Thursday, 12 September 2024.

(10.00 am)

LADY JUSTICE THIRLWALL: Good morning.

MR SKELTON: Good morning, my Lady.

LADY JUSTICE THIRLWALL: Mr Skelton.

Opening statement by MR SKELTON

MR SKELTON: My Lady, I represent the Families of Children A, B, L, M, N and Q. Over the last two days your Counsel have provided a detailed and invaluable overview and summary of the events that occurred at the Countess of Chester Hospital from the murder of Child A on 8 June 2015 to the commencement by Cheshire Police of Operation Hummingbird in May 2017.

They have set out with impressive clarity how there was a spike in the number of deaths in the neonatal unit in 2015 and 2016, what steps were taken to investigate its causes and how concerns grew in 2015 and further into 2016 that the deaths may have been connected with Lucy Letby. With great care and acuity, they have also identified the key healthcare governance policies and procedures that were applicable at the time, and have raised important questions about whether they were properly applied by the hospital.

This Inquiry has not yet heard oral evidence from the many key witnesses who worked at the hospital so

your Counsel must, of necessity, exercise caution lest it be thought that they are unfairly pre-judging the culpability of those witnesses. For the time being at least, their focus must be on the incontrovertible facts and the many serious questions that those facts give rise to.

My Lady, on behalf of the Families of Lucy Letby's victims, I need have no such professional reservations. So building on the invaluable foundations of your Counsel's opening I'm going to summarise and identify briefly and bluntly what went wrong at the hospital, why it went wrong, and the difficult task that you now face.

First, what went wrong.

The spike in mortality that occurred with the deaths of Child A on 8 June, Child C on 14 June and Child D on 22 June 2015 was, as to be expected, recognised straight away by the staff on the neonatal unit including the consultants, nurses and managers.

As Counsel to the Inquiry set out on Tuesday, this prompted various reviews and investigations which it was no doubt intended should have determined the causes of death in each case and identified any common factors between them.

There were, however, five basic failures which occurred right from the start and which continued for

the next two years.

First, there was a failure to conduct swift, careful and methodical investigations into why each death occurred, whether there were connections between the deaths, whether there were connections between the deaths and other deteriorations and collapses that had occurred on the unit, specifically Child B on 10 June.

That was a major and catastrophic failing. As your Counsel have explained in detail, many reviews, many discussions and investigations took place, but they were not conducted systematically and consistently, and so, as I will come on to, vital information was overlooked with fatal consequences for other children.

Second, the cluster of deaths and collapses should have been escalated to the Senior Trust Management immediately: the Medical Director, Ian Harvey; the Director of Nursing and Quality, Alison Kelly; the Chief Executive, Anthony Chambers; and right up to the board.

They should have overseen the investigations and they should have ensured that they were fully and fearlessly conducted until all possible connections had been identified and excluded. And if they felt this could not be done internally, then they should have ensured that it occurred externally as a matter of urgency and that such an investigation, as I have said,

directly addressed all possible causes of death, including deliberate harm.

Third, from the outset, and without prejudice and without pre-judgment, it should have been in the minds of those conducting and overseeing the investigations that the cluster of unexpected and unexplained deaths might have been caused by the criminal acts of a member of the hospital staff.

My Lady, neonates are by definition tiny and highly vulnerable patients, often born prematurely and with a range of problems that for at least a time put their little lives at grave risk. But most of them are successfully treated and most of them survive.

More importantly, if they do collapse or suffer any life-endangering conditions, those collapses and conditions and even their deaths will have identifiable medical causes and will not be unexpected.

As you will in due course hear from the medical witnesses, unexpected and unexplained collapses and deaths are rare and several such incidents at the same place in a short space of time are by definition even rarer.

Murders and assaults of patients by healthcare staff are rare too. But they do happen, and when they do, they attract immense public attention. In 1991,

Beverley Allitt, a nurse, murdered four infants, attempted to murder three others, and caused grievous bodily harm to a further six. Sir Robert Francis in his first report to this Inquiry has summarised the findings of the Inquiry that then ensued, chaired by Sir Cecil Clothier. Recommendation 13 of that Inquiry, which Sir Robert notes was described by its Chair as its "principal recommendation", states:

"Beverley Allitt's actions should serve to heighten awareness in all those caring for children the possibility of malevolent intervention as a cause of unexplained clinical events."

My Lady, this was a deliberately low bar. The Allitt Inquiry was not advising that the positions of crime should be uppermost in the minds of healthcare staff responding to any unexplained events involving children. That would be an unnecessary and unrealistic expectation in the context of a national system of healthcare and would create a culture of misplaced blame, fear and criminal investigation. But rather, the report was seeking to ensure that healthcare staff were prepared to think the unthinkable. That in certain situations, they kept their minds open to the possibility, rare as it might be, that criminal conduct was occurring.

That did not occur at the Countess of Chester Hospital in June 2015 and even when it did, on the part of some of the paediatric consultants, they were met with the obdurately closed minds of their managers and senior managers.

My Lady, whether or not the memory of Beverley Allitt and the Clothier Report's 13th recommendation was properly embedded in NHS culture in June 2015, a more pressing reality check had occurred any three weeks previously on 19th May 2015, when Mr Justice Openshaw had sentenced Victorino Chua to life imprisonment. Chua, as you know, was a nurse at Stepping Hill Hospital in Stockport, 43 miles away from the Countess of Chester. He'd been found guilty of murdering two patients, poisoning 19 other patients and attempting to poison seven others in 2011.

Like Allitt, he had done so insidiously, and he had used insulin. It had taken a protracted period of time to catch him and his prosecution and conviction attracted national attention.

It is difficult to understand why the events at Stepping Hill did not at the very least alert those at the Countess of Chester from the start that the cluster of unexpected deaths were the result of potential criminality and that active steps were required to rule

out that possibility, however remote it might be, for the sake of the patients' ongoing safety.

Fourth, the police and the coroner should have been informed at the outset. Not because a crime was suspected, but automatically and without blame or accusation, because the deaths were unexpected and they were unexplained.

This would, you may feel, have had a profound effect on the course of the subsequent events. It would have meant that external bodies were actively engaged from the start and able to provide advice and guidance on how the investigations should proceed at each stage, able to ensure that the investigations considered and ruled out criminal conduct, and most critically, it would have allowed the police to intervene and take over as soon as it was suspected that Letby had killed or harmed babies.

Fifth, the Families should have been told by the hospital that it was investigating the deaths with a view to finding out why they occurred and whether or not they were connected.

You will hear from some of the patients over the next few weeks about how they were kept in the dark about the collapses of their babies and the concerns and investigations that were being undertaken into their babies' deaths, both internally in the hospital and

externally ultimately by the Royal College of Paediatrics and Child Health and others.

They should have been told, not when those investigations had concluded, but as soon as they were initiated. Not telling them was morally indefensible. It is indicative of a healthcare culture that remains, even now, paternalistic and secretive. Additionally and of more practical importance it meant that the investigations themselves did not capture information that only the parents could have given or answered questions that only the parents would have asked.

My Lady, it is beyond the scope of this brief opening to provide fully what a full and fearless investigation of a child's death in hospital should have entailed in 2015 and what guidance should have been followed. That is a matter for this Inquiry to examine and to formulate.

LADY JUSTICE THIRLWALL: Presumably you'll have some views about that in due course?

MR SKELTON: Indeed, my Lady.

You may feel as a starting point that the blueprint has been set out by Dr Joanna Garstang in her statement to this Inquiry when she discusses the Joint Agency Response, JAR, or Sudden Unexpected Death in Infancy or Childhood, SUDIC. As I have stated, several of the key

features of those types of investigations -- urgency, open-mindedness, thoroughness, engagement with the police and the coroner, engagement with the Families -- are notable by their absence in the present case.

Turning to the remaining months of 2015. The key failings I have identified were made all the more defensible by the inexorable increase in the numbers of unexpected neonatal collapses and deaths. Child E collapsed on 3 August and died the next day. Child F collapsed on 5 August and survived. Child G collapsed and survived on 21 September. Child H collapsed and survived on 26 September. Child I collapsed and recovered on 30 September, but collapsed again and died on 23 October. And finally Child J collapsed and survived on 27 November.

These deaths were compounded by two factors. First, as with the unusual rashes that occurred in the first babies that Letby attacked, there was in fact important information in the possession of the medical staff that could and should have been readily identified and recognised as significant, namely Child F's abnormal blood results, the insulin combined with the low C-peptide. These were clear and objective indications for the first time that someone had deliberately or inadvertently administered insulin to the child and

thereby endangered his life.

Its importance is accepted, for example, by Dr Gibbs and Dr Brearey and emphasised, you may feel somewhat self-servingly, by Ian Harvey. It was indeed a major opportunity, finally, to identify potential criminality. Precisely the kind of information should have been captured by a robust investigation, particularly if, as should have been the case, the Clothier warning about potential staff malevolence had been heeded and the mechanism of murder by both Allitt and Chua had been properly heeded.

As your Counsel explained on Tuesday, a similarly clear and concerning blood result was obtained but not recognised in respect of Child L in April 2016, a further missed opportunity to sharpen up the mounting suspicion that babies were being deliberately harmed.

The second point is that at some point, in the latter months of 2015, the paediatric consultants began to suspect that Letby was the direct cause of the collapses and deaths, and that her actions had been deliberate, or, to call them by their proper name, that she had murdered or attempted to murder the babies.

Over the next few weeks you will be closely examining the evidence of the consultants and their medical and nursing colleagues about precisely when and

why those concerns arose, and when and how they were informally shared in unminuted meetings, in informal conversations, by email, and by messages.

Dr Jayaram, for example, states in his written evidence to the Inquiry that it was not until his return to work in November 2015 after the death of Child I in October that he first thought that Letby could be deliberately harming babies. But you will see what followed was more whisper than deliberate and practical investigation into the deaths.

For present purposes, from the Families' perspectives, as soon as it was suspected that Letby was harming babies, several steps should have been taken immediately. It was incumbent on the consultants to bring that concern unambiguously to the attention of the unit manager and the hospital's Executives who should in turn have briefed the board.

Safeguarding procedures should have been initiated with other view to protecting patients from potential harm. Letby should have been suspended from her nursing duties.

The police should have been notified by the hospital's Chief Executive or by any other Executive officer with the authority of the board. A plan should have been formulated for an investigation into whether

Letby had in fact harmed babies.

Whistleblowing policies should have been put in place to ensure there were no adverse and unjust repercussions and disincentives for any staff member, including the consultants, to provide information that would support or undermine the investigations, and the plan should have been made to approach the parents of the babies concerned so they were fully apprised of what might have happened to their children, however distressing and inflammatory that may have been.

In 2016, as your Counsel have set out, Child K collapsed on 17 February and died. Child L and M collapsed on 19 April and survived. Baby N collapsed and survived on 3 June and again on 15 June. Child O collapsed and died on 23 June, Child P collapsed and died on 24 June. Child Q collapsed on 25 June and survived.

Throughout these months, the five principal failings I have identified that arose in 2015 were continuing. But by this stage, they were also magnified by denial, defection and delay on the part of the hospital's Executives. There was denial that the babies had been killed or assaulted by Letby or by anyone else, and denial that anything needed to be done to investigate that possibility directly until the consultants produced

clear evidence that a crime had been committed.

There was delay in convening a meeting between the paediatric consultants and the Executives, including Alison Kelly and Ian Harvey. There was delay in initiating independent investigations into what happened, for example, by the Royal College of Paediatrics and Child Health, and there was of course delay in informing Cheshire Police. And there was deflection of the problem, as a statistical anomaly, or an as yet unidentified medical or system failure, or an unfounded and oppressive allegation against a junior nurse by senior doctors that justified a formal grievance procedure, not a safeguarding intervention.

These three failings by the Executives were also magnified by the utterly indefensible failure by anyone to trigger the hospital's whistleblowing and safeguarding policies which, as I've said, would have protected the paediatric consultants and other staff members and would have mandated measures to protect babies and find the root causes of their collapses and deaths, and just as critically, there was an inexplicable failure to provide clear information and instruction to external healthcare bodies and investigators, the CQC, the Royal College, the NHS, Dr Hawdon, that Letby was suspected as being a potential

cause of the deaths and collapses and that they needed to investigate that possibility. At the very least, advice could have been given by each of those bodies as to what next steps should have been taken, for example the need to contact the police.

Why did this happen? As is always the case with healthcare disasters from Bristol to Mid Staffordshire, the catastrophic failure to stop patients suffering harm resulted from a combination of human shortcomings, systemic weaknesses and damaging cultural norms. Addressing all of these fully is far beyond the scope of this opening statement but I'll seek to summarise at least some of the key issues.

First, human shortcomings. The paediatric consultants. My Lady the consultants deserve the gratitude of the Families for being the first to identify Letby as the connecting factor between the unexpected deaths and then the person who deliberately harmed the babies.

They acted with tenacity and courage in the face of difficult and defensive managers and, as Dr Jayaram makes clear in his statement, in genuine fear of adverse consequences for themselves, including the threat of professional misconduct proceedings.

However, it must also be recognised that the

consultants were in a position to initiate robust and comprehensive investigations of the deaths and collapses on the unit, but did not do so.

They were also in a position to trigger whistleblowing and safeguarding policies themselves, but did not do so.

Most critically, as soon as they suspected Letby had harmed babies deliberately, they should have articulated their suspicions clearly and formally in writing, and made sure that they were brought to attention of the senior managers and the board, and when those managers refused to take immediate and appropriate action, the consultants should have gone to the coroner or spoken to the police.

A key example of this failure, you may feel, was the inquest into the death of Child A which took place before coroner Nicholas Rheinberg on 10 October 2016. At that inquest, hospital staff, including Dr Jayaram, gave evidence under oath, but for reasons that will require clear justification when they give evidence, no one told the coroner there had been a concerning cluster of deaths at the hospital, that this was being investigated, and most critically, there was concern that a member of staff was involved and was harming babies deliberately.

Pausing there, it must be acknowledged that Dr Jayaram and others should never have found themselves in that position. It was a very difficult step for anyone to take in a court, given what was happening internally at the hospital. As I have already stated, the coroner should have been informed months before about all of these matters, and his guidance and intervention sought. Or at the very least, you may feel, the hospital's legal representatives should have been instructed to tell him before or during the inquest about what was occurring, or its Medical Director, Ian Harvey, should himself have attended and addressed the issue directly.

The most serious failings however must fall squarely on the managers of the neonatal unit, the hospital's Executive Management and its board, in particular, Eirian Powell, Alison Kelly and Ian Harvey. They failed to heed the lessons of Grantham and Stepping Hill and failed to act with professional curiosity and open minds when mortality increased in the neonatal unit and suspicions began to grow that Letby was the cause.

It is most striking that even now, eight or nine years later, they show so little insight into their own roles into what went wrong. So, for example, in his long and detailed statement to the Inquiry, Ian Harvey

simply doesn't accept personal responsibility for the fact that Letby wasn't caught sooner. He does not address the obvious applicability of safeguarding obligations or the whistleblowing policies, despite being one of the hospital's "Speak Up" champions.

He does not recognise that Letby's criminality was never adequately excluded as a possibility because he did not ensure that it was directly investigated, both internally in the hospital and externally by the Royal College and Dr Hawdon.

He does not accept that when he was told of suspicions about Letby he should have informed the police. Instead, he and others repeat the mantra that the paediatric consultants never presented evidence that she was connected to the deaths.

That is a misconceived argument for several reasons.

First, this was group of respected senior doctors with many years of experience treating a very large number of sick babies.

They were telling him and his fellow managers that they could find no other explanation for the deaths or connections between them other than one of the hospital's nurses. Absent obvious malice or irrationality, the authority, experience and unanimity with which they spoke should have been sufficient to

warrant speaking to the police and an agreed plan of investigation.

Second, it wasn't the consultants' job to provide the evidence. They had of course missed the abnormal blood results of Child F and Child L. But it was their job to raise concerns, and it was then for others, Ian Harvey, his colleagues and the board, to implement the governance policies, the mechanisms and investigations that were required to ensure that those concerns were addressed, and that patients were properly protected.

