Witness Name: Professor Sir Stephen Powis

Statement No.: NHSE/1

Dated: 25 March 2024

THIRLWALL INQUIRY

FIRST WITNESS STATEMENT OF PROFESSOR SIR STEPHEN POWIS

Contents

I, Professor Sir Stephen Powis, will say as follows: -

INTRODUCTION

1. I have been the National Medical Director of NHS England since early 2018. I was also Interim Chief Executive Officer of NHS Improvement between 1 August 2021 and 30 June 2022 (when NHS Improvement ceased to exist as a consequence of the organisations that worked together as NHS Improvement, Monitor and the NHS Trust Development Authority being abolished and their functions transferred to NHS England).

2. Lucy Letby committed appalling crimes that were a terrible betrayal of the trust placed in her as a member of the nursing profession. In the aftermath of Lucy Letby's conviction, NHS England issued a public statement, welcoming the then independent inquiry and giving a commitment to full cooperation and transparency, to ensure that every possible lesson is learned from this awful case. I was one of the signatories to that statement and I would like to reiterate its contents. In particular, I would like to emphasise that my thoughts remain focused on the families of those affected by Lucy Letby's crimes. I want to acknowledge the pain and anguish they have suffered and which they continue to suffer.

3. I also want to assure the Inquiry and the public that NHS England is focussed on ensuring that neonatal services are safe and effective. The ways in which we are doing this are described in detail in this statement. There have continued to be many clinical improvements in care for babies, including those born prematurely, since NHS England was established in 2012. As a result, there are much greater prospects in terms of survival and reductions in morbidity.

4. At the same time, the way that neonatal care is organised has also changed. This includes the introduction of formally recognised levels of care and the further development of networks to facilitate coordination of care across providers and a sustained focus on clinical best practice. The drive to improve maternity and neonatal care has evolved, reflecting changes in government policy; clinical best practice; structural changes (including those resulting from legislative change) and in response to recommendations and issues raised in previous inquiries, investigations and reviews. This is described in further detail below.

(1) Approach to the NHSE/1 Rule 9 Request

5. This witness statement was drafted on my behalf by the external solicitors acting for NHS England in respect of the Inquiry, with my oversight and input. The request received by NHS England on 2 November 2023 pursuant to Rule 9 of the Inquiry Rules ("the NHSE/1 Rule 9 Request") is broad in scope and goes beyond matters which are within my own personal knowledge. As such, this statement is the product of drafting after communications between those external solicitors and a number of senior individuals in writing, by telephone and video conference. This includes both current and former NHS England employees, and former employees of the legacy regulatory bodies, particularly Monitor and the NHS Trust Development Authority (referred to together, along with NHS Improvement, in this statement as the "Legacy Bodies"). I do not, therefore, have personal knowledge of all the matters of fact addressed within this statement. However, given the process here described, I can confirm that all the facts set out in this statement are true to the best of my knowledge and belief.

6. The statement has been produced following a targeted review of documents collated to date. In the time available, it has not been possible to review every potentially relevant document, and it is highly likely that relevant documents exist that have not been reviewed. I cannot exclude the possibility that it will require updating as further evidence emerges through our ongoing process of internal investigation and document review. NHS England will, of course, notify the Inquiry as soon as practicable if information comes to light that would have been included in this statement if it was known to us before the deadline for its production.

7. The NHSE/1 Rule 9 Request considers a relatively long period of time, with a focus on the period from 2012 to date. During this time, and as described in this statement, there have been a number of important changes. This includes but is not limited to structural changes as a result of legislative and policy developments. We have used two time periods within this statement:

    a. The first covers the period 4 January 2012 to 30 June 2016. We have adopted the date 30 June 2016 as the final date for this first time period because this is the day that LL worked her last shift on the neonatal unit and her offending came to an end. 2016 is also an important point in time for the NHS since it is when NHS Improvement became operational, marking a move

to a different way of regulating NHS providers. We have defined this as the "First Relevant Period".

b. The second covers the period 1 July 2016 to the present day. We have defined this as the "Second Relevant Period".

8. Occasionally we have referred to these two periods together, for instance when discussing consistent concepts that have remained unchanged throughout this entire time period. In such cases we have used the term the "Overall Relevant Period", meaning the First Relevant Period and the Second Relevant Period together.

9. This statement includes evidence from a range of sources, including those relating to legacy statutory bodies that are now, by virtue of statutory transfer, part of NHS England. Although we have sought to be clear about what role and responsibilities each legacy body had during the period that the Inquiry is considering, the evidence overall has been combined to represent the evidence and voice of NHS England. This recognises that the functions, staff and liabilities of the legacy statutory bodies (Monitor and the NHS Trust Development Authority) have transferred to NHS England. Accordingly, references throughout to 'NHS England', and 'we' represent the voice of the organisation at the present day, unless it is obvious from the context that the statement is describing the actions of NHS England before the legacy bodies merged into it. I have referred to all individuals (including myself) in the third person, by job title.

10. In order to ensure that the statement is as accessible as possible, some material which is primarily required for contextual or reference purposes, including NHS England's legal duties and functions and that of the most relevant legacy statutory bodies it is now responsible for, is contained within annexes at the end of the statement.

11. Each of the two Relevant Periods contains a programme of significant legislative reform of the NHS. In addition, and prior to the legislative reform in the Second Relevant Period, a policy programme for joint working led to a number of national NHS regulatory bodies coming together to work in an aligned way, but without any formal legal changes to each body's underlying legal status: first as NHS Improvement (in the case of Monitor and the NHS Trust Development Authority) and then as NHS Improvement and NHS England (in the case of those two bodies). These changes can be summarised as follows:

Date	Event
1991	• *NHS Trusts were introduced as separate statutory bodies.*
2004	• *Monitor (legally the Independent Regulator of Foundation Trusts until 2012) was established as the independent regulator of NHS Foundation Trusts.* • *NHS Foundation Trusts became operational.* • *The Countess of Chester Hospital was one of the first Trusts to be given NHS Foundation Trust status through Monitor's authorisation process.*
2012	• *The NHS Leadership Academy was set up as an independent organisation.*
June 2012	• *Health Education England was established as a special health authority.* • *The NHS Trust Development Authority was established to formally regulate and monitor NHS Trusts (becoming fully operational from 1 April 2013).* • *Monitor's role was expanded to reflect its role as the system regulator in relation to providers of NHS services (other than NHS Trusts).*
October 2012	• *The NHS Commissioning Board was established (becoming fully operational on 1 April 2013).* • *Clinical Commissioning Groups were established (becoming fully operational on 1 April 2013).*
1 April 2013	• *NHS Digital (legally the* Health and Social Care Information Centre*) was established.* • *The NHS Commissioning Board becomes fully operational, under the name "NHS England".* • *The NHS Trust Development Authority becomes fully operational.* • *The National Institute for Health and Clinical Excellence was renamed the National Institute for Health and Care Excellence (NICE) to mark its expansion into social care. (It was originally set up in 1999 as the National Institute for Clinical Excellence).* • *Clinical Commissioning Groups were established.*
1 April 2015	• *Health Education England was established.*
1 April 2016	• *Monitor and the NHS Trust Development Authority start to work together under the operational name NHS Improvement.*

Date	Event
February 2019	• *NHS England and NHS Improvement come together.* • *NHSX, a joint unit between NHS England, NHS Improvement and the Department of Health and Social Care became operational.*

1 July 2022	• *The NHS Trust Development Authority was abolished.*
	• *NHS Improvement and NHS England merged.*
	• *Integrated Care Systems were placed on a statutory footing:*
	  • *Integrated Care Boards were established to replace Clinical Commissioning Groups which were abolished.*
	  • *Local Authorities and Integrated Care Boards were required to establish Integrated Care Partnerships.*

1 February 2023	• *NHS England legally merged with NHS Digital*
1 April 2023	• *NHS England merged with Health Education England*

12. The title of the Secretary of State for Health has also changed during the Overall Relevant Period, being the Secretary of State for Health until 8 January 2018 and the Secretary of State for Health and Social Care from 8 January 2018 to date. For ease, we have referred throughout to the Secretary of State but have included at Annex 1 a table of the individuals who held this role during the Overall Relevant Period.

(2) Outline of this corporate witness statement

13. As I have said, this statement contains responses to topics and questions set out in Section 1 of the NHSE/1 Rule 9 Request. As suggested by the Inquiry, the statement adopts its own structure and deals with the Inquiry's questions and topics in a different order to the way they appear in the NHSE/1 Rule 9 Request.

14. Section 1 of this statement is separated into two parts:

    a. Part A aims to help the Inquiry to understand contextual matters such as NHS England's structure and role in the wider healthcare system, its role specifically as a commissioner of specialised services (including neonatal services) and, latterly, as the regulator of NHS Trusts and NHS Foundation Trusts. This part touches on several central concepts, including 'commissioners' and 'providers', and regulation and oversight versus directive performance management. This will help to explain the NHS provider landscape; the legacy regulatory bodies; the arrangements that

were in place in each Relevant Period; and subsequently the statutory transfer of these legacy bodies to NHS England. In addition, we explain in brief how the term 'quality' is used in the NHS.

b. Part B provides a high-level overview of what is meant by patient safety, as one of the core components of quality, as defined in Part A of this statement. Key patient safety structures and frameworks in place at a national level are described. This includes an explanation as to how we work with partner bodies and other regulators.

15. Section 2 describes how and when NHS England and the Legacy Bodies became aware of issues relating to neonatal services at the Countess of Chester NHS Foundation Trust. It also describes in more detail regional monitoring arrangements for quality, commissioned services and trust performance relevant to this Inquiry.

16. Section 3 of this statement is separated into three parts:

a. Part A explains how recommendations to address culture and governance issues made by previous inquiries into the NHS have been implemented, with a particular focus on maternity and neonatal services.

b. Part B describes NHS England's current procedures and policies, although some of this content is briefly introduced in Section 1.

c. Part C comments on the effectiveness of current policy, and also sets out initial reflections on lessons learned and recommendations for future action

17. It will be important to read these three Sections together, in order to enable a fully informed understanding of how the various parts fit together and why changes (whether legislative, policy or practice) took place when they did.

SECTION 1: STRUCTURE ROLES AND RESPONSIBILITIES

PART A: NHS ENGLAND IN CONTEXT

18. Part A of this Section explains the role of NHS England and its relationship with other key NHS statutory bodies in relation to matters of oversight and regulation. This section is structured as follows:

    (1) An introduction to the NHS

    (2) The national NHS landscape

    (3) NHS England's statutory role

    (4) NHS England's organisational structure

    (5) NHS England's commissioning role

    (6) Clinical Commissioning Groups

    (7) NHS Providers (NHS Trusts and NHS Foundation Trusts)

    (8) Provider Oversight

    (9) Regulation of Trusts

    (10) The Care Quality Commission

    (11) The 2022 Reforms – more integrated working

    (12) Creating the New NHS England

    (13) How NHS England works with other partners

(1) Introduction to the NHS

19. The National Health Service — the NHS — was established in 1948 by the government of the day under the first National Health Service Act of Parliament: the National Health Service Act 1946, which came into effect on 5 July 1948. At the time of its establishment, the NHS included the services we today refer to as the NHS, as well as public health functions. The NHS today does not include public health, except as

described below at paragraph 21. This has been the position throughout the Overall Relevant Period.[1]

20. The NHS in England is an ecosystem of commissioners of services, regulators and service providers, each with their own distinct role. The publicly funded health service (excluding public health) in England comprises primary care, secondary care, tertiary care, mental health and community care as more particularly described below. It is important to note that NHS England is not the same as 'the NHS in England', with the latter being the phrase often collectively used to refer to all bodies which make up the publicly funded health service in England (again, excluding public health except as below).

21. Public health functions are, for the most part, carried out by the Department for Health and Social Care (and its executive agencies (Public Health England, which is now the UK Health Security Agency)) and Local Authorities. However, the Secretary of State for Health and Social Care does routinely delegate some specific public health functions to NHS England on an annual basis. These functions are known as 'section 7A functions' and include neonatal immunisations, among others.

22. For the most part, the term 'NHS' is used as an umbrella term to mean all those performing their services with NHS monies and contracts.

(2) The national NHS landscape

23. Statutory NHS bodies, including NHS England, must act within their legal frameworks, and more widely public law. They perform the functions which Parliament sets for them under the direction of the government of the day.

24. Since 1948, successive governments have determined how the NHS should be organised, with many reforms being undertaken by legislation.

25. In the Overall Relevant Period, the NHS in England underwent two major legislative reforms, one in each of the Relevant Periods:

[1] See the definition of "the NHS" in section 64 of the Health and Social Care Act 2012 ("the 2012 Act"), which has been repealed and replaced by section 150 of 2012 Act, as a result of the Health and Care Act 2022 ("the 2022 Act") amendments). This is explained further in brief below.

a. The Health and Social Care Act 2012 ("the 2012 Act") significantly re-organised the NHS, with many of the changes coming into effect on 1 April 2013. The 2012 Act amended the National Health Service Act 2006 ("the 2006 Act") which remains the main piece of primary legislation governing the NHS. These 2012 changes were known as the 'Lansley Reforms'.

b. The Health and Care Act 2022 ("the 2022 Act") came into effect on 1 July 2022. The 2022 Act again amended the 2006 Act and re-organised the NHS (we have also referred to this as the 2022 Reforms). This is covered in paragraph 275 onwards, below.

26. In addition, and as described from paragraph 238, in the period between these two periods of legislative reform, there was also a policy programme of joint working that resulted in changes to the way that some of the national health bodies operated.

27. As a result of these reforms, the NHS today is very different, both in structure and in the way it operates, to what it was in the First Relevant Period. These differences are important background, particularly when considering the responsibilities that the various statutory bodies (including NHS England) have had during this period and how these responsibilities have changed over time.

(a) Regulation

28. In this statement, we frequently refer to regulation and to regulatory bodies. In the case of Monitor and the NHS Trust Development Authority, we also distinguish between arms-length regulation and more directive performance management ('command and control' regulation).

29. In recent years, including beyond the healthcare context, successive governments have generally moved away from very prescriptive regulation. There has been greater use of economic regulation and enforced self-regulation, including through the use of mandatory guidance or equivalents. The legislative reforms at the start of the First Relevant Period reflect the regulatory approach at that specific time, which then evolved within the First Relevant Period and continued to do so during the Second Relevant Period.

30. Regulation is different to contract management by commissioners. Whilst there are some commonalities, such as performance management and assurance, these tasks are performed for different purposes. This distinction between provider regulation and

contract management is important when considering the different roles of Monitor, the NHS Trust Development Authority and NHS England during the First Relevant Period.

(b) Commissioners

31. Throughout the Overall Relevant Period, there has been a distinction between commissioning and provision of NHS services, although there is less emphasis on this distinction now than there was during the First Relevant Period.

32. 'Commissioning' is the term given to the role of arranging (including by contracting) healthcare services. It involves the ongoing process of planning, agreeing and monitoring to ensure that appropriate healthcare services are being arranged and that these services are being delivered to the required standard. Commissioning includes, but is not limited to, entering into contracts with providers of NHS services and monitoring the performance of such contracts **[Exhibit SP/0001 [INQ0009274]].**

33. Prior to amendments made by the 2012 Act, statutory responsibility for providing or securing the provision of services for the purpose of the health service lay on the Secretary of State, rather than directly on national, regional or local NHS bodies (although trusts had the general function of providing services). At a national level, the Department of Health and Social Care discharged the Secretary of State's functions in relation to the NHS through part of the Department of Health and Social Care known as "the NHS Executive", headed by a civil servant known as the NHS Chief Executive.

34. At the regional level, Strategic Health Authorities were responsible for overseeing and managing the health service. At a local level, NHS services (including neonatal services) were commissioned by Primary Care Trusts, in exercise of functions directed by the Secretary of State. These commissioned services were provided by a combination of statutory NHS providers (trusts) and independent or third sector providers. Primary Care Trusts also provided some services, such as community health services, using their own staff and facilities.

35. The Secretary of State could issue a legal instruction to regional Strategic Health Authorities and local Primary Care Trusts to direct how they exercised those functions.

36. The changes made to the commissioning landscape due to the 2012 Act amendments are described below.

(c) Providers

37. Patients in England receive their services from 'providers' who have an arrangement to deliver these services with one or more commissioners. Depending on the type of services and the nature of the provider, these arrangements will take the form either of an NHS contract (which is a non-legally binding contract at law); a legally binding contract; or a primary care contract (such as a General Medical Services Contract). We have not discussed primary care contracting further within this statement. The different kinds of contracts for services provided in acute settings are explained in more detail at paragraph 151 below. For ease, we have referred to the arrangements in general for non-primary care acute services as being 'contracts'.

38. Many bodies hold contracts with the NHS and are part of the publicly funded health service, such as GP practices, dentists, independent hospitals, and community rehabilitation providers, but not all will be NHS bodies.[2] The term 'NHS body' is defined in section 275 of the 2006 Act to mean certain specific entities. In the First Relevant Period, the definition included NHS England; a Clinical Commissioning Group, a Special Health Authority, an NHS Trust and an NHS Foundation Trust. The definition is essentially the same following the 2022 Act amendments, except that a Clinical Commissioning Group has been replaced by an Integrated Care Board.

39. Providers are accountable to commissioners through their contracts for the services commissioned and through associated service specifications.

40. It is the responsibility of the provider to ensure that services are carried out in accordance with specifications, allocated budgets and taking into account appropriate clinical guidance and nationally determined healthcare standards, such as those set by the Care Quality Commission. In order to properly understand the comprehensive statutory framework for regulation of providers, it is important to consider both the role performed by Monitor (and latterly NHS England) and the Care Quality Commission, and the way that these bodies interact. This is described in more detail at various points in this statement, in particular in Part 2 of this Section 1 and in Section 2.

[2] In March 2014, there were: 160 NHS Trusts, 130 Foundation Trusts, 7,613 GP practices, 11,674 community pharmacies in England. On 31 March 2020, there were: 74 NHS Trusts,149 Foundation Trusts, 6,771 GP practices in England. In 2019/20, there were approximately 11,800 community pharmacies in England. As of 31 March 2022, there were 69 NHS Trusts, 144 NHS Foundation Trusts, 6,499 GP practices, and approximately 11,500 community pharmacies in England.

41. Providers employ their own staff, procure their own supplies, and oversee the day-to-day running of the services at the point of patient care. There is no centrally employed 'NHS workforce'. To be clear, the workforce of NHS Foundation Trusts is not employed or managed by NHS England. The position is the same for NHS Trusts except that NHS England today exercises an appointment role in relation to certain senior roles within NHS Trusts.

42. During the First Relevant Period and up until 1 July 2022, Health Education England was responsible for performing certain functions in relation to the training and development of the healthcare workforce. Further information about the role of Health Education England and the arrangements after 1 July 2022 is set out at paragraph below.

43. The day-to-day care and management of patients is the responsibility of the relevant provider. In hospitals for example, clinicians use their professional judgement and appropriate clinical guidelines to determine the treatment that a patient should be offered and receive. This judgement includes the patient's suitability for treatment options (assuming those are NHS-funded and commissioned services/treatments) as well as whether a patient should be admitted.

44. Clinical treatment decisions are made in accordance with operational policies and procedures set by the relevant provider and reflecting appropriate clinical guidance (including guidance issued by the National Institute of Health and Care Excellence) and service specifications set by the relevant commissioner. Most clinical staff operating within a provider will also be subject to professional regulatory requirements, such as, in the case of medical staff, the General Medical Council or, in the case of nurses and midwives, the Nursing and Midwifery Council. Further information about professional regulation is set out from paragraph 401.

45. In this statement, we will principally cover the arrangements and oversight of the delivery of secondary care services, meaning those provided in a hospital setting. In this sector, there are independent providers and two types of NHS body, NHS Trusts and NHS Foundation Trusts.

(d) Key reforms in 2012 ('Lansley Reforms')

46. Following the general election of 2010, the Government proposed extensive NHS reforms, known as the 'Lansley Reforms' after the then Secretary of State for Health Andrew Lansley. These reforms were intended to bring about a "culture of open

information, active responsibility and challenge" and "ensure that patient safety is put above all else, and that failings such as those in Mid-Staffordshire cannot go undetected". The actions taken following the Mid-Staffordshire inquiry, and other inquiries, are addressed in Part A of Section 3 below.

47. The proposals were set out in the White Paper "Equity and Excellence: Liberating the NHS" published 12 July 2010 ("2010 White Paper") and formed the basis of the Health and Social Care Bill introduced in the subsequent year, which became, on enactment, the 2012 Act. The proposals included an "independent and accountable" and "autonomous" NHS Commissioning Board supporting local "GP commissioning consortia" (later to be called Clinical Commissioning Groups) who would be responsible for commissioning NHS services in local areas.

48. The core policy objectives underpinning the reforms were:

    a. a patient-centred health system, with more choice and control by patients, helped by easy access to information about the best providers;

    b. a focus on clinical outcomes, with success measured by improved outcomes; and

    c. empowered health professionals, including through healthcare being run from the bottom up and clinically led commissioning.

49. The establishment of NHS England and Clinical Commissioning Groups extended and completed the 'commissioner provider split', with neither NHS England nor Clinical Commissioning Groups being able to provide healthcare services themselves. The Lansley Reforms also saw the establishment of the NHS Trust Development Authority, and an updated and extended role for Monitor, reflecting the policy objectives underpinning the reforms.

50. A focus on outcomes and the quality standards that delivered them was emphasised throughout the 2010 White Paper. This built on the work of Lord Darzi, whose report "High Quality Care For All: Next Stage Review Final Report" (published on 30 June 2008) set out a three-domain definition of quality. This definition was incorporated into the 2010 White Paper and remains the accepted core definition of 'quality' within the NHS:

a. the effectiveness of the treatment and care provided to patients — measured by both clinical outcomes and patient-reported outcomes;

b. the safety of the treatment and care provided to patients; and

c. the broader experience patients have of the treatment and care they receive.

51. To help deliver these quality-led improvements, the Lansley Reforms placed patient choice and provider competition at the forefront of how the NHS was intended to operate. Competition was understood to be focused on quality, rather than in a financial sense, with pricing nationally controlled through the National Tariff pricing structure. That said, the incentives to drive competition did include financial ones, such as contractual penalties for poor quality performance.

52. Commissioning was reformed in the following ways:

a. Establishment of the NHS Commissioning Board under section 9 of the 2012 Act by inserting a new section 1H to the 2006 Act. The Board was legally established on 1 October 2012, albeit without its full functions at that stage, following only partial commencement of section 9. The Board became fully operational on 1 April 2013 and adopted its operational name "NHS England" shortly after, with the agreement of the Secretary of State.

b. Establishment of local commissioning bodies, known as Clinical Commissioning Groups. A key feature of the Clinical Commissioning Group framework was that their members were the providers of primary medical services for the area of the Clinical Commissioning Group — i.e. the GP practices which served the Clinical Commissioning Group's population. Clinical Commissioning Groups were therefore intended to deliver a 'clinically-led' approach to the commissioning of local NHS services. The intention was that most NHS services would be commissioned by Clinical Commissioning Groups, supporting this clinically led approach.

53. The 2010 White Paper described NHS England as having five main functions, one of which was to provide national leadership on commissioning for quality improvement. This role was reflected in the statutory duties NHS England had, including the duty in section 13E of the 2006 Act to improve the quality of services.

54. The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 ("The Standing Rules

Regulations") placed further specific responsibilities on NHS England in relation to its commissioning role. For instance, the Standing Rules Regulations required that NHS England draft model commissioning contracts, which Clinical Commissioning Groups were required to incorporate in commissioning arrangements (per Regulation 17). They also included a requirement (at Regulation 34) that commissioning decisions made by NHS England and Clinical Commissioning Groups complied with relevant recommendations made by the National Institute for Clinical Excellence.[3]

55. In addition to these commissioning-specific reforms, there were other structural changes made in relation to previous arm's length bodies, including their abolition. This included changes to the role of the Independent Regulator of NHS Foundation Trusts and a statutory name change to Monitor, reflecting its operational name (these changes are described in detail below from paragraph 166) and the National Patient Safety Agency, which was abolished and whose functions were transferred to NHS England.

(e) The NHS Standard Contract

56. The model commissioning contract referred to above at paragraph 54 became the mandated NHS Standard Contract, which is usually updated annually. **[Exhibit SP/0002, INQ0014615]** Throughout the Overall Relevant Period, the NHS Standard Contract has been the key mechanism for ensuring that providers of NHS services are subject to consistent contractual conditions. It is mandated for use by commissioners when commissioning NHS-funded healthcare services (excluding primary care), including the commissioning of specialised services by NHS England (see paragraph 93 for further detail).

57. As explained above, providers of NHS services were incentivised to perform through the contractual requirements contained in the NHS Standard Contract, which included financial mechanisms and associated sanctions.

58. The contractual aspects of this incentives structure (as opposed to the regulatory penalties that could be imposed by Monitor, for instance) were contained within the NHS Standard Contract. Some incentives were mandated at a national level whilst others were agreed on a contract-by-contract basis locally. Broadly speaking, this was the position from the point the first mandated NHS Standard Contract was issued for

[3] And from 1 April 2013, the National Institute for Health and Care Excellence.

the 2013/2014 financial year. In 2016, the shorter-form version of the NHS Standard Contract was introduced for use in respect of some services, which saw a reduced number of sanctions for those service categories. Alongside this, there was also a relaxation of the financial sanctions for those NHS providers that had agreed to particular financial/sustainability arrangements. There was also a complete suspension of remaining contract sanctions for NHS providers in response to the COVID-19 pandemic.

59. More recently, as part of the wider move towards system working and closer collaboration between commissioners and NHS providers, the financial sanctions structure has been removed permanently from the NHS Standard Contract. The primary exceptions to this are in relation to any legacy locally-agreed Local Quality Requirements and "pay for performance" arrangements (e.g., where the Commissioning for Quality and Innovation Framework, which has been run as a national initiative by NHS England since its establishment, applies).

60. Further information about how the NHS Standard Contract is used and monitored as part of the commissioner-provider relationship is set out in Section 3B of this statement.

(3) NHS England's statutory role

(a) Introduction to NHS England

61. NHS England is an Executive Non-Departmental Public Body sponsored by the Department of Health and Social Care. It is called an Arm's Length Body as it is a public body established with autonomy from the Secretary of State. It was established on 1 October 2012 and is operationally distinct from the Department of Health and Social Care.

62. Up until 1 July 2022, when changed by the 2022 Act, NHS England's legal name was the National Health Service Commissioning Board. As noted above in paragraph 52, it operated under the operational name NHS England for almost all of this time.

63. NHS England's core legal function and purpose is to promote 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. It owes this duty concurrently with the Secretary of State (except that NHS England's duty excludes that part of the health service that is provided in

pursuance of statutory public health functions, and the Secretary of State's duty excludes the commissioning responsibilities given to NHS England).

64. For the purpose of discharging this core legal function and purpose, NHS England is responsible for commissioning certain services and for overseeing certain NHS bodies. For the purposes of this Inquiry, it is important to note that NHS England has been the commissioner of neonatal critical care services since 2012.

65. NHS England's role in respect of oversight has changed in recent years. Today, NHS England is responsible for the oversight of local commissioners and providers of those healthcare services. By contrast, during the First Relevant Period and up until 1 July 2022, NHS England was only responsible for the oversight of Clinical Commissioning Groups. Its role in relation to providers of healthcare services was primarily confined to interactions with them as a commissioner of services on its own behalf, although this did include contract management. Regulation of providers was the responsibility of the legacy regulatory bodies Monitor and the NHS Trust Development Authority (as described in detail below at paragraphs 166 to 252) as well as the Care Quality Commission (whose role has remained broadly consistent throughout the Overall Relevant Period).

66. The Secretary of State had a power to give directions to NHS England if, in the Secretary of State's opinion, it was failing to discharge one or more of its functions, properly or at all (section 13Z2 of the 2006 Act), but this power was never exercised. NHS England had a similar power with respect to Clinical Commissioning Groups (section 14Z21 of the 2006 Act), which it did exercise.

67. In summary, NHS England is not:

    a. a core political or governmental decision-making body;

    b. responsible for setting national health or public health policy; or

    c. a provider of patient services.

(b) <u>NHS England's relationship with the Department of Health and Social Care</u>

68. In general, and as described above, it is the responsibility of Ministers to direct national strategy and set funding levels.

69. The Department of Health and Social Care is responsible for setting policies that deliver the Government's strategic health objectives and, in turn, for making sure the legislative, financial and administrative frameworks are in place to deliver those policies, including the NHS Mandate as described in paragraphs 72 to 76 below.

70. NHS England works with the Department of Health and Social Care to contribute to the development of policy and to support the government of the day to understand the operational implications of their priorities. NHS England will involve and engage with other people and organisations across the healthcare sector, including service users as necessary before providing input. Central government is then responsible for selecting from the policy options and ensuring any policy selected is appropriately financed.

71. NHS England is responsible for determining how to operationalise those policies to ensure effective delivery and also for evaluating their impact. This is reported to government via the Department of Health and Social Care. During the Overall Relevant Period, NHS England's role in relation to Central Government decision making and policy development has remained broadly the same, with few notable exceptions (such as the NHS-led changes introduced through the 2022 Act).

72. In relation to funding, NHS England is party to a Framework Agreement with the Department of Health and Social Care **[Exhibit SP/0003 [INQ0009227]].** In addition, up until the 2022 Act came into effect, the Secretary of State would issue an annual 'Mandate' for NHS England. This set out the objectives which NHS England must seek to achieve and its budget, which established limits on the use of capital and revenue resources (in effect, this sets NHS England's financial allocation). This Mandate would be issued before the start of each financial year. Certain resources were ringfenced by the Mandate meaning that those sums could not be used for any other purpose, even if there was an underspend.

73. The Mandate and NHS England's financial allocation and associated resource limits has changed since 1 July 2022. The Mandate no longer needs to be issued annually and resource limits are now set in directions, not in the Mandate itself. As a result, the current Mandate **[Exhibit SP/0004 [INQ0009279]]** applies "until a new mandate is published".

74. Despite these changes, the accountability framework that the Mandate supports remains the same. NHS England is accountable to the Secretary of State for the

delivery of the Mandate. NHS England's Chair and Chief Executive Officer meet the Secretary of State periodically to provide assurance on progress against Mandate objectives. The Mandate is reviewed annually by Government and an assessment is laid before Parliament.

75. NHS England is required to produce a business plan that sets out how NHS England will deliver the objectives set out in the Mandate and reports on progress against this. It also produces an Annual Report on how it has exercised its functions during the year. NHS England's financial position is reported on annually through its Annual Accounts. I understand that NHS England's Business Plans for the years 2012 to 2023 have been provided to the Inquiry by way of general disclosure **[see [INQ0009245] [INQ0009222] [INQ0009229] [INQ0009241] [INQ0009244] [INQ0009248] [INQ0009250] [INQ0009266] [INQ0009273]]**.

76. The first Mandate was issued for the period April 2013 to March 2015 (the "First Mandate") **[Exhibit SP/0005 [INQ0009225]]**. This First Mandate specifically referenced NHS England's responsibilities as a commissioner, including those in relation to specialised care, noting the opportunity that this provided for improved standards and national consistency **[§92 Exhibit SP/0005 [INQ0009225]]**.

77. Importantly, emphasis was also placed in the First Mandate on NHS England working with Clinical Commissioning Groups and others to ensure that — whether NHS care is commissioned nationally or locally — the quality and value of the services should be measured and published in a similar way. The NHS Outcomes Framework, which is described in detail at paragraph 359 below, was one aspect of supporting this objective. The emphasis on consistent measurement and publication of these metrics reflected the focus on reducing health inequalities and unjustified variation.

(4) NHS England's organisational structure

(a) Introduction to NHS England

78. NHS England is governed by its Board which provides strategic leadership and accountability to Government, Parliament and the public.

79. Since establishment, NHS England has been able to determine its own operating structure under the legislation. It has always operated with a mix of clinical and non-clinical national directors and teams, and separate regional directorates and teams. Today, the regional teams are responsible for much of the oversight of and interactions

with the local NHS, as well as for NHS England's commissioning functions in the relevant region including the commissioning of neonatal services as one of the specialised services. Some specialised commissioning is undertaken nationally. NHS England's commissioning role is described in more detail at paragraph 87.

(b) NHS England's Regions

80. The size and function of regional teams has varied as NHS England has developed. Since April 2013, the regional teams have changed from four to seven teams. In the First Relevant Period, there were five regional teams for most of the time, North, Midlands and East, London, South East and South West, having increased from four regions when NHS England was first established.

81. The role of regional teams during the First Relevant Period included responsibility for much of the oversight of and interactions with local Clinical Commissioning Groups, as well as responsibility for NHS England's commissioning functions in the region (noting, as above at paragraph 79, that some specialised commissioning is undertaken nationally).

82. During the First Relevant Period, the North Regional Team had an executive team led by the Regional Director that included the following roles:

    a. Regional Medical Director;

    b. Regional Director of Nursing;

    c. Regional Commissioning Director;

    d. Regional Director of Operations and Delivery;

    e. Regional Director for Patients & Information.

83. More information about the structure, role and responsibilities of regional teams, including the North Regional Team specifically, is included within Section 2.

84. Until 2015, regional teams were supported by area teams. In the period 2013 to 2015, there were 27 area teams. Nine of these teams supported the North region. Each area team was led by a Director of Commissioning Operations and supported by a full management team. By 2016, area teams had been consolidated into regional teams and the term was no longer used from that time.

85. Regional directors report to the NHS England Chief Operating Officer.

86. In the First Relevant Period, Monitor and the NHS Trust Development Authority had similar regional arrangements, described in further detail below at paragraph 160. In the period 2017-2019, Monitor and the NHS Trust Development Authority's regional arrangements changed to reflect the establishment and operation of NHS Improvement. However, NHS England's regional teams remained separate from NHS Improvement's regional teams (whilst having working relationships) until 2019. From 2019, the NHS England and NHS Improvement regional teams were integrated. Each regional team was led by one Regional Director who worked for both organisations, with a move to seven regional teams to underpin this new approach: East of England, London, Midlands, North East and Yorkshire, North West, South East and South West.

(5) NHS England's commissioning role

87. The establishment of NHS England was a key part of the 2012 reforms. As noted in paragraph 79 above, NHS England has, from the outset, had responsibility for the commissioning of some NHS services itself. In addition, it had responsibility for overseeing the development and operation of Clinical Commissioning Groups, who were responsible for commissioning the majority of NHS services on a local footprint.

(a) Introduction to NHS England's commissioning responsibilities

88. NHS England's responsibilities as a commissioner are often referred to as its 'direct commissioning' responsibilities.

89. During the Overall Relevant Period, NHS England was responsible for commissioning the following:

    a. primary care services: However, from February 2015, NHS England had started to formally delegate this role to Clinical Commissioning Groups for GP services and further delegations have been made to Integrated Care Boards in the period since July 2022. NHS England, particularly through its regional teams, retained responsibility for commissioning dental, optometry, and community pharmacy services up until July 2022, when responsibility for commissioning these additional primary care services was delegated to some Integrated Care Boards;

b. prescribed specialised services (often provided as part of tertiary care), which include specialist neonatal care. These services, which are defined in statute, support patients with rare and complex conditions and include services for high consequence infectious diseases and specialist acute dental care;

c. certain military and veteran health services;

d. health services that support children and adults throughout the youth justice and criminal justice systems in England; and

e. a limited number of public health services (working closely with Public Health England/UK Health Security Agency and as delegated to it by the Secretary of State).

90. NHS England enters into arrangements with both independent and NHS providers when exercising its direct commissioning responsibilities. However, given the context of this statement, we have focused on providers of NHS services who are NHS Trusts or NHS Foundation Trusts (or collectively 'trusts'). Paragraphs 133 to 138 describe trusts in more detail.

91. Commissioning still takes place primarily at a more localised level (through area and regional teams initially and then through regional teams, once area teams were restructured). As a result, day-to-day commissioning contract monitoring and assurance also takes place at a regional level, with escalation processes in place to the appropriate part of the national NHS England structure.

92. The first Direct Commissioning Assurance Framework, published in 2013/14, explained that the Board had delegated assurance of direct commissioning to regional officers **[Exhibit SP/0006 [INQ0009226]]**. This Assurance Framework recognised the mutual interdependencies between NHS England assurance in relation to the services it commissioned, and its assurance of Clinical Commissioning Groups as commissioners themselves. By using common assurance themes, assurance discussions for both NHS England's direct commissioning responsibilities and Clinical Commissioning Group responsibilities could be appropriately aligned and supported by similar processes (such as data collection and analysis). This recognised that commissioners needed to be able to work "in unison to address any concerns around the quality of care across the whole health economy" **[page 6, Exhibit SP/0006 [INQ0009226]]**.

(b) Introduction to specialised commissioning governance arrangements

93. The governance arrangements for nationally commissioned specialised services are described further below, while detail about how the commissioning role is exercised at a regional level is set out in Section 2 of this statement.

94. While NHS England is not a provider of any patient services, it does establish transformation programmes and work alongside the providers and wider NHS to work out how these programmes are operationalised. This is consistent with its role in relation to quality improvement.

95. Under the 2006 Act and secondary legislation made under it (specifically the Standing Rules Regulations), the Secretary of State has required NHS England to arrange for certain specified services or facilities. This approach has been used from the outset of NHS England's establishment. The Standing Rules Regulations contain the list of services that are "Prescribed Specialised Services". This is the basis of NHS England's duties to commission specified services for rare and very rare conditions.

96. Specialist Neonatal Care Services have been included under these arrangements since NHS England was established in 2012. The Prescribed Specialised Services Manual sets out a description of each of the 143 Specialised Services, and how they are commissioned. It also contains the identification rules which describe how commissioners identify specialised services within the data flows that support the commissioning process.

97. NHS England's governance arrangements in relation to specialised services commissioning have evolved and developed during the Overall Relevant Period. These arrangements continue to evolve at the present day in the context of preparing for delegation of some specialised services commissioning to Integrated Care Boards.

98. However, while the governance arrangements have changed over time, it is important to reiterate that specialised services are almost entirely commissioned on a localised basis (primarily by regional teams). In contrast, the role of the national teams and associated governance structures supporting specialised commissioning is to identify learnings and disseminate these; to develop, review and modify national standards and specifications; and to manage the overall budget for specialised services.

99. Each regional team includes regional medical directors and regional chief nurses specific to specialised commissioning. They form part of the overall regional team, with ultimate reporting into regional directors who, in turn, report to the Operations Directorate (rather than on a service-specific basis).

100. In the First Relevant Period, up until 2015, the national governance arrangements for specialised services were as follows.

101. Partway through 2013, NHS England established a Directly Commissioned Services Committee to oversee the delivery of directly commissioned services within the overall strategy set by NHS England. This Committee's remit was not specific to specialised services and included within its scope all services for which NHS England has direct commissioning responsibility (as set out at paragraph 89). The Directly Commissioned Services Committee's responsibilities included the following:

    a. ensuring quality standards were defined and that services were delivered to those standards; and

    b. agreeing commissioning priorities and allocation of resources, and assuring appropriate service planning was in place.

102. This Directly Commissioned Services Committee was supported by the Specialised Commissioning Oversight Group, which had operational oversight and responsibility to take operational decisions specific to specialised commissioning. The Terms of Reference for the Specialised Commissioning Oversight Group describe the shared responsibility of national and regional teams in discharging the specialised services commissioning responsibilities, with the Group holding these teams to account for delivering high-quality specialised services within budget. In addition, the Group's role was to provide leadership and direction to the overall operating model, acting as a single voice for specialised commissioning within NHS England.

103. From the outset, specialised services commissioning was supported by a number of Clinical Reference Groups, which were established on a service-specific basis. These Groups were the primary forum in which issues relating to the service specification and design were considered. The current arrangements for Clinical Reference Groups are described further below.

104. With the move to a national commissioning approach for specialised services, there was a focus during this initial post-establishment period on developing and

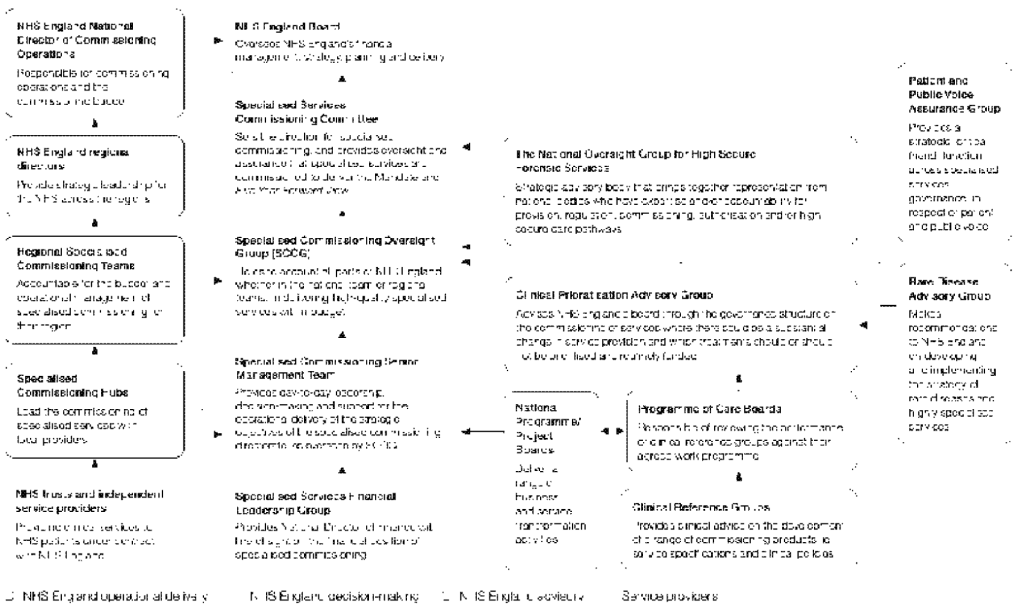
implementing national data collection systems. This was done alongside a structured quality assurance framework for specialised services and included the development of a number of quality dashboards, against which providers of specialised services could be measured and, crucially, which would enable benchmarking between providers. These quality dashboards enabled collation of data relating to patient outcomes and experiences and supported assurance of provider delivery against national service specifications for specialised services. The development and implementation of these dashboards were also intended to enable a move away from service audits as the primary way of measuring service delivery against specified standards. The dashboards were designed to be dynamic; able to measure performance against a smaller set of metrics and enable benchmarking.

105. Following an internal review of the governance arrangements for specialised services, the national governance arrangements changed in mid-2015 with the establishment of a standalone Specialised Services Commissioning Committee reporting directly to NHS England's Board. The purpose of establishing this Committee was to create a strategic agenda and focus for the governance of specialised services commissioning separate to the wider direct commissioning agenda.

106. The Specialised Commissioning Oversight Group continued in existence, but its reporting arrangements were updated, reflecting the establishment of the Committee. The Group remained focused on operational oversight and operational decision making.

107. The national specialised services governance arrangements in place in the period 2015/16 are set out below:

NHS England's management and governance structure for the commissioning of specialised services, 2015-16



Notes

1 The National Director of Specialised Commissioning is the chair of SCOG, a member of the Specialised Services Commissioning Committee and reports directly to the NHS England Board.

2 Regional specialised commissioning teams and hubs are supported by the Specialised Commissioning Senior Management Team in their day to day operations. They report to SCOG on their performance commissioning specialised services, but are held accountable by the regional directors for their specialised commissioning budgets.

Source: National Audit Office review of NHS England documents and interviews

108. There were further changes to the governance of specialised services as a result of the more integrated working arrangements put in place between NHS England and NHS Improvement in 2018. As part of these changes, the Specialised Services Commissioning Committee was disbanded, with the majority of its remit being transitioned to the new Delivery, Quality and Performance Committee and associated subcommittees.

109. There was also a separation of strategy and delivery, with the Specialised Commissioning Oversight Group being replaced by the Specialised Commissioning and Health and Justice Strategy Group and the Specialised Commissioning and Health and Justice Delivery Group. These arrangements remained in place until 2022. However, while these structural changes took place, the underlying principles around the role of the National Specialised Services Directorate and the reporting and accountability lines described above remained consistent throughout this period.

110. Finally, in 2022, NHS England set up a Delegated Commissioning Group for Specialised Services. This was to support the move towards delegation of some Specialised Services to ICBs. This Group acts as the advisory forum in respect of delegated Specialised Services. In parallel, a National Commissioning Group was established to act as the advisory forum in respect of the Specialised Services that will

continue to be commissioned by NHS England. These Groups will be responsible for approving national standards for the services within their respective remits, as well as for assuring and overseeing specialised services as set out in the Specialised Commissioning Assurance Framework. See paragraph 280 below for further information on the future of specialised services commissioning.

(c) Specialised commissioning national programmes of care

111. Specialised services are currently grouped into six National Programmes of Care as follows:

    a. Cancer;

    b. Mental Health;

    c. Blood and Infection;

    d. Internal medicine;

    e. Trauma; and

    f. Women and Children (which includes neonatal services).

112. These National Programmes of Care principally operate through a network of affiliated clinical reference groups, and task and finish groups. The Women and Children National Programme of Care covers services in women and children, congenital and inherited diseases. It consists of a Board and 15 Clinical Reference Groups, which include a Neonatal Critical Care Clinical Reference Group **[Exhibit SP/0007 [INQ0009288]]**.

(d) Neonatal Critical Care Clinical Reference Group

113. The Neonatal Critical Care Clinical Reference Group covers specialist neonatal services which provide care for all babies of, usually, up to 44 weeks' corrected gestational age that require ongoing medical care in a neonatal critical care facility.

114. The purpose of the Clinical Reference Group is to support the commissioning of high quality and efficient specialised services by providing expert advice, constructive challenge and problem solving to guide core commissioning activities.

115. The Clinical Reference Group is chaired by the Neonatal Specialty Advisor, appointed by NHS England since 2019.

116. One of the key roles of the Clinical Reference Group is to produce the tools used by the commissioning teams to contract for clinical services, such as the Neonatal Service Specifications.

117. NHS England produces and publishes these service specifications in respect of each Specialised Service. Service specifications operate to clearly define the care expected of organisations funded by NHS England to provide specialised care. These specifications are developed by expert clinicians, commissioners, patient and public health representatives and describe core and developmental service standards. Core standards refer to those which all funded providers should be able to demonstrate, with developmental standards functioning as those which may require future change in practice over time to ensure continued excellence.

(e) Neonatal Critical Care Specification

118. Neonatal care is the care a baby which is born prematurely or is unwell receives in a specially allocated unit referred to as a neonatal unit. Over 90,000 babies are born needing specialist neonatal support in the UK each year. Neonatal critical care services include all activity undertaken by Neonatal Critical Care Units, Local Neonatal Units and Special Care Units. This also includes associated retrieval services, transitional care (i.e., where the baby needs some medical care but is well enough to receive this at their mother's bedside) and associated outpatient services.

119. The Neonatal Critical Care Specification **[Exhibit SP/0008 [INQ0009232]]** details the categories of Neonatal Units (neonatal intensive care units, local neonatal units and special care baby units) and sets out what services will be provided at each level of unit. A version of this specification has been in use throughout the Overall Relevant Period.

120. If a baby is unwell and admitted to a neonatal unit the type of unit they are care for in depends upon the level of care required. Neonatal care is provided in three types of units:

    a. The highest level of care provided is in Neonatal Intensive Care Units (NICUs). NICUs provide care for the whole range of neonatal care including

for babies of less than 27 weeks of gestation or birthweights less than 800 grams;

b. Local Neonatal Units (LNUs) provide care for babies over 27 weeks gestation or multiples over 28 weeks gestation; and babies over 800 grams. They also provide short term intensive care where necessary.

c. Special care units (SCUs)provide care for babies over 32 weeks and short term high dependency care where necessary.

(f) Operational Delivery Networks

121. Operational Delivery Networks were launched in April 2013 following the publication of the NHS England strategy to sustain and develop clinical networks. The networks are focussed on coordinating patient pathways between providers over a wide area to ensure access to specialist resources and expertise.

122. Since their establishment Operational Delivery Networks have focused on coordinating patient pathways between providers over a wide area to ensure access to specialist support. For neonatal networks, their role has expanded since their establishment and their expanded role is reflected within the Neonatal Critical Care Clinical Network Specification.

123. In addition to their role of coordinating patient pathways, the role of the Operational Delivery Networks now include:

a. stewardship of resources across the network,

b. facilitating flexible, skilled and resilient staffing including by assessing current and future workforce needs and developing training plans;

c. improving quality, safety, experience and Outcomes across the network which includes creating a culture of ongoing service improvement, ensuring best practice models are embedded and contribution to improved quality performance;

d. working together with individuals and organisations at a local, system and national level.

e. Plan sustainable services that meet the needs of all patients and families including through working with providers and commissioners to address shortfalls from compliance with national standards.

f. Reducing inequalities in health, access, experience and outcomes through developing and implementing network pathways and protocols to reduce variation in service delivery and identifying health service needs of patient groups and review service provision across the network against identified need and identify gaps.

124. More recently, the term Clinical Network has been adopted, reflecting the wider role they have beyond specialised services **[Exhibit SP/0008 [INQ0009232]]** and these networks operate in accordance with a formal service specification, developed by the Neonatal Clinical Reference Group. However, as this is a fairly recent change, we have continued to use the term Operational Delivery Network in this statement.

125. Whilst each Operational Delivery Network is hosted by a local provider organisation, the responsibility for assuring governance arrangements for Operational Delivery Networks sits with NHS England regional specialised commissioning teams.

126. There are currently 10 Neonatal Operational Delivery Networks in the UK. The North West Neonatal Operational Delivery Network, which includes the Countess of Chester NHS Foundation Trust, is hosted by Alder Hey Children's NHS Foundation Trust **[Exhibit SP/0009 [INQ0009271]].** The aim of the North West Neonatal Operational Delivery Network is to support the delivery of high-quality, safe and effective services across the network's footprint. It has an essential role in facilitating cross-organisational collaboration and quality assurance. Further information about the Network's role is set out at paragraph 1008 below.

(6) Clinical Commissioning Groups

127. From 2013 to 2022, the commissioning of most NHS healthcare services, including hospital, ambulance and community health services as listed in section 3 of the 2006 Act, was the responsibility of Clinical Commissioning Groups (excluding those services that NHS England had a duty to commission, as listed at paragraph 89 above).

128. Clinical Commissioning Groups were established at the same time as NHS England, again, as part of the Lansley Reforms (see further detail at paragraph 46). Clinical

Commissioning Groups were GP-led organisations responsible for commissioning healthcare services for the residents of their designated area. Together, Clinical Commissioning Groups had responsibility for commissioning the majority of NHS services, including most hospital and ambulance services, and NHS 111.

129. NHS England was responsible for establishing and assuring the performance of Clinical Commissioning Groups and setting their annual funding allocation. NHS England's principal oversight tools were:

    a. designating the Accounting Officer and removing the designation;

    b. limited intervention powers that could only be exercised when a Clinical Commissioning Group was failing or at risk of failing; and

    c. issuing guidance, the majority of which did not have binding statutory force. Instead, Clinical Commissioning Groups were required to act rationally when having regard to it.

130. Powers of oversight were limited because Clinical Commissioning Groups were autonomous entities and NHS England had a statutory duty to promote the autonomy of Clinical Commissioning Groups.[4] This necessarily informed how NHS England exercised its assurance and performance functions.

131. NHS England was responsible for making funding allocations to Clinical Commissioning Groups for the purpose of commissioning local health services from providers. Annual funding allocations to the system by year are available online and a diagram of how healthcare sums are spent is exhibited to this statement **[Exhibit SP/0010, INQ0014773].**

132. Commissioning Support Units were established to provide support services to Clinical Commissioning Groups. They were created on the abolition of Primary Care Trusts and operate across the whole country. Commissioning Support Units deliver a range of support services that have been independently assessed to ensure that the NHS receives the benefits of scale, including clinical procurement services, business intelligence services and human resources. Commissioning Support Unit group staff are employed by the NHS Business Services Authority. Commissioning Support Units are hosted by (and are legally part of) NHS England, but have always been

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[4] See Section 13F of the 2006 Act which was added by the 2012 Act and repealed by 2022 Act.

operationally distinct. Commissioning Support Unit activities are included in NHS England's Annual Report and Accounts, except where otherwise indicated. Commissioning Support Units continue in operation today, servicing a wide range of organisations, including Integrated Care Systems, Integrated Care Boards, local authorities and non-NHS bodies.

(7) NHS Providers (NHS Trusts and NHS Foundation Trusts)

133. As explained above, there are two types of provider trusts in England: NHS Trusts and NHS Foundation Trusts. The key differences are the degree of autonomy they enjoy from central control by NHS England and the Secretary of State and up until July 2022 they had different regulators. Together, we refer to them as 'trusts' or NHS providers in this statement.

(a) NHS Trusts in the First Relevant Period

134. NHS Trusts as a type of provider organisation have existed since 1991. They are independent organisations with their own budgets and management structures. As a statutory NHS body, they are subject to a range of legislative provisions, and had an oversight regime that was specific to them.

135. From 1 April 2013, NHS Trusts were formally monitored and regulated by the NHS Trust Development Authority, which exercised many of the Secretary of State's functions in relation to NHS Trusts, pursuant to Secretary of State directions. In addition, and in the same way as described below at paragraph 157 in relation to NHS Foundation Trusts, NHS Trusts were regulated by the Care Quality Commission.

136. When considering the regulation of NHS Trusts, it is helpful to understand briefly the history of how NHS Trusts came into being:

    a. Before 1991, hospitals and hospital services were directly managed by the health authorities responsible for securing the provision of services to their population. Health authorities would arrange for some services to be provided by independent providers or voluntary organisations but, otherwise, there was no separation between NHS bodies responsible for arranging hospital services (commissioners) and those providing them (providers).

    b. This position first began to change with the National Health Service and Community Care Act 1990 and the 'internal market' reforms of the government of the day. These reforms introduced NHS Trusts as separate

statutory corporate bodies, responsible for managing and administering hospitals and providing both hospital and community health services for the purposes of the NHS.

c. NHS Trusts were independent; in that they were separate statutory bodies managed by a board of directors. They provided services under agreements with health authorities. These agreements took the form of NHS contracts and then, as now, were not enforceable as contracts in law (see section 9 of the 2006 Act).

d. However, NHS Trusts, at this time, were subject to a significant degree of control over their finances. For example, the Secretary of State set financial objectives; supplied the capital for NHS Trusts; and imposed spending limits. The Secretary of State also had powers to appoint and remove trust chairs and non-executive directors, intervene in the event of failure, and dissolve or merge trusts.

e. NHS Trusts were also subject to the Secretary of State's powers of direction. Originally, this power of direction applied only in certain limited areas (such as the terms and conditions of staff, and powers to generate income) but, following the changes introduced by the Health Act 1999, NHS Trusts were subject to a general power for the Secretary of State to direct them about the exercise of any of their functions.

137. From 1 April 2013, as described above, these powers over NHS Trusts were exercised by the NHS Trust Development Authority.

138. The legal position today essentially remains the same in terms of the status and oversight of NHS Trusts, with the exception that the oversight role in relation to trusts is now performed by NHS England. Over time and particularly since 2016, when NHS Improvement became operational, there has been a move towards the use of a common oversight process and structure for both NHS Trusts and NHS Foundation Trusts. This is described later in this statement at paragraph 155.

(b) NHS Foundation Trusts

139. NHS Foundation Trusts were introduced in 2003, in line with the NHS Plan published in 2000. The overall aims of the 2000 Plan were to enhance services, provide more choices to patients, and reduce the central control of the NHS. The policy was detailed

in the White Paper "Delivering the NHS Plan: Next Steps on Investment, Next Steps on Reform" (April 2002) **[Exhibit SP/0011 [INQ0009213]]**. It was envisaged in that White Paper that existing high-performing trusts would become Foundation Trusts with greater freedoms than existing trusts, including "the freedom to develop their board and governance structures to ensure more effective involvement of patients, staff, the local community and other key stakeholders." Foundation Trusts would have more financial control over their assets but would "operate to NHS standards, be subject to NHS inspection and abide by NHS principles".

140. The Health and Social Care (Community Health and Standards) Act 2003 was the legislation that first enabled NHS Foundation Trusts. It established the Independent Regulator of NHS Foundation Trusts (which was known operationally at the time as 'Monitor') and enabled NHS Trusts to apply to Monitor to become authorised as an NHS Foundation Trust. Details of the new arrangements were set out in "A Guide to NHS Foundation Trusts" (December 2002) **[Exhibit SP/0012 [INQ0009214]]**.

141. The first NHS Foundation Trusts became operational in April 2004, and by 2012 there were around 140 NHS Foundation Trusts across the country. The Countess of Chester Hospital was a 'first wave' trust, being authorised as an NHS Foundation Trust in 2004. Today there are 154.

142. In 2006, the Health and Social Care (Community Health and Standards) Act 2003 was, in a large part, repealed but with the legal provision which enabled the establishment of NHS Foundation Trusts re-enacted in Chapter 5 of Part 2 of the 2006 Act (being the key piece of legislation which continues to govern the NHS in England).

143. Like NHS Trusts, Foundation Trusts are statutory corporate bodies with a board of directors. However, NHS Foundation Trusts are a particular type of corporate body, namely 'public benefit corporations', and have greater freedoms than NHS Trusts. In particular, NHS Foundation Trusts are not subject to the Secretary of State power of direction; have financial freedom to manage their own budgets; decide on capital investment; borrow from third parties; and retain surpluses.

144. Whereas NHS Trusts are established in accordance with Establishment Orders issued by the Secretary of State, and their governance structure (including Board membership) is determined by the Order, regulations made by the Secretary of State and provisions of the 2006 Act, the governance structure of NHS Foundation Trusts is set out in their constitutions, which must be consistent with Schedule 7 of the 2006 Act

and are expected to follow a form which is consistent with a model published by Monitor (which remains current as of the present day).

145. One key distinguishing feature of NHS Foundation Trusts, in terms of their governance and constitution, is that they are membership organisations with a membership comprised of local people, patients, carers, and staff. They are also required to have a Council of Governors, elected from amongst the membership.

146. At least half of the governors on the Council of Governors must be elected by public or patient members; at least three governors must be elected by staff; and at least one governor must be elected by one or more qualifying local authorities. Governors are elected for a period of up to three years and are then subject to re-election.

147. Foundation Trust chairs and non-executives are appointed by the organisation's own Council of Governors rather than the Secretary of State (or an arms-length body exercising this power, as in the case of the NHS Trust Development Authority during the First Relevant Period). Additionally, the 2012 Act introduced new duties and powers for Governors, including:

    a. a general duty to hold the NHS Foundation Trust non-executive directors individually to account for the performance of the Board of Directors;

    b. a general duty to represent the interests of the members of the NHS Foundation Trust as a whole, and the interests of the public;

    c. a power to require one or more of the Directors to attend a meeting for the purpose of the governors obtaining information about the NHS Foundation Trust's performance of its functions or the directors' performance of their duties.

148. Foundation Trusts are required to take steps to secure that their governors are equipped with the skills and knowledge they require in their capacity as governors. Throughout the Overall Relevant Period, this has included the following national learning and development offers:

    a. GovernWell **[SP/0013, INQ0014798]**, which was jointly commissioned from 2013 by NHS Providers and the NHS Leadership Academy, and which has evolved since then to include other support tools, such as an induction toolkit.

b. guidance and information for governors published by Monitor (and, in some cases, as joint publications between Monitor and the Department of Health and Social Care), an example being the August 2013 publication **[SP/0014, INQ0014619]**"Your statutory duties: A reference guide for NHS foundation trust governors" (which remains in use as of the present date, but which was updated by NHS England in 2022 through the publication of an addendum **[SP/0015, INQ0014801]**, "System working and collaboration: The role of NHS Foundation Trust councils of governors").

c. products and publications issued by NHS Providers (the membership organisation for all NHS Trusts and NHS Foundation Trusts).

149. In addition, NHS Trusts and NHS Foundation Trusts are able to independently commission training and other organisational development support.

150. Further information about training and development for those in leadership roles in NHS Trusts and NHS Foundation Trusts, including the role of the NHS Leadership Academy, is set out below from paragraph 316.

151. There are also differences in the way that NHS Foundation Trusts contract. Unlike NHS Trusts, the arrangements that NHS Foundation Trusts enter into with commissioning bodies to provide services are contracts in law not NHS contracts (subject to section 9 of the 2006 Act). However, although this has a theoretical impact on how any contractual dispute is dealt with[5], NHS Foundation Trusts are still (like NHS Trusts) required to use the NHS Standard Contract and, in reality, this distinction does not otherwise have a practical impact on how commissioning contracting works in a NHS Foundation Trust context.

152. Throughout the First Relevant Period, NHS Foundation Trusts were monitored and regulated by Monitor. Trust applications to become a NHS Foundation Trust were assessed by Monitor to test whether the trust was financially sustainable, well led (in terms of governance processes and quality of leadership), locally accountable, and ready to take on the greater freedoms that NHS Foundation Trust status allows. In 2010, Monitor also introduced new criteria for testing trusts' governance arrangements for ensuring quality care (in light of the lessons from the failings in patient care at Mid

[5] NHS Contracts are not enforceable in the usual way through the courts, whereas the contracts that NHS Foundation Trusts enter into (even commissioning ones, using the NHS Standard Contract) have 'regular' contract status and as such can be enforced in court, in the usual way.

Staffordshire NHS Foundation Trust and the resulting inquiry into this, as discussed in Section 3A below).

153. Once authorised, the NHS Foundation Trust was subject to standard 'terms of authorisation'. These covered things such as a description of the services it was authorised to provide, a requirement to operate in accordance with national standards for healthcare, a list of assets designated as protected (and therefore subject to limits on disposal etc.), limits on amount of private work the NHS Foundation Trust could carry out, and a total borrowing limit. From 1 April 2013, the terms of authorisation were replaced by the Provider Licence (described in detail below).

154. The Countess of Chester Hospital was authorised by the Independent Regulator as a NHS Foundation Trust in 2004 as one of the first 10 trusts to be given Foundation Trust status.

(8) Provider Oversight

(a) Introduction to provider oversight

155. All providers of NHS services are subject to different types and degrees of oversight, monitoring and assurance. These primarily consist of the following:

    a. Registration and regulation by the Care Quality Commission, which is responsible for ensuring that the services provided by registered providers of health and social care in England are safe, effective, caring, responsive and well led. The Care Quality Commission carries out regular planned inspections of registered providers as well as unplanned ones (which can include when it becomes aware of potential issues). It has intervention powers, including powers to prosecute providers for failings in care. The Care Quality Commission also monitors reporting data from providers. The role of the Care Quality Commission is described in more detail below at paragraph 263 and in Section 2 of this statement.

    b. Contractual controls via the commissioning contracts entered into between the relevant commissioner(s) and the provider. These are described in more detail below.

    c. In the case of Foundation Trusts, NHS Trusts and certain types of independent provider of NHS services, the NHS Provider Licence **[Exhibit SP/0016 [INQ0009267]],** which all providers of NHS services are required to

hold and comply with, unless exempt under regulations made by the Secretary of State **[SP/0017, INQ0014621]**. Although the same NHS Provider Licence is used for each category of licensed provider, there are specific conditions that apply only to NHS Trusts and NHS Foundation Trusts (currently contained within Section 4 of the Provider Licence). There are also specific conditions for licensed NHS-controlled providers (currently these are contained within Section 5 of the Provider Licence) **[SP/0018, INQ0014725]**. NHS-controlled providers are entities ultimately controlled by one or more NHS Trusts or NHS Foundation Trust but this category does not apply to the Trust or Foundation Trust itself.

156. For the First Relevant Period, NHS Trusts were not directly subject to the NHS Provider Licence. However, the National Health Service Trust Development Authority Directions 2013 required that the NHS Trust Development Authority ensured that NHS Trusts complied with "such conditions which are equivalent to the conditions of any licence issued by Monitor…as the Authority deems appropriate to apply to English NHS Trusts". This position was repeated in 2016 Directions issued by the Secretary of State and remained the position until 1 July 2022.

(b) Trust oversight

157. Trusts are also the subject of additional requirements set out in statute. For the First Relevant Period and up until 1 July 2022, these frameworks were found primarily in the 2006 Act and in the 2012 Act.

158. A provider's compliance with these requirements is overseen by statutory regulators. This means that one of the core purposes of a statutory regulator is to monitor, oversee and account for the way in which providers are meeting the requirements they are subject to.

159. During the First Relevant Period, the key statutory regulators were:

    a. the Care Quality Commission;

    b. the NHS Trust Development Authority; and

    c. Monitor.

160. In the period from 1 April 2016 to 2022, Monitor and the NHS Trust Development Authority worked together as NHS Improvement with a stated policy intention of

working consistently and with a greater focus on support trusts rather than mere 'regulation', but their respective regulatory roles continued within this joint working structure.

161. NHS England was not a provider regulator until its role and functions changed on 1 July 2022, by virtue of the 2022 Reforms taking effect. As explained above, however, it did have commissioning oversight responsibilities in relation to those providers with whom it directly commissioned services. This was distinct to the regulatory role performed by Monitor and the NHS Trust Development Authority.

162. Understanding the policy intentions underpinning the establishment of both the NHS Trust Development Authority and Monitor is central when considering how providers were regulated during the First Relevant Period. Very broadly, and as expanded on below, Monitor was intended to operate in a way that was modelled on the way the financial services sector was regulated. The idea was that NHS providers would no longer be subject to a system of 'top-down' management, subject to political interference. Instead, both NHS providers and other providers would compete in a market governed by a rules-based system of regulation and patient choice — this was designed to stimulate innovation and improvements in both quality and productivity. NHS services would be provided on the basis of fixed national prices set out in a "National Tariff", so competition would be on the basis of quality of services and patient choice rather than price.

163. In the period from 2004 to at least 2016, there was a sustained focus on NHS Trusts becoming Foundation Trusts. This was often referred to as the "Foundation Trust pipeline". The 2010 White Paper included the ambition that all NHS Trusts would become Foundation Trusts and that it would "not be an option for organisations to decide to remain as an NHS Trust rather than become or be part of a Foundation Trust". This policy was reflected in the 2012 Act provisions for the abolition of NHS Trusts, although these were never in fact enacted and were ultimately repealed by the 2022 Act.

164. The flexibilities and freedoms that Foundation Trusts were granted were similarly reflected in the way that they were regulated. This was in contrast to the more hands-on oversight of NHS Trusts, which is better characterised as performance management and intensive support (rather than regulation in the broader sense). In terms of the key differences between the role of Monitor and that of the NHS Trust Development Authority, these included that Monitor did not have the power to direct

Foundation Trusts and that it did not have a formal role in relation to board-level appointments except where it had decided to exercise its enforcement powers. This is described in detail below.

(9) Regulation of Trusts

165. This part of the statement briefly describes how the NHS Trust Development Authority, Monitor and NHS Improvement performed their performance management, regulatory and oversight functions. This will be described in more detail in Section 2, when we describe the specific regional context and operation in relation to the Countess of Chester Hospital and other providers in the region.

(a) Introduction to Monitor (2004–2016)

166. Monitor was established in 2004 as the independent regulator of NHS Foundation Trusts — a category of healthcare provider with greater freedoms and 'independence' from central administration than NHS Trusts (see paragraph 139).

167. Under the 2012 Act, Monitor's role was expanded and it became an independent regulator for NHS Healthcare services in England. This meant, in practice, that it regulated both Foundation Trusts and other independent sector providers of health services. However, NHS Trusts continued to be regulated separately by the NHS Trust Development Authority — essentially, on the basis that the NHS Trust Development Authority was preparing (i.e. developing) NHS Trusts for Foundation Trust status. In exercising its functions, Monitor was required to protect and promote the interests of patients by promoting the provision of healthcare services which are economic, efficient and effective, and which maintain or improve the quality of the services.

168. Monitor was established as an executive non-Departmental public body operating under statutory provisions contained within both the 2006 Act and the 2012 Act. It operated within the same overall accountability structure and policy context as that described above at paragraph 179 for NHS England. Monitor was directly accountable to Parliament as well as the Secretary of State and was required to submit annual reports and annual accounts. Like NHS England, Monitor was able to determine its own operating structure under the legislation and, throughout its operation, this included a mix of national directors and teams, and separate regional directorates and teams.

169. As an Arm's Length Body, Monitor also entered into a Framework Agreement with the Department of Health and Social Care **[Exhibit SP/0019 [INQ0009230]]**. The 2014 Framework Agreement set out the principles that Monitor and the Department of Health and Social Care had agreed to operate under, as follows:

    a. working together in the interests of patients, people who use services and the public;

    b. respect for the importance of autonomy throughout the system;

    c. working together openly and positively; and

    d. mutual recognition of the Secretary of State's ultimate accountability to Parliament and the public.

170. In terms of its governance, Monitor had:

    a. a Board, which included a non-executive chair and at least four other non-executive members, all of whom were appointed by the Secretary of State;

    b. a chief executive appointed by the non-executive members of the Board, subject to the consent of the Secretary of State; and

    c. other executive members, all appointed by the non-executives and subject to the requirement that the executives had to be fewer in number than non-executives.

171. Monitor's Board was required to operate in accordance with the corporate governance code for Central Government departments. Essentially, this meant that the role of its Board was to establish and take forward Monitor's strategic aims and objectives; hold the executive team to account; and enable Monitor to meet its accountability responsibilities to be met. In order to perform this role, the Board was required to ensure that effective arrangements for assurance were in place (including assurance around risk management and governance).

172. Monitor set its own objectives. To ensure that these aligned with the Department of Health of Social Care's overall objectives for the health sector, Monitor was required to produce an organisational strategy every three years, with the aims of the strategy subject to Department of Health and Social Care agreement. In order to operationalise this strategy, and formalise the objectives that Monitor would work to, it was also

required to develop a business plan. As with the strategy, the business plan was subject to agreement with the Department of Health and Social Care. Department of Health and Social Care Ministers met with Monitor on a quarterly basis to discuss strategic and topical issues. Agenda items for these meetings could be suggested by either party. The Chair and Chief Executive of Monitor attended these meetings, one of which was generally chaired by the Secretary of State. The Framework Agreement makes clear the expectation that Monitor and the Department of Health and Social Care operated in an 'open book' way, i.e. that there was a mutual flow of information and appropriate onward third party sharing.

173. The Secretary of State also had the power (under section 63 of the 2012 Act) to issue guidance to Monitor on the objectives specified in NHS England's Mandate that were relevant to Monitor. We are not aware that this power was ever used.

174. A key part of its regulatory role was to licence providers of NHS healthcare services, and to enforce the conditions of the licence, under Chapter 3 of Part 3 of the 2012 Act. In this role, Monitor worked alongside the Care Quality Commission to take action, using its licence enforcement powers, when the Care Quality Commission reported that a hospital trust was failing to provide good quality care.

175. Monitor's regulatory powers and responsibilities are set out paragraphs 218 to 237. It operated alongside the NHS Trust Development Authority as NHS Improvement from 1 April 2016 until 1 July 2022.

(b) Introduction to NHS Trust Development Authority (2012–2016)

176. Since their creation, NHS Trusts have been subject to a significant degree of control over key aspects of their operation, including their finances, appointments and removal of trust chairs and non-executive directors. In the period prior to 1 April 2013, this oversight was carried out by Strategic Health Authorities, exercising the functions of the Secretary of State pursuant to directions. Strategic Health Authorities operated under the oversight of the NHS Executive (an executive agency, part of the Department of Health) and the Chief Executive of the NHS.

177. A targeted transition period (which included establishing the NHS Trust Development Authority) was developed to enable a smooth changeover from Strategic Health Authority oversight to the formal establishment of the NHS Trust Development Authority.

178. The NHS Trust Development Authority was a Special Health Authority established by the Secretary of State by Order under section 28 of the 2006 Act. The Order took effect on 1 June 2022, and the NHS Trust Development Authority became fully operational from 1 April 2013. As stated earlier at paragraph 49, the NHS Trust Development Authority was established primarily to exercise such functions as the Secretary of State directed in connection with the management of the performance and development of NHS Trusts, in particular with a view to those NHS Trusts becoming NHS Foundation Trusts. These were the functions that had previously been exercised by Strategic Health Authorities.

