Witness Name: Ian Trenholm
Statement No: 1
Exhibits:
Dated: 12/02/2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF IAN TRENHOLM

I, Ian Trenholm, Chief Executive of the Care Quality Commission, Citygate, Gallowgate, Newcastle upon Tyne NE1 4PA, will say as follows: -

1. I am employed by the Care Quality Commission (CQC) as Chief Executive, a post I have held since August 2018.

2. Prior to this I was Chief Executive of NHS Blood and Transplant from 2014, and previously Chief Operating Officer at the Department of Environment, Food and Rural Affairs (Defra). Prior roles have included Chief Executive of the Royal Borough of Windsor and Maidenhead and Strategic Director for Resources at Buckinghamshire County Council. I began my career as an Inspector in the Royal Hong Kong Police Force and then served with the Surrey Police for four years, before moving to the commercial sector.

3. I make this statement in response to the request from the Thirlwall Inquiry (the Inquiry) dated 6 November 2023, made under Rule 9 of the Inquiry Rules 2006 (SI 2006/1838). I adopt the abbreviations or acronyms deployed in the Rule 9 Request where appropriate. I am duly authorised to make this statement on behalf of CQC.

4. Save where it is stated otherwise, the contents of this statement are within my own knowledge. This statement is to the best of my knowledge and belief accurate and complete at the time of signing. Notwithstanding this, it is the case that CQC continues to prepare for its involvement in the Inquiry. As part of these preparations, it is possible that additional relevant material will be identified. In this eventuality the additional material will of course be provided to the Inquiry and a supplementary statement will be made, if required.

5. This statement has been prepared following consultation with current and, where necessary, former colleagues at CQC in order to provide as accurate an account as possible on behalf of CQC.

Overview of CQC and its functions (Q6)

6. CQC was established on 1 April 2009 by the *Health and Social Care Act 2008* (the 2008 Act) as the independent regulator of health and adult social care in England. CQC is an executive non-departmental public body, sponsored by the Department of Health and Social Care (DHSC), and accountable to Parliament through the Secretary of State for Health and Social Care.

7. Our functions, statutory duties and powers, which extend to England only, are set out principally in the 2008 Act[1]. They can also be found in the *Health and Social Care Act 2012* (the 2012 Act), the *Care Act 2014* (the 2014 Act), the *Health and Care Act 2022* (the 2022 Act) as well as in further primary and secondary legislation. In summary we are responsible for the registration, monitoring, inspection and regulation of services which fall within our regulatory remit.

8. We have a duty to conduct reviews of the carrying on of prescribed regulated activities and service providers, assess performance following the review, and to publish a report of our assessment as set out in section 46 of the 2008 Act.

9. The 2022 Act received Royal Assent on 28 April 2022 and added to the list of regulatory duties owed by CQC. Section 31 and 163 of the 2022 Act inserted 46A and 46B into the 2008 Act, which extended CQC's duties to conduct reviews, assess performance and to publish reports relating to, among other things, the provision of relevant health care, and adult social care, within the area of each Integrated Care Board (ICB) and the exercise of regulated care functions by English Local Authorities.

10. We also have a duty, under the *Mental Health Act 1983* (MHA), to monitor how services exercise their powers and discharge their duties when patients are detained in hospital, subject to community treatment orders or guardianship. In addition, we monitor how the *Mental Capacity Act 2005* (MCA) is being used by health and adult social care providers and how they use the Deprivation of Liberty Safeguards.

11. Our objectives when fulfilling these functions are set out in section 3 of the 2008 Act. Our purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and to encourage care services to improve. We report on how care is being delivered in England in our annual State of Care report.

<u>Requirement for registration with CQC</u>

[1] As set out in Section 2 of the 2008 Act.

12. Providers of 'regulated activities' must be registered with CQC unless a specified exemption or exception applies[2]. These regulated activities are:

    - personal care;
    - accommodation for persons who require nursing or personal care;
    - accommodation for persons who require treatment for substance misuse;
    - treatment of disease, disorder or injury (TDDI);
    - assessment or medical treatment for persons detained under the 1983 Act;
    - surgical procedures;
    - diagnostic and screening procedures;
    - management of supply of blood and blood derived products;
    - transport services, triage and medical advice provided remotely;
    - maternity and midwifery services;
    - termination of pregnancies;
    - services in slimming clinics;
    - nursing care; and
    - family planning services.

13. It is an offence to carry on a regulated activity without being registered, and we can prosecute those who do this. Registered persons can be an individual, a partnership or an organisation. CQC will register the relevant legal entity that will be carrying on the regulated activity. (IT/01 [INQ0010529]).

Enforcement and other powers

14. The 2008 Act gives CQC both civil and criminal enforcement powers to address issues of non-compliance with the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014* (the 2014 Regulations) and the *Care Quality Commission (Registration) Regulations 2009* (the 2009 Regulations). We also have powers to undertake civil and criminal enforcement action against registered persons who fail to comply with a condition of their registration or the relevant Regulations[3]. Further details of these powers are set out at paragraph 82 below.

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[2] Set out in Section 10 of the 2008 Act and defined in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

[3] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (as amended by a) Health and Social Care Act 2008 (Registration and Regulated Activities (Amendment) Regulations 2005 and b) Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012) and Care Quality Commission (Registration) Regulations 2009 (as amended by a) Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 and b) Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012).

15. CQC also has a wide set of powers that allow us to protect the public and hold registered providers to account. CQC's statutory powers are detailed in the 2008 Act and include powers of entry and inspection (sections 60 to 63 of the 2008 Act) and powers to require information and documentation (sections 64 and 65 of the 2008 Act). Failing to comply without reasonable excuse is an offence.

16. Section 48 of the 2008 Act provides CQC with the power to conduct a special review of, or investigation into, the provision of NHS care; adult social care services; the exercise of the functions of NHS England or an integrated care board; the exercise of the functions of English local authorities in arranging for the provision of adult social care services; and/or the exercise of functions by English Health Authorities. Special reviews or investigations may be conducted at CQC's discretion (with the approval of the Secretary of State), or upon the request of the Secretary of State.

17. The 2008 Act also gives CQC a general power to "do anything which appears to it to be necessary or expedient for the purposes of, or in connection with, the exercise of its functions"[4]. This includes co-operating with other public authorities in the United Kingdom.

Healthwatch England

18. CQC hosts Healthwatch England (HWE), the consumer champion for health and social care with a mandate to ensure the voices of people who use services are listened and responded to, with a view to making improvements in service provision and commissioning. HWE was established under the Health and Social Care Act 2012 as a statutory committee of CQC. It is funded through grant in aid. The Chair of HWE sits on CQC's Board. HWE is operationally independent but supported by CQC infrastructure.

National Guardian's Office

19. CQC also hosts the National Guardian's Office (NGO). The NGO and the role of the National Guardian were created in response to recommendations made in Sir Robert Francis KC's report '*Freedom to Speak Up'* (2015). The NGO leads, trains and supports a network of Freedom to Speak Up Guardians in England and conducts case reviews of organisations should it appear that a person's speaking up has not been handled according to best practice. The NGO is funded mainly by NHS England (NHSE) CQC also makes a contribution to the NGO. This is paid for by grant in aid. While the NGO is operationally independent of CQC, it is supported by CQC infrastructure. The *Care Quality Commission (Additional Functions) (Amendment) Regulations 2023*, detailing the legal status of the NGO, came into force on 28 November 2023.

[4] Paragraph 2, Schedule 4 of the 2008 Act

Maternity and Newborn Safety Investigation

20. On 1 October 2023, the functions of the Maternity and Newborn Safety Investigations (MNSI) programme were transferred to the Care Quality Commission pursuant to Directions from the Secretary of State[5]. The programme of investigations into maternity and newborn safety incidents began in 2018 as part of the national initiative to improve safety in maternity care and was previously overseen by the Healthcare Safety Investigation Branch (HSIB). NHS trusts are required to notify MNSI about certain patient safety incidents occurring in maternity care so that MNSI can carry out an independent investigation and, where relevant, make safety recommendations to improve services at local level and across the whole maternity healthcare system in England.

Governance of CQC (Q6d)

Board

21. CQC has a unitary Board made up of Non-Executive and Executive members. The Chair and other Non-Executive Members, who must make up a majority of the Board, are appointed by the Secretary of State. Legislation sets out requirements governing these arrangements, including Schedule 1 of the 2008 Act (as amended), the Care Act 2014 and the *Care Quality Commission (Membership) Regulations 2015*. The *Care Quality Commission (Membership) Regulations 2015*, which came into force in September 2015, include a requirement for the Board to have no fewer than six and no more than 14 members (not including the Chair).

22. During the 'proposed date range' (1 January 2015 to 19 October 2023), the membership of the Board changed. (Exhibit IT/02 [INQ0010481]) shows the membership of CQC's Board during the proposed date range and (Exhibit IT/03 [INQ0010514]) shows the current membership.

23. Throughout the proposed date range the Board ordinarily met monthly (save for August) in both public and private session. Between April 2020 and June 2020, as a result of the pandemic, the Board held weekly, one-hour Microsoft Teams calls in addition to the above. As from February 2023 the frequency of Board meetings was varied. The Board now has 6 formal meetings a year as well as meeting for two Board Strategy Days a year.

[5] The Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023

24. The Board is supported by a number of established committees, which provide assurance and advice to the Board on areas such as risk management and internal control, risks specific to the regulatory programme, and senior pay and succession planning.(IT/04 [INQ0010489]).

Executive Team

25. Our Executive Team (ET) meets formally twice a month. Current membership of ET is listed on our website. (IT/05 [INQ0010515]). Committees of ET meet to consider matters such as: strategic oversight, operational performance, and people, financial, and commercial resources. (IT/04 [INQ0010489]).

Corporate Governance Framework

26. CQC has a corporate governance framework. This sets out the responsibilities and procedures that we use to make sure we govern our organisation to a high standard. This framework was refreshed in 2021, and again in 2022. (IT/06 [INQ0010477]).

Framework Agreement

27. In addition, a signed Framework Agreement is in place between CQC and DHSC. This sets out our governance, as well as accountability, management and financial responsibilities and reporting procedures. It includes the Accounting Officer's accountability responsibilities to Parliament. It was last reviewed in 2021 and is currently in the process of being updated. (IT/07 [INQ0010474]).

Structure of CQC (Q6d)

28. From October 2013, under the then Chief Executive, CQC had five directorates. The majority of people worked in specialist teams in one of the three inspection directorates: (1) hospitals (including ambulances and mental health); (2) primary medical services and integrated care (including dentists, health and justice); and (3) adult social care (ASC). The two further directorates comprised: (4) Strategy and Intelligence and (5) Corporate Services (renamed Customer and Corporate Services and then Regulatory, Customer and Corporate Operations.

29. From April 2019, an additional Directorate, Digital, was created.

30. In March 2020 the Strategy and Intelligence Directorate was restructured and renamed the Engagement, Policy and Strategy Directorate and the Digital directorate was restructured and renamed the Digital and Intelligence Directorate.

31. After recruiting a new role of Executive Director of Operations, CQC began further restructuring to deliver our new regulatory approach. Regulatory Leadership teams were established, led by the Chief Inspectors with Directors heading up the different sectors within health and social care. Alongside Regulatory Leadership, we brought together our specialist sector teams into one Operations Group led by the Executive Director of Operations with Directors across four geographical networks: (1) London and the East of England; (2) Midlands; (3) North; and (4) South. These operate alongside National Operations and a central Hub. This has continued to evolve, in line with our strategy as outlined on our website. (IT/08 [INQ0010518]).

32. With effect from 31 March 2022, the Digital and Intelligence directorate was renamed the Technology, Data and Insight directorate. Following the departure of the Chief Operating Officer in August 2022, Kate Terroni took on this role, alongside being Chief Inspector of Adult Social Care. (The Chief Inspector of Adult Social Care role had itself been expanded to Adult Social Care and Integrated Care following the departure of Rosie Benneyworth in July 2022). In March 2023, the Chief Operating Officer role was reviewed and became Deputy Chief Executive. Kate Terroni continued to hold this role on an interim basis. In June 2023 James Bullion joined CQC as interim Chief Inspector of Adult Social Care covering adult social care and integrated care. The Regulatory, Customer and Corporate Operations directorate was renamed the Corporate Services directorate in December 2023. (IT/04 [INQ0010489]).

