Friday 13 September 2024.

(10.00 am)

LADY JUSTICE THIRLWALL: Ms Blackwell.

Opening Statement by MS BLACKWELL

MS BLACKWELL: My Lady, this opening statement is made on behalf of Ian Harvey, the former Medical Director of the Countess of Chester Hospital; Alison Kelly, the former Director of Nursing and Quality for the Countess of Chester Hospital; Anthony Chambers, the former Chief Executive of the Countess of Chester Hospital; and Susan Hodkinson, the former director of People and Organisational Development for the Countess of Chester Hospital.

Collectively I shall refer to them throughout as "senior managers".

We will use our time this morning to provide an overview of the way in which matters unfolded when the mortality rates in the neonatal unit arose, the action that was taken and the reasons behind the decisions that were made. But before we turn to these, each of the senior managers wishes to express their deepest sympathies to the Families of the babies who were harmed so cruelly by Letby. They are mindful of the trauma that the Families have gone through and continue to go through. They have read the statements produced by the

Families and have been deeply affected by the accounts of their experiences. They have read and listened carefully to the oral openings made by those who represent the Families. They recognise and pay tribute to the dignity and courage of all those Families.

Mr Harvey, Ms Kelly, Mr Chambers and Ms Hodkinson have reflected on their time at the Countess of Chester Hospital and will continue to reflect on their actions and decisions as, through this Inquiry, all the evidence relevant to the story of what happened will be brought together and examined for the first time. They know they will be asked difficult questions and they will answer those questions openly and honestly.

Indeed, this Inquiry, my Lady, has provided the senior managers with the first real opportunity to tell their story and they are grateful for this. They have deliberately refrained from responding to criticisms made of them by a number of individuals and organisations which have been reported in the media as they recognise that this is a complex case, the facts of which need to be carefully scrutinised by this Inquiry. They have made, and will continue to make, every effort to engage with and assist the Inquiry and the Families in understanding what they knew, when they knew it, and what informed their decision-making.

They have furnished the Inquiry, as my Lady knows, with extensive witness statements, answering all of the questions asked of them. These statements run into hundreds of pages referring to many, many other documents. They have done so willingly so that the Inquiry has the best possible evidence on which to make findings of fact and recommendations.

The senior managers hope, as no doubt do all Core Participants, that this Inquiry will fulfil its Terms of Reference fully, and through the evidence it has gathered and the evidence it will call for the first time produce a comprehensive account of what happened at the Countess of Chester Hospital so that the right lessons are learned, and real changes implemented where needed. They continue to hope that the Inquiry will do so unblinkered by hindsight bias and with an open mind.

In assessing the evidence, it is of the utmost importance that the Inquiry does so with an understanding of the somewhat detached circumstances of a procedure such as this. Words on pages cannot evoke the reality within which everyone was working over the relevant period. The senior managers, the consultants, the doctors and the nurses and others were ordinary, professional people working in a busy, demanding hospital environment and doing their best to react to an

unfolding picture where an apparently well-liked, caring, popular, experienced nurse was noted as having been on duty during the time when certain babies had collapsed or died.

They did not have the benefit of all the evidence to which the Inquiry now has access, neither did they have the time to reflect in the way that the Inquiry is now able. On any view, the circumstances of what happened as events developed in 2015, 2016 and 2017 were unique, challenging and complex.

There have been submissions made to the Inquiry that the senior managers lacked professional curiosity. On the other hand, criticism has also been made that there were too many reviews and reports commissioned as a reaction to the increased mortality rate.

There were a number of investigations, as my Lady knows. Concerns were not ignored. And it was rational, the Inquiry may find, for there to be investigations into the causes of a heightened mortality rate which didn't jump to the immediate conclusion that there was a single cause, that these deaths were being deliberately caused by an individual on the ward, but rather looked to the more likely one that there would be a complex and multifactorial explanation, as previous experience had shown.

That being said, my Lady, the senior managers accept that they believed that they needed to investigate so as to obtain evidence of wrongdoing before taking this matter to the police. There was nothing tangible being alleged beyond Letby's presence for a long period of time, they struggled to know what they might say to justify a criminal investigation. This was the cause of a significant delay in contacting the police, and for this they are truly sorry.

But the reviews were commissioned in good faith, not to conceal the truth, but to uncover it. Suggestions to the contrary run, in my respectful submission, against rhyme and reason. On the issue of when such matters should properly be brought to the attention of the police in a hospital setting, guidance is overdue and such recommendations as the Inquiry sees fit to make will be well appreciated.

We are confident that, having heard the evidence, the Inquiry will have a better understanding of the following five factors.

One, at all times, patient safety was prioritised.

Two, at all times, the senior managers acted honestly and in good faith.

Three, at all times, decisions were taken following the gathering of information and intense consideration

of the available options. These decisions about what would be appropriate and proportionate were taken in close consultation with those who had raised the concerns.

Four, at no time did senior managers prioritise the reputation of the Trust. They had no motive so to do, and this was not a driving factor.

And five, at no time did the senior managers seek to suppress concerns or attempts to blow the whistle and it will be a matter of exploration for this Inquiry as to why those who held concerns about criminality did not contact the NMC, the police or any of the other relevant external bodies.

LADY JUSTICE THIRLWALL: And who are you referring to there?

MS BLACKWELL: My Lady?

LADY JUSTICE THIRLWALL: Who is it that you're saying didn't refer, apart from obviously the --

MS BLACKWELL: Those who were involved in carrying out the clinical duties on the wards.

LADY JUSTICE THIRLWALL: So that's the doctors and nurses?

MS BLACKWELL: Yes.

As to the contact, my Lady, between some senior managers and some parents, it is accepted with regret that this was inadequate, both in terms of frequency and manner, and that this has caused hurt and anxieties to

those affected. And for this, the senior managers are deeply sorry. This was not done with an intention to deliberately cause anguish, nor did it involve a conspiracy of dishonesty.

At the time, they believe that they were providing the right level of information. They wanted to make sure that what they were saying was clear and accurate. In hindsight they could and should have communicated far better than they did.

The senior managers were all painfully aware that the Families had gone through the most unimaginable devastating experience of losing a beloved child and that they could potentially make this worse by sharing information that was inaccurate or incomplete.

They were conscious that every contact or communication from them caused huge distress and as a result, they sought to make contact when they had something of substance to report.

There were times when the picture was simply not clear and they did not actually know very much as investigations proceeded, but they appreciate that this resulted in long periods of silence, and would have left families feeling as if they were being kept in the dark.

LADY JUSTICE THIRLWALL: Can I just ask you, Ms Blackwell, because I appreciate you represent, as you've set out,

a number of senior managers, are they all involved in this communication --

MS BLACKWELL: No.

LADY JUSTICE THIRLWALL: -- of apology?

MS BLACKWELL: Well, they are all involved in the apology but --

LADY JUSTICE THIRLWALL: No, no, I understand that but in terms of the communication?

MS BLACKWELL: Yes. I started by saying "some senior managers" and as my Lady will know the evidence that you've heard so far relates primarily to Ian Harvey.

LADY JUSTICE THIRLWALL: I see. I just wanted to know whether the others were involved at all. I hadn't picked that up, but they weren't.

MS BLACKWELL: They were involved to a lesser extent.

LADY JUSTICE THIRLWALL: All right.

MS BLACKWELL: But they all offer their sincere apologies for the poor communication that took place.

The plain fact is, my Lady, that the Families should have had more support, the hospitals should have appointed a single point of contact early on so that the Families could contact someone at any time with any queries or concerns, and the additional benefit of that would have been the appointment of someone who could offer help and support, someone who could get to know

the parents and how and when they would prefer to be contacted.

This could also have improved the bereavement services which, from the witness statements of the Families which the senior managers have now had the opportunity of considering, appears was lacking. These lessons have been learned but the senior managers wish me to repeat on their behalf that they are sorry for the distress that their ill-conceived approach has caused.

I now turn to the actions taken by the senior managers and hope to put them in their proper context.

