Exper ev ew Team co s ders a s o appropr a e or a ro l e cl c a , w o as bee asked o lead a SAI rev ew process, o also be respo s ble or admi s er g .

4.4.1 How to ensure chairs and members of SAI review panels are equipped to deliver the job adequately and with enough time

T e Exper ev ew Team co s ders a e rs s ep ac ev g a sus a able s ua o across e reg o s o rev ew ow dec s o s are made regard g e level o SAI rev ew requ red. T s s ould be ormed by:
R

- T e reque cy by w c e c de ype occurs.
- W e er ere s a sa e y rev ew already o go g o explore a d address a y sa e y ssues.
- W e er e co duc o e rev ew s l kely o del ver more lear g a as already bee ac eved by prev ous rev ews.
- W e er ere s a sa e y mproveme pla already u derway.

I s w dely recog sed a ma y d v dual rev ews volv g e same c de ype o e do o lead o a g ble sa e y mproveme s. T ere ore, e prac ce o de g e eed or a SAI rev ew o e bas s o adverse pa e ou comes s ould be d scouraged a d s o l e w e curre gu da ce co a ed w e SAI procedure w c s a es,

"SAI reviews should be conducted at a level appropriate and proportionate to the complexity of the incident under review. In order to ensure timely learning from all SAIs reported, it is important the level of review focuses on the complexity of the incident and not solely on the significance of the event".

A approac a allows a se s ble per od o me for the early assessment of 'what happened', a d co s dera o o early orma o ga ered abou e care a d c de , mig e able a more s ruc ured a d ev de ce-based approac o dec d g w c cases requ re a -dep sys ems a alys s. Trea g e rev ew as a process, w ere rev ewers a d c a rs ca de erm i e a ev de ced-based s op po , mig be more success ul a a s a c approac w c assumes a all c de s ca be rea ed e same. O ne o e exper rev ew pa el members as suppor ed several NHS Trus me al eal eams o mpleme suc a approac . As a resul , me al eal eams repor ed a reduc o e umber o -dep rev ews, grea er e gageme rom s a a d a ormal sed process w ereby e rev ew s led by e eam lead; ow recog sed o be a mpor a aspec o e process.

A more lex ble approac s requ red o e able am l es o u ders a d e process a d w a ca del ver. For example, ca del ver lear g a d prov de a swers o ques o s bu ca o prov de jus ce. R

R

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

In ter t e ti all ecated t c nduct an SAI review, it will alway be nece ary t tipulate ti ca e , but n p i i rtant t at t ey are reali tic. T ey t all w at lea t t ix- nt r c lexpca e , and it w uld be rea nable t re uire a tructured pr ject nage nt apr ac t at can be nit red and uality a ured.

T e ec nd tep i t de ine t e c re c etepcie re uired :

- Pe ple acting a review lead and/ r c air review panel.
- T e ubject advi r upp rting t e pr ce .

Furt er re, a regi nal training curriculu and certi icati n pr ce t be agreed. All training pr vider acr t e regi n s uld meet t e mini uc ntent re uire nt in rder t enable c etepcy ac ieve nt. eF r uc an appr ac t w rk well, all HSC Tru t and independent pr vider re p n ible r delivering training uld be re uired t de n trate t eir c etepcy and kn wledge in rder t be appr ved a training pr vider . Re uiring all training pr vider t apply t be n a regi nal regi ter r pre erred pr vider li t w uld upp rt t e ac ieve nt e t i .

Finally, t upp rt t e i le p ntati n a training curriculu it wa c n idered t at a ent r ip and c ac ing appr ac c uld al be ad pted. A per n independent t e HSC Tru t in w ic t e incident ccurred c uld pr vide external upp rt t t e lead reviewer/c air. T i a t e added advantage pr viding an independent uality a urance c eck t e pr ce and it utc . e

4.5 SAI Reports: The extent they demonstrated a reasonable standard of review and positive contribution to patient safety in Northern Ireland

A previ u ly utlined in t e t d l gy in ecti n 3.0, t e Expert Review Tea reviewed 66 SAI rep rt a part t i review.

In undertaken t e review rep rt , it wa evident t t e Expert Review Tea t at aving tw eparate rep rt te latep r Level 1 and Level 2 review i n t w rking. T e de ign t e te latep al d e n t upp rt ta t write up t eir inding in a way t at deliver c n idence in t e tandard t e review r in t e appr priatene t e level review undertaken. Furt er re, t e te latep are de igned in a way t at li t i i rtpant in r ti n a being included, uc a t e ue ti n t at ave been a ked by patient and a ly i er b

Up n a e ing t e rep rt a igni icant adver e incident review, t e expectati n i t at it de n trate t at an e ective t d l a been u ed t underpin t e review. Indicat r an e ective t d l gy are:

- T e t d , t l and tec ni ue u ed by t e SAI review panel are clearly tated and appr priate t t e incident under exa nati i n.
- T e evidence up n w ic inding and c nclu i n are ba ed ave been clearly triangulated.
- An appr priate range ubject advi er ave been engaged in t e review q pr ce

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- The S e ew epo t outl nes the key elements of the p ocesses and p ocedu es ele ant to the expected standa ds of ca e and t eatment.
- The e s a clea account of:
  - what happened
    whe e pol cy, p ocess o p ocedu al expectat ons we e met
    whe e the e was a de at on f om p ocedu al expectat ons.

- Whe e de at on f om p ocedu al expectat ons s dent f ed, the e s an explanat on of:

  whethe the de at ons we e easonable and just f ed based on the p esentat on of the pat ent, the cl n cal needs at the t me, and the unfold ng s tuat on
  whethe the de at ons we e not easonable and the efo e not just f able.

- In the nstance of a non-just f able de at on f om the expected standa d of ca e, the e should be an nd cat on of whethe th s cont buted to o caused the ha m to the pat ent, and whethe the de at on ep esents a b each n standa ds to such an extent as to pose an ongo ng th eat to the safety of anothe pat ent should t eoccu .

  In all such nstances, a epo t should outl ne a human facto and systems-based explanat on of how and why the de at on(s) occu ed.

- Recommendat ons should add ess the most s gn f cant facto s dent f ed wh ch cont buted to o d ectly caused the nc dent.

n add t on to the abo e, all s gn f cant ad e se nc dent epo ts should del e the follow ng:

- Cla ty about the quest ons posed by the fam ly. The answe s to these quest ons should be ncluded n the f nd ngs sect on of the epo t.
- A good standa d of w t ng w th co ect use of g amma , punctuat on, and syntax. The e should be no abb e at ons, unless al eady n common usage n No the n eland.
- A eadable epo t w tten n non-techn cal language.

4.5.1 Expert Review Team Findings following review of 66 significant adverse incident reports, comprising Level 1 and Level 2 reviews

The Expe t Re ew Team found that all HSC T usts ut l sed the ele ant eg onal templates fo the Le el 1 o Le el 2 e ew epo ts. The efo e, the Expe t Re ew Team's findings a e as much a eflect on of the des gn of the templates as the qual ty of the epo ts assessed.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Style t uctu e of the epo t

The Expert Review Te m considered the present tion of the review reports nd there w s consensus th t both report templ tes would benefit from b sic front p ge th t simply st tes the n me of the reviewing org nis tion, the title of the report nd the public tion d te. It w s proposed th t ny demogr phic inform tion required for region l collection purposes could be ccommod ted within n ppendix.

In both the Level 1 nd level 2 report templates, space is provided to record 'what happened'. Mostly, this w s comprehensively completed. However, in m ny reports, the sequence of events w s recorded in too much det il nd t the expense of the det iled n lysis expected in the findings section of both reports, ccepting th t the Level 1 report is intended to be more succinct th n the Level 2 report.

In the Level 1 report, there is no 'findings' section but inste d, a section titled 'why it happened'. This title is erroneous. It implies that 'why' is determinable and utom tic lly infers th t the incident w s prevent ble. It does not promote b l nced, constructive, n lytic l process.

In the Level 2 reports, there w s 'findings' section, but this w s not structured. There were no uniform subhe dings to guide report uthor bout wh t they should be recording. For ex mple:

- Evidence th t shows th t expected st nd rds of c re were delivered s intended.
- Evidence of devi tions from the expected st nd rds of c re.

Some reports m de st tements of policy nd procedur l compli nce but did not s y wh t these were nd did not present n evidence b se for the reported levels of compli nce.

Some review reports st ted their findings in rel tion to hum n f ctors, such s te m elements, educ tion nd tr ining. However, in the m ajority of inst nces the Expert Review could not link these findings to system tic n lysis of these re s of concerns in keeping with the ppro ch of the N tion l p tient S fety Agency.[9] This indic tes th t the review p nel, the uthor of the SAI review report nd those signing off the reports did not fully underst nd how to effectively implement hum n f ctors ppro ch.

Some reports reviewed by the Expert Review Te m did outline devi tions in the c re nd m n gement of the p tient but did not m ke cle r the signific nce or seriousness of these in rel tion to the p tient outcome. As st ted bove, r rely w s this ccomp nied by ny structured or evidence-b sed expl n tion reg rding how nd why these devi tions occurred. As result, there w s l ck of outcome-focused recommend tions within the reports reviewed.

In st ting the bove, the Expert Review Te m is not inferring th t st ff who undertook the reviews or wrote the reports were f iling to deliver wh t w s required of them, r ther, the l ck of structure nd qu lity of the reports is consequence of:

a

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- A lac vestme t th se tas ed w th lead g the rev ews terms the r wledge, s ll base a d t me requ red t d the j b adequately.
- A rep rt structure that s t t r purp se Level 1 a d Level 2 templates).
- A lac e ect ve qual ty assura ce rep rts at se r ma ageme t levels acr ss HSC Trusts.
- A lac emp werme t HSC Trusts t ad pt a m ore c mprehe s ve appr ach a d a better style rep rt, based the pr c ples utl ed reg al p l cy a d gu da ce.
- A lac a e ect ve qual ty assura ce pr cess w th each HSC rga sat a d at a reg al level. There appears t be rel able pr cess thr ugh wh ch rep rts are peer rev ewed t e sure del very a acceptable sta dard rev ew, clud g utc me- cused rec mme dat s. N r are they qual ty assured w th a v ew t e sur g that there s a sta dard rep rt wr t g su table r shar g w th pat e ts a d the r am l es.

Expert Review Team findings in relation to specific indicators of a robust SAI review

These are the findings from the Expert Review Team's structured assessment of the 66 rev ew rep rts.

