THIRLWALL INQUIRY

WRITTEN CLOSING SUBMISSIONS ON BEHALF OF THE DEPARTMENT OF HEALTH AND SOCIAL CARE

Introduction

1. These written closing submissions are made on behalf of the Department of Health and Social Care ("the Department").

2. The Department begins by apologising for the profound loss and suffering of those families who were impacted by the events at the Countess of Chester Hospital. To lose a baby is the greatest sorrow imaginable, but to lose a baby in these circumstances is unconscionable. The Department is grateful to those who have felt able to play a role in this Inquiry, in particular, through the evidence which they have provided about their experiences. The Department has followed the evidence with considerable interest.

3. This Inquiry has shone a light on the events at the Countess of Chester Hospital and how Lucy Letby was able to offend – and continue to offend – for far longer than should ever have been possible. The Inquiry has heard evidence of failures in leadership and oversight within the Countess of Chester Hospital NHS Foundation Trust. The evidence has, however, been broader in scope than what occurred within the Countess of Chester Hospital. That evidence suggests wider and more fundamental issues for patient safety and safeguarding within the National Health Service.

4. Through the Secretary of State, the Department bears ultimate responsibility for the healthcare system, both at the time of the events being examined and now. It exercises oversight through a range of other bodies and systems. Those oversight mechanisms did not protect the babies born at the Countess of Chester Hospital.

5. The events at the Countess of Chester Hospital pose important questions for the healthcare system, how that system operated and how the various oversight mechanisms and bodies failed to prevent and detect more quickly what had occurred. The reasons for this failure are complex and multi-factorial, as are the actions required to strengthen the system to prevent such a failure occurring in the future.

6. For its part, the Department acknowledges that there has been a failure to learn from past incidents. Recommendations have been made but insufficient action has been taken. The Secretary of State has been unequivocal that this must change, describing the NHS as "broken" and announcing that it is the mission of the Government to build an NHS that is fit for the future.

7. The Inquiry has considered the role of the Department in the events at the Countess of Chester Hospital and, more broadly, its role over time in the evolution of the healthcare system. William Vineall, Director of NHS Quality, Safety and Investigations at the Department, endorsed the apology made by the former Secretary of State, Jeremy Hunt MP, acknowledging that "the Department is indeed ultimately responsible

for the NHS insofar as there were lessons not learned from Inquiries and systems not followed through from policies that could have helped potentially prevent part of this awful tragedy."[1]

8. As to those previous inquiries, the Department and NHSE have sought to assist the Inquiry by providing an updated analysis of the more relevant tables of recommendations. Those updated tables of recommendations are:
    a. The Allitt Inquiry: Independent Inquiry Relating to Deaths and Injuries on the Children's Ward at Grantham and Kesteven General Hospital During the Period February to April 1991 **[INQ0108012]**
    b. The Committee of Inquiry into the Personality Disorder Unit, Ashworth Special Hospital **[INQ0108016]**
    c. Royal Liverpool Children's Hospital Inquiry **[INQ0108017]**
    d. Bristol Royal Infirmary Inquiry **[INQ0108022]**
    e. Independent Inquiry into Care Provided by Mid-Staffordshire NHS Foundation Trust January 2005 - March 2009 **[INQ0108018]**
    f. The Mid-Staffordshire NHS Foundation Trust Public Inquiry **[INQ0108023]**
    g. The Berwick Review into Patient Safety **[INQ0108013]**
    h. Freedom to Speak Up Review **[INQ0108014]**
    i. Jimmy Saville Inquiry **[INQ0108358]**
    j. Liverpool Community Care Hospital **[INQ0108359]**
    k. Williams Review into gross negligence manslaughter in healthcare **[INQ0108360]**
    l. Gosport Independent Panel **[INQ0108361]**
    m. Kark Review of the fit and proper persons test **[INQ0108362]**
    n. Paterson Inquiry **[INQ0108363]**
    o. Messenger Review **[INQ0108364]**
    p. Independent Medicines and Medical Devices Safety Review **[INQ0108365]**
    q. Morecambe Bay investigation **[INQ0108369]**
    r. Ockenden independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust **[INQ0108370]**
    s. Independent investigation into maternity and neonatal services in East Kent **[INQ0108371]**

9. The Inquiry has fairly questioned why recommendations have not been implemented, why some have taken time to be implemented and why others have been implemented in part only. The Department accepts and acknowledges that there has been a failure to learn from past incidents. However, the reasons why a recommendation is not accepted or not implemented are complex: see the evidence of Baroness Bottomley[2] and Jeremy Hunt MP.[3] In addition, there are many examples of where inquiry recommendations have been accepted by governments and this has not produced the real change that had been expected.

10. In September 2024 the Health Services Safety Investigations Body ("HSSIB") published a report 'Recommendations but no action: improving the effectiveness of

[1] William Vineall, week 15, day 3, 71:25-72.4.
[2] Witness statement of Baroness Bottomley, INQ0107143_0009-0011, paragraphs 35-40.
[3] Witness statement of Jeremy Hunt MP, INQ0107827_0008-0010, paragraphs 32-40.

quality and safety recommendations in healthcare' **[INQ0108741]**. The report found that the significant volume of recommendations made to the healthcare system (often not costed and overlapping with previous recommendations) means providers struggle to prioritise and implement them. However, the report also found that the "failure to implement recommendations can impact public confidence in the healthcare system and compound harm to patients."[4]

11. At the outset, the Department recognised that the Inquiry would wish to explore whether there is scope to improve the way Trust Boards work, including their accountability and transparency and their engagement across the wider system, so that they can proactively raise the alarm and have the confidence to refer to the wider system when issues of equivalent severity to this case occur. Again, the evidence has brought these concerns into sharp focus. As will be set out below, the persistence of problems of culture and leadership within the NHS has been, and continues to be, of central concern to the Department and is at the heart of much of the work it undertakes to improve patient safety.

12. These closing submissions are structured as follows:
    a. Reporting and monitoring.
    b. Whistleblowing and raising concerns.
    c. Safeguarding of children.
    d. Culture and leadership.
    e. Candour.
    f. Manager regulation.
    g. Regulation and oversight.

Reporting and monitoring

13. Robust systems of reporting and monitoring are fundamental to effective oversight and to ensuring evidence-driven improvements over time. As such, tools to enhance reporting and monitoring have been at the centre of many patient safety initiatives implemented since the time of these events.

14. The NHS Patient Safety Strategy, led by NHS England ("NHSE") and first published in July 2019, was the first whole-NHS strategy designed to support the entire NHS system to achieve continuous improvement in safety and the reduction of patient harm while embracing an ethic of learning.[5] It consisted of a suite of measures supporting a programme of training and education. In the sphere of reporting and monitoring it included:
    a. The new Learn from Patient Safety Events ("LFPSE") service which replaced the predecessor National Reporting and Learning System ("NRLS") to improve the recording and analysis of patient safety event information to speed up identification of risks.
    b. The Patient Safety Incident Response Framework ("PSIRF") to deliver a new approach for responding to patient safety incidents, anchored in the principles

[4] Report from the Health Services Safety Investigations Body titled Recommendations But No Action: Improving Effectiveness Of Quality And Safety Recommendations In Healthcare, dates 16/09/2024, INQ0108741_0004.
[5] First witness statement of William Vineall, INQ0015468_0044-0045, paragraph 124.

of openness, fair accountability, learning and continuous improvement. The PSIRF became a contractual obligation for all providers of NHS services from 1 April 2024.

c. National Patient Safety Alerts issued by accredited national bodies that set out clear and effective actions to support providers to tackle safety critical issues and where failure to comply may lead to regulatory action by the Care Quality Commission ("CQC").

15. As explained in evidence by Mr Vineall, the component parts of the NHS Patient Safety Strategy enable a more sophisticated way to analyse large amounts of data and enable system learning. Although measures such as PSIRF are relatively new and their impact is still being evaluated, the feedback received to date has been positive.[6] Professor Mary Dixon-Woods said of developments including the new PSIRF that "thus far it appears that their design represents improvement on previous processes."[7] She notes that PSIRF adopts a learning-focused approach which seeks to focus minds on patient safety while still making clear that some incidents may require staff to trigger separate processes including referrals, multi-agency action, or police involvement:

> "The PSIRF is explicitly focused on learning for patient safety improvement, but recognises that some incidents may require a separate response. It identifies, for example, that some deaths may be subject to investigation by a coroner, that the police may need to be involved if there is suspicion of criminal activity, or that the individuals' fitness to practice or ability to do their job might need to be considered by their employer or a professional regulator."[8]

16. The Department and NHSE have also introduced significant changes to the investigatory, reporting and review processes within maternal and neonatal care specifically. These include:[9]

    a. The Perinatal Quality Surveillance Model (2020) **[INQ0012893]** and the neonatal quality process. These processes are used to escalate issues within maternity and neonatal services respectively. Both models are intended to ensure clear levels of oversight of services at system, regional, and national level. To achieve closer alignment of these processes, NHSE is working to revise the Perinatal Quality Surveillance Model (PQSM) and reflect the current neonatal quality process within its framework. The revised PQSM will bring intelligence and escalation routes for maternity and neonatal services closer together, so that Trusts that need further support are quickly identified and given the help they need.

    b. The national Perinatal Mortality Review Tool ("PMRT") was launched in England, Wales and Scotland in early 2018, and adopted in Northern Ireland in Autumn 2019. It aims to provide an objective, robust and standardised review to assist bereaved parents to understand why their baby died, and to ensure local and national learning to improve care and ultimately prevent future deaths.

    c. The PMRT is delivered by the MBRRACE-UK/PMRT collaboration, who produce annual reports which the Department uses to inform policy development within the maternity investigatory landscape.[10] MBRRACE-UK

[6] William Vineall, week 15, day 3, 191:23-192:12.
[7] Professor Mary Dixon-Woods, INQ0102624_0057, s.5.6.1.4.
[8] Professor Mary Dixon-Woods, INQ0102624_0056, s.5.6.1.3.
[9] First witness statement of William Vineall, INQ0015468_0050-0059, paragraphs 146-170.
[10] The 2024 report can be accessed at https://timms.le.ac.uk/mbrrace-uk-perinatal-mortality/surveillance/

also provides valuable intelligence on the use of the PMRT to the National Perinatal Safety Surveillance and Concerns Group in relation to the Perinatal Quality Surveillance Model. Under NHS Resolution's Maternity Incentive Scheme, Trusts that meet certain specified safety actions designed to improve the delivery of best practice in maternity and neonatal services are financially incentivised. Safety Action One asks that Trusts use the National PMRT to review perinatal deaths to the required standard.

d. The Maternity Services Dashboard brings together maternity information from a range of different sources. The dashboard was developed by NHSE (and NHS Improvement ("NHSI")) and published from 2016 in partnership with NHS Digital. It enables clinical teams in maternity services to track, benchmark and improve the quality of maternity services by comparison with their peers using a series of Clinical Quality Improvement Metrics and National Maternity Indicators. The National Maternity Indicators are published annually and drawn from external data sources including the National Maternity and Perinatal Audit ("NMPA"), MBRRACCE-UK, the CQC Maternity Survey, NHS Staff Survey, and General Medical Council ("GMC") Survey.

e. As of 1 October 2023, the Healthcare Safety Investigation Branch's Maternity Investigations Programme transitioned into the CQC and became the Maternity and Newborn Safety Investigations ("MNSI") programme, ensuring the continuation of maternity investigations that are independent, single-case investigations that follow a standardised process. The programme seeks to ensure greater consistency and more systematic learning to spur system improvements and prevent avoidable deaths and injuries in the future.

f. A Maternity Outcomes Signal System ("MOSS") is being developed by NHSE to help identify potential declines in critical safety of maternity care. The system will be driven by using real-time data to monitor routinely changes in trends of avoidable critical outcomes, with signals to prompt timely actions to reduce harm.

g. The MBRRACE-UK Real Time Data Monitoring Tool allows Trusts to monitor, filter and summarise the perinatal deaths reported to MBRRACE-UK for their organisation, and filter deaths according to certain characteristics. Data from the tool is already available to Trusts to view.

h. Subject to successful piloting, the MBRRACE-UK Real Time Data Monitoring Tool and MOSS are intended to be incorporated into routine practice at unit, Trust and Board levels, with national and regional access to and oversight of responses to signals.