As my Lady knows, at the time relevant for this Inquiry, the Countess of Chester was a 683-bed hospital with over 3,900 staff members, delivering services to over 450,000 residents in the Chester and West Cheshire area. The senior managers were there to provide strategic leadership in respect of to the entirety of the hospital and were responsible with the board for ensuring the provision of high quality patient care and ensuring there was a system to enable the escalation of concerns. Your Counsel has carefully described the layers of management in place to deliver this objective which included a neonatal Management Team and clinical lead.

And as you have heard, the increase in mortality

rates on the NNU resulted in a number of recommendations and investigations which were carried out in 2015 and 2016. These have been set out again in great detail by your Counsel and others in their opening statements.

These included the thematic review led by consultant neonatalologist and clinical lead for the NNU, Dr Brearey. Several consultants and nurses were involved together with the Risk and Patient Safety lead, issues were flagged within these reviews concerning elements of care, for example delayed cord clamping, cardio-tachograph interpretation and issues around the transport of very sick babies. Actions were subsequently identified in order to remedy these matters.

The Thematic Review had not found any common themes in relation to the deaths. None of the reviews or investigations identified any concerns that the increase in mortality rate was connected to an unnatural event or the result of foul play. Criticism has been made that the wrong questions were asked and incomplete information was provided to those charged with the task of investigating, and the Inquiry will want to hear from the senior managers about how decisions were made and will no doubt explore whether there were reasonable, albeit perhaps imperfect, attempts to get to grips with

a complex set of circumstances, or something more lacking.

On 11 May 2016 there was a significant meeting between Ian Harvey, Alison Kelly, the manager of the NNU, Eirian Powell, the Manager of Children's Services, Anne Murphy, and Dr Brearey, in which the Thematic Review was discussed. An action plan was agreed by all present at the meeting, which included action to be taken by those directly responsible for the management of the NNU. There was to be a review of any other babies who suddenly collapsed or deteriorated and a further deep dive into the neonatal deaths which had taken place. It was agreed that a follow-up meeting would be convened after a period of two months, that is in July 2016, to review the situation, and it was clear to senior managers in attendance that careful consideration had been given to each of the cases, including by specialist clinicians in neonatology.

All of the actions going forward from that meeting were considered appropriate and proportionate by all and, as my Lady knows, after the meeting, Dr Brearey sent an email in which he stated he'd found the meeting to have been helpful and informative.

As can be seen by consideration of the Thematic Review documents and the record of this subsequent

meeting, no concerns at that stage were raised about the deaths being unnatural or suspicious, nor were there any concerns raised in relation to Letby other than in relation to her wellbeing. The Inquiry will want to explore why this was the case.

Senior managers were aware that Letby had been on shift when a number of deaths had occurred for some time. However, it was understood that she was a specialist practitioner and therefore, because of her skills and training, more likely to be looking after the sickest infants on the NNU, often on her own. In addition to this, her willingness to work overtime when the acuity on the unit was over capacity meant she was on shift on a more frequent basis than other nursing practitioners.

Whilst senior managers were made aware that Letby had been moved to day shifts for three months, they had understood from what they were told that this was due to work-related stress and they were also told that there were no known performance management issues or complaints against her, and that she was considered by nursing colleagues to be a diligent nurse with excellent standards.

This picture, however, changed at the end of June 2016 when concerns were raised for the first time

to senior managers by Dr Brearey, who as I have said was present at the 11 May meeting, and Dr Jayaram, about Letby being concerned directly in the deaths.

This triggered numerous meetings, as my Lady is aware, throughout the remainder of June and July, attended by senior managers and consultants. However, aside from the link between Letby's shift pattern and the deaths, at that stage nothing specific was articulated by either Dr Brearey or Dr Jayaram, or any other consultant, to the senior managers, to identify what that wrongdoing might be.

For example, there was never any suggestion by Dr Jayaram that he had witnessed an event in February 2016 involving Letby that raised suspicion about her behaviour towards Child K, about which he kept silent until March 2017. Nor had there been anything raised with senior managers about Child F's insulin results back in August of 2015, for which accidental administration had been excluded as a cause but then about which no further action had been taken.

There was nothing raised about any failure in the care that Letby had given to any of the babies to indicate that her conduct had or might have contributed in any way to the deaths on the NNU.

These undefined concerns were not shared by nursing

staff. Indeed, as my Lady is aware, the NNU manager Eirian Powell was firmly of the view that Letby was a good and competent nurse.

In addition at this stage it appeared that there was also a doctor who had been on shift at the time of several of the incidents, and as my Lady knows the Coroner's Authorisation Form 1 had been issued in relation to all seven cases in which babies had died, the coroner had therefore been alerted and had the opportunity to investigate but no concerns or issues had been raised during that procedure.

In all of these circumstances, the Inquiry will want to ask what evidence was there available at that time upon which senior managers could have based a view that Letby was responsible? Whilst the concerns about Letby remained undefined, nevertheless, managers took action to better understand what was going on and to ensure that the NNU was safe. It was felt important from the outset that an open mind was preserved about the causes of the increase in deaths, and that all potential factors ought to be considered.

Incidents or issues within wards or units were, from their experience, almost always complex and multifactorial in terms of cause, rather than there being one single factor or indeed, actor.

A number of key actions were taken in June and July 2016, including, as my Lady is aware, the unit being redesignated as a Level 1 Special Care Unit, which meant it would no longer be looking after the very sick babies; a review commissioned with the Royal College of Paediatrics and Child Health; the coroner, the NMC and the Care Quality Commission were appraised of the concerns in relation to the increased number of deaths; Letby was deployed off the unit into a non-patient contact role; and there was an internal review and information-gathering exercise that was undertaken by a team of individuals as part of a Silver Command-type operation led by Stephen Cross.

A key objective of this operation was to collate more detailed information about each of the deaths and collapses which had occurred and the possible contributory factors, as well as looking at the staff involved and an analysis of the skill mix. A Position Paper was prepared by Ruth Millward and co-authored by Ian Harvey and Alison Kelly focusing on the significance of any increase in mortality. It was a detailed document that looked at Datix reporting and the information relevant to the NNU in the Risk Registers.

Of the four babies who suddenly deteriorated during the period January to June 2016, including Child M,

Child Q and Child N, none had been reported via the Datix system. Some of this information was used to inform a list of clinical reviews undertaken by Dr Gibbs and Anne Martyn looking at all the clinical records of all the babies who had collapsed and been transferred out of the hospital.

It was felt that this work, combined with the independent RCPCH review, would be capable of providing sufficient levels of information to enable the Senior Management Team to further consider the concerns raised about the increased mortality rate and also the as yet unspecified and unevidenced concerns about Letby.

At this time the senior management team had to balance the primary need to ensure that the NNU was safe with a need to be fair and have regard to the welfare of other staff to whom they owed a duty of care.

In addition to these aspects of responsibility, my Lady, the Senior Management Team had to be mindful of the impact on the whole unit and the hospital of any action being taken.

To be clear, Letby was off duty from 30 June 2016, due to return on 14 July. As such, there was no risk to patients during that period of time, and on her return from annual leave she was never again deployed in a patient-facing context.

Whilst there was some discussion about her return to the clinical environment, during the period that investigations continued, this would only ever have been contemplated whilst she was under the direct supervision of another nursing professional and in the event that could not be accommodated, therefore the decision was taken to place her in an administrative non-clinical setting.

As your Ladyship is aware, the RCPCH conducted a two-day visit at the beginning of September 2016 and carried out a number of interviews of staff, including the consultants and Letby. RCPCH reviewers never communicated to Ian Harvey or the hospital that Dr Brearey and Dr Jayaram had expressed concerns that there was deliberate harm at play. It was never communicated to Ian Harvey or the hospital that the RCPCH reviewers considered aborting their review process as a result. Had these significant concerns been raised with the hospital, this may well have altered the picture and subsequent actions.

As was acknowledged yesterday, my Lady, the agreed terms of reference as between the RCPCH and the hospital led to a misunderstanding as to what it was believed the RCPCH would be doing, and this Inquiry will wish to consider whether this was a missed opportunity for

reviewers to share in greater deal the concerns that they have since expressed to the Inquiry.

