Witness Name: William Vineall
Statement No.: 1
Exhibits: WV/XX
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THIRLWALL INQUIRY

FIRST WITNESS STATEMENT OF WILLIAM VINEALL

I, William Vineall, Director of NHS Quality, Safety and Investigations at the Department of Health and Social Care, 39 Victoria Street, London SW1H OEH will say as follows:-

Introduction

1. I make this statement on behalf of the Department of Health and Social Care ("the Department") in response to a Rule 9 request dated 21 November 2023. I am authorised to make this statement on behalf of the Department.

2. I am Director, NHS Quality, Safety and Investigations at the Department. I have held that post since 2020. Prior to that from May 2016 I was Director of Acute Care and Quality Policy. Part of my roles have included oversight of on-going inquiries or investigations pertaining to the responsibilities of the Department. Part of my role includes responsibility for the Department's patient safety policy, and from May 2016 until Spring 2023 part of my role included responsibility for the Department's maternity policy.

3. The events at the Countess of Chester which gave rise to this Inquiry were truly terrible and all those affected have my utmost sympathy. The Department is fully committed to supporting the Inquiry in its investigations.

4. By way of overview, I address within this statement:

    a. The Department's role and statutory functions; Departmental governance and decision-making structures; and the Department's use of, and relationship to, core Arm's-Length Bodies. I also discuss the Department's role in leading on change within the healthcare system.

b. In respect of patient safety: current procedures, policies and reviews, including key developments in patient safety from 2012 onwards; incident reporting; complaints, regulation and initiatives specifically aimed at improving patient safety in the context of maternity and neonatal care.

c. Communications between the Countess of Chester Hospital and the Department; departmental knowledge of concerns relating to the neonatal unit in the Hospital and/or Lucy Letby; and the details of actions taken by the Department (in respect of the period 2012-2016).

d. A summary of previous reviews and recommendations made by those reviews.

5. As this statement is made on behalf of the Department, it necessarily covers matters that are not within my personal knowledge. In preparing this statement I have been assisted by officials within the Department and its legal advisors. To ensure that the information provided is as comprehensive and accurate as possible and to avoid needless duplication of work, where relevant I have also deliberately made use of information provided to other recent inquiries, updated as appropriate. Save where it is stated otherwise, the contents of this statement are within my own knowledge. This statement is true to the best of my knowledge and belief. The statement is accurate and complete at the time of signing.

6. The events falling within the Terms of Reference of this Inquiry largely concern the healthcare framework for England and so that forms the primary focus of the material set out below, unless otherwise stated. Health and social care is largely devolved to the Welsh and Scottish Governments and the Northern Ireland Executive.

The Department's role and relevant statutory duties

7. 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 our operational ALBs. 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 also accountable to Parliament for the use of funding that it secures for health and care, which is allocated to the most appropriate level.

8. 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. Within this witness statement I do not attempt to set out a comprehensive list of all those responsibilities, but I include those under the National Health Service Act 2006 ("the 2006 Act") that are most relevant to the Inquiry's investigation. These are as follows:

   a. 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 2006 Act. Whilst the Secretary of State retains ministerial responsibility to Parliament for the provision of the health service (s.1(3) of the 2006 Act), NHS England ("NHSE")[1] is also subject to the duty to promote a comprehensive health service in England under s.1(1) concurrently with the Secretary of State, except in relation to the part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities (s.1H(2)). In relation to this duty, NHSE has responsibility for arranging the provision of services for the purposes of the health service in England (see s.1H of the 2006 Act) and for securing their provision through (since 1 July 2022) Integrated Care Boards ("ICBs"). I discuss NHSE and its statutory responsibilities in more detail in paragraphs 48-59 below.

   b. Under s.1A of the 2006 Act, the Secretary of State has a duty to exercise her functions in relation to the health service with a view to securing continuous improvement in the quality of services provided to an individual in respect of the prevention, diagnosis or treatment of illness or the protection and improvement of public health. This includes the continuous improvement in outcomes (s.1A(2)), in particular, in the efficacy and safety of the services provided and the quality of the individual's experience.

[1] As explained at paragraph 6 above, for the purposes of this statement I focus on the position in England.

c. Under s.1B of the 2006 Act, the Secretary of State must have regard to the NHS Constitution when exercising functions related to the health service (the NHS Constitution was enshrined in legislation by the Health Act 2009). I exhibit the NHS Constitution as **WV/1 [INQ0012857]**.

d. Section 1C of the 2006 Act imposes a duty on the Secretary of State to exercise her functions so as to have regard to the need to reduce inequalities between the people of England with respect to the benefits that they can obtain from the health service. In this context, the Secretary of State is also bound by the public sector equality duty under s.149 of the Equality Act 2010.

e. Section 1D of the 2006 Act previously imposed a duty on the Secretary of State when exercising her functions to have regard to the desirability of securing the autonomy of NHS bodies and providers when exercising their functions, and that unnecessary burdens are not placed upon them. Under this provision, where the Secretary of State considered that there would be a conflict between the duty to secure autonomy and the discharge of the duty to promote a comprehensive health service and secure that services are provided (s.1 of the 2006 Act) the Secretary of State must give priority to the duties in s.1. The s.1D duty was revoked as of 1 July 2022 by s.73 of the Health and Care Act 2022 as part of a suite of measures designed to promote collaborative working between NHSE and system partners.[2] The removal of this principle alongside the introduction of powers afforded to the Secretary of State to issue directions (see ss.43-46 of the 2022 Act, discussed more in paragraph 8(i) below), also served to enhance accountability.

f. Under s.1E of the 2006 Act, when exercising functions in relation to the health service, the Secretary of State must promote research on matters relevant to the NHS and the use of evidence obtained from research.

g. Under s.1F of the 2006 Act, the Secretary of State must exercise her functions so as to secure that there is an effective system for the planning and delivery of education and training to persons who are employed, or who are considering

[2] See 'Collaborative working' at ss.73-76 of the Health and Care Act 2022.

becoming employed in an activity which involves or is connected with the provision of services as part of the health service in England.

h. Under s.2 of the 2006 Act, the Secretary of State may do "anything which is calculated to facilitate, or is conductive or incidental to, the discharge of any function conferred on that person by this Act." That includes the issuing of guidance.[3]

i. The Secretary of State can also delegate certain functions relating to the provision of primary medical, dental and ophthalmic services and NHS pharmaceutical services to NHSE (ss.98A, 114A, 125A and 168A of the 2006 Act), and she can delegate her public health functions by direction under s.7B of the 2006 Act or by arrangement under s.7A of the 2006 Act.[4] The Secretary of State has a general power under s.8 of the 2006 Act to issue directions to NHS Trusts (but not NHS Foundation Trusts)[5] and special health authorities about the exercise of their functions. Prior to the commencement of relevant sections of the Health and Care Act 2022 on 1 July 2022, there was no general power for the Secretary of State to issue directions to NHSE about the exercise of its functions other than in an emergency scenario where such directions can be issued under s.253 of the 2006 Act. The Health and Care Act 2022 introduced a general power to direct NHSE in the exercise of its functions (s.13ZC of the 2006 Act, which came into force on 1 July 2022), subject to some specified exemptions (s.13ZD of the 2006 Act).

j. Under s.247D of the 2006 Act, the Secretary of State must publish and present to Parliament an annual report about the performance of the health service in England, which includes her assessment of the effectiveness of the discharge of duties under s.1A and s.1C of the 2006 Act by the bodies that provide services and support the NHS. In practice, this document is included as part of the Department's annual report and accounts which are published online.

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[3] See *R (Rogers) v Swindon NHS Primary Care Trust* [2006] EWCA Civ 392, [2006] 1 WLR 2649, at [17].

[4] By s.12 the Secretary of State may arrange with any person or body to provide, or assist in providing, anything which the Secretary of State has a duty or power to provide, or arrange for the provision of, under ss.2A or 2B or Schedule 1.

[5] As I explain below, since 2004 the Countess of Chester Hospital has been managed by the Countess of Chester Hospital NHS Foundation Trust.

k. The Secretary of State has a series of ancillary powers and duties under Schedule 1 to the 2006 Act, which include, under paragraph 13 of Schedule 1, the powers to commission or assist the conduct of research into any matters relating to the causation, prevention, diagnosis or treatment of illness or any other matters connected with services provided under the 2006 Act, and to obtain and analyse data, seek expert advice or provide monies or services to those undertaking research.

9. While the Department is responsible for overall health policy, NHSE has day-to-day responsibility for the NHS in England. NHSE supports and oversees the commissioning of health services and, since its merger with NHS Improvement ("NHSI"), which I discuss below, has responsibility for specific oversight of healthcare providers.

10. The Department's role in the healthcare system has evolved over time in line with the changes in the legislative framework that define its relationship to other bodies. The Department supports the Secretary of State in the discharge of her duty. The Department's responsibilities in relation to, and its relationship with, NHS bodies are underpinned by the legal framework, including the 2006 Act, as amended by the Health and Social Care Act 2012 and the Health and Care Act 2022. The legislative framework is designed to establish a clear set of interlocking responsibilities for the relationship between the Department and NHS bodies. More recently, the Health and Care Act 2022 updated this legislative framework to place increased focus on integration.

Health and Social Care Act 2012

Health and Social Care Act 2012 – Overview

11. The Health and Social Care Act 2012, which came substantively into force on 1 April 2013, made significant amendments to the 2006 Act. It gave effect to a wide range of structural changes to the NHS, with the abolition of Primary Care Trusts ("PCTs") and Strategic Health Authorities. Responsibility for NHS commissioning passed to the newly created NHSE and Clinical Commissioning Groups ("CCGs"). CCGs commissioned most NHS services and were supported by, and were accountable

to, NHSE. CCGs were clinically led groups made up of GP practices and other clinicians within defined geographical boundaries which covered the whole of England. CCGs were the appropriate commissioners under the 2006 Act, unless there was a specific duty on NHSE to commission that service. CCGs were subject to a number of duties more clearly set out in legislation than had been the case for PCTs. The new s.3(1F) of the 2006 Act conferred a duty on CCGs to act consistently with the duty of the Secretary of State, and NHSE, under s.1 NHS Act to promote a comprehensive health service.

12. The changes were predominantly to establish a more clearly 'rules-based' system, with individual NHS bodies' day-to-day operations being more clearly separated from the strategic role of ministers. To formalise this relationship, a system of assurance and assessment of NHS bodies was also introduced. Until 1 July 2022 this included the Secretary of State retaining a duty to set strategic direction for the NHS through a statutory mandate which set objectives for NHS England as well as capital and revenue resource spending limits, which was replaced annually (I discuss the mandate in more detail in paragraphs 21-26 below).

13. Prior to 2022, the three main statutory bodies for leadership, service commissioning and service improvement in the NHS were NHS England (formally titled the NHS Commissioning Board but, operationally, known as NHSE), Monitor (the licensing authority for Foundation Trusts) and the NHS Trust Development Authority (the "TDA," which had functions relating to the management of the performance and development of NHS Trusts). In 2016 the TDA was directed by the Secretary of State to work collaboratively with Monitor under a single leadership and operating model, known as NHS Improvement ("NHSI"). NHSI operationally merged with NHS England in 2018 and, as of 1 July 2022, this merger was formalised in law through the commencement of sections 33 and 36 of the Health and Care Act 2022.

Health and Social Care Act 2012 – Detail

14. Section 1G of the 2006 Act (introduced by Part 1 of the 2012 Act) conferred upon the Secretary of State a duty to keep the performance of the health service under review and to report annually to Parliament on its findings. The core duty to promote a comprehensive health service (s.1 of the 2006 Act), dating back to the founding of

the 2006 Act of 1946, remained in place but with the introduction of a new subsection (3), clarifying that the Secretary of State retained ministerial responsibility to Parliament for the provision of the health service.

15. By s.1(2) of the 2006 Act (as amended in 2012), the Secretary of State's core duty reflects the fact that the functions of commissioning services and the provision of services were no longer delegated by the Secretary of State, but instead directly conferred on the organisations responsible for providing them. NHSE and CCGs would be responsible for arranging services (that is for their commissioning and not for their provision).

16. The legal framework established in the 2006 Act, as amended, also provides the Secretary of State with certain powers to intervene in NHS decision-making by issuing statutory directions. Outside of emergency situations, the powers to issue directions to NHSE were very limited, largely to issuing directions on financial matters and in circumstances where the Secretary of State considered that it was, or was at risk of, failing or not acting in the interest of patients, and that failure was or was likely to be significant (see, for example, pursuant to ss.13Z2 and 253). The power to issue directions in the case of failure was never used.

17. The Health and Social Care Act 2012 evolved the Secretary of State's role to make clear that responsibility primarily lay in ensuring that the functions of commissioning services and the provision of services were being carried out effectively, through the power to set objectives for NHSE (via the mandate already mentioned), by overseeing the effective operation of the health service and through the power to intervene in the event of significant failure (under the new s.13Z2 of the 2006 Act).

18. Through the Health and Social Care Act 2012 (new s.1H of the 2006 Act), the NHS Commissioning Board was established. It was renamed NHS England by s.1 of the Health and Care Act 2022 but, operationally, had for some time been known as NHS England. For the purpose of discharging its s.1(1) NHS Act duty to promote a comprehensive health service, s.1H(3) of the 2006 Act requires NHSE:

    a. To commission services in accordance with the 2006 Act (as described in new s.3B of the 2006 Act), including services which could be more effectively commissioned at national level, or which it would be inappropriate or impractical for CCGs to commission. This could include child and adolescent

inpatient mental health services, some dental services, prison health services and health services for the armed forces.

b. When exercising functions in relation to CCGs (when issuing commissioning guidance under new s.14Z8, for example), to do so in a way as to ensure services are provided for those purposes in accordance with the 2006 Act.

19. With respect to public health and screening programmes, s.7A was introduced to the 2006 Act, granting the Secretary of State the power to arrange for the exercise of her public health functions – in practice, for the delivery of various national public health programmes - for which she has statutory responsibility, by one or more relevant bodies including NHSE. This power has been used for such programmes as cancer and non-cancer screening and vaccinations including for COVID-19, seasonal flu and routine childhood immunisation. The vehicle for delegating these functions to NHSE is an annual public health functions agreement which is published on the GOV.UK website (**WV/2 [INQ0012868]**). The agreements set out how NHSE is accountable for the delivery of such public health services and gives details of arrangements for expert support, deliverables and key performance indicators. The Health and Care Act 2022 updated s.7A of the 2006 Act and introduced a new s.7B which created a power for the Secretary of State to direct NHSE or an Integrated Care Board ("ICB") to discharge any of his public health functions.

20. Part 2 of the Health and Social Care Act 2012 made changes to the 2006 Act in relation to the public health and subsequent duties of the Secretary of State. This included the introduction of a duty on the Secretary of State to take such steps as she considers appropriate to protect the public in England from disease or other dangers to health (s.2A of the 2006 Act), and a duty for unitary and upper-tier local authorities to take such steps as each considers appropriate for improving the health of the people in its area (s.2B of the 2006 Act). Section 2B also gave the Secretary of State power to take such steps as she might consider appropriate for improving the health of the people of England.

The NHSE Mandate

21. By s.13A of the 2006 Act (which was added by the Health and Social Care Act 2012), the Secretary of State is required to publish and lay before Parliament a document known as 'the mandate.' The content of the mandate is subject to collective government agreement and the objectives in the mandate are reflected in NHS England's operational guidance. As originally enacted, the mandate was directed to the NHS Commissioning Board. From 2019 to 2022, the mandate was addressed to both NHSE and NHSI, and their joint operational guidance was addressed to both CCGs and NHS providers.

22. The mandate is the means by which the Secretary of State sets the strategic direction for NHSE by setting objectives it must meet and any requirements considered necessary for the purpose of ensuring NHSE achieve those objectives. The mandate was also (until 2022) the vehicle for giving statutory effect to NHSE's annual capital and revenue resource limits, which determined the funding envelope that the CEO had to work within in delivering objectives in the mandate as well as NHSE's many statutory functions. The Secretary of State has a duty to keep NHSE's progress in delivering its mandate under review, and to lay before Parliament and publish an annual assessment of its performance (which must be informed by NHSE's own annual report).

23. The aim of the mandate is to provide NHSE with a single annual set of objectives to promote stability and clarity and allow NHSE to develop effective planning solutions. A mandate continued to be issued annually until 2022 when further legislative changes contained in the Health and Care Act 2022 provided new flexibility for the Secretary of State to decide when the mandate should be updated. The 2022 changes also removed the duty from the Secretary of State to specify NHSE's annual capital and revenue resource limits in the mandate, instead setting these limits through financial directions which continue to be issued on an annual basis and, in light of the 2022 changes, are now laid before Parliament.

24. I exhibit to this statement the mandates (some of which were subsequently revised) which were issued from 2012 as follows:

    a. For April 2013 to March 2014 (**WV/3 [INQ0012879]**).

    b. For April 2014 to March 2015 (**WV/4 [INQ0012890]**).

c. For April 2015 to March 2016 (**WV/5 [INQ0012901]**).

d. For April 2016 to March 2017 (**WV/6 [INQ0012913]**).

e. For April 2017 to March 2018 (**WV/7 [INQ0012938]**).

f. For April 2018 to March 2019 (**WV/8 [INQ0012940]**).

g. For 2019 to 2020 (**WV/9 [INQ0012941]**).

h. For 2020 to 2021 (**WV/10 [INQ0012858]**).

i. For 2021 to 2022 (**WV/11 INQ0012859]**).

j. For 2022 to 2023 (**WV/12 [INQ0012860]**).

25. The most recent mandate, for 2023, was published in June 2023 (exhibited as **WV/13 [INQ0012861]**).

26. The Department supported the discharge of the Secretary of State's functions in respect of policy development and implementation both for the protection and improvement of the public's health. This included holding NHSE to account for the performance of their functions.

Health and Care Act 2022

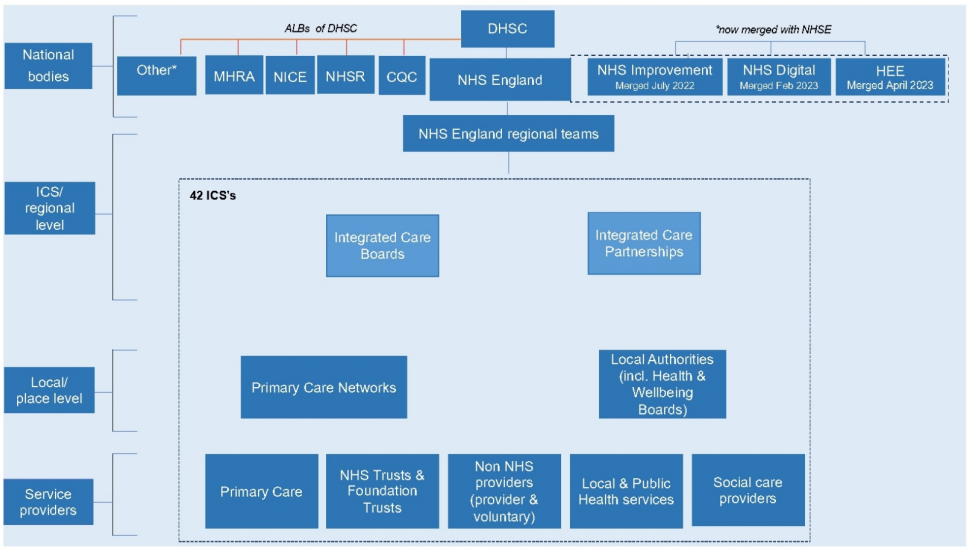
27. The commencement of relevant parts of the Health and Care Act 2022 on 1 July 2022 formalised the merger of NHSE and NHSI in law and thereby combined NHSE's overall system leadership with NHSI's specific oversight of providers of NHS services. The 2022 Act also gave Integrated Care Boards ("ICBs") statutory responsibility for the commissioning of most NHS services in England and created Integrated Care Partnerships ("ICPs"), which together comprise Integrated Care Systems. Integrated Care Boards have responsibility for NHS services with members from a wide range of NHS providers. The board is accountable for health outcomes and financial performance for the ICS area. Integrated Care Partnerships bring together the NHS, local government, voluntary, community and social enterprise sector representatives, and other partners to produce an integrated care strategy. Within ICSs, 'place-based partnerships' enable services to be organised at

a more local level. Groups of NHS Trusts and NHS Service providers also work together in 'provider collaboratives.'

28. Funding flows from the Department to NHSE, which allocates that funding for the NHS through ICBs. Health care providers (including NHS Trusts and Foundation Trusts) are now overseen at the national level by NHSE and are also accountable locally to NHS commissioners for the services they provide. NHS commissioners use their budgets to commission services from providers, which may be public sector bodies (NHS Trusts or Foundation Trusts), independent contractors (such as GP and dental practices), or private or voluntary sector organisations. NHSE is accountable through the Secretary of State to Parliament. Local authorities, in contrast, have a direct line of electoral accountability to their local population.

29. The Care Quality Commission ("CQC") has regulatory oversight of health and social care providers in England and monitors the overall performance of ICSs in relation to the provision of relevant health care and adult social care.

30. The current structure of the NHS and the Department's role within it is illustrated in broad terms in the following diagram. The relevant ALBs which are referred to within this witness statement are also included.



Departmental governance and decision-making

31. Decision-making on strategy, policy and implementation in the Department is, as it is across Government, largely carried out through submissions to the Secretary of State and other department ministers which set out an issue and recommendation and give information to note. The relevant ministers take decisions based on this advice and sometimes will call meetings to discuss the advice before making a decision. Urgent decisions are sometimes taken in meetings or in other discussions.

Secretaries of State and junior ministers

32. The Secretary of State is the head of the Department and is accountable to the Prime Minister, Cabinet, Parliament (through bodies such as the Health and Social Care Select Committee) and the public for the Department's performance. From the date of the implementation of the Health and Social Care Act 2012 to the present, the Secretaries of State for the Department (both 'Health' and 'Health and Social Care') have been:

    a. The Rt Hon Victoria Atkins MP (13 November 2023 – present);

    b. The Rt Hon Steve Barclay MP (25 October 2022 – 13 November 2023);

    c. The Rt Hon Dr Thérèse Coffey MP (6 September 2022 – 25 October 2022);

    d. The Rt Hon Steve Barclay MP (5 July 2022 – 6 September 2022);

    e. The Rt Hon Sajid Javid MP (26 June 2021 – 5 July 2022);

    f. The Rt Hon Matt Hancock MP (9 July 2018 – 26 June 2021);

    g. The Rt Hon Jeremy Hunt MP (4 September 2012 – 9 July 2018);

    h. The Rt Hon Andrew Lansley (now the Lord Lansley) (12 May 2010 – 4 September 2012).

33. In **Appendix A** to this statement, I list the junior ministers within the Department and a summary of their responsibilities / portfolios since 2012 to date.

The Chief Medical Officer, Deputy Chief Medical Officers and the Chief Scientific Adviser

34. The Department is also supported by the Chief Medical Officer ("CMO") who is the UK Government's principal medical adviser and the professional head of all directors of public health in local government and the medical profession in government. The CMO is an independent position at permanent secretary level in the Department and is a member of the Department's Executive Committee and Departmental Board. The CMO advises ministers across government on medical matters and works closely with CMO colleagues in the devolved governments. They are not involved in NHS structures.

35. From 2011 until September 2019 the CMO for England was Professor Dame Sally Davies. From October 2019 to the present date, Professor Sir Chris Whitty has served as CMO.