17. Many of these tools are relatively new but appear promising. In some cases, such as with the PMRT, implementation was initially variable but taking steps to encourage its use through the Maternity Incentives Scheme has brought about considerable improvement over time.[11] Professor Sir David Spiegelhalter noted that there had been real advances in data monitoring within the NHS and commended tools such as MBRRACE and MOSS specifically as being capable of playing a valuable role in identifying, understanding, and responding to patient safety incidents.[12] As he noted, building systems which can effectively identify aberrations in incidents involving neonates poses unique challenges, partly because necessary processes of risk-adjustment and weighting are particularly difficult in this cohort of patients. However, he was positive about the developments made in these systems and the benefits they could bring to patient safety.

[11] Professor Dixon-Woods, INQ0102624_0060, paragraph 5.9.
[12] Professor Sir David Spiegelhalter, week 15, day 3, 16:15-18:4.

18. The Inquiry has heard evidence about the number of different reporting tools available. As Sir David noted, having several different tools can be a strength: different forms of monitoring have different aims and capture different data.[13] He gave the example of retrospective monitoring systems compared to real-time monitoring systems: neither is better and both provide valuable, albeit different, information. Sir David endorsed having several systems, each of which has a different specific focus rather than having a single, generalised system which lacked specificity and focus.[14]

19. However, Sir David was clear that any system should be an asset not a burden.[15] The Department acknowledges that promoting strong reporting practices requires tools to be user-friendly and efficient and the introduction of new systems needs to be accompanied by training and support. The Department also recognises the importance of avoiding duplication in terms of data entry and different systems being capable of communicating effectively with each other. NHSE is working with MBRRACE-UK, NHS Resolution and MNSI (now part of CQC) to develop a Submit a Perinatal Event Notification ("SPEN") service, which will streamline reporting requirements, improve accuracy and reduce the reporting burden for health care professionals that engage with these organisations.

20. Although the Department considers robust mechanisms for reporting and monitoring to be fundamental, the evidence suggests that such systems are a necessary but not sufficient feature of a well-functioning patient safety system. Even when effective tools are in place, other factors can hinder effective reporting, monitoring, investigation, and oversight.

21. To be effective, reporting tools must be properly and consistently used. Although there were reporting tools in place at the Countess of Chester Hospital, there is evidence suggesting that the reporting and monitoring practices on the Neonatal Unit ("NNU"), and to some extent the wider risk management and governance processes within the Trust, were flawed in ways which may have contributed to external bodies not becoming aware of the problems sooner:
    a. There is evidence of poor reporting practices on the NNU at the relevant time, including inconsistent or incomplete use of Datix reporting.[16] For example, there appears to have been a widespread belief that Datix reports should only be made where there was an identified mistake or known error in care or equipment, meaning that staff did not routinely report sudden or unexplained collapses or deteriorations or even all deaths[17] (although several staff explained that they would report such incidents now and welcomed the wider change of practice). The Risk and Safety Lead, Debbie Peacock noted this approach "was certainly a flaw in the system. However, if they reported every collapse on Datix, it would be its own industry, I think. However, in this situation,

[13] Professor Sir David Spiegelhalter, week 15, day 3, 19:19-21:18.
[14] Professor Sir David Spiegelhalter, week 15, day 3, 28:18-30:16.
[15] Professor Sir David Spiegelhalter, week 15, day 3, 30:23-24.
[16] Ruth Millward, week 8, day 1, 143:19-145-18.
[17] Dr John Gibbs, week 4, day 2, 21:6-22:18; Dr Matthew Neame, week 4, day 3, 89:3-92:11; Dr Cassandra Barrett, week 4, day 3, 152:4-155:24; Dr ZA, week 5, day 1, 17:21-18:22; Dr V, week 5, day 1, 88:25-89:9; Dr Michael McGuigan, week 5, day 2, 81:5-17; Dr Elizabeth Newby, week 4, day 4, 8:15-21; witness statement of Ruth Milward, INQ0101332_0007, paragraph 26.

I would have thought it was relevant for us to be notified of the collapses, which we weren't."[18]

b. There is also evidence of a lack of clarity of who should complete reports, with some doctors saying the nurses routinely did them, some nurses saying only doctors did them, and other staff saying there was no fixed expectation.[19] Finally, some staff felt pressure not to report. Dr Gibbs said on this "you get criticised by having so many events in your hospital there is a disincentive to fill them in."[20]

c. There is evidence of inconsistent or incorrect categorisation of incidents. It is notable that many of the deaths on the indictment were not categorised as "serious incidents." As Sir Stephen Powis noted in his oral evidence, although 16 incidents were reported through the NRLS, only three were declared as serious incidents.[21] He considers that this was a missed opportunity in that, if more had been declared, that would have led to greater scrutiny at an earlier stage by NHSE.[22]

d. There was evidence that many incidents were mischaracterised as being of "low" or "no" harm which meant that they did not come to the attention of the CQC. Again, this appears to have contributed to the CQC not identifying and responding to trends which, had they been identified, could have caused greater scrutiny at an earlier stage.[23]

e. Although at least some of the Consultants on the NNU took an active role in monitoring trends in incident data and noted that there had been an increase in the mortality rate at a relatively early stage, most junior doctors and nurses appeared not to be involved in reporting or monitoring processes and were largely either unaware of the increased rate of incidents or lacked the experience to know what a normal rate would be and so did not appreciate the degree to which the rate was unusual.[24] As nurse Taylor put it "now I think I would be suspicious of so many babies collapsing, but at the time I genuinely wasn't. I thought that was part and parcel unfortunately of being premature."[25]

f. The above points suggest a lack of shared ownership or an insufficiently well embedded reporting culture within the NNU. At its most effective, reporting is not just the domain of one person, nor is it a one-way output. The ideal scenario is one where there is wide ownership of data at a local level and staff are encouraged not just to report but also to take responsibility for monitoring, analysing, and responding to trends as they occur. As Professor Dixon-Woods noted:

> "A healthy culture with a problem-sensing approach would foster active monitoring of safety issues, would ensure that any concerning evidence of deviance from expected standards or deterioration is identified early and understood, and would take steps to address issues."[26]

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[18] Debbie Peacock, week 7, day 2, 29:9-13.
[19] Dr John Gibbs, week 4, day 2, 22:23-23:1; Kathryn Percival-Calderbank, week 5, day 4, 128:7-130:9; Dr Elizabeth Newby, week 4, day 4, 10:7-14.
[20] Dr John Gibbs, week 4, day 2, 22:16-18.
[21] Sir Stephen Powis, week 15, day 4, 42:6-15.
[22] Sir Stephen Powis, week 15, day 4, 40:16-41:21,
[23] Chris Dzikiti, week 15, day 2, 47:24-48:13.
[24] Dr Rachel Lambie, week 4, day 3, 28:21-25; Dr Huw Mayberry, week 4, day 3, 134:2-18; Dr Cassandra Barrett, week 4, day 3, 161:12-164:13; Dr Susannah Holt, week 4, day 4, 130:7-132:5.
[25] Melanie Taylor, week 5, day 4, 45:19-46:22.
[26] Professor Mary Dixon-Woods, INQ0102624_0050, s.5.1.

g. Because the Trust did not communicate the nature of the suspicions and concerns about Letby to staff more widely (and, in some cases, sent communications which actively misrepresented the situation) many of those who spent time on the unit and who may have relevant information to bring to an investigation into the causes of the data trends were not included in the process of internal analysis or investigation.[27] Dr Bowles noted the problems this causes:

> "if I - I had been aware that there had been problems with babies on the unit, then obviously this would have been a huge red flag, but at that stage I had absolutely no knowledge of any problems on the unit.
>
> So it was like having a piece of a jigsaw but I didn't actually know there was a jigsaw. So, you know, it was standing alone as an isolated result, and obviously looking at it now it's very obvious what it was saying, but at that time I - I guess I just didn't - it didn't fire that suspicion."[28]

22. It is not only necessary for reporting mechanisms to be properly used, there also must be appropriate action taken when trends or concerns are identified. As Professor Sir David Spiegelhalter emphasised in his evidence, statistical analysis is valuable because it circumvents human bias and the instinct to explain problems away. However, although statistical analysis can tell you that a signal is unusual, it cannot tell you why it occurred. It is a trigger for investigation, not the end point of analysis. As Sir David noted, the data from the NNU was not so unusual that it made the unit an outlier, however, it was high enough that it should have triggered an investigation: "It was highest in its tier but I – that would not be considered generally an outlier but it would be sufficient to generate a signal and alert warranting investigation."[29]

23. It is notable that, although reporting practices may have prevented external bodies becoming aware of the increased mortality on the NNU, they did not prevent staff at the Countess of Chester Hospital from identifying an increased mortality rate at a relatively early stage, partly through their subjective perception of the rate of deaths and collapses. However, noticing this trend did not mean that staff identified the issue as a potential safeguarding concern and many of the investigations which followed were completed either without external bodies being involved, or with external bodies involved but not told of the full extent of the concerns.

24. As was noted by nurse Ashleigh Hudson in her evidence, the benefit of transparent involvement with external bodies and impartial, external oversight of statistical data is that it offers the clearest route to robust, objective investigation:

> "It's not just the increase in the statistics. It's this word "unexpected". What does that actually mean? Because we'd say unexpected, but then there would be narratives about each baby of why they think that happened and this is what happens in neonates.
>
> And I just think - wish that things were more frank and more on the surface. I can see why they weren't, but we're not going to be able to prevent this again unless we are frank and unless you have somebody who can come in with a bird's eye view that has - who is impartial, who can look at trends, but also look

[27] Melanie Taylor, week 5, day 4, 50:5-53:23; Ashleigh Hudson, week 5, day 4, 76:2-79:19; Kathryn Percival-Calderbank, week 5, day 4, 164:19-166:20.
[28] Dr Shirley Bowles, week 5, day 3, 103:13-105:12.
[29] Professor Sir David Spiegelhalter, week 15, day 3, 39:2-5.

at the patients themselves and the personal characteristics and the care of that patient to identify these things much earlier."[30]

25. Her assessment was that this objective oversight would also sidestep the obvious difficulties which the staff may have felt in "thinking the unthinkable." When asked about recommendation 13 of the Clothier Inquiry, Ms Hudson said:

> "that recommendation "heightened awareness", what does that actually mean? We're all aware that these things can happen, but people have a really hard time believing it's happening when it's happening. That's why we need that impartiality. That's why we need that outside eye looking in."[31]

26. Good reporting practices must be viewed as part of the solution but not the whole of the solution. In particular, strong reporting cultures do not view reporting as a one-way process whereby data is exported to external bodies. Instead, they encourage staff to take responsibility at the local level to understand and engage in reporting and monitoring. As Mr Vineall said when discussing the interaction between obligations of candour and patient safety reporting, tools such as the LFPSE are sophisticated and valuable, enabling NHSE to build a larger real-time data set. However, it remains incumbent on Trusts to take steps to understand data and act on issues of concern through all of the normal channels (such as those provided by local governance, learning, management, speaking up, and safeguarding procedures). One should also expect the organisation to be open and sensitive enough to respond to concerns when they are raised.[32]