Fundamental Standards (Q6b)

33. Central to the manner in which CQC regulates is the application of 'fundamental standards'. These are the standards which everybody receiving care has the right to expect and below which care must never fall. Introduced following the Mid Staffordshire NHS Foundation Trust Public Inquiry, led by Sir Robert Francis KC, they impose obligations that registered providers must meet in order to be registered with CQC.

34. There are 13 fundamental standards. These are set out in the 2014 Regulations. Regulations 5 and 20 came into force in December 2014 whilst the other provisions of these regulations came into force on 1 April 2015. They replaced the *Health & Social Care Act 2008 (Regulated Activities) Regulations 2010*, which set out the previous 16 essential standards.

35. The fundamental standards, as summarised on CQC's website, are: (IT/09 [INQ0010532]).

    - Regulation 9 - Person centred care;
    - Regulation 10 - Dignity and respect;

- Regulation 11 – Need for consent;
- Regulation 12 – Safe care and treatment ;
- Regulation 13 - Safeguarding services users from abuse and improper treatment;
- Regulation 14 – Meeting nutritional and hydration needs;
- Regulation 15 - Premises and equipment;
- Regulation 16 – Receiving and acting on complaints;
- Regulation 17 - Good governance;
- Regulation 18 - Staffing;
- Regulation 19 - Fit and proper persons employed;
- Regulation 20 - Duty of candour;
- Regulation 20A – Requirement as to display of performance assessments display of ratings.

Fit and proper persons requirements (6c)

36. Regulation 5 of the 2014 Regulations requires that directors of health service bodies (or those performing similar functions to directors) be fit and proper persons to carry out this role. CQC has issued *Guidance for providers on meeting the regulations* specifically dealing with the requirements of the 2014 Regulations, including Regulation 5. (IT/10 [INQ0010466]).

    For NHS bodies, Regulation 5 applies to executive and non-executive, permanent, interim and associate positions, irrespective of their voting rights.[6] Regulation 5 (3) sets out the requirements that must be satisfied in order to be appointed as a director or perform the functions equivalent to or similar to the functions of a director. The requirements are as follows:

    a) the individual is of good character,
    b) the individual has the qualifications, competence, skills and experience which are necessary for the relevant office or position or the work for which they are employed,
    c) the individual is able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the office or position for which they are appointed or to the work for which they are employed,
    d) the individual has not 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 providing a service elsewhere which, if provided in England, would be a regulated activity, and

[6] *CQC Guidance for providers on meeting the regulations* – March 2015

e) none of the grounds of unfitness specified in Part 1 of Schedule 4 apply to the individual.

37. CQC's expects providers to follow robust processes when assessing good character, having regard to the good character test in Schedule 4, Part 2 of the 2014 Regulations.[7] The CQC *Guidance for providers on meeting the regulations* outlines that whilst it is not possible to outline every character trait that a director or person fulfilling a similar function should have, it is expected that the processes followed take account of a person's honesty, trustworthiness, reliability and respectfulness. (IT/10) [INQ0010466]).

38. Our guidance also makes clear that, when appointing directors, providers are expected to be aware of, and follow, the various guidelines that cover values-based recruitment, appraisal and development, and disciplinary action (including dismissal for chief executives, chairs and directors) and to have implemented procedures in line with the best practice.[8] In addition, our guidance highlights that providers are required to have processes in place for assurance that a person has not been responsible for, or involved in, any serious misconduct or mismanagement in the carrying on of a regulated activity. This includes investigating any allegations and making independent enquiries.

39. Regulation 19 of the 2014 Regulations provides that, where providers employ people for the purposes of carrying on a regulated activity, fit and proper staff must be employed to carry out these roles. Those employed must be of good character, have the necessary qualifications, competence, skills and experience for the work to be performed, and be able by reason of their health of properly performing tasks for which they are employed.[9] This regulation requires providers to operate robust recruitment procedures.[10] Registered persons are required to take necessary and proportionate action to ensure that the requirements under Regulation 19 are complied with, including where those employed no longer meet the criteria for a fit and proper person.[11]

40. CQC's provider guidance includes details about requirements under Regulation 19, including the requirement to

> "inform others about concerns or findings relating to a person's fitness and to support related enquiries and investigations that others have carried out. [Providers] may

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[7] Schedule 4, Part 2 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/2936
[8] *CQC Guidance for providers on meeting the regulations* – March 2015
[9] Regulation 19 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/2936
[10] Regulation 19 (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/2936
[11] Regulation 19 (5) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/2936

inform bodies such as professional regulators, police, and safeguarding authorities about their concerns."[12]

Duty of candour (6c)

41. Regulation 20 of the 2014 Regulations requires registered persons to comply with the duty of candour. This constitutes one of the "fundamental standards".

42. Regulation 20 requires registered persons to act in an open and transparent way with "relevant persons" (people receiving care or treatment, or a person acting on their behalf, as defined in the regulation[13]) in relation to care and treatment provided to service users in carrying on a regulated activity. This regulation also defines "notifiable safety incidents" (as set out in paragraphs 44-45 below) and specifies how registered persons must apply the duty of candour if such incidents occur.

43. The duty of candour, as set out in Regulation 20, requires a registered person to notify the 'relevant person' that a notifiable safety incident has occurred as soon as reasonably practicable after becoming aware of the incident. The duty also requires a registered person to provide reasonable support to the relevant person in relation to the incident, including when giving such notification.[14] Regulation 20(3) outlines how this notification should be given to the relevant person.

44. In relation to health service bodies, a "notifiable safety incident" is defined at Regulation 20(8) of the 2014 Regulations as any unintended or unexpected incident that occurred in respect of a service user during the provision of a regulated activity that, in the reasonable opinion of a health care professional, could result in, or appears to have resulted in:

    (a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user's illness or underlying condition, or
    (b) severe harm, moderate harm or prolonged psychological harm to the service user.

45. Regulation 20(9) defines "notifiable safety incident" in relation to any registered person who is not a health service body.

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[12] *CCQ Guidance for providers on meeting the regulations* – March 2015

[13] "'Relevant person' means the service user or, in the following circumstances, a person lawfully acting on their behalf— (a) on the death of the service user, (b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or (c) where the service user is 16 or over and lacks capacity in relation to the matter." (Regulation 20(7) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/2936.)

[14] Regulation 20 (2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/2936

46. Notifications of incidents are required[15] to be followed up by a written notification to the relevant person, to include an account of the notification, details of any enquiries to be undertaken, the results of any further enquiries into the incident and an apology. CQC's guidance for providers details a number of points to be addressed in respect of the duty of candour, including the following in relation to Regulation 20(3):

> 'Providers must ensure that one or more appropriate representatives of the provider gives a meaningful apology, in person, to relevant persons. An apology is defined in the regulation as an expression of sorrow or regret.'[16]

47. Our guidance details that providers are required to make all reasonable efforts to ensure that staff operating at all levels within the organisation operate transparently and with an open culture, understanding individual responsibilities in relation to the duty of candour. In addition, the guidance highlights that systems should be in place to identify and deal with possible breaches of the professional duty of candour by professionally registered staff, this includes the obstruction of another in their professional duty of candour.[17]

CQC's role in registering, monitoring and inspecting NHS hospitals, including the inspection framework and methodology (Q6e, Q6f)

Registration

48. CQC's *Scope of Registration* (May 2022) outlines the regulated activities set out in Schedule 1 of the 2014 Regulations. (IT/01 [INQ0010529]). In relation to the regulated activity maternity and midwifery services this covers services where they are carried out by, or under the supervision of, a registered healthcare professional.

49. Providers can apply to us to be registered to carry out one or more regulated activities. As an example, acute NHS trusts may be registered to carry on regulated activities such as treatment for disease, disorder or injury (TDDI), surgical procedures, diagnostic and screening procedures, maternity and midwifery services, depending upon the trust. It is for the provider to determine which regulated activities it carries on and therefore which activities it requires registration for. CQC's *Scope of Registration* offers guidance to providers to help them decide whether they need to register with CQC and explains what we mean by regulated activities, who and what needs to be registered and which regulated activities they are most likely to need to register for. It includes a flow chart which can be

[15] Regulation 20 (3) (b) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014/2936
[16] *CQC Guidance for Providers on Meeting the Regulations* – March 2015
[17] *CQC Guidance for Providers on Meeting the Regulations* – March 2015

used by providers to check if they need to register for maternity and midwifery services.[18] (IT/01 [INQ0010529]).

50. When CQC decides whether to grant or refuse an application for registration of a service provider we must apply the test set out in section 12 of the 2008 Act. This provides that we must be satisfied that the requirements of the 2014 Regulations and the 2009 Regulations, and any other enactment which appears to us to be relevant, are being and will continue to be complied with in relation to the regulated activity for the application to be granted, otherwise we must refuse it. We have the power to grant an application subject to conditions and the power to impose, vary or remove conditions on the registration.

51. At the point of registration we are required to issue a certificate of registration. This sets out the regulated activities that the provider is permitted to carry on, and the locations at which the provider may carry on the regulated activities by means of a locations condition which forms part of the conditions of registration. Other conditions may be placed on the registration of providers, depending on the type of provider and the type of service being operated.

52. Following registration, we monitor and inspect services in accordance with our published guidance and inspection framework.

Ongoing regulation of NHS trusts

53. To explain our role in monitoring and inspecting NHS Trusts I will detail the inspection framework as it was during the proposed date range (1 January 2015 – 19 October 2023). During this period CQC had different service assessment frameworks and inspection methodology for hospitals, primary medical services and adult social care. We will refer to the relevant frameworks and guidance in place at the time.

54. It is important to note, however, that we have undergone wide organisational change and in November 2023 commenced the transition to a Single Assessment Framework. As discussed at paragraph 73 below the Single Assessment Framework approach is being rolled out over a transition period, from November 2023 to March 2024. Where relevant, we will refer to this new Framework.

55. Where we refer to NHS trusts, in this statement and in the documentation we reference, we are including Trusts and Foundation Trusts.

Relationship management with NHS Trusts

[18] As shown on page 58 of the *Registration under the Health and Social Care Act 2008 - Scope of Registration:* May 2022

56. Alongside our ongoing monitoring of NHS Trusts, we ensure an ongoing relationship as part of our regulatory oversight, and provide information about this on our website. (IT/11 [INQ0010500]). We allocate an inspector to be the relationship holder for each trust (an operations manager under the new Single Assessment Framework), in order to strengthen and manage this relationship. The relevant trust and relationship holder maintain contact through relationship management meetings. These meetings allow for the discussion of important matters and reduce duplication with other national bodies such as NHSE in ongoing contact with providers.

57. Face-to-face relationship management meetings will usually happen at least every three months. Relationship holders may also stay in contact with trusts more regularly, for example through teleconferences.

58. Relationship holders usually meet with senior and/or executive members of the trust's management team, together with any other member of staff the trust wishes to bring to discuss a particular issue. As part of the relationship management meeting, CQC may ask to meet staff or patient groups to establish a broader view of the trust's culture and quality performance and help us decide on priorities for inspection.

59. Prior to face-to-face relationship management meetings, relationship holders may fill in a template to inform the discussion, based on the information we hold. This may include information such as details about changes in practice, serious incidents or complaints or concerns they have received about the trust's services. Where completed we may share the template with the trust before the meeting for their comments and additions.

60. If a trust has any significant concerns about quality, we expect those to be raised with the relationship holder, together with the action the trust is taking to address them. If the trust has commissioned any external reviews, those should be disclosed these as a matter of course.

Inspection frameworks

61. Central to our inspection methodology, during the proposed date range and continuing under new framework, are the five key questions that we ask of all services we inspect:

    - Are they safe?
    - Are they effective?
    - Are they caring?
    - Are they responsive to people's needs?
    - Are they well-led?

