Wednesday, 11 September 2024

(9.58 am)

LADY JUSTICE THIRLWALL: Good morning, everyone. We will adopt the same timing today as we did yesterday, so an hour and a quarter also before the break. However, I have said to Mr de la Poer if it is more convenient to break a bit later or a bit earlier, we will take his lead.

Mr de la Poer.

Opening statement by MR DE LA POER

MR DE LA POER: My Lady.

We turn now to the role of governance and the board. We have heard about concerns and suspicions raised by clinical staff on the neonatal unit. We have heard about the response of managers. One question you will be considering, my Lady, is whether the structures and processes for the management and governance of the hospital contributed to a failure to protect babies on the neonatal unit from the actions of Letby? What was the board's oversight of corporate and clinical governance?

By way of background, the Countess of Chester Hospital NHS Trust operated two hospitals: the Countess of Chester Hospital and the Ellesmere Port Hospital. The vast majority of the Trust services were provided at

the Countess of Chester Hospital. It was the main Trust serving West Cheshire and also provided services to many Welsh patients.

The hospital has been authorised as a Foundation Trust by Monitor in April 2004. It was in fact one of the first ten hospitals to be given Foundation Trust status.

As a Foundation Trust, the hospital had a degree of independence from Central Government control. It was not subject to the performance management requirements of the Department of Health and had greater control over its own strategy and finances.

As a replacement for central control, accountability was meant to be provided locally, through members of the Trust and governors holding the hospital to account.

We turn now to consider risk management. The effectiveness or otherwise of risk management within the hospital is something that the Inquiry will be considering in some detail. And I pause only to note one example here. In May 2016, Ms Annemarie Lawrence took up the role of Risk Midwife. When Ms Lawrence became aware of the thematic review of neonatal mortality she requested a copy and one was provided to her. Having read this document she describes going through the table and noting, using a highlighter, that

Letby was a common factor in the case of most deaths.

Ms Lawrence, having sought the advice of Janet McMahon who had been her predecessor in the role, then went to her boss, Ms Millward, the Head of Risk and Safety, about what she had read.

Ms Lawrence's recollection of the conversation in her witness statement is that Ms Millward was "dismissive of her findings".

Ms Millward's recollection in her witness statement is that Ms Lawrence raised the fact that "one nurse was present at all or most of the deaths", and that she'd cautioned Ms Lawrence, speaking about it more publically, as it had been "unproven at this time".

Ms Millward says she took from the conversation that the concerns had been escalated to the executive team and were being looked at. Ms Millward says that at no point was there any suggestion that this was a deliberate act by the nurse. Instead, she took the implication to be that there may be clinical competence issues which needed to be raised with the nursing leadership or human resources.

Ms Millward states that she did not view this as a Risk and Patient Safety Team issue.

In that role as Head of Risk and Patient Safety, Ms Millward reported to Ms Kelly as Director of Nursing

and Quality. Ms Millward has explained to the Inquiry in her witness statement how she understood the system of risk and patient safety to operate. At the ward level, it was expected risks would be discussed. It was then the responsibility of local managers to add risks to the Datix system. The Datix system involves an electronic record which provides a risk-scoring methodology.

The use and lack of use of this reporting system in the case of babies named on the indictment is a matter commented upon by number of witnesses and is an area of investigation for the Inquiry.

The Risk and Patient Safety Lead aligned to the division, which in the case of the neonatal unit was the Urgent Care Division, was expected to provide a monthly report for discussion and approval at the monthly Divisional Governance Group.

Risk Registers existed for each ward or department and were known as Local Risk Registers. Above those were the Divisional Risk Registers. Any risk-scoring above 16 was referred to a senior level in the hospital, and added to the Executive Risk Register. For most of the period for which the Inquiry is concerned, the most senior committee responsible for the risk management was called the Corporate Directors Group.

This group was chaired by the Chief Executive, Mr Chambers, who was described in the Risk Management Strategy and Operational Policy as "the accountable officer".

The Corporate Directors Group met monthly. Its attendees included the Medical Director, Mr Harvey, the Director of Nursing and Quality, Ms Kelly, and the Director for Corporate and Legal Affairs, Mr Cross.

The Inquiry has identified that the neonatal unit concerns were referred to in the July 2016 Urgent Care Risk Register. However, the risk was characterised as follows:

"Potential damage to reputation of the neonatal service and wider Trust due to apparent increased mortality within the neonatal unit."

In other words, the risk was characterised in terms of reputational harm, rather than in terms of a risk to the safety of babies.

It is also noteworthy that the risk was only added in July 2016, six months after the February 2016 thematic review had clearly identified a "higher than expected mortality rate on the NNU in 2015".

Concerns regarding the mortality in the neonatal unit were not referred to in the Executive Risk Register until July 2016. In the minutes of the July 2016

Corporate Directors Group meeting, underneath the heading "Executive Risk Register Overview", it is recorded:

"RM [that is to say Ruth Millward] noted that there were seven current risks on the register, having added two associated with the neonatal unit."

The minutes do not specify what these two risks are, and there is no record of a discussion taking place regarding the risks. However, examination of the July 2016 Executive Risk Register informs that the two recorded risks were firstly "Temporary change to admission arrangements for NNU" along with "Independent review of the neonatal service from the Royal College of Paediatrics and Child Health" and second "Clinical lead has highlighted an apparent increased mortality within the NNU for 15/16".

We note that there is no record of the consultants' concerns of deliberate harm to babies in the Urgent Risk Register, the Executive Risk Register, nor the Corporate Directors Group meeting minutes.

The Inquiry will be seeking to understand why this is, and also why it appears that it took until July 2016, one year and one month after the first indictment baby death, and five months after the thematic review, for the concerns to be formally

recorded in these forums.

The Inquiry will be investigating whether the Trust developed a comprehensive risk management plan in a timely manner, recorded it in a single place, reviewed it and updated it as appropriate in accordance with its procedures.

If this proves not to have been the case, the Inquiry will be looking to understand whether this impacted upon the speed and manner in which the hospital addressed the increase in mortality on the neonatal unit and the concerns of the doctors about it.

I move from the topic of risk to the board.

As a Foundation Trust, the hospital's management structure was in part prescribed by statute; that is the National Health Service Act of 2006. The hospital was required to have a Board of Directors made up of Executive and Non-Executive Directors. The Board of Directors had the power and the overarching responsibility to run the hospital. These powers could be delegated to the board committees or individual Executive Directors. Ultimately, the board was responsible for the performance of the hospital.

The Board of Directors was a unitary board. That meant its Directors were supposed to make decisions as whole, sharing between them the responsibilities and

liability.

The hospital Board of Directors was made up of six Non-Executive Directors, including its Chair, and seven Directors, including its Chief Executive Officer.

The chair of the hospital board from 2012 to 2020 was Sir Duncan Nichol. Sir Duncan first joined the NHS in 1968 and was Chief Executive of the NHS Management Executive from 1989 to 1994.

As we will hear in greater detail, Sir Duncan's time as the NHS Chief Executive coincided with the murders and attacks committed by Beverley Allitt at Grantham Hospital.

Following the Clothier Inquiry into Allitt's attacks, Sir Duncan was responsible for the distribution of the Clothier Report across the NHS, writing to all health authorities and Trusts to draw it to their attention.

The Inquiry is interested to hear from Sir Duncan about the lessons he and the wider NHS learnt from the Allitt case, and why the parallel between Letby and Allitt was not drawn earlier at the hospital.

As Chair of the hospital board, Sir Duncan was responsible for leading the board and the Council of Governors. Sir Duncan's role was to be the agenda setter for both. He had particular responsibility for

ensuring the Directors and the Governors received accurate, timely and clear information which enabled them to perform their roles effectively.

In addition to Sir Duncan, there were five other Non-Executive Directors. Their role was to monitor, scrutinise and constructively challenge the management of the hospital.

The Inquiry has obtained witness statements from Mr Andrew Higgins, Mr James Wilkie, Mr Ed Oliver, Ms Rachel Hopwood and Ms Rosalind Fallon, each of whom sat as Non-Executive Directors for all or part of the period we are examining. They will give oral evidence to this Inquiry.

Mr Higgins also held, for part of his time on the board, the role of Senior Independent Non-Executive Director and Vice Chair. That role involved providing a sounding-board for Sir Duncan, and acting as an intermediary for the other Directors where necessary.

Ms Fallon, previously a nurse and midwife, was the sole Non-Executive Director with clinical experience.

In terms of the operational management of the hospital, that was a task for the Executive Director, headed by Chief Executive Mr Tony Chambers.

During the period the Inquiry is focused on, that is to say 2015 to 2017, the other Executive Directors, some

of whom Ms Langdale identified yesterday were as follows: Ms Ian Harvey, the Medical Director; Ms Alison Kelly, the Director of Nursing and Quality; Ms Debbie O'Neill, the Chief Finance Officer, that role was also filled by Mr Simon Holden on an interim basis from January 2016 to July 2016, and again from February 2017; Ms Susan Hodkinson, the Director of Human Resources and Organisational Development; Mr Stephen Cross, the Director of Corporate and Legal Services; Ms Lorraine Burnett, the Director of Operations, and Mr Mark Brandreth, the director of planning, partnerships and development. Mr Brandreth left the hospital around April 2016.

The NHS Foundation Code of Governance set out the board responsibility. First, for ensuring the quality and safety of healthcare services at the hospital; second, for applying the principles and standards of clinical governance as set out by external bodies; and third, for oversight of the effectiveness of the hospital's risk management and internal controls.

All members of the board, but particularly the Non-Executive Directors, had a duty to challenge and scrutinise.

There were two key mechanisms by which the board at the Trust discharged its responsibilities. The first

was through meetings of the board itself. A typical format for board meetings was for Executive Directors to present papers or reports, usually relating to their own areas of responsibility. The Non-Executive Directors might ask questions and discussion might follow about what had been presented.

Where actions required board approval, an Executive Director would typically recommend the steps which were proposed to be taken, and the board would give its approval, or on seemingly rare occasions, its rejection.

The second mechanism was through the board committees, which we will turn to in more detail shortly. Board committees sat below the board, were chaired by Non-Executive Directors and were responsible for providing assurance to the board on matters within their remit.

Corporate governance is an area in which the NHS has spent some time focusing on, not least following the recommendations of the Mid Staffordshire Inquiry.

Now, we've just referred to the NHS Code of Governance. NHS bodies also published guidance and codes. Monitor, for example, published guidance for NHS Trust boards in 2013 on how to govern effectively. The guidance built upon earlier guidance issued by the National Quality Board. It was titled "Quality

Governance: How Does a Board Know That Its Organisation Is Working Effectively to Improve Patient Care?".

The guidance was couched in the language of "quality", by which it meant safe and effective services with positive patient experience.

The guidance was organised around a series of questions posed to NHS trust boards, including: does quality drive the Trust strategy? Is the board sufficiently aware of potential risks to strategy? Does the board have the necessary leadership skills and knowledge to ensure delivery of the quality agenda? Does the board promote a quality-focused culture throughout the Trust? Are there clear roles and responsibilities in relation to quality governance?

Turning from the board to the Council of Governors. The hospital was also required, by virtue of its foundation trust status, to have a Council of Governors.

As with the Board of Directors, meetings of the Council of Governors were chaired by Sir Duncan Nichol. The Council of Governors sat above the board in the governance structure of the hospital. Their function was prescribed by statute. It was:

"To hold the Non-Executive Directors individually and collectively to account for the performance of the Board of Directors, and to represent the interests of

the members of the [Trust] as a whole and the interests of the public."

The Council were thus required to perform an accountability role and to ensure a link between leaders of the hospital and members of the public the hospital served.

Turning from the Council of Governors to the board committees.

The board sat the board committees. From around mid-2013 to mid-2019, there were seven board committees, and each was chaired by a Non-Executive Director. This included three committees chaired by Sir Duncan Nichol. The membership of committees was varied but generally consisted of a mix of Non-Executive and Executive Director, and managerial, clinical and administrative staff.

Ms Killingback, can I please invite you to put on screen INQ0002607. This shows the committee structure at the hospital. There are four board committees which the Inquiry is principally interested in.

The first is the Quality, Safety and Patient Experience Committee, often referred to as QSPEC.

The second is the Finance and Integrated Governance Committee.

The third is the Audit Committee.

The fourth is the People and Organisational Development Committee.

Thank you very much indeed, Ms Killingback, we can take that down.

Taking each of those four committees in turn, the Quality, Safety and Patient Experience Committee. This was responsible for the development, implementation and monitoring of matters relating to quality, safety and patient experience within the hospital.

The committee had terms of reference dated 17 June 2013, which set out its purpose and duties. That purpose included the monitoring of serious untoward incidents, review of the hospital Risk Register and Board Assurance Framework regarding quality, safety and patient experience, also assurance in all matters to do with risk, governance, quality and patient experience, and the monitoring of implementation of recommendations from national reports.

The increase in neonatal mortality at the hospital and the concerns about Letby were matters which fell squarely within the Quality, Safety and Patient Experience Committee's remit. A seemingly striking feature of QSPEC's monthly meetings during the period June 2015 and June 2016 is that the increase in the mortality rate on the neonatal unit was discussed just

once.

The only occasion on which mortality rates on the neonatal unit appear to have been raised was in a presentation to the committee on 14 December 2015. This was not followed up in the next meeting, which took place on 15 February 2016 or the subsequent meetings in March, April, May or June 2016.

One of the matters the Inquiry will be seeking to get to the bottom of is why was this so, given that attendees at that committee were, from February 2016 at the latest, sighted on the fact that concerns existed in the neonatal unit?

I turn now to the Finance and Integrated Governance Committee. This committee was, in the words of Non-Executive Director Mr Higgins, a "bit of a catch-all committee". A draft of its terms of reference dated 17 June 2015 put its remit in particularly broad terms, describing it as a committee as follows:

"With responsibility for gaining assurances in relation to risk controls for clinical risks, non-clinical risk, and corporate risk. It is the main committee through which the organisation is assured that risks are mitigated, through appropriate control mechanisms and adequate assurances provided that the hospital is able to achieve its objectives and to ensure

that the safety and quality of care, treatment and services provided by the hospital, for patients, is of a high standard."

So it would seem the Finance and Integrated Governance Committee was the main committee which provided assurance to the hospital that risks were mitigated and that the safety and quality of care at the hospital was of a high standard.

Its responsibilities included overseeing the implementation, monitoring and review of the Board Assurance Framework, ensuring that governance systems were effective and utilised appropriately, and also quality assuring and ratifying all policies, procedures and guidelines.

The Finance and Integrated Governance Committee was chaired by Sir Duncan Nichol. The hospital's Directors made up a significant proportion of its membership. From the Executive Director, there were Mr Chambers, Mr Harvey, Ms Kelly, Ms Hodkinson, Ms O'Neill, Mr Holden, Mr Cross, and Ms Burnett. All the Non-Executive Directors were members of this committee.

At least one of the Non-Executive Directors has since described the Finance and Integrated Governance Committee as "discredited", that an informal consensus was reached amongst the board that the committee was not

achieving its objectives, particularly in relation to risk assurance, with the committee meetings becoming dominated by operational performance and finance issues. We will examine its role during the evidence.

The third committee I have mentioned is the Audit Committee. The purpose of this committee was to provide assurance that appropriate systems of internal control and risk management were in place within the hospital. While much of the Audit Committee's work appears to have been focused on corporate and financial audit, its remit extended to clinical risk and audit too. The Audit Committee also had an independent scrutiny role over the other board committees. The Audit Committee was chaired by Non-Executive Director, Ms Rachel Hopwood. Its membership varied, but Mr Harvey, Mr Cross, Ms Hodkinson, Ms O'Neill, Ms Holden, Ms Kelly, Ms Burnett, Mr Higgins and Mr Wilkie were all members of the committee at some point.

And finally of those four committees that I have mentioned, the People and Organisational Development Committee. It had the purpose of setting out the relevant board committees -- forgive me. According to its terms of reference, the committee had delegated responsibility for managing and providing assurance for the workforce related risk. It was also responsible for

ratification of new and existing human resource policies and procedures, and the review and implementation of national guidance on workforce related topics, such as the Nursing and Midwifery Council revalidation process.

The People and Organisational Development Committee was chaired by Non-Executive Director Mr Oliver. Its membership included Ms Hodkinson and Mr Harvey.

Dealing with the board committees collectively they formed an essential function in governance of the Trust. They had delegated responsibility for scrutiny and assurance within each of their respective remits. Much of the day-to-day business of the board appears to have been performed through the various board committees. The board committees were also supposed to act as funnels for the escalation of issues to the board as a whole. Groups, boards and committees lower down in the governance structure of the Trust could feed information and escalate issues to the relevant board committees. In turn, board committees could escalate issues to be considered by the board.

Minutes of the board committee meetings were received at subsequent board meetings.

In the period June 2015 to March 2017, no board committee ever escalated to the board issues relating to neonatal mortality or Letby. The Quality, Safety and

Patient Experience Committee was in fact the only board committee where neonatal mortality was even discussed, and as we've already set out, during the period of Letby's attacks, QSPEC discussed the increase in the mortality rate on the neonatal unit just once. As we have said, the Inquiry will be asking why that was so.

While much of the Inquiry's focus will be on QSPEC due to its remit, the Inquiry will also examine the effectiveness of other board committees. Indeed, were or should those committees have been involved in identifying, raising or dealing with concerns regarding neonatal mortality at the hospital?

Indicators that there was ineffectiveness at board committee level have already been provided. In March 2019, a review into governance at the hospital, conducted by an organisation called Facere Melius found that the board committees were very operationally focused, and often left insufficient time for the consideration of individual items and tended to seek reassurance as opposed to forming an assurance function.

In his witness statement to the Inquiry, Mr Higgins has described that there was often a lack of time for discussion of board committee minutes in the meetings of the board Directors. Ms Fallon has told the Inquiry in her witness statement that the level of information

provided to the non-executive directors was often a problem in that papers were long, and unwieldy, with lots of data and little analysis. The Inquiry will be exploring these various issues.

I turn now to the Executive Directors Group. The Executive Directors sat and met in a separate group invariably described as the "Executive Team" or the "Executive Directors Group".

As we have already heard, this group met weekly and its meetings appear to have been where the concerns regarding neonatal mortality and Letby were most frequently discussed.

Now, before moving on to other matters, I should deal with the other structures within the hospital.

Each department of the hospital was designated to one of three divisions. During the period that the Inquiry is focused on, the hospital had three divisions: the Urgent Care Division, the Planned Care and Diagnostics Division and the Pharmacy, Estates and Facilities Division. Paediatrics, which included Neonatal Care Services, formed part of the Urgent Care Division. We pause to note that obstetrics, which is plainly a specialty directly connected to neonatology sat in a different division: the Planned Care and Diagnostics Division.

We will be investigating whether the placing of these two directly connected specialties into different divisions of the hospital had any impact on the speed at which action was taken.

Returning to Neonatal Care Services, could I please ask Ms Killingback to put on screen INQ0012232. What is on screen shows the purported operational management structure for the Paediatrics Department. The diagram suggests that Paediatrics contain three separate management hierarchies, one each for medical, nursing, and business performance.

Ms Karen Townsend, as Divisional Director -- and her name appears towards the top and in the centre, Ms Karen Townsend is depicted as the soul link between each of the management chain. The position appears to have been similar in December 2015.

You can take that down. Thank you very much.

Each division had a Medical Director. The Medical Director for the Urgent Care Division was Dr Martin Sedgwick, an acute cardiology consultant. Among Dr Sedgwick's responsibilities as Divisional Medical Director, was delegated responsibility for the implementation of risk management in relation to Urgent Care medical staff.

Below Dr Sedgwick sat the clinical leads for

paediatric services, Dr Jayaram, who we heard about yesterday, and also Ms Anne Murphy who fulfilled the equivalent nursing lead role for children's services. And then finally below Dr Jayaram were the neonatal team headed by Dr Brearey.

Moving forward to divisional boards. The Urgent Care Divisional Board was concerned with both strategic and operational issues affecting the Urgent Care Division. It met monthly. It received reports and feedback from the specialties and subgroups in its division. In turn, it was able to direct matters upwards to the Quality, Safety and Patient Experience Committee. The hospital's then policy for the reporting of incidents suggests that the divisional boards were meant to have an important role in risk management, including receipt of governance reports, which included incident data and other relevant governance/risk issues.

Sitting below the Urgent Care Divisional Board and the Planned Care Governance Board was the Women and Children's Care Governance Board. Its membership primarily comprised of medical and nursing staff from obstetrics, gynaecology, midwifery and paediatrics. As previously mentioned, it appeared that the Women and Children's Care Governance Board was a committee that did discuss neonatal mortality at a relatively early

stage.

Its duties and responsibilities included risk management assurance across its services, the monitoring of clinical incidents, and clinical performance and quality monitoring.

Minutes from its meetings were disseminated relatively widely. They were received by both the Urgent Care Divisional Board and the Planned Care Governance Board, as well as the Quality, Safety and Patient Experience Committee and Ms Kelly directly.

The Women and Children's Care Governance Board was chaired by Dr McCormack. Its membership from the Urgent Care Division included Dr Jayaram, Dr Brearey, Ms Rees and Ms Murphy.

A number of specialty review groups operated below the Women and Children's Care Governance Board to undertake first level review of incidents within their specialty. The Obstetrics Department had a primary review group and a secondary review group. The Neonatal Incident Review Group was the group responsible for the review of all neonatal incidents. It met monthly. Where it deemed appropriate, the Neonatal Incident Review Group could instigate further investigation of particular incidents.

Turning away from the local level and to the

Safeguarding Strategy Board. Now, the position of the Safeguarding Strategy Board in the governance structure of the hospital is currently unclear to the Inquiry legal team. But it reported directly to the Quality, Safety and Patient Experience Committee. Its basic function was to ensure that safeguarding was a strategic objective within the Trust and integral to the care it provided. What that meant in practice will be explored in evidence.

The Terms of Reference for the Safeguarding Strategy Board set out its duties. Those duties were expansive and included monitoring of safeguarding standards, ensuring that systems, processes and reporting mechanisms were in place to detect, prevent and respond to concerns about abuse or neglect. Also, approving safeguarding procedures and policies and ensuring the hospital reported safeguarding concerns to external agencies and ensuring improved communication occurred between teams through incident discussion and monitoring.

The increase in neonatal mortality at the hospital was not mentioned in the papers for meetings of the Safeguarding Strategy Board until November 2017, six months after the police investigation commenced.

The various groups, boards and committees we have

set out are those most relevant to the Inquiry's investigation into the effectiveness of the governance structure of the Trust. Though numerous, they are not exhaustive of the large number of such associations which existed in the Trust.

It will not have escaped your attention, my Lady, that there seems to have been significant overlap in remit between these various groups. Every group we have described, save for the People and Organisational Development Committee, had an apparent direct role in management of clinical risk. The Inquiry will be investigating whether overlap of responsibilities affected how the hospital identified and dealt with concerns raised about neonatal mortality.

The structure we have described contained a number of routes for issues to be referred from groups near the bottom of the hospital's governance hierarchy all the way to the board. One might have expected, for example, issues relating to neonatal mortality to be identified first in the Neonatal Incident Review Group, then raised at the Women and Children's Care Governance Board, which would then be referred to the Quality, Safety and Patient Experience Committee, and eventually appear before the board.

That is not what happened.

Indeed, one of the apparent features of the concerns about Letby is how they were raised outside these established processes and structures. Aside from the meetings of the Executive Directors Group, the increase in neonatal mortality and the concerns raised about Letby were rarely discussed. The Inquiry is very interested to learn why this was so.

Returning then to the board. The board met 16 times between June 2015 and May 2017. At five of those meetings the concerns regarding an increase in neonatal mortality were discussed. Four of those five meetings were Extraordinary Meetings of the Board of Directors held in private where the concerns regarding Letby were explicitly discussed.

The one public meeting where neonatal mortality was discussed took place in February of 2017. As we have already set out, a non-dissimilar picture seems to have played out in the board committees. From June 2015 to May 2017, the concerns about neonatal mortality were only evidence discussed in one board committee: the Quality, Safety and Patient Experience Committee. The concerns were never discussed in the Audit Committee, the Finance and Integrated Governance Committee, nor the People and Organisational Development Committee.