27. In describing effective participation in systems of governance and risk management in neonatal settings, Professor Dixon-Woods emphasised that those who do this best demonstrate active engagement at every level and make use of the tools available:

> "A unit with a healthy culture is likely to engage with audit findings such as these [the NNAP] guided by a spirit of learning, seeking, for example, to identify areas where improvement is required, sharing best practice, responding to NNAP recommendations on how to improve, and taking action.
>
> Another important marker of a healthy culture, particularly one that values learning, centres on high quality incident reporting, investigation, and continuous improvement. In neonatal care settings, one marker of a healthy culture would be consistent and high-quality use of the Perinatal Mortality Review Tool (PMRT) […] Among other things, the PMRT recommends the engagement of parents in the review process. Other markers would include taking part in morbidity and mortality review at both network and trust level and using the findings from incident investigations conducted locally and nationally as the basis of learning and improvement."[33]

28. The Department and its system partners have undertaken significant work to improve reporting, monitoring, and investigation systems in respect of patient safety because they contribute to clear-sighted, impartial analysis and play a fundamental role in effective oversight. However, although necessary to a safe system, they are not sufficient. They must be accompanied by robust measures of investigation and oversight, an effective system of regulation, alternative mechanisms to raise concerns,

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[30] Ashleigh Hudson, week 5, day 4, 113:1-13.
[31] Ashleigh Hudson, week 5, day 4, 116:4-117:19.
[32] William Vineall, week 15, day 3, 189:2-192:25.
[33] Professor Mary Dixon-Woods, INQ0102624_0031, s.3.6.6.

and a transparent and open culture within which staff are encouraged and supported to acknowledge and respond to incidents when they occur.

Whistleblowing and raising concerns

29. As set out above, effective routes through which staff and patients can raise concerns are a central component of a well-functioning healthcare system. Numerous previous inquiries have identified that an essential element in promoting patient safety is the ability of staff to escalate concerns and, more broadly, for complaints to be made and handled appropriately. The health of an institution may be judged by the way that it treats whistleblowers.

30. In response to a recommendation of Sir Robert Francis KC in his 'Freedom to Speak Up Review' of 2015 [**INQ0002387**], the then Government established an independent National Guardian in July 2016 to help drive positive cultural change across the NHS so that speaking up becomes business as usual. In his review, Sir Robert called for a more consistent approach across the NHS and a coordinated drive to create the right culture. In addition to driving cultural change, the National Guardian provides support and leadership to a network of more than 1,200 local Freedom to Speak Up Guardians which cover every Trust. Their role is to help and support staff who want to speak up about their concerns. The National Guardian issues guidance and training on how to speak up.

31. There has been a helpline in place for health and social care staff who need support to raise a concern since 2003. Since 2017, this service has been known as 'Speak Up Direct'. It is currently delivered by an organisation called Social Enterprise Direct. Support is available online or via a telephone helpline.

32. A national Freedom to Speak Up policy was published by NHSE in 2022 **[INQ0012907]**. It provides the minimum standard for local freedom to speak up policies across the NHS, so those who work in the NHS know how to speak up and what will happen when they do. All organisations providing NHS services were written to in the light of events at the Countess of Chester Hospital on 18 August 2023 by NHSE and were required, by January 2024 at the latest, to have adopted NHSE's updated national policy on speaking up. Though the CQC is primarily responsible for assuring speaking up arrangements, NHSE has also asked Integrated Care Boards to consider the extent to which all NHS organisations have accessible and effective speaking up arrangements.

33. For patients and their families, the Patient Safety Commissioner, appointed in 2022, is there to promote the safety and views of patients in relation to medicines and medical devices. The introduction (in 2016) of Maternity and Neonatal Safety Champions in Trusts also provides ways for concerns to be escalated to the highest levels of organisations and the NHS to coordinate action and find solutions. In his evidence, Dr McGuigan commended the introduction of such champions, noting that "in an organisation where it's a big organisation, there's lots of things happening, there's lots of people involved, you know, that -- that link between the execs, non-execs and the paediatricians and neonatologists I think is very helpful."[34]

[34] Dr Michael McGuigan, week 5, day 2, 137:25-139:15.

34. The introduction of Martha's Rule gives patients and their families who are concerned about physiological deterioration the ability to initiate a rapid review of their case 24 hours a day from someone outside of their immediate care team. Martha's Rule is currently being rolled out in 143 hospital sites. Insights from this work will inform any future rollout.[35] Early data from participating hospital sites across England shows that there were at least 573 calls made to escalate concerns about a patient's condition deteriorating in September and October 2024, including from patients, their family, carers and NHS staff.

35. In addition to whistleblowing routes, the formal NHS complaints system provides a process for complaints to be raised and investigated at the local level.

36. In the present case, the Inquiry has heard troubling evidence of how those who raised concerns were treated:
    a. Although a Speaking Up policy was in place, it does not appear to have been followed. The evidence of whether managers sought to follow it was confused in places and, to the extent that the policy was not complied with, it was not entirely clear why. Ms Kelly agreed it was not "activated" and said the process of "formalising" the concerns "fell by the wayside." [36] At the least, the degree of confusion suggests a lack of understanding of what the policy required.
    b. It is not clear that staff recognised the purpose or value of using formal processes to raise and investigate concerns. At times, those raising concerns and those handling them seem to have concluded that it was not necessary for the Speak Up process to be followed because, having informed the highest levels of Trust management, escalation had already occurred.[37] In some cases, staff were clearly well versed in the applicable policies (such as Dr Holt, who kept a copy of the NHS whistleblowing policy on her desk[38]) but still felt unable to be heard. As Dr McGuigan put it:

> "You'd have thought that it would be relatively easy for a Consultant to speak up within an organisation because they're people who have a relative amount of power within an organisation. You'd have thought that when all of the Consultants within a particular specialty are trying to say something that that would be relatively easy to have that voice heard, but that's not how it appeared to me looking back at the experience that happened over that period."[39]

    c. Once Letby commenced her grievance, the processes for raising concerns and those for managing and investigating grievances became tangled, with the grievance process arguably coming to take precedence over the investigation of the concerns and the concerns coming to be viewed through the grievance process, rather than as separate issues pertaining to patient safety. Witnesses appear to have been concerned about the possibility of a constructive dismissal claim and the costs of the same and have described a sense of "pressure" being exerted by both Letby's parents and the representation provided through the Royal College of Nursing ("RCN").[40] Dr Tighe spoke of "a laudable culture

[35] Third statement of William Vineall, INQ0107940_0004, paragraph 11.
[36] Alison Kelly, week 11, day 1, 65:9-18.
[37] Dr Susannah Holt, week 4, day 4, 135:17-137:21; witness statement of Dr Jim McCormack, INQ0101335_0027-0028, paragraphs 156-161.
[38] Dr Susannah Holt, week 4, day 4, 132:6-12.
[39] Dr Michael McGuigan, week 5, day 2, 137:9-17.
[40] See, for example, Susan Hodkinson, week 11, day 2, 102:17-103:11.

of minimising harassment and bullying, which paradoxically may have negatively influenced decision making" in circumstances where "[t]hey were also having to deal with a vexatious grievance procedure initiated by Ms Letby as a defensive tactic."[4142] Professor Bowers KC noted in his evidence that grievances are "very often" used as a "defensive manoeuvre" and this is not a problem confined to the healthcare services.[43]

d. Contrary to the policies in place at the time, there was a widespread misconception that those raising concerns had to "prove" or evidence their concerns to some particular standard before they should (or, for some, could) be acted on.[44] Ms Hopwood reflected upon this error:

> **"**I have reflected on that a lot, as you can imagine, because there was a whole board of, you know, of Executives and Non-Executives plus two paediatricians and none of us identified this as a whistleblowing. And I think the only thing that I can conclude is at that point, we, we went -- it was almost like, you know, we went down a rabbit hole of safety and trying to triangulate data which I think was quite common in terms of QSPEC, trying to find reasons.
>
> So rather as you rightly point out that initial actually we don't need to prove any data, this is, this is a theory, but it's protect -- it's a disclosure under the Act and therefore all the safeguards to the clinicians themselves under that Act should be – you know, should be actioned and the LADO should be informed and from that there would have been a conversation that ... Instead, we got into this triangulation of report, you know, can we find the reasons why this, you know, this is one scenario. But are there any other scenarios? And I think, you know, in the context of reasons for safety reasons and concerns, often being complex, multi-factoral, when actually the -- the reason was frighteningly simple."[45]

e. There was a tendency amongst middle and senior management to focus on the motivations of those raising concerns rather than the content of their concerns.[46] This also runs contrary to the policies which were in place at the time of the incidents. However, as Professor Dixon-Woods has noted, it is not an uncommon response:

> "A recurrent finding of inquiries and investigations is that, in the absence of formally available data showing a problem, suspicions nonetheless form among clinical colleagues, patients and relatives, or others, in advance of official signals but based on soft intelligence. The "credibility gap", a term used in the Shipman Inquiry, describes how these individuals may encounter scepticism or active resistance when they first raise concerns. Those who raise the concerns may be seen as unreliable, lacking in credibility, hysterical or over-imaginative, or badly motivated. Benign explanations may be offered for the issues at hand

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[41] Witness statement of Dr Sean Tighe, INQ0102067_0007, paragraph 19.

[42] In her evidence, Rachel Hopwood described the grievance as creating "an alternative narrative around victimisation and grievance when everything should have been focused on safety and obviously on taking the steps to report to LADO and safeguarding." [Rachel Hopwood, week 12, day 2, 149:9-23].

[43] Second witness statement of Professor John Bowers KC, INQ0108598_0008, paragraph 14.

[44] Karen Rees, week 7, day 1, 148:11-150:22; Anne Murphy, week 7, day 1, 40:24-42:12; Nicola Lightfoot, week 6, day 2, 32:3-23; Alison Kelly, week 11, day 1, 34:18-36:25.

[45] Rachel Hopwood, week 12, day 2, 131:8-132:6.

[46] Anne Murphy, week 7, day 1, 40:2-23; Karen Rees, week 7, day 1, 141:10-148:5; Susan Hodkinson, week 11, day 2, 43:3-45:2.

(as above, as a result of organisational sensemaking and satisficing), and, initially at least, appear much more plausible.

Perhaps ironically, disbelief is particularly likely when the events reported are so exceptionally transgressive and unusual that they defy credulity. One consequence is that any investigations conducted in response to such concerns may be misdirected or inadequate, and may not, for example, be designed to or be capable of investigating the possibility of extraordinary explanations, including a malign, and potentially criminal, actor."[47]

f. Many of those raising concerns also felt bullied or intimidated as a result. Dr McGuigan spoke of a sense that "the execs were after somebody's scalp"[48] and Dr ZA explained:

> "I very much took it to mention that if we continued to carry on raising our concerns, then my job would be at risk. I went home that night and with my husband worked out how long we could pay our mortgage and bills for if I were to lose my job, so it certainly felt real and that that was a genuine possibility."[49]

g. There is evidence that senior managers considered steps which would be incommensurate with basic principles of whistleblowing protection, both then and now, including looking to "manage out" the consultants or threatening them with referrals to the GMC. Dr Tighe described Ian Harvey raising the possibility of a referral to the GMC saying it would be inappropriate and he felt "frightened" on behalf of his colleagues.[50] His perception was that "The MD, CEO and other Board members seemed to have been more concerned about the reputation of the Trust and the welfare of Ms Letby than in taking the views of the paediatricians more seriously."[51] When asked about the discussion between herself and Mr Chambers around "managing out" the consultants, Ms Hodkinson said:

> Q. So why would you need to mitigate the Speak Out Safely/whistleblowing policy? Why would that need to be mitigated in this situation?
>
> A. I -- I don't know.
>
> Q. Well, can you guess?
>
> A. Potentially "how do you manage around that", but as I say I -- I think I just took a note of this at that stage and I know that I would have gone back to Tony about it because it really concerned me.
>
> Q. So given what's written next: "Action plan: to manage out the two Consultants."
>
> A. Yes.
>
> Q. Presumably you would have to do that by working around the SOS whistleblowing policy which protects them?
>
> A. Potentially.