179. Like Monitor, the NHS Trust Development Authority was party to a Framework Agreement **[Exhibit SP/0021 [INQ0009228]]** with the Department of Health and Social Care, through which it was accountable for the performance of its functions. This Framework Agreement was underpinned by annual objectives and business plans, subject to the same approval mechanisms as those described above at paragraph 168 for Monitor. The NHS Trust Development Authority, like NHS England and Monitor, had the ability to determine its operational structure under the legislation (and directions made by the Secretary of State). Throughout its operation, this included a mix of national directors and teams, and separate regional directorates and teams. Unlike Monitor, however, the NHS Trust Development Authority was subject to the Secretary of State's power to direct the body about how it exercised its functions (section 8 of the 2006 Act).

180. At the time of the NHS Trust Development Authority being established (and reflecting the policy objectives underpinning the 2012 reforms), the intention was that all NHS Trusts would over time become Foundation Trusts, either through applying in their own right to become one, or through being acquired by a Foundation Trust. An NHS Trust could be acquired either by application under Section 56A of the 2006 Act (as amended by the 2012 Act) or by Secretary of State dissolving the Trust and transferring its staff and property to a Foundation Trust (paragraphs 29 and 30 of Schedule 4 to the 2006 Act). Section 179 of the 2012 Act provided for the abolition of NHS Trusts — the policy intention being this would be enacted once all NHS Trusts had become or been acquired by Foundation Trusts.

181. With this in mind, the NHS Trust Development Authority's functions, as set out in the National Health Service Trust Development Authority Directions 2013 were to:

    a. performance manage NHS Trusts;

b. manage the Foundation Trust pipeline;

c. assure the adequacy of each NHS Trust's clinical quality, governance and risk management, as well as their compliance with relevant standards (this included monitoring their performance in terms of meeting the Care Quality Commission's requirements) and support them where it considered improvements could be made; and

d. make key appointments to NHS Trusts, including those of chairs and non-executive directors (pursuant to paragraph 3 of the 2013 Trust Development Authority Directions) and exercise the associated functions of the Secretary of State as contained in the National Health Service Trusts (Membership and Procedure) Regulations 1990. This included suspension and termination of the chairs and non-executive directors. This role meant that representatives from the NHS Trust Development Authority sat on appointments panels for NHS Trusts.

182. In addition, because the NHS Trust Development Authority exercised the Secretary of State's powers to direct NHS Trusts, it could take more formal intervention measures if necessary.

183. The NHS Trust Development Authority's role in managing the 'Foundation Trust pipeline' necessarily meant that it needed to play a direct role in supporting the development of NHS Trusts. This included robustly assessing the effectiveness of NHS Trust boards and senior leaders. Standardised support and development tools, such as the Board Governance Assurance Framework **[Exhibit SP/0021 [INQ0009217]]**, were utilised to enable the NHS Trust Development Authority to perform this role.

184. In performing this supportive and developmental role, the NHS Trust Development Authority needed to work closely with commissioners (both NHS England and local Clinical Commissioning Groups) as well as with Monitor and the Care Quality Commission. Given the focus in this statement on Foundation Trusts, we have not included detail about how the NHS Trust Development Authority operated in its NHS Foundation Trust pipeline/Trust development role.

185. In the period from 1 April 2016, the NHS Trust Development Authority operated as part of NHS Improvement. This is described in detail at paragraphs 238 to 243.

(c) Regulation of NHS Foundation Trusts 2013-2016

186. The background to the introduction of Foundation Trusts and Monitor's role has been set out at paragraphs 218 to 230. This section describes in more detail how Foundation Trusts were constituted and what Monitor's role was as an arms-length regulatory body.

187. Unlike NHS Trusts, NHS Foundation Trusts are public benefit corporations. Each NHS Foundation Trust has a constitution, which must comply with the specific requirements in Schedule 7 to the 2006 Act. This which means that the governance structures for a Foundation Trust are quite different to those of an NHS Trust. These requirements include:

    a. the requirement to have a constitution (and, via statutory guidance issued by Monitor, this needed to comply with the model core constitution requirements);

    b. arrangements for individuals to be members of the NHS Foundation Trust (reflecting its public benefit corporation status);

    c. the establishment of a Council of Governors, elected by the members, whose role it is to:

        i. hold non-executive directors individually and collectively to account for the performance of the board of directors; and

        ii. represent the interests of the members of the corporation as a whole and the interests of the public.

        iii. the requirement to take steps to secure that the governors are equipped with the skills and knowledge they require to perform their role;

        iv. the requirement for meetings of the Council of Governors to be open to the public;

        v. to provide (via its constitution) for powers of the directors to be delegated to a committee of directors or to an executive director;

        vi. specific requirements around certain directors, including the requirement that one of the directors must be a registered medical practitioner or dentist, and another a registered nurse or midwife;

vii. sets out the general duty of the board of directors, and each director individually, to act with a view to promoting the success of the Foundation Trust so as to maximise the benefits of it as a whole and for the public; and

viii. annual accounting and annual report requirements.

188. As public benefit corporations, NHS Foundation Trusts have more freedom to manage budgets, set their own pay rates and borrow money to invest in new facilities and services. NHS Foundation Trusts can also retain any surpluses generated which can be reinvested in patient care or to pay debts.

189. However, despite these increased flexibilities and freedoms, Foundation Trusts remain subject to the Care Quality Commission's regular safety and quality inspections, as described below at paragraph 265.

190. NHS Foundation Trusts were originally regulated by an independent regulatory body, the Independent Regulator of Foundation Trusts, which was established in 2004. It operated under the name Monitor, with its name being formally changed the 2012 reforms. At the same time, its role was expanded reflecting its role as the system regulator in relation to providers of NHS services (the exception being NHS Trusts, as explained above at paragraph 134).

191. Monitor's expanded role was a key part of the 2012 reforms, particularly in terms of its role to licence providers of NHS healthcare services, and to enforce the conditions of the licence, using the enforcement powers it was given in Chapter 3 of Part 3 of the 2012 Act. However, Monitor was established as an arms-length regulatory body and it was intended that it would operate as such, i.e. without the more directive performance management role as per the NHS Trust Development Authority.

192. From the outset, Monitor worked closely alongside the Care Quality Commission, other national partner regulatory organisations, including the NHS Trust Development Authority, and commissioners (both NHS England and Clinical Commissioning Groups) to discharge its regulatory responsibilities; assess whether any intervention was required; and, ultimately, to take enforcement action.

193. Monitor had a range of intervention and enforcement actions that it could take, as well as its role in supporting Foundation Trusts who were failing, or at risk of failing. These intervention and enforcement powers included:

a. the ability to impose additional Provider Licence conditions (see below for detail on the Licence) (section 111 of the 2012 Act). This power was specific to Foundation Trusts. This could include, for instance, requiring the licensee to have in place sufficient board and management capacity and capability to address failures, such as implementing a required plan;

b. as part of its licence enforcement powers, which apply to all licensees;

c. impose discretionary requirements on the licensee where it had breached the conditions of its licence (section 105 of the 2012 Act); and

d. seek/accept statutory enforcement undertakings from any licensed provider who is reasonably suspected of breach of the conditions of their licence (section 106 of the 2012 Act).

194. Monitor did not have a direct role in making or approving appointments to Foundation Trust boards (in contrast to the NHS Trust Development Authority). However, it could (and did) exercise its intervention powers to effect leadership change, where it was assessed that the current leadership arrangements were insufficient (either in capacity or capability or both).

195. More broadly, however, Monitor had a role to play in relation to supporting the development of senior leaders within Foundation Trusts. This included board induction days for chairs and chief executives, as well as training for non-executive directors, through targeted developmental programmes, such as the NHS Trust Non-Executive Directors' programme, run in conjunction with the Cass Business School. The NHS Leadership Academy also played a key role in this development support, as described at paragraph 316 of this statement.

196. Similarly, Monitor and the NHS Trust Development Authority carried out a joint survey of medical directors in NHS Trusts and NHS Foundation Trusts in the period December 2013 to January 2014 and targeted support was developed as a result.

(d) The Provider Licence

197. In the period up to 1 April 2023, providers of secondary care services in England, who were not NHS Trusts, were required to hold a licence, the Provider Licence. Since 1 April 2023, this requirement has extended to include NHS Trusts as well. The Provider Licence comes with standard conditions **[Exhibit SP/0016 [INQ0009267]]**.

However, the standard conditions of the provider licence included the following, and have remained constant throughout the period 2013-2023:

a. General conditions: covering areas such as the provision and publication of information; fit and proper persons requirements (reflecting the requirements in Schedule 7 of the 2006 Act[6]); requirements for the providers to be registered with the Care Quality Commission.

b. Pricing conditions: including those relating to the National Tariff and associated reporting requirements about compliance with the Tariff.

c. Choice and competition conditions: incorporating the key policy requirement around providing information for patients to enable them to exercise choice around the provider they access and not to engage in anti-competitive behaviour.

d. Integrated care condition: requiring licence holders not to do anything which could be regarded as detrimental to the integration with other NHS health services, which included for this purpose social care and other health-related services.

e. Continuity of services conditions: these conditions were designed to assist Monitor ensure the continuity of NHS services, in the event that a provider became financially distressed or insolvent.

f. Governance conditions: applying only to Foundation Trusts (i.e. not to other providers regulated by Monitor who were subject to the provider licence framework). The key governance condition was FT4, which contained detailed requirements as to the governance arrangements required of Foundation Trusts. This included requirements to implement effective board and committee structures; systems and/or processes relating to oversight and leadership of, and accountability for, the collection and use of information relating to quality of care. It also required Foundation Trusts to establish and effectively implement systems and/or processes for the following:

[6] It should be noted that these requirements do not include the distinct fit and proper persons requirements introduced under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. These are described in more detail below, and compliance with which is regulated by the Care Quality Commission.

i. ensuring compliance with the Foundation Trust's statutory duty to operate efficiently, economically and effectively;

ii. timely and effective scrutiny by the Board;

iii. compliance with healthcare standards, including those specified by the Care Quality Commission and legal requirements (for example those arising directly under statutory framework governing Foundation Trusts or the more general statutory obligations applying to public bodies, such as equality law);

iv. effective financial decision-making, management and control.

198. Foundation Trusts were also expected to follow the Code of Governance for Foundation Trusts **[Exhibit SP/0022 [INQ0009246]]** (which reflects the requirements of the UK Corporate Governance Code) and to report on this in their Annual Report. The Code replicated the Provider Licence requirement for Foundation Trusts to ensure adequate systems and processes were maintained to measure and monitor its economy, efficiency and effectiveness as well as the quality of the healthcare delivery. Reviews had to be conducted at least annually into the effectiveness internal control systems, and this review had to be reported to members.

(e) Fit and proper persons during the First Relevant Period

199. Many sectors have requirements that stipulate what basic standards are expected of leaders of the bodies in that sector. These are often referred to as what constitutes 'fit and proper persons'. In the NHS secondary care sector 'fit and proper' can apply to both bodies and individuals.

200. During the First Relevant Period, there were two separate statutory requirements that imposed fit and proper persons requirements in relation to director and non-executive director appointments to NHS Foundation Trust boards. Only one of these also applied to Foundation Trust Governors. This position remained unchanged until 31 March 2023, when the new Provider Licence was issued. The current position is described in Section 3, Part B.

201. The first of these were the requirements under Schedule 7 of the 2012 Act, which were incorporated into, and extended by, the Provider Licence Condition G4. These requirements also applied to Governors, whereas the Care Quality Commission requirements, described below, did not.

202. Condition G4 defined an unfit person by reference to both individuals and bodies corporate. The criteria included are essentially objective, i.e. the fact of a conviction.

203. In the case of an individual, an unfit person included an individual who:

    a. had been adjudged bankrupt or whose estate had been sequestered and (in either case) had not been discharged;

    b. had been convicted in the British Islands of any offence in the preceding five years and a sentence of imprisonment (whether suspended or not) was imposed on him for a period of less than three months (without the option of a fine); or

    c. was subject to an unexpired disqualification order made under the Company Directors' Disqualification Act 1986.

204. The definition for bodies corporate focused on similar categories, including bodies corporate where, for instance, an administrator or receiver had been appointed.

205. The full requirements of Condition G4 (as they were up until 31 March 2023, when a new version of the Provider Licence was implemented) are exhibited to this statement **[Exhibit SP/0023 [INQ0009269]]**.

206. The second set of requirements applying to trusts were, from November 2014, the requirements in regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (known as the Fit and Proper Person Regulation). These were part of the regulations setting fundamental standards and other requirements for providers of health and social care registered with Care Quality Commission, including Trusts — the requirements are therefore enforced by the Care Quality Commission.

207. Compliance with the Fit and Proper Person Regulation was the responsibility of the Care Quality Commission. Although as a healthcare standard set by the Care Quality Commission, Foundation Trusts had a duty under the conditions of their licence (and NHS Trusts under their NHS Trust Development Authority equivalent conditions) to establish and effectively implement systems and processes to secure compliance with the Fit and Proper Person Regulation requirements, breach of which could potentially lead to Monitor investigation/enforcement.

208. The fit and proper persons requirements under the Fit and Proper Person Regulation were much broader than the Condition G4 requirements and incorporated subjective elements, alongside the accepted objective ones (e.g., not being excluded by virtue of a previous conviction). The Fit and Proper Person Regulation required that trusts do not appoint or have in place a person as an executive director (which included associate director roles) or a non-executive director unless the individual could satisfy the following:

    a. being of good character (assessed by reference to the matters to be considered listed in Part 2 of Schedule 4 to the Fit and Proper Person Regulation);

    b. having the necessary qualifications, skills and experience;

    c. being able to perform the work they are employed for, after reasonable adjustments have been made;

    d. having not been responsible for, or privy to, contributed to or facilitated any serious misconduct or mismanagement in the course carrying on a regulated activity (or which if provided in England would be a regulated activity;

    e. none of the grounds for unfitness specified in Part 1 of Schedule 4 to the Fit and Proper Person Regulation applying.

209. Each Trust needed to hold information relating to each director (to be supplied on request to Care Quality Commission) as specified in Schedule 3 to the Fit and Proper Person Regulation.

210. As with the 2012 Act and Condition G4, the Fit and Proper Person Regulation listed the criteria that automatically meant an individual was unfit and therefore ineligible for appointment. Many of these were the same as the criteria contained within the 2012 Act and Condition G4 but there were some important additions, including:

    a. the specific inclusion of safeguarding offences and associated inclusion on the children's or adults' barred lists; and

    b. individuals who "have been responsible for, been privy to, contributed to or facilitated any serious misconduct or mismanagement (whether unlawful or not) in the course of carrying on a regulated activity, or discharging any functions relating to any office or employment with a service provider".

211. Individuals also had to meet the "good character" and "not responsible for serious misconduct or mismanagement" requirements. The Fit and Proper Person Regulation included certain aspects that had to be considered as part of the "good character" assessment. This required consideration of whether a person has been convicted of any offence or whether the person has been erased, removed or struck off a register of professionals maintained by a regulator of healthcare or social work professionals.

212. The Care Quality Commission assessed trusts' compliance with the Fit and Proper Person Regulation during its inspections and reported on this aspect as part of the well-led sections of the inspection report. However, day to day, the onus was on the provider organisation to ensure that it had complied with the fit and proper persons requirements, at initial appointment and at other key points during an individual's employment/appointment to the organisation or on receipt of information or an allegation that a director is not 'fit and proper.' The provider's assessment of an individual's fitness would be recorded on the individual's personnel file or in other provider-based systems.

213. Although compliance with the Fit and Proper Person Regulation was primarily managed by the Care Quality Commission, both aspects were directly incorporated into the provider licence framework by virtue of the general requirement in Condition G7 to be and remain registered with the Care Quality Commission (and thereby satisfy the requirements of registration) and the specific requirements in Provider Licence Condition FT4, that included ensuring compliance with healthcare standards, including those of the Care Quality Commission, and complying with all applicable legal requirements. Condition FT4 also included a requirement on Foundation Trusts to establish and effectively implement systems and/or processes to ensure a range of matters, including that there was sufficient capability at Board level.

214. In practice, therefore, Monitor's oversight and assurance of Foundation Trust governance included assuring compliance with the requirements around fit and proper persons both under the 2012 Act and licence Condition G4, and in terms of requiring ongoing compliance with the Care Quality Commission's regulatory framework.

215. The same two-part structure applied in relation to NHS Trusts, except that the general fit and proper requirements (e.g. around bankruptcy and criminal convictions) were contained in the National Health Service Trust (Membership and Procedure) Regulations 1990, and not the 2012 Act.

216. The NHS Leadership Academy played a key role in supporting the development of individuals in leadership roles, as described below at paragraph 316 of this statement.

217. The current position in relation to fit and proper persons is set out in Section 3, Part B of this Statement.

(f) How Monitor exercised its regulatory powers

218. During the period 2013-2016, Monitor operated with a combination of national and regional governance structures. Regionally, it was organised into four regions: London, Midlands and East, North, and South. Each of these regions was responsible for regulating healthcare providers within its jurisdiction and as with NHS England's commissioning responsibilities, day-to-day oversight by Monitor was carried out at a regional level. This included assessing and enforcing each NHS Foundation Trust's compliance with its licence conditions, including consideration of risks to financial sustainability and good governance, based on information on performance, quality of care and financial health, and taking appropriate regulatory action.

219. At this regional level, Monitor operated as part of a collaborative regional structure that included close working with the equivalent structures in operation by the NHS Trust Development Authority, the Care Quality Commission, commissioners (both NHS England and Clinical Commissioning Groups) and other partners. Monitor regulated NHS Foundation Trusts via the NHS Provider Licence and in accordance with its statutory enforcement powers, as described in its Enforcement guidance. Foundation Trust compliance with the Provider Licence was monitored in accordance with Monitor's Risk Assessment Framework **[Exhibit SP/0024 [INQ0009240]]**.

220. Monitor could become aware of an issue relating to patient safety or quality as a result of:

    a. submissions made by the provider (whether regular or 'by exception');

    b. other information, such as plans, reports and forecasts, shared by the provider. This would include Quality Accounts, which providers of NHS services have been required to complete since 2009;[7]

[7] As per the Health Act 2009 (as amended).

c. information shared with it by a commissioner of services, which could include the commissioner making Monitor aware of recent Care Quality Commission activity or concerns;

d. information shared with it directly by the Care Quality Commission;

e. information shared with it by another third party, such as one of the medical Royal Colleges; and

f. safeguarding concerns, including those raised via regional and local safeguarding board arrangements.

221. For example, in its Annual Report and Accounts for 2015/16, Monitor set out in table form **[SP/0025, INQ0014638]** a list of Foundation Trusts it had found in breach of their provider licence during the 2015/16 period. 17 Foundation Trusts were listed, with a short form explanation of the breach and the regulatory action taken by Monitor as a result. In several cases, the breach includes governance breaches, and the key information relied on in more than one case was Care Quality Commission issues and/or inspection findings. A further table within the same document listed those Foundation Trusts that were under investigation. The Countess of Chester NHS Foundation Trust was not referred to in any capacity within this Report.

222. For the most part, this information sharing took place at a regional level and was coordinated through the structures and processes in place regionally to facilitate information sharing between the regulatory bodies, commissioners and providers. If a serious concern was raised through one of these mechanisms, an initial screening teleconference would take place, to decide whether or not to convene a risk summit. The key quality-related regional structures that facilitated this are described in Section 2 of this statement.

223. In tandem with this risk summit, Monitor would conduct its own assessment (against the Risk Assessment Framework) to decide whether a formal investigation to establish what, if any, enforcement action was appropriate. Monitor followed a formal approach to intervening in individual Foundation Trusts and would only consider using its statutory enforcement powers if it felt that the outcome of its formal investigation warranted this, consistent with the prioritisation criteria set out in its Enforcement Guidance.

224. Although Monitor was not directly responsible for assessing or regulating the safety or quality of the care a Foundation Trust was providing (this being the role of the Care Quality Commission), evidence of poor quality care or safety issues could potentially indicate a failure of governance. For instance, it could suggest that the Foundation Trust was not complying with its licence conditions to have in place systems to secure the quality of care provided to patients (as per Condition FT4). Using its Risk Assessment Framework, Monitor would assign a risk rating to the two key elements that it assessed in relation to Foundation Trusts. This risk rating was a number rating from 1 to 4 for financial sustainability, whereas a red/green/under review rating was used for governance. These ratings indicated where there was a cause for concern and would inform whether a formal investigation was commenced, so as to enable a detailed assessment of the scale and scope of the risk, and ultimately whether any enforcement action was appropriate.

225. Foundation Trusts were required to carry out an external review of their governance every three years, under the 'Well Led' framework. Monitor explicitly aligned this with the Care Quality Commission's characteristics of 'good' under their well led domain when the Well Led Framework was updated in 2015 **[Exhibit SP/0026 [INQ0009237]].** However, although these reviews were aligned, they were separate reviews, in order to enable Monitor and the Care Quality Commission to perform their separate, respective regulatory responsibilities.

226. Monitor's remit focused on board and committee level effectiveness, covering strategy, planning, capability and culture, process and structures and measurement. In contrast, the Care Quality Commission looked at the patient experience at ward and service level, to see whether the outcomes being delivered demonstrated that the board's policies were operating effectively. The Care Quality Commission's approach was known as 'ward to board' inspection. In carrying out that inspection, the Care Quality Commission could (and did) ask Foundation Trusts how they assured their governance arrangements, including asking for information about any independent reviews and whether/how they had been acted on.

227. Monitor's Well Led Framework had four main domains for review and involved a comprehensive assessment of how well the Foundation Trust was run. Reviews, which were commissioned externally by Foundation Trusts, needed to be carried out using the Framework guidance. The four domains were: strategy and planning; capability and culture; process and structures; and measurement. Within those domains, the Framework included considering whether:

a. the board was sufficiently aware of potential risks to the quality of current services;

b. the board shaped an open, transparent and quality-focused culture;

c. there were clear roles and accountabilities in relation to board governance (including quality governance);

d. processes for escalating and resolving issues and managing performance were clearly defined and well-understood; and

e. the board actively engages patients, staff, governors and other key stakeholders on quality and operational performance (including whether staff actively raise concerns and those who do, including external whistleblowers, are supported).

228. At the end of the Well Led Review process, the Foundation Trust Chair was required to write to Monitor to advise them that the review had taken place; set out any material issues that had been identified and explain what the proposed action plan was to address these.

229. Recognising the inter-dependencies between their regulatory roles, Monitor and the Care Quality Commission (along with the NHS Trust Development Authority) worked closely together throughout this period. This is reflected in the memorandum of understanding that the Care Quality Commission and Monitor entered into in 2015 **[SP/0027, INQ0009234]** and in the tri-partite special measures guidance published in February 2015 by Monitor, the Care Quality Commission and the NHS Trust Development Authority **[SP/0028, INQ0009233].** This tri-partite guidance was issued in light of the findings of the 2013 Keogh Review discussed below.

230. Under the approach described in this guidance, special measures would apply to both NHS Trusts and Foundation Trusts that had serious failures in quality of care and where there were concerns that existing management cannot make the necessary improvements with support. The Care Quality Commission would focus on identifying failures in the quality of care and judging whether improvements had been made, and where necessary using its enforcement powers. The NHS Trust Development Authority and Monitor would use their powers to support improvement in the quality of care provided, including appointing an improvement director to support the board of

the trust concerned, and reviewing (and, if necessary, making changes to) the trust's leadership (see paragraph 232 below for further on this).

(g) The Keogh Review

231. In 2013, at the request of the Prime Minister at the time, the then National Medical Director Sir Bruce Keogh led a review of 14 NHS Trusts, nine of which were Foundation Trusts and five of which were NHS Trusts. All of the trusts had high mortality rates.

232. As a result of the Keogh Review, 11 of the 14 trusts were placed into special measures. In each of the 11 trusts, special measures action was enforced by the NHS Trust Development Authority (in relation to those that were NHS Trusts) and by Monitor (for those that were Foundation Trusts). What this meant in practice was that each trust was:

    a. required to implement the recommendations of the Keogh Review, with external teams sent in to help them do this, alongside their progress being tracked and published. In each case (whether NHS Trust or Foundation Trust), an improvement director was appointed by the NHS Trust Development Authority or Monitor, to provide assurance around each trust's progress. Monthly progress action plans had to be published on the trust's website;

    b. subject to a review by the NHS Trust Development Authority or Monitor to assess the quality of leadership at each trust, following which leaders assessed as being unable to lead the improvements required would be removed; and

    c. partnered with a high-performing NHS organisation to provide mentorship and guidance in improving the quality and safety of care.

233. In conjunction with these measures, the then Secretary of State announced that he had asked the NHS Leadership Academy to develop a programme to identify, support and train outstanding leaders.

234. During the First Relevant Period, Foundation Trusts in special measures were only able to exit them following an inspection by the Care Quality Commission 12 months after the commencement of the special measures. When carrying out this one-year on inspection, the Care Quality Commission had the ability to carry out a comprehensive

inspection (i.e. of all the services provided by the trust) or a targeted inspection focused on specific areas. The scope of the re-inspection was determined jointly by the Care Quality Commission and the NHS Trust Development Authority (for NHS Trusts) or Monitor (for Foundation Trusts). Irrespective of overall scope, the re-inspection always looked at the Well Led key questions.

235. In August 2014, the Care Quality Commission published its 'one year on' report into the 11 trusts that had been placed into special measures. The overall conclusion it reached was that significant progress had been made in 10 of the 11 trusts. However, it was recommended that five remain in special measures, with a further inspection in 6 months to assess progress. One trust (Medway NHS Foundation Trust) had failed to make significant overall progress and needed to remain in special measures while further urgent support was provided, or a longer-term solution identified.

236. The Care Quality Commission noted the following factors that provided a strong indication that improvements would be able to be successfully implemented:

    a. strength of leadership;

    b. accepting the scale of the challenges faced;

    c. alignment or engagement between managers and clinicians; and

    d. willingness to accept external support form a 'buddy' trust.

237. Operationally, at a national level, the Chief Executives of each organisation met regularly. Monitor also brought Foundation Trust leaders together for supportive sessions and representatives from the Care Quality Commission were frequently invited to attend these sessions to offer support and to facilitate the sharing of best practice.

(h) NHS Improvement (2016-2019)

238. The move to a joint way of working between Monitor and the NHS Trust Development Authority was announced in June 2015 by the Secretary of State. This reflected the understanding that had become clear in the period from 2012 that many NHS Foundation Trusts had similar developmental and support needs to NHS Trusts and that, in order to drive improvements in operational performance and quality of care, a consistent approach was required; one that applied regardless of organisational form.

239. On 1 April 2016, towards the end of the First Relevant Period, the NHS Trust Development Authority and Monitor were brought together to create "NHS Improvement", under a formal joint working arrangement. (Legally, Monitor and the NHS Trust Development Authority remained in existence until they were merged with NHS England on 1 July 2022).

240. A number of NHS England teams moved to operate as part of NHS Improvement. This included:

    a. the National Patient Safety Team, which transferred from NHS England;

    b. the Advancing Change Team;

    c. the National Reporting and Learning System team; and

    d. Intensive Support teams from NHS Interim Management and Support.

241. The National Patient Safety team and National Reporting and Learning System aspects of NHS Improvement's role from the end of the First Relevant Period are described in at paragraph 357 below.

242. Acting together as NHS Improvement, Monitor and the NHS Trust Development Authority were therefore responsible for regulation of Foundation Trusts and performance management of NHS Trusts, collectively referred to as provider oversight and governed by the Single Oversight Framework. This Single Oversight Framework replaced the separate frameworks that had been in place previously (namely Monitor's Risk Assessment Framework **[SP/0024, INQ0009240]** for NHS Foundation Trusts and the NHS Trust Development Authority's Accountability Framework for NHS Trusts **[SP/0029, INQ0009223]**). The Single Oversight Framework is described in more detail below.

243. No changes to primary legislation were implemented at this point to enable the establishment and operation of NHS Improvement, although 2016 Directions issued by the Secretary of State required the NHS Trust Development Authority to work collaboratively with Monitor, under a single leadership and operating model, to ensure "quality of care, patient safety and financial sustainability across the health service."

244. Although each body remained legally separate, with its own board and committees, a shared leadership model was facilitated by joint appointments of board members (i.e. individuals appointed as directors of both Monitor and the NHS Trust Development

Authority), including the chairs and chief executives, and the practice of the boards and committees "meeting in common" (i.e. a Monitor and the NHS Trust Development Authority board meeting held at the same time and with a common agenda, in effect meeting as a single board).

(i) Single Oversight Framework

245. Prior to September 2016, when the Single Oversight Framework was introduced, there was an oversight framework which applied to NHS Foundation Trusts and a separate accountability framework which applied to NHS Trusts boards. These are described above.

246. The Single Oversight Framework was introduced in September 2016 **[SP/0030, INQ0009287]** and was deliberately closely aligned with the Care Quality Commission's regulatory structure and approach, with the aim of supporting more trusts to achieve 'good' or 'outstanding' ratings. It replaced the above two pre-existing frameworks and applied to the oversight of both NHS Trusts and NHS Foundation Trusts. This move to a Single Oversight Framework reflected Monitor and the NHS Trust Development Authority coming together under the operational name NHS Improvement on 1 April 2016.

247. The Single Oversight Framework initially had five themes or areas of focus: quality of care; finance and use of resources; operational performance; strategic change; leadership and improvement capability. Each contained a number of metrics or indicators, based on which NHS Improvement would assign trusts to one of four segments, depending on the assessed level of support they required. These segments were as follows:

    a. Segment 1: trusts with no support needs

    b. Segment 2: trusts with some support needs who would be offered targeted support

    c. Segment 3: trusts with significant concerns, who would be given 'mandated support'

    d. Segment 4: trusts with major or complex concerns and who would be subject to 'special measures'

248. Trusts were assessed against NHS Improvement's definition of success, which incorporated:

    a. finance and use of resources;

    b. quality;

    c. operational performance;

    d. strategic change;

    e. leadership and improvement capability.

249. Those trusts who were assessed as being in segments three and four were generally subject to formal enforcement action. In the case of Foundation Trusts, this still required a formal assessment to determine that they were in breach, or suspected of being in breach, of their Licence.

250. Although the Provider Licence provisions continued not to formally apply to NHS Trusts during this period, they were applied "in effect" as NHS Trusts had to comply with equivalent conditions. NHS Improvement would also accept undertakings from NHS Trusts to take action (similar to the statutory enforcement undertakings for Foundation Trusts) and requirements could be imposed in a similar way to those for Foundation Trusts.

251. The creation of NHS Improvement and the development of the Single Oversight Framework marked a shift away from more traditional performance management and arms-length regulation to a regulatory and oversight role underpinned by a comprehensive development and support offering for Foundation Trusts, as well as Trusts.

252. This change in approach was the basis for much of NHS Improvement's work from 2016, which included providing trusts with the tools that they could use to enable them to develop and improve the quality of care they were providing.

253. During 2016 to 2019, the oversight of Clinical Commissioning Groups was subject to a separate framework – the Clinical Commissioning Group Improvement and Assessment Framework. The framework aligned with NHS England's Mandate and planning guidance, with the aim of unlocking change and improvement in a number of

key areas. Each Clinical Commissioning Group received a performance rating based on the following four indicators:

a. Better health: how the CCG is contributing to improving the health of its population

b. Better care: focussing on care redesign, performance of constitutional standards, and outcomes, including in important clinical areas

c. Sustainability: focussing on financial sustainability

d. Leadership: assessing the quality of the CCG's leadership, planning, partnership working and governance.

254. With the coming together of NHS England and NHS Improvement in 2019 alongside the move to system working through (non-statutory) Integrated Care Systems, the two frameworks were replaced by a single NHS Oversight Framework which applied to both commissioners and providers. There have been iterations of this system-based oversight approach since August 2019, reflecting a greater emphasis on system performance alongside the contribution of individual healthcare providers and commissioners to system goals.

255. The current version of the oversight framework is the NHS Oversight Framework **[SP/0031, INQ0009264],** which was first published very shortly before 1 July 2022 to reflect the 2022 Act putting Integrated Care Systems on a statutory footing (in particular establishing statutory Integrated Care Boards) and effecting the merger of NHS Improvement and NHS England.

256. The current Oversight Framework is characterised by five key principles, one of which is "autonomy for ICBs [Integrated Care Boards] and NHS providers as a default position". This is, in turn, underpinned by the statutory duties that NHS England has, including those around efficiency and effectiveness but also the 'new' duties introduced as a result of the 2022 Reforms (such as the Triple Aim).

257. This reflects the evolution of the commissioner/provider relationship during the Overall Relevant Period and is now based on a more collaborative, mutually-supportive relationship with a greater emphasis on system performance. In addition to the principle of autonomy, there is "a greater emphasis on system performance and quality of care outcomes, alongside the contributions of individual healthcare providers and

commissioners to system goals" and "matching accountability for results with improvement support".

258. In addition, the delivery of good quality healthcare services and a focus on continuous improvement is underpinned by associated legal and contractual duties on those regulating, commissioning and providing NHS healthcare services.

259. In particular, NHS Trusts and NHS Foundation Trusts are subject in their own right to legal duties around health and safety; complaints and raising concerns; data protection; medicines management and safeguarding. Compliance with these duties informs the oversight of providers by NHS England, the Care Quality Commission and others but legal enforcement can also occur outside the health family, such as through health and safety prosecutions, judicial reviews, claims for clinical negligence; and other civil and criminal liability, all of which would arise directly against the provider in question.

260. NHS England's fundamental expectation in terms of policies and procedures relating to areas such as safeguarding and raising concerns is that each provider will ensure it complies with its statutory, regulatory and contractual obligations. This principle applies whether NHS England is acting as the regulator with responsibility for provider oversight or as the commissioner of neonatal services.

261. The way in which NHS England seeks this assurance is through the Oversight Framework and the associated oversight metrics (the current version of which is the NHS oversight metrics for 2022/23). The metrics are used to indicate potential issues and prompt further investigation. The metrics align with the five national themes of the Oversight Framework:

    a. Quality of care, access and outcomes;

    b. Preventing ill health and reducing inequalities;

    c. People;

    d. Finance and use of resources; and

    e. Leadership and capability.

262. Importantly, while the Oversight Framework provides a common structure through which oversight is delivered, it recognises that oversight needs to be informed by "the

unique local delivery and governance arrangements specifically tailored to the needs of different communities". The purpose of the Oversight Framework is stated as being to:

a. ensure the alignment of priorities across the NHS and with wider system partners;

b. identify where ICBs and/or NHS providers may benefit from, or require, support; and

c. provide an objective basis for decisions about when and how NHS England will intervene.

(10) The Care Quality Commission

263. As noted above at paragraph 155 all NHS providers must be registered with the Care Quality Commission. The various interdependencies between the Care Quality Commission and Monitor/the NHS Trust Development Authority and latterly NHS Improvement have been set out above in describing the way that Monitor, the NHS Trust Development Authority and NHS Improvement regulated NHS Trusts and NHS Foundation Trusts during the First Relevant Period.

264. These interdependencies are important when considering the knowledge that NHS England (and the legacy bodies that now form part of NHS England) had about the neonatal unit at the Countess of Chester Hospital. Section 2 of this statement describes what was known, when and how but to briefly summarise key aspects of the Care Quality Commission's regulatory approach. We note particularly the following points:

a. The Care Quality Commission is (and has been throughout the Overall Relevant Period) the primary body responsible for regulating the quality of care being provided by regulated providers of healthcare services.

b. Throughout the Overall Relevant Period, it has assessed regulated providers against fundamental standards of care. The wording of these has changed during the period but the underpinning concepts that inform these fundamental standards have remained largely constant.

c. Unlike other regulatory bodies, including Monitor/NHS Improvement, the Care Quality Commission carries out "live", "on-site" inspections of providers,

including NHS Foundation Trusts. While the NHS Standard Contract and the Provider Licence provide for the right of inspection, these powers are rarely used, with both commissioners and other regulators seeking to derive efficiencies and reduce regulatory burden by utilising the information obtained by the Care Quality Commission during its inspections.

d. The Care Quality Commission shared access to the key systems that were also used by Monitor/NHS Improvement and NHS England to perform their regulatory, oversight and commissioning functions. In particular, all of these bodies used the National Reporting and Learning System, which was the primary reporting system during the First and Second Relevant Periods that NHS Foundation Trusts would use to report serious incidents. The Care Quality Commission's notification requirements reflected this common reporting system for NHS Foundation Trusts (and NHS Trusts), as distinct from other non-NHS regulated providers who had to report incidents directly.

e. In addition to its inspections, the Care Quality Commission monitored provider performance using intelligence gathered in a number of ways. During the First Relevant Period, this was known as "Intelligent Monitoring". This is described further below. Again, however, this monitoring used several shared data sources, including the Mothers and Babies: Reducing Risk through Audits (MBRRACE-UK) programme and the National Child Mortality Database. These shared national programmes of data collection and analysis are part of the National Clinical Audit and Patient Outcomes Programme, which is a programme of clinical audits commissioned on behalf of NHS England by the Healthcare Quality Improvement Partnership. The Care Quality Commission is one of several partner organisations that works closely with the Healthcare Quality Improvement Partnership. This is described in more detail in Section 1, Part B of this statement.

f. Monitor/NHS Improvement, NHS England and the Care Quality Commission all operated at both national and regional levels and had both national and regional structures that facilitated multi-agency working and information sharing. These national structures are described in Section 1, Part B of this statement. Regional structures are described in Section 2 below.

(a)Inspections of regulated providers

265. During a routine comprehensive inspection, the Care Quality Commission will assess how well a provider is meeting all the inspected standards. Whilst these standards have changed slightly over the last 15 years, they have always focused on matters of safety and quality. Part of the routine inspection may include an unannounced inspection.

266. A focused inspection is, as the name suggests, a more targeted assessment and will involve focusing on relevant aspects of the inspected standards, but will not always involve looking at all of them.

267. Following an inspection, each provider will receive an overall rating of either: outstanding, good, requires improvement or inadequate. In addition to this overall rating, providers will also be given service-by-service ratings.

(b) Intelligent Monitoring

268. Alongside its inspection programme, the Care Quality Commission also monitors regulated provider performance. During the First Relevant Period it used a tool called "Intelligent Monitoring" to highlight specific areas of care that the Care Quality Commission would then follow up through inspections and other activity with regulated providers. The indicators used in Intelligent Monitoring were related to the five key questions used during inspections (as above).

269. In the First Relevant Period, these reports were made publicly available. The reports that relate to the Countess of Chester Hospital are referred to in Section 2 of this statement.

270. NHS England understands that the Care Quality Commission would also take the results of their intelligent monitoring analysis and group the 160 acute and specialist NHS trusts into six priority bands for inspection. These bands were intended to provide an indicator as to the overall risk that a provider might not meet one or more of the regulatory standards.

271. At the time that NHS Improvement was established, there was a desire to enhance the effectiveness and timeliness of how the Care Quality Commissioning's monitoring information about providers was shared with NHS Improvement, to order to ensure that there were "sufficient early warning of quality issues at providers" **[SP/0032, INQ0014772]**.

272. Although the term "Intelligent Monitoring" is no longer used, the Care Quality Commission continues to monitor a range of data sources to inform its regulation of providers. Some of these data sources are the shared ones referred to briefly above and which are discussed in more detail in section 2 and Section 3B of this statement.

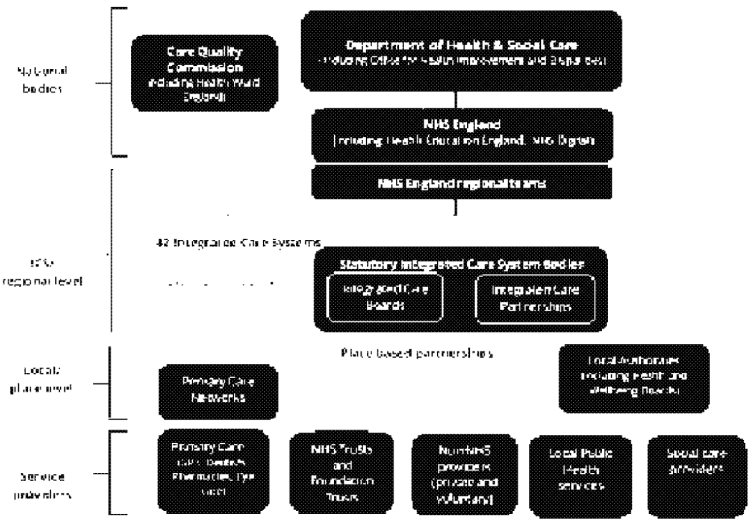
273. The Care Quality Commission's approach to regulation has evolved throughout the Overall Relevant Period, with its remit expanding to incorporate assurance of Integrated Care Systems (including Integrated Care Boards and Local Authorities). From 18 July 2022, the Care Quality Commission has used its new single assessment framework, with an early adopter programme commencing from 21 November 2022. Well led assessments for all NHS Trusts and NHS Foundation Trusts were due to begin from 6 February 2023.

274. In addition to the above routine regulatory processes, the Care Quality Commission carries out service-specific programmes of inspection. In 2022, it commenced a maternity inspection programme. Information gathered as part of this programme, including through the Maternity Surveys carried out by the Care Quality Commission is shared with NHS England in order to inform the exercise of our performance assessment, improvement and regulatory functions. This is described in Section 2 of this statement.

(11) The 2022 Reforms — more integrated working

275. The below diagram sets out how the 2022 reforms discussed below are designed to bring about more integrated ways of working across the NHS:

The structure of the NHS in England



Source: *'The Structure of the NHS England,'* House of Commons Research Briefing, 10 July 2023 (Tom Powell)

(a) Five Year Forward View

276. The 'Five Year Forward View' published in October 2014 **[SP/0033, INQ0009239]** set out a vision to transform the NHS by 2020. This argued for a radical upgrade in prevention and public health, for patients to gain greater control of their own care; and for the NHS to take decisive steps to break down barriers in how care was being provided. It recognised a need for national leadership of the NHS to act coherently together, but to provide meaningful local flexibility.

277. The Five Year Forward View was a joint publication by NHS England; the Care Quality Commission; Health Education England; Monitor; Public Health England; and the NHS Trust Development Authority. The Five Year Forward View focused on addressing three identified gaps:

    a. The health and wellbeing gap: the need to reduce demand on the NHS by shifting focus towards prevention and addressing health inequalities.

    b. The care and quality gap: to harness technology and innovation to reduce variations in the quality of care, including in relation to safety and outcomes in care.

c. The funding and efficiency gap: to ensure that additional funding for the NHS is used to improve efficiencies, transform services and achieve financial sustainability.

278. Publication of the Five Year Forward View marked a move away from the fragmented structure that formed a core part of the Lansley Reforms towards greater integration, with innovation and new care delivery options encouraged through the "New Care Models" programme and associated flexibilities. Financial performance and efficiency remained a key focus, however (reflecting one of the three gaps above).

(b) Integrated Care Boards

279. Integrated Care Boards (like their predecessors Clinical Commissioning Groups) play a key role as part of the NHS oversight structure and as emphasised in the NHS Oversight Framework discussed in Section 1, Part B below.

280. Since 1 April 2023, joint working agreements between NHS England and each Integrated Care Board have been in place for the commissioning of 59 specialised services that have been identified as suitable and ready for further integration. This includes commissioning of neonatal critical care services. Under these agreements, the commissioning assurance and oversight of the delegated services are delegated to a joint committee of NHS England and each Integrated Care Board. NHS England retains certain aspects in respect of the function of arranging the provision of specialised services, including the responsibility for drafting the Service Specifications.

281. The role of Integrated Care Boards will evolve further as NHS England builds on the current scope of delegations to Integrated Care Boards. The intention is that, from April 2024, commissioning and oversight of some specialised services (including neonatal critical care) will be fully delegated to Integrated Care Boards. NHS England's "Roadmap for integrating specialised services with Integrated Care Systems" (31 May 2022) **[Exhibit SP/0034 [INQ0009259]]** sets out the case for delegation. Consistent with the 2022 Act, a key advantage of delegation is that it will enable Integrated Care Boards, who hold the budget for their specific population's needs, to oversee and commission services in an integrated way so that the 'care pathway' is joined up and provides the best for the patient. This is particularly important in the case of neonatal services, which interface with a number of other locally commissioned services, maternity services being a key example.

282. Delegation will be accompanied by a formal delegation agreement (made under the powers set out in section 65Z5 of the 2006 Act) and builds on the existing arrangements in place for primary care, while reflecting the specific needs of specialised services. Alongside this, there will be a transfer of commissioning hub teams to ensure continuity and transfer of corporate memory as part of the delegation. A new assurance framework, co-developed by NHS England and a number of Integrated Care Boards, will also be implemented. Key requirements of this include:

    a. That specialised services must continue to be commissioned using national standards;

    b. 10 core commissioning requirements, which include ensuring provider adherence to national standards (or that appropriate improvement plans are in place);

    c. Full alignment with the Oversight Framework and the NHS 'system by default' operating model.

283. In addition, a Framework for Quality and Assurance is being developed.

(c) Sustainability and Transformation Partnerships

284. As a direct result of the Five Year Forward View, the establishment of Sustainability and Transformation Partnerships was announced in December 2015 (through the Delivering the Forward View: NHS planning guidance 2016/17-2020/21 in December 2015 **[SP/0035, INQ0009243]**). This marked a key shift in that it:

    a. reduced the focus solely on individual organisations, with a requirement for organisations to work collaboratively, across a 'place' footprint and for the totality of the population within that footprint;

    b. committed to multi-year planning and allocations, spanning the period October 2016 to March 2021;

    c. encouraged integrated pathways, spanning primary, secondary and community care, with an expectation that social care was also aligned;

    d. directed focus on a number of nationally set areas of focus, including seven-day services; investment in prevention; improved cancer outcomes.

285. Regional teams led on the development of Sustainability and Transformation Partnership footprints and the appointment in March 2016 of leaders for each Sustainability and Transformation Partnership area. Working with Sustainability and Transformation Partnership leaders to progress the vision of the Five Year Forward View and the associated NHS planning guidance was a major area of focus for the regional teams in the period from December 2015.

286. Alongside the development of Sustainability and Transformation Partnerships, another parallel policy development was being implemented in the form of the devolution agenda, which was part of the Government's overall northern powerhouse approach. Greater Manchester was the first significant devolution deal to affect the NHS and devolution generally was an area of national and regional focus during the period from 2015-2018.

287. Further steps were taken towards integration at the national regulator level in 2016, when NHS Improvement was established. This close collaboration was expanded in 2019, when NHS Improvement and NHS England began working as a single organisation.

(12) Creating the new NHS England

288. In order to reduce duplication and help bring people, skills, digital, data and technology expertise together into one organisation, NHS England legally merged with NHS Digital on 1 February 2023, and with Health Education England on 1 April 2023. Information on these legacy bodies which now form part of the new NHS England is set out below.

(a) Health Education England

289. Health Education England was established as an Executive Non-Departmental Public Body pursuant to section 96 of the Care Act 2014 on 1 October 2014 and the Special Health Authority, known by the same name, established in 2012[8] was abolished.

290. Health Education England's function was to provide national leadership and co-ordination for the training and development of the workforce. Health Education England was responsible for planning, education and training of the future workforce,

[8] Pursuant to the Health Education England (Establishment and Constitution) Order 2012

and development of the existing workforce working alongside commissioners and service providers.

291. Health Education England served the wider healthcare system (including private and third sector providers) but had no remit over social care.

292. Health Education England had six levers to achieve its purpose of improving the quality of patient care:

    a. Workforce planning: Each year they identified the numbers, skills, values and behaviours that employers told them were needed for future. Ensuring that the shape and skills of workforce evolve with demographic and technological change.

    b. Attracting and recruiting the right people to the education and training programmes they plan to commission.

    c. Workforce Transformation: Supporting the work of Local Workforce Action Boards in workforce transformation activities.

    d. Commissioning education and training programmes for medical students: Using commissioning levers to best effect so that medical students can learn to provide safe, high-quality care for patients.

    e. Lifelong investment in people: Encouraging employers to continue to provide high-quality care for patients through ongoing training.

    f. Leadership Academy: Developing better leaders, delivering better care: To develop outstanding leadership in health, in order to improve people's health and their experiences of the NHS.

293. Additionally, Health Education England supported healthcare providers and clinicians to take greater responsibility for planning and commissioning education and training through the development of Local Education and Training Boards, which were statutory committees of Health Education England.

294. Local Education and Training Boards were responsible for education and training at regional level. Their main role was to:

a. plan and commission high-quality education and training in order to secure future workforce supply with the right numbers and right skills to improve health outcomes;

b. identify the local education and training needs of health and public health staff required to build skills and meet future service needs; and

c. bring providers and relevant stakeholders together to develop the workforce in line with local health needs and the service transformation agenda.

295. NHS England assumed responsibility for the activities previously undertaken by Health Education England following the merger.

(b) NHS Digital and NHSX

(i) *NHS Digital*

296. NHS Digital was the operational name used by the 'Health and Social Care Information Centre', established under section 252 of the 2012 Act.

297. That name reflects what NHS Digital did: designing, developing, deploying and operating national digital products, platforms and information technology systems for the NHS; and collecting, analysing, curating, publishing and sharing health data and, to a lesser extent, adult social care data. This was for the direct care of patients (e.g. through the national digital products and systems we provided) and for secondary use purposes (such as for planning and commissioning health and adult social care services, and for research). NHS Digital was, therefore, a delivery organisation.

298. NHS Digital's statutory functions were principally set out in Chapters 2 and 3 of Part 9 of the 2012 Act. Its core statutory functions were summarised as:

a. establishing and operating information systems for the collection and analysis of data, where directed by the Secretary of State or NHS England under section 254 or requested by other eligible bodies under section 255 of the 2012 Act;

b. publishing data under section 260 of the 2012 Act and in accordance with the Code of Practice for Statistics;

c. disseminating data under section 261 of the 2012 Act and other relevant legislation, including in relation to the COVID-19 pandemic, under

Regulation 3 of the Health Service (Control of Patient Information) Regulations 2002 ("COPI Regulations"); and

d. exercising IT system delivery functions of the Secretary of State or NHS England when directed to do so under Regulation 32 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013/259 ("the NICE Regulations"); and supplying digital, data and technology services under section 270(1)(d) of the 2012 Act.

299. In relation to its role as a national statistics provider, NHS Digital was a large independent producer of statistical publications across health and care in England, producing around 80 series of publications, comprising around 300 individual publications a year. Publications were drawn from record level administrative datasets, surveys, clinical datasets and collections and covered the health of the population, patients' interactions with different care settings (including primary, secondary, mental health and social care), and cross-cutting areas, such as workforce.

300. NHS Digital was not the only producer of health and care statistics across England, with a number of other organisations producing statistics including NHS England, Office for National Statistics, the Department of Health and Social Care and UK Health Security Agency. These organisations worked closely together where statistics were on similar themes.

301. NHS Digital was accountable to the Secretary of State. The Department of Health and Social Care set out the Government's objectives for NHS Digital via remits which also outlined the operating context for NHS Digital, its accountability and funding flows.

302. As part of the 2022 reforms, NHS Digital's functions and staff transferred to NHS England and now operate as part of NHS England's Transformation Directorate.

(ii) NHSX

303. In February 2019, the Secretary of State announced a new joint unit between NHS England, NHS Improvement and the Department of Health and Social Care called NHSX. Its aim was to focus on technology, data, innovation and digital capability. This new unit brought together policy, strategic skills and expertise across these organisations to support the delivery of the Secretary of State's technology

vision, launched in 2018 and to support the NHS Long Term Plan published in January 2019.

304. NHSX was not a legal body, but a working unit of the two teams, under the leadership of one Chief Executive (with dual appointments). It was responsible for coordination and consistency, setting national policy, developing and agreeing clear standards for the use of technology in the NHS. It was designed to be the single point for accountability for national digital transformation programmes and have oversight over NHS Digital.

(13) How the NHS works with other partners

(a) NICE

305. The National Institute of Health and Care Excellence (NICE) was established as a body corporate under the 2012 Act. Previously, it existed as a Special Health Authority known as the National Institute for Clinical Excellence, using the same acronym.

306. During the First Relevant Period, the National Institute for Health and Care Excellence (Constitution and Functions) and NHS England (Information Functions) Regulations 2013 ("the 2013 NICE Regulations") made under the 2012 Act conferred on NICE the power to make three categories of recommendation:

    a. a general power to give advice or guidance, provide information or make recommendations about any matter concerning its core activity;

    b. NICE Technology appraisal recommendations; and

    c. NICE highly specialised technology recommendations.

307. NHS England and Clinical Commissioning Groups should have regard to NICE recommendations but they are not mandatory. This is in contrast to "technology appraisal recommendations" and "highly specialised technology appraisal recommendations", with which commissioners must comply under the 2013 NICE Regulations.

308. NICE and NHS England work together to manage access to new drugs and medical technologies. As per section 234(1)(a) of the 2012 Act, NHS England can also direct NICE to prepare a quality standard in relation to the provision of NHS Services. For

example, NICE has, this year, produced a quality standard on Neonatal Parenteral nutrition **[Exhibit SP/0036 [INQ0009285]]**.

309. In 2016 NHS England and NICE agreed a Memorandum of Understanding covering 2016 – 2019, in relation to the "innovative activities in the fields of medical technologies and observational data" that NHS England had commissioned NICE to carry out. This is the main document setting out the overarching relationship between NICE and NHS England. It covers the following fields:

    a. Cancer Drugs Fund;

    b. Commissioning Support Documents / Evidence Summaries;

    c. Rapid Evidence Summaries;

    d. Medical Technology Innovation Briefings;

    e. Commissioning Through Evaluation Projects;

310. Further information on the activities within each of those fields is set out in Schedule 3 of the Memorandum of Understanding **[SP/0037, INQ0014777]**.

311. A key area of NICE's work is clinical guidelines, quality standards, and indicators, all of which are publicly available on NICE's website.

    a. Clinical guidelines are evidence-based recommendations, developed by independent committees and consulted on by stakeholders.

    b. Quality standards set out priority areas for quality improvement. They highlight areas with identified variation in current practice

    c. Indicators measure outcomes that reflect the quality of care, or processes linked by evidence to improved outcomes

312. During the First Relevant Period, the focus of NHS England's working with NICE was on the development of quality standards. The topics for quality standards are considered and determined through cross-organisation input, including NICE, NHS England, and Department of Health and Social Care. Previously "The Three Sectors Meeting Terms of Reference" **[SP/0038, INQ0014800]** set out those key partners and a decision-making tree for how clinical guidelines and quality standards would be initiated. The Three Sectors Meeting then became the "Cross Agency Topic

Prioritisation Group" ("CATPG"), also including representatives of NICE, NHS England, and Department of Health and Social Care. CATPG determines the priority of new and updated NICE guideline topics, and the coordination and alignment with other guidance and policy. Further information is set out in the Terms of Reference for the CATPG **[SP/0039, INQ0014799].**

313. The initial library of Clinical Guidelines and Quality Standards had to be selected for development each year as new topics were developed. The development stage is now completed, and NICE have moved into systematic review and product maintenance stage.

314. The NICE CGQS Development Process sets out the processes for topics to be developed to publication as a Clinical Guideline, Quality Standard, or Indicator.

315. By way of example of the development of a clinical guideline, "QS potential topics 2016 – 17" set out an overview of the topics for consideration in the quality standards work for that year, including new topics, and current standards that required update. One topic on the 2016 – 2017 programme was "Developmental follow-up of pre-term babies", which was then published in August 2017 **[SP/0040, INQ0014806]**.

(b) NHS Leadership Academy

316. The NHS Leadership Academy was set up as an independent organisation in April 2012, following an announcement by the Secretary of State in May 2011. Its principal purpose is the stewardship of the leadership agenda including developing outstanding leadership in health with a continual focus on improving the experiences and health outcomes of patients. The Academy continued the pre-existing NHS graduate management training scheme and Top Leaders programmes as well as delivering a suite of leadership development programmes through partners. In order to broaden its reach, the NHS Leadership Academy became part of Health Education England in 2017.

317. In April 2019, the NHS Leadership Academy transferred to the NHS Trust Development Authority, and so became part of NHS Improvement and through joint working therefore within the body known as 'NHSEI'. However, it was not legally or formally part of NHS England.

318. By the National Health Service Trust Development Authority (Leadership Academy) Directions 2019, the Secretary of State directed the NHS Trust Development Authority

to maintain and provide for the operation of the Leadership Academy as a unit of the Trust Development Authority, and to work collaboratively with Monitor and NHS England in carrying out those activities. The Academy was based in NHS England's People Directorate, but from 2019 to 1 July 2022 it was required to be operated as a separate unit.

319. On 1 July 2022, the NHS Leadership Academy's staff and activity transferred to NHS England upon the abolition of the Trust Development Authority. Legally, there is no longer a requirement to have a separate unit called the NHS Leadership Academy - its activities are pursued under the general functions of NHS England, rather than any specific legislation.

(c) Devolved administrations

320. Nationally, multiple teams and individuals in NHS England work with the devolved nations. By way of illustrating this, NHS England's Chief Nursing Officer attends regular meetings with the chief nursing officers of the devolved administrations. A similar arrangement applies in relation to the National Medical Director and the chief medical officers of the devolved administrations, but noting that England is unique among the Four Nations in having both a Chief Medical Officer (who fulfils a government role) and a National Medical Director, who works solely for NHS England.

321. NHS England is under a duty to consider the cross-border implications of the way it commissions local services, as were Clinical Commissioning Groups and now Integrated Care Boards. This means that for the most part the principal level of engagement with, for example, the Welsh Health Boards will generally be at the regional team level. This is covered in Section 2.

PART B: QUALITY AND PATIENT SAFETY

322. In this section we explain what is meant in the NHS by the terms 'quality' and 'patient safety' and cover in high level the key structures and processes for quality and patient safety during the First Relevant Period outside of the regulatory oversight role performed by Monitor and the NHS Trust Development Authority, which is described above in Section 1, Part A. We touch on developments since the First Relevant Period, but much of this will be drawn out in further detail below in Section 2 (which describes how these structures and processes operated in practice) and Section 3 (where we provide more background on why some of these systems were introduced or changed as a result of previous inquiries, learning from incidents or other findings).

323. We do not address how the safety or wider quality of patient care is considered at the day-to-day ward, clinician and treatment level in the NHS, but at the more senior accountable board levels.

(1) Overview

324. We have briefly explained at paragraph 50 above what the term 'quality' means in an NHS context and how this relates to patient safety. The current definition of quality, as set out by the National Quality Board **[SP/0041, INQ0009256]** refers to the extent to which healthcare is safe, effective, delivers a positive experience, is well led, sustainably resourced and is equitable.

325. Patient safety specifically, as a core component of this wider concept of quality, is about maximising success in healthcare. It is the avoidance of unintended or unexpected harm to people during the provision of healthcare and the reduction of risk of unnecessary harm to an acceptable minimum.

326. The delivery of good quality healthcare services and a focus on continuous improvement is underpinned by associated legal and contractual duties on those regulating, commissioning and providing NHS healthcare services, some of which have already been drawn out in Part A.

327. The following examples establish an expectation that NHS bodies will deliver and/or oversee quality services, including services that continuously improve patient safety:

    a. Legal duties, including those set in the form of national healthcare standards by the Care Quality Commission and enforced by the Care Quality Commission exercising its inspection duties, as well as by virtue of the Provider Licence, provider/system oversight frameworks, and the commissioner/provider relationship.

    b. Other regulators' mandatory standards, such as those set by the Human Tissue Authority or the Human Fertilisation and Embryology Authority.

    c. Observance of clinical standards set by national regulatory bodies, such as NICE and the professional regulatory bodies and Royal Colleges.

    d. Clinical governance requirements, ordinarily described as being based on the 'seven pillars' of clinical governance, which are: audit, risk management, clinical effectiveness, training and education, patient and public involvement,

information systems, and staff management. The effectiveness of the structures and process providers have in place to enable clinical governance are regulated by provider regulatory bodies (the role of commissioners is noted separately, below at f).

e. Wider reporting requirements, including reporting certain events to external bodies or independent systems. This includes reporting via the Coroner and Medical Examiner, the Health Services Safety Investigation Body (as it is currently named), the Care Quality Commission, and various other confidential enquiries and clinical outcome review programmes.

f. Commissioner Requirements: National frameworks, including the NHS Standard Contract (in particular NHS Standard Contract condition 37 and 38), incorporate standard requirements around quality, ensuring that all commissioned providers of NHS services are operating to the same overall expectations. As part of the overall commissioner/provider relationship and the ongoing assurance process this relies on, providers will report to commissioners about issues relating to quality, including patient safety, and provide assurance around clinical governance processes and structures to manage such issues.

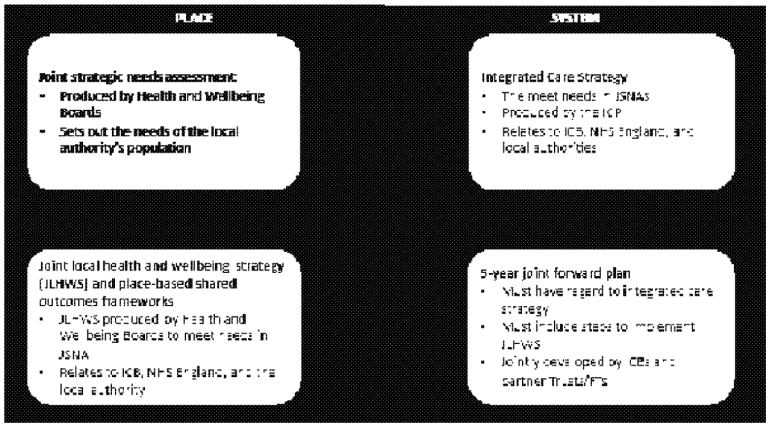
g. Governance Requirements: as set out in Part A of this statement, a Foundation Trust is required under the Provider Licence to meet specific governance conditions, which include requirements around compliance with healthcare standards.

328. Each provider of NHS services will have its own patient safety and wider quality planning, assurance and improvement mechanisms. This includes the reporting arrangements each provider has in terms of national systems and processes, but also their own internal processes and structures for the identification, examination, management and improvement of patient safety and wider quality matters. Hospitals, general practices and other providers are responsible for the safety of their patients and sharing local information about risks and best practice.

329. Patient safety today is supported from neighbourhood and place to system, via Integrated Care Systems, to support the provision of safe care and help to tackle problems that cut across care settings. Integrated Care Systems facilitate partnership working across health and care, and more widely. This includes through the statutory

Integrated Care Board and Integrated Care Partnership joint committee arrangement between the Integrated Care Board and local authorities within their areas. Integrated Care Systems operate at neighbourhood, place and system level. Further detail, from the King's Fund, is provided at Annex 8.

330. There are various planning related duties that apply to the Integrated Care Board, Integrated Care Partnership and partners, which are summarised in the illustration below:



Source: Statutory guidance on the preparation of integrated care strategies , Department of Health & Social Care (July 2022)

331. Most NHS bodies ensure they meet the various requirements and maintain a focus on quality and patient safety specifically by having an identified board committee that focuses on quality of care, including patient safety, as well as an officer who leads on this aspect of work. That board committee will in turn receive information from and oversee the management of quality, including patient safety, by subsidiary groups and individuals.

332. Quality is also enshrined in the NHS Constitution, which provides that the NHS aspires to the highest standards of excellence and professionalism and to provide high quality care that is safe, effective and focused on patient experience. The NHS Constitution contains pledges that the NHS is committed to achieve, which go above and beyond legal rights. This includes the right for patients to be treated with a professional standard of care, by appropriately qualified and experienced staff, that meets required levels of safety and quality. The commitment to quality of care means that the NHS

welcomes feedback from patients, families, carers, staff and the public. The NHS Constitution is covered in more detail in Section 3, Part B.

(2) NHS England and Quality, including Patient Safety

(a) Policy development

333. In the period 2010-2015, the Government published "Policy paper 2010 to 2015 government policy: patient safety" **[Exhibit SP/0042, INQ0009276]**. This policy referenced Domain 5 of the NHS Outcomes Framework, which contained indicators intended to measure patient safety and which were how NHS England was held to account by the Government for the way in which it delivered on patient safety.

334. In the period following this first paper:

    a. NHS England was established and was given relevant statutory duties under section 13R of the 2006 Act; and

    b. NHS England was given responsibility for the National Reporting and Learning System as part of the 2012 Reforms, with this transferring from the National Patient Safety Agency. During the First Relevant Period, NHS England discharged this responsibility by arranging this function to Imperial College Healthcare NHS Trust and receiving regular data from it.

335. In the period 2012-2018, a significant number of patient safety initiatives were directed by the Government and, in particular, the Secretary of State at the time, who made patient safety an explicit priority for his leadership. These were supported/implemented as appropriate by NHS England and/or NHS Improvement.

336. In 2016, with the establishment of NHS Improvement, the Secretary of State directed the NHS Trust Development Authority to exercise NHS England's patient safety functions. In practice, this resulted in the transfer of the National Patient Safety Team from NHS England to NHS Improvement. This direction was set out in the NHS Trust Development Authority (Directions and Miscellaneous Amendments etc.) Regulations 2016.

337. The transfer of the responsibility for these patient safety functions from NHS England to NHS Improvement was accompanied by a transfer of the National Reporting and Learning System from Imperial College Healthcare NHS Trust to the NHS Trust Development Authority. The National Reporting and Learning System team moved to

sit with the National Patient Safety Team, as part of NHS Improvement. This enabled improved alignment between the patient safety duties related to collecting information about what goes wrong in healthcare and using that information to provide advice and guidance on improving safety to the NHS. The table at Annex 2 provides further detail.

338. In 2018, the incoming Secretary of State, asked the new incoming NHS National Director of Patient Safety in NHS Improvement to create the NHS's first overarching patient safety strategy. This was published in 2019 by NHS England and NHS Improvement (who were, by this point, operating as a single body, NHS England and NHS Improvement).

339. The NHS Patient Safety Strategy 2019 **[SP/0043, INQ0009251]**, which was updated in 2021 **[SP/0044, INQ0009255]** and again in 2023 **[SP/0045, INQ0009277]**, set a vision for the NHS to improve patient safety continuously. However, the Strategy did not (and, in its current iteration, does not) seek to direct the whole of the NHS. Elements of the NHS, such as workforce and financial planning, clinical training/education and guidance and estates and facilities maintenance, remain subject to each provider's own strategic leadership and implementation.

340. Instead, the NHS Patient Safety Strategy aims to:

    a. improve the way the NHS learns about patient safety — termed 'insight';

    b. build capability and capacity to address safety challenges — termed 'involvement'; and

    c. focus on key improvement priorities where additional national activity can add value — termed 'improvement'.

341. In order to do this, the Strategy builds on two foundations: a patient safety culture and patient safety systems.

342. The Strategy is in its fifth year of operation and has demonstrated success in implementing initiatives, hitting milestones and improving outcomes[85].

343. Since 1 July 2022, the NHS National Patient Safety team has formally been in the new NHS England.

(b) England's statutory role

344. As noted in Part A of this statement, NHS England has explicit statutory responsibilities in relation to quality and was envisaged, in the Lansley Reforms, as having a national role in promoting a drive to improve quality.

345. This is reflected in the statutory duties that NHS England has in relation to quality. Section 13E of the 2006 Act requires that NHS England "exercise its functions with a view to securing continuous in the quality of services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness, or the protection or improvement of public health". Section 13E(2) further specifies that NHS England must, in particular, "act with a view to securing continuous improvement in the outcomes that are achieved from the provision of the services". The outcomes that are relevant for the purposes of section 13E(2) are as follows:

    a. the effectiveness of the services;

    b. the safety of the services; and

    c. the quality of the experience undergone by patients.

346. These outcomes reflect the definition of quality, as explained at paragraph 50 of this statement.

347. When discharging this duty, NHS England must have regard to any document published by the Secretary of State for the purposes of section 13E and the quality standards prepared by NICE (under its own duty, found in section 234 of the 2012 Act).

348. These duties are general and are intended to be incorporated into everything that NHS England does. This means that they do not relate to the work of any single team, but are discharged (on both national and regional footprints) through NHS England's wider system of quality governance.

349. As part of the 2012 Reforms, the National Patient Safety Agency (a Special Health Authority established in 2001) was abolished on 1 June 2012. Prior to that, it had been responsible for certain patient safety related functions, the key aspect of which was the function of improving the safety of NHS care by promoting a culture of reporting and learning from adverse events. NHS England inherited some of the functions of the National Patient Safety Agency as part of the structural reforms implemented by the

Lansley Reforms. This transfer took effect in the period prior to NHS England's full operational establishment on 1 April 2013, as part of the transition arrangements incorporated within NHS England's status as a Special Health Authority for the period October 2011 to 1 April 2013.

350. The specific functions that NHS England inherited from the National Patient Safety Agency took the form of two key statutory duties, both of which were (and remain) contained within section 13R of the 2006 Act, which requires that NHS England:

    a. establish and operate systems for collecting and analysing information relating to the safety of services provided by the health service (section 13R(1));

    b. give advice and guidance for the purposes of maintaining and improving the safety of the services provided by the health service (section 13R(4)).

351. NHS England's governance facilitates a focus on quality as follows:

    a. As explained in Part A, NHS England was (and remains) governed by its Board, which provides strategic leadership and accountability to Government, Parliament and the public. Board members bring a wide range of experience, skills and perspectives to the Board. Together, they set the strategic direction of the organisation and ensure there is robust and open debate during Board deliberations.

    b. Matters relating to quality and specifically patient safety are reported to the Board (through the structures described below at d) and discussed as appropriate at each Board meeting.

    c. The NHS England Board is supported in its operation by committees which undertake detailed scrutiny in their respective areas of responsibility and provide the Board with regular reporting and assurance. They are led by non-executive directors (as Chairs) and include a dedicated quality committee, which is currently constituted as the Quality Committee. Further committees and groups report to this, notably the Quality and Performance Committee and the Executive Quality Group.

    d. NHS England's Regional (and during the First Relevant Period, Area) structures support this focus on quality, with equivalent governance processes and structures in place and reporting arrangements to enable appropriate

escalation to the national structures, principally via the Executive Quality Group. This is covered further in Section 2.

352. For a period of time between 1 April 2016[9] and 1 July 2022, the NHS Trust Development Authority was directed to perform part of NHS England's statutory role in relation to the National Reporting and Learning System. Following the disestablishment of the Trust Development Authority, and transfer of its functions to NHS England, these duties reverted back to NHS England and are performed by the National Patient Safety Team, which is overseen by the National Director of Patient Safety and discussed at paragraph 337.

(c) Patient Safety incident investigation and management policies

353. In the Overall Relevant Period, there were two principal systems setting out expectations for how the NHS should identify and manage certain significant patient safety incidents and other defined 'serious incidents' and some changes to their underlying guidance:

a. 2010-2013: the "National Framework for Reporting and Learning from Serious Incidents Requiring Investigation" published in 2010 by the National Patient Safety Agency **[SP/0046, INQ0014613]**; and

b. the "Serious Incident Framework", first published in 2013, published by NHS England (2013–2015) **[SP/0047, INQ0009224]** and refreshed in 2015, by NHS England (2015–2023) **[SP/0048, INQ0009236]**.

354. In 2022, a new policy for incident management was announced when NHS England published the Patient Safety Incident Response Framework **[SP/0049, INQ0009265]**.Some "early adopters" across the country had implemented requirements of this policy beforehand in order that their experience would assist to inform the national roll out in 2022 **[SP/0050, INQ0014722]**.

355. The Patient Safety Incident Response Framework replaces the 2015 Serious Incident Framework. The Patient Safety Incident Response Framework is one of the key initiatives under the Patient Safety Strategy. It sets out the NHS's approach to

[9] See paragraph 2 of The National Health Service Trust Development Authority (Directions and Miscellaneous Amendments etc.) Regulations 2016

developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

356. Compliance with the Patient Safety Incident Response Framework is a contractual requirement under the NHS Standard Contract. As such, it is mandatory for all services provided under that contract, including neonatal services. The rationale for incorporating PSIRF as a contractual requirement is to emphasise and support the development and maintenance of an effective patient safety incident response system.