Indicator 1: The methods, tools and techniques used by the review panel are clearly stated and appropriate to the incident under examination

The ll w g l st descr bes what was u d t be c mm ly rec rded terms the meth d l gy a d appr ach t rev ew g SAIs:

- The patient's notes were reviewed.
- A tabular timeline established.
- Relevant staff were interviewed.
- Family was invited to participate in the review.

The ab ve eleme ts are t su c e t t be c s dered a meth d l gy, r d they pr v de clar ty regard g the appr ach ta e by the releva t rev ew pa el. As prev usly art culated th s rep rt, the pr mary reas r th s s a lac u dersta d g ab ut what c st tutes a a r a d reas able rev ew, w th a reg al appr ach that s t l m t g a d t embrac g a t l- t meth d.

Indicator 2: The evidence upon which findings and conclusions are based has a clear triangulated evidence-base

N e the rep rts rev ewed sat s ed the Expert Rev ew Team that there was a tr a gulated, a d thus val dated, ev de ce-base r what was wr tte the d gs sect the rep rts. Th s represe ts a u acceptable s tuat . A cred ble rev ew a ms t establ sh what happe ed, h w t happe ed a d why t happe ed.

A SAI Rev ew Pa el Cha r u dersta ds the mp rta ce tr a gulat g a d val dat g rmat a d u dersta ds the da gers t del ver g th s sta dard pract ce. The SAI rep rts rev ewed dem o strated a reg -w de lac adhere ce t

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

defenda e e ew p act ce. Th s s most y due to a ack of t a n ng, an unc ea competency f amewo k and nsuff c ent p ofess ona supe s on.

Ind cator 3: An appropr ate range of subject adv sers have been engaged n the process

Rega d ng the ndependence and app op ateness of su ject ad se s, n 93% of epo ts th s was e the unc ea o a sent. Rega d ng e e ant expe ence of su ject ad se s, th s was unc ea n 45% of the epo ts e ewed. The ack of c a ty was n pa t nf uenced y the des gn of the eg ona epo t temp ate wh ch d d not equ e p ec s on n the eco d ng of th s nfo mat on.

Ind cator 4: The key elements of processes and procedures relevant to the effect ve care and management of the patient's cond t on are recorded

Th s was m iss ng f om a most a epo ts e ewed. It s not a cu ent equ ement of the eg ona epo t temp ate, and ts a sence unde nes the ack of app ec at on a out what s necessa y fo a st uctu ed and c ed e e ew.

Each epo t shou d g e a c ea account of:

1) What happened.
2) Whe e po cy/p ocess/p ocedu a expectat ons we e de e ed as expected.
3) Whe e the e was de at on f om po cy/p ocess/p ocedu a expectat ons and an exp anat on fo such de at ons.

A though the e was a c ea account of what happened, few epo ts p o ded an ana ys s that ena ed the eade to know whe e expectat ons we e de e ed, whe e they we e not, and whe e the des gn of the p ocess fo ca e de e y and management was ncomp ete.

Th s s a s gn f cant sho tcom ng n the SAI p otoco wh ch does not equ e systems ased ana ys s as pa t of ts app oach to conduct ng SAI e ews o w th n ts eg ona epo t temp ate.

Repo ts of e ews must dete m ine:

- What was expected.
- Whe e the e dence suppo ts that the standa d of ca e was de e ed as expected.
- Whe e the e dence shows de at on f om what was expected.
- Whe e the e dence shows the e was a p e-ex st ng def c ency n the des gn of ca e and t eatment equ ements and assoc ated systems and p ocesses.

Whe e de at on f om po cy, p ocess o p ocedu a expectat ons s dent f ed, the e s an exp anat on of any o a of the fo ow ng:

- Whethe the de at ons we e easona e and just f a e based on the p esentat on of the pat ent, the c n ca needs at the t me and the unfo d ng s tuat on.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Whethe the e t ons we e not e son ble n the efo e not just f ble.

Whe e e t ons n c e st n s n the c e n t e tment el e e we e ent f e , the e w s l ttle e ence eg ng the e son bleness of such e t ons. It s ccepte c oss ll om ans of cl n c l p ct ce th t somet mes t s necess y to o th ngs ffe ently th n wh t s outl ne n pol cy n p oce u e. Cl n c l p ofess on ls e t ne to pply the cl n c l s lls n to h e cle e son why ffe ent pp o ch n ny g en s tu t on s ght fo the p t ent un e the c e. It s poss ble to m a e co ect ec s on t the t me c e s el e e to lte the no m al pl n n fo th s to be l te contempl te s cont buto to n nc ent th t occu e l te . The ghts n w ongs of these ec s ons must be c efully contempl te , longs e the ppl c t on of p nc ples such s the subst tut on test (th t s, wh t woul s m l ly qu l f e g oup of p ofess on ls, p o ng c e un e the s me/s m l set of c cumst nces, e son bly h e one). The e w s no e ence f om the epo ts e ewe th t these co e p nc ples h e been ppl e .

The s tu t on s uncompl c te f the e ew p nel n the c e te m g ee th t n unjust f ble e t on occu e . The p oblem ses when the e s ffe ence of op n on between the c e te m n the SAI e ew p nel. In ll such nst nces, the SAI e ew p nel must pply the subst tut on test.

The e w s no n c t on n ny of the epo ts e ewe s to whethe the c e te ms h g ee o s g ee w th the f n ngs n conclus ons of the SAI e ew p nel.

M ny epo t utho s n SAI e ew p nels t e to w conclus ons eg ng cont buto y f cto s n c us l f cto s. Howe e , the e w s l c of obustness n the e ence-b se on wh ch such mpo t nt conclus ons we e be ng m a e. In some c ses, whe e f n ng of c us l ty h been m a e, t w s cle f om the content of the epo t n the Expert Review Team's cl n c l nowle ge th t the conclus on of c us l ty woul not st n up to n epen ent sc ut ny. It s the l c of obust e ence b se fo such conclus ons th t cont butes to the w ely-hel ew, suppo te by some membe s of st ff u ng focus g oups, th t cultu e of bl me pe es e ews.

Reg ng the hum n f cto s n systems-b se n lys s, epo t utho s n the e ew p nels cle ly t e to un e t e th s n lys s n p esent ts outputs n the e ew epo t. Howe e , b se on most of the epo ts ssesse by the Expe t Re ew Te m, the e s l c of un e st n ng bout how th s nee s to be pp o che , n how the f n ngs nee to be st uctu e n p esente . The es gn of the eg on l epo t templ te w ll h e fu the compoun e th s.

Indicator 5: Recommendations to address the most significant influencing factors to the identified contributory and causal factors

The qu nt t t e ssessment of the 66 SAI epo ts e ewe by the Expe t Re ew Te m e e le :

- The e w s l c of cl ty bout whethe the epo t m a e ecommen t ons. k Th s w s foun n 14 (21%) of the SAI epo ts.

k

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Reco e io s were o ly e i 26 (39%) of he SAI re or s, bu wh hey were ryi g o chieve w s u cle r.
- I er of s whe her here w s correl io be wee he i ci e , he re or co e , he reco e io s, i 30 (45%) of he SAI re or s his w s cle r, i 32 (48%) i w s u cle r, i 4 (6%) i w s ifficul o ke ju ge ebou his.
- I er of she ro ri e ess of reco e io s, i 22 (33%) of he SAI re or s he reco e io s see re e so ble, bu i 40 (61%) hey i o . I 4 re or s (6%) i w s ifficul o ke ju ge ebou his.
- Reg r i g y correl io be wee reco e io s he subseque c io l , his w s cle r i 29 (44%) of SAI re or s while i 36 (55%) i w s o . I 1 re or (2%) i w s ifficul o ke ju ge ebou his.

I o re or w s here evi e ce h s ruc ure ro ch w s ke o he for ul io of reco e io s. The regio l gui ce o SAIs oes o escribe y require se for his ei her o he regio l re or e l es.

A ex le of s ruc ure ro ch o reco e io s is:

- Cle r i e ific io of he i e e reci ie of he reco e io .
- A cle m e e of wh is require .
- A cle m e e bou wh he reco e io shoul eliver.
- A cle m e e of wh risk he reco e io is e o co i .
- A cle r s e of he sco e of he reco io e (loc l, regio l).

Indicator 6: Regarding the non-technical aspects of SAI reports

SAI review re or s shoul here o he followi g o - ech ic l require se p

- Cl ri y bou he ques io s ose by he f ly i he swers o hese ques io s.
- A goo s r of wri i g, wi h he correc use of gr r, u c u io , sy x, wi h o bbrevi io s, u less lre y i co us ge e wi hi he o ul io of Nor her Irel .
- A re ble re or , wri e i o - ech ic l l gu ge.

E ch of he re or s w s ssesse i rel io o hese f c ors. Reg r i g he level of f ly ei g ge e u ers i g, it is the Expert Review Team's ers ec ive h s SAI review re or s i o eliver y evi e ce, or le s co vi ci g evi e ce, of co li ce wi h c our.

The s r of wri i g w s v ri ble s w s he use o -use of ech ic l l gu ge.

Reg r i g he egree of s isf c io ie f ly igh h ve wi h he re or rese e , he l y ers of he Ex er Review Te co si ere h hey woul be s isfie wi h 16 (24)% of SAI re or s reviewe . They co si ere h hey woul o be s isfie wi h (23) 35% of he SAI re or s were u ble o e er e i o i io of heir s isf c io wi h he re i i g 27 (41%). p

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Regar g e clus o of ev e ce a pa e a /or fam ly ques o s a bee aske a respo e o ur g e SAI rev ew process ere was ev e ce 15 (23%) of SAI repor s rev ewe a s a appe e . I 44 (66%) of SAI repor s ere was o suc ev e ce w le 7 (11%) of SAI repor s was u clear.

Regar g rea ab l y a compre e s o of SAI rev ew repor s e lay members of e Exper Rev ew Pa el co s ere mos repor s 89 of 132[3] (67%) as easy o rea erms of s ruc ure a flow bu s roppe o 26 of 66 (39%) erms of ease of compre e s o of repor co e s.

Wider Consideration from Structured Assessment of 66 SAIs

O n co s era o of e mpl ca o s of e overall f gs of e s ruc ure assessme of e 66 SAI rev ew repor s e Exper Rev ew Team co s ere e ecessary s eps o e sure SAI rev ews a e r repor s are of goo qual y rea able respo o fam ly ques o s a prov e ev e ce a accep able s a ar of rev ew.