The position was perhaps slightly different lower

down the governance structure. The death of Child A was discussed at the Women and Children's Care Governance Board as early as its meeting on 18 June 2015. The minutes for that meeting noted the Datix incident report which had been opened in respect of Child A's death, as well as the obstetrics secondary review which had been undertaken.

However, it does not appear that the increase in the neonatal mortality, or consultants' concerns, were escalated quickly through this forum either. In October 2015 meeting of the Women and Children's Care Governance Board, the minutes quote:

"Moderate harm incidents related to neonates that sadly died ... and three unexpected neonatal deaths."

However, no substantive discussion of this is recorded and no resulting actions are identified.

The meeting of the Quality, Safety and Patient Experience Committee on 14 December 2015 was the first time that concerns about an increase in neonatal deaths were discussed at board committee level.

Mr Higgins chaired the meeting. Sir Duncan Nichol, Ms Hopwood, Ms Kelly and Ms Hodkinson were in attendance. As Ms Langdale has already described, Ms Fogarty presented Dr Brigham's "Review of Neonatal Deaths and Stillbirths at the Countess of Chester

Hospital -- January 2015 to November 2015" at this meeting. While the minutes of the meeting referred to an increase in both stillbirths and neonatal deaths, there was no mention or query of the fact that the paper presented was an obstetric review only and did not consider neonatal aspects of care. The committee appeared to have been assured or perhaps reassured by the paper.

Following the meeting, the Quality, Safety and Patient Experience Committee action log was updated to record the issue of neonatal and stillbirth review as completed.

The same paper was referred to in the minutes for the meeting of the Women and Children's Care Governance Board four days later on 18 December 2015. it is unclear what exactly was discussed about the paper at that meeting. Nevertheless, the minutes of the meeting summarised the position that no themes had been identified in the paper and each case would continue to be reviewed at multi-disciplinary meetings.

The minutes for the December 2015 meeting of the Quality, Safety and Patient Experience Committee were received at the board meeting on 2 February 2016, though the minutes were indicated to be available on request only. Attendees of the board meeting, including

Sir Duncan Nichol, Ms Hopwood, Ms Kelly and Ms Hodkinson, each of whom had been present at the December 2015 Quality, Safety and Patient Experience Committee meeting.

The minutes of the board meeting record no discussion of Dr Brigham's paper, nor neonatal mortality. It appears that although the increase in neonatal mortality had reached the attention of a board committee it had not yet made its way to discussion by the board itself.

As it transpired, the mortality rate on the neonatal unit did not appear as an item for discussion in board or board committee meetings for the rest of the period of Letby's attacks.

The minutes of the Women and Children's Care Governance Board during this period contained perhaps tangential reference to neonatal mortality. The minutes of the 14 January 2016 meeting noted a case review into Child D's death as well as an ongoing inquest into the death of Child A.

However, yet again, there appears to have been no substantive discussion of these matters.

At the meeting of the Women and Children's Care Governance Board on 21 April 2016, the action plan arising from the Stillbirth and Neonatal Death Review

was marked as complete. It was not until its 16 June 2015 meeting that the thematic review of neonatal mortality, which, my Lady, you will recall took place on 8 February 2016, was discussed by the Women and Children's Care Governance Board.

The minutes of the meeting noted a higher than expected mortality rate on the neonatal unit in 2015 but stated that "no common theme was identified across the cases".

Letby's last shift on the neonatal unit was on 30 June 2016. At no point during the period of Letby's attacks did the Women and Children's Care Governance Board escalate the issue of neonatal mortality to the Quality, Safety and Patient Experience Committee, nor did the Quality, Safety and Patient Experience Committee escalate the issue to the board.

The Inquiry will be seeking to understand why the concerns which were being expressed at the neonatal unit level were not escalated more quickly and clearly through the designated channels. And we will also be investigating if they had been, what should have happened.

My Lady, I turn now to the first involvement of the board.

It was following Letby's final attack that the

matter was eventually brought before the board by the Executive Directors. Between 24 June 2016 and 30 June 2016, following the deaths of Child O and Child P, a significant number of meetings took place between the paediatric consultants and senior management at the hospital. Counsel to the Inquiry has already set out an outline of this series of meetings already and the heavy involvement of the Executive Directors.

By the 30 June 2016, the board chairman, Sir Duncan Nichol, was included, meeting with both the Executive Directors and the consultant paediatricians.

On 5 July 2016 it appears that the Non-Executive Directors were informed of the concerns raised. This was not, however, at the public meeting of the board on that day. In fact, there was no mention of neonatal mortality or the potential involvement of a nurse at that meeting. Rather, it seems that prior to the public convening of the board, a private meeting of the Non-Executive Directors was held. This private meeting was not minuted although Ms Fallon has provided to the Inquiry a copy of the brief handwritten note she took during it.

Those handwritten notes and Ms Fallon's witness statement to the Inquiry suggest that the Non-Executive Directors were informed at the private meeting about the

concerns regarding neonatal mortality; also, about the plan to downgrade the neonatal unit and the proposal for an external review.

It is unclear whether the Non-Executive Directors were at this stage told about the concerns specifically raised about Letby. Ms Fallon states in her witness statement that she did not learn of the suspicions regarding a nurse on the neonatal unit until she and Mr Oliver asked Sir Duncan about it on 12 July 2016.

An extraordinary meeting of the Board of Directors was held on 14 July 2016. All the Directors except Ms Hodkinson, Mr Higgins and Mr Oliver attended the meeting. Dr Stephen Brearey and Dr Jayaram were also present.

During the meeting Mr Chambers informed the board that there had been an unexplained increase in neonatal mortality at the Trust. The board were told that a peer review had been undertaken which was inconclusive and that Mr Harvey would undertake his own review of the data.

The official minutes record Dr Jayaram asking for one matter not to be minuted. In a set of handwritten notes for the meeting, Dr Jayaram was noted to set out Letby's association with the neonatal deaths refer to Letby as "the elephant in [the] room".

Mr Chambers and Mr Harvey set out to the board the next steps to be taken. The neonatal unit was to be downgraded. The review was to be undertaken by the Royal College of Paediatrics and Child Health in August 2016. Mr Harvey told the board that the review team would be briefed on "the explicit concerns" which would be discussed as part of the references and interviews.

According to the minutes a number of questions were asked by the Non-Executive Directors of the meeting. Mr Wilkie queried the reasons for not involving the police and asked how confident the hospital were that all risks posed by Letby was being removed. Ms Fallon asked how long Letby had been on the unit and for how many of the babies Ms Letby had been on shift. Ms Hopwood asked about the practicality of Letby continuing to work under supervision.

The need for continued monitoring was raised at the meeting. Sir Duncan said that he and Mr Higgins as Chair of the Quality, Safety and Patient Experience Committee would be in very close contact with the Royal College review. Ms Hopwood stated that another board meeting should be held following the review as a minimum.

Following its 14 July 2016 Extraordinary Meeting,

the board did not discuss neonatal mortality nor the concerns raised about to be Letby again until the new year.

Lack of official discussion by the board does not appear to have been substituted by informal discussion. None of the Non-Executive Directors have recalled such informal discussions about neonatal mortality or the reviews undertaken. Mr Wilkie does, however, describe in his witness statement to the Inquiry, approaching Ms Kelly on 15 July 2016, the day after the Extraordinary Meeting of the board.

Mr Wilkie says he told Ms Kelly he was concerned about the decision that Letby should be supervised rather than removed from the neonatal unit. He asked that his concerns be passed on to Mr Chambers.

Neonatal mortality did appear as an item for discussion at the committees lower down the governance structure following this, however.

At the meeting of the Women and Children's Care Governance Board on 21 July 2016 a new risk was identified in the minutes, and we have referred to that already: "Potential damage to reputation of neonatal service and wider Trust due to apparent increased mortality within the neonatal unit".

This would seem to be a reference to the risk

entered onto the Urgent Care Risk Register in the same terms. It appears that the Women and Children's Care Governance Board, whose remit specifically included clinical performance and risk management, did not query the fact that the risk was framed in terms of reputation as opposed to patient safety.

At the same meeting the deaths of Child O and Child P were recorded as National Patient Safety Alert Level 2 incidents. The Quality, Safety and Patient Experience Committee met on 15 August 2016. The meeting as usual was chaired by Mr Higgins. Sir Duncan Nichol and Ms Fallon also attended.

At the meeting, Ms Millward, the hospital's Head of Risk and Patient Safety, presented the document titled "Position Paper -- Neonatal Unit Mortality" prepared by herself and Ms Kelly.

The conclusions of this paper have previously been presented to the executive team. Counsel to the Inquiry has already outlined the findings of that position paper, namely that the only firm conclusion it drew was that the rise in neonatal mortality could not be explained by common cause fluctuations. It offered some possible explanation for at least part of the rise. The position paper made no mention of or attempt to consider the concerns raised about Letby. Nor were these

concerns raised or discussed at the meeting of the committee.

The minutes of the meeting were recorded by Mr Higgins and said there would be an official update and initial review in relation to neonatal mortality at the next meeting of the Quality and Safety Patient Experience Committee.

That meeting came the following month on the 19 September 2016. It was chaired by Mr Higgins and with Sir Duncan Nichol, Mr Harvey, Ms Hodkinson, Ms Hopwood and Ms Fallon in attendance. At the meeting, Mr Harvey provided a verbal update on the review undertaken by the Royal College of Paediatrics and Child Health earlier that month. He told the committee that final report was awaited, but that the external review team had not raised any immediate concerns.

Mr Harvey also noted the recommendation for the hospital to commission a forensic review of the deaths. Neonatal mortality was not mentioned at subsequent meetings of the Quality, Safety and Patient Experience Committee until February 2017, after a version of the Royal College's report had been published. The question arises as to why, when Sir Duncan Nichol had identified an apparent need for himself and Mr Higgins, as chair of the Quality, Safety and Patient Experience Committee, to

remain close with the external review.

Did that committee only ever consider the review once it was published? And then, by way of an oral update provided by Mr Harvey?

By the end of November 2016, following receipt of a finalised Royal College report, and as Letby's grievance procedure drew to a close, the executive team appeared to have realised a need to return to the Board of Directors. The minutes of the meeting of the Executive Directors Group on the 30 November 2016 noted that Mr Harvey was to talk with Sir Duncan Nichol about next steps with the board. That conversation appears to have taken place shortly afterwards, although Sir Duncan says he cannot recall the details of it.

This brings us to the second Extraordinary Meeting of the board. On 30 December 2016, Mr Chambers, Mr Harvey and Sir Duncan met, it seems in preparation for a proposed forthcoming Extraordinary Meeting of the board. A handwritten note of the meeting recorded discussion of the proposed distribution of the report of the RCPCH, including the query:

"Unredacted version > [should] it go anywhere?"

The notes gave an apparent answer to that:

"Redacted version to be used."

The Inquiry will be investigating how the Royal

College report was distributed and used by senior management at the hospital.

It was at this meeting it appears that the roadmap forward was set out.

First would be the board meeting, where the external review would be formally accepted and an action plan presented.

Second would be the meeting with the paediatric consultants. The statement from Letby was to be shared with the board and the paediatric consultants.

Third would be contact with the coroner, with a meeting to take place by the end of January.

Fourth and finally, as recorded towards the end of the handwritten note:

"Endorse transition of [Letby] into unit".

The Extraordinary Meeting of the board was held on 10 January 2017. All the Directors attended except Mr Higgins. Mr Harvey presented a paper he had prepared summarising his recommendations to the board. He told the board about an in-depth review which had been commissioned, namely a case review undertaken by Dr Hawdon, the minutes recorded Mr Harvey's summary of its findings:

"The case review very much reinforce[s] what is in the [Royal College] review, it comes down to issue of

leadership, escalation, timely intervention and does not highlight any single individual."

Mr Chambers told the board that once they had received the final four cause of death reviews from Alder Hey Hospital, a line could be drawn under them. Mr Chambers described the concerns raised about Letby as unsubstantiated. As Counsel to the Inquiry noted yesterday, Mr Chambers is recorded as saying that the grievance procedure had exonerated her. He told the board: the hospital would do everything it could to manage a safe transition of Letby back to the neonatal unit. Ms Hodkinson read Letby's statement to the board.

The board were asked to accept the Royal College report, support the executive team in implementing the recommendations described in the review, and support the executive team in assisting Letby's return to the neonatal unit. The minutes recorded that the board duly ratified each of these decisions.

Sir Duncan Nichol has publicly said that the board were misled by Mr Chambers and Mr Harvey at this meeting. In his statement to the Inquiry, Sir Duncan Nichol says this:

"At the time, I had no cause to question Ian Harvey's reports. Subsequently, I felt that I and the board had been misled by not being told about

Dr Hawdon's lack of capacity to complete the case reviews in sufficient depth. I had read the RCPCH's (unredacted) report and Dr Hawdon's case review summaries, and was relying on the advice of Ian Harvey, Tony Chambers, and his fellow Executive Directors."

The Inquiry will be looking at the information provided to the board on 10 January 2017, and how it was presented to them. Were the Non-Executive Directors misled? Was the information and were the documents they were provided with sufficient and accurate to enable them to perform their role? Why did the Non-Executive Directors not ask to see copies of the grievance outcome, or Dr Jane Hawdon's review, before supporting Letby's return to the neonatal unit? Did the board perform its function of challenging the actions recommended by the Executives, or did it simply ratify decisions already made?

It is notable that the same day as the board meeting, Mr Chambers, Ms Kelly, Ms Rees, Letby and Ms Cooper, the Royal College of Nursing representative supporting Letby, met. Mr Chambers told Letby that the board were clear in their support for her return to the neonatal unit.

The second step in the roadmap, the meeting with the paediatric consultants, took place on 26 January 2017.

Mr Chambers, Mr Harvey, Ms Kelly, Ms Hodkinson and Mr Cross attended from the Executive team. Ms Hopwood was the sole Non-Executive Director present.

You will recall, my Lady, that this is the meeting where Mr Chambers and Mr Harvey both said that there was a need to draw a line under Letby. Ms Hopwood understood her role at the meeting to be merely one of observer. What function a Non-Executive Director was to perform as observer at this meeting is currently unclear.

The board met again on 7 February 2017. All the Directors were present except Mr Higgins and Ms Fallon. This was the only public meeting of the board in the period June 2015 to May 2017 where neonatal mortality was discussed. The minutes record that Mr Chambers provided an update to the board, informing them that Dr Hawdon's case review had been completed. Mr Chambers summarised that the review did not identify a single causal factor for the increase in neonatal mortality or raise concerns regarding unnatural causes.

There was no apparent mention of the fact that Dr Hawdon had recommended broader forensic review of the deaths of Child A, Child I, Child O and Child P, which she considered remained unexplained and unexpected.

We move forward in Spring 2017. As we've already

set out, it was from February 2017 that the consultant paediatricians increased further the pressure they were exerting to the Executives to investigate their concerns about neonatal mortality and its association with Letby. This was not seemingly reflected in the meetings of the Quality, Safety and Patient Experience Committee or the Women and Children's Care Governance Board.

The Quality, Safety and Patient Experience Committee met on 20 February 2017. The meeting was chaired by Mr Higgins, and attendees included Sir Duncan Nichol, Ms Kelly and Mr Harvey. Mr Harvey provided a verbal update on the reviews carry out into neonatal mortality, informing the committee that the Royal College's report had been published and an in-depth secondary mortality review had been carry out by Dr Hawdon. An action plan was to be formulated based on the recommendations of the references.

Three days later the Women and Children's Care Governance Board met and noted its receipt of the Royal College's report. There seems to have been no substantive discussion of the report. The minutes simply recording the Women and Children's Care Governance Board would await direction from the Executive team regarding next steps.

On 28 March 2017, Sir Duncan Nichol was told that

the consultant paediatricians were assisting on a police investigation. There was no discussion of this at the board meeting on 4 April 2017.

Sir Duncan has suggested that around this time there would almost certainly have been informal contact between him and Non-Executive Directors, not least to explain the forthcoming Extraordinary Meeting of the Board of Directors, although he was unable to recall detail of any such contacts or discussions.

My Lady, this brings us to the third Extraordinary Meeting of the board. The third Extraordinary Meeting of the board was convened for 13 April 2017. The meeting was attended by all the Directors except Mr Holden.

Simon Medland QC, as he was then, the barrister whom the Trust had instructed to meet with the consultant paediatricians, also attended. The minutes of Mr Medland's meetings with the paediatricians the previous day were shared with the board. He relayed the consultants' view that the matter needed to be escalated to the police.

Although Mr Medland was recorded as stating that his view that there was no evidence of a crime, he told the board:

"You need to accept that if something is still

unanswered or there are still genuine concerns in well-minded people, you should go to the police".

Mr Medland also suggested an alternative of approaching a police member of the Child Death Overview Panel. The cause of action the board appears to have agreed on was not yet to contact the police, but instead to return to Dr Hawdon to enquire what she meant by further forensic review.

However, at least some of the Non-Executive Directors did consider there remained genuine concerns on the part of the paediatricians. Delay also appears to have been on the mind of the board. Mr Wilkie asked whether the Trust could truthfully say that there had not been delay on its part.

Mr Higgins said that there was "A need for something bombproof as quickly as possible".

Ms Fallon asked about the timeline to speak with Dr Hawdon, and Ms Hopwood said she felt "it had got away from us".

During the meeting Sir Duncan referred to the Beverley Allitt case. You will recall, my Lady, that Sir Duncan was Chief of the NHS Management Executive at the time of Beverley Allitt's crimes and was tasked with the dissemination of the Clothier Inquiry Report across the NHS. There was no reference to the Allitt case in

the previous Extraordinary Meetings of the Board of Directors. The board also discussed communications with the parents of the babies who had died. Mr Harvey told the board that the hospital had endeavoured to keep the families up to date, although there were things to be learned. Mr Chambers stated that the hospital had written to the families advising them in an open and transparent way of what the hospital knew.

The Inquiry is concerned to understand the basis on which Mr Harvey and Mr Chambers made these assertions to the board. We will hear that parents of babies who were attacked by Letby were not contacted by the hospital in advance of the Royal College review; that parents received letters from the hospital informing them of the publication of the Royal College report hours before it was due to go live; that parents struggled to arrange meetings to talk with Mr Harvey; and that parents were never told by the Trust that concerns had been raised about the potential involvement of a particular nurse.

I now turn to the events which led to the police.

By the time the board next met on 2 May, the decision to invite a police investigation had all but been made by the Executive team. The board were updated both the meetings with the Child Death Overview Panel and Superintendent Nigel Wenham. There was also some

discussion of communication with parents and the deterioration in the relationship between the paediatricians and the Executive team. The latter is another issue which the Inquiry intends to explore, namely when did the board, particularly the Non-Executive Directors, become aware of a deterioration in the professional relationships between the consultant paediatricians and the Executive team, and what did they do about it?

Why did it take until July 2016 for the increase in neonatal mortality to be discussed at a board meeting?

Why, when informed of the concerns about neonatal mortality, did the board take the actions that it did?

Although it did not in fact occur, in January 2017 the board approved Letby's planned return to the neonatal unit. Sir Duncan Nichol knew about the grievance procedure and its outcome. The Trust did not formally invite a police investigation until May 2017.

We conclude the topic of governance and the role of the board with this final observation, my Lady: while it is right that the Inquiry scrutinises, whether collectively, each of these committees and the board operated as they should have, when doing so, we do not intend to lose sight of the fact that governance is both about whether control and direction was imposed as it

should have been, but also about whether individuals were held to account. The Inquiry will be relentless in its focus on the people attending all of these many meetings: what they knew, what they should have known, what they said and what they didn't say, and, when all of that is established, why.

My Lady, that concludes the governance part of this opening statement.

I'm a little early so I would propose to move on to the next chapter, if that's convenient to you.

LADY JUSTICE THIRLWALL: Yes, it certainly is convenient. If it suits you, then let's get on with it.

MR DE LA POER: So we turn now, my Lady, to consider the role and involvement of external bodies in the events at the Countess of Chester Hospital.

We will consider what information was raised, when it was raised, and what was done. And we shall start with an explanation of the role of the main external bodies to be considered.

A local authority has an overarching responsibility for safeguarding and promoting the welfare of all children and young people in their area. Every local authority was required by section 13 of the Children Act 2004 to establish a Local Safeguarding Children Board, which was responsible for developing

policies and procedures for safeguarding children within its area.

Membership of the board was defined by the Act. In addition to representatives of the local authority, membership included the police, NHS England, and any NHS Trusts or Foundation Trusts that had most of their hospitals in that area.

The Countess of Chester Hospital was in the area of the Local Safeguarding Children Board of Cheshire West and Cheshire Council. Ms Kelly was one of its board members.

One of the duties of a Local Safeguarding Children Board was to collect and analyse information about child deaths. In England, Local Safeguarding Children Boards were required by statute to ensure that a review of each child death resident in their area was undertaken by a Child Death Overview Panel. These panels had a fixed core membership drawn from the same organisations represented on the Local Safeguarding Children Board.

The function of the Child Death Overview Panel was to review every child death, to determine whether that death was preventable, and whether action could be taken to prevent future deaths.

Patterns or trends in the local data were to be reported to the Local Safeguarding Children Board.

Where neglect or abuse was suspected, a referral would be made to the board for consideration of whether a Serious Case review was required.

The Countess of Chester Hospital was in the area of the Pan Cheshire Child Death Overview Panel. That panel acted on behalf of the Local Safeguarding Children's Boards for Cheshire East, Cheshire West, Cheshire, Halton and Warrington. As we will describe, two of the seven deaths in respect of which Letby was convicted of murder were considered by the Pan Cheshire Death Overview Panel. The other five deaths were reviewed by panels in Lancashire, Merseyside, and a panel in Wales.

Local authorities were required to designate an officer or team of officers to manage allegations against people that work with children. These were known as Local Authority Designated Officers, or LADOs. The Local Authority Designated Officer for Cheshire West and Cheshire Council was Paul Jenkins. The Local Authority Designated Officer would oversee and direct investigations into an allegation. They would work with other agencies, such as the police and social care. Letby was not referred to the Local Authority Designated Officer until 29 March 2018.

NHS England is the commissioner of Neonatal Critical Care Services and has been since 2012. It is also the

successor of the Independent Regulator of Foundation Trusts, also known as Monitor, which was responsible for regulating the provision of healthcare services with a focus on board and committee level effectiveness.

In April 2016, Monitor and the NHS Trust Development Authority, were brought together under a formal joint working arrangement to create NHS Improvement. In February 2019, NHS England and NHS Improvement came together and in July 2022 officially merged as NHS England.

The neonatal unit at the Countess of Chester Hospital was one of nine neonatal units that formed the Cheshire and Merseyside Neonatal Network established in 2004. As Counsel to the Inquiry explained yesterday, Ms Julie Maddocks was a director of the network and Dr Nimish Subhedar was its clinical lead. The Neonatal Network had a Steering Group chaired by Ms Maddocks which met quarterly. Part of the role of the Steering Group was to monitor performance which included considering neonatal mortality.

The network also had a Clinical Effectiveness Group chaired by Dr Subhedar. It met bimonthly. There would be discussion of mortality reviews across the network of those meetings.

The Royal College of Paediatrics and Child Health is

a charity whose membership is made up of child health professionals, predominantly paediatricians. It provides the mandatory training pathways for doctors in the United Kingdom who wish to train in paediatrics. Its Royal Charter gives it the power to act as a consultative body on paediatrics. As stated previously, the Royal College of Paediatrics and Child Health undertook an invited review of the neonatal unit at the Countess of Chester Hospital on the 1 and 2 September 2016, providing its report to the hospital on 28 November 2016.

The Care Quality Commission is the independent regulator of healthcare in England. It is responsible for regulating providers of care such as NHS Foundation Trusts. It monitors and inspects those it regulates and has the power to take civil or criminal enforcement action where regulatory standards are not met. The Countess of Chester Hospital NHS Foundation Trust was registered with the Care Quality Commission on 1 April 2010. The Care Quality Commission carried out an inspection at the hospital in February and March 2016 and published its inspection report on 29 June 2016.