According to the report, the RCPCH review team were told that Letby was an enthusiastic, capable and committed nurse who had worked on the unit for four years. Her nursing colleagues were reported to think highly of her and there were apparently no issues of competency or training. According to the report, the consultants explained that their allegation was based on Letby being on shift on each occasion an infant died, combined with a "gut feeling"; there was no other evidence to link Letby to the deaths.

The unit was non-compliant, the report said, on issues of nursing, medical staffing levels, environment and accommodation for parents and support from the community neonatal team and postnatal follow-up. Leadership at the Trust level appeared to be somewhat remote, according to the report, from the day-to-day issues taking place within the unit.

The report also made clear that the Trust had a policy for reporting incidents, and there was a Women and Children's Care and Governance Board which considered all incidents and reports; however, attendance at these meetings by medics at these meetings was not high. Only 10 of the 13 deaths were reported as

incidents on the Neonatal Incident Summary. Other areas of the hospital appeared to report well but the NNU had for some time been less systematic in reporting. And for the cluster of 13 to 14 deaths being considered in the review, not all were reported to the Pan Cheshire CDOP.

The RCPCH sent its recommendations to Ian Harvey, including that immediate steps be taken to formalise the investigation being undertaken in respect of Letby including what the allegation was and what the process would be to investigate it.

The RCPCH suggested that this was a human resources issue. They felt that Letby had been mis-managed and had a strong case for a grievance procedure.

They also recommended that there be a detailed forensic Case note Review of each of the deaths since June 2015 using at least two senior doctors with expertise in neonatology and pathology in order to determine all the factors around the deaths. As my Lady knows, four individuals with the "appropriate expertise and experience" who would be able to conduct this work were identified. Attempts were made by Ian Harvey to contact all four and unfortunately two were unavailable to assist at the time and the third was uncontactable but the fourth, Dr Jane Hawdon, was available to carry

out the work immediately. And so it was decided to proceed with her to ensure that the work was carried out as quickly as possible.

Dependent upon her findings, consideration would then be given as to whether a further review or different course was required and Dr Rennie, one of the RCPCH's recommended reviewers, had offered to conduct a second review of any of the cases about which Dr Hawdon raised a concern.

Whilst this was not complete fulfilment of the RCPCH's proposal, it was felt that it was an appropriate and pragmatic way to progress matters. As my Lady is aware, neonatology is a very specialised field and there is a limited pool of clinicians qualified to undertake this kind of review. The RCPCH was informed of the Trust's approach and expressed agreement that this seemed to be a good plan.

In November 2016, as my Lady is aware, Dr Hawdon reported to Ian Harvey providing her opinion on the cases and recommending an expert perinatal pathology review which Dr McPartland, a consultant pathologist at Alder Hey Hospital, was asked to carry out.

In January 2017, Dr McPartland provided her report which contained a detailed clinical explanation of each case. She concluded that a cause of death for some

remained unascertained and once senior management started to receive feedback from these external investigations via the RCPCH and Dr Hawdon and Dr McPartland, there were deepening concerns as to how the NNU was being managed and the care that was being given.

But still, none of the independent experts pointed to any criminal wrongdoing and the Inquiry will want to know why.

The senior managers relied on clinicians to report and record clinically significant events as well as raise concerns in relation to their patients in accordance with long-established processes. Senior managers were not and could not have been aware that a number of objective abnormal clinical findings were not detected, were not reported or not recorded, nor were they aware that the near miss incidents were not being recorded or escalated by the NNU and in particular that unexplained collapses which had not resulted in harm had not been recorded by Datix as they should have been. Had they been visible then this may have alerted outside agencies as well.

Notwithstanding the extensive review work conducted, questions remained unanswered and by March 2017 it was felt that further review work would not bring clarity to

the situation. In particular, as my Lady is aware, the consultants were now making it plain that only investigation by the police would suffice, and at this stage the Trust sought legal advice about approaching the police. In hindsight, and whilst done with the best of intentions, this was unhelpful and it led to further delay in speaking with the police representative on the CDOP.

This meeting was eventually arranged for the 27 April 2017. Stephen Cross, Dr Jayaram and Dr Holt were in attendance, together with Ian Harvey, and Superintendent Wenham indicated that he would speak to the Chief Constable about the concerns raised and provide guidance as to how the matter should be reported.

There were then a number of meetings with the police during which it's believed the consultants shared key documents and even then the police considered that there was no, and I quote:

"... direct allegation or suggestion of significant negligence or act that could constitute a criminal act."

It is crucial to understand, my Lady, that the responsibility to keep babies safe is shared by everyone from those who work on the ward all the way up to the board. It is a collective responsibility.

Following concerns about Letby being raised, as just described, the Board of Directors were kept updated as and when developments occurred and had opportunity to hold the senior managers to account.

The senior managers collectively welcomed this Public Inquiry. They have faith that your Ladyship and your legal team will ensure that it is conducted free of hindsight bias and unrestricted by pre-constructed narrative. The information which we all now have at our disposal following the lengthy police investigation, the trials, and the Inquiry Rule 9 process is quite distinct from the incomplete information available eight or nine years ago. We fully expect that decisions made and actions taken will be put into their proper context and analysed in a dispassionate and measured way.

Ian Harvey, Alison Kelly, Anthony Chambers and Susan Hodkinson have worked in the healthcare setting for many, many years and have never come across criminal behaviour such as this. Indeed, the vast majority of professionals within the NHS are motivated with the highest of aims. They come to work every day, often in difficult circumstances, to help save lives. They do so by working long hours in the most challenging of environments. There is a tremendous amount of trust within the NHS between professionals, which will be

acknowledged by this Inquiry.

The senior managers have however all been deeply affected by what happened at the hospital. Whilst I do not suggest in any way that there is any parity whatsoever with what the Families of those killed and harmed by Letby have experienced, it has been the most significant event of any of their professional lives. They all chose to work in the NHS to help deliver exceptional care to patients and to save lives, and that a nurse could be responsible for these heinous crimes is profoundly disturbing. It is not something that any of them ever expected to be happening on the neonatal ward of the hospital, it being so against the natural order of what was contemplated or foreseen.

My Lady, that completes the opening.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Ms Blackwell.

Opening Statement by MS RICHARDS

LADY JUSTICE THIRLWALL: Ms Richards.

MS RICHARDS: My Lady, this opening statement is based on behalf of the Care Quality Commission.

LADY JUSTICE THIRLWALL: Thank you.

MS RICHARDS: Before going any further it's right that the CQC acknowledges at the outset, as others have done, the profound and terrible loss and suffering of the Families

of the babies harmed and killed at the Countess of Chester Hospital by Lucy Letby.

The depth of and the enduring nature of those losses and of that suffering was evident from the submissions yesterday made on behalf of the Families by Mr Skelton KC and Mr Baker KC. It is even more powerfully evident from the witness statements that have been made to this Inquiry by the parents, and we wish to express our deepest and heartfelt sympathies to them.

What I will say this morning draws primarily on the CQC's written opening statement of 30 August, but I also intend to touch on some of the matters raised in the opening statements made by Counsel to the Inquiry insofar as they relate to the CQC, and there are five matters which I will briefly address.

First, and in very brief terms, the role and responsibilities of the Care Quality Commission.

Secondly, the evidence which the CQC has provided to the Inquiry thus far and in particular whether further evidence may be necessary in order to answer some of the questions posed by Counsel to the Inquiry's opening statement.

Thirdly, the CQC's involvement in those matters which fall within Part B of the Terms of Reference, primarily its inspection of the hospital in

February 2016 and its resultant report of that inspection published in June 2016.

Fourthly, I'll refer briefly to some of the issues which the Inquiry is exploring under Part C of its Terms of Reference.

And fifthly, I will address the recent review commissioned by the Department of Health and Social Care, which published an interim report into the operational effectiveness of the Care Quality Commission in late July 2024.

So my Lady, beginning with the role and responsibilities of the Care Quality Commission, this is an outline only. These are matters set out in rather more detail in the first witness statement Ian Trenholm, the CQC's then Chief Executive, in a statement dated 12 February 2024.