36. The CMO is assisted by Deputy Chief Medical Officers ("DCMOs"). These are senior experts who assist the CMO and provide advice to policy officials. Usually, there is a DCMO for Health Protection and a DCMO for Health Improvement (although in practice all DCMOs in post worked on health protection as part of the response to the Covid-19 pandemic). Since 2012, the DCMOs for Health Protection have been: David Walker (2013-2015); John Watson (2013-2017); Jonathan Van-Tam (2017-2022); Thomas Waite (interim, 2021-2022, 2022-present substantive). Since 2012, the DCMOs for Health Improvement have been: Reverend Gina Radford (2015-2019); Jenny Harries (2019-2021); Jeanelle De Gruchy (2021 to present).

37. In addition to the above full time DCMOs, Dr Aidan Fowler, (a former consultant surgeon) is the NHSE National Director of Patient Safety and uses the DCMO title when working on projects relevant to the CMO. His role is different to the other DCMOs as he is substantively based in NHSE.

38. The Department is further supported by a Chief Scientific Adviser ("CSA") who advises on scientific aspects of health and acts as the Chief Executive Officer of the National Institute for Health Research ("NIHR"). From 2016 until August 2021 the role of CSA was held by Professor Sir Chris Whitty, from October 2019 to August 2021 concurrently with the CMO role. From August 2021, the post of CSA has been held by Professor Lucy Chappell. CSAs have no role in NHS structures.

The Permanent Secretary

39. The Permanent Secretary is the most senior civil servant in a department and supports the Secretary of State by ensuring ministers receive advice on strategy and objectives for health and social care. From 2010 to 2016, the Permanent Secretary for the Department was Dame Una O'Brien. Since 2016, Sir Chris Wormald has held the position. The Permanent Secretary sets standards and manages risk and assurance. He is also the Accounting Officer for the Departmental Group. The Departmental Group consists of the Department, its executive agencies and its sponsored non-departmental and other specific Arm's-Length Bodies ("ALBs"). The CEO of each of the ALBs acts as that ALB's Accounting Officer and is responsible to the Permanent Secretary as the Principal Accounting Officer. I discuss a number of relevant ALBs more in paragraphs 41-96 below.

40. The structures that are most relevant to Departmental governance are:

    a. The Departmental Board chaired by the Secretary of State: the Departmental Board is an advisory board made up of members of the Department's leadership team, ministers and Non-Executive Directors. It meets quarterly to discuss how the Department is performing against its objectives; to identify potential threats, emerging issues and opportunities that could have an impact on policy; and to provide oversight of delivery partners, including the ALBs. The Board's work is at the discretion of the Secretary of State, with whom the powers and responsibilities ultimately lie.

    b. The Audit and Risk Committee ("ARC"): the ARC is a sub-committee of the Board, which advises the Departmental Board and the Department's accounting officer on risk management, corporate governance and assurance arrangements for the Department and its subsidiary bodies and reviews the comprehensiveness of assurances and the integrity of financial statements.

    c. The Executive Committee ("ExCo") chaired by the Department's Permanent Secretary: ExCo oversees the management of the Department. This involves considering strategy, finance, performance, and core departmental business including the Secretary of State and other ministers' priorities; system wide finance; matching resources to priorities; and departmental pay policy decisions. ExCo meets monthly, except in August, and ad hoc when the

Department's business needs require. ExCo does not create departmental policy. Its role is to set standards and procedures in the Department.

Arm's Length Bodies

41. In addition to the work that the Department carries out directly, it also works through ALBs to deliver its strategic objectives. An ALB is a specific category of public body (classified by the Cabinet Office) that delivers a public service but is not a ministerial government department. ALBs are discrete bodies operating with varying degrees of operational independence but generally not under day-to-day ministerial control. Each ALB has a Senior Sponsor within the Department and a small supporting team. Those teams will engage with their ALBs across the full range of their business, including their corporate strategies, annual business plans, mandates, remit letters (as they apply), finance and performance information, key risks, board appointments, upcoming publications, public and parliamentary accountability, and day-to-day operational issues. ALBs will also be engaged to contribute their expert knowledge and input to relevant policy issues being considered by the Department and, where relevant, across wider government. Sponsor teams will have frequent and varied interactions with many different levels of their ALBs as the main point of contact between the Department and the ALB.

42. DHSC has two different types of ALB: Executive Agencies and Executive Non-Departmental Public Bodies. Executive Agencies may be considered the 'shortest arm' of the Department. Unlike other ALBs, they are not legally separate from the Department (i.e. they do not have a separate legal identity) but are operationally independent whilst remaining accountable to it. There are two Executive Agencies within the Department: the UK Health Security Agency and the Medicines and Healthcare Products Regulatory Agency.

43. The Department also works with four Special Health Authorities, a form of body which is unique to the Department. These are separate legal entities that are created by secondary legislation to carry out functions of the Secretary of State. They are subject to ministerial direction to a greater extent than Executive Non-Departmental Public Bodies, but less so than Executive Agencies. In the Department, the Special Health Authorities are treated the same as the Cabinet Office recognised ALBs.

There are a number of special health authorities including, for example, NHS Resolution (which manages negligence claims against the NHS in England) and the former NHS Trust Development Authority ("TDA"), which previously exercised functions in relation to NHS trusts and which I discuss more in paragraph 57 below. Health Education England (which I discuss below) was originally a Special Health Authority, prior to its establishment as a Non-Departmental Public Body.

44. Non-Departmental Public Bodies are separate legal entities that are set up in primary legislation and have a greater degree of independence from the Department than Special Health Authorities or Executive Agencies with their own statutory functions. These Bodies carry out administrative, commercial, executive or regulatory functions. They are not under day-to-day ministerial control, although a minister will be responsible to Parliament for their performance and effectiveness. NHS England and CQC are examples of Non-Departmental Public Bodies.

45. ALBs are accountable to Parliament, either directly or via the Secretary of State. The Secretary of State, or the Department on her behalf, sets their strategic direction and holds them to account for the delivery of agreed objectives through a number of mechanisms including:

    a. The power for the Secretary of State to appoint and remove chairs and non-executive board members.

    b. Accountability through the Accounting Officer of the ALB, who holds the primary responsibility for ensuring that the organisation discharges its responsibilities properly and uses its resources in accordance with the requirements of HM Treasury's 'Managing Public Money'. This includes preparing the governance statement, which forms part of the ALB's annual report and accounts. Accounting Officers are appointed by the Principal Accounting Officer, except for the Accounting Officer of NHSE, which under the 2006 Act has to be the Chief Executive (who is appointed by the Chair).

    c. Framework agreements between the department and each ALB, setting out the relationship between the sponsored body and the Department, including the lines of accountability, the way in which the ALB will provide assurance to the Department on its performance, the core financial requirements with which

the ALB must comply, and the relationships between the ALB and other bodies in the system.

d. Annual business plans and performance reporting against agreed plans. Each ALB must produce an annual business plan, to be agreed with the Department, demonstrating how its objectives will be achieved and forecasting its financial performance. Standard practice is a quarterly accountability review is conducted with each ALB by its Senior Departmental Sponsor, to provide assurance that the ALB is delivering against its objectives, managing its finances, identifying and managing risks and working well with partner organisations. The practice is different for NHSE, given the size and scope of the organisation. A formal accountability review takes place each year to review the past year's performance against objectives and to look forward to the next year. In addition, the annual reports and accounts of executive agencies, special health authorities and non-Departmental public bodies must be laid before Parliament.

e. A programme of reviews that focus on thematic issues but can also look at individual ALBs. This programme ensures that each ALB is reviewed at least every five years. The Department tailors reviews to ensure that they focus on the areas that will add value and not duplicate other work. The review team work closely with the ALBs involved to ensure the process is relevant and supports effective delivery.

46. The Secretary of State also retains formal powers to intervene in the event of significant failure, including where an ALB is not acting consistently with what the Secretary of State considers to be the interests of the health service. These failure powers apply to non-departmental public bodies established or amended by the Health and Social Care Act 2012 and the Care Act 2014 (they are not needed for executive agencies or special health authorities, where Ministers are able to exert direct control). As a first step, the Secretary of State can issue a direction to the body.[6] If the organisation fails to comply with the direction, then the Department may discharge the functions to which the direction relates or arrange for another

[6] The Secretary of State's power to issue directions can be found within ss.8, 13YB, 13ZC, 13ZF and 14Z61 of the 2006 Act.

organisation to do so. In all cases, the Secretary of State must publish the reasons for the intervention.

47. I am asked to set out the ALBs with which the Department works to deliver its objectives in areas that relate to (i) patient safety in hospitals, (ii) NHS management and external scrutiny and (iii) the regulation of healthcare professionals and services from 2012 to the present. I address below:

    a. NHS England (and, previously, NHS Improvement);

    b. Clinical Commissioning Groups / Integrated Care Boards;

    c. Health Education England (now part of NHSE);

    d. NHS Digital (now part of NHSE);

    e. NHS Trusts and NHS Foundation Trusts;

    f. The Care Quality Commission;

    g. The National Institute for Health and Care Excellence;

    h. The Medicines and Healthcare products Regulatory Agency;

    i. NHS Resolution.

NHS England (and, previously, NHS Improvement)

48. NHSE is an executive non-departmental public body of DHSC. It leads and oversees the funding, planning and delivery of healthcare in England. It is accountable, through its Board, to the Secretary of State who agrees accountability arrangements that set the strategic direction for NHSE through regular mandates. NHSE allocates much of its funding to ICBs and supports them in commissioning services based on local need. NHSE holds local commissioning organisations (such as ICBs) and NHS providers (e.g. NHS Trusts and Foundation Trusts), to account. The NHSE operating framework sets out how accountability should work under the structures created by the 2022 Act. I exhibit as **WV/14 [INQ0012862]** the operating framework for NHSE. Broadly, its responsibilities are allocated as follows:

a. Individual providers are responsible for delivering safe, effective, efficient, high-quality services in line with national standards, their statutory duties and their contracts and agreements with integrated care boards and NHSE.

b. NHSE has statutory accountability for oversight of both Integrated Care Boards ("ICBs") and providers of NHS services. NHSE also has statutory powers to appoint ICBs and NHS trust chairs and Chief Executives. Chairs of ICBs are appointed by NHSE with the approval of the Secretary of State. Foundation Trust Chief Executives are appointed by the non-executives and the Chair, who are in turn appointed by the Council of Governors of the Foundation Trust. NHSE also has statutory powers to annually assess each integrated care board and set financial objectives for systems.

c. Working alongside others, NHSE also has powers to intervene if integrated care boards or providers are failing to discharge their functions, in line with the enforcement guidance.

49. The NHSE annual assessment process for ICBs should be informed by feedback from stakeholders including health and wellbeing boards. Local authorities also scrutinise health services through health overview and scrutiny committees ("HOSCs"). NHS bodies are also subject to oversight from a range of other organisations, including the CQC and Healthwatch.

50. NHSE has delegated responsibility for commissioning primary medical services and most other primary medical services (pharmaceutical, general ophthalmic and dental services) to ICBs but retains overall accountability for the discharge of its responsibilities for primary care under the 2022 Act. NHSE requires assurances from ICBs that its functions are being discharged safely, effectively and in line with legal requirements. NHSE has published an Assurance Framework for primary care services which sets out these requirements.

51. As set out above, the NHS Commissioning Board was established as a Special Health Authority on 31 October 2011 and then established as a non-departmental body through the Health and Social Care Act on 1 April 2013. It was renamed NHS England by s.1 of the Health and Care Act 2022 but, operationally, had for some time been known as NHS England. In 2018, NHSE operationally merged with NHSI (they were jointly referred to as NHSEI, however for the purposes of this statement

I will refer to them by their separate titles). The 2022 Act formalised this merger by abolishing and transferring the functions of NHSI (which encompassed the NHS Trust Development Authority and Monitor) to NHSE. Along with its existing responsibility for commissioning services, the merger with NHSI meant that NHSE also became responsible for overseeing and holding NHS providers to account.

52. From 2012 to the present, the NHSE Board was chaired by Sir Malcom Grant (until 2018) Lord David Prior (until March 2022) and then by Richard Meddings. The CEOs were Sir David Nicholson (2013-2014), Sir Simon Stevens (until July 2021) and then Amanda Pritchard from July 2021 to date. The NHSE National Medical Director provides clinical and professional leadership for all medical professionals, taking leadership responsibility for improving all aspects of clinical care and outcomes. Professor Sir Stephen Powis has been the National Medical Director since 2018. He was preceded by Professor Sir Bruce Keogh. Ruth May has held the post of Chief Nursing Officer since 2019, providing clinical and nursing workforce advice to the Government and Board.

53. Following the operational merger in 2018, NHSE and NHSI functioned as one integrated organisation. Until 1 July 2022, NHSI also retained an individual Board, chaired by Baroness Dido Harding until October 2021, then Andrew Morris until June 2022. Amanda Pritchard was CEO until July 2021, followed by Professor Stephen Powis on an interim basis until June 2022. The NHSI and NHSE Boards met quarterly as individual Boards and together as a joint Board (also on a quarterly basis).

NHS England – powers

54. Whilst the Secretary of State maintains ministerial responsibility to Parliament for the provision of the health service in England (s.1(3) of the 2006 Act), NHSE is subject to the duty to promote a comprehensive health service in England under s.1(1) concurrently with the Secretary of State, except in relation to the part of the health service that is provided in pursuance of the public health functions of the Secretary of State or local authorities. NHSE also has a number of other statutory duties under the 2006 Act (introduced through amendments made by the Health and Social Care Act 2012 and the Health and Care Act 2022) including:

a. Arranging the provision of services for the purposes of the health service in England (s.1H of the 2006 Act);

b. Acting with a view to securing that health services are provided in a way which promotes the NHS Constitution, and promoting awareness of the NHS Constitution among patients, staff and members of the public (s.13C);

c. Exercising functions effectively, efficiently and economically (s.13D);

d. Seeking to secure continuous improvement in the quality of services (s.13E);

e. Promoting patient involvement in decisions relating to the prevention or diagnosis of illness in the patient, or their care or treatment (s.13H);

f. Seeking to enable patients to exercise choice (s.13I);

g. Obtaining appropriate advice about the prevention, diagnosis and treatment of illness or the protection or improvement of public health from those who have a broad range of professional expertise (s.13J);

h. Promoting research (s.13L);

i. Promoting education and training (s.13M);

j. Promoting integration of services where this would improve the quality of those services or reduce inequalities in terms of access to services or the outcomes achieved in the provision of services, including integration of health and health-related or social care services (s.13N);

k. Collecting and analysing information relating to the safety of the services provided by the health service (s.13R); and

l. Having regard to the impact on health services to persons who reside in areas that are close to the border with England (s.13O).

55. Prior to 1 July 2022, NHSE held various powers including to issue guidance (s.14Z8 of the 2006 Act) and to conduct an annual assessment of the performance of each CCG (s.14Z16 of the 2006 Act). It has tightly prescribed powers to give directions to ICBs and, previously, CCGs where they are failing to discharge its functions, or there is a significant risk that they may do so (s.14Z21 of the 2006 Act, which related to CCGs is now repealed; s.14Z61 is in force and applies to ICBs).

56. As noted above, CCGs were replaced with ICBs under the Health and Care Act 2022 from 1 July 2022. ICBs are statutory NHS organisations responsible for developing a plan to meet the health needs of the population, managing the NHS budget and arranging for the provision of health services in their Integrated Care System ("ICS") area. They are also responsible for commissioning the majority of NHS services, including primary care and some specialised services (which were previously commissioned by NHSE).

57. Following the merger with NHSI under the Health and Care Act 2022, NHSE also became responsible for regulating NHS Foundation Trusts, NHS Trusts and independent sector providers of NHS services through provider licences. The requirement to hold a licence was also extended to NHS Trusts from April 2023. NHSE monitors and enforces compliance by providers with their licences. NHSI had encompassed two legal bodies: the Trust Development Authority ("TDA") and Monitor (the sector regulator for health services in England), responsible for overseeing and regulating NHS Foundation Trusts and NHS Trusts, as well as independent providers that provide NHS-funded care.

58. The operationally merged NHSE and NHSI held a number of regulatory, oversight and management functions over NHS Trusts and Foundation Trusts including: the NHS Oversight Framework (the NHS Oversight Framework of 2022 is exhibited as **WV/15 [INQ0012864]**), ensuring the alignment of priorities across the NHS; identifying where NHS commissioners and/or NHS Trusts and Foundation Trusts may benefit from, or require, support; and providing an objective basis for decisions about when and how NHSE and NHSI would intervene. They also held oversight functions in respect of NHS Trusts and Foundation Trusts, including: the Recovery Support Programme; licensing; the NHS tariff; and intervention in case of failure. NHSE also set the NHS Standard Contract for use by commissioners for all contracts for healthcare services other than primary care. NHSE was responsible for commissioning primary care and all specialised services throughout the relevant period (delegating commissioning of primary medical care to CCGs for some time prior to the establishment of ICBs).

59. I have set out above (at paragraphs 21-26) how the Department sets the strategic direction for NHSE through the statutory mandate. In addition to satisfying these formal requirements, Ministers and senior civil servants meet NHSE leadership

frequently to discuss progress on the delivery of key government commitments for health and care and to resolve associated challenges. Individual policy teams across the Department also maintain regular contact with their counterparts in NHSE to underpin this ministerial and senior level engagement and to collaborate on shared challenges.

Clinical Commissioning Groups / Integrated Care Boards

60. NHS CCGs were clinically-led statutory NHS bodies responsible for the planning and commissioning of healthcare services for their local area. They were created following the Health and Social Care Act 2012 and replaced Primary Care Trusts on 1 April 2013. As I have explained above, CCGs were replaced with ICBs under the Health and Care Act 2022 from 1 July 2022. I have addressed the oversight and accountability of CCGs and ICBs to NHSE in paragraphs 55-56 above.

61. The Department's interactions with ICBs (and their predecessor bodies) are communicated via NHSE in line with the oversight and accountability arrangements described above. The Department has regular formal and informal communication (at all levels) with NHSE about NHS performance and delivery and information exchange relating to local and regional matters would take place through these arrangements. On the occasions when Ministers speak directly to ICBs, NHSE would usually be involved.

Heath Education England

62. Health Education England ("HEE") was initially established as a Special Health Authority in 2012 and then converted to an Executive Non-Departmental Body in 2015 under the provisions of the Care Act 2014. The Care Act 2014 set out the functions and constitution of HEE and those of its Local Education and Training Boards (which were abolished as statutory sub-committees of HEE in the Health and Care Act 2022). HEE was established to deliver a better healthcare workforce for England and was accountable for ensuring a secure workforce supply for the future. Prior to its merger with NHS England, HEE was responsible for promoting high quality education and training that is responsive to the changing needs of

patients and local communities. I exhibit the Framework Agreement between HEE and the Department (published in September 2022) as **WV/16 [INQ0012865]**.

63. In April 2023 HEE was abolished and its functions were transferred to NHSE. Since this time, NHSE has held HEE's responsibilities for planning, recruiting, educating and training the health workforce. As explained within the Explanatory Memorandum to the Health Education England (Transfer of Functions, Abolition and Transitional Provisions) Regulations 2023, the policy intention is to ensure that service, workforce and finance planning are integrated in one place at a national and local level for the NHS in England. It will simplify the national system for leading the NHS, ensuring a common purpose and strategic direction. This intends to produce a wider societal benefit in that the NHS workforce is more closely aligned to service need, with the aim of better care standards and workforce availability which could potentially minimise the impact of illness and disease and benefit the workforce.

64. HEE was accountable to the Secretary of State for Health and Social Care. The Department published a mandate for HEE which set out its contribution to the health and care system and deliverables for the year. There were quarterly accountability meetings with the HEE Chair, Chief Executive and other relevant Executive Directors, chaired alternately by the Senior Department Sponsor and the responsible Minister which reviewed the finances, performance and risks associated with delivery of the mandate. There was also regular informal communication with the sponsor team to manage day to day operational matters.

65. I discuss the role of education and training within the healthcare workforce as a tool for improving patient safety in paragraph 124 below.

NHS Digital

66. NHS Digital ("NHSD") was the operational name for the Health and Social Care Information Centre. The Health and Social Care Information Centre was initially established as a Special Health Authority in 2005, before being abolished and re-established as a Non-Departmental Public Body under provisions in the Health and Social Care Act 2012. On 1 February 2023 it was abolished and its functions were formally transferred to NHSE. It was chaired by Noel Gordon until September 2020

and then by Laura Wade-Gery. Its CEOs were Sarah Wilkinson until June 2021 and then Simon Bolton (on an interim basis) until the date of abolition.

67. NHS Digital designed, developed and operated national IT and data services for the NHS and adult social care. Its responsibilities included:

    a. Collecting, analysing and publishing health and adult social care data;

    b. Making the recording of data as easy as possible for health and adult social care staff;

    c. Providing national technology for health and adult social care services;

    d. Improving the quality of health and adult social care information and data;

    e. Publishing national indicators for health and adult social care, to measure quality of care and progress against policy initiatives; and

    f. Giving advice and support to health and adult social care organisations on information and cyber security.

68. The relationship with NHS Digital was governed by sponsorship arrangements in line with Cabinet Office guidance, including Managing Public Money, with a formal Framework Agreement, and an annual remit letter setting out the delivery expectations that DHSC had for the ALB. I exhibit the Framework Agreement between NHS Digital and the Department (published in August 2022) as **WV/17 [INQ0012866]**. The Department frequently used the power in section 254 of the Health and Social Care Act to direct NHSD to establish information systems. There were quarterly accountability meetings with the NHS Digital Chief Executive and other relevant executive directors, chaired by the Senior Departmental Sponsor, as well as monthly finance meetings, meetings with the head of corporate governance and board secretary.

69. There was also regular informal communication by the sponsor team with officials in NHS Digital to troubleshoot issues raised by the DHSC policy teams, and to manage day-to-day operational matters. Engagement between the DHSC and NHS Digital did not however have to go via the sponsorship team, and many policy and other teams in DHSC would talk directly to the relevant teams in NHS Digital,

particularly when discussing data requirements and collections. NHS Digital was also subject to a rolling programme of Government Internal Audit Agency audits.

70. Prior to its abolition, NHS Digital played a core role managing data, including in relation to patient safety incident reporting (discussed more in paragraphs 128-145 below).

NHS Trusts and NHS Foundation Trusts

71. NHS providers include the hospitals, mental health, community and ambulance services responsible for providing NHS services to patients. Since the 1990s (following the introduction of the National Health Service and Community Care Act 1990) NHS providers of acute and community care have been organised into 'Trusts' and (from 2003) a variant of this known as 'Foundation Trusts' (established by the Health and Social Care (Community Health and Standards) Act 2003). The relevant legislation gave more structure to provider organisations, putting in place boards with chairs, non-executives and executives, and allowing the development of both stronger governance and greater organisational autonomy. This was accompanied by the splitting of purchaser and provider functions in the system, which also opened up the possibility of competition between providers. These changes were also accompanied by the development of a stronger cadre of NHS managers (as envisaged by the Griffiths report in 1983) and an accompanying strengthening of managerial oversight of both finances and performance.