(d) Patient safety incident reporting tools

357. The following three patient safety incident reporting tools have been used during the Overall Relevant Period to record patient safety incidents. Each tool is reliant on individuals reporting information onto it and this then informs the analysis and monitoring each tool enables.

a. **The National Reporting and Learning System**, which was created in 2003 to identify themes and support patient safety with both mandatory and voluntary elements. Patient safety incidents are defined as any unexpected or unintended event occurring in healthcare that could have, or did, lead to harm to one or more patients. The aim of the tool is to identify rare, unusual and emerging risks that might happen multiple times a year across the whole of the NHS, and to share learning across the system via patient safety alerts. It is not intended as an oversight tool for regulation or as a means of identifying local safety issues.

b. **The Strategic Executive Information System**, which was primarily used as a mechanism for NHS provider trusts to notify regional and national health bodies about incidents that met the definition of a 'Serious Incident' or a "Never Events", being the two specific types of event listed by NHSE England in guidance published each year (the list for 2015/2016) **[SP/0051, INQ0014625].**

c. **Learn From Patient Safety Events Service.** This is a new national NHS service for the recording and analysis of patient safety events that occur in healthcare, to replace both the National Reporting and Learning System and Strategic Executive Information System.

358. The key differences between the operation of these three systems is summarised in the table contained at Annex 2. In addition, Annex 3 sets out the conclusions of a rapid review NHS England's national patient safety team carried out in relation to patient safety and incident reporting data held on the National Reporting and Learning System and the Strategic Executive Information System that related to neonatal cases at the Countess of Chester Hospital during the period January 2015-December 2016.

(3) The NHS Outcomes Framework

359. The NHS Outcomes Framework was developed in December 2010 and continued to be used even after the 2012 legislative reforms to the 2006 Act came into force in April 2013. Its had three main purposes:

    a. to provide a national overview of how well the NHS is performing;

    b. to provide an accountability mechanism between the Secretary of State and NHS England; and

    c. to act as a "catalyst for driving up quality throughout the NHS by encouraging a change in culture and behaviour".

360. The NHS Outcomes Framework remains in use today, although its title has changed in the most recent version to the Quality and Outcomes Framework, and other mechanisms are increasingly used to measure quality.

361. Information gathered via the NHS Outcomes Framework was published quarterly until March 2022, when publication was changed to being annual.

362. The NHS Outcomes Framework 2013/14 **[SP/0052, INQ0009218]** included five domains. Each domain had a small number of overarching indicators, as well as a number of improvement areas. Each domain was focused on improving health and reducing health inequalities. The domains in the 2013/14 NHS Outcomes Framework were:

    a. Domain 1: preventing people from dying prematurely;

    b. Domain 2: enhancing quality of life for people with long-term conditions;

    c. Domain 3: helping people recover from episodes of ill health or following injury;

d. Domain 4: ensuring that people have a positive experience of care; and

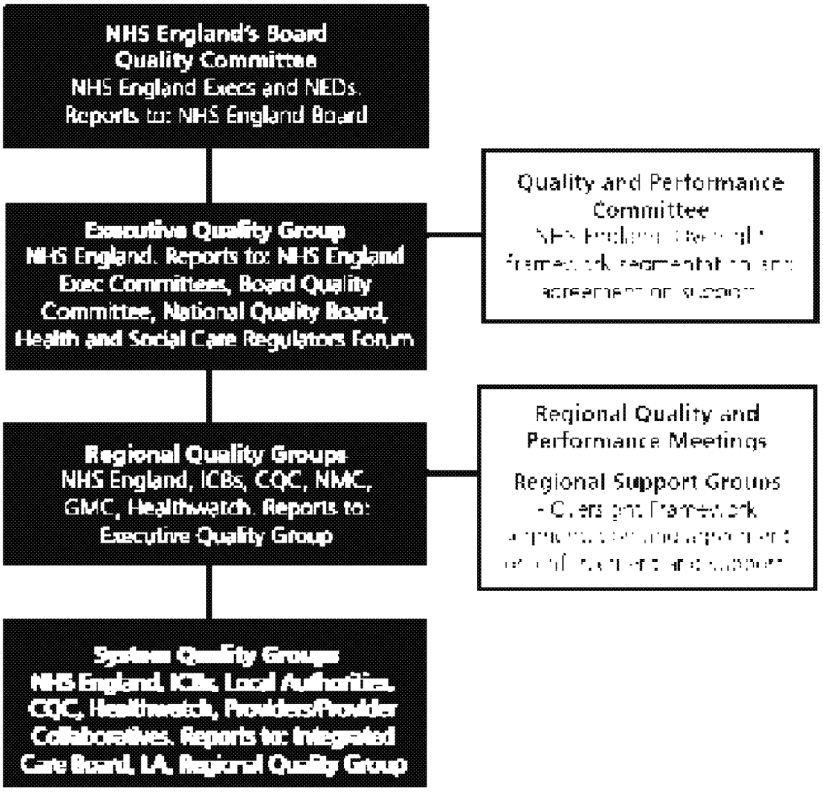
e. Domain 5: treating and caring for people in a safe environment; and protecting them from avoidable harm.

363. As explained earlier in this statement, at paragraph 77, the NHS Outcomes Framework formed part of the Mandate to NHS England. NHS England's annual report on its progress against the Mandate incorporated an assessment of its progress against the NHS Outcomes Framework. The Government published a response to NHS England's report, again on an annual basis.

(4) National Quality Board and System Quality Groups

364. The National Quality Board was established in 2009 to consider the risks and opportunities for quality and safety across the whole system, by bringing together the Department of Health and Social Care, Care Quality Commission, NHS England, NICE and others. Its membership has necessarily evolved over the time it has been in operation, reflecting the legislative reforms that have taken place. During the First Relevant Period, Monitor, the Care Quality Commission and NHS England were all members.

365. The National Quality Board has overseen the development of a dedicated quality governance system at system, regional and national levels. This governance was reviewed and updated in 2022, as part of implementing the 2022 Act. The current structure is as follows:



366. Today, the National Quality Board provides advice, recommendations and endorsements on matters relating to quality, aiming to support delivery of the NHS Long Term Plan's ambition for quality in the NHS. It has six key aims:

    a. supporting system transformation;

    b. digital transformation;

    c. research and innovation;

    d. support for the health and social care workforce;

    e. patient safety; and

    f. improving population health and health inequalities.

367. The National Quality Board is jointly chaired by NHS England's National Medical Director and the Care Quality Commission's Chief Inspector of Hospitals. Membership is made up of senior clinical and professional leaders from the NHS and partner organisations, alongside patient and public representatives **[SP/0053, INQ0009272]**.

368. Since its establishment, the National Quality Board has played an important role in publishing guidance for quality governance structures. In the pre-2022 period, this took the form of guidance around Quality Surveillance Groups. These structures and the key guidance documents are described in more detail below at paragraph 378.

(5) NHS England and the Care Quality Commission, the General Medical Council and the Nursing and Midwifery Council

(a) Care Quality Commission

369. Under section 290 of the 2012 Act, the Care Quality Commission and NHS England were given duties to cooperate with each other in the exercise of their respective functions.

370. In January 2013, following the 2012 reforms taking effect, NHS England and the Care Quality Commission signed a Partnership Agreement **[SP/0054, INQ0009221]** to set an initial framework for the strategic working relationship between the two organisations.

371. The Partnership Agreement recognised the respective roles of the two organisations, with the Care Quality Commission being the independent regulator of health and social care providers in England, which protects and promotes the health, safety and welfare of people who use health and social care service, and the NHS Commissioning Board in its role of ensuring that the NHS delivers continuous improvements in outcomes for patients within resources available.

372. The Partnership Agreement reflected the shared fundamental goal of the two organisations of working in a way which supported and promoted the delivery of safe and good quality care for the public. It set out three initial priorities with a view to achieving that goal:

    a. Establishing information sharing arrangements, to ensure proactive sharing of information and intelligence about the quality of care in order to spot potential problems early and manage risk.

    b. Implementing the mechanisms which had been proposed by the National Quality Board in its document "Quality in the new health system: Maintaining and improving quality from April 2013" (January 2013) **[SP/0055,**

INQ0009219], on how the healthcare system should prevent, identify and respond to serious failures in quality.

c. Establishing ways for the two organisations to work together at a local and regional level, and with wider stakeholders, and in light of the National Quality Board's proposals to establish regional Quality Surveillance Groups.

373. The Partnership Agreement established that there would be an annual meeting of the boards of both organisations, including Chairs and Chief Executives, in order to set joint strategic priorities. More frequent (e.g. quarterly) meetings of lead officials were then held with a focus on delivery and allocation of respective resources. This is covered this in more detail in Section 2.

374. Alongside the Partnership Agreement, there are other particular arrangements for the two organisations to work together.

375. Throughout the Overall Relevant Period, there has been a shared commitment to establish and refine an operating model for quality governance. One of the key aspects of this model was the establishment of Quality Surveillance Groups, which have (as of 1 July 2022) been replaced by System Quality Groups. Both structures are described further below.

(b) Joint Strategic Oversight Group

376. In addition, the Joint Strategic Oversight Group provides a national forum for intelligence sharing among national partners, including the General Medical Council, the Nursing and Midwifery Council and the Care Quality Commission. In the period prior to July 2022, the Joint Strategic Oversight Group also included representatives from the legacy statutory bodies, including NHS Improvement (Monitor and the NHS Trust Development Authority) and Health Education England. This is also described further below.

377. The Joint Strategic Oversight Group was established in May 2017 and continues in operation at the present day. It meets on a bi-monthly basis and its purpose is to:

a. develop and agree an aligned and consistent approach to joint working to ensure timely and appropriate intervention and support for trusts in special measures for quality reasons and for challenged trusts; and

b. exchange learning, intelligence and information to aid future improvement, particularly in providing support and interventions for trusts with significant quality issues.

(c) Quality Surveillance Groups

378. During the First and Second Relevant Periods, Quality Surveillance Groups were a crucial means of facilitating NHS England's engagement with the Care Quality Commission and other regulators, including the General Medical Council and the Nursing and Midwifery Council. They remain a key part of the quality governance structure in place at both system and region but have been updated to reflect the 2022 legislative reforms.

379. The background to Quality Surveillance Groups was published in 'Quality in the new health systems — maintaining and improving quality from April 2013' (published January 2013) **[SP/0055, INQ0009219]**. The report recognised the need for collaboration across commissioning, regulation and performance monitoring in pursuit of a shared commitment to quality, whilst confirming that individual organisations should retain their distinct responsibilities.

380. The report introduced Quality Surveillance Groups as "a new approach for supporting collaboration across the system and facilitating the sharing of information and intelligence on quality" and sought to ensure "a clear and agreed approach to taking swift and coordinated system-wide action in the event of a serious quality failure being identified, in order to rapidly protect patients and service users".

381. The model for Quality Surveillance Groups was to operate at both regional and area team footprint. Detailed guidance on the establishment of Quality Surveillance Groups was published alongside the report in January 2013 **[SP/0056, INQ0009220]** and there have been various iterations since.

382. Local Quality Surveillance Groups were described in these documents as the "backbone of the network" of bodies concerned with quality matters. This is because they were closest to the detail and most aware of concerns, and because they facilitated taking coordinated action to mitigate quality failures. These local groups were facilitated and chaired by the NHS England area leads, but their membership included representatives from the Care Quality Commission and wider stakeholders (Clinical Commissioning Groups, Healthwatch, Local Authorities and others).

383. The regional Quality Surveillance Groups were then a point of escalation for the local groups to "assimilate risks and concerns from local QSGs, identifying common or recurring issues that would merit a regional or national response". Again, regional Quality Surveillance Groups were chaired by relevant regional NHS England directors and had representation from the Care Quality Commission. At the regional level, Quality Surveillance Groups were required to include representation from the General Medical Council and the Nursing and Midwifery Council to secure their routine involvement.

384. The role of Quality Surveillance Groups was described from the outset as being proactive forums for collaboration, providing the health economy with:

    a. a shared view of risks to quality through sharing intelligence;

    b. an early warning mechanism of risk about poor quality; and

    c. opportunities to coordinate actions to drive improvement, respecting statutory responsibilities of and ongoing operational liaison between organisations.

385. Once a concern was identified by a Quality Surveillance Group it was for organisations to take relevant actions depending on their statutory functions, such as: contractual action (by commissioners); regulatory/enforcement action; or improvement support.

386. As described in the National Quality Board's report which established these groups, NHS England in its role as commissioner of certain services could raise matters with the Care Quality Commission through these groups. It would do so where it had concerns about whether providers were meeting the essential standards of quality and safety. Similarly, NHS England could raise matters with the professional regulators (the General Medical Council and the Nursing and Midwifery Council) through the groups if there were issues relating to regulated professionals.

387. In turn, the Care Quality Commission was able through these groups to share information and intelligence about providers with other parts of the system, including NHS England, as relevant to its role around quality. The professional regulators would also use Quality Surveillance Groups to share information and intelligence they had that related to wider system or organisational problems. This would include, for example, information arising from investigations of individual practitioners or in relation to the regulator's roles relating to education and training of practitioners.

(d) System Quality Groups

388. In January 2022, the National Quality Board replaced the guidance on Quality Surveillance Groups and Risk Summits with a new operating model for quality governance **[SP/0057, INQ0009258]**. This was part of preparing for the 2022 reforms to take effect, and for the transition to formal Integrated Care System working. Further guidance was issued in June 2022 by the National Quality Board on Quality Risk Response and Escalation in Integrated Care Systems **[SP/0058, INQ0009260].**

389. As a result, all Integrated Care Systems are expected to have a System Quality Group, with the National Quality Board setting the expectations for quality governance in Integrated Care Systems. As was the case with Quality Surveillance Groups, System Quality Groups are not statutory bodies, and do not act as a substitute for each statutory body's own internal quality arrangements to ensure compliance with their statutory duties.

390. The updated model retains the regional quality structures (now known as Regional Quality Groups), which are chaired and facilitated by NHS England's regional teams. The regional groups continue to include representation from the Care Quality Commission and the professional regulators (and others, such as local authorities and the Health Service Ombudsman). They have two principal objectives:

    a. maintaining and safeguarding quality;

    b. supporting and enabling improvement.

391. NHS guidance states that the minimum requirements for System Quality Group members include: the Integrated Care Board; local authorities; provider collaboratives; regional NHS England and NHS Improvement teams; regulators (Care Quality Commission and Health Education England); primary care; local maternity systems; patient safety specialists; and at least two lay members with lived experience. System Quality Groups must meet at least quarterly and are chaired by Integrated Care Board executive quality leads.

392. System Quality Groups will have the full range of health and care services and providers of the Integrated Care System within their remit, including services commissioned by the NHS jointly with local authorities or by local authorities. System Quality Groups should provide a forum for engagement, intelligence sharing, learning and quality improvement across the Integrated Care System. The actions System

Quality Groups take will vary, depending on the individual statutory responsibilities of the members. They may include, for example, improvement support, performance management, contractual action, regulatory or enforcement action.

(e) Care Quality Commission and Regulators' Emerging Concerns Protocol

393. Importantly, in relation to emerging concerns and the involvement of professional regulators, it should also be noted that the Care Quality Commission and others concerned with quality and safety, and public protection, have also developed an Emerging Concerns Protocol.

394. The protocol was first published in 2018, having arisen as an action following a forum convened by a meeting of system regulators and professional regulators in October 2016. Professional regulators (such as the General Medical Council and the Nursing and Midwifery Council), the Local Government and Social Care Ombudsman, Health Education England, and the Parliamentary Health Standards Ombudsman are signatories to the Protocol.

395. This protocol sits along other specific arrangements which the Care Quality Commission has with individual signatories, such as the General Medical Council/Care Quality Commission Joint Working Group, Nursing and Midwifery Council/Care Quality Commission Joint Working Group and memoranda of understanding. Its purpose is to provide a clearly defined mechanism "for organisations which have a role in the quality and safety of care provision, to share information that may indicate risks to people who use services, their carers, families or professionals." It aims to facilitate earlier sharing of concerns, and identifies three categories that such concerns may fall into:

    a. concerns about individual or groups of professionals;

    b. concerns about healthcare systems and the healthcare environment (including the learning environments of professionals); and

    c. concerns that might have an impact on trust and confidence in professionals or the professions overall.

396. The protocol sets out underpinning principles and a process for how concerns should be raised with respective bodies, and what information should be shared between them and when. For example, it explains what the nature of concerns that the respective professional regulators would like to be informed about (including concerns

about individual professionals' fitness to practise) and summarises their key activities and responsibilities.

397. Where an organisation initiates a concern under the protocol, it contacts other relevant partners (which may be some or all of the signatories) and arranges for a Regulatory Review Panel to be convened to facilitate shared consideration of the concern and coordinated intervention.

398. A Regulatory Review Panel is an opportunity for regulatory partners to collaborate and discuss how best to use their respective regulatory powers. Meetings of a Regulatory Review Panel are to be attended by individuals within organisations who have the delegated authority to take relevant decisions. It will be decided during the meetings whether no action needs to be taken, whether further investigation is needed, and/or whether regulatory action is required. In the latter case, the organisations will decide which body or bodies should take such action and when, including whether coordinated action is needed.

399. As explained in the protocol, NHS England is not a signatory but it expressly supports its use, agrees strongly with its principles and it has sought to align the National Quality Board guidance on quality surveillance with it.

400. As noted in the protocol, and in practice, a Regulatory Review Panel may decide that matters relevant to such emerging concerns need to be referred to the Quality Surveillance Groups (which would now be understood as the equivalent structures under the post-July 2022 landscape, e.g. System Quality Groups). Model terms of reference for the current System Quality Groups require these groups to work in close partnership with professional and system regulators, including sharing and considering intelligence gathered through the Emerging Concerns Protocol processes.

(f) General Medical Council

401. In addition to the quality governance structures summarised above, which enable sharing between NHS England and professional and system regulators, NHS England also has responsibilities for engaging with the General Medical Council about fitness to practise matters through the Responsible Officer requirements.

402. In summary, designated bodies under the Medical Profession (Responsible Officers) Regulations 2010 (as amended) are required to appoint a Responsible Officer.Responsible Officers are accountable for the local clinical governance

processes in particular healthcare organisations, focusing on the conduct and performance of doctors. Their duties include evaluating a doctor's fitness to practise and liaising with the General Medical Council to make recommendations based on which the General Medical Council can decide whether a doctor should be revalidated.

403. Responsible Officers also liaise with the General Medical Council in individual fitness to practise cases. Responsible Officers can make referrals to the General Medical Council which lead to investigations in relation to a doctor's behaviour, health or performance. The General Medical Council publishes 'thresholds guidance' which explains to Responsible Officers the thresholds for referrals and the process for making referrals. Additionally, the General Medical Council has Employer Liaison Advisors who can assist Responsible Officers to understand the thresholds and processes. If there are serious concerns about a doctor's fitness to practise, to the extent that there is a threat to patient safety, the Responsible Officer should immediately refer the doctor to the General Medical Council.

404. Where a doctor works for an NHS Trust or Foundation Trust, their Responsible Officer will usually be the single Responsible Officer for that body. For both NHS Trusts and Foundation Trusts, the Responsible Officer is appointed by the boards of those organisations and will typically be a senior clinician. It can be the Chief Medical Officer, but it does not have to be. A Responsible Officer must be a registered medical practitioner and have been a registered doctor for the preceding five years.

405. As Responsible Officers within NHS Trusts and Foundation Trusts must be registered medical practitioners and fit to practise, they will themselves have Responsible Officers. NHS England ordinarily hosts these higher-level Responsible Officers. The higher-level Responsible Officer will submit revalidation recommendations to the General Medical Council for all Responsible Officers connected to them. The recommendation will be based, as it is for all doctors, on information from appraisals and from routine monitoring of performance and fitness to practise. Assessment of fitness to practise of the Responsible Officers includes how a doctor carries out his/her functions as a Responsible Officer.

(g) Nursing and Midwifery Council

406. The Nursing and Midwifery Council is the independent regulator for nurses and midwives in the UK, and for nursing associates in England (this role only exists in England). NHS England and the Nursing and Midwifery Council work together

nationally to agree key strategic matters including supporting the Nursing and Midwifery Council in the development of regulatory standards and codes of practice. As an example, NHS England working closely with the Nursing and Midwifery Council during the recent pandemic, including on the opening of the temporary Nursing and Midwifery Council register for COVID-19.

407. Like the General Medical Council, the Nursing and Midwifery Council operates guidance and has an Employer Link Service to support referrals. It is expected that referrals are made by appropriately authorised individuals within employing organisations (e.g., within NHS Trusts and NHS Foundation Trusts). Individual fitness to practise concerns in relation to those regulated by the Nursing and Midwifery Council are not routinely discussed or raised with NHS England. Intelligence, information and opportunities for learning and improvement which arise from investigations and other activities by the Care Quality Commission is often shared with NHS England, primarily through the regional and local quality governance structures described above.

(6) Healthcare Safety Investigation Branch/The Health Services Safety Investigations Body

408. The House of Commons Public Administration Select Committee, in its March 2015 report, "Investigating Clinical Incidents in the NHS", recommended the establishment of a new body to conduct patient safety investigations.

409. In response, the Department of Health report "Learning not blaming…" (July 2015) committed to establishing an independent patient safety function. An Expert Advisory Group was tasked by the Secretary of State to advise on the establishment of the function and provide advice on the purpose, role and operation of a new body, which it did in its Report of the Expert Advisory Group: Healthcare Safety Investigation Branch (May 2016) **[SP/0059, INQ0009242]**. The Chair of the Expert Advisory Group was Dr Mike Durkin, who at the time was Director of Patient Safety at NHS England.

410. Following the above, the Healthcare Safety Investigation Branch was established pursuant to the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) Directions 2016 ("the Healthcare Safety Investigation Branch Directions"). These directions required the NHS Trust Development Authority to establish the Healthcare Safety Investigation Branch as an independent division

responsible for investigating patient safety incidents in the NHS in England. The Healthcare Safety Investigation Branch became operational in April 2017.

411. Although the Healthcare Safety Investigation Branch was hosted by the NHS Trust Development Authority, it was operationally independent for funding and employment purposes. The NHS Trust Development Authority had specific obligations under the Healthcare Safety Investigation Branch Directions to take reasonable steps to protect the independence of Healthcare Safety Investigation Branch from the other activities of the NHS Trust Development Authority. As part of discharging this duty, the NHS Trust Development Authority established an independent advisory group. This independent advisory group provided external input and advice to the investigations carried out by the Chief Investigator and their staff. Its independence was emphasised by its reporting and accountability obligations, with the Healthcare Safety Investigation Branch reporting directly to the Secretary of State and being accountable to Parliament through the Department of Health and Social Care.

412. The purpose of the Healthcare Safety Investigation Branch was to conduct independent investigations into patient safety incidents in the NHS in England. The Healthcare Safety Investigation Branch was responsible for investigating incidents or accidents, which in the view of the Chief Investigator evidenced (or likely evidenced) risks affecting patient safety, and for making recommendations to improve patient safety across the NHS. 'Risks affecting patient safety' included, but were not limited to risks:

    a. resulting in repeated, preventable or common occurrences of safety risks or harm to patients;

    b. indicating a systemic problem with significant impact in more than one setting; or

    c. involving new or novel forms of harm, or new or novel risks of harm.

413. The Healthcare Safety Investigation Branch was also responsible for promoting a culture of learning and improvement within the NHS, and for sharing best practice and lessons learned from its investigations.

414. The Healthcare Safety Investigation Branch was run operationally by a Chief Investigator. The Chief Investigator was appointed by the NHS Trust Development Authority but only with the approval of the Secretary of State. The role of the Chief

Investigator was to develop and publish investigation principles to govern investigations carried out by the Healthcare Safety Investigation Branch, identify incidents or accidents for investigation, oversee those investigations and ensure that the Healthcare Safety Investigation Branch was meeting its objectives. The Chief Investigator was supported by a team of investigators and other staff members.

415. Later, the National Health Service Trust Development Authority (Healthcare Safety Investigation Branch) (Additional Investigatory Functions in respect of Maternity Cases) Directions 2018 set an additional specific duty on the Healthcare Safety Investigation Branch to investigate certain qualifying maternity cases. This duty applied in relation to all cases of early neonatal deaths, term intrapartum stillbirths and cases of severe brain injury in babies, as well as all cases of maternal deaths in England. Such investigations were required to consider, amongst other things:

    a. any specific concerns raised by or on behalf of the mother and on behalf of the baby and, where appropriate, concerns raised by their family;

    b. any specific concerns raised by any person engaged by the provider who was involved in the care the mother or baby received, or by any other person, as the Healthcare Safety Investigation Branch thought appropriate; and

    c. how the findings of the investigation compared to the "Key Recommendations for Care" in Every[10] Baby Counts and in any other relevant guidance issued by NICE.

416. The Healthcare Safety Investigation Branch was required to report on the investigation within six months from when the qualifying maternity case was initially referred to it. It also had to consider whether any cases indicated deficiencies in practice that should be considered more widely. Separately, the Chief Investigator had to publish a report yearly drawing together themes and learning from the maternity investigations, with any necessary recommendations.

417. In order to deliver these maternity and neonatal specific functions, the Maternity and Newborn Safety Investigations programme was established in 2018. It operated as part of the Healthcare Safety Investigation Branch until 1 October 2023, when the Care

[10] 'Every Baby Counts' is the language used in the Directions. But, presumably, this should be a reference to Each Baby Counts, which was a national quality improvement programme led by the Royal College of Obstetricians and Gynaecologists.

Quality Commission took on hosting responsibility for Maternity and Newborn Safety Investigations, pursuant to The Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023.

418. During 2015, it was recommended[11] that the Healthcare Safety Investigation Branch should be established in primary legislation to secure its independence and safeguard the principles protecting information from its investigations from disclosure. In response, the Government published a draft Bill[12] in September 2017, which was scrutinised by Parliament in 2018 and 2019. The Bill proposed the establishment of the Health Services Safety Investigation Body, which would be named to distinguish it from the Healthcare Safety Investigation Branch that it would replace.

419. Ultimately, rather than the Bill, the vehicle for establishing the new Health Services Safety Investigation Body was the 2022 Act, and the Health Services Safety Investigation Branch was established on 1 October 2023. As described in the Department of Health and Social Care Policy Paper on the Health Services Safety Investigation Branch (March 2022), the Health Services Safety Investigation Branch was to be established on an independent statutory footing, with independence as a "crucial way of ensuring that patients, families and staff have trust in its processes and judgements".

420. In the intervening period between the NHS Trust Development Authority being abolished on 1 July 2022, with its functions transferring to NHS England, and 1 October 2023 when the Health Services Safety Investigation Branch was established, transitional arrangements were implemented to enable the Healthcare Safety Investigation Branch to continue its investigations and activities. To cover this transitional period, the Secretary of State made directions on 1 July 2022, which established the Healthcare Safety Investigation Branch as a division of NHS England.

421. As was the case in the earlier 2016 Healthcare Safety Investigation Branch Directions, the 2022 Healthcare Safety Investigation Branch Directions required NHS England to maintain and protect the Healthcare Safety Investigation Branch's independence and, to support this, further required NHS England to establish a group of independent advisors to meet with the Chief Investigator to ensure the independence of reports.

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[11] By the Public Administration Select Committee, in their report 'Investigating Clinical Incidents in the NHS', published on 24 March 2015.

[12] Health Service Safety Investigations Bill.

The 2022 Healthcare Safety Investigation Branch Directions also placed a duty on the Chief Investigator to report to NHS England on matters relating to budget, staffing and administrative efficiency, but report to the Secretary of State in relation to the performance of functions by the Healthcare Safety Investigation Branch. NHS England was responsible for paying the Healthcare Safety Investigation Branch its annual budget allocation, after providing these figures to the Secretary of State.

422. As noted above, the Health Services Safety Investigation Branch was established on 1 October 2023 and, as a result, the transitional arrangements relating to the Healthcare Safety Investigation Branch came to an end. The Health Services Safety Investigation Branch is a fully independent Arm's Length Body of the Department of Health and Social Care and is no longer hosted in any way by NHS England.

423. Part 4 of the 2022 Act is now in force and makes provision for the new body, its constitution and its procedures. I would note the following, in particular:

    a. The Health Services Safety Investigation Branch has the function of investigating "qualifying incidents," which are incidents that occur during the provision of healthcare services and have, or may have, implications for the safety of patients.

    b. The Health Services Safety Investigation Branch must determine and publish the criteria it will use to determine the incidents it will investigate, the principles that will govern investigations, the processes that will be followed in carrying out investigations, and the processes for ensuring that, so far as reasonable and practicable, patients and their families are involved in investigations.

    c. The purpose of the Health Services Safety Investigation Branch's investigations is to identify risks to the safety of patients and address those risks, by facilitating the improvement of systems and practices in the provision of healthcare services.

    d. The Health Services Safety Investigation Branch may investigate such incidents that occur during the provision of healthcare services in any setting in England, including in the NHS or in the independent sector.

(7) Independent scrutiny

(a) The Medical Examiner System

424. We are aware that Dr Alan Fletcher, the National Medical Examiner, has been asked to provide a personal witness statement to the Inquiry. The detailed content contained within his statement is not repeated here.

425. In brief, however, in June 2018, the Department of Health and Social Care published its response to the consultation on plans for reform of the death certification system in England and Wales and the approach to introduce a medical examiner system nationally and initially on a non-statutory basis from April 2019. By way of actioning this, NHS England was asked to implement this non-statutory system.

426. As a result, hospital trusts in England (and local health boards in Wales) were asked to set up medical examiner offices. This was accompanied by the appointment of a National Medical Examiner for England and Wales. In March 2019, Dr Alan Fletcher was appointed to this role. The National Medical Examiner team sits within NHS England's National Patient Safety Team.

427. The initial focus for medical examiners is on the independent scrutiny of the cause of death in respect of non-coronial deaths that occurred in their own organisations. This scope is intended to expand, with the introduction of a statutory system, as described below and in greater detail in paragraph 434 onwards.

428. The role of the national medical examiner is to provide professional and strategic leadership to regional and trust-based medical examiners. The role supports medical examiners in providing better safeguards for the public, patient safety monitoring and improvement, and informs the wider learning from deaths agenda.

429. Each NHS region has a regional medical examiner and a regional medical examiner officer to support medical examiner offices. Regional medical examiners oversee the provision of services and provide an independent line of advice and accountability for medical examiners at trusts in their region.

430. A government White Paper, "Integration and Innovation: Working together to improve health and social care for all", was published in February 2021 and confirmed that the government intended to put medical examiners on a statutory footing.

431. The purpose of the medical examiner system is to:

a. provide greater safeguards for the public by ensuring independent scrutiny of all non-coronial deaths;

b. ensure the appropriate direction of deaths to the coroner;

c. provide a better service for the bereaved and an opportunity for them to raise any concerns to a doctor not involved in the care of the deceased;

d. improve the quality of death certification; and

e. improve the quality of mortality data.

432. Specifically, in scrutinising deaths, medical examiners:

a. seek to confirm the proposed cause of death by the medical doctor and the overall accuracy of the medical certificate of cause of death;

b. discuss the proposed cause of death with bereaved people and establish if they have questions or any concerns relating to the death;

c. support appropriate referrals to senior coroners; and

d. identify cases for further review under local mortality arrangements and contribute to other clinical governance processes.

433. Each medical examiner office in England is required to provide regular submissions to the National Medical Examiner. This includes important information for quality assurance of the medical examiner office, such as the number of cases referred for clinical governance review due to concerns, including deaths in hospitals of people with learning disabilities or severe mental illness, and the number of cases notified to coroners.

434. In June 2021, NHS England and NHS Improvement sent a system wide letter explaining these developments and asking that acute trusts should put measures in place to extend medical examiner scrutiny to all non-coronial deaths across all non-acute sectors by the end of March 2022. Specialist, mental health and community trusts and GP practices were asked to work with established medical examiner offices to make plans for how deaths of their patients could be scrutinised, with each organisation being required to work with one established medical examiner office. Integrated Care Systems and Clinical Commissioning Groups were asked to facilitate partnership working across systems **[SP/0060, INQ0009257]**.

435. In June 2022, the government announced that it intended to implement the statutory medical examiner plan from April 2023, using the relevant provisions from the Coroners and Justice Act 2009 (as amended by the 2022 Act). NHS England sent another letter to NHS healthcare providers and Integrated Care Boards in July 2022, setting out what local health systems needed to do to prepare for the statutory system. Acute trusts were asked to ensure that medical examiner offices based at their trusts had adequate workforce and support in processing patient records from other healthcare providers.

436. In April 2023, the government confirmed the move was continuing towards the statutory medical examiner system, with full introduction due to take place in April 2024 (having been postponed from April 2023).

437. The relevant provisions of the Coroners and Justice Act 2009 and the 2022 Act were commenced on 1 October 2023, with draft regulations also being sent to stakeholders.

438. In 2023, the Chief Medical Examiner published Good Practice Guidance on escalating thematic issues and maximising the impact of medical examiner scrutiny. This note confirms that Medical Examiners should escalate and share information around trends, themes and systemic issues to existing clinical and quality governance processes.

439. If a medical examiner determines that the death is reportable then they will refer it to a coroner. However, the Good Practice Guidance confirms that a medical examiner should also consider whether there is a need to notify the coroner of certain deaths that form part of a wider concern identified.

(b) Office of the Chief Coroner

440. In 2019 the Chief Coroner produced guidance around death referrals and Medical Examiners. This guidance confirms that if coroners, based on reports of death, have cause for concern about any possible issues in a hospital (and in due course, in the community) they should raise this with their local medical examiner, or the regional medical examiners (or the National Medical Examiner and the Chief Coroner as appropriate) and agree any action.

441. As set out in the witness statement of the National Medical Examiner, Dr Alan Fletcher, medical examiner offices work closely and have strong working relationships with their local coroner's office. Dr Fletcher's evidence is that he has been impressed at the success of the engagement between medical examiners and coroners and the

strong working relationship between the two offices. Dr Fletcher has regular meetings with the Chief Coroner, has met with the Coroner's Society on several occasions, attends the Chief Coroner's annual conferences, and has supported the Royal College of Pathologists' joint training between coroners and medical examiners.

442. NHS England and the coronial service also work together in relation to Coronial "Prevention of Future Deaths" ("PFD") reports made under paragraph 7, Schedule 5, Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. A coroner has a duty to issue such a report where they believe that action needs to be taken to prevent future deaths. Whilst the majority of PFD reports are addressed directly to individual organisations (healthcare or otherwise), on occasions where the coroner is concerned that there is a national healthcare issue which needs to be addressed, they will address their PFD report to NHS England or to Department of Health and Social Care (or the Secretary of State for Health), who will often share it with NHS England so that NHS England can input pertinent information into the Department's response to the Chief Coroner. Reports concerning national healthcare related issues may also be sent to national organisations such as the Care Quality Commission, NICE, one of the Royal Colleges, or national charities as well as or instead of NHS England, depending on the issues covered. NHS England may also receive PFD reports in its direct commissioning role.

443. PFD reports relating to deaths in health and social care settings can help to identity what went wrong and the actions needed to prevent a similar incident reoccurring. They also may provide points of learning that are applicable beyond the organisation in which this took place which can inform wider system learning.

444. PFD reports received by NHS England (either directly or via Department of Health and Social Care seeking NHS England input into its response to the coroner) which relate to neonatal deaths sadly tend to relate to deaths on the day of birth, or within a week, mainly due to birth asphyxia / hypoxia. They are most often due to issues with the delivery, including delayed delivery and prolonged labour. Common themes in such reports include:

    a. issues with CTG monitoring;

    b. changes to national guidance, such as on issues relating to babies who are small or large for gestational age, Reduced Fetal Movement;

c. midwifery issues: competency, training and experience of midwives, safety of midwife-led birthing units, and the recruitment and retention of midwives

d. failings or inadequacies in the internal investigations carried by trusts;

e. poor communication between teams; and/or

f. a lack of continuity of care.

SECTION 2: THE COUNTESS OF CHESTER HOSPITAL – NHS ENGLAND'S AWARENESS OF EVENTS AND RELEVANT INTERACTIONS

(1) Introduction

445. In this section of the statement we have set out NHS England's understanding about when and how NHS England first became aware of any concerns about the neonatal unit at the Countess of Chester Hospital NHS Foundation Trust. This includes the knowledge of Monitor/NHS Improvement and any of the other legacy organisations that now form part of NHS England, referred to in this statement as "the Legacy Bodies". The Countess of Chester Hospital NHS Foundation Trust is referred throughout this section as "the Countess of Chester Hospital" or "the Hospital".

446. Our understanding of events in this section is based on the evidence currently available to NHS England, namely our review of the documents we have disclosed to the Inquiry and the recollections of key individuals involved at the time.

447. In summary, and based on the above, it seems that neither NHS England nor the Legacy Bodies were aware of any specific concerns about the safety of neonatal services at the Hospital until the last day of the First Relevant Period, 30 June 2016.

448. This was the day when the Countess of Chester Hospital reported two Serious Incidents relating to neonatal deaths via the Strategic Executive Information System. It was also the day that LL worked her last shift on the neonatal unit. However, NHS England was not aware of this at the time and was not informed that there were any concerns about a particular individual or the identity of this individual (LL) until much later, in March 2017.

449. To assist with this section of the statement, the timeline below sets out key events from the perspective of NHS England and the Legacy Bodies up until the police launched Operation Hummingbird.

Date	Event
January 2012	LL began working at the neonatal unit at the Countess of Chester Hospital.

Date	Event
29 June 2016	Care Quality Commission published its report of the Countess of Chester Hospital, following a routine inspection that took place in February 2016
30 June 2016	LL worked her last shift on the neonatal ward
30 June 2016	Two Serious Incidents are reported by the Hospital's Compliance Manager, both involving the "unexpected deterioration and death of a neonate".
6 July 2016	NHS England North Regional team ordered a 72 hour review of the two reported deaths
7 July 2016	The Hospital's Compliance Manager reported another Serious Incident regarding concerns around the mortality rate on the neonatal ward. The decision was jointly made by NHS England, Clinical Commissioning Group and the Hospital to downgrade the neonatal unit from level 2 to level 1. The downgrading decision triggered the inclusion of the neonatal unit on the Regional Specialised Commissioning Team's weekly 'Hotspot' report for the first time.
31 July 2016	The North Regional Quality Surveillance Group was briefed about the mortality concerns by the North Region Director of Nursing.
12 August 2016	The Assistant Regional Director of Specialised Commissioning for the North regions attended a call with the Hospital to discuss the external review the hospital had commissioned from the Royal College of Paediatrics and Child Health (RCPCH). The review was scheduled to take place in early September 2016.
November 2016	The Cheshire and Merseyside Quality Surveillance Group increased the neonatal unit surveillance from routine to enhanced.

Date	Event
21 December 2016	Following the Hospital's refusal to provide a copy of the draft RCPCH report to NHS England, the North Regional team requested assistance from the North Regional Medical Director of NHS Improvement.
3 January 2017	The North Regional Medical Director of NHS Improvement met with the Medical Director of the Hospital, who indicated that the final RCPCH report was expected in February 2017.
3 February 2017	The Regional Team was informed that the RCPCH report had been leaked to the media. A copy of the embargoed report was finally provided to NHS England by the Hospital shortly in advance of the Sunday Times reporting on the issue.
29 March 2017	The Neonatal Network informed NHS England that paediatric consultants at the Countess of Chester Hospital had raised concerns about additional cases that had not been addressed in the Royal Colleges' report. These concerns had not previously been reported to NHS England. NHS England also became aware for the first time that a concern was held by the Hospital's clinicians that there was a connection between a particular individual and the neonatal deaths. NHS England was not informed about the identity of this individual.
19 April 2017	The Hospital informs NHS England that it will be referring some of the neonatal deaths to the Child Death Overview Panel (which included a police representative).
27 April 2017	The Child Death Overview Panel met with the Hospital. The police decide that an investigation may need to take place.
18 May 2017	The police formally launch Operation Hummingbird. A Serious Incident Escalation Report was completed by the Patient Safety Lead at NHS England (North) regarding the investigation.

450. Described below in further detail is the emerging picture as it unfolded from the perspective of NHS England and the Legacy Bodies during the Overall Relevant Period. In particular, this section describes the timing and context of awareness about the following:

a. concerns about the safety of services at the neonatal unit at the Countess of Chester Hospital;

b. an increase in the mortality rate on the neonatal unit at the Trust;

c. the possibility that an individual was responsible or materially involved in the incidents; and

d. the possibility that criminal conduct might have occurred.

451. Also described below are the steps NHS England and the Legacy Bodies took as they became aware of the above matters and were increasingly concerned about how these matters were being handled by the Hospital. To assist the Inquiry, I have structured the remainder of this section of my statement as follows:

a. Important context regarding the interactions with the Countess of Chester Hospital

b. Interactions with the Countess of Chester Hospital during the First Relevant Period

c. Decision to downgrade the unit

d. Events leading up to Operation Hummingbird

e. Events following the launch of Operation Hummingbird

f. Events following the arrest of LL

452. As a reminder, the defined time periods used throughout this statement are:

a. The First Relevant Period: 4 January 2012 to 30 June 2016.

b. The Second Relevant Period: 1 July 2016 to the present day.

c. The Overall Relevant Period: The period spanning the First and Second Relevant Periods.

(2) Important context regarding the interactions with the Countess of Chester Hospital

453. Before turning to describe what NHS England and the Legacy Bodies knew and how they interacted with the Countess of Chester Hospital during the Overall Relevant Period, it is important to briefly explain the following elements of the context:

    a. Key changes in NHS structures, as relevant to the Hospital;

    b. Key changes in data reporting, as relevant to the Hospital;

    c. The regional landscape: Monitor/NHS Improvement;

    d. The regional landscape: NHS England; and

    e. The inspections conducted by the Care Quality Commission.

(a) Key changes in NHS structures, as relevant to the Hospital

454. As set out in more detail in Section 1 of this statement, during the First Relevant Period NHS England and the Legacy Bodies operated as separate organisations. Monitor and the NHS Trust Development Authority formed NHS Improvement from 1 April 2016. From 2019, NHS England and NHS Improvement aligned their operations to enable de-facto single organisation working, in advance of the formal statutory merger that took effect from 30 June 2022.

(b) Data reporting, as relevant to the Hospital

455. As part of the creation of NHS Improvement on 1 April 2016, two other teams (based at national and regional levels) were also transferred to NHS Improvement from NHS England, which are relevant in the context of the events surrounding the Countess of Chester Hospital: the National Patient Safety Team, and the National Reporting and Learning System Team.

456. The National Reporting and Learning System was monitored by NHS England at a national level only. Any issues or concerns identified through this national database and the national team's monitoring of it was shared with relevant regional team(s). Depending on the nature of the issues/concerns identified, NHS England regional teams would take the information into account when liaising with their counterparts in the Legacy Bodies and/or use it to inform commissioning/provider interaction and performance management.

457. In addition to the National Reporting and Learning System, the other key data system used by Regional NHS England teams during this period was the Strategic Executive Information System. As explained in more detail in Section 1, this was the data system used by providers and commissioners to report and monitor Serious Incidents throughout the Overall Relevant Period. Unlike the National Reporting and Learning System, NHS England's regional teams did have access to the Strategic Executive Information System.

458. The Legacy Bodies did not have direct access to the Strategic Executive Information System and instead relied on either commissioners sharing relevant information with them or on matters of relevance being directly reported to them by providers. For instance, the Legacy Bodies required NHS Foundation Trusts to inform them about relevant serious incidents (i.e. any incidents which may reasonably be regarded as raising potential concerns over compliance with their licence).

459. As discussed in more detail of Section 3 of this statement, MBRRACE-UK are commissioned by the Healthcare Quality Improvement Partnership (HQIP) to undertake the Maternal, Newborn and Infant Clinical Outcome Review Programme (MNI-CORP) on behalf of NHS England, the Welsh Government, the Scottish Government Health and Social Care Directorate, the Northern Ireland Department of Health, the States of Guernsey, the States of Jersey, and the Isle of Man Government. The aims of the MNI-CORP are to collect, analyse and report national surveillance data and conduct national confidential enquiries in order to stimulate and evaluate improvements in health care for mothers and babies. During the First relevant period, MBRRACE-UK would publish an annual Perinatal Mortality Surveillance Report on extended perinatal deaths in the UK during for each calendar year. The methods used and analysis undertaken by MBRRACE-UK during this period meant that the report for each calendar year was published 18 months after the end of the relevant calendar reporting year. This reporting timeframe was not atypical for clinical audits of this type.

(c) <u>The regional landscape: Monitor/NHS Improvement</u>

460. The primary focus in this Section 2 is on the regional operations. This was where the commissioner-provider relationship was managed and where day-to-day provider oversight was performed.

(i) The regional landscape of Monitor

461. As described in Section 1, during the First Relevant Period Monitor operated with a combination of national and regional governance structures. The relevant region in relation to the Countess of Chester Hospital was the North Region.

462. Each region was responsible for regulating healthcare providers within its jurisdiction. As a foundation trust, the Countess of Chester Hospital held a provider licence and the North Regional Monitor team were responsible for assessing and enforcing compliance with the licence conditions, including consideration of risks to financial sustainability and good governance, based on information on performance, quality of care and financial health. As explained in Section 1, Monitor had a range of enforcement powers and regulatory action it could take where actual or potential breaches of the provider licence were identified. Its focus, both nationally and regionally, was on those Foundation Trusts that were struggling or who required additional support. Well-performing providers were less closely scrutinised, as is normal in all regulatory environments.

463. The routine reporting requirements that all NHS Foundation Trusts were required to comply with, and which the Countess of Chester Hospital reported against, fell into four broad categories:

    a. annual submissions, such as strategic and operational plans;

    b. in-year submissions, such as financial and other service performance information;

    c. exception reports: the Risk Assessment Framework noted that this was "other information that may have material implications for a licence-holder's compliance … e.g., a report by a medical Royal College that identifies concerns relevant to the trust's governance of quality (and therefore to the trust's compliance with its licence)"; and

    d. other: this included the periodic reviews Monitor expected Foundation Trusts to commission and report on (specifically governance reviews).

464. As part of the North regional health system, Monitor operated as part of a collaborative regional structure that included close working with the equivalent structures in operation by the NHS Trust Development Authority, the Care Quality Commission, commissioners (both NHS England and Clinical Commissioning Groups) and other partners.

465. In general, Monitor would be informed by the Care Quality Commission that it was inspecting a Foundation Trust (however it was not given an annual schedule of inspections and information was generally shared in an informal way, either shortly prior to or at the same time as the inspection commenced). If the Care Quality Commission found concerns during its inspection, and particularly if a Foundation Trust was found to require improvement or was rated inadequate, Monitor would be informed and would support the Foundation Trust to implement the action plan it had agreed with the Care Quality Commission.

466. Monitor's Risk Assessment Framework emphasised the reliance placed on inspections and judgments made by the Care Quality Commission, noting that "Monitor does not intend to duplicate [the Care Quality Commission's] regulation" but that "issues relating to quality of care can arise from or reflect poor governance", bringing them within Monitor's remit. As noted in Section 1, Foundation Trusts were also required to report to Monitor the outcomes of a Care Quality Commission inspection or review.

(ii) The regional landscape of NHS Improvement

467. As explained in Section 1, Monitor operated as part of NHS Improvement from 1 April 2016. Although this resulted in changes to the way the organisation operated, it did not fundamentally change the regional structures in place. One practical impact of the change was that NHS Improvement teams operated across the combined NHS Foundation Trust/Trust footprint, meaning that the overall number of organisations each Regional Director was responsible for increased.

468. A key part of each NHS Improvement Regional Director's role was to work with all Trusts (NHS trusts and Foundation Trusts) to enable them to exit quality and/or financial special measures, undertake use of resources assessments and to support and empower Chairs and Chief Executive Officers to deliver performance standards, financial control and patient care improvements.

469. NHS Improvement's primary focus shortly after it was established was on financial management at a provider level, due to the concerns that existed at the time around financial performance. Whilst NHS Improvement did have several workstreams that related to quality, it relied primarily on the oversight provided by the Care Quality Commission and commissioners when it came to assessing the quality and safety of particular services. If there were concerns about a potential breach of license conditions then NHS Improvement would intervene.

470. As explained in Section 1, from 1 October 2016, NHS Improvement used information obtained from its Single Oversight Framework to offer targeted support to providers before serious concerns arise, as well as identifying and acting on more serious concerns, such as where there had been a license breach. Oversight was based on the principle of earned autonomy — with providers in segments 1 and 2 experiencing higher autonomy and those in segments 3 and 4 receiving mandated support.

471. Throughout the period May 2016 to April 2019, the Executive Regional Managing Director for the NHS Improvement North Region was supported by an executive team that included the following roles:

    a. Regional Chief Operating Officer;

    b. Operational Regional Director of Finance;

    c. Regional Medical Director;

    d. Regional Nurse Director.

472. Within the Regional team, Delivery and Improvement Directors were responsible for smaller areas within the Region. One of these areas was Cheshire and Merseyside.

473. The members of the North regional team during the Overall Relevant Period are set out in the table contained at Annex 5.

474. There were 73 NHS provider organisations that fell within the Executive Regional Management Director's remit. These organisations included acute, community, mental health and ambulance Trusts. The Countess of Chester Hospital was one of these 73 organisations (an acute trust).

(iii) The regional landscape of NHS England

475. As set out in Section 1, NHS England is organised into regional teams (there are now seven regional teams). Each regional team has sub-regional arrangements after Local Area Teams were absorbed into regional structures from 2015.

476. The relevant regional team responsible for the Countess of Chester Hospital throughout the First Relevant Period was the North Regional Team, supported by the Cheshire, Warrington and Wirral Area Team, with a Director of Commissioning Operations responsible for that local area. We have set out members of these teams in tables contained at Annex 7.

477. NHS England's Regional teams placed and managed the commissioning contracts with providers that were commissioned as part of NHS England's direct commissioning responsibilities. The North West Specialised Commissioning team funded 21 neonatal units across the region, delivering three levels of neonatal care:

    a. **Level 1** Special Care Baby Unit - Caring for neonates >32 weeks with an anticipated birth weight above 1000g.

    b. **Level 2** Local Neonatal Unit. In addition to above: caring for neonates >27 with an anticipated birth weight above 800g.

    c. **Level 3** Neonatal Intensive Care Unit. In addition to above: caring for neonates <27 with an anticipated birth weight below 800g.

478. The North Region held a contract with the Countess of Chester Hospital for the provision of specialist neonatal services. The Regional Specialised Commissioning team had primary responsibility for monitoring and managing contractual performance. As described below, the Countess of Chester Hospital was commissioned to provide a Level 2 Local Neonatal Unit, but this was downgraded to a level 1 unit on 7 July 2016.

479. These teams also performed a number of important day-to-day surveillance and monitoring roles. This included the oversight and surveillance of serious incident management within NHS-funded care. It also included assurance of Clinical Commissioning Group management of serious incidents in the care they commissioned. Clinical Commissioning Groups were required to ensure that there was appropriate escalation and information sharing when serious incidents raised actual or potential significant implications for the wider healthcare system or where an incident might cause widespread public concern. In order to perform this role, each local area team had a specific role for this function.

480. At a regional level, NHS England therefore had a dual role in relation to serious incidents:

    a. As the commissioner, it would discharge the duties set out in the Serious Incident Framework and monitor contractual performance. As discussed in Section 1, all providers were contractually obliged to comply with the Serious Incident reporting framework. If issues were detected around serious incidents that had an impact on the quality and safety of commissioned services, then NHS England regional teams could take action as the commissioner. This would be done in consultation with the relevant Clinical Commissioning Group lead commissioner for the provider. This action might include enhanced monitoring and reporting or temporary changes in commissioned services. The downgrading of the neonatal

unit at the Countess of Chester Hospital was an example of this. This is described in detail below at paragraph 514.

b. An oversight role (consistent with its patient safety responsibilities at the time) to ensure there was effective serious incident reporting and subsequent management of serious incidents by the lead commissioner (being the relevant Clinical Commissioning Group). The experience of the North Regional team at the time was that there was a wide spectrum in the approach taken by providers when reporting serious incidents. Some providers over-reported (in the sense that an incident was reported that did not meet the relevant threshold set out tin the framework), whilst many other providers under-reported.

481. However, as explained above, it was Monitor (and later NHS Improvement) who remained the responsible regulatory body in terms of any regulatory action against a Foundation Trust where quality problems were identified as a result of poor governance. Quality problems might include poor serious incident reporting and/or management.

482. Regional teams had much wider responsibilities to those described above and these teams were required to contribute to various national strategies. For example, during the 2015-2016 period, the North regional team would have spent considerable time working on the devolution agenda, the commissioning response to the NHS Five Year Forward View, the new strategy for the North and new models of care for mental health.

(d) The inspections conducted by the Care Quality Commission

483. The context around the role of the Care Quality Commission is important because, as explained in Section 1, it is the body within the regulatory system that has primary statutory responsibility for carrying out regular site visits and on-the-ground inspections of care delivery. These inspections look at, amongst other things: whether regulated providers have appropriate staffing arrangements in place, both in terms of capacity and capability; whether clinical governance systems and processes are appropriate and effective; whether patients feel well cared for; and how incidents (including but not limited to patient safety incidents) are identified, investigated and learned from.

484. As a result of the on-the-ground nature of the Care Quality Commission's inspections, other regulatory bodies such as NHS England and its Legacy Bodies placed — and continue to place — considerable reliance on its assessments. As discussed in Section1, whilst NHS England and NHS Improvement had inspection rights under the Standard Contract and Provider Licence, these were rarely exercised unless there were significant concerns about the quality and safety of the services commissioned

(for example, where there were concerns around staffing levels or the cleanliness of the facilities).

485. The standards of care that the Care Quality Commission applied to regulated providers during the First Relevant Period and the way in which it monitored provider performance in between inspections is described in Section 1 of this statement. This Section 2 describes what information the Care Quality Commission published in relation to the Countess of Chester Hospital specifically.

486. Intelligent Monitoring reports were produced by the Care Quality Commission for the Countess of Chester Hospital in:

    a. October 2013;

    b. March 2014;

    c. July 2014;

    d. December 2014;

    e. May 2015.

487. In the First Relevant Period, these reports were made publicly available and would have been considered by the Cheshire, Warrington and Wirral Area Team at the time of publication. They were not, however, shared with NHS England or the Legacy Bodies in advance of publication.

488. For most of the First Relevant Period, and informed by the results of its Intelligent Monitoring, the Care Quality Commission rated the Countess of Chester Hospital as being in priority band six. Band six was the lowest priority band for inspection.

489. The last Intelligent Monitoring reports published by the Care Quality Commission in May 2015 downgraded the Trust to level five based on the following six identified "risks":

    a. Potential under-reporting of patient safety incidents resulting in death or severe harm

    b. Composite indicator: In-hospital mortality — Cerebrovascular conditions

    c. Composite indicator: In-hospital mortality — Genito-urinary conditions

    d. Composite indicator: In-hospital mortality — Neurological conditions

e. Maternity Outlier alert: Puerperal sepsis and other puerperal infections

f. SSNAP Domain 2: overall team-centred rating score for key stroke unit

490. A rating of five meant that the Countess of Chester Hospital was still regarded as a well-performing trust overall and the risks identified above would not have raised any particular concern with NHS England or Monitor at the time given the nature of the issues identified. Further, as set out below, there were a number of under-performing trusts which required more significant improvement.

491. A further routine inspection of the Countess of Chester Hospital was carried out in February 2016, with the Care Quality Commission's report being published on 29 June 2016. As discussed further below at paragraph 510 below, this report indicated that there were some concerns around the safety of services for children and young people at the Hospital, although these concerns related to staffing levels generally rather than the specific incidents involving LL.

492. On the basis of our review of available documents and discussions with key individuals, we are not aware that NHS Improvement was informed in advance of the Care Quality Commission's 2016 planned inspection of the Countess of Chester. The general practice of the Care Quality Commission at this time was to inform Monitor/NHS Improvement prior to an inspection, but there was no arrangement whereby an annual schedule of inspections, for instance, was shared. Often Monitor/NHS Improvement would be informed shortly before the inspection was due to take place.

493. A significant change of rating or other concerns identified by the Care Quality Commission would have been shared with the relevant regional team, but this was not the case for the June 2016 report. In additional, neither the Executive Regional Managing Director nor the North Regional Medical Director recollect this report raising any particular concerns about more systemic issues at the Hospital such that further scrutiny or intervention was warranted.

(3) Interactions with the Countess of Chester Hospital during the First Relevant Period

494. This part of Section 2 sets out the interactions of NHS England and the Legacy Bodies with the Countess of Chester Hospital during the First Relevant Period. As mentioned above in the introduction to this section, there is nothing in the documents currently available to NHS England to indicate or suggest that any particular concerns were held by NHS England or the Legacy Bodies about the neonatal unit during this period.

(a) Interactions between Monitor/NHS Improvement and the Hospital

495. During the period up until 30 June 2016, Monitor had no contact with the Countess of Chester Hospital outside of its routine review of the annual submissions provided by the Hospital. This annual review was required by the licence in the First Relevant Period and it formed part of Monitor's overall application of its Risk Assessment Framework. No by-exception reporting requirements were required by Monitor or proactively made by the Countess of Chester Hospital.

496. As previously noted in Section 1 of this statement, the Countess of Chester Hospital was one of the first trusts to be authorised as a Foundation Trust, acquiring this status in 2004. Throughout almost the entirety of the First Relevant Period, the Countess of Chester Hospital was considered by Monitor and NHS Improvement to be a high-performing organisation. It was working with its partner organisations to develop the 'West Cheshire Way', an early stage integrated care system, as described in its Strategic Plan Document for 2014-19. It was not on Monitor's radar as a Foundation Trust requiring additional support or intervention and its reported performance did not suggest it was an outlier in any respect.

497. This was in contrast to the challenges that other providers were experiencing, both in the North Region and nationally during this First Relevant Period. By way of illustration, Monitor's annual reports during this period show that nationally:

    a. In 2011/12, Monitor identified ten foundation trusts in significant breach of their "terms of authorisation". Overall, 17 trusts were found in significant breach and required enhanced monitoring.

    b. In 2012/13, seven foundation trusts were found in significant breach of their terms of authorisation, and five trusts formerly in significant breach were found to have returned to compliance. By the end of March 2013, 19 trusts were in significant breach. Enforcement action was taken in respect of 18 trusts and the 19th was placed into special administration.

    c. In 2013/14, Monitor no longer assessed whether foundation trusts complied with their terms of authorisation, but rather whether they met the conditions of the NHS Provider Licence (issued by Monitor). By 31 March 2014, 27 foundation trusts were in breach of their licence. Eight trusts were placed in special measures.

d. In 2014/15, nine foundation trusts were found to be in breach of their licence, and a further nine foundation trusts were under investigation. 12 foundation trusts were placed into special measures.

e. In 2015/16, 17 foundation trusts were found to be in breach of their licence, and a further six were under investigation. 10 foundation trusts were placed into special measures.

f. In 2016/17, 44 foundation trusts were in breach of their licence, and six were under investigation. Eight foundation trusts were placed into special measures.

498. In relation to the North region specifically during the period 2015/16, there were three foundation trusts who were found to be in breach of their licence and two trusts who remained in special measures. The Countess of Chester Hospital was not one of these trusts.

(b) Interactions between NHS England and the Countess of Chester Hospital

499. As described above, the Countess of Chester Hospital was regarded as a high-performing organisation overall by Monitor and was placed in the lowest inspection band by the Care Quality Commission for most of the First Relevant Period. There were no concerns raised with NHS England by the Care Quality Commission during this period, such that it identified any particular need to conduct any contractual audits of the Trust's premises.

500. However, there were concerns with the reporting of Serious Incidents across the region generally. Following the Kirkup Investigation into the maternity services at the University Hospitals of Morecambe Bay NHS Foundation Trust, which published its report in March 2015, a Maternity themed North Region Quality Surveillance Group took place to review the findings The Quality Surveillance Group agreed that:

a. local teams would facilitate a Maternity Thematic Quality Surveillance Group across their area to understand how maternity services operated locally; and

b. a North of England Maternity Group would be established to provide specific focus and support to maternity specific quality surveillance and improvement.

501. The initial assessment of the Cheshire and Merseyside local area took place between on 23 April and 12 May 2015, with the aim of informing a draft response to the Report of the Morecambe Bay Investigation, Dr Bill Kirkup CBE (March 2015) ('the Kirkup Report') by July 2015. The objective was to review the available intelligence with the aim of establishing the current assurance level in relation to the quality and safety of maternity

services within Cheshire and Merseyside. In addition, these assessments aimed to start identifying any areas of concern or where further in-depth analysis was required.

502. At the North Regional Quality Safety Group meeting held on 5 June 2015, various concerns arising the initial review were discussed. This included low reporting of maternity-related serious incidents. The North Regional Quality Safety Group agreed the following preliminary actions would be taken:

    a. a thematic review of maternity-related serious incidents would be undertaken in the region, to be fed back into the review process;

    b. Healthwatch (Cheshire) was to undertake a review of patient experience related to maternity services and feedback to the Quality Surveillance Group;

    c. Clinical Commissioning Groups would be encouraged to undertake an active role in the Maternity Strategic Clinical Network and Programme;

    d. data collated from the Commissioning for Value website was to be fed back to Quality Surveillance Groups;

    e. Clinical Commissioning Groups would highlight the importance of providers reporting 'near miss' incidents; and

    f. trust data from questionnaires linked to the Kirkup report would be analysed and included in a wider report **[Exhibit SP/0061, INQ0014622]** .

503. A report titled "North of England Maternity Thematic Review QSG Report" was prepared in March 2016. One of the key findings of this report was that across the North region there appeared to be a disproportionately low reporting of Serious Incidents, despite the high-risk nature of these services. However, there were no immediate concerns identified regarding the quality or safety of services **[Exhibit SP/0062, INQ0014627]** . This report contained an analysis of the National Reporting and Learning System for each local area. As the reported noted, higher incident rates did not necessarily mean an organisation was less safe; it may instead mean that the organisation had a more robust culture of reporting. For Cheshire and Merseyside, the Countess of Chester Hospital had the fourth highest rate of reporting serious incidents, which was in the middle of the range **[Exhibit SP/0062, INQ0014627]**.

504. The low reporting of maternity-related serious incidents was discussed further at the Regional Quality Safety Group meeting held on 18 March 2016 and the following additional actions were agreed:

a. an analysis of provider data from maternity questionnaires was to be prepared;

b. there was to be more of a focus on community midwifery and the wider pathway, i.e. ante/postnatal, public health issues around smoking, obesity, breast feeding etc; and

c. consideration was to be given to using the NCT's framework to look at the whole maternity pathway from a service user perspective.

505. As explained above, NHS England was routinely informed, via the Strategic Executive Information System, of Serious Incidents and Never Events. Each Regional Team would monitor the Strategic Executive Information System for reports relating to providers in their region. Where an incident was reported that related to a directly commissioned service, such as specialised neonatal services, the Specialised Commissioning team would be notified. The incident reporting framework and NHS England's role in relation to this is set out in Section 1 of this statement and discussed in further detail above.

506. In the period 4 June 2015 to 22 June 2016, eight serious incidents were reported by the Countess of Chester Hospital (which was not an outlier).

507. In the period 1 April 2015 to 31 March 2016, one Never Event was reported, relating to "Retained foreign object post-procedure"; this incident has no connection to neonatal services or LL **[SP/0063, INQ0014628]**.

508. NHS England understands that in July 2015, Dr Stephen Brearey, the head consultant on the neonatal unit at the Countess of Chester Hospital, carried out a review of three unusual deaths that occurred in June 2015 in the unit. A subsequent thematic review was ordered by Dr Brearey in February 2016, which found common links in nine unusual deaths that had occurred since June 2015. NHS England did not know about these matters at the time; they were not reported as Serious Incidents via the Strategic Executive Information System, but NHS England is of the opinion that they ought to have been.

509. In May 2016, MBRRACE-UK published its report UK Perinatal Deaths for Births from January to December 2014. The adjusted mortality rate (per 1,000 births) for the Countess of Chester Hospital was 1.28, which was slightly below the average of 1.33. This resulted in the Countess of Chester Hospital being rated as having a "yellow" risk rating (all other providers within the North West region had a similar or higher ("amber" or "red") risk rating). The NHS England Specialised Commissioning North Regional Leadership Group considered this report and wrote to the providers within the region on 8 August 2016 to address the action required **[SP/0064, INQ0014641]**.

510. As mentioned above, the Care Quality Commission published its 2016 inspection report on 29 June 2016. It gave the Countess of Chester an overall rating of "good". The only overall domain rating that was not good was for "Are services at this trust responsive?" (i.e. the services meet people's needs), which it rated as "Requires improvement". NHS England does not have any record or specific recollection of receiving a copy of this report prior to publication.

511. At a sub-level, the service-specific ratings found more areas for improvement. In the case of services for children and young people, for instance, the service was rated "Requires improvement" for "Safe". This rating was explained as being specifically linked to staffing levels, staff training and ratios of sufficiently qualified staff per shift.

512. The inspection team who carried out the 2016 inspection included a senior neonatal midwife, a consultant paediatrician and neonatologist, among other specialists, and an inspection manager, nine inspectors and others. I have not quoted extensively from the 2016 inspection report, but it is of note that the Care Quality Commission found a "positive incident reporting culture" and that "staff were confident and competent in raising matters of concern, incidents were subject to investigation and feedback was used to underpin practice changes to avoid reoccurrence".

513. The 2016 report noted that the Countess of Chester Hospital had a "well-developed approach to governance and risk management", with an accessible and visible executive team. The report went on to state that "From our review of the BAF [Board Assurance Framework], risk registers, governance and committee structures it was evident that risk and performance issues were escalated to relevant committees and onwards to the board through clear reporting structures and processes". The Care Quality Commission was satisfied that appropriate processes were in place to meet the requirements of the Fit and Proper Persons regulation.

(4)Decision to downgrade the unit

514. This part of Section 2 explains how NHS England and the Legacy Bodies first became aware of concerns about neonatal deaths at the Countess of Chester Hospital after it reported two Serious Incidents on 30 June 2016, and a further Serious Incident on 7 July 2016 through which the Hospital reported concerns about an overall increase in its mortality data. These Serious Incident reports were made via the Strategic Executive Information System.

515. First, the Countess of Chester Hospital reported two related Serious Incidents, 2016/ I&S and 2016/ I&S, on I&S June 2016. Both incidents were described as involving the

"Unexpected deterioration and death of a neonate". Incident 2016/ I&S took place on I&S June 2016, was categorised by the Hospital as a Serious Incident on 29 June 2016 and reported formally as such on 30 June 2016. Incident 2016/ I&S took place a day later on I&S June 2016 but was categorised and reported on the same dates as for incident 2016/ I&S The NHS England North Regional Team noted both incidents promptly on the same day that they were reported (i.e. on 30 June 2016) **[SP/0065, INQ0014629] [SP/0066, INQ0014630] [SP/0067, INQ0014631]**.

516. NHS West Cheshire Clinical Commissioning Group is stated on the incident reports as being the lead commissioner in terms of overseeing the investigation, and this is further reflected in the text entry added to the incident report, "*SI to be managed by NHS West Cheshire CCG*". As described above, a Clinical Commissioning Group was normally named as the lead commissioner as it was not always possible to identify which service(s) might be affected by a particular incident and doing this ensured that no serious incidents would be overlooked when reported.

517. NHS England's Quality and Experience Lead for Cheshire and Merseyside emailed the NHS West Cheshire Clinical Commissioning Group on 30 June 2016 to clarify whether the Countess of Chester Hospital had intended to report two separate incidents and to request that the Hospital be asked to add further detail about these incidents. **[SP/0068, INQ0014632]**

518. NHS England now knows that LL worked her last shift on the neonatal unit on 30 June 2016.

519. On 5 July 2016, the NHS England North Regional Lead for Safeguarding, (who was also the Deputy Director Quality & Safeguarding for Cheshire & Merseyside), asked colleagues within the Regional Team to "*check STEIs and collate any incidents that have been reported in the last 12 months*" by the Countess of Chester Hospital in preparation for an internal meeting scheduled for the following morning (i.e. 6 July) "*to discuss a number of serious incidents that have occurred at the Countess of Chester on the Neonatal unit and a potential review we will need to do this week*". **[SP/0069, INQ0014634]** This was common practice whenever there were significant concerns about an incident or where multiple incidents had been reported.

520. This meeting took place as planned on 6 July, with a number of follow-up actions stemming from this meeting. In particular, the Quality and Experience Lead made contact with the Countess of Chester Hospital to request the 72-hour review of the two reported deaths referred to above at paragraph 515. This was provided by reply on the same day by

email from the Head of Risk and Patient Safety at the Countess of Chester Hospital. The email stated as follows:

> *"I can confirm that the initial review was held yesterday and that this has triggered a number of areas for deeper dive, including peer review of the x-rays undertaken on triplet 2 and a further review by obstetricians regarding delivery and possibility that the liver sub-capsular haematoma [identified on PM] occurred in the perinatal period. No clear cause of death was identified for triplet 1 from the initial review." (square brackets in original).* **[SP/0070, INQ0014635] [SP/0071, INQ0014633]**

521. On 7 July 2016, a joint decision was made to downgrade the unit. This was a coordinated action between the Hospital, Cheshire West Clinical Commissioning, NHS England Specialised Commissioners and the Neonatal Network. The Hospital publicly announced the decision that same day.

522. The reason for downgrading the unit was the increase in the mortality rate on the neonatal ward. This was reported by the Countess of Chester Hospital as a separate Serious Incident on 7 July 2016. The report was made via the Strategic Executive Information System (incident number 2016 **I&S**) **[SP/0072, INQ0014636]**. It describes temporary changes were being made to the admission arrangements for the neonatal unit for the following reasons:

> *"Information from The Countess of Chester Hospital NHS Foundation Trust re neonatal services. We are temporarily changing the admission arrangements for our neonatal unit to focus predominantly on lower risk babies, who are born after 32 weeks. This decision is being taken with the support of the Cheshire and Merseyside Neonatal Care Network. Due to an increase in neonatal mortality rates for 2015 and 2016 compared to previous years. In light of this, we have asked for an external review of our neonatal service from the Royal College of Paediatrics and Child Health and The Royal College of Nursing, which is expected to be completed by the end of August. While this takes place, we will be closing three intensive care cots at the Chester neonatal unit. A total of 13 cots will continue to provide specialist and high dependency care for newly born and premature babies born at 32 weeks and above.*
>
> *By way of summarising our position:*
>
> *We have identified a change in what our internal data and information is telling us.*
>
> *We are acting responsibly in requesting an external review to help us understand this change.*
>
> *At the same time we are responding to the advice of our neonatal clinicians in how most importantly we support the needs of expectant or new mums and their babies."*

523. The "immediate action taken" was described in the report as follows:

"Escalation to Executive Team, NHS England, CCG & CQC. Internal analysis of data and clinical case reviews whilst awaiting an independent [sic] review with amendment to the admissions criterion implemented, supported by the Neonatal network. Press release is drafted for release today, with identified patient families [sic] to be contacted."

524. The downgrading decision also triggered the inclusion of the Hospital's neonatal unit on the Regional Specialised Commissioning Team's weekly 'Hotspot' Report for the first time **[SP/0073, INQ0014637]**. Neonatal services at the Countess of Chester Hospital featured regularly on the Hotspot Report throughout the First Relevant Period and Second Relevant Period thereafter. The hotspot reports were used by the North regional team to ensure that particular concerns or issues within the region remained on the agenda for the regional senior leadership team to discuss. The downgrading was also noted in the Quality Report produced for the Regional Leadership Team meeting held on 19 July 2016 **[SP/0074, INQ0014640].**

525. The North Regional Quality Surveillance Group was briefed about the mortality concerns at the Countess of Chester Hospital by the North region's Director of Nursing on 31 July 2016 **[SP/0075, INQ0014760]**. This briefing described the daily monitoring now in place, "with weekly executive reviews of any transfers out/capacity issues/incidents of Maternity and NNU [neonatal unit]."

