THIRLWALL INQUIRY

OPENING STATEMENT ON BEHALF OF THE CARE QUALITY COMMISSION

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1. At the outset, the Care Quality Commission wishes to acknowledge the extraordinary grief and suffering of the families and to extend its deepest sympathies to them. It acknowledges the importance of receiving answers to the questions which the Inquiry is investigating and of learning lessons for the future.

The role of the Care Quality Commission

2. The Care Quality Commission **['CQC']** is the independent regulator of health and social care in England.[1] CQC's primary functions involve the registration, monitoring, inspection and regulation of those services which fall within its regulatory remit (see in particular section 2 of the Health and Social Care Act 2008). It regulates the bodies which provide health care, rather than the people who work within them (many of whom will be subject to separate professional regulation by regulators such as the Nursing and Midwifery Council and the General Medical Council). Providers of health care are required to register with CQC[2] and to meet fundamental standards set out in regulations, including standards of person-centred care, dignity and respect, safe care and treatment, and safeguarding service users from abuse and neglect.[3] CQC conducts inspections of registered providers and makes findings about the quality of care being delivered and recommendations for improvement. Its findings and recommendations are published in reports. Section 2 of the Health and Social Care Act 2008 stipulates that CQC's main function in performing its functions is to protect and promote the health, safety and welfare of people who use health and social care services.[4]

Provision of statements and documents to the Inquiry

3. The following statements have so far been requested by, and provided to, the Inquiry:

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[1] For the purposes of this opening statement, CQC will focus on the regulation of health care.
[2] As at 19 August 2024 there are 35,626 registered providers on CQC's register, of which 222 are NHS Trusts.
[3] See the Health and Social Care (Regulated Activities) Regulations 2014.
[4] For more detail about CQC's role and responsibilities see the First Statement of Ian Trenholm [INQ0012634].

a. Two statements from Ian Trenholm[5] [INQ0012634, INQ0017809]. These provide (amongst other matters) an overview of the role and responsibilities of CQC and a description of CQC's interactions with the Countess of Chester Hospital during the relevant period.

b. Two statements from Ann Ford[6] [INQ0102609, INQ0107911]. Whilst these deal predominantly with matters of document searches and disclosure, the second statement of Ann Ford also addresses the question of what information CQC had - before, during and after the February 2016 inspection – regarding: increased neonatal mortality at the hospital, any concerns regarding increased neonatal mortality, and any concerns in relation to Letby (whether identified specifically by name or not).

c. Statements from Elizabeth Childs [INQ0102368], Mary Potter [INQ0102608], Dr Benjamin Odeka [INQ0102611] and Helen Cain [INQ0102617], all of whom were involved in the February 2016 inspection by CQC of the Countess of Chester Hospital.[7]

4. A request for a statement from another member of the inspection team from the February 2016 inspection (Julie Hughes) has recently been received from the Inquiry and this statement was provided to the Inquiry on 28 August 2024 [INQ0107914].

5. CQC has also volunteered to the Inquiry a statement from Deborah Lindley, an inspector and the relationship owner at CQC for the Countess of Chester Hospital in 2016 [INQ0107913].[8] The statement describes a call received from the Countess of Chester Hospital on 29 June 2016 (as to which see further paragraph 15 below).

6. In line with its disclosure obligations and cooperating fully with the Inquiry CQC has so far provided in the region of 3435 documents to the Inquiry.

7. CQC is of course willing to provide any further statements or documents that the Inquiry may require.

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[5] Ian Trenholm was, at the time of making the witness statements, the Chief Executive of CQC. He stepped down from this post in June 2024. CQC's interim Chief Executive since 1 July 2024 has been Kate Terroni.
[6] Ann Ford was CQC's Head of Hospital Inspection at the time of the 2016 inspection of the Countess of Chester Hospital and is now the Director of Operations Network North within the CQC. She led the work of the inspection team throughout the February 2016 inspection.
[7] Elizabeth Childs was the Inspection Chair for the February 2016 inspection; Mary Potter and Benjamin Odeka were special advisers and part of the Children and Young People inspection team; and Helen Cain was the lead inspector for the Children and Young People's services.
[8] The relationship owner is CQC's main point of contact with the hospital.