Third, it wasn't for Ian Harvey to judge the validity of the consultants' concerns and suspicions and whether the evidence amounted to sufficient proof of Letby's guilt. He was not a neonatalologist, a pathologist, a police officer or prosecutor; rather it was incumbent upon him to respond without judgment and with the 13th Clothier recommendation uppermost in his mind.

Instead, as I've said, the consultants were treated by him as a problem that wouldn't shut up and go away. The edict to them from Ian Harvey on 29 June 2016, that emails should "cease forthwith" was inappropriate and oppressive, and external investigations by the Royal College and Dr Hawdon were flawed for the reasons

I have given.

So over time, an upside down situation evolved in which the consultants' suspicions were never satisfactorily allayed and meanwhile they themselves were put under investigation for making unfounded allegations against an innocent junior nurse to whom, in a quite extraordinary turn of events, they were forced to apologise.

My Lady, it is difficult to conceive of a more unfortunate and indefensible response to allegations of the utmost gravity: the murder and assault of multiple babies by a healthcare professional. Ian Harvey and his colleagues should have readily appreciated how difficult it was, professionally and personally, for the consultants to pursue their suspicions about Letby, and they should have supported, not undermined, them.

Turning then to the systems of governance. I have already outlined that the Inquiry will need to look carefully at the relevant policies from investigating neonatal deaths in the hospital in 2015 and 2016. An important and conspicuous theme of your Counsel's opening is that data collection, correlation, and discussion was patchy and inconsistent within the hospital. Little or no thought was given to the whistleblowing and safeguarding policies and from the

witness evidence so far obtained, this appears to have been driven by a combination of ignorance, oversight and avoidance that should simply not have occurred in a modern NHS hospital.

Yesterday, Counsel to the Inquiry raised serious questions about the efficacy of the board's grip and challenge in respect of the raised mortality in the neonatal unit, despite the degree of authority, experience and knowledge that they individually and collectively held.

Further, as they outlined, at the relevant time there was a multitude of procedures and forums for the consideration of infant deaths and other serious incidents, such as unexpected and unexplained collapses. You've heard, for example, about Datix, Sudden Unexpected Death in Childhood, serious untoward incidents, informal debriefs, formal hot debriefs.

You've also heard about the various groups that capture and discuss relevant issues and themes both inside and outside the hospital such as the neonatal mortality meetings, the Quality, Safety and Patient Experience Committee, the Urgent Care Risk Register, the Executive Risk Register, the Cheshire Clinical Effectiveness Group and the Local Child Death Overview Panels and Safeguarding Children's boards.

The plethora of procedures and forums is in itself striking. To the lay observer, it is unclear which one of these procedures and forums were the right ones, or the most important ones, for capturing and assisting the type of problem that arose in the neonatal unit at the Countess of Chester; namely a cluster of unexpected and unexplained infant deaths and collapses.

As your counsel have indicated, it is also unclear how the systems of alert and analysis of incidents interrelated and shared data effectively.

While each of them had obvious purpose and value their combination, if used properly, placed a heavy and potentially impossible bureaucratic burden on healthcare staff, including the paediatric consultants themselves. This created an obvious risk that they would not be used, or that they would be used inadequately or inconsistently, thereby of course undermining their efficacy with the result that significant issues would inevitably be missed.

You will in due course hear from Dr Brearey, Dr Jayaram and others as to how stretched and unsupported the medical staff felt and how they needed to carve out time to give attention to the investigations.

Cultural norms. I will deal with this very briefly

because you will be hearing expert evidence in short order.

LADY JUSTICE THIRLWALL: Thank you.

MR SKELTON: It is another complex issue, but it appears obvious from the evidence that your Inquiry has so far gathered that the effective and timely response of the hospital to concerns that Letby was harming children was undermined by several cultural factors.

Sense-making, whereby healthcare staff and managers failed to recognise transgressive behaviour and instead focused on other causes.

Comfort-seeking behaviour and confirmation bias whereby staff rejected suspicions about Letby, approached the available information without objectivity, dismissed dissent and focused on reputational and employment grievance issues.

Professional reticence, both in the ways that concerns and suspicions were articulated and discussed, and how they were escalated.

I note in this regard how few written records there were about the specific concerns that rose in respect of Letby and even fewer that deal directly in terms with her potential criminality.

Institutional secrecy, both within and without the hospital. Ian Harvey's email to "cease communications

forthwith" is an example of this.

So too is the absence of clear and unambiguous information provided to the Royal College to Dr Hawdon, the CQC and the NHS, and of course the delay contacting the police.

Demonisation and lack of support of the perceived whistleblowers.

The deterioration of interpersonal and professional relationships, into conflict.

The emotion and anger expressed at meetings.

The growing schisms between the doctors and nurses and doctors and managers.

And above all, the appalling loss of perspective within the management team about the manifest priority of patient safety, the need to protect babies from what could have been, and turned out to be, a determined and ruthless serial killer.

My Lady, you have the task of determining how the interplay of human weakness, poor governance and unhelpful cultural norms led to the failure to stop Lucy Letby from murdering and attempting to murder the children in her care.

The facts relating to those matters will no doubt crystallise over the next 12 weeks. But more formidable is the task of making recommendations to ensure that the

interplay of those factors doesn't recur. There you are up against longer standing cultural forces, including the profound reticence to call out colleagues who may be harming patients. I will address you on these matters of course fully next year.

My Lady, in conclusion, I'd like just to say two things.

First, on behalf of the Families I would like to acknowledge that in its written opening statement, the Countess of Chester has clearly reflected carefully on the events of 2015 and 2016 and has appropriately acknowledged the serious mistakes that were made and the serious consequences that those mistakes had.

As will be apparent from this opening statement, the Families consider that these mistakes arose from the start of the in-depth events in June 2015, and that Letby should have stopped much sooner. Precisely when will be a critical question for you to determine.

But also on behalf of the Families, having heard or read the long and detailed opening statements of Counsel to the Inquiry, I would urge that the hospital's Chief Executives exercise a greater degree of reflection and insight than they have demonstrated in their written evidence and their written opening. Their continuing denials and deflections are painful to bear. It is

hoped and expected that by the time they appear to give evidence before you in a few weeks' time they will demonstrate far greater understanding of what went wrong at their hospital and acceptance of their personal accountability.

My Lady, finally I must make a request to the public and to the media. As you've said in your opening remarks on Tuesday, of recent weeks and days there has been a great deal of speculation about Lucy Letby's guilt and there are strongly held and articulated questions in some quarters that she may be the unlucky victim of a miscarriage of justice.

You rightly said that those raising those questions would not have been present at Lucy Letby's trials, and so unlike the juries that convicted her, they are not in a position to weigh up the evidence and reach an informed view.

They are not, for example, aware that Lucy Letby was not convicted on the basis of questionable statistics but because the factual and expert medical evidence demonstrated beyond reasonable doubt that she had harmed the children at the hospital. You are not conducting an assessment of all the available evidence about Lucy Letby's guilt, and this Inquiry will not consider those matters over its forthcoming evidence. But she

was assisted at the time by a first rate defence team, and it is important for the public to understand the decision-making that occurred within that trial about the use of expert evidence, for example, before coming to a view about what may now amount to a miscarriage.

It is also important that people monitoring the Letby case don't demonstrate precisely the type of mindset and fallibilities that I have described in this opening statements; fallibilities that demonstrated closed-mindedness when it comes to facts that don't support your own opinions.

I would urge those people as a starting point to consider the Court of Appeal judgment that has rejected outright Letby's application to appeal her convictions. It takes about 90 minutes to read. It is the result of very careful analysis by very experienced senior judges; in the clearest terms it upholds the convictions and arguments that continue to underpin speculation about her trial.

Finally I'd also urge you to follow the evidence that will be given to this Inquiry. As you, my Lady, stated in your opening remarks, you are not investigating her guilt. But you are investigating those that worked with her, those that knew her, and ultimately those who suspected that she was committing

murder.

Those witnesses who give evidence to you will be seeking to explain why those suspicions arose and why she was not caught sooner. That, not Letby's conviction, must now be the focus of everyone's attention. Thank you, my Lady.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Mr Skelton.

Opening statement by MR BAKER

MR BAKER: My Lady, I speak on behalf of the Families of Child C, Child D, Child E, Child F, Child G, Child H, Child J, Child K, Child O, Child P and Child R.

I am also instructed by the Family of Child U, a child not named on the indictment, but whose Family are assisting the Inquiry. I have prepared a written opening, I will not read it out. I have also prepared a speaking note which I will send to the Inquiry at the conclusion of these openings.

LADY JUSTICE THIRLWALL: Thank you very much.

MR BAKER: You have heard over the course of two days of an opening presentation by the Counsel to the Inquiry and her team, Rachel Langdale KC and her team are to be congratulated on preparing and delivering an impressive, meticulous and forensic introduction to these events. The Families are grateful for the care that has been put

into operation of this Inquiry by all concerned, but also for a very genuine empathy shown by the Inquiry team towards their needs.

In the time allocated to me I cannot match the level of detailed analysis that is contained within that opening.

Letby was convicted of murdering five of the babies whose Families I represent, and attempting to murder four more. The convictions and indeed the indictments do not however tell the full story. Child K died when she was only a few days old, having been attacked by Letby, and her parents believe with justification that she was murdered by her. The position is also complicated by the fact that the jury could not reach a verdict in relation to the charge that Letby attacked Child J, causing her to collapse twice on 27 November 2015. I have indicated in my written opening that the parents have no doubt that Letby attacked their daughter on that date, but also that a further collapse on 17 December 2015 which did not form part of the indictment was caused by the actions of Letby.

Both are entitled to reach those views based on the evidence that they have seen.

My Lady, the position of the Families in this

Inquiry is unique. They are anonymised by ciphers, as are their children. Some are concerned that this has the effect of dehumanising them in the eyes of the public and media, and has cultivated an environment where people feel able to express vile opinions through social media, an environment where the serial killer who murdered or attacked their children is, by contrast humanised or even venerated.

My Lady, you have met the Families. You will know that they are real people. You will understand that they have a simple and reasonable aim: to live normal lives as disconnected from the monster who harmed them as possible. They have no interest in becoming permanent attractions at a ghoulish sideshow. Their request is to be allowed to grieve in private or for their surviving children to never know of the role that they played in this story.

More tragically still, they feel that revealing their identities would cause them to become the focus for ill-will. My Lady, what has society come to, where the parents of murdered or injured children should live with this fear? Everybody who recklessly promotes conspiracy theories, or who parrots without questioning the same tired misconceptions about this case, should be ashamed of themselves.

The Families, along with the jury, collectively sat through ten months of evidence and in the case of Family K, two trials. They did so with impressive dignity. They heard the evidence against her and have no doubt that she was guilty. The jury had no doubt that she was guilty. The trial was overseen by an experienced High Court judge and reviewed comprehensively and with care by the Court of Appeal.

This process conducted with scrupulous fairness and with exhausting detail is arrogantly ignored by those who criticise the outcome. Those individuals offer superficial opinions based upon second or thirdhand accounts, expressing conclusions that it might be generous to call on occasion "half-baked".

In the meantime, the Families, the jury, the judge, the Court of Appeal, and even the team who represented Letby at trial, must remain silent while others use the losses suffered by those Families as currency to build their own reputations. This is an intolerable burden for the Families to bear, and as I have said before, it is harmful and toxic to them.

The complexity of the open anything of this Inquiry demonstrates the depth of analysis that is required to understand the events at the Countess of Chester. This is not an issue to express casual opinions about.

There is, however, some measure of relevance in this background noise, as Mr Skelton, King's Counsel, pointed out. It reveals a common and basic cognitive bias. As a society, we are too quick to make judgments debated upon first impressions. We idolise or demonise those who fit our own stereotypes. We prefer our monsters to look like monsters, to be easy to identify and to be far removed from ourselves. It creates a profound cognitive dissonance when monsters do not fit a stereotype. It is sometimes hard to accept that evil can be banal.

The cognitive biases of individuals who see a young woman working in a caring profession and cannot conceive of a darkness that may lay beneath the surface are easy to understood, but we should not be so naive: to be successful, a serial killer must hide in plain sight.

In her opening Rachel Langdale, King's Counsel, marked upon the respect that so many patients expressed towards Harold Shipman who they regarded as a diligent and caring doctor; until, that is, the truth was known.

We can add to that list many other superficially charming or apparently normal individuals who were later revealed to be monsters. It should be no surprise to this Inquiry that in so far as other respectable and responsible professions may attract sexual predators, so healthcare professions may equally allow those

harbouring malign or homicidal ideations to live out their fantasies unchecked. It is, as Mr Skelton points out, thankfully rare, but it is a risk that hospitals and Trusts should be alive to.

In examining this issue we should guard against the notion that a serial killer such as Letby was entirely unpredictable, or unthinkable, in 2015 and 2016. Counsel to the Inquiry was correct in her opening statement to refer to the case of Beverly Allitt. Her name appears within a list that includes Harold Shipman, Colin Norris, Ben Geen and Victorino Chua.

The latter case, as Mr de la Poer and Mr Skelton observed, is particularly apposite, because the sentencing remarks made by Mr Justice Openshaw were made a matter of weeks before Letby commenced her killing spree.

You may conclude that it is surprising in the extreme that individuals working at a Hospital Trust a little over 40 miles away and a matter of weeks or months later might regard the possibility that a nurse or healthcare worker would harm patients as unforeseeable or unthinkable.

Allitt will remain a constant presence throughout this Inquiry and the facts of that case are remarkably similar to this one. The Families note that the

Clothier Report was particularly critical of the Grantham Hospital's response to those remarkably similar events and that a delay in two weeks before calling the police, having received the same abnormal insulin results that were received by the Countess of Chester Hospital following the collapse of Child F in July 2015. The Clothier Report described that delay as "feeble and indecisive". It allowed further crimes to be committed, including a further murder. The Family will say that albeit feeble and indecisive, in its reaction to these events, the Grantham and Kesteven Hospital did considerably better than the Countess of Chester did 25 years later, even though the Countess of Chester Hospital should have had the benefit of accumulated knowledge that had been acquired in the intervening period.

There was and is no upswelling of the public opinion in support of Beverley Allitt who was convicted of murdering four children, attempting to murder three others by various means, and causing grievous bodily harm to six more, all remarkably similar to this case. Following her conviction, she eventually confessed to her crimes.

The Families will begin by asking not only why did this happen, why did it happen again?

Why was a reaction to these crimes palpably worse in 2015 and 2016 than it had been in 1991?

Why did the Trust fail to recognise what was happening sooner?

Why did it not exercise greater curiosity over the events, and investigate them more clearly?

Why did it not avail itself of structures and systems that should have safeguarded children?

Why did the Trust not call the police as soon as suspicions were actually raised?

Why did a culture develop that put reputation and personal promotion above the need to protect vulnerable patients?

Why had a culture been allowed to develop whereby a hospital saw the need to focus on grievances expressed by a serial killer as taking priority over investigating their crimes?

A set of circumstances described by Mr Skelton as "unfortunate", but which I would describe as "surreal".

Why did the failsafe that led to Allitt being apprehended not work in this case?

The Families are aware of Mr Harvey's comment that all would have been different if he had known about the insulin and C-peptide results of Child F. They have no sympathy. They would say that he had every opportunity

to investigate Child F's case. He is ultimately responsible for the lack of proper investigation into the collapses and deaths that preceded and followed Child F.

Although the response of the individuals and organisations when concerns were felt or expressed is clearly a key issue, the Families would not want the Inquiry to lose sight of the fact that greater curiosity from the outset had the potential to prevent harm at a very early stage and may have prevented harm altogether.

The Families say this for the following reasons: The deaths and collapses were unexpected and unexplained. You will hear evidence that death is far from common in the neonatal setting. Dr Davies, an obstetrician, observed in her analysis of Child D's case that it is simply not normal for a term baby to die. Dr Brearey in his evidence commented that unexpected neonatal collapse is extremely unusual. You would not normally expect it to happen without some warning first.