62. *How CQC monitors, inspects and regulates NHS trusts* (Updated November 2022) set out how CQC monitored and inspected NHS trusts, shared information and the steps taken post-inspection. (IT/12 [INQ0010478]). Alongside this we had various inspection frameworks, depending on the service. Of particular relevance to the questions posed by this Inquiry, over the proposed date range, there was:

    - The *Health Assessment Framework*, which applied to all health services (IT/13 [INQ0010470]).
    - *Inspection framework: NHS acute hospitals. Core Services for Children and Young People* (IT/14 [INQ0010484]).
    - *Inspection framework: NHS acute hospitals (specialist children's hospital)* (IT/15 [INQ0010502]).
    - *Inspection framework: Maternity framework (acute, community, independent)* (IT/16 [INQ0010483]).

63. Structured using the five key questions, these frameworks covered the following:

    - areas to inspect
    - interviews / focus group observations
    - service-specific considerations
    - Key Lines of Enquiry (KLOEs) and related prompts for inspectors.

64. Each of the five key questions was broken down into a subset of questions, called KLOEs. When CQC carried out inspections, up to November 2023, we used KLOEs to help us decide what we needed to focus on. For example, the inspection team might have looked at how risks were identified and managed to help them understand whether a service was safe. We used different KLOEs in different sectors. Using the KLOEs helped us make sure we were consistent in what we looked at under each of the five key questions and that we focused on the areas that mattered most.

65. The three broad phases of the inspection approach (outlined below) were:

    - monitoring and information sharing;
    - inspection; and
    - after inspection.

66. Prior to undertaking an inspection, we would review the information we held on a service. The exact information reviewed varied depending on service type. 'CQC Insight' (discussed further at paragraphs 193 below) continues to be used to monitor quality of care. We have specific Insight tools for the different health and care sectors which aim to: bring together information from people who use services, knowledge from our inspectors

and data from our partners; indicate where the risk to the quality of care provided is greatest; monitor change over time for each of the measures; and point to services where the quality may be improving.

67. We also continue to gather information directly from a service via statutory notifications and relationship management meetings, as well as information from national, regional and local stakeholders.

68. Further information on the data we collect and use is discussed at paragraphs 101 and 194ff below.

69. In the past, frequency principles, based on a service's existing rating, were the primary trigger for inspection. Information of concern received through the monitoring and information sharing phase could also trigger a smaller focused inspection to examine specific KLOEs. More significant concerns could also have prompted a comprehensive inspection. More recently, notably since the start of the Covid-19 pandemic, we have adopted a risk-based approach to triggering an inspection. Regulatory history plays an important part in making the decision to inspect a provider.

70. Most inspections continue to be either unannounced or have a short notice period (normally two weeks). In some cases, inspections are announced, for example an inspection of the Well-Led key question across an NHS Trust, which necessitates interviews and discussions with all senior board members and therefore requires a degree of coordination.

71. The size of an inspection team varies according to the provider and service type, but broadly continues to be made up of our inspectors and be supported by Specialist Professional Advisors and Experts by Experience. The former are akin to peer reviewers, who provide specialist advice to support our regulatory activity in an ad hoc role undertaken alongside their existing employment. The latter are patients, people who use services and carers who have experience of a service.

72. Following an inspection, we can ask for additional information from the provider to confirm evidence gathered during the inspection. After a period of quality assurance and factual accuracy review with the provider, a written report is published on our website. This will continue to be the case. In most cases, our inspection reports continue to include ratings.

<u>New inspection framework – the Single Assessment Framework</u>

73. As noted above (at paragraph 54), the Single Assessment Framework is a redesign of our approach to regulating services. In July 2022, we published an update on our website on the developing work on our new approach to regulation and the Single Assessment

Framework, with a further update in December 2023. (IT/17; IT/18 [INQ0010517]; [INQ0010516]). We started the rollout of this new assessment framework in the South region and with 'early adopter' providers that volunteered to take part (a small number of providers across various types of services and sectors). Planned assessments and subsequent feedback from these providers has helped to shape our approach as we have rolled out this new Framework.

74. Whilst quality ratings and the five key questions will remain central to our approach to regulation, we have replaced our KLOEs and prompts with new 'quality statements'. These will reduce the duplication in our current separate assessment frameworks and allow us to focus on specific topic areas under each key question. Our assessments across all types of services at all levels will be based on this Single Assessment Framework. Assessments of local authorities and integrated care systems will use a subset of the quality statements.

75. The principle of our on-site and off-site work, analysing data, and the approach to incorporating the opinions of those who work in and use services continues, but with a more structured approach to scoring and rating individual quality statements, rather than scoring only the five key questions. We expect that the new approach will help providers take a structured approach to improvement, will take less time to carry out, and will provide the public with clearer comparisons with other services and offer a more granular view than the single word judgement offers.

76. The evidence we will collect will fall into six categories:

- people's experiences;
- feedback from staff and leaders;
- observations of care;
- feedback from partners;
- processes; and
- outcomes of care.

77. For each quality statement we will state which evidence we will always need to collect and look at, although this may vary by the type of service under assessment. It may also depend on the level at which we are assessing, for example a newly registered service.

Ratings

78. There are four ratings that we give to health and social care services:

- Outstanding – awarded when the service is performing exceptionally well;
- Good – awarded when the service is performing well and meeting our expectations;

- Requires Improvement – awarded when the service is not performing as well as it should be and we have told the service how it must improve;
- Inadequate – awarded when the service is performing badly and we would normally have taken some form of action against the person or organisation that runs it.

79. These ratings were used throughout the proposed date range (1 January 2015 – 19 October 2023) and will continue to be used in the new Single Assessment Framework. Ratings can help people to compare services and make choices about their care.

80. The characteristics for ratings were included in the *Health Assessment Framework* and the provider guidance for each sector details the process for aggregating ratings. (IT/13; IT/12 [INQ0010470] ; [INQ0010478]). Under the Single Assessment Framework, ratings will be determined using a scoring framework. When we assess evidence, we will assign scores to the key evidence categories for each quality statement that we're assessing. Ratings will be based on building up scores from quality statements to provide an overall rating.

81. It is a legal requirement for providers to display their ratings, although there are a small number of services that we did not, and do not, have a duty to rate (for example dentists).

Enforcement action and other steps that can be taken by CQC

82. CQC has powers to undertake civil and criminal enforcement action against registered persons who fail to comply with a condition of their registration or the relevant regulations[19], and those carrying on regulated activities without registration. These powers continue to apply under the new Single Assessment Framework. CQC's Enforcement Policy is included at Exhibit (IT/19 [INQ0010495]).

83. CQC's civil enforcement powers, as set out in the 2008 Act (as amended by the 2014 Act), include powers to cancel or suspend a registered person's registration (sections 17,18 and 30 to 31), to impose, vary or remove conditions of registration in respect of a registered person (sections 12 (5), 15 (5), and 31) or to serve a "warning notice" where the test set out in sections 29 and 29A is met.

84. Criminal enforcement action can be taken, in response to breaches of certain regulations and sections of the 2008 Act, against any registered person, and against any unregistered

[19] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (as amended by a) Health and Social Care Act 2008 (Registration and Regulated Activities (Amendment) Regulations 2005 and b) Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012) and Care Quality Commission (Registration) Regulations 2009 (as amended by a) Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 and b) Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012).

person where they are carrying out regulated activities without registration. It can also be used against any person who obstructs us during an inspection and against registered or unregistered persons where they have made a false or misleading statement in any application to us. CQC's criminal enforcement powers include cautions, fixed penalty notices and prosecution. CQC also has powers under section 91 of the 2008 Act that enable us to consider the actions of an individual director, manager or secretary of the body corporate, where there is evidence that they have committed an offence or with their consent, connivance or neglect allowed an offence to be committed.

85. We can issue Requirement notices where we identify breaches of regulation that have not placed people using the service at immediate risk of harm. The requirement notice requires the provider to send us a report detailing what action is being taken by them to comply with regulation and the timeframe they will do this in. Under the new Single Assessment Framework, Requirement Notices will be named 'Action Plan Requests.'

CQC's recent work in relation to women's experience of maternity care

86. This information is to follow.

CQC's involvement with Quality Surveillance Groups (Q6i)

87. **Quality Surveillance Groups** ('QSG') were set up in 2013 by the National Quality Board ('NQB') as a result of their 2010 *Review of early warning systems in the NHS* report , following the Healthcare Commission's review of failings at Mid Staffordshire NHS Foundation Trust. The NQB report set out how different parts of the system needed to work together to identify potential and actual serious quality failures, and take corrective action in the interests of protecting patients.

88. The distinct roles and responsibilities of different organisations within the system means that no one organisation will have a complete picture of the quality of care. Information held by one organisation may not cause concern on its own, but when combined with intelligence held by others it might point to a potential problem requiring further investigation.

89. The NQB established a network of QSGs across the country to facilitate collaboration between different parts of the health system. The QSGs involve CQC and NHS England (NHSE), Health Education England (HEE), Public Health England (PHE), National Institute for Health and Care Excellence (NICE), NHS Digital and DHSC, and were developed with the additional guidance of HWE, the General Medical Council (GMC), Nursing and

Midwifery Council (NMC), Local Government Association (LGA) and Association of Directors of Adult Social Services (ADASS).

90. There are 28 local QSGs and four regional QSGs. CQC is represented in both types. The guidance asserts that a CQC Head of Inspection (now Deputy Director) attends at local QSG level, and Deputy Chief Inspector (now Director) at regional level. (IT/20 [INQ0010522].

91. Local QSGs engage in surveillance of quality at a local level and will consider information and intelligence, but will also work together to take co-ordinated action to mitigate quality failure. This can result in:

    - actions/investigations by individual member organisations (including CQC);
    - triggering risk summits;
    - deciding to keep a provider under review; and/or
    - collecting further information about a provider for review at a future QSG meeting.

92. Local QSG meetings should be held every 2 months.

93. The regional QSGs provide an escalation mechanism for local QSGs, assimilating risks and concerns from local QSGs and identifying common or recurring issues that merit a regional or national response. Regional QSGs can lead to:

    - actions / investigations by individual organisations (including CQC);
    - making recommendations for local QSGs;
    - identifying issues for a regional or national response and following this up; and/or
    - triggering risk summits.

94. Regional QSG meetings should be held every 3 months.

95. The regional QSGs can come together at a national level via the NHSE Quality Assurance Group (QAG). Regional groups should report to the QAG where there are national implications, or implications for other regions. Depending on the nature of the concern, when action is needed at a national level it may be best led by one of the national oversight bodies.

96. QSGs are not statutory bodies and have no legislative status or formal powers. Once a QSG identifies a concern about the quality of care provided in their area, its members can take contractual action, regulatory or enforcement action, and/or provide improvement support and performance management in line with their existing responsibilities. Its purpose is not to performance-manage CCGs or any other organisations and should not

interfere with the roles of the constituent organisations. It does not substitute the need for individual organisations to act promptly when concerns become apparent.

97. Since 2022, QSGs have been replaced by System Quality Groups. (IT/21 [INQ0010486]).

CQC's use of data available to other organisations (6j)

98. We monitor changes in quality of care by collating what people who use the services that we regulate tell us, information gathered in the course of inspections and data from our partner organisations.

99. We use data gathered nationally by other organisations including:

- patient survey data;
- information from the NHS;
- patient opinion feedback; and
- the NHS Friends and Family Test.

100. We also form partnerships with charities and other organisations to gather feedback from people who contact them about their experience of care.

101. CQC currently draws on a range of data when considering quality of care in relation to newborn children, including the following:

- National clinical audit data (National Maternity and Perinatal Audit (NMPA), National Neonatal Audit Programme (NNAP), Mothers and Babies Reducing Risk through Audits and Confidential Enquiries-UK (MBRRACE-UK))
- Patient safety incidents data
- Staff survey data (from NHSE and GMC)
- NHS Patient Surveys (including CQC Maternity Survey)
- NHSE data/dashboards (including National Maternity Dashboard)
- NHS Resolution Maternity incentive scheme
- NHSE patient level datasets (Hospital Episodes Statistics (HES) / Material Safety Data Sheet (MSDS)

102. Further information on our use of data, including CQC Insight, is covered in paragraphs 193 below.

CQC's work with regulators, employers and patient groups (Q6k)

103. We work in partnership with many national organisations to share information about services and people's experiences of them. These close working relationships increase efficiency by reducing duplication and making the best use of shared information and resources.