T ey agree o a umber of ge eral ssues a ee o be a resse regar g e proce ure a s mpleme a o f e overall s a ar a cre b l y of e SAI repor w c se s ou e f gs co clus o s a recomme a o s of e s g f ca a verse c e rev ew process are o mprove. T ese clu e:

- A reg o al framework a makes clear w a e approac o lear g from u expec e a u e e arm s e e o el ver; a s w a are s measurable markers of success.
- A reg o al approac o SAI rev ews a el vers recog se er a o al goo prac ce e sc e ce of rev ew.
- A reaso able amou of me o co uc a effec ve rev ew a clu e e pa e a fam ly e process a empa e c mea gful a respec ful way.
- A s gle ew repor empla e a reg o al s yle gu e a e ables a co s s e approac o SAI rev ews across e reg o bu s flex ble e oug o allow SAI rev ew repor wr ers o remove a a sec o s o e empla e.

T ere s o s gle ac v y a w ll ac eve e above. T e Exper Rev ew Team w s o make clear a re-wr g e reg o al s a ar s w ll o ac eve e s a ar of prac ce a arme pa e s a e r fam l es are r g fully ema g of s spec al s f el across e HSC. T s s a s a ar of prac ce a s comparable o o er us r es w ere e ac v y of rev ew g a , lear g from u expec e arm i g c e s el ver e core compo e s ecessary for a ev e ce-base rev ew u er ake by ves ga ors w o are sk lle for e job so e r g lesso s are lear e a e r g safe y mproveme s are mpleme e .

[3] T e e omi a or s ca or s 132 as ere was o co se sus. 132 rev ews were u er ake 2 of eac 66 repor s. O re by eac lay rev ewer.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

It is th t R vi w Team's assertion that th must b a omp h nsiv alib ation of th a oa h to th qui m ent fo , and d liv y of, SAI vi ws a oss No th n l land.
A n w a oa h must a hi v :

- G at fl ibility in an a oa h that fo us s on th o o tunity fo l a ning c and saf ty imp ov m ent.
- A low numb of in-d th vi ws. Wh a ly ass ssm ent indi at s that this d th of vi w is n ssa y, th should th n b a ability and a a ity in th syst m to do this w ll.
- A o ss by whi h individuals and/o o ganisations who want th o o tunity to deliver 'Investigating Well' training to HSC staff, are asked to undertake an ass ssm ent o ss so that it an b d t min d that th y hav th ight c knowl dg and skills to d liv su h t aining. This would f ably th n l ad to a gional gist of f d ovid s f om whi h individual HSC T usts an sou t aining.
- A gist of individuals and o ganisations who a autho is d and hav b n ass ss d as om p t nt to l ad th vi w of un t d ha m v nts that m e t th th shold fo an in-d th fully ind nd nt vi w - fo am l , m ental h alth homi id , moval of a body a t in o , in- ati nt sui id .

No th n l land is in th nvious osition of having only si HSC T usts. This ovid s an o o tunity to s t th om pass in a way that is not ossibl in gions with la g o ulations. A hi ving this s t and d signing a fit-fo - u os a oa h to vi wing and l a ning f om SAIs will qui unifi d and oo ativ wo k a oss all involv d o ganisations. Fu th mo , it will qui f ontlin s nio lini ians to b a d to ovid st aightfo wa d, -to- ass ssm nt, fl tion and f dba k to oll agu s in n ighbou ing T usts about th a and t atm ent ovid d to ati nts wh n th out om e onstitut s un t d and unint nd d h alth a ha m. This is a o l m ent of of ssionalism and c lini ians of all dis i lin s n d to m e t this hall ng h ad-on. It should not b th as that t ust d ind nd nt lini al o inion has always to b sought f om outsid c of No th n l land.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

5.0 Co io

The work undertaken for this review has, a ongside other re ated projects, determined that the SAI procedure and its imp ementation across Northern Ire and is not working as intended.

It frequent y fai s to:

- Answer patient and fami y questions. I
- Determine where safety breaches have occurred.
- Achieve a systemic understanding of those safety breaches.
- Design recommendations and action p ans to reduce the opportunity for the same or simi ar safety breaches in future.

Patients l and their fami ies are not fu y enab ed to engage with the process as partners and their questions are not a ways sought. They do not a ways receive open, honest and straightforward answers to their questions. The witness testimonies of patients and fami ies are not routine y co ected and, when they are, they are not treated as they shou d be; that is, as evidence in the same way staff testimonies are treated. The current situation is not tenab e and must change.

Front ine staff, who come to work to he p and support patients to achieve the best qua ity of hea th they can, consider the current process to be b ame-orientated and not earning-orientated. It does not embrace the basic princip es of a credib e review process, a reasonab e expectation of fair treatment, or the right to know of any criticism that is to be made and its re evant evidence-base. Staff are most frequent y engaged as passive recipients to the process, which is not a good p atform for earning and positive change.

The SAI review reports arge y do not evidence a defendab e approach to the review and identification of earning arising from unexpected patient harm. There are severa contributory factors, inc uding:

- Staff asked to ead the reviews are most y asked to do this on top of pre- l existing work commitments, inc uding front ine patient care duties.
- The eve of training provided to staff that are tasked with eading SAI reviews is insufficient and is not informed by regiona y agreed competencies or a core patient safety training strategy or curricu um.
- The regiona timesca es a owed for undertaking a comp ex review, inc uding l meaningfu engagement with a patient and their fami y, are unrea istic and ead to a bureaucratic process.
- The regiona report temp ates are not designed to support the de ivery of a qua ity, evidence-based report.

It is worth noting that since this review was commissioned, a number of Pub ic Inquiries, patient reca and ookback exercises have been initiated in Northern Ire and. The Expert Review Team considers that such engthy inquiries and arge-sca e pieces of work cou d be avoided by a robust system for deriving and imp ementing earning from SAIs. Ineffective systems and processes for review l

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

and identi i ati n ea ning eme ging m SAIs, n t n y damage pub i n iden e and t ust in the SAI p ess, but a s adve se y impa t n the t ust patients, thei ami ies and the pub i in the hea th a e system as a wh e.

The e is n w an imp tant pp tunity t a hieve bette E patients, sta and Hea th and S ia Ca e se vi es a ss the egi n. It is patent y evident that E ntinuing as we have been is n t an pti n. The xpe t Review Team has made ive e mmendati ns that, i imp emented, sh u d t ans m the u ent app a h t ea ning m and p eventing e u en e ha m within Hea th and S ia Ca e in N the n l e and. The RQIA k wa d t w king in pa tne ship with D H, PHA, HSC T usts, patients, ami ies and a e s t de ive n a new and imp ved egi na system ptimising the ea ning m adve se in idents whi h u in Hea th and S ia Ca e se vi es and ensu ing eve y pp tunity is E seized t imp ve the sa ety Hea th and S ia Ca e se vi es.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

6.0 Re ati s e

The following recommend tions re intended to deliver new region l policy for reporting, investig ting nd le rning from dverse events.

Re ati 1: e

The Dep rtment of He lth should work coll bor tively with p tient nd c rer represent tives, senior represent tives of Trusts, the Str tegic Perform nce nd Pl nning Group, Public He lth Agency nd Regul tion nd Qu lity Improvement Authority to co-design new region l procedure b sed on the concept of critic l success f ctors. Centr l to this must be focus on the involvement of p tients nd f milies in the review process.

Re ati 2: e

He lth nd Soci l C re org nis tions should be required to evidence they re chieving these critic l success f ctors to the Dep rtment of He lth.

Criti al su ess fa t rs

Appendix D provides n ex mple of the critic l success f ctors the Dep rtment of He lth m y wish to use to commence the work of redesigning the region's ppro ch to le rning from SAIs.

A exa le f p riti al su ess fa t r a its re bje tives:

- F milies nd p tients re supported s ctive p rtners in the review process s much s they wish to be involved, including the involvement of n ppointed dvoc te.
- P tients/f milies experience comp ssion te nd emp thetic ppro ch, which includes the method nd frequency of cont ct throughout the review process.
- The voice of the p tient nd f mily is he rd, their testimony is c ptured nd they h ve the s me st tus s ny profession l contributing inform tion to the review process.
- The p tient nd f mily h ve n med source of support outside of the review p nel. The role of this individu l is cle rly defined, including their uthority to ct in the best interest of the f mily.
- Questions sked by the p tient nd f mily re responded to fully, with honesty nd integrity.
- The p tient nd f mily re encour ged to contribute to nd influence the terms of reference for incidents identified s requiring in-depth.
- P tients/f milies re t ken through the interim findings of the review nd they re provided with enough time to en ble them to re d, comment on nd influence the content of the fin l report.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

How in i i HSC org nis tions e i er these objecti es is for them to etermine. Howe er, wh t m ust be req ire from HSC org nis tions is e i ence of chie ement n n eq opport nity to be in o e . his m ust be i te by p tients n f mi ies who h e experience nexpecte he thc re h rm of n t re th t w rr nts e ic te re iew.

he Expert Re iew e m recommen s th t co-pro ction mo e , in o ing front ine st ff, p tients n their f mi ies, be opte region y to sh pe ny w y forw r .

Implementing this recommendation will achieve:

Me ningf in o ement of p tients n f mi ies s p rtners in the SAI re iew process. his sho incorpor te restor ti e process e i ere within c t re of e rning n impro ement. he inci ent of h rm n its res ting imp ct is one which the p tient n their f mi y m ust m an ge n i e with. herefore, it is essenti th t the p tient n their f mi y re t the centre of the re iew process if their tr st in the He th n Soci C re ser ice concerne is to be ret ine .

This recommendation should address the risk of:

F rther oss of p b ic confi ence in the systems of e rning from he thc re h rm n , import nt y, risk of nnecess ry h rm to p tients/f mi ies.

Recommendation 3:

he Dep rtment of He th sho imp ement n e i ence-b se ppro ch for etermining which erse e ents req ire str ct re , in- epth re iew. his sho c e r y o t ine th t the e e of SAI re iew is etermine by signific nce of the inci ent n the e e of potenti eficit in c re.

What is required:

RQIA h s fo n thro gho t its inspection n re iew work, wi espre pr ctice, where erse o tcome for the p tient often ri es the req irement for Le e 2 or Le e 3 re iew. his pr ctice m ust ch nge. Not nexpecte h rm, irre ersib e h rm, n nexpecte e ths re ttrib te to mist kes in the c re or tre tment pro i e .