He would not normally expect a baby born in good condition beyond 30 weeks' gestation to collapse suddenly and he felt that survival rates for babies born in a good condition at 33 weeks should be 98%.

The babies involved were not critically unwell despite what may be said in the media. In some cases they were vulnerable but in others not even particularly vulnerable. Some were waiting to go home. The collapses when they occurred were unforeseen and unexpected. These were not babies who had been predicted to be at risk of collapse and sudden death.

An account of babies given over and over again by their Families and medical professionals is that they were stable, improving. Child E and Child F were almost ready to go home. They all seemed to be doing well and nobody can understand why they were collapsing and dying. Resonance again to Allitt and all those who followed her.

Collapses occasionally involved complications that were in themselves unusual, such as the dislodgement of endotracheal tubes.

Given the prevalence of dislodgment of endotracheal tubes in this case, my Lady may see it as a common evidence but the evidence suggests that it is not at all common, it is very uncommon. You will hear evidence that it generally occurs in less than 1% of shifts. As a sidenote, you will hear that an audit carried out by Liverpool Women's Hospital recorded that whilst Lucy Letby was working there, dislodgment of endotracheal

tubes occurred in 40% of shifts that she worked.

One may wonder why. This is a relevant issue, we would say, for Part C and a potential for systems to identify such profound variations from the norm.

The babies did not respond to timely resuscitation manoeuvres in a way that would be expected. Child C, for example, showed signs of life after a prolonged and unsuccessful resuscitation in a way that was at odds with what would be expected. The medical professionals who witnessed it couldn't understand it. There was no natural mechanism to explain it.

The collapses and deaths involved unusual features that could not be explained by those who witnessed them, including unexplained skin changes. Two babies who collapsed were found to have been given manufactured insulin to cause hypoglycaemia. The deaths occurred at a rate that was entirely at odds with experience on the unit through previous years: three deaths occurred in June 2015 alone, the same number or more as had occurred annually in preceding years. The Families would ask why the unexpected spike in deaths did not trigger greater curiosity or investigation, and why established systems were ignored or failed.

The Families asked why was there not greater curiosity, why were the collapses and deaths not

properly investigated?

Why were Families and coroners offered definite conclusions as to why their babies had collapsed or died?

Why is it that in some cases Families were encouraged not to have post-mortems and to accept a natural cause of death? Was this due to a lack of insight? A lack of curiosity? Or was that because somebody was covering something up?

Why were the external bodies not better informed? Why were they misled, as the Families believe they were?

Looking at the reaction to suspicions when they were actually raised, it is clear that there is evidence to suggest that from the point of October 2015 onwards, consultants were beginning to feel or express concern that there may be a malign influence at work in the unit.

The Families of Child J, K and Children O and P, who follow on from the death of Child I in 2015, are obviously concerned to discover that there were suspicions that Lucy Letby was deliberately harming patients before their children suffered harm.

They considered there was a failure to safeguard their children in the presence of a suspected or known threat, or at least one that had been identified by some

senior clinicians on the unit. They will ask why the existence of those concerns did not lead to earlier escalation and safeguarding and insofar as concerns were raised and escalated, as it was clear as time went on that this did happen in a more persistent and vocal way, why were these concerns not acted upon sooner or and more effectively?

To all the Families affected by Lucy Letby's crimes it is an anathema that those that provide healthcare to children would owe strict safeguarding duties and have a clear structure to deal with safeguarding concerns where they suspected that parents or other family members were causing harm to their children, but would not regard themselves as owing similar duties or have similar structures that were concerned relating to harm caused by a colleague.

As a sidenote, my Lady, when considering your recommendations, it is important to note that the IICSA final report of 2022, Recommendation 13, suggests that there be mandatory safeguarding reporting for suspected sexual offences. That is an issue we would flag up now but return to later.

The reason why steps were not taken to recognise and act upon suspicions sooner is a key issue for this Inquiry to explore. The Families believe that attempts

to blow the whistle and escalate concerns were suppressed by the management at the Countess of Chester Hospital at the cost of further harm to victims. They believe that seven babies were murdered or harmed in the period following October 2015 because proper steps were not taken to explore those concerns, and that each successive delay allowed more harm to be caused.

The Families who are represented within this group believe that proper safeguarding in response to those concerns would have avoided harm and saved lives.

I will come on now, my Lady, to talk about communications, candour, honesty and transparency.

LADY JUSTICE THIRLWALL: Thank you.

MR BAKER: The failure to provide clear, complete and truthful information to the Families about the condition of their children, and any issues that have arisen in relation to their care in hospital, causes genuine and persistent harm. It causes parents to speculate as to why their children came to suffer harm, it prevents further questions being asked by parents that might have highlighted other concerns. It causes them to blame themselves for passing on illness or disease or genetic abnormalities to their children. It erodes the trust that they have in their own judgment and public trust in the probity of medical professionals or healthcare

organisations and institutions.

It affects the parents' relationships with other or future children, their experience of childbirth and pregnancy. It causes them to worry about the health of their surviving children, and their safety and the safety of others who are in the healthcare system.

If the Families accepted the information given to them by medical professionals at the Countess of Chester Hospital, they feel guilt and shame now that the truth has been revealed. They feel that they failed their children by not advocating more persistently on their behalf.

That sense is wrong but it is nonetheless potent. By the time the truth became known some, such as the parents of Child G, had made decisions and taken irrevocable steps based on incomplete, dishonest or fraudulent information.

If the Families questioned the advice they were given, they were put into conflict with the Trust, left to fight battles on their own with all the stress and anxiety that accompanies that process.

The truth when it was revealed did not provide them with comfort, as the damage had already been done. When the truth was revealed for the Families, it was done in a hurried and unexpected way, often not through proper

channels but through leaks to the media and newspapers and some even during the course of Lucy Letby's criminal trial. All the Families continued to discover new information during the Crown Court trial, and some will continue to discover it through this Inquiry.

The first issue identified by the Families in this group is that information wasn't provided about their children's condition. That's distinct from the duty of candour which I will discuss in a moment because it relates to the Families' experience about not being informed about their children's condition. It does not relate to failures to inform them of instances of poor healthcare or near misses, nor does it relate to failures to inform them about suspicions surrounding Lucy Letby.

Multiple examples in the Families' witness statements had family members discovering information about their baby's condition years after the event. And some Families, such as the Families of Child D, Child J and Child G, they were unaware of the number of times their children had collapsed until they heard evidence given at the Crown Court. Others were not kept up to date with the condition of their children despite attending the ward regularly. The Family of Child G were informed that the deterioration in her condition,

leading to her collapse on 7 September 2015, was "neonatal sepsis" and there was no evidence to support that conclusion, and it remains a dubious one in the eyes of those who treated her. Her collapse was unexplained but they were not told.

The Family of Child K were not informed that their child's endotracheal tube had dislodged on three occasions causing her to desaturate or that she required active resuscitation. Her parents believed that had this information been provided to them, they would have asked questions about how this could have occurred and were left with the sense that this information could have provided them with an opportunity to advocate for their daughter, and question why the tube was repeatedly dislodged.

The Family of Child F were not informed that he had suffered a prolonged episode of hypoglycaemia and were instead told that he had suffered an infection in his long line, but was responding well to antibiotics. The first time that Mother F discovered that her child had suffered an episode of hypoglycaemia coincided with being told by the police that he required an MRI scan to look for signs of hypoglycaemic damage to his brain. She was then left to work out how this damage may have occurring by undertaking her own research.

This is important. Providing accurate and timely information permits parents to take part in decision-making, consent to treatment, and provides them with the opportunity to advocate for their children. It is therefore an important element in achieving person-centred care in accordance with Regulation 9 of the Health and Social Care Act Regulations of 2014.

On a more basic level, providing accurate information to parents is a bedrock of compassionate healthcare. Parents should have the opportunity to know as much or as little about the condition of their child as they choose. Discovering that a child who you assumed to be doing well is in fact critically unwell is shocking and traumatising.

Discovering years after the event that your child's learning disabilities were caused by an episode of hypoglycaemia as a newborn deprives you of the opportunity to understand their condition and seek appropriate rehabilitation or support and advocate on their behalf through healthcare and education systems.

It may also dispel an insidious sense experienced by many Families that their condition was in some way caused by them. The effects of removing agency from parents are obvious and stark but eloquently summed up by Mother H in her witness statement and I quote:

"I felt as though [Child H] was not my baby because I did not have much of a say. I had to hand over all care and I was limited to seeing her at visiting hours."

The lack of support persisted beyond the point where harm had been caused. The Families whose children survived were provided with little, if any, information about what had happened to them. Those who lost babies were not provided with adequate bereavement support. It is not asking much that a hospital provide bereavement support to those who have suffered loss.

Mother EF was so moved by the inadequacy of the support provided to her following the death of Child E that she trained to become a bereavement counsellor.

Coming on to candour, you have heard, my Lady -- and will hear -- about the duty of candour as it was introduced in December 2014, and what it is intended to achieve. The duty was not followed, my Lady, in respect of any of the Families whom I represent at any point. The Families would like to know why this was the case, and whether the duty of candour is sufficiently robust in its present formulation.

It is notable that many parents found out about the suspicions regarding Lucy Letby for the first time through news reports, or when they were contacted by the police. Father C heard about investigations into the

unit when a friend sent him a link to an article in the Cheshire Chronicle. Mother C first became aware of the article when she received it from him. She was heavily pregnant at the time and had attended multiple appointments at the Countess of Chester Hospital. She attended, on her own will, the Bereavement Office at the Countess of Chester Hospital, and then refused to leave until she had been seen.

It was only then, after waiting, that she was informed that her son was part of a police investigation. She should not have been put in that position. She should not have been forced to be "difficult" in order to find out such basic information about her child.

Mother and Father C were only informed that there was a suspicion of deliberate harm by a member of nursing staff when they received a telephone call from Cheshire Police between 6 am and 7 am on the day of Lucy Letby's arrest.

Mother and Father G had the same experience, as did Mother and Father H.

Child K's parents were unaware that there had been any issues with their daughter's care until they were contacted by the police in May 2017.

The Family of Child J first became aware of issues

in the unit when they read about it in the newspapers.

There are also examples of parents not being informed about suspected substandard care in relation to their children.

Mother OPR was unaware that Datix reports had been created in respect of her son's care until she attended the Crown Court trial.

The Family of Child H were unaware that their daughter had been the victim of suboptimal or negligent care.

Mother D was told that there was no requirement for IV antibiotics earlier, during her labour, despite this being contrary to guidelines, and despite it having been identified in a Datix report complete following the death of Child D.

Mother D was not given any explanation as to why her daughter, who was stable when Mother D was sent away from the unit, had suddenly and unexpectedly deteriorated and died. Within the same Datix report, it is noted there had been an opportunity to provide an additional dose of intravenous antibiotics to Child D.

Her parents were never informed about this. Jane Hawdon's report in October 2016 identified the delay in providing antibiotics as "major suboptimal care" and "probably relevant" to outcome. Despite this,

Mother and Father D were not informed of issues in relation to the care provided to their daughter. In February 2018, Child D's case was discussed at a meeting with Margaret Bowron, Queen's Counsel, and described by her as "indefensible".

There is no evidence that the parents were shown proper candour and that this conclusion was communicated to them at this time.

This lack of transparency, we would say, extended to the interactions with the coroner, who was provided with witness statements from the Trust in 2016 that identified that no errors were involved in the care provided to Child D, an impression that was not corrected until the coroner was informed of police investigations in 2017.

The Families were unaware that the Countess of Chester Hospital had requested an investigation from the Royal College of Paediatrics and Child Health and the Royal College of Nursing and many have heard about that for the first time when they received a letter from Ian Harvey dated 8 February 2017. The full report was not sent to the Families and they were not able to access this for many months.

The Families were not provided with Jane Hawdon's report which was available from October 2016 and which

had been provided to the consultant paediatricians at the hospital, along with the Royal College report on 3 February 2017.

The Families were given little, if any, notice that a report would have been released before they received a letter in 2017, with some only being contacted after the report had been released to the public, and this caused considerable distress, and in the case of Family OPR, had been directly contrary to an undertaking given to the coroner's office. The lack of proper communication was woeful. It compounded the harm to the Families, and eroded what trust, if any, was left.

When the version of the RCPCH report was finally provided to the Families, it was different. It had been redacted from the final report that had been provided to the Countess of Chester Hospital, and all references to the suspicions regarding Letby had been removed.

The Families regard the decision to redact the report before sending it to them as a blatant lack of transparency and candour on the part of the Trust. They regard it as dishonest. If they had known about these concerns, they would have asked why the police had not been contacted. Had the Families been aware that suspicions expressed were in the unredacted RCPCH report, they would have contacted the police themselves.

They were similarly concerned that the report and the Royal College did not itself recognise that the suspicions raised by the consultants warranted immediate involvement of the police.

Finally coming on to honesty.

The Families do not regard the lack of candour or transparency in the Countess of Chester Hospital's communications with them as a product of uncertain principles, rules or policies. They believe that the management of the Countess of Chester Hospital were dishonest, that they covered up and suppressed the concerns that were being expressed about Lucy Letby's conduct in the unit, and the harms she had caused to their children. The motives for doing this may be multifarious, but the need to protect reputations appears to be a common refrain.

If that was the motive, it should be condemned in the strongest possible terms. The reputation of a Trust and its managers is subordinate to the need to protect patient safety and the need to provide injured parties with truth and recompense.

The Families will say that the excuses advertised in some statements that it is better to protect the reputation of an NHS hospital because of the greater good that it serves are feeble and self-serving. The

reputation of a hospital and of the NHS as a wider organisation is predicated upon its ability to serve its community. Dishonesty corrupts its reputation and erodes trust in both the hospital and the NHS.

The Families will say that the Trust's interactions with them, especially following June 2016, were lacking in transparency and were dishonest. There are numerous examples of this, but the experiences of Mother C we will say are particularly apposite. She was contacted by Sian Williams on 3 February 2017 and informed that there had been a leak of information regarding investigations in the unit, and that an article would be published in the Sunday Times that weekend.

Having picked up a copy of the report upon returning from holiday, she wrote a long letter to Ian Harvey on 7 February 2017. That letter set out a poor history of communication from the Trust and included the words:

"The report does strike me as having some suspicion that there were some unusual features of the deaths of the babies on the unit and that perhaps there was something going on in the unit that caused or at least contributed to the increase in mortality."

Mother C subsequently attended a meeting with Ian Harvey in February 2017. She describes that meeting in her witness statement. I quote:

"Ian Harvey apologised to us for the poor communication. He advised us that some small areas that could be improved upon had been noted in the review of Child C's care but nothing of concern. There was nothing that could have been changed about his care that would have affected the outcome and prevented his death. We were relieved to hear this. This is what we wanted to hear and we are aware that nothing ever goes perfectly, so we had expected some areas of improvement to be noted. The conclusion of the investigation would allow us to move forward and not have this investigation and uncertainty hanging over us."

If the Inquiry accepts Mother C's evidence on this issue, Ian Harvey lied to her. At the time of the meeting, he was in possession of a report from Jane Hawdon that criticised the quality of care provided to Child C, and concluded that his death may have been preventable, had the standard of care been better. Ian Harvey was aware at the time of this meeting that serious concerns had been expressed by consultants in the unit that Lucy Letby had been deliberately involved in harming patients on the unit, including Child C. He was aware that the Mother and Father C had been provided with an incomplete version of the Royal College report which omitted references to that issue.

Ian Harvey wrote to Mother and Father C, as he did to other affected Families, on 3 March 2017 stating that the review had "indicated that a small number of areas of investigation are required and I aim to undertake this as quickly as possible". This is despite him advising some media outlets in February 2017 that the Trust had acted swiftly and that the reviews had been complete.

You may think it notable that Tony Chambers had received a letter on 1 March 2017 signed by seven consultants on the unit, expressing their concerns that "the unexpected collapses had not even yet been adequately investigated", levelling legitimate criticism of the quality and independence of investigations undertaken thus far and requesting a "broad forensic review".

My Lady, it is implausible that Mr Harvey was unaware of the strength of feeling amongst the consultants in the unit at this stage, or that he did not recognise the limits of the investigation undertaken.