The Care Quality Commission is an executive non-departmental public body, it is established under the Health and Social Care Act 2008, sponsored by the Department of Health and Social Care and accountable to Parliament through the Secretary of State for Health and Social Care. It is the independent regulator of health and social care in England. It has a range of functions but its primary functions focus on registration, monitoring, inspection and regulation of those health

and social care services that are described within the regulatory remit of the 2008 Act.

I should perhaps make clear that what CQC regulates is the bodies that provide the services, not the individuals who work within those services; those individuals will be subject to separate professional regulation from bodies such as the Nursing and Midwifery Council and the General Medical Council.

Providers of healthcare and social care are required to register with the CQC and to give an indication of the scale of that, as at 19 August there were over 35,000 registered providers on CQC's register, 222 of which were NHS Trusts.

Those registered providers are required to meet certain fundamental standards which are set out in the 2014 Regulated Activities Regulations. Those are the standards which the Countess of Chester Hospital was expected to meet, and they include standards of person-centred care, dignity and respect, safe care and treatment, safeguarding service users from abuse and neglect, receiving and acting on complaints, good governance, the fit and proper persons requirement and the duty of candour.

Part of CQC's role is to conduct inspections of registered providers and having regard to those

standards, make findings about the quality of care being delivered, and make recommendations for improvement. Those findings and recommendations are then published in a report and that was the process that was undertaken in 2016 in relation to the Countess of Chester Hospital.

CQC's statutory objective under the 2008 Act in performing its functions is to protect and promote the health, safety and welfare of people who use health and social care services.

There are then two bodies whose work are relevant to this Inquiry which are independent of CQC but hosted by it. Again, these are matters set out in Mr Trenholm's statement. They are Healthwatch England, that operates as a statutory committee of the Care Quality Commission but operationally independent of it, although its Chair sits on the CQC's board. That's a champion for health and social care with a mandate to ensure the voices of people who use services are listened to and responded to.

And then the National Guardian's Office, in response to Sir Robert Francis' Freedom to Speak Up Report and you, my Lady, will be hearing evidence from the National Guardian, Dr Jayne Chidgey-Clark, in December 2024. The National Guardian's Office is supported by CQC's infrastructure but it operationally independent

of it.

My Lady, turning then to my second topic, the provision of evidence to this Inquiry. The following statements have so far been requested by and provided to the Inquiry by CQC.

Two statements from Mr Trenholm, the then Chief Executive of the CQC, which provide a more detailed account of the CQC's role and responsibilities, how it approaches the task of inspection, and reporting, and also give a chronological description of CQC's interactions with the Countess of Chester Hospital during the relevant period.

There are two statements from Ann Ford. Whilst these deal predominantly with matters of disclosure and document searches, her second statement also addresses the question which I'll come back to, of what information CQC had before, during and after the February 2016 inspection on the issues that lie at the heart of this Inquiry.

You then have a statement from Elizabeth Childs, the Inspection Chair for the February 2016 inspection; from Helen Cain who was the Lead Inspector for Children and Young People's Services in that inspection; and then from two specialist advisers who formed part of the inspection team for Children and Young People's

Services, Mary Potter and Dr Odeka. All those witnesses are scheduled to give evidence to this Inquiry in the oral hearings in November 2024.

You then have a statement from another member of the inspection team from February 2016, Julie Hughes, and a statement which the CQC volunteered to the Inquiry from Deborah Lindley, the relationship owner with the Care Quality Commission for the Countess of Chester Hospital. That means she was the main point of contact between them, and that statement describes a call received from the Countess of Chester Hospital on 29 June 2016 which again I'll come on to.

My Lady, the Care Quality Commission is of course willing to provide any further statements or documents that the Inquiry may require, and that's a matter which has been the subject of some internal reflection in the course of this week, in particular in light of some of the questions identified by Ms Langdale in her meticulous and thorough opening statement.

We've had some brief discussion with your team but it does seem to us that not all of the questions raised by Ms Langdale -- very properly and pertinently raised by Ms Langdale -- will necessarily be capable of being answered by those who have so far given statements to the Inquiry, or who are scheduled to give oral evidence

in November. We have indicated we will write to your team next week with some suggestions as to who may be able to assist, but if I can just, in the interests of transparency, identify those four areas that we think further evidence may be required.

The first is this: the existing statements which you have described, the information that was specifically provided by the Trust to the CQC for the inspection and information that was specifically requested by the CQC of the Trust for the purposes of the inspection. But Counsel to the Inquiry's opening statement has rightly pointed out that there will have been data available to CQC through one or more of the reporting mechanisms that have been discussed this week.

It seems to us it may be that the Inquiry would be assisted by the provision of evidence describing the systems for ensuring that such data is available to those conducting the inspection, and how or indeed whether that system worked in the circumstances of the present case. We're looking into whether those are matters that can be addressed by the existing witnesses but it may be that the Inquiry would be assisted, for example, by the provision of a statement from one of CQC's data analysts.

LADY JUSTICE THIRLWALL: Very well.

MS RICHARDS: My Lady, the second matter is this: Counsel to the Inquiry's opening asked questions -- again very properly -- about aspects of the overall regulatory judgments recorded in CQC's report of June 2016. Some of those judgments are not specific to the Children and Young Person's services and were not made therefore by or on the basis of the work undertaken by the Children and Young Person's inspection team. There are some overarching judgments in terms of in particular matters of governance, candour, and so on.

It may therefore be that those are questions which the individuals currently scheduled to give evidence will not be able to answer, and we will make suggestions to your team next week of an appropriate witness involved in the inspection who may be able to give some form of overarching perspective on the judgments that were recorded in the CQC's report.

LADY JUSTICE THIRLWALL: Is that the person who actually made those judgments or is it somebody else?

MS RICHARDS: My Lady, our aim would be to have someone who has direct knowledge of the making of those judgments.

LADY JUSTICE THIRLWALL: Good. Thank you.

MS RICHARDS: My Lady, then the third area for evidence arises out of Counsel to the Inquiry's Part C opening, paragraph 49. Ms Langdale has identified a specific

issue for the CQC arising out of the statement of Professor Sir David Spiegelhalter in relation to a system for the collection of data which his statement suggests he helped the CQC set up in 2007.

LADY JUSTICE THIRLWALL: Yes.

MS RICHARDS: Ms Langdale has identified a number of questions. I don't know as I stand here the answer to those questions, but we will ascertain the answers and identify an appropriate witness to provide a written statement to the Inquiry addressing that.

LADY JUSTICE THIRLWALL: Thank you very much.

MS RICHARDS: Then finally in relation to further evidence, reference has been made by Counsel to the Inquiry and indeed by Counsel for the Department of Health and Social Care, and indeed in our own written opening, to the recent review undertaken which is very critical of the work of the Care Quality Commission. That, the interim report which was published at the end of July, post-dates the corporate evidence which the CQC provided to the Inquiry and we've indicated to your team, my Lady, that we'll provide a statement from the CQC's proposed corporate witness, who is the interim Chief Executive Kate Terroni, and that will address matters relating to that review.

LADY JUSTICE THIRLWALL: Very well.

MS RICHARDS: My Lady, if I can then turn to my third topic which is the February 2016 inspection and the CQC's interactions with the Trust prior to that inspection.

As Counsel to the Inquiry's opening statement pointed out, and it's paragraph 820 of chapter 4, an engagement meeting between the CQC and the Trust took place on 21 July 2015. That was from CQC's perspective an entirely routine engagement meeting at which a number of matters were discussed. It was attended by, from the Trust, Mr Harvey, Mr Chambers, Ms Kelly and Ms Millward. Mr Trenholm's statement explains that one purpose of such engagement meetings with Trusts is to provide an opportunity for them to raise any significant concerns outside of the inspection cycle.

There is a relatively full set of minutes of that meeting referred to in Counsel to the Inquiry's opening statement, and it's not I think disputed that no issue about neonatal deaths was drawn to CQC's attention during that meeting.

The inspection which the CQC then undertook in February 2016 was a routine, planned inspection. It was part of the CQC's programme of announced inspections which took place between 2013 and 2016. Eight core services were inspected of which one was Children and Young People's Services and that includes Neonatal

Services.

Prior to that inspection, in accordance with its standard process, CQC received from the hospital a provider information return. That contained data and information relevant to the eight services to be inspected, so including Children and Young Person's Services.