104. Our inspection colleagues have an ongoing relationship with organisations, including: NHSE; HWE; NGO; and the National Data Guardian. We also engage with other partner organisations, such as the Parliamentary and Health Service Ombudsman (PHSO), professional regulators such as the NMC, Health and Care Professions Council (HCPC), GMC and the Royal Colleges. We work with these bodies to support delivery of our regulatory activity and gather different types of information regularly, as well as in the lead-up to an inspection.

105. Relationships with strategic partners and other organisations are governed through Memorandums of Understanding (MoUs) and associated agreements. These set out clear expectations and objectives, providing a framework for information exchange and operational working, establishing clear evaluation criteria, and signalling publicly our intent to work together.

106. These agreements include:

- **Memorandum of Understanding (MoU)**: A statement of intent to work together, which includes an overview of the main reasons for doing this and sets the legal context of the partnership.
- **Joint Working Protocol (JWP)**: A description of the more detailed working arrangements at operational, policy and strategic levels, including specific mechanisms, objectives, deliverables and governance.
- **Information Sharing Agreement (ISA)**: An agreement that sets out details for routine and responsive information exchange, specifying data, frequency, exchange mechanisms and security.

107. **NHS England**: The ways in which CQC and NHSE work together are set out in the existing MoU and supporting operational guidance. These documents are due to be updated in 2024 to reflect changes to the way in which CQC works, as well as changes at NHSE. Our current MoUs refer to NHSE's predecessor organisations (Monitor and Trust Development Authority (TDA)). (IT/22; IT/23 [INQ0010504; INQ0010467]).

108. **Professional regulators**: Health and care regulators 'register' health and care professionals. CQC has MoUs with relevant regulators such as the GMC, NMC and HCPC. Each MoU sets out a framework to support the working relationship between the CQC and the relevant professional regulator with the purpose of promoting patient safety

and high-quality health and adult social care in England. The latest versions of these MOUs are exhibited: NMC (signed 17 September 2018); GMC (signed 29 January 2013); and HCPC (signed 22 September 2014).(IT/24; IT/25; IT/26 [INQ0010471]; [INQ0010496]; [INQ0010469]).

109. **Emerging concerns protocol**: Together with seven other health and social care regulators and bodies, we have signed an agreement to help share concerns with each other more effectively. The Emerging Concerns Protocol provides a clearly defined mechanism to share information and intelligence that may indicate risks to users of services, their carers, families or professionals. (IT/27 [INQ0010492]).

110. **Patient groups**: As set out above, Healthwatch England (HWE) is the consumer champion for health and care. HWE is a key strategic partner of CQC. We also have a duty to take account of the views and experiences of Local Healthwatch organisations or contractors (section 4 (1)(c) of the 2008 Act). We continue to work with other groups to inform our work, including input from frontline maternity staff and people who use maternity services.

111. The National Quality Board ('NQB') champions the importance of quality and drives system alignment across health and care on behalf of CQC, NHSE, NHS Digital, UK Health Security Agency (UKHSA), NICE, the Office for Health Improvement & Disparities, DHSC and HWE. The NQB is chaired by Professor Stephen Powis (National Medical Director, NHSE) and Dr Sean O'Kelly (Chief Inspector of Healthcare, CQC).

112. The NQB meets five times per year, to provide advice, recommendations and endorsement on matters relating to quality, acting as a collective to influence, drive and ensure system alignment. The NQB also set up the QSG, as noted in paragraphs 87 above. The NQB reviewed progress following the establishment of the QSG in 2013 and, based on changes to the health system, the NQB updated the relevant guidance.

113. The Health and Social Care Regulators Forum was established in 2014 and meets 3 times per year. The forum aims to jointly identify, develop, share and promote good practice across health and social care, specifically relating to professional system regulation. I chair the meetings of the Forum and where I am unable to attend the meeting a CQC colleague will usually deputise.

114. The Forum includes CQC, GMC, General Pharmaceutical Council, HCPC, HEE, Local Government and Social Care Ombudsman (LGO), NMC and PHSO. Representatives from the following have also been included as provisional attendees: Patient Safety Commissioner, General Dental Council (GDC), Professional Standards Authority, Social Work England, General Osteopathic Council, General Chiropractic Council, General

Optical Council, NHSE, Medicines and Healthcare Products Regulatory Agency and Health Services Safety Investigations Body.

115. The National Joint Strategic Oversight Group (JSOG) was established in 2018 as a forum of healthcare regulators and related arms-length bodies, and meets every other month. The group's original remit was to: a) advise on national policy and intensive support for challenged systems, including the approach to special measures for quality and financial reasons; b) review and recommend intensive support for challenged providers and/or systems escalated by regional JSOGs, taking into account the content of the local health system and including support for JSOG partners; c) share information about emerging concerns and risks across providers and systems; and d) exchange learning, intelligence and information to aid future improvement. Subsequent revisions to the Terms of Reference included the maintenance of critical services and resilience during the Covid-19 pandemic, and a further update in October 2021 to reflect an increased focus on systems.

Current procedures and policies (Q37-53)

Evidence of processes within Trusts for responding to concerns or complaints regarding neonatal care supporting a rating of outstanding or good

116. For non-specialist Trusts, neonatal services were covered in the core service framework for Children and Young People's (CYP) services , and neonatal services in specialist children's trusts would have been inspected as a standalone service with its own framework. (IT/14; IT/15 [INQ0010484]; [INQ0010502]). From 2018, CQC's methodology introduced a policy on additional services and neonatal care was considered to be additional service, with a separate inspection framework. Criteria for being considered an additional service included where the service represented a significant proportion of the provider's range of services, we had identified it as potentially being rated outstanding or we identified it as being high risk.

117. In carrying out an inspection of CYP and neonatal services, we would look at how people's concerns and complaints are listened to, responded to and used to improve the quality of care, as part of the Responsive key question.

118. The inspection framework included how the service implemented the NHS Constitution. (IT/28 [INQ0010533]). The Constitution establishes the principles and values of the NHS in England, setting out rights to which patients, public and staff are entitled and pledges which the NHS is committed to achieve. The Constitution's 'Complaint and Redress' section gives people the right to:

- have their complaint about NHS services acknowledged within three working days and properly investigated thereafter
- to be kept informed of progress and to know the outcome of any investigation into the complaint
- to take a complaint to the independent PHSO or LGO if the way the complaint has been dealt with by the NHS has not been satisfactory
- to receive compensation where there has been harm caused by negligent treatment.

119. As part of our assessment of how well led a trust is, we would look at the culture within a service. Prior to the Single Assessment Framework, we would have used the Trust-wide well-led inspection framework . (IT/29 [INQ0010535]). Under the KLOE 'Is there a culture of high quality, sustainable care?' we would consider, for example: whether staff feel supported, respected and valued; is the culture centred on the needs and experiences of people who use services; does the culture encourage openness and honesty at all levels in response to incidents; are there cooperative, supportive and appreciative relationships among staff? The framework set out the evidence we looked for in support of those enquiries. We looked at whether staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally where appropriate. This was not unique to the Neonatal Services inspection framework, but a standard line of enquiry across the health assessment framework.

120. As part of our assessment, we also look at the following professional standards and good practice:

    - NMC – *Openness and honesty when things go wrong: the professional duty of candour*. (IT/30 [INQ0010513]).
    - National Reporting and Learning Service (NRLS) – *Being open: communicating patient safety incidents with patients, their families and carers*. (IT/31 INQ0010487]).
    - *Duty of Candour – CQC Guidance*. (IT/32 [INQ0010491]).

121. *Inspection framework: NHS acute hospitals (specialist children's hospital)* included KLOEs under the Responsive key question in relation to how people's concerns and complaints were listened and responded to, and how they were used to improve the quality of care, with additional guidance given to inspectors within the Responsive key question in the Inspection framework: NHS acute hospitals. Core Services for Children and Young People and additional prompts on whether there was a culture of high-quality, sustainable care under the Well-Led key question. (IT/15; IT/14 [INQ0010502]; [INQ0010484]).

122. As noted above at paragraph 78, CQC uses rating characteristics to determine the rating for a trust. (IT/13 [INQ0010470]). For a trust to be rated as 'good' in responding to concerns and complaints, our inspection framework for NHS acute hospitals set out that we would expect to see;

> *'People know how to give feedback about their experiences and can do so in a range of accessible ways, including how to raise any concerns or issues. People who use the service, their family, friends and other carers feel confident that if they complain, they will be taken seriously and treated compassionately. They feel that their complaint or concern will be explored thoroughly and responded to in good time because the service deals with complaints in an open and transparent way, with no repercussions. The service uses the learning from complaints and concerns as an opportunity for improvement. Staff can give examples of how they incorporated learning into daily practice.'*[20]

123. For a trust to be considered 'outstanding' in its response to concerns and complaints, the ratings characteristics require that the trust show:

> *People who use the service and others are involved in regular reviews of how the service manages and responds to complaints. The service can demonstrate where improvements have been made as a result of learning from reviews and that learning is shared with other services. Investigations are comprehensive and the service uses innovative ways of looking into concerns, including using external people and professionals to make sure there is an independent and objective approach.*[21]

CQC requirements / guidance on trust policies and procedures (Q38 + Q39)

124. The Inquiry has asked if CQC imposes requirements and or provides guidance on trust policies in relation to any of the following areas:

Safeguarding policies for babies

125. Registered providers are required to meet Regulation 13 of the 2014 Regulations. The intention of this regulation is to safeguard people who use services from suffering any form of abuse or improper treatment while receiving care and treatment, and to require service providers, including trusts, to establish and effectively operate systems and processes to immediately investigate any such allegations. Improper treatment includes

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[20] *Key lines of enquiry, prompts and ratings characteristics for adult social care services* – pages 60 - 61

[21] *Key lines of enquiry, prompts and ratings characteristics for adult social care services* – pages 60 - 61

discrimination or unlawful restraint (including inappropriate deprivation of liberty under the *Mental Capacity Act 2005*). It also includes degrading treatment or treatment that significantly disregards the needs of the service user.

126. CQC's guidance for providers[22] sets out that in order to meet the requirements of Regulation 13, providers must protect people from abuse, unlawful discrimination and restraint. (IT/10) [INQ0010466]). The guidance also states that where a provider becomes aware of any allegation or evidence of abuse, they must take appropriate action without delay, which must include investigation and may also include referral to an appropriate body. This applies whether the third party or occurrence is internal or external to the provider.[23]

127. In respect of neonatal care, CQC does not set specific requirements in this area, but we look to national standards and guidance set by recognised bodies to regulate against, including:

- Royal College of Nursing (RCN) – *Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff*. (IT/33 [INQ0010523]). This guidance sets out indicative minimum training requirements in order for staff to have the competencies to recognise child maltreatment, opportunities to improve childhood wellbeing and to take effective action as appropriate to their role.
- HM Government – *Working together to Safeguard Children 2023: a guide to multi-agency working to help promote the welfare of children*. (IT/34 [INQ0010537]). This guidance covers the legislative requirements that apply to individuals, organisations and agencies; a framework for the three local safeguarding parties to work together to safeguard local children; a framework for the two child death review partners to review all deaths of children normally resident in the local area.

128. CQC can prosecute where a registered person breaches parts of the regulation and that breach results in avoidable harm to a person using the service or if a person using the service is exposed to a significant risk of avoidable harm. We do not have to serve a warning Notice prior to prosecution. We may also take other regulatory action.

Reporting patient safety incidents

129. We expect providers to have appropriate systems in place to report incidents. These apply to all of the regulated activities, not limited to neonatal services.

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[22] *CQC Guidance for providers on meeting the regulations* – March 2015

[23] *CQC Guidance for providers on meeting the regulations* – March 2015

130. Registered persons are required to submit notifications to us about certain matters. As applies to NHS providers, the guidance is provided at exhibit (IT/35 [INQ0010530]). There are a number of circumstances set out in the 2009 Regulations that require a 'statutory notification' to be submitted to us. We hold a range of forms to enable providers to submit statutory notifications to us depending on the event. The framework regarding notifications is set out in regulations 12, 14-18, and 20-22 of the 2009 Regulations.