72. While Trusts (and to an even greater extent Foundation Trusts) had a degree of autonomy, this autonomy was not absolute. The Department of Health and NHS England from its inception in 2013 both continued to hold significant formal and informal power over provider organisations. Different policy frameworks and approaches have shifted this balance somewhat over time, though not in a single direction. The formation of Foundation Trusts in the 2000s was explicitly designed to increase both provider autonomy and the role of commissioners to deliver services efficiently. Unlike Trusts, Foundation Trusts could not be directed by the Secretary of State. Instead, they were overseen by a board of governors and were subject to relatively light-touch regulation of fundamental quality issues and financial health. NHS Trusts that met certain requirements around performance, clinical

standards and governance and leadership could apply for Foundation Trust status, gaining additional freedoms and flexibilities which are set out in legislation. Foundation Trusts were independently regulated by Monitor (and later by successors NHS Improvement and NHS England) who determined whether NHS Trusts were ready to become Foundation Trusts and that Foundation Trusts continue to be financially sustainable, well-led and locally accountable. There was a clear ambition for all Trusts to become Foundation Trusts by 2014. This, however, was not realised, in part because of concerns about care quality, particularly following the inquiries into Mid Staffordshire NHS Foundation Trust (final public inquiry report, 2013) and failings in care at other providers. This led to a more active oversight and regulation of the provider sector and less differentiation in approach (leading to eventual full convergence in effect) between Trusts and Foundation Trusts.

73. Around a third of provider organisations are Trusts and the rest are Foundation Trusts. The shift to closer supervision of providers came at the same time as a greater focus in the thinking and activity of NHS England on care integration in order to meet demographic need. As a result, provider organisations retain quite a lot of formal autonomy while in practice they are encouraged and required to work as part of their wider systems.

74. Patient safety is one of the core responsibilities for a Trust or Foundation Trust Board as well as being a critical area of focus for the regulatory oversight of NHS England (and predecessor bodies with that role). Legislation requires every NHS Trust (under regulation 4(1)(c) of the National Health Service Trusts (Membership and Procedure) Regulations 1990) and NHS Foundation Trust (under section 30 and schedule 7, para 16(2) of the 2006 Act) to include a medical (or dental) practitioner as an executive member. The Medical Director is the formal professional lead for all medical staff within these organisations, responsible for promoting quality, safety, clinical standards and ensuring the clinical voice is part of all aspects of trust business.

75. The Department has regular formal and informal communication (at all levels) with NHSE about NHS performance and delivery and information exchange relating to individual NHS Trusts and NHS Foundation Trusts would take place through these arrangements. As with ICBs, there are occasions when the Department has direct

contact with an NHS provider, however this would usually be done with NHSE's involvement.

76. The Department has a number of routes through NHSE and regular official-level fora with them through which it is informed about individual NHS Trusts and NHS Foundation Trusts. These include meetings with NHSE and the CQC to discuss providers and systems with patient safety challenges which are in or at risk of entering tier 4 of the NHS Oversight Framework and in receipt of national support via the Recovery Support Programme.

The Care Quality Commission

77. The CQC is an Executive Non-Departmental Public Body established in April 2009 under the Health and Social Care Act 2008. It is the independent regulator of health and social care in England and is responsible for the registration, inspection and monitoring of health and adult social care services, including both NHS and independent providers. Since April 2022 the CQC has been chaired by Ian Dilks. Before Mr Dilks, the CQC was chaired by David Prior (2013-2015) and then Peter Wyman (2016-2022). The CEO is Ian Trenholm. Prior to this, David Behan was CEO from 2012-2018.

78. The CQC inspects and monitors all providers of health and adult social care who carry out 'regulated activities' to provide an independent evaluation of the extent to which these services are safe, effective, caring, responsive and well-led. Ratings are provided on a four-point scale: outstanding; good; requires improvement; and inadequate. The Health and Social Care Act 2008 provides for the CQC to review the provision of relevant health care and adult social care (and the exercise of functions of the ICB, its partner LAs and providers, within the area of the ICB, relating to the provision of that care) and to assess the functioning of the system.

79. Through inspections and monitoring, the CQC checks whether the essential requirements for safety and quality are being met. Where poor care is identified, the CQC is empowered to take enforcement action including by issuing warning notices or penalty notices, commencing prosecution, or by suspending or cancelling a provider's registration. The CQC can also take enforcement action in relation to

breaches of fundamental standards and can bring criminal prosecutions in certain cases.

80. The work of support, improvement and intervention that is done in response to CQC inspections or in response to other intelligence (including the NHS's own 'National Oversight Framework' assessments) about provider challenge or failure is the responsibility of the relevant provider regulator (NHS TDA, Monitor, NHS Improvement and NHS England at different points over the last decade).

81. The relationship between the Department and CQC is governed by the Framework Agreement (exhibit **WV/18 [INQ0012867]**), which sets out key working arrangements and expectations. In practice however, there is frequent formal and informal contact between the Department and the CQC of various kinds. This includes:

    a. Regular meetings between the Department and CQC (e.g. quarterly Budget and Assurance meetings, Quarterly Assurance Review meetings, twice-yearly meetings between CQC Chair and DHSC Director General of Secondary Care and Integration);

    b. Commissions for information from ALBs including the CQC, coordinated by the DHSC ALB Sponsors Oversight Team);

    c. The CQC's fortnightly forward look of inspection reports indicate any provider rated as either outstanding, good, requires improvement or inadequate.

82. The Department may also become aware of concerns held by the CQC through embargoed copies of the CQC's press notices sent to the sponsor team concerning prosecutions, fines imposed and providers put into 'special measures'; concerns raised by MPs who have been briefed by CQC about their local services; or through public CQC reports.

The National Institute for Health and Care Excellence

83. The National Institute for Health and Care Excellence ("NICE") was re-established as an executive non-Departmental public body by the Health and Social Care Act 2012, having been established in 1999 as a special health authority. NICE drives

best practice and value for money in the health and care system through the translation of research into authoritative, evidence-based recommendations and guidance, including on the use of medicines.

84. The relationship with NICE is governed by a Framework Agreement. I exhibit the Framework Agreement between the Department and NICE (dated 2018) as **WV/19 [INQ0012869]**. Formal meetings and accountability take place at senior level, including annual accountability meetings between NICE's Chair and Chief Executive and the responsible minister, and quarterly accountability meetings with the NICE senior team and senior departmental sponsor. These are supported by regular informal communication with the sponsor team to manage day-to-day operational matters.

85. NICE's guidance is formally commissioned by the Department or NHS England and NICE is then responsible for developing its guidance independently in line with its methods and processes which are periodically reviewed to ensure that they remain fit for purpose.

86. The NHS Constitution states that patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if their doctor believes they are clinically appropriate. NHS organisations in England are legally required to make funding available for NICE recommendations made in technology appraisal or highly specialised technology appraisals, usually within three months of a final recommendation being published.

87. NICE guidelines covering specific conditions and diseases provide comprehensive best practice guidance for healthcare professionals and are developed by experts based on a thorough assessment of the evidence and engagement with stakeholders. NICE guidelines are not mandatory but healthcare professionals are expected to take them fully into account in their decision making.

The Medicines and Healthcare products Regulatory Agency

88. The Medicines and Healthcare products Regulatory Agency ("MHRA") regulates medicines, medical devices and blood components for transfusion in the UK. The MHRA is currently chaired by Amanda Calvert, Michael Whitehouse and Professor

Graham Cooke (as interim co-chairs). It was previously chaired by Stephen Lightfoot (2020 – July 2023); Sir Michael Rawlins (2014-2020); Sir Gordon Duff (2013-2014); and Sir Alasdair Breckenridge (2003-2012). Dame June Raine has been its CEO since September 2019. This role was previously occupied by Dr Ian Hudson (2013-2019) and Sir Kent Woods (2004-2012).

89. The MHRA is, within the limits of its responsibilities, responsible for:

a. Ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy;

b. Securing a safe supply chain for medicines, medical devices and blood components;

c. Promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines;

d. Educating the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;

e. Enabling innovation and research and development that is beneficial to public health; and

f. Collaborating with partners in the UK and internationally to support its mission to enable the earliest access to safe medicines and medical devices and to protect public health.

90. In relation to medicines, including vaccines, the MHRA decides whether manufacturers should be granted licences to make, assemble or import them and whether applications to vary licences for marketing authorisations should be granted as information about the medicines and vaccines develop. These decisions are based on considerations related to safety, quality and effectiveness. NICE decides whether medicines are cost effective and should be made available on the NHS. The NHS in England is legally required to provide funding for new medicines within 90 days of a positive NICE recommendation under normal circumstances. These organisations are able to consider wider factors in their decision-making, including the need for the medicine in the UK given the circumstances at the time.

91. The MHRA also carries out a number of regulatory activities such as inspecting facilities and conducting safety tests; approving and inspecting clinical trials; monitoring the safety of medicines while on the market; regulating the importation of licensed medicines; and helping to set and enforce advertising regulations for medicines. The MHRA also has powers of enforcement in relation to medical devices under the Consumer Rights Act 2015, the Medicines and Medical Devices Act 2021, and the General Product Safety Regulations 2005. These powers include issuing compliance, suspension and safety notices, with further non-compliance resulting in prosecution. The MHRA also has further powers of enforcement in relation to medicines in other legislation, including in the Human Medicines Regulations 2012 and the Medicines Act 1968.

92. The Department's relationship with the MHRA is governed by the Framework Agreement (dated March 2016), which I exhibit as **WV/20 [INQ0012870]**. Quarterly accountability meetings chaired by the Senior Department Sponsor are held with the MHRA Chief Executive and other Agency Directors. The Agency Chief Executive also meets with the Second Permanent Secretary and the Senior Department Sponsor on a regular basis and meets the relevant Minister as part of an annual accountability review and through ad hoc meetings. This is supported by regular informal communication with the sponsor team to manage day-to-day operational matters.

NHS Resolution

93. NHS Resolution is the operational name for the NHS Litigation Authority. The NHS Litigation Authority was established as a Special Health Authority in 1995 to administer schemes for meeting the liabilities of health service bodies. NHS Resolution's main function is to provide indemnity cover for negligence claims against the NHS for both primary and secondary care in England. The two main clinical schemes are the Clinical Negligence Scheme for Trusts ("CNST") and the Clinical Negligence Scheme for General Practice ("CNSGP"). All NHS Trusts and Foundation Trusts are members of CNST. Other members include NHS commissioners, some independent sector providers, and some health ALBs. The costs of the scheme are met by membership contributions. All GPs and others

providing NHS primary medical services are automatically covered by CNSGP and the costs of the scheme are funded by NHSE. NHS Resolution also administers legacy schemes for liabilities relating to abolished NHS bodies and the costs of these schemes are funded by the Department. Its three other areas of business are Practitioner Performance Advice, Primary Care Appeals and Safety and Learning.

94. NHS Resolution has a strategic objective to collaborate to improve maternity outcomes with the aim of working with others to see what more can be done to support the national maternity safety ambition to halve rates of stillbirth, neonatal and maternal death and brain injuries that occur during or shortly after birth by 2025 (which I discuss in more detail in paragraphs 146-147 and 215-216 below). It is responsible for two schemes aimed at improving safety in maternity services: the Early Notification Scheme and the Maternity Incentive Scheme.

95. The Early Notification Scheme proactively investigates specific brain injuries at birth to determine if negligence has caused the harm, improve the experience for the family and share learning rapidly with the individual trust and the wider system to support safety improvements and prevent the same things happening again. The Maternity Incentive Scheme supports the delivery of safer maternity care through an incentive element to trust contributions to the CNST. The scheme works by creating an incentive fund by charging trusts an additional 10% of their maternity contribution to the CNST. Trusts that can demonstrate they have achieved all ten safety actions recover the element of their contribution to the incentive fund and will also receive a share of any unallocated funds. Trusts that do not meet all ten safety actions do not recover their contribution but may be eligible for a smaller discretionary payment to help them make progress against any actions they have not achieved.

96. The relationship with NHSR is governed by the Framework Agreement, which I exhibit as **WV/21 [INQ0012871]**. Formal meetings and accountability take place at senior level with quarterly accountability meetings held with the NHS Resolution Chair, Chief Executive and other relevant executive directors, and chaired by the Sponsor Director. These are supported by regular informal communication with the sponsor team to manage day to day operational matters.

Other bodies

97. In addition to the ALBs which are connected to the Department, there are a number of other organisations which are not ALBs and are independent of the Department but which I identify here for completeness because they play relevant roles in patient safety. These include:

    a. The Parliamentary and Health Services Ombudsman (which I discuss more in paragraphs 202 below, in relation to complaints);

    b. The Patient Safety Commissioner (which I discuss more in paragraphs 187-188 below, in relation to patient safety); and

    c. The regulators of medical professionals.

98. Professional regulation is conducted by independent regulatory bodies with the autonomy to set their own standards and processes. These include the General Medical Council ("GMC"), which regulates doctors in the UK,[7] and the Nursing and Midwifery Council ("NMC"), which regulates nurses and midwives in the UK and nursing associates in England. Regulators have four key roles:

    a. Setting the standards of competence and conduct that health and care professionals must meet in order to be registered and practise;

    b. Checking the quality of education and training courses to make sure they give students the skills and knowledge to practise safely and competently;

    c. Maintaining a searchable register of regulated professionals; and

    d. Investigating complaints about registered individuals and deciding whether action may be required in respect of their registration.

99. 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. However, risk of harm is most effectively managed by those closest to patient care and professional regulation is only one part of a much broader system of regulation and quality assurance in healthcare settings.

[7] By the end of 2024 the GMC is due to assume regulatory oversight of anaesthesia associates and physician associates.

100. The General Medical Council ("GMC") has described how there should be four layers of regulation for practitioners who work in an employed environment as part of wider clinical teams:

a. Individual regulation - The most effective protection against poor practice is the individual practitioner. Their own values, supported by professional ethics, should be what most effectively ensures good care for every patient.

b. Team regulation - Team-based regulation reflects the importance of team working and requires health professionals to take responsibility for the performance of the team and to act if a colleague's conduct, performance or health is placing patients at risk.

c. Workplace regulation - This layer of regulation reflects the responsibility that the NHS and other healthcare providers have for ensuring that their staff, and those who use their facilities, are fit for their roles. This is expressed through effective leadership, management and clinical governance in the organisation that provides, or arranges the provision of, care.

d. National regulation - The professional regulatory bodies provide a national framework of assurance. Professional regulation is expressed through work on standards, education, registration and licensing, including revalidation and fitness to practise.

101. Finally, there is system level regulation of the bodies that provide health and social care services. As the system regulator in England, the CQC is responsible for overseeing all NHS and independent sector providers. The CQC requires providers to have procedures for ongoing monitoring of staff to ensure they meet fit and proper persons requirements, and that providers have effective and accessible systems for identifying, receiving, handling and responding to complaints.

102. The Government sets through legislation the overall aims and powers of the professional regulatory bodies. It does not oversee their operational performance. Regulators are directly accountable to Parliament and are responsible for operational matters concerning the discharge of their statutory duties.

The Department's role in leading on change within the healthcare system

103. The Department has an important role within the healthcare system, which includes several high-level responsibilities:

a. Providing direct support and advice to Ministers to help shape and deliver policy to meet the Government's objectives;

b. Setting the strategic direction for the system, by leading the key strategic debates and linking into the wider government agenda;

c. Driving accountability, by holding others to account and being held to account by Ministers and Parliament;

d. Acting as the guardian of the frameworks for health and social care, including but not limited to legislative, financial, administrative and policy frameworks, designed to ensure the systems work to enable services to be delivered; and

e. Acting as the trouble shooters, who step in and help put things right if the system fails to work as it should.

104. I am asked to comment on how the Department leads on changes in how the health service in England operates and ensures that it is fit for purpose. In the above paragraphs of this statement, I have set out how the healthcare service in England has changed over time and the Department's role in securing those changes. The department sets the overarching direction for the NHS and leads major policy changes, most obviously through the mandate to NHSE discussed in paragraphs 21-26 above, which sets the objectives that NHSE should seek to meet.

105. The Department also oversees the legislative framework for the NHS and develops changes to that framework as required by policy or other drivers. As set out in greater detail below, to make changes to legislation, the Department tends to develop proposals with input and support and engagement from NHSE and wider stakeholders. Following that consultation, the Department manages the legislative process and any cross-government engagement needed, such as the collective agreement process.

106. 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 ICBs and NHS providers. For example, NHSE oversees the process of reconfigurations of NHS services, leads interventions with underperforming providers, and proposes changes to the NHS contract.

107. Further, the Department also uses its high-level role to commission work looking at the overall operation of the health and social care system. A recent example of this was in November 2022 when the Department commissioned The Rt Hon Patricia Hewitt to conduct a review of how the oversight and governance of integrated care systems can best enable them to succeed, balancing greater autonomy and robust accountability. The review considered how best to empower local leaders to focus on improving outcomes for their populations and published its findings in April 2023 with the Government's response published in June 2023. I exhibit the Hewitt Review's report as **WV/22 [INQ0012872]** and the Government's response as **WV/23 [INQ0012873]**.

108. A second example is the most recent reforms to the English healthcare system brought about by the Health and Care Act 2022. This was introduced by the Department because it was felt that the 2012 Act needed amendment, in particular, to facilitate greater collaboration and build on the changes already underway in the NHS to facilitate greater integration, including the establishment of non-statutory ICSs and the publication of the NHS Long Term Plan in 2019 (**WV/24 [INQ0012874]**). It built upon NHS recommendations in September 2019 to Government and Parliament for an NHS Bill. Developing the work of non-statutory sustainability transformation partnerships and integrated care systems, the Act changed the statutory framework by establishing Integrated Care Boards ("ICBs") and Integrated Care Partnerships ("ICPs", a statutory joint committee), to bring together the NHS, local authorities, and others, to understand and plan how best to address health and care needs in their area. The Act also abolished Clinical Commissioning Groups. Overall, these reforms aimed to formalise the evolution and improvement of the system since the last significant statutory change in 2012. I exhibit the White Paper 'Integration and innovation: working together to improve health and social care for all' as **WV/25 [INQ0012875]**.

109. The 2022 Act supports local flexibility and autonomy by creating significant space for local leaders to design and develop the right arrangements for their areas. The legislation sets a minimum expectation in some elements to ensure consistency

where that is helpful, such as requirements around the need for certain members of an ICB.

110. A number of features of the existing system have persisted over many years, but over time there have been different emphases on ways of securing improvement. However, with every legislative change the Department aims to ensure that the statutory framework remains coherent. In order to ensure that policy initiatives, primary and secondary legislation, and the work of ALBs in the health service operate effectively together the healthcare system relies upon a clear strategic direction set by the Secretary of State through the mandate to NHSE. Ministers set out high-level strategic priorities through the mandate to NHSE and NHSE's annual planning guidance shapes system planning in ICBs. The Secretary of State keeps progress against the mandate under review, setting out her views in an annual assessment which is laid in Parliament and published.

111. System-level accountability is critical to overseeing the performance of the system when issues have to be addressed by more than one organisation. It is also important to hold individual organisations to account for their performance and their delivery of their statutory duties. NHSE is now responsible for holding to account NHS providers (NHS Trusts and NHS Foundation Trusts) and ICBs – both for their performance and ensuring they meet their statutory duties. NHSE therefore plays a key role in ensuring that the oversight, regulation and support of individual providers continues to be done well and is undertaken in a complementary way to the oversight of systems. Local authorities, who contribute to the work of integration led by the ICS, are not accountable to NHSE but to their local electorate and to the Secretary of State for Levelling Up, Housing and Communities.

112. A corollary of the new emphasis on integration is that s.46B of the 2008 Act (as inserted by the 2022 Act) places a new duty on the CQC to review and assess the performance of ICSs in respect of the provision of relevant health care and adult social care within the area of each ICB. The CQC will review and assess ICSs, with the Secretary of State setting the objectives and priorities for these reviews which must include the quality and safety of services, integration of services and leadership.

113. At a system level, the Health and Care Act 2022 requires ICPs (committees of ICBs designed to bring together local government and stakeholders including voluntary and community services) to set out an integrated care strategy for addressing the health and care needs of their area for five years. The ICBs must have regard to that strategy when exercising their functions including in developing their commissioning priorities in their annual Joint Forward Plan. These arrangements reflect the relationships between good health and care outcomes and factors beyond the health and care system – such as housing, education and the local economy. It also reflects the importance of good health and care for the wider wellbeing and prosperity of those living within the ICS footprint.

114. The Health and Care Act 2022 simplified the mechanism by which commissioners and those delivering health and care services coordinate services. NHSE are working to support ICBs to share their best practice. At a local authority level, Health and Wellbeing Boards have duty to formulate Local Health and Wellbeing Strategies, and five-year joint forward plans must set out the steps ICBs will take to implement these Joint Local Health and Wellbeing Strategies. In developing these strategies Health and Wellbeing Boards are required to take account of the ICS and the joint Forward Plan, and in turn the ICB and ICP must involve the Health and Wellbeing Board when preparing or revising these plans. The Act also imposes a number of duties on ICBs to listen to and engage with local people, and NHS England have produced comprehensive guidance on working with people and communities to complement this approach. This is one example of how the Department has designed and adapted new legislation in light of existing structures.

115. I set out in the section below developments in patient safety policy, and the Department's role in leading some of these changes.

Patient Safety: current procedures, policies and future initiatives

116. In what follows I first set out how patient safety policy has developed over time, including the key changes since 2012 (this includes the introduction of the NHS Patient Safety Strategy in 2019) and the background to these changes. I then seek to address patient safety in the specific context of maternity and neonatal care and

identify several specific initiatives seeking to improve the quality and consistency of care in these areas.

Developments in patient safety

117. Until around 1997, there was, in broad terms, less statutory oversight of quality and safety by Government bodies. High-profile cases of care failures (e.g. Bristol Royal Infirmary in 1998) led to the Government taking a more active approach from the late 1990s with the establishment of NICE in 1999 and the Commission of Healthcare Improvement (a predecessor of the CQC) in 2001.

118. The inquiries into Ayling, Neal, Kerr, Haslam and particularly Shipman highlighted in the 1990s and early 2000s, growing concerns about the efficacy of the UK's system of professional regulation. While Parliament did not approve all the reforms sought in the Health Act 1999, the Act did provide for arrangements through which changes to the operation and governance of the professional regulators could more easily be made through secondary, rather than primary legislation. Following the fifth report of the Shipman Inquiry in 2005, the Government published two reviews of professional regulation in 2006 in respect of medical professionals ('Good Doctors, Safer Patients' followed (which I exhibit as **WV/26 [INQ0012876]**) and non-medical professionals (which I exhibit as **WV/27 [INQ0012877]**). These included:

    a. measures to reduce the size of the councils governing professional regulators to ensure consistency and enable them to function effectively (see White Paper 'Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century' which I exhibit **WV/28 [INQ0012878]**);

    b. the abolition of arrangements through which health professionals elected members of governing councils;

    c. the abolition of professional majorities on governing Councils;

    d. the lowering the standard of proof from the criminal standard to the civil standard for panels assessing the evidence about professionals' conduct;

e. proposals for periodic revalidation of health professionals' registration to ensure that their behaviour and skills continued to meet the standards required; and

f. strengthening annual appraisal arrangements for doctors.

119. These measures were put in place through the Health and Social Care Act 2008, with the reforms to governance of the Councils paving the way for a period of reform in which the ground was laid for the implementation of revalidation processes the next decade. In 2011, the Government published a White Paper entitled 'Enabling Excellence' (exhibited as **WV/29 [INQ0012880]**), which set out further reforms to the regulators and sought to enable more flexible arrangements through which the regulators could respond more quickly to changing circumstances and to lessons learned from inquiries and investigations.