And then again, in accordance with standard procedure on 15 February a further request was made to the trust by CQC for some additional information. That included information in relation to paediatric incidents, and there was data provided which included information on incidents occurring in the neonatal unit.

My Lady, those who were involved in the infants of the Children and Young Person's Services have explained in their statements their understanding of the significance of that information. Whether that information should have led to further requests or questions or given rise to concerns on the part of the inspection team will plainly be a matter to be explored in their oral evidence to this Inquiry.

The main inspection itself then took place between 16 and 19 February. It included an inspection of the neonatal unit. There were two further unannounced visits, one out of hours on 26 February, that did not

include the neonatal unit, and then one on 4 March which did include a visit of Neonatal Services.

There were no particular triggers for those visits; they were again part and parcel of what CQC seeks often to do on an inspection visit.

As part of the inspection of Children and Young People's services, inspectors spoke to a wide range of staff including nurses -- not Letby -- the neonatal unit manager Ms Powell and number of junior doctors and consultants including Dr Brearey and Dr Jayaram. On the neonatal unit, inspectors spoke with six parents. Details of who was spoken to and who attended the various meetings are set out in the exhibits to the statement of Mr Trenholm and in the documents that have been provided to the Inquiry.

During the inspection on the afternoon of the 17 February 2016 -- and the significance of that date does not need to be spelled out -- the inspection team held a focus group, and that was attended by a number of consultants working at the hospital across a range of different services. It was not specifically concerned with children's or neonatal services alone, but there were consultants working in those services who attended the meeting.

The contemporaneous handwritten notes that would or

should have been made from that meeting have not been found despite extensive searches, but we do have images of a member of the inspection team's notes in her diary, which have been disclosed to the Inquiry and addressed in a statement she has provided.

These suggest that some concerns were raised about the staffing levels, of bullying culture, and a lack of support from the leadership team. It is not CQC's understanding that those were specifically related to either the children's services or neonatal, but were part of the more general expression of concerns.

On 29 June, CQC published its report on the hospital, the overall rating was "requires improvement", services for children and young people were rated as overall as "good", but in response to sub-question "Are services for children and young people safe?" The assessment there was "requires improvement", that was for a number of reasons, including the nursing staffing levels on the neonatal unit.

My Lady, Core Participants were invited by the Inquiry to address a number of topics in their written opening statements. We have done so. I want to make clear that what's set out in the CQC's written opening represented its preliminary thinking, but the CQC will wish to reflect further on those, and indeed other

matters in light of the opening statements and in particular in light of the oral hearings over the coming 12 weeks, and to return to these issues in its closing submissions in rather greater depth.

That being the case, I don't propose to say very much about some of these topics but before I leave the question of the February 2016 inspection, I do wish to say something on behalf of the CQC in relation to one of the key issues posed: when did you know about the suspicions or concerns at the Countess of Chester Hospital?

As far as the CQC can ascertain, it first became aware that the Trust had concerns about mortality and increased numbers of deaths on the neonatal unit on 29 June 2016, the day its inspection report was published, when Alison Kelly phoned CQC Inspector Deborah Lindley to inform her of an increased number of deaths on the neonatal unit. That was followed by a telephone call between Alison Kelly and Ann Ford of the CQC, and then an email from Alison Kelly to Ann Ford on 30 June which provided the CQC had requested an overview of the issues and of the actions that were being taken.

CQC had not been told previously of any concerns regarding Letby or possible criminal activity, and were

not told on that date of any such concerns, so the materials supplied on 29 June identified issues in relation to neonatal mortality but nothing in relation to possible deliberate wrongdoing or harm.

As far as CQC can ascertain, it first became aware of the suspicion of criminal activity only in May 2017, following an engagement call with the Trust in mid-May 2017, and CQC then became aware that contact had been made with the police a few weeks previously, and on 16 May the Trust shared with the CQC a briefing on the involvement of the police which said:

"We're acting from a position of caution to check nothing's been missed. Police input is the only avenue left open to us to ensure we've been completely thorough in this process."

So in sum, CQC currently understand the position to be that specific concerns regarding increased neonatal mortality were not expressly raised with the CQC by anyone within the Trust before or during the inspection or at any time prior to 29 June 2016, and that the possibility of criminal activity or deliberate harm was not raised with the CQC until May 2017.

We will of course keep that understanding under review in light of the evidence that emerges during the oral hearings, and for the avoidance of doubt, it is

CQC's position that the concerns which it has now seen through the disclosure made in this Inquiry, being ventilated within the Trust in the second half of 2015 and early 2016, should have been clearly and unambiguously drawn to CQC's attention, whether by management or clinicians.

However, and importantly, the CQC fully recognises that the question of what the CQC was as a matter of fact told or not told by the Trust before, during and after the inspection, is by no means the end of the story, and that further questions arise for CQC to answer. Those questions will include: what should the CQC have understood from the underlying data it had received from the Trust or the data it had from the reporting mechanisms? Should that data have put it on notice that there were potential areas of concern? Should the CQC have asked the Trust for more or different information, or should it have asked more specific questions about neonatal mortality than those it spoke to during the inspection?

My Lady, one theme this week has been that of curiosity, professional curiosity, and the Inquiry will no doubt ask whether the CQC in its interactions with the Trust should have displayed more professional curiosity in relation to neonatal mortality.

My Lady, in addressing this matter in our written opening we drew attention to, and I'm not going to repeat, various matters set out in the witness statements that the CQC has provided to the Trust from those involved in the inspection.

But it's apparent to the CQC in particular having reflected on Counsel to the Inquiry's opening statement that it cannot at this stage give "yes" or "no" answers to these "should" questions, to this issue of whether the inspection represented a missed opportunity or series of missed opportunities.

We wish to hear the evidence, the oral evidence of the witnesses whose testimony will be material to those questions and continue to reflect on those questions in light of the oral evidence.

My Lady, in our written opening we did allude to a concern that the fact that, as far as we can ascertain, matters were not expressly raised with the CQC during the inspection, whether that in itself raises questions for CQC as well as for those involved on behalf of the Trust. Was the CQC at that time sufficiently visible as an organisation that encouraged and would be responsive to whistleblowing concerns? Was there something about the CQC at that time, either as an organisation or in terms of how it conducted this

inspection, that discouraged or appeared to discourage whistleblowing? Those are not easy questions to answer. Again I do not have an answer at this stage but we will continue to reflect on those questions as the evidence is explored by the Inquiry over the coming weeks.

There is one factual matter about which CQC does take a more definite position, and that is in relation to the provision of the Thematic Review that was undertaken by the Trust, and discussed as you've heard, at a meeting on the 8 February only a week or so before the inspection.

Counsel to the Inquiry's opening said at paragraph 882 that it's presently unclear whether CQC accepts it received the review in advance of the inspection or not. My Lady, I hope it is clear from our written opening -- and if not I make it clear now -- that CQC's position is that it did not receive that Thematic Review in advance of or indeed during that inspection.

The issue arises because in Alison Kelly's email to the CQC on 29 June 2016, she said "an in-depth Thematic Review has been undertaken internally".

She then made reference to a subsequent peer review by a consultant from Liverpool Women's Trust. Ms Kelly recorded these had failed to identify any cause or

common theme, but added:

"These reviews were submitted as part of our recent CQC inspection data pack."

My Lady, we didn't think that's right. We've listed the relevant evidence in our written opening, I won't go back through it. But we understand from the evidence available to the Inquiry, which we did not see at the time, that the Thematic Review was primarily produced by Dr Brearey and we've seen from Dr Brearey's evidence, he says he wanted to make Mr Harvey aware of it before the CQC inspection.

There may be some factual dispute in relation to that, between Dr Brearey and Mr Harvey, but that as we understand, it is what Dr Brearey says. We have found no evidence that a Thematic Review or peer review was provided to CQC. The inspectors themselves have addressed that in their statements; as I say, I won't go through that. Dr Odeka met with Dr Brearey and interviewed him during the course of the inspection. He has no recollection of it. We have searched our records and not found any contemporaneous documentation to suggest the Thematic Review was provided. Nothing that we have seen in Mr Harvey's evidence to this Inquiry suggests that having been sent the Thematic Review by Dr Brearey, he provided it or asked that it be provided

to Dr Brearey. And we're not aware of the basis for the assertion in Alison Kelly's email about the Thematic Review and whether that was mere speculation on her part because she would have expected that to happen. Those are all no doubt matters that will be clarified or examined further during the evidence.