The February 2016 inspection of the Countess of Chester Hospital

8. The Countess of Chester Hospital was registered with CQC on 1 April 2010.[9]

9. In February 2016 CQC undertook a routine, planned inspection of the Countess of Chester Hospital as part of its scheduled programme of announced inspections.[10] Eight core services were to be inspected, one of which was services for Children and Young People (which included neonatal services).[11] Prior to that inspection, and in accordance with the standard process, CQC received from the Countess of Chester Hospital NHS Foundation Trust ("the Trust") a Provider Information Return (PIR) containing data and information relating to services provided at the Hospital, including in relation to Children and Young People's services.[12] On 15 February, in preparation for the inspection and again in accordance with its usual process, CQC made a data request to the Trust, including in relation to paediatric incidents, and the data provided included information on incidents occurring in the neonatal unit.[13]

10. On 16-19 February, 26 February and 4 March 2016 CQC carried out the routine inspection of the Hospital. The services inspected included the neonatal unit. As part of the inspection, an out-of-hours unannounced visit was carried out on 26 February and a further unannounced visit was undertaken on 4 March (including, on this latter occasion, a visit of the neonatal services). There were no particular triggers for these visits.[14]

11. During the inspection, on the afternoon of 17 February 2016, the inspection team held a focus group attended by a number of consultants working at the Hospital across a number of different services.[15] Contemporaneous notes from this focus group meeting have not been found, despite extensive searches, but images of a member of the inspection team's notes have – these suggest that some concerns were raised about staffing levels, a bullying culture and a lack of support from the leadership team.[16] A meeting was also held the same day between the inspection team and the Trust's Medical Director, Ian Harvey.[17]

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[9] Second Statement of Ian Trenholm at paragraph 6 [INQ0017809].
[10] Second Statement of Ian Trenholm at paragraph 59 [INQ0017809].
[11] Second Statement of Ian Trenholm at paragraph 60 [INQ0017809].
[12] Second Statement of Ian Trenholm at paragraph 16 [INQ0017809]. CQC also received, in advance of the inspection, feedback on the Hospital from the Royal College of Nursing [INQ0017429] and the Health and Care Professions Council [INQ0017329]: see the Second Statement of Ian Trenholm at paragraphs 18-19 [INQ0017809].
[13] Second Statement of Ian Trenholm at paragraph 20 [INQ0017809].
[14] Second Statement of Ian Trenholm at paragraphs 23-24 [INQ0017809].
[15] Second Statement of Ian Trenholm at paragraph 68 [INQ0017809].
[16] Second Statement of Ian Trenholm at paragraph 68 [INQ0017809]; Second Statement of Ann Ford at paragraph 4.13; [INQ0017319]; Statement of Julie Hughes [INQ0107914].
[17] Second Statement of Ian Trenholm at paragraph 69 [INQ0017809]; Second Statement of Ann Ford at paragraph 4.14; [INQ0017319].

12. On 29 June 2016 CQC published its report on the Countess of Chester Hospital [INQ0017433]. The overall rating for the Hospital was "Requires Improvement". Services for children and young people were rated overall as "Good". However, in response to the question "Are services for children and young people safe?" the assessment was "Requires improvement", for a number of reasons including that *"nurse staffing levels on the neonatal unit did not meet standards recommended by the British Association of Perinatal Medicine (BAPM)"*[18] and that the neonatal unit lacked storage space and resources for the care of patients who required strict infection control measures.

13. The Inquiry has detailed written statements from four of those involved in the inspection on behalf of CQC (see paragraph 3 c above), all of whom are scheduled to give oral evidence in November.