His letter to the parents was therefore at best a serious distortion of the truth; at worst, an outright lie.

Mother C requested a full and unredacted copy of the

Royal College report having appreciated the one she had seen was incomplete. When Ian Harvey wrote to her on 28 April he did not attach a full copy of the report but referred to the earlier disclosure.

His letter is notable in two respects. Firstly, the version of Jane Hawdon report attached to the letter is incomplete and omits a supplementary conclusion categorising the standard of care received by Child C, and secondly and perhaps more importantly it omitted to mention that he had on the previous day attended a meeting with the representatives of the Cheshire Constabulary following which he had been advised to write a formal letter to the Chief Constable of the Cheshire Constabulary requesting a forensic review.

A specifically incomplete and misleading letter was sent to Mother E and F on the same date.

The Families regard the approach of the Trust during this period as going beyond a lack of candour. They believe that the senior management of the Countess of Chester deliberately misled them in order to hide the truth, in order to protect their own reputations and those of the Trust. Their actions represented a gross derogation of their duties of managers of a public body, and the families would like to know why a culture has developed that would allow this to happen.

The Families also believe that the lack of transparency shown towards them is evidenced in the Countess of Chester Hospital's interactions with other individuals and organisations. The Families note that Jane Hawdon does not appear to have been informed of the suspicions regarding Lucy Letby when she prepared her report, information that she would have regarded as relevant. Had she been informed, she would have contacted Ian Harvey and urged him to follow the appropriate Trust safeguarding and governance processes.

She was not informed of the pattern of deaths and unusual incidence had ceased with the removal of a member of staff. Had she been informed, she said she would have contacted Ian Harvey and urged him to follow appropriate Trust safeguarding and governance procedures.

The Families are concerned the Countess of Chester's motivations in providing imperfect information to Jane Hawdon were motivated by a desire to whitewash the truth and the Families will say there is no other or better explanation.

The Families also note that inaccurate or incomplete information was provided to the coroner. They are concerned that this information was hidden from the coroner as a means of avoiding scrutiny that an inquest

might bring to bear.

And the Families are also concerned that the use of external bodies such as the Royal College and review by Jane Hawdon were not undertaken with a genuine desire to find out the truth behind the incidents that had occurred; they were concerned that they were chosen because they would undertake a superficially comprehensive but in reality incomplete review of the issues being complained of since the Royal College in particular was entirely ill-equipped to explore whether crimes were being committed by a member of staff.

The report from the Royal College when it was obtained emphasised the positive more loudly than the negative issues, allowing censure to be drowned out by congratulation.

The process by which the report was redacted and edited before being provided to the Families might provide them with the impression that the Royal College and the Countess of Chester were fulfilling their key duties whilst hiding key facts from them.

My Lady, in conclusion, the Families fully support the aims of this Inquiry. The themes discussed above are a summary of their key concerns, which should not be taken to be final or comprehensive.

I of course adopt every word and submission made on

behalf of the other Families by Mr Skelton, and agree with him entirely.

The Families are indeed thankful of the opportunities to give their accounts of their experiences and in due course, hear the accounts of others and their explanations for their actions.

The Families' ultimate goal is to ensure that their experiences are not repeated. The desire is however tainted by the sadness of events that brought the Families to this Inquiry.

In my final words, I would like to return to one central theme that runs through the evidence of all the parents.

To them, their babies were miracles. They were often conceived against the odds, sometimes facing adversity from the moment of their births. Lives that were hoped for and cherished, every moment filled with hope and potential.

The babies had conquered considerable adversity when they were attacked or murdered, and this sense of hope interrupted is profoundly poignant. This is encapsulated perfectly in the words of Father G:

"For me, what happened has damaged my faith as every day I would sit there and pray. I would pray for God to save her. He did. He saved her. But the devil found

her."

My Lady, that's all I have to say.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Mr Baker.

If I can thank you and Mr Skelton for the considerable efforts that you have made on behalf of the parents, which is no more than they deserve, I appreciate, but the Inquiry is grateful for the fact that we have so many witness statements from them despite the rollercoaster of emotions that they must have been through in recent weeks and months, and of course in the years before that, so I am grateful to you both.

MR BAKER: Thank you, my Lady.

LADY JUSTICE THIRLWALL: We will rise now until 11.30.

(11.15 am)

(A short break)

(11.30 am)

LADY JUSTICE THIRLWALL: Mr Kennedy?

Opening statement by MR KENNEDY

MR KENNEDY: My Lady, I make this opening statement on behalf of the Countess of Chester NHS Foundation Trust.

My Lady, at the time that we drafted our written opening note, we had not had sight of many of the statements provided to the Inquiry by parents whose

babies were harmed or murdered by Letby. As we said in that opening statement, the traumatic nature of the events was laid bare in the statements that the parents provided for the criminal proceedings. This impression is magnified by the statements that they had provided for your Inquiry. They bring home the horror of these events.

As we said in our written opening, the babies, their parents and Families have been and will remain in the Trust's thoughts throughout. The Trust has the utmost sympathy for their suffering.

We agree with Mr Skelton, King's Counsel, when he echoes the words of the Secretary of State when commissioning this Inquiry, that "losing a child is the greatest sorrow any parent can experience".

But we would add this: those who have not experienced that loss will never truly understand the magnitude of their loss, nor will they truly understand the impact of hopes for the future being destroyed.

My Lady, the Trust is committed to being open, honest and transparent in its contribution to this Inquiry. It does not and will not seek to shirk or avoid its responsibilities for the events you are about to inquire into.

In our written opening we identified failings on

behalf of the Trust. As the evidence unfolds, we will continue to review the Trust's position so that when we come to prepare closing submissions, we hope to be able to provide you and the Families with our considered and reasoned analysis of where things went wrong, how things should have been done better, what lessons the Trust has learned and still needs to learn.

That said, my Lady, you will understand, and I hope the Families will appreciate also, that we represent a range of different disciplines amongst the Trust employees and former employees, and navigating and reconciling their different perspectives and positions may be a challenging task and it may at times be an impossible task, but we will do the best that we are able to do.

My Lady, I don't propose to read out my written opening, nor to revisit the all the issues that we addressed. What I propose to do in this opening is just to touch on three or four key aspects of the Inquiry as revealed by either the opening statement of your counsel, or by the written openings of other Core Participants.

Those are: firstly communication; secondly, the chronology of what was known or suspected about Letby and when; thirdly, investigations; and finally, I will

say a word or two, if I may, about changes.

My Lady, I can provided an electronic copy of my speaking note in due course.

LADY JUSTICE THIRLWALL: Thank you.

MR KENNEDY: My Lady, in terms of communication, the opening statements on the part of the Families and the opening statement on the part of your counsel identify multiple concerns so far as communication is concerned. They are amplified by what my learned friend Mr Baker, King's Counsel, has said to you just now.

We anticipated some of those points, and I would like, if I may, just to reiterate those points now, as we set out in our written opening.

The Trust accepts that from July 2016, there were significant communication failings, such that it failed in its duty of candour towards parents.

I identify six points.

First, in July 2016, when the neonatal unit was downgraded and the RCPCH review was commissioned, for some parents, there was no contact at all. For others, efforts to make contact were unsuccessful, whether because they were half-hearted or ill thought through.

Second, again as Mr Baker has told you, some parents learned about the downgrading of the unit or the RCPCH review through the news media.

Third, in many instances, the communication plan put in place was reactive rather than proactive; that is, the focus appeared to be on families and patients who were likely to make contact with the Countess, rather than on those who could reasonably be identified as being intimately affected by the issues that had resulted in the downgrade.

Fourth, between July 2016 and the announcement of the downgrade and the College review and February 2017, there does not appear to have been any formal communication strategy at all, with the effect that there was no or no meaningful communication provided to the Families.

When there was communication in February 2016 it was frankly haphazard and for a parent to have the College report delivered by taxi out of the blue was inexcusable.

Finally, when information was provided, it was provided in an inaccessible form and I have in mind Dr Howden's review, which was comprehensible only by the informed reader or doctor, but certainly not by the layperson and which omitted to include, vitally, her conclusions in relation to the particular child that she was addressing.

My Lady, for those failings the Trust apologises

without reservation.

My Lady, the Family Groups have flagged three further communication issues, and if I may just address those briefly with my observations.

First, they have questioned the provision of information at around the time of the collapses. I have in mind particularly what my learned friend Mr Baker has said to you just before the break.

In our written opening we concluded, largely based on the statements the parents had made to the police, that communication at around the time of collapses and/or death was generally satisfactory.

Now that we have seen the statements from the Families, we will review that position. We have endeavoured, as part of the evidence outline exercise that you indicated, to flag to your counsel the additional evidence that may exist which may clarify or assist in understanding the issue that is raised. We will continue to do that as part of the evidence outline exercise.

Second --

LADY JUSTICE THIRLWALL: Sorry to interrupt you, Mr Kennedy. Endeavour to flag the additional evidence which may exist?

MR KENNEDY: Endeavour to point to evidence which may

assist.

LADY JUSTICE THIRLWALL: Assist. I'm so sorry, I misheard you.

MR KENNEDY: Assist in clarifying the position.

I have in mind that in the core bundle, there are, is a more limited set of medical records and there is a greater bundle albeit not a complete bundle, available on relativity and we are doing an exercise of cross-checking both to try and assist.

LADY JUSTICE THIRLWALL: Thank you.

MR KENNEDY: Thank you.

Second, both my learned friend Mr Skelton and Mr Baker have raised the question of what could the Trust and what should the Trust have said about suspicions about Letby both before and after July 2016? As we observed in our written opening, this is a complex issue. It involves balancing of competing interests. In our written opening we identified the following issues that the Inquiry may wish to consider.

First, the need to be open and transparent to further patient choice and autonomy and promote patient safety.

Second, the risks of inaccuracy in communication, or unhelpful vagueness, if disclosure is made at an early stage.

Third, a loss of confidence in service provision if concerns turn out to be misplaced.

And fourth, the impact that such communication may have on the potentially innocent individual concerned, both from a wellbeing and employment perspective.

We don't have an easy answer to that, and it may be that is something we can return to when we provide our closing submissions.

The third point that has arisen through the Families, particularly the Families' opening statements, is the lack of information provided by the Trust once the police investigation commenced in May 2017. We recognise that from material disclosed by the Inquiry that similar concerns were expressed through the Family Liaison Officer in the course of the criminal proceedings.

Now that this issue has been identified, we will endeavour to clarify what instructions, if any, the Trust was given about communication or not communicating with the Families.

We would observe at this stage, subject to that further clarification, that it would seem likely that there would have been some restrictions imposed by the police on the Trust about providing information to the Families concerning Letby. But again, we will revisit

that if we may, in the course of your Inquiry.

My second point was that the suspicions and concerns about Letby, as is apparent from the title to Chapter 1 of your counsels' submissions, that is the core theme for this Inquiry. We have suggested that March 2016 is an important date and a point after which there was an opportunity to act.

My Lady, I don't propose to revisit the detailed chronological review that my learned friends undertook on Tuesday and Wednesday; nor indeed the features that I set out in our opening. We would just point out the following points as being relevant to a consideration of the position by March 2016.

Firstly, there had been what is referred to as an Executive Serious Incident Panel on the 2 July 2015. That considered the deaths of Babies A, C and D. This had been attended by Dr Brearey, Ms Powell, Ms Millford, Ms Peacock and Alison Kelly. There would be a further Serious Incident Panel for Baby E in August.

By October 2015, Ms Powell's review of the mortality in the neonatal unit had identified Letby as being present at the events reviewed.

In November 2015, Dr Brigham's review had notified "a perceived increase in the number of stillbirths and neonatal deaths", and that review was discussed at QSPEC

in December.

In February 2016, the thematic review of neonatal mortality attended by Dr Brearey and Dr Subhedar had identified a higher than expected mortality rate on the neonatal unit for 2015.

The results of that review, and the follow-up exercise, were communicated to members of the Senior Management Team on 21 March 2016. Therefore, by 21 March 2016, the information available to those in senior clinical, managerial and Executive posts was such that we recognise that there were legitimate questions concerning the Trust's response to concerns about mortality. More importantly, there was a clear opportunity to act.

Whether actions should have been taken before March 2016 will clearly need to be explored in oral evidence. Without hearing obviously the evidence, we suggest at this stage that up to that point the reasonable focus was on identifying a clinical explanation for events. It is, we submit, important to keep in mind the realities of medical practice in a busy acute hospital.

Whilst periods of elevated morbidity and mortality will occur from time to time, instances of deliberate harm by healthcare staff are exceedingly rare. When

a period of elevated mortality is observed, the cause is therefore likely to be a product of random variations in outcome due to medical factors, particularly where numbers are small. Insofar as the cause is related to a member of staff, it is far, far more likely to be a competency issue than be due to criminality.

The criticism is made that there was an unwillingness to think the unthinkable. My Lady, that may well be a valid criticism but it is one that we suggest that carries greater force the later in the chronology one proceeds.

Earlier in the chronology -- and I bear in mind everything that my learned friend Mr Skelton in particular has said about Allitt and others, but earlier in the chronology, you may feel that it was understandable to be reluctant or to fail to think the unthinkable.

My Lady, we identified in our written submissions the themes that we believe the Inquiry should explore concerning the adequacy of the Trust's subsequent response. I don't propose to repeat them. They've been set out in similar terms, and amplified by your counsel in her opening on Tuesday.

A word, if I may, about investigations, reporting and debriefs.

My Lady, a common theme from the written opening statements are questions about the quality of the local investigations, and whether there was a failure properly to utilise the reporting structures within the Trust. This too, clearly, will be an important issue for the Inquiry to address.

I want, if I may, just to address three points.

First, the use of Datix and internal investigation; second, the failure to use accepted or normal reporting mechanisms; and thirdly, as I indicated, the question of debriefs.

Your counsel in her review on Tuesday, for understandable reasons, took you through a chronological review of deaths and responses to deaths. It may be helpful just briefly to look at matters from the perspective of the actions that were taken, to try to perhaps bring together the points that she was making.

I just identify these points. Firstly, the deaths of Babies A, C, D, E, I, O and P, so that is all of the deaths on the indictment, were all reported under the Trust's Datix system.

Second, for all of those babies, save for Baby I, there was a Serious Incident Panel meeting, or as it's sometimes termed, an Executive Serious Incident Panel meeting. That was attended by a clinician or

clinicians, by members of the Risk and Patient Safety Team, and by one or both of Alison Kelly and Ian Harvey.

Third, the deaths of Babies A, E, D and I were reported to the Neonatal Incident Review Group. The deaths of Babies O and P were recorded as National Patient Safety Alert Incidents Level 2.

The deaths of all babies on the indictment who died at the Countess of Chester were reported to the coroner. Your core bundle contains the relevant form for each of those babies.

Finally, in terms of actions at the hospital, the deaths of Babies D, O and P were recorded on NHS England's Strategic Executive Information System.

Briefly as to what happened locally, so outside the hospital, in terms of wider investigation the available witness evidence indicates that each of the deaths was notified, whether under the CDOP procedure in England, or the CDRP process in Wales.

In contrast, we accept that the available evidence suggests that non-fatal collapses were not or not consistently reported on Datix.

The opening note for Family Group 1 refers to a section of the RCPCH report which cites guidance from the British Association of Perinatal Medicine to the effect that:

"All infants who suffer a sudden and unexpected cardio-respiratory collapse within the first week of life should undergo comprehensive investigation to determine the underlying cause."

My Lady, we understand from the evidence of Dr Brearey that that guidance may not be applicable in the non-fatal cases or some of the non-fatal collapses that you are considering. That is because that guidance is directed at term, or near term, babies. I think in 2011 the guidance was babies born at or after 37 weeks. But significantly who were deemed well enough to have routine postnatal care. The updated guidance which was published in 2022 is available on Relativity.

It differs, at least to this extent, to the 2011 guidance, in that the threshold for a term of near term baby is lower, so that it captures babies born at or after 35 weeks' gestation.

