THIRLWALL INQUIRY

WRITTEN OPENING STATEMENT ON BEHALF OF THE DEPARTMENT OF HEALTH AND SOCIAL CARE

Introduction

1. On 18 August 2023 Lucy Letby was convicted of the murder of seven babies and the attempted murder of six others. Earlier this year she was convicted of one further count of attempted murder. Following the first conviction and subsequent sentencing, the then Secretary of State for Health and Social Care established this Inquiry. Before doing so he met with the families of Letby's victims. In announcing the Inquiry, the then Secretary of State explained that collectively we have a duty to get those families answers, to hold people to account and to make sure lessons are learned. The Chair and Inquiry Legal Team have rightly placed the families at the heart of this process. The Department welcomes and endorses that approach.

2. The events at the Countess of Chester Hospital pose profound questions for the healthcare system; how that system operated; and how the various oversight mechanisms and bodies failed to prevent and detect more quickly what had occurred. The Department of Health and Social Care ("DHSC") comes to the Inquiry in a spirit of candour and welcomes the Chair's clear expectation that all others should do likewise. In considering how the healthcare system operated, the Department acknowledges that the Inquiry will wish to consider the role it played. For its part, the Department accepts that recent investigations, such as the Independent Review of maternity services at the Shrewsbury and Telford Hospital NHS Trust, chaired by Donna Ockenden [**INQ0002375**], and the Independent Investigation into maternity and neonatal services in East Kent, chaired by Dr Bill Kirkup [**INQ0002376**], demonstrate that there is a failure to learn from past incidents.

3. In July 2024 a new Government was formed. The new Secretary of State has acknowledged that, in the past, recommendations have been made but action has not been taken. That is not good enough: the system must change. The Secretary of State has spoken candidly of that system. He has described how the NHS is "broken", however getting it back on its feet and building an NHS that is fit for the future is the mission of the Government. To that end, the Secretary of State has commissioned Professor Ara Darzi (Lord Darzi) to conduct an immediate and independent investigation of the NHS. Lord Darzi will be considering data and intelligence across a broad range of measures assessing patient access to healthcare, the quality of healthcare being provided and the overall performance of the health system **[INQ]**. The Inquiry will be kept updated as to Lord Darzi's investigation. As discussed in more detail below, recent investigations into the Care Quality Commission ("CQC") and Nursing and Midwifery Council ("NMC") have identified serious deficiencies within those organisations.

4. This opening statement seeks to address, so far as is possible, the matters in respect of which the Chair has specifically invited comment from Core Participants. The Department anticipates it will have more to say at the conclusion of the evidence and at the time for making detailed closing submissions.

5. This opening statement addresses the following topics:

    a. The role of the Department;
    b. Patient safety;
    c. The Countess of Chester Hospital;
    d. Escalating concerns and whistleblowing;
    e. Culture;
    f. Management in the NHS; and
    g. Recommendations.

The role of the Department of Health and Social Care

6. As explained within the first witness statement of William Vineall, the Director of NHS Quality, Safety and Investigations at the Department of Health and Social Care [**INQ0015468**]: in broad terms, the Department's role is to support and advise the Government's health and social care ministers (including the Secretary of State) by shaping policy, assisting in the setting of the strategic direction for the health and care system and implementing agreed policy – often through oversight of its operational arm's length bodies. This includes the three main functions that the Department oversees in England: the National Health Service ("NHS"), public health, and adult social care. The Department is accountable to Parliament for the use of funding that it secures for health and social care, which is allocated to the most appropriate level. The Department also oversees the legislative framework for the NHS and develops changes to that framework as required by policy or other drivers. The Inquiry will hear evidence as to the legislative and policy changes which have occurred in recent decades.

7. The Secretary of State has a wide range of powers and duties as a result of various Acts of Parliament and secondary legislation and is accountable to Parliament for these responsibilities. Those responsibilities include: the statutory duty to continue the promotion in England of a comprehensive health service designed to secure improvement in the physical and mental health of the people of England and in the prevention, diagnosis and treatment of physical and mental illness: s.1(1) of the National Health Service Act 2006.