120. The serious failings at Mid-Staffordshire NHS Foundation Trust from 2005 to 2009 led to a sharp focus on reinforcing the whole regulatory regime, which had not detected and responded to early warning signs at the hospital. In response to the 2013 Mid-Staffordshire NHS Foundation Trust Public Inquiry report, the Government produced a comprehensive two-volume response setting out numerous measures designed to lead to an enhanced regulatory system for quality and safety in the NHS (which I exhibit as **WV/30 [INQ0012881]** and **WV/31 [INQ0012882]**). This included: the appointment of three Chief Inspectors to lead the CQC's regulatory approach in the three distinct sectors of the NHS, primary care and social care; greater emphasis on transparency including quarterly reporting by Trusts to the Ombudsman regarding complaints data and any lessons learned; a statutory duty of candour on providers to ensure patients are informed when things go wrong (see paragraphs 123, 141, and 237 below), and a professional duty of candour on individuals and the introduction of a new fit and proper person test for Board-level appointments (introduced in 2014: see paragraphs 250-256 below).

121. Following consultation in 2021 (the analysis of which was published in February 2023 (**exhibit WV/32 [INQ0012883]**)), the Government is currently preparing a series of statutory instruments for each professional regulatory body which seek to modernise their workings and give them the powers and flexibilities to make their systems fairer and faster and more effective in public protection.

122. I discuss below at paragraphs 234-244 the Government's responses to various inquiry reports which the present Inquiry has asked me to consider.

123. Since 2012, the Department has taken a number of measures aimed at raising patient safety standards and fostering a transparent safety culture across the NHS. I go on to discuss a number of these initiatives in more detail in what follows, however, in overview, these changes include:

a. A more intelligence-driven model of CQC regulation informed by ongoing monitoring of the safety and quality of care (introduced in 2021).

b. A statutory duty of candour (implemented across the NHS in 2014 as regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014) which is enforced by the CQC to ensure that providers of NHS services tell patients if their safety has been compromised in certain circumstances and, if so, to apologise. Professional regulators, such as the General Medical Council and the Nursing and Midwifery Council, also made the duty of candour a professional requirement for their registered members (since 2014). In December 2023, the Department announced that it would lead a review into the effectiveness of the statutory duty of candour for health and social care providers in England. The terms of reference for the review are published online (which I exhibit as **WV/33 [INQ0012885]**).

c. Enhancing legal protections for 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 Freedom to Speak Up Guardians across healthcare in England supported by a National Guardian to lead positive culture change in the NHS and make speaking up the norm.

d. Establishing the first Patient Safety Commissioner in 2022 to champion 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, continuing the work of the Healthcare Safety Investigation Branch ("HSIB"), which was established in 2017. I discuss the

introduction and role of these bodies in more detail in paragraphs 162-169 below.

f. Beginning to implement 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. I discuss the introduction and role of Medical Examiners in more detail in paragraphs 176-180 below.

124. 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 to replace the National Reporting and Learning System ("NRLS"). LFPSE will improve the recording and analysis of patient safety event information to speed up identification of risks (I address this in more detail in paragraphs 139-140 below).

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 (see paragraph 138 below).

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 (see paragraphs 136-137 below).

d. The Framework for Involving Patients in Patient Safety (2021) expected 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. Nominated 'Patient Safety Specialists' in all NHS organisations to oversee or lead on safety activities for their respective organisations.

f. A first-ever Patient Safety Syllabus 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. Level 1 'Essentials for patient safety' is intended for all NHS staff and Level 2 'Access to practice' is intended for those who have an interest in understanding more about patient safety and access the higher levels of training.

125. It is envisaged that existing structures and frameworks can be used to further cement these initiatives. Oversight bodies and regulators and the existing accountability frameworks play a key role in securing consistent improvements in patient safety across the field. The ICS structure encourages a more collaborative approach between the different bodies involved in the healthcare system and, being subject to assessment by the CQC in respect of the functioning of the system for the provision of relevant health care and adult social care, there are existing mechanisms in place to enable problems to be identified and support to be provided.

126. In addition, the new cross-ALB, multi-professional National Patient Safety Committee (the successor to the National Patient Safety Alerting Committee) plays a strategic role in considering existing national patient safety planning, response and improvement by national bodies to ensure join-up, consistency and no gaps in national patient safety systems. It aims to focus efforts on the most significant patient safety challenges in terms of the scale of harm and develop a nationally agreed operational process to improve cross-ALB responses to urgent patient safety issues.

127. Finally, the National Quality Board ("NQB") champions the importance of quality and drives system alignment of quality across health and care on behalf of NHSE, NHS Digital, the CQC, the UK Health Security Agency, NICE, the Office for Health Improvement and Disparities, the Department, Healthwatch England and the Health Services Safety Improvement Body. The NQB provides advice, recommendations and endorsement on matters relating to quality, and acts as a collective to influence, drive and ensure system alignment of quality programmes and initiatives.

Patient safety incident reporting

128. Ensuring efficient incident reporting is a key requirement to improving patient safety. Before I address patient safety in the specific context of maternity and neonatal services, I will first set out a general overview of the current framework for patient safety incident reporting. However, I should make it clear that the detailed expertise relating to the operation of this framework, the analysis and learning generated by it, and the current initiatives for ongoing change and further development, lies with NHSE and its National Patient Safety Team.

129. One of the drivers of the increased focus on patient safety reporting was lessons learned from the aviation industry. For example, in the US, the Aviation Safety Reporting System is central to the safety record of the airline industry. The benefits to safety in this context are well described and its successes were admired and thought to have useful application in healthcare. The Institute of Medicine, which is the American national, non-governmental, advisory scientific body for medicine (now the National Academy of Medicine), recommended adopting patient safety reporting as an approach to gain understanding on patient safety risks in hospitals through collecting safety reports and solutions.

130. Patient safety reporting began to exist internationally throughout healthcare such as the Advanced Incident Management System run by the Australian Patient Safety Foundation in South Australia and the Danish Patient Safety Database. In the UK (England), the National Patient Safety Agency established the NRLS in 2003.

131. The NRLS has been the largest single source of patient safety incident data in England and one of the largest such databases in the world. It was introduced to collect patient safety incident reports from frontline NHS staff and has seen year on year increases in reporting with over 2 million incidents now reported annually.

132. Acute hospitals, mental health services, community trusts, ambulance services and primary care organisations reported incidents to the NRLS where any patient could have been harmed or has suffered any level of harm. The level of harm experienced by the patient is recorded. In certain cases, it is mandatory for providers to report patient safety incidents to the CQC under the Care Quality Commission (Registration) Regulations 2009 (providers may fulfil this obligation by reporting their data to NRLS which the CQC can access). Other reporting is voluntary.

133. The vast majority of reported incidents are "no harm" (70%) or "low harm" (27%) events, but all represent opportunities to advance safety. 3% of events cause higher degrees of harm (including 0.3% resulting in severe harm and 0.3% in death).

134. The largely voluntary nature of reporting to the NRLS served to encourage openness and continual increases in reporting to facilitate learning from errors. Examples of the types of incidents voluntarily reported to the NRLS include instances of a patient slipping or falling while in a care setting, a patient developing a pressure ulcer, or an incorrect medication dosage being given to a patient.

135. The vast majority of NRLS data comes as a secondary use of what is already reported within providers' Local Risk Management Systems and used within hospitals to manage and respond to safety and other issues. The value of data collection nationally is the ability to undertake surveillance for new, emerging or under-recognised risks which might appear unique at a local level, but nationally can reveal important patterns.

136. A parallel system to NRLS, the Strategic Executive Information System ("StEIS"), has been operating as the main reporting mechanism under NHSE Serious Incident Framework ("SIF") of 2015 (I exhibit this as **WV/34 [INQ0012886]**). The SIF governs how safety incidents are investigated. It should be clear from the SIF that there is an obligation to report and to investigate serious incidents, including ones that lead to unexpected or avoidable death, or unexpected or unavoidable injury resulting in serious harm. The successor to the SIF is the Patient Safety Incident Response Framework or PSIRF.

137. In summary, NRLS and StEIS will be replaced by LFPSE for all providers when rollout of the new system is completed (rollout is ongoing). The current Serious Incident Framework will be replaced by the PSIRF in April 2024. The PSIRF is being implemented across the NHS to provide updated guidance on how providers should respond to patient safety incidents and how and when an investigation should be conducted. PSIRF promotes a proportionate approach for responding to patient safety incidents by removing the requirement of the SIF for repeated investigations of similar incidents that yielded limited new learning. Compassionate engagement of those affected by patient safety incidents (patients, families and staff) is a core element of the PSIRF.

138. NRLS data about incidents causing severe harm and death (approximately 10,000 a year) has to date been reviewed manually by a small group of clinicians to characterise new, emerging or under-recognised risks, and determine how they might be addressed. This has resulted in various actions, of which the most-high profile is the issue of a National Patient Safety Alert which instructs providers to take specific action by a set date to reduce risks (5-10 alerts are issued each year and non-compliance can lead to enforcement action by CQC). For every alert, around 20 other issues are managed through specialist networks, professional associations and industry partners. Data is also routinely shared with national organisations with responsibility for patient safety (e.g. CQC, MHRA and HSIB/HSSIB) who use it alongside other data to fulfil their statutory functions. Data is also shared with others (e.g. Royal Colleges to support speciality-specific learning with universities and research institutions) and via ad-hoc requests.

139. The aim of LFPSE is to provide a better centralised system to record information about patient safety events across all settings. LFPSE will significantly enhance the NHS's capabilities for processing and analysing records of patient safety events, building upon manual evaluation. LFPSE will allow:

    a. NHS organisations and staff to record details of patient safety events, and access their data to better understand local recording practices and culture, supporting local safety improvement work; and

    b. NHSE to scan more effectively and efficiently for new and under recognised risks, and to contribute insights to national learning initiatives.

140. LFPSE aims to make it easier for staff to report incidents and will use new technologies, such as Artifical Intelligence/machine learning, to provide more detailed analyses to support improvements.

141. A statutory responsibility for all NHS employees to make a report, in substance, exists. Under regulation 16 of the Care Quality Commission (Registration) Regulations 2009, regulated providers must notify the CQC of deaths that cannot be attributed to the course which that individual's illness or medical condition would naturally have taken if that individual was receiving appropriate care or treatment. In addition, regulated providers must notify the CQC of all specified incidents short of death that affect the health, safety and welfare of people who use services. The

definition of the incidents that must be reported is set out in regulation 18(2) and is both detailed and wide, but it encompasses serious injury. The notification requirements are not limited to injuries or death that might have been preventable. All providers must send their notifications directly to the CQC unless the provider is (relevantly) a health service body, local authority or provider of primary medical services and it has previously notified NHSE (i.e., using the NRLS). The CQC can prosecute for a breach of this regulation. Reports are not required to be made to the CQC if notification has been made to NHSE because data is already shared routinely between NHSE and the CQC in order to avoid providers having to make duplicate reports. Providers carrying out regulated activities within the independent sector, as well as within the NHS, may be subject to CQC regulation and thus to these obligations.

142. The reporting obligation under the Regulations to the CQC and also to NHSE is further underpinned by reporting requirements contained in the NHS Standard Contract. The NHS Standard Contract 2023/24 with Providers Service Condition 33 (Patient Safety) materially provides as follows at paragraphs 33.1 and 33.4:

> "33.1 The Provider must comply with the arrangements for notification of deaths and other incidents:
>
> > 33.1.1 to CQC, in accordance with CQC Regulations and Guidance (where applicable); and
> >
> > 33.1.2 to any other relevant Regulatory or Supervisory Body, any NHS Body, any office or agency of the Crown, or to any other appropriate regulatory or official body, in accordance with Good Practice and the Law; …"
>
> "33.4 The Provider must ensure that it is able to report Patient Safety Incidents to the National Reporting and Learning System and to any system which replaces it."

143. In addition, as noted above, there is a statutory duty of candour placed on health service bodies under regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This is a duty owed to patients and their families or carers rather than to a regulatory or similar body but, for regulated

healthcare staff, this duty of candour is underpinned by the requirements of their regulators. Whist this statement does not purport to set out an account of how each regulator addresses the issue of reporting matters relating to patient safety, the ethical guidance from regulators on this topic is unlikely to be limited to the issue of the duty of candour towards patients only. See, for example, the GMC's Guidance on 'Raising and acting on concerns about patient safety', which is focussed on patient safety concerns more broadly.

144. The statutory obligations outlined above are imposed on health service providers rather than directly on individual staff as employees. Providers are responsible for seeing that the statutory obligations are complied with in their organisations and are expected to have policies clarifying the operational requirements of the patient safety framework and Regulations which staff must adhere to.

145. The NHS Patient Safety Strategy (which aims to achieve continuous improvement in safety), the Learn from Patient Safety Events Service and the Patient Safety Incident Response Framework together represent a Safety Management System. For example, the new PSIRF requires both proactive and reactive approaches to safety, and balances resources dedicated to learning from patient safety events with those assigned to improvement. There is ongoing work to secure improvement in safety management. However, as I noted at paragraph 128 of this statement, the further development of policy proposals in this area is led by NHS England.

Patient safety in the context of maternity and neonatal care

146. 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 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 Government's ambition.

147. In November 2017 the 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: see the Government's 'Safer Maternity Care' report of November 2017 (**WV/35 [INQ0012891]**). In pursuit of this, a number of 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.

148. Following the concerns raised in the reports of the Ockenden Review of Maternity Services at the Shrewsbury and Telford Hospital NHS Trust and the Independent Investigation into maternity and neonatal services in East Kent, the Department introduced additional governance structures to drive forward improvement at a local and national level. I will discuss these reviews and the response to them in more detail in **Appendix B** and in the Department's review of the Inquiry's 'Review of Implementation of Recommendations from Previous Inquiries into Healthcare Issues' (**Appendix C**), but to provide an overview, they included:

    a. The Maternity and Neonatal National Oversight Group, chaired by Maria Caulfield MP, Minister for Mental Health and Women's Health Strategy. This group brings together key experts from across the maternity improvement programmes to drive forward improvement across maternity and neonatal services and oversee the implementation of recommendations from the Ockenden and Kirkup Reports and other maternity reviews.

    b. The Maternity and Neonatal New Actions Forum, chaired by Dr Bill Kirkup to lead action in relation to recommendations 2 and 3 of his report. Dr Kirkup is leading work with healthcare partners to help ensure teams in maternity and neonatal care across England can work together more collaboratively and to improve the culture, so the best quality, compassionate care is provided.

    c. A Regional Forum for East Kent, which brings together the NHS, the CQC and MPs of those who have been affected to facilitate information-sharing and updates.

149. 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.

150. The Department has further introduced a number of changes to the investigatory, reporting and review processes to improve patient safety in maternal and neonatal care which I discuss in more detail in the remainder of this section.

The Perinatal Quality Surveillance Model

151. In addition to the general reporting requirements described above, there are additional measures which apply where concerns are reported which relate to neonatal services and/or staff members in the context of those services.

152. Under the Perinatal Quality Surveillance Model developed by NHSE, all trusts are expected to report concerns relating to neonatal services to regional and national level groups (**WV/36 [INQ0012893]**). Concerns are then escalated by regional Perinatal Quality Surveillance Groups to the National Maternity Safety Surveillance and Concerns Group.

153. This reporting framework provides for consistent and methodical oversight of maternity services so that the system can proactively identify trusts that require support at an early stage before serious issues arise and provide the necessary support. The model is integrated into ICS structures so that each ICS has clear lines of accountability to address quality concerns as soon as they are identified.

154. In addition, all trusts are expected to have procedures in place to enable qualifying cases of neonatal death to be reported to the Maternity and Newborn Safety Investigations Programme (which I discuss below in paragraphs 162-169). The programme investigates cases of early neonatal death, which is defined as when a baby dies within the first week of life (i.e. days 0–6), from any cause.

The National Perinatal Mortality Review

155. 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.

156. The PMRT is delivered by the MBRRACE-UK/PMRT collaboration and funded in England by the Department. Broadly, the Department's expectation is for:

    a. The provision of a national web-based review tool for use by all maternity services to review all stillbirths and neonatal deaths that sets out questions and principles to support Trusts in providing a standardised review process; and

    b. The collation and analysis of the data inputted into the tool to produce annual national reports on the key themes arising from the reviews, and recommendations intended to improve safe maternity care and safe outcomes for babies.

157. The fifth annual PMRT report was published on 14 December 2023. The report and recommendations are considered by the Department and a summary of the report and recommendations is sent to Ministers. The reports enable the Department to further the aims of facilitating an objective, robust and standardised review process which provide answers to bereaved parents and facilitate local and national learning to improve care and prevent future deaths. Going forward, the Department will use the PMRT's annual reports to support its consideration of how to ensure greater independence to PMRT investigations and to inform policy development regarding the maternity investigatory landscape (as committed to in the Department's publication of its factual summary following a consultation on coronial investigations of term stillbirths, which I exhibit as **WV/37 [INQ0012894]**).

158. MBRRACE-UK also provides valuable intelligence on the use of the PMRT to the National Perinatal Safety Surveillance and Concerns Group discussed in paragraphs 151-154 above 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 incentivised. Safety Action One asks that Trusts use the National PMRT to review perinatal deaths to the required standard.

The Maternity Services Dashboard

159. The Maternity Services Dashboard brings together maternity information from a range of different sources. The dashboard was developed by NHSE (and NHSI) in partnership with NHSD to help local maternity systems track, benchmark and improve the quality of maternity services. The dashboard enables clinical teams in maternity services to compare their performance with their peers on a series of Clinical Quality Improvement Metrics ("CQIMs") and National Maternity Indicators ("NMIs"), for the purposes of identifying areas that may require local clinical quality improvement. The CQIMs are sourced from the Maternity Services Dataset (MSDS) and are published on a monthly basis. NMIs are annually published indicators drawn from external data sources such as the National Maternity and Perinatal Audit, MBRRACE-UK, CQC Maternity Survey, NHS Staff Survey and the GMC Survey. These indicators have been selected to provide a holistic picture of the performance of maternity services and cover five different domains including mortality and morbidity, choice and continuity of carer, clinical care and health promotion, organisational culture and user experience. The dashboard also shows descriptive statistics and demographic data (sourced from MSDS), which provides a profile of the maternity population and activity within a given provider. This includes data on, for example, number of bookings, deliveries and births, maternal age, BMI and ethnicity.

160. The MSDS is an administrative dataset used by providers of maternity care in England for clinical purposes. It is submitted to, analysed and published by NHS Digital on a monthly basis, (now part of NHSE) in order to build a national picture of maternity services activity in that month. The MSDS information captured from NHS-funded maternity services provides reliable information for local and national monitoring, reporting for effective commissioning, monitoring outcomes and addressing health inequalities.

161. The Department frequently accesses Maternity Services Data Set outputs and the Maternity Dashboard as part of its oversight of maternity services, in particular to monitor underlying factors which influence the National Maternity Safety Ambition.

The Maternity and Newborn Safety Investigations Programme, HSIB and HSSIB

162. The Maternity and Newborn Safety Investigations Programme was originally part of the Healthcare Safety Investigation Branch ("HSIB"), itself established in 2016 as an organisational arm of the Trust Development Authority (under Secretary of State Directions given to the TDA and later transferred to NHS England), following recommendations to set up an independent organisation to investigate patient safety incidents and concerns in NHS funded care across England with a specific focus on system-wider learning and improvements. The HSIB's remit was to carry out a small number (up to 30) of national investigations each year to identify the contributory factors that led to harm (or the potential for harm) to patients and make recommendations to improve healthcare systems and processes (rather than determine individual blame or liability) to reduce risk and improve patient safety.

163. Recommendation 23 of the Morecambe Bay Investigation Report called for clear standards to be drawn up for incident reporting and investigation in maternity services, including the mandatory reporting and investigation of serious incidents of maternal deaths, late and intrapartum still-births and unexpected neonatal deaths. From April 2018, HSIB became responsible for a specific subset of local NHS maternity investigations relating to intrapartum stillbirth, early neonatal death, or severe brain injury diagnosed in the first seven days of life and also maternal deaths.

164. Part 4 of the Health and Care Act 2022 provided for the establishment of a new statutory independent arm's-length investigating body called the Health Services Safety Investigations Body ("HSSIB") with powers and independence to:

    a. Conduct investigations into incidents that occur during the provision of healthcare provided in NHS services and by the independent sector and have or may have implications for the safety of patients. Investigation reports will make recommendations and require organisations to publicly respond to these measures, within a specified timescale.

    b. Prohibit disclosure of information held by the HSSIB in connection with its investigatory function save in limited circumstances set out in the Health and Care Act 2022 to create a 'safe space' whereby participants can provide information to the HSSIB in confidence for the purposes of an investigation.

c. The HSSIB will provide advice, guidance and training to organisations to improve the standard and quality of investigations and to encourage the spread of a culture of learning within the NHS.

d. A power has also been introduced to enable the Secretary of State to direct the HSSIB to investigate particular qualifying incidents or groups of qualifying incidents.

165. As a result, all of the HSSIB's investigations are carried out within a safe space, with material protected accordingly. Investigations conducted by the Maternity and Newborn Safety Investigations Programme do not follow safe space principles, have a different purpose and investigatory process and are looking to achieve different outcomes, and it was therefore determined that HSSIB would not be the appropriate body to conduct such investigations. The HSSIB also provides advice, guidance, and training to NHS bodies, upon request.

166. The CQC took over responsibility for HSIB's work on the safety of maternity services in October 2023, which coincided with the establishment of the HSSIB. Ministers determined that the most appropriate and streamlined mechanism for delivering independent maternity investigations would be for the function to sit within and be hosted by the CQC. As of 1 October 2023, the programme became known as the Maternity and Newborn Safety Investigations ("MNSI") programme and is now hosted by the CQC.

167. The maternity investigations 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.

168. The Department expects the programme to investigate all qualifying cases referred to it, in line with the Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023 (which I exhibit as **WV/38 [INQ0012895]**). When the programme sat within the HSIB, the Department received regular updates and an overview of the programme's work through the HSIB Quarterly Accountability Review. Since transition to the CQC in October 2023, this information will be fed back to the Department as part of the CQC Quarterly Accountability Review updates.

169. The Department has commissioned a process evaluation of maternity investigations and review tools through the National Institute for Health and Care Research which will explore whether the Maternity and Newborn Safety Investigations programme has met its anticipated requirements and resulted in system level quality improvements in maternity care and improved outcomes for parents and families. The evaluation is expected to conclude in December 2024.