The Nursing and Midwifery Council is the regulatory body for nursing and midwifery professionals in the United Kingdom. It was established by a statutory

instrument, the Nursing and Midwifery Order 2001, which provides that its overarching objective is the protection of the public.

It operates a register of qualified nurses and misses and publishes the Code of professional standards applicable to them. It is required by the Code to act upon allegations made to it that the fitness to practise of a registrant is impaired. It has the power to seek disclosure from third parties, and to impose interim measures of conditions of practise or suspension whilst carrying out an investigation. Conditions of practise can include matters such as a requirement to work only under supervision, or avoid a particular area of practics.

Where the fitness to practise of a registrant is found to be impaired, sanctions included suspension and strike off. The NMC operated an employer-linked service that provided support to employers of nurses with fitness to practise concerns.

The Nursing and Midwifery Council was notified that there were concerns about Letby on 6 July 2016, but did not seek a fitness to practise referral until two years later on 3 July 2018 after she had been arrested. It did not impose an interim suspension order until more than two years after that on 20 November 2020, after she

had been charged.

The General Medical Council is the regulator of doctors in the United Kingdom. It operates a register and has the power to investigate concerns about the fitness to practise of its registrants. It publishes guidance on standards of professional conduct and performance, including in particular Good Medical Practice 2013, the professional standards applicable to doctors.

The Royal College of Nurses is a union and professional body for nurses. It has a membership in excess of 500,000 people. It is not a regulator. It provides advice, support and legal representation to its members.

Finally, in terms of those bodies providing external scrutiny, the British Medical Association, that is the trade union and professional body for doctors and medical students in the UK, and provides representation and support to them. It is not a regulator, its primary role is in employment matters.

My Lady, I wonder if that would be a convenient moment before we turn to a fresh topic?

LADY JUSTICE THIRLWALL: Very well, thank you very much Mr de la Poer. We will resume at 11.32.

(11.17 am)

(A short break)

(11.33 am)

LADY JUSTICE THIRLWALL: Mr de la Poer.

MR DE LA POER: My Lady, I turn now to guidance aimed at keeping children safe.

There were number of duties imposed on the Trust and the professionals employed there that were applicable when children suffered or were at risk of suffering harm. The local practice in Cheshire at the time required all child deaths to be reported to the coroner, irrespective of the circumstances of death. All child deaths also had to be reported to the Child Death Overview Panel.

Unexpected or unintended events in a hospital that led to harm had to be reported to NHS England and the Care Quality Commission. Serious incidents and "Never Events" had to be reported as such to NHS England. "Never events" are a particular type of clearly defined and wholly preventable serious incidents, including those which have the potential to cause serious patient harm or death.

In 2004, the Royal College of Paediatrics and Child Health, together with the Royal College of Pathologists, co-published guidance in relation to Sudden and Unexpected Deaths in Infancy. That guidance was based

on Sudden and Unexpected Infant Deaths which occurred in the community and does not mention such deaths occurring in hospital.

This version was in force throughout the period of June 2015 to July 2016, as such, it did not apply to the situation facing those working at the Countess of Chester Hospital where the deaths occurred.

Although the RCPCH and Royal College of Pathologists's Sudden and Unexpected Deaths in Infancy 2004 Guidance did not apply to the situation with which we are concerned, we mention it because some of the language mirrored that used in a piece of statutory guidance in relation to child safeguarding which was published in 2013 and subsequently updated in 2015.

That statutory guidance was called Working Together to Safeguard Children: A Guide to Interagency Working to Safeguard and Promote the Welfare of Children. It is commonly referred to simply as "Working Together". The relevant edition during the time we are concerned with was dated March 2015.

The Working Together Guidance itself makes clear that it was to be complied with unless exceptional circumstances arose. The guidance expressly stated that it was to be read and followed by health services professionals. It set out the need for organisations to

have in place arrangements that reflected the importance of safeguarding and promoting the welfare of children.

There was specific guidance in Working Together as to the steps to be taken following an unexpected death of a child. The process also applied where professionals were uncertain whether the death was unexpected.

Working Together defined an unexpected death as follows:

"The death of an infant or child which was not anticipated as a significant possibility for example, 24 hours before the death; or where there was an unexpected collapse or incident leading to or precipitating the events which lead to the death."

This language is used in the guidance published by the RCPCH in 2004. Under Working Together, following an unexpected death, the local designated paediatrician, the coroner and the police were to be informed. The guidance anticipated that police conducted an investigation, stating that:

"In any case of a sudden expected death of an infant or child, the police have a duty to investigate the death on behalf of the coroner."

A Senior Investigating Officer within the police retained overall responsibility for the investigation.

The guidance anticipated the designated paediatrician initiating and information sharing and planning discussion between the lead agencies such as health, police and social care.

My Lady, the evidence we have obtained demonstrates that this guidance was not complied with. Unexpected deaths did not trigger a police investigation. The Senior Investigating Officer was not notified of the instances of unexpected death.

An important issue that we shall explore in evidence, and one that we will return to, is the extent to which this guidance on unexpected deaths was properly understood by those working at the hospital and by connected external agencies.

There is evidence of a failure to understand what process, if any, was to be followed for an unexpected child death in a hospital. It appears that there was a belief that an exception existed for unexpected deaths in hospital, and the guidance did not apply.

Working Together guidance makes no exception for unexpected deaths in hospital. The Inquiry will hear evidence from Dr Joanna Garstang, a Clinical Associate Professor of Child Protection. Her statement to this Inquiry explains that unexpected child deaths in hospital should have been investigated in the same way

as unexpected child deaths in the community were.

Although Working Together did not state explicitly that its guidance on unexpected deaths applied to deaths in hospital, local guidance did. The Pan Cheshire Local Safeguarding Childcare Board published its own guidelines for the management of sudden unexpected deaths in infancy and childhood.

These local guidelines divided unexpected deaths into those that were "unexpected and unexplained", and those which were "unexpected and explained", a division not found in Working Together to Safeguard Children.

For an unexpected and explained death, the guidelines did not need to be followed if a satisfactory explanation is determined. For an unexpected and unexplained death, the guideline was to be followed.

These guidelines had a dedicated section on unexpected deaths on a hospital ward or hospital setting. There was even a flowchart showing the steps to be taken following an unexpected death headed "Child Death in Hospital/Community".

You may consider, consistent with the evidence of Dr Garstang, that this made plain that the same process applied irrespective of location.

This local guideline provided that where there was an unexpected and unexplained death in a hospital, the

senior nurse on duty will inform the police, and the location where the child collapsed will be treated as a scene of Sudden Unexpected Death in Infancy and Childhood investigation.

A rapid response multi-disciplinary meeting was required within 72 hours. A local child death review was required within one to eight weeks.
A multi-disciplinary case discussion meeting was required within two to six months.

My Lady, there is little evidence demonstrating that the local guideline was adhered to, certainly not in respect of the unexpected and unexplained deaths the Inquiry will be considering. It would appear that only in the case of the death of Child C, where there was an initial strategy meeting some 18 days after the death, does there appear to have been some form of implementation of the guideline.

For those deaths that were unexpected but explained, the local guideline anticipated discussion with the parents and the coroner to decide an explanation for the death. The Inquiry will explore the extent to which such discussions were held. Where the parents or staff had any concerns about the child's management, the guidelines stated that thorough investigation was needed.

Of note it provided that:

"The police will be involved if it is considered there were suspicious circumstances around the child's death or concerns have been raised about neglect or inappropriate medical or nursing care."

Before we leave the topic of Sudden and Unexpected Death in Infancy guidance, we note that in November 2016, the RCPCH and Royal College of Pathologists published updated guidance which brought it into line with the Working Together Guidance and the local Pan Cheshire guidance and expressly included reference to the sudden collapse and death of a child on a neonatal unit.

We turn from the sudden unexpected death in infancy guidance to a Memorandum of Understanding.

In addition to the guidance in relation to expected child deaths, there was a Memorandum of Understanding on investigating patient safety incidents involving unexpected death or serious untoward harm. On the face of the document, it appears to have been agreed in 2016 between the Department of Health on behalf of the National Health Service, the Association of Chief Police Officers and the Health and Safety Executive, it was archived in the National Archives in 2013, and was not replaced. It was archived possibly because it referred

to organisations abolished following restructuring of the National Health Service.

The Memorandum of Understanding contained a protocol for the National Health Service patient safety incidents involving unexpected death or serious untoward harm requiring investigation by the police and/or the Health and Safety Executive. It was not specific to child deaths.

The foreword states that:

"Investigation should take place only where there is clear evidence of a criminal offence having been committed."

Paragraph 1.1 of the protocol stated that:

"The investigation would normally be required if an incident had arisen from or involved criminal intent, recklessness or gross negligence."

Paragraph 2.7 sets out the type of incident that might prompt the trust to involve the police. Included were those where there was evidence or suspicion that the actions leading to harm or adverse consequences were intended.

Guidelines to the NHS were issued to accompany the Memorandum of Understanding. We will look at this document in detail during the evidence. For the time being it is sufficient to observe that it provides what

are described as "case studies" which appear to be held up as examples of good practice.

In the first, it is suspected that a device had been tampered with and as a result, the police were called.

The Guidelines to the NHS were archived at the same time as the Memorandum of Understanding. Despite a recommend to this effect in 2018 by Professor Norman Williams in his "Gross Negligence in Healthcare" report, the Memorandum of Understanding and the guidelines have yet to be replaced.

The Inquiry has been informed by the Department of Health and Social Care that a working group established following Professor Williams' report is working on this, and "it is currently being finalised with a view to publishing as soon as possible."

The Inquiry Will be seeking to understand why there was no such guidance in place from 2015 to 2017, and why there is still no such guidance in place.

I turn now to consider the reports to external bodies. The Inquiry will explore the circumstances in which suspicions about Letby were raised externally. My Lady, you may consider that a troubling feature revealed by the evidence is that all too often, it appears that a high threshold was believed to exist for raising concerns of potential harm to babies, namely

that some sort of proof of criminality was necessary before those with the responsibility to investigate concerns could be notified.

This is troubling, my Lady may think, because it is contrary to the clear guidance which safeguarding provides. Child protection, or safeguarding as it is now referred to, sets a low threshold for raising concerns in respect of child safety. It was not necessary for those with concerns about the safety of babies at the hospital to embark on their own investigation or evidence-gathering exercise before making referrals.

Working Together provided that any allegation that a person working with children had "behaved in a way that has harmed a child, or may have harmed a child, or that they may possibly have committed a criminal offence related to a child" should be reported immediately to a senior manager within the organisation, and the Local Authority Designated Officer should be informed within one working day. That provision was not, as we shall see, complied with.

The local guidance contained in the Pan Cheshire Child Death Overview Panel protocol stated that:

"Where, at any stage, a child may have been or likely to be harmed, there will need to be interagency

child protection and/or criminal investigation led by the police."

It also provided that where a suspicion arises that neglect or abuse may [and I stress the word 'may'] have been a factor in the child's death, the case should be highlighted to the chair of the relevant Local Safeguarding Children Board and Serious Case review procedures should be followed.

The Nursing and Midwifery Code of Professional Standards imposes on nurses a duty to "share information if you believed someone may be at risk of harm".

It required them to:

"Acknowledge and act on all concerns raised to you, investigating, escalating or dealing with those concerns where it is appropriate for you to do so."

The General Medical Council's Good Medical Practice required a doctor to "take prompt action" if they thought "patient safety, dignity, or comfort is or may be seriously compromised."

It provided that where a doctor had "concerns that a colleague may not be fit to practise and may be putting patients at risk", advice must be sought from a colleague, defence body or the General Medical Council. Where there were still concerns, it was necessary to report them.

The General Medical Council published specific guidance in 2012 titled "Raising and acting on concern about patient safety" which stated that all doctors had a duty:

"... to raise concerns where they believed that patient safety or care is being compromised by the practice of colleagues."

And that a doctor did:

"... not need to wait for proof -- you will be able to justify raising a concern if you do so honestly on the basis of reasonable belief."

The General Medical Council also published in 2012 guidance titled "Protecting children and young People. The responsibilities of all doctors".

It provided that:

"All doctors must act on any concerns they have about the welfare or safety of a child or young people."

It states that:

"... it is vital that all doctors have the confidence to act if they believe that a child or young person may be being abused or neglected. Taking action will be justified, even if it turns out that the child or young person is not at risk of suffering, abuse or neglect, as long as the concerns are honestly held and reasonable, and that the doctor takes action through

appropriate channels."

This guidance requires doctors to "have a working knowledge of local procedures for protecting children and young people in their area" and requires them to know what to do when concerned that a child or young person is at risk of, or is suffering abuse or neglect.

It provides specific advice on sharing information stating this:

"You must tell an appropriate agency, such as your local authority children's services, the NSPCC or the police promptly if you are concerned that a child or young person is at risk of, or is suffering abuse or neglect unless it is not in their best interests to do so. You do not need to be certain ... the possible consequences of not sharing relevant information will, in the overwhelming majority of cases, outweigh any harm that sharing your concerns with an appropriate agency might cause."

It advises that "any decision to delay sharing information must be taken cautiously" and makes the point that "in sharing concerns about possible abuse or neglect, you are not making the final decision about how to best protect a child or young person."

The April 2014 Whistleblowing Guidance for Workers and Employers in Health and Social Care makes a similar

point. It states:

"If you believe that something is wrong, you do not need proof. Speaking out early could stop the issue from becoming more serious, dangerous, or damaging."

In respect of patient safeguarding it identifies that:

"It is not the worker's responsibility to investigate or decide if abuse has happened, only to make sure that the appropriate agencies are told about their concerns or suspicions."

The Care Quality Commission published a guide on raising a concern with them. It stated that everyone working in health and social care had a duty to put patients first and protect their safety.

It encouraged and recommended attempting to resolve a concern within the organisation first. Where that could not be done or had already been tried, the guidance provided that:

"The concern could be raised in confidence with the Care Quality Commission."

It explained that raising a genuine concern about the safety of patients would be justified if done honestly and reasonably, even if the concern is mistaken.

The Inquiry will explore the extent to which all of

this guidance was understood and complied with.

There were concerns about the increase in neonatal deaths, in particular unexpected deaths, and there were concerns that Letby might be harming children long before the disclosure to the police on 27 April 2017, the referral to the Local Authority Designated Officer on 29 March 2018, and the fitness to practise referral to the Nursing and Midwifery Council on 5 July 2018.

We turn now to consider the timeline of the involvement of external bodies.

We are going to look at when they became involved, as matters unfolded, and what information was provided to them. We begin with July 2015.

On 3 July 2015, a report concerning Child D was made on the NHS England Strategic Executive Information System. This was the mechanism for reporting Serious Incidents or Never Events. In his forth statement to the Inquiry, Professor Sir Stephen Powis, the National Medical Director of NHS England, explains that a death in itself would not constitute a Serious Incident. An act or omission in the delivery of healthcare that resulted in death or harm would lead to a Serious Incident being declared. We will examine where an unexpected death fits into this process.

The reason given for reporting Child D was

documented by NHS England to be "unexpected/potentially avoidable death". However, the Serious Incident being reported was the delay in recognising signs of sepsis when Child D was born on 20 June 2015.

On 9 July 2015, the earlier death of Child A on 8 June 2015 was reported to the NHS England's National Reporting and Learning System. This is the national database to which patient safety incident reports are uploaded.

Reporting to the National Reporting and Learning System satisfied the obligation on the Countess of Chester Hospital to report patient safety incidents resulting in severe harm or death to the Care Quality Commission as reports to this system were shared with the Care Quality Commission.

Incidents could be reported as "no harm", "low harm", "moderate harm", "severe harm", or "death/fatal". If a patient safety incident was recorded as resulting in severe harm or death and the report suggested an ongoing risk to patient safety,

Professor Sir Stephen Powis explains in his fourth statement to the Inquiry that NHS England's National Patient Safety Team would look for evidence of escalation of concerns. The description in the report of Child A's death was:

"Sudden and unexpected deterioration and death or patient on the neonatal unit after full resuscitation requiring post-mortem".

The incident was categorised as being of the "no harm" severity. We will explore in evidence why this is death and others were categorised as "no harm" events and whether that was a proper categorisation.

On 16 July 2015 a review of the death of Child D was undertaken by a Death Review Panel in Wales chaired by Dr Lawrence Dixon. This was less than a month after Child D's death on 22 June 2015, which had been the third death on the neonatal unit within a fortnight.

We have explained that local authorities in England had a statutory duty to ensure that all child deaths were reviewed by a Child Death Overview Panel. This statutory duty did not apply in Wales. The panel that reviewed Child D's death had been set up informally and had no specific statutory footing. Its remit appears to have been narrower than that for Child Death Overview Panels in England.

Certainly its reviews appeared rather more succinct.

My Lady, you may query why the death of Child D in Cheshire was being reviewed by a panel in Wales. Prior to the 2015 edition of Working Together, the 2010 edition had provided that the Child Death Overview Panel

in the area where the death occurred would be notified of the death. For all deaths at the Countess of Chester Hospital, that would have resulted in the Pan Cheshire Child Death Overview Panel being notified of their deaths. The 2010 guidance envisaged there being liaison with the Child Death Overview Panel where the child resided, if different, to determine which would take responsibility for the review.

The obvious benefit of that system was that where there was a cluster or pattern of deaths in one area involving children who lived in different areas, the Child Death Review process would be better able to detect and interrogate that cluster.

However, this process of liaising between Child Death Overview Panels was not repeated in the 2015 edition of Working Together. The 2015 edition simply stated that the Local Safeguarding Children Board was:

"... responsible for ensuring that a review of each death of a child normally resident in the LSCB's area is undertaken by a [Child Death Overview Panel]."

The Pan Cheshire Child Death Overview Panel Protocol published in July 2015 was not particularly clear on this point. Certainly the practice that appears to have been followed at the time was that only the panel in the area where the child resided was notified. The result

was that the seven deaths we are focusing upon were reported to four different panels. The ability of any one of them to detect a pattern was thereby diminished. This suggests there was a significant issue with the system, which requires to be addressed.

Returning to the review of the death of Child D. It was conducted before the post-mortem report was available, and before the Obstetric Secondary Review Team's case review. A panel in England would not usually undertake a review whilst other investigations were ongoing. The notes of the panel's review, which are extremely brief, do not refer to the fact that Child D was one of three deaths in less than a fortnight. They do not refer to the fact a serious incident had been reported to the Strategic Executive Information System. The note simply records that Child D died at the Countess of Chester Hospital two days after birth. The panel gave a cause of death of "complications of delivery".

(Pause) No further action was recommended. No further review was planned.

On 21 July 2015, the Care Quality Commission met with Mr Harvey, Mr Chambers, Ms Kelly and Ms Millward. The notes of this meeting do not indicate discussion of neonatal issues or the recent incidents of unexpected

neonatal deaths. This will be explored in oral evidence.

We turn then to August 2015. The report of a death of Child C on 14 June 2015 was uploaded to the NHS England's National Reporting and Learning System on 14 August 2015. It was reported as being in the "no harm" severity category.

Similarly, the reports of the death of Child E on 4 August 2015 was uploaded to the National Reporting and Learning System on 24 August 2015 in the "no harm" severity category.

Moving to September 2015. On 9 September 2015, the report of a death of Child D was uploaded to NHS England's National Reporting and Learning System but it was categorised as "moderate harm" that categorisation is at odds with the draft report of the Obstetrics Secondary Review Team's review on 28 August 2015, which that characterised Child D's case as having a "severe severity level".

On 16 September 2015 there were meetings of both the Steering Group and the Clinical Effectiveness Group of the Cheshire and Merseyside Neonatal Network, both were attended by Dr Brearey.

Quarterly reports containing data on each neonatal unit in the network were supposed to be prepared for

Steering Group meetings. Those reports contained data on neonatal mortality. As I have indicated, part of the Steering Group role was to monitor performance of the neonatal units. That included, as Dr Subhedar's statement to the Inquiry explains Identifying:

"... variations in clinical outcomes which would be included in neonatal mortality."

However, no quarterly report was prepared for the meeting on 26 September 2015. Indeed, it appears no quarterly report had been prepared for the previous meeting on 4 June 2015 either.

The last quarterly report was prepared for the Steering Group meeting on 12 March 2015. It showed three deaths in 12 months at the Countess of Chester Hospital, with zero deaths in three of the four quarters covered.

The notes of the meeting on 16 September 2015 do not describe any discussion of the recent neonatal deaths at the Countess of Chester Hospital. The Inquiry will explore in evidence why that was the case, and whether there should have been discussion within that forum.

The notes of the meaning of the Clinical Effectiveness Group on the same day describe three deaths at the Countess of Chester Hospital that were "under review" and would be discussed at subsequent

meetings. Dr Brearey's statement to the Inquiry is that the deaths of Child A, Child C, and Child D were discussed during the meeting.

He also states that he raised informally with Dr Subhedar after the meeting the fact that there had been five deaths on the unit since June 2015. But he did not mention any concerns about Letby.

Two days later on 18 September 2015, the Local Safeguarding Children Board had a meeting. This was attended by Ms Kelly and Dr Mittal as well as Detective Chief Superintendent Nigel Wenham of the Cheshire Police. The notes do not indicate that there was any discussion of or concerns raised in relation to neonatal mortality or incidences of unexpected death.

We move from September to November 2015.

There was a further meeting of the Clinical Effectiveness Group of the Cheshire and Merseyside Neonatal Network on 12 November 2015. This was attended by Ms Powell and Dr Brearey.

The discussion of mortality included three deaths at the Countess of Chester Hospital, one of which appears to be the death of Child E. The notes of the meeting do not expressly describe the death as unexpected. They do not describe any discussion of concerns of deliberate harm or increased mortality.

Dr Subhedar's evidence to the Inquiry is that if there had been concerns, he would have expected them to be raised at the Steering Group, rather than this Clinical Effectiveness Group. Indeed, he states he would have considered it inappropriate for staffing factors relating to the deaths to be discussed at the Clinical Effectiveness Group. Similarly, Dr Brearey's statement to the Inquiry is that he did not think the Clinical Effectiveness Group an appropriate forum to raise concerns about Letby.

He does state that he approached Dr Subhedar again after this meeting. The Inquiry will explore if and why there was a culture that deemed raising safeguarding concerns in a clinical effectiveness meeting was inappropriate.

On 27 November 2015 the report of the death of Child I on 23 October 2015 was uploaded to NHS England's National Reporting and Learning System. The severity categorisation was again "no harm".

We move forward to December 2015. There was a meeting of the Cheshire and Merseyside Neonatal Network Steering Group on 3 December 2015. My Lady, in the light of the points made by Dr Subhedar and Dr Brearey, it might be thought that this was an appropriate or alternative opportunity to raise the

issue of increased mortality at the Countess of Chester Hospital, and any concerns relating to it. The notes do not indicate that this was done. They do not suggest any discussion of the increased mortality at the hospital.

At this meeting, unlike the previous two Steering Group meetings, a Quarterly Data Report had been prepared. It did not however contain mortality data from the Countess of Chester Hospital. This was a third meeting in a row without neonatal mortality data from the Trust.

On 18 December 2015, the Pan Lancashire Child Death Overview Panel, chaired by Mike Leaf, reviewed the death of Child E that had occurred on 4 August 2015. Some delay between a death and a review between a panel was not unusual. The Child Death Overview Panel review was the final stage of the review process, occurring after all other investigations were complete. This meant there could be a delay of months or years before a child death was reviewed by a panel.

Child E's death had been reported to the panel as one that was "unexpected" but with "a clear medical explanation for the death", discussed with and accepted by the coroner. The report to the panel did not identify any features of concern as to the circumstances

of Child E's death.

Mr Leaf's statement to the Inquiry is that the Pan Lancashire Child Death Overview Panel was unaware that Child E was the fourth death at the hospital since the start of June 2015. It was unaware that there had been a further child death at the hospital since. The panel would not normally ask about the hospital neonatal mortality without a particular reason to do so. No ongoing concerns had been communicated to the panel.

The panel concluded that the death was an expected one with no modifiable factors identified. No recommendations were made, and no further steps were taken.