8. The Department is responsible for overall health policy. NHS England ("NHSE") has day-to-day responsibility for the NHS in England. The way that the Department leads on non-legislative changes depends on the content of the change. Some changes are led predominantly by the Department with input from NHSE and with NHSE managing implementation. Some are led

jointly. Generally, operational changes are led by NHSE in line with their oversight and support duties towards Integrated Care Boards ("ICBs") and NHS providers.

Patient safety

9. Patient safety is a priority for the Government's vision for the NHS. When things go seriously wrong, it is the role of government to look closely across the system to understand what happened and put measures in place to prevent the same issue from happening again. There have been some efforts over the last decade to do so, including commissioning independent inquiries to get to the bottom of events, identify the failings and make specific, system-wide recommendations. The aim of these initiatives has been to encourage a positive culture of learning from patient safety incidents, put a widespread focus on reducing avoidable harm, improve safety and provide explanations to those affected. But these have not always delivered change in a consistent manner, and recommendations have not always been adopted.

10. The Inquiry will hear detailed evidence about initiatives in patient safety. Many of these developments have taken place in light of recommendations made by previous inquiries, including the inquiries by Dame Janet Smith and Sir Robert Francis KC. Some of these initiatives, including those specifically in relation to maternity and neonatal care, were introduced in the years following the events at the Countess of Chester Hospital, and others have been developed since then; many of those in place at the time were superseded.

11. Since 2012, previous Governments have taken a number ofmeasures aimed at raising patient safety standards and fostering a transparent safety culture across the NHS. These changes include:
    a. Introducing, in 2021, a more intelligence-driven model of CQC regulation informed by ongoing monitoring of the safety and quality of care. However, in July 2024, the Department published interim findings of the review of the CQC which found significant failings in effectiveness of the regulator.
    b. 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. The duty is enforced by the CQC to ensure that health and social care providers tell patients or service users if their safety has been compromised in certain circumstances and, if so, to apologise. Since 2014, professional regulators, such as the General Medical Council ("GMC") and the NMC, also made a professional duty of candour a requirement for their registered members. In December 2023, the Department announced that it would lead a review into the effectiveness of the statutory duty of candour. The terms of reference for the review and a call for evidence document are both published online [**INQ0012885**]. Responses to that review are currently being analysed. In July 2024, the Government said that it intends to legislate to introduce a duty of candour for public servants to promote a more open and accountable culture.

c. Enhancing legal protections in 2018 for NHS whistle-blowers (by prohibiting certain NHS employers from discriminating against job applicants because it appears to the employer that the applicant has made a 'protected disclosure'), alongside longstanding protections for all whistleblowers under the Public Interest Disclosure Act 1998. There are also more than 1,200 local Freedom to Speak Up Guardians across healthcare in England, supported by a National Guardian, established in 2016, to lead positive culture change in the NHS and make speaking up the norm.
d. Establishing the first Patient Safety Commissioner in 2022 with a statutory remit to amplify patient voice in relation to the safety of medicines and medical devices.
e. Establishing the Health Services Safety Investigations Body ("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.
f. Implementing medical examiners on a non-statutory basis from 2019 to provide independent scrutiny of the causes of all non-coronial deaths and engage with the bereaved about any of their concerns. The introduction of medical examiners is part of a broader process of reform to the death certification, registration and coronial processes in England and Wales. Placing medical examiners on a statutory footing will come into force on 9 September 2024. Under a statutory regime, all deaths will become legally subject to either a medical examiner's scrutiny or a coroner's investigation.
g. Introducing Martha's Rule in 2024/2025 in 143 pilot sites across the country as an escalation process for patients, families and staff to seek an urgent review from a separate care team if they have concerns about physiological deterioration.

12. Professional regulation of healthcare professionals is conducted by independent regulatory bodies with the autonomy to set their own standards and processes. These include the GMC, which regulates doctors in the UK, and the NMC, which regulates nurses and midwives in the UK and nursing associates in England. Professional regulation is an essential component of a system which seeks to ensure that the public can trust that healthcare professionals are safe to practise. Professional regulation is only one part of a much broader system of regulation and quality assurance in healthcare settings. Those closest to the point of care are often best placed to spot and deal with safety risks and issues effectively and quickly, sharing information as required. Oversight and regulation are therefore designed to both support the large number of frontline teams and clinicians who care for their patients safely and provide a high quality of care, while also investigating and sanctioning those who are falling short and ensuring that the relevant issues are addressed. Parliament sets through legislation the overall functions and powers of the professional regulatory bodies. It does not oversee their operational performance, which is the responsibility of the Professional Standards Authority. Regulators are directly accountable to Parliament or the Privy Council and are responsible for operational matters concerning the discharge of their statutory duties.