Inquiry Topics

14. In its *Note on Core Participant Opening Statements* the Inquiry provided a (non-exhaustive) list of topics that it considered should be addressed in Opening Statements. CQC has adopted the structure indicated by the Inquiry and responds to the questions posed below (insofar as relevant to CQC). In relation to topics (d), (f), (g), (h) and (i), what is set out below represents CQC's preliminary thinking, but CQC wishes to reflect further on these matters, not least as the evidence (particularly evidence relevant to Part C of the Inquiry's Terms of Reference) is heard, and will return to these issues in closing submissions.

a. When did you know about the suspicion or concerns at the Countess of Chester Hospital and was your response at the time good enough? *If so, why? If not, why not and how have you addressed this so that this could not happen again?*

15. CQC first became aware of concerns about mortality and increased numbers of deaths on the neonatal unit of the Countess of Chester Hospital on 29 June 2016 (the day its inspection report was published) when Alison Kelly (Director of Nursing and Quality at Countess of Chester NHS Foundation Trust) telephoned CQC Inspector Deborah Lindley to inform her of an increased number of deaths of newborn babies in the neonatal unit (see Ian Trenholm's Second Statement at paragraph 73; Ann Ford's Second Statement at paragraph 3.17; Deborah Lindley's statement at paragraphs 8 and 9).[19] This was followed by a telephone call between

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[18] The report added that *"Between January 2015 and January 2016, 11 incidents were recorded that relates to the acuity of patients and staffing breaching BAPM standards and on seven occasions in that period the neonatal unit had been closed to admissions"* [INQ0017433 page 107]; see further page 113.

[19] In view of the importance of establishing precisely when and how CQC first became aware of concerns regarding deaths on the neonatal unit, arrangements have been made by CQC to obtain a

Alison Kelly and Ann Ford and then an email from Alison Kelly to Ann Ford on 30 June 2016 which provided (as requested by CQC) an overview of the issues and of the action being taken [INQ0017411]. CQC was informed that the Countess of Chester Hospital had commissioned an independent review from the Royal College of Paediatrics and Child Health and that the Hospital was taking a number of other actions, as listed in the email. CQC was **not** told of any concerns regarding Letby or possible criminal activity.

16. CQC first became aware of a criminal investigation into these deaths following an engagement call with the Trust in May 2017 (see Ian Trenholm's Second Statement at paragraph 94; Ann Ford's Second Statement at paragraphs 3.18 and 3.19; and the CQC email of 16 May 2017 [INQ0017303]).[20] CQC was informed that contact had been made with the police a few weeks previously [INQ0017303].[21] The Trust shared with CQC on 16 May 2017 a briefing on the involvement of the police (*"We are acting from a position of caution to check nothing has been missed and police input is the only avenue left open to us to ensure we have been completely thorough in this process"*) [INQ0017359].

17. CQC has reflected on whether it could or should have realised or suspected that there was a concerning increase in neonatal mortality prior to it commencing its inspection in February 2016, or during the inspection, or at any time earlier than 29 June 2016. On the basis of the information and evidence currently available to it,[22] CQC does not believe so. It notes the following in particular:

    a. In accordance with the usual inspection process, CQC was provided with information prior to its 2016 Inspection in the form of the Provider Information Return and in response to additional data requests (see Helen Cain's statement at paragraphs 12-19 and 27-44). Some information regarding neonatal deaths was provided prior to inspection (see the Neonatal Mortality Meeting Record for 10 September 2015 and for 26 November 2015 [INQ0005445 and INQ0003288])[23] and Datix Listing report

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statement from Deborah Lindley to confirm this call, and this statement was provided to the Inquiry on 28 August 2024.

[20] The statements of Ian Trenholm and Ann Ford refer to CQC becoming aware of a criminal investigation on 15 May 2017 following an engagement call with the Trust. On reviewing CQC's computerised records system as described in Deborah Lindley's statement at paragraphs 14-16, CQC cannot in fact say if that call took place on 15 May: the email of 16 May [INQ0017303] refers to there having been such a call (*"Following on from the stakeholders call with the trust"*), but does not give the date of the call.

[21] Tony Chambers (Chief Executive of the Trust) wrote to the Chief Constable on 2 May 2017 requesting that the police conduct a forensic investigation into the circumstances surrounding the deaths *"with a view to excluding any unnatural causes"* [INQ0003080].