My Lady, then just briefly moving on from 2016, you will have seen from our written opening that in relation to the period after May 2017, we have reflected on what CQC did or didn't do, and have concluded that once it was informed of the police involvement, it should have been more proactive in seeking assurance as to the safety of the newborns on the neonatal unit and that its own role at that stage was too passive.

We've set out in the written statement, and I won't repeat it now, the approach that would now be adopted by reference to CQC's Specific Incident guidance and Criminal Cases Assessment Progression Panel guidance, both of which post-date the events in question.

My Lady, turning then briefly to the fourth topic, areas for consideration in Part C. Ms Langdale has in her opening explained that there are a number of issues where the Inquiry will wish to hear the views of the witnesses being called in Part C and that will include CQC's corporate witness. I won't anticipate that

evidence. I'll just say something very briefly on whistleblowing, candour, culture and CCTV.

In relation to whistleblowing, that is an area where substantial work has been undertaken by CQC since the events in question. Whistleblowing plays a more key role in CQC's practice now. There are a number of inspections that have either been solely triggered on the basis of whistleblowing concerns or have been partly triggered in response to whistleblowing concerns.

We have issued guidance to both providers and staff, as to how matters can be raised with the CQC. We are however keen to consider, reflect on and learn from the evidence that you well be hearing in Part C and indeed from the experts who have provided reports to the Inquiry. It is apparent to us, not least from the statements of Dr Chidgey-Clark, the National Guardian, and Mr Behrens, the former Parliamentary and Health Service Ombudsman, that more needs to be done and we will be carefully considering the evidence that the Inquiry gathers and anticipate returning to whistleblowing in our closing submissions.

On the question of candour, your Ladyship knows that the CQC has the power to take regulatory action where it believes there's been a breach of the duty of candour by a registered provider. It has issued updated guidance

on the statutory duty of candour that post-dates the events in question, that's June 2022.

We've noted and are considering further Professor Dixon-Woods' observations regarding the monitoring of compliance with the duty of candour and the difficulties that can arise.

Your Ladyship knows that the Department of Health and Social Care has undertaken a review of the statutory duty of candour, the Care Quality Commission responded to the Inquiry's call for evidence at the end of May 2024, that again post-dates the provision of a CQC's corporate statements so we anticipate if it is an issue we will address in a statement from the Interim Chief Executive, Ms Terroni, so that you have well before December a copy of or information about the evidence that the CQC submitted to the Department on issues relating to and problems relating to the duty of candour.

My Lady, then briefly in relation to the question of culture, we agree, of course, that leadership and culture can impact on patient safety. CQC's perspective is it's highly specific to institution, it's particularly sensitive to changes in leadership and closely related to that is the Fit and Proper Persons Test and CQC's role in that regard.

My Lady, we've detailed in the written opening, so I won't repeat it here, what CQC's role is in relation to that. CQC does not itself assess individuals to determine whether they are fit and proper persons. Its role is to ensure that the NHS bodies being inspected address that issue properly and have proper processes in place, and it has a role in feeding back information to Trusts if it has concerns about the processes being undertaken.

My Lady, lastly on Part C matters, CCTV. The CQC's position on the provision of CCTV in neonatal units is that that is a complicated and fact-specific question for individual Trusts. The CQC does not have a position on its universal adoption in neonatal units. But we have got published guidance on how CCTV should be used for those Trusts who introduce it, and that explains that the use of CCTV or indeed other forms of surveillance will be checked by CQC against the seven principles articulated in that guidance which I won't repeat.

My Lady, then the fifth and final topic: the review of the Care Quality Commission. The Inquiry will be aware that on 26 July the Department of Health and Social Care published an interim report of its review into the operational effectiveness of the Care Quality

Commission. That review examines in particular the suitability of the single assessment framework introduced by the CQC in November 2023. For the avoidance of doubt, that was not the approach to inspection that applied at the time of the inspection at the Countess of Chester Hospital.

The report finds in its interim review significant failings in the internal workings of CQC, and a deterioration in the ability of CQC to identify poor performance and supported drive to improve quality.

My Lady, the Care Quality Commission has accepted in full the findings set out in that interim review. It has accepted the recommendations and work is under way to address the problems identified. Amongst other steps, it has appointed Professor Sir Mike Richards to conduct a targeted review of how the single assessment framework is currently working for NHS Trusts and where CQC can make improvements. That was an interim review and the final report of the review is expected shortly. We understand it is likely to be published in early October.

The consequence of that review is that a significant process of internal reflection and/or a programme of work is under way within the Care Quality Commission to address the problems that have been identified. As

indicated earlier, the corporate witness, Kate Terroni, who gives evidence to you in December, will be able to explain the work that is being carried out by CQC and the changes being implemented. But we fully expect that there will be more for the CQC to learn as an organisation from this Inquiry's examination of the evidence relevant to Parts B and C and from the findings and recommendations which this Inquiry will no doubt make in due course.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Ms Richards.

Just before you go, I'm very conscious that there's a lot being done and a lot of effort being put into dealing with our questions as well as the other very important matters that you've identified.

Just one additional question, if I may, I hope it won't make too much work for anyone, but you say, correctly, that the February 2016 inspection found that children's services were "good" but that safety "required improvement", and that was on account of staffing levels. Now, it's my recollection from reading other CQC reports at about that time, irrespective of this Inquiry, that that was not an uncommon finding that safety requires improvement because of staffing levels. It seems to have been a problem --

MS RICHARDS: My Lady, that --

LADY JUSTICE THIRLWALL: -- which was more widespread --

MS RICHARDS: That is certainly my understanding as well and I will take further instructions and we will ascertain whether there is further evidence that we can but before the Inquiry relevant to that particular question. I imagine there will be.

LADY JUSTICE THIRLWALL: Thank you very much indeed.

MS RICHARDS: Thank you, my Lady.

LADY JUSTICE THIRLWALL: Thank you.

Opening Statement BY MR BEER

MR BEER: This is the opening statement on behalf of NHS England. I hope my speaking note has found its way to you in advance of that.

LADY JUSTICE THIRLWALL: It has, for which thank you very much.

MR BEER: Thank you. At the heart of this Inquiry are the Families whose babies were harmed or killed by Letby at the Countess of Chester Hospital. On behalf of the entire NHS, NHS England wishes again unreservedly to apologise to all of the parents and the Families affected for what they've been through, and for the mistakes and system failures in the way these crimes were reported and investigated.

This includes the lack of compassion and candour in

the way information was shared by the hospital, and for the lack of support provided to the Families and all those affect by these unspeakable events.

You have rightly asked that Core Participants are candid and that they meaningfully reflect on their own role and recognise where responsibility lies. In the course of responding to the Inquiry, NHS England has reflected on its role, and that of the legacy bodies that now form part of it, and the ways in which it may have contributed to the missed opportunities, including those that may have contributed to a delay in the commencement of the police investigation.

NHS England continues to learn more about the events that took place at the Countess of Chester Hospital and it's committed to listening, to learning and to implementing change where it is found to be needed.

Over the course of this week, we have heard from all those who are Core Participants in the Inquiry. What we have heard has been distressing.

NHS itself has sought to be candid. It has set out its position in its written opening statement and does not intend to repeat any of that detail through me now.

Instead, in reflecting on what others have said, it has focused on the central themes it considers to underpin the events at the Countess of Chester Hospital

and the questions requiring exploration through oral evidence, and these include firstly where the balance lies between trust and curiosity from ward to board and beyond.

Secondly, how safeguarding and a culture of safe and supported curiosity can be enabled and facilitated, whilst recognising the limits of process and policy without the right culture.

Thirdly, the significance of how patient safety incidents are reported, investigated, and learned from. Fourth, the importance of timely and accurate data alongside clear and robust governance for review, interrogation, triangulation and sharing.