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[47] Professor Mary Dixon-Woods, INQ0102624_0037, s.4.1.3.
[48] Dr Michael McGuigan, week 5, day 2, 113:5-16.
[49] Dr ZA, week 5, day 1, 61:19-62:7.
[50] Witness statement of Dr Sean Tighe, INQ0102067_0002-0003, paragraph 5; Dr Sean Tighe, week 5, day 2, 194:3-13.
[51] Witness statement of Dr Sean Tighe, INQ0102067_0010, paragraph 22(e).

> Q. Well, not potentially; you would have to, wouldn't you? Because they would say: we were whistleblowers, we were doing the brave thing that the policy told us to do, and now you are managing us out?
>
> A. I -- it -- as I say, nothing further happened around this.[52]

National policy versus local implementation

37. It is notable that many of these barriers existed despite the legislation and policies in place at the time, which Professor John Bowers KC judged to have been adequate.[53] The legislation and policies appear not to have been acknowledged or adhered to. Part of this may be due to the fact that Freedom to Speak Up was at an early stage in 2015-2016 and was less embedded and well known at that time. Those including Professor Dixon-Woods and Sybille Raphael of Protect identified concerns about inconsistent implementation and, in some places, a gap between the policies and reality. As Ms Raphael put it:

> "no one at -- at a senior management level feels responsible for ensuring that whistleblowing is done properly, that whistleblowing is effective, and the NHS has lots of wonderful policies but what matters is not the policy, it's how it's implemented and no one seems to be responsible for ensuring that these policies are indeed implemented and that they work, that they are effective."[54]

38. Others are more optimistic that the system is now largely in place. Sir Robert Francis KC said on this:

> "I think that the system of guardians is now I think 100% in place in that everyone has a guardian. Most organisations have in addition what one might call assistant guardians; they call them ambassadors or champions or whatever. So there is a system of people to whom members of staff can safely go to share a concern, get support and advice about what to do about it. […] So, there -- but it took a long time to get there and so not everywhere had a guardian at all for quite some time. So, but I think that is -- we are now pretty well there."[55]

39. The Department has undertaken a substantial amount of work to make speaking up easier. The Inquiry has heard evidence that some NHS staff are now more likely to speak up.[56] However, the Department acknowledges that effective implementation is an ongoing task. As Sir Stephen Powis said in his evidence, there is more work which could be done, including potentially through strengthening the independence of Freedom to Speak Up Guardians or the powers of the National Guardian's Office. Given the value inherent to local implementation and maintaining autonomy at the local level, some of this work will properly fall to Trusts. Again, as Sir Stephen noted, individual organisations, for good reason, have a degree of independence in how they use funding and this extends to what resources they give to Freedom to Speak Up Guardians.[57]

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[52] Susan Hodkinson, week 11, day 2, 170:8-171:4.
[53] First witness statement of Professor John Bowers KC, INQ0106946_0001-0002, paragraph 1; oral evidence, week 12, day 4, 62:5-22.
[54] Sybille Raphael, week 12, day 4, 40:17-24.
[55] Sir Robert Francis KC, week 4, day 1, 182:10-184:13.
[56] See, for example, Dr Huw Mayberry, week 4, day 3; Elizabeth Marshall, week 5, day 4, 208:11-209:11.
[57] Sir Stephen Powis, week 15, day 4, 147:7-149:2.

40. It is also notable that the evidence does not generally suggest that the culture at the Countess of Chester was poor or unusually bad. In fact, many members of staff, particularly junior doctors and nurses, praised it for having a friendly and supportive atmosphere and said they would have felt comfortable raising concerns.[58] Nurse Bissell said on this, "I just felt I'd always - I was continually sort of training and developing as a nurse, so I felt that it was a good place to work. I felt supported by my colleagues and I enjoyed it. You know, I really enjoyed my job."[59] Nurse Hudson noted that there was "a really solid foundation of senior members of staff who knew what they were doing… I never felt out of my depth, because if I didn't know I would immediately go to somebody else who knew the answer."[60] However, the decision not to share the concerns more widely or seek input from more junior members of staff meant that those who felt comfortable were not necessarily aware of the concerns or asked to consider them.

41. Regardless, it is vital that every member of staff who is worried about the safety of a baby can voice concerns and that these concerns are thoroughly considered and, where appropriate, investigated by the Trust. For this to happen, each Trust must have clear processes in place within an environment that is open and transparent.

42. A culture of openness and honesty is vital for patient safety. It is why the Secretary of State has been clear that the Government will not tolerate NHS managers who silence whistleblowers and wants NHS staff "to have the confidence to speak out and come forward" if they have concerns. The National Guardian's latest report on speaking up to Freedom to Speak Up Guardians for 2023/2024 showed that guardians handled more cases than ever before (over 30,000 cases, representing a 27% increase on the previous year). However, there remains a persistent number of cases where guardians indicate that the person speaking up to them may be experiencing detriment for doing so (in 2023/2024, this equated to 1,285 cases or 4%). It suggests that too many managers in the health service are still not protecting those who raise concerns from victimisation or bullying. A separate NHS Staff Survey analysis by the National Guardian's Office revealed the percentage of workers feeling secure enough to raise concerns about unsafe clinical practice reached a five-year low at 69.4% in 2023**.** [61] Such results show the importance of having a culture where every worker feels safe to speak up and confident that their concerns will be heard and addressed. The Government will consider what further actions are required to make speaking up the norm in the NHS.

Whistleblowing and employment law tensions

43. The Inquiry has heard evidence of a perceived tension between whistleblowing measures and Human Resources and / or employment law processes and this appears to have been a problem within the present case. In 2018, the Government enhanced legal protections for NHS whistleblowers by prohibiting certain NHS employers from discriminating against job applicants because it appears to the

[58] See, for example, Dr Matthew Neame, week 4, day 3, 67:4-8; Dr Rachel Lambie, week 4, day 3, 3:11-7:23; Dr Huw Mayberry, week 4, day 3, 111:21-115:14; Dr Cassandra Barrett, week 4, day 3, 148:1-152:3; Melanie Taylor, week 5, day 4, 16:8-17:17; Elizabeth Marshall, week 5, day 4, 198:8-200:7.
[59] Kate Bissell, week 5, day 4, 178:3-6.
[60] Ashleigh Hudson, week 5, day 4, 74:15-20.
[61] Report from the National Guardian Freedom to Speak Up, 'Listening to the Silence – Freedom to Speak Up in the NHS staff Survey 2023', dated July 2024, INQ0107924_0030.

employer that the applicant has made a 'protected disclosure'. This sits alongside longstanding protections for all whistleblowers under the Public Interest Disclosure Act 1998. Professor Bowers KC concluded that the current law surrounding whistleblowing / protected disclosures is generally adequate to the task of encouraging staff to speak up about patient safety or child protection concerns but that there remains a need for, amongst other things, cultural change and greater knowledge of the system by staff.[62]

44. Professor Bowers KC did not accept that there was any inherent tension between whistleblowing processes and employment / HR processes. They are separate processes despite a degree of overlap and, although it requires judgement to decide which is more appropriate to use, that does not mean they are in conflict with each other.[63] However, he felt they could be improved. On whether existing policies equip managers to take decisions where staff are suspected of deliberate harm, Professor Bowers KC said:

> "I think generally, they do. But I would say two things: firstly, there's a tendency to consider employment issues separate to the issues of patient safety so that we look as employment lawyers, for example, at whether the employee might have a potential claim for constructive dismissal or have a valid grievance and perhaps put issues of patient safety into another box and maybe that can be dealt with by having within the employment sphere an overriding objective of some sort to take into account patient safety in all the employment decisions…"[64]

45. As Mr Vineall acknowledged in his oral evidence, the interactions between grievance processes and patient safety are a problem that some whistleblowers have plainly felt keenly. One does, however, have to be careful not to introduce more systems which could get in the way of what should be natural responses to speaking up through existing mechanisms.[65]

Safeguarding of children – responses to specific questions asked by the Inquiry

46. The Inquiry has asked that organisational core participants address specific questions about safeguarding, in its 'Further Note on Written Closing Submissions' dated 4 February 2025. Some of those issues have been touched upon elsewhere in these closing submissions and these are not repeated here, but to assist the Inquiry, please note in particular paragraph 41 regarding Question 3(e), paragraph 99 regarding Question 3(k), and otherwise under the heading 'The Child Death Review Process' at paragraphs 87-91.

47. As more than one witness before the Inquiry has confirmed (see, for example, Dr Joanna Garstang[66]) safeguarding is everyone's responsibility. 'Working Together to Safeguard Children 2023' **[INQ0012897]** applies to all organisations and agencies that have functions relating to children.

48. While the day-to-day responsibility for safeguarding in the health system sits with NHSE and other statutory bodies, the Secretary of State for Health and Social Care

[62] First witness statement of Professor John Bowers KC, INQ0106946_0005-0007, paragraph 4.
[63] Professor John Bowers KC, week 12, day 4, 98:19-24.
[64] Professor John Bowers KC, week 12, day 4, 63:4-64:2.
[65] William Vineall, week 15, day 3, 163:6-165:23.
[66] Dr Joanne Garstang, week 3, day 4, 131:3-10.

retains overarching responsibility for the effectiveness of the health system as a whole, including its role in safeguarding children and vulnerable adults. Whilst specific statutory duties apply to certain agencies, all individuals and organisations within the health system have a responsibility to identify and act on concerns.

49. In respect of the Countess of Chester NHS Foundation Trust, the CQC, the Royal College of Paediatrics and Child Health ("RCPCH") and the Nursing and Midwifery Council ("NMC"), the following specific duties apply:
    a. Under section 11 of the Children Act 2004, NHS Trusts and NHS Foundation Trusts must make arrangements to ensure their functions are discharged with regard to safeguarding and promoting the welfare of children. Whilst there is no explicit duty for the hospital itself, there are obligations for the wider Countess of Chester Hospital NHS Foundation Trust under section 11.
    b. Under section 3 of the Health and Social Care Act 2008, the CQC's main statutory objective is to protect and promote the health, safety and welfare of people who use health and social care services. Monitoring safeguarding arrangements for people using the services CQC regulates and making sure that providers fulfil their responsibilities to safeguard children and adults ensure compliance with that objective. Regulation 13 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 explicitly states that service users must be protected from abuse and improper treatment in accordance with this regulation. The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2025 come into force on 30 March 2025. These Regulations remove the expiry date in the 2014 Regulations to ensure that they continue to have effect after 31 March 2025.
    c. The RCPCH has a role in promoting and supporting child safeguarding through the development of guidelines, competency frameworks, and resources for healthcare professionals, including 'Safeguarding children and young people: roles and competencies for paediatricians' of August 2019.
    d. The NMC's overarching statutory duty is to protect the public, which encompasses promoting and maintaining the health, safety, and wellbeing of the public. This duty inherently includes safeguarding children and vulnerable adults.