[22] This position will of course be kept under review, particularly as the Inquiry hears oral evidence from relevant witnesses who were involved in the inspection.

[23] Helen Cain's statement (at paragraph 31) gives the references INQ0017350 and INQ0017349 for these meetings. The Inquiry's chronology, however, uses INQ0005445 and INQ0003288.

[INQ0017331]).[24] However, the information contained within these materials did not raise any specific concerns and did not suggest the neonatal unit was an outlier in this respect warranting particular attention (see Helen Cain's statement at paragraphs 12-19; 24; 57).[25] .

b. As part of the inspection, a meeting between CQC and service leads took place on 17 February 2016, attended by (amongst others) Dr Stephen Brearey and Eirian Powell (neonatal unit manager) [INQ0017339 pages 206 – 214]. Neonatal mortality was discussed at this meeting [page 207]. However, the records do not indicate that neonatal mortality was given any particular prominence by attendees or that those attending from the Trust informed CQC that there was an increase in mortality, or that there were concerns about this issue, and witnesses have no recollection of any concern about increases in neonatal mortality being raised (see Dr Odeka's statement at paragraphs 78-79; Elizabeth Childs' statement at paragraphs 63-65; Helen Cain's statement at paragraphs 89-94; Mary Potter's statement at paragraphs 56-62).

c. A number of the documents and statements provided to the Inquiry indicate that by the time of CQC's inspection, there *were* concerns within the Trust about neonatal mortality. This issue will no doubt be explored in further detail with relevant witnesses from the Trust. As observed by Helen Cain in her statement, *"Information regarding concerns about increases in neonatal deaths, or concerns about unexpected or unexplained neonatal deaths, is clearly relevant. These matters should have been raised with me or another member of the CQC team during the inspection, if the interviewees had knowledge of them."*[26] CQC is unsure why these concerns were not explicitly drawn to its attention prior to or during the inspection, whether by clinicians or by senior management within the Trust; they should have been.

d. In her email of 30 June 2016 [INQ0017411], Alison Kelly stated that an "*in depth thematic medical review"* had been undertaken internally by the Trust, followed by *"a subsequent Peer Review (by a Consultant from Liverpool Women's Trust)".* She

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[24] Referred to in Helen Cain's statement as "table of neonatal incidents" and discussed at paragraphs 49-56 of her statement. For ease of cross-reference, the entry referred to in paragraph 49 of her statement is row 200 of INQ0017331; the entry in paragraph 50 is row 187; the entry in paragraph 51 is row 188; the entry in paragraph 52 is row 270; the entry in paragraph 53 is row 293; the entry in paragraph 54 is row 301; the entry in paragraph 55 is row 366; and the entry in paragraph 56 is row 130 of INQ0017331. Helen Cain's statement incorrectly states that the date range for this table is between 1 December 2015 and 31 January 2016: in fact the table describes incidents from September 2014 onwards.

[25] As explained by Helen Cain in her witness statement at paragraph 31, the records of the Neonatal Mortality Meetings *"confirm that sessions were held to identify learning from neonatal deaths. The notes demonstrate that the Trust was reviewing the cases to assess any lessons learned and included a summary and discussion of the case, any actions taken and if record keeping was satisfactory".* This is standard practice.

[26] At paragraph 118. See also the statement of Elizabeth Childs at paragraph 67.

recorded that these reviews had *"failed to identify any cause or common theme"* for the identified increase in the number of neonatal deaths and added that "*these reviews were submitted as part of our recent CQC inspection data pack"*. As far as CQC can ascertain, Alison Kelly's email is incorrect insofar as it suggests that the reviews were submitted to CQC as part of the inspection

i. CQC understands from evidence available to the Inquiry (but not seen by it at the time) that Dr Stephen Brearey wrote the report of the thematic review and that, aware of the CQC inspection, "*wanted to make Ian Harvey aware of the review and draft report before 16 February"* (statement of Dr Brearey, paragraph 201 [INQ0103104]).[27]

ii. However, CQC's understanding is that these reviews were not provided to it prior to (or during) the 2016 Inspection and CQC would make the following observations.