13. The NHS Patient Safety Strategy, led by NHSE and first published in July 2019, is the first whole-NHS strategy designed to support the entire NHS system to achieve continuous improvement in safety and the reduction of patient harm while embracing an ethic of learning. Major delivery programmes or initiatives include:
    a. The new Learn from Patient Safety Events ("LFPSE") service which has 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. 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 CQC.
    c. The Patient Safety Incident Response Framework ("PSIRF") to deliver a new approach for responding to patient safety incidents, anchored in the principles of openness, fair accountability, learning and continuous improvement. The PSIRF became a contractual obligation for all providers of NHS services from 1 April 2024.
    d. The Framework for Involving Patients in Patient Safety (2021) expects all NHS organisations to appoint 'Patient Safety Partners' (patients, carers and other lay people) in supporting the organisation's governance and management of patient safety.
    e. Over 800 'Patient Safety Specialists' across healthcare organisations (predominantly Trusts and ICBs) to oversee or lead on safety activities for their respective organisations, provide leadership and expert support to their organisations and facilitate delivery of the NHS Patient Safety Strategy.
    f. A first-ever Patient Safety Syllabus launched in 2021 to support education and training for all NHS staff. The Syllabus was published in May 2021 and e-learning training in levels 1 and 2 of the syllabus were launched in October 2021.

14. Measures have also been taken to raise patient safety in the specific context of maternity and neonatal care.

15. In November 2015, the then Secretary of State announced a new ambition to reduce the rate of stillbirths, neonatal and maternal deaths and brain injuries that occur during or soon after birth in England by 50% by 2030. In February 2016, the National Maternity Review's Better Births report, commissioned by NHSE, set out a vision for maternity services across England to become safer and more personalised, delivering against the then Government's ambition. In response, the NHSE Maternity Transformation Programme, now the Maternity and Neonatal Programme, was established to provide the infrastructure for the implementation of this ambition, and the vision set out in Better Births. In October 2016 the Department published Safer Maternity Care, which outlined an action plan to achieve the then Government's ambition.

16. In November 2017, the then Government's ambition was updated and extended to halve the 2010 rates of stillbirths, neonatal and maternal deaths and brain injuries that occur during or soon after birth and reduce the rate of pre-term births from 8% to 6%, both by 2025 [**INQ0012891**]. In pursuit of this, initiatives have been introduced which seek to improve the safety of babies in hospital by making maternity and neonatal care safer, more personalised and more equitable for women, babies, and families. These are set out in NHSE's Three-Year Delivery Plan for Maternity and Neonatal Services, published on 30 March 2023, which was also in response to previous inquiries, including the Ockenden **[INQ0002375]** and Kirkup **[INQ0002376]** reports. The plan commits to further increase neonatal cot capacity throughout 2023/24 and 2024/25, and sets out a responsibility for ICBs to consider national guidance, such as implementing the recommendations of the neonatal critical care transformation review, when agreeing staffing levels with Trusts. In addition, the Government responded to the Kirkup report on 20 July 2023.

17. NHSE has also established a series of coordinated projects led by various groups, dedicated to ensuring the NHS has the right data to identify maternity and neonatal services with safety risks in advance of them materialising.

18. The Department and NHSE have introduced changes to the investigatory, reporting and review processes to improve patient safety in maternal and neonatal care. These include:
    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 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 to help local maternity systems track, benchmark and improve the quality of maternity services.
    d. 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.

e. The Neonatal Critical Care Review ("NCCR") was published by NHSE in 2019 and led to significant investment via the NHS Long Term Plan between 2020/21 and 2023/24 [**INQ0012896**]. The review highlighted 10 actions for focus and investment, including improvements to neonatal capacity, supported by £45M capital investment; development of the neonatal workforce, backed by funding for medical and clinical neonatal staff; and measures to improve parent and family experience. Local implementation plans have been developed by NHSE Regional Teams in response to the NCCR and implementation of these plans is routinely reviewed at a national level by the Neonatal Implementation Board.

f. In July 2018 the Department assumed, from the Department of Education, responsibility for the child death review process. The child death review process was established in 2006 (and became compulsory from 1 April 2008) so that the deaths of all children would be systemically reviewed to identify learning and support bereaved families.