131. Regulation 18 of the 2009 Regulations sets out a range of events or occurrences which providers must notify us of so that, where needed, we can take follow-up actions. Registered persons must send these notifications directly to us unless the provider is a health service body and it has followed the below process. A health service body, as defined by the 2009 Regulations, includes an English NHS body, which is defined in section 97 of the 2008 Act to include an NHS trust or NHS Foundation Trust.[24]

132. Registered persons must notify us of incidents that affect the health, safety and welfare of people who use services. The list of notifiable incidents includes: certain types of injury; abuse or allegations of abuse; incidents involving the police (not applicable to an English NHS body); applications regarding deprivation of liberty; and events which could prevent the provider's ability to continue to carry on the regulated activity safely. (IT/36 [INQ0010527]). Some examples of events which have necessitated a Regulation 18 notification include: staff shortages; utility access; damage to the premises; and malfunction or failure of safety devices such as fire alarms.

133. We must also be notified in relation to where there is a death of a service user (Regulation 16); the absence of the registered person, changes to details of the registered person, and what suitable arrangements are put in place for this (Regulations 14 and 15); and where there is a death of the service provider (Regulation 21).

134. The 2009 Regulations state that in some circumstances, where the provider is a health service body, notifications about the death of a service user and other incidents impacting on the health or safe care and treatment of a service user do not need to be submitted to CQC. For this to be the case, the provider must have already submitted the information to the NHS Commissioning Board (now NHSE). In practice this would be through the National Reporting and Learning System (NRLS).

135. This would include those notifications relating to: deaths of people using the service (Regulation 16); allegations of abuse (Regulation 18(2)(e)); events that stop or may stop

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[24] "*a National Health Service trust all or most of whose hospitals, establishments and facilities are situated in England, NHS England, an integrated care board, an NHS foundation trust or a Special Health Authority performing functions only or mainly in respect of England*".

the service from running safely and properly (Regulation 18(2)(g)); or serious injuries of people using the activity (Regulation 18(2)(a) and (b)).

136. The 2009 Regulations also allow for providers of NHS primary medical services such as GPs to make notifications via NRLS. However, in reality, very few GP practices have access to this method of notification as the NRLS system was originally designed for use primarily within secondary care, where local risk management system (LRMS) software is common. GPs are required to notify CQC using our forms, similar to other non-NHS providers, although they may also use NRLS (in addition to the forms) on a voluntary basis.

137. The notifications to NHSE via NRLS are shared with us under a data sharing agreement and are incorporated into our intelligence and monitoring . (IT/37 [INQ0010475]). NRLS is currently in the process of being replaced by the Learn from Patient Safety Events (LFPSE) service . (IT/38 [INQ0010508]). Our Data Sharing Agreement continues to apply to the LFPSE service.

138. CQC expects providers to have proper policies and processes in place to enable the reporting of statutory notifications A failure to comply with the requirements of Regulations 12 and 14-20 of the 2009 Regulations is an offence.

139. Serious incidents were previously investigated using the NHSE Serious Incident Framework . (IT/39 [INQ0010510]). This framework describes the circumstances in which a heightened level of response to a serious incident may be required, and the processes and procedures for achieving that response. This was to ensure that serious incidents were identified correctly, investigated thoroughly and learned from so to prevent similar incidents happening again. This framework has recently been replaced by NHSE's Patient Safety Incident Response Framework. (IT/40 [INQ0010519]). Organisations are expected to transition to the new framework within 12 months of its publication and transition should have been completed by Autumn 2023.

140. CQC sample checks, as part of our inspections, whether individual Management Reviews or Root Cause Analyses were completed by a trust, to contribute to a multi-agency Serious Case review. We look to see whether changes to practice were implemented as a result, and how regularly the service holds mortality and morbidity meetings when serious incidents occur (including who attends them and if they are minuted). We will also consider how the neonatal service responds to national patient safety alerts.

Investigating a neonatal death

141. We have set out the power that CQC has to proceed with enforcement in paragraphs 82-84 above. In particular CQC may investigate breaches of regulation 12 (safe care and

treatment) and it is possible for a neonatal death to be investigated in accordance with the legislation but that will depend upon the circumstances of the death and whether any failures to comply with the requirements of the regulation are attributable to a failure by a Registered Person.

142. As noted elsewhere, all registered persons are subject to the duty of candour in respect of notifiable safety incidents. In addition, child deaths must be reported through the Child Death Overview Panels (CDOP), which conduct case reviews to help prevent further deaths. Government guidance Working together to Safeguard Children 2023: a guide to multi-agency working to help promote the welfare of children sets out the framework for the CDOP. (IT/34 [INQ0010537]). CQC looks at the arrangements for reviewing and investigating safety and safeguarding incidents and events when things go wrong, and whether all relevant staff, services, partner organisations and people who use services are involved in reviews and investigations.

Escalation of concerns

143. The escalation of concerns is considered as part of our trust-wide 'Well-Led' assessment. It includes consideration of an organisation's speaking-up arrangements, its culture, and the implementation of the Freedom to Speak Up (FTSU) Guardian role. We look at whether the culture encourages openness and honesty at all levels in response to incidents.

144. The NHS Standard Contract requires services to have in place one or more FTSU guardians to fulfil the role set out in the NGO Guidance, and comply with the requirements of that guidance. (IT/41) [INQ0010462]). The NGO and NHSE have produced a range of guidance and other materials including the guidance for Trust boards and guidance on the training of workers which we take into account in our assessments. This is also part of our assessment of the 'Well led' key question. (IT/42; IT/43 [INQ0010509]; [INQ0010472]).

145. CQC's guidance on whistleblowing includes a specific section on advice for registered providers which states they must meet the regulations and national standards of quality and safety. (IT/44 [INQ0010465]). The published assessment frameworks focus on the outcomes that people who use a service should expect when a provider is meeting those standards and include prompts about how providers and staff can achieve the outcomes.

146. The KLOEs prompted inspectors to examine if the culture encouraged openness and honesty, with the organisation and with those using their services, and asked:

'Do leaders and staff understand the importance of staff being able to raise concerns without fear of retribution, and is appropriate learning and action taken as a result of concerns raised?'

147. Within the Single Assessment Framework, this is covered in the quality statement:

'We foster a positive culture where people feel that they can speak up and that their voice will be heard.'

148. As set out in CQC's whistleblowing guidance (IT/44 [INQ0010465]), providers should ensure that people who use their services receive care, treatment and support from staff who are confident about reporting any safeguarding and other concerns without worrying about the consequences. There should be an open culture in the service that allows staff to feel supported to raise concerns, both inside and outside of the organisation. Providers should also make it easy for staff to raise concerns and contribute to good practice, and they should make sure their employees are aware of their rights under the Public Interest Disclosure Act 1998.

149. Large organisations may wish to identify one or more senior managers outside the usual line-management arrangements as having a lead role for receiving concerns from staff in confidence. The arrangements should reassure staff that their concerns will be received supportively and addressed appropriately without fear of reprisals of any kind.

Duty of Candour

150. As noted in paragraphs 41-47 above, registered providers are required to meet Regulation 20 of the 2014 Regulations regarding the Duty of Candour.

151. There are two types of duty of candour notifications – statutory and professional. Both have similar aims, but CQC's guidance relates to the statutory duty, which we regulate. The professional duty is overseen by regulators of specific healthcare professions, such as the GMC, NMC and GDC.

152. The definition of a 'notifiable safety incident' is set out in the 2014 Regulations (Regulation 20(8) and (9), as noted in paragraphs 44-45 above). Definitions of harm vary slightly between health service bodies and all other providers, and it is therefore possible for an incident to trigger the harm threshold for NHS Trusts, but not for other service types, and vice versa.

153. We also expect the provider to have in place a process to report concerns around fitness to practise to professional regulators.

154. CQC does not investigate every notifiable safety incident, as this responsibility lies with the provider. Our role is to regulate the provider and ensure that it is discharging its responsibility to carry out all aspects of the duty of candour. We will, however, investigate specific incidents where we have concerns about the operation of provider processes in this area.

155. We approach the monitoring of the duty of candour through the lens of the service: i) being well led; ii) having an open and safe culture; iii) meeting the regulatory requirements of the duty of candour. When we hold monitoring calls, assess the data and information we receive, or visit the provider on inspection, we will look for evidence that all three factors are met.

156. The ultimate responsibility for ensuring the duty of candour is complied with lies with the registered person, but where we believe this is not happening we can use our enforcement powers. This includes warning and requirement notices, imposition of conditions and criminal prosecution.

Complaints

157. Registered providers are required to meet Regulation 16 of the 2014 regulations in relation to receiving and acting on complaints. The intention of this regulation is to ensure people can make a complaint about their care or treatment, and providers must have an effective and accessible system for identifying, receiving, handling and responding to complaints. All complaints must be investigated thoroughly, and any necessary action taken when failures have been identified. When requested, providers must supply CQC with a summary of complaints, responses and other related correspondence or information.

158. We consider complaints as part of our trust-wide assessment. Our approach includes interviews with the complaints lead and other senior managers and Board members. We will also look at staff complaints procedures and policies, as well as reviewing complaints data.

159. We can prosecute providers for a breach of Regulation 16(3), which requires providers to provide information on complaints to CQC when requested, and no later than 28 days after we make any such request. We can move directly to prosecution without first serving a warning notice and, in addition, can take other regulatory action in response to breaches of this regulation. Guidance to providers on meeting Regulation 16 is available on CQC's website . (IT/45 [INQ0010525]).

160. Many elements of these areas of policy and practice are of necessity qualitative in nature and it is difficult to objectively say if these policies and the associated Regulations are

effective if measured through the lens of things such as numbers of prosecutions or warning notices. Work carried out in 2018 by the Manchester Business School and the Kings Fund identified our work as having 8 impact levers. (IT/46 [INQ0010490]). Whilst we have seen improvement and leadership focus on these topics over the last few years, we are still seeing concerns in all of these areas within maternity services and across hospital services.

CQC view on policies (Q40 + Q41)

161. Any information regarding the effectiveness of individual trust policies and practice are, where relevant, covered in our judgements about the quality of care in regulated services are shared through our inspection reports and ratings. Under the methodology in use during the 'proposed date range', we produced a report after each inspection, which in most cases include ratings showing our overall judgement of the quality of care. Our reports set out what our findings are on each of the five key questions and what they mean for the people who use the service, describing good practice as well as concerns found. We clearly set out any evidence about breaches of regulations.

162. CQC's guidance on how providers can meet the regulations has not been revised in light of the LL case, and nor have the regulations that underpin our work.

163. CQC does not set our own national standards or guidance, or comment on the efficacy of those standards. CQC assesses how well a provider implements national best practice and national standards. Where best practice has been updated nationally we will update our assessments to reflect this.

CCTV (Q42)

164. We do not hold information on the number of trusts that have CCTV installed in neonatal units, or the areas that any such installation covers.

165. CQC's powers to impose conditions of registration under sections 12(5) and 15(5) of the 2008 Act are broad and could cover a condition to install overt surveillance in the form of CCTV. Any such condition would have to be consistent with the Surveillance Camera Code of Practice, and lawful in that it does not breach s.6(1) of the Human Rights Act 1998, particularly Article 8(1) which is the right to respect for private and family life.

Management of controlled drugs (Q43)

166. As with other providers we regulate, CQC expects trusts to meet our fundamental standards. This includes how they ensure that medicines are managed safely, including controlled drugs. Regulation 12 of the 2014 Regulations requires that registered persons ensure 'the proper and safe use of medicines.'

167. Under the proposed date range, Inspectors would consider the KLOEs on controlled drugs when assessing whether this regulation was being met. These KLOEs covered the management, administration and storage of medications.