1. Elizabeth Childs (Inspection Chair of CQC's 2016 inspection) states that she is not aware that an increase in neonatal deaths, unexpected deaths, unexplained deaths, or correlation between the deaths and a member of the nursing staff, was information available to the inspection team prior to conducting the inspection. Ms Childs is clear that she would have expected this information to be provided to CQC by the Trust (Elizabeth Childs' statement at paragraphs 31-34).

2. Helen Cain (lead inspector for the Children and Young People's service in the 2016 Inspection) has no recollection of these reviews having been provided to CQC pre-inspection and suggests, given the relevant dates, that it could not have been as part of the Provider Information Return. Ms Cain notes that it is possible that this information was provided during/post review without having been requested by CQC and without context and so was not identified by CQC. However, CQC is not aware of any evidence to indicate that this in fact happened (and if these reviews had been provided in this way,

[27] See also Dr Brearey's statement to the General Medical Council at paragraph 33 [INQ0006890]. Copies of the thematic review are at INQ0003217 and INQ09006817 [Core Bundle B49-B61, B62-77]. It appears also that a meeting to discuss the thematic review was held on 8 February 2016 [INQ0003217]. Details of the *"subsequent Peer Review"* are not clear from Alison Kelly's email, but are assumed to be a reference to the involvement of Dr Nimish Subhedar (consultant neonatologist at Liverpool Women's NHS Foundation Trust), whose statement suggests that he participated as an external panel member in the thematic review [INQ0102685, paragraphs 20-31].

they should have been specifically brought to CQC's attention). See Helen Cain's statement at paragraphs 59-65.

3. Dr Benjamin Odeka was a Specialist Advisor as part of the Children and Young Person's Inspection Team in the 2016 Inspection. He has addressed this issue in his witness evidence and also has no recollection of having been provided with the peer or thematic reviews prior to the 2016 Inspection. Importantly, Dr Odeka interviewed Dr Brearey during the course of the 2016 Inspection and, to the best of his recollection, Dr Brearey did not raise any concerns about neonatal deaths at the Countess of Chester Hospital at that point. See Dr Odeka's statement at paragraphs 52-56, 71-79 and 89-90.[28]

4. CQC has searched its records and has not found any contemporaneous documentation to suggest that the thematic review had been provided to it.

5. Nothing in Ian Harvey's statement to the Inquiry suggests that having been sent the thematic review by Dr Brearey, he provided it to, or asked that it be provided to, CQC.[29]

18. Having been made aware of concerns about neonatal mortality on 29 June 2016, CQC then engaged with the Trust regarding the actions it was taking in response to the increase in neonatal mortality. For a detailed chronology of the actions taken by CQC in response to the initial concern see Ian Trenholm's Second Statement at paragraphs 73-93. In particular, CQC was aware that the Royal College of Paediatrics and Child Health ("RCPCH") was carrying out a review, that a number of other steps (which appeared appropriate) were being undertaken, and that the unit would be only be accepting Level 1 babies. Following the publication of the RCPCH report in February 2017, CQC met with the Trust (including with Tony Chambers, the Chief Executive) to discuss the findings of the report [INQ0017299 and INQ0017300]. CQC subsequently requested, and received, the action plan developed to implement the recommendations of the review and sought, and received, updates on the progression of the plan [see paragraphs 86-92 of Ian Trenholm's Second Statement for further details]. CQC considers that the actions taken by it during this period, following notification of the increase in neonatal mortality, were reasonable and proportionate; based on the information available to it (in particular the steps that were being taken by the Trust and the RCPCH review) and it was

[28] Dr Odeka's handwritten notes of his interview with Dr Brearey on 17 February 2016 are at INQ0017339 pages 60-64.
[29] See paragraphs 102-121 of Ian Harvey's statement [INQ0107653].

sufficiently assured as to the safety of the neonatal unit.[30] CQC did not, at this time, have any knowledge that criminal conduct was suspected and/or that an individual nurse was implicated.