C e r g i nce is necess ry which inc es the imp ement tion of system of e r y, str ct re c se ssessment, t king p ce within one to two weeks of the inci ent occ rring. his wi e i er gre ter egree of c rity reg r ing the egree of ri nce from expecte c re n tre tment st n r s, n , on this b sis, proportion te ecision c n be m a e reg r ing the s bseq ent e e of re iew req ire .

T

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

The Ex e e iew Team sugges s:

- In all cases whe e the e is conce n that an identified va iance may have cont ibuted to the outcome fo the patient, an in-depth examination of those va iances is equi ed.
- Whe e a se ious b each in the expected standa ds of safe ca e is identified, an in-depth examination is wa anted – even if the va iance itself is not considered to have contributed to the patient's outcome.
- Whe e the incident ep esents issues known to have been p eviously examined individually, that conside ation is given to conducting a st uctu ed, in-depth, whole system eview athe than epeating anothe individual incident eview which, by its natu e, is unlikely to include systems-based lea ning and imp ovement.

In all the above suggestions, it is expected that the e will be involvement and engagement with the ha med patient and thei family.

O the conside a ions ha should be inco o a ed in o a decision-making ocess: r

- It should be conside ed whethe a fu the Level 2 o Level 3 eview will achieve mo e lea ning than has al eady been achieved by a p evious eview.
- It should be conside ed whethe a safety imp ovement plan, ega ding issues elevant to this SAI, is al eady unde way. If yes, then the value of an individual incident eview should be dete mined. Conside ation must be given to inco po ating this case into the p e-existing safety imp ovement p oject.

Im plemen ing his ecommenda ion will achie e an a oach ha :

- Is p opo tionate. r
- Makes app op iate use of public funds.
- Allows eview panels to focus in-depth eviews on those cases whe e the e is the g eatest oppo tunity fo lea ning and imp ovement.
- Enables the elevant clinical teams and se vice manage s to etain owne ship of incidents that do not each the th eshold fo a level 2 o 3 eview. This ensu es ecognition of the skill, competence and integ ity of staff that a e ent usted with the delive y of safe patient ca e.

In summation, this ecommendation should add ess the isk of pe petuating a situation whe e the volume of level 2 eviews equi ed exceeds the capacity and capability to delive to a c edible standa d. The esulting p opo tionality will also suppo t measu able imp ovements in safety and quality. This will also se ve to add ess the isk of p olonging the dissatisfaction with the p ocess that has been exp essed by patients, thei families, and f ontline staff.

r

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Recommendation 4:

The Department of Health should ensure the new Regional procedure and its system of implementation is underpinned by 'just culture' principles and a clear evidence-based framework that delivers measurable and sustainable improvements.

Recommendation 5:

The Department of Health should develop and implement a regional training curriculum and certification process for those participating in and leading SAI reviews.

What is required:

There are several issues that must be addressed if the overall standard of how serious incidents are reviewed and learnt from is to improve. These include:

- A regional framework that makes clear the key factors for success[4], against which each Trust/DoH (SPPG) is performance managed.
- A regional approach that delivers international good practice in the science of review. The development of a standard operating procedure that focuses on the practice of investigating rather than performance targets would support this.
- A process that embraces a just and fair culture where staff are supported through a constructive learning process and not scapegoated should deficiencies in systems or processes be found.
- A quality assurance system that makes explicit the accountability of senior managers within each Trust/DoH (SPPG) organisation, alongside a mechanism for holding them to account for SAIs signed-off as acceptable.
- A regional training curriculum, competency framework, certification or accreditation process and mentorship programme.
- Investigators of SAIs must demonstrate that they have the competencies to do so and have completed a programme of training in line with regional curriculum requirements.
- Educators/trainers and mentors must demonstrate that they have the right knowledge and competencies. Furthermore, they must complete an assessment process in order to be included on a region-wide approved provider register. Only providers on this register can provide review training to Trusts/DoH (SPPG).
- A fair and reasonable amount of time to conduct a credible review must be provided. This must include time to engage and involve the family/patient in an empathetic, meaningful and respectful way.
- A single new report template and regional style guide must be designed. This must facilitate a consistent approach to report formulation and presentation, with enough flexibility to allow a report writer to adapt it to meet the needs of the review conducted.

[4] That is the critical success factors and the core objectives for each success factor are agreed, and adopted by all Trusts and HSCB.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

A new a a must a ieve:

y

- Greater flexibilit in approach, that focuses on the opportunit for learning and safet improvement.
- A lower number of in-depth RCA reviews. However, where earl assessment indicates that this depth of review is necessar , there must then be the y capabilit and capacit in the s stem to do this well.

Im plementing t is e mmendati n will a ieve:

An approach to learning from harm that HSC staff and the public can have confidence in, in terms of:

- Learning lessons.
- Measurable safet improvement.
- Transparenc .
- Alignment with the core principles and hallmarks of a robust review process.
- Restoration and reconciliation.

T is e mmendati n s uld add ess t e isk f:

A s stem of learning that is overwhelmed b too man reviews, few of which lead to measurable improvements in safet or learning of an significance. This will enable the HSC Trusts to develop a flexible and innovative approach to learning from harm; one which engages the patient and their famil in the process and mitigates the risk of perpetual mistrust.

There is no single activit that will achieve the above recommendations. There must be a comprehensive recalibration of the approach to the requirement for, and deliver of, SAI reviews across the region.

y

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Append A A s by Category and by H C Organ sat on N

N	A Level	Belfast rust	orthern rust	astern outh rust	outhern rust	Western rust	A	Pr mary Care	otal N
Mate nit el ted N	Level 1 N	2	5	3	0	4	0	0	14
N	Level 2 N	0	0	1	1	0	0	0	2
			0	2				0	3
N	Level 2 N	0	0		1	0	0	0	1
			0	1				0	1
N	Level 2 N		1 N		0	0	0	0	1
			0	3	0	1	0	0	5
Refe ence to P iv te Hospit l/Nu sing Home N	Level 1 N	1	1 N	N	0	1	1	0	4
								0	0
P ima e N	Level 1 N	0	0	0	0	0	0	4	4
								0	1
Othe Level 1 SAIs N	Level 1 N	0	0	1	0	0	3	0	4
Othe Level 2 SAIs N	Level 2 N	5	3	2	11	4	0	0	25
Othe Level 3 SAIs N	Level 3 N	1	0	0	0	0	0	0	1
otal A s reports to be assessed N	**N**	**11**	**10**	**13**	**14**	**10**	**4**	**4**	**66**

ource Information provided by HSCB and HSC Trusts. Categories suggested by Do N

N

WIT-85850

Append her gan sat ons that were offered the portun ty to Input Into th s Revcew c

gan sat on c
Me i ine & Heal h are ro u egula ory Agen y (MH A) c
Nor hern Irelan A ver e In i en Cen re (NIAIC) c
Heal h an Safe y Exe u ive Nor hern Irelan (HSENI) c
Poli e Servi e for Nor hern Irelan (PSNI) c
Safeguar ing Boar for Nor hern Irelan (SBNI) c
Nor hern Irelan A ul Safeguar ing Par ner hi (NIASP) c
Informa ion Commi ioner Offi e (ICO) c
Bri i h Me i al A o ia ion (BMA) c
General Me i al Coun il (GMC) c
General Den al Coun il (GDC) c
Nor hern Irelan Me i al an Den al Training Agen y (NIMDTA) c
Pharma eu i al So ie y Nor hern Irelan (PSNI) c
Nor hern Irelan So ial Care Coun il (NISCC) c
oyal College of Nur ing (CN) c
Nur ing an Mi wifery Coun il (NMC) c
Heal h Care Profe ional Coun il (HCPC) c
Nor hern Lo al Me i al Commi ee (NLMC) c
Ea ern Lo al Me i al Commi ee (ELMC) c
Sou hern Lo al Me i al Commi ee (SLMC) c
We ern Lo al Me i al Commi ee (WLMC) c
UNISON c
Uni e he Union c
Nor hern Irelan Publi Se or Allian e (NIPSA) c

c

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Append mprovements Suggested by Staff

Durin the en a ement process, staff were asked to share any su estions they felt would improve the SAI review process or patient and family en a ement. Staff su estions were used to formulate the followin su ested improvements.

Suggested mprovements to the SA process

lass f cat on of nc dents

- The identification of incidents requirin an in-depth review must be driven by a g structured assessment, which identifies:
    - a si nificant learnin opportunity
    - the presence of si nificant care lapses, or care concerns
    - the depth and ran e of family questions

  Eliminatin the determination for an in-depth review based on incident type and/or patient outcome alone can minimise the number of reviews with little impact on improvin safety.
- Incidents involvin suicide should not automatically be classified within the SAI process.

T mescales for onduct ng SA rev ews

- Overwhelmin ly, HSC staff consider that the timescales for conductin SAI reviews need to allow reater flexibility and take account of the complexity and the needs of the patient and family.
- A structured timescale approach that outlines the importance of capturin factual accounts and situational context within the first 48 hours post-incident, g and early capture of information from families followed by a realistic period to allow an initial assessment of the information before determinin what subsequent review is required, alon with its depth and approach.

Terms of Reference

- The terms of reference for SAI reviews should be specific to the incident and referred to as key lines of enquiry to reflect a more learnin -based approach.
- Terms of reference must include patient and family questions, where the patient and family have questions.
- The practice of pre-determined terms of reference that are used for all SAIs should desist as it provides no meanin ful structure for the review process.

Staff nvolvement

- Staff said that to achieve a 'just culture' and optimal learnin they needed to be g more involved in the process, specifically:
    - Their team leaders need to be involved in decisions over what to review, at what depth, and why

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Invo v aff n an ar y invi a ion o cap ur a fu accoun of wha ha happ n an h i ua iona con x of h ay, hif , or r van p rio
- Th r n o b a hif away from on y r vi wing ocum en o ngaging invo v aff in conv r a ion abou wha ha happ n
- Mor group arning approach cou b u i i , uch a af r-ac ion r vi w
- rovi ing f back on a high qua i y raf of h r vi w r por , ha h ir comm n ar i n o an ak n accoun of by h r vi w pan
- In formu a ing r commen a ion
- In con ribu ing o h ign of ac ion p an
- In par icipa ing in a po r vi w arning v n .

Communication with Staff

- S aff invo v in an inci n hou r c iv no ifica ion ha an SAI ha b n r qu an b provi wi h a copy of h agr rms of r f r nc or k y in of nquiry, a w a informa ion abou who i con uc ing h r vi w.
- S aff invo v in an SAI ough o xp c h ir am a r o r c iv up a r por r gar ing h progr of h r vi w o ha h who am i inform abou hi .
- S v ra aff hough a w b i or har ar a hou b ab i h o k p ho aff invo v in an inci n up o a on h progr of h SAI r vi w whi main aining confi n ia i y.