(5) Events leading up to Operation Hummingbird

526. At the time that the unit was downgraded, NHS England intended this to be a short term measure to address immediate safety concerns and enable the completion of the external review that the Countess of Chester Hospital had commissioned from the Royal College of Paediatrics and Child Health and the Royal College of Nursing ("the Royal Colleges"), following which the downgrade could be reviewed. NHS England supported the decision to involve the Royal Colleges, which was made on or around the date of the Serious Incident reported by the Hospital on 7 July 2016 set out above. The expected timeframe for completion of the review was initially August 2016.

527. On 12 August 2016, the Assistant Regional Director of Specialised Commissioning for the North region, briefed Regional colleagues and the NHS West Cheshire Clinical Commissioning Group about the Countess of Chester Hospital update call he had attended that same day **[SP/0076, INQ0014679]**. The update was further shared with the Chief Nurse for the North region later that day. In this update, it was noted that:

a. the Royal Colleges' review had been delayed (due to the Colleges' needing to reschedule) but was due to take place on 1–2 September;

b. the weekly data reports had not shown any further issues or trends; and

c. a face-to-face meeting between NHS England and the Hospital would be arranged once the Royal Colleges' review was available.

528. Neonatal mortality at the Countess of Chester Hospital was discussed at the North West Operational Delivery Network meeting held on 12 September 2016 **[SP/0077, INQ0014639]**. The following actions were discussed:

a. The Hospital had asked the Royal Colleges' to perform an external review of neonatal deaths at the Trust (scheduled for 2/3rd September 2016). The North West Operational Delivery Network would be represented at the review and network data had been offered to the review panel.

b. The North West Operational Delivery Network management team had reviewed mortality rates at the Hospital and benchmarked them against other Operational Delivery Network local neonatal units. This data showed a greater than expected mortality rate at the Hospital, which was approximately 1.5 to 2-fold higher than comparable units. Furthermore, the mortality rate appeared to be rising.

c. Review of nationally collected data from MBRRACE-UK in 2013 and 2014 did not identify the Hospital as an outlier for neonatal mortality. Data from 2015 would not be available routinely until next year. ODN/locality mortality rates were reviewed annually against published national data from MBRRACE-UK and National Data Analysis Unit.

d. The Chester & Merseyside Clinical Effectiveness Group had a process in place for ensuring neonatal deaths in the locality are reviewed locally by each provider and that lessons learnt are shared with other providers. This included local trust assessment of the care provided using a grading system. However, this process was currently a 'work in progress' and needed to be strengthened and made more robust. There was also a national initiative to try and standardise the methodology used for reviewing all perinatal deaths.

e. The North West Operational Delivery Network data group was currently developing a monthly activity and outcomes' dashboard. Neonatal mortality at

Operational Delivery Network and locality levels was one of the data items to be collected and monitored monthly. Mortality data was also presented in the quarterly reports received by the three locality Steering Groups.

529. On 14 September 2016, NHS England requested an update from the Hospital as to the timeframe for completion of the review and a copy of the report, when available. No further timeframe was provided by the Hospital.

530. The question of what level of surveillance NHS England should apply in relation to the Countess of Chester Hospital was discussed again at various points during October 2016. This included discussions at the following meetings:

    a. The Cheshire and Merseyside Quality and Surveillance Group met on 4 October 2016, following which it was agreed that there would be a discussion between NHS England and NHS West Cheshire Clinical Commissioning Group colleagues about whether enhanced surveillance could be applied to a unit of a hospital, while the rest of the hospital remained on routine surveillance **[SP/0078, INQ0014642]**.

    b. The North Regional Quality and Surveillance Group met on 16 September 2016, and the Deputy Director Quality and Safeguarding for Cheshire and Merseyside provided the Group with an update on the Countess of Chester Hospital. It was noted the Royal Colleges' review had been carried out from 1–2 September 2016 had gone "well" and that it had therefore been agreed that the level of surveillance should be "downgraded to routine" (although NHS England's understanding is that the hospital remained on routine surveillance at the time). **[SP/0079, INQ0014687]**.

531. In November 2016, the Quality Surveillance Group increased the surveillance in place for the neonatal unit (rather than the hospital as a whole) from routine to enhanced. This decision was made in light of the following concerns:

    a. the Countess of Chester Hospital's failure to deliver commissioned services;

    b. ongoing concerns around high rates of mortality in the neonatal unit at the Hospital;

    c. concerns around governance, reporting and management of high mortality at the Hospital;

d. the potential for significant impact on the wider network; and

e. the fact Commissioners were awaiting the outcome of the external reviews, resulting in lack of assurance.

532. The neonatal unit remained on enhanced surveillance throughout the period discussed in this section of the statement.

533. The Countess of Chester Hospital sent a letter to NHS England on 16 December 2016 informing it that it had received the draft Royal Colleges' report in November 2016 for factual accuracy review. The Hospital stated that it was not "comfortable" sharing the draft report with NHS England. It indicated that it was in the process of developing a communications plan and action plan, which would be shared some time in the new year. The Hospital was unwilling to commit to any specific timeframes for doing so.

534. On 16 December 2016, the NHS England Assistant Regional Director of Commissioning for the North Region sent an email to the Hospital requesting a copy of the Royal Colleges' report and the outcome of the forensic deep dive. The Hospital responded to say that they were awaiting the final Royal Colleges' report and completion of the forensic deep dive. The Hospital refused to share the initial report, saying that they did not consider it appropriate to do so until the deep dive had been completed. The Hospital reiterated that it did not consider there were any immediate risks or concerns that required further action.

535. On 21 December 2016, concerned by the response from the Hospital, NHS England's North Regional Team requested assistance from the North Regional Medical Director of NHS Improvement. NHS England felt at this stage that a request from NHS Improvement to the Hospital would have greater weight, coming from the Hospital's regulator rather than the commissioner.

536. In light of this request, the North Regional Medical Director of NHS Improvement met with the Medical Director of the Hospital on 3 January 2017. The North Regional Medical Director made a note of his meeting, which is exhibited to this statement **[SP/0080, INQ0014771]**. The note of the meeting records the following key points made by the Hospital Medical Director:

a. Paediatricians at the Hospital were concerned about an increase in neonatal deaths.

b. The preliminary investigation suggested that the Trust was not an outlier.

c. The Royal Colleges' review had been very thorough; the report would be provided in due course but no immediate concerns. The Hospital had seen a draft of the report, which included additional actions to be taken, including a further review by a pathologist at Alder Hey Children's NHS Foundation Trust, before the full report could be shared.

d. The Hospital anticipated the full report would be available in February. They would be developing a communications plan and a process through which it would be shared [with stakeholders].

537. Shortly after this, NHS England understands that, on 10 January 2017, the Hospital Board met and were briefed by the Hospital's Chief Executive Officer. Neither NHS England or NHS Improvement would normally be informed at the time of any private board meetings and were not informed of any such meetings held during the First Relevant Period.

538. On 11 January 2017, the North Regional Medical Director of NHS Improvement briefed NHS England's North Regional team on his meeting with the Countess of Chester Hospital's Medical Director. The response the Medical Director provided was essentially the same as that which had been given previously to members of the NHS England Regional Team. NHS England remained concerned by the Hospital's lack of openness about the review and timescales for when further information would be shared.

539. On 24 January 2017, the Regional Team became aware that the Countess of Chester Hospital had developed a communications plan for managing publication of the Royal Colleges' report. Again, a copy of the embargoed report was requested from the Hospital but was not provided.

540. On 3 February 2017, NHS England's North Regional Team was advised that the Royal Colleges' report had been leaked to the media. A copy of the embargoed report was finally provided to NHS England by the Hopsital shortly in advance of the Sunday Times reporting on the issue. The report was discussed at the Regional Leadership Group meeting on 13 February 2017 **[SP/0081, INQ0014645]**.

541. The Regional Specialised Commissioning Team (North) Hotspots report for 9 February 2017 noted that the Countess of Chester Hospital had published the Royal Colleges' review report and that the review concluded that there was "no single cause or factor identified as a means of explaining the increase in their mortality rates but gives a series of recommendations that the Trust is already implementing" **[SP/0082, INQ0014644]**.

542. On 23 February 2017, the members of the North Region Specialised Commissioning team met with the Medical Director of the Countess of Chester Hospital. The meeting had been arranged by the North Regional Specialised Commissioning team, in light of their ongoing concerns about the Hospital's openness and willingness to share information **[SP/0083, INQ0014656]**. A timeline of events compiled by NHS England's North regional team on 4 April 2017 suggests that the Hospital's Medical Director also stated during this conversion that he had commissioned a Queen's Counsel to review the Royal Colleges report as the clinicians at the hospital did not accept its "content" **[SP/0084, INQ0014692]**.

543. Following this meeting, the Director of Commissioning Operations for NHS England's North regional team facilitated a meeting that was held on 28 February 2017 to start to populate a Quality Risk Profile for the Countess of Chester Hospital. Officials from NHS England, NHS Improvement and NHS Cheshire and Merseyside Clinical Commissioning Group attended this meeting. The completed Quality Risk Profile was subsequently circulated on 8 March 2017 **[SP/0085, INQ0014647]**, and was further updated during the First Relevant Period on 28 March **[SP/0086, INQ0014648]**, 5 April **[SP/0087, INQ0014652]**, and 11 May 2017 **[SP/0088, INQ0014677].**

544. The Quality Risk Profile was a tool developed by NHS England for Quality Surveillance Groups to monitor quality and safety issues at a local level. The tool combined qualitative (local intelligence from stakeholders) and quantitative (data from NHS England's quality dashboards) intelligence and provided a framework to ensure a consistent approach to assessing risk. It enabled routine surveillance based on specific criteria, and identification of significant quality risks and where action needs to be escalated. The tool could be used, for example, when persistent or increasing quality concerns have been identified in a provider but routine or enhanced quality assurance processes and targeted quality assurance visits have not given assurance they will be resolved.

545. The February Quality Risk Profile noted a number of issues relating to poor governance, culture, safety and effectiveness at the Hospital. The Profile formally noted the concerns that the Specialised Commissioning team had about partnership working with the Hospital, in relation to both vascular services and neonatal services. In relation to neonatal services specifically, the Profile stated that there were "issues regarding communication and engagement with Provider involving Neonatal Service". Concerns around safe staffing levels for certain services are also noted, including in relation to services commissioned by the Specialised Commissioning team. The issues identified in the Quality Risk Profile reflected the pattern that the Specialised Commissioning team had noted and highlighted since the unit had been downgraded.

546. The Countess of Chester Hospital featured on the 3 March 2017 Hotspot Report, with a degree of assurance around risk reflected in both the narrative and "no change" risk rating applied **[SP/0089, INQ0014646]**.

547. On 10 March 2017, the North regional specialised commissioning team and the Neonatal Network met with the Countess of Chester Hospital again to review progress in implementing the recommendations made by the Royal Colleges. The Hospital reported that consultants did not accept that the independent review conducted by the Royal Colleges had captured everything. The Hospital's medical director was accordingly seeking further information from the coroner and amending the report **[SP/0090, INQ0014653]**.

548. On 29 March 2017, the Neonatal Network informed NHS England that paediatric consultants at the Countess of Chester Hospital had raised concerns about additional cases that had not been addressed in the Royal Colleges' report. These concerns had not previously been reported to NHS England. The Countess of Chester Hospital declined to share the clinicians' concerns with NHS England at that time, on the basis that it was still in discussions with the clinical staff concerned and it had commissioned an external report from a Queen's Counsel.

549. On the same day, NHS England's Regional Clinical Director for the North spoke by telephone to the Hospital's Medical Director. It is clear from the Regional Clinical Director's note of this conversation that he no longer felt that a full picture was being given by original explanation about this being accounted for by rotas and skill level. This was the first time that NHS England understood that there was a concern held by the Hospital's clinicians that there was a connection between a particular individual and neonatal deaths. However, all that the Hospital's Medical Director was willing to divulge at that point was that the Trust was about to make "a significant announcement" after they had spoken to an "appropriate body" the following Monday. Whilst it was clear something very serious was going on, no further details were forthcoming **[SP/0091, INQ0014651]**.

550. These fresh concerns were reflected in the increased risk rating applied in the 31 March 2017 Hotspot Report **[SP/0092, INQ0014649]**.

551. On the 5 April 2017, NHS England's Regional Clinical Director for the North emailed the Medical Director of the Hospital to follow-up on the meeting that took place on 23 February 2017, during which he had agreed that he would provide a copy of the Queen's Counsel external report by the end of March. This had not happened, and the email reminded the Medical Director of that action and requested "a copy of the report at your earliest convenience". The Regional Clinical Director emphasised that the issues at the Countess of Chester Hospital had been discussed "within the senior members in

NHS England Specialised Commissioning, NHS England North Region and Director Commissioning Operations Teams". He also asked that the Hospital Medical Director communicate by email so that NHS England had a clear written record of the matters being discussed, due to the seriousness of the issues and his increasing concerns about transparency. The email requested the following information:

a. a copy of the brief given to the independent Queen's Counsel;

b. a written record (if there was one) of the concerns expressed by the two paediatricians, so that NHS England could understand the "precise nature of their concerns";

c. whether there was a proposed timeline of events: "For example, do you know when the legal advisor is due to meet with the clinicians and when the outcome of that meeting is to be reviewed" **[SP/0093, INQ0014658].**

552. Shortly afterwards, the Regional Clinical Director forwarded a copy of this email to colleagues within the Regional Team (both Specialised Commissioning and to the Director of Commissioning Operations) **[SP/0094, INQ0014657]**.

553. Also, on that same day (5 April), key messages from the North Regional Leadership Group meeting that had taken place earlier that week were circulated. The following key message was included in relation to the Countess of Chester Hospital:

> "*There are still concerns in relation to the Neo Natal Service following the review into the high numbers of patient deaths. Members of the RLG [regional leadership group] are working with the Trust and members of the North Regional Team to understand these more fully.*" **[SP/0095, INQ0014654] [SP/0096, INQ0014655]**

554. On 6 April 2017, the Director of Nursing at the Countess of Chester Hospital sent the Director of Nursing, Specialised Commissioning North Region at NHS England, a copy of the Hospital's draft action plan **[SP/0097, INQ0014650]**.

555. On 13 April 2017, the Head of Quality for Specialised Commissioning for the North West region met with the Director of Nursing for a 1:1, during which issues relating to the Countess of Chester Hospital were discussed. The Director of Nursing provided comments on the draft action plan and subsequently shared this with the North Regional Team **[SP/0098, INQ0014659]**.

556. NHS England's North Regional Clinical Director contacted the Trust's Medical Director by email on 19 April 2017, requesting an update "as to the decision after your Board

meeting", explaining that he needed to "report back to colleagues today". **[SP/0099, INQ0014660]**

557. The Trust's Medical Director replied on the same day, confirming the following:

> *"Following our Board meeting — having completed the College review and the further case review — we have consulted further with the external, independent case reviewer and since we have 4 cases in which, in the reviewer's opinion, the death is unexplained we are following the process that would be the case in the event of an unexplained death out of hospital and are consulting with the CDOP [Child Death Overview Panel]. I have a phone call scheduled with the Chair of the CDOP tomorrow and will feed back further after this."* **[SP/0099, INQ0014660]**

558. A Child Death Overview Panel is a multiagency group of professionals set up to review the deaths of all children normally resident in their area (and, if appropriate, deaths in their area of non-resident children) in order to learn lessons and share any findings for the prevention of future deaths. The panel usually comprises health and social care professionals and the police and is arranged by the senior professionals who have primary responsibility for the child. The function of these panels is discussed further at paragraph 838 below. NHS England is unaware whether this was the first time that the Countess of Chester Hospital engaged with the Child Death Overview Panel in respect of the incidents involving LL.

559. Immediately following receipt of the email dated 19 April 2017 mentioned above, the Regional Clinical Director shared with colleagues his concerns that the Countess of Chester Hospital was delaying involving the police. He proposed that NHS England "allow this call [between the Hospital Medical Director and the Chair of the CDOP] to occur and then if they don't call the police after speaking to CDOP then perhaps consider we insist" **[SP/0100, INQ0014661] [SP/0099, INQ0014660] [SP/0101, INQ0014662]**.

560. The Regional Clinical Director replied to the Trust's Medical Director, **[SP/0102, INQ0014666]** again on 19 April, asking whether the clinicians who had raised concerns were still concerned following receipt of the Queen's Counsel report and when a copy of the report would be provided to the Specialised Commissioning team. The Regional Clinical Director also queried what the Trust's Medical Director had said in terms of deaths "out of hospital".

561. The Hospital's Medical Director replied just over 15 minutes later, as follows:

"We are going through this process because there isn't yet a complete and definitive answer in all cases. You are correct this reflects the "out of hospital procedure" that is the process that CDOP run. As you will be aware the College review did indicate that the CDOP needed to review its processes to see whether they could have detected the cluster earlier. Re the process, I shall appraise you after my conversation tomorrow. I don't think that there was ever an agreement that the individual case report would be shared — this contains identifiable data — this would need a conversation." **[SP/0103, INQ0014663]**

562. The Specialised Commissioning team were unanimous in their view that this response was inadequate and evasive **[SP/0104, INQ0014664]**. Following a discussion at the regional level, the Chief Nurse for NHS England North offered to "pick up with the Trust directly" **[SP/0105, INQ0014665]**.

563. The North Regional team remained concerned by the response and discussed concerns about the time it would take for the Child Death Overview Panel to complete its process **[SP/0102, INQ0014666] [SP/0106, INQ0014667] [SP/0107, INQ0014668] [SP/0108, INQ0014669].** However, the view of the Chief Nurse (which was accepted by the Regional Team) was that it would not have been appropriate for NHS England to speak directly with the police without first discussing with the Hospital and NHS Improvement. This was in the context of the fact that the police were already involved in the process as part of the multiagency Child Death Overview Panel, and this was not normally a lengthy process **[SP/0109, INQ0014670] [SP/0110, INQ0014671] [SP/0111, INQ0014672] [SP/0112, INQ0014673]**.

564. On 27 April 2017, the Medical Director for the North region for NHS Improvement and the Regional Chief Nurse met with the Hospital's Medical Director and Legal Director. The Medical Director for the North region for NHS Improvement took a note of this meeting which is exhibited to this statement. **[SP/0080, INQ0014771] [INQ0003193, disclosed by Facere Melius]**

565. The Regional Chief Nurse briefed the Regional Clinical Director following her meeting with the Countess of Chester Hospital and he in turn provided a high-level briefing to colleagues in the NHS England National and North Regional Specialised Commissioning teams as follows:

"In summary the CDOP team met with the representatives from CoCH. There was a police officer on the panel.

They are aware of the issues that we were concerned about and the police are going to discuss it with the Chief Constable and scope the work that needs to be done. They will decide on that next week. Even if they conclude they need to investigate the CDOP panel will still review the cases causing concern.

There are some other processes that have been agreed about information sharing and points of contact.

[The Chief Nurse and NHS Improvement Medical Director] were satisfied with what was agreed.

[The Chief Nurse] feels that as commissioners we need to step back and allow the police and CDOP to proceed." **[SP/0113, INQ0014674]**

566. On 4 May 2017, the Regional Chief Nurse wrote to the Hospital's Medical Director to enquire whether he had received any update from the police. The response of the Medical Director was to suggest that a further update be provided when they were due to meet next on 15 May 2017. **[SP/0114, INQ0014675]** That meeting subsequently postponed by the Hospital's Medical Director.

567. On 5 May 2017, the Hospital's Medical Director provided the following further update:

"Further to previous correspondence Tony, Stephen and I met with the ACC, Det Supt and DCS Wenham (who is on the CDOP). In short:

There will be an investigation but it will be described as an invited police investigation to investigate unexplained deaths, not a criminal process.

They are drawing up TORs to share with us and agree next week.

We are forwarding details of the 13 babies and parents and the nurse.

They will be advising the Coroner(s) and then jointly with us discussing with all the parents before it gets out by other routes i.e. the Coroner adjourning a forthcoming inquest.

They will then liaise re the investigation and analysis- they already have an SIO, analyst and Liaison Officer identified.

I&S

They have you as the point of contact for NHSE.

Think that's the major points- I will keep you updated." **[SP/0115, INQ0014676]**

568. Shortly after this email exchange, the Regional Chief Nurse agreed to be the NHS England, NHS Improvement and Clinical Commissioning Group Single Point of Contact in relation to the police investigation.

569. Subsequently, on 12 May 2017, the Countess of Chester Hospital Medical Director informed the Regional Chief Nurse that the police were "*minded <u>not</u> to hold an investigation*" (emphasis in original). He noted, however, that the paediatricians had sent a document to the police, "*which was a very prejudiced view, effectively pointing the finger at one nurse*". He also explained that the police wanted to speak with the Hospital's Paediatric Lead (who had sent the email) and that an indication would be provided on 15 May whether they would or would not be proceeding. He went on to say:

> "*My own feeling is that unless there is something that the Paediatricians haven't disclosed previously that evidences criminal activity there will not be an investigation.*" **[SP/0116, INQ0014678]**

570. On 16 May 2017, the Cheshire Assistant Chief Constable sent NHS England and NHS Improvement a copy of a letter sent the Chief Executive of Countess of Chester Hospital regarding the investigation into the neo-natal deaths **[SP/0117, INQ0014681]**. That same day, a teleconference was arranged between representatives from the Countess of Chester Hospital, NHS England and NHS Improvement.

571. During this period, the Regional Chief Nurse briefed the Chief Nursing Officer for England via email on the situation and their investigation **[SP/0118, INQ0014680]**.

572. On or around 17 May 2017, NHS Improvement informed the Department of Health and Social Care that the police were about to launch a forensic investigation into the deaths at the Trust's neonatal unit **[SP/0119, INQ0014682]**.

(6) Events following the launch of Operation Hummingbird

573. On 18 May 2017, the police formally launched Operation Hummingbird. A Serious Incident Escalation Report was completed by the Patient Safety Lead at NHS England (North), setting out the background and updating on the police investigation **[SP/0120, INQ0014696]**. The Regional Chief Nurse remained the Single Point of Contact on behalf of NHS England, NHS Improvement and the West Cheshire Clinical Commissioning Group.

574. On 4 June 2017, the Regional Chief Nurse arranged a conference call between NHS England, NHS Improvement, West Cheshire Clinical Commissioning Group and the

Hospital to ensure that the appropriate governance processes and support were in place for the Hospital **[SP/0120, INQ0014696]**.

575. In light of Operation Hummingbird, NHS England's North Regional team decided that a Quality Surveillance Group risk summit would not aid progress at this point. A decision was also made to postpone the peer review to avoid any interference with the police investigation **[SP/0121, INQ0014684]**.

576. In June 2017, MBRRACE-UK published its report which found neonatal and stillbirth mortality at the Countess of Chester Hospital between January and December 2015 was 10% higher than expected. A subsequent analysis done by NHS England in December 2019 in connection with a Desk Top Review of maternity and Obstetric services for the North West region showed that the data collected by MBRRACE-UK over the period 2015-2017 for the Countess of Chester Hospital was as follows **[SP/0122, INQ0014720]**:

	2015			2016			2017		
Trust	**Stillbirth Adjusted Rate per 1000 births**	**Neonatal Adjusted Rate per 1000 births**	**Perinatal Adjusted Rate per 1000 births**	**Stillbirth Adjusted Rate per 1000 births**	**Neonatal Adjusted Rate per 1000 births**	**Perinatal Adjusted Rate per 1000 births**	**Stillbirth Adjusted Rate per 1000 births**	**Neonatal Adjusted Rate per 1000 births**	**Perinatal Adjusted Rate per 1000 births**
Countess of Chester	3.51	1.91	5.42	3.5	1.49	5	3	0.81	3.80

577. On 10 July 2017, the Hospital's Nursing manager updated the Regional Chief Nurse on the police investigation via email. She set out the investigation was continuing and would take some time, with regular update meetings being held between the Hospital and the Lead Police Investigator **[SP/0123, INQ0014699]**.

578. That same day, the Quality Manager for the Quality Surveillance Team in Specialised Commissioning wrote to a senior paediatrician at the Hospital informing him of the date of the forthcoming peer review. On 14 July 2017, the Hospital's Medical Director responded requesting that the peer review be postponed as it "*would not only be of very limited benefit but would also place additional stress on the staff on the unit at a time when we are trying to protect them*". This position was endorsed on the same day by the Regional Chief Nurse and the Medical Director for NHS Improvement for the North region **[SP/0124, INQ0014683]**. The Neonatal Critical Care peer review was postponed until 27 February 2018, during which no immediate risks or serious concerns were found. **[[INQ0003235], disclosed by Facere Melius]**

579. NHS West Cheshire CCG meet with the Countess of Chester Hospital NHS Foundation Trust on 5 October 2017 to review the Hospital's action plan. The Cheshire & Merseyside Quality Surveillance Group meeting minutes dated 1 December 2017 recorded that the

Quality Risk Profile for the Hospital was subsequently "closed" and the Hospital had been stepped down to routine surveillance (after being put on enhanced surveillance in August 2017) **[SP/0125, INQ0014685]**. There was no further update when the matter was discussed again at the next Cheshire & Merseyside Quality Surveillance Group meeting on 2 February 2018 **[SP/0126, INQ0014689]**.

580. On 12 January 2018, the Head of Quality in Specialised Commissioning requested an update from the Hospital, who shared the hospital's plan for the safe reinstatement of the neonatal unit with the North West Neonatal Operational Delivery Network. A decision was made not to upgrade the unit following a discussion with the Regional Chief Nurse and the Director of Nursing. This decision was made following police advice that the investigation could continue until April 2018. This was set out in an email from the Chief Nurse on 23 January 2018 **[SP/0127, INQ0014688]**.

581. On 11 May 2018, a meeting of the Hospital with the Head of Quality for Specialised Commissioning and the North West Neonatal Operational Delivery Network was convened to review the Hospital's plan. The aim of the meeting was to ascertain that the Hospital had in place plans to safely recommence the service once the police investigation was over. NHS England informed the Hospital that without the outcome of the police investigation and assurance that the service was safe, it would not be ungraded back to level 2. This was communicated by the Head of Quality for Specialised Commissioning in writing on 22 May 2018. The Regional Chief Nurse was made aware of this meeting and agreed with the decision **[SP/0128, INQ0014713]**.

582. The Regional Chief Nurse chaired an NHS England Incident Coordination meeting on 4 June 2018, with NHS England, NHS Improvement, West Cheshire CCG, Countess of Chester Hospital and a representative from Cheshire & Wirral Partnership NHS Foundation Trust acting as incident coordinator **[SP/0129, INQ0014697] [SP/0130, INQ0014693]**. It was agreed in this meeting that the Memorandum of Understanding (2007) system would be used as the system wide coordination approach **[SP/0131, INQ0014686]**. Lead personnel from each organisation were identified to sit on the Incident Coordination Panel. The police would also present at the meeting, which was due to meet the following week at the Countess of Chester Hospital.

(7) Events following the arrest of LL

583. Following the arrest of LL on 3 July 2018, the Regional Chief Nurse for NHS England North wrote to colleagues from NHS England and Improvement to inform them that Specialised Commissioning North had assessed "the neonatal capacity in the region with our network to ensure that, should there be any operational issues following the police action, babies

needing any level of neonatal care can be safely accommodated" **[SP/0132, INQ0014691]**.

584. On 4 July 2018, the Regional Chief Nurse was informed that Liverpool Women's Hospital would also be a part of the police investigation **[SP/0133, INQ0014694]** **[SP/0134, INQ0014695]**.

585. A further incident coordination meeting took place at the Countess of Chester Hospital on 10 July 2018. There were updates from all attendees, including an update from the police. It was agreed that the Regional Chief Nurse would continue to be the single point of contact for the group, with support from the Medical Director for NHS Improvement, North region and the Regional Medical Director for NHS England, North region. It was also agreed that the group would meet again in three months time. **[SP/0135, INQ0014698]**

586. The Regional Chief Nurse sent an update via email on 15 July 2018. This email set out the actions of the Incident Coordination Group and provided reassurance that service continuity plans were in place, and family and staff support had been established **[SP/0136, NQ0014700]**.

587. At the Cheshire & Merseyside Quality Surveillance Group on 30 August 2018 it was noted that the neonatal unit should remain on enhanced surveillance.

588. On 12 September 2018, the Head of Quality, Specialised Commissioning (North) at NHS England received an update from the Countess of Chester Hospital. This concerned the action plan over a report provided by a neonatologist (Dr Jane Hawdon) into the deaths of the 13 babies, the monitoring and maintaining of staff competencies, and the road map agreed with the North West Neonatal Operational Delivery Network in December 2017. The Hospital did not wish to share Dr Hawdon's report but offered to discuss it with NHS England. The Hospital also noted that staff competencies were being upheld and monitored and that there had been no change to the road map **[SP/0137, INQ0014765]**.

589. A further Incident Panel Coordination meeting took place on 22 October 2018 to discuss updates from the police and the Hospital, safeguarding, and support for staff families and individuals, amongst other things **[SP/0138, INQ0014703]** **[SP/0139, INQ0014702]**. The police advised that the investigation was still ongoing and Liverpool Women's Hospital had shared information regarding three cases. The police considered that more information would likely be able to be shared in early January 2019. The Hospital set out that staff support was ongoing, and no other serious incidents or deaths had occurred since LL had left the unit. The Regional Chief Nurse requested that the next meeting take place in January 2019.

590. The next Incident Panel Coordination meeting took place on 28 January 2019. The police advised that the investigation remained ongoing and that no further cases had been added. The Trust updated that they had contacted LL with the agreement of the police to ensure that appropriate support was in place. It was also noted that a Care Quality Commission "Regulation 12 investigation" would need to take place following the police investigation and be completed within three years of the allegation. It was agreed that the next meeting would take place in April 2019 **[SP/0140, INQ0014706]**.

591. On 4 April 2019, the Hospital's neonatal lead sent the Regional Chief Nurse a proposed roadmap for increasing the unit's acuity and capacity **[SP/0141, INQ0014707] [SP/0142, INQ0014708] [SP/0143, INQ0014709] [SP/0144, INQ0014710] [SP/0145, INQ0014711]**. On 5 April 2019, a meeting was arranged with the Regional NHS England and NHS Improvement teams, along with the North West Neonatal Operational Delivery Network, to discuss the designation of the neonatal unit. It was agreed that any changes to the current level of the unit would need to be agreed by the Hospital, Commissioners and the police. The Regional Chief Nurse noted that the Hospital had undertaken work to ensure the unit was safely run **[SP/0146, INQ0014712] [SP/0147, INQ0014714]**.

592. On 10 June 2019, LL was arrested for a second time on suspicion of eight counts of murder and nine counts of attempted murder. On 13 June 2019, she was bailed pending further enquiries. NHS England subsequently made a decision on 24 June 2019 to keep the neonatal unit at level 1. **[SP/0148, INQ0014716] [SP/0149, INQ0014717]**

593. On 1 July 2019, NHS England received a copy of the audit of the Royal College of Paediatrics and Child Health action plan conducted by the MIAA (an NHS Shared Service body established in 1990). The audit indicated that the action plan provided "significant assurance". **[SP/0150, INQ0014718]**

594. Over the next 16 months the Regional Chief Nurse remained in contact with the police regarding the progress of their investigation. Discussions also continued between NHS England and NHS Improvement regional teams and the Hospital concerning whether the neonatal unit met the standards to be re-instated to deliver level 2 neonatal services.

595. In early 2020, an intelligence review of maternity services in the North West was carried out by NHS England to highlight any significant or emerging risks and to recommend any actions for improvement. The Countess of Chester Hospital was found to have met all ten safety actions relating to the Maternity Safety Strategy established by the Department of Health and Social Care **[SP/0151, INQ0014723]**.

596. LL was arrested and charged with eight counts of murder and ten counts of attempted murder in November 2020.

SECTION 3: PREVIOUS INQUIRIES, CURRENT POLICY AND EFFECTIVENESS

597. In this Section 3 of the statement, we cover the following:

a. NHS England's overall assessment as to whether recommendations to address culture and governance issues made by previous inquiries into the NHS have been implemented into wider NHS practice, and specifically in ways/places that will impact maternity and neonatal services, and the effectiveness of such implementation;

b. How NHS England understands key concepts, including: culture and governance, and NHS England's role in relation to each;

c. NHS England's current policies and recent reviews NHS England is either leading on or involved in in relation to the above themes and with a particular focus on neonatal services;

d. NHS England's views on effectiveness of the current culture, governance, management structures and processes, regulation and other external scrutiny in keeping babies in hospital safe and ensuring the quality of their care;

e. Our reflections on the events involving LL and areas of possible further change to consider. This includes, but is not limited to, NHS England's views on how accountability of senior managers could be further strengthened.

598. We have divided Section 3 into three parts, as follows:

a. Part A, where we describe how previous inquiries, investigations and reviews have informed key policies, procedure and practice.

b. Part B, where we describe NHS England's current policies and procedures in further detail where this has not been covered in Section 1 of this statement.

c. Part C, which sets out NHS England's views on effectiveness, our reflections on the events involving LL and areas for possible further change to consider.

599. Overall, what is clear is that current policies and procedures have been appropriately informed and updated by recommendations and learnings made in previous inquiries, investigations and reviews. We have touched already in this statement on key previous inquiries, investigations and reviews and how they informed particular responses by NHS England (whether national and/or regional).

600. There is a detailed and structure programme of work currently underway in relation to maternity and neonatal services. Although this is led by NHS England, other Arms Length Bodies, such as the Care Quality Commission and the Royal Colleges, including the Royal College of Midwives and the Royal College of Obstetricians and Gynaecologists, are important partners in this work. We have described this current work below at 695.

601. Fundamentally, however, NHS England's view is that neonatal services are safe and effective and that the key issues that the events relating to LL raise are common to the NHS generally, rather than neonatal services specifically. We have expanded on this below.

PART A: Previous inquiries, investigations and reviews

602. This Part A is divided as follows:

(1) Introduction

(2) Thematic review of previous recommendations

(3) Neonatal focused reviews

(1) Introduction

603. The statutory and regulatory landscape described in Section 1 is important context when understanding the shared responsibilities all those working within the NHS have to ensure safe patient care. Without wishing to repeat that content here, we would like to emphasise the following points:

a. All provider organisations are independent, responsible corporate entities;

b. NHS Trusts and NHS Foundation Trusts are additionally statutory bodies in their own right;

c. All providers of NHS services are subject to statutory, regulatory and contractual duties, including those relating to patient safety and governance;

d. NHS Trusts and NHS Foundation Trusts are governed by a Board, which includes executive and non-executive directors. (Foundation Trusts additionally have a Council of Governors). Provider Boards are ultimately accountable for the performance of the organisation, which includes assuring itself as to effectiveness and regulatory compliance;

e. NHS England operates as one of several Arms Length Bodies that have a shared responsibility to oversee patient safety; and

f. The responsibility for implementation of recommendations made by inquiries, investigations and reviews will often be led by the Department of Health and Social Care, with input from NHS England and other partner organisations.

604. It is clear that one of the key influences for changes to NHS structures, policies and processes has been (and remains) learnings from previous inquiries, investigations and reviews. This applies to those areas that are not the sole remit of the NHS, such as safeguarding, where important changes were made by the government of the day and the responsible departments following the findings of the Victoria Climbie Inquiry (2003).

605. We have touched already on some specific ways that this has resulted in action, for example, the updating of the Serious Incident Framework in 2015 and the thematic reviews carried out in relation to maternity care at a regional level following the Kirkup report.

606. Looking at previous inquiries, investigations and reviews, we have identified the following key recurrent themes:

a. Patient safety;

b. Raising concerns and complaints;

c. Organisational structure and governance;

d. Leadership and regulation of managers; and

e. External scrutiny and assurance.

607. To inform our response to the Inquiry, we have conducted a targeted thematic review of previous inquiries, investigations and reviews. This is described below at paragraph 611.

608. Sadly, there is a particular category of previous inquiry, investigation and review that relates to cases where patients or service users have been deliberately harmed, abused or killed by individuals caring for them. It seems to us that the common feature in all these cases is particular patient vulnerability. While all patients are vulnerable to some extent, previous instances of patient safety failings have highlighted the particular vulnerability of certain patients. For example, elderly patients (Gosport and Shipman), individuals with learning disabilities (Winterbourne View, Connor Sparrowhawk), individuals receiving mental health care (the review into the Greater Manchester Mental Health Foundation Trust), children and babies (Clothier, Bristol, LL).

609. Neonatal babies fall into this category of especially vulnerable patients. However, as with the other categories of particularly vulnerable patients, the failings that enabled LL to murder or attempt to murder the babies that she did are not on the whole unique to a neonatal setting. Rather, the failings are those that have been consistently identified in previous inquiries, investigations and reviews into patient safety incidents:

    a. Concerns raised (by individuals operating within the health and care setting in question and/or families) but not taken seriously and/or not acted on;

    b. The portrayal of those who raise concerns as trouble-makers or similar;

    c. Retaliatory referrals to professional regulatory bodies or punitive employment processes;

    d. Missed opportunities to prevent harm;

    e. Inadequate incident reporting and investigation;

    f. Inadequate death certification and/or review;

    g. Insufficient external scrutiny.

610. There are two neonatal-specific risks we have identified in light of how we understand LL murdered or attempted to murder her victims and these relate to her use of air and milk. As was recognised in the Report of the Gosport Independent Panel[13] in the context of elderly patients, neonatal babies are particularly susceptible to the adverse effects of drugs and other substances. Although insulin as a method of killing or harming patients has been used in non-neonatal settings, the particular vulnerability of neonatal babies to insulin (and air and milk) is recognised.

(2) Thematic review of previous recommendations

(a) Methodology

611. In the course of drafting this statement, we have carried out a thematic review of a wide range of previous inquiries, investigations and reviews that we consider are most directly relevant to the Inquiry's Terms of Reference and the issues you have asked us to respond to in this context.

[13] Specific paragraph references: 2.24, 2.25.

612. In terms of methodology for this thematic review, we defined the following types of inquiry, investigation and review as being 'in scope' if they related to one of the themes listed below at paragraph 613:

    a. Statutory inquiries;

    b. Independent investigations and reviews;

    c. Policy reviews.

613. The themes that we worked to in this thematic review are as follows:

    a. Neonatal services;

    b. Patient safety (including the use of insulin and specific risks arising in a neonatal context);

    c. Raising concerns and complaints;

    d. Trust structure and governance;

    e. NHS leadership and regulation of managers; and

    f. External scrutiny and assurance.

614. The earliest inquiry we have identified as being in scope is the Clothier Inquiry. While it is important to recognise the passage of time and the changes that have taken place during the period since the Clothier Inquiry report was published (February 1994), we consider that it remains relevant in light of the similarities with the LL case. We discuss the Clothier Inquiry further at paragraph 674.

615. A number of these previous inquiries, investigations and reviews took place prior to the establishment of NHS England in 2013. As such, our ability to comment on the implementation in respect of those is limited.

616. However, some of the Legacy Bodies were in existence prior to this and would have been involved. Where possible we have drawn on that context to inform our response on the extent of implementation and effectiveness.

617. In addition, many of these earlier inquiries, investigations and reviews remain central to improvements and reform within the NHS today (for example the Fundamental Review of Death Certification and Investigation in England, Wales and Northern Ireland ("the Luce Review", 2003) and the third report of the Shipman Inquiry (also 2003, but which

acknowledges the Luce Review), which both made recommendations around changes to death certification and the implementation of a medical examiner system). However, the extent of structural change that has taken place in the Overall Relevant Period is important context when considering some of the older inquiries, investigations and reviews.

618. Figures 1 & 2 below presents in timeline for some of the inquiries, investigations and reviews we have identified as being particularly relevant, alongside key legislative, policy and organisational developments.

Figure 1: Timeline of First Relevant Period.

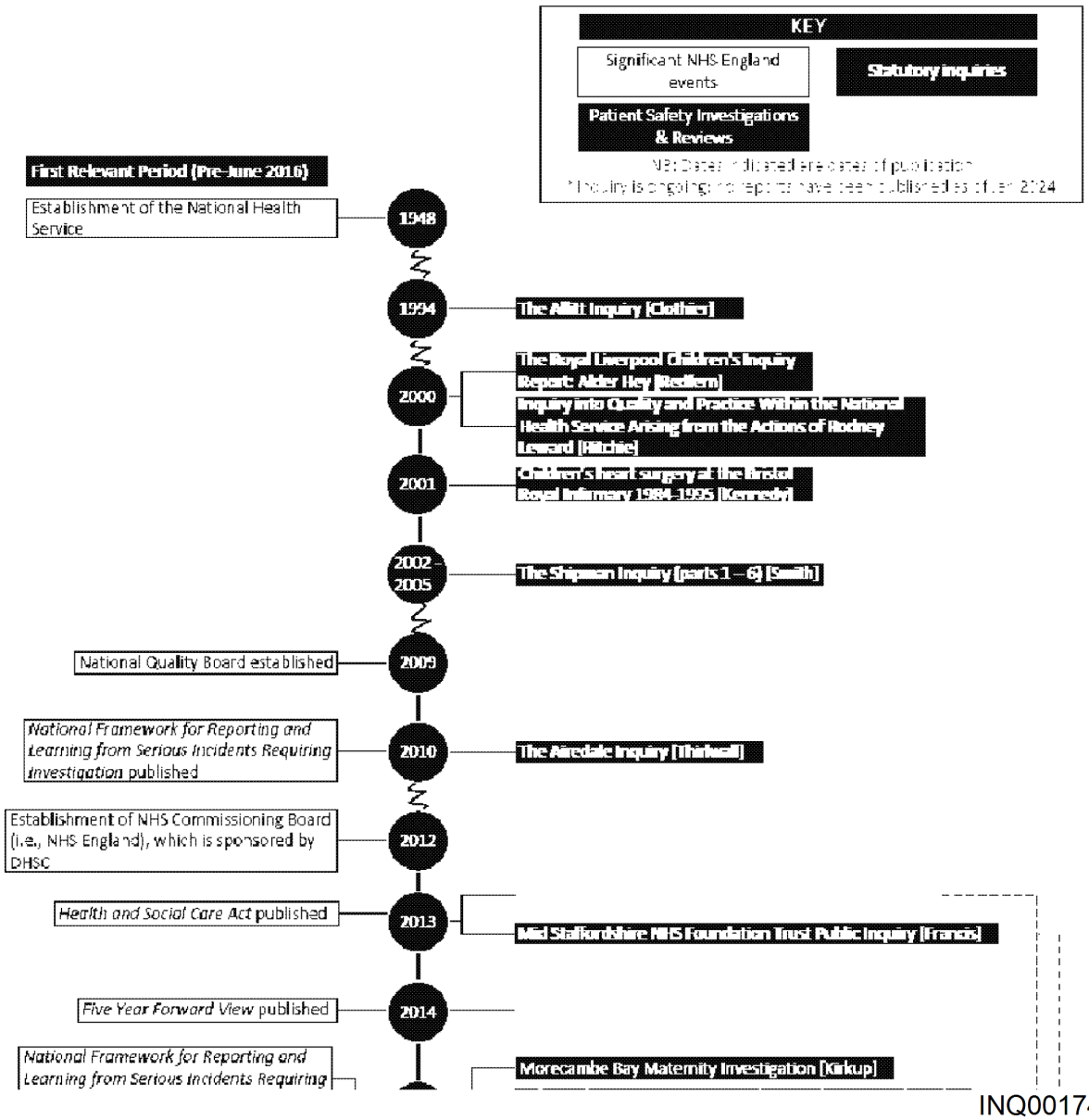
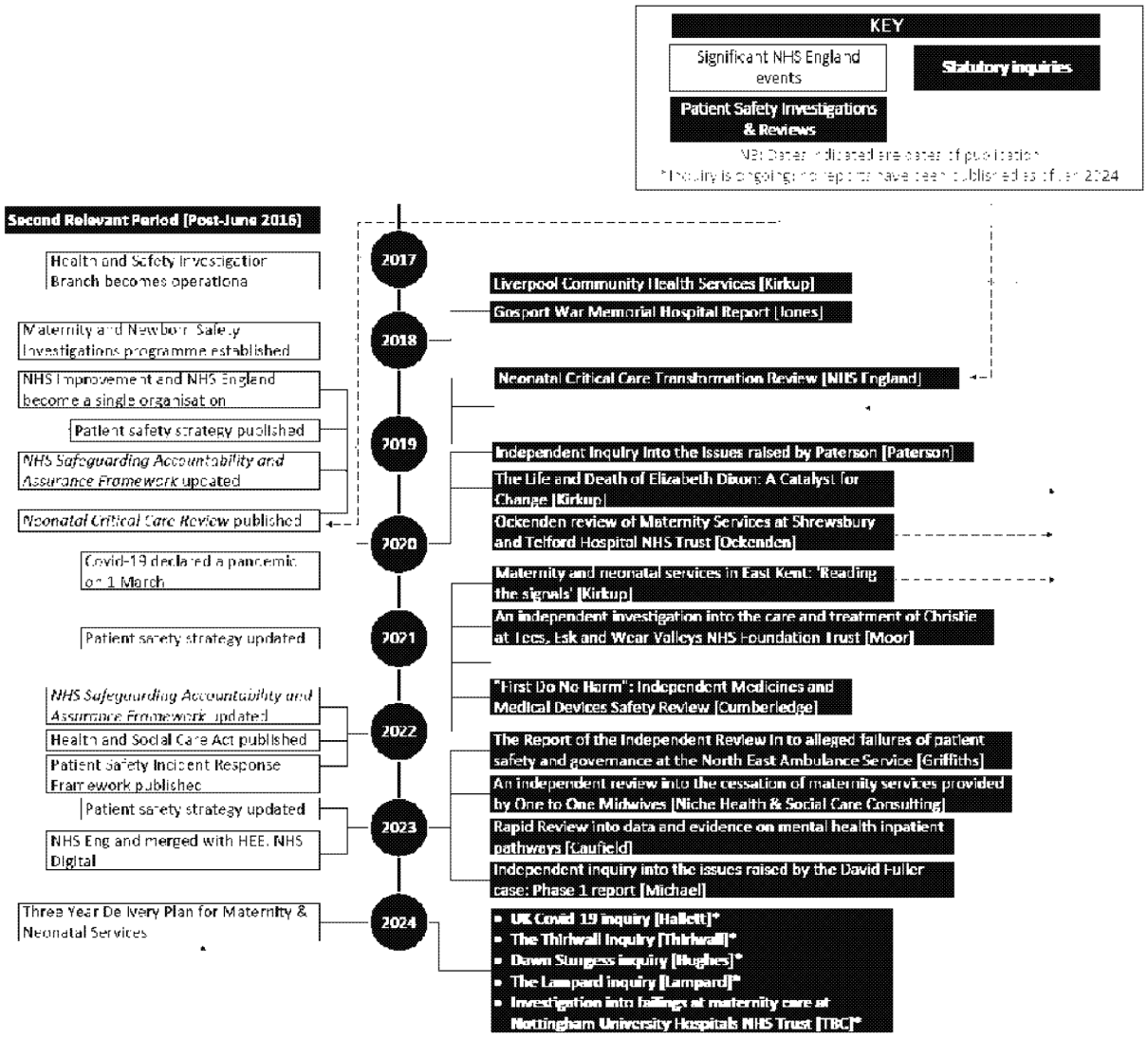


Figure 2: Timeline of Second Relevant Period.



619. Many of the reviews provide wide ranging recommendations that have relevance across every theme. For example, the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (February 2013) ("the Francis Inquiry") contained a number of fundamental recommendations in respect of patient safety, freedom to speak up, culture and governance that apply to the NHS as a whole, no matter what specific service is under consideration. However, as requested in the NHSE/1 Rule 9 Request, we have focussed on assessing the extent to which recommendations relating to these previous inquiries, investigations and reviews have been implemented in ways and/or places that will impact maternity and neonatal services.

620. Neonatal-specific current work and the way in which previous maternity and neonatal inquiries, investigations and reviews have informed the development of NHS England's current Three Year Delivery Plan for Maternity and Neonatal Services **[SP/0152, INQ0012643]** ("Three Year Delivery Plan") is described below at paragraph 695.

(b) Governance and culture

621. Underpinning all the themes we have identified is the question of culture and the role that this plays in enabling (or, conversely, hindering) high quality and safe care. Related to this is the role leaders play and the way in which they are supported and developed but also how their fitness and effectiveness is assessed and assured.

622. Governance structures and processes should complement and support a culture of openness and learning. The significance of these 'fundamental standards of behaviour' was recognised in the Friancis Inquiry report, which recommended as follows:

> *"Enshrined in the NHS Constitution should be the commitment to fundamental standards which need to be applied by all those who work and serve in the healthcare system. Behaviour at all levels needs to be in accordance with at least these fundamental standards".*

623. Within this overarching recommendation, a number of specific recommendations were set out, including:

    a. Amendments to the NHS Constitution, including to refer to all relevant professional and managerial codes by which NHS staff are bound, including the Code of Conduct for NHS Managers (Recommendation 9).

    b. Reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to

be not only encouraged but insisted upon. Staff are entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting (Recommendation 12).

c. A governance system that enabled compliance with fundamental standards, as well as providing assurance around its effectiveness (Recommendations 14 and 15).

624. The NHS Constitution **[SP/0153, INQ0014793]**, which (as described in Section 1) is the responsibility of the Department of Health and Social Care, reflects the recommended additions referred to above and includes a specific section on the responsibilities that staff have to the public, patients and colleagues. These responsibilities, which cover both legal duties staff are subject to, as well as aims they should work to, include the following:

a. To accept professional accountability and maintain standards of professional practice as set by the appropriate regulatory body;

b. Raise any genuine concern about a risk, malpractice or wrongdoing; and

c. Be open with patients and families if anything goes wrong; welcome and listen to feedback and address concerns promptly.

625. In addition, the NHS Constitution and the associated Handbook summarises the legal rights that staff have. This includes the right to "raise any concern with their employer, whether it is about safety, malpractice or other risk, in the public interest".

626. In addition to the fundamental standards contained within the NHS Constitution, many staff working within the NHS will be subject to professional regulation and required, as a result, to operate in accordance with the standards of their profession. In the case of nurses specifically, they are required to obtain and maintain registration with the Nursing and Midwifery Council. Throughout the Overall Relevant Period, the Nursing and Midwifery Council has set out in the form of The Code the professional standards of practice and behaviour that apply to nurses (and midwives and nursing associates).

(a) Governance

627. For the purposes of this statement, we have approached questions of governance as encompassing:

a. the systems, processes and controls that are in place to provide a sound framework for clear and accountable decision-making by senior managers across an organisation;

b. the responsibilities, behaviour and approach of senior managers in decision-making;

c. the systems through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This involves monitoring systems and processes to provide assurance of patient safety and quality of care across the organisation, and how this information informs ongoing action. These systems are often referred to as clinical governance.

628. This means that governance encompasses the following:

a. processes;

b. structures;

c. behaviours and underlying culture, which shapes the behaviour of everyone in a system or organisation, the quality of care it provides and its overall performance.

629. As emphasised in Section 1 of this statement, each NHS Trust and NHS Foundation Trust is responsible as a statutory body for ensuring compliance with all applicable statutory and regulatory requirements for the delivery of safe, effective, efficient, high-quality services, both now and longer term. NHS Providers are also responsible for meeting the financial and performance requirements set out in NHS priorities and operational planning guidance **[SP/0154, INQ0014751]** and complying with their Provider Licence **[SP/0016, INQ0009267]** (more detail on the Provider Licence is at paragraph 197 and Care Quality Commission fundamental standards. It is ultimately the role of the Board of each individual NHS Trust and NHS Foundation Trust to assure itself as to the organisation's compliance with these various requirements and as to the organisation's effectiveness.

630. Governance is the means by which those NHS Trust and NHS Foundation Trusts direct and control their organisations so that decision-making is effective, risk is

managed and care is delivered safely and effectively in a caring and compassionate environment.

631. Regulatory bodies like NHS England are integral in providing guidance, oversight and support to NHS Trust and NHS Foundation Trust Boards but are necessarily removed from day-to-day operation and there is a level of presumed autonomy and effectiveness, on which the NHS Oversight Framework is built.

(b) Culture

632. Organisational culture as a concept is widely acknowledged as hard to define. NHS England does not have a specific definition of culture, but we draw on the following definition:

> *"Culture is a set of shared, taken-for-granted implicit assumptions that members of an organisation hold and that determines how they perceive, think about and react to things (Schein 1992). In other words, it is 'the way we do things around here'. Every interaction in an organisation both reveals and shapes its culture – for instance, how staff talk to or about patients, and how they talk to each other. Culture reflects what an organisation values: quality, safety, productivity, survival, power, secrecy, justice, humanity and so on. If there are strong values of compassion and safety, new staff learn the importance of caring and safe practice. If they observe senior staff behaving aggressively or brusquely, they assimilate that. In short, if we want to improve care, we must focus on nurturing appropriate cultures."* **[SP/0155, INQ0014620]**

633. People are key to organisations, and individuals will each interpret culture according to their own beliefs and practices. In larger organisations therefore, it is not unusual to have an umbrella culture, with underlying subcultures emerging based on work role, profession or other allegiances for example **[SP/0156, INQ0014624]**. Culture is also constantly evolving and will change over time, including in response to events or as people leave and join teams and organisations.

634. Within the NHS, we interpret culture to mean the values, beliefs and shared ways of thinking held, and how these influence decisions, actions and behaviour. This includes how things are arranged and accomplished, including the processes followed and policies in place, as well as how they are talked about, actioned and modelled. Examples include approaches to quality improvement and patient safety, the management of risk, and the accepted ways of responding to staff concerns and

patient feedback or complaints. Patient experiences of care, and measures of how valued staff feel, can therefore be taken as proxy indicators of culture.

635. Safety culture is part of this and should protect against punitive approaches leading to longer-term reluctance to report serious incidents or near misses. A positive safety culture is one where the environment is collaboratively crafted, created, and nurtured so that everybody (individual staff, teams, patients, service users, families, and carers) can flourish to ensure evidence-based, personalised safe care by:

    a. Continuous learning and improvement of safety risks;

    b. Supportive, psychologically safe teamwork; and

    c. Enabling and empowering speaking up by all.

636. As set out in Section 1 of this statement, the NHS is comprised of multiple statutory and other organisations that operate at local, regional and national level. NHS care is delivered by around 1.3 million FTE staff across many different settings and thousands of organisations. As so much of culture emanates from people and their leaders, each organisation operating within the NHS will have its own culture, and sometimes different delivery sites, specialties or teams within a hospital will have their own subcultures. While the vast majority of these staff work hard to embody the values and behavioural expectations of the NHS, as set out in the NHS Constitution, it is unfortunately the case that occasionally there will be individuals who do not adhere to those values and mechanisms to hold them accountable. There may also be NHS leaders who do not adequately address poor behaviours effectively. While the structures and processes can, and should, work to prevent and detect malpractice, a determined 'bad actor' may still be able to evade these mechanisms. This is why leadership, supported and enabled by the other central aspects we cover in this statement, is so important to fostering an open and positive culture in teams and organisations.

(i) NHS England's responsibilities in relation to Culture

637. The continual challenge for the NHS in this context is to ensure common values, good governance and behaviours and a positive, system-wide culture whilst allowing local teams and systems to plan and deliver patient care that meets the needs of local populations. Each organisation and team must have an understanding of its own

culture, influenced by a shared understanding of the culture that the NHS aspires towards, rooted in a strong emphasis on quality of care and patient safety.

638. As emphasised at various points in this statement, in NHS Trusts and NHS Foundation Trusts it is the responsibility of the Trust Board to set and oversee the values and culture of their organisation and ensure that the values and commitments set out in documents such as the NHS Constitution and NHS People Promise are embedded within their organisation.

639. A range of Arm's Length Bodies support the Department of Health and Social Care in aspects of good governance and culture as set out in Section 1 of this statement. NHS values are set at the highest level by the Department of Health and Social Care through the NHS Constitution and the Government's Mandate to NHS England **[SP/0004, INQ0009279]**. Professional behaviours and values are further mandated by the professional regulatory bodies, such as the Nursing and Midwifery Council. NHS England has also sought to influence and inform culture, through national initiatives, including the NHS People Promise **[SP/0157, INQ0014794]**. These are described further below at paragraph 701.

640. The NHS Constitution has been referred to already above at paragraph 624 and in Sections 1 and 2B of this statement.

641. In terms of NHS England's current Mandate, NHS England is required to seek to achieve the outcomes contained in the Education Outcomes Framework in meeting its workforce, education and training responsibilities. The Framework is annexed to the Mandate and includes the following outcome related to value and behaviours

> *"NHS values and behaviours*
>
> *Healthcare staff have the necessary compassion, values and behaviours (including supporting colleagues) to provide person centred care and enhance the quality of the patient experience through education, training and regular continuing personal and professional development, that instils respect for patients".*

642. It is clear from all of these foundational publications that there is a consistent set of values, behaviours and aims that are needed to support a compassionate, inclusive and open 'NHS culture'. Such a culture should, through collective leadership, foster effective, patient centred working practices, working environments that support

colleagues to deliver high quality care and inclusive NHS organisations that are attractive places to work and develop careers.

643. Leaders at all levels and across all organisations operating within the NHS must model and embed these values in high pressured and resource constrained environments. NHS England seeks to support and enable this nationally through training and development initiatives, as well as through its regional offices in the form of more localised support for providers. An enhanced offering for learning and development has been a focus for NHS England throughout the Overall Relevant Period (as described in Section 1 of this statement) and the continuing focus on this can be seen through the publication of the Directory of Board level learning and development opportunities which sits as part of the NHS England Fit and Proper Person Test Framework for board members **[SP/0158, INQ0014781]**. The NHS Culture and Leadership Programme also reflects the importance NHS England places on providing tools to enable individual Trusts to understand and improve their culture **[SP/0159, INQ0014795]**. Further information on leadership development and support is set out at paragraphs 969 to 980.

(ii) NHS England and system-wide culture

644. We recognise that, along with government and other Arm's Length Bodies, NHS England has an important role in influencing culture and setting the overarching values through the following:

    a. its actions and processes when supporting and assuring systems and providers;

    b. the tone of the policy and governance documents it produces;

    c. in modelling "what good looks like";

    d. in overseeing the implementation of guidance by local systems (our oversight role is covered in Sections 1 and 3A of this statement) and

    e. in facilitating the sharing of best practice.

645. In a patient safety context, the NHS Patient Safety Strategy plays a central role in setting clear expectations around patient safety behaviours and actions and NHS England has sought to share best practice, including through illustrative case studies to help drive improvements **[SP/0160, INQ0014747]**.

646. Many of the key NHS England documents influencing culture across the NHS have already been referred to, but these include the NHS Long Term Plan, the NHS People Plan **[SP/0161, INQ0014726]** and the NHS People Promise **[SP/0157, INQ0014794]** which include a range of core expectations and actions required by all those working as part of the NHS. The NHS People Plan, which was published in July 2020[14], included an update on NHS England's response to Tom Kark KC's review of the Fit and Proper Persons Test ('The Kark Review'), as well as work by NHS England to develop a set of board competency frameworks for board positions in NHS provider and commissioning organisations, and work to build confidence around building confidence to speak up. The current position in relation to these important aspects is described further below.

647. These are backed up by the NHS Long Term Workforce Plan and emphasised in the annual Planning Guidance. Supporting these aims there are a wide range of policy guides, practical how to guidance, support packs, online training, expert support including site visits, networks, and patient and public engagement that seek to reiterate and amplify these values and expectations for the organisations from whom we commission or oversee.

648. NHS England also plays a role, in times of public concern, in assuring the public that NHS services are safe and that, where needed, action is being taken. Following the conviction of LL, on 18 August 2023, NHS England publicly wrote to all commissioners and providers of NHS services **[SP/0162, INQ0014761]**. The letter highlighted the significant work that has taken place in the period since 2015 to make the NHS a safer place including the roll-out of medical examiners and the new Patient Safety Incident Response Framework. It also emphasised the critical importance that NHS England places on freedom to speak up arrangements and asked NHS leaders to ensure that there is proper implementation and oversight of freedom to speak up. All of the matters raised in the letter of 18 August are dealt with in more detail at various points in this statement.

(iii) Measuring culture

649. NHS England measures culture in a range of ways to inform itself on the overall culture within the NHS but also to ensure that other organisations working within the

[14] At the time, NHS England was operating as NHS England and NHS Improvement. For ease in this Section of the statement we have referred to NHS England throughout.

NHS, including NHS Trusts and NHS Foundation Trusts, have regular culture metrics that they can use to inform their own improvement work and to benchmark themselves against others, so as to facilitate learning and the sharing of best practice. This also facilitates the NHS People Plan commitments around ensuring staff have a voice and the NHS Long Term Workforce Plan.

650. Two of the most important tools NHS England uses to support this dual aim are the NHS staff survey and People Pulse. Together, these provide a consistent and standardised framework to understand, measure and improve employee experience. NHS England monitors and interprets survey results to understand the national picture and identify any trends that could inform and shape our strategic approach, but we are clear that it is primarily the responsibility of NHS organisations and their boards to review their own results and determine appropriate action plans. NHS England has published guidance to support this **[SP/0163, INQ0014749]**.

651. It is important to emphasise that the NHS Staff Survey and People Pulse results are not intended to be used as a ranking of best to worst performing or as a punitive mechanism. The focus instead is on learning and improvement. Consistent with this, NHS England can now recognise those organisations who have been able to improve their scores.

652. However, provider results would form part of the overall information considered as part of the regional provider oversight relationship and, if a provider was placed into segment 3 or 4, this might involve a focussed review of staff engagement and other information, as part of agreeing the appropriate support and improvement plan for the provider. (Note that Integrated Care Boards are also required to participate in the NHS Staff Survey and People Pulse and are also segmented by NHS England, in accordance with the NHS Oversight Framework).

653. The NHS Staff Survey is conducted annually and provides a comprehensive view both nationally and on an organisational basis of the responses to the survey questions. All survey results, including those on an organisational basis (down to directorate level) are publicly available.

654. The most recent results are the 2023 results, which were published in March 2024. Updated questions were included in the 2022 survey around patient safety, with respondents asked to comment on errors, near misses and incidents and on the reporting of errors, near misses and incidents.

655. People Pulse was refreshed in 2021 to operate as a quarterly survey focussed on patient experience (and replaced the previous Staff Friends and Family Test). This recognised the clear link between staff engagement and patient safety **[SP/0164, INQ0014808]**.

656. Both the NHS Staff Survey and People Pulse are mandated through the NHS Standard Contract.

657. The spread and scale of good practice is facilitated through the Staff Engagement and Experience Team who support this via NHS Futures.

658. The results of the NHS Staff Survey and People Pulse also inform national programmes of work, where this is considered the most appropriate way of addressing issues raised.

(iv) Listening to Patients

659. At a service delivery level NHS England and ICBs have a statutory duty to promote the involvement of patients in their care. NHS England and ICBs also have a duty to involve patients and representatives in the planning and development of proposals in respect of services. There is statutory guidance published by NHS England setting out how all NHS bodies should work with people and communities.

660. In terms of patient engagement and involvement there are a number of different ways NHS England carries out engagement. We set out in Section 2 above the detailed statutory framework that applies in relation to patient and carer complaints and the other ways in which concerns can be raised or external scrutiny sought. There are many more mechanisms both for individuals to ask questions and to provide feedback, including:

661. CQC maternity patient feedback surveys - CQC publishes patient experience surveys in secondary care under their National Patient Survey Programme. This includes a maternity patient survey. On the same day that CQC publish the national survey results, NHS England publishes the Overall Patient Experience Scores. These are a statistical series measuring overall patient views of care and services provided by the NHS.

662. We are currently rolling out a Neonatal Patient feedback tool known as the Patient Reported Experience Measure or PREM. Patient experience measure is patient-reported perception their journey across the continuum of care and of the healthcare

provider. A number of Patient Reported Experience Measures exist specific to particular types of care, such as inpatient stays, general practice appointments, outpatient visits, maternity care, care homes or domiciliary care. As set out at paragraph 699 a PREM is currently being commissioned for neonatal services.

663. The Friends and Family Test (FFT) is an important feedback tool that Provider Trust use. that supports the fundamental principle that people who use NHS services should have the opportunity to provide feedback on their experience. It asks people if they would recommend the services they have used and offers a range of responses. When combined with supplementary follow-up questions, the FFT provides a mechanism to highlight both good and poor patient experience. This kind of feedback is vital in transforming NHS services and supporting patient choice

664. Through including service user representation on many different policy development groups and listening to the feedback from service user involvement and engagement groups in order to drive improvement. In maternity and neonatal care we have established Maternity and Neonatal Voices Partnerships in every system to work with women and families to improve care and we recently published guidance, that was co-produced with service users and commissioners, which sets out areas of Integrated Care Boards and trusts to consider when commissioning and supporting effective Maternity and Neonatal Voice Partnerships, consistent with the requirements of the Three Year Delivery Plan.

665. The Medical Examiner system critically provides families an immediate option to discuss and ask questions of an independent clinician where there has been a death that has not been reviewed by the Coroner.

(v) Culture and Equality, diversity and Inclusion

666. The NHS People Plan commits the NHS to "welcome all, with a culture of belonging and Trust. We must understand, encourage and celebrate diversity in all its forms." Recommendation 2 of General Sir Gordon Messenger's review into Leadership for a collaborative and inclusive future ("The Messenger Review") sets recommendation around embedding inclusive leadership; committing to promote equality opportunity and fairness standards and more stringently enforcing existing measures to improve equal opportunities and fairness. NHS England considers that any form of racism is unacceptable and has no place in health and care. However, we know that it does still exist. Trust, transparency and perceptions of fairness are key to creating

organisational cultures of inclusion. The NHS equality, diversity and inclusion improvement plan forms part of NHS England's response to Recommendation 2 of the Messenger Review setting out targeted actions to address the prejudice and discrimination – direct and indirect – that exists through behaviour, policies, practices and cultures against certain groups and individuals across the NHS workforce.

667. NHS England also jointly published guidance in November 2022 "Combatting Racial Discrimination against minority ethnic nurses, midwives and nursing associates" **[SP/0165, INQ0014748]**. This provides advice on the action nurses can take if they witness or experience racism. It also supports those in leadership roles to be inclusive leaders.

668. Well-Led Reviews, the Workforce Race Equality Standard (WRES) and Workforce Disability Equality Standard (WDES) data, also allow NHS England to assess how well leaders are adopting the behaviours we all need to see. Information from these other sources informs how NHS England performs its oversight role, in accordance with the Oversight Framework (which is described in Section 3A of this statement).

(3) Neonatal focused reviews

669. We have focussed in this sub-part on the most recent neonatal specific reviews that have or are being carried out by NHS England that are relevant to the Inquiry's Terms of Reference are:

    a. The Neonatal Critical Care Review;

    b. Getting it right first time neonatal services report; and

    c. Three-year delivery plan for maternity and neonatal services.

670. Before turning to the Neonatal Critical Care Review, we have briefly explained the context to this and the continuum of work that has been underway in relation to maternity and neonatal services since NHS England's establishment in 2013.

671. We would like to reiterate that the maternity and neonatal specific work described below is also informed by learnings from foundational previous inquiries, investigations and reviews. NHS England considers that these underpin all improvement work within the NHS, including neonatal.

672. The list that follows is not intended to be comprehensive but recognises milestone inquiries, investigations and reviews that we consider have had a sustained and

ongoing impact on the NHS. They are listed chronologically. Maternity and neonatal specific inquiries, investigations and reviews are not listed because they are dealt with at paragraph 674, below.

a. The Shipman Inquiry (final report published January 2005);

b. The Department of Health Winterbourne View Review and Concordat (December 2012);

c. The Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry ("The Francis Inquiry") (February 2013);

d. The Independent review into issues that may have contributed to the preventable death of Conor Sparrowhawk (October 2015);

e. Freedom to Speak Up, An Independent Review into creating an open and honest reporting culture in the NHS, by Sir Robert Francis QC (February 2015);

f. The report of the Gosport Independent Panel into Gosport War Memorial Hospital (June 2018);

g. The Kark review of the Fit and Proper Persons test ("The Kark Review") (2019);

h. The Messenger review into Leadership for a collaborative and inclusive future ("The Messenger Review") (2022).

673. From this list, (a), (b), (c), (d), (f) all involved the deaths, harm or abuse of patients who had particular vulnerabilities. The reports in each of these cases drew out common failings, including:

a. Concerns raised by staff and/or families, which were either not taken seriously or were not acted on;

b. Portrayal of those who did raise concerns as 'trouble-makers' and, in many cases, the initiation of retaliatory professional regulatory referrals or employment processes;

c. Missed opportunities to prevent harm;

d. Inadequate oversight and assurance by Boards and senior leaders;

e. 'Insufficient curiosity' by leaders and the Board; and

f. Misinterpretation of data or failure to 'join the dots'.

674. Building on the list above of foundational previous inquiries, investigations and reviews, the table below summarises those that directly relate to maternity and neonatal services.

Date	Inquiry, independent review or other key report	Key themes relating to Neonatal Care
1994	**Clothier Inquiry** This inquiry considered the case of Beverly Allitt, a nurse working on paediatric ward convicted of murder using air and insulin. Whilst this took place many years before NHS England came into existence, we note from the government response that action was taken.	Sufficient training, recruitment checks; Appropriate workforce; Failures of management and communication. Coroners to send post mortem report to relevant consultant. Review of paediatric pathology services to ensure engagement with every unexplained death. Untoward Incident recorded for failure of any monitoring equipment alarm
2015	**Morecambe Bay Investigation** The findings and recommendations of the independent investigation, chaired by Dr Bill Kirkup, were published in March 2015. The report identified significant concerns across a number of areas within the Trust, the wider NHS, professional and regulatory bodies. It made 18 recommendations specific to the Trust and a further 26 to the wider NHS.	Training and development of staff Recruitment and retention of workforce Process for investigating incidents and responding to complaints Board role in assuring quality of care Mortality recording of perinatal deaths Medical Examiner Review of Neonatal Deaths
2016	**Better Births: Improving outcomes of maternity services in England – A Five Year Forward View for maternity care** [redacted] Commissioned by NHS England as part of actioning the	Personalised care Continuity of carer Safer care Better postnatal and perinatal mental health care Multi-professional working

Date	Inquiry, independent review or other key report	Key themes relating to Neonatal Care
	Morecambe Bay recommendations.	Working across boundaries Payment system reform
2019	**Neonatal Critical Care Transformation Review** As described in Section 2, the NCCR was commissioned as a result of a recommendation for a review of neonatal services in the Better Births Report (2016) **[SP/0166, INQ0014626]** which looked in detail at maternity services. A draft report was produced in 2017 with the final report published in 2019. The Review is the core reference point for a number of neonatal specific improvements which we are implementing across neonatal services.	Increase neonatal capacity Develop workforce Develop and invest in support for parents Expanding the workforce in neonatal care
2019	**Neonatology: GIRFT Programme National Specialty Report [SP/0167, INQ0012352]** To assist with implementation of the NCCR, NHS England commissioned a GIRFT neonatology speciality review, which was initiated in 2019. The GIRFT review for neonatology included deep dive visits at both Trust and network level. These reports were intended to complement and support the Neonatal Critical Care Review by providing greater detail of the issues and concerns set out in that Review. GIRFT produced two national reports in April 2022: • "Neonatology: GIRFT Programme National Specialty Report April 2022 **[SP/0168, INQ0014731]** • "Neonatology – Workforce: GIRFT Programme National Specialty Report"	Strengthening Networks Improving patient Pathways Optimising Clinical Outcomes Reducing medication errors Improving family experience

Date	Inquiry, independent review or other key report	Key themes relating to Neonatal Care
	[SP/0169, INQ0014730] .	
First Report 2020 Final report 2022	**Ockenden review** Donna Ockenden's reports on maternity failings at Shrewsbury and Telford Hospital NHS Trust highlighted themes common to the inquiries, investigations and reviews set out above including concerns around leadership and teamwork, listening to and supporting families, provision of bereavement care, escalation of concerns and provider Board oversight. Following her first report published in December 2020, NHS England wrote out to all trusts to identify the immediate actions they were required to take. Trusts were required to respond to NHS England to confirm the action that they had taken within two weeks of that letter. This was followed up one year later to ensure improvement actions had been taken. Trusts were similarly contacted after publication of her final report.	Listening to and supporting Families Bereavement care Importance of Local Maternity Systems Multidisciplinary Training Escalation of Concerns Provider Board oversight Implementation of NHS Saving Babies Lives Endorsed recommendations of NCCR.
2022	**'Reading the signals: maternity and neonatal services in East Kent** The East Kent report was published in October 2022 by Dr Bill Kirkup ("Reading the Signals"). This report was the result of the independent investigation into maternity services in East Kent. Following the publication of the report, NHS England wrote to Provider Trusts, Local Maternity and Neonatal Systems and ICB chairs to reconfirm the requirement for their Boards to remain focused on delivering personalised and safe maternity and neonatal care and take	Identifying poorly performing units through identifying valid maternity and neonatal outcome measures and improving data Giving care with compassion and kindness Teamworking with a common purpose Responding to challenge with honesty.