168. Under the new Single Assessment Framework we have a quality statement on 'Medicines Optimisation' to enable us to assess trusts on all aspects of medicines optimisation. The quality statement on medicines states:

We make sure that medicines and treatments are safe and meet people's needs, capacities and preferences by enabling them to be involved in planning, including when changes happen.

169. This quality statement further explains that there should be appropriate arrangements for the safe management, use and oversight of controlled drugs.

170. In addition to the above requirements set out under the 2014 Regulations, NHS Trusts meet the definition of a "Designated Body" in the Controlled Drugs *(Supervision of Management and Use) Regulations 2013* (the 2013 Regulations). Designated Bodies are required to appoint a Controlled Drugs Accountable Officer (CDAO).

171. Under Regulation 10(3) of the 2013 Regulations, CQC is required to maintain and publish a list of accountable officers in England. This register can be found on our website . (IT/47 [INQ0010488]).

172. CQC expects individuals who are applying for addition to our register as a CDAO to meet the requirements of the 2013 Regulations. We have a process in place to receive, assess and make decisions on notifications from individuals who apply to be added to our register of CDAOs.

173. This includes ensuring that those who apply meet relevant conditions of the 2013 Regulations. For example, Regulation 8(1) requires that the CDAO is a

"fit, proper and suitably experienced person".

174. In addition, Regulations 8(6), (7) and (8) reference additional conditions that must be met in order that a person can be appointed a CDAO. For example, a CDAO does not, or only exceptionally prescribes, supplies, administers or disposes of controlled drugs as part of their duties as an officer. Should CQC receive an application from an individual who

indicates that they handle controlled drugs as part of their role or is not employed at the required seniority within their organisation, we will undertake further investigations into their suitability for the role.

175. CQC's expectation of CDAOs is that they are responsible for all aspects of controlled drugs management within their organisation, in line with the requirements of the 2013 Regulations.

176. In 2013, DHSC issued guidance in relation to the requirements of the 2013 Regulations. *The Controlled Drugs (Supervision of management and use) Regulations 2013*: Information about the Regulations is comprehensive guidance that includes all aspects of controlled drugs management. (IT/48 [INQ0010464]). Our expectation is that CDAOs follow both the 2013 Regulations and this guidance.

Guidance / policies regarding security arrangements for medication storage and administration (Q44)

177. CQC does not produce any specific guidance for NHS Trusts in relation to security arrangements and/or policies for the storage and administration of medicines generally or for neonatal or maternity units. We expect providers to follow national guidance, as set out below.

178. Regulation 12(2)(f) and 12(2)(g) of 2014 Regulations provide that registered providers must, where equipment or medicines are supplied by the service provider, ensure that there are sufficient quantities of these to ensure the safety of service users and to meet their needs, and ensure the proper and safe management of medicines;

179. It is important to note that controlled drugs would fall within the definition of "medicines" within these regulations. CQC does provide a general self-assessment tool , including for secondary care, available on our website that trusts can use to consider a range of aspects of how they must safely manage controlled drugs. (IT/47 [INQ0010488]). This tool is focused on governance, and also includes prompts on access to controlled drugs, storage as well as how concerns and incidents in relation to controlled drugs are reported, escalated, investigated and resultant learning shared.

180. Our KLOE on medicines made reference to a requirement that providers should follow relevant national and professional guidance when it comes to medicines. (IT/49 [INQ0010485]). In this case, relevant guidance includes:

- *Professional guidance on the safe and secure handling of medicines* (Royal Pharmaceutical Society) (IT/50 [INQ0010520]).

- *HBN 14-02 Medicines storage in clinical areas* (NHSE) (IT/51 [INQ0010497]).
- *Professional guidance on the administration of medicines* (Royal College of Nursing). (IT/52 [INQ0010521].
- *HBN 09-03 Neonatal units: planning and design* (NHSE) (IT/53 [INQ0010499]).
- *HBN 09-02 Maternity care facilities: planning and design* (NHSE) (IT/54 [INQ0010498]).

181. For controlled drugs, relevant guidance includes *NICE guideline NG46 – Controlled drugs: safe use and management.* (IT/55 [INQ0010494]). This states that trusts need to consider how they will restrict access to controlled drugs, and that this is supported by appropriate risk assessments and policies/processes.

182. Generally, in hospital NHS trusts the pharmacy service will order and be the point of receipt for medicines for the hospital. The pharmacy service will operate a stock control system. Within this system, stock will be issued to wards and departments against an agreed stock list. The process for management of controlled drugs will vary depending on the controlled drug's schedule and the local assessment of controlled drug risks.

183. Medicines storage systems of controlled drugs, items requiring refrigeration (including insulin that has not been opened), and medical gases may vary within a ward or department and is also likely to vary between wards and departments and NHS hospitals to meet the needs of the services being provided. The design and age of the medicines storage room and cupboards may vary, and the security process may be either manual (e.g. physical keys or a coded keypad) that do not leave a digital footprint or electronic (which can include swipe cards, electronic keys and fingerprint access) which may leave such a footprint.

184. The vast majority of cupboards, including controlled drug cupboards, are not electronic and would be opened with a key or using a coded keypad. Ordinarily, therefore, there would be no record of someone accessing the cupboard unless they removed an item where there is a legal requirement for it to be recorded, such as for certain controlled drugs.

185. Within professional guidance there is limited reference to the need for services to record the particulars of access to areas where medicines are stored. NHSE guidance and Royal Pharmaceutical Society guidance state the preference for electronic access to medicines storage areas to facilitate audit trail, but not the specific details to be recorded. (IT/51; IT/52 [INQ0010497]; [INQ0010521]).

> *"Electronic keys and appropriate electronic access cards are preferred to ensure suitable audit trails of storage access can be maintained." [HBN 14-02]*

"Electronic locking systems that secure areas used to store medicines may use electronic keys, swipe cards or fingerprint and other technology that open the lock and lock immediately on closing the door. These systems allow cards or keys to be allocated to individual authorised persons, enabling audit of access to take place… Requirements for electronic medicines storage, issuing and locking systems are agreed locally." [RPS]

186. All records in trusts should be kept securely with a proportionate audit trail of change, modifications, and deletions. Equally, all trusts should have policies that support secure record retention and destruction processes, based on DHSC guidance (referred to above paragraph 176).

187. All trusts should undertake an audit of the safe and secure storage of medicines. This audit should assess the storage of medicines within wards and departments against trusts' own policies, procedures and guidelines. We would expect these documents to be based on national guidance or best practice.

Provision for families suffering the death of a baby on a neonatal unit (Q45)

188. In addition to CQC's inspection framework for Children and Young People, the 'core service' inspection framework for neonatal services prompted consideration, under the 'Caring' key question, of the bereavement support and emotional wellbeing available to parents. (IT/15 [INQ0010502]). For example, the framework prompted inspectors to consider how appropriate bereavement support was provided, and if carers were signposted to any support groups. The framework went on to ask if bereaved families were provided with information and support to make informed choices. It also included standards and best practice, for example:

Sands Guidelines – '*Pregnancy Loss and death of a baby*'. (IT/56 [INQ0010528]). These guidelines focus on principles of care that all practitioners should be aware of when working with bereaved parents: the care that should be offered to parents experiencing different types of perinatal loss; information about the care and support that should be offered to parents after a pregnancy loss or death of a baby; guidance for staff, managers, trusts and trust boards regarding the support and training that should be available to staff and the policies and service provisions that should be in place to ensure that parents receive the best care possible. The main element of providing high quality bereavement care to parents includes good communication, informed choice and individualised care.

Medical records (Q46)

189. There is no requirement for medical records to be marked to show that (i) a mother has suffered a neonatal death and/or (ii) that a parent has suffered a neo-natal death (so that they do not need to provide a full history of this). CQC does not, therefore, expect records to be marked in this way. We have not issued guidance in relation to this.

190. Regulation 17(2)(c) of the 2014 Regulations requires the keeping of accurate, complete and contemporaneous records in respect of each service user. Consequently, we would expect there to be a record within a patient's medical notes of any care and treatment that they received relating to a neonatal death.

Data

191. Providers are expected to monitor their own data in line with national guidance to continuously improve people's care and treatment. Providers and systems may conduct local analysis of trends and we expect them to share any analysis with us if requested.

192. In addition, when requested, providers must provide a written report to CQC setting out how they assess, monitor and (where required) improve the quality and safety of their services.25

Data collated by CQC - CQC Insight

193. We use CQC Insight (referenced in paragraph 66 above) to monitor potential changes to the quality of care. CQC Insight brings together in one place the information we hold about services, and analyses it to monitor services at provider, location, or core service level. This helps us to decide what, where and when to inspect and provides analysis to support the evidence in our inspection reports. CQC Insight produces monitoring reports, which we will share with trusts. We also share the reports with other key partners including NHSE, clinical commissioning groups and Healthwatch.

194. Our inspectors and assessors regularly check CQC Insight. If it suggests an improvement or decline in the quality of care for a service, we may follow this up between inspections. We may ask for further information and also discuss at our regular relationship management meetings. We may also decide to re-inspect that service.

195. For all NHS trusts, CQC Insight gives inspectors:

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[25] Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2014

- Facts and figures: contextual and descriptive information such as levels of activity, staffing and financial information.
- A ratings overview: the trust's latest CQC ratings with information about the direction of potential change suggested by the performance monitoring indicators.
- Intelligence overview: a summary of the analysis of the indicators selected to monitor performance. It is presented at provider, key question and, where available, core service level.
- Performance monitoring indicators: these show a trust's performance compared with national standards or with other providers. They also indicate changes in a trust's performance over time, including benchmarking from 12 months before. All indicators are mapped to ours five key questions and quality statements (previously KLOEs).
- Featured data sources: this might include, for example, the findings from national surveys, incident reports, mortality ratios and outliers. We coordinate our monitoring activities for 'complex providers' that operate across sectors and, where possible, combine information about each of their services within our Insight model.

Data collected by providers

196. CQC expects providers to submit the following national data returns:

- safety of neonatal services data, including statutory reporting requirements, such as the notifications that registered providers are required to submit to CQC;
- routine national data collections for every neonatal activity, including submissions to defined commissioning datasets run by NHSE, for example Hospital Episode Statistics (HES) and Maternity Services Data;
- national datasets created to support quality initiatives, for example national clinical audits such as the National Neonatal Audit Programme (NNAP) and National Maternity and Perinatal Audit (NMPA); and
- information relating to people's experience, for example a data collection of experiences of parents from neonatal services.

197. Arrangements to ensure that data and notifications are submitted by providers to external bodies vary depending upon the submission requirements.

198. We have set notifications from providers to CQC as a high-priority data source for monitoring and to determine any follow-up response. We do this in a number of ways:

- We track notifications submitted to the Strategic Executive Information System (StEIS) / National Reporting and Learning System (NRLS) / Learning from Patient Safety Events (LFPSE) that map to death, serious injury, abuse / allegations of abuse, or events that stop a service. These notifications are flagged to our Operations colleagues to review and decide whether to carry out any further assessment or inspection activity.

- We present notifications data alongside other information about services as indicators to support identification of trends / themes in reporting.

199. We track consistency of reporting to the NRLS to help understand patterns for each service.

200. This notifications data is reported to NHSE's reporting systems, in the first instance, before being sent to CQC as a file transfer that is downloaded and then uploaded into CQC systems. This data is sent to CQC on a weekly basis. NHSE's systems are currently undergoing transformation.

201. However, there are challenges with CQC's use of the data noted above as relates to NHS providers. This includes determining whether the issues are related to reporting practice, including the culture around reporting, making it difficult to determine whether levels of reported events suggest a safety issue or an issue with reporting itself. Therefore the focus for CQC is more on patterns of reporting, rather than the specific numbers of events reported. This is something that CQC may look at with individual NHS Trusts where we have determined that there may be a risk a trust is not submitting the required events to the national reporting systems. Other issues include the inability to identify specific services within the incidents reported, i.e., the clinical speciality that the event occurred in, or enough of the details. The high volume of overall incidents reported per service is also a factor.