We move forward to 2016 and begin with January. On 21 January 2016 the Clinical Effectiveness Group of the Cheshire and Merseyside Neonatal Network met. The notes indicate that the discussion of mortality included a review of the death of Child I. The notes of the meeting do not describe the death as having been unexpected and there is no evidence suggesting any concerns relating to neonatal mortality at the hospital were raised.

In his statement to the Inquiry, Dr Brearey explains that he did not think it appropriate to discuss the association of increased mortality with Letby at

a meeting with professionals from every hospital in the network present. Following this meeting, Dr Brearey again discussed the increased mortality with Dr Subhedar. He asked Dr Subhedar to act as an external panel member for the thematic mortality review that took place the following month.

Dr Subhedar does not recall any concern about the involvement of a member of staff being raised during this discussion. The Steering Group of the Cheshire and Merseyside Neonatal Network met on 29 January 2016. The Quarterly Data Report prepared for this meeting contained for the first time since March 2015, mortality data from the Countess of Chester Hospital. That data showed eight deaths in 12 months.

There were zero deaths in the fourth quarter of 2014 to 15, but three deaths in the first and second quarters of 2015/16 and two deaths in the third quarter.

That data was in stark contrast to the last available Quarterly Data Report containing mortality data from the Countess of Chester Hospital, prepared for the meeting in March 2015, which showed three deaths in 12 months with three of the four quarters having zero deaths. The disparity in data appears not to have been appreciated at the Steering Group meeting. Dr Yoxall was the director of the neonatal unit at the Liverpool

Women's Hospital. He sat on the Steering Group. He explains in his statement to the Inquiry that the presentation of the data did not include historic or expected death rates.

The quarterly reports only provided data over four quarters, so 12 months in total. Dr Yoxall states that if the data had been properly considered, it is likely it would have prompted a discussion and an explanation from the Countess of Chester Hospital would have been requested. In fact, the notes of the meeting do not indicate any discussion of increased mortality or any concerns relating to unexpected deaths or deliberate harm at the Countess of Chester Hospital.

We move then to February 2016. Dr Subhedar attended the Countess of Chester Hospital on 8 February 2016, to take part in the thematic review meeting. Counsel to the Inquiry addressed you yesterday about this meeting, and the report that was produced by Dr Brearey following it.

Dr Subhedar does not recall at the review there being any detailed discussion about nurse staffing, or about any one individual nurse. He states that this is his belief that Letby's potential involvement was either not discussed or was not discussed in any detail.

However, he also accepts that "some concerns must

have been alluded to at the thematic remind meeting around members of staff being implicated in some way".

Dr Brearey's evidence on this point is that Letby was discussed at the meeting. After the individual deaths were discussed, he states he "raised the issue of staffing analysis and association with a nurse".

Dr Subhedar's evidence is that his view was that the correct approach was to perform an evaluation of staffing around each death before concluding that any individual staff member was implicated.

My Lady, you may question -- the question you may consider arises is why additional analysis was required to that already carried out and contained in the table of staff on duty that had already been prepared.

We pause now to acknowledge that we have reached the stage in the chronology where the Care Quality Commission carried out their inspection.

The Trust was inspected by the Care Quality Commission from 16 February 2016 to 19 February 2016, with unannounced visits on 26 February and 4 March.

Part of the inspection was of the Children and Young Person Service at the hospital including the neonatal unit. The head of the inspection, the Care Quality Commission, sought information from the Countess of Chester Hospital and third parties. It has proven

difficult for the Care Quality Commission to provide a clear and comprehensive account of what information was gathered prior to and at the inspection.

We are aware that data was obtained through Provider Information Returns and in response to Data Requests.

Of the data we do know that the Care Quality Commission received, there is a table prepared by Countess of Chester Hospital of Children and Young Person Service incidents. It contains analysis of some 431 incidents in the Children and Young Person Service covering paediatric services in addition to the neonatal unit in the period of 1 December 2014 to 30 November 2015.

The final page of the analysis states that 11 cases were subject to further investigation, one of which was an unexpected neonatal death.

The Care Quality Commission also received, in response to a data request made the day before the inspection on 15 February 2016, a 25-page table of neonatal unit paediatric incidents in the period 1 December 2015 to 31 January 2016. This table had a column titled "Actual Harm" and entries were coloured green for "none", yellow for "low", orange for "moderate" and red for "severe".

As I have indicated when describing the reports to

the National Reporting and Learning System, amongst the green entries indicating no harm incidents were child deaths on the neonatal unit.

There are eight entries relating to deaths on the neonatal unit characterised this way. Two entries appear to reference to Child A's death on 8 June 2015, and describe "sudden and unexpected deterioration and death of a patient on the neonatal unit requiring post-mortem."

One appears to be a reference to the death of Child E, described as "unexpected death following GI bleed".

One appears to refer to the death of Child I.

In addition to this table and in any event, the reports of deaths to NHS England's National Reporting and Learning System are shared with the Care Quality Commission. They had a means then to be aware of the deaths that had occurred.

The inspection itself comprised focus groups, core interviews with senior members of staff and Executives conducted by the Trust-wide inspection team and interviews and observations in specific service areas such as Children and Young Person Services.

We have obtained a witness statement from Elizabeth Childs, who was part of the Trust-wide

inspection team. She took part in the core interviews with senior staff including Mr Chambers, Mr Harvey, Ms Kelly and Ms Millward. Notes of the interviews with Mr Chambers and Ms Kelly and Ms Millward are yet to be located and provided by the Care Quality Commission.

Ms Childs does not recall a discussion in the cause of unexplained or unexpected neonatal deaths. She is certain that there was no mention of a suspicious correlation of those deaths with a member of staff. She explains that her expectation is that those with concerns about increased mortality rates would raise concerns with CQC inspectors.

There was a focus group for the consultants at the Trust. The full set of notes of this have not located or provided. The evidence that is available suggests that issues raised at this focus group by consultants included a lack of support for management and a bullying culture.

The inspection of Children and Young Persons services was let by Helen Cain, a children's nurse who was employed by the Care Quality Commission as an acute hospital inspector.

In addition, there were two specialist advisers, Benjamin Odeka, a consultant in paediatrics and gastroenterology, and Mary Potter, a registered

children's nurse.

All three have provided statements to the Inquiry. All three state that they would expect concerns about an increase in neonatal mortality, concerns about in expected or unexplained neonatal deaths, and any correlation between the deaths and a member of staff to be raised with them. All three state that they do not recall such matters being raised.

We have been provided with notes made by these three inspectors. They do not refer to increased mortality or concerns about unexpected or unexplained deaths or possible deliberate harm.

In his statement to the Inquiry, Dr Brearey states that neonatal mortality was not brought up by the Care Quality Commission inspectors. He describes that one of his colleagues, Doctor ZA, told an inspector that "We have some serious patient safety concerns and don't feel like we are being listened to, but that this was ignored", and the inspectors left before there was time to expand upon the concerns.

My Lady may be concerned as to a system of monitoring inspection that was not alert to the increased mortality, despite Care Quality Commission receiving reports to the National Reporting and Learning System, and apparently tracking the Strategic Executive

Information System.

My Lady, we will explore in evidence why the Care Quality Commission did not detect prior to or during the inspection the concerns on the neonatal unit. It is notable that Letby attempted to murder Child K in the early hours of 17 February 2016, the second day of the inspection.

The questions that arise are as to the adequacy of the information obtained by the Care Quality Commission, whether the information that was available was fully considered, whether there was a missed opportunity by the inspectors to discuss and ask questions that would have elicited those concerns, or a missed opportunity by the staff interviewed in not sharing those concerns.

My Lady will note in this context the recent publication on 26 July of 2024 of Dr Penelope Dash's interim report titled "Review into the operational effectiveness of the Care Quality Commission".

Whilst this review is of the single assessment framework introduced in 2023, one of the concerns identified in that report was the lack of focus on outcomes, it being noted that there was "surprisingly little evidence of assessments and inspections considering the outcomes of care".

In the case of the Countess of Chester Hospital, the

evidence gathered appears to show that the Care Quality Commission was oblivious to the rise in mortality, and that the connected concerns relating to the unexpected nature of the deaths and the suspicions relating to Letby.

My Lady, that brings us to March 2016.

The Cheshire and Merseyside Neonatal Network Clinical Effectiveness Group met on 16 March 2016. It was attended by Dr Brearey and Ms Powell. Two deaths at the Countess of Chester Hospital were considered in the mortality review. Yet again, there is no indication in the notes of this meeting that there was any discussion of any concerns in relation to the rise in neonatal deaths at the hospital.

On 23 March of 2016, the Merseyside Child Death Overview Panel, chaired by David Hunter, a former Detective Chief Superintendent, conducted a review of the death of Child C. The death had been reported to the panel as unexpected, but with a cause of death as found by the pathologist Dr Kokai. No concerns or suspicion is raised in the report.

The panel in that review did not identify any modifiable factors and no modifications or recommendations or learning points were identified. For reasons that are unclear, the dead was classified as

"perinatal/neonatal event" rather than unexpected death.

In this statement to the Inquiry, Mr Hunter states that the panel was unaware of the increase in neonatal mortality at the Countess of Chester Hospital. They were unaware of any concerns about Letby.

Mr Hunter considers that Dr Brearey's concerns should have been shared with the panel. The lack of knowledge of the increase of deaths "denied the panel vitally important information relevant to its role as an independent scrutineer".

We move forward now to May 2016.

The Cheshire and Merseyside Neonatal Network Steering Group met on 12 May 2016. Yet again there was no Quarterly Data Report for the meeting. Had there been, based on the previous and subsequent data report, it would have shown 11 neonatal deaths over the previous 12 months at the Countess of Chester Hospital. Again, the note of the meeting does not indicate that there was any discussion of neonatal mortality at the meeting.

Two deaths at the Countess of Chester Hospital were discussed at the Cheshire and Merseyside Neonatal Network Clinical Effectiveness Group on 18 May 2016 . There is no indication in the note of this meeting of discussions, of concerns, in relation to neonatal mortality at the Countess of Chester Hospital or the

matters that had arisen in the thematic review attended by Dr Subhedar.

June 2016.

Following the deaths of Child O and Child P, on 23 June and 24 June 2016, Ian Harvey contacted the Royal College of Paediatric and Child Health by email on 28 June 2016 asking whether they offered an independent review service, "for individual practice or for departments where there are concerns".

The next day on 29 June 2016, the Care Quality Commission Inspection Report was published. Services for Children and Young People were rated as good overall, and good in the categories effective, caring, responsive, and well led. The rating in the safety category was "requires improvement". The issues raised relevant to the safety category related to staffing levels, storage space, safeguarding training and inconsistent recording of daily checks of resuscitation equipment and controlled medication.

The report found that:

"There were robust systems for reporting actual and near-miss incidents. Staff were familiar with, and encouraged and supported, to use the Trust's procedures for reporting incidents."

The report also found:

"Incidents were reported appropriately with the majority being low or no harm", and that, "no 'never' events or serious incidents" were reported between November 2014 and January 2016 within Children's Services.

It is not clear how the CQC finding of "no serious incidents" was made given the report made to the Strategic Executive Information System, that is to say the system for reporting serious incidents, on 3 July 2015, in respect of Child D.

Moreover, whilst the majority of incidents reported were "low harm" or "no harm" the Inquiry will need to consider whether an unexpected neonatal death ought properly to have been reported in such a manner.

It is also not clear what the basis for saying "incidents were reported appropriately", in circumstances in which number of senior management witnesses speak about an unsatisfactorily low level of reporting of incidents using Datix on the neonatal unit.

By way of example, this was a matter which was discussed just four months after the CQC inspection at an Executive Team Meeting, at which meeting the Head of Risk and Safety is recorded as raising her concern about the lack of Datix reporting on the neonatal unit.

The minutes of the relevant meeting in July 2016

record "Near miss incidents were not escalated. No Datix or individual case review."

The Inquiry will explore in evidence what approach was taken to the reporting of near miss incidents and asking where incidents were not reported and Datix forms not completed, why this was so.

Ms Kelly's conclusion at that meeting, in direct contradiction of the CQC finding was:

"It was clear from what the Head of Risk and Safety was saying that the NNU were not following the Trust's risk management processes and that incidents were not getting reported via Datix as they should have been."

The inspection report, that is to say the CQC inspection report, does not comment on neonatal mortality rates or the incidents of unexpected deaths.

In respect of safeguarding, the report found that policies and procedures were in place and staff were aware of their roles and responsibilities, and knew how to raise matters of concern appropriately.

My Lady, the basis for this finding will be explored in evidence.

As we have explained, the Inquiry will consider in detail the extent to which staff were in fact familiar with the requirements of national and local safeguarding procedures, given that they do not seem to have been

followed.

The report found that staff were noted to be unfamiliar with the term "duty of candour" but could describe the principle and the circumstances in which it was used.

On the day the inspection report was published, 29 June 2016, Ms Kelly contacted the Care Quality Commission by telephone, reporting that the Trust had identified an increase in neonatal deaths in 2015/2016 and 2016/2017, compared to previous years. She reported that there had been two neonatal deaths that weekend.

The next day, 30 June 2016, Ms Kelly followed up with an email to the Care Quality Commission reporting the increased neonatal mortality.

The email referred to the thematic review and asserted that it had been submitted as part of the Countess of Chester Hospital's "CQC inspection data pack". It is presently unclear whether the Care Quality Commission accepts that it received the review in advance of the inspection or not. Ms Kelly's email does not describe any concerns or suspicions in relation to Letby but does state that amongst the actions being taken was a "deep dive into staff rotas regarding staff on duty at the time of the deaths".

The deaths of Child O and Child P were reported to

NHS England using the Strategic Executive Information System on 30 June 2016. The reasons state for reporting the deaths was that they were in the category of "unexpected/potentially avoidable death".

My Lady, you may take the view that this category applied to other unexpected deaths, not reported as serious incidents.

In his first statement to this Inquiry, Professor Sir Stephen Powis, on behalf of NHS England, states that this was the first time NHS England became aware of any specific concerns about the safety of neonatal services at the Countess of Chester Hospital.

However, he makes the point that NHS England were not aware at this stage of any concerns about any particular individual. The reports to the Strategic Executive Information System did not raise concerns of potential deliberate harm by Letby.

There was also, on 30 June 2016, a discussion and an exchange of emails between Mr Harvey and Sue Eardley. She was the Head of Invited Reviews at the Royal College of Paediatrics and Child Health.

Mr Harvey stated that he was keen that the review was "as soon as possible". Ms Eardley's email reply stated that a visit was planned in August and that the review team could give immediate feedback "if we see

anything of urgent concern". She attached a proposal for the review and draft terms of reference.

My Lady, the Royal College of Paediatrics and Child Health had developed the Invited Review Service in 2012. Reviews were undertaken in response to a request from a healthcare organisation. They were undertaken for a fee on behalf of an authorised individual of such an organisation, typically the Medical Director or Chief Executive.

There were different types of invited review. The type undertaken for the Countess of Chester Hospital was a service review. This was described in the guidance in place at the time as a "invitation to visit and comment upon a current service with terms of reference that were usually rooted in the quality, safety and efficiency of that service".

They were intended primarily to "Assess compliance with formal standards".

The proposal sent by Ms Eardley identified the concerns as being that the neonatal service was an "Adverse outlier for neonatal mortality in the last 12 to 18 months".

It identified that staff at the unit were:

"Seeking a further independent review to consider the wider service, to provide assurance had there are no

common factors to the death, and that in each case, there were no missed opportunities to take action that could have prevented or mitigated the situation."

There were four proposed terms of reference, the fourth of which was "Are there any possible common factors linking the recent neonatal deaths?"

We move, then, to July 2016.

On 1 July 2016, reports were made to NHS England's National Reporting and Learning System in respect of both Child O and Child P. The reports for each child stated that they had suffered a sudden collapse requiring resuscitation. These were not reports of the deaths. In respect of Child O, the report was of a delay in obtaining an intraosseous access. In respect of Child P, the report was a delay in obtaining a sodium bicarbonate infusion.

On the same day, Ms Kelly forward the email she sent to the CQC to Ms Paula Wedd, the NHS West Cheshire Care Commissioning Group's Director of Quality and Safeguarding.

In the body of the email, Ms Kelly explained that she had contacted the CQC before the CCG because of the impending release of the CQC inspection report.

On 4 July 2016, Ms Kelly send an email to the Nursing and Midwifery Council's Employer Link service

asking to book a call to discuss that service and to discuss allegations against a nurse.

This appears to be the first occasion on which it is documented that allegations relating to Letby were raised with an external body.

On 5 July 2016, Dee Appleton-Cairns from Human Resources at the Countess of Chester Hospital spoke to Ian Pace, an associate in the Employment and Pensions Group, at the solicitors' firm DAC Beachcroft LLP.

Ms Appleton-Cairns disclosed to Mr Pace the increased neonatal death rate and the fact staff were pointing interesting fingers at each other. She described a consultant making a reference to Beverley Allitt.

The note of the discussion indicates that Ms Appleton-Cairns was satisfied that there were "no malicious issues involved" but Mr Pace asked how she could be sure. He advised her that the employment aspects of the matter pale into insignificance given the potential issues involved and the suspicions that the death rate could be attributable to one in particular individual.

He advised Ms Appleton-Cairns that the priority was to investigate the issues that were arising, given the potential consequences and suspicions that have arisen.

He made arrangements for the hospital to be advised by Corinne Slingo on how to take things forward from a regulatory perspective it is. Ms Slingo was the Head of Healthcare Regulatory and a partner at the firm. Ms Kelly spoke to Tony Newman, a regulation adviser at the Nursing and Midwifery Council on 6 July 2016. An email exchange that followed contains a note of the discussions discussed. It identifies that Ms Kelly told Mr Newman that there had been an increase in mortality and that analysis had identified that one nurse had been present at nearly all events.

Some clinicians were concerned that she "may present a serious risk to public safety although no evidence is available at this time".

The email identifies Letby by name as the nurse. Ms Kelly stated that there was to be a meeting that day to decide if she would be reported to the police to investigate.

My Lady, despite the matters disclosed and the indication that a report to the police was being considered, this discussion did not trigger any fitness to practise or safeguarding process. No referral to the Nursing and Midwifery Council was made by Ms Kelly, nor did Mr Newman recommend that one should be. He did not advise a referral to the Local Authority Designated

Officer. His advice to Ms Kelly was that the Nursing and Midwifery Council would need to be advised of the decision to report the matter to the police and any action taken by the police.

Mr Newman's statement to the Inquiry explains that he realised that this was a unique situation. He checked with a lawyer, in the Fitness to Practise Team, who agreed with the advice he had given. He states that he was "clear at that time that there wasn't evidence yet to refer".

His statement does not explain, and the point will need to be explored in evidence, why he considered referral inappropriate, or what threshold he considered applied before a referral was made.

The email subsequent to this conversation between Mr Newman and Ms Kelly records that the Executive Directors at the Trust were due to discuss that day (that is to say 6 July 2016) whether to report Letby to the police.

What is less clear, as matters stand, is what consideration and discussion there was so far as the NMC was concerned if the decision to contact the police was deferred pending further investigation.

My Lady, a theme that will be explored in evidence is the extent to which those who advise the Countess of

Chester Hospital were alert to child safeguarding policies or principles, and whether they were aware of what to do where suspicions and concerns exist about a member of staff harming babies.

A recurring theme across much of the evidence the Inquiry has received is a potential misunderstanding of the evidential threshold required to report to external bodies or to trigger an external investigation. Having reviewed the Letby documentation recently, an Executive at the Nursing and Midwifery Council raised a concern internally as to the absence of any mention of safeguarding in that documentation. It was noted that there had been a failure to include clinical advisers in the process who could have provided a safeguarding lens to fitness to practise cases.

Returning to the chronology, on 7 July 2016, when the decision was made to downgrade the neonatal unit, the Countess of Chester Hospital made a Serious Incident report to NHS England's Strategic Executive Information System. The report gives the increase in neonatal mortality as the reason for the downgrade.

It asserts that the Trust was acting responsibly in requesting an external review, a reference to the involvement of the Royal College of Paediatric and Child Health. The report does not refer to the suspicions of

deliberate harm by Letby that had, within the previous two days, been raised with the Nursing and Midwifery Council and DAC Beachcroft LLP.

In his fourth statement to the Inquiry, Professor Sir Stephen Powis, on behalf of NHS England, states that it is unclear why the increased mortality was reported as a Serious Incident at any earlier point in 2016, following the completion of the thematic review "in light of the concern about the then unexplained spike in mortality". My Lady, you may conclude that there were grounds for reporting such concerns even prior to that.

Also, on 7 July 2016, Ian Harvey responded to Ms Eardley's invited review proposal in the draft terms. He confirmed that he wished to proceed with the review. He provided amended terms of reference which expanded significantly the fourth term dealing with mortality so that the terms of reference read, and I'll quote them in full:

"To consider concerns about the neonatal unit with specific reference to:

"Are there any identifiable common factors or failings that might in part, or in whole, explain the apparent increase in mortality in 2015 and 2016?

"The reviewers will then make recommendations for the consideration of the Chief Executive and Medical

Director of the Hospital as to:

"Whether there is a basis for concern about the Neonatal Unit in light of the findings of the review; [and]

"Possible courses of action which may be taken to address any specific areas of concern which have been identified."

These amendments were agreed by Ms Eardley, an issue which will be explored in evidence is whether this was an appropriate term of reference for an invited review. As we have explained, such a review was concerned with the extent to which a service complied with standards. It was not a tool intended to be a forensic investigation into increased mortality.

On 8 July 2016, Ms Kelly emailed Mr Newman at the Nursing and Midwifery Council. She informed him that a detailed review was under way and a meeting of the Executive Team was planned for the following week. She did not, as Mr Newman had previously requested, advised him what conclusion had been reached at the meeting to consider whether to report the matter to the police.

On 12 July 2016, he made a note stating he had advised her to "investigate locally first".

The Cheshire and Merseyside Neonatal Network Steering Group met on 13 July 2016. A quarterly data

report included mortality data from the Countess of Chester Hospital was available for this meeting. It showed a total of ten deaths over four quarters.

The notes of the Steering Group indicate that there was a discussion as to the redesignation of the neonatal unit and that the Trust was "reviewing the data/reviews carried out relating to mortalities to identify any missed factors".

There is nothing to indicate any specific discussion about the deaths or any suspicions in respect of Letby.

On 18 July 2016, Ms Slingo, the partner at DAC Beachcroft LLP, advised Susan Hodkinson on whether the concerns relating to Letby should be reported to the police.

Ms Slingo's advice, as recorded in the follow-up email, was that:

"There does not currently appear to be any reason to formally alert the police to these issues as there is nothing upon which one might reasonably base a suspicion of a criminal offence having been committed."

The rationale for this was that the current evidence of concern was "potentially circumstantial".

The fact of one nurse on shift on more occasions than others, but that deaths, deteriorations, occurred when the nurse was not on shift. She noted that 75% of

the deaths had been through the coronial system with no common features or issues arising.

Ms Slingo described the decision as to whether to report the matter to be finely balanced and to be kept under review with "a very low threshold for moving this to a decision to notify the police".

Seemingly by way of an explanation of this threshold, she gave the analogy of the Trust reaching a position that there was enough evidence to exclude Letby under their usual policy, as being a "key moment to consider the level of evidence to report her to the police too".

No advice was apparently requested or given as to the safeguarding obligations on the hospital and its staff, no advice was requested or given about any referral to the Local Authority Designated Officer, or Nursing and Midwifery Council. Working Together to Safeguard Children required reports of "possible criminal offending" to be made to the Local Authority Designated Officer.

My Lady may consider that this safeguarding threshold for referral to external bodies appears to have been ignored.

My Lady, I just have one more paragraph to conclude this, if I may. I'm conscious of the time.

On 27 July 2016, the reports of the deaths of Child O and Child P were uploaded to NHS England's National Reporting and Learning System. Rather than being characterised as "no harm" severity, they were both characterised as "death". The characterisation of severity on this system in the case of other babies who were murdered is a matter the Inquiry will be investigating.