Date	Inquiry, independent review or other key report	Key themes relating to Neonatal Care
	steps assure itself, and the communities it serves, that the leadership and culture across their organisation(s) positively supported the care and experience provided. Specifically, every Trust and ICB was expected to review the findings of this report at its next public board meeting, and for boards to be clear about the action they would take, and how effective assurance mechanisms are at 'reading the signals'.	
2023	**Three Year Delivery Plan for Maternity and Neonatal Services**	This consolidates the improvement actions committed to from the previous inquiries, investigations and reviews contained within this table, as well as other key publications. This includes Better Births, the NHS Long Term Plan, the Neonatal Critical Care Review, and reports of the independent investigation at Shrewsbury and Telford Hospital NHS Trust and the independent investigation into maternity and neonatal services in East Kent. The intention of the consolidation process was to enable focus at Trust, ICB and NHS England level. The Delivery Plan also includes clear and targeted actions for respective parts of the system to take.

(a) Morecambe Bay

675. In September 2022, NHS England's Executive Quality Group considered the Final Assessment of the Morecambe Bay Recommendations, which had been jointly developed and agreed with the Department of health and Social Care (as the overall responsible body for implementation of the report recommendations). The Final Assessment is exhibited to this statement **[SP/0170, INQ0014779]** but, in summary, the conclusions from this Final Assessment were that:

a. The majority of recommendations had been implemented and no further action is planned;

b. There are five recommendations that require further work and/or action to complete full implementation. Of these, only two remain the responsibility of NHS England to action and NHS England has begun this process. The recommendations in question are recommendations 20 and 21, which relate to safe provision in rural areas and educational opportunities and challenges in smaller units respectively. The others are for the Care Quality Commission and the Department of Health and Social Care to take forward.

c. There were no recommendations where no action has been undertaken.

(vi) Independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust, and Maternity Review, and the Independent Investigation into maternity and neonatal services in East Kent

676. Implementation of the recommendations made in both these reviews is actioned and overseen as part of the Maternity Transformation Programme and the Three Year Delivery Plan, with the Maternity and Neonatal Board overseeing delivery of the Plan and the effectiveness of the Transformation Programme.

677. Following publication of the final report of the Independent Maternity Review into Shrewsbury and Telford Hospital NHS Trust in March 2022, the Department of Health and Social Care and NHS England commissioned an Independent Maternity Working Group, actioning the specific recommendation contained in the Final Report that such a group be commissioned. In the final report of the independent review, the purpose of this Working Group is described as being to "make plans to guide the Maternity Transformation Programme around implementation of these IEAs [immediate and essential actions] and the recommendations of other reports being prepared". The latter included the review into East Kent, which was underway at the time. This purpose is carried through to the Terms of Reference for the Working Group **[SP/0171, INQ0014745]**.

678. As recognised in the Working Group's Terms of Reference, maternity and neonatal care are within scope "given the interdependencies between these services". The Group is co-chaired by independent leads, one from the Royal College of Midwives and one from the Royal College of Obstetricians and Gynaecologists. NHS England's National Deputy Chief Nursing Officer is a member of the Working Group, alongside Workforce colleagues. The Group meets monthly and submits an annual report to

NHS England, the Department of Health and Social Care and the Secretary of State for Health and Social Care.

(b) Neonatal Critical Care Review

679. The Neonatal Critical Care Review was commissioned following the "National Maternity Review: Better Births Improving outcomes of maternity services in England. A Five Year Forward View for maternity care" (published 2016, "Better Births"). Better Births highlighted several challenges facing neonatal medical and nurse staffing, nurse training, the provision of support staff and cot capacity. It went on to recommend as follows:

> *"4.58 …A review of the safety and sustainability of neonatal services (particularly in remote and rural settings) was specifically recommended in the Report of the Morecambe Bay Investigation. In the time frame in which the National Maternity Review was conducted, it was not possible to review neonatal services concurrently. A dedicated review should be taken forward, in light of the findings of this review and its consequences for neonatal services. The neonatal review should include the payment arrangements for neonatal services, in the context of the wider payment system for maternity services, and whether a neonatal tariff should be developed."* **[SP/0166, INQ0014626]** *(emphasis added).*

680. NHS England commissioned the Neonatal Critical Care Review in response to this recommendation.

681. The Neonatal Critical Care Review was carried out in two phases, as follows:

    a. Phase one: an evidence review undertaken by the NHS England Neonatal Critical Care Clinical Reference Group across several work streams;

    b. Phase two: translation of the evidence review into a specific action plan for Regional Specialised Commissioning Teams, Neonatal Operational Delivery Networks and Local Maternity Systems, to inform commissioner plans and, where required, service change.

682. The findings of the review were published in the form of recommendations. Initial recommendations linked to specific themes were presented to local maternity planning systems in August 2017 with the full evidence review completed in October 2017.

683. The final report of the Neonatal Critical Care Review was published in 2019 and has been followed by financial investment via the NHS Long Term Plan between 2020/21 and 2023/24. This funding has been focussed on enabling delivery of the following objectives:

a. Developing improved neonatal capacity;

b. Developing the expert neonatal workforce;

c. Enhancing the experience for families, through care coordination and investment in improved parental accommodation; and

d. Implementation Infrastructure.

684. The Neonatal Critical Care Review report sets out ten actions, which aligned with one or more of the above objectives.

685. The report set out that a national Neonatal Implementation Board would be established to bring together those responsible for neonatal and maternity services, to oversee the delivery of the action plan. This Neonatal Implementation Board would operate as an additional work stream (Work Stream 10) of the Maternity Transformation Programme. It would be a new work stream recognising that the implementation of the Neonatal Critical Care Review and the NHS Long Term Plan commitments in relation to neonatal service is an important and discrete area of work with its own governance.

686. Work Stream 10 was to pull together existing national programmes of work as well as recommending the initiation of other national and regional work aligned with existing work programmes to ensure the delivery of the commitments in the NHS Long Term Plan. The Neonatal Implementation Board would report jointly to the national Maternity Transformation Board and the national Specialised Commissioning Delivery Group. The Neonatal Implementation Board was established in June 2019 and developed from the existing task and finish group. Its latest terms of reference were published in February 2022 **[SP/0172, INQ0014729]** which sets out the responsibilities, accountability and membership of the NIB.

687. The Maternity Transformation Board (one of the bodies to which the Neonatal Implementation Board jointly reports) was established as part of the Maternity Transformation Programme following publication of the National Maternity Review in February 2016. It originally had oversight of the plans set out in Better Births by bringing together a wide range of organisations to lead and deliver across 9 work

streams. Work Stream 10 was added following the Neonatal Critical Care Review, and is the only work stream focussed on neonatal services.

688. Neonatal Critical Care services are one of the 149 specialised services directly commissioned by NHS England which support people with a range of rare and complex conditions, including Neonatal Critical Care Services. Specialised Commissioning Teams work across regional and national footprints to support the commissioning and delivery of specialised services and the implementation of national policies. The Neonatal Critical Care Review report set out that Specialised Commissioning and the Maternity Transformation Board would work in partnership to ensure that the plans were delivered, working through regional commissioning teams and the development of regional neonatal critical care commissioning plans.

689. The wider infrastructure relating to the implementation of the actions in the Neonatal Critical Care Review report is set out within Action 9 of that report.

690. Since December 2019 the Neonatal Implementation Board has held a total of 30 bi-monthly meetings, and has maintained a risk register and actions log to track progress against the actions in the context of the Neonatal Critical Care Review report. The Neonatal Implementation Board has provided oversight and assurance at a national level in relation to the actions in the Neonatal Critical Care Review report, including use of a standard set of metrics. Since its inception the Neonatal Implementation Board has also received regional updates in relation to neonatal matters, as well as reports on the Getting It Right First Time review for neonatology and surveys of workforce provision. Regions have reported on the status of their services including any developments and challenges, and presented relevant data in relation to those services. Discussions and reports at Neonatal Implementation Board meetings have addressed various aspects of regional neonatal provision, including capacity, workforce, challenges during the pandemic and outcomes.

691. Pursuant to the Neonatal Critical Care Review report, regional commissioners, together with Operational Delivery Networks, Trusts and Maternity Clinical Networks were to develop 5-year Neonatal Critical Care Implementation Commissioning plans for each neonatal ODN area. Each plan was required to set out how the actions in the actions of the Neonatal Critical Care Review report would be taken forward, including investment and funding required. The Operational Delivery Networks for each area were to provide their implementation plans by March 2020. These have been received

by the Neonatal Implementation Board. Since that time the Neonatal Implementation Board has received and reviewed updates to local implementation plans.

692. In a paper to the Executive Quality Group on 11 September 2023 and then the Quality Committee on 14 September 2023, an update was provided in relation to the National Critical Care Review including progress against the actions in the Neonatal Critical Care Review report as at that time **[SP/0173, INQ0014778] [SP/0174, INQ0014758] [SP/0175, INQ0014757].**

(ii) NHS Long Term Plan

693. The NHS Long Term Plan published in January 2019 built on measures that were already being implemented following Better Births. It set out key aims to halve still births, maternal mortality, neonatal mortality and serious brain injury in newborn babies. It also committed to improve continuity of care during pregnancy, birth and after birth and mental health services for pregnant women and new mothers.

694. Targeted funding was made available to support NHS Long Term Plan objectives. In order to implement the Neonatal Critical Care Review, significant investment was made into neonatal services via the NHS Long Term Plan between 2020/21 and 2023/24. This is described further below.

(iii) Three Year Delivery Plan

695. The actions set out in the Neonatal Critical Care Review report are now incorporated within the "Three year delivery plan for maternity and neonatal services" **[SP/0152, INQ0012643]** (March 2023).

696. The Three Year Delivery Plan forms the critical framework through which NHS England and others working within maternity and neonatal services, including NHS Trusts and NHS Foundation Trusts, will action the objectives set out in the Plan and measure the effectiveness of implementation (the Plan describes how objectives will be actioned, with specific responsibilities assigned to particular parts of the maternity and neonatal system, and how success will be determined).

697. The plan was produced in response to feedback from the system that clarity was required about who is responsible for doing what, and to bring the asks of services and systems into one place. The Three Year Delivery Plan and associated Technical Guidance **[SP/0152, INQ0012643]** sets out clear responsibilities and measures of success across services and systems. NHS England's governance oversight and assurance of the Three Year Delivery Plan is described in detail in Section 2 of this statement, with overarching responsibility sitting with the Maternity and Neonatal Programme Board.

698. The Three Year Delivery Plan was co-developed with input from a wide range of people including service users, staff providing frontline care, stakeholders, and those leading services. This included contributions from an Independent Working group chaired by the Royal College of Midwives, and Royal College of Obstetricians and Gynaecologists.

699. The plan sets out the ambitions for maternity and neonatal services under four key themes – the commitments relevant to neonatal are shown below:

    a. Theme 1: Listening to and working with women and families with compassion

        i. Parents are partners in their baby's care in the neonatal unit through individualised care plans utilising a **family integrated care** approach

        ii. Create a patient reported experience measure (**PREM**)

        iii. During 2023/24, continue to publish and lead implementation of their Local Maternity and Neonatal System (LMNS) alongside neonatal ODNs

        iv. Commissioned and funded Maternity ***and Neonatal*** Voice Partners; PAGs

    b. Theme 2: Growing, retaining, and supporting our workforce

        i. Continue to invest (**Neonatal Nurse Quality Roles**) and grow the Neonatal Workforce (**Neonatal AHPs and Neonatologists/ANNPs**)

        ii. Strengthen neonatal clinical leadership with a national **clinical director for neonatal** and **national neonatal nurse lead.**

        iii. Ensure junior, speciality and associate specialist obstetricians, and **neonatal medical staff** have appropriate clinical support and supervision in line with RCOG guidance and **BAPM** guidance

        iv. Work with royal colleges and professional organisations to understand and address the challenges involved in recruiting and training the future **neonatal medical workforce**

    c. Theme 3: Developing and sustaining a culture of safety, learning, and support

i. By April 2024, offer the perinatal **culture and leadership programme** to **all maternity and neonatal leadership** teams

ii. Throughout 2023, support **transition to PSIRF [Patient Safety Incident Response Framework]** with national learning events.

iii. During 2023/24, test the extent to which the **Perinatal Quality Surveillance Framework** has been effectively implemented.

iv. By March 2024, provide targeted delivery of the **maternity and neonatal board safety champions continuation programme**

d. Theme 4: Standards and structures that underpin safer, more personalised, and more equitable care

i. Neonatal care is provided in units with clear **neonatal designation** of the level of care to be provided

ii. Convene a **taskforce** to progress the recommendation for an early warning system to detect safety issues within maternity and neonatal services (Maternity and Neonatal Outcomes Group)

iii. Procure an electronic patient record system – that complies with national specifications and standards, including the digital maternity record standard and the maternity services data set and can be updated to meet maternity and **neonatal module specifications** as they develop.

iv. The national maternity early warning score (MEWS) and updated newborn early warning trigger and track (NEWTT-2) tools to improve the detection and care of unwell mothers and babies, enabling timely escalation of care.

700. We would like to particularly draw out the following current areas of focus, as per the Three Year Delivery Plan:

a. Listening to families. Key initiatives include the Maternity and Neonatal Voices Partnerships **[SP/0176, INQ0014797]**, the development of a neonatal patient feedback tool (currently known as the Patient Reported Experience Measure) and work with the Patient Safety team to enhance how patient experience

data informs the operation of Patient Safety Incident Response Framework (see paragraph 354).

b. Equality and inclusion. This forms a core area of focus throughout all NHS England's current initiatives and is described in more detail below at paragraph 666. Maternity and neonatal specific ambitions are set out in the Three Year Delivery Plan, which also recognises that significant health inequalities exist in maternity and neonatal care in England.

c. Workforce. As part of the NHS Long Term Plan investment provided to support the implementation of the Neonatal Critical Care Review recommendations from 2020/21 and the investment committed following the first Ockenden Report there has been a significant and incremental investment in the neonatal workforce. We have described recent progress in relation to workforce and planned further work below.

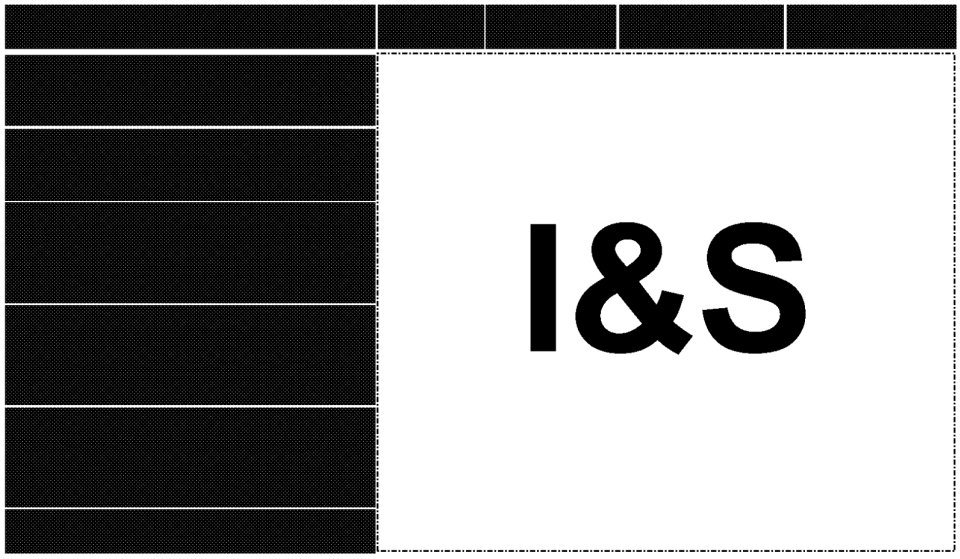
(c) Neonatal workforce initiatives

701. Neonatal specific initiatives in relation to Workforce need to be seen in the wider context of the work NHS England is doing around People and Workforce, through the NHS People Plan and the NHS People Promise. This is described at paragraph 646.

702. What follows is an overview of recent neonatal specific initiatives.

703. Staffing shortages has been a consistent theme noted in previous inquiries, investigations and reviews (whether general or maternity/neonatal specific).

704. NHS England has worked to address neonatal workforce shortages, with targeted investment to enable additional roles to be recruited to. The table below illustrates the investments made in the neonatal workforce over the last four years:



705. NHS England monitors the recruitment to the neonatal workforce, including nursing staff, neonatal Allied Health Professionals and neonatal medical staffing through the Neonatal Implementation Board. On this basis, we are satisfied that considerable progress has been made to recruiting to additional roles that have been funded by NHS England. This includes the following additional funded roles:

a. Neonatal cot side nurses, with 549 of 558 new cot side nursing posts recruited to as of the most recent reporting date.

b. Neonatal nurse quality roles, to support cot-side clinical training and clinical governance. 44 of the 98 roles have been recruited to as of the most recent reporting date.

c. Neonatal allied health professionals, with 124 of the 182 funded roles recruited to, as of the most recent reporting date.

d. Neonatal medical establishment of I&S in 2023-24 rising to I&S in 2024-25 to support neonatal units increasing compliance against the British Association of Perinatal Medicine standards and core safety activities, in relation to safety governance, clinical leadership and the Perinatal Mortality Review Tool.

e. Operational Delivery Network education and workforce leads, to support the providers in the recruitment and retention of neonatal staff.

706. Pay bandings for neonatal staff are set out in Annex 9.

707. Nationally, NHS England has strengthened neonatal clinical leadership by appointing the first ever national Neonatal Clinical Director **[SP/0177, INQ0014759]** and national Neonatal Nurse lead role **[SP/0178, INQ0014750]**.

(i) Training

708. NHS England is also actively supporting, primarily through Operational Delivery Networks, further support around training and induction of neonatal staff. Recently, this has included:

    a. Additional funding (£ **I&S**) for Professional Midwifery Advocates and Professional Nurse Advocates to support staff wellbeing and provide restorative clinical supervision in maternity and neonatal services.

    b. National retention programme **[SP/0179, INQ0014791]**, operationalised through each of the NHS England regions.

    c. An updated Core Competency Framework for maternity and neonatal services, published in May 2023 **[SP/0180, INQ0014790]**.

709. There remain issues with the proportion of staff within neonatal units that have undertaken the specialist training for neonatal nurses known as "Neonatal Qualified in Specialist training" and a number of provider trusts do not currently meet the requirement under the neonatal critical care standard contract service specification for 70% of nurses within a neonatal unit to have undertaken specialist training. The recent expansion of staff is a factor in this imbalance.

710. Once the "Neonatal Qualified in Specialist training" is completed, the expectation is that staff will undertake an extended role, including looking after the sickest infants. Midwives completing maternity preceptorship training move up automatically into a Band 6 on completion of the training, whereas this does not current happen automatically for neonatal nurses completing the "Neonatal Qualified in Specialist training". As a result, there appears to be fewer nurses willing to undertake the specialist training.

711. NHS England is currently considering whether any healthcare training could be provided across specialties, for example through a joint induction period for staff from nursing, medical and allied health professions.

(ii) Neonatal culture

712. Although our overall view is that there are no neonatal-specific culture issues, there are initiatives underway to further support a positive culture of safety and continuous improvement. The Perinatal Culture and Leadership Programme is the key initiative to through which this support is enabled.

713. The Perinatal Culture and Leadership Programme aims to improve the quality of care by enabling leaders to drive change with a better understanding of the relationship between leadership, safety improvement and safety culture. This programme recognises that processes are important for ensuring safety but if you do not have psychologically safe culture then processes do not go far enough.

714. This training that the Perinatal Culture and Leadership Programme is around team leadership development in order to tackle the concerns raised by in previous inquiries, investigations and reviews that professions often work in silos. It is provided in three phases.

    a. Phase 1 concentrates on the perinatal senior leadership team and supports each team to problem solve together and plan for the future.

    b. Phase 2 includes an online culture survey for each of the maternity and neonatal units to gain insight into a team's safety culture, to help identify strengths and opportunities and to understand the role that relationships have in supporting improvement.

    c. The final phase builds on the feedback of the culture survey through the assignment of an experienced leadership development coach to provide individual support to every maternity and neonatal site in England to support them to make improvements to address their local challenges.

715. The aim is that all NHS Trusts with a neonatal unit will finish phase 1 by March 2024 with phase 2 and 3 being completed by January 2025.

716. The training is provided using a "quad" system, with representatives from four different groups undertaking the training together - a midwife, obstetrician, management representative and either a nurse or doctor from neonatal services.

(iii) Neonatal Infrastructure

717. The Three Year Delivery Plan made a commitment to "over the next three years, undertake a national maternity and neonatal unit infrastructure compliance survey and report, to determine the level of investment needed for an environmentally sustainable development of the maternity and neonatal estate across England".

718. NHS England is actioning this commitment by undertaking a Maternity and Neonatal Services Infrastructure Review. The objectives of this infrastructure review are to:

    a. assess the current state of the maternity and neonatal estate across England, including its impact on patients, the environmental impact and condition

    b. identify the future needs of the maternity and neonatal estate, considering population growth, technological change

    c. identify opportunities to improve the maternity and neonatal estate, ensuring that it meets the needs of patients and staff

    d. develop recommendations for how best to invest in the maternity and neonatal estate to achieve the identified opportunities for environmental and experiential improvements

719. The Maternity and Neonatal Services Infrastructure Review is intended to be delivered over a period from 2024 to 2026 and will incorporate review and update of applicable Health Building Notes (described in detail at paragraph 873). This programme also supports the wider process being undertaken to periodically review all estates related technical guidance documents.

(d) GIRFT neonatal services report

720. GIRFT is a national programme designed to improve the treatment and care of patients through in-depth review of services, benchmarking, and presenting a data-driven evidence base to support change. It was first conceived and developed to review elective orthopaedic surgery and address a range of observed and undesirable variations in orthopaedics.

721. NHS Improvement then facilitated the expansion and development of this concept into a national programme, GIRFT. GIRFT has been applied across 40 surgical and medical specialities and other cross-cutting themes. It consists of five key strands:

    a. a broad data gathering and analysis exercise;

b. direct clinical engagement;

c. a national report, that draws on both the data analysis and the discussions;

d. an implementation phase where the GIRFT team support trusts, commissioners, and Integrated Care Systems to deliver the improvements recommended; and

e. best practice guidance and support for standardised and integrated patient pathways and elective recovery work in 'high volume/low complexity' specialities.

722. GIRFT has produced a data-driven national report into neonatal services across England, outlining measures to improve services for babies, their families and the NHS staff who care for them ("GIRFT Neonatology Review"). The review commenced in 2020, with the final report published in 2022.

723. The GIRFT Neonatology Review built on the Neonatal Critical Care Transformation Review, and made various recommendations relating to the following:

a. Organisation of the neonatal services;

b. The need for more intensive care cots;

c. The reconfiguration of neonatal services;

d. Improvements in neonatal transport;

e. Specific recommendations to improve clinical care.

724. We are aware that Dr Eleri Adams has been asked by the Inquiry to provide a witness statement. Having had sight of that statement, it is clear that it explains the following:

a. the purpose of the GIRFT Neonatology Review in the context of the Neonatal Critical Care Review;

b. the scope and purpose of deep dive visits;

c. the methodology and data sources

d. visits to ODNs;

e. visits to Trusts (paragraphs 42 to 50).

725. We refer the Inquiry to these parts of the statement of Dr Adams in relation to these aspects.

PART B: Current NHS England policies and procedures

726. In the NHSE/1 Rule 9 Request, there are a number of questions about what guidance NHS England provides NHS Trusts and NHS Foundation Trusts on their policies relating to, among other matters, safeguarding, complaints and raising concerns.

727. The Inquiry has also asked us what our expectations are around the processes and procedures in place in relation to trusts investigating concerns or complaints (whether raised by staff or parents) regarding neonatal care and for reporting concerns to external bodies.

728. The Inquiry then also asks us about the data collected in relation to neonates, the arrangements in place relating to the monitoring and analysis of data and data trends at a local and national level, as well as how systems operate for reporting concerns.

729. The underlying thread throughout this section and the various questions raised by the Inquiry is the issue of how concerns about patient safety and quality can be raised or otherwise identified, and the corresponding systems and arrangements in place to facilitate the raising or identification of concerns.

(1) Identifying Patient Safety and/or Quality Concerns

730. The table below sets out the various means by which concerns relating to neonatal services may be identified. The first column in this table sets out where each matter is dealt with in further detail in this statement below:

	Patients / carers	**Workforce**	**Provider organisation**	**Escalation routes**
Safeguarding (paragraphs 733- 760)		Duty to raise concerns, in compliance with statutory and professional obligations	Determine operational arrangements Report, monitor and respond accordingly	Where an individual has concerns regarding safeguarding then that concern would be raised via a safeguarding

	Patients / carers	Workforce	Provider organisation	Escalation routes
		Specific duties for Designated roles		alert process, or using one of the methods referred to in this table
Complaints **(paragraph 788 to 810)**	To provider in first instance		Determine operational arrangements Report, monitor and respond accordingly	Parliamentary and Health Service Ombudsman
Whistleblowing (PIDA) **(paragraphs 761 - 787)**		To provider in first instance	Comply with statutory requirements	Escalation to NHS England and/or the CQC. Potential claim to the employment tribunal under the Public Interest Disclosure Act 1998 for compensation if the individual suffers as a result of speaking up
NHS Freedom to speak-up **(paragraphs 761 - 787)**		Ability for NHS workers to raise concerns with their employer	Determine operational arrangements Engage senior managers, or refer to human resources process, or refer to	Escalation to FTSU senior lead or non-executive lead External referral to CQC or NHS England Potential claim to the employment tribunal under

	Patients / carers	Workforce	Provider organisation	Escalation routes
			patient safety process as appropriate Investigate and respond accordingly	the Public Interest Disclosure Act 1998 for compensation if the individual suffers as a result of speaking up (depending upon whether legislative criteria are met)
Employment processes		(If protected by employment arrangements)		Potential claim to employment tribunal depending upon the circumstances
Patient Safety Incident Reporting **(paragraphs 815 - 829)**	Able to raise concerns to either a member of staff, organisation in question or to an Integrated Care Board or NHS England or to record an incident directly via the national incident recording eForm (which is provided only to the National Patient Safety Team)	Populate local risk management systems with information relating to patient safety incidents, or record directly to the online Learn From Patient Safety Events service	Determine operational arrangements Report, monitor and respond accordingly Ensure local risk management systems are connected to Learn From Patient Safety Events or submitting batch upload data to the National Reporting and	Provider may escalate incidents and risks to Integrated Care Boards, who are able to escalate to NHS England regions, who can in turn escalate to NHS England nationally.

	Patients / carers	Workforce	Provider organisation	Escalation routes
			Learning System. For those still working under the Serious Incident Framework, identify "serious incidents" and record on StEIS notifying relevant commissioner.	
Care Quality Commission reporting requirements **(paragraphs 830 - 835)**	Able to report directly		Comply with statutory reporting requirements (including under the Maternity and Newborn Safety Investigations programme)	Consideration by CQC which may prompt further action
Coroner referrals **(paragraphs 440- 444)**	Raise concerns via Medical examiner if no referral made or confirm concerns to Coroner where referral made	Comply with obligations to refer to medical examiner and/or direct to Coroner	Comply with obligations to refer to Coroner as set out in legislation and guidance.	Judicial review of decision by Coroner not to proceed and/or of inquest Attorney General Fiat process under section 13 Coroners Act 1988
Medical examiner	Required that medical examiners seek views from the		Refer, monitor and respond accordingly including	Regional and national medical

	Patients / carers	Workforce	Provider organisation	Escalation routes
(paragraphs 424- 439)	bereaved about the care of the deceased		referring relevant cases where there are concerns about the care received by the deceased to the provider's clinical governance processes.	examiner structures
Professional regulatory bodies (such as the GMC/NMC) **(paragraphs 401- 407)**	Able to directly report	Comply with professional obligations, including self-referral	Comply with obligations to report concerns	Professional Standards Authority for Health and Social Care
Responsible Officer and Higher Level Responsible Officer framework (doctors only) **(paragraphs 811 to 813)**		Report concerns to Nominated responsible officer		Higher Level Responsible Officer General Medical Council
Raising concerns via the Controlled Drugs Accountable Officer system **(paragraph 814)**		Report concerns to Controlled Drugs Accountable Officers		Controlled Drugs Accountable Officer Local Intelligence Network

731. We will address each matter in this table in turn below. We will provide an outline of each regime and the role of NHS England within each regime. In doing so we hope to provide the Inquiry with the context of the role of NHS England in relation to the various matters raised within the NHSE/1 Rule 9 Request.

732. In the following part of the statement, we will consider the data systems, arrangements, programmes and audits in place in relation to patient safety and also specifically in relation to neonates.

(2) Safeguarding

733. The position in relation to safeguarding has advanced since the period prior to 2015, and following the reforms implemented by way of changes to the Care Act 2014. Numerous inquiries have also identified learnings during the period since 2015 from a safeguarding perspective. This part explains the role of NHS England in relation to safeguarding.

(a) Statutory framework for safeguarding

734. There are no safeguarding obligations that are specific to babies. In legal terms, safeguarding responsibilities arise from duties to adults (e.g., under the Care Act 2014 and the Care Act statutory guidance) at risk of abuse and neglect, and in respect of children (e.g., under the Children Act 2004 and the national "Working Together to Safeguard Children" guidance, which is published by the Secretary of State for Education, "Working Together").

735. The Working Together guidance is published under section 11 of the 2004 Act as statutory guidance, which means that all those who have safeguarding duties must have regard to the guidance when performing their duties and good reasons would be needed to lawfully depart from it.

736. NHS England's role and documents it publishes within the wider framework of the national Working Together guidance is discussed below. However, the full statutory framework that applies to safeguarding (or the background to its introduction) is not set out in this statement. In summary, we consider the following key aspects to be key in the context of the Inquiry:

    a. NHS partners, including NHS England (in both its national and regional capacity) and providers of NHS services, play a key role in relation to

safeguarding. This is alongside representatives from the police, local authorities and others;

b. To be effective, safeguarding relies on strong partnership working. As Working Together emphasises, this means "strong partnership working between parents/carers and the practitioners working with them".

c. Safeguarding is closely connected with other areas described below, including raising concerns and external scrutiny.

737. In terms of children, section 11 of the Children Act 2004 is a key duty. It requires certain bodies to make arrangements for ensuring their functions, and any services they commission, are discharged having regard to the need to safeguard and promote the welfare of children. The duty applies to local authorities and a range of other bodies, including NHS Foundation Trusts, NHS Trusts, Integrated Care Boards and NHS England.

738. In discharging their duties under section 11, the bodies must have regard to guidance given by the Secretary of State for Education, namely the Working Together Guidance. Chapter 4 of the current version of Working Together, published in December 2023, describes the role of different bodies as relevant to safeguarding.

739. In terms of the role of NHS organisations, the roles of NHS England and Integrated Care Boards (formerly clinical commissioning groups') are described as follows:

"NHS England is responsible for ensuring that the health commissioning system as a whole is working effectively to safeguard and promote the welfare of children. It is accountable for the services it directly commissions or delegates, including healthcare services in the under 18 secure estate (for police custody settings see below in the policing section). NHS England also leads and defines improvement in safeguarding practice and outcomes and should also ensure that there are effective mechanisms for safeguarding partners to raise concerns about the engagement and leadership of the local NHS. Each NHSE region should have a safeguarding lead to ensure regional collaboration and assurance through convening safeguarding forums."

740. NHS Trusts and NHS Foundation Trusts must also have regard to this key piece of guidance, and must arrange for their functions to be discharged having regard to the need to safeguard and promote the welfare of children. Responsibilities for

safeguarding form part of the organisations' statutory functions, and each organisation's executive board is responsible for effectively discharging those statutory functions. Providers' safeguarding duties are reflected within the wider contractual and regulatory framework, within which NHS services are commissioned and provided.

741. The Working Together guidance recognises that "Local safeguarding arrangements will need to reflect health and care infrastructure such as ICBs, Integrated Care Systems, local maternity and neonatal systems, provider collaboratives, primary care networks and NHS specialised commissioning arrangements".

742. Additionally, as the Working Together guidance sets out, professionals operating within health and care settings have certain roles and are expected to meet certain competencies to protect children from harm. These are described in an "Intercollegiate Document" which is published by the Royal College of Nursing but developed by over twenty other organisations (including the Royal College of Midwives). Although this is not an NHS England document, it is helpful context in understanding the responsibilities professionals operating within health and care settings have and the expectations around how these roles operate.

743. The Working Together guidance also recognises child deaths reviews as part of the wider safeguarding framework, which are dealt with further at paragraphs 838 to 840 below.

(b) The Intercollegiate Document

744. The Intercollegiate Document applies across the UK. It was first published in 2006, and was revised in 2010, 2014 and 2019, to respond to relevant policy development as mentioned in its foreword.

745. The Intercollegiate Document is not intended to replace contractual arrangements between NHS commissioners and providers, or between NHS organisations and their staff, but it aims to set out a consistent framework of indicative minimum training requirements and competencies. The framework identifies five levels of competence, ranging from Level 1 to 5. In summary:

    a. Level 1: All staff including non-clinical managers and staff working in healthcare services.

b. Level 2: Minimum level required for non-clinical and clinical staff who, within their role, have contact (however small) with children and young people, parents/carers or adults who may pose a risk to children.

c. Level 3: All clinical staff working with children, young people and/or their parents/carers and/or any adult who could pose a risk to children who could potentially contribute to assessing, planning, intervening and/or evaluating the needs of a child or young person and/or parenting capacity (regardless of whether there have been previously identified child protection/safeguarding concerns or not).

d. Level 4: Named professionals. These are professionals which all providers of NHS funded health services must have. There should be a dedicated named nurse, named doctor and a named midwife (if the organisation provides maternity services). Named practitioners have a key role in promoting good professional practice within their organisation, providing advice and expertise for fellow practitioners, ensuring safeguarding training is in place and working closely with others with responsibilities for safeguarding across the organisation and wider system. Appendix 2 of the Intercollegiate Document provides a template role description for named professionals.

e. Level 5: Designated professionals. Integrated Care Boards (formerly Clinical Commissioning Groups) are required to employ, or have in place a contractual arrangement, to secure the expertise of designated safeguarding practitioners whose role is to provide advice and expertise to organisations and agencies across the local health economy (including, in particular, the Integrated Care Board, NHS England, and local authorities). Appendix 3 of the Intercollegiate Document provides a template role description for designated professionals.

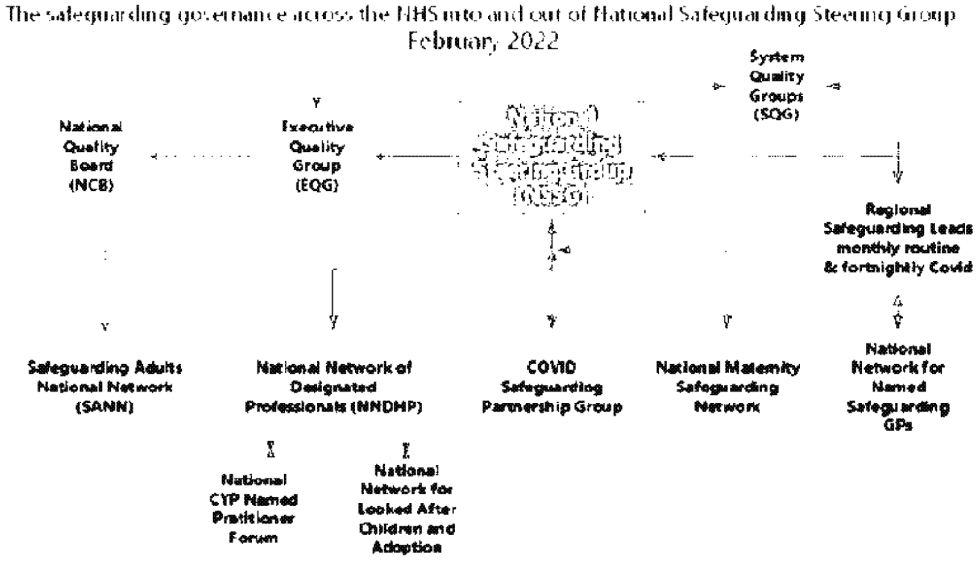
(c) Professional standards in respect of safeguarding

746. In addition, health professionals will also be required to comply with the standards of their profession. For instance, the General Medical Council publishes 'Protecting Children and young people: The responsibilities of all doctors' which again (like Working Together to Safeguard Children Guidance) signposts to the Intercollegiate Document. The Royal College of Nursing published 'Safeguarding Children and

Young People - Every Nurse's Responsibility', which again refers to the Intercollegiate Document.

(d) Governance structures for fulfilling NHS England's statutory safeguarding responsibilities

747. The Chief Nursing Officer for NHS England has executive lead responsibility to ensure the effective discharge of NHS England's statutory safeguarding responsibilities, and has a number of forums through which oversight is sought. These include the National Safeguarding Steering Group and its sub-groups and networks, (which includes the National Maternity Safeguarding Network and the National Network of Designated Healthcare Professionals for Children). The following diagram shows these safeguarding governance structures:



748. The Chief Nursing Officer is responsible for providing overall assurance to the NHS England Board, and assurance is secured through the annual review process assisted by NHS England's Regional teams. Each NHS England Region provides an annual safeguarding assurance report to the National Safeguarding Steering Group for assurance purposes, and to enable common issues, emerging trends and learning to be identified from across the health system.

749. NHS England also facilitates national sharing of best practice and safeguarding improvements with a view to ensuring the health system as a whole is working effectively to safeguard and promote the welfare of children. There are various way in which this is done. For example:

a. Through ensuring that the NHS Standard Contract, has standard conditions for providers relating to safeguarding. Namely, Standard Condition 32, which requires providers to, in brief summary:

   i. ensure service users are protected and to take appropriate action to respond to allegations and disclosures of contrary behaviour;

   ii. nominate lead professionals and ensure the relevant commissioner is informed of those professionals;

   iii. comply with relevant specified law and guidance relating to safeguarding;

   iv. implement comprehensive programmes for safeguarding;

   v. evidence that it is addressing safeguarding concerns, when reasonably requested by the commissioner;

   vi. include in relevant policies a comprehensive programme to raise awareness of the Intercollegiate Guidance, discussed above.

b. Through establishing safeguarding peer groups and forums for safeguarding professionals and system leaders **[SP/0181, INQ0014736]**.

c. Through making available the NHS Safeguarding App, as a resource for healthcare professionals, carers and the public.

d. Establishing the NHS Safeguarding Accountability and Assurance Framework, discussed below at paragraphs 750 to 756.

e. Ensuring, through statutory guidance, that Integrated Care Boards appoint senior executives at Board level who have responsibility for safeguarding, as discussed below at paragraphs 757 to 760.

(i) NHS Safeguarding Accountability and Assurance Framework

750. Consistent with its national leadership role in relation to safeguarding in the NHS, NHS England has developed and published a "Safeguarding children, young people and adults at risk in the NHS Safeguarding Accountability and Assurance Framework" ("the NHS Safeguarding Accountability and Assurance Framework") **[SP/0181, INQ0014736].** The current version of the Framework was published in July 2022 **[SP/0181, INQ0014736].** Prior versions were published in March 2013 **[SP/0182,**

INQ0014618]; in July 2015 (to address relevant duties coming into force under the Care Act 2014 in April 2015) **[SP/0183, INQ0014623]**; and in May 2019 **[SP/0184, INQ0014715].**

751. As stated in the NHS Safeguarding Accountability and Assurance Framework, the document is intended to provide the minimum standards that all those working in NHS funded care settings should work to, but it is not intended to constrain the development of other effective local safeguarding practice and arrangements (e.g., those developed by local safeguarding partners).

752. The current NHS Safeguarding Accountability and Assurance Framework aims to draw together and describe the safeguarding roles and responsibilities of NHS organisations, regulators and individuals working in NHS funded care settings (e.g., NHS Trusts and NHS Foundation Trusts) and NHS commissioning organisations. It seeks to clarify the relevant legal framework and cross refers to relevant statutory guidance. For example, it cross refers to the Intercollegiate Document and requires compliance with it, and the Working Together guidance.

753. The NHS Safeguarding Accountability and Assurance Framework describes NHS England's role in relation to safeguarding, in terms of (a) its system leadership role and facilitating peer support between safeguarding professionals; (b) its role as a direct commissioner of certain services (e.g., primary care, and specialised services); (c) its role in assuring Integrated Care Boards in their commissioning role.

754. The latter involves formal quarterly assurance reviews of Integrated Care Boards, which regional chief nurses are accountable for. This has involved developing the safeguarding commissioning assurance toolkit, to assist local commissioners to optimise their commissioner role under NHS Standard Contract which they hold with providers.

755. As set out in the NHS Safeguarding Accountability and Assurance Framework, NHS providers are required to demonstrate that safeguarding is embedded at every level in their organisation and they must be able to assure themselves, regulators, and commissioners that safeguarding arrangements are robust and are working. The framework states that robust arrangements include the following:

    a. Identification of a named nurse, named doctor and named midwife (if the organisation provides maternity services) for safeguarding children. Identification of a named nurse and named doctor for children in care.

Identification of a named lead for adult safeguarding and a Mental Capacity Act (MCA) lead – this role should include the management of adult safeguarding allegations against staff. This could be a named professional from any relevant professional background.

b. Safe recruitment practices and arrangements for dealing with allegations against staff.

c. Provision of an executive lead for safeguarding children, adults at risk and prevent.

d. An annual report for safeguarding children, adults and children in care to be submitted to the provider's board.

e. A suite of safeguarding policies and procedures that support local multiagency safeguarding procedures.

f. Effective training of all staff commensurate with their role and in accordance with Intercollegiate Document (and equivalent document intercollegiate document for adult safeguarding), the Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff 2019, Looked After Children: Roles and Competencies of Healthcare Staff 2020 and the Adult Safeguarding: Roles and Competencies for Health Care Staff 2018.

g. Safeguarding must be included in induction programmes for all staff and volunteers.

h. Providing effective safeguarding supervision arrangements for staff, commensurate to their role and function (including for named professionals).

i. Developing an organisational culture where all staff are aware of their personal responsibilities for safeguarding and information sharing.

j. Developing and promoting a learning culture to ensure continuous improvement.

k. Policies, arrangements and records to ensure consent to care and treatment is obtained in line with legislation and guidance.

756. NHS providers demonstrate compliance with the NHS Safeguarding Accountability and Assurance Framework by way of the annual assurance process.

(ii) Integrated Care Board Executive Leads

757. For completeness, I also note that in May 2023 NHS England published guidance to Integrated Care Boards requiring every Integrated Care Board in the country to identify a member of its Board who shall have explicit responsibility for each of the following population groups: Children and young people; Children and young people with special educational needs and disabilities; Safeguarding (all age), including looked-after children; Learning disability and autism (all age); and Down syndrome (all age). **[SP/0185, INQ0014789]**

758. In relation to safeguarding, NHS England anticipates that, for most Integrated Care Boards, the Executive Lead will be the Integrated Care Board's Director of Nursing. This reflects at the local level the national position that NHS England's Regional Chief Nurse is responsible for providing overall assurance to the NHS England Board on the effectiveness and quality of safeguarding arrangements across England. The role of the Executive Lead for safeguarding is to lead on supporting the chief executive and the Integrated Care Board to ensure the Integrated Care Board performs its functions effectively as relevant to safeguarding. This would also include ensuring compliance with the Safeguarding Accountability and Assurance Framework, referred above.

759. The Executive Lead for Children and Young People's role is to lead on supporting the Chief Executive of the Integrated Care Board to ensure it performs its functions effectively and in the interests of children and young people (i.e. age 0 to 25). The Lead is expected to have a line of sight for delivery of all children and young people commitments led by the Integrated Care Board including, as mentioned explicitly in the guidance, "improving outcomes for babies (for example, through implementing the recommendations of the neonatal critical care review or work of the Local Maternity and Neonatal System" **[SP/0167, INQ0012352]**. The neonatal critical care review is discussed below.

760. Although the guidance is to Integrated Care Boards, its intentions are to secure visible and effective board-level leadership within Integrated Care Systems for addressing issues faced by these population groups. The implementation of the roles is intended to provide key contact points at a senior level between the Integrated Care Board, wider Integrated Care System partners and NHS England's regional and national teams. It is expected that appointed executive leads will have a good understanding of the law, policy, guidance and best practice and that they work closely with wider

Integrated Care System partners to promote integrated working for the benefit of these population groups.

(3) Whistleblowing and Freedom to Speak Up

(a) The Role of NHS England

761. In this part, we describe the processes and procedures in relation to concerns raised by an NHS worker (which includes an employee, secondee, contractor, student, volunteer, agency or temporary staff member, locum or governor delivering NHS care). These concerns will be raised in the context of the role of that individual as an NHS worker, and the processes and policies in relation to whistleblowing and freedom to speak up will apply. This is distinct from complaints raised by service users, which we deal with separately in the section below.

762. It should be noted that the area of Freedom to Speak Up and Whistleblowing is distinct from other policy areas in that NHS England does itself publish guidance to providers in the form of national guidance which is intended to set a minimum standard to which providers should comply.

763. Prior to 2016, there was no national whistleblowing guidance published by NHS England or NHS Improvement, Monitor or the NHS Trust Development Authority, though they would have had their own policies and associated processes for receiving and responding to whistleblowing.

764. Delivering one of the recommendations from the Freedom To Speak Up (FTSU) Review by Sir Robert Francis, NHS Improvement published the first 'National Policy for Raising Concerns (whistleblowing)' on 1 April 2016 **[SP/0186, INQ0014643]**, which all NHS organisations were expected to adopt as a minimum standard. That followed a public consultation exercise with feedback received from over 100 stakeholders.

765. The policy was designed to cover 'whistleblowing' and other types of concerns from staff that might not meet the legal definition of a public interest disclosure, but which were still potentially relevant to the effective running of an NHS organisation (e.g. poor team culture).

766. The national policy has always provided for the raising of concerns externally, specifically to NHS England and its legacy organisations and/or the Care Quality Commission.

767. In 2016, NHS England also published sector specific guidance on whistleblowing for primary care organisations, which included a version for the national policy in its annex.

768. NHS England is aware from case reviews by the National Guardian's Office that not all organisations adopted the national policy. In 2016, it was not considered to be the role of NHS Improvement to enforce this.

769. NHS England has since published a Freedom to Speak Up policy for the NHS **[SP/0187, INQ0014746]** (the "Freedom to Speak Up Policy") which provides the minimum standard for local Freedom to Speak Up policies across the NHS. All NHS organisations and others providing NHS healthcare services in primary and secondary care in England are required to adopt the Freedom to Speak Up Policy as a minimum standard to normalise speaking up for the benefit of patients and workers.

770. Through general condition 5.10 of the NHS Standard Contract, NHS England requires providers of NHS services to:

    a. appoint and at all times have in place one or more Freedom to Speak Up Guardians to fulfil the role set out in and otherwise comply with the requirements of National Guardian's Office guidance;

    b. ensure that the commissioner of those services and the National Guardian's Office are kept informed at all times of the identity of the Freedom to Speak Up Guardian(s);

    c. co-operate with the National Guardian's Office in relation to any speaking up reviews and take appropriate and timely action in response to the findings of such reviews;

    d. have in place, promote and operate (and ensure that all sub-contractors have in place, promote and operate) a policy and effective procedures, in accordance with Freedom to Speak Up policy and guidance, to ensure that staff have appropriate means through which they may speak up about any concerns they may have in relation to the services provided under the contract and how they can be improved;

    e. ensure that nothing in any contract of employment, or contract for services, settlement agreement or any other agreement entered into by the provider (or any sub-contractor) with any member of staff will prevent or inhibit, or purport

to prevent or inhibit, that member of staff from speaking up about any concerns they may have in relation to the quality and/or safety of care, nor from speaking up to any regulatory or supervisory body or professional body in accordance with their professional and ethical obligations, nor prejudice any right of that member of staff to blow the whistle; and

f. include a mandatory provision in any settlement agreement or other agreement entered into by the provider (or any sub-contractor) with any member of staff in relation to the termination their employment or engagement setting out the matters referred to in e. above.

771. NHS England also requires NHS organisations and those providing NHS healthcare services in primary and secondary care in England to appoint a senior lead responsible for Freedom to Speak Up. The senior lead responsible for Freedom to Speak Up provides senior support for the Freedom to Speak Up Champion and is responsible for reviewing the effectiveness of their organisation's Freedom to Speak Up arrangements. NHS organisations with boards are also required to appoint a non-executive director responsible for Freedom to Speak Up. The non-executive director responsible for Freedom to Speak Up provides more independent support for the Freedom to Speak Up Guardian, providing a fresh pair of eyes to ensure that investigations are conducted with rigour and helping to escalate issues, where needed **[SP/0187, INQ0014746].**

772. NHS England and the National Guardian's Office have published a reflection and planning tool **[SP/0188, INQ0014734]** for use by senior leads for Freedom to Speak Up to identify strengths in themselves, their leadership teams and their organisations, and any gaps (the "Freedom to Speak Up Improvement Tool").

773. In partnership with the National Guardian's Office, NHS England has published a guide for leaders in the NHS and organisations delivering NHS services (the "Freedom to Speak Up Guide") **[SP/0189, INQ0014733]**. This was most recently updated in June 2022, and is now called the FTSU Guide. It is aimed at leaders because smaller organisations do not have boards. This guidance is supplemented by a self-review tool, most recently called a self-reflection tool. The purpose of this guidance was to expand the focus of FTSU beyond FTSU Guardians and ensure that boards and senior leaders were aware of their responsibilities in ensuring FTSU arrangements they put in place are effective. NHS England also provides a range of resources to

help NHS organisations and those providing NHS healthcare services to develop their Freedom to Speak Up arrangements, including videos, podcasts, and case studies.

774. By 30 January 2024, NHS England expected all NHS Trusts to have adopted the Freedom to Speak Up Policy, applied the Freedom to Speak Up Guide and Freedom to Speak Up Improvement Tool, and provided assurance to their public boards. Integrated Care Boards are expected to ensure that their own staff have access to routes for speaking up, including Freedom to Speak Up Guardian(s), to have used the Freedom to Speak Up Guide and Freedom to Speak Up Improvement Tool to map the plan for the next three years. They are also expected to put systems in place to capture and measure speaking up data.

775. NHS England expects all NHS organisations to ensure:

a. their relevant departments, such as human resources, and their freedom to speak up guardians are aware of the national Speaking Up Support Scheme offer;

b. their policies and processes reflect the principles in the guide for leaders in the NHS and organisations delivering NHS services;

c. workers have easy access to information on how to speak up and the Speaking Up Support Scheme, and actively refer individuals to the scheme;

d. they are mindful of those workers who may have cultural barriers to speaking up or who are in lower paid roles and less confident to do so, and also those who work unsociable hours and may not always be aware of or have access to the policy or processes supporting speaking up;

e. they communicate with all their workers by identifying the best channels to do so; and

f. they reflect on any learning to build healthy cultures in which every worker feels safe to speak up.

(b) Speaking Up to NHS England and other bodies

776. NHS England expects staff to speak up externally if they do not want to speak up within their organisation. Anyone who works in NHS healthcare, including pharmacy, optometry and dentistry can speak up to NHS England. This encompasses any

healthcare professionals, clinical and non-clinical workers, receptionists, directors, managers, contractors, volunteers, students, trainees, junior doctors, locum, bank and agency workers, and former workers. Staff working in NHS healthcare can speak up to NHS England about:

a. GP surgeries;

b. dental practices;

c. optometrists;

d. pharmacies;

e. how NHS trusts and NHS Foundation Trusts (including ambulance trusts and community and mental health trusts) are being run;

f. NHS procurement and patient choice; and

g. the national tariff.

777. NHS England has a webpage dedicated to "Speaking up to NHS England" which provides detail as to how concerns can be raised, including providing an address, telephone number and dedicated email address for doing so.

778. As a prescribed person[15], NHS England publishes an annual report which sets out the number of whistleblowing cases it received that it considered to be qualifying disclosures[16], and how they were taken forward **[SP/0190, INQ0014796]**.

779. The Freedom to Speak Up Policy also signposts staff to the Care Quality Commission (if they wish to raise quality and safety concerns about the services the Care Quality Commission regulates) and the NHS Counter Fraud Authority (if they wish to raise concerns about fraud or corruption in the NHS).

780. The Department of Health and Social Care has partnered with Social Enterprise Direct to deliver 'Speak Up', which provides free, independent, confidential advice about the speaking up process in the NHS.

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[15] Public Interest Disclosure (Prescribed Persons) Order 2014.

[16] A disclosure of information which, in the reasonable belief of the worker making the disclosure, is made in the public interest and tends to show one or more of the types of wrongdoing or failure listed in section 43B(1)(a)-(f) of the Employment Rights Act 1996.

(c) Support for those who speak up

781. NHS England has developed a Freedom to Speak Up in Healthcare in England programme, in partnership with the National Guardian's Office and Health Education England. This programme is delivered in three parts: -

a. Speak Up: Core training for all workers (including volunteers, students, and those in training) on what speaking up is and why it matters.

b. Listen Up: Training for all line and middle managers focussed on listening up and the barriers that can get in the way of speaking up.

c. Follow Up: Training aimed at senior leaders (including executive board members and their equivalents, non-executive directors and governors) to help them understand their role in setting the tone for a good speaking up culture and how speaking up can promote organisational learning and improvement.

782. NHS England also provides 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 through the Speaking Up Support Scheme. The Speaking Up Support Scheme was introduced in 2019 (known then as the Whistleblowers Support Scheme) as a response to the recommendations from the Freedom to Speak Up Review. The Speaking Up Support Scheme provides a structured programme of support which includes:

a. health and wellbeing sessions;

b. one-to-one psychological wellbeing support;

c. career coaching;

d. personal development workshops; and

e. a range of practical support through group sessions.

783. We are exploring with the National Guardians Office whether it can include a notification of national policy adoption in the quarterly data return it gets from all organisations with a FTSU Guardian.

(d) Recent work in relation to speaking up

784. In November 2023, NHS England established a Task and Finish Group to bring together a group of subject matter experts to explore the effectiveness of escalation routes in cases of speaking-up in the context of complex cases, such as those involving a combination of suspected criminal conduct and patient safety concerns. **[SP/191, INQ0014766]**

785. This group is jointly chaired by Sir Andrew Morris and Dr Jayne Chidgey-Clarke, National Freedom to Speak Up Guardian. The membership of the group includes representation from a number of bodies including NHS England, Health Services Safety Investigations Body, Health and Care Professions Council, and Care Quality Commission.

786. The Task and Finish Group met for the second time on 15 January 2024 and a further meeting is to take place in February 2024, at which it is anticipated that a draft set of recommendations will be agreed.

787. The Group's primary focus is on considering the escalation routes in suspected criminal or serious patient safety cases, and whether there is potential to make improvements. It was also agreed at the Group that we would refresh the communications for Freedom to Speak Up, to ensure the policy and the roles and responsibilities of all partners is clear and better understood. This is particularly important as there is a recognition that over the last few years, there has been a lot of changes to senior leadership positions in the NHS, which reinforces the need to ensure the roles and responsibilities for Freedom to Speak Up is clear at every level: provider, Integrated Care Systems, regional and national levels.

(4) Addressing concerns raised by patients, carers and others

788. There is a detailed statutory framework that applies in relation to patient and carer complaints. This is supplemented by regulatory and contractual requirements, and by guidance, which includes guidance published by NHS England. All providers of NHS services and all commissioners, including NHS England in its direct commissioning role, are subject to these requirements.

789. This framework provides for various stages in relation to complaints, progressing through internal consideration and investigation of complaints through to external scrutiny and review. It also requires that each body subject to this framework ensures

appropriate governance and oversight of the processes and structures put in place to comply with the requirements. Concerns that do not take the form of a complaint will generally be dealt with informally and many NHS Trusts and NHS Foundation Trusts will have a Patient Advice and Liaison Service (PALS), who assist with this more informal aspect.

790. I would like to emphasise that there are no specific requirements in relation to investigating concerns or complaints that are specific to neonatal care.

791. The same fundamental requirements in relation to concerns and complaints apply in relation to all NHS services. These are:

    a. the statutory duties that all providers and commissioners of NHS services are subject to, by virtue of the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 ("the 2009 Complaints Regulations");

    b. the rights and pledges contained within the NHS Constitution, described further below at paragraphs 795 to 796;

    c. the Parliamentary and Health Service Ombudsman complaints standards; and

    d. the contractual obligations contained within the NHS Standard Contract, described below at paragraph 802.

792. Each of these matters is dealt with in turn below, and I then turn to the Patient Advice and Liaison Service and requirements relating to the monitoring and recording of complaints.

(a) Statutory complaints requirements

793. All providers and commissioners of NHS services are subject to a statutory duty[132] to handle complaints in accordance with the requirements of the 2009 Complaints Regulations. This includes primary care providers and independent sector providers.

794. The 2009 Complaints Regulations place a number of requirements on providers in relation to the handling and consideration of complaints. In summary, by virtue of the 2009 Complaints Regulations, providers must have arrangements in place to ensure the following.

a. Complaints are dealt with efficiently; properly investigated; and that appropriate action is taken in light of the outcome of a complaint.[17]

b. The Chief Executive Officer is designated as the Responsible Person (i.e. the person responsible for ensuring compliance with the requirements of the Complaints Regulations and ensuring action is taken in light of a complaint outcome).[18]

c. There is a complaints manager designated, who is responsible for managing the procedures for handling and considering complaints.

d. Complainants are treated with respect and courtesy; receive appropriate assistance to help them make a complaint; receive a timely and appropriate response (including progress updates); and are informed in writing of the outcome of the investigation of their complaint.

e. Written complaint investigation reports must be signed by the Responsible Person and explain how the complaint has been considered; the conclusions reached, any remedial action required and the Trust's view on what action it has taken/it intends to take. The written report must also set out the complainant's right to complain to the Parliamentary and Health Service Ombudsman.

f. Records are maintained of each complaint received, its subject matter and outcome.

g. An annual report is prepared, which provides an overview of all complaints received in the preceding year; the subject matter and outcomes (with a focus on thematic issues arising).

(b) NHS Constitution

795. These statutory requirements are reflected in the NHS Constitution, which provides as follows in relation to complaints and redress:

"Complaint and redress

[17] Regulation 3(1) and (2) of the 2009 Complaints Regulations.

[18] Regulation 4(2) of the 2009 Complaints Regulations.

Your rights

You have the right to have any complaint you make about NHS services acknowledged within three working days and to have it properly investigated.

You have the right to discuss the manner in which the complaint is to be handled, and to know the period within which the investigation is likely to be completed and the response sent.

You have the right to be kept informed of progress and to know the outcome of any investigation into your complaint, including an explanation of the conclusions and confirmation that any action needed in consequence of the complaint has been taken or is proposed to be taken.

You have the right to take your complaint to the independent Parliamentary and Health Service Ombudsman or Local Government Ombudsman, if you are not satisfied with the way your complaint has been dealt with by the NHS.

You have the right to make a claim for judicial review if you think you have been directly affected by an unlawful act or decision of an NHS body or local authority.

You have the right to compensation where you have been harmed by negligent treatment.

796. The NHS also pledges to:

a. "ensure that you are treated with courtesy and you receive appropriate support throughout the handling of a complaint; and that the fact that you have complained will not adversely affect your future treatment

b. ensure that when mistakes happen or if you are harmed while receiving healthcare you receive an appropriate explanation and apology, delivered with sensitivity and recognition of the trauma you have experienced, and know that lessons will be learned to help avoid a similar incident occurring again

c. ensure that the organisation learns lessons from complaints and claims and uses these to improve NHS services"

(c) The Parliamentary and Health Service Ombudsman Complaints Standards

797. In December 2022, the Parliamentary and Health Service Ombudsman issued Complaints Standards[19]. These standards include details of the Parliamentary and Health Service Ombudsman's expectations on how providers and commissioners will handle complaints, together with a model complaint handling procedure and detailed guidance on how the Complaint Standards can be applied in practice.

798. Prior to these standards being issued, the Parliamentary and Health Service Ombudsman published a document "My expectations for raising concerns and complaints in 2014". This was published in response to the government's response to the inquiry into the failings at Mid Staffordshire NHS Foundation Trust, Hard Truths. NHS England had no role in relation to that document.

799. NHS England expects providers to comply with the above, as part of their overall statutory and regulatory compliance.

(d) Contractual requirements

800. Providers of NHS services are also subject to contractual requirements around complaints and concerns, by virtue of the NHS Standard Contract.

801. As the commissioner of specialist neonatal services, NHS England requires the providers it enters into arrangements with for the delivery of these services to comply with the terms of the NHS Standard Contract, which in turn requires that the provider complies with its statutory obligations around complaints.

802. Throughout the Overall Relevant Period, the NHS Standard Contract has included provisions equivalent to the current Service Condition 16.2.1, which requires that the contracted party complies with the following:

    a. publish, maintain, and operate a complaints procedure in compliance with the fundamental standards of care and other applicable law and guidance;

    b. provide clear information to service users, their carers and representatives, and to the public, displayed prominently in the services environment as appropriate, on how to make a complaint or to provide other feedback and on how to contact Local Healthwatch

[19] See NHS Complaints Standards, Summary of expectations (December 2022)

c. ensure that this information informs service users, their carers and representatives, of their legal rights under the NHS Constitution, how they can access independent support to help make a complaint, and how they can take their complaint to the Parliamentary and Health Service Ombudsman should they remain unsatisfied with the handling of their complaint by the provider;[20]

d. continually review and evaluate the services they provide, act on insight derived from those reviews and evaluations, from feedback, complaints, audits, clinical outcome review programmes, patient safety incidents, and from the involvement of service users, staff, GPs and the public (including the outcomes of surveys), and must demonstrate at review meetings the extent to which service improvements have been made as a result and how these improvements have been communicated to service users, their carers, GPs and the public.[21]

803. The fundamental standards of care (incorporated as above into the NHS Standard Contract), require in respect of complaints that:

a. any complaint received by an NHS Trust must be investigated and necessary and proportionate action must be taken in response to any failure identified by the complaint or investigation;[22]

b. every NHS Trust must establish and operate effectively an accessible system for identifying, receiving, recording, handling, and responding to complaints by service users and other persons in relation to the carrying on of the Trust's regulated activities (which include, inter alia, treatment of disease, disorder or injury, personal care, surgical procedures, diagnostic and screening procedures, maternity and midwifery services, nursing care, and ancillary activities[23;24]

c. an NHS Trust must provide to the Care Quality Commission, when requested to do so and within 28 days of receiving such a request, a summary of:

d. complaints made to the NHS Trust under the Trust's complaint system;

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20 NHS Standard Contract Condition 16.2.2
21 NHS Standard Contract Condition 3.4
22 Regulation 16(1) of the 2014 Regulations
23 Regulation 16(2) of the 2014 Regulations
24 Schedule 1 of the 2014 Regulations

e. responses made by the NHS Trust to such complaints (and any further correspondence with the complainants in relation to such complaints); and

f. any other relevant information in relation to such complaints as the Care Quality Commission may request.[25]

804. The way in which Regional Teams considered complaints and concerns data as part of their management of commissioned providers and overall provider oversight during the First Relevant Period and the early part of the Second Relevant Period has been described above in Section 2.

(e) Patient Advice and Liaison Service

805. In terms of how Trusts operationalise these statutory, regulatory and contractual requirements, most will have a Patient Advice and Liaison Service, which provides a point of contact for patients, families and carers. Patient Advice and Liaison Service assists with resolving concerns or problems and also signpost to the complaint process.

(f) Recording and monitoring of complaints

806. From the above, it is clear that the following bodies have a role in relation to complaints handling by NHS Trusts and NHS Foundation Trusts:

a. the Care Quality Commission, who are the body to which commissioned providers of neonatal services must report to, under the terms of the NHS Standard Contract, as summarised above;

b. the Parliamentary and Health Service Ombudsman, to whom complainants can refer complaint-related issues to, pursuant to the 2009 Complaints Regulations and whose published Complaint Standards set out expectations for NHS Trusts and NHS Foundation Trusts, including through the publication of a model complaint handling procedure and detailed guidance on how the Standards can be applied in practice;

c. NHS England as commissioner, when monitoring and managing performance of the NHS Standard Contract requirements (but noting that the Care Quality Commission is the designated body to whom complaints data must primarily

25 Regulation 16(3)(c) of the 2014 Regulations

be reported to and who would be the key regulatory body that assesses complaints compliance and effectiveness, as part of its regulation of compliance with the assessed standards);

d. NHS England in its assurance and oversight role as the recipient of NHS Trust and NHS Foundation Trust annual reports;

e. Integrated Care Boards (preforming a similarly dual role as NHS England, i.e. in both the capacity of commissioner of services and system assurance).

807. As a commissioner, NHS England maintains records of complaints made to it in that context. These records are kept for a minimum of 10 years, in accordance with NHS England's retention of records schedule **[SP/0192, INQ0014735].**

808. Beyond this, however, where a complaint is made directly to a provider, that provider would maintain its own records and NHS England does not have access to this information. Each NHS Trust and NHS Foundation Trust is required to provide aggregated data on their complaint statistics. Prior to the COVID-19 pandemic, this data needed to be submitted quarterly. However, this has subsequently been reduced to an annual return in order to minimize the burden on providers. The data is published on the (old) NHS Digital website **[SP/0193, INQ0014792]**.

809. NHS England monitors trends and themes in relation to complaints (using a range of data sources, including the annual reports submitted by NHS Trusts and NHS Foundation Trusts). This is carried out as part of the Freedom to Speak Up directorate.

810. NHS England will sometimes also support through carrying out targeted reviews of provider complaints processes. For completeness we note that one such recent review was carried out in relation to the Countess of Chester Hospital. This review took place in May 2022 **[SP/0194, INQ0014732]**, when NHS England's National Head of Complaints was part of a team that visited the Countess of Chester Hospital to review their complaints process. This review was requested by the Deputy Director of Nursing for NHS England's North West Regional Team, in light of concerns raised by the Care Quality Commission in its 30 September 2022 inspection report.

(5) Responsible officers and reporting to professional regulatory bodies

811. There are requirements upon certain individuals nominated or appointed as Responsible Officers by designated bodies pursuant to the Medical Profession

(Responsible Officers) Regulations 2010. Designated bodies include NHS England, Integrated Care Boards, NHS Trusts and NHS Foundation Trusts. Every designated body must nominate a responsible officer. The responsibilities of responsible officers are in summary:

a. to ensure that the designated body carries out regular appraisals on medical practitioners;

b. to establish and implement procedures to investigate concerns about a medical practitioner's fitness to practise raised by patients or staff of the designated body or arising from any other source;

c. where appropriate, to refer concerns about the medical practitioner to the General Medical Council;

d. where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the General Medical Council, to monitor compliance with those conditions or undertakings;

e. to make recommendations to the General Medical Council about medical practitioners' fitness to practise;

f. to maintain records of practitioners' fitness to practise evaluations, including appraisals and any other investigations or assessments.

812. These obligations are not imposed upon provider bodies but on individual practitioners nominated or appointed to the role of responsible officer.

813. The above regulations relating to responsible officers apply only in relation to professionals registered with the General Medical Council. There are no equivalent regulations relating to other registered professionals. However, NHS England has a general expectation that where concerns arise in relation to an individual who is a member of a regulated profession then where concerns arise an appropriate reference would be made to their regulatory body.

(6) Controlled Drugs Accountable Officers

814. There are information sharing functions relating to the management and use of controlled drugs, and this is dealt with at paragraphs 896 and 900 below in the context of medicines management.

(7) Patient safety incident reporting

815. The above parts have addressed concerns raised by NHS workers, and by service users. We now describe the Patient Safety Incident Response Framework and the expected improvements this will enable in patient safety response and learning.

816. By way of brief background, concerns about the effectiveness of the previous Serious Incident frameworks have been raised in almost every previous inquiry, investigation and review into the NHS or a specific NHS organisation, from the Government response to the Freedom to Speak Up Consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation.

817. In the period 2015-2016 a number of specific reports brought this issue to the fore. These reports included:

    a. the Public Administration Select Committee report in March 2015 on investigating clinical incidents in the NHS;

    b. the Government of the time's response "Learning not Blaming" to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation in July 2015;

    c. the Parliamentary and Health Service Ombudsman's report on complaints investigations related to harm in December 2015;

    d. the Care Quality Commission's report on learning from Serious Incidents in acute hospitals in June 2016; and

    e. the Care Quality Commission's Learning, Candour and Accountability report in December 2016.

818. In response to these reports, in March 2018, NHS Improvement launched an engagement programme around the future of NHS patient safety investigation to gather thoughts and feedback to support the development of a new approach **[SP/0195, INQ0014690]**. A summary of that work was published in November 2018 **[SP/0196, INQ0014704]**.

819. At the same time the National Patient Safety Team launched a consultation on developing the NHS's first overarching Patient Safety Strategy **[SP/0197, INQ0014705].** This work, in combination with the engagement exercise on the future of NHS patient safety investigation, led to the commitment in the new NHS Patient Safety Strategy published in July 2019 to create a new 'Patient Safety Incident Response Framework'.

820. A draft 'introductory' version of the Patient Safety Incident Response Framework was published in March 2020 and tested by 24 'early adopters' including 17 provider organisations alongside their commissioning bodies. The early adopter programme was independently evaluated, with the learning from this process informing the development of the Patient Safety Incident Response Framework published in 2022 alongside a 12-month preparation guide.

821. Implementation of Patient Safety Incident Response Framework is required by the NHS Standard Contract and organisations were expected to implement the Patient Safety Incident Response Framework in the Autumn of 2023.

822. The new Patient Safety Incident Response Framework has four key aims:

    a. Compassionate engagement and involvement of those affected by patient safety incidents.

    b. Application of a range of system-based approaches to learning from patient safety incidents.

    c. Considered and proportionate responses to patient safety incidents.

    d. Supportive oversight focused on strengthening response system functioning and improvement.

823. Unlike the predecessor Serious Incident Framework 2015, the Patient Safety Incident Response Framework makes no distinction between 'patient safety incidents' and 'Serious Incidents'. Instead, the Patient Safety Incident Response Framework promotes a proportionate approach to responding to patient safety incidents.

824. Organisations are required to develop a thorough understanding of their patient safety incident profile, ongoing safety actions (in response to recommendations from investigations) and established improvement programmes and to use that information

to inform what the organisation's proportionate response to patient safety incidents should be.

825. The organisation's understanding of their patient safety incident profile should then be used alongside effective stakeholder engagement, including with patients and the public, to create a Patient Safety Incident Response Plan. This Plan is then used to guide how the organisation responds to individual incidents. the form the response takes. NHS England has published a template Incident Response Plan as part of the core materials to support the Patient Safety Incident Response Framework. This suite of guidance documents relating to the Patient Safety Incident Response Framework is provided with this statement **[SP/0198, INQ0014737] [SP/0199, INQ0014743] [SP/0200, INQ0014742] [SP/0201, INQ0014738] [SP/0202, INQ0014739] [SP/0203, INQ0014740] [SP/0204, INQ0014741]**.

826. The Inquiry has specifically asked about the process of engaging with families in respect of patient safety incidents.

827. The Patient Safety Incident Response Framework emphasises the central importance of engagement and involvement with families. Under the Patient Safety Incident Response Framework there will be greater engagement with those affected by an incident, including patients, families and staff. Ensuring they are treated with compassion and able to be part of any investigation.