Other data sources

202. We also review data, which we use to determine if a service needs to be assessed or inspected, from the following programmes:

- Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries (MBRRACE-UK) – perinatal and maternal deaths should be reported to MBRRACE-UK based on a range of criteria . (IT/57 [INQ0010501]).
- Maternal and Newborn Safety Investigations (MNSI) – certain perinatal deaths, severe brain injuries in babies and maternal deaths should be reported to MNSI based on a range of criteria . (IT/58 [INQ0010536]).

- National Data Collections – the arrangements for submission to these datasets are led by NHSE and arrangements set out in commissioning arrangements. Datasets such as Hospital Episode Statistics (HES) has achieved relatively good quality levels, such as completeness and accuracy of data submitted.
- National Clinical Audits – CQC has been working in partnership with NHSE and the Health Quality Improvement Partnership (HQIP) to make better use of data collected through the National Clinical Audit Programme. We review services that have been flagged as having statistically worse outcomes, and increasingly audit bodies are flagging services to CQC that have not submitted data to audits. In 2024, HQIP will be updating their guidance for audits about how they manage outliers which will include how non-participation and non-submission are treated.

National Neonatal Audit Programme

203. Those organisations that collect and analyse national data relating to neonates would be expected to publish trends in this data at a national and regional level, for example the National Neonatal Audit Programme (NNAP) data dashboard. (IT/59 [INQ0010506]). CQC monitors trends from these published data sets as part of our regular activity.

HQIP National Audit programme

204. As part of the HQIP National Clinical Audit and Patient Outcomes Programme (NCAPOP), audit bodies share data with CQC relating to agreed and validated clinical metrics, which we include as part of our routine monitoring programme and in future will be included in our assessment of providers. Some audit bodies also opt into an outlier programme, in which they share with CQC and providers statistical outliers for selected metrics, some of which include mortality / morbidity metrics. These are shared with operational colleagues within CQC who follow up with providers as part of routine engagement.

Outliers programme

205. Prior to the Covid-19 pandemic, CQC ran a formal outlier's programme which included analysis of mortality outliers from the Dr Foster Unit at Imperial College London, analysis of HQIP National Clinical Audit outliers and CQC-run analyses on maternity outliers.

206. The mortality outliers were identified by the Dr Foster Unit rather than analysis undertaken by CQC. For each of the outliers, the unit will have written to the relevant trust to inform them of the outlier, as well as informing CQC. Similarly, National Clinical Audit outliers were identified by specific audits which contact the trust as part of their validation process, and report verified outliers to CQC.

207. Due to the impact of Covid-19 on mortality data the Dr Foster Unit ceased generation of mortality outliers. CQC also stopped generating non-maternity related mortality outliers. However, as maternity-related outliers (including perinatal and late-neonatal mortality) continued to be generated and monitored, we continue to receive outliers from a range of audits.

NQB Framework

208. We expect providers to follow the NQB's Learning from deaths framework (IT/60 [INQ0010511]).

[ ] This guidance focuses on investigating and learning from individual cases rather than analysing trends.

Raising and acting on concerns (Q51)

209. Staff working within NHS trusts should not feel inhibited from reporting any suspected criminal activity. Whistleblowers have employment protections under the Public Interest Disclosure Act 1998 where they make a 'qualifying disclosure' about concerns at work. Further information on the escalation of concerns has been discussed above (from paragraph 143).

210. The NGO and the role of the Freedom to Speak Up Guardian, hosted by CQC and funded by NHSE and CQC, were created in response to recommendations made in Sir Robert Francis KC's report 'The Freedom to Speak Up'. (IT/61 [INQ0010493]). Sir Robert found that NHS culture did not always encourage or support workers to speak up, and that patients and workers suffered as a result.

211. The NGO reports that there are now over 1,000 Freedom To Speak Up Guardians in the NHS, independent sector organisations, national bodies and elsewhere. These guardians support people to speak up when they feel they are unable to in other ways.

212. The NGO's 2023 report Listening to workers highlights the importance that culture can play in speaking up and the importance of adopting a speak up culture. (IT/62 [INQ0010503]). Although the report is focussed on Ambulance trusts, the considerations around culture can be applied to most NHS departments.

> *A healthy Speak Up, Listen Up, Follow Up culture is an essential element in any business strategy, whether you work in a large or small organisation, in a clinical or other setting. In a clinical setting, it can save lives and improve patient care. In all organisations, it provides everyone with a sense of unity and understanding about*

what's required to support excellent service delivery. It is key to successful outcomes and the safety and wellbeing of workers.

A healthy speak up culture is influenced by, and influences, behaviours and performance. Fostering an environment that actively encourages people to speak up with their ideas, questions and challenges encourages a sense of belonging.

213. NHSE have implemented 'Freedom to Speak up' arrangements, seeking to improve the quality of speaking up arrangements for staff across the NHS. Information from NGO's Making speaking up business as usual suggests that, in the year 1 April 2022 – 31 March 2023, 25,382 cases were raised with Freedom to Speak Up Guardians. (IT/63 [INQ0010507]).

214. Although not a requirement under the 2014 Regulations, we expect that all trusts incorporate Freedom To Speak Up into their own policies to encourage employees to raise concerns where these arise as best practice.

215. Under the new Single Assessment framework, freedom to speak up is part of our new quality statements under the Well Led domain. As noted in paragraph 147, this quality statement requires providers to

> 'foster a positive culture where people feel that they can speak up and that their voice will be heard.'

216. CQC encourages people, including staff members working in the NHS, to raise concerns with us in a number of ways. We have provided a number of options for people to contact us directly to encourage people to come forward with any concerns they may have. We have published guidance, Raising a concern with CQC , to support staff who have information to share. (IT/64 [INQ0010473]). Concerns can be shared with us via our 'Give Feedback on Care' form, via email, or via telephone. Where English is not a person's preferred language, we will arrange an interpreter for the call. We also use a service called 'SignLive' to support people to communicate with us via British Sign Language.

217. The above processes are intended to encourage staff to share concerns either directly with their employer, or with us at CQC if they do not feel safe to share these directly.

218. In addition to encouraging staff members to raise concerns via their employer and other appropriate bodies such as CQC, Regulation 17 of the 2014 Regulations contains a requirement on providers of services to seek and act on feedback on the services provided, for the purposes of continually evaluating and improving. Our guidance on this regulation expands further to explain this feedback can be from people using the service,

those lawfully acting on their behalf, their carers and others such as staff. (IT/65 [INQ0010526]).

219. Although the regulation does not specifically address the raising of suspected criminal activity by a member of staff, it does require providers to seek and act on feedback from staff.

220. As part of our inspection framework, Inspectors, during their inspections, would look at how well Trusts were meeting this regulation. The KLOE, and Single Assessment Framework, prompts regarding the escalation of concerns are set out in paragraphs 146-147 above.

221. Inspectors speak to staff about their experiences of speaking up, as well as reviewing records held by the trust on how they have responded to previous concerns raised by staff. Should inspectors find that staff were not supported to speak up or were inhibited to do so, we would consider if any regulatory response was required. This could include taking enforcement action where the failing resulted in a breach of Regulation 17 of the 2014 Regulations

Accountability of Senior Managers (Q53)

222. As noted above in paragraphs 82-84, we are able to take civil and criminal enforcement action against the registered provider or registered manager.

223. CQC also has powers under section 91 of the 2008 Act that enable us to consider the actions of an individual director, manager or secretary of the body corporate, where there is evidence that they have committed an offence or with their consent, connivance or neglect allowed an offence to be committed.

224. Through our monitoring and inspection processes, we consider how well providers, including NHS trusts, manage the performance of their staff and senior managers.

225. Although the regulations do not include how trusts should ensure accountability with senior managers, within our inspection framework inspectors used the KLOEs to assess how well NHS trusts managed the performance of their staff. This included the following prompts areas for consideration under the 'Well-Led' domain:

    - Do leaders have the skills, knowledge, experience and integrity that they need – both when they are appointed and on an ongoing basis?

- Are there mechanisms for providing all staff at every level with the development they need, including high-quality appraisal and career development conversations?
- Is action taken to address behaviour and performance that is inconsistent with the vision and values, regardless of seniority?

226. Under the new Single Assessment Framework inspectors refer to the following quality statement under the 'Well-Led' key question, which states:

> "We have inclusive leaders at all levels who understand the context in which we deliver care, treatment and support and embody the culture and values of their workforce and organisation. They have the skills, knowledge, experience and credibility to lead effectively. They do so with integrity, openness and honesty."

227. The effectiveness of each Trust in holding their senior managers to account will be reported on in our published inspection reports. Where it is identified that these areas are not being met, inspectors will determine if a breach has occurred and what, if any, action is needed.

Reflections (Q50)

National picture (Q50a)

228. CQC has not previously collected detailed data on all neonatal services in England to offer a national picture on this provision. Recent investment in new technology systems in combination with our new methodology means in future we will be able to offer provider, regional and national perspectives on neonatal services, alongside those offered by NHSE and others.

229. Neonatal outcome data is available from the Neonatal Medicine Research Group based at Imperial College. However, this is not yet included in the trust data routinely provided to CQC, unless there was a neonatal inspection and the data was requested by CQC.

230. Neonatal mortality data is published by the Office for National Statistics (ONS). This provides a national picture of trends in mortality rather than trust-specific mortality figures. Whilst the information is useful to understand national trends, it does not identify risk for the regulation of individual neonatal units.

231. In 2015, we launched a thematic review looking at current practice in relation to the management of new born infants whose health was deteriorating, with particular focus on the diagnosis and management of hypertension (high blood pressure), the management

of respiratory support technologies (including tracheostomies) and how well the services work together to identify and follow up on any complications during pregnancy. As part of this work, we looked at around 20 neonatal services offering different levels of care in England.

232. We found variability in the way that different NHS trusts identify and manage clinical risk in newborn babies. The report set out that this inconsistency is as a result of the limitations of available guidance and agreed best practice.

233. The review made a number of recommendations in managing deteriorating babies, including:

> To help monitor newborn babies who are at risk, all trusts should use ongoing clinical judgement and assessment alongside a trigger tool, for example Newborn Early Warning Trigger and Track (NEWTT), or a similar tool. These tools should be validated and trusts should ensure that they are using them consistently in line with their intended use.
>
> There is a need for national guidance on which babies require blood pressure monitoring and the frequency of observations. NHS England should ask NICE to develop guidelines on assessment of blood pressure and management of hypertension in newborn babies, infants and children, to include the use of age-appropriate reference ranges.

234. These recommendations were included in our report *'Identifying and managing clinical risks in newborn babies and providing care for infants in the community who need respiratory support'*, published in July 2016. (IT/66 [INQ0010468]).

235. The National Maternity Review's report, '*Better Births*' set out an ambition to reduce the rates of stillbirths, neonatal deaths, maternal deaths and brain injuries in babies that occur during or soon after birth by 50 per cent by 2025. (IT/67 [INQ0010505]). CQC is a member of the maternity transformation board tasked with delivering this aim and shares this ambition strongly.

236. CQC's strategy has an overall aim to tackle inequalities and focus on ensuring providers build a safety culture. (IT/08 [INQ0010518]). Black and Asian babies remain at higher risk of perinatal death (1.6 times higher in 2021) and maternity care is known to be high risk. Last year we commissioned a series of interviews with midwives from ethnic minority groups to explore their experiences of working in maternity services and their insights into safety issues. Some of the early findings from that work featured in our 2022/23 State of Care report. (IT/68 [INQ0010480]). The project is ongoing and currently involves

interviews with obstetricians from ethnic minority groups, exploring similar topics. We aim to publish the findings from the research once complete.

237. Maternity is separate to neonatal care, and neonatal units will not always have been inspected as part of the programme. However, it is recognised that the safety or risks in neonatal units cannot be considered in isolation from maternity care. Neonatal safety starts before birth, with babies born at term, in good condition, having better outcomes and prematurity being the main reason for admission to level 3 neonatal units.

238. CQC continues to work closely with front line maternity staff and people who use maternity services. In May 2022 we facilitated a roundtable event for NHS maternity staff. The virtual event brought together representatives from NHS trust maternity services across the country to discuss the challenges they face and what changes might be needed to overcome them. The event was co-designed with key stakeholder organisations, including those representing people both using and working in maternity services. The insight gathered has helped shape the framework used for our national programme of maternity inspections, noted below.