19. The above notwithstanding, CQC has reflected on the events that have given rise to this Inquiry and has the following observations:

    a. CQC considers that, following it having been informed of the involvement of the police in May 2017, it should have been more pro-active in seeking assurance that newborns on the neonatal unit were safe. Ian Trenholm's Second Statement sets out the chronology of CQC's interactions with the Trust from May 2017 to November 2020 (when Letby was charged), at paragraphs 95-121. CQC took a relatively passive approach during the course of the police investigation, deferring to that investigation, rather than consciously considering what its own role in the assurance of safety should be (although CQC did attend the Incident Coordination Group set up by NHS England in response to the investigation [Ian Trenholm's Second Statement, paragraph 111]). CQC staff have since developed more robust professional curiosity and the expectation is that given the same circumstances, they would now be more pro-active in their engagement with this hospital trust or any others.

    b. CQC was not approached by whistleblowers raising relevant concerns about the Countess of Chester Hospital. Had such concerns been raised, CQC would have considered them and determined the appropriate regulatory response. Whilst the Inquiry will no doubt explore with relevant witnesses why the concerns being discussed internally within the Trust were not expressly raised with CQC around the time of the inspection, CQC must also reflect internally and ask itself whether at the time it was sufficiently visible as an organisation to encourage and be responsive to whistleblowing concerns. This is a tricky question to answer and CQC will continue to reflect on this as evidence is explored and shared by the Inquiry. However, CQC (and other NHS stakeholders) have sought over recent years to improve the conditions for, and circumstances and relationships which facilitate, whistleblowing. Whistleblowers now play a more key role in CQC's practice. Since completing its comprehensive inspection programme which started in September 2013 and moved to "next phase" of inspections in September 2016, CQC is now more well known within NHS organisations. A number of inspections have now been carried out by CQC triggered solely by whistleblowing complaints, and in a considerable number of inspections whistleblowing has been part of the reasons for carrying out an inspection. See, more generally, Ian Trenholm's First Statement at paragraphs 209 -221. CQC considers it to be more likely that, if the events

[30] CQC will of course keep this assessment under review as the Inquiry's hearings progress and evidence is heard.

which took place in the Countess of Chester Hospital were to be repeated today, whistleblower complaints would be made directly to CQC, thus enabling earlier regulatory action to be taken.

20. It is, however, important to note that the events leading to this Inquiry raise issues of particular complexity. The babies who died were murdered in ways that were deliberately designed to disguise the cause of their deaths. Concerns about deaths on the neonatal unit at the Countess of Chester Hospital were not raised with CQC by the Hospital or staff until some months after its inspection. And statistical national mortality data that would have shown the Countess of Chester to be an outlier in this regard was not available to CQC prior to it being made aware of the concerns in June 2016 by the Trust. As such, while CQC considers its practice has improved in the ways set out above, CQC cannot say that, as a result of these developments, the events leading up to this inquiry *could never* be repeated.

d. Advice and help. *What advice or assistance is available to nurses and doctors from their unions, regulators or any other organisation in circumstances where they are worried about the safety of any baby in hospital? Is this sufficient and can it be improved? Should there be greater scrutiny of hospitals by external organisations when concerns are raised by nurses and doctors?*

21. Others may be better placed than CQC to describe the advice and assistance that may be available from unions or professional regulatory bodies.[31]

22. As set out above CQC considers facilitating effective whistleblowing practices to be of the utmost importance and CQC encourages everybody to raise safety concerns. CQC has published guidance on raising a concern and provides various mechanisms for reporting concerns (see Ian Trenholm's First Statement at paragraph 216). Of particular relevance is the CQC's *Whistleblowing: Guidance for providers who are registered with the Care Quality Commission* (2013) [INQ0010465] and *Raising a concern with CQC – A quick guide for health and care staff about whistleblowing* [INQ0010473]. These guides explain how people can raise concerns, how CQC handles whistle-blowing disclosures, and how the Public Interest Disclosure Act 1998 provides protection to whistle-blowers (see Ian Trenholm's First Statement at paragraphs 145, 148, 209 and 220).