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

The Countess of Chester Hospital

20. In October 2016, the Department became aware of the change in admission arrangements to the Countess of Chester Hospital neonatal unit to focus predominantly on lower risk babies which had been introduced in July 2016 **[INQ0012916]**. This had occurred because the Trust had decided to close three intensive care cots following an increase in neonatal mortality rates in 2015 and 2016 when compared to previous years. The statement explained that the Trust had requested an independent review of the neonatal service by the Royal College of Paediatrics and Child Health and the Royal College of Nursing. The Inquiry will hear evidence about that review.

21. On 16 May 2017, the Department was first notified by NHSI about the planned announcement of the police investigation into deaths at the Countess of Chester Hospital. That investigation became Operation Hummingbird and resulted in the arrest and conviction of Lucy Letby.

22. The Department is not routinely involved in day-to-day events in Trusts. At the relevant time this was the responsibility of the Trusts and Foundation Trusts themselves, Monitor (for Foundation Trusts), the NHS Trust Development Authority (for non-Foundation Trusts), and sometimes for NHSE through their regional teams. The Department had arrangements in place to keep track of performance and quality issues in the NHS. These arrangements relied upon the oversight work undertaken by CQC and bodies such as the NHS Trust Development Authority, Monitor and NHSE (these bodies are now all merged into NHSE following the 2022 Health and Care Act). Then as now it was expected that where significant issues were identified, the Department would be informed either through the relevant policy team (e.g. the mental health team for issues with mental health care) or, where an organisation was in 'Special measures' (or its successor the National Recovery Support Programme), through regular discussions with the Department.

23. The Department acknowledges that it would have been better if there had been more robust arrangements to share information between the Trust, NHSE and DHSC at the time. The Department will continue to work with NHSE and others to identify further opportunities for improvement in sharing information and insight and identifying key actions as a result. Today, there are more sophisticated processes in place in providers, ICBs, regions and nationally intended to support intelligence sharing, risk mitigation, management and escalation of quality, including safety. Over the last 18 months or so, NHSE has strengthened and matured system structures that support escalation of operational and strategic issues. It is currently consulting on a new 'NHS Oversight and Assessment Framework' which describes NHSE's approach to the oversight of ICBs and Trusts **[INQ /INQ].**

24. It is the policy of the Government that these working relationships should be closer to promote greater information sharing, including with the Department, and increase provider and system challenge. The Inquiry will wish to explore whether there is scope to improve the way Trust boards work, including 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.

Escalating concerns and whistleblowing

25. As previous inquiries have identified, an essential element in promoting patient safety is the ability of staff to escalate concerns and, more broadly, for complaints to be made and handled appropriately. The health of an institution may be judged by the way that it treats whistleblowers. As for the Countess of Chester, the Inquiry will hear from those involved in blowing the whistle

in Letby's case and the Trust's response. The Inquiry will consider the allegations that whistleblowers in this case struggled to be heard.

26. 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 local Freedom to Speak Up Guardians which covers 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.

27. 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. All organisations providing NHS services were written to in the light of events at the Countess of Chester Hospital on the 18 August 2023 by NHSE and were required 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 ICBs to consider the extent to which all NHS organisations have accessible and effective speaking up arrangements.

28. If serious concerns are raised about a staff member, after local investigation by the Trust, they should be escalated to a professional body – for example, the NMC for midwives and nurses so they can consider if practice should be restricted. Any investigation of a concern or complaint made about a staff member must be objective and take into consideration any account from the staff member themselves. The role of the neonatal safety champion in the Trust is also crucial, as they provide an avenue to bring safety concerns to the highest levels and co-ordinate across different groups to find swift resolutions.