50. The nature and content of the safeguarding duties are necessarily context dependent. For example, the Department has its own safeguarding policy (it is 13 pages in length). That policy explains:

> "Policy statement
>
> 1. The Civil Service is committed to ensuring high standards of conduct in all that it does. For Civil Servants, these standards are enforced by the Civil Service code and departmental policies.
>
> 2. In the course of their work, an employee may come across something that they think is fundamentally wrong, illegal or endangers others within the department or service users and members of the public. This policy focuses specifically on where the concern is about a child or vulnerable adult being at harm or at risk of harm. It details the need for employees to speak up and offers guidance on how to raise those concerns through the right channels.
>
> 3. This policy does not supersede or replace any existing DHSC business area specific policies, processes and procedures that are in place to manage children and/or vulnerable adults at risk; it is designed to complement them.

4. Many employees will spend most of their work time in an office environment or at home. There are several ways that employees may come across information suggesting a child or vulnerable adult has been harmed or is at risk of harm, these include, but are not limited to:

• Witnessing inappropriate behaviour

• Conversations with colleagues and customers

• Private Office cases

• Complaints

• Correspondence related to general safeguarding failures

• Raising a concern (including whistleblowing) disclosures

5. While it may be a difficult and upsetting situation for the employee, it is imperative that they act responsibly by speaking up and do not assume someone else will come forward or deal with the matter. It is also important that an employee does not try to investigate the matter. They should focus on ensuring that they escalate the matter appropriately to ensure that the right authority is informed, who will then lead the response to protect the child or vulnerable adult."

51. Under the heading 'How to raise a concern', the following guidance is provided:

"How to raise a concern

9. When an employee has safeguarding concerns there are a variety of routes which they can use to speak up. These include:

• Speaking to their line manager: This might be a line manager or another manager the employee feels comfortable talking to. The manager will be able to either help them identify the most appropriate route for raising the concern or arrange for them to speak to someone who can help.

• External agencies: Where a child or vulnerable adult is at risk the employee should speak to the local police or local child/adult social care service who will lead on the response to protect the child/vulnerable adult (Annex A gives information of organisations to contact and sources of help and advice). The department and its employees should be prepared to work in partnership with other agencies and contribute, as required, to any investigation that may take place.

• Whistleblowing policy: If an employee is concerned they have been asked to do something, or is aware of the actions of other employees, which they consider to be in breach of the Civil Service Code, fundamentally wrong, illegal, or have the potential to endanger others, they should raise a concern using the Department's Raising a concern (including whistleblowing) policy.

• Dispute Resolution Policy: If an employee is concerned that another employee is being bullied, harassed or discriminated against, these should be raised using the Department's Dispute Resolution Policy. However, if the concern relates to sexual harassment, there is specific guidance.

10. If an employee has safeguarding concerns but is in doubt about what to do, they can speak with their line manager who will be able to help them use the most appropriate route for raising the concern. Where an employee doesn't wish to speak with their line manager, they can seek support from their Countersigning Officer, a Nominated Officer (Speak Out), or the departmental EAP service (Please see Support Services on the DHSC intranet)."

52. At Annex A, sources of advice are listed. At paragraph 15 the policy explains:

> "15. If a child or adult is at harm or risk of harm, you should contact:
>
> • Police - In an emergency, call 999. To report a non-emergency call 101 or contact your local Police Station, the number for which can be found in the telephone directory.
>
> • Social Services - For child social care services, you can find your local contacts here: https://www.gov.uk/report-child-abuse-to-local-council
>
> • Adult social care services - Local contacts can be found here: https://www.nhs.uk/service-search/Local-Authority-Adult-Social-Care/LocationSearch/1918"

53. Other sources of help are provided: "If you are unsure who you should inform, there are other organisations that can offer advice and guidance".

54. In respect of abuse of children which may take place within a hospital, the Department would usually rely on the NHSE accountability and assurance mechanisms (led by the National Safeguarding Steering Group). Safeguarding is firmly embedded within the core duties and statutory responsibilities of all organisations across the NHS and health system. There is a duty on NHS organisations, agencies and the independent sector to make arrangements for ensuring that their functions are discharged with regard to safeguarding and promoting the welfare of children, as legislated for in the Children Act 2004. The Department expects leaders, managers and frontline practitioners of all relevant organisations to have regard to and follow the statutory guidance 'Working Together to Safeguard Children 2023'. The Department also has a responsibility to provide assurance to the Secretary of State for Health and Social Care of the health sector's contribution to child safeguarding, with oversight of the NHS bodies to ensure they are meeting their duties and identifying the need for policy decisions.

55. Whilst the Department is not directly involved in day to day running of healthcare organisations, it does exercise oversight through various arm's length bodies and by developing policies and systems. The Department therefore would not ordinarily expect its own individual employees to encounter situations in which specific safeguarding issues in the NHS would arise. However, the Department's clear expectation is that if a member of its staff became aware of concerns about the possibility of harm to a baby in a hospital, or elsewhere, that member of staff should act in accordance with the Department's safeguarding policy and in appropriate circumstances to contact the police to investigate those suspicions of criminality.

56. If a member of staff within a hospital is concerned that another member of staff may be harming a baby who is in the hospital, that member of staff should speak up about that concern and follow organisational procedures. In the first instance they should raise their concern with a senior manager. Working Together is clear that the employer is expected to report allegations to local authority designated officers (LADO) within one working day, regardless of whether they have also been made directly to the police. Ultimately, Working Together is clear that practitioners should not assume that someone else will pass on information that they think may be critical to keep a child safe: individuals are expected to report those concerns to an appropriate authority such as the local authority children's social care, LADO or the police.

57. The same obligations apply to Human Resources professionals and union representatives: if someone holds a safeguarding concern they must act in the best interests of the child.

Culture and leadership

58. A healthy, positive workforce culture is a critical factor in the success of the NHS and in patient safety: the culture of an organisation and its workforce (along with other factors) shapes the decisions, actions and behaviours staff exhibit. This, in turn, affects the quality and safety of the service provided and, ultimately, patient outcomes. A blame culture, poor teamworking and leadership issues can all inhibit staff from raising concerns and from appropriate learning and action being taken when they do. As Mr Vineall noted in his evidence:

> "And I think it does come back, as we said in these statements, to having boards that are, you know, curious rather than looking for security, as the board in this instant wasn't, are sensitive about quality of patient care, do listen to patient stories, aren't defensive and don't enable tribalism amongst their different groups of professionals, which clearly was the case here."[67]

59. Poor leadership and workforce cultural issues have been raised repeatedly in previous investigations, inquiries and reports of maternity and neonatal services, including failures to hear concerns raised by staff and patients. Recent reports into major safety failures in the NHS including The Parliamentary Health Service Ombudsman report from June 2023, the report of the Inquiry into the issues raised by the David Fuller case (published in November 2023), and the report of the Infected Blood Inquiry chaired by Sir Brian Langstaff, published in May 2024, have all echoed previous concerns of defensive cultures and a failure to learn from past incidents. This undermines those places where safety improvements have been made. It is clear that solutions are required which all Trusts can implement and consistently adopt.

60. To understand better the problems and solutions in this area a number of reviews have been commissioned. In his 2022 report 'Leadership for a collaborative and inclusive future' Sir Gordon Messenger referred to "an institutional inadequacy in the way that leadership and management is trained, developed and valued."[68] Sir Gordon described encountering "too many reports to ignore of poor behavioural cultures and incidences of discrimination, bullying, blame cultures and responsibility avoidance. We experienced very little dissent on this characterisation; indeed, most have encouraged us to call it out for what it is."[69] The recommendations made by Sir Gordon were accepted and NHSE are taking forward their delivery (see the Department and NHSE's analysis of the recommendations made by Sir Gordon **[INQ0108364]**).

61. Although much effort and many initiatives have been introduced aiming to promote the way safety is approached in the NHS, in particular over the last ten years since the Mid Staffordshire Inquiry, it is also equally clear – and the Department acknowledges this – that progress to improve patient safety is unevenly distributed, as demonstrated by recurring problems highlighted in various inquiries. The Department acknowledges that the development of cultures of safety and learning in the NHS is inconsistent and needs to be improved. The frequency of major patient safety crises and systemic

[67] William Vineall, week 15, day 3, 186:25-187:6.
[68] Report of Sir Gordon Messenger, INQ0002377_0004.
[69] Report of Sir Gordon Messenger, INQ0002377_0004-0005.

problems in the NHS are a reminder that safety culture development has proved to be and continues to be very challenging.

62. Culture is not a standalone area of work. Most obviously, good culture and good leadership are manifestly connected. Previous reviews and inquiries have painted a broadly consistent picture of incurious Boards unresponsive to key patient safety concerns; of defensive and on some occasions bullying behaviour which does not create a culture in which speaking up is easy or welcomed; and of professional tribalism, with associated tolerance of poor behaviour and poor care. The Inquiry may consider that some of the evidence heard, particularly that set out above concerning the treatment of those who raised concerns, is suggestive of a similar pattern:
    a. The processes for governance and escalation through committees to the Board appear in some cases to have been unclear or ill managed. Ruth Millward, the Head of Risk at Patient Safety, considered that the ward to board reporting arrangements were "not sufficiently robust" to ensure the concerns on the NNU were heard at divisional and executive levels, meaning that "key information did not reach the appropriate Groups and committees for oversight or closer involvement."[70] At the regional level, Dr Subhedar acknowledged flaws in the oversight of the CMNN and in the national systems of monitoring in place in 2015, although he also identified improvements since that time.[71]
    b. There is concerning evidence which brings into question the extent to which senior managers within the Trust were candid: with parents and families, with the Board, with staff, with Letby, and with external bodies including the Coroner, the CQC, the RCPCH, and NHSE. In the view of some witnesses, there were clear failures of candour.[72] Dr Holt was unequivocal on the failings she felt had occurred on this score:

> "the bottom line is that people who have accessed the NHS deserve honesty and we are allowed not to have all the answers at that time but they deserved to know that there were some suspicions around whether the deaths were natural and could be explained by medicine or not. I don't think we can hide information from essentially the general public, our stakeholders. […] I think it was cruel and I think we should do better."[73]

    c. Some witnesses raised concerns about favouritism and bias in how Letby was treated.
    d. Some witnesses have suggested a refusal to acknowledge or a desire to conceal the true nature and extent of the concerns being raised by the very highest levels of management. Professor Dixon-Woods noted that phenomena such as "institutional secrecy" and "cultural entrapment" are common and disrupt meaningful reflection on issues when they arise:

> "what I'm describing, cultural entrapment, these normal heuristics and biases is what explains why this happens and this can happen anywhere, any time. This is normal behaviour and I think understanding this will be helpful for preventing the next disaster of this nature in the

[70] Witness statement of Ruth Millward, INQ0101332_0056-0057, paragraphs 262-267; oral evidence, week 8, day 1, 133:4-25 and 160:7-162:9.
[71] Dr Nimish Subhedar; week 10, day 3, 52:17-53:18.
[72] See, for example, Mother C, week two, day 1, 119:13-15; Mother H, INQ0107013_0019, paragraph 155; Mother O&P&R INQ0107648_0017, paragraph 163; Father O&P&R, INQ0107970_0020, paragraph 147.
[73] Dr Susannah Holt, week 4, day 4, 148:14-149:5.

sense that this isn't necessarily bad people, this is people getting trapped in a normal process of sense-making.