The Neonatal Critical Care Review (2019)

170. 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 (**WV/39 [INQ0012896]**). The review highlighted 10 actions for focus and investment. Local implementation plans have been developed by NHS England Regional Teams in response to the NCCR and implementation of these plans is routinely reviewed at a national level by the Neonatal Implementation Board. The following progress has been made against the NCCR actions:

    a. Action 1: Review and Invest in Neonatal Capacity – in 2022/23 £**I&S** capital was allocated across a number of providers to deliver an overall increase of more than 50 cots. The schemes are being implemented over the spending review period up until March 2025.

    b. Action 2: Develop Transport Pathways – good progress is being made. A number of regions have invested in and/or reconfigured their transport services to improve their performance.

    c. Action 3: Develop the Neonatal Nursing Workforce – funding in the Long Term Plan between 2021/22 and 2023/24 provided c£**I&S** to support the recruitment of over 550 cot side neonatal nurses, network level Education and Workforce roles and provider-based nurse clinical governance and quality roles.

    d. Action 4: Optimise Medical Staffing – further investment was made available in 2023/24 and specifically targeted at increasing medical staffing to address medical staff shortfalls on rotas in Local Neonatal Units to meet British Association of Perinatal Medicine standards and to make provision in medical

staff time for core safety and clinical governance work. This investment is £I&S in 2023/24 with a full year effect of £I&S in 2024/25.

e. Action 5: Develop Strategies for the Allied Health Professionals ("AHPs") – within the Long Term Plan funding there was an allocation for network level AHPs to support the development of strategies. Further funding (c£I&S for 2023/24 also enabled the recruitment of cot side AHPs.

f. Action 6: Develop and Invest in Support for Parents – all the Operational Delivery Networks have a network level Care Coordinator role. There are a large number of providers where the accommodation and facilities for parents are limited and/or inadequate. The Care Coordinators are completing a stocktake of the gaps and looking at options to improve access. The capital implications of any building works required to secure the improvements will need to be considered.

g. Action 7: Develop Local Implementation Plans – all regional teams are required to have a local NCCR implementation plan. The plans will be refreshed to take account of the recently published 3 Year Delivery Plan for Maternity and Neonatal Services; bringing together all the priorities for both services post the Ockenden and East Kent reviews.

h. Action 8: Ensure neonatal services are integrated into maternity planning – all regional commissioning teams and Neonatal Operational Delivery Networks ("ODNs") are working on the collaborative relationship with maternity leads. Local Maternity Systems have evolved into Local Maternity and Neonatal Systems. There are challenges in a number of areas where there are multiple LMS footprints and one ODN needs to try and attend all the different groups. At a national level the specialised commissioning Director lead for neonatal services, the National Specialty Advisor and the national Neonatal Nurse Lead are all active members of the weekly Maternity and Neonatal Leadership Group meetings. The Maternity Transformation programme has been refocused to become the Maternity and Neonatal programme.

i. Action 9: Establish national infrastructure to oversee implementation – the Neonatal Implementation Board meets bimonthly to review progress on the NCCR actions. The Board is jointly chaired by the national specialised

commissioning Director lead, and the National Speciality Advisor. The Board is part of the Maternity and Neonatal Programme governance structure and contributes to all the other groups in that structure.

j. Action 10: Establish national reporting of regional outcomes – there are multiple data sources and data flows on neonatal activity and outcomes. There needs to be a review of all the data flows to streamline the number of data sources and the burden of data inputting for clinical teams. A specific project will need to be established to undertake this work.

The child death review process

171. 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. Responsibility for delivery was given to Local Safeguarding Children Boards ("LSCBs"). If areas had a population of 500,000 or more, they had to establish a Child Death Overview Panel ("CDOP") and implement a process for investigation in all cases of children who have died suddenly and unexpectedly.

172. Statutory guidance for the process was set out within the 'Working Together to Safeguard Children' guidance and a set of statutory forms were produced to assist LSCBs with data collection and to give panels as much information as possible to review each death.

173. In 2016 a review into the role and function of LSCBs recommended that the Department of Health should be the sponsoring department, and a national database to collate the information gathered by CDOPs should be established.

174. Following a consultation on revisions to the statutory guidance held in 2017, a revised version of the Working Together to Safeguard Children guidance was produced which reflected the broad multi-agency nature of child safeguarding, placing obligations on local authorities, the police, and CCGs (as they then were). The 2018 guidance introduced changes which provided those three key agencies with the freedom to develop local multi-agency safeguarding arrangements in line with the needs of their local area in light of the removal of the statutory requirement

for LSCBs. It also outlined statutory changes in the Child Death Overview Process reflecting that the statutory responsibility for such reviews will lie with CCGs (as it then was) and local authorities.

175. Alongside this, Child Death Reviews Statutory and Operational Guidelines were introduced: see the Child Death Review Statutory and Operational Guidance (England) issued in October 2018 (**WV/40 [INQ0012899]**). This guidance assists the professionals responsible for commissioning and delivering the child death review process and aims to reduce variability of practice between CDOPs to enable a more consistent approach. In April 2018, the National Child Mortality Database was commissioned to identify patterns in child deaths, and preventable action to reduce preventable child mortality in England by the Healthcare Quality Improvement Partnership ("HQIP") on behalf of NHSE. The Department for Education retained responsibility for the Working Together to Safeguard Children guidance and the 2018 guidelines were jointly issued by the Department for Education and DHSC. However, the responsibility for child death review policy specifically, which previously lay with the Department for Education, transferred to DHSC in July 2018.

Medical Examiners

176. Medical examiners were introduced initially in a non-statutory capacity in medical examiner offices hosted by NHS acute trusts. The required amendment to the Coroners and Justice Act 2009 has been made through the Health and Care Act 2022, to host medical examiners in England in NHS bodies rather than local authorities. The operational implementation of the medical examiner system is the responsibility of NHSE but DHSC is the lead department for the cross-government programme of death certification reform, DHSC are working closely with NHSE, the National Medical Examiner, the Ministry of Justice and Government Registry Office.

177. The central aims of the medical examiner system are to:

    a. Provide a service to the bereaved, increasing transparency and offering them the opportunity to raise concerns;

    b. Enhance patient safety by ensuring that all non-coronial deaths are scrutinised by an independent medical examiner;

c. Support the appropriate direction of deaths to the coroner; and

d. Contribute to improvement of the quality of death certification.

178. Medical examiner scrutiny extends to all non-coronial deaths and so includes neonatal deaths, however, it is not a replacement for other child death review processes. Medical examiners complete independent scrutiny before a non-coronial death can be registered as they will not have been involved in care of the child prior to death.

179. The National Medical Examiners report for 2021 indicated that, as of 31 December 2021, 1,427 senior doctors had completed medical examiner training and 330 staff had completed medical examiner officer training, with further training of both elements planned. The Royal College of Pathologists, the lead Royal College for medical examiners, has worked with NHSE to publish a series of good practice papers, including papers on child deaths, and escalating thematic issues (exhibited as **WV/41 [INQ0012900]** and **WV/42 [INQ0012903]** respectively).

180. The importance of death certification and the introduction of medical examiners has been underlined in numerous reports and inquiries since the original recommendation in the Shipman Inquiry's third report which highlighted the need for patterns of deaths to be better identified. Subsequent inquiries including the second volume of the report of the Mid Staffordshire NHS Foundation Trust Public Inquiry, the Morecambe Bay Investigation and 'Learning from Gosport' report all emphasised the importance of these mechanisms. 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. Under these reforms, all deaths will become legally subject to either a medical examiner's scrutiny or a coroner's investigation. The draft regulations were published on 14 December 2023.

<u>The roles and expectations of the Department and other ALBs in the implementation of relevant policies and procedures</u>

How the Department supports the amplification of patient concerns across the health system

181. The NHS Constitution states that the NHS is accountable to the public, communities and patients that it serves. To be accountable, the Department must work in partnership with those who use health services as well as the various bodies involved in the provision of care, to understand what the needs and concerns of patients truly are. As part of this, the Department is subject to a statutory duty under the 2006 Act to consult Healthwatch England (a committee of the CQC and statutory champion for patient and social care user views) on the objectives set in the NHSE Mandate. This helps ensure that the central aims pursued are informed by the needs, experiences and concerns of those people who use the health service.

182. Healthwatch is the independent national champion for people who use health and social care services. Its purpose is to understand the needs and experiences of health and social care users and speak out on their behalf. Healthwatch consists of:

    a. Healthwatch England; and

    b. Over 150 Local Healthwatch organisations commissioned by Local Authorities.

183. Local Healthwatch's role is to find out what people want from their local health and social care services, and to share these views with those running services to help improve them. Local Healthwatch also provide information and advice to the public. Local Authorities have a legal duty to ensure that an effective Local Healthwatch is operating in their area and Local Healthwatch's are accountable to their Local Authority. The Department provides grant funding to Local Authorities each year to support them to discharge their legal duty to commission a Local Healthwatch in their area.

184. Meanwhile Healthwatch England is a statutory committee of the CQC. It provides leadership and support to Local Healthwatch organisations but has separate statutory functions, which include escalating concerns and providing advice about health and social care services. As a committee of the CQC, Healthwatch England is hosted within that organisation and its chair is a Non-Executive Director of the CQC's Board, appointed by the Secretary of State. The Department meets quarterly with Healthwatch England. Healthwatch England periodically produce reports on specific topics that they have identified as being important to health and social care users. These reports typically draw together user views and often make recommendations for action. Healthwatch England also produce an annual report,

which sets out their activity and progress over the last year as well as a forward look of priorities over the forthcoming year.

185. The Department has published health overview and scrutiny committee principles, which state the primary aim of health scrutiny is to strengthen the voice of local people and provide local accountability (exhibit **WV/43 [INQ0012904]**). As such, local government Health Overview and Scrutiny Committees ("HOSCs") "…should ensure that local people's needs and experiences are considered as an integral part of the commissioning and delivery of health services, and that those services are effective and safe." HOSCs are a fundamental way for democratically elected local councillors to voice the views of their constituents, hold the whole system and relevant NHS bodies and relevant health service providers to account and ensure that NHS priorities are focused on the greatest local health concerns and challenges.

186. Through inspections and monitoring, the CQC checks whether the essential requirements for safety and quality are being met. In the most recent strategy the CQC commits to deliver regulation 'driven by people's needs and experiences of care'.

187. More recently in 2018 Baroness Cumberlege's Independent Medicines and Medical Devices Safety Review was commissioned by the Secretary of State to focus on how well the healthcare system listen and responds to patients and public views with particular respect to specific medicines and devices. The report was published in 2020. The report was clear in its finding that the healthcare system failed to listen to patients' concerns on the issues covered by the review (harm caused by sodium valproate, primodos and pelvic mesh). In response to a key recommendation made in the review, the DHSC legislated in the Medicines and Medical Devices Act 2021 for the post, and then appointed Dr Henrietta Hughes in 2022 as England's first ever Patient Safety Commissioner in England with a core role is to promote the safety and views of patients and the public in relation to medicines and medical devices.

188. Measures such as the introduction of a new Patient Safety Commissioner to promote the safety of patients and the importance of their views in the context of the use of medicines and medical devices provide direct mechanisms to amplify the concerns of patients within the healthcare system.

189. In terms of broader legislation, reforms to the legislative framework bringing integrated care to the fore have re-enforced the importance of patient involvement. Under the Health and Care Act 2022, each ICB has a duty to "promote involvement of each patient…in decisions which relate to the prevention or diagnosis of illness in the patients or their care or treatment."

Investigating neonatal deaths and the wider safeguarding of babies in hospitals

190. In the above, I addressed a number of initiatives relevant to the investigation of neonatal deaths. In respect of these:

    a. The child death review process: since July 2018, the Department assumed responsibility for child death review policy from the Department for Education.

    b. The Maternity and Newborn Safety Investigations programme: the Department developed the directions that govern the MNSI programme. The programme is hosted by the CQC. The Department holds the CQC to account by seeking assurance that it is delivering its statutory functions, which includes the delivery of the MNSI programme.

    c. The Perinatal Mortality Review Tool ("PMRT"): The PMRT is commissioned by HQIP on behalf of the Department and the Welsh and Scottish governments. The PMRT is delivered by the MBRRACE-UK/PMRT collaboration and the Department's expectations of the tool are set out in the contract between the Department and the HQIP. The tool is commissioned by the Department in order to enable and facilitate its use by Trusts, though its use is not mandated. The PMRT is delivered by the MBBRACE-UK team at the National Perinatal Epidemiology Unit in Oxford and they have produced a wide range of resources available to support the use of the tool.[8]

Escalating concerns

191. In response to a recommendation of Sir Robert Francis KC in his 'Freedom to Speak Up Review', the Government established an independent National Guardian to help

[8] The tool can be found at https://www.npeu.ox.ac.uk/pmrt/implementation-support.

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.

192. Workers who want to speak up can also receive support from Speak Up Direct, a service the Government has set up to provide workers with advice and support about speaking up. Support is available online or via a telephone helpline.

193. The Department provides funding to and sponsorship of organisations who play a direct role in escalating concerns, including the CQC, the National Guardian's Office and NHS England.

194. The CQC monitor and assesses NHS organisations and has a Freedom to Speak Up quality statement against which NHS organisations are assessed which reads: "We foster a positive culture where people feel that they can speak up and that their voice will be heard." CQC's monitoring against this quality statement includes looking at speaking up cultures, raising of concerns and Freedom to Speak Up Guardians.

195. One of the core functions of the National Guardian's Office is to lead, train and support the network of Freedom to Speak Up Guardians. This includes: providing a structured training programme, which all Guardians must complete; running a series of networks for Guardians that provide peer-to-peer support and learning; providing support for Guardians in their roles through things like fortnightly bulletins, monthly newsletters, webinars and an annual conference; collecting and publishing data from Guardians about the state of the Guardian role and the speaking up cases that are being brought to Guardians; providing a range of resources to develop Guardians, such as guidance, information on the Guardian role and case studies. The National Guardian's Office also aim to drive improvements in the NHS through initiatives such as providing e-learning (called 'Speak Up, Listen Up, Follow Up') for anyone who works in healthcare that aims to help learners understand the role they can play in a healthy speaking up culture; and undertaking 'Speak Up reviews' which seek to identify learning, recognise innovation and support improvement, and,

ultimately, improve the experience of workers, patients, and the public (see exhibit **WV/44 [INQ0012906]**).

196. In respect of Freedom to Speak Up Guardians, NHSE is responsible for the NHS Standard Contract which requires all organisations that provide services under the NHS Standard Contract to appoint a Freedom to Speak Up Guardian. NHSE are also responsible for:

    a. The national Freedom to Speak Up policy for the NHS (see exhibit **WV/45 [INQ0012907]**). This policy provides the minimum standard for local freedom to speak up policies across the NHS, so that those who work in the NHS know how to speak up and what will happen when they do. NHS organisations were asked to adopt this policy by 31 January 2024.

    b. Providing Freedom to Speak Up Guidance for leaders, which is designed to help senior leaders in NHS organisations who provide services to the NHS develop a culture where leaders and managers encourage workers to speak up and where matters raised by workers drive learning and improvement.

    c. Providing a Speaking Up Support Scheme, which offers a range of support for past and present NHS workers who have experienced a significant adverse impact on both their professional and personal lives, to move forward, following a formal speak up process (see exhibit **WV/46 [INQ0012908]**).

Whistleblowing

197. The Employment Rights Act 1996 (as amended by the Public Interest Disclosure Act 1998) protects workers against detrimental treatment on the grounds that a person has made a 'protected disclosure.' In 2018, the Government enhanced legal protections available for whistle-blowers to prohibit discrimination against job applicants on the grounds that they have spoken up in the past through new regulations which prohibit certain NHS employers from discriminating against job applicants because it appears to the employer that the applicant has made a protected disclosure.

198. The Department, NHSE and all other ALBs have whistleblowing policies and procedures in place that comply with the Public Interest Disclosure Act 1998 and

best practice guidance. The Act prohibits the use of confidentiality clauses that seek to prevent staff from speaking out on issues of public interest.

199. Within this legal framework:

a. The Department is a 'prescribed person' in respect of matters relating to the provision of public health services. Prescribed persons have a particular role in the whistleblowing process, which is to provide workers with a mechanism to make their public interest disclosure to an independent body where the worker does not feel able to disclose directly to their employer and the body might be in a position to take some form of further action on the disclosure (I exhibit this as **WV/47 [INQ0012909]**).

b. The CQC is a 'prescribed person' in respect of matters relating to the provision of health and social care.[9]

c. The National Guardian's Office is a 'prescribed person' in respect of matters concerning the freedom to speak up arrangements and cultures in the NHS in England, including where cases of issues raised by workers may not have been handled in accordance with good practice.

d. NHSE is a 'prescribed person' in respect of the regulation and performance of English NHS Trusts and Foundation Trusts; matters relating to the delivery of primary medical, dental, ophthalmic and pharmaceutical services in England; matters relating to the licensing and oversight of providers of NHS health care services; and matters relating to NHS England's oversight and support of England's integrated care boards pursuant to its functions under the National Health Service Act 2006.

Complaints

[9] By the Public Interest Disclosure (Prescribed Persons) Order 2014 the CQC is a prescribed person for the purposes of matters relating to: (a) the registration and provision of a regulated activity as defined in s.8 of the Health and Social Care Act 2008 and the carrying out of any reviews and investigations under Part 1 of that Act; or (b) the functions exercised by the Healthwatch England committee, including any functions of the Care Quality Commission exercised by that committee on its behalf; or (c) any activities not covered by (a) or (b) in relation to which the Care Quality Commission exercises its functions.

200. Anyone has the right to make a complaint about any aspect of NHS care, treatment or service. More information on how to make a complaint about NHS services is available online at https://www.nhs.uk/using-the-nhs/about-the-nhs/how-to-complain-to-the-nhs/ (exhibit **WV/48 [INQ0012910]**).

201. The NHS complaints system is underpinned by the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009, which set out the requirements on providers in relation to complaint handling. This system applies to neonatal services in the same way as other complaints.

202. A complaint about service provision may be made to either the service provider or the commissioner of the service. The first step is normally to raise the matter (in writing, electronically, or orally) with the service provider or with the commissioner of the service. If local resolution is unsuccessful, the complainant has the right to refer their complaint to the Parliamentary and Health Service Ombudsman, who will make their decision on whether to take the complaint forward.

203. If complainants need assistance in making a complaint, officers from the Patient Advice and Liaison Service ("PALS") are available in most hospitals. Additionally, assistance can also be provided by the Independent NHS Complaints Advocacy Service.

204. The Department's role in the NHS complaints system comprises the following:

    a. Responsibility for the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. These Regulations set out the statutory framework for complaint handling by NHS bodies (and local authorities in relation to their social services functions).

    b. Responsibility for the provisions in s.223A of the Local Government and Public Involvement in Health Act 2007 which require local authorities to make arrangements for the provision of an Independent Complaints Advocacy Service for their area. This provides help to people making, or thinking about making, a complaint, including help writing a complaint letter or attending meetings.

    c. Provision of funding to local authorities for the Independent Complaints Advocacy Service, which is administered as part of the Local Reform and

Community Voices Grant – an annual grant provided to Local Authorities by the Department.

205. Ministerial responsibility for patient complaints over the last 10 years has sat with the following individuals:

a. Maria Caulfield MP (October 2022 – present);

b. Caroline Johnson MP (September 2022 – October 2022);

c. Maria Caulfield MP (September 2021 – September 2022);

d. James Morris MP (July 2022 to September 2022);

e. The Rt Hon Nadine Dorries MP (July 2019 – September 2021);

f. Jackie Doyle-Price MP (June 2017 – July 2019);

g. Philip Dunne MP (July 2016 – January 2018);

h. The Rt Hon Ben Gummer MP (May 2015 – July 2016);

i. Sir Norman Lamb MP (September 2012 – May 2015).

206. In respect of other ALBs relevant to the complaints process:

a. Regulation 16 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires NHS providers to have an effective and accessible system for identifying, receiving, recording, handling and responding to complaints from people using the service, people acting on their behalf or other stakeholders.

b. When requested to do so, under Regulation 16(3), providers must provide the CQC with a summary of complaints, responses and other related correspondence or information when requested to do so and by no later than 28 days beginning on the day after receipt of the request. The CQC can also prosecute providers for a breach of Regulation 16(3). In addition, the CQC may take any other regulatory action in response to breaches of this regulation and must refuse registration if providers cannot satisfy the CQC that they can and will continue to comply with this regulation.

c. NHSE provides guidance and information to the public on the NHS complaints system, including how to complain, who to complain to, what to expect, and

how to get help. Because NHSE is the commissioner of some NHS services (and because the NHS complaints system allows complainants to complain to the commissioner), NHSE itself also handles and responds to some complaints about NHS services.

207. The Department does not hold information or records detailing how many times neonatal units have conducted investigations into complaints or how many of those complaints have been upheld. That information sits with the investigating body, typically NHS Trusts, and would not normally be shared with the Department unless it were to be specifically requested through NHSE.

The Department's role in the development of policies, procedures, guidance and training pertaining to the safeguarding of babies in hospitals

208. The Department does not lead on neonatal care, which instead sits within NHSE. Ngzoi Edi-Osagie has recently been appointed as the National Clinical Director for Neonatology and Louise Weave-Lower is the National Neonatal Nurse Lead. The role of the Department is one of policy and oversight.

209. In respect of policy, as I have explained above, the Department has a significant role in policy at a high-level, including by setting the NHS Mandate. In respect of oversight, the Department's mandate to NHS England sets out an expectation that NHS England should continue to work with the NHS and other partners on improving patient safety, quality of care and health outcomes, including through the 3-year delivery plan for maternity and neonatal services to deliver safer, more personalised, and more equitable care. The Department oversees NHS England's work in relation to maternity through representation at the Maternity Programme's Governance Board. NHSE also provide updates to the Minister on maternity and neonatal care through the Maternity and Neonatal National Oversight Group.

210. The NHS and all partner organisations also came together in 2016 to form the national Maternity Transformation Programme, now the Maternity Programme, discussed in paragraph 146 above. The implementation of this, including through the published three-year delivery plans, lies mainly with NHSE. The work is informed by reviews including the Neonatal Critical Care Transformation review, also

conducted by NHSE (see 'Implementing the Recommendations of the Neonatal Critical Care Transformation Review' which I discussed in paragraph 170 above).

211. Although of wider import than the safeguarding babies in hospitals / trust settings, the Department also supports the Department for Education in producing the Government's statutory guidance Working Together to Safeguard Children (as discussed in paragraphs 172-175 above). This guidance applies to NHS organisations and agencies and the independent sector, including NHSE and ICBs, NHS Trusts, NHS Foundation Trusts and General Practitioners.

212. This guidance cross-references the intercollegiate guidance on roles and competencies for healthcare staff (see exhibit as **WV/49 [INQ0012911]**), which the Royal College of Midwives and RCPCH (among others) supported. It also cross-references NHSE's accountability and assurance framework, which sets out how NHSE assures that the NHS is delivering its responsibility relating to safeguarding children, young people and adults at risk (see exhibit as **WV/50 [INQ0012912]**). These documents set out the expectations about competence relating to child safeguarding for all healthcare staff.

Evaluating the developments in patient safety

213. As part of its role in implementing and overseeing the patient safety initiatives outlined above, NHSE conduct statistical analysis to consider the impact and success of these measures.

214. The Patient Safety Strategy, introduced in 2019, set the target of saving 1,000 lives and £ **I&S** per year. While recognising that the reasons that patient safety incidents occur are often complex and may result from an interplay of factors, NHSE estimates from June 2023 indicate that the work delivered under the Strategy is at least halfway to achieving that aim, with significant numbers of lives saved and harms avoided including due to improvements in medication safety and the care of pre-term infants (see exhibit **WV/51 [INQ0012914]**).

215. In respect of maternity and neonatal care, the National Maternity Safety Ambition aims to halve the 2010 rates of stillbirths, neonatal and maternal deaths and brain injuries occurring during or soon after birth by 2025. The interim ambition sought a

20% reduction in these rates by 2020. In 2017, an additional ambition to reduce the pre-term birth rate from 8% to 6% was also introduced.