LADY JUSTICE THIRLWALL: That's a convenient moment. Thank you very much indeed, Mr de la Poer.

We will resume at quarter to 2.

(12.47 pm)

(The Short Adjournment)

(1.44 pm)

LADY JUSTICE THIRLWALL: Mr De la Poer.

MR DE LA POER: My Lady, we reach the point in the timeline of the involvement of external bodies at August 2016. And on 2 August 2016, Ms Kelly send an email to Ms McGorry of NHS England, included within this email were copies of the recent Neonatal Dashboard and a summary of actions taken so far by the Trust.

On 31 August of 2016 Ms Kelly had further contact with Mr Newman of the NMC. In her email to him, she provided an update of the internal work which had been undertaken, saying:

"Nothing of significance had been identified within this."

The Inquiry will be investigating whether this was a reasonable and accurate summary of the internal work which included that both which Mr Gibbs and Nurse Martyn had undertaken and the staffing review conduct by Ms Kelly's deputy, Sian Williams.

In her email, Ms Kelly also stated:

"There has been no indication to discuss this matter with the police at this time."

We now turn to look at the Royal College of Paediatrics and Child Health Invited Review in greater detail.

That Invited Review Team visited the Countess of Chester Hospital on 1 and 2 September 2016. In addition to Ms Eardley, the review team was made up of Dr David Milligan, a retired consultant paediatrician who acted as lead reviewer, Dr Graham Stewart, a consultant paediatrician, Alex Mancini, a neonatal nurse, and Claire MacLaughlan, a lay reviewer who had previously trained as an intensive care nurse.

It appears that some, but not all, members of the review team were aware of the suspicions in relation to Letby prior to the visit.

The review team had been given considerable

documentation by the Trust for the purpose of their review. This included a spreadsheet showing staff on duty at the time of, or the shift prior to, ten deaths on the unit. It demonstrated that Letby was on duty for eight of the ten deaths and the shift before for the remaining two.

Ms Eardley's statement to the Inquiry is that Mr Harvey may have advised her of "the nurse issue" during their initial call on 30 June 2016, but that she cannot recollect.

It would appear from her statement that she will accept that at some point prior to the visit she was aware:

"... that there were suggestions of concern about a nurse in that the doctors had seen a pattern of attendance when studying the rotas."

Though she does not recall potential police involvement being discussed.

Mr Harvey's recollection as set out in the statement he provided to the Inquiry is that:

"I am sure that I mentioned to Sue Eardley over the phone that consultants had raised a concern about one individual."

Dr Milligan's evidence is that the review team had been made aware of concerns around potential criminality

prior to the visit. He recalls seeing in the documentation provided ahead of the visit a list of seven or eight unexplained deaths together with the names of nursing staff on shift, and he noticed that Letby was present for all but one or two. This may be a reference to a spreadsheet that has already been described.

Dr Milligan emailed Ms Eardley on 26 August 2016 stating that having looked at most of the documentation.

"A number of questions arise from that, not least that one individual appears to have been present for all but one of them."

Dr Stewart, however, does not recall any specific nursing concerns arising from the pre-visit information. His statement to the Inquiry is that if he had been aware of concerns about Letby, he would have questioned whether an invited review was appropriate, and he would have advised the Trust that the police should be involved if any criminality was suspected.

Similarly, the evidence of Claire McLaughlan and Alex Mancini is that they were unaware of the concerns about Letby prior to the visit. Ms McLaughlan states that if she had been aware, she would not have participated in the review and would have advised the RCPCH that the fourth term of reference which referred

to identifying common factors, which might explain the increase in mortality, was misleading.

Ms Mancini's statement to the Inquiry explains that she had seen the staff rota but did not assume, and saw no documents expressing, any concern or complaint about Letby.

My Lady the significance of any prior knowledge of suspicions relating to Letby is that the guide on Invited Reviews, both the 2014 and the 2016 edition, provides that the RCPCH would not take on cases where:

"... the expected scope includes behavioural, misconduct, bullying, harassment, or possible mental health concerns ..."

Or where the police were involved.

Whatever the extent of any advance warning the review team had of the concerns relating to Letby, those concerns dominated the first two interviews on 1 September 2016, the first day of the visit.

The first interview was with Mr Harvey and Ms Kelly. Mr Harvey's first contribution as documented in the contemporaneous notes was:

"... correlation of one nurse -- paediatricians see as elephant in the room. Lucy Letby. Pattern of babies collapse doesn't seem to follow normal pattern and respond to resuscitation in normal way. Multifactorial.

Want to think the worst -- but nothing else is pointing to it. Director of corporate affairs was [detective chief inspector] before he retired. Huge nettle to grasp."

Mr Harvey was also noted to say during this initial interview, again I quote:

"... had to intervene with the neonatal lead as junior doctors had been referring to her as 'nurse death'. Ripples through the team and trying to function. Can't see how to conclude without calling the police. Unless there is something to satisfy the medical staff they can call the police."

Ms Kelly was noted to have had said:

"Paediatricians thinking she is the common denominator. No issues with competency of the nurse. No issues with training. Highly thought of by the unit."

And:

"Clinicians threatened to go to the police."

The notes indicate that Mr Harvey was asked either "what is the tipping point?" Or "what is the tipping point, not police"

To which he responded:

"Need to pull together before we press the nuclear button."

Ms Eardley recalls that Mr Harvey stated that a Non-Executive Director at the hospital who was a former senior ranking officer had advised against the police until all other avenues had been exhausted.

The next meeting was with Dr Brearey and Dr Jayaram. There was a detailed discussion of the neonatal deaths. Both doctors expressed their concern in respect of Letby. The notes indicate that they stated:

"... identified one nurse present at all collapses. Didn't think it was significant. Agreed to keep an eye on things. As the year progressed, each subsequent mortality not huge concern but by end 2015, numbers stacked up a little ..."

And later:

"... it's how the babies collapsed. No indication. Didn't respond physiologically how they should have done. Seven of them so not always the same one ... Nurse on shift at all times. Spoke to Ian [and] Alison ..."

And later:

"... decided to put the nurse on dayshifts not nights ... no [unexpected] collapses at night when she was on days but collapses happened in daytime -- all never individually realised they had all thought the same thing."

And:

"Went to senior execs ... said potentially foul play here ..."

And:

"Need to have the nurse off the unit till sorted out ... Implications of police -- service stops. Not sure on looking at it from inside ... would love to know the obvious reasons why they have happened."

And, finally:

"Expected exec to call the police."

Notwithstanding the disclosure of suspected criminality in these two initial meetings, the review team decided to continue with the review. The statement of Robert Okunnu, the Chief Executive of the Royal College of Paediatrics and Child Health queries "why the Invited Review Team did not stop the review after learning this information".

We have highlighted already that the Guide on Invited Reviews provided that cases where the scope included behavioural or misconduct issues would not be taken on. It provided that where such issues came to light during an invited review:

"... review should be completed in relation to its original remit unless advised to the contrary in order to avoid prejudicing other investigations by a public authority or regulator, but the reviewers cannot

investigate or suggest solutions for any of the above."

It states that "clear scope boundaries should be agreed before further work takes place".

The evidence we have obtained demonstrates that the review team did give consideration as to whether to continue with the review. Dr Stewart explains that he expressed his view to the team that the commissioners of the review had not been honest and transparent, and that it may be better to leave at that stage.

Following discussion, it was agreed that the review could continue but would follow closely the terms of reference and could include recommendations on how to progress.

In her statement, Ms Eardley explains that consideration was given to aborting the review but as the interviews had been set up and staff prepared, the review team agreed to continue. She accepts that no consideration was given to specifying scope boundaries to avoid prejudicing other investigations as required by the guidance. She accepts with hindsight that the review should have been aborted when concerns of potential criminality were raised.

The RCPCH subsequently commissioned an external review of its Invited Review Service which resulted in a report by Helen Crisp in 2021. Ms Crisp spoke to

Dr Milligan, Dr Stewart and Ms McLaughlan. The report states on this issue that the reviewers felt that they had a duty to complete the work, and would let the RCPCH down if they "walked out".

Not any did the review continue without any clear scope boundaries agreed but a decision was taken by the team to interview Letby. She had not been on the original list of interviewees, but was added to it during the first day of the visit. Ms Eardley's statement to the Inquiry explains that the review team felt strongly that she should have "an opportunity to give her perspective". It was decided, however, that she would only be interviewed by Claire McLaughlan and Alex Mancini. Dr Stewart explains that this was because "of their expertise and because they were both women, which might have been less threatening than bringing her before the complete panel".

Mr Okunnu's statement on behalf of the Royal College of Paediatrics and Child Health describes the interview of Letby as "highly unusual", and one that should not have taken place.

Letby was interviewed, along with her colleague acting as Royal College of Nursing representative, Nurse Hayley Griffiths. The note of the interview describes that Letby described being scapegoated and

very vulnerable. She contended that there was no reason or evidence to redeploy her. The statement of Nurse Griffiths to the Inquiry describes the interviewers asking, after Letby had left the interview room distressed "Does she know what is going on here and what she is potentially being accused of?"

Contained in the disclosure of Letby's Facebook documents is a message she sent that evening in which she stated that the interviewers told her "off the record" that they thought an investigation into the deaths would be recommended and she needed to prepare herself, as she would play a big part.

Claire McLaughlan and Alex Mancini cannot recall having had such an off-the-record discussion with Letby and this will be explored in evidence with them.

The review team interviewed a significant number of people involved with the neonatal unit over the course of the two-day visit. These will be explored in evidence but of particular note were the following: first, the interview with a number of consultants. Dr V, Dr Gibbs, Dr Saladi, Dr Holt and Doctor ZA, where one of the noted comments was:

"What is striking is that the collapses were unexpected and did not respond to resuscitation. Several of the babies showed strange mottling

centrally."

Second, the interview with the senior nurses at which Ms Powell described the line taken on Letby as "unfounded and malicious", describing Letby as "clever, exceptional, and very professional".

The doctors were described as tunnel visioned about Letby's presence and their concerns were described as "wanted her off the unit. Just the presence -- gut instinct".

And third, the interviews with Andrew Higgins, Non-Executive Director, who explained that he was aware of the allegations, and that there had been long debates as to how to deal with them, including "involvement of police". After internal briefings, the Board instead agreed to get an external review. The notes appear to attribute to Mr Higgins the comment:

"Need to keep the shutters down and contain the situation, not sure where to go next."

We will ask whether that was said, and if so, what was meant by it. In his statement to the Inquiry, Mr Higgins does not recall saying that, but thinks that the comment related to "the need to contain the situation so that no further incidents could occur and the facts behind the recent deaths could be established".

At the start of the second day of the visit on 2 September 2016, the review team met with Mr Harvey and Ms Kelly. Mr Milligan advised them that consideration had been given to aborting the review and starting again. There was said to be "big concern" about Letby, and a formal process was advised "so she knows where she is". Ms McLaughlan advised that a process was needed for the protection of Letby and the Trust and that Letby would have a good case for constructive dismissal if nothing happens.

An independent case note review of all the deaths by two independent people was recommended.

At the end of Day 2 there was a feedback session with Mr Chambers, Mr Harvey and Ms Kelly. The review team repeated their advice for an in-depth independent case review. They advised a human resources process for Letby.

The review visit was followed by a letter from the Royal College of Paediatrics and Child Health to the Countess of Chester Hospital dated 5 September 2016, setting out the recommendation for investigation against Letby. In respect of Letby it described:

"A process of investigation needs to be put in place which sets out the nature of the allegation and the process you will follow to investigate it."

What it appears was being suggested was an internal investigation.

It also provided detail of the recommendation for a forensic case note review of the deaths. It advised that there should be a review of each death since July 2015 using at least two senior doctors with expertise in neonatology and pathology. The letter listed five "minimum elements" the investigation should comprise, including examination of the post-mortem findings, any additional information which might identify cause of death and details of all staff with access to the unit from four hours before the death of each infant.

My Lady, the Royal College of Paediatrics and Child Health Guide on Invited Reviews provided that where concerns were raised over safety or staffing, the expectation was that the client -- here the Trust -- would notify the regulatory authorities promptly of the review, its recommendations and action plan.

If, during the review or follow-up period, it was seemed that insufficient action had been taken by the client, the Royal College of Paediatrics and Child Health could take further action, including reporting the findings directly to the appropriate regulatory or commissioning authority.

Nowhere in the notes of the interview or in the letter following the visit is there evidence that the Trust was advised to report the matter to the police, the Local Authority Designated Officer the Nursing and Midwifery Council, or any other external agency. There was no evidence the Invited Review Team considered doing this themselves.

In his statement to the Inquiry, Dr Stewart states that he gave verbal feedback, not documented in the notes, that:

"Any concerns of criminality should be addressed by involving the police."

The 2021 Crisp Report states that when Mr Harvey had been "reluctant to involve the police", the review team did not press him on it, and they were unclear of how far to take matters.

Ms Eardley accepts with hindsight that there should have been contact within the police, and that the review was probably not the appropriate course of action for senior management to follow.

The Royal College's recommendation for a forensic case note review led to the Countess of Chester Hospital instructed Dr Jane Hawdon to prepare a report. She is a consultant neonatologist at the Royal Free London NHS Foundation Trust. At the relevant time she was employed

at Bart's Health NHS Trust. Whereas the Royal College of Paediatrics and Child Health had recommended instructing two experts, she was the only expert initially instructed. Counsel to the Inquiry has already set out the work that she undertook earlier and will not repeat it here.

This brings us to September 2016. On 12 September 2016, there was a board meeting of the Cheshire and Merseyside Neonatal Network. A paper was prepared for this meeting by Dr Subhedar titled "Neonatal Mortality at Countess of Chester Hospital". It explained that he had previously acted as an external reviewer of mortality reviews in 2015 but no major deficiencies in care or recurring themes were identified.

The paper explains that an operational delivery network management review of mortality rates benchmarked against other local neonatal units showed the Countess of Chester Hospital was 1.5 to twofold higher and appeared to be rising.

On 16 September 2016, the Pan Cheshire Child Death Overview Panel, chaired by Dr Mittal, and attended by Detective Sergeant Paul Hughes, the coroner's officer and other health and Local Authority representatives reviewed the death of Child I. This was the first of

the seven deaths to be reviewed by this panel.

Despite the panel noting that Child I's case was subject to a review by the Royal College of Paediatrics and Child Health, it was decided that the case could be closed with the coroner reviewing the report on behalf of the panel. The death was classified as a perinatal/neonatal event, not an unexpected death.

My Lady, there was a discussion at the meeting that indicates a potential lack of understanding of the local Sudden Unexpected Death in Infancy and Childhood guidelines that we have already described.

The notes of the meeting contain a query that was raised as to whether there should be a Rapid Review Meeting for an unexpected child death in a hospital.

This may have arisen because of what the RCPCH National Guidance said at the time. However, a Rapid Review Meeting was a requirement for unexpected and unexplained child deaths in the local guidelines, and as we have explained, those guidelines applied irrespective of the location of death.

That this query was raised may demonstrate a lack of understanding in the guidance which should have been followed. The query raised at the meeting was not answered. The issue, was itemised for discussion at the next panel meeting.

The statement to the Inquiry of Charles Massey, Chief Executive and Registrar of the General Medical Council, states that concerns relating to the neonatal unit were first raised with the GMC Employment Liaison Advisor on 30 September 2016.

This appears to have been to inform the GMC about the downgrading of the neonatal unit, the commissioning of the RCPCH review and to inform the GMC that there were no concerns at that time about any of the doctors involved.

We move now to October 2016.

On 10 October 2016 the deaths of Child O and Child P were reviewed by the same Welsh Death Review Panel that had reviewed the death of Child D on 16 July 2015. The reviews may have been conducted by email. The note of the reviews is extremely brief. The cause of death for each child is stated to be "extreme prematurity (one of triplets)".

There is no reference to the serious incident report or the wider issues on the unit.

Of the seven babies murdered by Letby at the hospital between June 2015 and June 2016, four were from English resident families and were reviewed by three different English Child Death Overview Panels. Three were from Welsh resident families and considered by

Welsh Child Death Review Panels. We will explore in oral evidence how evidence was communicated and shared across the English and Welsh panels in practice, and whether the system was able to detect increases in neonatal deaths from the hospital.

Dr Jayaram contacted the British Medical Association on 24 October 2016. He was seeking support following the grievance raised by Letby. A note of his webchat with Hope Nisbet shows that he disclosed that all the consultants at the Countess of Chester Hospital had expressed concern at the significant increase in unexplained neonatal deaths and near misses when Letby was in charge of the babies or near the cot side.

Dr Jayaram wanted assistance as to what he may be asked at the Human Resources meeting and whether he would be putting himself at risk if he raising the possibility of deliberate harm by Letby.

Dr Jayaram's case was assigned to an employment advisor, Tom Carver. The two spoke on 25 October 2016. It appears to have been agreed that Dr Jayaram would not explicitly raise the possibility of deliberate harm at the grievance meeting and would instead restrict himself to saying that the consultant body had:

"... noticed a sudden spike in the deaths rates, only [link] was involvement of the complainant, we

didn't have any specific concerns but felt bound to raise these concerns with the Exec Team."

The plan was to refer to the awaited RCPCH report if further questions were asked.

It is notable, my Lady, that disclosure to yet another external agency had not provoked any consideration of, or advice on, safeguarding. There was no recommendation to make a referral to the Local Authority Designated Officer. There was no advice as to whether there was a need for a Nursing and Midwifery Council referral.

November 2016.

On 11 November 2016 Tom Carver of the British Medical Association accompanied Dr Jayaram to the grievance meeting. The notes of the meeting show that Dr Jayaram denied that there had been a push to move Letby, and denied that there had been a suggestion that if Letby was not moved, the police would be called.

And Dr Jayaram was asked whether "deliberate intent" by Letby was suggested, he responded that he was not there to speculate, and could "only say that the consultants had concerns and they escalated these to the Executive board". Mr Carver intervened at this point to say that speculation should be avoided and was unfair.

The Pan Cheshire Child Death Overview Panel met on

20 November 2016, and gave further consideration to the query raised at the previous panel meeting on 16 September 2016, as to whether a Rapid Review Meeting was required following a sudden and unexpected death in hospital. It was noted that:

"The meeting felt that the response should be on a case-by-case basis, and the safeguarding doctor should be involved in the discussion with the designated doctor and a rapid response should be arranged if deemed appropriate."

It is currently unclear why the panel "felt" this way or what steps had been taken to consider the local guidelines, which appear clear and did not support an apparently *ad hoc* approach being taken in respect of unexpected and unexplained deaths where they occurred in hospital.

The Invited Review reports to the RCPCH were sent to the hospital on 28 November 2016. We say reports, because there were two versions. There was what was described as a "confidential report" which included references to the allegations made against Letby. There was then a "dissemination copy" in which the references to allegations against Letby were removed.

The confidential report, when dealing with the suspicions in respect of Letby, describes the neonatal

lead and subsequently all of the consultant paediatricians had identified that Letby was rostered on shifts for all deaths and had, "become convinced by the link".

The report describes this as:

"... a subjective view with no other evidence or reports of clinical concerns about the nurse beyond this simple correlation"

And that:

"... the consultants explained that their allegation was based on Nurse L being on shift on each occasion an infant died (although not necessarily caring for the infant) combined with 'gut feeling'."

My Lady, this use of the term "gut feeling" appears to be a misattribution. It was in the interview with the nurses that the consultant concerns were described as a "gut feeling". The notes of the interviews do not suggest that the consultants themselves reported that this was a gut feeling at all.

Both versions of the report state that there were "no obvious factors which linked the deaths". A number of findings and recommendations were made as to staffing, neonatal reviews, transport and operational practice. The neonatal unit was found not to comply with professional standards on nurse and medical

staffing levels, environment, accommodation for parents, support from the community neonatal team and postnatal follow-up.

The report noted that the Child Death Overview Panel had not been alerted to the cluster of deaths and recommended that it considered its processes. The neonatal unit was noted to be less than systematic in incident reporting, and a recommendation was made that death/near-miss review required strengthening. The report repeated the recommend for an independent external review of unexpected deaths.

As to the preparation of two reports, a subsequent internal review carried out by Dr Mike Linney on 11 April 2018 queried whether a report that needed separate redaction due to human resources issues had overstepped its brief. As Ms Eardley recognises in her statement to the Inquiry, a consequence of producing two reports, one of which was silent on the concerns raised in respect of Letby, was that it enabled the Trust to share only a sanitised version of the report with the concerned consultants. Indeed, it was the sanitised report that was shared with external agencies and was subsequently published by the Trust in response to the scrutiny the Trust was under.

Neither the disseminated nor the confidential

version of the reports recommended that concerns about Letby be escalated externally, whether to the police, the Local Authority Designated Officer, or the Nursing and Midwifery Council.

They do not make any reference to discussions during the review visit of potential police involvement. This appears to have been by design. Initial drafts of the report obtained by the Inquiry do contain some references. For instance, in one draft, there is the comment:

"Delayed to call police -- remember Stepping Hill".

"Stepping Hill" may be a reference to the Stepping Hill Hospital in Stockport where a nurse was wrongly accused of murder and another nurse, Victorino Chua, was subsequently convicted in May 2015 of murdering two patients, the poisoning of 19 other patients, and the attempted poisoning of seven more patients. We observe in passing that Chua committed these crimes by injecting insulin into saline solution bags which he left for other members of staff to administer. During a police search of Chua's house, a letter written by him was discovered in which he described himself as an "evil person".

Chua was sentenced on 19 May 2015. In his sentencing remarks, Mr Justice Openshaw described what

Chua did as "inexplicable" and those remarks are available on the Judiciary website.

Returning to the confidential version of the draft RCPCH report, in another part it is stated that Letby was moved off the neonatal unit, "apparently due to the risk of the consultants approaching the police with the allegations". References to the police were removed by the time of the final draft.

As to why no recommendation was made to call the police, in her statement to this Inquiry, Ms Eardley explains that she:

"... considered that the responsibility for dealing with the concerns raised by the paediatricians and deciding whether to call the police lay in the hands of the Countess of Chester Hospital Trust board or the paediatricians who were close to the cases."

She acknowledges with hindsight that the review team should have recommended that the police be called. She acknowledges that they should have pressed harder for the management of the hospital or the consultants to do so.

When providing the report, the Royal College stated.

"It remains your report, though, and we will not distribute or share it more widely without your permission."

There was no suggestion that the Royal College of Paediatrics and Child Health was reserving the right to report its findings directly to the appropriate regulatory or commissioning authorities if the Trust failed to do so as the guide on Invited Reviews allows.

A point that we will explore in evidence is the lack of any follow-up after the report was sent. The letter enclosing the report anticipated a follow-up conversation three months after the completion of the review. The guide on Invited Reviews provided for feedback, three to six months following a review, to discuss implementation of the recommendations. There appears to have been no such follow-up with the hospital.

On 29 November 2016, Tony Newman of the Nursing and Midwifery Council attended an introductory Employment Liaison Service meeting at the hospital with Ms Kelly and Ms Hodkinson. This was some four months following the contact made with him for advice as to whether a fitness to practise referral was required.

The notes of the meeting demonstrate that Letby was discussed. It was noted that she had been "removed from the unit for her own protection".

It was determined that there were "no grounds for a referral" and that the hospital was "appropriately

managing this person with a view to a phased approach to return to the neonatal unit."

In his statement to the Inquiry, Mr Newman states his recollection is that there were:

"... no allegations or evidence to suggest [Letby had] caused deliberate harm at this point and the concern remained only that she was present at each incident."

My Lady, it might be difficult to reconcile that contention with the fact that Mr Newman had previously been told that clinicians were "concerned" that Letby may present a "serious risk" to public safety and consideration was being given as to whether she should be reported to the police. Why these concerns were deemed not to meet the threshold for referral or engage safeguarding processes, particularly in light of a proposal to return her to the neonatal unit, will be explored in evidence.

To complete our review of 2016, we turn to December.

On 16 December 2016, the Countess of Chester Hospital informed NHS England that it had received the draft Royal College of Paediatrics and Child Health Invited Review report in November 2016 for factual accuracy review, but that it was not "comfortable" sharing that draft. It will be observed that the final

versions of the report had in fact already been received by the hospital at that stage.