SAI Review

- Curr n y, h SAI proc i p rc iv a a n ga iv r vi w ha o no uppor a 'ju cu ur '. I mu b man a ha h a p c of car ha m e or xc car an ar , a w a ho a p c ha cou hav b n improv , ar r por on. Thi inc u in rv n ion ha may hav mi iga h impac of h inci n .

SAI Review Panel

- Wh r i i i n ifi ha h r w r , or may hav b n ignifican car ap , aff con i r a ica SAI r vi w pan from ou i h Tru wa r quir . Thi inc u h a r vi w r an h ubj c a vi or /fi xp r . S aff con i r ha uch a am n o b appoin by an x rna ag ncy uch a h HSCB/ HA.
- Th r hou b a of comp nci , ki an know g r quir of h chair of an SAI r vi w pan / a r vi w r, an h ubj c a vi or /fi xp r a k o work wi h hi in ivi ua .

Independence

S aff r cogni tha achi ving comp in p n nc wa no f a ib . How v r, h y con i r ha :

P

P

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- The le e ewe /ch shoul not come f om the se ce n ol e n the nc ent.
- Mento sh p shoul be l ble fo le e ewe s/ch s to suppo t them n m ant n ng object ty n mp t l ty.
- l e lly non-cl n c n w th the ght n est g to y sk lls n competenc es shoul ch the SAI e ew p nels.
- A l y pe son o t ne f m ly oc te shoul be nclu e n the SAI e ew p nels. Th s woul suppo t meet ng f m ly nee s n w t ng epo t th t s un e st n ble by non-techn c n.
- Opt m al use of nte ent ons such s web-confe enc ng n emote web-b se nte ews coul be ut l se to suppo t n ol ement of n epen ent techn c ns w thout the excess e cost often ssoc te w th th s.

Staff Support

- St ff n ol e n n nc ent must be g en p otecte t me to p ep e n tten nte ews o meet ngs u ng the SAI e ew.
- St ff in ol e in an inc ent must be g en the oppo tun ty fo p sto l/psycholog c l suppo t to e l w th t um at c nc ents.
- A p te m eb ef post nc ent must become no m al p ct ce.
- All SAI te ms must nclu e n m n st to to suppo t ts smooth el e y n to ensu e th t the t me of f ontl ne p ofess on lly qu l f e st ff s use , pp op tely.
- Co po te te ms espons ble fo p t ent s fety must h e the necess y competenc es equ e to p o e suppo t n mento sh p to SAI le s/ch s.
- St ff ske to le SAIs must h e ece e m n mum of two ys t n ng plus mento sh p n co ch ng suppo t so th t they c n le the p ocess competently.
- St ff equ e to con uct the n t l e ews of nc ents befo e ec s on s m a e to p og ess to SAIs nee to know how to con uct st uctu e e ew n wh t nfo m at on s equ e to o th s competently.

Advocacy

- No the n l el n nee s to eng ge w th p t ent oc cy o g n s t ons to e elop system whe e l y people c n become cc e te oc tes fo f m l es follow ng p t ent s fety nc ents.
- Publ cly fun e n epen ent oc cy shoul be l ble fo p t ents/f m l es th t equ e th s n whe e the e e conce ns bout the equ cy of c e n /o t e tment offe e .

Recommendations

- St ff nee p otecte t me to p t c p te/le n Qu l ty Imp o ement Act on pl ns eme g ng f om SAI e ews.
- Mult sc pl n y st ff shoul be b ought togethe to help e elop outcome-focuse ecommen t ons. Th s shoul not be the sole om an of the SAI e ew p nel.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Recomme o s from SAI rev ews shoul be be chm arke g s core cr er , he e ms serv ces volve he c e mus be v e o comme o he ppropr e ess of he recomme o s m a e.
- Whe co empl g whe her recomme o s or s o ccep e how s re e , ue co s er o mus be g ve o pre ex s g s fe y qu l y mproveme projec s lre y u erw y or pl e .
- Recomme o s from SAI rev ews ee o be ou come focuse r ve c o pl s h el ver me sur ble sus ble mproveme s he qu l y s fe y of c re.

Learning

- There mus be more form al processes for ssem i g le r g from SAI rev ews. The Oxfor Mo el evelope he 1990's successfully u l se by Mersey C re NHS Trus s ex mple of h s.
- E ch Trus mus be requ re o emo s r e o o ly wh h s le r bu how h s mprove . Th s w ll r ve ssem i e le r g.
- RQIA o her reg o l bo es mus show how he le r g w h v u l Trus s s c p ure use for le r g cross Nor her lrel .

SAI Review Reports

- Fee b ck from ll key s ff volve shoul be co s ere he f l s o of SAI rev ew repor . Th s ssures f c u l ccur cy gre er e g geme by fro l e profess o ls.
- A mee g w h ll s ff ssoc e w h he c e , who prov e form a o o he SAI rev ew p el, shoul be co uc e o e ble f gs, co clus o s recomme o s o be scusse gree .
- The SAI rev ew repor empl e shoul be rev se o clu e sec o h llows gre er r cul o of p e f m ly e g geme .

Action Plans

- How c o pl s re evelope mus be l e w h goo pr c ce, r her h copy g p s g recomme o s o c o pl empl e. Th s oes o el ver sus ble or me sur ble ch ge.

General

- The pr c ce of re rospec ve recor keep g he 72 hours pos c e ee s o be e ble . Where h s s o poss ble for wh ever re so , ccou s of volveme mus be collec e .
- SAI rev ews shoul focus less o ss g g bl me sc pego g, s e embr ce he pr c ples of ‘jus cul ure’ jus f ble ccou b l y.
- The SAI process shoul be rev ewe o ex m i e how bes o rev ew fu ure c e s more propor o e w y.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Sugges e rove n s for a en an fa ly engage n e

Infor on for Pa en s/Fa l es

- Patie ts/families should be better i formed of the SAI review process. For example, there could be better quality i formatio leaflets available, or a video or podcast explai i g the process on the DoH or RQIA's website.
- The SAI process must be explai ed to patie ts/families before the process comme ces so they ca have realistic expectatio s.

Co n ca on w ih Pa en s/Fa l es

- There must be clear sta dards of how a patie t a d family should be commu icated with duri g the SAI process, with patie ts/families asked for formal feedback at the e d of the process via a questio aire or o li e survey tool. This should also accommodate requests for a o ymity.
- The terms of refere ce/key li es of e quiry must be shared with patie ts/families prior to a SAI review comme ci g, a d these must i clude the patie t a d family questio s alo gside tech ical cli ical/process-based questio s.

Pa en an Fa ly Engage n e

- Trusts must demo strate their commitme t to the SAI process a d to the patie ts/families affected by SAIs by e suri g se ior ma ageme t are actively i volved i commu icatio s with families. This is particularly importa t at the start a d e d of the process.
- Staff must receive trai i g from experie ced advocates a d families who have experie ced the SAI review process so they k ow how to achieve a d mai tai positive e gageme t with a family.

n

n

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Append c amples of Cr t cal Success Factors

The fa tors listed below are examples of riti al su ess fa tors (CSF), previously developed by an HSC organisation in the UK and provided to this review by Maria Dineen, member of the Expert Review Team. This list is not intended to serve as a definitive list; rather, its purpose is to provide an initial starting point for a wider onversation about what the riti al su ess fa tors ould look like in Northern Ireland.

Cr t cal Success Factor 1

We cons stently value and engage mean ngfully w th pat ents and the r fam l es through the ent re rev ew (nclud ng compla nts) process.

The ore obje tives for this CSF are proposed as:

- Patients/families experien e a ompassionate and empatheti approa h. c
- The voi e of the patient and family is heard.
- The patient and family are well informed throughout the pro ess.
- Questions asked are responded to with honesty and integrity.
- Patients/families are provided with the oppo tunity to ontribute to and /or c influen e the terms of referen e for in idents identified as requiring in-depth review.
- Patients/families are taken through the draft review report, and provided enough time to enable them to read, omment on and influen e the ontent of the final report.

Cr t cal Success Factor 2

We cons stently value and engage mean ngfully w th staff throughout the ent re rev ew (nclud ng compla nts) process

The ore obje tives for this CSF are proposed as:

- Staff experien es a ompassionate and empatheti approa h.
- The voi e of the staff involved in an in ident is heard. This in ludes their experien e of 'the day', and the ' ontext' in whi h the in ident o urred.
- Staff involved are well informed throughout the review pro ess.
- Staff are treated fairly and equitably, in line with NHS Improvements Just Culture Guidan e.
- Staff involved in the in ident, and other key staff informants to the review, are fa ilitated in reading the draft report and providing feedba k on it relating to fa tual a ura y, tone and style.
- Staff involved in the in ident and servi e(s) in whi h the in ident o urred are a tively engaged in designing the a tion plan to deliver measurable and meaningful improvement.

c

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Critic cc ss F ctor 3:

We wi consist nt y show th t me s r b improv ments in st nd rds, s f ty nd q ity occ rs, is s st in d, nd nown bo t by st ff.

The core objectives for this CSF are proposed as:

- There is a corporate action planning/lessons learnt group that acts as a repository for those issues identified in one division, but which have wider implications for other services / divisions within the Trust. A central approach will ensure these issues are assessed and addressed corporately. k
- Within each division the safety governance group, lessons learnt and recommendations arising from reviews are a standing agenda item.
- Recommendations are targeted towards i) the local team ii) the local service/division and iii) corporate wide. Further they are mostly addressing systems improvement and not individual practice. k
- There is an action planning method/approach that facilitates engagement of staff involved in service delivery and sets out clearly the range of activities required to deliver the intent of the recommendation.
- All action plans include how success is to be measured and at what frequency to assure sustainability.
- Recommendations are formulated to make clear their intent (i.e. what needs to be achieved if they are accepted and implemented).
- Staff are aware of the improvements implemented in their service and division as a consequence of reviews conducted, and more widely across the organisation.

Critic cc ss F ctor 4:

Incid nts wi b r vi w d proportion t y i. .: right v , right d pth, nd right br dth of r vi w ccording to th vo me nd magnit d of rrors (if ny).