That said, so acknowledging the points made by my learned friend Mr Skelton and the point made by Dr Brearey perhaps in response, we acknowledge that it will be an important question for your Inquiry as to whether non-fatal collapses should have been reported on Datix, and if the Trust did not uniformly do that, whether it was an outlier.

We just make these three short points at this stage.

First the Inquiry will need to consider whether the Datix reporting system is or should be outcome driven. Is it intended to capture failings in care regardless of the harm which results, or should it constitute a record of patient deteriorations?

Second, the Inquiry will need to bear in mind that premature babies who require care on a neonatal unit, such as at the Countess, are likely to experience deteriorations or episodes of instability. Some of those episodes will be more serious than others. There may be a difficulty, we suggest, and the Inquiry may wish to consider, in articulating the threshold for a "reportable" deterioration.

And third, how those two factors should be balanced so that significant patient safety incidents are not lost in the reporting or potential reporting of common or more routine occurrences.

My Lady, if I may, a word about the root of reporting.

Your counsel and others have questioned an apparent failure to follow normal reporting structures and provides devised by the Trust and set out in its policies. We make three brief points that we would invite you to bear in mind.

First, you may want to consider whether the nature

of the concerns being reported, or being raised, were such that they did not fit neatly into the reporting processes or structures in place.

Second, even if it is correct that an inappropriate reporting process was followed, so sending an email rather than reporting through a recognised structure, even if an inappropriate process was followed, that could not and should not detract from or diminish the seriousness of the issue that was being raised, ie, the substance of the concern is more important than the mechanism of its delivery.

Third, you may wish to consider that given the nature of the concerns being raised, can it be said that an email to an individual or individuals at the top of the reporting structure is inappropriate?

My Lady, a word or two, if I may, about debriefs. My learned friends for Family Group 1 have flagged up the use or non-use of debriefs. We agree that that is an issue that the Inquiry will wish to investigate. The evidence in your core bundle shows that there was what is sometimes referred to as a "hot debrief", following the death of Baby C and the death of Baby I. And there is evidence, as your counsel indicated on Tuesday, of attempts to organise a debrief following the death of Baby D.

Again, as this issue has arisen as perhaps an important one, we will endeavour to do some more work behind the scenes and see if we can assist you further as to whether there is any additional information about debriefs, and whether, for instance, the plan for a debrief for Baby D was successful. And if we may, my Lady, we'll liaise with your counsel in that regard.

LADY JUSTICE THIRLWALL: Thank you.

MR KENNEDY: But may I just say this at this stage: we understand why it might be felt that a debrief can serve as an adjunct to an investigation into the cause of death or it may serve to prevent future deaths. We particularly understand that point being made when it is felt that the investigation that was in fact carried out was deficient.

However, it is important to understand and bear in mind the purpose or objective of a debrief. It was set out in the Royal College report at paragraph 4.3.5 in the following terms:

"Following an incident, there is a team debrief organised almost immediately to reflect on the situation and provide support and learning."

There is other guidance available that indicates that there is a need for acknowledgment of traumatic events, and the provision of practical and emotional

support for those involved. And, my Lady, you'll recall what my learned friend Ms Langdale said on Tuesday about the effects on those who were providing care during these events.

So debrief, we would suggest, is intended to be a source of peer-to-peer support, to improve staff wellbeing and learn lessons after traumatic events. It's unlikely to be appropriate mechanism for establishing that an individual's acts or omissions caused the event.

My Lady, a word, if I may, again arising from what has been said in the written openings of others, about hindsight. I touched on it in my written opening. I don't propose to reiterate what I've said there.

The point is just this: in the evidence that we have seen, at times a contrast is drawn between the information provided by clinicians about the causes of death or collapse and the information that the Families learned from the criminal trial.

It is sometimes said that it was only following the criminal investigations that Families have had answers about what happened to their children. Mr Baker particularly has mentioned that before the break.

We recognise how distressing it must be to discover this so many years later. But we say we would suggest

it must be borne in mind that the criminal justice process brought to bear a different magnitude of investigation and analysis. Whilst you will obviously wish to inquire into the adequacy of the information provided by the clinicians at the Countess of Chester at the time of collapses or death, we suggest that they should not be faulted simply because they did not provide the answers that were subsequently provided through the criminal justice process, with, as I say, its much greater focus on the investigation of causes of death.

My Lady, can I then turn as my last point just to say a word or two about changes.

We appreciate, because it was an issue you asked us to address, and it is obviously an issue that is at the forefront of the Inquiry's mind, it will also be an important issue for the Families and perhaps for the wider public.

We address this in our written opening and so, if I may, I just highlight one or two points, again, trying to pick up, if I may, what has been said in opening statements by others.

Firstly, there have been changes in the divisional structure within the Countess of Chester to bring paediatrics -- and that includes neonatology -- and

obstetrics into a single division. As your counsel explained in, in 2015 and 2016, obstetrics was within a Planned Care Division, and paediatrics and neonatology within an Urgent Care Division.

A new Women and Children's Division is now led by a tripartite management team who are members of the Operational Management Board that provides assurance on effective management to the Trust board.

Second, the Trust has opened a neonatal unit which is larger and more modern where it is possible to facilitate family integrated care. You may hear more about that in the course of this Inquiry.

Third, a new Women and Children's Unit is under construction.

Fourth, there have been changes in what I will refer to as service oversight. The Clinical Lead for Neonatal Risk has dedicated time to oversee risk management, and a Perinatal Assurance and Improvement Board oversees perinatal services generally. There are Executive and Non-Executive Safety Champions for the neonatal unit and maternity services and the Executive Champion is the Deputy Chief Executive.

Fifth, the current board has implemented a programme of governance changes from ward level to board level.

And finally, the Trust has endeavoured to strengthen

its Speak Up initiatives, and has replaced previous initiatives with the Freedom to Speak Up Initiative.

My Lady, can I end my opening in this way: the Trust welcomes your Inquiry. Its work is vitally important in providing answers to the parents of babies harmed or murdered by Letby. The Trust remains committed to assist in any way it can, and it recognises that the Inquiry will identify failings on its part and potentially on the part of others. That is a vital exercise, so that it, and the wider NHS, may learn from those failings.

My Lady, that is the opening statement on behalf of the Trust.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Mr Kennedy.

Opening statement by MS JONES

MS JONES: My Lady, I, with Victoria Butler-Cole, King's Counsel, represent the Nursing and Midwifery Council instructed by the NMC's in-house legal team. May I first take this opportunity to express on behalf of everyone at the NMC our sincere and heartfelt condolences to the Families and loved ones of the babies who were harmed or killed by Lucy Letby.

We know that having a baby is one of, if not the most, important moment in any parents' life. Every

child's life is sacred and protecting babies and children from harm is fundamental. To have a baby's life intentionally harmed or taken away is devastating. It grossly undermines basic human morals and should never, ever be allowed to happen. Our thoughts are with the Families of those involved in this Inquiry who are rightly front and centre of the Inquiry's investigatory process.

As your Ladyship will know, the NMC is the regulatory body for individual nursing and midwifery professionals in the UK. Our overarching objective is the protection of the public. Our principal functions are to establish high professional standards of education, training, conduct and performance for nurses, midwives and nursing associates and to ensure the maintenance of those standards.

The NMC maintains a register of over 826,000 nursing and midwifery professionals eligible to practice. The NMC investigates fitness to practise concerns about individual nurses, midwives and nursing associates.

We welcome the Inquiry and its wide Terms of Reference and we will do all we can to cooperate and assist your Ladyships and Counsel to the Inquiry in its important work.

We agree with your Ladyship's opening message last

year that babies in neonatal units absolutely must be kept safe and well and that any barriers that hinder that proposition must be identified and eradicated so that the unacceptable and heinous acts committed by Lucy Letby can never be repeated.

On the request of the Inquiry team we have already provided four witness statements, three from Andrea Sutcliffe, former Chief Executive and Registrar of the NMC, and one from Helen Herniman, Acting Chief Executive and Registrar of the NMC who was present on the first day of the Inquiry and who sits with me today. Tony Newman, Regulation Adviser for the NMC's Employer Link Service has also provided a statement to you and we will support him in giving evidence. We have also provided a significant number of documents by way of disclosure.

In this opening statement, I will not seek to repeat what we have already said in our written submissions and I do hope that a copy of this opening note has now been provided to your Ladyship.

LADY JUSTICE THIRLWALL: It is in front of me.

MS JONES: Excellent. Instead I would like to focus our submissions on four key matters that have been raised by Counsel to the Inquiry and Core Participants in their written statements.

Before I turn to those matters it is important for me to say that the NMC has reflected on the steps it could and should have taken at the time it became involved in 2016, and we have identified a number of areas of improvement. At the end of 2022 we established an internal working group to prepare for and learn the lessons arising from Lucy Letby's trial.

As we have outlined in our opening written statement and witness statements, the NMC has taken serious steps to review its processes, to learn lessons and to implement or begin to implement practical measures to ensure that it can play its part in the prevention of the deplorable acts committed by Lucy Letby but the NMC continues to reflect and learn lessons and we intend to listen closely to the evidence of the Inquiry and learn from any further evidence that the Inquiry uncovers.

We stand ready to engage with the Inquiry on implementing any recommendations that the Inquiry considers necessary to direct towards us.

We are also in a process of reflection. As your Ladyship will know, the NMC commissioned Nasir Azfal and Rise Associates to undertake a review into our organisational culture. That review was published on 9 July this year. It made 36 recommendations to us. The commissioning of the review was unconnected to the

Lucy Letby case, but the review has raised serious concerns over how we regulate.

We have already, but do so again, apologise wholeheartedly with the failings identified in that review. We are committed to learning the lessons identified, to improve the cultural behaviours that strike at the heart of our organisation, and to better our regulatory performance.

The review included number of recommendations relevant, we believe, to the Inquiry's Terms of Reference, particularly in respect of safeguarding and collaborative working with other agencies; recommending that complex and serious cases should be managed by a specialist team; recommending that there needs to be a clearly defined process for managing fitness to practise cases when a criminal case is under way; and that all staff should have an awareness of their safeguarding obligation.

The review also noted the lack of a clinical voice in decision making, and recommended that the NMC, and I quote:

"... must ensure that the right people are in the right place at the right time to enable the right decisions to be made, whether that's clinical, safeguarding, legal, or other specialist areas."

We agree. We have accepted all of the recommendations and I will speak later about the steps we are taking to work towards their implementation.

Turning then to the four matters, if I may. First, I will seek to briefly explain our fitness to practise investigation process and update the Inquiry on the regulatory actions that the NMC has taken.

Having heard Counsel to the Inquiry's excellent opening submissions, we appreciate that it is a particular focus of this Inquiry to understand why the NMC did not impose any condition on Lucy Letby's practice or suspend her from practising until she was charged with murder, and why an NMC fitness to practise investigation was not commenced until 5 July 2018.

The Nursing and Midwifery Order 2001 grants the NMC powers to take action where a concern is raised about a nurse, a midwife, or nursing associate's fitness to practise and where action needs to be taken to protect the public and maintain public trust and confidence in the profession. We have powers of self-referral and disclosure but we can only investigate and reach a decision in a case if we have sufficient evidence of a concern to commence an investigation. We rely on the referrer to provide the information to us because the referrer is closest to the source of the risk and events

happening on the ground.

The advice that the Employer Link Service or anyone responding to an enquiry about a fitness to practise concern is dependent on the quality of the information on which it is based.

Before taking action, the NMC expects employers to act first to deal with concerns unless the risk to patients or the public is so serious that the NMC must step in to make immediate action.

Once a referral has been made to the NMC, the NMC can place a case on hold if the registrant is subject to an investigation by a third party, for example the police, where there are clear and compelling reasons to do so, and if it is in the public interest.

Where criminal proceedings are likely, it is common practice for the police to ask the NMC to put on hold the fitness to practise investigation until the conclusion of the criminal trial. This is because there is often a real and significant risk that our investigation will prejudice the other investigation and it is impractical to run the investigations concurrently.

It is also often the case that the outcome of a police investigation will be relevant to our own decision on whether to take regulatory action.

As you heard from your counsel, my Lady, throughout a fitness to practise investigation, the NMC does have the power to seek and impose an Interim Order, temporarily suspending practice or restricting the practice of the registrant. An Interim Order will be imposed where there is sufficient evidence of a case against a registrant and if it is necessary to protect the public or if it is otherwise in the public interest or the registrant's own interest. The registrant has the right to appeal that Interim Order.

Turning to the Lucy Letby investigation. The information we received from Alison Kelly in 2016 was that there was not sufficient evidence to initiate a referral. On 6 July 2016, when Alison Kelly first told the NMC's Employer Link Service of the concerns regarding a rise in neonatal mortality rates and concerns that Lucy Letby may present a serious risk to public safety, we were told that there was no evidence available at that time to support those concerns. As the Link Service advisor recalls in his witness statement, "the whole tenor of the call was that there was no specific evidence".

Alison Kelly stated that the Countess of Chester Executive Team was to meet on 6 July that day to decide whether to report Letby to the police. We were not

informed that discussions surrounding reporting Letby to the police had already taken place on 29 June. We were not provided with crucial documentation we now know the hospital possessed, such as the table prepared by Eirian Powell dated 19 January that year or the schedule preparing on 15 February. We were not told of the meetings that had been taking place between senior management, which Counsel to the Inquiry outlined in her opening statement.

As a result, our Employer Link Service advisor advised Alison Kelly that we needed to know both the Trust board's decision, whether to report to the police, and any subsequent action taken by the police.

LADY JUSTICE THIRLWALL: Yes, I'm just wondering, Ms Jones, if a call is received with the information that a nurse may present a serious risk to public safety, is there no sort of natural curiosity as to, you know, "Well, why are you saying that? Why are you phoning?"

MS JONES: And I will come on to that actually later on in my opening note, my Lady.

LADY JUSTICE THIRLWALL: Very well.

MS JONES: To proceed with the chronology, if I may, on 31 August 2016 when Alison Kelly replied to a request for an update from our Employer Link Service advisor, she explained that there was nothing significant

identified from a "thorough internal review", and although Lucy Letby had been placed on non-clinical duties there had been "no indication to discuss the matter with the police" and the medical director had commissioned an external review. No referral was made at that time.

Similarly, on 29 November 2016, at a meeting between Alison Kelly and others and our Employer Link Service advisor, Alison Kelly explained that "initial feedback" from the review by the Royal College of Paediatrics and Child Health was that there was "no immediate risk to patient safety which had been identified and therefore no referral will be made" and "no grounds for referral for the individual involved, ie, Letby". We were not sent the RCPCH reports.

We do appreciate Counsel to the Inquiry's concern that we did not initiate an investigation at this point, and it is worth stating that had we commenced a fitness to practise investigation, our legislative powers limit the scope of our investigation to narrowly focus on the professionals on our register. And we would welcome the Inquiry's careful scrutiny of who in this type of situation is best placed to investigate an unexplained increase in mortality rates and who would have had the Investigatory Powers Act jurisdiction to do so.

On 18 May 2017, we received a Countess of Chester Hospital press release that Cheshire Police have announced its own investigation into the neonatal deaths at the hospital. Our Employer Link Service spoke to Alison Kelly to obtain further information.

Alison Kelly advised that Letby had been placed on restricted duties, that the police investigation had just begun, and that Letby had, and I quote:

"... not been arrested, charged, or suggested to be a suspect as yet. She is a witness and she as well as numerous other colleagues will be interviewed as witnesses by the police."

The Employer Link Service advised Alison Kelly to keep us regularly updated with any meaningful developments.

As your Ladyship knows, it was only on 5 July 2018 when a fitness to practise referral was made to the NMC by Alison Kelly and that referral was made on the NMC's request after the NMC had learned through regular media monitoring of Lucy Letby's police arrest. The NMC opened a fitness to practise investigation that day.

My Lady, we fully accept that we should have been more proactive in this period. We should have asked for an update on what decision had been made within a few days of Alison Kelly making initial contact with us, and

we should have found out whether the Countess of Chester Hospital were taking all the appropriate steps to protect patients and to ensure concerns were being fully investigated.