29. The Inquiry poses the question of whether greater help and assistance should be available to nurses and doctors in circumstances where they are worried about the safety of any baby in hospital. It is vital that any staff member who is worried about the safety of a baby is able to voice concerns and that these concerns are thoroughly considered and, where appropriate, investigated by the Trust. For this to happen, each Trust must have clear processes in place within an environment that is open and transparent – and we accept that more needs to be done to achieve this ambition. The NHSE Culture and Leadership programme that is being implemented in maternity and neonatal services is integral to this so that staff feel encouraged and supported to raise concerns and know they will be handled promptly and objectively. Whilst it is too early to assess its impact, the Government will take further action if required.

30. 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) **[INQ].** It also states that 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 **[INQ].** 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.

31. The Government is committed to building a better culture within the health service. In July 2024, the Department published the interim findings of a review into the operational effectiveness of the CQC, led by Dr Penny Dash, which the Secretary of State noted that demonstrated that the organisation is "not fit for purpose" **[INQ].** The report identified clear failings in the way the CQC assesses organisations in relation to the present model of regulation. The Secretary of State said that the report enabled people "across the health and social care system, including from within the CQC, the opportunity to speak up about what I believe are systemic and cultural problems" and said that 'to fix the NHS we must create a culture that values and listens to the voices of those who can see where the problems are.' Pending completion of the final report, Dr Dash has been asked to undertake further work and make recommendations on how the Government can maximise the effectiveness of key patient safety bodies. The Department will keep the Inquiry updated as Dr Dash continues her work in the autumn.

32. The NMC also recently commissioned a report looking at its own culture **[INQ0102783].** The report, which was published in July 2024, is deeply concerning. The Government is clear that whistleblowers must be supported to speak up, knowing that their concerns will be listened to and acted upon. The review makes clear recommendations for the NMC, and the Government expects the NMC's Council to ensure swift and robust action is taken to deliver against the 36 recommendations set out in the report.

Culture

33. The NHS is delivered in England by a 1.5 million strong workforce. The culture of that 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 lack of a culture of reporting, poor teamworking and leadership issues can inhibit staff from raising concerns or appropriate action being taken when they do. A healthy and positive workforce culture is therefore a critical factor in the success of the NHS.

34. The persistence of 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. For example, the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust concluded that many poor outcomes experienced by mothers or their babies were the results of delays in escalation and failure to work collaboratively across disciplines. Additionally, the report of the investigation into maternity and neonatal services at East Kent describes an environment in which staff were not supportive or encouraging to each other and there was "a bullying culture"; freedom to speak up at the Trust was not good. Recent reports into major safety failures in the NHS have also highlighted defensive cultures and a failure to learn lessons 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. The Government will consider what further actions are required to achieve this.

35. Reports over the last year reflect earlier findings in relation to institutional, leadership and workforce culture in NHS care:

    a. The Parliamentary Health Service Ombudsman report from June 2023 posed questions on how to "embed an honest, open and unafraid culture in our healthcare system that supports staff and patients to challenge and learn" [**INQ0014545_0007**].
    b. In his report of November 2023, Sir Jonathan Michael, chair of the Independent Inquiry into the issues raised by the David Fuller case, said that "the failures of management, governance, regulation and processes, and a persistent lack of curiosity, all contributed to the creation of the environment in which he [Fuller] was able to offend." **[INQ].**
    c. The recent report of the Infected Blood Inquiry, chaired by Sir Brian Langstaff, observed that "It is a sad fact that very few inquiries into aspects of the health service or parts of it have ended without recognition that the culture needed to change." **[INQ].**

36. More broadly, Sir Gordon Messenger in his 2022 report 'Leadership for a collaborative and inclusive future' referred to "an institutional inadequacy in the way that leadership and management is trained, developed and valued." [**INQ0002377_0004**]. 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."

The recommendations made by Sir Gordon were accepted and NHSE are taking forward their delivery.

37. The present Inquiry may consider that various reviews and inquiries have over many decades identified persistent issues of culture. These inquiries paint 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. It will be for the Inquiry to consider whether these matters played any part in events at the Countess of Chester.

Management in the NHS

38. NHS senior managers are expected to ensure the delivery of safe, high-quality care and the best outcomes for patients as well as creating the conditions for a positive, open and learning organisational and workforce culture through effective governance and assurance.