Fifth, the openness of providers of NHS services to external scrutiny and advice, and the ways in which culture and leadership impact on this.

Sixth, the role of senior leaders in advancing the right culture, including through proactive assurance and direct engagement between frontline staff and managers.

And lastly, the approach to involving the police when unexplained harm has occurred to patients.

Compassion and candour should be the touchstones for all engagements with parents of neonatal babies, and indeed all patients. Neonatal care can be especially stressful and daunting for parents. Kindness and an

emphasis on ensuring that the voices of parents are heard are essential to ensuring personalised care.

Neonatal babies are vulnerable and do not have a voice of their own. They are reliant on others speaking for them. This includes their parents, but also all staff, clinical or otherwise, who have a vital role in safeguarding babies from harm, in advocating for their interests and ensuring that clinical information is shared openly and clearly with parents and agencies.

Neonatal services and the NHS more widely are very different today compared to 2015. In a neonatal context specifically, 2015 and 2016 were pivotal years with the publication of the Morecambe Bay Investigation Report in March 2015, and the Better Births Report in February 2016, shining a light into services that had in many cases not been subject to the same degree of scrutiny as other services.

This signalled the beginning of a sustained and ongoing focus by NHS England and others on improving NHS neonatal services with the findings of subsequent investigations in the period from 2016, including the Neonatal Critical Care Review in 2019, contributing to this work.

It also raised the profile of neonatal services with provider Trusts. This was further strengthened through

measures including the introduction of board level maternity and neonatal champions.

In 2015, Foundation Trusts like the Countess of Chester were afforded considerable autonomy. This was even more so for ostensibly high-performing Trusts, as the Countess of Chester was considered to be at the time. Although Foundation Trusts had to comply with quality governance arrangements, in accordance with the provider licence, there was a strong emphasis on financial performance and organisational autonomy.

As Lord Darzi's report has noted, the commissioning and regulatory landscape was complicated with a number of bodies, each with separate responsibilities. By 2016, steps had been taken to try to address this, but there remained a split between NHS England as commissioner and Monitor as the regulator of Foundation Trusts.

Serious incident reporting, to which I shall return in more detail, was one of the primary ways that external bodies, including NHS England, clinical commissioning groups and the CQC would be alerted to serious patient safety incidents.

However, the effectiveness of this system relied on providers like the Countess of Chester reporting incidents appropriately.

Freedom to Speak Up, the duty of candour, and the Fit and Proper Person Test were all relatively new concepts at that time and were at varying degrees of implementation and sophistication across the NHS.

LADY JUSTICE THIRLWALL: Mr Beer, just before you move on, can I just ask you a couple of questions, if I may?

MR BEER: Yes.

LADY JUSTICE THIRLWALL: When you set out that the Countess of Chester was ostensibly a high performing Trust, where is that taken from? I'm sure we've got the evidence somewhere.

MR BEER: Yes, I think that's reflected in either the first or the second corporate witness statements --

LADY JUSTICE THIRLWALL: Thank you very much.

MR BEER: -- of Professor Sir Stephen Powis, the National Medical Director, and there is underlying material referred to there which essentially stands up what he says.

LADY JUSTICE THIRLWALL: Thank you.

MR BEER: Now, the three-year delivery plan for maternity and neonatal services requires clear and consistent actions for the system across four themes, one of which is to grow, retain and support the neonatal workforce. Foundation and NHS Trusts are subject to the same single oversight framework that strengthened internal assurance

within each Trust through the range of measures introduced in the period since 2015, including the requirements that the Perinatal Quality Surveillance Model processes must be integrated into board governance.

The previous provider regulators, Monitor and NHS Trust Development Authority, no longer exist and their responsibilities now lay in one body: NHS England.

The NHS system working has been further strengthened, including through the establishment of integrated care boards, ICBs. All NHS providers, regardless of whether they're an NHS Trust or an NHS Foundation Trust, our partners within their relevant integrated care system and ICBs provide an important role in ensuring system oversight.

Independent enhanced external scrutiny measures continue to be developed and implemented, including the National Medical Examiner system and the rollout of Martha's Rule, the ongoing development and trialling of faster and more advanced signalling tools and defined governance to support the interpretation of signals through the Perinatal Quality Surveillance Model. And lastly, a new way of responding to patient safety incidents through the Patient Safety Incident Response framework and associated changes to the reporting

systems used, including the recognition that a defined "serious incident" threshold is unhelpful, and the adoption of one single reporting platform called the Learn From Patient Safety Events Service, used at both local, regional, and national levels.

LADY JUSTICE THIRLWALL: And again, just for my understanding, the Perinatal Quality Surveillance Model, how does that fit with what we were hearing about yesterday from Counsel to the Inquiry, or the day before, the work of Professor Knight and others?

MR BEER: Yes. As I understand it, the MBRRACE led by Professor Knight is essentially a subset of that.

LADY JUSTICE THIRLWALL: Very good. So maybe there needs just to be a bit more explanation, not now, but in due course, so we can see what's actually happening.

MR BEER: Yes, I'm going to mention another monitoring system later in my oral address, and one issue that your Counsel has identified is the issue of whether it can be extended or not.

LADY JUSTICE THIRLWALL: Yes.

MR BEER: So as to capture neonates, essentially.

LADY JUSTICE THIRLWALL: Very good. Well, thank you, you'll deal with that in due course.

MR BEER: Thank you.

The hospital's approach to incident identification,

reporting and investigation will be a key issue for exploration in the oral evidence. It seems to be generally acknowledged that there was under-reporting of incidents in the neonatal unit. The reason for this and what steps were taken to address this issue by those in leadership positions at the hospital will require careful consideration.

We note the points of factual disagreement around what was reported, when, and how. All providers, including this hospital, were required to comply with the Serious Incident Framework and to report incidents that met the threshold for declaration as a serious incident.

Reporting was undertaken via the Strategic Executive Information Management System, known as StEIS. NHS England, Clinical Commissioning Groups and the CQC all had access to the StEIS and were alerted in that way to incidents raised as Serious Incidents by providers, meaning that this was one of the primary ways in which patient safety could be monitored and acted upon by NHS England and others.

The NHS Serious Incident Framework was updated in 2015 in response to the Morecambe Bay Investigation report. NHS England is aware that some witnesses have referred to the fact that the 2015 Serious Incident

Framework removed the requirement previously specified in the Framework routinely to report unexpected neonatal deaths as a serious incident. This is correct.

And the change reflected and move away from an approach where certain types of incident were automatically classified as a serious incident to encourage a broader approach to incident response with the focus being on learning from incidents.

But as the updated Framework made clear:

"There is no definitive list of events or incidents that constitute a serious incident. Where lists are created, there is a tendency to not appropriately investigate things that are not on the list, even where they should be investigated, and equally, a tendency to undertake full investigation of incidents where that may not be warranted, simply because they seemed to fit a description of an incident on a list."

The removal of a requirement to report unexpected neonatal deaths was, therefore, part of this overall change, and reflected the removal of all previously specified categories of serious incident, unexpected neonatal deaths being one category on that list.

To be clear, however, the Serious Incident Framework was not ambiguous. It defined a "serious incident" as:

"An event in healthcare where the potential for

learning is so great, or the consequences to patients, families, carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response."

Clearly, the deaths and other incidents involving unexpected harm suffered by babies on this neonatal unit met that definition.

What is known in this case is that only a very small number, of neonatal deaths -- four -- were reported as Serious Incidents during the relevant period. None of the incidents involving harm, short of death, were reported as Serious Incidents. None of the four cases reported as Serious Incidents indicated a concern about a specific individual or about potential foul play more generally, and it was not until the final serious incident raised on 5 July 2016 that broader concerns about a general increase in morbidity and mortality were reported.

The evidence describes starkly how individuals within the hospital, its executive, corporate and ward roles, were made aware in the period between June 2015 and June 2016 of at least 13 deaths on the neonatal unit. The neonatal unit at the hospital was at that time a Level 2 Neonatal Unit, meaning that it was not treating the most critically ill babies.