However, without a fitness to practise referral about Lucy Letby, the NMC did not have the power to apply for an Interim Order and restrict or suspend her from practice, but we absolutely accept, my Lady, that we could have provided and should have provided greater critical scrutiny and we could have done more to support Alison Kelly and the hospital to raise the concerns with the police sooner.

We now have a more robust process in place for the quality review of advice line calls through benchmarking and peer review and calls like the one that Alison Kelly made to the Employer Link Service are discussed at those meetings.

We are also continuing to reflect in our approach to clinical and safeguarding advice being sought at appropriate times during our regulatory process.

An improvement that we have made very recently, my Lady, that we hope will address the concern you just raised with me about why was there not the professional curiosity that should have been displayed at that time, is that we have now published guidance to address

learnings that we have in fact identified from a different review, that we believe translate to this Inquiry as well. The learnings that we have identified are through engaging with families involved in the second Ockenden Maternity Review on the Nottingham University NHS Trust Maternity Services.

Our guidance is titled Our Culture of Curiosity, is available on our website, and it promotes and emphasises the need for a culture of curiosity in our fitness to practise investigations, and that is right at the start of that screening process when we first hear of concerns from places like the Countess of Chester Hospital.

We are rolling out this guidance across the organisation and our intention is that it will ensure that those receiving fitness to practise concerns will scrutinise more closely the information they are being told and the conclusions reached by others before we decide not to investigate.

We further hope that it encourages staff to consider if there are other reasonable and proportionate investigative steps that we should take to clarify what has happened.

LADY JUSTICE THIRLWALL: So should I infer from that that this is the first time that this sort of guidance has been given to people who take the calls?

MS JONES: As I understand it -- but certainly our corporate witness can update you further when she comes to give evidence, my Lady -- is that this guidance is new for the organisation to particularly promote that culture of curiosity.

LADY JUSTICE THIRLWALL: Very well. Well, I'll look forward to hearing about that.

MS JONES: Thank you, my Lady.

Once the fitness to practise investigation in respect of Lucy Letby had been opened, we conducted an immediate Interim Order Risk Assessment, as you have heard from your Counsel. However, we decided not to apply for an Interim Order because at the time we considered that the fact of the arrest alone did not provide the evidence needed to apply for one.

As your Ladyship knows, the police had informed us that the rest was a step taken to gather evidence and interview under caution.

The police did not provide any further detail to us explaining the information they had to form the grounds to arrest Lucy Letby, and we were reassured that Lucy Letby was subject to bail conditions that we understood prevented her from working in any healthcare setting as we were told by the police on two occasions in 2018 and 2019, though we do appreciate that this did

not accurately reflect the exact bail conditions imposed on Lucy Letby at the time, and we fully accept that we should have formally requested the bail sheet sooner. This is an area where we need to provide further training and guidance to colleagues.

Multiple Interim Order Risk Assessments were carried out at regular intervals while the substantive fitness to practise investigation was on hold awaiting outcome of the police investigation and once Lucy Letby was charged by the police, the NMC applied for and obtained on 20 November 2020 an Interim Order suspending her from practicing as a nurse. That order remained in force until she was struck off the register until 12 December 2023 after having been found guilty of numerous counts of murder and attempted murder on 18 August 2023.

My Lady, whilst the bail conditions were a factor in our decision not to apply for an Interim Order, the key reason for our decision not to apply prior to charges being laid against Lucy Letby was that we considered we had insufficient evidence to do so. At the time, our guidance on Interim Orders did not expressly refer to an evidential threshold that needed to be reached, but it was our view at the time, based on our interpretation of case laws, that sufficient evident or prima facie

evidence was required for an Interim Order application.

On 2 October 2019, our guidance was updated to state as such, following challenges that had been made to a number of interim orders in the High Court in Northern Ireland.

My Lady, we have seriously reflected on the decision not to apply for an Interim Order until Lucy Letby was charged and we have determined that our guidance in place at the time was not sufficiently clear to allow us to act on an extraordinary case such as this one, in which a serious police investigation was under way in relation to potentially multiple incidences of murder.

We accept that it was not right for the NMC to wait to apply for an Interim Order until Lucy Letby was charged, and we consider that in this case, the fact of the arrest could have been sufficient to justify an Interim Order application given the serious nature of the concerns and the absolute importance of maintaining public safety, and also public confidence in the profession and the NMC.

On 25 March of this year, my Lady, we amended our Interim Order guidance to take account of this learning. The guidance now makes clear that we do not always need to wait until a person has been charged before applying for an interim order, but the seriousness of the

concerns and the importance of maintaining public safety and public confidence must be considered. We have moved the emphasis of the guidance away from a prima facie evidence test, we now guide decision-makers to focus more on the cogency of evidence and to give more flexibility to our decision-makers to act on the basis of the known risk, where there is evidence that the risk being seriously considered by other agencies such as the police.

My Lady, there is still no clear case law though on whether an Interim Order suspending someone who has not been arrested or who has been arrested but not charged, might be proportionate, and they, the interim orders, are always subject to a review by the High Court.

While it is our view that the amended Interim Order guidance should address the concerns that arise from this matter, we would very much welcome the Inquiry's view as to its appropriateness.

However, we have also heard from Counsel to the Inquiry's opening that there is concern that a further hurdle to applying for an Interim Order may have been the fact of the lack of an investigation or evidence gathering by the NMC to support an application.

The NMC will seriously reflect on this concern, and seek to assist your Ladyship on whether it was a barrier

when our corporate witness attends to give evidence.

LADY JUSTICE THIRLWALL: Who is your corporate witness? Can we have a --

MS JONES: I believe it's currently being decided with Counsel to the Inquiry, we are in discussions. It will either be Andrea Sutcliffe or Helen Herniman.

LADY JUSTICE THIRLWALL: Thank you.

MS JONES: Thank you.

With the exception of Alison Kelly, no other referrals have been made to the NMC in respect of nurses connected with the neonatal unit at the Countess of Chester Hospital.

We appreciate that the Families raise concern that there has not been disciplinary action of the senior members of the Countess of Chester Hospital Management Team. Alison Kelly is the only senior member of that Management Team that is currently registered with the NMC.

The other professionals named in Lucy Letby's trial are no longer on the NMC's register. Although Anthony Chambers was previously registered as a nurse, he relinquished his registration on 30 April 2003, Eirian Powell came off the register on 1 February 2013 and Karen Rees came off the register on 31 May 2020, therefore we have no powers to take any action against

any of these individuals currently. However, we do have an alert system in place for all three individuals, so if they were to return to our register, we are able to consider any allegations at that stage.

In respect of the fitness to practise investigation of Alison Kelly, the investigation is progressing as expediently as possible but we fully appreciate that the length of fitness to practise investigations can be frustrating for all parties involved.

As your Ladyship knows, we received a referral from the doctors of the hospital on 20 May 2020 in respect of Alison Kelly, and on advice from the police, we were asked to put our investigation on hold on 15 February 2021 to allow them to conduct investigations and that stay continued until the conclusion of Lucy Letby's trial on 18 August 2023, after which the fitness to practise investigation was restarted.

The NMC did apply for an Interim Conditions of Practice Order in respect of Ms Kelly, which was considered by an NMC panel on 27 and 28 March this year, but the panel decided to make no order.

The NMC continues to investigate the matter in line with its normal processes and procedures, the investigation has moved past the screening stage and it is now at the investigation stage.

However, the police have indicated to us that they would wish to interview certain key witnesses to our investigation ahead of us, which has impacted on the pace of our investigation, but we are continuing to work closely with the police, giving the police investigation primacy so as not to pre-judge their lines of inquiry.

Secondly, my Lady, I will address the advice and help that is available through the NMC for clinicians to raise concerns. The NMC provides general guidance through its website on raising concerns. It also operates a referrals helpline to help those who are considering raising a concern. The Employer Link Service offers advice to employers about whether to make a referral, and a telephone helpline and website offer advice to individuals about what steps to take in respect of concern.

It is right to state, as has been stated by the Countess of Chester Hospital in their opening written statement, that the scope of the NMC advice to those who hold suspicions of deliberate harm being caused to patients by a staff member is limited.

We are limited to explaining how a referral can be made and whether the NMC should intervene, but not on what the organisation should do to address the concerns locally. The NMC has to ensure that it can maintain its

independence.

However, the NMC has learned from its actions in this matter that, as I've said earlier, we needed to be more proactive when employers raised concerns with us to find out what happened steps they are taking locally to address the issues. We should have proactively scrutinised the information provided to us by Alison Kelly and we could and should have contacted the General Medical Council and the Care Quality Commission to discuss the concerns.

Since Lucy Letby's conviction, we have introduced measures to ensure that these lessons are embedded in guidance, training and practice which are outlined in Ms Herniman's statement.

In listening to the Counsel to the Inquiry's opening, we have been struck by the repeated and numerous occasions when the consultants raised concerns about Lucy Letby with the Management Team of the hospital. The NMC was not contacted by any of those consultants. Though in saying that, we do not seek to criticise them in any way.

We have already identified that we should and could have advised Alison Kelly to ask the consultants who had raised concerns to contact the NMC directly so we could have discussed the concerns with them. But on having

heard the opening statement of Counsel to the Inquiry, we would like to understand what, if any, barriers the consultants face in making a direct referral to us at the time, and whether there is anything further that the NMC can do to ensure that anyone who has a concern in the future feels able to contact us directly to initiate a referral.

Third, my Lady, I'd like to address some short matters regarding information-sharing with parents and the duty of candour.

We have heard and read of the Families' terrible experiences of information not being shared with them either at all or in a timely way.

We note that NHS England has stated in their opening written statement that between 2015 and 2017 the NMC could have played a role in how information was shared with parents in respect of regulatory referral made to the professional regulatory body and as part of revalidation. Respectfully, we disagree with that submission. The NMC only received referrals as your Ladyship knows from the hospital in respect of Lucy Letby in July 2018 and in respect of Alison Kelly in May 2020.

And it is only once a referral has been received by us that we can begin an investigation and engage with

those parties affected by it thorough our fitness to practise process. Our discussions with Alison Kelly in 2016 through the Employer Link Service would not have been prompted information-sharing with parents, because no referral was made, and the Trust had commissioned its own investigation.

However, if and when a fitness to practise investigation does contact those involved, we now have in place the public support service where we provide dedicated support to those who are involved in the fitness to practise process including families.

In respect of the duty of candour, we welcome the Department of Health and Social Care review into the effectiveness of the statutory duty of candour and on 29 May this year, we responded to their call for evidence.

Fourth and finally, my Lady, if I may, I would like to return to the independent culture review. In response to the comments made by the DHSC in its opening written statement, I would like to explain the actions that the NMC has already taken in respect of the independent cultural review, which was only published some months ago.

We understand the importance of culture in relation to our role of protecting the public and promoting and

maintaining the health, safety and wellbeing of the public. The NMC's Open Council will sit in less than two weeks on 24 September to review the 36 recommendations of the review, and to approve the plan that will address the delivery of those recommendations.

This plan will be subject to further review and refinement as we receive feedback from stakeholders, and recommendations from this Inquiry. In addition, we have already taken a number of immediate actions to address the findings which I don't have time to repeat fully here but which are set out in Ms Herniman's statement and on our website, and some of those immediate actions consist of the following and I'll just highlight three.

First, we are actively working on a new behavioural framework for launch imminently.

Second, we are doubling the amount we spend on learning and development so that by October we should be able to start rolling out improvements in leadership, line management, safeguarding, casework and tackling some behaviours such as micro-aggressions.

Thirdly, we are addressing the pace and quality of our fitness to practise casework which remains a significant priority.

In conclusion, we are grateful for the opportunity to appear at this Inquiry and we stand ready to assist

your Ladyship and Counsel to the Inquiry.

That concludes our opening submissions unless I can be of any further assistance.

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

MS SCOLDING: Good afternoon, my Lady. I note the time. I am not sure, my Lady, if you want me to start now, as it is 12.40, or whether you would rather I commenced after the lunch adjournment.

LADY JUSTICE THIRLWALL: Well, you choose. Either start now and go all the way through to 1.10 or --

MS SCOLDING: I'm happy to start now.

LADY JUSTICE THIRLWALL: Whichever you'd prefer.

MS SCOLDING: That's fine by me, my Lady, as long as everyone can cope with not being fed quite as quickly as they may be.

LADY JUSTICE THIRLWALL: I will give them an hour.

Opening statement by MS SCOLDING

MS SCOLDING: I am grateful. I represent the Royal College of Paediatrics and Child Health. With me today are my instructing solicitor Mr Stuart Marchant, the Chief Executive of the Royal College, Mr Okunnu and Professor Steve Turner, the current President. I shall call the organisation either the "Royal College" or the "RCPCH" during the course of my submissions.

My Lady, you have a written note of my submissions, which I shall deviate from slightly, but not entirely.

LADY JUSTICE THIRLWALL: Thank you very much.

MS SCOLDING: I start these submissions by expressing the sincerest and deepest condolences to the parents and family who are here today or who are listening remotely.

As an organisation whose role and existence is dedicated towards the health and wellbeing of children, it is a source of profound shock and sadness that someone whose role was to protect and preserve life, then chose instead to take it.

We recognise that the death of a child is devastating, and we thank all parents for nevertheless having the courage to want to institute this Inquiry, and to seek answers and ensure that lessons are learned.

For our part, the Royal College stands ready to assist you, my Lady, in this task as much as we are able, to cooperate in the work and to implement your recommendations.

As you already know, from the powerful and eloquent opening of my learned friends on Tuesday and Wednesday, the College submitted an Invited Review Report in respect of the neonatal service at the Countess of Chester in final form in November 2016. This report did not directly assist in uncovering the causes of the

children's injury and death, and in some ways, we recognise, contributed to both the uncertainty and delay which had continued after the concerns had been raised about the death of these children.

We are profoundly sorry for that.

We also apologise for our actions in relation to the paediatricians on the neonatal unit, all of whom are College members. Several decisions made at the time, the decisions to produce the Invited Review Report in two versions, and not to reference the concerns about Letby in the dissemination or public version of the report, dissemination being the term used at the time, compounded their anxieties and doubtless made their decisions about next steps more difficult.

Because the Royal College saw the report as being owned by the commissioning client, the Countess of Chester Medical Director, it did not directly share a copy of the report with the paediatricians who participated with the review, or with the parents about whose children the review concerned.

When the paediatricians approached the College to express their concerns about the issues about the Countess of Chester they were not given a full enough hearing. Again, we are profoundly sorry for those mistakes.

My Lady, you have already heard that the Royal College of Paediatrics and Child Health is a registered charity and membership organisation whose aims are:

To advance the teaching and practice of paediatric medicine; to improve the health of children; and to improve the standards of care towards them.

It provides the relevant accreditation and training standards for paediatricians working in the United Kingdom, and also undertakes policy work, research and advocacy on behalf of its members, of which there are over 23,000.

It also undertakes an amount of work internationally in respect of child health and paediatrics. It would not however, describe itself as the UK's specialist organisation for neonatology, that is the British Association for Perinatal Medicine whose membership consists both of neonatal paediatricians and other associated clinicians, but a number of our members are also members of that organisation.

The Royal College today seeks to split its oral submissions into two areas. The first concerns the review of September 2016. We wish to be clear about what should or should not have happened before, during and after that visit and with the report that was then produced and we wish to be both open and reflective

about the mistakes that were made.

The second of our submissions concerns the College's role as the membership organisation for paediatricians and allied professionals. Our role is to try to help and communicate their expertise to the Inquiry, to assist it in making recommendations about improving both patient safety and parent care in neonatology but also in paediatric services more generally. We hope that you will find our submissions on what needs to change in the health service both constructive and useful.

We have filed detailed written submissions on both these subjects, my Lady, and also filed evidence about them so I don't intend to go word for word and given the approach of lunchtime it would be rash for me to do so. But I will highlight certain areas which I consider are of particular importance.

My Lady, you have heard from Counsel to the Inquiry who has expressed with clarity the essence of the issues which arise in respect of the review of 2016. I now turn to that.

The Royal College was asked by Ian Harvey, the then Medical Director of the Countess of Chester Hospital, to conduct an Invited Review in July 2016 into its neonatal service following concerns raised by paediatricians about the rise in neonatal mortality.