The core objectives for this CSF are proposed as:

- The Trust has an achievable and defined method/process through which harming incidents that meet the threshold for Duty of Candour (i.e. moderate harm and above) are assessed to determine the depth of review required and with what degree of independence.
- The Trust has a clear categorisation system for incidents that meet the threshold for Duty of Candour (and above) so that there is clarity between those that occurred despite good care, and those that were caused by mistakes in care delivery. (E.g. Category A means care and treatment was appropriate, and category D means there were several lapses in care and treatment that may have contributed to the outcome).
- The Trust assigns the review of cases where there may have been a contribution to the harm because of mistake to a case reviewer who has the right competencies to lead and deliver a more complex review.

k

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

- Term s re ere e r review are be p ke a d make lear the releva t te h i al que ti that mu t be a ked a d a wered, al g ide a y amily que ti that have bee p ed.
- The Tru t ha a review ramew rk, a d appr a h, that all w a ra ge meth d a d t l t be empl yed t meet the di rete requireme t ea h review.
- The Tru t ha i pla e a pr e t e able early pre ervati i rmati i ludi g mem ory apture, that the a e me t i ide t a d a y ub eque t review i well i rmed a d a be expl red t the right depth a d breadth.

ritical Success Factor 5:

Reviews are conducted using appropriate methods and tools, and in line with good project management principles, assuring delivery within an agreed and realistic timescale.

The re bje tive r thi CSF are pr p ed a :
C

- The Tru t will have e ugh ta trai ed t u dertake the a e ree i g eleme t the review j ur ey withi 10 w rki g day i ide t urre e.
- The Tru t will have e ugh ta trai ed t a higher level k wledge a d mpete y t delivery th e review that are ateg ri ed C r D (i.e. are/ ma ageme t a bit 'hit r mi ' r eri u lap e are ide ti ied).
- The Tru t will mmit t a tepped review pr e i ludi g lear b u darie r the review ari i g r m are ully rmulated term s re ere e that make lear the e e ary te h i al que ti a well a i ludi g amily que ti .
- Sta a ked t a t i a a e ree i g r lead reviewer/ a e reviewer apa ity will have the ne e ary adju tme t made t their pre-exi ti g diary mmitme t that they have a air am ou t dedi ated time t deliver the review pr je t.
- Spe iali t advi r will be all ated t the app i ted a e reviewer i a timely ma er that av idable delay d t ur.
- The Tru t will e ure r all ateg ry C a d D review that there i rea able admi i trative upp rt pr vided t the a e i ve tigat r that w rki g pra ti e are a e i ie t a p ible. (Categ ry C a d D - i.e. are/ ma ageme t a bit 'hit r mi ' r eri u lap e are ide ti ied).

ritical Success Factor 6:

Review reports are consistently produced and meet the following standards:

- Well writte .
- U der ta dable by a -te h i ia .
- Rea ed (i.e. evide e a d t pi i rie tated).
- Clear i di g , lu i a d re mme dati .
- A wer all amily que ti where it i p ible t d .
- A e ible. **C**
- Validated.

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

The co e o ec ves fo h s CSF a e p oposed as:

- The T us has a p ac cal app oach o p oof ead ng epo s ha ncludes ns gh s f om:
    - a echn cal adv so
    - a lay pe son
    - someone ho has good g amma , and spell ng
    - someone ho s good a fo ma ng documen s, us ng 'sma epo ' echnology.

- The T us has a ell-des gned epo empla e ha ncludes:
    - ackno ledgemen s
    - con en s l s
    - an execu ve summa y
    - in oduc on (case ove v e and con ex of ca e, as ell as ou come and easons fo he ev e)
    - a fam ly sec on
    - a f nd ngs sec on (ha as del ve ed o a easona le s anda d, ha could have een mp oved, any s gn f can o se ous lapses n ca e w s anda ds.)
    - wha has changed / mp oved s nce he nc den
    - wha add onal lessons lea n a ose f om h s ev e
    - conclus ons
    - recommenda ons
    - append ces

- Bo h he pa en / fam ly and he s aff nvolved a e p ov ded h he oppo un y o ead and commen on he epo hen n good d af fo ma . The commen s a e l s ened o and nco po a ed n o he f nal epo documen as fa as s poss le o do so. Whe e s no , hey a e adv sed of h s and hy no .
- Rev e epo s a e en empa he cally and compass ona ely.
- Rev e epo s a e en n pla n language so hey unde s anda le y all eade s.
- S aff equ ed o e ev e epo s have a men o ho can suppo he developmen of he ng and p esen a on sk lls.

w

w

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

Referen e

[1] orting and Follow-u of S rious Adv rs ncid nts (SA s) in North rn r land, HSC B (Nov mb r 2016). Availabl at: htt s://hscboard.hscni.n t/download/PUBL CAT ONS/ olici s- rotocols-and-guid lin s/Proc dur -for-th -r orting-and-follow-u -of-SA s-2016. df Cit d Jun l 2022

[2] Francis, , Th Mid Staffordshir NHS Foundation Trust Public nquiry (F bruary 2013). Availabl at: htt s://www.gov.uk/gov rnm ent/ ublications/r ort-of-th - mid-staffordshir -nhs-foundation-trust- ublic-inquiry Cit d Jun 2022

[3] Sir Liam Donaldson, Th ight Tim e th ight Plac : An x rt xamination of th a lication of H alth and Social Car gov rnanc arrang m ents for nsuring th quality of car rovision in North rn r land (D c mb r 2014). Availabl at: htt s://www.h alth-ni.gov.uk/ ublications/right-tim e-right- lac Cit d Jun 2022

[4] Th Report of the Inquiry into Hyponatremia related Deaths, Justice O'Hara (January 2018). Availabl at: htt ://www.ihrdni.org/ Cit d Jun 2022

[5] HSCB, PHA. nformation L afl t – What N d to Know About a S rious Adv rs ncid nt for S rvic Us rs/Family M emb rs/Car rs. Availabl at: htt s://hscboard.hscni.n t/download/PUBL CAT ONS/QUAL TY%20AND%20SAF ETY/sai l arning r orts/English-Communication-with-th -S rvic -Us r-Family-and-Car rs-following-a-S rious-Adv rs - ncid nt. df Cit d Jun 2022

[6] H alth and Social Car (form) Act (North rn r land), 2009. Availabl at: htt s://www.l gislation.gov.uk/nia/2009/1/cont nts Cit d Jun 2022

[7] CQC, L arning Candour and Accountability: A r vi w of th way NHS trusts r vi w and inv stigat th d aths of ati nts in England (D c mb r 2016). Availabl at: htt s://www.cqc.org.uk/sit s/d fault/fil s/20161213-l arning-candour-accountability-full-r ort. df Cit d Jun 2022

[8] Harm ed Pati nts Allianc Pati nt Saf ty Congr ss: Good ngag m ent aft r harm, D liv ry of car to nabl r cov ry, (2020). Availabl at: htt s://harm ed ati ntsallianc .org.uk/w -cont nt/u loads/2020/11/Pati nt-Saf ty-Congr ss-Pr s ntation-2021-v225790. df Cit d Jun 2022

[9] Syst ms Analysis Of Clinical ncid nts Th London Protocol, Sally Taylor-Adams & Charl s Vinc nt, m p rial Coll g London. Availabl at: SYSTEMS ANALYS S OF CL N CAL NC DENTS (im p rial.ac.uk) Cit d Jun 2022
l

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.



The Regulation and Quality Improvement Authority

The Regul d Qu l y Impr veme Au h r ỳ

7th Floor, V ctor a House
15-27 Gloucester Street,
Belfast
BT1 4LS



Tel: 028 9536 1111 i



Ema l: nfo@rq a.org.uk



Web: www.rq a.org.uk i



Twi er: @RQIANews i

Received from DoH on 09/11/2022. Annotated by the Urology Services Inquiry.

SECTION C – Details of concerns raised/complaints reported

1. Please provide full details of any concerns and/or complaints raised by you, specifying the nature of those concerns in as much detail as possible.

I have attached the letter of compliant (dated 05/12/16) forwarded to Governance office which details the main areas of concern / Complaint raised by Patient 16's family. The subsequent SAI report details the sequence of events and Mr O'Brien and his colleagues are interlinked within the Compliant.

The main concern I have is the lack of response from Mr O'Brien to numerous letters from Consultant Oncologists and Consultant surgeons alongside numerous phonecalls from Patient 16 and his family regarding the problems he was encountering because of a stent which was in place for 15 months when guidance on good practice suggests that they should only remain in place for up to 6 months. The outcome of this was a range of complications which resulted in sepsis and the requirement for a nephrostomy tube. Furthermore the lack of Consistent Care and attention by Dr O'Brien bec continued and impacted on the treatment options available to my father on account of delays in stent removal and insertion.

(See overleaf)

Continued at PAT-000154.
Annotated by the Urology Services Inquiry.

SECTION D - Details of concerns held but NOT raised/reported

1. Please provide full details of any concerns you held at the relevant time specifying the nature of those concerns in as much detail as possible.

My father had a spinal injury which resulted in years of involvement with various departments across most of the hospitals in Northern Ireland. He advised us, his family, that the lack of consistent care provided by Mr O'Brien in the Urology Department in Craigavon Area Hospital was the worst he had ever encountered. He described one particular incident on 31.03.15 when he was advised to attend for admission for insertion of a stent. Upon arrival at the designated time he was advised that he was not on the list for the procedure and following on was only admitted after a number of hours waiting for the issue to be resolved.

2. Please explain why you did not raise your concern(s) at the time and state if there was something that prevented you from raising your concern(s).

We were grateful for the care my father received over the years and did not want to formalise our concerns at an earlier stage of our involvement with Mr O'Brien and the Urology Department in case it had an impact on the patient/consultant relationship. My father found Mr O'Brien to be arrogant and dismissive in his dealings with him.

to advise that we are still waiting for the stent to be removed.

And similarly, whenever -- that was October when they were advised and shortly after that a phone call from me to Urology, again informing him that dad was starting to have after-effects, and I suppose to put it in perspective, this is a man [redacted] suffered a [redacted]. So he was very au fait with the whole world of neurology, orthopaedics, and urology was another thing. Certainly that he had a really long-standing relationship with his consultants.

And I suppose he was very taken aback at the fact that all through his life, I mean those 30 years, all he had to do was to make a phone call to that particular department. And that consultant, I mean that message would be relayed and the consultant would then come back to him and say look we'll bring your review forward, or try this medication, or whatever. So whenever that wasn't happening in response to the communication from both Oncology and the surgeons in relation to this particular, the stent being in place, he was quite dismayed because it was a very different experience to the one he had had all his life.