Where it becomes pathological is when people are also -- when that is overlayered with denial, defensiveness, inability to accept challenge and that's what we saw, for example, with East Kent. There were multiple signs that things were going very badly wrong there, but people kept -- the senior level of the organisation kept interpreting it as unhelpful criticism, hostility, et cetera, et cetera.

In teamwork, when we study this in healthcare, when you're training a team in how to handle an emergency, we know that there's a problem called loss of situation awareness which has been found in every high stress human endeavour, including the aviation industry. So loss of situation awareness means you forget how to -- you get trapped in your first understanding of the situation and when healthcare teams are being trained this is a known risk, so you train them what to do, which will include, for example, having somebody else on the team to offer a challenge. You train them that this is a problem they're going to fall into and you have various processes so you can essentially release them from getting stuck with that.

We do not have an equivalent for something that's unfolding over a longer time at board level or senior executive level or managerial level. They may not realise that they're stuck in this loop of the first understanding unless something disrupts it."[74]

63. The centrality of good leadership to patient safety and to culture more generally cannot be underestimated. The Mother of Child K put it succinctly but powerfully in her evidence: "If you don't change the behaviour of the management then it doesn't matter what other safeguards are in place."[75]

64. With this in mind, the Department and NHSE have placed significant focus on measures aimed at building strong leadership as a tool to improving culture. These include:
    a. Implementing the NHSE Perinatal Culture and Leadership programme within maternity and neonatal services so that staff feel encouraged and supported to raise concerns and know they will be handled promptly and objectively. Sir Stephen Powis described this as the key means by which NHSE seeks to influence the culture of individual NNUs.[76]
    b. Implementing the Fit and Proper Person Test ("FPPT") through the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which requires all Trusts to ensure that all executive and non-executive director posts (or anyone performing similar or equivalent functions) are filled by people that meet the requirements of the FPPT. The regulations place a duty on Trusts to ensure that their directors are compliant with the FPPT and the CQC has a power to take enforcement action against Trusts which do not comply with the requirements of the FPPT.
    c. Implementing a statutory duty of candour for NHS Trusts and NHS Foundation Trusts from November 2014 and for all other health and social care providers registered with the CQC from April 2015. Since 2014, professional regulators,

[74] Professor Mary Dixon-Woods, week 3, day 4, 30:3-35:19.
[75] Witness statement of Mother K, INQ0107998_0041, paragraph 171.
[76] Sir Stephen Powis, week 15, day 4, 179:23-180:23.

such as the GMC and the NMC, also made a professional duty of candour a requirement for their registered members.

d. NHSE is currently leading work to implement the accepted recommendations in the Kark review discussed above, which aim to enhance accountability of senior managers and improve patient safety outcomes.

e. In August 2023, NHSE published the Fit and Proper Persons Framework, which relates to the first four recommendations. This introduced a standardised reference system and a means of retaining information regarding background checks for individual directors. The Framework came into effect on 30 September 2023. Organisations are now expected to have fully implemented the Framework (since 31 March 2024).

f. NHSE continues to implement the measures recommended in the Messenger review, designed to improve NHS culture and leadership. This includes the development of a leadership and management development framework, which will introduce a national set of professional standards for managers and leaders, as well as a code of practice, and a core development curricula.[77] Building on the original recommendations, in November 2024 the Secretary of State announced that he had asked Sir Gordon Messenger to consider how the development of a more systematic approach to talent management could be accelerated and how best to attract top leaders to the most challenging roles.

65. The evidence the Inquiry has heard has demonstrated the value of these measures but shown there is more work to be done to embed them. Most clearly, the evidence of many families raised concerns about communication and the level of candour offered by the Trust at the time of incidents and, in some cases, for many years after.

Candour

66. As was noted by Professor Mary Dixon-Woods, effectively implementing a measure such as the duty of candour poses considerable challenges and requires considerable support:

> "The challenge of implementing something like the duty of candour was significant because it required so much organisational engineering, culture and behaviour change and so on, and again it goes back to what I was saying earlier, I think a lot of that could have been much better supported.
>
> The practice of saying "Hey, we've got a new duty, you've got to implement it", and leaving it up to the Trust to figure out how to do it themselves I think is one that we have shown many, many times means that you get extreme variation in how well it is done and it's -- the costs involved are often underestimated, so this was something the Trust had to find from existing resources and if they were already struggling this was going to be -- this was going to be really very hard for them, so it's also a cultural disposition and if you are a Trust who basically just doesn't do this kind of thing, doesn't have the right disposition, if we like, then it was particularly prone to problems."[78]

67. In December 2023, the Department announced that it would lead a review into the effectiveness of the statutory duty of candour for providers **[INQ0012885]**. The results of a call for evidence were published in November 2024 **[INQ0108709]**. As Mr Vineall

[77] See INQ0108673 for guidance on this.
[78] Professor Mary Dixon-Woods, week 3, day 4, 104:15-105:13.

explained in evidence, this review shows that the duty of candour is functioning effectively in some places but is somewhat underwhelming in totality.[79] On 26 November 2024, the Department also launched a 12-week public consultation on options to bring NHS managers into regulation **[INQ0108711; INQ0108672]**. This includes seeking views on a new professional duty of candour to cover managers (in the same way this applies to all regulated healthcare professionals) and a duty on managers to ensure that the existing statutory duty of candour is complied with in their organisation. The Government will use the findings from the consultation on bringing managers into regulation and those from the call for evidence to help inform the Department's final response to its review of the statutory duty of candour.

68. In addition, in July 2024, the Government announced its intention to legislate to introduce a duty of candour for public servants to promote a more open and accountable culture. This was reiterated in the Government's interim response to the Infected Blood Inquiry in December 2024.

69. Candour, like culture, however, is a measure enhanced by good leadership. One of the most significant areas of further work concerns the proposal for managers to be regulated. The events examined in this Inquiry brought about a renewed focus on whether additional measures are required to enhance the accountability of senior NHS managers and whether extending regulation to senior managers would be an effective means of ensuring patient safety. The Government committed in its manifesto to introducing professional standards for, and regulation of, NHS managers, ensuring those who commit serious misconduct can never do so again **[INQ0107944]**.

70. The Inquiry has heard extensive evidence from those working at every level within the NHS of the value such regulation might bring but also the challenges and complexity inherent to such a step. As Mr Vineall explained in evidence, it has been clear since the Messenger Review in 2022 that the Department and NHSE need to have more structured long-term arrangements and it was the decision of the Government to go ahead with manager regulation. It promises to be a significant tool for bolstering this and reflects Ministers taking a lead on this issue.[80]

71. However, the problems which regulation aims to tackle are intractable and complex and there is a need to ensure that any measures introduced are considered and appropriate, and that any new responsibilities are accompanied by the requisite training and support. Careful thought must also be given to the scope of regulation and how any additional regulation would sit alongside regulation by other professional bodies (it is notable that, in the present case, many of the senior managers were already regulated by virtue of their membership in healthcare or other professional bodies).

Manager regulation

72. This Inquiry has demonstrated the importance of the roles played by managers within the NHS. As Lord Darzi's recent investigation into the NHS **[INQ0108739]** concluded, the problem is not too many managers, but too few with the right skills and capabilities. The evidence from the Countess of Chester Hospital strengthens the case for further action to ensure managers act appropriately.

[79] William Vineall, week 15, day 3, 182:14-183:14.
[80] William Vineall, week 15, day 3, 149:14-25.

73. The Inquiry has heard evidence from many witnesses about the need to improve the regulation of managers within the NHS. As noted in paragraph 67, the public consultation on manager regulation began on 26 November 2024. In the accompanying Written Ministerial Statement, the Secretary of State made clear that "ensuring strong and accountable NHS leadership will be critical to fixing a broken NHS and delivering our Health Mission. We know the important role that high quality leadership plays in fostering a positive, compassionate, and transparent culture within the NHS while ensuring that local organisations are anchors of growth and opportunity in the areas that they serve." The consultation closed on 18 February 2025 and received strong engagement across the sector and wider public, with just under 5,000 responses in total. The Department is grateful to those who submitted their views to the consultation. The Department is considering all the responses before setting out its next steps for implementation.

74. Witnesses have offered a range of views on the degree to which managers should be regulated. The Department will consider that evidence as it responds to the consultation and shapes an optimal model of regulation for swift and effective implementation. As many witnesses have explained, regulation should be accompanied by support. This means ensuring that managers are properly trained. Mr Vineall noted that "a corollary of having better managers is that you have better training."[81] The Government recognises this, and the Secretary of State has committed to establishing a College of Executive and Clinical Leadership to support the development of NHS managers and leaders.

75. Regulation is an opportunity to promote higher standards, enhance accountability and support better NHS leaders. However, as Mr Vineall noted in his evidence, although manager regulation should help, it does not negate the need for Boards more broadly to take responsibility at a local level:

> "And I think, you know, we have got -- we have got to get boards to do more work to look at their culture themselves.
> We promulgate, we exhort, we set policy, we encourage. Our ministers can use their political position, we can use our official position in terms of issuing guidance, but, in the end, you are sending it out to a group of people who are responsible for an organisation. That isn't something you are in day-to-day charge of.
> And maybe one of the solutions in a sense, going back to what I was saying earlier today, is that if you had a more structured programme of training both for managers and clinicians, in some of these governance issues you might get greater openness […] if you have the right culture and the right governance you probably get better patient outcomes.
> So there is more we can do. But there is also more the NHS can do and I think NHS England have been pretty, pretty enthusiastic in taking forward the leadership and development and training programme.
>
> But as Jane [Tomkinson, Chief Executive Officer of the Countess of Chester Hospital] said there's a point at which you have to get, you know, a sensible reception from the other side. And, you know, with somebody like her at the helm you are obviously going to get it because she recognises the issue. You do have some places where the whole thing is a bit intractable and we have to do more to make sure that that stops."[82]

[81] William Vineall, week 15, day 3, 199:7-8.
[82] William Vineall, week 15, day 3, 187:7-188-11.

Regulation and oversight

76. The events at the Countess of Chester raise profound questions for the regulatory and oversight systems in place within the NHS. The Inquiry has rightly examined in detail the question of how these incidents went undetected and unprevented for as long as they did.

77. The evidence suggests that there are many factors which contributed towards this:
    a. Several of the organisations and individuals involved have acknowledged actual or potential missed opportunities where information was either not shared, or not shared in full; the existence or significance of evidence was not recognised; or there was a failure to ask more questions or press harder for information which may have led to greater scrutiny and, in turn, to detection.[83]
    b. There is evidence which suggests a lack of transparency on the part of some in senior management at the hospital. This includes with external bodies such as NHSE, the CQC, the NMC, the RCPCH, the Coroner, clinical reviewers, clinical governance groups, and the police. There have also been concerns raised of a lack of transparency internally, including with the Board, the safeguarding doctors, and the wider staffing body.[84] Regardless of the reasons for this, many were not given a full or complete picture and were not told of the extent of the suspicions and concerns that senior managers were aware of. In some cases, such as with the provision of the RCPCH report, it took repeated requests for information before material was provided and, when it was, it was provided on an incomplete basis without making clear that relevant content had been removed.
    c. As discussed above, there is evidence of failures on the part of healthcare staff to follow the systems and processes which may have led to external bodies being notified at an earlier stage. In addition to the issues identified above with respect to reporting incidents to NHSE, no safeguarding referrals were made to the Local Authority Designated Officer and, despite the requirements of the Working Together Guidance, the police were not notified in cases where they should have been. These processes are designed to result in multi-agency involvement in relevant cases and, if followed, could have led to early and greater scrutiny.