The Royal College, like a number of other Medical Royal Colleges, provides this service as a mechanism for peer review of the workings and functioning of paediatric care in various settings and to recommend various improvements and alterations. The review process usually involves, and did in this case, interviewing staff members, managers and other relevant individuals, examining various documents and reaching conclusions usually after a one or two-day visit.

In this case, the review team included two experienced paediatricians, one of whom was a leading neonatologist, the other a more general paediatrician. One was a specialist neonate nurse and there were two lay reviewers, both of whom had backgrounds in regulation and standards setting within the NHS and hospitals, and in particular in paediatric care.

Following the review, two other paediatricians quality assured the review by reading it and commenting upon it.

You will be hearing oral evidence from those reviewers in due course.

The College notes that in her opening statement, Counsel to the Inquiry set out that communication from the Countess of Chester to parents was poor, and that the Families were not told about the Invited Review

process. We entirely share this conclusion. It is not Royal College's practice as part of an Invited Review to inform parents or indeed paediatricians within a healthcare organisation that we have been commissioned to undertake such. It is the responsibility of the commissioning healthcare organisation to make any communications to parents, families and employees.

The College however accepts that it did not follow up after the 2016 Invited Review to check that this report was shared with parents and others, and we apologise for this. The College's 2024 Invited Review practice requires much more rigorous follow-up and documentation of such.

The Invited Review made a number of criticisms of the Countess of Chester neonatal unit. It concluded that there was considerable understaffing both of doctors and nurses, there was insufficient consultant presence to safely cover the paediatric wards, and insufficient junior and training doctors available.

The review also found that the unit only partially adhered to a culture of safety, and that the governance was only partially adequate.

Obviously that review will be gone through in some detail when the reviewers come to find the report. In particular, there was no clear responsibility for

following up lessons learned, which had been undertaken by the Morbidity and Mortality Panel of the hospital. There was no systematic reporting of all deaths to the relevant systems and organisations and the internal review of deaths which had taken place did not use a recognised process, nor did it include examination of all staff on the unit at that time.

The Invited Review made a number of recommendations to improve the processes for investigations into neonatal deaths more generally with the requirement for all such deaths to be treated as a serious incident, which would then lead to greater examination, and if required, formal investigation, with a clear forum for recommendations being actioned, including letting the relevant Clinical Commissioning Group, as the body which was responsible for organising and paying for the patients' care at the time, know of all deaths.

The review also revealed that the Management Team of the hospital had not realised how busy the neonatal unit was and only identified this issue when it reviewed the data. The Royal College again made various recommendations about better data-gathering in this respect.

The report also identified that not every case of death or serious injury had involved either

a post-mortem or a thorough investigation and examination, and in particular, that the post-mortem process had not included systematic tests for toxicology, blood electrolytes or blood sugar.

The Royal College was also concerned that the Child Death Overview Panel had not been alerted to the cluster of deaths at the hospital.

What the review team did not however conclude was that there were any common factors that it could pursue to explain the increase in that mortality but found that as there had not been a systematic exploration of the deaths, it made a recommendation of a detailed case review by two separate specialist experts. The nature of what the Royal College recommended was set out by Ms Langdale in her opening statement on Tuesday and I shall not repeat it here.

But the Royal College also recommend also, as was the need to in enquire -- I apologise, my Lady --

LADY JUSTICE THIRLWALL: That's all right.

MS SCOLDING: -- as to whether what was commissioned by the hospital was then adequate. The Royal College's submissions is that the Case Note Review recommendation was not fully implemented by the Countess of Chester.

There are four particular factors with the conduct of the review that the Royal College wishes to highlight

in this opening.

Firstly, the written evidence of the reviewers before you, my Lady, is that the Senior Executive Team of the hospital underplayed concerns about Letby before and during the review. The reviewers in their evidence describe there being disbelief displayed by the senior team that intentional harm may be occurring.

Second, the reviewers were given information by Dr Brearey and Dr Jayaram about their suspicion that the deaths on the unit were intentional. The review was not aborted after this information was provided. Knowing this on the first morning of the review, the Royal College considers that the review should have been halted and the reviewers reporting back to the College urgently.

Third, the review team interviewed Letby.

Fourth, in discussions between the review team and the Medical Director of the hospital, he identified that he had advice from colleagues within the Trust not to involve the police until after the Royal College had completed their review.

The Royal College has very carefully considered what should have happened in the light of the subsequent criminal investigation, and commissioned an independent review of its Invited Review Service in 2019. This has

led to changes which I will touch on briefly this afternoon, in the way that the service is operated and run.

I stress here that the views of the Royal College in respect of what I'm about to say are not those of the individual reviewers whose evidence you will hear, as some of whom --

LADY JUSTICE THIRLWALL: Hear from many of them or some of them?

MS SCOLDING: You are going to hear from all of them who are able to come and give evidence. I think there is one individual who is too unwell to do so.

LADY JUSTICE THIRLWALL: Very well.

MS SCOLDING: You will hear from some of whom have differing perspectives about what should have happened before, during and after the review.

The Royal College's view, however, is that all the reviewers acted both in good faith and made reasonable professional observations. They were, however, never in a position to determine Letby's culpabilities, nor to validate the allegations made by Dr Brearey and Dr Jayaram. College reviews are not forensic tools.

Fundamentally, therefore, the review by its nature and as recorded in its Terms of Reference, were never intended to answer the questions of Letby's culpability.

We are sure that we shall hear from the hospital as to why they commissioned the review and the rationale for it, but ultimately, it was a sidestep rather than a step forward.

The Royal College accepts that the review was flawed in the following ways.

Firstly, it was set up quickly without the usual expected due diligence. In particular, there was no meeting between the Medical Director and lead reviewer to discuss the issues, and the Terms of Reference were not discussed as they should have been.

That meeting may well have revealed that the review could not provide what the hospital wanted, as the review could not have determined if the deaths were suspicious, and the Invited Review Team obviously did not have the expertise, governance, methodology or skills to undertake such a quasi-criminal investigation.

The College now considers that if more probing questions had been asked in advance of the review, it would quickly have been realised that the information shared by the hospital to the Royal College was inadequate, and that the review could not have solved the problems with which the hospital faced, and ultimately, it is likely that the review would not have been commissioned.

Second, the Terms of Reference as agreed sought to do something which the reviewers could not have undertaken, which was to find a reason for the deaths.

The Terms of Reference and the way that they were drafted, the Royal College submits, led to a misunderstanding between the hospital and itself. The hospital thought that the review would be in effect an analysis of the deaths by way of a Case Note Review. That term was never mentioned by the Royal College, whose approach was to take a standard review as set out within its Invited Review guide to examine whether factors such as poor hygiene, understaffing, may have contributed to the deaths which occurred on the unit in 2015 and 2016. A Case Note Review is a very different beast, and one which is very different from the review commissioned by the hospital.

Third, the head of the Invited Review service, Ms Eardley, and the lead clinical reviewer, Dr Milligan, were aware and had been told that there were concerns raised about Letby, but no significant detail was provided. Dr Milligan, in his written evidence to you, my Lady, does remember seeing a staff rota which identified that Letby was on duty during the shifts when the babies died, but did not consider this particularly significant at the time.

Three of the reviewers were not told of the concerns about Letby until the day of the review itself. That was not right. All the reviewers should have known about and discussed these issues in advance of the review.

Fourth, the review should have been aborted after the full review team heard the views of Dr Brearey and Dr Jayaram on the morning of 1 September 2016. They set out their view that there was some form of foul play, as is described in the contemporaneous notes taken by the reviewers at the time, and available to you, my Lady, on Relativity.

The review team discussed aborting the review but decided to carry on in order to examine the issues which could have given rise to unexpected or unexplained deaths. At the time, the guide for reviewers was not clear. It recommended that criminal issues should not be investigated in a review, but did not instruct reviewers to terminate such a review if criminal acts came to light.

The Royal College now sets out in its handbook that a review should not be carried out where criminality is suspected, as it is not the right body to carry out such a task.

The Royal College accepts that it did not provide

adequate advice to the reviewers in respect of how to manage the situation which arose in September 2016 during the course of a review in the training or advice that it provided, or in the guide that it supplied, and that there should have been an adequate escalation process to the Royal College's programme board of senior clinicians to provide advice if necessary.

The Royal College also considers that it was a mistake by the review team to interview Letby as part of the review. The rationale given by the reviewers is that Letby had not been suspended from duties; she had been moved from clinical duties on the neonatal unit which was considered to be highly unusual in the experience of the reviewers, without adequate Human Resources process being followed, and no investigation having been undertaken of the allegations raised.

Nursing staff had praised to the reviewers her care of the children, and she had been on shifts when the deaths had taken place. The review team considered it was important to hear from her about the culture of the ward, the staffing and the events that led to the deaths.

Letby had understood from colleagues at the Countess of Chester, and Counsel to the Inquiry identified those particular assurances that were given, that the review

would decide if she could return to clinical duties on the neonatal ward.

The Royal College recognises that it did not provide adequate advice in the guidance it gave to reviewers about interviewing individuals in this situation. The reviewers proceeded in good faith but without recognising the significant risks of undertaking this review.

Immediately following the review, the team provided written and oral feedback to the Medical Director. The recommendation made was for a detailed forensic Casenote Review of each of the deaths since July 2015. There was also a recommendation made that steps should be taken to formalise the investigation in respect of Letby, including setting out what the allegations were, and the processes to be followed.

The review team recognised that there were passionate staff committed to providing high quality care to patients, that the paediatric team and nurses were highly regarded and that they were a strong team which was cohesive and supported each other.

The hospital's focus at the meeting where oral feedback was discussed was, from the handwritten notes of the reviewers made at the time on what the cause or causes could be of the unexpected deaths. As I have

already explained, that was not the purpose of the review.

The report did not address the allegations against Letby made by the paediatricians, and whilst there were informal discussions between the review team about the possibility of directly inflicted injury leading to the death of infants, this was not something that they further explore.

Some of the 2016 team and the evidence that they will give to you, my Lady, consider that with hindsight, there was a much clearer indication of the evidence and what conclusions should have been reached, but the focus of the review, as far as they were concerned, was on the other factors which could have led to the deaths.

It is the view of the College in 2024, shared to varying degrees by the 2016 reviewers, that the report was too light touch, given the issues it had raised about relevant child death procedures not having been followed through thoroughly.

It did not take seriously enough the prospect that criminal activity could have taken place, and the next steps that followed from that understanding.

The opening written submission of Mr Harvey, Mr Chambers and Ms Kelly characterised the report as providing a level of reassurance that the situation was

being managed reasonably and appropriately. How consistent that view is with the finding that the Royal College identified that not all deaths were explicable and required a detailed Casenote Review is a matter for you, my Lady, to consider and make decisions upon.

The final reports, one of which did not contain details about Letby and the other one which did, albeit without naming her, was sent to the Medical Director in November 2016. At that time, the Royal College did not disseminate the report any further, but it did set an expectation that it would be shared by stakeholders who had participated in the review, and those affected by it, even if it was not to be made public.

As far as the report, the written report, is concerned, the Royal College wishes to acknowledge the following.

Firstly, it should have recommended that the police were called, or a forensic investigation proceeded with, given the allegations made. It was a mistake not to do so. In particular, while quality assuring the report, the Programme Director for the Invited Reviews Team at the Royal College, a distinguished paediatrician, observed somewhat presciently in November 2016 when he was in the process of reading it that the situation reminded him of Grantham, where Beverley Allitt had

murdered children, and where he had been involved in the aftermath of the arrest of Beverley Allitt, and queried why the police were not involved given the context of so many unexplained deaths.

The Royal College's expectation was that the full report, ie, the version which mentioned Letby, sent to the Medical Director, would be shared with consultants and senior nurses and others who had contributed to the review.

The Royal College did not know that the full version was not shared with clinicians and nurses until February 2017 when Dr Brearey and Dr Jayaram asked for the notes of the review team. The Royal College did not own the report once it had been submitted; it was for the Trust to do with as they wished because of the confidentiality terms governing invited reviews.

The Royal College accepts that it should have insisted that this full version was shared with staff and parents, and we understand why this may lead, as Mr Baker KC indicated this morning, to the College being seen as hiding key facts.

The College usually followed up on Invited Reviews more thoroughly than happened in this case. It knew that an independent Casenote Review was being commissioned by the Trust, and considered that the Trust

had therefore undertaken the follow-up. It did not ask to see the Casenote Review or to have it sent to the relevant reviewers, nor did it undertake any further follow-up. It should have done so, asking what steps were being taken to allay suspicions and/or to ensure that the clinicians saw the full unredacted version of its November 2016 report. There should have been the follow-up to ensure that relevant investigations had taken place, and its recommendations had been implemented. That now happens in all reviews undertaken by the College.

The Royal College also accepts that it did not inform regulators or other bodies about what they'd found, even after the paediatricians contacted the Royal College in January 2017, to ask for the notes of their interview and to identify that they hadn't seen the full report. They should have done so.

The College also accepts that whilst there was limited discussion of the report at its Programme Review Board immediately after the review had been undertaken, there were no formal lessons learned, report or guidance given to the future until 2020 when an external review commissioned by the Royal College, which Counsel to the Inquiry identified on Tuesday and Wednesday, identified several changes that should be made. The

contemporaneous discussion at the Invited Review Programme Board in 2016 and 2017 was not as detailed as it should have been about this review, given the problems and issues which arose.

The Royal College has made significant changes since 2016 in the way that the review programme is run and commissioned, as I've identified, a Lessons Learned report. As a result of this, the Royal College has changed its handbook to clarify the interviewing of staff, provided an escalation process for reviewers who come across difficult situations whilst reviewing, adopted new guidance on when to cease a review in the light of findings, provided more guidance and more training to reviewers, ensured more due diligence before a review and better briefing of the review team, has established a Casenote Review service so that people can come and have that provided to them, if that's what they wish to do, and implemented greater accountability and oversight of this review process.

Alongside this, my Lady, there have been some changes in NHS practice which the Inquiry may wish to consider as to whether, if they had been in place in 2016, the review of deaths and the pattern of difficulties may have come to light earlier. For example, there is now a perinatal mortality tool which

has been in place since 2018 which could have been used by the hospital to assess the deaths, as opposed to the system undertaken at the time, which the Royal College found to be *ad hoc* and not consistent.

There is also now realtime data provided by MBRRACE which could again have assisted in identifying concerning trends at the time that they were happening.

The work following NHS England's Neonatal Critical Review of 2001 in respect of both Neonatal Networks and individual Neonatal Ward units and the development of a Patient Safety Alert System known as MOSS also may be of some use to my Lady when examining whether there are now greater safeguards in place to identify, as Dr Bill Kirkup so memorably says, the signals from the noise.

Part C, however, of your terms of reference, my Lady involves the effectiveness of NHS management, governance structures and processes in the external scrutiny and regulation in keeping babies in hospital safe and whether changes are necessary, including the role that NHS culture may have played.

You raised specific questions in the Terms of Reference about the effectiveness of current culture, and its impact upon the safety of babies and what changes to regulations should be made.

The Royal College, in seeking to answer these questions, has drawn upon the expertise of its members to seek to assist you. In particular, to understand the background to the delivery of paediatric and neonatal services within the NHS, which may assist you to understand the systemic and cultural issues which arise in this case.

Last Friday, the Royal College published a Case For Change in Children's Health Services in England. Its findings are disappointing. It found that children are waiting longer than adults to access healthcare, paediatric services are not recovering at the same rate as adult services post the pandemic, and there is a growing gap between demand and capacity. This has also coincided with an unprecedented increased demand for Children's Health Services which is forecast to grow further due to both preventable and non-preventable increases in childhood illness.

The College's overall view is that children's healthcare has not, over the past 15 years, been a priority, either in respect of community, hospital, or specialist care services, particularly in comparison to adult health services. It has been too easy for paediatric services, which are often only a small part of the operation of most large, general, geographic area

hospitals, to be sidelined or not given sufficient oversight.

This is particularly the case at board level where there is no requirement at present to have a representative on the board whose role is to look at children's healthcare.