23. CQC notes that Regulation 17(e) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 explicitly requires service providers to seek out, and act on, feedback on the

[31] CQC notes, for example, the evidence available to the Inquiry from the British Medical Association (statement of Professor Philip Banfield [INQ0013010]), the General Medical Council (statement of Charles Massey [INQ0014549]), the Hospital Consultants and Specialists Association (statement of Stuart Lythgoe [INQ0013290], the Royal College of Nursing (statement of Patricia Marquis [INQ0015452]) and the Nursing and Midwifery Council (statement of Andrea Sutcliffe [INQ0002412]).

services provided in carrying on a regulated activity. CQC inspectors consider the extent to which Trusts are meeting their Regulation 17 obligations (see Ian Trenholm's First Statement at paragraphs 218-220). Further, as part of a "well-led" assessment, CQC will consider an organisation's speaking-up arrangements, its culture, and the implementation of the Freedom to Speak Up Guardian role (see Ian Trenholm's First Statement at paragraph 143; see also the statement of the National Guardian for the NHS, Dr Jayne Chidgey-Clark, which describes how the NGO has worked in partnership with CQC to ensure that Freedom to Speak Up arrangements are inspected within the Well Led framework[32]). CQC notes that there are now over one thousand Freedom to Speak Up Guardians across the NHS, independent sector organisations, and national bodies.[33]

24. As to the question of whether greater scrutiny of hospitals by external organisations following the raising of concerns is needed, while CQC would always welcome greater scrutiny in principle, it considers the level of external scrutiny of hospitals following whistleblowing to be adequate. In all cases where concerns are raised with CQC, it will consider whether to signpost the person raising those concerns to another organisation or, if safety of care is in issue, CQC will consider whether to carry out an inspection. Further, there are already mechanisms in place for the sharing of information between regulators (both formally and informally) and this assists in ensuring that hospitals are adequately scrutinised by external organisations – for example the *Emerging Concerns Protocol* (see further Ian Trenholm's First Statement at paragraphs 107-115).

f. Management in the NHS and Regulation. *Were senior managers held accountable for decisions made? Was this good enough to keep babies safe? What is the current position and could it be improved? How should accountability of senior managers be strengthened? Should they be regulated?*

25. In relation to the senior management of healthcare providers, CQC regulates services and not individuals. As such it is not directly responsible for holding individuals to account. Others (e.g. NHS England, the Trust itself) may be better placed to address the question of accountability. However, CQC does play an indirect role in ensuring that senior management is properly held to account in the following ways:

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[32] INQ0014485 at paragraphs 19 and 84. Dr Chidgey-Clark refers also to the NHS Staff Survey and the inclusion of questions to capture workers' perceptions of the speaking up culture, noting that a *"strong correlation exists between these survey figures and CQC ratings"* (paragraph 69).
[33] That more still needs to be done to support the work of Freedom to Speak Up Guardians is apparent from the statement of Dr Chidgey-Clark, as well as the written statement of Rob Behrens (Parliamentary and Health Service Ombudsman) [INQ0014599] at paragraphs 75-77.

a. CQC assesses how "well led" an organisation is at both Trust Level and Core Service Level[34] and its assessment is published in its reports.

b. By Regulation 5 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 directors/those performing similar functions are required to be fit and proper persons. CQC issued "*Guidance for providers on meeting the regulations*" relevant to the application of this requirement in March 2015 [INQ0010466].[35]

c. Regulation 19 of the 2014 Regulations seeks to ensure that providers only employ 'fit and proper' staff who are able to provide care and treatment appropriate to their role. The guidance makes clear that CQC must refuse regulation if providers cannot satisfy CQC that they can and will continue to comply with Regulation 19.