828. The 'Guide to engaging and involving patients, families and staff following a patient safety incident', **[SP/0198, INQ0014737]** published alongside the Patient Safety Incident Response Framework, sets out expectations for how organisations should engage with all those affected by patient safety incidents. Organisations should work hard to answer any questions and to involve those affected in patient safety incident investigations. Put simply, involvement should begin from the point at which an incident is identified and throughout any investigation, in so far as the patient/family wish to be involved. It should also extend beyond the close of any investigation if the patient/family wish to be involved in ongoing improvement work.

829. Work is underway to explore how to support patients' ability to input their experiences of safety events to support learning. At present this may come through local or national complaints, online feedback, Patient Advice Liaison Services, or direct to the national safety team. A discovery phase has been completed to explore the best way for patients to record their experiences, the output from which was published in October

2023 **[SP/0205, INQ0014788]**. This report recommends that future additions to the Learn From Patient Safety Event service (see further below at paragraph 843) should be designed to enable local response to, and management of, any safety issues raised alongside feeding relevant data into the national team as part of their surveillance work; and the continuation of the ability for anonymous reporting by patients and families if they so choose.

(a) Obligations to Report Incidents to the Care Quality Commission

830. In addition to the above systems of patient safety incident reporting, providers also have a statutory responsibility to notify Care Quality Commission about a specified set of patient safety incidents.

831. Regulation 16 of the Care Quality Commission (Registration) Regulations 2009 requires providers to notify Care Quality Commission of the deaths of service users where the death "cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care and treatment".

832. Regulation 18 of the Care Quality Commission (Registration) Regulations 2009 requires providers to notify Care Quality Commission of 'injuries' to service users that are permanent, cause prolonged pain or prolonged psychological harm or require action to be taken to prevent death of the service user.

833. In practice, NHS Trusts and NHS Foundation Trusts satisfy this reporting requirement by entering incident information onto the reporting systems managed by NHS England. Currently that may be either the National Reporting and Learning System or the Learning From Patient Safety Event Service (explained at Annex 2). Information entered onto either of these systems is shared with the Care Quality Commission.

834. While the Patient Safety Incident Response Framework no longer distinguishes between serious incidents and other patient safety incidents, the 'threshold' for reporting in the Care Quality Commission (Registration) Regulations do not require incidents to be reported which do not meet the thresholds of Regulation 16 or 18, above.

835. In the case of both Regulation 16 and 18 the test involves the "reasonable opinion of the registered person" in deciding whether or not a report should be made. Determining when an incident has occurred, the extent to which that incident has

caused harm, and the level of harm caused, are all judgements. In this sense, the Care Quality Commission reporting requirements remain more closely aligned with the former Serious Incident frameworks.

(b) Maternity and Newborn Safety Investigation Programme

836. Separately to the requirements of Regulations 16 and 18 of the Care Quality Commission (Registration) Regulations 2009 are the obligations to report in the context of the Maternal and Newborn Safety Investigation programme. This programme is conducted by the Care Quality Commission pursuant to the Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023. Pursuant to these Directions the Care Quality Commission is required to undertake various investigations, including those relating to intrapartum stillbirths, early neonatal deaths where a baby dies within the first 0-6 days of life, and those arising from severe brain injuries arising within the first 7 days of life.

837. NHS England is not responsible for this programme, which is hosted by CQC.

(c) Statutory Child Death Reviews

838. It is mandatory under the Children Act 2004 for a child death review to take place following the death of a child and it is a statutory requirement for child death review partners in England to carry out child death reviews. Under the Children Act 2004, 'child death review partners' are defined as the local authority and any Integrated Care Board. The work in this area was sponsored by the Department of Health and Social Care and the Department for Education and the "Child Death Review Statutory and Operational Guidance (England)" was published jointly by these departments.

839. Child death reviews are part of the wider framework relating to the safeguarding of children, with the learning from child death reviews being shared with the National Child Mortality database (see further below in the table at paragraph 862), with a view to identifying trends in, or similarities between, deaths.

840. You have asked us whether NHS England had any involvement in setting up Child Death Overview Panels. We can confirm that NHS England did not have any involvement at a national level in relation to the setting up of Child Death Overview Panels or in how the panels operate.

(8) Data Systems, Monitoring and Audits

841. Above we have addressed the way in which concerns relating to patient safety and quality are identified and the relevant processes and procedures that apply. In this part we will address the issue of the systems, arrangements, programmes and audits by which data is gathered in relation to patient safety events and in relation to neonates more broadly for the purposes of monitoring and benchmarking.

(a)Learn from Patient Safety Events

842. As described in Section 1B, NHS England has developed and is in the process of implementing an updated data system through which incident reporting data will be obtained, analysed and shared. This is alongside the introduction of the Patient Safety Incident Response Framework (referred to at paragraphs 354 to 356 above).

843. There are a number of planned areas for further development of the Learn From Patient Safety Events Service currently being explored by the National Patient Safety Team, including;

    a. exploring how to support patients' ability to input their experiences of safety events to support learning. A discovery phase has been completed to explore the best way for patients to record their experiences as referred to above in relation to the Patient Safety Incident Response Framework at paragraphs 924 to 930.

    b. adding a streamlined maternity safety notification module to the service, as some types of maternal and neonatal issues currently require reporting to several different systems or organisations. The National Patient Safety Team are working with users to create an efficient system that re-uses the Learn From Patient Safety Event platform and reduces duplicated effort for staff, with better data sharing between key partners.

844. All organisations are expected to have connected to Learn From Patient Safety Event Service by the end of the 2023/24 financial year.

(b) Data sets and clinical audits

845. The care of a neonate within the neonatal unit is informed by separate clinical interactions in maternity prior to the neonatal stay (**Figure 3**). Similarly, information collected during the neonatal stay is necessary to inform subsequent care packages in

other clinical services. Neonatal data is inputted into Badgernet (acquired by System C from CleverMed in 2023) by each neonatal unit in England and the data is used for the following important data flows:

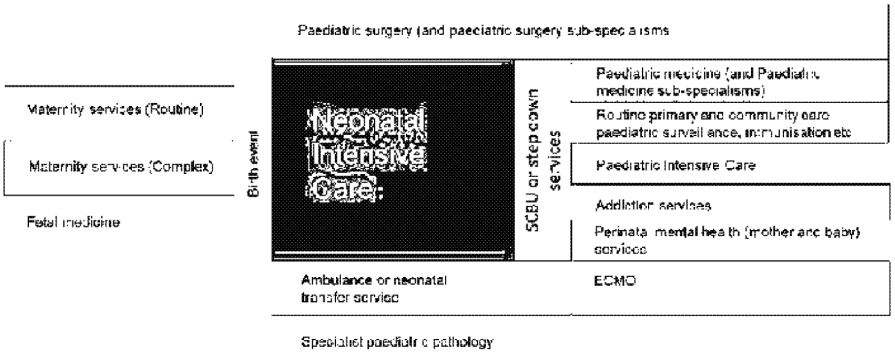
a. Neonatal Critical Care Minimum Data Set (NCCMDS) – Sourced from Badgernet data by NHSE and required as a weekly submission of data to the Secondary Uses Service (SUS) for onward distribution to commissioners.

b. National Neonatal Audit Programme (NNAP) – Sourced from Badgnet data by the Royal College of Paediatrics and Child Health.

c. National Neonatal Research Database (NNRD) – Sourced from BadgerNet data by the Neonatal Data Analysis Unit (NDAU), Imperial College London, who maintain and administer the database.

846. Badgernet (System C) is a commercial provider and trusts are not obligated to procure this system. In practice the Badgernet system has been used by all trusts on the basis of it being considered the best system for neonatal data, despite its use not being mandated.

Figure 3: Interactions with neonatal intensive care in the healthcare setting



847. Figure 4 below shows the current data flows and uses of Badgernet data locally and nationally for various different purposes, including safety audit and quality improvement, research, service evaluation, commissioning and benchmarking.

(c) Requirement to provide information for data sets

848. The 2012 Act enables organisations to be mandated to provide data for the purposes of specified Information Standards Notices. NHS Trusts and NHS Foundation Trusts have been mandated in this way, as described further below.

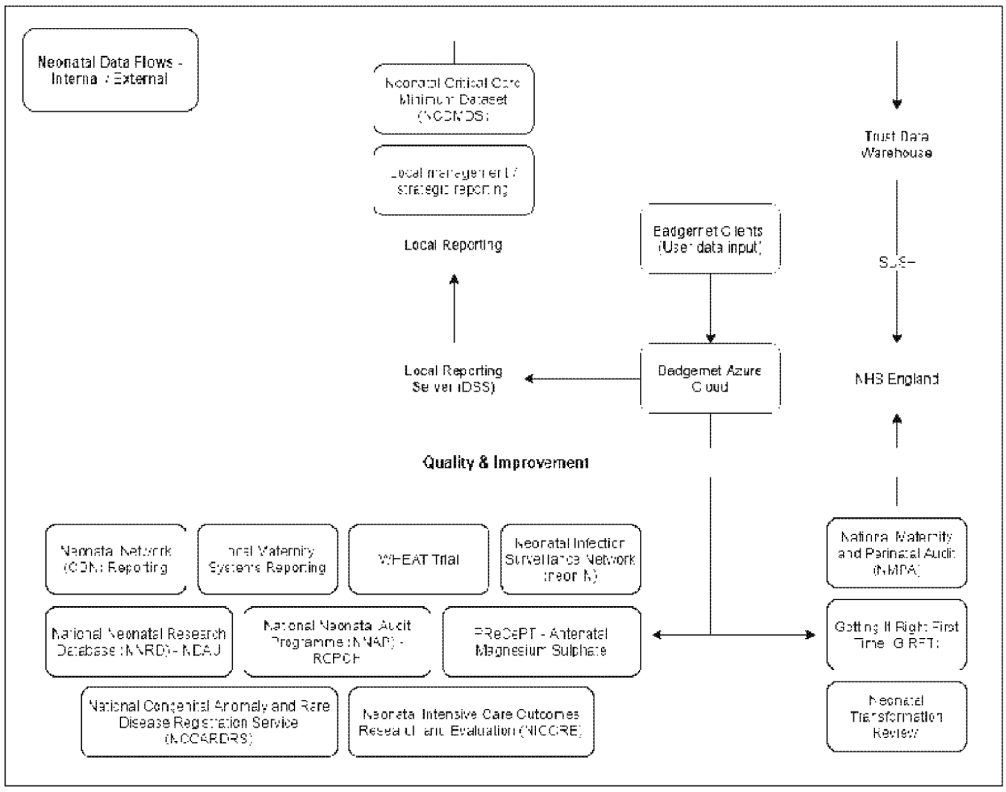


Figure 4: Neonatal Data Flows – Internal/External.

(d) Maternity services data set

849. Although the focus here is on neonatal data sets, the interconnected nature of maternity and neonatal services means that we need to briefly explain the Information Standards Notice DCB1513: Maternity Services Data Set ("**Maternity Services Data Set**") **[SP/0206, INQ0014701]**. This is the national information standard for data relating to NHS-funded maternity services. It sets out requirements for the collection and submission of operational and clinical data relating to each stage of the maternity care pathway, thereby enabling secondary uses of the data for such purposes as commissioning, payment, planning, outcomes monitoring and addressing health inequalities.

850. The Maternity Services Data Set is a patient-level data set that captures information about activity carried out by maternity services relating to a mother and baby, from the point of the first booking appointment until mother and baby are discharged from maternity services. It provides detail as to the data to be submitted to NHS England. [Exhibit].

851. From a neonatal perspective, the data to be submitted includes data relating to neonatal admission, provisional diagnosis relating to a neonatal admission, and the subsequent diagnosis relating to a neonatal admission. Whilst this data set is not focussed on information relating to a neonate, it does gather some limited information in relation to a neonate.

852. All information within the scope of the Maternity Services Data Set will be collected in relation to each baby until the point at which they are discharged from maternity services. This information is submitted to NHS England on a monthly basis and provides a national picture of maternity service activity in that month.

853. Data collected in this way is then utilised in the Maternity Services Dashboard **[SP/0207, INQ0014776]**. The Maternity Services Dashboard supports the recommendation from Better Births to develop a nationally agreed set of indicators and Clinical Quality Improvement Metrics to help local maternity systems track, benchmark and improve the quality of maternity services. Additional demographic data, including data on maternal age, BMI and ethnicity informs a population based understanding.

854. The National Maternity Indicators are annually published indicators drawn from external data sources such as MBRRACE-UK, the Care Quality Commission Maternity Survey, NHS Staff Survey and the General Medical Council Survey. These indicators have been selected to provide a holistic picture of the performance of maternity services. They cover five different domains including mortality and morbidity, choice and continuity of carer, clinical care and health promotion, organisational culture and user experience.

(e) <u>Neonatal data set</u>

855. The current Information Standards Notice relating specifically to neonatal care data is reference DAPB1595 Amd 30/2022 which was approved on 26 May 2022 and published on 13 June 2022. It is named Neonatal Data Set, Version 2.0. This Information Standards Notice replaces previous notices and is described as follows:

"The Neonatal Data Set (NDS) is a secondary uses, patient-level, data set that captures key information recorded for the purposes of direct care at each stage of the neonatal critical care pathway including:

a. *demographics*

b. *diagnoses*

c. *daily interventions and treatments*

d. *care processes*

e. *outcomes*

f. *follow up health status at age 2 years.*

Data are currently captured for all babies admitted to NHS-funded neonatal units, primarily in respect of:

a. *mothers of babies admitted*

b. *babies admitted.*

Data is submitted to the Neonatal Data Analysis Unit at Imperial College London on a quarterly basis. Following receipt, any personal information is removed before adding to the National Neonatal Research Database (NNRD).

The data supports national audits, national policy development, national quality improvement, and approved research studies."

856. The full extent of data collected pursuant to the Neonatal Data Set Information Standard Notice is set out in the following:

a. Data Set Specification — Episodic Daily (Amd 30/2022);

b. Data Set Specification — Two Year Follow Up (Amd 30/2022).

857. The data provided in relation to this data set are extracted from the BadgerNet system operated by all trusts in relation to neonatal data.

858. The Neonatal Data Analysis Unit website states that the National Neonatal Research Database "is available to support audit, evaluations, bench-marking, quality

improvement and clinical, epidemiological, health services and policy research to improve patient care and outcomes". The Neonatal Data Set is a national resource for use by all researchers and is also used for service evaluations and audits.

(f) Neonatal critical care minimum dataset

859. The Information Standards Notice in respect this data set is under reference SCCI0075 and 112/2015 and is described as follows:

"The Neonatal Critical Care Minimum Data Set (NCCMDS) provides a record of what happens to a patient when they receive neonatal critical care in a Neonatal Intensive Care Unit (NICU), Maternity Ward or Neonatal Transitional Care Ward. Version 1.0 of the NCCMDS was introduced in April 2007.

The primary purpose of the NCCMDS is to allow the operation of the National Tariff Payment System (NTPS) within neonatal critical care. It supports the NTPS by specifying and facilitating the capture of data needed to generate a Neonatal Critical Care Healthcare Resource Group (HRG) for each calendar day (or part thereof) of a period of neonatal critical care.

The HRGs are, in turn, used for:

a. *Reimbursement*

b. *Commissioning*

c. *cost monitoring*

d. *workload planning (clinical and non-clinical)*

e. *benchmarking.*

Data is collected by specified providers of neonatal care and sent directly to NHS Digital's Secondary Uses Service (SUS), as a subset of the Admitted Patient Care Data Set (in turn a subset of the Commissioning Data Sets, ISB 0092).

This information standard is maintained by the National Casemix Office within NHS Digital. It is related to SCCI0076 Paediatric Critical Care Minimum Data Set, in that it shares common fields and values, including an agreed list of Critical Care Activity Codes."

(g) Monitoring of data trends and clinical audit trails

860. Service Condition 26.1 of the NHS Standard Contract provides that a provider must:

a. participate in any national programme within the National Clinical Audit and Patient Outcomes Programme;

b. any other national clinical audit or clinical outcome review programme managed or commissioned by HQIP; and

c. any national programme included within the NHS England Quality Accounts List for the relevant Contract Year.

861. The National Clinical Audit and Patient Outcomes Programme is commissioned by the Healthcare Quality Improvement Partnership ("HQIP"), on behalf of NHS England. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Outcomes Programme, which comprises of a number of projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded primarily between NHS England and the Welsh Government.

862. Among the projects within the National Clinical Audit and Outcomes Programme are the following.

Audit / Programme	**Purpose**	**Reports produced**	**Frequency**
National Maternity and Perinatal Audit	This audit is led by the Royal College of Obstetricians and Gynaecologists in partnership with the Royal College of Midwives, the Royal College of Paediatrics and Child Health and the London School of Hygiene and Tropical Medicine. It is intended to assist in understanding the maternity journey by bringing together information about maternity care and information about hospital admissions. The audit is one strategy used to understand the care and	Annual clinical audit – reporting against a specific set of maternity and perinatal measures including timing of birth, modes of birth, maternal measures, and measures of care for newborn babies. The audit makes recommendations for potential service improvements. Organisational Surveys – intended to provide an overview of care	Annual Clinical Audit – most recent report is from 2022 and reports on data from 1 April 2018 to 31 March 2019. Organisational Surveys – most recent report is from 2019, and

Audit / Programme	Purpose	Reports produced	Frequency
	outcomes experienced by women and birthing people, and to highlight areas of potential service improvement. The reports produced by this audit programme use centralised data primarily in England from the Maternity Services Data Set referred to above.	provision in maternity services in all settings across England, Scotland and Wales. Sprint Audits – to evaluate the feasibility of introducing new clinical measures.	prior to that 2017. Sprint Audits – ad hoc and dependent upon the matter being reported on.
Paediatric Intensive Care Audit Network	This audit network was established in 2001 by the Universities of Leeds, Leicester and Sheffield. This is an audit database recording details of the treatment of all critically ill children in paediatric intensive care units. This audit reports on the following five key metrics relevant to paediatric intensive care services: • case ascertainment including timeliness of data submission; • retrieval mobilisation times; • emergency readmissions within 48 hours of discharge; • unplanned extubation in PICU; and • mortality in PICU. The audit gathers data directly from providers by way of either referral, admission or transport forms. These forms gather patient details, admission details, diagnoses and procedures, daily interventions and discharge information. The reason for gathering each type of data is explained in the audits Web Admission Dataset	State of the nation reports.	The most recent report published in 2023 describes paediatric critical care activity occurring in PICUs in the UK and ROI during 2020 to 2022 **[SP/0208, INQ0014767].**

Audit / Programme	Purpose	Reports produced	Frequency
	Manual [**SP/0209, INQ0014769**]. The information is then used to report against the key metrics referred to above and to make recommendations within annual reports for improvement in the provision of services based on the analysis of the data received.		
Maternal, Newborn and Infant Clinical Outcome Review Programme	This programme is undertaken by MBRRACE-UK. It aims to provide robust national information to support the delivery of safe, equitable, high quality, patient centred maternal, newborn and infant health services. MBRRACE-UK conducts the following as part of this programme: • surveillance of all maternal deaths; • confidential enquiries into maternal deaths during and up to one year after the end of a pregnancy; • confidential enquiries into cases of serious maternal morbidity; • surveillance of perinatal deaths including late fetal losses, stillbirths and neonatal deaths; and • confidential enquiries into stillbirths, infant deaths and cases of serious infant morbidity.	MBRACCE-UK produces three types of reports: • confidential enquiry into maternal deaths reports; • perinatal mortality surveillance reports; and • perinatal mortality and morbidity confidential enquiry reports. An online interactive tool is also published which can be used by Trusts to see their own data and to benchmark against others.	The first perinatal mortality surveillance report for Trusts and Health Boards was published in December 2015 in respect of births from January to December 2013. The most recent perinatal mortality surveillance reports were published in October 2023 in respect of data to 2021. Multiple reports are now being published annual as state of nation themed reports

Audit / Programme	Purpose	Reports produced	Frequency
			alongside the perinatal mortality surveillance report.
National Child Mortality Database Programme	This is a national programme delivered by the University of Bristol which collates data collected by Child Death Overview Panels in England from reviews of all children who die at any time prior to their eighteenth birthday. The purpose of doing so is to ensure that lessons are learned from deaths, and that learning is shared as widely as possible, and actions taken locally and nationally to reduce preventable child deaths in future. Each year the programme publishes a Child Death Review Data Release online on the website of the programme. This programme publishes annual reports and thematic reports.	Reports are published on the website of the National Child Mortality Database, recent examples including a thematic review of vulnerability which increases the risk of poor outcome in infants, and infection related deaths of children and young people in England. The reports draw out learning and recommendations for service providers and policy makers, and are produced utilising data from the National Child Mortality Database	No annual report. Frequency depends upon the nature of matters to be reported on and nature of the report.
National Neonatal Audit Programme	This programme is delivered by the Royal College of Paediatrics and Child Health and relies upon data extracted from the BadgerNet system. It assesses whether babies admitted to neonatal units receive consistent high-quality care in relation to the specified audit measures that are aligned to a set of professionally agreed guidelines and standards. The audit measures vary year on year but are categorised into the following themes:	Interactive reporting tool providing access to audit results, which enables the user to: • view annual summary reports for a neonatal unit or network for the years 2014 to 2022 • view and compare results for specific NNAP audit measures for neonatal units, unit	Online interactive tool most recent data is for 2022. Most recent summary report is for 2022 (data gathered from 1 January to 31 December 2022). **[SP/0210, INQ0014768]**

Audit / Programme	Purpose	Reports produced	Frequency
	• Outcomes of neonatal care • Optimal perinatal care • Maternal breastmilk feeding • Parental partnership in care • Neonatal nurse staffing • Care processes • Overall network performance	designations or networks • view whether a 2022 result for a unit or network is outside the expected range • download unit specific poster to display in units Annual summary data reports published in December the following year summarising key messages and national recommendations.	
Perinatal Mortality Review Tool Programme	This programme is commissioned with the aim to improve the quality of reviews of the deaths of babies who die soon after birth. The PMRT is designed so that high quality, standardised review of care of the mother during pregnancy and childbirth, and the care of the baby after child-birth is carried out. The PMRT is a web based interactive tool that guides the review process to ensure that all aspects of care are considered and are reviewed against national guidelines and standards. The review is led by the hospital where the baby died and identifiable information is used. The report of the review produced by the PMRT is included in medical records and used as the basis of discussion at follow up meetings with parents.	Annual reports of findings from reviews completed using the PMRT. **[SP/0211, INQ0014770]** Local summary reports.	The programme commenced in 2018 with the first annual report being published in October 2019. The most recent report from October 2023 reports on 2022 data.

Audit / Programme	Purpose	Reports produced	Frequency
	The programme is led by MBRRACE-UK.		

863. Each of the above use data either directly obtained from providers and/or other information obtained via one of the above Information Standards. Information specific to neonatal services, as explained above, arises in all cases from data input into the BadgerNet system by individual neonatal units. The output from these audits and programmes provides valuable information to enable lessons to be learned and improvements in the quality of maternity, neonatal and perinatal services across the NHS. The National Maternity and Perinatal Audit also feeds into the Maternity Services Dashboard referred to above via the National Maternity Indicators to assist in providing a holistic picture of the performance of maternity services.

(h) Local Reporting and Monitoring of Data

864. In addition to the above, NHS England expects that services will utilise data from their systems at a local level, alongside that referred to above, in order to obtain assurance and monitor data trends.

865. In June 2023 NHS England wrote to each of its Regions to gather information about how assurance is received at a local level in relation to the safety of neonatal services. NHS England asked all regions the following questions:

a. what data you are looking at routinely to provide commissioner assurance

b. what groups/meetings you have routinely in the region to review neonatal services – any concerns, identify trends, pick up outliers etc

c. are there any processes followed to pick up in real time any concerns

d. how are follow up actions documented and followed up in formal governance structures

e. are there clear roles and responsibilities set out about who has the lead or receiving and acting on the information

866. The responses to these queries revealed that there are varying approaches adopted in relation to each region. NHS England is currently in the process of considering the

responses from each region with a view to understanding what reflects the most appropriate practice at a local level.

(i) Development of an Early Signals Monitoring Tool

867. In May 2023, a Maternity and Neonatal Outcomes Group was set up by NHS England to address the first recommendation in the independent report "Maternity and neonatal services in East Kent: 'Reading the Signals' report". Dr Edile Murdoch, Chair of the Maternity and Neonatal Outcomes Group, is leading a programme of work, supported by Bill Kirkup and David Spiegelhalter, to further improve the use of data in maternity services. The group is developing an early warning surveillance tool using more timely outcome data to identify potential issues earlier for Trust Boards to act on as well as identify the services needing support. Recommendations from this group will be reported later in the autumn, with the tool intended to be operational before the end of 2024.

868. On neonatal data, NHS England are working with national partners such as the Neonatal Audit Programme and the National Maternity and Perinatal Audit to reduce the burden for providers and improve data quality. The Maternity and Neonatal Outcome Group is one of a number of groups established to ensure that the NHS has the right data to identify maternity and neonatal services with safety risks in advance of them materialising, so as to channel the appropriate support under the Perinatal Quality Surveillance Model. All of these groups are coordinated by a Reading the Signals Data Coordination Group, and sit alongside the Maternity and Neonatal Outcomes Group.

(9) Security

869. The Inquiry have asked us to explain NHS England's role in relation to various security arrangements on neonatal wards, including CCTV and medicines management. We address these below.

(a) CCTV

870. NHS England provides best practice guidance on the design and planning of healthcare buildings, the adaptation/extension of existing facilities, and the safe operation of healthcare facilities (including maternity and neonatal units) through Health Technical Memoranda and Healthcare Building Notes. These technical guidance notes address various core subjects around the construction and operation

of the NHS built environment, and sit alongside other NHS estates related guidance such a Estates Technical Bulletins contained in miscellaneous NHS estates related standards and guidance **[SP/0212, INQ0014787]**.

871. When responsibility for these technical guidance notes transferred to NHS England in 2017, NHS England commenced a rolling review programme to update all 107 technical guidance notes on the NHS built environment. NHS England routinely undertakes prioritisation exercises as part of this rolling programme to prioritise technical guidance notes for review. Those relevant to maternity and neonatal (described below) are due to be updated in 2024 as part of this rolling programme.

872. Simultaneously, NHS England is preparing a national infrastructure survey to assess the current condition of the maternity and neonatal estate, identify future needs and opportunities for improvement, and develop recommendations for investment **[SP/0213, INQ0014809]**.

873. Guidance relating to the security of maternity care facilities is contained in Health Building Note 09-02 **[SP/0214, INQ0014616],** originally published by the Department of Health and Social Care and then the Department of Health in 2013 and which remains relevant. Similarly, guidance relating to neonatal units is contained in Health Building Note 09-03 **[SP/0215, INQ0014617],** originally published by the Department of Health and Social Care and then the Department of Health in 2013 and which also remains relevant[26].

874. Both of the above Health Building Notes recognise the importance of security as a design consideration. Health Building Note 09-03 recognises the importance of security for staff, mothers and babies and provides at paragraph 5.1:

> *"A robust system must be in place for their protection. Babies born in hospital should be cared for in a secure environment to which access is restricted. An effective system of staff identification is essential. A robust and reliable baby security system should be enforced, such as closed-circuit television, alarmed mattresses. Strict criteria for the labelling and security of the newborn infant are essential" ('Safer childbirth: Minimum standards for the organisation and delivery of care in labour'; RCAnae, RCM, RCOG and RCPCH, 2007).*

[26] Further guidance on the use of CCTV is provided in HBN 26 Surgical Procedures in Acute General Hospitals, HBN 10-02 Facilities for Day Surgery Units, and HBN 16 Mortuaries. We have not set out the contents of these in detail here but focussed on those Health Building Notes directly relevant to maternity and neonatal units.

875. Health Building Note 09-03 does, however, note that security systems should not compromise the ability of staff to carry out their work or to respond to emergencies when required.

876. Reference is made to Health Building Note 09-02[27] which further provides that:

a. Babies born in hospital should be cared for in a secure environment to which access is restricted.

b. An effective system of staff identification is essential.

c. A robust and reliable baby security system should be enforced, such as baby tagging, closed-circuit television, alarmed mattresses.

d. Strict criteria for the labelling and security of the newborn infant are essential.

e. The number of entry and exit points to the unit should be reduced to a minimum. Public access and egress should be limited to one door, which should be in the vicinity of and with good natural surveillance from the reception desk/staff communication base; although security should not solely rely on the presence of staff/observation.

f. The use of centrally managed access control using one of the following systems should be considered essential: swipe card, proximity or biometric recognition. Swipe cards are considered the least secure, with biometric recognition being the most secure. Digital code locks should be avoided. Where this is not possible, access/egress controls to wards should be operated at ward level.

g. The importance of CCTV as an aspect of security management is noted, with a particular focus on its relevance to preventing and/or detecting abductions.

"Overt and well-publicised CCTV cameras should be installed at all entrances to the unit. Where the unit is only one department within a larger health facility building, consideration should be given to installing CCTV at all exits from the building in order to maximise the opportunity for detecting, identifying and apprehending an abductor. Previous infant abductions have

[27] This in turn refers to general security guidance, contained within Health Building Note 00-01 and Health Technical Memorandum 00.

shown that abductors generally plan their abductions thoroughly, which includes visiting different maternity units to establish security strengths and weaknesses. CCTV should ideally be monitored and recorded at the security control room. Digital recording is now normal practice as it allows for instant retrieval of images while the system is still recording and being used during an incident."

h. A system of electronic tagging of babies may be considered but it is noted in that some centres have experienced practical difficulties with such mechanisms.[28]

i. A separate, differently-coloured identification badge is commonly used to denote staff permitted access to young children and infants.

j. An integrated security system should link the building/fire door alarm system to the baby tagging, and CCTV systems to an appropriate monitoring station.

k. Signage should be displayed alerting users of the security systems in place, for example CCTV cameras and baby tagging systems.

l. Security systems in place should not impede movement of staff or safe transfer of mother or baby in the event of an emergency.

m. The need to provide system security to deter potential criminal behaviour and to reassure parents should be balanced with the need to create a welcoming atmosphere on the unit.

n. In birthing rooms, the woman should be able to control access of visitors from the bedhead. Staff should be able to override this from the staff base.

877. Health Building Note 09-03 recognises that the need for security requires consideration alongside the issue of access and provides:

a. Balanced with the need for security is the issue of access. All doors between the maternity area and the neonatal unit, and also those within the neonatal unit, should be designed to maximise convenience as well as safety and security. If automatically locking magnetic doors are to be used, consideration

[28] Health Building Note 09-02 notes here a publication called 'Safe and Sound: Security in NHS maternity units' (National Association of Health Authorities and Trusts, 1995)

should be given to difficulties that may arise in wheeling incubators/cots from room to room in an emergency when the security doors have locked down (paragraph 5.3).

b. Access must be ensured for mothers on trolleys or in wheelchairs. Widths of doors, corridors and corners should be considered so that mothers have access to all clinical areas (paragraph 5.4).

878. Health Building Note 09-03 further provides in relation to entrances and reception areas to neonatal units that entrances to such units should be controlled and visible from staff bases, "either directly or through CCTV links and an intercom link".

879. In addition to the above, both the Information Commissioner's Office and the Care Quality Commission publish guidance on CCTV.

880. The Care Quality Commission's guidance for NHS providers on the use of surveillance, including CCTV, in care settings is based on the more general guidance provided by the Information Commissioner's office. Both recognise that the use of security mechanisms, such as CCTV, require a balancing exercise that takes into account privacy, human rights and data protection interests. The concept of privacy by design, which forms part of the legal principles contained within applicable data protection legislation, emphasises that providers of health services should consider privacy from the outset (including by considering less intrusive methods). This can be done by undertaking a Data Protection Impact Assessment in relation to proposed new or changed means of processing personal data.

881. Additionally, where monitoring (including via CCTV) is carried out by way of covert surveillance purposes, public bodies are subject to the statutory constraints imposed by the Regulation of Investigatory Powers Act 2000. Any information obtained through covert surveillance is subject to UK data protection legislation and oversight by the Information Commissioners Office.

882. There are particular sensitivities around the use of surveillance in clinical settings, as distinct from points of entry to and egress from maternity and neonatal units. In a neonatal setting, this would include enabling appropriate privacy to allow for skin-to-skin contact and breastfeeding, among other such matters. As noted, use of surveillance requires a carefully weighing-up of patient safety and privacy / human rights considerations. NHS England considers that decisions on the use of CCTV and other surveillance methods in clinical settings are best taken locally, duly informed by a

careful assessment of risk (including the risk that routine CCTV surveillance may deter patients from seeking medical treatment), the relative benefits and disbenefits of CCTV, and the availability of other less intrusive surveillance methods, which inevitably requires careful consideration of the particular constraints of the built environment at each individual location. Therefore, while the use of CCTV will form part of NHS England's forthcoming review of the technical guidance notes for maternity and neonatal settings, NHS England considers it unlikely that the use of CCTV could, or should, be mandated in all maternity and neonatal units.

883. NHS England does not hold information as to the number of Trusts that have installed CCTV in neonatal or maternity units, but this will form part of the proposed maternity and neonatal survey which is due to be circulated shortly. NHS England will be better informed as to the position once it has received and considered the results of that.

(b) Medicines Management

884. In addition to the above guidance relating specifically to neonatal and maternity units, Health Building Note 14-02 **[SP/0216, INQ0014727]** is also relevant. This relates to medicines storage in clinical areas and provides best practice guidance on storage facilities for medicines, including controlled drugs in clinical areas. It applies to medicines generally and is not specific to controlled drugs. There is no separate Health Building Note relating to neonatal and maternity units specifically in the context of the management and use of drugs.

885. A range of other bodies publish guidance or otherwise regulate medicines management. Examples include:

    a. guidance published by the Royal Pharmaceutical Society for Great Britain (see, for example, its Professional Guidance on the Administration of Medicines in Health Care Settings and on the Safe and Secure Handling of Medicines);

    b. the Care Quality Commission, whose regulatory remit includes assessing whether regulated providers have proper and safe management of medicines[29]; and

[29] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

c. Professional regulatory bodies, such as the Nursing and Midwifery Council (whose Code contains medicines management specific obligations).

886. Providers of NHS services are required, as responsible corporate entities, to comply with applicable regulatory and statutory requirements, which includes those relating to medicines management.

887. Underlining this, guidance of this nature would fall within scope of the NHS Standard Contract, which requires that provider must "comply, where applicable, with the registration and regulatory compliance guidance of any relevant Regulatory or Supervisory Body". This reflects NHS England's expectations around provider compliance with guidance of this nature.

888. The NICE guidance document "Controlled drugs: safe use and management" provides further guidance in relation to the safe use and management of controlled drugs. Compliance with this is also required under the terms of the NHS Standard Contract, which states that a provider must "comply, where applicable, with the recommendations contained in NICE Technology Appraisals and have regard to other Guidance issued by NICE from time to time".

889. Along with NHS Trusts and NHS Foundation Trusts, NHS England is subject to a statutory duty to ensure that there are appropriate systems in place for safe management and use of controlled drugs. This duty arises under the Controlled Drugs (Supervision of Management and Use) Regulations 2013 ("the 2013 Controlled Drugs Regulations").

890. One of the requirements of the 2013 Controlled Drugs Regulations if that NHS England (as well as other designated NHS bodies, including NHS trusts and NHS Foundation Trusts) appoint Controlled Drugs Accountable Officers, whose role it is to ensure that systems are in place for the safe management and use of controlled drugs. As a commissioning body, NHS England's Accountable Officer must ensure that any person or undertaking that provides the body or group with relevant services:

a. establishes and operates appropriate arrangements for securing the safe management and use of controlled drugs; and

b. reviews as appropriate those arrangements.

891. The Controlled Drugs Regulations 2013 further provide that the arrangements that both provider bodies and commissioning bodies are required to establish and operate must include:

a. appropriate arrangements for compliance with the Misuse of Drugs Act 1971;

b. systems for recording concerns relating to the safe management and use of controlled drugs;

c. incident reporting systems for untoward incidents relating to the safe management or use of controlled drugs; and

d. up to date standard operating procedures in relation to the management and use of controlled drugs, which cover best practice relating to the prescribing, supply and administration of controlled drugs and clinical monitoring of patients who have been prescribed controlled drugs.

892. NHS England has further responsibilities in terms of monitoring and auditing the management and use of controlled drugs by providers it commissions, and that providers have equivalent appropriate arrangements for monitoring and auditing the management and use of controlled drugs.

893. NHS England discharges these obligations by requesting quarterly occurrence reports from providers it commissions, which set out detail of any concerns that the provider has regarding the safe management and use of controlled drugs or confirming that it has no such concerns. All provider designated bodies are required to make such submissions to NHS England on a quarterly basis. A populated example of the current form of returns is exhibited with this statement.

894. NHS England does not undertake an audit of compliance of individual provider bodies against their statutory duties. It relies upon the submissions and declarations provided in the quarterly occurrence reports by each designated body's Controlled Drugs Accountable Officer and the fact that each provider body has an appointed Controlled Drugs Accountable Officer, who is in their own right, subject to their own obligations under the 2013 Controlled Drugs Regulations.

895. In addition to seeking such assurance through quarterly occurrence reports, provider Controlled Drugs Accountable Officers are also required to share concerns about matters within scope of the 2013 Controlled Drugs Regulations with NHS England's Controlled Drugs Accountable Officer.

896. The role of NHS England under the 2013 Regulations does not extend to the provision of guidance in relation to the security arrangements and policies for the storage and administration of controlled drugs. However, NHS England does have a role in the facilitation of cooperation between responsible bodies who are part of a local intelligence network and enabling concerns raised to be addressed by relevant bodies. We have briefly described this below.

897. NHS England must also establish and operate "local intelligence networks". Those local intelligence networks may include any responsible body in that area. A responsible body includes NHS England, NHS trusts and NHS Foundation Trusts, Integrated Care Boards and the Care Quality Commission, amongst others. NHS England Regional ("local lead") Controlled Drugs Accountable Officers convene a number of local intelligence networks that meet periodically to discharge this duty.

898. The purposes of local intelligence networks are to facilitate cooperation between the responsible bodies who are members of that local intelligence network in connection with:

    a. identification of cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by relevant persons;

    b. consideration of issues relating to the taking of action in respect of such matters; and

    c. taking of action in respect of such matters.

899. An NHS England Controlled Drugs Accountable Officer also has power to request that the controlled drugs accountable officer of a designated body provide occurrence reports on a quarterly basis. This reporting provides details of concerns that the designated body has regarding the management and use of controlled drugs in relation to individuals or confirms that it has no such concerns.

900. Each local intelligence network meets periodically, on either a quarterly or bi-annual basis depending upon the regional arrangements. Meetings cover both widely applicable matters such as identifying themes and trends, as well as more specific issues particular matters and any individuals identified as being involved, in order to consider whether any action may need to be taken in relation to that individual. Local

intelligence network meetings may also be convened at any point to facilitate the sharing of information about the safe management and use of controlled drugs.

901. Insulin is an example of a non-controlled drug. Non-controlled drugs are not regulated in the same way as controlled drugs. As a result, NHS England has no specific statutory role in relation to medicines that are not controlled drugs. However, NHS England considers the management and use of controlled drugs to in effect be additional requirements in relation to what is otherwise considered to constitute the safe and secure management and use of medicines and good governance. Whilst there are therefore no specific statutory obligations in relation to the management and use on non-controlled drugs, the guidance of the Royal Pharmaceutical Society and principles in the NICE guidance note referred to above remain applicable. The Care Quality Commission's regulatory oversight would also look more broadly at medicines management (i.e. not just in relation to controlled drugs).

(c) Electronic records for drug storage cabinets

902. NHS England does not provide guidance specifically in relation to electronic records in respect of who accesses drug storage cabinets. This is a matter for each provider body to determine depending upon arrangements within the provider body and individual setting and taking into account the specific obligations noted above in relation to controlled drugs.

903. Our understanding is that whilst some provider bodies have implemented the use of electronic drug storage cabinets which retain an electronic record of access, this is not consistently adopted and in most cases implementation of such measures is incremental as opposed to taking place across the provider body in a single exercise.

904. Guidance is provided by the NHS Specialist Pharmacy Service in relation to "retaining and storing pharmacy records in England". This guidance applies to pharmacy departments and services commissioned by or contracted by NHS England. The guidance adopts the NHS England Records Management Code of Practice, **[SP/0217, INQ0014762]** in terms of the retention period for controlled drugs registers, with the retention period being 2 years (in accordance with the Misuse of Drugs Regulations 2001).

(10) Bereavement Care

905. Bereavement care services for women and families who suffer pregnancy loss is critical. To further support women and families, in 2022/23 NHS England provided I&S of national funding to support trusts to expand the number of staff being trained in bereavement care and increase access to specialist bereavement services.

906. In 2023/24, NHS England are investing I&S in bereavement care to enable all trusts to implement a seven-day provision by no later than the end of this financial year and increase the number of staff trained in bereavement care. This should include training in post-mortem consent as well as the purpose and procedures of post-mortem examinations.

907. NHS England has also included training for staff who come into contact with bereaved parents in the national core competency framework which sets out the minimum expected training for all maternity units.

908. NHS England does not mandate what is to be provided to individuals families suffering a neonatal death, or the actions that should be taken by Trusts in individual circumstances. These are matters to be determined by the professionals working with the service users.

909. NHS England is however part of a core group of baby loss charities and professional bodies which leads the National Care Bereavement Pathway and which developed the "Neonatal Death Full Guidance Document". This guidance provides a pathway for Trusts to improve bereavement care for parents in England after pregnancy or baby loss. Other bodies that are part of the core group leading the National Bereavement Pathway include the Neonatal Nurses Association, the Royal College of Nursing, and the Royal College of Midwives. It is the expectation of NHS England that Trusts would have regard to the pathway in delivering bereavement care to parents and families.

910. Similarly, NHS England expects that any parents suffering a neonatal death would have access to any Patient Advice and Liaison Service (referred to above in relation to raising concerns and complaints at paragraph 805) operated within the provider organisation. The Patient Advice and Liaison Service is intended to offer confidential advice, support and information on health related matters and should be available as a point of contact for parents and other family members in these circumstances.

911. Separate to the Neonatal Death Full Guidance Document **[SP/0218, INQ0014721]** is the British Association of Perinatal Medicine "Palliative Care (Supportive and End of Life Care) A Framework for Clinical Practice in Perinatal Medicine" **[SP/0219, INQ0014614]** which provides at various points for support to be provided to the family in circumstances of a child death.

912. The Neonatal Death Full Guidance Document makes reference to counselling at various points, including for advice about bereavement counselling that is available to parents and other family members, including genetic counselling, as being one of the matters Trusts should be aware that parents may want to discuss at follow up appointments, and that staff should flag with families any counselling services available via the care provider as well as access to counselling and further support via secondary care such as GPs and health visitors. This guidance document also has a section on the expectations relating to mental health, as follows:

    a. Policies and practices should be in place to offer bereaved parents ongoing follow-up care, further assessment and treatment for mental health problems.

    b. Mental health assessment and treatment should be offered to women as well as their partners, other children and family members (where applicable) after any type of baby loss.

    c. Sufficient time must be available in follow-up appointments with bereaved parents to enquire about their emotional well-being and offer assessments for mental health conditions where necessary.

    d. Good communication is crucial between staff and healthcare teams regarding parents who may be at risk of developing or who have been diagnosed as having mental health problems after a baby loss.

913. The guidance document also states in relation to antenatal care in subsequent pregnancies that: "Parents should be offered regular contact with staff, emotional support and screening for mental health difficulties".

914. NHS England recognises that if left untreated then perinatal mental health issues can have long lasting impacts on a woman and the wider family. Perinatal mental health services are specialist services to provide care and treatment for women with complex mental health needs, and offer women with mental health needs advice for planning a pregnancy. As part of the NHS Long Term Plan, I&S investment was committed to

mental health, which was intended to also provide for service developments for perinatal mental health **[SP/0220, INQ0014775]**. The Mental Health Implementation Plan **[SP/0221, INQ0014719]** published in 2019 included:

a. Increasing the availability of specialist Perinatal Mental Health community care for women who need ongoing support from 12 months after birth to 24 months

b. Improving access to evidence-based psychological therapies for women and their partners

c. Mental health checks for partners of those accessing specialist Perinatal Mental Health community services and signposting to support as required.

915. There are three types of perinatal mental health service currently available:

a. Specialist Mother and Baby Units: these provide inpatient care to women who experience severe mental health difficulties before, during and after pregnancy.

b. Specialist community perinatal mental health services: since 2019, there has been a specialist perinatal mental health service in every Integrated Care System area of England.

c. Maternal mental health services: as of November 2023, there are 38 services in operation. Services are planned to be operational in all 42 Integrated Care System areas by the end of March 2024. These services will offer timely access to specialist assessment and evidence-based psychological treatment to women experiencing moderate to severe or complex mental health difficulties with a significant association with a trauma or loss in the maternity/perinatal/neonatal context.

916. Clinicians are responsible for conducting appropriate screening for mental health concerns and referring, as appropriate, to mental health services. NHS England has, via the NHS Long Term Plan and Three Year Delivery Plan, signalled a clear commitment to ensuring that appropriate perinatal and maternity mental health services are available where clinicians determine that they are required by service users.

PART C: Effectiveness, reflections and possible further change

(1) Introduction

917. In Part C of Section 3 of this statement, we cover issues relating to Section C of the Inquiry's Terms of Reference, which is focused on the following:

> *"The effectiveness of NHS management and governance structures and processes, external scrutiny and professional regulation in keeping babies in hospital safe and well looked after, whether changes are necessary and, if so, what they should be, including how accountability of senior managers should be strengthened. This section will include a consideration of NHS culture".*

918. Our response to this overarching issue should be read in the context of the detailed responses we have provided elsewhere in this statement. We would like to reiterate the sentiments expressed at paragraphs 2 to 4 of this statement.

919. We emphasised the importance of good governance and the role of NHS leaders and Boards in our letter of 18 August 2023, issued in the wake of the verdicts relating to LL. In that letter we said:

> *"Good governance is essential. NHS leaders and Boards must ensure proper implementation and oversight."* **[SP/0162, INQ0014761]**

920. In that letter, we asked all NHS leaders and Boards to urgently ensure a range of matters relating to speaking up and data. This is addressed in more detail in Section 761 to 787 of this statement and below at paragraphs 931 to 939.

921. The remainder of this part of Section 3 of the statement is structure as possible:

(2) NHS England's overall view on the effectiveness of those matters mentioned in the Inquiry's Terms of Reference

(3) The effectiveness of neonatal services in particular

(4) Future changes

(5) Reflections and lessons learned

(6) Concluding remarks

(2) NHS England's view on effectiveness

922. In providing our overall view on effectiveness, our response is informed by the thematic review described above at paragraph 611 and in addition, in responding to these issues, NHS England has:

    a. Sought the views of key internal stakeholders on the question of effectiveness and to provide a fully informed view to the NHS England Board as to assurance of current effectiveness;

    b. Tested these issues and our proposed response with the Board, following which the Board has agreed to establish a steering group to oversee ongoing assurance work around the issues raised.

923. We have set out NHS England's overall views on effectiveness by theme but there are clear inter-relationships between each.

(a)Patient safety

924. During the Overall Relevant Period, the NHS's understanding and approach to patient safety has evolved and developed considerably. NHS England shares the views that have been expressed in previous inquiries, investigations and reviews as to the effectiveness of the earlier patient safety incident reporting arrangements. The fundamental shift that the transition to the Patient Safety Incident Response Framework represents reflects this. In particular, it is intended to address concerns previously expressed around low reporting and inadequate or defensive responses to incidents. Taken with the Patient Safety Strategy, these communicate a clear and consistent move to a patient safety approach underpinned by a learning culture.

925. It is too early, however, to give a fully informed view as to the effectiveness of the recent changes in relation to how patient safety incidents are reported and learned from. The Patient Safety Incident Response Framework is still in the process of being fully embedded into provider organisations ways of working. Emerging evidence **[Exhibit SP/0222, INQ0009278]** does show that the NHS Patient Safety Strategy is making progress towards the anticipated benefits set out in 2019: improving outcomes and saving an additional 1,000 lives. The latest figures from June 2023 indicate that we are halfway to achieving that aim.

926. Examples of the impact that the National Patient Safety Strategy has already had include:

a. an estimated 291 fewer cases of cerebral palsy have occurred since September 2019 due to the administration of magnesium sulphate during pre-term labour as part of the PReCePT (Prevention of cerebral palsy in pre-term labour) programme, supported by the Patient Safety Collaboratives **[SP/0223, INQ0014786]**;

b. work supported by the Maternity and Neonatal Safety Improvement Programme to ensure optimal cord management during labour has saved up to 465 lives since 2020 **[SP/0224, INQ0014785]**; and

c. we estimate 414 fewer deaths and 2,569 fewer cases of moderate harm due to long term opioids following the work of our Medication Safety Improvement Programme since November 2021 **[SP/0225, INQ0014784] [SP/0226, INQ0014764]**

927. Both the NHS Patient Safety Strategy and the Patient Safety Incident Response Framework have been well received by the health and care system. The intention is that all providers are operating using the Patient Safety Incident Response Framework and have transitioned to the Learning From Patient Safety Events System by April 1 April 2024. Through its regional teams NHS England is tracking the declared transition points for NHS Trusts and NHS Foundation Trusts and, as at 16 January 2024, there were around 110 Trusts who have fully transitioned to the new system.

928. From 1 April 2024 there will be a contractual requirement on all Trusts to comply with the Patient Safety Incident Response Framework and the Care Quality Commission will look at compliance. NHS England will continue to monitor the impact of the Framework and remain flexible to change any aspect identified that could provide improvement.

929. Early adopters of the Patient Safety Incident Response Framework are reporting improved safety cultures, identification of more effective risk reduction strategies and early signs of harm reduction, due to their revised approach.

930. We have described above in Section 3A the neonatal specific work that is currently underway and highlighted areas where further work is required. We summarise suggestions to consider for future change below at paragraph 1018.

(b) Raising concerns and complaints

(i) Freedom to Speak Up

931. While NHS England considers national policies and guidance around Freedom to Speak Up to be effective, we acknowledge that there is variation across the NHS in terms of how well these processes have been implemented and embedded. These issues are common across all service types.

932. There is more to be done to ensure that concerns that are raised are actively and curiously listened to and responded to, and that individuals raising concerns are not detrimentally affected by doing so. There are also related issues around equity and equality and the work that needs to be done to tackle how able all those working within the NHS are to raise concerns. Addressing these issues requires a coordinated approach by NHS England, its partner organisations (including the Care Quality Commission and the professional regulatory bodies), as well as from provider organisations themselves.

933. The most recent annual figures **[SP/0227, INQ0014755]** show that there has been a 25% increase between 2021/22 and 2022/23 in the number of cases raised with Freedom to Speak Up Guardians, with a total of 25,382 in this period. Each individual organisation will carry out more detailed analysis of their own specific figures and so will have a better understanding of trends and themes that may arise around the numbers of individuals speaking up and what barriers individuals may face. The NHS England guidance encourages Trusts to take action to establish whether arrangements are effective and what barriers may be present.

934. NHS England's target is for all organisations providing NHS services to adopt the national Freedom to Speak Up policy and apply the Freedom to Speak Up Guide by January 2024.

935. Whilst NHS England can put in place national policies, it is the role of every NHS Board to assess how effective the speaking up arrangements in place are at an organisational level. However, it is clear from reports and feedback that the application of the policy is not consistently applied across NHS organisations. For example, the National Guardian's Office report into NHS Ambulance Trusts published in 2023 highlights that there is still further work in embedding Freedom to Speak Up processes in the ambulance sector **[SP/0228, INQ0014753]**.

936. Freedom to Speak Up is part of the Care Quality Commission Well Led framework. As such, the Care Quality Commission will consider whether arrangements for speaking up are sufficient and working well.

937. In 2022 NHS England asked **[SP/0229, INQ0014783]** Integrated Care Boards to consider how they will gain assurance that all NHS organisations across the Integrated Care System have accessible speaking up arrangements, in line with the guidance and policy, considering the different barriers that workers face when speaking up and actions to reduce those barriers.

938. The effectiveness of a Freedom to Speak Up policy comes down to local leadership and a Board understanding its role. This must include checking and challenge of data as well as asking difficult questions. The NHS Freedom to Speak Up Guide emphasises the role that senior leaders have in speaking up. This is re-enforced through the work that NHS England carries out in respect of Board development. We expect that the NHS providers will use the results of the NHS Staff Survey to inform how well their policy is embedded because the Survey asks whether staff feel secure raising concerns about unsafe clinical practice and whether the organisation would address the concerns.

939. We also consider the continued work of training and development within the NHS critical for effective Freedom to Speak Up processes. The new NHS England framework for line managers aims to address the culture required to provide a safe space to speak up **[SP/0230, INQ0014782]**. This seeks to ensure that NHS England is modelling what "good" looks like in relation to freedom to speak up.

(ii) Support for those who speak up

940. The Speaking Up Support Scheme is a related scheme which was also introduced in 2019 as a response to the recommendations from the 2015 'Freedom to Speak Up, An Independent Review into creating an open and honest reporting culture in the NHS', chaired by Sir Robert Francis. This scheme focuses on providing support to NHS workers who have raised concerns, and the recommendation was that this should as a minimum include remedial training or work experience, advice and assistance in relation to applications for appropriate employment, the development of a pool of employers prepared to offer trial employment and guidance to employers. This scheme was piloted in primary and secondary care but it was found not to be workable in the form introduced for a number of reasons. As a result, the support scheme now

in place does not align with the recommendations made by Sir Robert Francis but focuses on supporting people including having in place commissioned providers to provide psychological support and career coaching.

(iii) Recommendations for future action

941. The Freedom to Speak Up Task and Finish Group and other current joint programmes of work between NHS England and the National Guardian's Office have been referred to above at paragraph 773.

942. In terms of future action, we are aware that there has been a private members bill in order to increase the protection of whistleblowers in Great Britain. This followed concerns raised by parliamentarians and whistleblowing support organisations about the effectiveness of the Public Interest Disclosure Act 1998 in providing adequate and comprehensive protection to whistleblowers and the public. The government has committed to undertaking a review of the UK's whistleblowing legislation. In October 2022, it said the scope and timing of this review would be set out in due course. NHS England do not have a position on this. However, we do consider that care is required in relation to any recommendations the Inquiry might make in respect of whistleblowing and Freedom to Speak Up to ensure that they are achievable for the NHS, considered in view of the outcomes of the planned review of the effectiveness of the Duty of Candour and build on the role of existing structures.

943. The Inquiry has asked us whether we consider that the structures and processes for the management and governance at Trusts inhibits clinicians, managers, nurses, midwives from reporting any suspected criminal activity by a member of staff. These structures and processes include those that provide for speaking up. NHS England's view is that if the policies and procedures described in this statement are implemented appropriately, we do not consider that the current processes inhibit reporting of criminal activity. However, the Freedom to Speak Up Task and Finish Group is continuing to actively consider whether the escalation processes to enable this could be made clearer. There does also remain concern from individuals around the impact of speaking up and a perception that an individual may suffer detriment if they speak up. We continue to address this through the refreshed Freedom to Speak Up communication plan and continuing provider board development. Responsibility rests with the leadership of each organisation to socialise and emphasise the importance of speaking out, ensuring that staff perceive their place of work as a safe place to do so and can demonstrate that action will be taken.

944. The professional regulatory bodies also play a key role here in terms of investigating referrals made to them (some of which may be, or may be perceived to be, retaliatory in nature). The current timescale within which referrals are investigated and determined can be lengthy. This impacts on the wellbeing of all individuals involved and can lead to conflict. The effectiveness of any support provided to individuals would be impacted by the length of any investigation undertaken by a regulatory body for many reasons including the protracted impact on an individual's personal welfare but also because of the impact that being under investigation has on an individual's ability to find work.

(c) Organisational structure and governance

945. We acknowledge that concerns around the effectiveness of Board governance continue to be raised in inquires, investigations and reviews. Whilst not all providers will achieve good or outstanding ratings in the Well-led assessment of Care Quality Commission, given the regularity with which issues around governance are raised and the number of providers who are currently challenged, it is clear that there remains work to be done to embed good governance at provider Trust level.

946. NHS England works closely with the Care Quality Commission to inform the joint well-led framework and support reviews of trust leadership and governance as part of their ongoing development. In doing so we seek to ensure the effectiveness of provider Trust governance.

947. We consider that the structural arrangements are largely effective in their current form and that there is sufficient guidance available to support robust governance. This includes the updated Code of Governance for NHS Foundation Trusts and NHS Trusts described at paragraph 198.

948. In our view, areas for further improvement would best be focussed on the following:

    a. Training and development for Boards to enable them to operate an active style of governance, supported by the "Insightful Board" guidance (currently under development).

    b. Further work to recruit, develop and support both non-executive directors and NHS Foundation Trust Governors.

    c. Maintain focus in improving the diversity of holders of non executive directors and Governors, both in terms of their general life background and their skills

and consider whether there should be a requirement for a minimum number of clinically experienced individuals performing these roles (recognising that Governors are elected);

d. Active implementation of the aligned remuneration structure for non-executive directors in NHS Trusts and NHS Foundation Trusts. NHS England and the Department of Health and Social Care are in discussion about when and how the effectiveness of the alignment will be formally reviewed, as per the commitment at the time. Relatedly, it may also be worth exploring the ability to appropriately remunerate "over time";

e. Review of the effectiveness of the role of NHS Foundation Trust Governors;

(d) Fit and Proper Persons

949. The Fit and Proper Persons Framework is one of several ways in which senior NHS leaders effectiveness and appropriateness is assessed. It needs to be seen in this context and alongside the following:

a. The fundamental standards of behaviour and values, as set out in the NHS Constitution;

b. Statutory and regulatory obligations (as incorporated into contracts of employment/terms of appointment);

c. Professional regulation, where this applies;

d. Organisational policies and procedures, such as those relating to safeguarding, patient safety reporting and raising concerns;

e. Employment appraisal and assurance processes; and

f. Board assurance and well-led reviews.

950. The approach to how leaders are assessed to be fit to hold office within the NHS has evolved and strengthened during the Overall Relevant Period. This has been closely informed by the findings of previous inquiries, investigations and reviews but in particular the findings of the Kark Review and the Messenger Review. The resulting reports highlighted areas that were not working well and presented recommendations for change.

951. In 2019 the government asked NHS England (then operating as NHS England and NHS Improvement) to engage with as diverse a range of stakeholders as possible to consider each of the seven recommendations in the Kark Review.

952. A considered programme of work was carried out by NHS England and NHS Improvement, with the aligned Boards of NHS England and NHS Improvement considering options for future change a number of times in the period 2019-2021 **[SP/0231, INQ0014802] [SP/0232, INQ0014803] [SP/0233, INQ0014804], [SP/0234, INQ0014805]**.

953. Following a pause due to the COVID-19 pandemic, this work was recommenced in early 2021. It was agreed that we would implement five of the seven recommendations **[SP/0235, INQ0012639]**. In relation to the other two, one was outside of our remit (the extension of the Fit and Proper Person Framework regime to Social Care) and we reserved our position on the recommendation to 'disbar for serious misconduct', proposing instead an extended referencing approach to capture misconduct to prevent re-employment within the NHS. This latter requirement has now been implemented, through the updated Guidance issued in September 2023 and further updated in January 2024 **[SP/0236, INQ0012645]**.

954. Whilst we agree these issues should be revisited, and set out below some considerations for the Inquiry and any legislator in relation to the issue of regulation of managers, we would also note that the impact of recent changes should be held in the balance of considerations. Those changes may prove to be a similar deterrent and less costly to the taxpayer.

955. On the Fit and Proper Persons Framework specifically, NHS England recongises that this is the first interation of the framework and has committed to reviewing it after 18 months from publication to assess how effectively it has been embedded and its impact within NHS organisations.

956. It is too early, therefore, to provide an informed view on the effectiveness of the updated Fit and Proper Person Framework and the key additional elements introduce, particularly those relating to references and the use of the NHS Electronic Staff Record to ensure relevant information is transferable to other NHS organisations as part of their recruitment processes. All NHS provider organisations have been asked to ensure that the updated framework is implemented by 31 March 2024.

(ii) Regulation of managers

957. As described above, formal regulation and associated ability for managers to be disbarred are two key recommendations from the Kark Review that have yet to be implemented, with the overall decision-making role in this context resting with the Department of Health and Social Care.

958. NHS England organised a round table discussion at the end of August **[SP/0237, INQ0014774]** at which it was agreed that there was support for the following overarching principles:

    a. that any work in this area should be done solely in service of ensuring high quality patient care and public confidence in the leadership of the NHS;

    b. that the starting point must be that the vast majority of managers do a good job and should be supported to continually improve;

    c. any regulatory system must be fair, rational, transparent, consistent, and proportionate; we do not want to introduce unnecessary barriers for existing NHS staff, clinicians or people from other industries who might consider senior operational roles in the NHS;

    d. and any process for implementation should avoid unnecessary burden on organisations.

    e. There was in addition a strong emphasis on the need to ensure a clear support and development strand in any response so that it was a balanced package that sent the right signals to a key workforce in healthcare.

959. On 25 September 2023 NHS England contributed to a Department of Health and Social Care options paper providing early stage consideration of the options for regulation of senior managers **[SP/0238, INQ0014763]**.

960. Four different main options were considered for enhancing the accountability of senior NHS managers which ranged from strengthening existing measures through to forms of statutory regulation:

    a. **Option 1** would be to continue with the new measures introduced by NHS England, implement the remaining Kark recommendations, while continuing to drive delivery of General Sir Gordon Messenger's recommendations;

b. **Option 2**: An accredited voluntary register, akin to those already held and quality assured by the Professional Standards Authority for Health and Social Care (PSA). The PSA already has powers to quality assure voluntary registers and do so for a range of professions in health and care. An alternative or interim measure could be for another body, such as the NHS Confederation or NHS Providers to run an assured voluntary mechanism. As a low cost model it could cast the net to a larger group of NHS managers.

c. **Option 3**: A statutory barring mechanism, which is a negative list of people who are unsuitable to practise a particular profession, such as the Companies House disqualified persons register, or the barring list for teachers, as recommended by Kark.

d. **Option 4**: Full statutory regulation, which would require membership of a positive list of people who are qualified and suitable to practise a particular profession. This would put managers on a similar regulatory footing as medical and nursing colleagues. It would mean that alongside an ability to prevent those who do not meet the criteria for entry to the register from working as a senior leader, and enabling those who are found wanting to be removed, it would also set requirements to maintain those standards which would then require employers to provide the training, support and development needed to maintain their professional registration so that they continue to be fit to lead at board level, whether as executives or non-executives.

961. NHS England's Chief Executive Officer and National Medical Director spoke at the Health and Social Care Select Committee on 14 November 2023 and expressed the then NHS England position around the regulation of senior NHS managers. It remains the NHS England position that we need to have appropriate accountability and safeguards as well as the appropriate support, training and investment in our leaders to make sure that they are able to carry out very complex roles.

962. Any system introduced will need to consider:

a. duplication and differentiation: Many NHS managers have a clinical background and are therefore already regulated professionals for managerial matters. Commonality for non-clinical managers needs careful consideration,

and how to manage regulation for those with other regulatory requirements needs to be considered to prevent duplication and issues of conflict.

b. the entry level of regulation: the cohorts of managers in scope of regulation, and to what standards needs to be determined. Clinical staff undergo CPD, peer review and regulation immediately upon entering practice.

c. the emphasis on development and improvement so that management accountability ties together with the provision of training, education and support

d. the cost of implementation and running a system;

e. the operational scale and burden of any system;

f. the identity of the "regulator"

963. The practical implications and operation of regulation would need to be worked through to determine feasibility, but in principle NHS England would support looking to move further in regulating senior management and leadership in the NHS where they are not already in regulated professions.

964. However, support for regulation is based on a recognition that it involves much more than the ability to disbar – it must be a fair and transparent process that involves setting codes of practice and standards as well as providing professional support. We have seen historically that where systems are punitive this deters open and honest dialogue. A regulatory approach that was purely punitive would not assist in providing the highly trained, open and supportive leadership necessary in the NHS.

965. We also consider that it is essential that any formal regulation process is independent of NHS England. It is an important longstanding principle in health professional regulation that the regulating body is, and is seen to be, independent of both the government of the day and independent of the profession that it regulates, so that decisions are not seen to be mediated either by politics, media pressure or professional self-interest.

966. If we bring in regulation of managers it will be essential that it does not become overly bureaucratic and that we learn lessons from the systems that are currently in place such as the financial services approved persons regime. As noted above, there is significant concern around the time it takes for investigation processes to complete for

the current clinical regulatory bodies and the negative impact this has on the wellbeing of all individuals involved in the investigation as well as on service provision. This potential issue must be borne in mind when developing proposals for the regulation of managers in the NHS.

967. The challenges of recruiting managers to NHS Trusts and NHS Foundation Trusts is well known. Any additional regulation of managers will need careful design to ensure that it does not to create a system which disincentivises good managers from being willing to take on roles at more challenged Provider Trusts or units.

968. As with a number of areas in the scope of this inquiry, on manager regulation, it will also be important to consider the current regulatory and oversight landscape to ensure that additional agencies or obligations do not create further burdens and there is consideration of whether the current regulatory and oversight arrangements remains appropriate or could be streamlined.

(e) Training and development

969. More widely, NHS England is actively implementing recommendations from the Messenger Review into leadership across health and social care. These recommendations are focused 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. NHS England's Management and Leadership Development Programme, working where possible in collaboration with Social Care, is taking forward the delivery of Messenger recommendations together with relevant recommendations from recent reviews including the Fuller Inquiry, Ockenden Review and Kirkup:

    a. In April 2024, NHS England and Social Care are seeking to launch a National Induction Scheme for all new starters in health and social care (recommendation 1a of Messenger). Creation of a management code and standards supported by an accredited development pathway covering the management of people, operations (including data and analytics), finance and self (recommendations 1b and 3 of Messenger) will be undertaken in 2024. These standards will enable us to provide an anchor to hold together recruitment, performance and development for NHS leaders around a common set of standards and competencies; enabling us to also more reliably

assess future leadership potential and build better talent development pipelines.

b. In June 2023, NHS England published the first NHS Equality, Diversity and Inclusion Improvement Plan. The plan contains six targeted high impact actions for all NHS organisations to take, designed to address the prejudice and discrimination that exists through behaviour, policies, practices and cultures against certain groups and individuals across the NHS workforce (recommendation 2).

c. NHS England is due to launch the Board-level Leadership Competency Framework by March 2024, with a Board-level appraisal framework to follow by September 2024. NHS England will also deliver a new Board-level induction framework for new Chairs and Non-Executive Directors (recommendation 6). These new leadership tools are described below, under (i) "Our Leadership Way".

d. The Management and Leadership Development Programme is currently working with partners and stakeholders to produce a three year roadmap for delivery beyond 2023/24.

(i) Our Leadership Way

970. Pre-Covid-19, there was an extensive consultation exercise on the development of a 'Leadership Compact' which would define the NHS leadership ethos, by which we mean how leaders are expected to behave towards each other and their teams, delivering on a day-to-day basis the NHS People Promise. Our 2020 People Plan confirmed our public commitment to these and "Our Leadership Way" **[SP/0239, INQ0014752]** was published in 2022. Our Leadership Way complements the NHS People Promise.

(ii) Management and Leadership Framework

971. In addition, we are currently seeking to develop a Management and Leadership Framework that sets out code of conduct, standards of competence and core training curriculum content for all levels of managers and leaders across the NHS. This is currently in a draft stage and has not yet received NHS England Board approval.

(iii) Leadership Competency Framework

972. A separate, specific Leadership Competency Framework is also being developed for chairs, chief executives and all board members operating within Integrated Care Boards and NHS provider organisations. It is designed to support the following:

    a. appointment of diverse, skilled and proficient leaders to deliver high-quality, equitable care and the best outcomes for patients, service users, our workforce and wider communities;

    b. help organisations to develop and appraise all board members;

    c. support individual board members to self-assess against the proposed competency domains and identify development needs.

973. We have worked with a wide range of stakeholders to develop the Leadership Competency Framework. Stakeholder feedback has helped describe what we do when we operate at our best and to design the proposed six leadership competency domains, which reflect the NHS values, and will support board members to perform at their best. These domains are draft and subject to final signoff but currently cover the following:

    a. Driving high-quality and sustainable outcomes

    b. Setting strategy and delivering long term transformation

    c. Leading for equality and inclusion, and reducing health and workforce inequalities

    d. Providing robust governance and assurance

    e. Creating a compassionate, just and positive culture

    f. Building a trusted relationship with partners and communities.

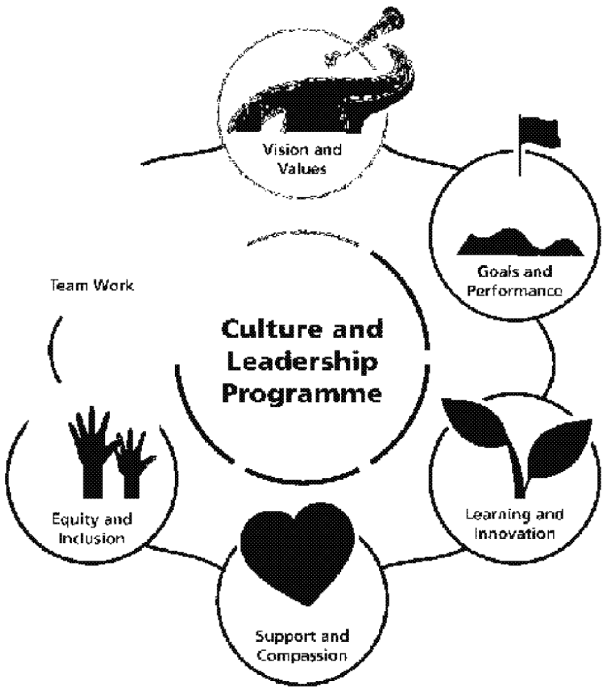
974. The competency domains should be incorporated into all NHS board member job/role descriptions and recruitment processes and will form a core part of board member appraisals, the ongoing development of individuals and the board as a whole. The competency domains in this framework will also be built into national leadership programmes and support offers for board directors and aspiring board directors. NHS England expects all board members will actively engage in ongoing development to enable continued, greater achievement across the competency domains over time,

and should be supported to do so. Board members are able to refer to the NHS England directory of board level learning and development opportunities for existing development offers available.

(iv) Culture and Leadership Programme

975. In addition to the specific Neonatal Culture and Leadership programme set up under the Three Year Delivery Plan and described at paragraph 695 there is an established NHS wide Culture and Leadership Programme. The Culture and Leadership Programme provides a practical, evidence-based approach to help NHS organisations understand how colleagues working within the organisation or system perceive the current culture and guides the creation of a leadership strategy. This programme was initially set up following the Francis Inquiry and has developed over the years to reflect recommendations and learnings arising from in subsequent inquiries, investigations and reviews.

976. The Culture and Leadership Programme resources are based on the elements and behaviours identified as necessary for high quality, equitable care cultures. These have been distilled into Six Cultural Elements



977. They rest on the principle of 'compassionate diverse and inclusive leadership', which empowers staff at all levels, as individuals and in teams, to take action to improve care

within and across organisations – 'leadership of all, by all and for all'. Five Cultural Elements sat at the heart of the model: Vision and Values; Goals and Performance; Learning and Innovation; Support and Compassion; and Team Work. These reflected both people and performance facets of organisational culture. A sixth cultural element, Equity and Inclusion, was added in 2021 following recommendations from an independent formative evaluation **[SP/0240, INQ0014724]**.

978. Initially the Culture and Leadership programme was created on a "self-service" web-based distribution model for materials. However, it became apparent that some organisations required more support. Therefore, a team was established in 2017 to coach and guide organisations who were identified as being in Single Oversight Framework (SOF) 3 or 4. This support consisted of site visits, involvement in programme meetings and sharing or signposting to good practice. By 2024, approximately 100 NHS organisations have had some level of support, typically from Acute, Mental Health, Community sectors, Ambulance and Integrated Care System.