There is also significant variation, my Lady, in the extent to which the integrated care systems and bodies consider the needs of children and young people in their strategies, priorities and funding decisions. There is, for example, no ring-fence funding for neonatal units at present.

In respect of structures, cultures and training, the Royal College has, in its written submissions and in its evidence to you, set these out in some detail, but highlights a number here.

Firstly, it considers that the culture of hospitals still militates against speaking up and raising concerns. A culture of safety, furthermore, relied upon organisational resourcing and prioritisation, which is not always present.

The safety culture in place in many paediatric services are, according to our members, reactive rather than proactive in nature. Most structures currently in place tend to deal with what happened has gone wrong,

rather than seeking to stop events happening in the first place. Royal College members report that while their managers are supportive of patient safety in the abstract, where the money, time or staff is then needed, those resources can often not be found.

In respect of the regulation of hospital managers, the Royal College supports their formal regulation but does not consider that it's best placed to assist you on how that regulation should work in practice.

Essential, however, to any good patient safety culture is to have sufficiently well trained staff who operate to the required standards and are provided with adequate support. Without these, patient safety suffers.

The 2023 General Medical Council Training Survey found that just over 50% of paediatric trainees consider their workload to be "heavy" or "very heavy".

10% of units had gaps in medical staffing in 2020, with 15% of units having gaps in nurse staffing.

The National Neonatal Audit Programme, run in part by the Royal College, observed in 2022 that the continuing decline in neonatal staff levels is of serious concern.

Paediatric waiting lists have doubled over the past two years so that there are now more than 50,000

children waiting for outpatient care for over a year and over 400,000 children on the waiting list for consultant treatment.

There is also a significant shortage of professionals, such as psychologists and counsellors, available to support families in neonatal and paediatric units during what is often an exceptionally emotionally difficult period, whilst their children are in intensive or special care. And many units do not have such support staff in place. You heard from the parents' counsel, and you will have seen in the parents' witness statements, the limited support they often had after their children's death. That is all unacceptable but unfortunately far too common.

Community paediatricians, who are often the designated safeguarding doctors within hospitals or within local community services, to whom safeguarding referrals should be made and who are responsible for organising safeguarding training and escalating concerns, have had their numbers reduced by a third over the past 15 years.

More worryingly, the long-term workforce plan for the National Health Service published in June 2023 says little to nothing about the Children's Health Workforce. No additional places were promised for child nursing,

despite the shortages plainly identified by the profession.

Turning to some other matters, in respect of data, the Royal College considers that the exchange of data between maternity and neonatal settings is not sufficient, something which the Royal College considers needs to improve in order to improve patient outcomes more generally. The Royal College considers that there should be a national audit tool to report neonatal outcomes in maternity care to provide better data and create improvements in patient safety.

Turning to patient safety training materials, there are national patient safety materials, there are patient safety training materials run by, organised and promoted by the Royal College, and there is a National Patient Safety Syllabus. However, this does not always translate in a sufficient training for frontline staff, in particular given the staffing shortages I have outlined, as it makes it more difficult to free up staff for this sort of training.

There have been many recommendations, and there are many recommendations, made by different bodies to prevent future deaths.

Clinicians need to be given the time and space to digest and learn from all these different sources.

Alongside the numerous bodies making recommendations, the Royal College's view is that the current system of regulation of NHS staff, and the different individuals within it, are Byzantine in its nature.

You may well be familiar, my Lady, with the implementation of what has become known as Martha's Rule, which gives the right of a patient to request a further review in the event of a suspected deterioration. We recognise and welcome this change, but consider that for it to be implemented adequately, there must be a full complement of staffing, and that in respect of children, the review must ensure that those with paediatric training are involved in the second opinion.

The Royal College has been asked by the Inquiry about CCTV observation of neonates. We do not have an official position on the use of CCTV, but their use within mental health settings has been the subject of research, and evidence to show that it offers significant benefits for patient safety and care quality is inconclusive in that setting.

If CCTV surveillance in a paediatric ward were to be introduced, it would need to be seen as a pressing requirement and to be supported by clear evidence of benefit, given that it would lead to significant

intrusion into the child and the family's right to privacy, as what we have already described as a particularly difficult time in their lives.

I end this submission, my Lady, as I began it: to express our heartfelt condolences and sympathies to the families of those who lost babies or whose babies were injured, and whose lives have been irreparably damaged by the events at the Countess of Chester Hospital.

Thank you, my Lady.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Ms Scolding, and for continuing over into the lunch break. We will break now and we will start again at 2.15.

(1.18 pm)

(The Short Adjournment)

(2.15 pm)

LADY JUSTICE THIRLWALL: Mr Cohen.

Opening statement by MR COHEN

MR COHEN: My Lady, as you know, I act for the Department of Health and Social Care and I begin, on behalf of the Department and the Secretary of State, by expressing our sincere sympathy and condolences for the families of all those affected by these matters.

My Lady, the Department has previously provided you with a written opening statement.

LADY JUSTICE THIRLWALL: Yes. Thank you.

MR COHEN: And I don't propose to repeat the content of that in its entirety.

Before establishing this Inquiry, the then Secretary of State for Health and Social Services met with the victims' Families. In announcing the Inquiry, he explained that collectively, we have a duty to get those Families answers, to hold people to account, and to make sure lessons are learned.

You and the Inquiry Legal Team have rightly placed the Families at the heart of this process. The Department welcomes and endorses that approach.

My Lady, the events at the Countess of Chester Hospital pose profound questions for the healthcare system, how that system operated, and how the various oversight mechanisms and bodies failed to prevent and detect more quickly what had occurred.

The Department comes to the Inquiry in a spirit of candour, and welcomes your clear expectation that all others should do likewise.

In considering how the healthcare system operated, the Department acknowledges that the Inquiry will wish to consider the role it played. For its part, the Department accepts that recent investigations such as the Independent Review of Maternity Services at the

Shrewsbury and Telford Hospital NHS Trust, and the Independent Investigation into Maternity and Neonatal Services in East Kent, demonstrate a failure to learn from past incidents.

The new Secretary of State has acknowledged that, in the past, recommendations had been made but action has not been taken. That is not good enough. The system must change. The Secretary of State has spoken candidly, describing how the NHS is "broken".

Recent investigations into the Care Quality Commission and Nursing and Midwifery Council have identified serious deficiencies within those organisations.

Getting it back on its feet and building an NHS that is fit for the future is the mission of the Government. To that end, the Secretary of State commissioned Professor the Lord Darzi to conduct an immediate and independent investigation of the NHS. And, my Lady, you will know that report was released and announced this morning.

LADY JUSTICE THIRLWALL: Yes.

MR COHEN: In this opening statement, the Department seeks to address, so far as is possible, the matters in respect of which you have specifically invited comment from Core Participants, though the Department

anticipates it will have more to say at the conclusion of the evidence and the time for making detailed closing submissions.

My Lady, taking the first of those headlines, patient safety. Patient safety is a priority for the Government's vision for the NHS. The Inquiry will hear detailed evidence about the many initiatives in patient safety undertaken in the last decade or so. These are summarised at paragraph 11 of the Department's written opening.

The NHS Patient Safety Strategy, led by NHS England and first published in July 2019, is the first whole NHS strategy designed to support the entire NHS system to achieve continuous improvement in safety and the reduction of patient harm, whilst embracing an ethic of learning.

Measures have also been taken to raise patient safety in the specific context of maternity and neonatal care, including through the establishment of NHS England Maternity Transformation Programme, now the Maternity and Neonatal Programme.

Further initiatives have since been introduced as set out in NHS England's three-year delivery plan for neonatal and maternity services, including increased neonatal cot capacity and responsibility for Integrated

Care Boards to consider national guidance, such as implementing the recommendations of the Neonatal Critical Care Transformation Review when agreeing staffing levels with Trusts.

My Lady, the Department and NHS England have introduced changes to the investigatory reporting and review processes to improve patient safety in maternal and neonatal care. These include the Perinatal Quality Surveillance Model and the Neonatal Quality Process, the National Perinatal Mortality Review Tool, launched in England, Wales and Scotland in early 2018 and adopted in Northern Ireland in the autumn of 2019, the Maternity Services Dashboard, published from 2016, to help local maternity systems track, benchmark and improve the quality of maternity services.

As of 1 October 2023, the Healthcare Safety Investigation branch's Maternity Investigations Programme transitioned into the CQC and became the Maternity and Newborn Safety Investigations Programme, ensuring the continuation of independent, single-case maternity investigations with greater consistency and more systematic learning to spur system improvements and prevent avoidable deaths and injuries in the future.

The Neonatal Critical Care Review was published by NHS England 2019 and led to significant investment by

the NHS long-term plan between 2020/21 and 2023/24.

Then in July 2018 the Department assumed, from the Department of Education, responsibility for the Child Death Review process.

My Lady, although many initiatives have been introduced to promote safety in the NHS, it is equally clear, and the Department acknowledges this, that progress is unevenly distributed, as demonstrated by recurring problems highlighted in various inquiries. The Department acknowledges that the development of cultures of safety and learning in the NHS needs to be improved.

The frequency of major patient safety crises and systemic problems in the NHS are a reminder that safety culture development has proved to be, and continues to be, very challenging.

Turning now to the Countess of Chester Hospital. In October 2016 the Department became aware of the change in admission arrangements to the Countess of Chester Hospital Neonatal Unit to focus predominantly on lower-risk babies which had been introduced in July 2016, and of the request for an independent review.

On 16 May 2017 the Department was first notified by NHS Improvement about the planned announcement of the police investigation into deaths at the Countess of

Chester Hospital. The Department is not routinely involved in day-to-day events in Trusts. At the relevant time, this was the responsibility of the Trusts and Foundation Trusts themselves; Monitor, the NHS Trust Development Authority; and sometimes NHS England, through their regional teams.

The Department had arrangements in place to keep track of performance and quality issues in the NHS. And then, as now, it was expected that, where significant issues were identified, the Department would be informed.

However, the Department acknowledges that it would have been better if there had been more robust arrangements to share information between the Trust, NHS England, and the Department at the time, and will continue to work with NHS England and others to identify further opportunities for improvement.

LADY JUSTICE THIRLWALL: Can I just ask you; you say it would have been better. Well, yes, but should it have been, otherwise?

MR COHEN: My Lady, I think that's implicit, yes.

LADY JUSTICE THIRLWALL: Well, it could be explicit. You could say the arrangements should have been more robust. That's really the position.

MR COHEN: My Lady, yes, and there are now more

sophisticated processes in place.
LADY JUSTICE THIRLWALL: Yes.
MR COHEN: With providers, Integrated Care Boards, regions, and nationally, intended to support intelligence sharing, risk mitigation, management and escalation of quality and safety concerns.
It is Government's policy that these working relationships should be closer to promote greater information sharing, including with the Department, and increase provider and system challenge.
The Inquiry will wish to explore whether there is scope to improve the way Trust boards work, including but their accountability and transparency and their engagement across the wider system, so that they can proactively raise the alarm and have the confidence to refer to the wider system when issues of equivalent severity to this case occur.
That brings me, my Lady, to the escalation of concerns and whistleblowing. As previous inquiries have identified, an essential element in promoting patient safety is the ability of staff to escalate concerns and, more broadly, for complaints to be made and handled appropriately. The health of an institution may be judged by the way that it treats whistleblowers.
In response to a recommendation of Sir Robert

Francis, King's Counsel, in his Freedom to Speak Up Review of 2015, the then Government established an independent National Guardian in July 2016 to help drive positive cultural change across the NHS. In addition to driving cultural change, the National Guardian proves support and leadership to a network of local Freedom to Speak Up Guardians, which cover every Trust.
It is vital that any staff member who is worried about the safety of a baby is able to voice concerns, and that these concerns are thoroughly considered and, where appropriate, investigated by the Trust.
Each Trust must have clear processes in place within an environment that is open and transparent, and we accept that more needs to be done to achieve this. The NHS England Culture and Leadership Programme that is being implemented in maternity and neonatal services is integral to this. Whilst it is too early to assess its impact, the Government will take further action if required.
The National Guardian's latest report on speaking up to Freedom to Speak Up Guardians for 2023 to 2024 showed that guardians handled more cases than ever before. However, there remain a persistent number of cases where guardians indicate that the person may be experiencing detriment for speaking up.

A separate NHS staff survey by the National Guardians Office revealed the percentage of workers feeling secure enough to raise concerns about unsafe clinical practices reached a five-year low in 2023. The Government will consider what further action required to make speaking up the norm in the NHS.
LADY JUSTICE THIRLWALL: So this is beyond what the Department are doing, is it? This is a Government -- I noticed several times in this document there's reference to the "Government" rather than the "Department".
MR COHEN: My Lady, I think that's not intended to indicate that matters are going beyond the Department. The Department speaks for the Government in this regard.
LADY JUSTICE THIRLWALL: Very well. Thank you.
MR COHEN: Turning to culture. At paragraphs 33-37 of our written opening, we address this matter.
Issues of poor leadership and workforce culture have been raised repeatedly in previous investigations, inquiries, and reports of maternity and neonatal services, and undermine the safety improvements which have been made. It is clear that solutions are required which all Trusts can imprisonment and consistently adopt. The Government will consider what further actions are required to achieve this.

My Lady, you may consider that various reviews and inquiries have, over many decades, identified persistent issues of culture, painting a broadly consistent picture of incurious boards, unresponsive to key patient safety concerns, of defensive -- and on some occasions bullying -- behaviour, which does not create a culture in which speaking up is easy or welcomed, and professional tribalism with associated tolerance of poor behaviour and poor care.
It will be for the Inquiry to consider whether these matters played any part in the events at the Countess of Chester.
Turning now to management in the NHS.
My Lady, NHS Senior Managers are expected to ensure the delivery of safe, high-quality care, and best outcomes for patients, as well as creating the conditions for a positive, open and learning organisational and workforce culture through effective governance and assurance.
Boards have primary responsibility for oversight of the conduct of executive leaders, and take appropriate disciplinary action when it is required. Executive leaders who are healthcare professionals are also subject to statutory regulation by professional regulatory bodies.

In 2013 Sir Robert Francis recommended the implementation of a Fit and Proper Person Test for NHS Directors to improve the accountability of Directors. The Health and Social Care Act 2008 Regulated Activities Regulations 2014 require all Trusts to ensure that all executive and non-executive director posts, or anyone performing similar or equivalent functions, are filled by people that meet the requirements of the Fit and Proper Persons Test. The Care Quality Commission may take enforcement action if it considers that a Trust has not complied.

In August 2023 NHS England published the Fit and Proper Persons Framework, which introduced a standardised reference system and a means of retaining information regarding background checks for individual Directors. Since 31 March 2024, organisations are expected to have fully implemented this framework.

In the light of the events at the Countess of Chester Hospital, there has been a renewed focus on whether additional measures are required to enhance the accountability of Senior NHS Managers, and whether extending regulation to Senior Managers would be an effective means of ensuring patient safety.

The new government committed in its manifesto to introducing professional standards for, and regulation

of, NHS Managers, ensuring those who commit serious misconduct can never do so again.

Detailed work will be required to determine the most appropriate and effective means of regulating Senior NHS Managers.

My Lady --

LADY JUSTICE THIRLWALL: I know that there was a process ongoing last year looking at regulation for accountability of senior managers, but I just wondered -- I assume some of the detailed work has already done -- when we might expect an outcome.

MR COHEN: My Lady, yes. It may be that that is a matter that the Department's witness can address when he comes to speak to you in the course of this Inquiry.

LADY JUSTICE THIRLWALL: Very well.

MR COHEN: My Lady, the Department has sought to prove assistance to this Inquiry. It will continue to do so.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Mr Cohen.

There are still three more opening submissions to be made, but they will be tomorrow starting at 10.00. So I hope, unusually for this Inquiry, we will have an early finish which I think may be welcome to quite a few people in the room, and allow you to get on with the enormous amount of preparation that you have to get on

with. So I will rise now and we will start again at 10.00 tomorrow.

(2.35 pm)

(The hearing adjourned until 10.00 am the following day)

I N D E X