The annual mortality rate for the unit in the years prior to 2015/16 was around three deaths. An unexpected increase in mortality of the scale seen therefore warranted greater and more intense scrutiny. Despite this, as I've said, only four incidents were reported as Serious Incidents, one of these being the 7 July 2016 report relating to the overall increase in mortality on the unit.

Given the national focus on maternity and neonatal services in the period from 2015 onwards, including the role of robust incident investigation, in supporting gave care and enabling learning, NHS England finds it all the more surprising that so few incidents were reported as Serious Incidents. It considers the failure by the hospital to report each incident in the period June 2015 to June 2016 of unexpected harm or death as a serious incident was a missed opportunity.

The failure to report earlier the overall increase in mortality and morbidity via the Serious Incident Framework, including whilst Letby remained on the unit and continued to offend, was a further missed opportunity by the hospital, which Counsel to the Inquiry has highlighted as a key area for exploration during oral evidence.

After Letby was removed from the neonatal unit, NHS

England was made aware in early 2016, July 2016, of an increase in mortality on the unit.

As the Commissioner, NHS England, should have been made aware sooner. The fact that NHS England was not made aware reflects a significant failure of the hospital's governance.

From the point of NHS being first made aware to March 2017, there was an ongoing lack of candour by the hospital in the terms of the information it shared with external bodies. However, NHS England has also reflected on its response to the information that it was given in early June 2016. Having done so, it considers that it gave too much deference and placed too much reliance on a belief that those in senior leadership roles at the hospital were demonstrating the right patient safety behaviours and culture.

It did not apply sufficient curiosity to what it was told, and there were missed opportunities when different regulatory levers could have been considered, but were not.

LADY JUSTICE THIRLWALL: Can I just ask you, interesting use of the word "deference" there from NHS England to the Foundation Trust, and I would just like to explore it a little bit with you. I mean, I wondered, before I read this, that perhaps it was more that, "Well, leave

them to get on with it", rather than deferring to them. But it may, be from what you say, that I may have misjudged that.

MR BEER: I think that may be right. As I understand our evidence and our position, it wasn't a question of institutional separation, "And that's their role and not ours", it was that an assessment was made of what they were doing and what they were saying, and as I've said, there was a belief that they were actually demonstrating the right behaviours and taking the right action. So it wasn't, I think, a simple "That's their responsibility and not ours."

LADY JUSTICE THIRLWALL: Thank you.

MR BEER: As your Counsel has rightly identified, an important issue to be explored in the oral hearings is the extent to which, if at all, Working Together was applied in relation to any of the deaths with which this Inquiry is concerned, particularly in relation to the reporting and investigation of sudden and unexpected deaths.

NHS England has engaged actively with Dr Joanna Garstang, who will be one of the first witnesses to give evidence after the parents in relation to designing and developing a document, to be called a protocol, that will aim to give clearer and easier-to-understand

guidance on Child Death Reviews.

Turning to the police, it took too long for the hospital, or any of the individuals who held serious concerns about the potential reasons for the unexpected increase in mortality on the unit, to involve the police.

Reflecting now, particularly with the knowledge it now has, about the criminal offences committed, NHS England considers, on its own and on behalf of NHS Improvement, that it could have done more to scrutinise the actions being taken by the hospital during the nine months that elapsed between when it first became aware that there was an unexplained increase in mortality and morbidity to when the police became involved.

Your Counsel has referred to the work that's currently under way by the Department of Health and Social Care to develop an updated Memorandum of Understanding between the NHS, the police and other stakeholders. We agree that this update is necessary, and will be valuable in helping to guide how the system works together when carrying out investigations.

Culture and leadership play a central role in how effectively patient safety incidents are responded to. NHS England interprets culture to mean the values, beliefs and shared ways of thinking held, and how those

influence decisions, actions and behaviours. That includes how things are arranged and accomplished, including the processes followed and the policies in place, as well as how they are talked about, actioned and modelled, and may vary, based on the organisation, work role, profession or speciality.

It's clear in this case that the culture and leadership of the Countess of Chester did not support an effective response. It also seems that the events illustrate the limits of processes and structures without the right leadership and culture to underpin them.

Turning to potential recommendations.

NHS England recognises that there are some areas where the Inquiry may wish to consider making recommendations to address some of the missed opportunities discussed in the opening statement. These include further guidance and training to be provided to NHS staff to deal with concerns about unexplained clinical events resulting in patient harm and/or near misses, including a framework for reporting these concerns to the police.

As I've said, a new Memorandum of Understanding between the police and NHS may assist in this.

Secondly, a new duty on providers to share invited

clinical reviews with, and report suspected criminality or significant unexplained events, where patient harm is identified, to other statutory bodies such as NHS England, ICBs and the CQC.

We note in this regard that the Department of Health and Social Care is also currently considering the operation, including compliance and enforcement of the Statutory Duty of Candour to Health and Social Care providers in England.

Third, existing social media, communication and professional policies, including those of professional bodies such as the GMC and NMC, should be strengthened to ensure appropriate use and increase safeguards around sharing of information; a requirement for a minimum number of non-executive directors on the board to have a clinical background, and for one of those Directors to chair the Trust's Quality Committee.

In her Part C opening, Counsel to the Inquiry raises important considerations on the factors that have the highest likelihood of ensuring effective implementation of recommendations made by an Inquiry. In our view, the Maternity Neonatal Outcomes Group's development of the MOSS tool provides a good, ongoing working example of translating an Inquiry's recommendation into the real world.

That includes, firstly, the establishment of a task-specific working group with a broad range of stakeholders in the group.

Secondly, close and sustained working, in this case with Dr Bill Kirkup, who wrote the recommendation that the group was then tasked with implementing.

Thirdly, ongoing and active involvement from subject matter experts as part of that working group approach, particularly in the case of the MOSS, Professor David Spiegelhalter.

And fourthly, ensuring that, as part of the group's implementation work, there's clear guidance to govern how the MOSS tool is used, that roles and responsibilities for all those using the MOSS, local, regional and national, are clear, and that the wider infrastructure for implementation has been planned for, including training and support on deployment.

NHS England will continue to reflect on recommendations during the oral evidence provided during the Inquiry and may, if we may, make further suggestions on recommendations in our closing statement.

In terms of concluding reflections, NHS England finishes by reflecting on what all those participating in this Inquiry owe to the Families of Letby's offending: a candour, a willingness, an openness to

reflect and learn, and a commitment to ensuring areas for further remedial action are identified and taken forward.

NHS England welcomes the opportunity to work with the Inquiry, to continue to learn and reflect on the awful events at the Countess of Chester, and to contribute to the development of recommendations for future action.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Mr Beer. You're the last of the opening statements, so I'll just take the opportunity to say that I'm grateful to everyone for the opening statements that I have received, and obviously what goes into an opening statement is entirely a matter for the Core Participants.

I did, however, ask that the opportunity might be taken for reflection and views on recommendations, and I am grateful in particular to those who have taken the opportunity to do that, and who have provided thoughtful and useful reflection and helpful suggestions in relation to recommendations at this early stage.

So thank you very much indeed.

Now, Ms Langdale, would you just like to briefly say what's going to happen next week?

Housekeeping by MS LANGDALE

MS LANGDALE: Yes. Next week we will start to hear from the parents. As my Lady knows, the public will not be in the building and people will not be present in the building; it will be simply Counsel to the Inquiry, my Lady and the representatives of the parents. Some of the parents' evidence will be audio available to the media; some of it won't be, in some cases, but it will be available on the transcript as soon as reasonably practicable. It may have to have some jigsaw identification redactions at various points, but the evidence of the parents will be available on the transcript in due course for everyone.

LADY JUSTICE THIRLWALL: Thank you. And then, when we return to being open in the building, we are moving from this very fine Council Chamber to a different room upstairs, and all of that will be explained no doubt on the website or at the door.

MS LANGDALE: That's right, my Lady. We're upstairs in a room that may be more appropriate for taking witness evidence.

LADY JUSTICE THIRLWALL: Very good. Thank you very much indeed, Ms Langdale. Thank you all very much, we'll adjourn now until 10.00 next Monday.

(11.33 am)

(The hearing adjourned until 10.00 am the following Monday)

I N D E X