979. An impact evaluation was published in 2022 and compared results across four key metrics for 35 trusts who had used the Culture and Leadership Programme between 2018-2020 with the average of all other NHS Trusts in England **[SP/0241, INQ0014728]**. The evaluation demonstrated the positive impact of the Culture and Leadership Programme as follows:

    a. staff engagement improved by 0.07 points, more than twice the national average (0.03 points)

    b. registered nurse turnover reduced by 1.4 percentage points between 2015/16 and 2019/20 (almost twice the national average of 0.8 percentage points).

    c. Care Quality Commission ratings improved, with a 9% increase in Trusts rated Good or Outstanding and none were rated as Inadequate by the end of the period.

    d. Single Oversight Framework (now superseded by the NHS Oversight Framework) scores improved, with the greatest improvement seen in Trusts moving from level 4 (special measures) to level 3 (mandated support), followed by Trusts moving from level 3 to level 2 (targeted support)

980. Although the Culture and Leadership programme is a voluntary programme we consider that it is something that will continue to have a positive impact in the culture of the NHS as a whole.

(f) External scrutiny and assurance

981. We have noted the numerous recommendations made in previous inquiries, investigations and reviews around the need to make sure that there is appropriate regulation and scrutiny of NHS care. In paragraphs 1014 to 1018 below, we caution that any proposed changes to regulators needs to be carefully considered, so as to avoid further complicating the regulatory landscape.

982. There has been considerable change since the First Relevant Period, which we have sought to draw out throughout this statement. In structural terms these changes include:

a. There is a system of local, regional and national oversight and structures in place to ensure joint working between NHS bodies and the creation of the new NHS England in 2022 was a significant step to supporting closer alignment at national level.

b. Transition of governance and oversight of specialised commissioning (including neonatal) in view of planned delegation from April 2024 is a specific focus.

c. For NHS Trusts, Foundation Trusts and Integrated Care Boards, NHS England's NHS Oversight Framework describes how oversight now operates. It aims to empower local health and care leaders in addition to Care Quality Commission activity to assess the functioning within each Integrated Care Board. The new systems are still evolving and we will need to continue to assess effectiveness.

983. During the development of the Health and Care Act in 2021 a clause was proposed that would have required "each NHS Trust in England to publish the reports produced by Royal Colleges of invited reviews of the Trust, including any conclusions and recommendations." At that point in time Parliament decided not to include the clause on the basis that the mechanisms already in place were sufficient and achieve the right balance. This issue has also been considered in earlier inquiries, investigations and reports. The overall view has been that there were in principle sufficient expectations

around this type of information being shared and that mandating publication could discourage some providers from commissioning reviews, and in some cases a review may not be relevant to patient safety or able to be disclosed due to confidentiality considerations. NHS England suggests that a further review of whether such a provision is required may now be appropriate.

984. We consider that there may be further action to be taken in respect of the regulation of NHS services. Options to consider may include having a more formal approach to agreeing a 'lead regulator' model where concerns are raised in respect of a provider Trust.

985. We highlighted in respect of Freedom to Speak Up, the need for a reduction in the time needed to process cases through professional regulators, and building understanding of individual impact.

986. We also consider that there is a continuing need to ensure appropriate systems are in place for effective data reporting, analysis and criteria for escalation, particularly in respect of neonatal mortality and serious incidents. Over time, NHS England is looking at audits moving to real time data reporting and analysis. The Federated Data Platform plays into this project, but this is a long-term ambition. Data improvements require further sustained investment.

987. As the delegation of neonatal services takes place over the next few years, NHS England will continue to evaluate the roll and requirements in respect of assurance and oversight as well as the balance of oversight and escalation between NHS England national and regional teams and Integrated Care Boards.

(i) Medical examiners

988. The development and implementation of the non-statutory medical examiner system has been an important additional way in which external scrutiny and review of deaths can be enabled. NHS England continues to support this as it evolves into a statutory scheme.

989. There are currently 126 medical examiner offices in England, most of which are based in acute NHS Trusts and NHS Foundation Trusts. NHS England does not understand that there is currently any intention for any further medical examiner offices to be established or that any more are required at this point in time. At the end of financial year 2022/23 approximately 90% of the estimated workforce required was in post in

medical examiner offices. As at 30 September 2023, medical examiner offices reported they had recruited 94% of the required medical examiner offices workforce.

990. As at the end of 2022/23, medical examiners were already providing scrutiny of 85-95% of deaths in hospital. Medical examiner offices reported they scrutinised 62,023 deaths in hospitals and 14,204 deaths in outside of acute hospitals in the last quarter of 2022/23. Overall, as at September 2023 we estimate that medical examiners in England have provided independent scrutiny of 640,000 deaths

991. Medical examiners, through early identification of issues with care, present an opportunity for the NHS to address issues and concerns. Because they are independent, medical examiners can give the bereaved a voice, ensuring their views are given due consideration. Medical examiners provide insight within days of a death, and early feedback from the medical examiner system demonstrates this can help prevent complaints and appeals that may be more painful and damaging if they arise later.

992. It is important to note that a medical examiner's role is not to investigate or review services but to pass on concerns they detect, including themes or patterns. This would include concerns in relation to clusters of cases displaying similar characteristics. In the first instance, the expectation is that these are raised with the healthcare provider for consideration and review through established clinical governance processes. Medical examiner offices are expected to share anonymised trends or patterns of concern regarding a locality or an organisation with the regional medical examiner. Cross border information sharing is provided for in terms of England/Wales, with the Lead Medical Examiner for Wales reporting to the National Medical Examiner.

993. The Medical Examiner Office have been involved in discussions around extending their scrutiny to neonatal deaths since around 2020. This has recently been formalised with the publication of the Good Practice Guidance March 2022. There has not yet been an overarching review of the effectiveness of the medical examiner system in England. Further, given that the medical examiner system has only recently included child and neonatal deaths it is too early to review the effectiveness for this cohort. The medical examiner office guidance on Child Deaths sets out how medical examiners should interact with the statutory child death review process in order to avoid unnecessary overlap, duplication or confusion.

(ii) Recommendations for future action

994. Overall, the medical examiner system is still in the process of being implemented and neonatal death scrutiny in particular is in the early days. However, we consider the following future action is worth consideration:

a. Effectiveness Review. As the system is still being implemented, there has not yet been an overarching review of the effectiveness of the medical examiner system in England to date. In the future, it is likely that the Office for National Statistics will carry out a comprehensive analysis of death certification in order to consider the statistical impact of medical examiners. We presume that this would consider whether it ensures that death certificates are more accurate, how many cases are referred to coroners and how many go to inquest.

b. Expansion to primary care settings. Medical examiner scrutiny of deaths is now being extended from deaths in the acute setting to deaths in non-acute settings.

c. Identification of Issues. The inquiry asks us to identify all examples of the medical examiner system spotting potential problems since 2021. There is currently no national reporting system used by medical examiners to record and report cases reviewed and issues identified. As such we do not have a database of all incidents picked up. Each quarter, each medical examiner office provides numerical and qualitative data reports to the National Medical Examiner about what that individual medical examiner office is seeing. However, partly as a result of the qualitative nature of the report, the extent to which incidents are escalated will vary across individual offices. Many issues will be escalated and resolved locally with escalation only occurring where themes are identified. Themes identified through medical examiner scrutiny have included:

i. Continued delays in accessing healthcare identified as a contributory factor in deaths;

ii. Difficulties in accessing primary care, resulting in late presentations of conditions

iii. A range of issues relating to end-of-life care, including insufficient observation/ monitoring in "ready for discharge" holding wards; patients brought to hospital despite having made advance plans to die at home; final espied lengths of stay under 24 hours and patients dying in hospital due to insufficient community capacity for palliative and end of life care;

iv. Issues with planning discharges, identifying a need from prompt and appropriate referral to palliative care;

v. An unexpected rise in metastatic cancers in younger patients; and

vi. Unusual number of deaths after chemotherapy.

d. National Database. The Department of Health and Social Care is responsible for commissioning a bespoke case management system for medical examiners and we support the National Medical Examiner in engaging with the Department on this.

(g) The effectiveness of neonatal care

995. Neonatal services have improved considerably since 2015/2016 both in terms of service effectiveness and patient safety and making sustainable improvements across maternity and neonatal services remains a major priority for NHS. We are strengthening the services delivered further through targeted investment within the funding envelope agreed with Government, leadership and support for quality and safety improvement. However, as outlined, maternity and neonatal services face significant challenges. While we have made good progress, and there are encouraging signs, sustainable improvement will take time and require continued focus and investment. The actions contained in the Three Year Delivery Plan have been included to target actions that will improve the safety and effectiveness of maternity and neonatal services. However, we recognise that this plan was only published in March 2023 and so is still only part way through implementation.

996. As we have described in this statement, the care provided within neonatal services has also changed since the First Relevant Period. This is as a result of the increasing complexity of care due to a number of factors, including increasing survival at the margins of viability. Analysis by the National Institute for Health Research identified that the number of babies born at 22 weeks given respiratory life support increased three-fold after NHS guidelines changed in 2019 **[SP/0242, INQ0014807]**.

997. Following LL's conviction, the NHS England Clinical Programmes Director for Specialised Commissioning wrote out to each of the NHS England Regions to request information as follows:

a. what data they are looking at routinely to provide commissioner assurance;

b. what groups/meetings they routinely in the region to review neonatal services – any concerns, identify trends, pick up outliers;

c. any processes followed to pick up in real time any concerns;

d. how are follow up actions documented and followed up in formal governance structures; and

e. are there clear roles and responsibilities set out about who has the lead for receiving and acting on the information?

998. All seven Regions responded and the information was fed into a paper provided to NHS England's Executive Quality Group on 11 September 2023 and then to NHS England's Quality Committee on 14 September 2023 **[SP/0173, INQ0014778]**. This included a recommendation to review the roles and responsibilities of Operational Delivery Networks to ensure compliance with the Operational Delivery Network specification and to strengthen accountability. In addition, there was a recommendation for work to continue to identify best practice in terms of Operational Delivery Network and commissioner assurance of perinatal mortality surveillance. We recognise that there is further work to be done to ensure a suitably standardised approach to mortality surveillance by NHS England's Regional teams (and Integrated Care Boards as they take on delegated responsibilities).

(i) National Maternity Safety Ambition

999. The NHS is making progress on the National Maternity Safety Ambition announced by the then Secretary of State for Health Jeremy Hunt in 2015 to halve the rates of stillbirths, neonatal death, maternal death and brain injury in babies between 2010 and 2025, and to reduce the national rate of pre-term births. We exceeded the interim target of a 20% reduction in stillbirth and neonatal mortality by 2020. However, the latest available data shows that the neonatal mortality rate rose from 1.3 per 1000 live births in 2020 to 1.4 in 2021 (although this remains 30.4% lower than in 2010). The increase is expected to be in part due to the impacts of Covid-19 but due to the lag in maternity data we do not yet have the Office of National Statistics data that fully

reflects neonatal mortality after the COVID-19 period and that would be comparable to the previous data set findings. Neonatal mortality and preterm birth data is due to be published by the Office of National Statistics in February 2024.

(ii) National Neonatal Audit Programme

1000. We have described the National Neonatal Audit Programme, which is commissioned by the Healthcare Quality Improvement Partnership as part of the National Clinical Audit and Patient Outcomes Programme. The annual audit and report it produces provides an important assessment of key outcomes of neonatal care, measures of optimal perinatal care, maternal breastmilk feeding (during admission and at discharge), parental partnership, neonatal nurse staffing levels, and other important care processes **[SP/0243, INQ0014744]**.

1001. The latest report was published in October 2023 and covers babies discharged from neonatal care between January and December 2022. This highlighted that there is still a variation in mortality rate between different neonatal networks from 4.8% to 8% which are not explained by the differences in the measured background characteristics of babies cared for by networks. These figures reflect the position prior to the publication of the Three Year Delivery Plan. It must also be borne in mind that these figures do not take into consideration all of the factors that impact on neonatal mortality including in particular, the health of women within the local communities. Whilst there may be some element of the variation that results from differences in the provision of neonatal care, the figures do not necessarily represent differences in the quality of care provided at the neonatal units within the networks.

1002. As described at paragraph 699, the actions we have identified in the Three Year Delivery Plan have been developed to tackle the variation in mortality rate and provide an opportunity for improvement across all neonatal network areas.

(iii) *National oversight*

1003. NHS England has placed an increased focus on neonatal services at a national level, by:

a. The creation and appointment in 2023 of two new posts of National Lead Nurse for Neonatal Services and Neonatal National Clinical Director. This ensures, for example, that there is specific senior representation at leadership level;

b. Appointing a national Neonatal Service User Voices Representative; and

c. A rename and reset of the Maternity Transformation Programme, as a result of the Three Year Delivery Plan in 2023, to become the Maternity and Neonatal Programme. This ensures, for example, that there is wider read across as reports now have both services data.

d. Establishment of Patient Safety Champions for Neonatal Services. Providers now have neonatal safety champions for their unit and each Provider Board has a Maternity and Neonatal Safety champion which provides "floor to board" representation of neonatal services.

(iv) *Role of Integrated Care Boards*

1004. As the commissioners of most NHS services (and particularly including most maternity services) Integrated Care Boards and Clinical Commissioning Groups before them have always played an important role as part of the shared system responsibility for oversight, improvement and contractual performance monitoring.

1005. We have put plans in place to delegate the commissioning of neonatal services to 20 Integrated Care Boards within three regions (East of England, North West and Midlands) from 1 April 2024, with delegation to all other Integrated Care Boards occurring from 1 April 2025. This means that Integrated Care Boards will become responsible for commissioning neonatal care services from the Provider Trusts.

1006. To support the effective delegation of these services, NHS England has been commissioning these services jointly with Integrated Care Boards since 1 April 2023. Delegation will mean that the same organisation will be responsible for commissioning of all services associated with the mother and baby pathway including maternity care, foetal medicine, maternal medicine, placenta accreta syndrome, neonatal services, neonatal transport and perinatal pathology. This will allow specialised services and patients to fully benefit from the focus of ICBs on their local population's health and ensure that the specialised elements of pathways are part of the integrated design and delivery of the overall provision of care to mothers and babies.

1007. Neonatal Services will continue to be subject to national service specifications and evidence-based clinical policies published by NHS England to ensure consistent access of provision of services across the country. As delegation takes effect, NHS England will continue to keep these arrangements under review.

(v) *Neonatal Operational Delivery Networks*

1008. As described in Section 1 of this statement, Neonatal Operational Delivery Networks are perhaps the most established of all NHS networks. The role of the Operational Delivery Networks has expanded greatly since the crimes of LL and they now carry out important proactive roles in relation to operational delivery, quality improvement and clinical outcomes. The Operational Delivery Network Specification **[SP/0244, INQ0014756]** was developed to support consistency and set the expectations on Operational Delivery Networks. Critically, the Operational Delivery Networks have a far greater presence at a unit level and the relationships between Provider Trusts and the networks has evolved during the Further Relevant Period and this continues at the present day. We do know that there is a variation between the activity and impact of the Operational Delivery Networks and are seeking to reduce variation in the way that they function and discharge their roles and responsibilities. For example, we have described the further work that is needed to review and standardise reporting across the networks including the process for the reporting of neonatal mortalities.

1009. The new NHS England Neonatal Clinical Director and Neonatal Lead Nurse will be instrumental in ensuring that there is a closer link between the Neonatal Operational Delivery Networks and the national team.

(3) Overall effectiveness of current systems

1010. Overall, we would highlight the extent of change since the First Relevant Period, while acknowledging the further work that is ongoing and which remains necessary. On balance, and on the basis of what we currently know about the events involving LL, we consider that systems now in place or currently being put in place would help to bring concerns of patient safety harm to NHS England's attention sooner, if a situation like this should ever arise again:

a. Structured external scrutiny of deaths, including through the medical examiner system. Once the statutory system (expected April 2024) is fully in force, this will ensure that there is scrutiny of every death, other than those already investigated by the Coroner;

b. A fundamental shift in how patient safety incidents are reported, responded to and learned from, through the introduction of the Patient Safety Incident Response Framework, which encourages more open reporting of patient safety incidents, and is linked with a move to one, single data system through

which all incidents will be reported (the Learning from Patient Safety Events Service). Importantly, real-time data entered by staff working within an NHS Trust or NHS Foundation Trust is uploaded onto the Learn From Patient Safety Event Service (meaning NHS England sees the same information that the Trust sees);

c. Greater collaboration and stronger system-based working, with a central role under the NHS Oversight Framework and the Three Year Delivery Plan for Integrated Care Boards;

d. More active incident monitoring by Operational Delivery Networks, working closely with commissioners, and accompanied by a formal specification within which Operational Delivery Networks operate and which sets out NHS England's expectations about this role and relationship;

e. Closer, more coordinated working between NHS England and other key regulatory bodies, including the Care Quality Commission. This is particularly the case in relation to maternity and neonatal services, where coordinated and focused work has been carried out by both bodies in recent years, particularly in response to the Shrewsbury and Telford Independent Maternity Review;

f. Mandatory reporting requirements for providers in relation to specific neonatal incidents, in the context of the Maternal and Newborn Safety Investigation programme (and pursuant to the Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023;

g. Enhanced scrutiny and assurance within each NHS Trust and NHS Foundation Trust, including through Maternity and Neonatal Champions, which will support a more open culture of incident reporting and system-based review, risk-led action and improvement from ward to Board.

1011. In structural terms we have noted:

a. There is a system of local, regional and national oversight and structures in place to ensure joint working between NHS bodies and the creation of the new NHS England from 1 April 2023 was a significant step to supporting closer alignment at regional and national level.

b. Transition of governance and oversight of specialised commissioning (including neonatal) in view of planned delegation from April 2024 is a specific focus.

c. For NHS trusts, NHS Foundation Trusts and Integrated Care Boards, NHS England's Oversight Framework describes how oversight now operates. It aims to empower local health and care leaders in addition to Care Quality Commission activity to assess the functioning within each Integrated Care Board. The new systems are still evolving and we will need to continue to assess effectiveness.

1012. The Perinatal Culture and Leadership programme is the key means by which we are seeking to influence the culture of individual neonatal units and their relationship with maternity care by bringing maternity and neonatal managers together to work towards building positive team culture. A different culture at the Countess of Chester Hospital unit and more effective scrutiny of data and staff concerns may have had an impact on the manner in which the matter was dealt with within the neonatal unit and at Board level. It may, for example, have resulted in the concerns raised by the clinicians being dealt with in a different manner. This could have had an impact on the later incidents.

1013. For reasons described earlier in this statement, we consider that it is possible that real time data may have flagged the spike in neonatal deaths and incidents at an earlier point but there remains more work to be done to develop and embed early surveillance capabilities and systems.

(4) Future changes

1014. We welcome recommendations from the Inquiry, alongside outcomes of other investigations and reviews, that can be used to inform future strategy and guidance as well as any necessary reprioritisation of existing plans. We are very open to working with the Inquiry to consider where programmes and processes could be improved however, we are keen to ensure that any significant recommendations made by the Inquiry does not stall the speed and success of implementation and delivery of the Three Year Delivery Plan.

1015. In relation to recent previous inquiries, investigations and reviews we have found it beneficial to work with the relevant review body, for instance through holding operational working groups in the same way as in relation to the Independent Maternity Review (led by Donna Ockenden), currently underway into maternity

services at Nottingham University Hospital NHS Trust. The benefit from this is that it enables us to feed-in live learning to the strategy development process.

1016. As we have set out in this statement, there have been considerable changes both across the NHS as a whole and within a neonatal services context, with further changes to be implemented. However, we consider that future changes may be warranted, as summarised in the table below at paragraph 1018.

1017. Before summarising the key areas we have identified for potential further change, we consider it important to note the following learnings the NHS has derived from the overall outcomes of previous inquiries, investigations and reviews:

a. Reactive change. The public and government response to inquiries, investigations and reviews is commonly to plan immediate action. While this is understandable, on occasion the results can be too reactive and add to, rather than improve, the existing arrangements. It is also essential to ensure that any rapid changes are fully informed by current policy and processes, which as we have emphasised are constantly evolving.

b. Changes to regulators. One solution often proposed is a new regulatory body or an increased remit for existing regulatory bodies. Dr Kirkup noted, in his report in East Kent, the "bewildering array of regulatory and supervisory bodies" that were already in existence and the fact that the role of the regulators "was made more difficult by the extent to which problems were denied", with this denial running "right through the Trust, from clinical staff to Trust Board level". While Dr Kirkup acknowledged that there was, on an individual regulator basis, a case to be "made that the distinctive role of each organisation should have added positively to identifying and addressing the problems", the reality was different. In NHS England's view, this illustrates the need for caution around incremental reactive action in response to specific incidents. It also highlights the issues arising where multiple regulators share similar duties, namely: confusion, dilution of intelligence and the opportunity for missed information, increased regulatory burden. We therefore respectfully suggest that any recommendations around regulators should only occur within consideration of a more focused and rational overall regulator framework.

c. Actionable and targeted implementation. We understand the need for an inquiry to demonstrate that appropriate positive action will be taken that will improve services for patients and reduce likelihood of never events (such as criminal activities) occurring against vulnerable individuals within healthcare settings. However, would like to highlight the comments made within the East Kent report that NHS Trusts already have many recommendations and action plans resulting from previous initiatives and investigations. However, we have seen in the past this can lead to detailed and often overlapping recommendations that become difficult for the NHS to implement successfully. Given the financial and workforce pressures facing the NHS, we respectfully request that the impact of recommendations on current improvement programmes, as well as any direct and indirect burden both financially and to the workforce, must be considered before additional recommendations are made.

1018. Please find below a summary of the key areas we have identified for potential further change:

Theme	**Areas for potential future change and key current work underway**	**Paragraph reference**
Patient safety	• Continued active implementation and evaluation of the Patient Safety Incident Response Framework • Full transition to the Learn from Patient Safety Events Service • Early surveillance monitoring tools (with work underway on this) • Further consideration around the use of security measures on neonatal wards/units (including CCTV and drugs security arrangements)	924 to 930
Raising concerns and complaints	• Further focussed work around equity and equality issues in relation to raising concerns and complaints • Support for those who raise concerns (including considering the speed of professional regulatory investigations) • Joint work with the National Guardian's Office to enhance data reporting and monitoring	931 to 944
Trust structure	• Training and development for Boards	945 to 948

Theme	Areas for potential future change and key current work underway	Paragraph reference
and governance	• Further work to recruit, develop and support NEDs and Foundation Trust Governors • Improve the diversity of holders of non-executive directors and Foundation Trust Governors (both in terms of life background and skills and whether there should be a requirement for a minimum number of clinically experienced individuals performing these roles) • Review of the implementation of aligned NED remuneration across NHS Trusts and NHS Foundation Trusts • Review of the role and effectiveness of NHS Foundation Trust Governors	
NHS leadership and regulation of managers	• Review of the effectiveness of the strengthened Fit and Proper Persons Framework • Reconsideration of the potential for formal regulation of managers	949 to 980
External scrutiny and assurance	• Potential mandatory requirement for providers to publish invited reviews and/or notify the relevant Integrated Care Board(s) and NHS England of such reviews.	981 to 1009

(5) Lessons learned

1019. Building on what we have set out above, you have asked us a number of questions about lessons learned. Given the specific nature of these questions, we have included the questions as per the NHSE/1 Rule 9 and responded to each in turn. We would like to emphasise that our answers below are based on the evidence available to us at the current time.

(a) Should concerns, including any concerns regarding hospital or clinical data from the Countess of Chester neonatal unit, have been raised with NHS England earlier than they were?

1020. Without repeating the detailed consideration of these issues set out in this statement, the timeline of events set out in Section 2 of this statement makes clear that NHS England was only able to take prompt action (which involved downgrading the unit)

after it became aware through the Serious Incident reporting arrangements of mortality concerns. On the basis of our review of the available evidence, this awareness happened after the Countess of Chester Hospital reported two Serious Incidents via the Strategic Executive Information System relating to neonatal deaths on 30 June 2016 and this was followed by a further Serious Incident report relating to increased mortality rates generally, which the Hospital made on 7 July 2016. On this basis, it seems reasonable to consider that if the Countess of Chester Hospital had reported earlier deaths in 2015 as Serious Incidents, pursuant to the Serious Incident Framework in place at the time, then NHS England would have been made aware at an earlier stage about concerns regarding the neonatal unit.

1021. Clinically audited mortality data, obtained as part of the national clinical audit process, provided a clearer view of the overall increased mortality on the unit. However, this too was only available to NHS England 18 months after the events. This is not a criticism of MBRRACE but a reflection of the processes that were in place at the time. NHS England recognises that this meant that concerns were not raised as promptly as they could have been and we have described the changes already made that are intended to improve the timeliness of incident reporting and the further work that is required to move towards real-time reporting.

1022. Overall, and as summarised at paragraph 1010 above, we consider that systems now in place or currently being put in place are much improved since the First Relevant Period and provide a greater level of scrutiny and oversight that could prevent or curtail a situation like this from arising again.

(b) Were existing processes and procedures for raising concerns used, including whistleblowing and freedom to speak up guardians? Were they adequate?

1023. We have described at paragraph 763 the emergent arrangements around speaking up in the Frist Relevant Period and the ways in which these have evolved and strengthened during the Further Relevant Period.

1024. While we understand that concerns were raised internally within the Countess of Chester Hospital by clinicians we do not have the details about what internal processes were followed by the Countess of Chester Hospital and so cannot comment on whether existing processes and procedures for raising concerns were used or whether in the circumstances they were adequate.

1025. We do not have any record of concerns being raised directly with NHS England or any of the Legacy Bodies under either the complaints framework or the whistleblowing or freedom to speak up frameworks.

(c) Whether systems, including security systems relating to the monitoring of access to drugs and babies in neonatal units, would have prevented deliberate harm being caused? Have NHS England had any role in relation to enhanced monitoring and drug security systems being introduced since?

1026. We have described in Section 3B NHS England's role in relation to security systems on neonatal units, including in relation to drugs. As emphasised in that part, the deployment of security arrangements is a matter for local determination, with providers expected to operate consistently with best practice guidance and their regulatory and statutory obligations.

1027. Looking in brief at some of the specific mechanisms you have asked us to comment on:

a. CCTV does have a role to play in discouraging and/or detecting criminal behaviour. However, there are legal and practical issues that require careful consideration in terms of its use and effectiveness. We have described those at paragraph 880. There is no mandated national requirement around how CCTV is used in neonatal wards, although the estates guidance described at paragraph 873 provides best practice expectations;

b. Further consideration around the security systems and monitoring for uncontrolled drugs is warranted. This includes the potential merits of electronic drug storage. As we have noted, this will form part of NHS England's upcoming Maternity and Neonatal Services Infrastructure Review. As with CCTV, there are important practical implications that need considering, to ensure an appropriate balance between security and appropriate clinical access to drugs;

c. We have described in detail at paragraph 815 the changes that have taken place in the Further Relevant Period in relation to incident reporting and the ongoing work to fully implement the Patient Safety Incident Response Framework. We would simply reemphasise here the fundamental shift intended through these changes to a culture of open reporting and learning-driven response.

d. Early monitoring tools remain under development. NHS England is exploring the development of an early monitoring tool for maternity and neonatal services, to operate within the Perinatal Quality Surveillance Model. Further detail is provided above at paragraph 867 as to the current position. Such a system will identify concerns within a service (which could arise from a single incident occurring depending upon the nature of the incident and what is determined within the system to be an appropriate trigger point warranting a response), as well as identifying the correct approach to adopt in the context of that particular concern having arisen. However, whilst such a tool will assist in the early identification of concerns and providing consistent and appropriate responses to those concerns, it remains to be seen how effective such a tool might be in assisting in the prevention of deliberate acts of harm prior to those acts occurring.

(d) Were existing processes used for reporting concerns to Care Quality Commission or any other external scrutiny body where appropriate?

1028. We cannot comment on what concerns were raised with the Care Quality Commission or conclusively at this stage on what other processes or external bodies might have been used.

1029. However, we do know that the following external scrutiny was sought by the Countess of Chester Hospital:

a. Independent Royal College Review;

b. External pathology review;

c. Review by a Queen's Counsel; and

d. Child Death Overview Panel.

1030. Today, the additional external scrutiny available would also include medical examiner review.

(e) Did the structure and processes for the management and governance of the hospital contribute to a failure to protect the babies on the neonatal unit from the actions of LL?

1031. NHS England is not able to comment on this in detail at this stage as it does not know enough about how the structure and processes were used in fact.

(f) Was the management structure and governance of the Countess of Chester typical for neonatal settings in other hospitals?

978. NHS England is not able to comment on this in detail at this stage as it does not know enough about what management structure and governance at the Countess of Chester were at the time.

(6) Concluding Remarks

1032. Like everyone, NHS England was (and remains) horrified by LL's actions.

979. Immediately following her conviction, NHS England publicly wrote to the NHS system, a letter setting out the key improvements that are already in place that we consider would prevent such a crime occurring again, while also emphasising the immediate actions we expected all Boards to take to ensure robust arrangements were in place to enable concerns to be raised.

1033. The changes and improvements that have taken place during the Overall Relevant Period have been described in this statement. The NHS today is a very different place than it was in the First Relevant Period, when the crimes of LL occurred. This is true of neonatal services but also across all services in terms of raising concerns, leadership and governance. As such, whilst NHS England strives for improvement to service quality, with the enactment of the 2022 Act and creation of Integrated Care Boards, and given the other measures and policies underway, there is an argument for a period of stability to allow organisations to cement the new ways of working.

1034. There is further work to be done, as we have described in this statement. In neonatal services good progress is being made in the implementation of the Three Year Delivery Plan, the important work arising out of Reading the Signals – particularly in relation to data and the commitments set out in the Neonatal Critical Care Review and the Three Year Delivery Plan.

1035. We consider the processes and frameworks that we have in place have improved neonatal services and will continue to do so as they are implemented and embedded into practice.

1036. Overall, as a result of the actions described in this statement, and particularly those taken during the Further Relevant Period and the ongoing current work, NHS England has increasing confidence in the effectiveness of current governance and management structures, the safety culture within the NHS as a whole and in general in

hospitals, in keeping neonatal babies in hospital safe and ensuring the quality of their care.

1037. That said, NHS England recognises that there is further work to do and that when there is a recurrence of concerns identified in reviews it may indicate that some of the actions previously taken have not been fully delivered the desired results. We have drawn out particular areas where we consider further changes may be warranted. We continue to seek to improve the governance and culture of the NHS as a whole and neonatal services and are keen to learn from the events involving LL.

1038. Before recommendations to improve patient safety are made, it is important to ensure that the NHS bodies implementing those recommendations have sufficient capacity and resources to take the required action and monitor the impact, including consideration of finance, staff and technology infrastructure. This must be achievable without risk that the implementation and adoption of any new way of working would detract staff time from providing effective patient care.

1039. In the current period, it must be borne in mind that many NHS commissioners and providers are under very significant financial pressures. It is well documented that despite government investment in the NHS, there has been historic under-funding to keep pace with demand. Significant resourcing issues remain in key services (including maternity), capital, technology and diagnostics. NHS England has undergone a re-structure which has reduced the single organisation by up to 40% of the previous combined size of NHS England, Health Education England and NHS Digital. Integrated Care Boards likewise are going through similar efficiency review processes. Provider Trusts in turn are under extreme financial pressure and must identify cost-reducing efficiency savings to remain within their financial budget. The financial and operational pressures trusts are facing means that the efficiency savings they must deliver are estimated to be on average around 5% which is significantly higher than in previous years. In a recent survey carried out by NHS Providers of NHS Provider Trusts, the majority of respondents identified insufficient capital funding to address maintenance backlogs, enable strategic transformation of their estates (including digital), deliver net zero ambitions and tackle care backlogs **[SP/0245, INQ0014780]**.

1040. It is also essential to recognise that more recent initiatives are not yet embedded, including those set out in the Three Year Delivery Plan, the strengthened Fit and Proper Person Framework and the Patient Safety Incident Response Framework.

These need sufficient time before analysis of effectiveness can be carried out. That said, we are clear that waiting for analysis of effectiveness should not prevent the introduction of new measures where there is clear evidence for change.

1041. We look forward to working with the Inquiry as it takes forward consideration of these important issues.

Annexes

- **Annex 1** — List of Secretaries of State from the 1 April 2013 to present.

- **Annex 2** — Comparison between the National Reporting and Learning Service and the Learn From Patient Safety Events Service.

- **Annex 3** - Project Columbus and NHS England's rapid review of patient safety and incident reporting data

- **Annex 4** - Individuals who were in key roles in NHS England between June 2015 and the present.

- **Annex 5** — Individuals who were in key roles in NHS Improvement between June 2015 and the present.

- **Annex 6** — Individuals who were in key roles in the NHS England Regional Team that had the Countess of Chester Hospital in its remit between June 2015 and the present.

- **Annex 7** - North Regional Team organogram.

- **Annex 8** - Integrated Care Systems Explained.

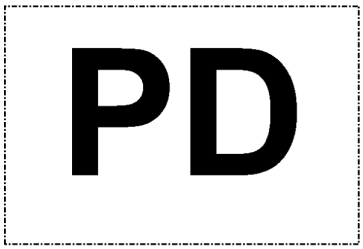
- **Annex 9** – Pay structures of neo-natal staff.

- **Annex 10** – Pay structures of very serious managers.

- **Annex 11** - Index of exhibits referred to in this statement.

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_____

Dated: 25Th March 2024

ANNEX 1: Secretaries of State from 1 April 2013 to present

This annex sets out the names of the Secretaries of State for Health from the date of the implementation of the 2012 Act onwards. Note that from 8 January 2018, this role has been called the Secretary of State for Health and Social Care.

Name	Term
The Right Honourable Jeremy Hunt MP	4 September 2012 – 9 July 2018 (Secretary of State for Health until 8 January 2018, Secretary of State for Health and Social Care thereafter)
The Right Honourable Matt Hancock MP	9 July 2018 – 26 June 2021
The Right Honourable Sajid Javid MP	26 June 2021 – 5 July 2022
The Right Honourable Steve Barclay MP	First term: 5 July 2022 – 6 September 2022 Second term: 25 October 2022 – 13 November 2023
The Right Honourable Therese Coffey MP	6 September 2022 – 25 October 2022
The Right Honourable Victoria Atkins MP	13 November 2023 - present

ANNEX 2: Comparison between the National Reporting and Learning Service and the Learn From Patient Safety Events Service	**Position to date** **(Separate systems for reporting patient safety incidents, and Serious Incidents under the Serious Incident Framework)**		**Position going forwards** **(Single service for reporting all patient safety incidents)**
	National Reporting and Learning System	**Strategic Executive Information System**	**Learn From Patient Safety Events Service**
Purpose	One of two key NHS England data systems that incident reporting needed to be uploaded to (the other being the Strategic Executive Information System). Served as a national database to collect	One of two key NHS England data systems that incident reporting needed to be uploaded to (the other being the National Reporting and Learning Service). Served as a national system for reporting	Comprehensive system for all incident reporting. Removes the need to upload data on the Strategic Executive Information System in addition to the National Reporting and Learning Service.

	patient safety incident records from organisations across the NHS.	all Serious Incidents under the Serious Incident Framework.	
Managed by	National Patient Safety Team, NHS England	National Patient Safety Team, NHS England	National Patient Safety Team, NHS England
Data uploaded	Manual batch extraction and upload of incident reports made to local risk management systems required (most incidents are collected via this route). Individual incident eForm (mostly used by Primary Care organisations)	Separate to local systems; manual creation of incident record required in addition to that recorded to local risk management systems	Real time interface between local systems and national data system; no separate manual batch extraction and upload required. Investigation and response information can be appended to initial event record in an upgrade currently being rolled out. "Real time" data enabled Additional separate Online Incident Reporting

			capability for those not using local risk management systems
Anonymous reporting enabled - note the distinction between the anonymity of the reporter and the anonymity of the people involved in the incident	Information about incidents available in national systems is anonymised. Local version of the record will include identifiable information regarding patients and staff involved within the local risk management system. Option for users to record anonymously via an eForm but this is then only visible to the national team, not the provider in question.	StEIS users requested to avoid including patient and staff names and identifying details, however the level of information provision is still sensitive and there is no automatic cleansing of the information provided. Patient confidential information may be required as part of investigation but this will be unlikely to be recorded on StEIS. The person recording the information is usually	Patient and staff information may be included in the version of the record on local risk management systems but the record is cleansed before storage in the national system to remove information about the recorder, staff or patients involved. Users have the option to record anonymously or by logging in, and to make this available to the provider in question or not.

		identified in the record.	
Who has direct access	National Patient Safety Team, NHS England HSIB (now HSSIB) when it was part of NHS England	National Patient Safety Team, NHS England NHS England Regional Teams (to their own region) Clinical Commissioning Groups / Integrated Care Boards (to their own area/providers) HSSIB CQC Providers (to their own information) Legacy bodies (for example the NHS Trust Development Authority) and specific	National Patient Safety Team, NHS England NHS England Regional Teams (pending completion of development work which is imminent) Integrated Care Boards (pending completion of development work which is imminent) Providers (to their own information) The public, to interactive aggregate quantitative data (pending completion

		commissioning functions (ie specialised commissioning teams)	of development work which is imminent)
Third party sharing	Regular full database copies prepared and made available to Care Quality Commission, MHRA, HSSIB Specific extracts from the database prepared and made available to other organisations/partners according to individual Data Sharing Agreements Including weekly updates to Care Quality	Specific extracts from the database prepared and made available to other organisations/partners according to individual Data Sharing Agreements	Regular full database copies prepared and made available to Care Quality Commission, MHRA, HSSIB. Specific extracts from the database prepared and made available to other organisations/partners according to individual Data Sharing Agreements

	Commission and MHRA		
Data Processing	Data is reviewed and processed by the National Patient Safety Team for the purposes of national learning and improvement. Most data validation is performed at the point of data entry/submission. Semi-automatic anonymisation process is in place to minimise the risk of identification of individuals involved in the incident. Manual redaction supplements	Data is reviewed by providers, commissioners and regional teams. Data is not routinely processed or published. Data is reviewed by the national patient safety team for the purposes of national learning and improvement	Data is reviewed and processed by the National Patient Safety Team for the purposes of national learning and improvement. Data is automatically anonymised using Named Entity Recognition anonymisation algorithm to enable more effective data processing and cleansing. The algorithm's efficiency will continue to improve over time.

	automatic anonymisation Statistical data was published up to the point where transition to LFPSE began at which point statistical data publication was paused due to the transition of the data set (see below row)		Manual redaction supplements automatic anonymisation
Published thematic reporting and data analysis	• National patient safety incident data reports. These set out counts of reports by degree of harm, incident type, care setting of occurrence, reporting rates, and reporting lags. • Organisation patient safety incident data reports. These set out counts of reports by degree of harm, incident type, care setting of occurrence, reporting rates, and reporting lags at Trust level • Monthly data on patient safety incident reports. These provide a rolling data source to show number	Data is not routinely published except for Never Events data. This is published monthly as an overall cumulative total for the current financial year by reporting organisation, month of occurrence, Never	New Recorded Data Dashboard to enable access to as near to real time aggregated patient safety incident data, with ability to isolate particular areas of interest through filters and drill down tools. This will be publicly

	of patient safety events reported in the previous 12 months. data publication was paused once transition to LFPSE began.	Event type, and brief description	available (roll-out imminent). Further statistical analysis and publication of data from LFPSE will be considered following completion of transition and stabilised data collection. Any publication will be experimental in the first instance.

ANNEX 3 - Project Columbus and incident review/look back

1. In June 2023, in anticipation of the trial involving LL coming to an end and a verdict being reached, NHS England established Project Columbus. Whilst the trial was not declared an incident within the context of NHS England's Emergency Preparedness Resilience and Response, Project Columbus was established and managed along recognised and well established incident response processes. Taking this approach is not uncommon when responding to an event that impacts on public confidence and requires active coordination and support to manage the information needs that result. Adopting an incident response approach enabled a structured multi organisational way of working, with clear roles and responsibilities. It also supported the scale and pace of work required, with the potential for a verdict to be reached any time in the period shortly following establishment of Project Columbus. External participants and wider stakeholders were also familiar with an incident response approach, and it enabled NHS England to support the local system. This is not uncommon and a similar approach has recently been adopted in relation to managing issues in relation to reinforced aerated autoclaved concrete (RAAC).[30]

2. The Senior Responsible Officer for Project Columbus was the Chief Operating Officer, to whom all NHS England regions report. In turn he reported into the Quality and Performance Committee.

3. The potential scope of work for Project Columbus is described in the terms of reference agreed at the time of its establishment [**Exhibit PID/TOR, SP/246, INQ0014754**]. Consistent with an incident response approach, Project Columbus was designed to be flexible and to adapt as the trial progressed and understanding of the circumstances developed. In summary, however, Project Columbus operated as follows.

4. A Strategic Oversight Group provided strategic direction and took key decisions. This Group consisted of key national directors and the North West Regional Director. The Senior Responsible Officer chaired this Group. Meetings were held on a weekly basis, with additional ad-hoc meetings when required. Senior representatives from the Countess of Chester Hospital were invited to attend the first part of the weekly standing meetings to provide an update but they were not members of this Strategic Oversight Group and once an update had been provided, meetings were conducted on an NHS England-only basis.

5. A Management Group supported the Strategic Oversight Group and had broader membership, including senior representatives from the Countess of Chester Hospital and NHS Cheshire and Merseyside Integrated Care Board (noting that representatives from the Hospital also attended meetings of the Strategic Oversight Group). Representatives from the Department of Health and Social Care attended meetings of the Management Group from time-to-time.

6. The Management Group was chaired by the National Director of Emergency Planning and Incident Response.

7. In that context, areas of potential public and media interest were identified and targeted work was carried out to help inform NHS England's understanding of issues raised by LL's trial and its operational response. This also supported Department of Health and Social Care officials from time to time in briefing ministers. Understandably, given the

[30] https://www.england.nhs.uk/long-read/reinforced-aerated-autoclaved-concrete-raac/

shocking nature of LL's (at the time) alleged offending, it identified questions which were important to consider.

8. Until the trial began, there was nervousness around commencing analysis of any evidence around any deaths. In part this was because the Countess of Chester's external review remained ongoing, as did the police investigations. We stood ready to support the police.

9. However, as the trial progressed, we felt it necessary to carry out a rapid and limited review around the effectiveness of the patient safety and incident reporting data systems managed by NHS England. There was therefore a discussion within the patient safety team as to when the appropriate time would be to conduct an analysis of the data held on the National Reporting and Learning System and the Strategic Executive Information System, in order to assess whether these systems had functioned as intended or whether there were immediate risks around the effectiveness of these data systems that needed to be more formally considered. In June 2023, therefore, a rapid piece of work was carried out by the national patient safety team to determine what information relating to incidents on the neonatal unit at the Countess of Chester Hospital during the period January 2015-December 2016 had been reported to either the National Reporting and Learning System and/or the Strategic Executive Information System and how these had been identified and analysed at the time. The Countess of Chester Hospital were aware of the review and provided information to the review team to help learnings.

10. This work was led by the patient safety team and the conclusions were reported to the National Director of Patient Safety in July 2023, following which he verbally briefed the Project Columbus structures described above. Although this rapid review and the subsequent briefing by the National Director of Patient Safety were not formalised or minuted, assurance was able to be provided that the data systems had operated as intended and that there did not appear to be any immediate issues regarding the effectiveness of these systems requiring immediate action or that suggested the national patient safety team could not continue to operate in accordance with its standard practices. This does not, of course, mean that work is not needed to strengthen and improve data collection and analysis overall and we have described in paragraphs 824-851 of this statement the ongoing work in this regard. This includes the transition currently underway from the data systems that were in use in 2015-2016 to the new Learn From Patient Safety Events Service.

Rapid review of Countess of Chester incident reporting data

11. It is really important that the conclusions of the rapid review, described below, are read alongside paragraphs 340-341 and Annex 2, where we have described in detail the way in which the National Reporting and Learning System and the Strategic Executive Information System operate; their purpose; what data is collected; and how it is analysed. To briefly reiterate key points in the context of the rapid review:

    a. The primary purpose of the National Reporting and Learning System is to enable the detection of new or under-recognised patient safety incidents that could require national action to prevent them happening elsewhere. This can be done through the issuing of Patient Safety Alerts, that require healthcare providers to take specific actions to reduce the risk of harm. The analysis of data reported to the National Reporting and Learning System does not routinely respond to individual reports of known major patient safety risks. However, where data suggested that a service or practitioner was unsafe, these concerns would be escalated if it was unclear that appropriate action was not already

underway. The National Reporting and Learning System was not designed to be used to support performance management or regulatory oversight of providers.

b. The Strategic Executive Information System enabled the reporting of incidents that had been formally declared as serious incidents or never events. In contrast to the National Reporting and Learning System, the Strategic Executive Information System could support performance management by commissioners of providers and regulatory oversight. However, the effectiveness of the Strategic Executive Information System was strongly dependent on appropriate identification and reporting of incidents by providers.

12. In order to carry out the rapid review, data held on both the National Reporting and Learning System and the Strategic Executive Information System was considered. Incident data was considered as being "in-scope" if it met the following conditions:

    a. The word "neonatology" was included;

    b. It had been submitted by the Countess of Chester Hospital; and

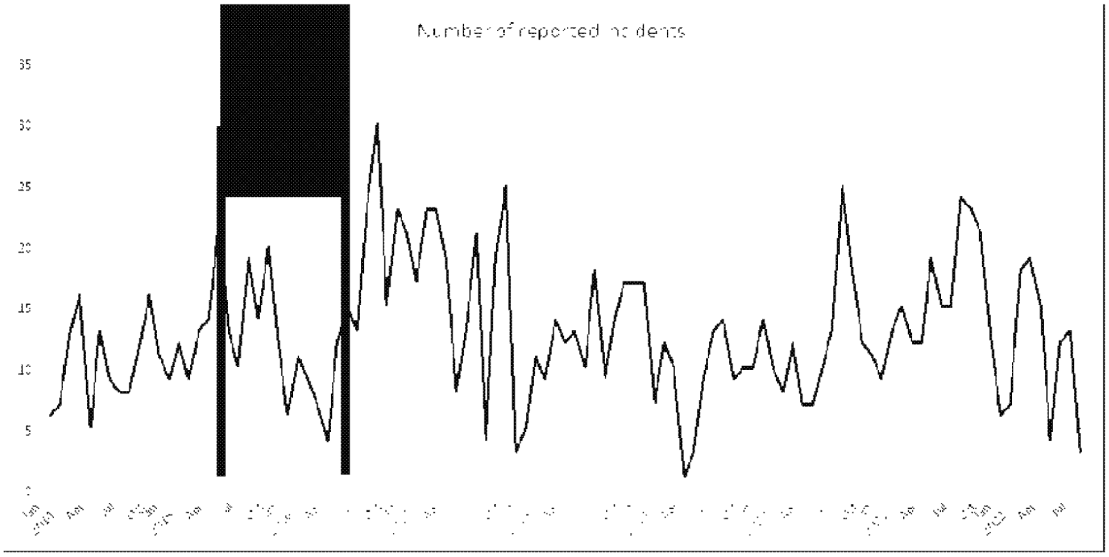
    c. The incident was reported in the period January 2015-December 2016.

13. When data satisfying these criteria was reviewed, NHS England found that the Countess of Chester Hospital had reported the following total number qualifying incidents:

    a. 167 incidents reported in 2015; and

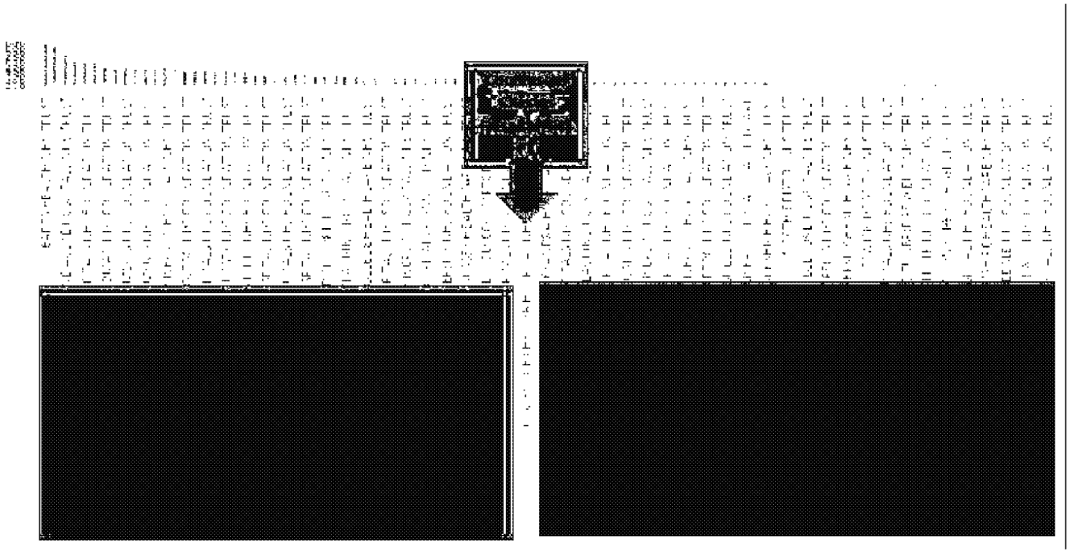
    b. 168 incidents reported in 2016.

Figure 1: Number of incidents reported to the National Reporting and Learning System under neonatology sub-speciality fields by the Countess of Chester Hospital NHS FT, per month.



14. At the time that the rapid review was carried out, NHS England's understanding was that there were 31 cases relating to incidents meeting the above criteria that had been considered by external reviewers. Of this 31, the Countess of Chester Hospital was able to identify that 18 incident reports had been raised. The remainder had not been reported by the Countess of Chester Hospital to either of the national data systems. There are a number of reasons why incident reports might not have been raised for all cases, as we have previously described in Sections 1 and 2 of this statement. The conclusions reached by the national patient safety team at the time of the rapid review were that this difference in the number of incidents and those formally reported was in keeping with reporting patterns within many trusts

Figure 2: Number of incidents reported to the National Reporting and Learning System under neonatology speciality fields June 2015-June 2016 per reporting trust (not adjusted for neonatal unit size or for level of care neonatal unit provides). All reporting trusts other than



the Countess of Chester Hospital have been anonymised.

15. The data provided by the Countess of Chester Hospital was compared with what was held on NRLS to determine whether there were themes or alerts that had not been identified and which could have enabled earlier indications of issues on the neonatal unit. A cross-match for 17 of the 18 incident reports could be made and of those, 16 had been extracted and reviewed at the time by the national patient safety team as per the routine monitoring and review of data uploaded onto National Reporting Learning System.

16. The following aspects are of note:

    a. sudden death and sudden collapse of a neonate is cited in 11 of the cases, 4 of which were unexpected repeat arrests. The routine review of data entries to the data systems had identified all of these plus a further 3 incidents within the period in question. All of these varied in presentation and there were no discernible themes given the small numbers.

    b. the Countess of Chester Hospital identified 1 case of long line issues, either broken/damaged or not in situ. This incident was noted at the time by the national patient safety team, along with a further 12 cases where long lines

were indicated. 2 of these were out of scope either as the fault was identified on insertion by a doctor (n=1) or were out of the period in question (n=1). The review also found 7 occasions where a long line was found to be damaged or not in place within the period in question. It does not appear that these incidents were reported on the Strategic Executive Information System. Without denominators of number of lines inserted or normal rate of breakage or accidental removal it is not possible to determine whether these numbers are significant. However, in some cases the lines were found 'on the baby's abdomen' or 'lying in the cot' and there is no indication that this was followed up at the time. These incidents would not have met the threshold criteria against which national patient safety incidents were assessed (i.e. all incidents categorised as involving death or severe harm, which represents around 0.5% of the total number of incident reports received and amounts to about 1000 cases per month that are reviewed by the national patient safety team).

c. the Countess of Chester Hospital also identified some cases of medication errors (n=3), transfusion issues (n=2), and equipment availability (n=1), all of which had been picked up in the routine review at the time. Whilst other medication errors were detected, there were not significantly large numbers of these.

d. the most commonly reported incident by the Countess of Chester Hospital on the National Reporting and Learning System for this period related to issues with the governance and running of the milk fridges which supplied stored breast milk.

e. communication issues were also commonly detailed in incident reports with labour ward, between staff groups, with Liverpool Women's hospital and the North West Transfer team were found. These recorded poor communication or frustration with a lack of effective communication.

f. there were periodic incidents related to the closure of the neonatal unit related to staffing issues and staff shortages but, again, these were in relatively small numbers.

g. there were no incidents recorded related to concerns of medical staff related to care of the neonates by nurses in any of the National Reporting and Learning System reports examined.

h. there were a small number of incidents related to point of care testing being inaccurate, blood spot testing being missed, failure to check gentamicin levels prior to administration, a clamp removed from a line and an umbilical clamp being found in a neonate's nappy. None of these were in significant numbers but all occurred within the time span in question. None appear to be related to the cases involving LL.

i. there are 3 Serious Incident reports on the Strategic Executive Information System which relate to neonatal fatalities, but it has not been possible to link these to either the incident report number provided by the Countess of Chester Hospital or to National Reporting and Learning System numbers as the date of incident does not match any of the incidents reviewed to date.

17. The overall conclusion reached following the incident review was that there was no evidence of any clear themes in these incidents that occurred in sufficient volume to

provide early warning of an issue via reported incidents on the National Reporting and Learning System. There is also little evidence that new or under recognised issues were identified in incidents which could have alerted NHS England via the current clinical review processes.

18. As part of the rapid review, a targeted analysis was also carried out of data held on the National Reporting and Learning System for incident reports raised by the Countess of Chester Hospital in relation to neonatal incidents involving death or severe harm. This analysis suggests that none of the incidents that are now known to involve criminal activity resulting in death or severe harm were reported to the National Reporting and Learning System with a degree of harm of death or severe harm until the final murders which occurred in late June 2016. These were the deaths of two triplets on adjacent days. These appear to have been reported to the National Reporting and Learning System, with the report uploaded in late July 2016, slightly over a month after the deaths occurred (although they were reported much sooner via the Strategic Executive Information System, as discussed below). Looking at the reports, the deaths are reported in very brief and neutral language.

19. The National Reporting and Learning System reports of the death of two triplets were cross checked by the team with data held on the Strategic Executive Information System, where they were also reported in brief neutral language alongside text noting these deaths were part of wider concerns on mortality rates that had been reported externally (see paragraphs 497-498). A separate Strategic Executive Information System report indicated that by early July 2016 the neonatal unit had changed its admissions policy to reduce the acuity of its patients and to have fewer intensive care cots (see paragraph 505). These Strategic Executive Information System reports would have provided the assurance required that issues were already known to the appropriate parties and action was in place to address them and therefore no additional national action was taken.

20. It does appear from this targeted analysis that the death of a baby was reported to the Strategic Executive Information System in June 2015. In accordance with the approach described in Section 2, this would therefore have been known to the NHS England Regional team, as well as to the Care Quality Commission. However, the report describes the baby's collapse shortly after birth and admission to the neonatal unit in poor condition and suggests the cause of death is likely to be sepsis after premature rupture of membranes. This is a recognised patient safety issue with a range of longer-term improvement activities linked to it, so did not trigger an individual response for its potential to lead to a Patient Safety Alert or similar action. There was nothing in the report indicating concern about a specific professional and the baby's condition was described as very poor on admission to neonatal care, so such a report in isolation would not normally trigger further action by the patient safety team.

21. In summary, the deaths of 3 neonatal babies were reported by the Countess of Chester Hospital during the qualifying period. In 2015, 1 death appears to have been reported as a Serious Incident, but with text that suggested that the death was due to sepsis. It appears no other Serious Incidents or National Reporting and Learning System incidents with a degree of harm of death or severe harm were reported during this period, until the deaths of two babies which were reported to both the National Reporting and Learning System (in late July 2016) and to the Strategic Executive Information System (on 30 June 2016), the latter of which was on the same day that LL worked her final shift on the ward.

ANNEX 4: Individuals in Key Roles at NHS England

June 2015 – Present

TABLE 1: NHS England (April 2013 – March 2019)

This table lists those holding national executive team positions in NHS England (legally known as the NHS Commissioning Board) from June 2015 through to March 2019.

Key Leader	Role	Notes
Sir Simon Stevens	Chief Executive Officer (April 2014 - July 2021)	Board member
Paul Baumann	Chief Financial Officer (May 2012 - November 2018)	Board member
Matthew Style	Acting Chief Financial Officer (November 2018 – March 2019)	Board member
Jane Cummings	Chief Nursing Officer (April 2013 - December 2018)	Board member
Dame Barbara Hakin	National Director: Commissioning Operations (April 2013 – December 2015)	Board member (non-voting)
Richard Barker	Former Interim National Director: Commissioning Operations (January 2016 – May 2016)	Board member (non-voting)
Matthew Swindells	National Director: Operations and Information (May 2016 - September 2018) Deputy Chief Executive (September 2018 – July 2019)	Board member (non-voting)
Tim Kelsey	National Director for Patients and Information (July 2012 - December 2015)	Board member (non-voting

Professor Sir Bruce Keogh	National Medical Director (April 2013 - January 2018)	Board member
Professor Stephen Powis	National Medical Director (March 2018 - present)	Board member
Karen Wheeler CBE	National Director: Transformation & Corporate Operations (April 2014 - June 2017)	Board member (non-voting)
Dr Emily Lawson	National Director: Transformation & Corporate Operations (November 2017 – July 2021)	Board member (non-voting)
Ian Dodge	National Director: Strategy and Innovation (July 2014 – June 2022)	Board member (non-voting)
Pauline Phillip	National Director for Emergency and Elective Care (December 2015 - December 2022	
Rosamund Roughton	National Director: Commissioning Development (April 2013 – October 2017)	
Tim Kelsey	National Director for Patients and Information (April 2013 – December 2015)	
James Palmer	Medical Director for Specialised Commissioning (2013 – Present)	
Jonathan Fielden	Director of Specialised Commissioning (2016 - 2017)	
Celia Ingham – Clarke	Medical Director for clinical effectiveness (2016 – present)	

TABLE 2: NHS England and NHS Improvement (April 2019 – June 2022)

This table lists those holding national executive team positions in NHS England and NHS Improvements from April 2019 through to June 2022. During this period NHS England and NHS Improvement were working together, through a Board-in-common.

Key Leader	Role	Notes

Sir Simon Stevens	Chief Executive Officer (April 2014 - July 2021)	Board member
Amanda Pritchard	Chief Operating Officer (July 2019 – July 2021) Chief Executive Officer (August 2021 – present)	Board member Board member
Bill McCarthy	Interim Accounting Officer (June 2019 – July 2019)	Board member
Mark Cubbon	Interim Chief Operating Officer (August 2021 – December 2021)	Board member
Sir David Sloman	Chief Operating Officer (December 2021 – August 2023)	Board member
Julian Kelly CB	Chief Financial Officer (April 2019 - present)	Board member
Dame Ruth May	Chief Nursing Officer (January 2019 - present)	Board member
Professor Sir Stephen Powis	National Medical Director (March 2018 - present) Interim Chief Executive Officer NHSI (1 August 2021-30 June 2022)	Board member
Dame Emily Lawson	National Director: Transformation & Corporate Operations (November 2017 – July 2021)	Board member (non-voting)
Ian Dodge	National Director: Strategy and Innovation (1 July 2014 – June 2022)	Board member (non-voting)
Prerana Issar	Chief People Officer (1 April 2019 until March 2022)	
Em Wilkinson Brice	Interim Chief People Officer (March 2022 – April 2023) Deputy Chief People Officer (September 2019 - March 2022)	
Hugh McCaughey	National Director of Improvement (April 2019 – March 2022)	
Pauline Phillip	National Director for Emergency and Elective Care (December 2015 - December 2022)	
Matthew Gould	CEO of NHSX / National director for Digital Transformation (July 2019 - May 2022)	

Teresa Fenech	Director of Nursing, Specialised Commissioning, NHSE (2015 – 2019)	
John Stewart	Director, Specialised Commissioning NHSE, (2017 – Present)	
James Palmer	Medical Director for Specialised Commissioning (2013 – Present)	
Celia Ingham – Clarke	Medical Director for clinical effectiveness (2016 – present)	
Aidan Fowler	National Director of Patient Safety – (April 2018 – present)	

TABLE 3: NHS England *new* (July 2022 – present)

This table lists those holding national executive team positions in the new NHS England following legal merger with NHS Improvement and other legacy bodies.

Key Leader	**Role**	**Notes**
Amanda Pritchard	Chief Executive Officer (August 2021 – present)	Board member
Julian Kelly	Chief Financial Officer / Deputy Chief Executive (April 2019 - present)	Board member
Professor Sir Stephen Powis	National Medical Director (March 2018 - present)	Board member
Dame Ruth May	Chief Nursing Officer (January 2019 - present)	Board member
Steve Russell	Chief Delivery Officer (February 2022 – present)	
Mike Prentice	National Director for Emergency Planning and Incident Response (April 2022 – present)	
John Stewart	Director, Specialised Commissioning NHSE, (2017 – Present)	

Teresa Fenech	Director of Nursing and Taskforce Director (2019 – 2022)	
Sir David Sloman	Chief Operating Officer (December 2021 – August 2023)	
Sir Jim Mackey	Interim Chief Operating Officer (September 2023 – October 2023)	
Dame Emily Lawson	Interim Chief Operating Officer (November 2023 – present)	
Sarah-Jane Marsh	National Director for Urgent & Emergency Care and Deputy Chief Operating Officer (January 2023 – present)	
Jacqueline Rock	Chief Commercial Officer (January 2022 - present)	
Dr Tim Ferris	National Director of Transformation (June 21 – August 2023)	
Dr Vin Diwaker	Interim National Director of Transformation (August 2023 – present)	
Chris Hopson	Chief Strategy Officer (June 2022 - present)	
Dr Navina Evans	Chief Workforce, Training and Education Officer (April 2023 – present)	
Duncan Burton	Deputy Chief Nursing Officer (April 2021 - Present)	
Celia Ingham – Clarke	Medical Director for clinical effectiveness (2016 – present)	
Aidan Fowler	National Director of Patient Safety – (April 2018 – present) Deputy Chief Medical Officer (March 2020 – Present)	

ANNEX 5: Individuals in Key Roles at NHS Improvement

June 2015 – March 2019

TABLE 1: MONITOR (June 2015 – March 2016)

This table lists those holding national executive team positions in NHS Monitor from June 2015 through to March 2016.

2015/16 was a transitional year which saw the NHS Trust Development Authority (NHS TDA) and Monitor preparing to work more closely together under the banner of NHS Improvement. Between January 2016 and March 2016, changes were made to the executive team to reflect this transition. For ease of understanding, the table below sets out the executive team before joint working took effect.

Key Leader	Role	Notes
Dr David Bennett	Chief Executive (November 2012 – October 2015)	Board member
Jim Mackey	Chief Executive (November 2015 - December 2017)	Board member
Miranda Carter	Executive Director of Assessment / Provider Appraisal (November 2012 - March 2016)	
Catherine Davies	Executive Director of Cooperation and Competition (October 2012 - March 2016)	
Fiona Knight	Executive Director Organisation Transformation (July 2013 - March 2016)	
Professor Hugo Mascie-Taylor	Medical Director and Executive Director of Patient Clinical Engagement (May 2014 - March 2016)	

Kate Moore	Executive Director of Legal Services (September 2004 - March 2016)	
Jeremy Mooney	Executive Director Strategic Communications (January 2015 - March 2016)	
Adam Sewell-Jones	Executive Director Provider Sustainability (August 2015 - March 2016)	
Stephen Hay	Managing Director of Provider Regulation (October 2004 - March 2016)	Board member
Adrian Masters	Managing Director of Sector Development (September 2005 - March 2016)	Board member
Ruth May	Executive Director of Nursing (from July 2015 to March 2016)	

TABLE 2: NHS TRUST DEVELOPMENT AUTHORITY (June 2015 – March 2016)

This table lists those holding national executive team positions in the NHS Trust Development Authority (NHS TDA) from June 2015 through to March 2016.

2015-16 was a transitional year which saw the NHS TDA and Monitor preparing to work more closely together under the banner of NHS Improvement. Between January 2016 and March 2016, changes were made to the executive team to reflect this transition. For ease of understanding, the table below sets out the executive team before joint working took effect.

Key Leader	Role	Notes
Jim Mackey	Chief Executive (November 2015 - December 2017)	Board member
Robert Alexander	Deputy Chief Executive (November 2015 – March 2016) Chief Executive (April 2015 - October 2015) Director of Finance (June 2012 - March 2015)	Board Member

Elizabeth O'Mahony	Acting Director of Finance (April 2015 - April 2016)	Board Member
Robert Checketts	Director of Communications (June 2012 - January 2016)	Board Member (non-voting)
Peter Blythin	Director of Nursing (June 2012 – March 2016)	Board Member (non-voting)
Ralph Coulbeck	Director of Strategy (June 2012 - March 2016)	Board Member (non-voting)
Dr Kathy McLean	Medical Director (June 2012 - March 2016)	Board member

TABLE 3: "NHS Improvement" (April 2016 – March 2019)

This table lists those holding national executive team positions in NHS Improvement from April 2016 through to March 2019.

Note that from 1 April 2016, the membership of the Monitor Board was identical to that of the TDA Board, and two Boards met jointly to form the NHS Improvement Board. There were no legislative changes associated with the creation of NHS Improvement however and the two organisations continued during this period as separate legal entities.

Key Leader	**Role**	**Notes**
Jim Mackey	Chief Executive (November 2015 - December 2017)	Board member
Ian Dalton	Chief Executive (December 2017 - June 2019)	Board member
Robert Alexander	Executive Director of Resources / Deputy Chief Executive NHSI (April 2016 - January 2018)	Board member
Stephen Hay	Executive Director of Regulation / Deputy Chief Executive (April 2016 – March 2019)	Board member
Ruth May	Executive Director of Nursing (April 2016 - January 2019)	Board member

Dr Kathy McLean	Executive Medical Director NHSI (April 2016 – March 2019). Also Chief Operating Officer from November 2017.	Board member
Elizabeth O'Mahony	Chief Finance Officer (July 2017- March 2019)	
Jeremy Marlow	Executive Director of Operational Productivity (June 2016 – 2019)	
Adrian Masters	Executive Director of Strategy (April 2016 - 2019)	
Helen Buckingham	Executive Director of Corporate Affairs (April 2016 - March 2017)	
Ben Dyson	Executive Director of Strategy (June 2016 – March 2019)	
Adam Sewell-Jones	Executive Director of Improvement (April 2016 - January 2019)	

ANNEX 6: North region(s) – relevant directors (2015 – present)

This table lists those holding key regional positions in NHS England and its legacy bodies.

Further detail on individuals working with the regional structures will be set out in Section 3.