And that, as a family, to watch him suffer unnecessarily, you know, given the fact that he had

already come through all of the, you know, Personal Information redacted by USI [redacted], the intensive rehabilitation that that required and his resilience was always incredible and to find then that he wasn't being listened to, that was very, very difficult to watch and he was suffering, and he knew why he was suffering and he could relay that very clearly and he was a very articulate and intelligent man and that was why we found it so difficult to accept that no one was coming back. 14:09

14:09

And the communication, certainly from ourselves, both dad would have rang and I rang and whatever, and you never got a response to that. You know, the message was relayed obviously but no one, the secretary didn't come back to say, well, the consultant, you know, he's on a waiting list, he will be seen in a couple of months, in the meantime maybe you should try this or... So it was that lack of reciprocation of communication which was particularly upsetting. 14:10

1 Q. Can I just ask a little bit about that, if I may? 14:10

A. Yes.

2 Q. You talk about both Oncology and Urology?

A. Yes.

3 Q. Did you experience, or did your father rather, experience the same problems in communicating with both the Oncologist and with the Urologist? 14:10

A. In terms of Oncology, there were very set patterns for reviews. So you usually knew it was kind of within six or eight weeks each time. Now obviously going through

the treatment he seen them a lot more that, but in the follow-up to that, once the treatment was completed, the chemotherapy, the review appointments were very steady and it was at each of those that the discussion would be made in relation to the stent. 14:11

And I suppose it was the implication then eventually where radiotherapy was mentioned as a treatment option and I think that was first mentioned in January. And we really were -- that was something, and not that we had any sense of feeling that this was going to be a solution to his problems, but we could see it as possibly extending life and for that reason dad was very willing to give it a go. 14:11

But then because of the stent removal and reinstallation of that again was very dependent on the treatment happening. I suppose, you know, Oncology were actually relaying that to us and obviously from the documentation they were informing Urology. But, again, it's the fact that I could never understand why that had to be in the format. I could never understand why there wasn't a system on the internet or, indeed, by e-mail or, you know, by phone to say, look, this person's cancer pathway is very much dependent on your intervention and, therefore, you know it was that kind of lack of sense of -- and I felt it from the Oncology as well. 14:11 14:12

was confirmed very much in the follow-up appointment with a consultant surgeon that he was dealing with, just to say that how you're describing, the symptoms you're describing probably are in relation to that and I will again make contact with Urology.

And I think, that was whenever I started, round about the December of that year. And at that point after the treatment, I think, from memory, it was probably in situ for about six months. But there was an eight month delay again before it was actually removed. And just all of the complications around it being in for so long, in dwelling for so long, were very much I think came to bear for dad, you know.

And when we went to visit him after that procedure he was able to describe how they had said it was encrusted and all of the things and the urosepsis, which he maintained, you know, he was probably, only that he responded well to the antibiotic régime, it could have been a very different outcome even at that point.

12 Q. What did you feel about the level of communication from the Urology Department to your father about the removal of the stent?

A. I have concerns on two levels. I have concerns, as I say, the fact that there was no reciprocation of communication. So all we would have asked for was someone to get back and say we've spoken with one of the consultants or whatever and, you know, we can

assure you he is on a waiting list, we can assure you that it will be carried out, obviously we're under severe pressure at the moment or whatever.

But there was never anything like that. It was almost like you were speaking, you would give your message but there was never anyone to come back to you. So as I say, that communication I felt just wasn't reciprocal. There was nothing coming back. It was very much I'm making this phone call. 14:20 14:21

Now, again, looking through the documentation, the GP would have told us and Macmillan nurse would have said that they would have made contact, but there is no reference to that in the documentation so I don't know if that ever happened. But certainly it felt like it was coming from various quarters and no one was getting a response to it. So that communication, but I also could never understand why there wasn't a more robust mechanism for recording people who needed intervention, you know. 14:21 14:21

So it doesn't matter, to me it's irrelevant who the letter is addressed to, what the salutation is, whether it is filed or it is not filed. Surely there is a system that can go in place which shows this person is about to breach the timeline for this intervention happening, you know. And a good IT system surely would be able to do that. 14:21

Now obviously then the pressures of operations and availability of that facility, a lot of that is out of control of the consultant or whatever. But it's just, we always felt, and you know reading the documentation, something was filed away, the letter was filed away. 14:22
Well to me that's not good enough. You know, that should have been put on a system that red-flagged that this person is now, the stent is in place, it needs to be removed within a particular timeframe. And to think that that wasn't in place in that department, I mean 14:22
I don't know enough about it, but certainly from a layperson I feel that there must be a more effective and efficient way of recording those.

13 Q. What about whenever you complained, I think that was about four months before you got a response, is that 14:23
correct?

A. Yes. So, again, the timeline for that was probably one that we weren't expecting. Just for the record, making a complaint was not something that either myself or my father did easily. In fact after the first, after the 14:23
operation where the stent was taken away, I talked to dad at that point because I was just so frustrated with the way things were going. And I said, look, do you want me to put this on a more formal basis? And he said no, I do not. He said, you know, these people 14:23
have saved my life over the years, I relish and respect the patient relationship with consultants and he said, I don't want to engage in that.

But I suppose as time progressed and, as I say, that particular, I suppose the crux of that was that day that we were informed that treatment options were no longer available. He just was so dismayed that he said, yes, go ahead. 14:24

And within that period of time we made that complaint and, as I say, because of the grief and the fact that you are not in a situation where you can, I suppose, rationalise things, the fact that that time meant 14:24 nothing to me, the fact that it was three months. But I suppose then as time progressed and, again you can see from the index, I started, again, to have to make contact with the SAI.

14:24

When they advised me that it was going to be a SAI. Again I knew nothing, no idea what that meant so I had to research all of that myself. I thought, what does that mean? And that was never the intention. It wasn't that in any way you were trying to apportion 14:24 blame or anything like that, it was just a case of, look, something has to be done here, this patient's experience cannot be replicated, somebody has to intervene.

14:25

So you know, whenever they said, I kind of had a look at that and then I made a number of communications. Now I have to say they were always responded to, be that via an e-mail to say, we can't give you a

timeframe but certainly this is how the complaint is progressing, we need to speak with such and such, we're having a meeting. So there was definitely a lot of communication. But I suppose it was the time. I thought surely there has to be - this can happen within a better timeframe.

So I also had to, at that point, involve the Ombudsman and I felt that was whenever things started to move at a greater pace once that intervention happened. And I have to say, you know, the outcome of that, I respect the recommendations and if they were put in place I would be extremely content. But there was never an opportunity to discuss the findings.

14:25

14:25

14:26

And I certainly requested that in a meeting, and as you'll see from the documentation we were unfortunate at the time whenever we had actually both - [redacted] Personal Information redacted by USI [redacted] whenever the meeting; it was sprung upon me. I mean I was given a few days warning. And I said, look it, I can't accommodate that at the moment but certainly I really would appreciate - and it was only when I started to prepare for the filling in the questionnaire I realised, no, this still hasn't...

14:26

14:26

14 Q. You still have not that had?

A. I still haven't come to a closure in relation to that. And, again, that was pre-empted this time around you

Urology Department. Can you recall how he was advised?

A. Yes. I think there was a meeting with, following the decision to proceed with chemotherapy, there was a meeting set up with Urology. So we attended that meeting. And it was at that meeting, it was an out-patient meeting and we were advised, I'm just trying to, is there a sequence of? 14:14

7 Q. If I can maybe direct you?

A. Yes, can you direct me.

8 Q. I will direct you to that point. Basically you go on in that paragraph on that page to talk about, he was advised to come in to get a stent put in. 14:14

A. Yes.

9 Q. And that would have been I think in May, or sorry, March of '15, 31st March '15, but when your father arrived he wasn't on a list? 14:14

A. Yes. Obviously it was the 26th March 2015 relating to page 104 in terms of the sequence, and it was at that meeting with, I think it was with the doctor, Consultant O'Donoghue, I'm not quite sure. Again, there was another person there on that particular occasion and we were advised that, you know, the stent would be inserted prior to treatment commencing and that happened all very quickly. 14:15

14:15

And as I say, he was advised to attend then for admission on the 31st, but it was on that particular day, and I can see from the submission from Mr. O'Brien that there was some level of confusion about surgery

lists et cetera. But this was a gentleman with a spinal injury in a wheelchair who, you know, was in for a procedure and we sat around in a corridor. We clearly could see that there was great confusion as to where he was to be placed, on whose list he was et cetera, et cetera. 14:16

And absolutely, the staff in these Departments are absolutely incredible. Like I have the utmost respect for all people in the world of medicine, and the mismatch between demand and capacity in all of these departments is something that we all acknowledge, but it's just a little bit of respect for the person in question. And he should never have been privy to that information that he wasn't on a list and that there were issues with that. And it was - the sense of relief when he was finally advised that he was going to be, have the procedure because the thought of having to come back on another day and go through the pre-op et cetera, et cetera. 14:16

So that was, you know, a day that particularly sticks out in my mind as one where he -- and there were many days that were difficult, but that certainly was one for him, as was the follow-up to the stent being taken out. I mean that week afterwards he spent in a High Dependency Unit. As I say, because he had such an awareness of his own condition and the complications, he foresaw exactly what was going to happen to him. 14:16 14:17

37 Q. So that was then changed I believe a few months later.
A. Yes.
38 Q. Did you have any comment on that, did that happen easily or was there a problem there?
A. Well again, you know, if you refer back to it, it was at the request of dad ringing again to say that he had been told that it should be changed within 12 weeks and he hadn't had an appointment. And you know, there is reference there where they're advising that he wasn't on a waiting list for that, didn't appear to be on a waiting list for that and that's in the documents. 14:44 14:44

And, again, that doesn't surprise me because there didn't seem to be a robust mechanism for flagging these patients up again for procedures which were required. It's not - I understand, as I say, there's a waiting list and all of the demands that go with that. But if someone requires a procedure as part of their journey for cancer treatment, you can't wait. It's not something that you can postpone. One was very much dependent on the other. 14:44 14:44
39 Q. Yes. I would just say that that would normally be a radiology as opposed to a urology procedure?
A. Okay.
MR. HANBURY: So it's complicated. Thank you. That's all I have. 14:45
CHAIR: Thank you. Mr. Wolfe?
MR. WOLFE QC: Mr. Hanbury has pinched most of my questions. Could I just ask you this: If you turn to

page PAT-000145 please, and this is at page seven of the questionnaire and the box in the middle of page, No. 3, details a number of contacts with Mr. O'Brien's secretary, do you see that?