239. In July 2022, we announced we would commence a new maternity inspection programme. The aim of the programme was to help maternity services improve, both at local and national levels, and provide an overview of the quality and safety of maternity care across England. The programme included all NHS acute hospital maternity services that we hadn't inspected and rated since April 2021.

240. As of 21 December 2023, the national maternity inspection programme has inspected 131 maternity units using a bespoke framework. The dedicated team ensure that the inspectors and specialist advisors bring high levels of expertise to the inspections. The framework is focussed on safety following the Ockenden review of maternity services at the Shrewsbury and Telford Hospital NHS Trust and references the updated *Saving Babies Lives Care* Bundle, which sets an expectation that trusts will be compliant with the new guidance by 2024. (IT/69 [INQ0010512]).

241. This inspection programme has also been exploring what trusts are doing to address the known inequalities in maternity care and outcomes for women and pregnant people. It has highlighted a number of areas where there are no clear national standards set by the Royal College of Obstetricians and Gynaecologists. For example, there is inconsistency within NHS trusts around how the care and treatment of women is assessed and prioritised, and the requirement for neonatal life support equipment is open to variation and interpretation. Consideration should be given to setting national standards to address these areas.

242. We will be producing a summary report of the programme and carrying out follow up work as part of our normal service assessment activity, using our new methodology. A national report is planned for publication in May 2024 followed by an improvement resource offer back to the sector based on the good practice we have seen.

243. The NHS Patient Survey Programme is delivered by the CQC on behalf of NHS England and the Department of Health and Social Care. We undertake maternity surveys as part of this Survey Programme. These surveys ask about patients experiences of care, with data provided at national and trust level to support regulation and local service improvement. The Maternity Survey usually runs every two years, though more recently has been run on an annual basis.

244. It is important to note the survey does not include women whose babies have died or are still in neonatal care at the time of the survey.

245. The findings from our maternity surveys, and any other surveys completed for the NHS Survey Programme can be found online at https://nhssurveys.org/.

246. We use the results from the survey to build an understanding of the risk and quality of services and those who organise care. Where survey findings provide evidence of a change to the level of risk or quality in a service, provider or system, we use the results alongside other sources of people's experience data to inform targeted assessment activities. The results are also used by NHS England and the Department of Health and Social Care for performance assessment, improvement and regulatory purposes.

247. Our most recent maternity survey was from 2022. This survey looked at the experiences of women and other pregnant people who had a live birth in early 2022. Women and other pregnant people who gave birth between 1 and 28 February 2022 (and January if a trust did not have a minimum of 300 eligible births in February) were invited to take part in the survey. Fieldwork took place between April and August 2022. Responses were received from 20,927 women and people who had recently given birth. Details of our findings in the 2022 maternity survey are available on the CQC website here: https://www.cqc.org.uk/publication/surveys/maternity-survey-2022

248. We also undertook surveys in 2013, 2015, 2017 and these reports are available using the URL at point 245.

249. Our 2022/2023 annual *State of Care* report states that ten per cent of maternity services are rated as inadequate overall, while 39% are rated as requires improvement. (IT/68 [INQ0010480]). Safety and leadership remain particular areas of concern, with 15% of services rated as inadequate for their safety and 12% rated as inadequate for being well-led.

250. CQC also has *Specific Incident Guidance* that requires colleagues to undertake an initial assessment of incidents where service users, including neonates, children and young people, have sustained avoidable harm or have been exposed to a significant risk of avoidable harm. (IT/70 [INQ0010482]). We are usually alerted to any such incidents through information sent to us by the trust or members of the public, monthly from reporting systems notifications from the NHS, or from other bodies such as Coroners. Following internal review, we may instigate a criminal investigation which can result in criminal enforcement action being taken, including the issuing of fixed penalty notices or prosecution of a registered person.

251. In 2021 we prosecuted East Kent Hospitals University Foundation NHS Trust for failure to provide safe care and treatment to a mother and her baby, exposing them to a significant risk of avoidable harm. In 2022, we prosecuted the Rotherham NHS Foundation Trust for failing to provide safe care and treatment to four babies, exposing them to a significant risk of avoidable harm.

252. In 2022 we also prosecuted a private unregistered clinic that performed ultrasounds for expectant mothers, for a breach of section 10 of the 2008 Act. A Fixed Penalty Notice was initially issued, however, following failure to pay a prosecution was brought against three defendants: the limited company and two individuals (directors). The two individuals were prosecuted in their capacity as directors of the limited company, contrary to section 10 of the 2008 Act and by virtue of section 91.

253. In 2023, we prosecuted Nottingham University Hospitals NHS Trust for failing to provide safe care and treatment to a mother and her baby, exposing them to a significant risk of avoidable harm. We continue, through our National Enforcement team, to assess and investigate other maternity and neonatal deaths across England.

254. Since 2017, we have employed a National Professional Advisor for babies, children and young people who is both a midwife and a specialist community public health nurse (Health visiting) who provides advice and leadership on how we regulate children and young peoples services.

Implementation of Recommendations (Q50b)

255. We continue to monitor recommendations from previous Inquiries into the NHS to ensure learning from these are implemented both in CQC and into wider NHS practice. We also monitor any emerging issues during such inquiries, and consider any action that may be appropriate prior to the publication of a report.

Mid Staffordshire NHS FT public inquiry (2013)

256. Chaired by Sir Robert Francis KC, this public inquiry led to a number of changes. (IT/71 [INQ0010463]). For example, as noted above, we introduced 'fundamental standards'. In addition, the Duty of Candour requirement (paragraphs 41 and 151) was given a legal footing in regulation 20 of the 2014 Regulations, enabling CQC to monitor and take action where registered persons are not open and transparent when things go wrong. CQC has since bought a number of successful prosecutions against Registered Providers, across all sectors of health and social care that we regulate, for failing to meet this requirement.

Kirkup investigation (2015)

257. Dr Bill Kirkup chaired the independent investigation to review the care provided by the maternity and neonatal services of the University Hospitals of Morecambe Bay NHS Foundation Trust. The report, published in 2015, identified a number of recommendations that we have acted upon to improve services. (IT/72 [INQ0010534]).

Kirkup investigation (2020)

258. Following the independent investigation into Maternity and Neonatal services in East Kent (chaired by Dr Kirkup and published in 2022), a key action area was in monitoring safe performance. (IT/73 [INQ0010524]). CQC has developed an increasingly rigorous approach to the regulation of maternity services, including using data more effectively. Both the overall understanding of risk and response to specific incidents has improved and operational colleagues are better supported to understand what the data is saying. That support comes from analysts who are linked to specific regional networks and involved with the NHS forum and from a team of senior specialists with experience in secondary and specialist care. The team of specialists include the leaders of the national maternity inspection programme who, with their experience of maternity unit inspections, are able to benchmark accurately. The platform in use currently supports the identification of heightened risk through a system of red flags showing where there is data suggestive of poor or worsening performance when benchmarked nationally.

259. A second key action area was in standards of clinical behaviour. To address this we made sharing information easier for patients and relatives with an online 'Give Feedback On Care' webform. There is a focus on hearing the voice of patients – particularly from harder to reach and underrepresented groups through direct conversations on inspections, the use of experts by experience and by working with Healthwatch.

260. All core service inspection visits require an element of observation of care and staff interactions with patients. Maternity is no exception and all reporting of the 'Is it Caring?' key question requires the inspection team to record how many patients have been spoken with.

261. Staff would not usually behave inappropriately knowing that an inspection team member is present, so more objective data such as the NHS Friends and Family Test, the NHS Maternity and Inpatient Survey data and direct feedback from bespoke surveys or from comment cards is used to assess whether staff are delivering care with kindness.

Ockenden review (2022)

262. We are also responding to the recommendations from the Independent review of maternity services at the Shrewsbury and Telford Hospital (chaired by Donna Ockenden and published in 2022. (IT/69 [INQ0010512]). One essential action listed was around financing a safe maternity workforce. Regulation 18 of the 2014 Regulations requires registered persons to ensure sufficient numbers of suitably qualified, competent, skilled and experienced persons are deployed. As staffing was one of the KLOEs within both the maternity core service inspection framework and the National Maternity Inspection Programme, we already had systems in place to assess workforce. We use our regulatory powers to address any concerns identified with staffing levels.

263. Under the new Single Assessment Framework inspectors refer to the following quality statement under the 'Safe' domain, which states: "We make sure there are enough qualified, skilled and experienced people, who receive effective support, supervision and development." They work together effectively to provide safe care that meets people's individual needs.

264. The Ockenden Report also identified that

> "Trust boards must have oversight of the quality and performance of their maternity services. In all maternity services the Director of Midwifery and Clinical Director for obstetrics must be jointly operationally responsible and accountable for the maternity governance systems."

265. Under the Effective and Well Led key questions, inspection teams assessed maternity governance systems using the questions set out in our KLOEs.

266. Under the new Single Assessment Framework inspectors refer to the following quality statements under the 'Effective' and 'Well-Led' domains, which state respectively:

- "We routinely monitor people's care and treatment to continuously improve it. We ensure that outcomes are positive and consistent, and that they meet both clinical expectations and the expectations of people themselves.
- We have clear responsibilities, roles, systems of accountability and good governance. We use these to manage and deliver good quality, sustainable care,

treatment and support. We act on the best information about risk, performance and outcomes, and we share this securely with others when appropriate".

267. The inquiry has asked whether we think the recommendations of previous inquiries have had an impact. We do not have evidence that all prior recommendations have been implemented and all have had an impact. When taken together it is clear that this greater focus on maternity services has been important. Our maternity inspection programme has however shown that despite multiple recommendations for maternity services, we have found shortfalls in the quality and safety of care, including concerns about the identification and management of risk to women and babies and strong safety narrative where quality and safety is well understood and embedded throughout the service.

268. Concerns about the effectiveness of the current culture, governance, management structures and processes, regulation and other external scrutiny (Q50c + Q50d)

269. As referenced in paragraph 242 above, the *State of Care* is our annual assessment of health and social care across England. We have raised specific concerns about maternity services in our *State of Care* reports published in 2021, 2022 and 2023. (IT/74; IT/75; IT/68) [INQ0010476]; [INQ0010479]; [INQ0010480]). In our latest report, published on 29 October 2023, we set out that many people are not receiving the safe, good quality maternity care that they deserve. Our report notes issues around leadership, staffing and communication.

270. This 2023 *State of Care* report identifies, at paragraphs 235-237, that through our maternity inspection programme (referenced above) we are seeing that services and staff are under huge pressure, and many people do not receive safe, high-quality treatment. Findings from the programme indicate that leadership remains an area of concern, with the quality of leadership varying between trusts. We also have concerns about problematic working relationships between service level managers, neonatal, midwifery and obstetric leaders.

271. This *State of Care* report also reflects on the significant staffing issues in many trusts visited. This was further evidenced in comments received to us via our 'Give Feedback on Care' service, where feedback indicates that whilst maternity staff are doing their best, patients did not feel they were a priority and did not get the help they needed. Feedback indicated further concerns around communication, with some people reporting they did not receive key information about the care of themselves or their baby.

272. We also highlighted ongoing ethnic inequalities across a number of areas, including maternal and neonatal health care.

273. In its August 2023 Quality Watch report *Stillbirths and neonatal and infant mortality* , the Nuffield Trust highlighted that in 2021 the infant mortality rate among Black ethnic groups was substantially higher than any other groups, with 6.6 deaths per 1,000 live births. Asian ethnic groups had the second highest infant mortality rate at 4.8 deaths per 1,000 live births. By comparison, White ethnic groups consistently had the lowest infant mortality rates with 3 deaths per 1,000 live births in 2021. (IT/76 [INQ0010531]).

274. Where we identify areas for improvement within hospitals, including neonatal units during our inspections, we publish reports of those findings. This is always done with the aim of driving improvements to the quality of care and safety of babies. Our annual State of Care reports further on standards of care across England to identify where changes are needed to improve safety.

Statement of Truth

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

Signed: PD

Dated: 12/02/2024