Key Leader	**Role**
Monitor (2012-2019)	
Lyn Simpson	Director of Delivery and Development: North (August 2013 - March 2016)
NHS Improvement (2016 – 2019)	
Lyn Simpson	Executive Regional Managing Director North (April 2016 - March 2019)
Vince Connelly	Regional Medical Director, NHS Improvement, North (November 2016 – Present)
Gaynor Hales	Regional Director of Nursing (2016 – 2019)
Helen Dabbs	Regional Director of Nursing, Delivery and Improvement, North (2015 – 2018)
NHS England (2013 – 2019)	
Richard Barker	North Regional Director (April 2013 – March 2019)
Damien Riley	Regional Medical Director (North) (April 2015 – June 2016)

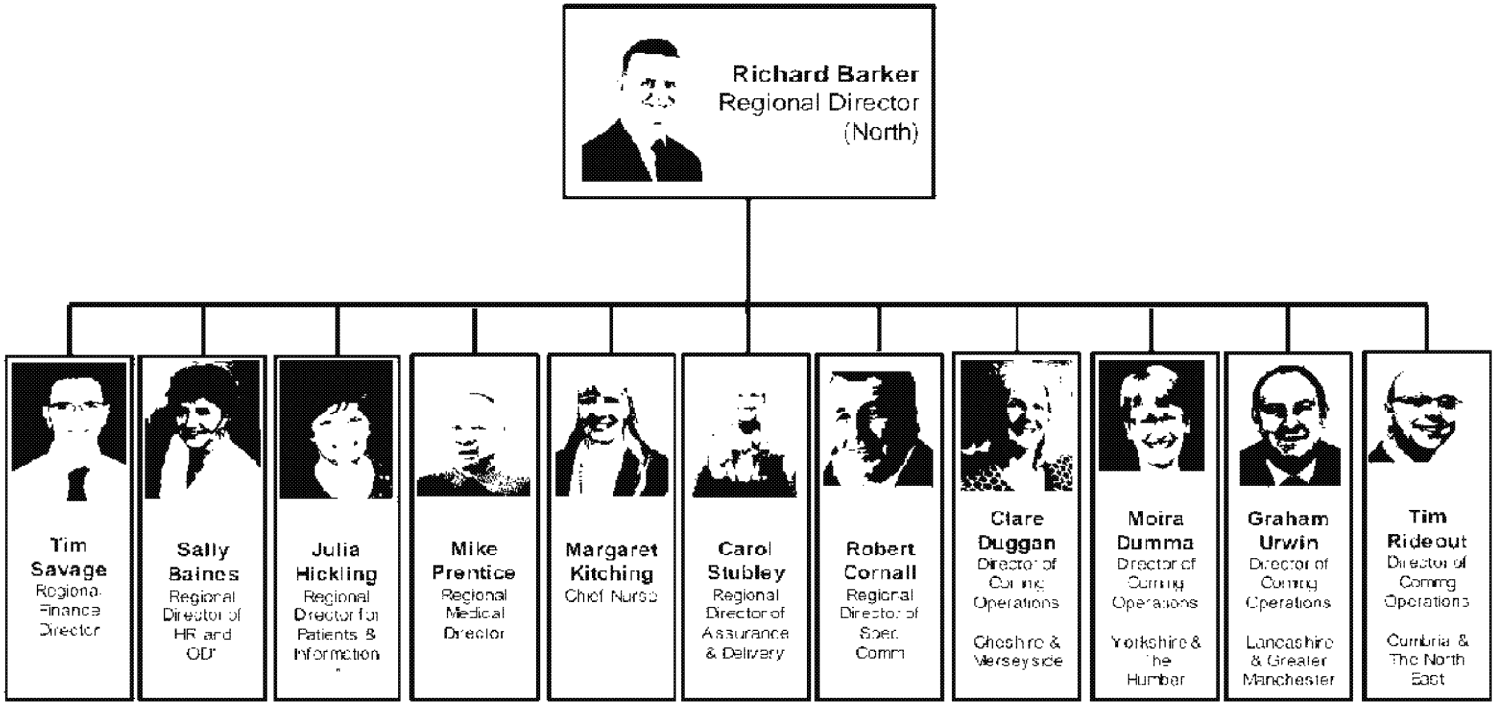
Mike Prentice	Regional Medical Director (North) (June 2016 – April 2022)
Alison Rylands	Regional Clinical Director, Specialised Commissioning, North (April 2015 – June 2016)
Michael Gregory	Regional Clinical Director, Specialised Commissioning, North (June 2016 – March 2019)
Andrew Bibby	Assistant Regional Director of Specialised Commissioning (North West) (April 2015 – March 2019)
Sue McGorry	Head of Quality, Specialised Commissioning (North West) (April 2015 – present)
Alison Tonge	Regional Director of Specialised Commissioning (North) (April 2015 – November 2015)
Robert Cornall	Regional Director of Specialised Commissioning (North) (November 2015 – March 2019)
Margret Kitching	Chief Nurse North (April 2015 – March 2019)
Lesley Patel	Director of Nursing, Specialised Commissioning, North (April 2015 – May 2021
NHS England and NHS Improvement (2019-2022)	
Bill McCarthy	North-West Regional Director (February 2019 - July 2021)
Amanda Doyle	North-West Regional Director (August 2021 – June 2022)
Vince Connelly	Regional Medical Director, NHS Improvement, North (November 2016 – Present)
Linda Charles – Ozuzu	North-West Regional Director of Commissioning (September 2019 – present)
Vaughan Lewis	Regional Medical Director and CCIO (April 2019 – Present)
Michael Gregory	Medical Director – Commissioning, North west (April 2019 – June 2022)
Andrew Bibby	Regional Director of Health & Justice and Specialised Commissioning (North West) (April 2019 – Present)

Sue McGorry	Head of Quality, Specialised Commissioning (North West) (April 2015 – present)
Lesley Patel	Director of Nursing, Specialised Commissioning, North (April 2015 – May 2021
Vaughan Lewis	Regional Medical Director (April 2019 – Present)
Jackie Bird	Chief Nurse North West (2019 – 2021)
Hayley Citrine	Chief Nurse North West (April 2021 – November 2022)
Jackie Hanson	Chief Nurse North West (December 2021 – present)
James McLean	Chief Nurse North West (2022[?] – present)
NHS England *new* (2022-present)	
Richard Barker	North West Regional Director (June 2022 – present)
Michael Gregory	Medical Director – Commissioning, North west (April 2019 – June 2022)
Sue McGorry	Head of Quality, Specialised Commissioning (North West) (April 2015 – present)

ANNEX 7: North Regional Team organogram

NHS England

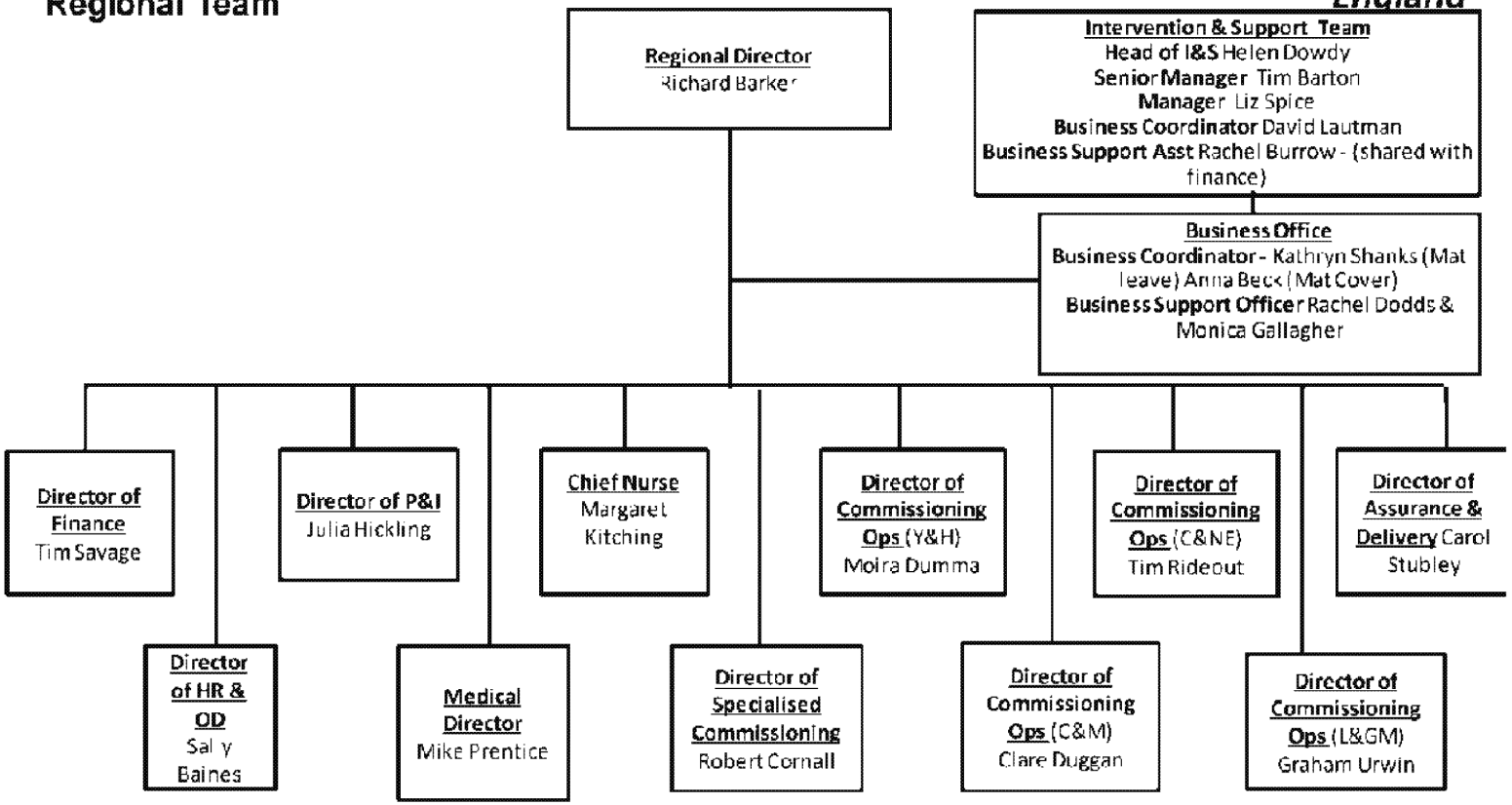
Regional Team (North)



*Embedded teams. Also report to relevant National Director

North
Regional Team

NHS England



North
VSM Matrix

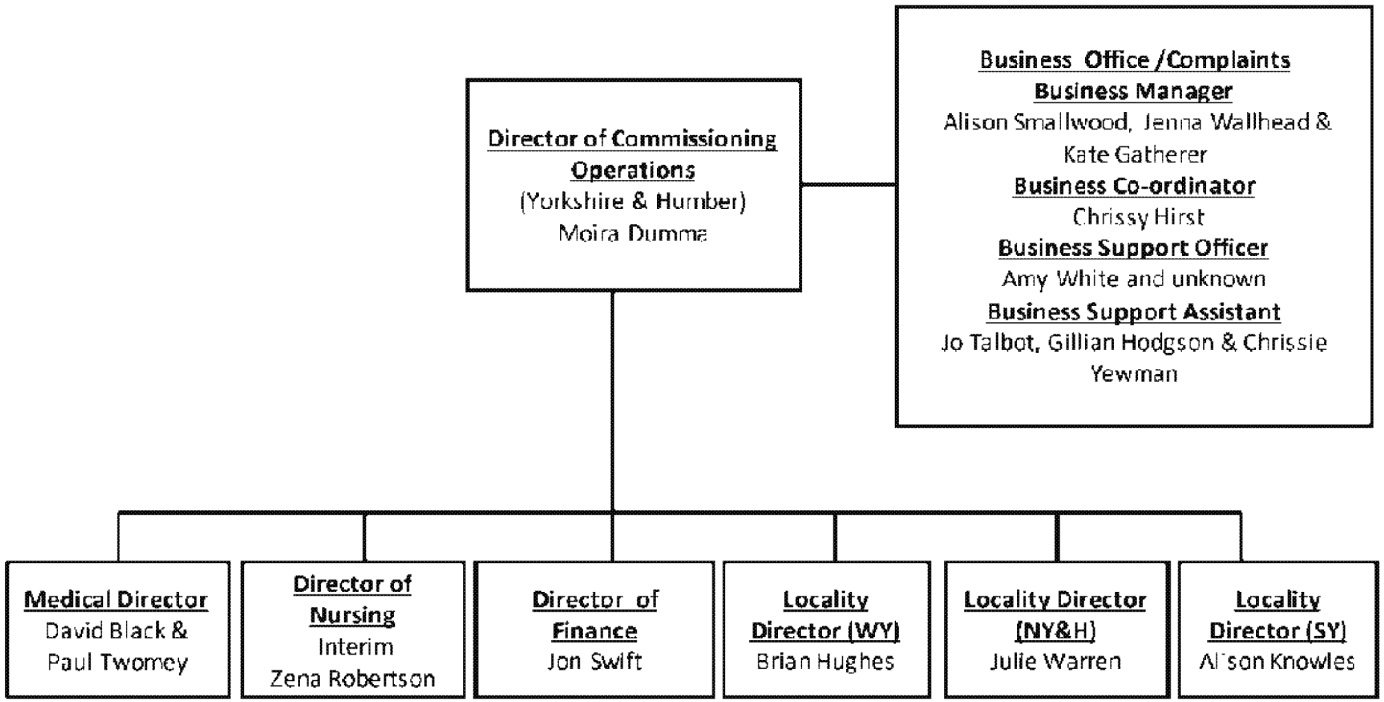
NHS England

	RICHARD BARKER REGIONAL DIRECTOR (NORTH)	**CLARE DUGGAN** DIRECTOR OF COMMISSIONING OPERATIONS	**TIM RIDEOUT** DIRECTOR OF COMMISSIONING OPERATIONS	**GRAHAM URWIN** DIRECTOR OF COMMISSIONING OPERATIONS	**MOIRA DUMMA** DIRECTOR OF COMMISSIONING OPERATIONS
	MIKE PRENTICE REGIONAL MEDICAL DIRECTOR	**DR KIERAN MURPHY** MEDICAL DIRECTOR	**CRAIG MELROSE** MEDICAL DIRECTOR	**RAJ PATEL** MEDICAL DIRECTOR	**DAVID BLACK/PAUL TWOMEY** MEDICAL DIRECTOR
	MAGERET KITCHING CHIEF NURSE	**HAZEL RICHARDS** DIRECTOR OF NURSING	**BEV REILLY** DIRECTOR OF NURSING	**TRISH BENNETT** DIRECTOR OF NURSING	**ZENA ROBERTSON** DIRECTOR OF NURSING
	TIM SAVAGE REGIONAL DIRECTOR OF FINANCE	**PHIL WADESON** DIRECTOR OF FINANCE	**AUDREY PICKSTOCK** DIRECTOR OF FINANCE	**IAN CURRELL** DIRECTOR OF FINANCE	**JON SWIFT** DIRECTOR OF FINANCE
					BRIAN HUGHES - WEST LOCALITY DIRECTOR
	CAROL STUBLEY REGIONAL DIRECTOR OF ASSURANCE & DELIVERY	**ANDREW CRAWSHAW** DIRECTOR OF DELIVERY	**ALISON SLATER** DIRECTOR OF DELIVERY	**JANE HIGGS** DIRECTOR OF ASSURANCE & DELIVERY	**ALISON KNOWLES - SOUTH** LOCALITY DIRECTOR
					JULIE WARREN - NORTH LOCALITY DIRECTOR
		TONY LEO DIRECTOR OF COMMISSIONING	**CHRISTINE KEEN** DIRECTOR OF COMMISSIONING	**ROB BELLINGHAM** DIRECTOR OF COMMISSIONING	(See Locality Directors above)
	SALLY BAINES DIRECTOR OF HR & OD				
	JULIA HICKLING DIRECTOR OF P&I				
	ROBERT CORNALL REGIONAL DIRECTOR OF SPEC COMM	**FRANCES CAREY** REGIONAL SPEC COMM FINANCE DIRECTOR	**MICHAEL GREGORY** REGIONAL SPEC COMM CLINICAL DIRECTOR		

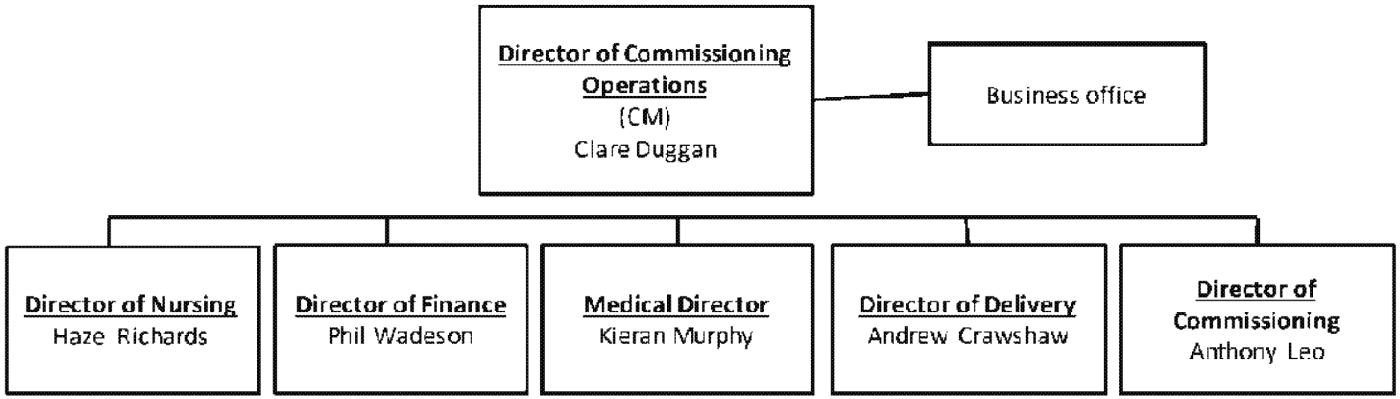
name.

North
Yorkshire & Humber – Area Structure

NHS England



North
Cheshire & Merseyside – Senior Team



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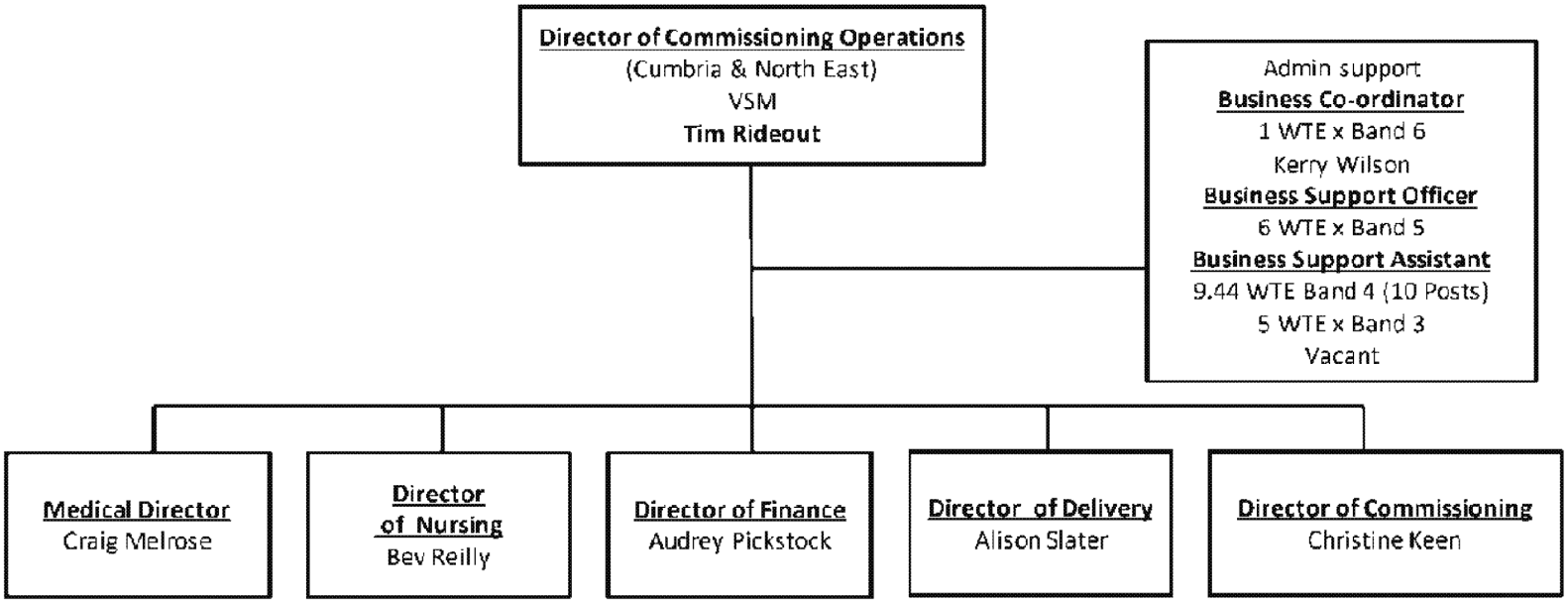
North
Cumbria & North East – Senior Team



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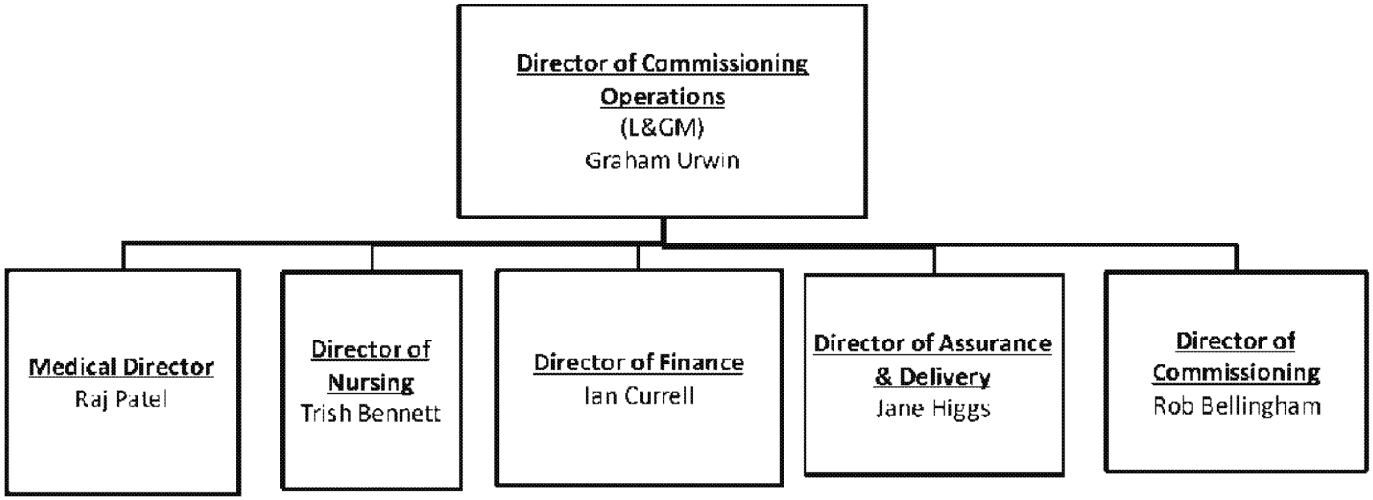
North
Lancashire & Greater Manchester – Senior Team



Annex 8

Integrated care systems explained

Making sense of systems, places and neighbourhoods

- Policy and reform
- Integrated care

- 19 August 2022
- 18-minute read

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Authors

- 

Anna Charles

On this page What are integrated care systems?

Back to top
Back to top

This explainer was originally published on 9 April 2020. It was updated on 19 August 2022.

What are integrated care systems?

Integrated care systems (ICSs) are partnerships that bring together NHS organisations, local authorities and others to take collective responsibility for planning services, improving health and reducing inequalities across geographical areas.

There are 42 ICSs across England, covering populations of around 500,000 to 3 million people.

ICSs have existed in one form or another since 2016, but for most of this time have operated as informal partnerships using soft power and influence to achieve their objectives. Following the passage of the 2022 Health and Care Act, ICSs were formalised as legal entities with statutory powers and responsibilities. Statutory ICSs comprise two key components:

- **integrated care boards (ICBs):** statutory bodies that are responsible for planning and funding most NHS services in the area
- **integrated care partnerships (ICPs):** statutory committees that bring together a broad set of system partners (including local government, the voluntary, community and social enterprise sector (VCSE), NHS organisations and others) to develop a health and care strategy for the area.

Working through their ICB and ICP, ICSs have four key aims:

- improving outcomes in population health and health care
- tackling inequalities in outcomes, experience and access
- enhancing productivity and value for money
- helping the NHS to support broader social and economic development.

ICSs are the centrepiece of the reforms introduced through the 2022 Health and Care Act and are part of a fundamental shift in the way the English health and care system is organised. Following several decades during which the emphasis was on organisational autonomy, competition and the separation of commissioners and providers, ICSs depend instead on collaboration and a focus on places and local populations as the driving forces for improvement.

Why are ICSs needed?

When the NHS was set up it was primarily focused on treating single conditions or illnesses, but since then the health and care needs of the population have changed. People are living longer with multiple, complex, long-term conditions and increasingly require long-term support from many different services and professionals. As a consequence, people too often receive fragmented care from services that are not effectively co-ordinated around their needs. This can negatively impact their experiences, lead to poorer outcomes and create duplication and inefficiency. To deliver joined-up support that better meets the needs of the population, different parts of the NHS (including hospitals, primary care and community and mental health services) and health and social care need to work in a much more joined-up way. ICSs are the latest in a long line of initiatives aiming to integrate care.

As argued in The King's Fund's vision for population health, an integrated health and care system is just one of the four pillars of a population health system. Evidence consistently shows that it is the wider conditions of people's lives – their homes, financial resources, opportunities for education and employment, access to public services and the environments in which they live – that have the greatest impact on health and wellbeing. Health inequalities are wide and growing but they are not inevitable, as evidence shows that a concerted approach, combining the NHS and wider policies to address the social and economic causes of poor health, can make a difference. ICSs therefore also have a critical role to play in driving forward efforts to improve population health and tackle inequalities in their local areas. These goals are clearly set out in the four functions of ICSs (see above), and the new Triple Aim for NHS bodies (which was amended to specifically include consideration of inequalities).

The triple aim is a legal duty on NHS bodies which requires them to consider the effects of their decisions on:

- the health and wellbeing of the people of England (including inequalities in that health and wellbeing)
- the quality of services provided or arranged by both themselves and other relevant bodies (including inequalities in benefits from those services)
- the sustainable and efficient use of resources by both themselves and other relevant bodies.

To meet these objectives, ICSs need to reach beyond the NHS to bring togetherlocal authorities, VCSE organisations and other local partners.

These are complex reforms, and it is vital that they are underpinned by a clear narrative describing how they will benefit patients, service users and communities. Working alongside National Voices, Age UK and the Richmond Group of charities, The King's Fund has developed a joint vision that sets out what integrated care and partnership working could mean for people and communities. It will be important for ICSs to not lose sight of these core objectives, and to find ways to hear from local communities and involve them directly in their work.

Where did ICSs come from?

ICSs have been developing for several years. They evolved from sustainability and transformation plans/partnerships (STPs) – geographical groupings of health and care organisations formed in 2016 to develop 'place-based plans' for the future of health and care services in their areas. Since then, local systems have been strengthening these partnerships and working through them to plan and improve health and care.

Over recent years, the work of ICSs (and before them STPs) has focused on a number of areas, including:

- reaching a shared view between system partners of local needs and the resources available for health and care
- agreeing a strategic direction for local services based on those needs and resources
- driving service changes that are needed to deliver agreed priorities
- taking a strategic approach to key system enablers, for example by developing strategies around digital technologies, workforce and estates
- establishing infrastructure and ways of working to support collaborative working, for example by putting in place new governance arrangements to enable joint decision-making and agreeing system-wide leadership arrangements
- strengthening collaborative relationships and trust between partner organisations and their leaders.

Until July 2022, there was no statutory basis for these arrangements. STPs and ICSs were voluntary partnerships that rested on the willingness and commitment of organisations and leaders to work collaboratively. This meant that progress sometimes had to be made through workarounds to the legislative framework, creating complex and protracted decision-making processes and leading to concerns around transparency and accountability. This has all changed with the 2022 Health and Care Act and the establishment of ICSs as legal entities. However, it is also important to recognise the limitations of what this legislation can realistically achieve. It is not possible to legislate for collaboration and co-ordination of local services; this requires changes to behaviours, attitudes and relationships among staff and leaders right across the system.

In contrast to previous attempts at NHS reform, national NHS bodies have adopted a relatively permissive approach allowing the design and implementation of ICSs to be locally led within a broad national framework. As a result, there are significant differences in the size of systems and the arrangements they have put in place, as well as wide variation in the maturity of partnership working. The statutory requirements for ICSs have created greater consistency in their governance arrangements and responsibilities, but still leave significant flexibility for systems to determine their own arrangements. This means that much remains to be seen in terms of how the reforms are implemented locally.

Variation in how ICSs have developed means they can be complex and difficult to understand. But systems of care and the health needs of local populations are themselves complex in ways that don't lend themselves to simplicity and standardisation. The flexibility ICSs have been given has the advantage of enabling them to develop arrangements to suit their local contexts, respond to population needs and build on their existing strengths, and could help to engender a greater sense of local ownership of and commitment to the changes than in previous NHS restructures.

What do ICSs look like?

How ICSs are structured

As set out above, statutory ICSs include two key parts: an ICB and an ICP. This section sets out further detail on each of these structures and the interface between them.

Integrated care boards (ICBs)

The role of the ICB is to allocate the NHS budget and commission services for the population, taking over the functions previously held by clinical commissioning groups (CCGs) and some of the direct commissioning functions of NHS England. The ICB is directly accountable to NHS England for NHS spend and performance within the system. ICBs may choose to exercise their functions through delegating them to place-based committees (see below) but the ICB remains formally accountable.

Each ICB must prepare a five-year system plan setting out how they will meet the health needs of their population. In developing this plan and carrying out their work, the ICB must have regard to their partner ICP's integrated care strategy and be informed by the joint health and wellbeing strategies published by the health and wellbeing boards in their area. In addition, the ICB and its partner NHS trusts and foundation trusts must develop a joint plan for capital spending (spending on buildings, infrastructure and equipment) for providers within the geography.

The ICB operates as a unitary board, with membership including (at a minimum); a chair, chief executive officer, and at least three other members drawn from NHS trusts and foundation trusts, general practice and local authorities in the area. In addition, at least one member must have knowledge and expertise in mental health services. ICBs

have discretion to decide on additional members locally. Each ICB must also ensure that patients and communities are involved in the planning and commissioning of services.

ICBs must not appoint any individuals to their board whose membership could reasonably be regarded as undermining the independence of the health service. This requirement is intended to ensure that private sector organisations do not exert undue influence and that their participation is to the benefit of the system, reflecting sensitivities around private sector involvement in the NHS.

Integrated care partnerships (ICPs)

The ICP is a statutory joint committee of the ICB and local authorities in the area. It brings together a broad set of system partners to support partnership working and develop an 'integrated care strategy', a plan to address the wider health care, public health and social care needs of the population. This strategy must build on local joint strategic needs assessments and health and wellbeing strategies and must be developed with the involvement of local communities and Healthwatch. The ICB is required to have regard to this plan when making decisions.

There is significant flexibility for ICPs to determine their own arrangements, including their membership and ways of working. Membership must include one member appointed by the ICB, one member appointed by each of the relevant local authorities, and others to be determined locally. This may include social care providers, public health, Healthwatch, VCSE organisations and others such as local housing or education providers.

Take a look at our diagram illustrating the structure of integrated care systems and other key local planning and partnership bodies.

This dual structure was designed to support ICSs to act both as bodies responsible for NHS money and performance at the same time as acting as a wider system partnership. It remains to be seen how this will work in practice, including how the two bodies will relate to one another and what dynamic will emerge between them. For example, it may be difficult for ICPs to have real clout in the system and drive the agenda of their ICS when much of the resource and formal accountabilities sit with the ICB.

Some systems are further ahead in embedding these arrangements than others, and in many cases the formation of the ICP lagged behind the initial establishment of the ICB (which was held to tighter deadlines due to the legislative timetable).

Systems, places, neighbourhoods

A key premise of ICS policy, and a core feature of many of the systems that have been working as ICSs the longest, is that much of the activity to integrate care, improve population health and tackle inequalities will be driven by commissioners and providers collaborating over smaller geographies within ICSs (often referred to as 'places') and through teams delivering services working together on even smaller footprints (usually referred to as 'neighbourhoods'). This is important as ICSs tend to cover large geographical areas (typically a population of more than 1 million people) so

aren't well suited to designing or delivering changes in services to meet the distinctive needs and characteristics of local populations.

This three-tiered model of neighbourhoods, places and systems is an over-simplification of the diverse set of arrangements seen in reality, but the terminology is now in widespread use within the health and care system. National policy and guidance has made it clear that ICSs will be expected to work through these smaller geographies within their footprints.

An overview of neighbourhoods, places and systems

Neighbourhoods (covering populations of around 30,000 to 50,000 people*): where groups of GP practices work with NHS community services, social care and other providers to deliver more co-ordinated and proactive care, including through the formation of primary care networks (PCNs) and multi-agency neighbourhood teams.

Places (covering populations of around 250,000 to 500,000 people*): where partnerships of health and care organisations in a town or district – including local government, NHS providers, VCSE organisations, social care providers and others – come together to join up the planning and delivery of services, redesign care pathways, engage with local communities and address health inequalities and the social and economic determinants of health. In many (but not all) cases, place footprints are based on local authority boundaries.

Systems (covering populations of around 500,000 to 3 million people*): where health and care partners come together at scale to set overall system strategy, manage resources and performance, plan specialist services, and drive strategic improvements in areas such as workforce planning, digital infrastructure and estates.

* Population sizes are variable – numbers vary from area to area and may be larger or smaller than those presented here. Systems are adapting this model to suit their local contexts, for example some larger systems have an additional intermediate tier between place and system.

Map 2 An example of the places and neighbourhoods within an ICS

There is no simple answer for which activities should sit at which level due to wide variation in the scale and characteristics of local areas. As a consequence, the exact division of roles and responsibilities between ICSs and their constituent places and neighbourhoods has not been laid out in legislation or guidance. Instead, there is freedom for this to be determined locally with an expectation that decisions should be based on the principle of subsidiarity , meaning ICSs will take responsibility only for things where there is a need to work at scale. Local systems are taking different approaches to applying this principle, for example West Yorkshire ICS has agreed three 'subsidiarity tests' to determine whether something should be led by the wider system or by the local places within it.

ICSs will be expected to delegate significant responsibilities and budgets to place-based partnerships, as stressed by the government's integration White Paper and the guidance document *Thriving places*. The 2022 Health and Care Act made provision for the formation of place-based committees (which can be established as subcommittees of the ICB) but left flexibility for local areas to determine how these should be formed and how they will operate. Outside of the legislation, the recent integration White Paper set out a greater degree of formality and national oversight of these arrangements, and outlined plans to introduce minimum expectations around place-level governance, leadership arrangements and a new shared outcomes framework from April 2023.

For more detail on the formation of place-based partnerships, and the relationship between place and system, see our report, *Developing place-based partnerships*.

What does this mean for commissioning?

The 2022 Health and Care Act entailed significant structural change for NHS commissioning. CCGs were abolished, with their functions and many of their staff transferred into ICBs. ICBs have also taken on some commissioning responsibilities from NHS England, including the commissioning of primary care and some specialised services (with a plan for further delegation over time), giving local systems a greater say in how budgets for these services are spent in their area.

These shifts build on changes to commissioning that have been underway for several years. Before their abolition, many CCGs had been working more closely together at a system level through joint management structures or formal mergers and the number of CCGs had fallen significantly. At the same time, many CCGs were working more closely with local councils at 'place' level to align and integrate commissioning for NHS and local authority services, and some larger CCGs were organising some of their functions across a system-wide footprint and other functions around place footprints.

The legislation has also changed procurement and competition requirements, removing the requirement for mandatory competitive retendering (supported by a new provider selection regime, due to be implemented by December 2022).

This is all part of a shift towards strategic commissioning and a more collaborative approach to planning and improving services. This means that, instead of focusing on procurement and contract management, the role of commissioners is to work closely with key partners across the system (including with providers) to understand population needs, determine key priorities and design, plan and resource services to meet those needs.

What does this mean for NHS providers?

NHS providers are increasingly being expected to look beyond their organisational priorities to focus on system-wide objectives and improving outcomes and reducing inequalities for the communities they serve. While the legal functions and duties of NHS trusts and foundation trusts remain largely unchanged under the recent reforms, they

are also expected to participate in multiple collaborative forums, including membership of the ICB and forming collaboratives with other providers. NHS trusts and foundation trusts are also now bound by a new duty to collaborate with local partners and a shared duty to promote the triple aim (see above).

NHS providers are already playing a critical role in the changes underway in many systems, contributing to and/or leading work at ICS level to plan and transform services and improve system performance, and collaborating with other local providers (including those from outside the NHS) at place and neighbourhood levels to redesign care pathways and deliver more integrated services for local people.

The policy intention is that commissioners and providers should increasingly be working hand in hand to plan care for their populations. While distinct commissioning and provision responsibilities still formally sit in separate organisations, in practice the division is becoming increasingly blurred (for example, as providers are represented on the ICB). Fundamentally, a key principle in the reforms is that providers are part of the ICS – just as much as the ICB and ICP are – and as such they are being asked to take on wider responsibilities for the performance of the whole system.

What does this mean for local government?

Since ICSs first began developing in 2016, the involvement of local government has varied widely. The King's Fund has argued that, for ICSs to succeed, they will need to function as equal partnerships with local government not just involved but jointly driving the agenda alongside the NHS and other key partners. Importantly, partnerships between local government and NHS organisations are also developing at the level of 'place', which is usually coterminous with local authority boundaries.

The involvement of local government in ICSs and place-based partnerships can bring three key benefits. The first is the opportunity to join up health and social care at all levels in the system, creating better outcomes and a less fragmented experience for patients and users. The second is the potential to improve population health and wellbeing and tackle inequalities through the leadership of public health teams as well as NHS and local government acting together to address wider determinants of health such as housing, local planning and education. Finally, the involvement of local government can enhance transparency and accountability through supporting engagement with local communities and providing local democratic oversight.

Within the new statutory ICS structures, the involvement of local government has been formalised through the ICP and through the direct representation of local authorities on the ICB. In addition, ICSs must draw on the joint health and wellbeing strategies of their local health and wellbeing boards in producing their integrated care strategies and five-year system plans.

However, now that ICBs have significant NHS budgets and responsibilities, there is a risk of their focus on NHS resources and performance crowding out wider system priorities and undermining the sense of equal partnership many systems have worked hard to nurture. This is already causing tensions between the NHS and local government in some areas.

What does this mean for VCSE organisations?

VCSE organisations play a critical role within local health and care systems both as service providers and as vehicles for community engagement and voice. They are therefore important strategic partners for ICSs in terms of delivering improvements in health and wellbeing and reducing inequalities – which often involves working more closely with communities.

The involvement of VCSE organisations within formal ICS structures is open to local determination, but national guidance has set clear expectations that they should be involved both within the governance structures (for example, through membership of the ICP) and in delivering key workstreams.

Resource constraints and the diversity of the sector can both act as barriers to the participation of VCSE organisations, and their involvement in shaping priorities, plans and decisions at system level remains limited in many cases. In some systems, VCSE alliances or infrastructure organisations are playing an important role in bridging this gap, while other ICSs have identified funding for a dedicated post or function. Importantly, VCSE organisations also have an important role at place and neighbourhood levels.

What does this mean for oversight and regulation?

Despite the focus on collaboration and system-working in recent years, the primary focus of NHS regulators has continued to be on managing the performance of individual organisations. The interventions and behaviours of the regulators have sometimes made it more difficult for organisations to collaborate. Over time, national and regional NHS bodies will be expected to shift their focus to regulating and overseeing systems of care (alongside their existing responsibilities in relation to individual organisations), increasingly working alongside local systems to support them to change and improve services.

In line with this ambition, NHS England is developing a new operating model. This will build on changes that have already been made to the work of its national and regional teams (including bringing together the regulation of commissioners and providers through the merger of NHS England and NHS Improvement). A new integration index is also under development to better measure the success of efforts to integrate care from the perspective of patients, carers and the public.

At the same time, the CQC is adapting its approach to monitoring and inspection to better reflect system working. The 2022 Health and Care Act introduced a duty on the CQC to review health care and adult social care in each ICB, including looking at how partners in the ICS are working together.

How will we know if ICSs are working?

ICSs will be accountable nationally to NHS England, via their ICB, for NHS spending and performance. They will be expected to achieve financial balance and to meet national requirements and performance targets.

In addition to these national accountabilities, ICSs also have the potential to nurture different forms of oversight to drive local improvements in care. This is because ICSs are partnerships in which local organisations exercise collective leadership and work towards developing a sense of mutual accountability for resource use and outcomes. This may take the form of peer challenge and support from partners within an ICS, drawing on local data on performance and outcomes.

Importantly, to really understand whether their work is making a difference, ICSs will need to use insights from local people including patients, service users and families. As we have argued in previous work, the best way to understand whether integration is delivering results is through the eyes of people using services.

Where next?

The coming months will be a critical period for the development of ICSs as they begin operating as statutory bodies. Ultimately, whether or not these reforms succeed will come down to how they are implemented locally, and whether the right national conditions can be created to support their work.

It won't be easy to find the bandwidth to do the hard work of changing ways of working at a time when health and care services are under such pressure, and there is a risk that established ways of working will be recreated within the new structures. To avoid this, ICSs will need to keep sight of their core objectives and the ethos of system working behind their development.

Evidence from previous attempts to integrate care indicates that these changes will take time to deliver results. This means that local and national leaders need to make a long-term commitment to the development of ICSs and avoid the past mistake of moving swiftly to the next reorganisation if desired outcomes are not rapidly achieved.

ANNEX 9 - Pay structures of neonatal staff – 2023/24

Agenda for change - pay rates

This pay system covers all staff except doctors, dentists and very senior managers.

A neonatal nurse will typically start at Band 5.

A chief nurse would be in Band 8d.

Pay scale	Entry step point	Years until eligible for pay progression	Intermediate step point	Years until eligible for pay progression	Top step point
Band 5	I&S				
Band 6					
Band 7					
Band 8a					
Band 8b					
Band 8c					
Band 8d					

Consultants on the 2003 contract

The vast majority of consultants in England work under the 2003 national consultant contract. Only a small number appointed before 1 November 2003 still retain the pre-2003 contract.

Threshold	Years completed as a consultant	Basic salary
1	I&S	
2		
3		
4		
5		
6		
7		
8		

ANNEX 10 - Pay structures of very senior managers

'Established' pay ranges for non-clinical managers in NHS trusts and foundation trusts:

Small Acute NHS Trusts and Foundation Trusts (£0-£200m turnover)	Lower quartile	Median	Upper quartile
Chief Executive	I&S		
Deputy Chief Executive			
Director of Finance/Chief Finance Officer			
Director of Workforce			
Medical Directors/Chief Medical Officer			
Director of Nursing/Chief Nursing Officer			
Chief Operating Officer			
Director of Corporate Affairs/Governance			
Director of Strategy/Planning			
Director of Estates and Facilities			

Medium Acute NHS Trusts and Foundation Trusts (£200-400m)	Lower quartile	Median	Upper quartile
Chief Executive	I&S		
Deputy Chief Executive			
Director of Finance/Chief Finance Officer			
Director of Workforce			
Medical Directors/Chief Medical Officer			
Director of Nursing/Chief Nursing Officer			
Chief Operating Officer			
Director of Corporate Affairs/Governance			
Director of Strategy/Planning			
Director of Estates and Facilities			

Large Acute NHS Trusts and Foundation Trusts (£400-£500m)	Lower quartile	Median	Upper quartile
Chief Executive			
Deputy Chief Executive			
Director of Finance/Chief Finance Officer			
Director of Workforce			
Medical Directors/Chief Medical Officer			
Director of Nursing/Chief Nursing Officer			
Chief Operating Officer			
Director of Corporate Affairs/Governance			
Director of Strategy/Planning			
Director of Estates and Facilities			

Extra Large Acute NHS Trusts and Foundation Trusts (£500-£750m)
Chief Executive
Deputy Chief Executive
Director of Finance/Chief Finance Officer
Director of Workforce
Medical Directors/Chief Medical Officer
Director of Nursing/Chief Nursing Officer
Chief Operating Officer
Director of Corporate Affairs/Governance
Director of Strategy/Planning
Director of Estates and Facilities

I&S

Chief Executive	I&S
Deputy Chief Executive	
Director of Finance/Chief Finance Officer	
Director of Workforce	
Medical Directors/Chief Medical Officer	
Director of Nursing/Chief Nursing Officer	
Chief Operating Officer	
Director of Corporate Affairs/Governance	
Director of Strategy/Planning	
Director of Estates and Facilities	

ANNEX 11: Index of Exhibits – Section 1

Exhibit	Relativity reference	Title	Author	Dated
Exhibit SP/1	INQ0009274	What is commissioning and how is it changing?	The Kings Fund	20 July 2023
Exhibit SP/2	INQ0014615	NHS Standard Contracts for 2012/13	Department for Health and Social Care	23 December 2011
Exhibit SP/3	INQ0009227	Framework Agreement between the Department of Health and NHS England, published 2014	Department of Health and NHS England	2014
Exhibit SP/4	INQ0009279	The Government's 2023 Mandate to NHS England	Department of Health	15 June 2023
Exhibit SP/5	INQ0009225	The Mandate: A Mandate from the Government to the NHS Commissioning Board: April 2013-March 2015	Department of Health	November 2013
Exhibit SP/6	INQ0009226	Direct Commissioning Assurance Framework	NHS England	28 November 2013
Exhibit SP/7	INQ0009288	Neonatal Critical Care Clinical Reference Group Terms of Reference	NHS England	undated
Exhibit SP/8	INQ0009232	Neonatal Critical Care Services: Service Specification	NHS England	undated
Exhibit SP/9	INQ0009271	North West Operational Delivery Network Terms of Reference	North West Operational Delivery Network	undated
Exhibit SP/10	INQ0014773	How funding flows in the NHS	The King's Fund	April 2020
Exhibit SP/11	INQ0009213	Delivering the NHS Plan: Next Steps on Investment, Next Steps on Reform	Department of Health	April 2002
Exhibit SP/12	INQ0009214	A Guide to NHS Foundation Trusts	Department of Health	December 2002

Exhibit SP/13	INQ0014798	GovernWell	NHS Providers	Undated
Exhibit SP/14	INQ0014619	Your statutory duties: A reference guide for NHS foundation trust governors	Monitor	August 2013
Exhibit SP/15	INQ0014801	Addendum to your statutory duties – reference guide for NHS foundation trust governors	NHS England	27 October 2022
Exhibit SP/16	INQ0009267	NHS Provider Licence, Standard Conditions	NHS England	31 March 2023
Exhibit SP/17	INQ0014725	Protecting and promoting patients' interests – Licence exemptions: guidance for providers	Department of Health	March 2015
Exhibit SP/18	INQ0014725	Licensing application guidance for NHS-controlled providers	NHS England	December 2020
Exhibit SP/19	INQ0009230	Framework Agreement between the Department of Health and Monitor	Department of Health	2014
Exhibit SP/20	INQ0009228	Department of Health and NHS Trust Development Agency Framework Agreement	Department of Health	March 2014
Exhibit SP/21	INQ0009217	Board Governance Assurance Framework for Aspirant Foundation Trusts, Board Governance Memorandum	Department of Health	15 December 2011
Exhibit SP/22	INQ0009246	Code of Governance for Foundation Trusts	Monitor	July 2014
Exhibit SP/23	INQ0009269	NHS Provider Licence, including General Condition G4	NHS England	withdrawn 27 March 2023
Exhibit SP/24	INQ0009240	Risk Assessment Framework	Monitor	August 2015
Exhibit SP/25	INQ0014638	Monitor: annual report and accounts 2015/16	NHS Improvement	21 July 2016
Exhibit SP/26	INQ0009237	Well Led Framework for Governance Reviews	Monitor	April 2015

Exhibit SP/27	INQ0009234	Memorandum of Understanding Between Monitor and the Care Quality Commission	Monitor and the Care Quality Commission	February 2015
Exhibit SP/28	INQ0009233	A Guide to Special Measures	Monitor, the Care Quality Commission, and the NHS Trust Development Agency	February 2015
Exhibit SP/29	INQ0009223	Delivering High Quality Care for Patients: The Accountability Framework for NHS Trust Boards	NHS Trust Development Agency	April 2013
Exhibit SP/30	INQ0009287	Single Oversight Framework	NHS Improvement	September 2016
Exhibit SP/31	INQ0009264	NHS Oversight Framework	NHS England	27 June 2022
Exhibit SP/32	INQ0014772	BM1661P NHSI Oversight Framework a report	NHS Improvement	26 May 2016
Exhibit SP/33	INQ0009239	Five Year Forward View	NHS England	October 2014
Exhibit SP/34	INQ0009259	Roadmap for Integrating Specialised Services with Integrated Care Systems	NHS England	31 May 2022
Exhibit SP/35	INQ0009243	Delivering the Forward View: NHS Planning Guidance 2016/17 - 2020/21	NHS England, NHS Improvement, the Care Quality Commission, Health Education England, the National Institute of Health and Care Excellence and Public Health England	22 December 2015
Exhibit SP/36	INQ0009285	National Institute of Health and Care Excellence (NICE) Quality Standard on Neonatal Parenteral Nutrition	National Institute of Health and Care Excellence	22 March 2022
Exhibit SP/37	INQ0014777	Memorandum of Understanding: NICE and NHS England	NHS England, National Institute of Health and Care Excellence	Undated

Exhibit SP/38	INQ0014800	The Three Sectors Meeting Terms of Reference	National Institute of Health and Care Excellence	
Exhibit SP/39	INQ0014799	Cross Agency Topic Prioritisation Group Terms of Reference	National Institute of Health and Care Excellence	
Exhibit SP/40	INQ0014806	Developmental follow-up of pre-term babies, published August 2017	National Institute of Health and Care Excellence	9 August 2017
Exhibit SP/41	INQ0009256	A Shared Commitment to Quality for Those Working in Health and Care Systems	National Quality Board	2021
Exhibit SP/42	INQ0009276	2010 to 2015 Government Policy: Patient Safety	Department of Health	8 May 2015
Exhibit SP/43	INQ0009251	The NHS Patient Safety Strategy: Safer Culture, Safer Systems, Safer Patients	NHS England	July 2019
Exhibit SP/44	INQ0009255	NHS Patient Safety Strategy: 2021 Update, published February 2021	NHS England	February 2021
Exhibit SP/45	INQ0009277	NHS Patient Safety Strategy Priorities for Leaders and Patient Safety Specialists	NHS England	2023
Exhibit SP/46	INQ0014613	National Framework for Reporting and Learning from Serious Incidents Requiring Investigation	NHS National Patient Safety Agency	2010
Exhibit SP/47	INQ0009224	Serious Incident Framework	NHS England	March 2013
Exhibit SP/48	INQ0009236	Serious Incident Framework	NHS England	March 2015
Exhibit SP/49	INQ0009265	Patient Safety Incident Response Framework	NHS England	August 2022
Exhibit SP/50	INQ0014722	Patient Safety Incident Response Framework 2020: An introductory framework for implementation by nationally appointed early adopters	NHS England	March 2020

Exhibit SP/51	INQ0014625	Never Events List 2015/16	NHS England	27 January 2016
Exhibit SP/52	INQ0009218	The NHS Outcomes Framework 2013-14	Department of Health	13 November 2012
Exhibit SP/53	INQ0009272	National Quality Board Terms of Reference	National Quality Board	29 June 2023
Exhibit SP/54	INQ0009221	Agreement Between the Care Quality Commission and the NHS Commissioning Board	NHS Commissioning Board (NHS England) and the Care Quality Commission	January 2013
Exhibit SP/55	INQ0009219	Quality in the New Health System: Maintaining and Improving Quality from April 2013	National Quality Board	January 2013
Exhibit SP/56	INQ0009220	How to Establish a Quality Surveillance Group: Guidance to the New Health System	National Quality Board	January 2013
Exhibit SP/57	INQ0009258	National Guidance on System Quality Groups	National Quality Board	January 2022
Exhibit SP/58	INQ0009260	National Guidance on Quality Risk Response and Escalation in Integrated Care Systems	National Quality Board	June 2022
Exhibit SP/59	INQ0009242	Report of the Expert Advisory Group: Healthcare Safety Investigation Branch	Expert Advisory Group	May 2016
Exhibit SP/60	INQ0009257	System Letter: Extending Medical Examiner Scrutiny to Non-Acute Settings	NHS England	8 June 2021

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Exhibit	Relativity reference	Title	Author	Dated
Exhibit SP/61	INQ0014622	Report to Regional Quality Surveillance Group Meeting	NHS England	5 June 2015

Exhibit SP/62	INQ0014627	North of England Maternity Thematic Review QSG Report	North of England Maternity Group, NHS England	March 2016
Exhibit SP/63	INQ0014628	Summary of Never Events reported on STEIS by organisation: 1 April 2015 to 31 March 2016	NHS England	5 September 2016
Exhibit SP/64	INQ0014641	NHS Specialised Commissioning North Regional Leadership Group letter to providers	NHS Specialised Commissioning North Regional Leadership Group	8 August 2016
Exhibit SP/65	INQ0014629	RE: Countess	Peter Groggins	30 June 2016
Exhibit SP/66	INQ0014630	Countess Incident	Peter Groggins	30 June 2016
Exhibit SP/67	INQ0014631	Countess 2nd incident	Peter Groggins	30 June 2016
Exhibit SP/68	INQ0014632	RE: Countess	Peter Groggins	30 June 2016
Exhibit SP/69	INQ0014634	RE: Confidential: Urgent Meeting tomorrow morning	Peter Groggins	7 July 2016
Exhibit SP/70	INQ0014635	Query re NNU Incidents	Peter Groggins	6 July 2016
Exhibit SP/71	INQ0014633	Countess of Chester Serious Incidents: 20 May 2015 to 5 July 2016	Peter Groggins	6 July 2016
Exhibit SP/72	INQ0014636	COCH NNU Closure	Peter Groggins	7 July 2016
Exhibit SP/73	INQ0014637	Hotspots Report July 7 2016	Regional Specialised Commissioning Team (North)	8 July 2016
Exhibit SP/74	INQ0014640	07. 5g Specialised Commissioning North Region Quality Report QRT 1 2016 for RLG	Lesley Patel	19 July 2016
Exhibit SP/75	INQ0014760	NHS England North (Cheshire & Merseyside) Exception Report 01 June 2016 to 31 July 2016	Hazel Richards	31 July 2016

Exhibit SP/76	INQ0014679	FW: Notes: Tel-conf call re COCH Neonatal update	Margaret Kitching	16 May 2017
Exhibit SP/77	INQ0014639	Neonatal Mortality at Countess of Chester Hospital (COCH)	North West Neonatal Operational Delivery Network	12 September 2016
Exhibit SP/78	INQ0014642	NHS England (North) Cheshire & Merseyside Quality Surveillance Group Meeting Pack	Cheshire & Merseyside Quality Surveillance Group	4 October 2016
Exhibit SP/79	INQ0014687	North Regional Quality Surveillance Group: Draft Minutes and Action Points	North Regional Quality Surveillance Group	16 September 2016
Exhibit SP/80	INQ0014771	Note of meeting with Countess of Chester Hospital	Vincent Connolly	21 December 2016
Exhibit SP/81	INQ0014645	Paper 05a: NHS England North (Cheshire & Merseyside) Exception Report 1 November 2016 – 10 February 2017	Hazel Richards	15 February 2017
Exhibit SP/82	INQ0014644	Hotspots Report 9 February 2017	Regional Specialised Commissioning Team (North)	9 February 2017
Exhibit SP/83	INQ0014656	Action notes of progress meeting with Ian Harvey re neonatal services at the Countess of Chester	Lesley Patel	23 February 2017
Exhibit SP/84	INQ0014692	Countess of Chester Neonatal Services, Timeline	Sue McGorry & Lesley Patel	3 July 2018
Exhibit SP/85	INQ0014647	Countess of Chester Hospital NHS Foundation Trust Risk Summary Template (Version 2)	Unknown	7 March 2017
Exhibit SP/86	INQ0014648	Countess of Chester Hospital NHS Foundation Trust Risk Summary Template (Version 4)	Unknown	28 March 2017
Exhibit SP/87	INQ0014652	Countess of Chester Hospital NHS Foundation Trust RISK SUMMARY TEMPLATE	NHS England	4 April 2017
Exhibit SP/88	INQ0014677	Quality Risk Profile Domains: Acute Hospital	NHS England	May 2017

Exhibit SP/89	INQ0014646	Hotspots Report 3 March 2017	Regional Specialised Commissioning Team (North)	3 March 2017
Exhibit SP/90	INQ0014653	Countess of Chester Neonatal Services, timeline	Sue McGorry	4 April 2017
Exhibit SP/91	INQ0014651	Re: Countess of Chester	Margaret Kitching	4 April 2017
Exhibit SP/92	INQ0014649	Hotspots Report 31 March 2017	Regional Specialised Commissioning Team (North)	31 March 2017
Exhibit SP/93	INQ0014658	Neonatal services	Michael Gregory	5 April 2017
Exhibit SP/94	INQ0014657	Email to Ian Harvey	Michael Gregory	5 April 2017
Exhibit SP/95	INQ0014654	RLG Key Messages	Kirsty McBride	5 April 2017
Exhibit SP/96	INQ0014655	NHS England North Regional Specialised Leadership Group meeting	NHS England North Regional Specialised Leadership Group	4 April 2017
Exhibit SP/97	INQ0014650	Neonatal External Review – Action Plan	Countess of Chester Hospital	February 2017
Exhibit SP/98	INQ0014659	Neonatal External Review – Action Plans AK comments	Countess of Chester Hospital	April 2017
Exhibit SP/99	INQ0014660	Update on Chester	Michael Gregory	19 April 2017
Exhibit SP/100	INQ0014661	RE: Update on Chester	Michael Gregory	19 April 2017
Exhibit SP/101	INQ0014662	RE: Update on Chester	Michael Gregory	19 April 2017
Exhibit SP/102	INQ0014666	RE: Update on CoCH	Michael Gregory	19 April 2017
Exhibit SP/103	INQ0014663	Update on CoCH	Michael Gregory	19 April 2017

Exhibit SP/104	INQ0014664	RE: Update on CoCH	Lesley Patel	19 April 2017
Exhibit SP/105	INQ0014665	RE: Update on CoCH	Margaret Kitching	19 April 2017
Exhibit SP/106	INQ0014667	RE: Update on CoCH	Margaret Kitching	19 April 2017
Exhibit SP/107	INQ0014668	Response from Ian Harvey	Michael Gregory	26 April 2017
Exhibit SP/108	INQ0014669	RE: Response from Ian Harvey	Lesley Patel	26 April 2017
Exhibit SP/109	INQ0014670	Re: Response from Ian Harvey	Margaret Kitching	26 April 2017
Exhibit SP/110	INQ0014671	Re: Response from Ian Harvey	Richard Barker	26 April 2017
Exhibit SP/111	INQ0014672	RE: Response from Ian Harvey	Margaret Kitching	26 April 2017
Exhibit SP/112	INQ0014673	Re: Response from Ian Harvey	Richard Barker	26 April 2017
Exhibit SP/113	INQ0014674	Update on Countess of Chester	Michael Gregory	27 April 2017
Exhibit SP/114	INQ0014675	SET ME UP A FILE FOR CoC RE: Conference call notes (with logos)	Ian Harvey	4 May 2017
Exhibit SP/115	INQ0014676	Re: Conference call notes (with logos)	Ian Harvey	5 May 2017
Exhibit SP/116	INQ0014678	Update	Ian Harvey	12 May 2017
Exhibit SP/117	INQ0014681	Re: Countess of Chester Hospital Investigation ~[RESTRICTED]~	Richard Barker	17 May 2017
Exhibit SP/118	INQ0014680	Factual position regarding review of neonatal services	Countess of Chester Hospital	16 May 2017
Exhibit SP/119	INQ0014682	RE: For info: Police investigation into Countess of Chester Hospital	Jacqueline Dunkley-Bent	17 May 2017
Exhibit SP/120	INQ0014696	Countess of Chester Incident Coordination Call	Nicola Pollard	4 July 2018

Exhibit SP/121	INQ0014684	RE: NNU Visit Notification Letter - CoC	Ann Butler	20 July 2017
Exhibit SP/122	INQ0014720	Maternity and Obstetric Services: North West Desk Top Review	Pauline Bradshaw	12 December 2019
Exhibit SP/123	INQ0014699	Countess of Chester NHS Foundation Trust: Incident Coordination Panel Meeting	Nicola Pollard	10 July 2018
Exhibit SP/124	INQ0014683	Re: NNU Visit Notification Letter - CoC	Lyn Simpson	14 July 2017
Exhibit SP/125	INQ0014685	NHS England (North) Cheshire & Merseyside Quality Surveillance Group meeting	Cheshire & Merseyside Quality Surveillance Group	1 December 2017
Exhibit SP/126	INQ0014689	NHS England (North) Cheshire & Merseyside Quality Surveillance Group meeting	Cheshire & Merseyside Quality Surveillance Group	2 February 2018
Exhibit SP/127	INQ0014688	Re: Neonatal services COC Update	Lyn Simpson	23 January 2018
Exhibit SP/128	INQ0014713	Countess of Chester Neonatal	Michael Gregory	17 April 2019
Exhibit SP/129	INQ0014697	Re: CoC – comms support & actions	Paul Dickens	4 July 2018
Exhibit SP/130	INQ0014693	RE: COC	Kathy McClean	3 July 2018
Exhibit SP/131	INQ0014686	Memorandum of Understanding: Investigating patient safety incidents involving unexpected deaths or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health and Safety Executive	National Health Service, Association of Chief Police Officers and Department of Health	February 2006
Exhibit SP/132	INQ0014691	Countess of Chester Neonatal Services	Lesley Patel	3 July 2018
Exhibit SP/133	INQ0014694	FW: Police Investigation into Neonatal Deaths at Countess of Chester Hospital	Nicholas Smith, Care Quality Commission	4 July 2018

Exhibit SP/134	INQ0014695	Private and Confidential	Christine Griffith-Evans	4 July 2018
Exhibit SP/135	INQ0014698	Countess of Chester NHS Foundation Trust: Incident Coordination Panel Meeting	Nicola Pollard	10 July 2018
Exhibit SP/136	INQ0014700	Countess of Chester – Updated briefing	Robin Scott	15 July 2018
Exhibit SP/137	INQ0014765	FW: Neonatal meeting. Actions	Sue McGorry	29 October 2018
Exhibit SP/138	INQ0014703	Countess of Chester NHS Foundation Trust Incident Coordination Panel Meeting	Nicola Pollard	22 October 2018
Exhibit SP/139	INQ0014702	Agenda: Countess of Chester NHS Foundation Trust Incident Coordination Panel Meeting	Nicola Pollard	22 October 2018
Exhibit SP/140	INQ0014706	Countess of Chester NHS Foundation Trust Incident Coordination Panel Meeting	Nicola Pollard	28 January 2019
Exhibit SP/141	INQ0014707	Supporting evidence Countess of Chester	Stephen Brearey	8 April 2019
Exhibit SP/142	INQ0014708	Intensive Care Activity at Countess of Chester July 2016 to Jan 2019	Stephen Brearey	8 April 2019
Exhibit SP/143	INQ0014709	"Road Map" for extending admission criteria and capacity of the NNU at the Countess of Chester NHS Foundation Trust	Stephen Brearey	8 April 2019
Exhibit SP/144	INQ0014710	Level 3 bespoke placements in Arrowe Park Hospital	Yvonne Griffiths	19 March 2019
Exhibit SP/145	INQ0014711	Consultant Paediatricians' Neonatal CPD 2017-2018	Stephen Brearey	19 March 2019
Exhibit SP/146	INQ0014712	Report following NHS England meeting	Susan Waters	16 April 2019
Exhibit SP/147	INQ0014714	Countess of Chester Hospital Neonatal Unit restrictions meeting with Margaret Kitching	Nicola Pollard	5 April 2019

Exhibit SP/148	INQ0014716	Downgrading of the Countess of Chester Neonatal Unit – summary of actions	Sue McGorry & Abby Peters	24 June 2019
Exhibit SP/149	INQ0014717	Downgrading of the Countess of Chester Neonatal Unit – summary of actions	Sue McGorry & Abby Peters	24 June 2019
Exhibit SP/150	INQ0014718	Independent Assessment: The implementation of the Neonatal Action Plan	MIAA Solutions	1 July 2019
Exhibit SP/151	INQ0014723	Intelligence review of maternity services in the North West	NHS England	2020

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Exhibit	Relativity reference	Title	Author	Dated
Exhibit SP/152	INQ0012643	Three year delivery plan for maternity and neonatal services	NHS England	30 March 2023
Exhibit SP/153	INQ0014793	Introduction to the NHS Constitution	Department of Health and Social Care	8 March 2012
Exhibit SP/154	INQ0014751	2023/24 priorities and operational planning guidance	NHS England	23 December 2022
Exhibit SP/155	INQ0014620	Developing collective leadership for health care	Michael West Regina Eckert Katy Steward Bill Pasmore	May 2014
Exhibit SP/156	INQ0014624	Understanding Organisational Culture	Charted Managemen t Institute	Revised November 2015
Exhibit SP/157	INQ0014794	Our NHS People Promise	NHS England	July 2020
Exhibit SP/158	INQ0014781	Directory of board level learning and development opportunities	NHS England	August 2023

Exhibit SP/159	INQ0014795	Changing healthcare cultures – through collective leadership	NHS England	Undated
Exhibit SP/160	INQ0014747	Safety culture: learning from best practice	NHS England	15 November 2022
Exhibit SP/161	INQ0014726	NHS People Plan	NHS England	July 2020
Exhibit SP/162	INQ0014761	Verdict in the trial of Lucy Letby (letter)	NHS England	18 August 2023
Exhibit SP/163	INQ0014749	Listening well guidance: a blueprint for organisations to develop a local listening strategy	NHS England	21 February 2023
Exhibit SP/164	INQ0014808	MSC Quarterly Staff Survey Slide Pack	NHS England	23 March 2021
Exhibit SP/165	INQ0014748	Combatting racial discrimination against minority ethnic nurses, midwives and nursing associates	NHS England Nursing & Midwifery Council NHS Confederation	1 November 2022
Exhibit SP/166	INQ0014626	Better Births: Improving outcomes of maternity services in England. A Five Year Forward View for maternity care.	National Maternity Review	2016
Exhibit SP/167	INQ0012352	Implementing the Recommendations of the Neonatal Critical Care Transformation Review	NHS England	December 2019
Exhibit SP/168	INQ0014731	Neonatology: GIRFT Programme National Specialty Report	Getting It Right First Time	April 2022

Exhibit SP/169	INQ0014730	Neonatology – Workforce: GIRFT Programme National Specialty Report	Getting It Right First Time	April 2022
Exhibit SP/170	INQ0014779	Executive Quality Group: Final Assessment of the Morecambe Bay Recommendation – Paper 4	Stephen Anderson Michele Upton	26 September 2022
Exhibit SP/171	INQ0014745	Independent Maternity Working Group: Terms of Reference	Independent Maternity Working Group	01 August 2022
Exhibit SP/172	INQ0014729	Maternity Transformation Programme: Neonatal Implementation Board Terms of Reference	NHS	February 2022
Exhibit SP/173	INQ0014778	Paper 5 - Neonatal Services for NHSE Quality Committee	NHS England	11 September 2023
Exhibit SP/174	INQ0014758	NIB 2022/23 - Q4 assurance review	NHS England	To be confirmed
Exhibit SP/175	INQ0014757	Neonatal Implementation Board: Neonatal Priorities – 2023-24	NHS England	To be confirmed
Exhibit SP/176	INQ0014797	Maternity and Neonatal Voices Partnerships guidance	NHS England	28 November 2023
Exhibit SP/177	INQ0014759	Job description and person specification for National Clinical Director for Neonatology	NHS	To be confirmed
Exhibit SP/178	INQ0014750	Job description and person specification for Clinical Fellow – Neonatal Nursing Leadership	NHS England NHS Improvement	To be confirmed
Exhibit SP/179	INQ0014791	Looking After Our People – Retention hub	NHS England	To be confirmed

Exhibit SP/180	INQ0014790	Core competency framework v2: Minimum standards and stretch targets	NHS England	20 June 2023
Exhibit SP/181	INQ0014736	Safeguarding children, young people and adults at risk in the NHS: Safeguarding accountability and assurance framework	NHS England	21 July 2022
Exhibit SP/182	INQ0014618	NHS Safeguarding Accountability and Assurance Framework was published by NHS England on 21 March 2013	NHS England	21 March 2013
Exhibit SP/183	INQ0014623	Safeguarding children, young people and adults at risk in the NHS: Safeguarding Accountability and Assurance Framework 2015	NHS England	July 2015
Exhibit SP/184	INQ0014715	Safeguarding children, young people and adults at risk in the NHS Safeguarding Accountability and Assurance Framework 2019	NHS England	May 2019
Exhibit SP/185	INQ0014789	Executive lead roles within integrated care boards	NHS England	10 May 2023
Exhibit SP/186	INQ0014643	Freedom to speak up: raising concerns (whistleblowing) policy for the NHS	NHS Improvement NHS England	April 2016
Exhibit SP/187	INQ0014746	Freedom to speak up policy for the NHS	NHS	June 2022
Exhibit SP/188	INQ0014734	Freedom to Speak Up: A reflection and planning tool	National Guardian's Office	23 June 2022
Exhibit SP/189	INQ0014733	Freedom to speak up policy for the NHS: A guide for leaders in the NHS and organisations delivering NHS services	NHS	2022

Exhibit SP/190	INQ0014796	Freedom to Speak Up – annual report on whistleblowing disclosures	NHS	11 January 2024
Exhibit SP/191	INQ0014766	Task and Finish Group: Codifying Escalation Routes in Suspected Criminal/Serious Patient Safety Cases	NHS England	November 2023
Exhibit SP/192	INQ0014735	Corporate Records Retention and Disposal Schedule	NHS England	April 2023
Exhibit SP/193	INQ0014792	Data on Written Complaints in the NHS, 2021-22	NHS Digital	24 November 2022
Exhibit SP/194	INQ0014732	Countess of Chester Hospital NHS Foundation Trust Review (Complaints Department)	Helen Chadwick (Complaints Manager – NHSEI) North West	25 May 2022
Exhibit SP/195	INQ0014690	The future of NHS patient safety investigation	NHS Improvement	March 2018
Exhibit SP/196	INQ0014704	The future of NHS patient safety investigation: engagement feedback	NHS Improvement	November 2018
Exhibit SP/197	INQ0014705	Developing a patient safety strategy for the NHS: Proposals for consultation	NHS Improvement	14 December 2018
Exhibit SP/198	INQ0014737	Engaging and involving patients, families and staff following a patient safety incident	NHS England	August 2022
Exhibit SP/199	INQ0014743	Guide to responding proportionately to patient safety incidents	NHS England	September 2022

Exhibit SP/200	INQ0014742	Oversight roles and responsibilities specification	NHS England	August 2022
Exhibit SP/201	INQ0014738	Patient Safety Incident Response standards	NHS England	August 2022
Exhibit SP/202	INQ0014739	Patient Safety Incident Response Framework Preparation guide	NHS England	August 2022
Exhibit SP/203	INQ0014740	Patient safety incident response policy	NHS England	
Exhibit SP/204	INQ0014741	Patient safety incident response plan	NHS England	
Exhibit SP/205	INQ0014788	The Learn from Patient Safety Events (LFPSE) Service – patient and family discovery report	NHS England	13 October 2023
Exhibit SP/206	INQ0014701	Maternity Services Data Set	NHS Digital	9 December 2018
Exhibit SP/207	INQ0014776	Maternity Services Dashboard	NHS England	Undated
Exhibit SP/208	INQ0014767	Paediatric Intensive Care Audit Network National Paediatric Critical Care Audit State of the Nation Report 2023	PICANet	2023
Exhibit SP/209	INQ0014769	Admission Dataset Definitions Manual	PICANet	December 2023
Exhibit SP/210	INQ0014768	National Neonatal Audit Programme (NNAP) Summary report on 2022 data	National Neonatal Audit Programme	December 2023

Exhibit SP/211	INQ0014770	Learning from Standardised Reviews When Babies Die: National Perinatal Mortality Review Tool, Fifth Annual Report	Perinatal Mortality Review Tool	December 2023
Exhibit SP/212	INQ0014787	Complete list of NHS estates	NHS England	13 November 2023
Exhibit SP/213	INQ0014809	Survey for maternity and neonatal services	NHS England	9 February 2024
Exhibit SP/214	INQ0014616	Health Building Note 09-02: Maternity care facilities	NHS England	31 January 2024
Exhibit SP/215	INQ0014617	Health Building Note 09-03: Neonatal units	NHS England	31 January 2024
Exhibit SP/216	INQ0014727	Health Building Note 14-02: Medicines storage in clinical areas	NHS England	2021
Exhibit SP/217	INQ0014762	Records Management Code of Practice: A guide to the management of health and care records	NHS England	August 2023
Exhibit SP/218	INQ0014721	Neonatal Death: Full Guidance Document	National Bereavement Care Pathway for Pregnancy and Baby Loss	January 2020
Exhibit SP/219	INQ0014614	Palliative Care (Supportive and End of Life Care) A Framework for Clinical Practice in Perinatal Medicine	British Association of Perinatal Medicine	August 2010
Exhibit SP/220	INQ0014775	Perinatal Mental Health Programme	NHS England	Undated
Exhibit SP/221	INQ0014719	NHS Mental Health Implementation Plan 2019/20 – 2023/24	NHS England	July 2019
Exhibit SP/222	INQ0009278	NHS Patient Safety Strategy: Progress So Far	NHS England	undated
Exhibit SP/223	INQ0014786	PReCePT – using magnesium sulphate to reduce cerebral palsy in pre-term babies	NHS England	20 June 2023

Exhibit SP/224	INQ0014785	Saving pre-term babies lives through optimal cord management	NHS England	20 June 2023
Exhibit SP/225	INQ0014784	Reducing long-term opioid use	NHS England	20 June 2023
Exhibit SP/226	INQ0014764	Saving babies' lives version three: a care bundle for reducing perinatal mortality	NHS England	July 2023
Exhibit SP/227	INQ0014755	A summary of speaking up to freedom to Speak Up Guardians: 1 April 2022 – 31 March 2023	National Guardian's Office	Undated
Exhibit SP/228	INQ0014753	Listening to Workers: Speak Up Review of Ambulance Trusts in England	National Guardian's Office	February 2023
Exhibit SP/229	INQ0014783	Integrated care boards, integrated care systems and Freedom to Speak Up	NHS England	June 2022
Exhibit SP/230	INQ0014782	New NHS England framework for line managers.	NHS Employers	10 November 2023
Exhibit SP/231	INQ0014802	Kark review update & Fit and Proper Persons Test	NHS England	25 March 2021
Exhibit SP/232	INQ0014803	Kark review update & Fit and Proper Persons Test	NHS England	24 June 2021
Exhibit SP/233	INQ0014804	Kark review update & Fit and Proper Persons Test	NHS England	30 September 2021
Exhibit SP/234	INQ0014805	Equality, Diversity and Inclusion Update	NHS England	19 May 2022
Exhibit SP/235	INQ0012639	Letter from Sir Andrew Morris relating to Kark Report	Sir Andrew Morris	Undated
Exhibit SP/236	INQ0012645	NHS England Fit and Proper Person Test Framework for board members	NHS England	16 January 2024
Exhibit SP/237	INQ0014774	NHS management meeting note	NHS England	31 August 2023
Exhibit SP/238	INQ0014763	Draft paper providing early stage consideration of the options for regulation of senior managers	Department for Health and Social Care	25 September 2023

Exhibit SP/239	INQ0014752	Our Leadership Way	NHS Leadership Academy	8 February 2023
Exhibit SP/240	INQ0014724	Independent formative evaluation regarding addition of Equity and Inclusion	NHS England	2021
Exhibit SP/241	INQ0014728	An evaluation of the implementation of the NHS Culture and Leadership Programme	NHS England	December 2021
Exhibit SP/242	INQ0014807	Effect of national guidance on survival for babies born at 22 weeks' gestation in England and Wales: population based cohort study	National Institute for Health Research	31 August 2023
Exhibit SP/243	INQ0014744	National Neonatal Audit Programme: Summary report on 2021 data	Healthcare Quality Improvement Partnership, Royal College of Paediatrics and Child Health	2022
Exhibit SP/244	INQ0014756	Neonatal Critical Care Network Specification	NHS England	13 July 2023
Exhibit SP/245	INQ0014780	Stretched to the limit: tackling the NHS productivity challenge	NHS Providers	Undated

ANNEX 11: Index of Exhibits – Documents referenced in Annex 3

Exhibit SP/246	INQ0014754	2023 06 19 Project Columbus vF	NHS England	19 June 2023