A. Mm-hmm. 14:45

40 Q. Does that purport to be a comprehensive description of your contacts with Mr. O'Brien's secretary?

A. It's certainly - I can't recall whether there were anything additional to that. But certainly they would have been, as I say, both myself and dad would have made contact. But we would have been advised by other, as I said, by the Macmillan nurse and the GP that they had also made contact. But there's no reference to that within the documentation so I can't say if that happened. 14:46

41 Q. And in terms of the contact that you were making with Mr. O'Brien's secretary, again just for the avoidance of any doubt, can you try to recall the kind of information you were giving to her and what you were expecting from that interaction? 14:46

A. From recollection it would have been asking if there was kind of a timeframe, could we have any idea when it was likely that the procedure would happen. And as time progressed I can certainly remember it would have been trying to explain some of the symptoms that he was having that appeared to be in relation to the stent being in place for too long. So it would have been dad advising her of his symptoms. 14:47

And as I say, we would clearly have been told that that

would have been passed on and it clearly was, but it was the fact that no one ever got back to say that information has been passed to the correct source and this will be the action that we will take as a result of that.

42 Q. Did anyone on, you say no one got back to you. No one, literally no one. Literally. Not a secretary and not a medic?

A. No. I have no recollection of anyone ever returning a phone call or advising. As I say, then we would have been waiting on our next appointment with another discipline, be that Oncology or the surgeon just to kind of see if there had been any further movement.

43 Q. Did anyone in Urology ever apologise for how your father had been treated throughout this process?

A. Certainly the phone call with Mr. O'Brien on that evening of 1st December 2016, he did, he certainly indicated that he was sorry for the way things had occurred but that a lot of it was out of his control.

But I suppose I can certainly recall being extremely upset and annoyed during that conversation, both with Oncology and Mr. O'Brien. It all occurred on the same day. He advised me that he was actually making the phone call and he wasn't at work at the time because he was recovering from a procedure himself. And I do remember saying to him that I am sure that his experience was very different from that of my father's. But as I say, he certainly acted within - following

that there was an appointment sent out immediately and I think dad was then admitted on, shortly after that for the stent to be removed.

44 Q. You've recorded in your questionnaire response at page PAT-000147 that your father found Mr. O'Brien to be arrogant and dismissive in his dealings with him? 14:49

A. I suppose that certainly would have been in relation to dad's concerns over the stent being in too long and the experience that he had as a result of that. So it was that period of time when he was extremely ill and he just - he found, there was a sense of non-acceptance of there being any issue in terms of delay and how that would... 14:49

While certainly it was acknowledged that the issues that dad was encountering or was encountering as a result, that they were in relation to that, I suppose there was a dismissiveness about that. Now that didn't, in relation to previous experiences with Mr. O'Brien, he was very thorough and I mean in terms of his involvement with his patients, dad would have said his ward rounds, he was very -- under -- explained procedures, et cetera. 14:50 14:50

But in relation to that, I think it was just that particular thing that dad felt that it was dismissed the fact that this was very much an issue that shouldn't really have, that could have been avoided. He didn't have to go through that suffering. If things 14:50

had of happened as they should have in terms of the timeframe that was acceptable for that procedure to take place. So that's - when I discussed that, that's in relation to that particular experience that he had.

45 Q. But ultimately, in fairness to Mr. O'Brien, there was an apology for aspects of that? 14:51

A. The apology I think was in relation to the fact that, you know, we were frustrated by how things had progressed and the fact that things were not happening in the timeframe that we were expecting it, yeah. 14:51

MR. WOLFE QC: Thank you.

CHAIR: Patient 16's Daughter, thank you very much for coming along today, your evidence has been very helpful to us. Is there anything else that you feel that you haven't covered either in your evidence or in the papers that we have that you feel you would like the Inquiry to know? 14:51

A. No, I think from a family's perspective, as I say, in an ideal world there are so many financial implications and I think Urology is a Department that could well-benefit from an injection of budget that would oversee some of these issues. As I say, we certainly respect the difficulties that Mr. O'Brien would have had as Head of that Department and trying to deal with that mismatch between demand and capacity. 14:52 14:52

But just I suppose in terms of code of conduct, it is just having respect for the people involved. It's having a more robust means of communication. And

probably maybe just even overlooking a review of how patients with cancer who have involvement with a number of disciplines, I think there is an easier way, there has to be a more joined-up approach in terms of multidisciplinary work. 14:52

And I think from Personal Information redacted by 's experience we saw that. You know, we saw disciplines working very much together where she had joint appointments with consultants from both Belfast and South Eastern Trust who came together 14:53 and that worked really well, and there was that advocacy as well service where, again, where there were issues we were automatically able to make a phone call and someone would look into that issue for us. 14:53

Whereas with this, with dad's experience, you felt you were very much as a family working alone. So I think, I certainly still feel very strongly about the recommendations that I would have made as part of the initial complaint and I think they are very much 14:53 embedded in your Terms of Reference. So I would hope they would be actioned.

So I would just like to take this opportunity to thank Mr. Swann for the proactive way in which he has dealt 14:53 with the concerns raised, and certainly the Inquiry, for allowing the families and patients to air their experiences. I just hope that there will be recommendations that can be actioned that will make the

journey for people and the safety of practice will very much be addressed.

CHAIR: Thank you very much, Patient 16's Daughter. We appreciate you for coming.

MR. BOYLE QC: Madam, I am not rising to ask a question. But there is one aspect of the transcript that I may have misheard, or it may have been mis-transcribed and it's because of various 'ologies that we are dealing with. 14:54

14:54

You may recall that when you were asking questions of Patient 16's Daughter she gave a answer she had been able to view Dr. O'Brien's response, she said that's been very useful. But obviously there's a response from blank as well that we are not privy to, and there was an 'ology used. 14:54

CHAIR: The word was "Oncology", Mr. Boyle.

MR. BOYLE QC: Yes, and in the transcript it currently reads "Urology".

CHAIR: I am sure that will be corrected before their transcript goes up on the web-site. Thank you, Patient 16's Daughter. Thank you very much again. Ladies and Gentlemen, that is us until 10 o'clock tomorrow morning. 14:55

14:55

THE HEARING WAS CONCLUDED

number of questions that I would like addressed and also that, to forward into them the initial complaint. And that happened at that point in time, but unfortunately, because of the size of the document or whatever happened, it has bounced back. But you know, certainly that was the first time really that I had a chance to speak.

18 Q. When was that?

A. That was February of this year, it is the final...

19 Q. So February '22? 14:28

A. Yes. But again, as I said, there was an issue with the e-mail that I sent. It was only whenever I re-sent it again more recently that I realised it bounced back. So that's certainly an issue on my behalf but that conversation certainly was very useful. But it should 14:29 really have happened at the beginning, I think.

I suppose I found the Patient Client Council were very good at explaining what exactly the SAI entailed et cetera. So I think that sort of advocacy service should be available to people who have to go through 14:29 the process.

CHAIR: Okay. Thank you. That is really very helpful. I don't have anything else that I want to ask you, but I am sure my colleagues will have a few questions.

DR. SWART: Thank you for telling that story, it must 14:29 be difficult still. I am quite interested in how things can improve generally in healthcare in terms of involving families in serious incident investigations. And clearly you were a little bit floored by the

Mr. Keane had mentioned it too, that Cyclophosphamide was a dangerous drug as well. And I think it was actually in one of the books they handed to me in the Thorndale Unit, invasive bladder cancer. I can't remember, it's like a green and white book, I think the solicitor has it, and it does mention the Cyclophosphamide in it and then me and my wife, it sort of highlighted it more to us. 10:29

47 Q. And in the Thorndale Unit what information did they give you then? 10:29

A. On the 31st January?

48 Q. When you had your book about the bladder cancer?

A. Just take it home with you and read it. I went in that day and it was my [redacted]'s birthday that evening and my wife was panicking to get things organised for his birthday. And I says, I shouldn't be too long here, it was only about 2 o'clock and I think it was near six before I got out of it. 10:29

But when I was on the treatment table the two nurses, they had to put a camera up in, and whatever they seen on the screen they called for Mr. Jacob and he come in and looked at it. And he went to his table and he started to write and the nurses started to hand me all these pages and sheets, and don't read too much into it, that's what they told me. 10:29 10:30

49 Q. Right.

A. So I still didn't know what was wrong with me but I knew there was something bad.

50 Q. They didn't sit down and talk to you at that time to explain --

A. Nobody said there was a possibility of cancer.

51 Q. Okay.

A. So that was another, but I don't know when it was. 10:30
Good enough, it moved pretty quickly then. Every two weeks there was something, maybe 'til the end of February or March-time and then there was a long lull then to the operation in the City Hospital. But at that time, like I was really, whenever I wasn't being 10:30
looked at by anybody, I was too much time to think about things and worry.

52 Q. Yes.

A. And my wife was saying we'll plant these wee flowers for summer. I says, I mightn't see summer, you know, 10:30
I couldn't live really.

53 Q. Mm-hmm?

A. So then I had to go to the Tower Hill in Armagh. Dr. Damien O'Donnell sent me to it for - and I had a [redacted] 10:31
[redacted].

Personal Information redacted by USI

54 Q. At that time, you know, if the Trust at that time could have handled that whole information thing a bit better, what do you think they could have done? What would be your advice to them having gone through this? 10:31

A. Well, I would highlight, I don't know if they're still using that drug, but if there's anybody still using it please keep an eye on them patients because it can lead to a lot of trouble.

55 Q. And what do you think you would have liked to have known as a patient?

A. Well, I would like to have even a yearly check-up. Like I was going to my doctor, my GP regularly, maybe every two/three months for a long time. And then once the glaucoma in the eyes started to set-in I was more focussed on it. I had to get, as they call them, a "trapdoor" in each eye to let the pressure out and I was seeing Mr. Rankin in the Royal Hospital. I suppose really the "noughties", as they call them, was more to do with my eyes and still would have the weakness in the muscles as well. 10:31 10:32

And the bladder, the bladder was still, the bladder always played up, you know. I was up two/three times at night. I would only go to the toilet for a small while and then it would sort of get sore and then things would stop. So there always was a wee problem in my eyes. But it wasn't the end of the world and I wasn't going to torture the doctor about it. But no urology was ever mentioned from 2001. Mr. Wilson in the Poly Clinic in Banbridge and he just says, you're okay. 10:32 10:32

56 Q. And by the time you were diagnosed with your bladder cancer and you needed to have an operation, did you get given appropriate information at that time? 10:32

A. Oh Mr. Keane was excellent. He was a big loss to Belfast.

57 Q. Yes.