So we turn to 2017.

On 3 January 2017, the North Regional Medical Director of NHS Improvement, Vincent Connolly, met with Mr Harvey. Mr Connolly's pocket notebook indicates he was told that paediatricians were concerned about an increase in neonatal deaths over the last 18 months but that the Royal College of Paediatrics and Child Health had done, "a very thorough report" and there were no immediate concerns. The note refers to an independent review by a neonatologist and suggests there would be a further review by a pathologist.

On 6 January 2017, Ian Harvey contacted Ms Eardley at the Royal College of Paediatrics and Child Health notifying her of the proposed publication of the report. He asked whether there was anything she would not want published. Ms Eardley replied, apparently after taking advice from the review team, stating that either version of the report could be published, but she suggested a conversation with Letby, Information Governance or Human Resources, if the confidential version were to be published.

On 27 January 2017, Ms Eardley spoke to Dr Brearey, who told her that Mr Harvey had not shared the

confidential report with the paediatricians; that is to say the version containing details about the allegations against Letby.

In her statement to the Inquiry, Ms Eardley states that she was "surprised and frustrated" that the confidential version had not been shared.

A chronology subsequently prepared by the RCPCH indicates that she contacted Mr Harvey on 31 January asking him whether and when the report would be shared with the paediatricians.

February 2017.

Ahead of its publication, the Royal College of Paediatrics and Child Health Invited Review report was sent to members of the Local Safeguarding Children's Board on 7 February 2017, including Councillor Nicola Meardon, Emma Taylor, Director of Children's Service, and Helen Brackenbury, Executive Director of Children and Families.

It is not clear whether any action was taken in response to receipt of the report by the Local Safeguarding Children's Board.

Dr Gibbs contacted the British Medical Association on 7 February 2017. He explained that there had been an increase in neonatal deaths and non-fatal patient collapses between June 2015 and July 2016 and that he

and his consultant colleagues felt that the rise in mortality and morbidity had "not yet been adequately explained nor investigated sufficiently".

Dr Gibbs sent the same message to the Medical Defence Union.

The Trust published the dissemination version of the Royal College of Paediatrics and Child Health report on 8 February 2017.

On the same date, Mr Jared Ross, medicolegal advisor at the Medical Defence Union, wrote to Dr Gibbs advising him on his obligations as contained in the General Medical Council's good medical practice. Mr Ross provided copies of the guidance published by the General Medical Council and by the Care Quality Commission on raising concerns, and he provided the following advice to Dr Gibbs: first, all doctors have a duty to act when they believe patient safety is at risk or patient care or dignity is being compromised.

Second: Dr Gibbs needed to follow GMC guidance on raising and acting on concerns, a copy of which was attached, by raising his concerns with the appropriate officer in his organisation.

Third: that he may wish to consider that it might be appropriate to go elsewhere if his concerns are not fully addressed, such as the GMC or the CQC.

Fourth: that the General Medical Council suggests that they or other external bodies should be contacted if he couldn't raise the issue locally, or he was not satisfied adequate action had been taken having raised the issue locally, or there was an imminent serious risk to patients and the regulator or other external body had a responsibility to act or intervene.

The British Medical Association also responded to Dr Gibbs on 8 February 2017 asking if he would like his case to be added to a group case created through Dr Jayaram, which, after clarification, he agreed to on 28 February 2017.

It does not appear that Dr Gibbs was given any further support or any safeguarding advice by the British Medical Association.

Dr Jayaram was also in contact with the British Medical Association on 8 February 2017. He told them that Letby was returning to her role, and the consultants wanted to push their concerns further. Dr Jayaram intended to write to the Trust setting at their concerns, "keeping it internal".

Mr Carver's advice to Dr Jayaram was that:

"... neither he nor his consultant colleagues should speak to the media about this issue. It could create difficulties for them, as it was likely to be seen as

taking the matter externally before all internal processes had been exhausted."

Dr Jayaram was advised to seek legal support before considering doing anything other than writing to the Trust.

Mr Carver was sent on 13 February 2017 a draft of the consultants' letter requesting that the coroner be asked to undertake a full investigation of all deaths and unexpected collapses in the period June 2015 to July 2016. On 14 February 2017 a copy of the consultants' letter was sent by Mr Harvey to both Ms Eardley and Dr Hawdon.

Dr Hawdon was told that paediatricians had made allegations against a member of staff. She replied to Mr Harvey's email stating that she perceived there to be a combination of professional pride from the paediatricians along with concern over unexpected and unexplained events.

She explained that unexpected collapse in an otherwise stable baby was rare, and there had been more cases here than she would have expected. She had commented that was insufficient detail in the records as to whether collapse was purely out of the blue and unexplained, due to slow deterioration that was missed until collapse or due to a "sinister cause", ranging

from "not spotting or escalating the babies ... to active harm".

The Care Quality Commission attended an engagement meeting with Tony Chambers, Ian Harvey, Alison Kelly, Sian Williams and Ruth Millward on 17 February 2017. There was discussion of the recently published RCPCH report. Mr Harvey is noted to have stated in the meeting that there were lessons to be learned around transport processes and in the incident reporting system. The notes do not indicate that there was any disclosure to the CQC of the concerns in relation to Letby.

Mr Harvey met with Michael Gregory of NHS England on 23 February 2017 to discuss progress following the publication of the Royal College of Paediatrics and Child Health report. Again, these notes indicate that there was no disclosure of the concerns in respect of Letby.

On 28 February 2017, Dr Jayaram sought advice from Mr Carver of the British Medical Association on the request that he engage in mediation with Letby. Mr Carver advised him that he could not be forced to engage but tactically "it may not be sensible to dismiss this option at this stage".

On 3 March 2017, Mr Carver advised him to attend the

preliminary meeting. Dr Subhedar of the Cheshire and Merseyside Neonatal Network joined the meeting between Mr Harvey and the paediatricians at the Countess of Chester Hospital on 28 February 2017. Dr Subhedar declined to be a co-signatory to a follow-up email subsequent to this meeting but provided text to the consultants to be included in that email, which stated that he supported Dr Hawdon's recommend of further review for several cases where the cause of death or deterioration remained unexplained.

His proposed text pointed out that staffing levels could not explain the excess in neonatal mortality at the Countess of Chester Hospital because it was not an outlier in staffing, which suggested there was a different explanation for the increased number of unexplained deaths.

On 24 March 2017, the Pan Cheshire Child Death Overview Panel chaired by Hayley Frame reviewed Child A's death. The delay in undertaking the review resulted from the fact that there have in inquest in Child A's case, the panel "did not find any issues with the death" of Child A and the case was closed.

Whilst the minutes described the death as unexpected the form classifying the death does not. Instead, recording it as "perinatal/neonatal death". No

modifiable factors are identified. The section on whether or not referrals to the police or Serious Case Review Panel were to be made was not completed.

There was discussion by the panel of the concern expressed in the RCPCH report that it had not been alerted to the cluster of neonatal deaths at the Trust. It was noted that a trend would be difficult to identify because deaths would come to the panel at different times.

There was also discussion as to whether a sudden unexpected death in a hospital was "not always treated with the same concern". It was noted that "on a number of occasions the rapid response process is not followed". One person commented that, "the [sudden unexpected death] process for hospital deaths should be identified within the guidelines."

It was agreed that a discussion between professionals should always occur and if there was concern, then the Sudden and Unexpected Death in Infancy and Childhood protocol should be followed.

My Lady, this may be yet another example of misunderstanding of the local guidelines. Those guidelines did already identify the processes for unexpected death in a hospital as we have already set out.

One of the attendees at the Child Death Overview Panel was Detective Chief Superintendent Nigel Wenham. In his statement to the Inquiry, he explains that it was at this meeting that he first became aware of an increase in neonatal deaths at the Trust. He describes being very concerned, and was "absolutely clear" in his own mind that further examination was required.

On 27 March 2017 there was a paediatrics meeting at the hospital attended by Mr Chambers, Mr Harvey, Ms Hodkinson, Dr Jayaram and Dr Brearey, Dr Subhedar and Ms Maddocks -- and here I need to correct myself, I had previously identified Ms Maddocks as a "Dr Maddocks", I understand that she a nurse -- that Nurse Maddocks from the Cheshire Merseyside Neonatal Network also attended.

The notes record that in response to Mr Chambers asking "I need to know if we do an individual case note review or phone the police", Nurse Maddocks stated:

"Given the information, on the balance of probability, illegal activity has caused the deaths".

Dr Subhedar was noted to say:

"We cannot see an alternative to the police review."

In his statement to the Inquiry however, Dr Subhedar states that it was in fact his view that a forensic detailed review was still required, and that the information about nurse staffing in the thematic review

report was insufficient to trigger police referral.

On 28 March 2017, Dr Jayaram informed Mr Carver at the British Medical Association that he intended to take a step back as the Trust had agreed to contact the police, and "he would not look to contact the police himself - he would let the Trust do this".

Disclosure from NHS England suggests that Nurse Maddocks contacted them on 29 March 2017 disclosing that the paediatricians at the Countess of Chester Hospital felt additional cases required review and queried whether a police investigation was required.

Dr Michael Gregory, NHS England's Regional Clinical Director for Special Commissioning North, spoke to Mr Harvey that afternoon. A subsequent email described what was discussed. It stated that Dr Gregory told Mr Harvey that there were "mounting concerns about what we had heard".

Mr Harvey told him that the Countess of Chester Hospital intended to make a "significant announcement" on Monday. He explained that:

"There is a member of staff whose presence has been seemingly disproportionate, but as we discussed when we met, this was originally accounted for by rotas and skill level.

"However, when pushed about staff members

[Mr Harvey] stated that this matter was best dealt with when they make the significant announcement about the decision that they have taken to speak to an 'appropriate body' on Monday".

Dr Gregory's email concludes:

"Clearly something very serious is going on, and they must have their hands tied somewhere, but it would be speculation to guess what."

NHS England state that this was:

"The first time they had understood that there was a concern held by the hospital's clinicians that there was a connection between a particular individual and neonatal deaths."

The following day on 30 March 2017 the Trust received advice from Corinne Slingo of DAC Beachcroft LLP. The note of the discussion she had with Ms Hodkinson describes consultant concern regarding "a number of cases where unnatural, unnamed causes of death" and the "[consultants] think the Trust should call the police".

Ms Slingo's email to Ms Hodkinson following the conversation dated 4 April 2017 summarises the advice given. Ms Slingo's advice was that if the matter was to be referred to the police, it would be more helpful for it to be "the Trust's decision than for the Trust to

await a potential whistleblower situation".

She advised that the police may need to consider corporate manslaughter issues and would be prone to share information with the Care Quality Commission, who would need to explore potential regulatory breaches.

It was noted that "a full police investigation would be highly disruptive".

It does not appear that the advice was positively to report the matter to the police, but Ms Slingo advised how to engage the police in a "constructive way" if a decision was made actively to engage them, such as inviting a local police detective to a meeting with the coroner.

I turn now to April 2017.

On 11 April 2017 Dr Jayaram informed Mr Carver at the British Medical Association that the hospital was considering whether to make a referral to the police, and had been asked that the consultants meet with Simon Medland QC. Mr Carver advised that this was, "a reasonable request from an employer".

The British Medical Council had, through Mr Carver, provided much support to Dr Jayaram in his role as an employment advisor. The evidence does not indicate any regard to, or advice on, child safeguarding policy.

On 13 April 2017, Ian Harvey contacted Dr Hawdon,

informing her that Queen's Counsel had been instructed to give a perspective on the reviews and next steps.

He asked her to clarify what she meant by "broader forensic review" as had been recommended in her report almost six months earlier. He also asked her whether she had concerns that there was anything other than natural causes in her review of the cases.

Dr Hawdon replied the same day explaining that a broader review would be along the lines recommended by the Royal College of Paediatrics and Child Health, eg "who was on duty, who was perhaps unattended with the babies, did observation charts alert to recurrent or incipient decline?"

As to whether she had concerns, she explained that completely unexplained death on a neonatal unit is rare, so, "by definition", more than one unexplained death does arouse suspicion. She observed that on some occasions the neonatologists had, she thought, been misled by the post-mortem report.

It would appear that by late April NHS England were becoming increasingly concerned by the situation at the hospital. Dr Gregory emailed Ian Harvey on 19 April 2017 requesting an update to which Mr Harvey replied that as Dr Jane Hawdon had identified four cases of unexplained death. The hospital was:

"... following the process that would be [the] case in the event of an unexpected death out of hospital and are consulting with the Child Death Overview Panel."

There are three observations to make about this communication.

First, a point that we have made more than once: neither the local nor the national Working Together Statutory Guidance differentiated in the approach to be taken to unexpected deaths in and out of hospital.

Two, all child deaths had to be referred to the Child Death Overview Panel. And three: five months had elapsed since Dr Hawdon had identified cases of unexplained death having reviewed the outstanding post-mortem reports.

Dr Gregory forwarded Mr Harvey's email to colleagues at NHS England expressing his concern that the Trust were "avoiding the issue that we wished to see (contacting the police)."

There were a series of internal emails at NHS England as to escalating to the police. The view of Robert Cornall, Regional Director of Specialised Commissioning North on 26 April 2017 was "We should just refer to the police now".

Regional Chief Nurse Margaret Kitching's view was that the Trust should be given the opportunity to seek

advice from the police first. She stated that Mr Chambers was unhappy at Dr Gregory's accusation of evasiveness and he wanted to exhaust internal processes first as involving the police could cause distress to the families.

On 27 April 2017, Hayley Frame, the chair of the Pan Cheshire Child Death Overview Panel and Detective Chief Superintendent Wenham attended a meeting at the Countess of Chester Hospital with Mr Harvey, Mr Cross, Dr Jayaram, Dr Holt and Dr Mittal.

Ms Frame's evidence to the Inquiry is that it was only during this meeting that she became concerned that deliberate harm had not been excluded. Detective Chief Superintendent Wenham recalls that the term "angel of death" was used at the meeting to describe Letby.

On 28 April 2017 Mr Harvey informed both Ms Eardley and Dr Jane Hawdon that "perhaps not surprisingly" the only route left was a police investigation.

And so we reach May 2017.

On 2 May 2017 Detective Chief Superintendent Wenham briefed senior officers at Cheshire Police headquarters. It was agreed that a letter would be secured from the Countess of Chester Hospital inviting the police to investigate the Neonatal Unit. Mr Chambers' letter to Chief Constable Simon Byrne formally requesting

a forensic investigation was dated the same day.

The police met with Mr Chambers, Mr Cross and Mr Harvey on 5 May 2017, when the name "Operation Hummingbird" was first used. Mr Harvey informed NHS England that day that there would be an investigation, but it would be described as "an invited police investigation to investigate unexplained deaths".

The police met with Mr Chambers, Mr Harvey and Mr Cross again on 12 May 2017. It was decided that the police would meet with Dr Jayaram following the letter he had sent to the police on behalf of the paediatricians dated 10 May 2017.

Effectively pointing the finger at one nurse.

Mr Harvey informed Margaret Kitching at NHS England that the police were minded not to hold an investigation, but the paediatricians had sent a document, "which was a very prejudiced view, effectively pointing the finger at one nurse". He stated that his "own feeling" was that there would not be an investigation unless there was something "new" disclosed by the Paediatricians. He anticipated that the police would assist "in a message that will allow us to close down the speculation here and deal with the issues of culture".

The meeting between the police and paediatricians

took place on 15 May 2017. It was attended by Dr Brearey Dr Holt and Dr Jayaram. They explained the basis for their concerns: that they were suspicious of an unnatural cause of death and felt they had excluded everything else. Detective Chief Superintendent Wenham describes this meeting as:

"... the most critical and important event following the Child Death Overview Panel meeting on 24 March 2017."

That afternoon, Cheshire Constabulary deciding that there were sufficient grounds to suspect a criminal offence and to launch a criminal investigation.

Following the announcement of the police investigation, Kristian Garsed, Regulation Advisor in the Employer Linked Service at the Nursing and Midwifery Council, spoke to Ms Kelly on 18 May 2017.

Ms Kelly advised Mr Garsed that several medical colleagues were quite strong in their view that Letby may be the cause of the heightened neonatal mortality. She is noted to have described Letby's "very good professional history and high degree of clinical credibility". It was also noted that she stated that other staff were present on a senior number of relevant occasions, and we will explore in evidence the basis for and the accuracy of that assertion by Ms Kelly.

Despite concerns communicated to Mr Garsed, and notwithstanding the launch of a police investigation, no fitness to practise referral was made by Ms Kelly nor requested or advised by Mr Garsed. Mr Garsed instead advised Ms Kelly that there was nothing that could amount to an identifiable or sustainable allegation of impairment of fitness to practise. Ms Kelly was advised to wait for the police investigation to develop. Mr Garsed commented that if Letby was "identified" as having been involved in deliberate endangerment or murder then a referral would be necessary.

My Lady, the Inquiry will be considering the appropriateness of the seemingly high threshold for undertaking a referral, and whether this was indicative of insufficient regard to challenged safety concerns.

Why the allegation which had provoked a police investigation due to there being grounds to suspect a criminal offence was not considered to be an "identifiable or sustainable allegation of impaired fitness to practise" is unclear. Without a referral, the Nursing and Midwifery Council were not in a position to, and did not, commence an investigation, obtained disclosure, or consider whether any interim measures were required to protect the public.

In her statement to the Inquiry, Andrea Sutcliffe,

then Chief Executive and Registrar of the Nursing and Midwifery Council, observes that the impression that may have been given that a referral would any be required in the event of findings of deliberate endangerment, was too high a bar.

She acknowledges that the Nursing and Midwifery Council Employment Liaison Advisers could have provided greater critical scrutiny and done more to support Ms Kelly and the Trust to raise concerns with the police sooner.

Letby remained a registered nurse, free to work without any restriction imposed upon her by the Nursing and Midwifery Council, and had been since concerns were first raised to the NMC in July 2016.

As we will see, she remained free to work without restrictions imposed upon her by her regulator until November 2020 after she was charged.

Returning to 2017, we move to June.

On 5 June 2017, the Local Safeguarding Children Board met. Ms Kelly, who had been a member of the board throughout, presented a paper titled "Neonatal review and police investigation into the increase in neonatal mortality at the Countess of Chester Hospital Foundation Trust".

She briefed the board on its contents.

The paper describes the increase in neonatal deaths and the invited review by the RCPCH. It concluded:

"In summary, the Trust can demonstrate that the concerns raised had been taken seriously and it has been open and transparent with the coroner, regulators, parents, wider stakeholders, and the public."

Neither the report nor the minutes of the meeting demonstrate any disclosure of the suspicions of deliberate harm by Letby.

The minutes of the meeting show that a query was raised as to why the Child Death Overview Panel had "not picked this up". Dr Mittal explained that the data was fragmented because of the time it took for a death to come to the panel and the cluster was masked because some of the children did not live in Cheshire.

Mr Garsed of the Nursing and Midwifery Council met with Ms Kelly on 15 June 2017. He was informed that Letby was still employed and working, but in a non-clinical role. Notwithstanding her continued employment and the absence of any formal restriction on her ability to work as a nurse, no fitness to practise referral was sought or advised.

October 2017.

On 9 October 2017 Alison Kelly notified the Nursing and Midwifery Council that the police investigation was

progressing to the next stage, with interviews of a significant number of staff anticipated. After this, there was no contact between the hospital and the NMC in the nine months that followed.

We move forward to 2018, in particular March.

On 29 March 2018 Ms Kelly made a referral to the Local Authority Designated Officer. She had met with Emma Taylor, Director of Children's Services, and given her an envelope said to contain confidential information relating to the neonatal investigation. When Ms Taylor opened the envelope she saw Letby's name and date of birth. Ms Kelly asked whether "this referral" should have been sent earlier, and Ms Taylor confirmed it should have been. Ms Kelly was told that a formal referral was required.

In his statement to the Inquiry, Mr Jenkins, the Local Authority Designated Officer, comments that:

"What is concerning in this case is that when professionals have reached the point of thinking the unthinkable, the matter was not referred to the Local Authority Designated Officer Service."

He confirms that whilst referrals are normally made by a designated safeguarding lead at an organisation, an individual clinician who was concerned could make a referral if their organisation was not doing so.

Mr Jenkins spoke to Ms Kelly on 27 March 2018. He was assured that Letby was not working directly with children or families.

He told Ms Kelly that a referral was required. It followed on 29 March 2018. Whilst the police investigation was ongoing, and with Letby having been moved to administrative duties, no formal meeting was arranged by the Local Authority Designated Officer.

We move now to the Nursing and Midwifery Council referral.

Following the arrest of Letby, the Nursing and Midwifery Council contacted Ms Kelly on 3 July 2018. She confirmed a referral would be made. It was sent on 5 July 2018. It contained a brief chronology and stated that Letby was on duty on a number of occasions when incidents had taken place.

A senior lawyer at the Nursing and Midwifery Council, Richard Reid, undertook an assessment of the referral. He concluded that there was little information with which to progress the referral, and insufficient grounds to obtain an interim order against Letby without her being charged. His view was that there was no prima facie case.

It is not clear that any formal requests for evidence were made upon receiving the referral, but

Mr Reid did speak to Melissa Andrews, a police officer, on 26 July 2018. She confirmed that the only evidence was the correlation between Letby's presence and the deaths, and she'd been arrested to facilitate questioning.

On 6 July 2018, the Director of Fitness to Practise, Matthew McLelland, reached the same conclusion as Mr Reid: that there were no grounds to apply for an interim order due to a lack of evidence and because the "fact of the arrest is not in itself sufficient".

My Lady, the significance of an interim order for conditions or suspension was that it would have either restricted the circumstances in which Letby could work, such as by imposing a condition of "close supervision", or prevented Letby from working as a nurse. Without such an order, there were no restrictions on her ability to work beyond those imposed by her bail conditions. An obvious question that arises is whether the delay in waiting until Letby was arrested to seek a referral inhibited the ability to progress and investigate the referral.

It appears that any concerns the Nursing and Midwifery Council had about the absence of an interim suspension order were initially assuaged by their initial but mistaken understanding that Letby's bail

conditions prevented her working a nurse. On 20 July 2018 a legal assistant at the Cheshire Constabulary informed the Nursing and Midwifery Council that Letby's bail conditions prevented her from working in any healthcare setting or having unsupervised contact with anyone under the age of 16.

It was not until May 2019, so approximately ten months later, that it was appreciated that Letby's bail conditions only prevented her working with babies or children in a healthcare setting, not working in a healthcare setting altogether. Assurance was, however, given by the police that there were system markers in place that would notify the police if there was a Disclosure and Barring Service check made in respect of Letby.

The discovery of the true position in respect of Letby's bail conditions coincided, and may have provoked, internal discussions at the Nursing and Midwifery Council as to whether an interim order should in fact be sought.

On 22 May 2019, Leeann Mohamed, a lawyer in case preparation and presentation, states that she was inclined to apply for an interim order on public interest grounds, given the seriousness of the allegations.

On 30th May 2019, Angela Wilding, an investigation lawyer, echoed the original view of Richard Reid that there was insufficient evidence to establish a prima facie case. However, on 10 June 2019, she wrote that the Nursing and Midwifery Council was very anxious that there was not an interim order in place and she was more inclined to apply for one.

By 2 July 2019, the view she took was that an interim order should be sought. She considered, after further thought, that the fact of arrest would be sufficient to make an application given the severity of the allegations.

Others, however, remained of the view that the fact of arrest remained an insufficient evidential basis to justify an interim order in the absence of other evidence.

My Lady, the grounds for imposing an interim order were contained in Article 31(2) of the Nursing and Midwifery Order 2001. They were that such an order:

"... is necessary for the protection of members of the public or is otherwise in the public interest, or is in the interests of the person concerned, for the registration of that person to be suspended or be made subject to conditions."

The order itself does not establish any particular

evidential threshold but the Nursing and Midwifery Council's interpretation of the case law was that in order to obtain an interim order it was necessary first to show that there was a prima facie case against the registrant before the public interest or public protection grounds for an order could be considered.