216. The latest data indicates that good progress has been made against several elements of the ambition: since 2010, the stillbirth rate has reduced by 23%, and the rate of neonatal mortality has reduced by 30%. The rate of brain injuries occurring during or soon after birth is 2% lower than the 2010 baseline, and the pre term birth rate has reduced from 8% of all births in 2017, to 7.7% in 2021. There has however been a 26% increase in the maternal death rate. I exhibit the DHSC Annual Report and Accounts 2022-23 (for the period ended 31 March 2023) as **WV/52 [INQ0012915]**.

The Countess of Chester Hospital

217. The Countess of Chester Hospital is managed by the Countess of Chester Hospital NHS Foundation Trust. In 2004, it became one of the first Foundation Trusts to be established via the new regime for Foundation Trusts.

Background

218. I have set out above the relevant oversight mechanisms. In summary: NHSE has responsibility for managing the delivery of NHS services through local, regional, and national arrangements and the Department holds NHSE to account for this. As part of these arrangements, the Department has regular formal and informal communication (at all levels) with NHSE about NHS performance. The NHS' Oversight Framework which I exhibited in paragraph 58 above (**WV/16 [INQ0012864]**) outlines NHSE's approach to oversight of ICBs, NHS Trusts and NHS Foundation Trusts and is aligned with the ambitions set out in the NHS Long Term Plan and the NHS operational planning and contracting guidance.

219. Foundation Trusts are able to make some decisions around finance, appointments and setting up subsidiaries that are not open to a Trust. Unlike a Trust, a Foundation Trust cannot be directed by the Secretary of State or NHSE about the exercise of its functions. For Foundation Trusts, NHSE use the NHS provider licence (which has been in place since 2013) to set conditions that providers of NHS-funded healthcare

services must meet. A provider licence was introduced for independent providers in 2014. Following commencement of s.51 of the Health and Care Act, in April 2023, NHS Trusts are now required to hold a licence (previously NHS Trusts were held to equivalent standards as NHS Foundation Trusts via the 'shadow' licence). NHSE monitors and enforces the compliance of Foundation Trusts with the conditions of their provider licence.

220. The Department has formal and informal communication with ICBs. Formal oversight and accountability of ICBs and their performance is discharged with and through national and regional teams of NHSE. The Government takes an active interest in the progress of ICSs, and Ministers and officials will on occasion meet with ICBs to discuss particular issues or to understand progress within the system.

221. The NHS Provider Policy team (which covers NHS Trust and NHS Foundation Trust matters) has information-sharing and escalation routes through meetings with relevant individuals and teams within NHSE. Regular meetings between DHSC, NHSE and CQC include monthly discussions regarding NHS Trusts, Foundation Trusts and Integrated Care Boards in the Recovery Support Programme (see pages 20-22 of the NHS Oversight Framework (**WV/15** **[INQ0012864]**), who are in receipt of mandated support from NHSE to embed lasting solutions. The Recovery Support Programme was launched on 13 July 2021 and evolved from the Special Measures programmes for NHS Trusts and Foundation Trusts for Quality and Finance. I understand that these would have been the communication routes with NHS Improvement at the time. Likewise, in respect of patient safety matters, information would flow to and from the Department through NHSE.

222. The Department may from time to time request information from NHSE about local services for specific purposes, for example to prepare briefing materials for Ministers. Such requests would have been routed through NHSE / NHS Improvement rather than directly from the NHS Trusts, NHS Foundation Trusts or CCGs (now ICBs).

Countess of Chester Hospital – Details

223. In October 2016 the Department became aware of the change in admission arrangements for the Countess of Chester Hospital neonatal unit to focus predominantly on lower risk babies which had been introduced in July 2016. I exhibit as **WV/53 [INQ0012916]** the Trust's external communication from July 2016. This explained that 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.

224. These points were noted in a briefing paper prepared in relation to the Backbench Debate on Baby Loss on 13 October 2016. I exhibit as **WV/54 [INQ0012917]** the briefing note that was prepared. Materially, the briefing noted:

> "2. The MPs local acute trust, the Countess of Chester Hospital NHS Foundation Trust announced temporary changes to the admission arrangements for its neonatal unit in July 2016. The Unit now focuses on lower risk babies who are born after 32 weeks. The changes are supported by the Cheshire and Merseyside Neonatal Care Network and are expected to affect around one or two mothers a week whose delivery is before 32 weeks – these women will likely use the Arrowe Park Hospital, Wirral for delivery of their babies.
>
> 3. A CQC inspection in February identified no concerns for the outcomes of the babies on the neonatal unit. However, the Trust advises that, for babies with high dependency needs, there has been an increase in neonatal mortality rates for 2015 and 2016 compared to previous years.
>
> 4. To fully understand the changes in neonatal mortality rates, the Trust has asked the Royal College of Paediatrics and Child Health and the Royal College of Nursing to conduct an independent review of the neonatal service. While this is conducted the three intensive care cots at the Chester neonatal unit will close. 13 cots providing specialist and high dependency care for newly born and premature babies born at 32 weeks and above will continue in operation."

225. 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.

226. On 17 May 2017 the Department's Media and Campaigns office was made aware of further details and the public statement which the Trust proposed to make (see **WV/55 [INQ0012918]**). A briefing document was prepared which set out, amongst other matters, the number of births, stillbirths and neonatal deaths from 2013-2015 (**WV/56 [INQ0012919]**).

227. On the afternoon of 17 May 2017 a policy official provided me with a briefing on what the Department knew (**WV/57 [INQ0012920]**). This reflected information provided to him by Margaret Kitching, NHSE Regional Chief Nurse for the North.

228. On 18 May 2017 Cheshire Police announced their investigation into events at the Countess of Chester Hospital. Thereafter the Department engaged with NHSE from time to time about the progress of the police investigation and subsequently the arrest and trial of Lucy Letby.

Reviews of the Countess of Chester Hospital

229. The Department has not instigated any specific review of the Countess of Chester Hospital between June 2015 and the present date, save for sponsoring the present Inquiry.

230. As part of the general regulatory arrangements described above, the CQC conducted an inspection in February 2016. This identified no concerns for the outcome of babies on the neonatal unit and rated the Countess of Chester Hospital NHS Trust 'good' overall for Maternity and Gynaecology. However, during the CQC's inspection of the Countess of Chester Hospital in 2016, the CQC identified concerns about staffing levels and skills mix on the neonatal unit and paediatric wards and made clear to the Trust that action was needed to ensure sufficient numbers of staff, including those trained in advance paediatric life support. Inspectors also received some concerns from hospital staff about a lack of support

from management when they tried to speak up, which the CQC highlighted directly to senior Trust staff as an issue that they needed to address.

231. At the Trust's request, a review of neonatal services was subsequently conducted by the Royal College of Paediatrics and Child Health. This was concluded in October 2016 and I understand that concerns were raised in respect of medical and nursing rotas, decision-making and the levels of senior cover.

232. As explained above, the Department was aware of the Trust's statement in July 2016. The statement explained that the Trust had requested an independent review of neonatal service by the Royal College of Paediatrics and Child Health and The Royal College of Nursing.

233. In March 2020 the Trust commissioned Facere Melius to undertake an independent management review of the hospital. I first became aware of the review in June 2023. I understand that the review had proceeded sporadically. From September to October 2023 DHSC officials asked Facere Melius to ensure the review was finalised as quickly as possible. On 4 October 2023 the police announced a corporate manslaughter investigation at the Countess of Chester Trust. As a result of this and the establishment of the Inquiry, the position was reconsidered and the review was not finalised. However, I understand a copy was sent to the Inquiry in November. The Department has not been provided with a copy of the review.

Previous reviews and recommendations

234. The Inquiry has provided a table setting out certain recommendations made by various reviews and inquiries. At **Appendix B** to this statement, I provide a summary of the background to some of those reviews and inquiries, the key findings and recommendations made and an update on the current position. At **Appendix C** to this statement, I provide the Department's review of the Inquiry's 'Review of Implementation of Recommendations from Previous Inquiries into Healthcare Issues' (**Appendix C**). In the time available, the Department has taken the following approach to reviewing the Inquiry's Review table:

    a. For all inquiries from the Freedom to Speak up Review onwards (other than the Cwm Taf Inquiry and the Independent Inquiry into Child Sexual Abuse as

these are outside the remit of the DHSC), the Department has undertaken a line-by-line review of the recommendations for each inquiry and provided updates in a new column called "DHSC Comments" in the Inquiry's table, which are provided in Appendix C.

b. For all other inquiries / investigations, policy teams within the Department have provided a short summary on the background, key findings and changes made in response to key recommendations, as appropriate. These can be found in **Appendix B**. Where particular policies have been addressed within this statement, I have sought to not repeat the same material.

235. In this section of the statement, I seek to address the Inquiry's questions about which recommendations I consider have been successful in terms of improving culture and governance within the NHS. In providing that summary, I repeat some of the matters already addressed elsewhere within this statement.

236. 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 has been sustained focus and effort over the last decade to make care and quality improvements, 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 help create a positive learning culture, put a widespread focus on reducing avoidable harm, improve safety and give closure to families.

237. As a result of responses to inquiries and wider initiatives, the government and system partners have delivered several major patient safety initiatives. These have improved system governance and have delivered more robust regulation; enabled staff to speak up more freely and protect whistleblowers; and changed the way patient safety and investigations are approached in the NHS. For example, the statutory duty of candour introduced in 2014 requiring NHS providers to tell patients if their safety has been compromised and to apologise, and enhanced legal protections for whistleblowers alongside over 1,000 Freedom to Speak Up Guardians across all Trusts supported by the National Guardian have been key initiatives to create more transparency and openness. The regulatory bodies in the

system are now clearer about their role in detecting, confronting and managing failures in quality and governance.

238. In more recent developments, the NHS Patient Safety Strategy is implementing substantial programmes to achieve continuous improvement in safety, the impact of which is beginning to be seen. Emerging evidence shows that the NHS patient safety strategy is making progress towards the impact we anticipated in 2019: saving an additional 1,000 lives and £100 million per year. The latest figures from June 2023 indicate that we are halfway to achieving that aim.

239. NHSE's Patient Safety Incident Response Framework is introducing a new national approach to safety investigations and learning responses, with compassionate engagement of patients and families as a core component.

240. In 2022 the Department introduced the first Patient Safety Commissioner to champion patients' voices in relation to the safety of medicines and medical devices.

241. In October 2023 the Department set up HSSIB as a new non-departmental public body to conduct independent, expert-led national safety investigations which will get to the root cause of patient safety incidents within our health service and to embed system-wide learning. The aim is to encourage the spread of a culture of learning within the NHS through promoting better standards for local investigations and improving their quality and effectiveness.

242. In December 2023 the Department announced that it will undertake a review of the statutory duty of candour for health and social care providers. The review will consider the design of the statutory duty of candour and its operation (including compliance and enforcement) to assess its effectiveness and make advisory recommendations. The terms of reference for the review are published online (I exhibited these in paragraph 123 (b) above as **WV/33 [INQ0012885]**).

243. In high level summary, many patient safety incidents result from a complex interplay of factors such as the nature of tasks, equipment and consumables, the work and wider organisational environments and the people working in those environments. Deliberate recklessness or malicious actions are very rare but are high-profile when they do occur.

244. Recent reports into major safety failures in the NHS have highlighted defensive cultures and a failure to learn lessons from past incidents. This undermines major safety improvements that have been made elsewhere. It is therefore important to keep supporting the entire system to achieve continuous improvements in safety. This includes responding to patients and families in a compassionate way and for the NHS to do more to accept accountability and learn from mistakes.

245. In light of the Lucy Letby trial verdict, the Secretary of State asked officials in the Department in conjunction with NHSE to lead a review of relevant recommendations from previous inquiries and reviews. I exhibit that review as **WV/58 [INQ0012924]**. In addition, in October 2023 the House of Commons Health and Social Care Committee asked its Expert Panel to undertake an evaluation of progress that the Government has made against inquiry and review recommendations made on patient safety, including whistleblowing, in the NHS which it has accepted. The Committee and Expert Panel asked for evidence to be provided (**WV/59 [INQ0012925]**).

246. On 27 November 2023 Maria Caulfield MP, the Parliamentary Under Secretary of State, wrote to the Chairs of the Committee and Expert Panel. I exhibit her letter and enclosures as **WV/60 [INQ0015455, INQ0012926, INQ0012927, INQ0012928, INQ0012929, INQ0012930, INQ0012931, INQ0012932, INQ0012933, INQ0012934, INQ0012935, INQ0012936, INQ0012937]**. In that letter the Minister described some of the work which had been undertaken by the Government to address concerns about patient safety and whistleblowing in the NHS. However, she acknowledged shortcomings:

> "I accept that recent investigations, such as the Ockenden report into Shrewsbury and Telford Hospital and the East Kent report, demonstrate a failure to learn from past incidents and that there is still more to do to improve care and safety as well as improving the quality of investigations where harm occurs. Major NHS safety failures undermine the good work being done elsewhere."

247. In January 2024 the Department provided written evidence, which I exhibit as **WV/61 [INQ0012939]**. In that submission, the Department set out its assessment of whether particular recommendations had been implemented by the Government

and whether the interpretation and implementation of those recommendations was appropriate.

Regulation of senior management within hospitals

248. I am asked to identify the arguments for and against the regulation of senior management within hospitals.

249. 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 the whole of the registrant population was not seen to deliver sufficient improvements in public protection as it would only be likely to exclude individuals leaders very rarely.

250. NHS England is currently leading work to implement measures recommended in the Kark 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 Persons Test was recommended by Dr Bill Kirkup in his report into the problems at Liverpool Community Health Trust. The review was published in 2019 and made seven recommendations for the Government, CQC, NHS England and other relevant organisations. The Government accepted five of the recommendations.

251. In August 2023 NHS England published the Fit and Proper Persons Framework, which relates to the first four recommendations. This introduces a standardised reference system and a means of retaining information regarding background checks for individual directors. The new Framework came into effect on 30 September 2023 and all boards are now expected to have started work on implementing the Framework. By 31 March 2024 organisations will need to have fully implemented the Framework.

252. Beyond the steps already taken by NHS England, the Government is currently revisiting recommendation 5 on the power to disbar for serious misconduct and is exploring whether further mechanisms are needed to hold NHS managers accountable. This will be considered alongside the actions recommended by General Sir Gordon Messenger's review of leadership published in June 2022. The recommendations of the Messenger Review focus on strengthening leadership and management, with an emphasis on induction, more systematic training, development and talent management, and measures to ensure that the most capable leaders are deployed to the most challenging areas.

253. If it were to be assessed that measures beyond the implementation of the Kark review and the Messenger review were needed to assure an effective and proportionate system of regulation, options that have been suggested 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.

254. Regulation of particular workforces can serve a number of functions, some intentional and others a by-product of its intended primary purpose. The benefits of regulation could include:

    a. a list of managers who have met recognised standards and are 'fit to practise';

    b. providing a mechanism to exclude individuals who are not sufficiently qualified and those who have been deemed unfit for senior managerial roles;

c. supporting robust investigation and adjudication and appeal functions to ensure decisions to disbar were fair and consistent with employment and human rights legislation;

d. clearer and more consistent standards of competence and behaviour for admission to the register;

e. a requirement for registrants to undertake the training needed to attain professional registration and a requirement on employers to ensure training to retain registration; and

f. protection of professional titles, putting managers on a similar regulatory footing to clinical staff.

255. While regulation aims to have a positive effect on public protection, there are other consequences of statutory regulation. Arguments against regulation could include:

a. difficulty defining the skills and competencies required of senior managers, which are less easily and clearly delineated than the clinical competencies and knowledge need for clinical health professions;

b. weakening of local responsibility, autonomy and decision making, particularly ensuring that Boards and Chairs take responsibility for performance management of executives;

c. barriers to entry to these roles from other sectors;

d. difficulties in attracting talent, particularly for challenging board roles;

e. additional bureaucracy, resulting from the need to establish and maintain a new form of regulatory oversight. This would also result in further costs, either for the Government (who would normally fund a barring regime) or for registrants (who would normally fund a statutory positive register);

f. a risk of high levels of vexatious complaints to be made against managers as a result of the difficult roles and relationships they need to manage;

g. difficulty in making a case for individual personal responsibility for particular failings given the complex contextual factors that necessarily influence leadership decisions and the multiple actors in modern healthcare;

h. as many executive managers are also registrants with other professional regulatory bodies, avoiding the duplication and costs of dual regulation.

256. Ministers intend to consider the recommendations from the Thirlwall Inquiry before making a decision on whether to pursue the above statutory options. In the meantime, Ministers are seeking swift and comprehensive implementation of the recommendations from the Kark and Messenger reviews.

Conclusion

257. I have set out above a detailed chronology of the ongoing developments in patient safety which the Department has pursued since 2012. The enhancement of patient safety, including in respect of maternity care, is a central priority for the Department and many of the initiatives discussed were ongoing prior to the incidents at the Countess of Chester Hospital.

258. I am asked to summarise the changes which have been made since 2016 which have improved the safety of babies in neonatal units. I have referred to many of these above, but to summarise, I would point to the following measures:

a. The National Maternity Safety Ambition (2017), to which I have referred at paragraphs 215-216 above.

b. The Neonatal Critical Care Review (2019), to which I have referred at paragraph 170 above.

c. The Three Year Delivery Plan for Maternity and Neonatal Services (2023): NHSE's Three-Year Plan for Maternity and Neonatal Services sets out how NHSE will make maternity and neonatal care safer, more personalised, and more equitable for women, babies, and families. The plan acknowledges recent independent reports by Donna Ockenden on maternity services in Shrewsbury and Telford and by Dr Bill Kirkup on maternity and neonatal services in East Kent, and previously Morecambe Bay which have set out examples of poor care, and sets out how the NHS will take action to address that, including through pulling together the recommendations from those reviews.

d. The Perinatal Quality Surveillance Model, to which I have referred at paragraphs 151-154 above.

e. Maternity and Newborn Safety Investigations (2018, renamed in 2023), to which I have referred at paragraphs 162-169 above.

f. The Perinatal Mortality Review Tool (2018), to which I have referred at paragraphs 155-158 above.

259. In addition to the above, there have been numerous programmes of work which aim to improve maternity safety more generally. These include NHS Resolution's Maternity Incentive Scheme and the Care Quality Commission's Maternity Inspections Programme.

260. The events at the Countess of Chester Hospital did have an impact on other measures. The Government had previously accepted five of the seven recommendations made as part of the Kark Review. The Fit and Proper Person Test Framework was developed by NHSE in order to address recommendations 1-4 of that review. Following the prosecution of Lucy Letby, the then Secretary of State, the Rt Hon Steve Barclay MP, publicly committed to revisiting recommendation 5 (which concerns the power to disbar for serious misconduct) with NHSE with a view to strengthening patient safety measures. In September 2023 the Department committed to exploring introducing "Martha's Rule" which would formalise the right for families and patients to access a rapid review in cases of physiological deterioration in hospitals. The Department asked the Patient Safety Commissioner to look at how it could be made to work in the NHS and following recommendations, we are now considering the next steps for this vital work.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed: PD

Dated: 05.04.2024

APPENDIX A:

JUNIOR MINISTERS (2012 TO PRESENT)

Year appointed	Ministers of State	Parliamentary Under Secretaries of State
2010	Paul Burstow May 2010- September 2012 Minister of State (Community and Social Care)	Earl Howe May 2010- May 2015 Parliamentary Under Secretary of State (Quality)
	Simon Burns 2010 - September 2012 Minister of State (Health)	Anne Milton May 2010- September 2012 parliamentary Under Secretary of State (Public Health)
2012	Sir Norman Lamb 2012 – May 2015 Minister of State (Community and Social Care)	Anna Soubry September 2012 – October 2013 Parliamentary Under Secretary of State (Public Health)
		Dan Poulter September 2012- March 2015 Parliamentary Under Secretary of State (Care Quality)
2013		Jane Ellison October 2013 – July 2016 Parliamentary Under Secretary of State (Public health)
2014		George Freeman July 2014- July 2016 Parliamentary Under Secretary of State (Life Sciences)
2015	Alistair Burt May 2015 – July 2016 Minister of State (Community and Social Care)	Ben Gummer May 2015- July 2016 Parliamentary Under Secretary of State (Care Quality)
		Lord Prior of Brampton May 2015 - December 2016 Parliamentary Under Secretary of State (NHS Productivity) (Lords)
2016	Philip Dunne July 2016- January 2018 Minister of State (Health)	Baroness Nicola Blackwood July 2016- June 2017 Parliamentary Under Secretary of State (Public Health & innovation)
		David Mowat July 2016-June 2017 Parliamentary Under Secretary of State (Community Health & Care)

		Lord O'Shaughnessy December 2016- January 2018 Parliamentary Under Secretary of State (Lords)
2017		Steve Brine June 2017 – March 2019 Parliamentary Under Secretary of State (Public Health & Primary Care)
		Jackie Doyle Price June 2017 – January 2018 Parliamentary Under Secretary of State (Mental Health & Inequalities)
2018	Stephen Barclay January 2018 – November 2018 Minister of state (Health)	Jackie Doyle Price January 2018 – July 2019 Parliamentary Under Secretary of State (Mental Health, Inequalities & suicide prevention)
	Caroline Dinenage January 2018 – February 2020 Minister of State (Care and Mental Health)	
	Stephen Hammond November 2018 – July 2019 Minister of State (Health)	
2019	Chris Skidmore July 2019 – September 2019 Minister of State (Health)	Baroness Nicola Blackwood January 2019 – February 2020 Parliamentary Under Secretary of State (Lords)
		Seema Kennedy April 2019 – July 2020 Parliamentary Under Secretary of State (Public Health & Primary Care)
		Nadine Dorries July 2019 – May 2020 Parliamentary Under Secretary of State (Ministers for Patient Safety, Suicide Prevention and Mental Health)
		Jo Churchill July 2019 – September 2021 Parliamentary Under Secretary of State (Prevention, Public Health & Primary Care)
	Edward Argar September 2019 – July 2022 Minister of State (Health)	
2020	Nadine Dorries May 2020 – September 2021 Minister of State (Patient safety,	

	suicide prevention and Mental Health)	
	Helen Whatley February 2020 – September 2021 Minister of State (Social Care)	
		Lord Bethell March 2020 – September 2021 Parliamentary Under Secretary of State (Technology, Innovation and Life Sciences)
		Nadhim Zahawi November 2020 – September 2021 Parliamentary Under Secretary of State (COVID vaccine deployment)
2021		Maggie Throup September 2021 – September 2022 Parliamentary Under Secretary of State (Vaccines and Public Health)
	Gillian Keegan September 2021 – September 2022 Minister of State (Care and Mental Health)	Maria Caulfield September 2021- July 2022 Parliamentary Under Secretary of State (Patient Safety and Primary Care)
		Lord Kamall September 2021- September 2022 Parliamentary Under Secretary of State (Technology, Innovation and life sciences)
2022	Maria Caulfield July 2022- September 2022 Minister of State (Health)	
	Robert Jenrick October 2022 – December 2022 Minister of State (Health)	James Morris July 2022- September 2022 Parliamentary Under Secretary of State (Primary Care and Patient Safety)
	Will Quince September 2022 – November2023 Minister of State (Health and Secondary Care)	Neil O'Brien September 2022 – November 2023 Parliamentary Under Secretary of State (Primary Care and Public Health)
	Helen Whatley October 2022 – present	Caroline Johnson September 2022- October 2022

	Minister of State (Social Care)	Parliamentary Under Secretary of State (Mental Health and Public Health)
		Maria Caulfield October 2022 – present Parliamentary Under Secretary of State (Mental health and Women's health)
		Lord Markham September 2022 – present Lords Minister
2023	Andrew Stephenson November 2023 – present Minister of State (Health and secondary care)	Andrea Leadsom November 2023 – present Parliamentary Under Secretary of State (Public Health, Start for Life and Primary Care)

APPENDIX B:

Investigation and Inquiry summaries prepared by the Department of Health and Social Care for the Thirlwall Inquiry

Contents

The Allitt Inquiry (Clothier Inquiry)

Background to the Inquiry

1. The Clothier Inquiry was commissioned by the then Secretary of State for Health to investigate the circumstances surrounding the murder by Beverly Allitt of four children and the injuring of nine others in the children's ward of Grantham and Kesteven general hospital in 1991. The Inquiry report published in 1994.