78. Since the time of the events being examined, the Department has introduced many changes which serve to strengthen regulatory and oversight systems, including:
    a. Implementing medical examiners on a non-statutory basis from 2019 and a statutory basis from 9 September 2024, meaning all deaths are now legally

[83] See, for example: Sir Stephen Powis, week 15, day 4, 40:16-41:21; Chris Dzikiti, week 15, day 2; Ian Harvey, week 11, day 4: 103:13-24, 105:21-24, 196:16-24 and 198:6-14; Susan Eardley, week 8, day 4, 131:12-132:15; Eirian Powell, week 6, day 4: 195:8-20 and 213:4-215:3; Anne Murphy, week 7, day 1, 91:5-98:12; Ann Ford, week 9, day 5, 46:13-51:8; Ruth Millward, week 8, day 1: 133:4-25 and 160:7-162:9.

[84] See, for example: Nigel Wenham, week 10, day 3, 171:23-172:7; Dr Jane Hawdon, week 9, day 2: 14:6-15:23, 71:5-12, 71:5-72:22 and 23:25-25:16; Dr Jo McPartland, week 9, day 2: 146:17-147:13 and 155:18-156:23; Sir Duncan Nichol CBE, week 12, day 1, 77:21-80:16; James Wilkie, week 12, day 1, 208:4-10; Andrew Higgins, week 12, day 2, 38:13-39:8 and 60:11-61:23; George Oliver, week 12, day 2: 104:4-9, 105:12-17 and 110:3-9; Rachel Hopwood, week 12, day 2, 137:24-139:12; Rosalind Fallon, week 12, day 2, 194:18-195:5; Nicholas Rheinberg, week 12, day 5: 24:1-6, 35, 11-39:12, 42:6-25 and 52:23-58:8.

subject to either a medical examiner's scrutiny or a coroner's investigation **[INQ0108593; INQ0108594]**. Medical examiners are discussed in more detail below (see paragraphs 79-86).

b. Establishing HSSIB on 1 October 2023 as a new arm's length body to conduct independent, expert-led national safety investigations. HSSIB continues the work of the Healthcare Safety Investigation Branch ("HSIB") which was itself established in 2017.

c. In July 2024, the Department published the interim findings of a review into the operational effectiveness of the CQC led by Dr Penny Dash **[INQ0107918]**, which the Secretary of State noted demonstrated that the organisation is "not fit for purpose." Dr Dash's full report was published in October 2024. The Government accepted the recommendations in full and is holding the CQC to account for delivering them, including by introducing additional accountability meetings with the CQC senior leadership. The CQC now has experienced and respected new leadership, with Sir Julian Hartley appointed as the new Chief Executive (December 2024) and Professor Sir Mike Richards has been selected as the Secretary of State's preferred candidate for the Chair (this appointment is subject to a pre-appointment hearing by the Health and Social Care Select Committee).

d. The Secretary of State asked Dr Dash to carry out a separate review looking at patient safety across the health and care landscape in England, within the context of wider regulation and improvement of quality of care. The terms of reference were published on 15 October and the review is expected to be published shortly.

e. In July 2018, the Department assumed full responsibility for the child death review process from the Department of Education. In October 2018, the Department published the Child Death Review ("CDR") statutory and operational guidance along with a revised set of data collection forms. The child death analysis form published at this time enabled Child Death Overview Panels ("CDOPs") to select more than one category of death should it apply. Previously, when reviewing a death, CDOPs could only select one category of death (the first category that applied on the hierarchical classification).

f. As part of the Department's oversight role, the National Child Mortality Database ("NCMD") has led on updates to the CDOP forms to enable more detailed analysis. Changes to the forms are made via a thorough process, developed in consultation with relevant stakeholders and driven by recommendations primarily from CDOPs or other CDR professionals to ensure the forms reflect the latest practices. In 2019, supplementary forms were introduced, including for sudden and unexpected deaths and deaths on neonatal units. Later, in 2022, sub-categories of death on the specific perinatal/ neonatal event were included to provide a finer level of granularity and provide guidance to NCMD for national analysis. Other key changes over the years include questions added to record: the hospital where a child under 1 year of age was born not just where they died (2023); any questions or comments made by bereaved families throughout the CDR process to ensure their views and concerns are captured (2023); and to identify whether an inquest has been carried out following the death of a child (2024).

g. Publishing (on 17 December 2024) the new multi-agency agreement 'Investigating healthcare incidents where suspected criminal activity may have contributed to death or serious life-changing harm.' **[INQ0108740]**.

Medical examiners

79. The medical examiner scheme was introduced on a non-statutory basis in 2019 and a statutory basis from September 2024. Prior to this there had been many smaller pilot schemes and major consultations in 2016 and 2018. The Department acknowledges that it has taken a long time to implement the statutory medical examiner system. However, as explained by Mr Vineall in his oral evidence, this was the result of a number of factors including the need to introduce the required legislation, to resolve funding issues, and the impact of changes of government.[85] By 2022 the requisite legislation was in place and it was confirmed that funding would come through the NHS. The statutory scheme's implementation in September 2024 was first announced by the previous Government in April 2024, and the Government committed to the reforms in July 2024.

80. The reforms should also assist in swiftly identifying cases of deliberate harm by healthcare professionals. As Dr Alan Fletcher noted in his oral evidence, the knowledge that healthcare professionals may engage in acts of deliberate harm was central to the origin and introduction of the scheme and continues to be a primary focus within the training provided. When asked about whether the training refers to recommendation 13 of the Clothier Inquiry, Dr Fletcher explained:

> "Well, it is in the first line of their e-learning, of the training.
>
> As you will be aware from the statement the training is both e-learning, face to face continued, on the job and CPD coordinated by the Royal College of Pathologists, as the lead College. In the first line of the e-learning, Medical Examiners are reminded that their role had the germination from the murders committed by Harold Shipman, the issues at Morecambe Bay, Gosport War Memorial Hospital…"[86]

81. The Inquiry has heard evidence from many quarters in support of the valuable contribution the scheme could make to patient safety:
    a. Professor Dixon-Woods noted that "[t]he medical examiner service shows considerable promise, though it has not yet been subject to much evaluation given its newness and introduction just before the Covid-19 pandemic."[87] She commended the scheme as an example of good progress since the Mid-Staffordshire Inquiry and one of several developments in patient safety and neonatology since 2015 which "are likely to contribute to reducing the risk of a problem going undetected in neonatal care, though none is likely to eliminate it."[88]
    b. Sir Robert Francis KC commended medical examiners as a "safety valve" who "have the ability to pick up early warning signs of a problem developing in a hospital." He endorsed their introduction in strong terms:

> "I believe them to be one of the most valuable safety -- interventions for safety in every sense of the word that you could have because they are proactive, they are available and without -- they are not -- and I hope they don't become -- a bureaucratic process but they are able to review

[85] William Vineall, week 15, day 3, 135:20-139:16.
[86] Dr Alan Fletcher, week 13, day 2, 25:15-24.
[87] Professor Mary Dixon-Woods, INQ0102624_0061, s.5.10.
[88] Professor Mary Dixon-Woods, INQ0102624_0099, s.10.

notes, talk to people and so on in a slightly less formal way than would happen at an inquest."[89]

c. Dr Alan Fletcher emphasised that medical examiners "offer the opportunity for early detection and notification" and uniquely, serve to remove "the siloed elements of healthcare governance."[90] He noted "I have seen first hand how the system also provides a degree of deterrence knowing that somebody else is going to be looking at cases."[91] His evidence was that the system would likely have resulted in the earlier detection and prevention of the actions of Letby: "together collectively they would -- it would – I find it unconscionable that a correctly functioning office would -- that that would escape attention and not lead to escalation and investigation."[92]

d. Jeremy Hunt MP noted the value of the particular form of oversight offered by medical examiners in identifying patterns of incidents and expressed the view that it may have led to the incidents at the Hospital being detected earlier.[93]

e. In his oral evidence Dr McCormack (Consultant within the NNU who held senior risk management positions) commended the introduction of medical examiners, saying they offered a dedicated and confidential forum for discussing concerns and expertise on matters such as the coronial process, and assist by educating and reminding staff of cases such as Allitt and Stepping Hill.[94]

82. Dr Fletcher's evidence is that the different mechanisms of oversight were complementary and, although there were parallel processes, this did not mean there were gaps between which incidents might slip. As an example of this, he set out how the medical examiner system sat alongside the child death review and Sudden Unexpected Death in Infancy and Childhood ("SUDIC") processes:

> "I don't think there is a risk that the Child Death Review process will assume the Medical Examiner is undertaking an investigation, I don't think that -- I think that would be unlikely because the process has been well-established without Medical Examiner involvement for several years.
>
> The reason plainly that the Medical Examiner's role is not listed as a mandatory component of the SUDiC process, the Joint Agency Response, is because that statutory guidance predates -- that statute became apparent in 2018 and here we are six years later, having just established the statutory role of the Medical Examiner.
>
> There is a need for an update, I believe, and that provides us with the opportunity.
>
> I have always felt that there is a risk in any systems where somebody else is expecting somebody else to do something and in the end nobody does it and that's not -- that is the worst of all worlds.
>
> I think that -- it's my view that there is the layers of care and fierce devotion to this process means that the chance of that happening are remote to say the least and for child and neonatal deaths I -- I think -- I believe strongly that the

[89] Sir Robert Francis, week 4, day 1, 44:15-47:1.
[90] Witness statement of Dr Alan Fletcher, INQ0014570_0038, paragraph 148.
[91] Dr Alan Fletcher, week 13, day 2, 41:18-42:6.
[92] Dr Alan Fletcher, week 13, day 2, 57:9-58:14.
[93] Jeremy Hunt MP, week 15, day 1, 174:18-176:19.
[94] Dr Jim McCormack, week 5, day 2, 73:19-74:19.

strength and guidance that we provide, the education and training, will cement and clarify the roles and responsibilities here.

They are overlapping lenses that are looking at the same issue, a family and a deceased child, but from slightly different perspectives and we need to make sure we get that right."[95]

83. The Department will continue to work with its partners to monitor the implementation of the statutory medical examiner system to help ensure the scrutiny of the cause of death is thorough, the bereaved remain central to the process, and (through NHSE) to ensure that guidance both for medical examiners and for those working in areas which touch upon or interact with medical examiners (such as the child death review guidance) is kept up to date. The Department expects updated guidance from the National Medical Examiner on the deaths of children and neonates to be published very soon. The guidance will address issues such as how medical examiners should escalate concerns regarding the care of a baby or child and the need to remain vigilant for criminal activity or intent.

84. Sir Robert Francis KC and others have noted that one slight caveat to the independence of medical examiners is that they are examining deaths in the institution in which they are employed. See Sir Robert's evidence "To my mind, that still has a disadvantage potentially which is that the Medical Examiner is examining the causes of death in an institution in which they are employed."[96] Dr Fletcher addressed this point in evidence, in which he described the policy decision made by the Department as pragmatic, and he noted that there are additional lines of oversight beyond the doctors themselves, including regional reporting and reporting up to the national level.[97] A medical examiner can also seek support from the Regional Medical Examiner Office or the National Medical Examiner if they have concerns or feel conflicted. However, it should be noted that some of the deaths scrutinised by a medical examiner will not relate to the institution in which they are employed since medical examiner offices serve wide geographic areas comprised of hospitals, GPs and hospices.