The Nursing and Midwifery Council's guidance on interim orders had been updated on 2 October 2019 to reflect this interpretation. An example given on when there is sufficient evidence to establish a prima facie case was where an individual had been charged with a criminal offence.

The Council's guidance on the grounds for obtaining an order have since changed. It now states explicitly that there is no evidential threshold, but there must be some evidential basis that is cogent and not fanciful, frivolous, obviously contradicted, or entirely misconceived.

My Lady may consider that if such guidance was in place at the time, there would not have been any reluctance or hesitance to seek an interim order.

However, it is clear at the time the Nursing and Midwifery Council considered the lack of a criminal charge a hurdle to obtaining an interim order, notwithstanding Letby's arrest and a criminal

investigation of the utmost seriousness.

Another hurdle may have been the lack of investigation or evidence gathered by the Nursing and Midwifery Council to support such an application.

On 23 July 2019 somewhat belatedly, you may conclude, my Lady, given it was more than three years after concerns about Letby were first raised with them, the Nursing and Midwifery Council requested documents from the Trust linking Letby to the deaths. The request was not a statutory disclosure request, and on 30 July 2019 the Countess of Chester Hospital refused it.

It was not until Letby was charged in November 2020 that the Nursing and Midwifery Council sought an interim order. An 18-month suspension order was imposed on 20 November 2020 both on public protection and public interest grounds. The interim order remained in place thereafter.

Following her conviction, Letby was referred to the Fitness to Practise Committee. On 10 November 2023 Letby indicated that she did not contest the application to remove her from the register and she did not want to attend the hearing. The hearing took place on 12 December 2023. Letby was struck off.

My Lady, I wonder if that would be a convenient

moment?

LADY JUSTICE THIRLWALL: Yes, thank you. We'll resume again at 3.15.

(2.58 pm)

(A short break)

(3.14 pm)

LADY JUSTICE THIRLWALL: Mr De la Poer.

MR DE LA POER: My Lady, continuing with external bodies I deal briefly with the Royal College of Nursing.

The Inquiry have obtained a witness statement from Patricia Marquis, Director for England at the Royal College of Nursing. She states that the Royal College of Nursing is not aware of any enquiries being raised with them by their members in relation to the neonatal unit at the Countess of Chester Hospital.

Ian Harvey fitness to practise referral.

My Lady, the annex to the terms of reference for the Inquiry include at question 27, "What was the result of any referral or discussion with the GMC?"

On 20 July 2018 Dr Brearey, supported by a number of consultant paediatricians, Dr Jayaram, Dr Holt and Doctor ZA, referred Ian Harvey to the General Medical Council Fitness to Practise Team. The referral included documents setting out their concerns.

Those concerns included:

(a) a failure to act appropriately or timely in response to concerns raised by clinicians about the neonatal mortality rate and the possibility of unnatural causes for collapses and deaths from February 2016;

(b) failing to act appropriately in 2017 to concerns that they raised about the lack of investigations into neonatal deaths and sudden collapses;

(c) failing to share and misrepresenting the Royal College of Paediatrics and Child Health review.

(d) misusing the Trust's grievance procedures as evidence of wrongdoing by the consultants, and the innocence of the nurse in question;

(e) threatening paediatricians who would not enter into mediation with Letby;

(f) misleading the Trust board;

(g) misleading the public in media statements;

(h) misleading the clinicians as to the reason for the meeting with Simon Medland QC.

A case examiner advised that further investigation was "inevitable" and that if Mr Harvey was "found to have failed to act appropriately when the staff were raising repeated serious possibly criminal concerns about patient safety, this would be a very serious matter".

On 14 September 2018 Mr Harvey told the General

Medical Council that the allegations were "nothing new to him". He had retired and moved to France.

He queried what the process of voluntary erasure from the register was. The investigation proceeded. A detailed 26-page witness statement was obtained from Dr Brearey dated 29 January 2019.

Mr Harvey requested voluntary removal from the register on 29 July 2019 and repeated the request on 11 June 2020, whilst commenting that he was prepared, if necessary, to defend himself vigorously.

He described as one of his greatest regrets the "breakdown in the relationship between the executives and the consultant paediatricians".

The application for voluntary erasure was refused. The default position is that voluntary erasure will not be allowed by the General Medical Council where there are serious allegations or an ongoing police investigation. The General Medical Council instructed an expert, namely a consultant in general and respiratory medicine to opine upon whether Mr Harvey's conduct fell below the standard to be expected of a reasonably competent Medical Director.

The expert's initial report was dated 30 September 2020 but was caveated due to the significant evidence that was missing. His report,

following receipt of further evidence, is dated 8 February 2022.

The GMC expert made one finding that Mr Harvey's standard of care may have fallen seriously below the standard to be expected of a reasonably competent Medical Director. This was the allegation that Mr Harvey had misled the grievance process that the paediatricians had threatened to contact police if Letby was not removed from the unit. The paediatricians denied making that threat.

The expert additionally found that Mr Harvey's communication with the paediatricians fell below the standard to be expected of a reasonably competent Medical Director, but not seriously below that standard.

They identified in particular the failure to provide more regular updates and the confusion that arose at the meeting on 26 January 2017 to discuss the Royal College of Paediatrics and Child Health Invited Review Report and the Dr Jane Hawdon Report.

As a result of the instructed experts' conclusions the GMC case examiners decided to close the referral with no action. Following this, Mr Harvey's application for voluntary erasure from the medical register was granted.

Alison Kelly, fitness to practise referral.

On 18 May 2020, four consultant paediatricians at the Countess of Chester Hospital, Dr Brearey, Dr Jayaram, Doctor ZA and Dr Holt, referred Ms Kelly to the Nursing and Midwifery Council. The concerns raised included allegations that Ms Kelly mismanaged the concerns of the consultant body, failed to communicate effectively, failed to take appropriate action, made errors of judgement and damaging decisions and did not act with honesty and integrity at all times.

On 15 February 2021 the Nursing and Midwifery Council were asked to delay their investigation into Ms Kelly until after the conclusion of Letby's criminal trial.

Following Letby's conviction, four members of the public, one a nurse, also referred Ms Kelly to the Nursing and Midwifery Council. We understand that investigations are ongoing.

We turn now to the topic of the coroner.

The annex to the terms of reference for the Inquiry ask at question 19 what information about each of the deaths was provided to the coroner, and whether the Trust's provision of information to the coroner was appropriate.

The Coroners and Justice Act 2009 requires a coroner to conduct an investigation if there is reason to

suspect a death in their area was violent or unnatural, or the cause of death is unknown. An inquest must be held if the coroner suspects a violent or unnatural cause unless the post-mortem reveals a cause of death and the coroner does not think it necessary to continue the investigation.

Nicholas Rheinberg was at the time the Senior Coroner for Cheshire. He remained so until his retirement in March 2017. Dr Janet Napier and Alan Moore, who became the Senior Coroner on Mr Rheinberg's retirement, were his assistant coroners. Mr Rheinberg had published local guidance titled "Reporting Deaths to the Coroner" which required "all child deaths in the area" to be reported, irrespective of the circumstances of death.

Once a death was reported, if there was reason to suspect a violent or unnatural death, an investigation would be commenced. Where preliminary inquiries satisfied the coroner that the death was naturally occurring, the coroner would discontinue the investigation and his involvement would come to an end.

If it was not possible to determine if the death was natural or not, a post-mortem would be arranged. If the cause of death could not be ascertained or was unnatural, an inquest would be opened.

Mr Rheinberg's evidence to the Inquiry is that where there was a suspicion of criminality, he would instruct a forensic pathologist to carry out the post-mortem. In child death cases involving suspicion of criminality the forensic pathologist would work alongside the paediatric pathologist. In such cases the coroner would also consult with the senior police officer to discuss what ancillary action might be taken.

I turn now to consider the coroner's service and the procedural history.

The death of Child A was reported to the coroner by Dr Saladi on 9 June 2015. No medical cause of death was given. The reported circumstances of death included the fact that X-ray had revealed that an umbilical line, and a percutaneous line had been inappropriately positioned, and some time later, Child A suffered an apnoeic event and went into arrest.

An investigation was commenced into Child A's death on 22 June 2015, and the inquest was opened on 23 December 2015, after the post-mortem of Dr Shukla was unable to establish cause of death.

The inquest was heard on 10 October 2016 when the coroner recorded a narrative conclusion that stated:

"It cannot be determined what caused [Child A's collapse and subsequent death], and further, it cannot

be determined whether this was due to natural or unnatural event."

On 15 June 2015, a week after the report of the death of Child A, the death of Child C was reported to the coroner by Dr Gibbs. No cause of death was offered. It was reported that Child C had had a sudden collapse and died. An investigation was commenced on 16 June 2015 by assistant coroner Dr Napier.

A post-mortem was conducted by Dr Kokai, who considered that there was a natural cause of death. The investigation was discontinued on 26 November 2015 because the death had been found to be due to a natural cause.

On 22 June 2015, Child D's death was reported to the coroner by Dr Newby. It was reported that Child D had become profoundly mottled and apnoeic, losing heartrate and not responding to resuscitation. No cause of death was offered.

This marked the third reported death within a fortnight, and in none of them was a cause of death offered. No suspicion of potential deliberate harm was raised in any of the reports of these deaths.

Despite all three cases having been unexpected and unexplained, there was no police involvement on behalf of the coroner. The only limited evidence of engagement

with the process in the Sudden Unexpected Death in Infants and Children Guidance was the minutes of an initial strategy meeting on 2 July 2015, provided to the coroner which concluded that Child C's death did not meet the threshold for a Serious Case Review.

As with Child A and Child C, on 25 June 2015 an investigation was commenced into the death of Child D. The report of the post-mortem conducted by Dr McPartland, which we will return to shortly, described a natural cause of death.

The view of the assistant coroner Mr Moore was that the investigation could be discontinued.

After representations from Child D's family, however, an inquest was opened on 8 January 2016. Independent expert evidence was obtained by the coroner, including from Dr Mecrow, a consultant paediatrician. The inquest was scheduled to be heard on 25 May 2017 but was adjourned and did not proceed on that day due to the coroner being informed that there was to be a police investigation.

The coronial investigation was subsequently suspended on 27 November 2020 by assistant coroner Peter Sigee so as not to prejudice the police investigation. This decision was confirmed on 19 October 2021, following the Crown Prosecution Service

notifying the coroner that Letby was to stand trial charged with the murder of Child D.

The death of Child E was reported to the coroner on 4 August 2015. Unlike the reports of the deaths of Child A, Child C and Child D, a cause of death was proposed by Doctor ZA of Necrotising Enterocolitis and prematurity. There was nothing in the reported circumstances of death raising suspicion or concern. In light of the reported natural cause of death, accepted by Dr Napier, there was no post-mortem and neither an investigation was commenced nor an inquest opened.

Child I's death was reported to the coroner on 23 October 2015 by Dr Gibbs. No cause of death was offered. The reported circumstances of the death were that Child I had suffered an arrest the previous week, but had been resuscitated and ventilated and had been doing well for five days before having another arrest with resuscitation unsuccessful.

An investigation was opened by Dr Napier on 28 October 2015. The post-mortem report of Dr Kokai concluded that there was a natural cause of death. The investigation was discontinued on 12 February 2016, the coroner being satisfied that the death was due to natural causes.

The deaths of Child O and Child P were reported to

the coroner by Dr V on 27 June 2016. No cause of death was offered. The reports of these two deaths did not raise any suspicions of deliberate harm. In respect of Child O, it was reported that the child initially did well following birth but became quite unwell, requiring ventilation, initially improving but then deteriorating and couldn't be resuscitated.

In respect of Child P, the reported circumstances of death were that the child was not extremely premature and had been doing well initially, but that the abdomen had become distended, oxygen levels and heartrate had decreased, and there had been several episodes of resuscitation. Investigations were opened by Mr Moore on 30 June 2016, post-mortems were conducted by Dr Kokai who concluded there were natural causes of death in both cases.

My Lady, the deaths of Child O and Child P were reported to the coroner in circumstances where (i) the independent paediatric experts in Child D's case, Dr Mecrow, had described the collapse there as "wholly unexplained"; (ii) the death of Child A was proceeding towards an inquest hearing in circumstances where there remained no cause of death after post-mortem; and (iii) the worrying increase in neonatal mortality at the unit.

Following receipt of Dr Mecrow's report on

9 June 2016, Mr Rheinberg explains in his statement to the Inquiry that he will have shared the experts' puzzlement at Child D's wholly unexplained collapse. He did not suspect the possibility of criminality.

Upon receipt of the reports of the deaths of Child O and Child P, Mr Rheinberg's evidence to the Inquiry is that he discussed the matter with his officer, Christine Hurst, and they were both concerned about the number of neonatal deaths that had occurred and the deaths of Child O and Child P focused their concern.

Mr Rheinberg states in his evidence to the Inquiry that he would have sought a meeting with the Chief Executive of the Trust had it not been for the fact that a report from the Royal College of Paediatrics and Child Health had been commissioned. He was comforted by this report and anticipated it would have revealed any deficiencies in the neonatal department.

The contemporaneous documents show that prior to the report of the RCPCH being received, Mr Rheinberg was minded to discontinue the investigation into the deaths of Child O and Child P, after the post-mortem reports of Dr Kokai concluded that the causes of death were natural.

Mr Rheinberg's view as stated at the time was that the report of the Royal College of Paediatrics and Child

Health was, "not instituted because of specific concerns about the death in this instance" and there was no "clinical mismanagement" in those cases.

Nonetheless, the investigation remained open pending receipt of the Royal College of Paediatrics and Child Health report.

On receipt of that report, Mr Rheinberg reiterated the view that the investigation should be discontinued. He wrote on 26 January 2017 that:

"Nothing in the report throws any light on the deaths in questions and these being natural deaths with nothing to indicate gross human failure, I have no jurisdiction to hold inquests. If [parents] have any representations to make I will of course listen, but other than that, I will discontinue."

The investigation remained open after the Countess of Chester Hospital indicated that a full independent review of the deaths of Child O and Child P were being undertaken.

If this was a reference to the review by Dr Hawdon, the Countess of Chester Hospital was already in possession of the report of Dr Hawdon, and her subsequent review of the post-mortems for Child O and Child P, which concluded that both deaths remained unexplained.

Even after Dr Hawdon's report was provided to the coroner on 15 February 2017 no inquest was ever opened, and ultimately, the investigation into the deaths of Child O and Child P were suspended in June 2017 following the commencement of the police investigation.

I turn now to the evidence that was gathered by the coroner in these cases.

In Child A's case the post-mortem reports of Dr Shukla did not establish a cause of death. Child A had not suffered typical complications associated with inappropriate line insertion. A cross-pulmonary artery was found at post-mortem but was an incidental finding and was not considered to be indicative of cause of death. The inquest was due to be heard on 23 March 2016 but it was adjourned due to what Mr Rheinberg described as "particularly poor delays" by the Countess of Chester Hospital in providing evidence.

Mr Rheinberg had anticipated receiving a root cause analysis or Serious Incident report in respect of Child A. After waiting for such a report he was eventually, in September 2016, provided with a very brief summary report which Dr Brearey had written more than a year earlier on 1 July 2015.

Both Mr Rheinberg and those acting on behalf of Child A's family expressed disappointment at the

apparent lack of a thorough investigation by the hospital. The evidence gathered for the inquest hearing on 10 October 2016 included statements from a number of doctors involved in Child A's care. It did not raise concerns in relation to Letby, nor was it suggestive of deliberate harm.

The Inquiry will be considering why the concerns about Letby that by this stage had led to Letby being removed from the ward and had led to the commission of the review by the RCPCH were not communicated to the coroner.

In Child C's case Dr Kokai, the paediatric pathologist, performed the post-mortem on 16 June 2015, and indicated on the same day that the death was naturally occurring.

The cause of death was withheld pending histology and bacteriology investigations.

Following investigations, the cause of death was given in a post-mortem report dated 3 November 2015. Dr Kokai's view was that lung immaturity had caused widespread hypoxic-ischaemic damage to the heart and myocardium.

In Child D's case the post-mortem was carried out by Dr Jo McPartland. Her initial post-mortem report was date 26 August 2015 and was updated on

18 September 2015. She found acute pneumonia in the lungs which she concluded was likely present at birth although Child D had no levels of C reactive protein, suggesting an absence of inflammation. She considered there was a possibility of early onset sepsis. Her view was that the cause of death was pneumonia with acute lung injury.

An independent consultant paediatrician, Dr Mecrow, was instructed to comment on the adequacy of the care provided to Child D and Child D's mother. The "Opinions" section of Dr Mecrow's report starts:

"I feel I should start by commenting that Child D's death is disturbing. Not because I perceive there to be significant deficiencies in her care, but because her collapse was so sudden and unexpected."

Dr Mecrow went on to comment:

"Quite why Child D should have collapsed and become unwell after a period of more than 24 hours when she seemed to be making good progress is wholly unexplained."

Ultimately Dr Mecrow agreed with Dr McPartland's conclusions that pneumonia was likely present at birth and that on balance the cause of death was bacterial sepsis as a result of pneumonia. He explained however that there were a number of clinical and biochemical

features at odds with this diagnosis.

In Child I's case the post-mortem report was prepared by Dr Kokai. It was dated 10 February 2016 and found early stage chronic lung disease and irregularities in the brain.

Dr Kokai considered it, "justifiable to conclude that [Baby I's] death was as a result of natural causes". Those natural causes were said to be a "combination of several underlying pathological processes as a consequence of prematurity". The finding of natural causes led to the discontinuation of the investigation.

My Lady, you will recall that this was a cause of death that Dr Hawdon advised should be reviewed as Child I had been stable in the days preceding collapse.

The post-mortems of Child O and Child P were both undertaken by Dr Kokai on 28 June 2016 and both reports were dated 10 October 2016.

In respect of Child O, Dr Kokai's examination investigations did not explain the cause of the sudden collapse and progressive deterioration. However, Dr Kokai considered that the collapse fitted the diagnostic features of the condition, "Sudden Unexpected Postnatal Collapse". He concluded that Child O died of natural causes due to intra-abdominal bleeding from

a ruptured subcapsular haematoma of the liver. He attributed this to prematurity.

My Lady will recall that Dr Hawdon's review of this case in the post-mortem led her to conclude that the death was unexplained. She considered that the intra-abdominal bleeding was secondary to chest compressions following collapse. It did not explain the collapse or the death.

In respect of Child P, Dr Kokai was unable to identify any underlying disease or pathological condition to explain the death. His view was that Child P's unexpected and progressive deterioration fulfilled the definition of "sudden unexpected postnatal collapse" but the cause of that condition "remained unexplained". He nevertheless gave a cause of death as prematurity which he described as a "very substantial risk factor for unexpected death of neonates".

My Lady may wonder if prematurity as a risk factor for death was being conflated with being a cause of death. It was a third occasion where death was essentially being attributed to prematurity by Dr Kokai.

Dr Hawdon's view was that Child P was only mildly pre-term and was not expected to collapse and die. She considered that the death remained unexplained.

I turn to concerns relating to Letby and the

coroner.

Mr Rheinberg's statement to the Inquiry is that up until his retirement on 10 March 2017, he had, "not the slightest inkling or suspicion that anyone had deliberately harmed the children". He states he is satisfied that he was not informed that Letby was under suspicion during his tenure. He expresses surprise that the concerns of the consultants were not shared with him; his "door was always open".

His expectation was that those with concerns would pass on details of possible suspicions to him. Similarly, Mr Moore in his statement states that at no stage was there ever any mention by the Countess of Chester Hospital of suspicions or concerns that an individual had been responsible for the death of any baby.

Mr Rheinberg met with Mr Harvey and Mr Cross at the Countess of Chester Hospital on 8 February 2017 and, at the coroner's office on 15 February 2017. The second meeting was also attended by Mr Moore.

At the second meeting, Mr Rheinberg was given a copy of Dr Hawdon's report and the letter from the paediatrician seeking a coronial investigation of all the deaths and unexplained collapses from June 2015 to July 2016. Mr Rheinberg's evidence is that at neither

of these meetings or otherwise was he made aware of suspicions or concerns relating to the involvement of a nurse in relation to any of the deaths. His response to the paediatrician's request was that he did not have the power to conduct a broad investigation, and could only revisit deaths that had been through the coronial process if there was fresh evidence.

Amongst the documents said to be enclosed with the letter provided to the coroner at the meeting of 15 February 2017, was a document titled "Observations Additional to the RCPCH Review".

That letter refers to the fact a nurse had been rostered on the shifts for all deaths. Mr Rheinberg's evidence is that this document was not referred to during the meeting and either it was not provided to him or if it was, he may have overlooked it.

His evidence is that the suggestion that one nurse had been rostered on shift or all the deaths would have prompted him to ask the identity of the nurse in question, and he would probably have spoken to a police officer to determine if the police were aware of this correlation.

My Lady, that concludes all that we will say at this stage about the coroners.

I am going to ask you to invite Counsel to the

Inquiry to come forward to conclude this opening address.

LADY JUSTICE THIRLWALL: Thank you very much indeed, Mr De la Poer.

I will allow you just to move out of the way and call on Ms Langdale.

Further opening statement by MS LANGDALE

MS LANGDALE: My Lady, Part C. The Terms of Reference for Part C require the Inquiry to investigate the effectiveness or otherwise of NHS management and governance structures and processes for keeping babies in hospitals safe and well looked after.

To do so, the Inquiry will examine NHS culture and whether and how accountability of senior managers should be improved upon. The Inquiry will also consider the role of external scrutiny and professional regulation. My Lady, you can then decide whether changes are necessary and if so, what they should be.

This Inquiry does not exist in isolation. It is preceded by over 30 inquiries that have arisen in healthcare settings over the last 30 plus years.

Some, such as the Clothier Inquiry and the Shipman Inquiry mentioned yesterday, have arisen from cases where health professionals have deliberately harmed or murdered patients. Some, such as the

independent investigation into maternity and neonatal services in East Kent, have looked at particular services within hospitals. Others have focused upon specific issues such as the Messenger review of NHS leadership, and Tom Kark King's Counsel's examination of the Fit and Proper Person test as it applies to directors of hospitals.

However, what most of these Inquiries have in common is that they have, in same form, and to differing degrees, addressed issues of patient safety, culture, and governance. They have all found substantial failings and all made recommendations or identified areas of action for implementation.

The cost of public inquiries and what they achieve is a matter of public concern. Question 28 of a series of questions posed by this Inquiry and appended to the terms of reference is as follows:

"Whether recommendations to address culture and governance issues made by previous Inquiries into the NHS have been implemented into wider NHS practice?"

When beginning this Inquiry, you said, my Lady, in a video address:

"We all know that there have been many inquiries into events in hospitals and other healthcare settings over the last 30 years. I want to know what

recommendations were made in all these inquiries. I want to know whether they were implemented? What difference did they make? Where does accountability lie for errors that are made?"

In order to fulfil that commitment, the Inquiry legal team has prepared and published on the Inquiry website a review of implementation of recommendations from previous Inquiries into healthcare issues. The review table is a continuing piece of work, and we are grateful for the assistance of Sir Robert Francis via his first expert report and to Core Participants for their comments on our draft.

It is readily apparent on the face of the table how many recommendations have not been implemented at all, or have not been implemented effectively.

We will be asking witnesses giving evidence on behalf of their organisations why these recommendations have not been implemented, where they consider responsibility lies for the failure to implement, and what impact the failure to implement may have had.

We have also asked for and received statements on this issue from two former Secretary of State: Baroness Virginia Bottomley and the Right Honourable Jeremy Hunt MP. We anticipate, my Lady, that upon the conclusion of this Inquiry you will be in a position to

give a comprehensive answer to question 28.

The Inquiry's terms of reference include an explicit commitment to consider NHS culture. The more detailed question that is posed is, "What was the culture within the Countess of Chester Hospital? To what extent did it influence the effectiveness of the processes and procedures for raising concerns?"

It is imperative that this Inquiry does not simply repeat the work of previous inquiries, but rather, builds upon that work.

As Sir Brian Langstaff said very recently in his powerful report into the Infected Blood scandal:

"It is a sad fact that very few Inquiries into aspects of the Health Service or parts of it have ended without recognition that the culture needed to change."