39. Under current governance arrangements, Boards have primary responsibility for oversight of the conduct of executive leaders and take appropriate disciplinary action when it is required. Executive leaders who are healthcare professionals are also subject to statutory regulation through the relevant professional regulatory body. Regulators have the power to impose appropriate sanctions, up to and including removing their right to remain on the register and therefore to practice, in the event that concerns about poor conduct by medical and other regulated professionals in senior leadership roles are upheld.

40. In 2013, Sir Robert Francis KC recommended the implementation of a Fit and Proper Person Test for NHS directors to improve the accountability of directors [**INQ0017993_0334**]. It set out that such a test of fitness should include adherence to a code of conduct and that directors should be liable to disqualification from their role unless they are fit and proper persons. Following the Francis Inquiry, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 required all trusts to ensure that all executive and non-executive director posts (or anyone performing similar or equivalent functions) are filled by people that meet the requirements of the Fit and Proper Persons Test. The regulations place a duty on trusts to ensure that their directors are compliant with the Fit and Proper Persons Test. While it is the trust's duty to ensure that they have fit and proper directors in post, the CQC has the power to take enforcement action against the trust if it considers that the trust has not complied with the requirements of the Fit and Proper Persons Test.

41. NHSE is currently leading work to implement measures recommended in the Kark [**INQ0002381**] and Messenger reviews designed to enhance accountability of senior managers, strengthen leadership and management capability and improve patient safety outcomes. The Kark review was commissioned after an examination of the Fit and Proper Person Test was

recommended by Dr Bill Kirkup in his report into the problems at Liverpool Community Health Trust **[INQ].** The review was published in 2018 and made seven recommendations for the Government, CQC, NHSE and other relevant organisations. The then Government accepted five of the recommendations.

42. 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).

43. Statutory regulation of senior NHS managers has been considered on a number of occasions over the past two decades and Ministers and NHS leaders at the time concluded that, as the overwhelming majority of senior managers are highly capable and have strong public and patient service values, statutory regulation would be disproportionate: the cost and regulatory burdens of introducing statutory regulation for all senior NHS managers was not seen to deliver sufficient improvements in public protection as it would only be likely to exclude individual leaders very rarely.

44. In light of the events at the Countess of Chester Hospital, there has been a renewed focus on whether additional measures are required to enhance the accountability of senior NHS managers and whether extending regulation to senior managers would be an effective means of ensuring patient safety. The new Government committed in its manifesto to introducing professional standards for, and regulation of, NHS managers, ensuring those who commit serious misconduct can never do so again.

45. Detailed work will be required to determine the most appropriate and effective means of regulating senior NHS managers, but options include:
    a. An accredited voluntary register, akin to those already held and quality assured by the Professional Standards Authority under powers set out in the Health and Social Care Act 2012.
    b. Introducing a statutory barring mechanism, similar to systems used for teachers and company directors, which would result in a centrally held list of people who have been deemed to be unsuitable to practise a particular profession.
    c. Full statutory regulation, which would require membership of a register, denoting that an individual is qualified and suitable to practise a particular profession. This would seek to put managers on a similar regulatory footing as their medical and nursing colleagues, other healthcare professionals, accountants and lawyers.

46. As referred to above, 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.

Recommendations

47. The Department does not propose suggesting recommendations: however, it welcomes the opportunity to hear from others including the Inquiry as to steps which might be taken.

48. The Inquiry has invited views on the use of CCTV to observe neonates in hospitals. Healthcare providers are already able to install CCTV where it is deemed necessary and lawful to do so. The CQC provides detailed guidance for providers to consider and sets out how the CQC will regulate the use of surveillance technology **[INQ]**. The guidance is clear that CCTV can be used to protect people's safety, for example, from the risk of unsafe care or treatment. This is a decision for individual trusts.

49. The Department recognises the importance of parents feeling involved in and aware of the care their baby receives and being able to build much needed confidence between staff and parents. The Department acknowledges the potential of greater use of surveillance technology and bedside cot cameras, as one of the ways of achieving this. It is important to fully explore and understand the benefits, risks and impacts this could have.

Conclusion

50. The Department has sought to provide assistance to the Inquiry: it will continue to do so. The profoundly distressing events at the Countess of Chester Hospital and the impact which they have had requires the most careful attention.