Key findings and changes made in response

2. The Inquiry found failures in the management and communication of the hospital, the school of nursing which allowed Allitt to graduate (knowing that she was "psychiatrically disturbed") and the paediatricians and pathologists who failed to get to the bottom of what was happening. It also criticised poor recruitment processes, inadequate staffing levels, indecisive senior managers and poor operational procedures which compounded the problems. Detailed recommendations were made in relation to the recruitment, training and health screening of nurses, processes to be followed after the death of a child and the reporting of untoward incidents.

   A significant change since the publication of this Inquiry was the abolition of the United Kingdom Central Council for Nursing, Midwifery and Health Visiting (UKCC) and the establishment of the Nursing and Midwifery Council (NMC) in 2001. The NMC has a much broader view of regulation for the profession with a central focus on protection of the public as set out in legislation through the Nursing and Midwifery Order 2001.

3. Within the Order and professional standards there are a number of areas that relate to the recommendations from the Clothier Inquiry, including a requirement for health and character declarations at the point of registration, as well as a professional code focused on the delivery of safe and effective care. A revalidation process was also introduced by the NMC in 2015 requiring a mandatory revalidation for all registrants across a three-year cycle to provide greater strength to their protection of the public.

4. The NMC remains the regulator for the nursing profession, delivering key regulatory functions through setting professional standards, registration and revalidation.

Update on key recommendations

6. Regarding matters raised in the recommendations not covered in detail in the Witness Statement:

    a. Nursing standards: the NMC sets out that in order to become a qualified nurse, a university degree is needed. Part of the requirements is for a candidate to declare any past criminal convictions and allow the university to check whether they have a police record. The NMC also set outs the values and behaviours expected of nurses, also set out in the "The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates" The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates - The Nursing and Midwifery Council (nmc.org.uk).

    b. 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. The legislation is supported by statutory and operational guidance for NHS commissioners and local authorities as child death review partners: Child Death Review Statutory and Operational Guidance (England) (publishing.service.gov.uk). The guidance describes the processes that need to be followed before a Child Death Review Meeting (CDRM) is held and sets out that post-mortem examinations for children should be carried out by a pathologist who specialises in illnesses and conditions that affect babies and children.

    c. Arrangements in paediatric nursing: the National Quality Board (NQB) sets out guidance to Trusts about assessing the right level of staff and skills mix. This includes 12 month or more frequent reviews taking account of local needs, national guidelines and professional judgement.

7. More information on current arrangements for serious incident reporting is covered in the Witness Statement.

The Committee of Inquiry into the Personality Disorder Unit, Ashworth Special Hospital

Background to the Inquiry

8. This Inquiry was announced by the then Secretary of State for Health in 1997 in response to allegations made by a former patient, Mr Steven Daggett, about the misuse of drugs and alcohol, financial irregularities, possible paedophile activity and the availability of pornographic material on the Personality Disorder Unit (PDU) of Ashworth Special Hospital. The Inquiry was also asked to review the policies, clinical care and procedures on the Unit, its security arrangements; the management arrangements for assuring effective clinical care and appropriate security for patients; and the arrangements for visiting. The Inquiry's remit subsequently expanded to examine Ashworth Special Hospital as a whole and the wider treatment of personality disorders. The Inquiry was chaired by Peter Fallon QC and reported on 6 January 1999.

Key findings and changes made in response

9. The Inquiry found the former patient's allegations largely accurate. Failings identified included the following: the PDU was deeply flawed; security was grossly inadequate; medical staff demonstrated incompetence and poor performance; lack of clinical leadership; dysfunctional management, with a lack of clear operational policies and ill-defined lines of accountability; overly complex relationship with external organisations; and previous changes made by Government were ill-thought through. The Inquiry made 58 recommendations. The Government responded in its July 1999 report: 'The Secretary of State for Health's response to the Committee of Inquiry into the Personality Disorder Unit, Ashworth Special Hospital'.

   The recommendations formed the basis of wide-ranging work to improve the provision of care and security in the high secure estate. The issues identified in the Inquiry report have been addressed through the improved framework for safety and security, including the High Security Psychiatric Services Directions 2019 and

associated guidance and improved governance. The report and its recommendations remain relevant as an important historical document that has had wide-ranging implications for practice at all three high-secure hospitals in England. This is also evident in the close collaborative working between the three hospitals, which was further developed during the Covid-19 pandemic and continued since then.

Update on key recommendations

10. Regarding matters raised in the recommendations not covered in detail in the Witness Statement:

    a. Safety and security: In response to recommendation 7 of the Inquiry report, the Government commissioned the Tilt Review to look at all aspects of safety and security at Ashworth Hospital. The review was later expanded to cover all three high-secure hospitals in England. In addition, following the Fallon Inquiry report, the Secretary of State for Health issued a set of Directions to the three high security hospitals entitled the "Safety and Security in Ashworth, Broadmoor and Rampton Hospitals Directions 1999". The Tilt Review made several recommendations to improve and expand the Safety and Security Directions that were accepted in full by the Government. These Directions govern how all three hospitals manage safety and security and are reviewed and updated regularly. The latest iteration, "the High Security Psychiatric Services (Arrangements for Safety and Security) Directions 2019", and its associated guidance, can be found here: High security psychiatric services directions 2019: arrangements for safety and security - GOV.UK (www.gov.uk). These should be read alongside the "High Security Psychiatric Services (Arrangements for Visits by Children) Directions 2013" (High security psychiatric services directions 2013: arrangements for visits by children - GOV.UK (www.gov.uk)).

    b. Governance: NHS England and DHSC have strengthened governance of the three hospitals through the National Oversight Group (NOG) and the Clinical Secure Practice Forum (CSPF), which oversee all aspects of security and encourage close collaboration between the three hospitals.

Safety and security compliance at the three hospitals is audited by each hospital monthly, supported by an annual peer audit overseen by the Government Internal Audit Agency. The independent security adviser to NOG also contributes significant oversight via CSPF, and the development of the annual safety and security plan.

c. Updating the Mental Health Act: The Government remains firmly committed to updating the Mental Health Act and will bring forward a Mental Health Bill when Parliamentary time allows. The Government continues to take forward non-legislative commitments to improve the care and treatment of people detained under the Act, including piloting models of Culturally Appropriate Advocacy to provide tailored support to people from ethnic minorities to better understand their rights when they are detained under the Mental Health Act.

Royal Liverpool Children's Hospital Inquiry

Background to the Inquiry

11. Medical witnesses at the Bristol Royal Infirmary Inquiry drew attention to unethical retention of organs without consent at Alder Hey Hospital. The Royal Liverpool Children's Hospital Inquiry was commissioned to investigate the removal, retention and disposal of tissue and organs at Alder Hey Children's Hospital following hospital post-mortem examinations and the extent to which the Human Tissue Act 1961 had been complied with.

Key findings and changes made in response

12. The Inquiry found that thousands of organs had been removed, stored and used without consent. It recommended that the Human Tissue Act 1961 should be amended to make informed consent for lawful post-mortem and retention of body parts more explicit.

13. The concerns were addressed primarily through the passing of The Human Tissue Act 2004 which repealed and replaced the Human Tissue Act 1961. The 2004 Act sets out the requirement to obtain appropriate consent to carry out activities regulated under the Act. It also established the regulator, the Human Tissue Authority (HTA) with a remit covering removal, storage, use and disposal of human material and the range of activities for which a licence from the HTA is required. The 2004 Act sets out a number of offences regarding consent and licensing. The HTA can use powers to take regulatory action where they identify non-compliance with the Act.

Update on key recommendations

14. Regarding matters raised in the recommendations not covered in detail in the Witness Statement:

a. Regulation: The HTA regulates, through its licensing and inspections process, establishments which carry out full, limited, and minimally invasive post-mortem. Its remit is to ensure that post-mortem examinations are undertaken with appropriate consent or under the authority of the coroner and on suitable premises licensed for that purpose, which is a statutory requirement under the Human Tissue Act. The HTA publish sector-specific codes aiming to provide anyone undertaking activities relevant to each sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy. The HTA also publish Licensing Standards and Guidance for the Postmortem Sector.

b. Offences: Section 5 of the Human Tissue Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the Human Tissue Act (a scheduled purpose), including determining the cause of death, without appropriate consent.

c. Consent: Establishments meeting the consent standards will be able to demonstrate that their processes for seeking and gaining consent comply with the Human Tissue Act and the HTA's Codes of Practice. The standards also cover the documentation and information used to support the establishment's consent procedures and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

d. Governance and quality systems: Establishments meeting these standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping. In addition, they will have an effective system of risk management and suitable systems to deal with adverse events.

e. Traceability: Establishments meeting these standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal/disposition. HTA inspectors will test this through traceability audits carried out on site.

f. Premises, facilities and equipment: Establishments meeting these standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place, that they are safe, secure and clean and that there are effective contingency arrangements in place.

g. Support: The HTA provide information to support those who are bereaved and are affected by a post-mortem examination setting out what to expect, what will happen and what your rights are.

h. Further work: The Independent Inquiry into the issues raised by the David Fuller case was established to investigate how Fuller was able to carry out inappropriate and unlawful actions in the mortuaries at Maidstone and Tunbridge Wells NHS Trust and why they went apparently unnoticed. This first phase of the Inquiry, on matters relating to Maidstone and Tunbridge Wells NHS Trust, concluded in November 2023 with the publication of the Phase 1 Report. Phase 2 of the Inquiry will look at the broader national picture and consider if procedures and practices in other hospital and non-hospital settings, where deceased people are kept, safeguard the security and dignity of the deceased. Whilst the Phase 1 report makes clear 'responsibility for offences' lies with David Fuller, the report flags that the 'legislative and regulatory shield' did not provide protection for the deceased. Regulatory requirements were 'either insufficient or not followed' and that regulation 'should encourage good practice and discourage the bad'. The inquiry will examine the role of regulators and the effectiveness of the national regulatory and legislative framework in Phase 2 of the inquiry.

Bristol Royal Infirmary Inquiry

Background to the Inquiry

15. The Inquiry examined the management and care of children receiving complex cardiac surgery at Bristol Royal Infirmary between 1984 to 1995. Expert analysis showed that between 1991 and 1995 there were between 30 and 35 more deaths among children who underwent operations at the Infirmary, compared with the average of all UK centres. The problems were brought to light by a whistle-blower.

Key findings and changes made in response

16. The Inquiry found poor teamwork between professionals, "too much power in too few hands"; surgeons who lacked the insight to see that they were failing and to stop operating; lack of leadership; and inadequate processes from referral to diagnosis, surgery and intensive care (for example, intensive care unit and operating theatre on different floors and children had to be transported by a lift that could be also called by others). They also concluded a culture existed of not encouraging challenge where speaking out or openness was not safe or acceptable. The Inquiry made 198 recommendations across a range of issues.

17. A number of significant reforms were introduced as a result of the Inquiry, set out in the Government Response "Learning from Bristol" in January 2002. They included the establishment of the National Patient Safety Agency; reinforcement of the independence of the then Commission for Health Improvement (CHI) through legislation (NHS Reform and Health Care Professions Bill) and ability of the CHI to impose "special measures"; the operational independence of NICE; a reformed NHS complaints procedure; introduction of Patient Advice and Liaison Services (PALS); more focus on data and hospital performance with the establishment of the Office for Information on Health Care Performance as part of the CHI to monitor clinical performance from hospitals; hospitals publishing regular performance indicators and reports made by the CHI to the Secretary of State annually; better arrangements for independent inspections; single national system for monitoring and reporting of "adverse events" and "near misses"; leadership programmes for

NHS leaders; strengthened professional regulation; introduction of electronic patient records; and recruitment of more doctors, nurses and therapists.

Update on key recommendations

18. Many of the measures put in place in response to this Inquiry remain, including the reformed NHS complaints procedure, and PALS; inspection of trusts by the CQC, revalidation for clinicians and NHS England holding responsibility for overseeing the implementation of patient safety policies. Improvements continue to be made on the monitoring and responding to patient safety incidents including the new Patient Safety Incident Response Framework, rolled out from August 2022, and the Learn From Patient Safety Events Service rolled out from 2023. Action taken to support staff to speak up with concerns is covered in further detail under the Freedom to Speak Up Review. NICE remains the independent body which provides evidence-based guidance on health services, social care and public health. Its objective is to drive best practice in the health and care system through the development of authoritative, evidence-based recommendations and guidance, including on the use of medicine.

19. Regarding matters raised in the recommendations not covered in detail in the Witness Statement:

    a. Bereavement service for families in every Trust: there is a range of support in the NHS for families who have experienced bereavement, including therapy and counselling.

    b. Patient surveys: All eligible NHS trusts in England participate in the NHS Patient Survey Programme, asking patients their views on their recent health care experiences. The findings from these surveys provide organisations with detailed patient feedback on standards of service and care and can be used to help set priorities for delivering a better service for patients. The survey results are also used by the CQC to measure and monitor performance at both local and national levels.

    c. Incentives to consultants for quality of care: The Clinical Impact Awards Scheme rewards consultants or academic GPs who deliver national impact

above the expectations of their job role or other paid work. Awards are given for quality and excellence, acknowledging exceptional personal contributions.

d. Set up an NHS leadership centre: The NHS Leadership Academy offers professional development for health careers.

e. Public involvement in local services: The Health and Care Act 2022 established integrated care boards (ICBs) and integrated care partnerships (ICPs) in local areas to join up planning and provision of services, both within the NHS and with local authorities.

f. Quality of standards for paediatric heart surgery: the NHS Paediatric Congenital Heart Disease Specification sets out paediatric standards and service specifications for congenital heart disease services in England.

Independent Investigation into how the NHS handled allegations about the conduct of Clifford Ayling

Background to the Inquiry

20. The Inquiry examined indecent assaults at Ayling's surgery in Folkestone, in the 1990s. The report was published in September 2004. It was one of the three Inquiries announced in July 2001 by the then Secretary of State for Health. The other two Inquiries were to consider how the NHS handled allegations about the conduct of Richard Neale, a former gynaecologist and William Kerr and Michael Haslam, former psychiatrists (see below).

Key findings and changes made in response

21. The Inquiry found that although between 1971 and 1998 there were concerns and complaints, they were not investigated until 1998. Patients were reluctant to complain for different reasons, including concern they would not be believed or taken seriously. There was also a lack of a clear formal complaints procedure. The Inquiry also found that the prevailing culture was that managers did not interfere with clinicians' judgments and there was limited supervision. People working with Ayling, especially nurses and midwives, felt reluctant to challenge him and other doctors did not want to criticise other doctors as they felt this could weaken their own positions in the future. There was a lack of protection for staff to raise concerns and no clear process for them to do so. The report acknowledged that the NHS had shifted its emphasis towards assuring the quality of patient care and patient safety.

22. Given the common themes in the recommendations ("club culture", no formal complaints processes, inadequate professional regulation, low staffing levels), the Department set out its position in the Government response, which was published in February 2007. The response sets out the areas where many of the recommendations had already been implemented or were in the process of being implemented at the time.

Update on key recommendations

23. Over the period since the Inquiry, there have been significant reforms in the NHS to improve culture with emphasis on quality and safety, including stronger accountability and governance structures, whistleblowing and Speaking Up policies, PALS, stronger professional regulation including the role of regulators, appointment of a Medical Director in hospitals with accountability to boards.

24. Regarding matters raised in the recommendations not covered in detail in the Witness Statement:

    a. Raising complaints: The legislation governing the NHS complaints procedure is the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009. Further details about the NHS complaints procedure and other processes such as PALS are set out in the Witness Statement. Regarding complaints against doctors, the GMC have a range of actions they can take on doctor's registration ranging from giving a warning to referral to the Medical Practitioners Tribunal Service. In 2018, NHS England launched a complainant experience survey and toolkit to help organisations track the quality of their complaint handling.

    b. Support programmes for single-handed practitioners: The GMC sets and enforces the standards all doctors must adhere to and is responsible for ensuring that medical practitioners have the necessary skills and knowledge to join the UK medical register. It provides a range of resources to support its registrants. In order to deliver NHS primary care services, a medical practitioner must be registered with a licence to practise with the GMC, on the GMC's General Practitioner (GP) register and on the Medical Performers List (MPL), held by NHS England and the equivalent organisations in the Devolved Governments. The Performers List Regulations (PLR) provide NHS England with the ability to assess whether a medical practitioner is 'fit for purpose' to work independently to deliver NHS primary care services in England. Once a GP is included on the MPL, NHS England is able to provide support to enable them to deliver safe and effective care.

c. Chaperoning policy: For instances where doctors have to carry out intimate examinations, the GMC and the Medical Protection Society advise that doctors should always offer a chaperone, with the GMC offering specific guidance N_P Intimate examinations and chaperones - GMC (gmc-uk.org).

d. Arrangements between the NHS, police and CPS when there is an investigation: Following the Williams Review, a new MOU is being developed to replace the 2006 protocol ('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 & Safety Executive').

Committee of Inquiry to investigate how the NHS handled allegations about the performance and conduct of Richard Neale

Background to the Inquiry

25. The remit of the Inquiry was to examine the NHS's handling of the case, principally from 1985 to 1997, and whether effective procedures were operating in local health services in order to ensure appropriate remedial action was taken. Neale was struck off the medical register in Canada in 1985 because of serious incompetence after the death of two patients. Despite warnings to this country from Canada, he went on to practise in the Friarage hospital in Northallerton. He then went on to work in several other hospitals while in effect, dismissed. He was finally struck off for professional misconduct in the United Kingdom in July 2000, 15 years after he was struck off in Canada.

Key findings and changes made in response

26. The report considered that between 1985 and 1997 there were systems failures within the employment and complaints procedures within the NHS (notably the GMC) who missed multiple opportunities to investigate representations made to them. In addition, the Health Authority at the time failed to properly investigate the incidents in Canada; misleading job references were provided by health employers for Neale which were mishandled; complaints by concerned patients and his colleagues were not encouraged; he was not properly supervised. At the heart of these issues was the concern that although he had been struck off in Canada, he was able to practise medicine in the UK, and despite concerns and being suspended, he was able to find employment in other hospitals. Similarly, to the findings about Ayling, there was a culture that discouraged complaints and more junior staff found it difficult to raise complaints about his competence. Recommendations included:

    a. need for an overarching professional body to oversee all aspects of rules governing the appointment and employment of doctors and to prioritise the interests of patient safety;

b. improved adverse event reporting systems;

c. better complaints handling procedures; and

d. more rigorous job application and interviewing procedures.

27. Given the common themes in the recommendations ("club culture", no formal complaints processes, inadequate professional regulation, low staffing levels), the Department published a Government response with its position on the recommendations.
The response sets out the areas where many of the recommendations had already been implemented or were in the process of being implemented at the time.

Update on key recommendations

28. As mentioned elsewhere, over the period since the Inquiry, there have been significant reforms in the NHS to improve culture with emphasis on quality and safety, including stronger accountability and governance structures, whistleblowing and Speaking Up policies, PALS, stronger professional regulation including the role of regulators, appointment of a Medical Director in hospitals with accountability to boards.

29. Regarding matters raised in the recommendations not covered in detail in the Witness Statement:

a. Regulation of doctors: The GMC introduced a revalidation requirement in 2012 which applies to all licenced doctors in the UK working in all specialties in the NHS, and the private sector. It requires doctors to confirm to the GMC they are fit to practice. Doctors need to meet the standards set by the GMC to maintain their licence to practice.

b. Knowledge, skills, qualifications and experience: Since 1 April 2006, all doctors working as a GP in the UK health service must be on the GP Register, other than doctors in training, such as GP registrars. This requirement extends to locums. In addition to joining the register in order to practise, GPs also need to join the National Performers List. Through regulations amended in 2013, the Performers Lists provide the regulatory

framework to ensure that medical, dental and ophthalmic practitioners who contract with NHS England are qualified and competent to provide safe and effective primary medical, dental and ophthalmic services. In January 2024, the GMC refreshed its guidance on good medical practice which sets out the standards of patient care and professional behaviour expected of all doctors in the UK, across all specialties, career stages and sectors. The GMC also sets guidance to help employers understand their obligations when employing and contracting with doctors, including pre-employment checks.

30. Information on the duty of candour is included in the Witness Statement. In summary, it has been implemented since 2014 and applies to all CQC-registered providers. The Department announced a review of the duty in December 2023.

The Shipman Inquiry

Background to the Inquiry

31. The Shipman Inquiry was commissioned by the then Secretary of State for Health in 2000 and investigated the activities of the General Practitioner Dr Harold Shipman, from 1970 to 1998. The Inquiry followed after Shipman was found guilty on 15 counts of murder in January 2000.

Key findings and changes made in response

32. The first and sixth reports were factual; the second report looked at shortcomings in the original police investigation, with no formal recommendations. The third report examined the processes for death certification and the coroners' system and called for a radical overhaul of the coroner system including additional certification. The Department has since taken forward work on medical examiners.

33. The fourth report examined the regulation of controlled drugs and called for measures to prevent doctors stockpiling drugs as Shipman did. The Government largely accepted these recommendations but rejected the recommendation to create a new controlled drug inspectorate.

34. The fifth report examined the safeguarding of patients and looked at systems for monitoring the performance of doctors in general practice and the handling of complaints. The Government published a White Paper called 'Good Doctors, Safer Patients' in response and followed with primary legislation to reform governance of regulators and change the standard of proof for fitness to practice.

35. There are no outstanding recommendations. The Government largely accepted and implemented the Inquiry recommendations but as stated above, rejected the recommendation to create a new controlled drug inspectorate. Instead, regulatory requirements were introduced to place tighter controls on the procurement, storage, supply and prescribing of controlled drugs, and establish national and regional monitoring by the CQC and a network of regional NHS Controlled Drug Accountable Officers.

Update on key recommendations

36. The table provided by the inquiry sets out the current position in many of the recommendations which were addressed by the Coroners and Justice Act 2009. The Act for example created the Office of Chief Coroner to provide national leadership for coroners in England and Wales.