He cited the example of the Inquiry into children's heart surgery at the Bristol Royal Infirmary between 1984 and 1995.

The Bristol Report emphasised the need for a change in culture. It also recognised that there was a link between candour and safety, noting that being open and transparent about a "sentinel event" enables possible shortcomings to be treated as an opportunity to improve the quality, that is the safety, of the NHS.

Over a decade after the Bristol Report in 2001, and

a year following the Mid Staffordshire Inquiry Report, the Health and Social Care 2008 (Regulated Activities) Regulations 2014 came into force.

Regulation 20 is headed "Duty of Candour" and provides that NHS Trusts in England must act in an open and transparent way in relation to care and treatment of patients.

Whilst the duty of candour is a duty imposed on the health service body, individual doctors, nurses and midwives are also subject to professional obligations and standards. The statutory duty of candour and the professional duties of individuals have the same aim: to put the patient first and to be both open and transparent in a situation where something has gone wrong.

Sir Brian's view expressed to the Infected Blood Report was that whilst the legislative duties of candour cover healthcare organisations and the professional duties and professional regulators cover individual healthcare professionals, there remains a gap. Many leadership roles in the NHS Trusts are not subject to individual accountability for candour.

This Inquiry has explicitly within its terms of reference an obligation to consider how accountability of senior managers should be strengthened, consideration

of whether there should be an extension of the duty of candour forms part of that consideration, and witnesses within Part C will be asked to give their views about this.

The Nuffield Survey.

In addition to consideration of past recommendations from previous Inquiries, the Inquiry has also commissioned a report to shed light on to the current effectiveness of NHS management and governance. This should assist the Inquiry in establishing not only what ought to be, but what is, so that any recommendations you make, my Lady, are relevant to neonatal units as they operate today.

A detailed questionnaire was sent to 120 NHS Trusts in England with neonatal units to be completed by both medical and non-clinical directors. Analysis of the responses has been undertaken by the Nuffield Trust, an independent health services organisation specialising in health research and policy analysis. The Inquiry legal team will summarise during Part C the evidence obtained and analysed by the Nuffield authors.

Very briefly at this stage, most Trusts report difficulties in meeting staffing requirements in relation to both the number and the qualifications of healthcare professionals. 99 Trusts reported that they

had nursing vacancies, and 68 Trusts reported that they did not meet staffing standards for nurses.

The questionnaire asked about processes for raising concerns and complaints. There was broad consistency between the Trust's responses with the Patient Advice and Liaison Services, PALS, being widely cited as the mechanism available to families, and Freedom to Speak Up Guardians being cited as the appropriate avenue for staff.

Given the evidence obtained in Part B, PALS and Freedom to Speak Up Guardians are topics upon which the Inquiry has sought direct witness evidence.

108 respondents to the questionnaires reported having at least one concern/complaint in the previous year with 67 Trusts upholding at least one complaint. 24 Trusts had reported matters to a professional regulator in the previous year, half of which involved contacting the Nursing and Midwifery Council.

As you will know, my Lady, for children to be safeguarded effectively in hospitals and in the wider NHS, safeguarding policies need to accurately reflect the statutory obligations and guidance which underpins them.

Even more crucially, policies need to be practical and accessible to staff working within the organisation.

Anybody confronted with a safeguarding concern in relation to a staff member should be able to read a policy and immediately know what to do, and who to speak to. Policies are far easier to implement when their requirements are expressed in concrete rather than generic terms. Equally, however, adequately trained staff should not need to read policies when confronted with a safeguarding concern. They should know what to do when presented with a situation which potentially impacts upon the safety of a child.

We asked Trusts to provided us with their safeguarding policies. We were also provided with a wide variety of policies which included within them reference to safeguarding concerns being raised in relation to a member of staff. These policies typically included complaints concerns policies, professional standards or conduct policies, disciplinary policies, and infrequently, freedom to speak up and whistleblowing policies.

Knowledge and dissemination of safeguarding policies will be explored during Part C with Core Participants. Key to safeguarding is remembering that taking protective steps to ensure a child is kept safe is a neutral step designed to protect the child's welfare. Organisations instituting safeguarding measures should

not assume that steps cannot be taken until an allegation has been proved. It is wrong to do so. Where suspicions or concerns about harm arise, the protection of babies and children comes first.

It is essential that a safeguarding issue is recognised and treated as safeguarding rather than as an internal disciplinary matter or a grievance issue. But arguably, that is easier said than done. There will be consequences for a staff member who is moved from frontline responsibilities, both in terms of reputation and career development. Furthermore, will medical staff draw attention to a safeguarding issue if they believe that it will result in grievances and counter-grievances being raised? Or when they realise the damage it may do to a colleague or friend or to relationships in general?

How can the culture of the NHS change so that safeguarding referrals and investigations are expeditious and everyone appreciates that a safeguarding issues involves managing potential risk? Does employment law operate effectively in the context of a safeguarding investigation, or does it in fact hinder and not yet recognise that process?

Trusts were questioned about factors that might inhibit raising and acting upon concerns. They were also asked about the multiple routes for reviewing

evidence after a death, including external reviews such as Child Death Overview Panels. Feedback was also sought on data collection and the national reporting and monitoring of requirements relating to neonatal care.

As you have heard, these are all areas where the Inquiry has sought additional evidence in the form of witness statements in Part B.

The regulation of senior managers was a specific matter about which the Inquiry legal team sought information and views. To what extent could the regulation of senior managers assist with safeguarding and improve governance, either directly or indirectly? As a general proposition, would such regulation improve the quality and expedition of safeguarding, grievance, and/or disciplinary investigations? Would it provide a counterweight to the desire by some to prevent so called reputational damage to the institution for which they are working?

Would it prevent ineffective managers moving from Trust to Trust and taking ineffectiveness with them? Questionnaire response from NHS Trusts differed as to regulating senior managers with positions in support of regulation or against it, neutral or undecided. This is a topic you will hear about, my Lady, in oral evidence.

Many of the Trusts refer to their current objectives

to develop a positive safety culture and their engagement with the NHS England Perinatal Leadership Programme in accordance with the 2023 three-year delivery plan for maternity and neonatal services. Responses from Trusts indicate that many have processes in place or are actively working towards these objectives.

Indeed, for almost all the areas covered in the questionnaire, there are existing regulations, mechanisms or guidance in place in the NHS. Within neonatal services there appear to be additional reporting routes and requirements over and above those which apply to the NHS as a whole. However, policies and processes are not sufficient by themselves to ensure services are safe and effective. Culture and leadership are critical. It is for this reason that this Inquiry, within its analysis of the wider NHS, and when choosing which witnesses to call, has placed a particular emphasis on culture.

The Picker Survey. In recognition of the critical role of culture and leadership in the protection of babies, a second piece of work was undertaken by the Inquiry. To deepen understanding of the culture within NHS neonatal units, midwives, doctors, consultants, nurses and managers who work within, or in connection

with, neonatal units across the NHS were invited to give their views. This piece of work has been managed by the health research charity, Picker.

As with the Inquiry questionnaire, the Picker survey results will be set out in more detail during Part C, looking, for example, at some of the discrepancies; such as the fact that senior managers viewed their working relationships with other occupational groups much more positively than did those other groups view their working relationships with senior managers.

Experts.

The inquiry has also commissioned its own expert evidence within Part C.

Sir Robert Francis, King's Counsel, who has chaired a number of healthcare related public inquiries, most notably the Mid Staffordshire NHS Foundation Trust Inquiry, has been instructed. He has been asked by the Inquiry to consider, in the first part of his report, the extent to which past recommendations of relevant inquiries have been implemented.

A second expert, Professor Dixon Woods, has been instructed in relation to the specific issue of culture within the NHS. She was asked to define both healthy and unhealthy cultures, to consider how definitions of a healthy culture have changed over time, and comment on

any accepted practices for improvement in this area.

Professor Dixon Woods raises the issue of voiceable and unvoiceable concerns. We will explore in oral evidence with Professor Dixon Woods whether and, if so, why, concerns related to behaviour or conduct are harder to articulate, and the culture required with the NHS to enable people to do so.

As you have already heard, one of the factual areas that the Inquiry will consider is how the hospital responded to the grievance raised by Letby. In order to assist the Inquiry with areas of relevant employment law, the treatment of whistleblowers, and the handling of grievance allegations in hospitals, Professor John Bowers, King's Counsel, has been instructed. Whether and how grievance and disciplinary processes should be managed in situations where there is an underlying safeguarding issue is an area the Inquiry will need to report upon.

All of the experts, Sir Robert Francis, Professor Dixon Woods and Professor John Bowers, will be giving oral evidence to the Inquiry.

In addition, the Inquiry has received evidence from a number of witnesses expert in their field and independent from the events at the Countess of Chester. For example, the Inquiry will be greatly assisted in its

consideration of safeguarding, the Review of Child Death Overview Panels, and the reporting of sudden and unexpected deaths by Dr Joanna Garstang, who will be called to give oral evidence after the parents and at the beginning of the Inquiry.

Witness evidence.

A large number of witness statements have been sought in order to assist the Inquiry in Part C. In some cases, as I've said, witnesses will be called to give additional oral evidence but in the vast majority, their written statements will stand as their evidence to the Inquiry.

Statements have been sought from professional bodies, notably the General Medical Council, the Nursing and Midwifery Council, who are a core participant, the British Association of Perinatal Medicine, the British Medical Association, and the Royal College of Nursing.

As we have heard earlier, inspections of the neonatal unit were carried out in February 2016 by the Care Quality Commission, and following Letby's removal from the ward by the Royal College of Paediatrics and Child Health in September 2016.

As such, their evidence bridges events at the Countess of Chester Hospital being considered in Part B, and also the wider NHS issues being explored in Part C.

The role of both organisations in safeguarding is obviously important. Oral evidence will be heard from individuals from each organisation about their respective roles in the prevention of the deliberate acts of harm towards babies by a member of staff.

Where babies die in hospital, the issue of referral to the coroner arises. An investigation into a death by a coroner can provide an important check on whether, or to what extent, safeguarding procedures are being implemented properly. But to be effective, the investigation has to be provided with all the relevant information. The right questions have to be asked, and the answers given must be free of the desire to avoid criticism or prevent so-called reputational damage.

In short, coroner's inquests are opportunities to learn lessons. Are those opportunities taken? Evidence has been sought from the coroners, Mr Moore and Mr Rheinberg, and consideration given to the interactions between the hospital and the coroner to assist with the wider issue as to the operation of the coronial process following neonatal deaths.

Individual parents and healthcare professionals may feel challenged, ignored or sidelined when raising safeguarding issues. Without support, they may feel that it is difficult to pursue concerns, especially if

they do not have a close understanding of an organisation's practices and procedures.

The Inquiry has received evidence from organisations who offer support to families, such as the Patient Safety Commissioner, Stillbirth and Neonatal Death Charities such as BLISS, Sands, Spoons, and Tommy's. The parents of the babies named on the indictment have much to contribute in their evidence on the issue of bereavement as they have on many other issues relevant to the wider NHS. What services were offered to the parents and what services are offered nationally now to bereaved parents is a matter we will be hearing oral evidence about. It is an area upon which my Lady may wish to make recommendations in due course.

Organisations that support medical staff, including Doctors in Distress, the Hospital Consultants and Specialists Association, and NHS Practitioner Health, have been asked for statements. The Inquiry is interested to know what support is available for doctors on the ground facing difficult and challenging situations.

There are a large number of organisations that are involved in safety and monitoring in the widest sense, and many have provided evidence to the Inquiry. This includes MBRRACE, the National Neonatal Research

Database and Paediatric Intensive Care Audit Network. These organisations, along with the National Guardians Office, the National Association of Designated Safeguarding Leads, NHS Resolution and the National Institute for Health and Care Excellence, NICE, have all provided evidence to the Inquiry.

Since external scrutiny is an area that falls within the Inquiry's terms of reference, we have obtained evidence from Healthwatch England, Healthwatch Cheshire West and the Health Services Safety investigations Body. The Parliamentary Health Service Ombudsman and the Professional Standards Authority have also provided us with evidence, and the former ombudsman, Rob Behrens, will also be giving evidence to the Inquiry.

Data and statistics.

May I now turn to the topic of data. The collection, analysis and use of data is crucial to safeguarding and improving practice. Without data patterns, trends become difficult to detect. Effectiveness of policies cannot be determined. Lessons learned become lost and unlearned. But data can too easily become a burdensome mass of material that acts as a drag on expedition and innovation. It must be relevant and timely. It must be accessible. And most of all, it must be analysed objectively, promptly and

dispassionately, and with a proper regard for the safeguarding issues that need to be detected.

Data is dangerous if incomplete or unreliable. Healthcare professionals need to understand its importance and the damage to safeguarding if collection of data is slipshod or not prioritised.

The Inquiry has obtained statements from a number of organisations and individuals concerned with the collection and analysis of data as it relates to neonates. These include Professor Feltblower; Professor Elizabeth Draper and Dr Sarah Seaton, on behalf of PICANet, the Paediatric Intensive Care Audit Network; Professor Modi on behalf of National Neonatal Research Database; Karen Luyt on behalf of the National Child Mortality Database; Dr Murdoch on behalf of the Maternity and Neonatal Outcomes Group; and Professor Knight on behalf of MBRRACE UK, Mothers and Babies Reducing Risk Through Audit and Confidential Enquiries.

Among those the Inquiry has contacted is Professor Sir David Spiegelhalter. Sir David is the Emeritus Professor of Statistics at the University of Cambridge. His work mainly involves the medical sector. Among other important projects, he led the Statistical Team at the Inquiry into deaths of babies with

congenital heart disease at the Bristol Royal Infirmary, and he worked on the Statistical Team for the Shipman Inquiry.

In his statement, Sir David draws attention to the value of what he calls "formal statistical process control" as a more efficient means of detecting "clusters of failure". He points out that numerous previous inquiries have called for the establishment of statistical monitoring systems, and says that there are two broad types of system: retrospective audit and real-time prospective monitoring.

Sir David memorably remarks in his statement there are "a bewildering array" of retrospective audit systems for neonatal and perinatal outcomes. However, as a matter of common sense, when it comes to the early detection of a member of staff intent on causing harm, it will be the real-time prospective monitoring which will be most valuable.

Accordingly, while the Inquiry has collected substantial amounts of information about data collection in the NHS as it relates to maternity and neonatal services, given the Terms of Reference and central subject matter, our focus will necessarily be on real-time monitoring. What is feasible, what can it do, and what are the limitations?

The Care Quality Commission, an organisation we have already mentioned in the context of inspections which took place at the hospital during 2016 and 2017, monitors data gathered by other organisations. In terms of real-time data monitoring, according to Professor Spiegelhalter, during the period of the Inquiry's focus, the CQC utilised a sophisticated statistical method to monitor thousands of mortality indicators, including neonatal metrics. Sir David was involved in setting this tool up in 2007. He believes this tool is no longer in use. Is that the case? If so, why is it no longer in use, and with what has it been replaced, if anything?

This is something we will be exploring further with the CQC.

Dr Bill Kirkup's investigation into maternity services in East Kent led to the publication of "Reading the Signals" in 2022. Dr Kirkup's first recommendation was the establishment of a taskforce "to drive the introduction of valid maternity and neonatal outcome measures capable of differentiating the signals among the noise to display significant trends and outliers for mandatory national use."

This recommendation led to the creation of the Maternity and Neonatal Outcomes Group. Professor David

Spiegelhalter is one of the specialist advisers to this group. In a statement to the Inquiry, Dr Murdoch, the Chair of the Maternity and Neonatal Outcomes Group, describes a data driven early warning system in this way:

"Safety signals systems work through monitoring real-time changes in the trends of defined critical safety outcomes. A signal prompts an early critical review to understand the causes of the signal change. It is the subsequent assessment and review that will identify if there are safety issues to act upon."

In other words, automated analysis of data can draw attention to a potential safety issue but further investigation will be needed to see what is going on.

As Dr Murdoch says later in her statement:

"A safety signal system demonstrates unusual changes in signals, but cannot explain why the signal has changed."

The real-time system being developed by the Maternity and Neonatal Outcomes Group is called the Maternity Outcomes Signal System, or MOSS. As with any data system, parameters of which data is to be analysed need to be set. The agreed parameters for MOSS, no doubt developed after careful consideration of the objectives of the project, exclude pre-term babies (ie

those born before 37 weeks' gestation) and those who died more than 28 days after birth.

Accordingly, in its current form, it would not be capable of capturing or identifying any anomaly in relation to the deaths of Child A, B, E, I, O or P, who were all born pre-term.

MOSS represents an essential step forward, addressing a key concern of Dr Kirkup in relation to NHS maternity services. The data used by MOSS is taken from that gathered by MBRRACE, together with data taken from the Neonatal Data Analysis Unit, in relation to hypoxic-ischaemic encephalopathy at birth. Questions for the inquiry are: is this real-time system capable of being revised so that it would be capable of capturing patterns or trends or all neonates, whether full term or premature? Or, in fact, does MBRRACE already provide what is necessary?

Professor Knight will be called during the oral hearings. Professor Knight has provided a witness statement on behalf of MBRRACE answering a number of questions posed by the Inquiry. She deals with the position in 2015 to 2017, as well as the developments which have been made since that time.

MBRRACE undertakes surveillance of all stillbirths, late foetal losses and neonatal deaths up to 28 days of

age. Accordingly, all of the babies named on the indictment except Child I fell within the parameters of the data which MBRRACE considered.

Reports are made online, with responsibilities for reporting the deaths sitting within the Trust in which the death occurred. The data provided is analysed and then presented as both "a crude mortality rate" and "a stabilised mortality rate" or as "stabilised and adjusted mortality rate". The latter refers to the process whereby local risk factors are taken into account.

The figures provided by hospitals for the year 2015 were reported by MBRRACE in June 2017. The figures provided for 2016 were reported in June 2018.

It follows that MBRRACE's approach to data during the period we are examining was not capable of raising an alert to Letby's crimes at the time. Why did it take 18 months or more to produce such figures? Could the earlier production of this data have had an impact on what happened at the hospital?

In 2019 MBRRACE provided all NHS Trusts and Health Boards access to a real-time data viewer. It permits a user to log on and look at the most recent figures for their hospital, but it is reliant upon the timely provision of accurate data. Were staff at the hospital

reporting all the deaths properly? If not, why not? Is that now happening?

Professor Knight suggests that to make this tool more effective, a nominated person at each Trust should have responsibility for regularly logging into the real-time data viewer. Professor Knight proposes that such a person receives training in the interpretation of that data. Further, she suggests that there should be a pre-determined route to senior management in the event of any concern with a view to an action plan being developed.

At the conclusion of her statement, Professor Knight informed the Inquiry that during the first quarter of this year, MBRRACE were trialing a "process control function" which would automatically identify and flag unusual clusters of death. In other words, a real-time monitoring tool of the kind spoken about by Professor Spiegelhalter and Dr Murdoch. The Inquiry hopes that Professor Knight will be able to provide the Inquiry with an update as to the progress of that signalling function when she comes to give evidence at the end of the year.

Themes for recommendations.

I turn finally, my Lady, to the issue of recommendations. You will be considering what changes

are expressly indicated as a consequence of the evidence you read and hear in Part B, and any findings or conclusions you may make. Furthermore, you will determine what is necessary to keep babies in hospital, having heard the wider evidence in Part C.

As I have stated previously, we have asked all those who have provided written evidence or responded to questionnaires what recommendations they think this Inquiry should make. We will pick up on the various suggestions made within the oral evidence.

Whilst specific recommendations will be considered once the evidence has been heard, you may think that certain themes suggest themselves already.

CCTV, access to controlled drugs, and reporting of insulin results are highly relevant issues arising from our facts. Would CCTV in the neonatal units improve the safety of babies against malicious acts and deliberate harm? Should laboratory detection of exogenous insulin in a neonate raise an immediate alarm?

Data collection and analysis is crucial, both to identify matters of concern and to cross-check concerns that may be expressed as to the activity of a particular healthcare professional. What can be done to ensure that reliable and complete data is obtained?

The analysis of such data has to be expeditious if

it is to be valuable in the context of safeguarding. What can be done to ensure expedition? Once analysed, there must be a coherent and straightforward way of bringing the information to the notice of senior managers. What can be done to achieve that?

Senior managers bear the responsibility for ensuring that safeguarding is prioritised, that there are concrete and specific protocols in place ensuring that everyone knows in advance what will happen and within what timescale when a safeguarding issue is raised, that investigations are carried out expeditiously, and that any healthcare professional who may be affected adversely by such investigations is appropriately supported. They must ensure that patients and staff are encouraged to voice concerns. They must guard against the desire to protect the institution or to equate criticism with condemnation.

How is that to be achieved? How is the culture of senior managers to be improved? Are individual duties of candour required? Should the senior managers themselves be regulated? If so, how is that regulation to be implemented and enforced?

There is a clear relationship between safeguarding, criminal investigation, and employment rights and obligations. Lengthy processes damage morale and

arguably divert attention from the very purpose of neonatal wards, namely looking after the health and safety of babies.

What can be done to ensure that risk is appropriately managed without at the same time condemning a unit or ward to oppressive and time-consuming grievances or counter-grievances, or never-ending allegations or unlawful dismissal cases?

In terms of governance, how should hospitals ensure safety-critical information reaches the board level quickly and in a way that is easily understood so that it is acted upon?

Should the role of external regulators and inspectors be strengthened? If so, how is that to be achieved, particularly in circumstances where the regulators and investigators are subject to criticisms themselves of being ineffective?

What can be done with written procedures and protocols so that there is a clear, straightforward, coherent and predictable process when a safeguarding issue is raised, whether it be from data analysis or the concerns expressed by staff?

Is there a problem with public inquiries in that recommendations are not implemented or do not change the culture of the NHS, or are too detailed or individual to

be of practical value? Is there a problem with corporate memory so that lessons learned become unlearned over time? If so, how can that be prevented?

How do we ensure the recommendations of this Inquiry are implemented? Some inquiries monitor their recommendations to help ensure change. Is that the role and purpose of an inquiry? Should there be an Inquiries Unit to implement and monitor inquiry recommendations?

Is the desire to protect an institution's reputation or to avoid rocking the boat such that there needs to be, and embedded within each Trust, those with unique responsibility for safeguarding? Should those who have responsibility for safeguarding have access to data, potential whistleblowers, witnesses, and to senior managers, with the support of an external organisation and to whom they are responsible?

Should the NHS or Integrated Care Boards, for example, have a specific safeguarding unit that works within Trusts but is separate from them to ensure that data management is adequate, to review employment processes, and ensure protection for families and whistleblowers?

In terms of external scrutiny, how do we ensure that those bodies with responsibility for commissioning and oversight within the NHS are promptly notified if there

is an issue so that they can, where appropriate, support investigation and resolution of concerns?

Does the culture of the NHS need to change? If so, how? Does an inquiry such as this change it, not for now and the near future, but permanently?

My Lady, these questions and many more will be canvassed in the evidence in Part C. The answers are important to all those who work in the NHS and all of us that use its services. We look forward to the assistance of all of the Core Participants and their representatives in the months ahead.

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

MS LANGDALE: My Lady, can I give you an indication of whom you'll be hearing from tomorrow?

LADY JUSTICE THIRLWALL: Yes, please.

MS LANGDALE: Give me one moment.

In the morning it's Mr Skelton, King's Counsel, and Mr Baker, King's Counsel, on behalf of Families; moving on to Mr Andrew Kennedy, King's Counsel, for the Countess of Chester; Ms Samantha Jones on behalf of the Nursing and Midwifery Council; Ms Fiona Scolding, King's Counsel, on behalf of the Royal College; and then Mr Robert Cohen on behalf of the Department of Health and Social Care. And then you'll be hearing from the

remaining Core Participants on Friday.

LADY JUSTICE THIRLWALL: Thank you very much indeed. So we're moving on to the next stage with all the openings. That's just for those who are not familiar with the process. Thank you very much indeed. I will look forward to seeing everyone tomorrow morning at 10.00.

(4.22 pm)

(The hearing adjourned until 10.00 am the following day)

I N D E X