85. Dr Camilla Kingdon said medical examiners were "definitely a step in the right direction" but took the view that there was a need for specific expertise in paediatric care and/or neonatology if medical examiners were to serve as an efficient safeguard. She did not consider that a GP, for example, would necessarily have the requisite knowledge to challenge a neonatologist on review.[98] The evidence on this has cut both ways. Dr Fletcher was clear that he did not consider this was required and noted that virtually every specialism could make a similar claim, i.e., there is nothing specific to paediatrics/neonatology which means particular expertise is required that isn't true of e.g., cardiology, etc. He further noted that one benefit of the system is that the knowledge base of the examiners themselves and the wider system is growing as it embeds so knowledge of all specialist areas will similarly get stronger the more the system is used.[99]

86. Dr Fletcher raised three areas of development of the medical examiner system: digitisation of the Medical Certificate of Cause of Death (MCCD), consolidation of the

[95] Dr Alan Fletcher, week 13, day 2, 53:25-55:4.
[96] Sir Robert Francis KC, week 4, day 1, 122:14-17.
[97] Dr Alan Fletcher, week 13, day 2, 5:10-20.
[98] Dr Camilla Kingdon, week 13, day 2, 187:12-188:13; 185:13-186:3.
[99] Dr Alan Fletcher, week 13, day 2, 21:17-23:1; 61:13-63:16; 23:10-24:24.

medical examiner system and an evaluation of the effectiveness of the reforms. This is reflected in current activity by the Department, which is working to develop the digital MCCD and has conducted some initial testing, and it has secured funding to evaluate the effectiveness of the reforms. The Department is also working with NHSE and other partners across Government to monitor closely the implementation of the statutory system to help assure quality and achieve the consolidation to which Dr Fletcher refers.

The Child Death Review Process

87. The Child Death Review process plays a key function in understanding how and why children die and considering what interventions are needed to protect other children and prevent future deaths. Since assuming full responsibility for the process in 2018, the Department has had oversight of the Child Death Review guidance, and accompanying guidance at local level is in place to support all individuals involved in the reporting processes. This guidance, alongside wider forms and checklists, are utilised to ensure all relevant parties can be notified as soon as possible and that information is recorded accurately and completely, to support future learning at national and local level.

88. As noted by Dr Rajiv Mittal in his oral evidence, although the process of completing forms can be onerous, there have been improvements since the relevant time which have eased this, including digitalising the process:

> "now everything has become electronic, so they get an email directly from – so there is a central admin for CDOP and then the emails come directly from there and then they just need to complete the online form and it automatically goes back to CDOP. […] I get a copy of the Form A as well so it goes to many people like the named nurse for child death and also to me."[100]

89. The Department recognises that clinical time is valuable and it is important to ensure clinical expertise is utilised effectively, especially in the context of wide-ranging duties and demands. It is the responsibility of local systems and Trusts to determine their workforce needs and the Department expects them to provide administrative support and utilise quality improvement methodology to ensure staff are being used appropriately. In the context of CDR processes, there is a balance to be struck, and the requirements of the process should be proportionate.

90. On behalf of the Department, Mr Vineall referred to various concerns which arise from the evidence and acknowledged this was an issue which probably needs to be looked at.[101] Specifically, Mr Vineall identified the fact that the seven deaths went to four different CDOPs meant it was not possible to get any sense of patterns. Mr Vineall accepted that there may be logic in rethinking the management of the various processes and bodies involved, saying, "I think we do need to take away and look at that. I'm not positing a position because we haven't got one and we haven't been through it and we need the approval of our ministers, but I can see from the evidence presented that there is something fairly straightforward you could do to clear up this issue".[102] On the 2018 Guidance **[INQ0012899]**, Mr Vineall noted: "Our guidance has been pretty well received and was quite -- I think considered quite good but we last

[100] Dr Rajiv Mittal, week 10, day 3, 107:15-108:19.
[101] William Vineall, week 15, day 3, 174:24-25.
[102] William Vineall, week 15, day 3, 176:7-12.

updated it when we took over the responsibility in 2018 so obviously as and when the Department decides that that needs to be looked at again, this is an issue that we need to address in that."[103]

91. The Department recognises the issues raised throughout the Inquiry regarding the CDR Statutory and Operational Guidance and the SUDIC guidelines: the Department acknowledges that they require reviewing and updating.

'Investigating healthcare incidents where suspected criminal activity may have contributed to death or serious life-changing harm: A Memorandum of Understanding between regulatory, investigatory and prosecutorial bodies'

92. In response to the recommendations of the Williams Review in June 2018, the Department has overseen the production of a new agreement to replace the 2006 Memorandum of Understanding 'Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health and Safety Executive,' which was archived in 2014 **[INQ0014686]**.

93. The new Memorandum of Understanding ("MOU") reflects an agreement between 13 signatories. It helps support the development of a 'just culture' in healthcare which recognises the impact of wider systems on the provision of clinical care or care decision making. In a just culture, investigators principally attempt to understand why failings occurred and how the system led to suboptimal behaviours. However, a just culture also holds people appropriately to account where there is evidence of gross negligence or deliberate acts. This was set out in recommendation 3.5 of the Williams review into gross negligence manslaughter in healthcare. The new MOU also reflects the changes to the infrastructure and bodies within the healthcare landscape since the 2006 MOU **[INQ0014686]** was developed. Given its role in the healthcare system, the Department is not a signatory but led on the development of the document between all those who were signatories.

94. Due to resourcing issues following the COVID-19 pandemic and competing Departmental priorities, as well as the complexities of delivering an MOU with 13 signatory bodies, there was a delay in progressing the implementation of the new MOU. Mr Vineall accepted on behalf of the Department that the MOU could and should have been finished sooner.[104] However, it is hoped that it will assist in:
    a. facilitating efficient and effective coordination of appropriate approaches, patient safety learning responses and investigations, while taking steps to avoid prejudicing regulatory or criminal investigations or criminal proceedings;
    b. ensuring relevant information and confidential information is quickly, lawfully and efficiently shared between the relevant signatories where necessary to progress learning responses, investigations and proceedings;
    c. ensuring evidence is quickly identified, secured and handled in accordance with best practice; and
    d. allowing steps to be taken quickly to manage ongoing risk and as far as possible protect the public and service users.

[103] William Vineall, week 15, day 3, 176:19-24.
[104] William Vineall, week 15, day 3, 115:10-16.

95. Once the MOU has been in place for a year, the Department will liaise with signatories to review its ongoing effectiveness. As explained in Mr Vineall's fourth witness statement, this will include considering whether safeguarding should feature more prominently in the body of the MOU. If changes are required, the Department will coordinate the updates needed to make any necessary improvements.[105]

96. As Mr Vineall said in evidence, the new MOU may assist in cases where there is deadlock regarding whether to contact the police as it provides an authority to act. However, although the MOU provides direction on contacting the police in the specific circumstances it was designed to address, it does not override or replace other mechanisms which can and should be used.[106] During 2015-2016, the Working Together Guidance and SUDIC guidelines both had mechanisms which, had they been followed, arguably would have led to the police being notified of specific incidents.

97. Equally, as noted by Nigel Wenham (a former Detective Chief Superintendent) in his evidence, if a person suspects that a crime has been committed, it is open to them to contact the police just as any member of the public can, regardless of what formal guidance is in place in their place of work:[107]

> Q. […] Do you think there is a case for there being some guidance on healthcare staff being able to contact the police for example, directly without fear of unleashing awful consequences upon themselves or others?
>
> A. I mean, individuals can do that now. They, they can contact an organisation the police, and, and speak in confidence around any issues or concerns they have got.
>
> The police, I mean I've been out of policing for six years, but as an organisation we would always listen to people, we will treat that information with confidence and respond accordingly as to what we are told. But you'd have to make an assessment of what that information is. If there are any immediate safeguarding issues we would have to address that, whether it's safeguarding in relation to an individual or to do with children or a family we would respond and address that.
>
> Q. So could a doctor have called the police in 2015 and not given their name and not given any details but alerted the police to the possibility that somebody was murdering children?
>
> A. Well, clearly the answer to that would be yes and we would – someone would have responded to that and made an assessment of that piece of information.
>
> I was asked to comment in my statement whether, you know, the police should have been notified at an earlier stage and clearly with hindsight and looking back the obvious answer to that is yes. You know, we should have been notified and engaged with earlier.
>
> I think looking at the scenario and the events as we know a lot of those doctors involved did raise the concerns repeatedly and continued to raise those concerns and they were shut down, sadly.

[105] Fourth witness statement of William Vineall, INQ0108867_0003, paragraph 9.
[106] William Vineall, week 15, day 3, 111:16-112:22 and 131:4-19.
[107] Nigel Wenham, week 10, day 3, 190:11-191:19.

98. Mr Vineall noted that this can also be applied at an organisational level: "I think our expectation of a decently operating organisation was if they had a significant doubt about whether or not to go to the police then they should go to the police."[108]

99. The Department expects that the Child Death Review process and SUDIC guidelines should be followed in the event of a sudden and unexpected baby death.

The regulatory and oversight system

100. In addition to the measures set out above, which serve to introduce or strengthen specific regulatory or oversight mechanisms, the Department has noted the concerns raised in evidence that the system of regulation and oversight itself has structural flaws which limit its efficacy. Sir Robert Francis KC described the NHS as "less of a system than a series of entities, similar to planets which orbit round each other without necessarily connecting or communicating, at least not consistently."[109]

101. In his written evidence, Sir Robert Behrens echoed recommendation 5 of the Broken Trust report in respect of the regulatory system (paragraph 87):

> "There are significant overlaps in function leading to uncertainty about responsibilities and fractured leadership. […] I am calling on the Department of Health and Social Care to commission an independent review of the collective landscape of patient safety oversight bodies."[110]

102. Both Sir Robert Francis KC and Professor Dixon-Woods have queried whether the complexity of the system itself is a hinderance to effective oversight. Professor Dixon-Woods said:

> "The institutional complexity is pretty extreme. Some of it arises from requirements outside of healthcare entirely, for example health and safety legislation, data protection, that's not specific to healthcare. Within healthcare there is institutional complexity because of different legal regimes and different regulatory structures that have set up different bodies.
>
> It's hard to say whether we need that level of complexity but what we do need is coordination and coherence and synthetic overviews so that we don't end up losing information and that there's clarity about whose job it is to take action, whose role it is to take action in a particular circumstance."[111]

103. In his oral evidence on behalf of the Department, Mr Vineall acknowledged that there are a large number of oversight bodies and that steps have been taken to simplify the system, including the significant act of consolidation which brought various bodies together under NHSE.[112]

104. The Department is very mindful of the need to avoid over-complicating the system. As Mr Vineall noted in evidence there are many organisations within the system which

[108] William Vineall, week 15, day 3, 112:19-22.
[109] Report of Sir Robert Francis KC, Part 2, INQ0101079_0002, s.1.1.
[110] Witness statement of Sir Robert Behrens INQ0014599_0024, paragraph 87; referencing report: INQ0014545_0009.
[111] Professor Mary Dixon-Woods, week 3 day 4, 18:9-22.
[112] William Vineall, week 15, day 3, 167:13-19.

play a distinct and valuable role, including NHSE, the various Royal Colleges, the CQC, and professional regulators such as the GMC and NMC.[113]

105. As noted above, the desire better to understand these higher level issues led the Government, in October 2024, to publish terms of reference for Dr Dash to produce a second piece of work. This will assess whether the current range and combination of patient safety related organisations delivers effective leadership, listening, learning (including investigations and their recommendations) and regulation to the health and care systems in relation to patient and user safety (and to what extent they focus on the other domains of quality). The review is expected to be published shortly.

Conclusion

106. The Department does not seek to persuade the Chair to make any specific recommendations. We look forward to the publication of the Inquiry's report with interest, and remain at the Inquiry's full disposal should further information or evidence be of assistance.

[113] William Vineall, week 15, day 3, 166:9-167:1.