37. Regarding matters raised in the recommendations not covered in detail in the Witness Statement:

    a. Medical examiners and notification of deaths: As mentioned in the Witness Statement, the intention is to put medical examiners on a statutory footing. DHSC is the lead department on a cross government programme of death certification reform. It is a statutory requirement for an attending practitioner to complete the Medical Certificate of Cause of Death (MCCD), known as Attending Practitioner MCCD (AP MCCD). The General Medical Council sets out this obligation in guidance 'Treatment and Care Towards the End of Life', stating that this is part of their responsibility to their patients (https://www.gmc-uk.org/-/media/documents/treatment-and-care-towards-the-end-of-life---english-1015_pdf-48902105.pdf).This guidance was first published in 2010 and updated in 2022. The Notification of Death regulations 2019, set out the obligation for a medical practitioner to notify a coroner of a relevant death. If a medical practitioner is aware that someone other than a medical practitioner has reported a death to the coroner, the registered medical practitioner should still make a notification under the Regulations.

    b. Register of medical experts to provide advice to the police: The National Crime Agency holds an Expert Advisers Database, which is used to identify and source those experts who can add value to law enforcement investigations. In addition, in response to the Hamilton review in 2019, the GMC has completed a review of expert witness reports and processes, and has made appropriate amendments in line with the gross negligence manslaughter review. This includes confirming that experts can only

comment on incidents that occurred while they were in active clinical practice.

c. Controlled drugs (CDs): The Controlled Drugs (Supervision of Management and Use) Regulations 2013 contain measures relating to arrangements underpinning the safe management and use of controlled drugs in England and Scotland, and establish national and regional monitoring arrangements by the CQC (in relation to England) and regional NHS Controlled Drug Accountable Officers. NHS England and other 'designated bodies' such as NHS trusts and independent hospitals are required to appoint Accountable Officers who have a statutory duty to ensure systems are in place for the safe management and use of controlled drugs and to monitor and investigate incidents concerning controlled drugs. The regulations also require other organisations (responsible bodies) to share information about the misuse of controlled drugs within healthcare settings.

d. Pathology services: The Government announced £ I&S in November 2021 to digitise diagnostics care across the NHS to share patient results, tests and scans more easily and quickly between different hospitals and doctors.

e. Cremation regulations: The Cremation (England and Wales) Regulations 2008 (the 2008 Regulations) came into effect on 1 January 2009. They modernised and consolidated all previous regulations, replacing the Cremation Regulations 1930 (as amended). The 2008 Regulations were amended in 2016, 2017 and again in 2022.

f. Assessing fitness to practise (criteria/treatment of offences): Regulations which came into force in 2011 and amended in 2013, require all designated bodies to nominate or appoint a responsible officer. The Responsible Officer Regulations give specified senior doctors (responsible officers) in certain organisations (designated bodies) functions that ensure that all doctors work within a managed environment, in which their performance, conduct and behaviour are monitored against agreed national standards. Where there are concerns about a doctor's fitness to practise, the

Regulations empower responsible officers to instigate investigation of the doctor's performance and to ensure that the appropriate action is taken.

g. Mortality rate tool: The Primary Care Mortality Database (PCMD) allows authorised users to access mortality data provided at the registration of a death. This includes demographic details; cause of death; place of death; certifying GP details and coroner's details.

38. Information on other measures relevant to the recommendations of this inquiry, such as the GP register, support programmes for single-handed practitioners and processes for raising complaints, have been included in the Clifford Ayling section.

Northwick Park Hospital, NW London Hospitals NHS Trust (Healthcare Commission Investigation)

Note: This investigation was undertaken by the Healthcare Commission. The Department does not have access to Healthcare Commission or Trust/SHA records.

Background to the Investigation

39. The Trust had invited the Healthcare Commission ('the Commission') to look at the maternity unit at Northwick Park Hospital following nine maternal deaths between April 2002 and June 2004. A further maternal death occurred in March 2005 while the Commission's report was being finalised. As a result, the Commission carried out an unannounced inspection on 11 April 2005 and at its recommendation, the Department of Health introduced special measures at the maternity unit on 21 April 2005.

40. The Commission published its report in July 2005. In view of its findings, the Commission was concerned about the robustness of the action taken by the Trust following the maternal deaths. It decided to carry out a further, more detailed investigation to examine the care and treatment provided to the ten women who died, and the actions taken following each death. It published its second report in August 2006 with more in-depth findings on the maternal deaths and recommendations for the wider NHS.

Key findings and changes made in response

41. The July 2005 report found that the Trust's systems and processes for the management of risk in maternity services were not effective and highlighted a number of other concerns, including a lack of clinical leadership and poor inter and intra-professional relationships between midwives and consultant obstetricians. The August 2006 report identified that the Trust's maternity services were impacted by a lack of leadership, poor communication between staff, ineffective teamwork, and a lack of awareness of how this was affecting the safety of patients and the quality of care being provided. The Commission concluded that the working

environment and culture allowed the quality of care to fall below proper professional standards and poor working practices to flourish.

42. North West London Hospitals NHS Trust produced an action plan and London Strategic Health Authority was responsible for monitoring the implementation of agreed actions. The action plan covered improving the experience and clinical outcomes of patients, with improved complaints handling; staffing issues, including the recruitment of additional clinical staff, training and clinical leadership; and the management of risk, covering improved clinical governance systems, revised incident management reporting, management and leadership.

43. There were three national recommendations across the two reports. These related to the establishment of a national maternity dataset, the formation of trust networks to ensure access to interventional radiology, and the need for robust systems to be in place to monitor the quality and performance of the maternity services.

Update on key recommendations

44. Though not a direct consequence of this Investigation, since these reports were published, a range of work has been taken to address the national recommendations: improve maternity safety, including the establishment of a national maternity services dataset and better systems to monitor the quality and performance of maternity services. This work is being taken forward through NHS England's Three-Year Delivery Plan for maternity and neonatal services. More detail is set out in our Witness Statement. In relation to interventional radiology, specifically, this is not an area where concerns have been raised in recent times for maternity and neonatal services and the Department is not currently taking forward any work on this.

The Kerr/Haslam Inquiry

Background to the Inquiry

45. The Inquiry discovered that during Kerr's time in the NHS in Yorkshire, 38 former patients made disclosures to NHS staff of sexualised behaviour by Kerr. Of the 30 concerns raised prior to 1983, only one resulted in any action. In 1979, a patient's GP chose to discuss the concerns that she had raised with Michael Haslam, a colleague of Kerr, but Haslam did not take action. In 1983, a nurse raised concerns and the allegations were brought to the attention of the authorities. No investigation took place and the nurse in question was forced to move post. It was not until February 1997 when a patient made a formal complaint to police in Harrogate, that Kerr had sexually assaulted her between 1982 and 1986, that an investigation was launched. Kerr was convicted of indecent assault, one of 19 charges brought against him by the Crown Prosecution Service.

46. Kerr's boss, Haslam set up his psychosexual clinic in the 70s, and despite allegations of sexual abuse against him, he was awarded an honorary NHS consultancy and continued to practise privately and to work in medical management. He used experimental treatments to treat patients and although known to his peers, no questions were asked about them by either patients or his peers. The very few patients who submitted formal written complaints, all declined to take part in any formal disciplinary proceedings.

Key findings and changes made in response

47. The Inquiry found that members of the local healthcare community remained silent, despite a building body of evidence, because the pervading culture permitted inaction and there was inappropriate tolerance of unacceptable behaviour where no-one wanted to challenge a doctor. When concerns were raised, they were not acted upon, and the 'whistle-blower' was treated poorly. There was an absence of understanding about sexualised behaviour amongst clinicians and patients. There were several recommendations, calling for:

    a. awareness and agreement of treatments carried out in a hospital;

b. guidance on how to raise complaints of sexual abuse; support for patients including guidance on patient confidentiality;

c. data collection on sexual abuse/assaults and guidance about how to record relevant complaints including the performance of doctors;

d. complaints procedures, handling of, and investigation of, complaints; support to patients and staff for raising concerns; transparency of the relevant data; helpline to raise concerns anonymously;

e. common standards practises and procedures in professional regulation;

f. curriculum and professional training setting out responsibilities of a doctor and awareness of complaints procedures, patient confidentiality etc;

g. patient information about what to expect from the doctor; and

h. duty of candour.

48. Given the common themes in the recommendations ("club culture", no formal complaints processes, inadequate professional regulation, low staffing levels), the Department published a Government response with its position on the recommendations. The response set out the areas where many of the recommendations had already been implemented or were in the process of being implemented at the time.

Update on key recommendations

49. As mentioned elsewhere in this document and in our Witness Statement, over the period since the Inquiry, there have been significant reforms in the NHS to improve culture with emphasis on quality and safety, including stronger accountability and governance structures. An update on policies which are relevant to this inquiry has been provided in the Allitt, Neale and Shipman inquiry sections, covering in more detail information about appointment of doctors and expected standards, behaviours and values, complaints procedures and PALS, how to raise concerns, chaperoning policy, fitness to practice, whistle-blowing.

50. In respect of mental health services, following a GP referral, a mental health assessment is carried out to assess the patient's needs. The discussion covers the patient's condition, the diagnosis, possible causes, the treatments on offer, and how those might affect the patient's life. During treatment, there is a care co-ordinator to regularly review the treatment with the patient.

Mid Cheshire Hospitals NHS Trust Inquiry by the Healthcare Commission

Note: This investigation was undertaken by the Healthcare Commission. The Department does not have access to Healthcare Commission or Trust/SHA records.

Background to the Investigation

51. Following the conviction of ward Sister Barbara Salisbury of two counts of attempted murder, the Healthcare Commission launched an Investigation to establish if there had been systems failings to protect the safety of patients at Mid Cheshire Hospitals NHS Trust. The Investigation also considered whether these failings had been addressed.

Key findings and changes made in response

52. The Investigation identified poor record keeping, particularly concerning the handling of allegations made against Barbara Salisbury; mismanagement of complaints and allegations, inadequate levels of nursing staff; a lack of effective clinical governance arrangements and ineffective leadership. It also concluded that the management of medication had not been a priority for the trust and improvements to procedure and controls were slow.

53. The Investigation called for urgent action from the Strategic Health Authority to work with the trust to address concerns. An action plan was drawn up in 2006 to respond to each recommendation. The report contained no recommendations for DHSC.

Brief update on current position

54. Since the Investigation reported, the NHS complaints system has undergone substantial reform to improve local arrangements for managing complaints. There are also national measures in place to support staff to speak up about concerns and protect whistle-blowers. An update on current practice to address the key findings of this review has been provided in other sections.

Leeds Teaching Hospitals Inquiry

Note: This Inquiry was commissioned by Yorkshire and the Humber Strategic Health Authority (SHA). The Department does not have access to Trust/SHA records.

Background to the Inquiry

55. The report was commissioned by Yorkshire and the Humber Strategic Health Authority (SHA) in August 2008. It followed the conviction of Colin Norris, a staff nurse, who committed four murders and one attempted murder of elderly female patients at Leeds Teaching Hospital NHS Trust in 2002, by using medication to cause patient death. The Inquiry's view was that the trust's organisational systems and culture provided Norris with the opportunity to cause harm, although he was responsible for the murdering the patients.

What were the key points from this Inquiry?

56. The report acknowledged that cases of malicious and deliberate harm to patients by healthcare professionals were rare, but concluded that cultural, organisational and system factors provided Norris with the opportunity to cause harm. It highlighted that the Trust did not have robust monitoring procedures regarding supply and administration of medicines and concluded that earlier review of the unexpected deaths may have identified failings sooner. There were shortfalls in how the Trust dealt with relatives' complaints and concerns, and how they were supported. There were also issues concerning the trust's staff knowledge and understanding of clinical governance policies and processes, including ambiguity over patient safety. There were two recommendations for DHSC.

57. The Yorkshire and the Humber SHA, NHS Leeds and Leeds Teaching Hospitals NHS Trust put in place an action plan in 2010 which detailed actions against each recommendation and a progress update for each, with some having been completed by the time the plan was published.

Update on key recommendations

58. As mentioned in our Witness Statement, the patient safety landscape has changed considerably since 2008. In relation to medical examiners, the operational implementation of the medical examiner system is the responsibility of NHSE but DHSC is the lead department for the cross-government programme of death certification reform. DHSC is working closely with NHSE, the National Medical Examiner, the Ministry of Justice and Government Registry Office.

59. As set out in this document, work has taken place to address recommendations from other inquiries which are also relevant to the recommendations of this inquiry, including the regulation of controlled drugs, HR processes, complaints procedures, whistle-blowing.

Airedale Inquiry

Background to the Inquiry

60. In 2004 Sister Grigg Booth was charged with three offences of murder, one offence of attempted murder and 13 offences of administering noxious substances with intent to cause grievous bodily harm or harm. The victims of the alleged offences were patients at Airedale NHS Trust where Sister Grigg Booth had worked as a Night Sister for over a quarter of a century. A hearing in the criminal proceedings was listed for April 2006 but she died before then. The coroner recorded a verdict of accidental death. An Inquiry was established in 2009 and reported in June 2010.

Key findings and changes made in response

61. The report found a disconnect between what was happening and what the Board knew; failures by the Trust Board to recognise and act upon the fact that Sister Grigg Booth was part of a system that was not working. The report also highlighted the mismanagement of controlled drugs and a lack of compliance with the regulations, systems and processes of the time to assure patient safety. Senior managers knew or should have known that Night Nurse Practitioners were working beyond their scope of practice and administering opiates, against official hospital policy. Concerns were raised and nothing was done in response. There were also cultural issues, with staff reporting a lack of confidence in the HR policies, or the system for reporting grievances. Several of the recommendations were made at Trust level and related to corporate governance and HR structures. There were also recommendations concerning clear accountability, governance, training and development plans for NHS organisations and consideration from the Department of Health of any role in this.

62. The trust's Board of Directors commissioned an independent review of its leadership and governance by the Good Governance Institute. The trust's Annual Report and Accounts 2019/2020 provides detail of this review:

> *"During 2019/20, the Board of Directors commissioned an independent review of its leadership and governance by the Good Governance Institute based on NHS Improvement's well-led framework and the Care Quality*

Commission's well-led key lines of enquiry, using a well-established review technique that has as its basis the triangulation of evidence. The review activities included interviews with key individuals within Airedale and external stakeholders; a documentation review; and meeting observations. At the time of writing this report, the results have not been finalised but early findings show some key themes including; the Trust having high-quality, approachable and visible leadership; high professional standards and patient focused qualities; sound business flow and processes, with most governance support systems are seen as generally effective and comprehensive; a need to develop more robust Board to ward assurance; Ongoing development of performance management arrangements.

Update on key recommendations

63. Our Witness Statement sets out that patient safety is one of the core responsibilities of a Trust board. In relation to governance arrangements in trusts, the Code of governance for NHS Trusts sets out the common overarching framework for the corporate governance of trusts. The NHS oversight framework describes NHS England's approach to oversight of integrated care boards (ICBs) and trusts. Finally, work on professional training and development, openness and transparency in communication with patients and families is set out in this document and in our Witness Statement.

The Mid Staffordshire NHS Foundation Trust Public Inquiry

Background to the Inquiry

64. A non-statutory inquiry was commissioned in 2009 to examine the failings in care at Mid Staffordshire NHS Foundation Trust between 2005 and 2009. The Inquiry reported in February 2010. Following the publication of the report, a statutory inquiry was commissioned in June 2010 to examine the wider system and consider why issues at the Trust had not been detected sooner. The statutory Inquiry reported in February 2013. Both non-statutory and statutory Inquiries were led by Sir Robert Francis QC.

Key findings and changes made in response

65. The Francis report was comprehensive, highlighting failures within the trust but also on the part of commissioners, regulators and national government. It produced 290 recommendations, the great majority of which were accepted by the Government. There were key themes on openness, transparency and candour throughout the healthcare system (including a statutory duty of candour), fundamental standards for healthcare providers, improved support for compassionate caring and stronger healthcare leadership.

66. An initial Government response was published in March 2013, with a further response in January 2014 covering each of the recommendations. The Government accepted the majority of recommendations, mostly in full, some in principle or in part. Nine recommendations were not accepted. DHSC marked the anniversary of the report in 2014, and issued a further update against the recommendations in 2015 (*Culture change in the NHS Applying the lessons of the Francis Inquiries)*. Where the accepted recommendations required specific actions (such as provisions to create an offence of providing false or misleading information), these were put in place. In addition, the Department led work to reform the oversight of providers through measures (both legislative and administrative) to ensure CQC used clinically led, robust and authoritative inspection to identify failures in care or patient safety without fear or favour. Those organisations with the

most significant problems were placed in a 'special measures' regime which put in place structured intervention and support. This approach continues to form the basis of current practice.

Update on key recommendations

67. As mentioned in our Witness Statement, a range of reforms and improvements flowed from the Francis report. These together with further work on patient safety, with particular emphasis on building a culture of transparency and learning, have changed practice in the NHS in many ways, including the CQC inspection framework, the involvement of patients and the public in decisions about their care and services, and the oversight of local services. Further work has taken place since the Francis report to continue to promote and create a culture of openness, learning, candour, transparency and safety.

68. In relation to the recommendations, the Department issued an initial response in February 2013 with some early policies: Government initial response to the Mid Staffs report. It then published final response covering each of the recommendations including a detailed table in November 2013. A significant number of recommendations was agreed, with nine being rejected (while accepting the intent behind them - 19, 61, 64, 137,145,183,209,212,213): Hard Truths: The Journey to Putting Patients First: Volume One (publishing.service.gov.uk).

69. We marked the anniversary of the report in: 'Francis Effect' on NHS care one year on from Mid Staffs Inquiry". The Department subsequently did a full one-year on update in early 2015 to set out what we had done since November 2013 – including each recommendation, in: "Culture change in the NHS – Applying the lessons of the Francis Inquiries".

70. Work in respect of transparency and culture, including duty of candour, whistle-blowing and speaking up is set out in the Witness Statement.

Berwick Review into Patient Safety

Background to the Review

71. Professor Don Berwick, an international expert in patient safety, was asked by the then Prime Minister and Secretary of State for Health in 2013 to advise on how to improve the quality and safety of care in the NHS following publication of the Francis Report into care failings at Mid Staffordshire Hospital. Professor Berwick's independent Review was published in August 2013 and made 10 key recommendations in relation to advancing patient safety throughout the NHS.

Key findings and changes made in response

72. The report highlighted the main problems affecting patient safety in the NHS and made recommendations to address them. It said that the health system must:

    a. recognise with clarity and courage the need for wide systemic change;

    b. abandon blame as a tool and trust the goodwill and good intentions of the staff;

    c. reassert the primacy of working with patients and carers to achieve health care goals;

    d. use quantitative targets with caution - they should never displace the primary goal of better care;

    e. recognise that transparency is essential and expect and insist on it;

    f. ensure that responsibility for functions related to safety and improvement are established clearly and simply;

    g. give NHS staff career-long help to learn, master and apply modern methods for quality control, quality improvement and quality planning; and

    h. make sure pride and joy in work, not fear, infuse the NHS.

73. The Government responded to both the Mid Staffordshire Public Inquiry and Berwick reports in Hard Truths The Journey to Putting Patients First in January

2014 and Culture change in the NHS Applying the lessons of the Francis Inquiries.

Update on key recommendations

74. The Government response was clear that reducing harm remains a political imperative and set out a number of initiatives, including proposals for greater data transparency and changes to reinforce regulation.

75. They include greater independence to the CQC and key improvements to the way it regulates health and social care; a statutory duty of candour on providers and a professional duty of candour on healthcare professionals; NICE guidance on safe nursing staffing levels; leadership programmes for clinicians, nurses and midwives; data on consultant performance, a focus on lessons learnt from complaints; a new Fit and Proper person's test; a new criminal offence for providers that supply or publish false or misleading information; clinical training on patient safety and sharing of good practice; guidance about how to manage serious patient safety incidents; Local Education and Training Boards and deaneries – and individuals – to highlight persistent and serious patient safety concerns in training environments with the GMC; and consultation about refreshing the NHS Constitution.

76. Many of these policies as well as new policies and programmes continue today as mentioned in other sections of this document and in our Witness Statement.

The Independent oversight of NHS and Department of Health Investigations into matters relating to Jimmy Savile

Background to the Inquiry

77. In October 2012, the Secretary of State asked Kate Lampard CBE to provide independent oversight and assurance of the investigations at three NHS Hospitals (Leeds General Infirmary, Stoke Mandeville and Broadmoor) and of the smaller investigations, as well as the associations Savile had had with the Department of Health. He also asked her to produce a lessons learnt report, drawing on the findings from all published investigations and emerging themes. There were three main reports published between 2014-2015 into the activities of Jimmy Savile in relation to hospitals and hospice premises. Stoke Mandeville published in February 2015, Broadmoor in June 2014; Leeds General Infirmary published an initial report in June 2014 and a later report in February 2015. In addition, there were 40 separate investigations published into single incidents involving Savile at other Trusts.

78. Kate Lampard published an assurance report in 2014. The lessons learnt report, published on 26 February 2015, included 14 recommendations for the NHS, the Department of Health and wider government. In his statement on the same day, the Secretary of State accepted in principle 13 of the 14 recommendations.

Findings and recommendations

79. Several themes were identified as relevant to the wider NHS, which included security and access arrangements, including celebrity and VIP access; the role and management of volunteers; safeguarding; raising complaints and concerns (by staff and patients); fundraising and charity governance; and the observance of due process and good governance. The recommendations predominantly related to authorisation and control of access to and within hospitals by volunteers and high-profile visitors.

80. Nine of the 14 recommendations were for NHS providers to implement. The Chief Executives of Monitor and the NHS Trust Development Authority wrote to all NHS

foundation trusts (FTs) and NHS trusts to ask them to read the lessons learnt report and review their current practice against the recommendations. In particular, trusts were asked to:

a. develop an action plan to identify where additional action was needed against these recommendations;

b. provide assurance that the necessary action had been taken, or where this was in progress, the date by which it would be completed; and

c. report back on their proposed actions within three months.

81. All NHS trusts and all NHS foundation trusts responded. Reassuringly, the vast majority of responses were very detailed and considered, giving the Department confidence in the level of commitment across the sector to address the issues raised by the Savile investigations and the lessons learnt report. For individual recommendations, at least 80% of providers planned to have implemented them by September 2015. The responses were collated by Monitor and TDA who provided an update to the Secretary of State. A summary of findings was published on 26 November 2015.

Update on key recommendations

82. The actions the Government accepted from the review are now embedded in standard practice in the way Trusts operate. The NHS has also acted on recommendations relating to the authorisation and control of access to and within hospitals by volunteers and high-profile visitors. NHS England has produced guidance to support NHS providers in the appropriate recruitment and management of volunteers; the guidance includes identifying good practice to enable NHS trusts to formally review their volunteering programmes. NHS England » Recruiting and Managing Volunteers in NHS Providers – a practical guide.

83. The NHS Employment Check Standards outline the checking requirements for all individuals before starting any type of work or volunteering. This includes the criminal record checking requirements for eligible roles in the NHS. The Standards are subject to periodic review to ensure they accurately reflect changes to legal and regulatory requirements as they evolve. The Standards also offer advice about

introducing periodic DBS checks locally should an organisation choose to conduct such checks. The same Standards apply when appointing temporary workers and contractors.

84. NHS Employers continues to support NHS organisations to understand and meet the requirements of the NHS Employment Check Standards, including those required as part of the Disclosure and Barring Service (DBS) regime. In April 2023, it rolled out an e-learning package to support organisations to understand and meet requirements of the NHS Employment Check Standards, including DBS regime requirements. Launch of NHS employment checks training resource | NHS Employers

85. Safeguarding is firmly embedded within the core duties and statutory responsibilities of all organisations across the health system. NHS England's 'Safeguarding accountability and assurance framework' sets out how NHSE assures that the NHS is delivering its responsibility relating to safeguarding children, young people and adults at risk the safeguarding roles B0818_Safeguarding-children-young-people-and-adults-at-risk-in-the-NHS-Safeguarding-accountability-and-assuran.pdf (england.nhs.uk) Safeguarding requirements are included in the NHS Standard Contract to ensure compliance by NHS providers.