d. NHS England published a revised Fit and Proper Person Test Framework in 2023 [INQ0012645]. The purpose of the new Framework is to strengthen individual accountability and transparency for board members, thereby enhancing the quality of leadership within the NHS. It is a core element of a broader programme of board development, effective appraisals and values-based (as well as competency-based) appointments – all of which are part of the good practice required to build a 'healthy' board. The guidance is clear on the role of CQC providing assurance under Regulation 5 and CQC has incorporated this guidance into the well-led framework.

e. CQC also has the power to prosecute/take regulatory action where there has been a breach of Regulation 20 of the 2014 Regulations (duty of candour) (see further Ian Trenholm's First Statement at paragraphs 150-156 and Prof. Dixon-Woods' observations regarding monitoring compliance with the Duty of Candour at paragraph 7.3.1 of her report [INQ102624_0077]*)*. CQC has issued guidance (updated in June 2022) on the statutory duty of candour.[36]

26. As to the management of the Countess of Chester Hospital:

a. Following its 2016 inspection, Children and Young People's services at the Countess of Chester Hospital were rated "Good" under the domain of "well-led" and, at Trust Level, CQC considered there to be a well-developed approach to governance (see the Report at INQ0017433 and Ian Trenholm's Second Statement at paragraph 156-157). CQC is not in a position to judge whether these systems, or the way in which they were

[34] Core Services was the terminology used at the time of the 2016 inspection; Core Services are now referred to as Assessment Service Groups under CQC's current approach to assessment of registered providers.
[35] For concerns about the effective enforcement of Regulation 5 of the 2014 Regulations see Sir Robert Francis KC's *Expert Report* (30 May 2024) at paragraph 8.15 [INQ0101077_0067].
[36] *Regulation 20: Duty of candour* https://www.cqc.org.uk/sites/default/files/2022-12/20220722-duty-of-candour-pdf-version-FINAL-2.pdf

in practice operated in relation to the concerns regarding the neonatal unit and neonatal mortality, caused or contributed to the failure to protect babies on the neonatal unit or whether senior management at the Countess of Chester Hospital were properly held accountable for any such failures. CQC notes that there are written statements to the Inquiry from a number of doctors at the Trust which raise concerns as to the way in which hospital management responded; and that there are written statements to the Inquiry from key individuals in senior management at the Countess of Chester Hospital explaining their decision-making. These matters, some of which appear to involve disputed issues of fact, will no doubt be considered in some detail during the Inquiry's hearings and CQC will consider whether it has any further submissions to make once that evidence has been heard.

b. The Countess of Chester Hospital was inspected again in 2018. Its Children and Young Person Core Service was not inspected at this time. The inspection did, however, assess the "well-led" domain at Trust level – and this was rated "requiring improvement". (For further detail as to how the "well-led" domain was assessed see Ian Trenholm's First Statement at paragraphs119-120; 143).

27. As to the regulation of managers more generally, CQC understands that the question of whether senior managers should be separately regulated/regulated through their professional bodies is under review nationally by DHSC/NHSE and does not currently have a developed view on this issue. CQC notes Sir Robert Francis KC's observations in his *Expert Report* (30 May 2024) at Part 1 paragraph 9.1.7(d) [INQ0101077_0098] and Part 2 paragraphs 10.5 -10.6 [INQ0101079_0086].

g. Culture. *What is your current view about culture in hospitals and in neonatal units in particular and what requires exploration in oral evidence on this topic.*

28. CQC agrees that leadership and culture can impact on patient safety. However, culture is highly specific to institutions. It varies significantly between hospitals and within hospitals as well as across time (being particularly sensitive to changes in leadership at both Trust and service level). CQC does not, therefore, have a view as to the culture in hospitals or neonatal units across England generally at a specific point in time. Its monitoring can, however "…*offer insights into culture at NHS organisations, with CQC ratings and reports providing important evidence of quality and safety of care for boards, individual services, and patients and the public.*" (see Prof. Mary Dixon-Woods' *Report to the Thirlwall Inquiry: addressing Part C of the Terms of Reference* at paragraph 5.12 [INQ0102624_0062]). CQC assesses and addresses culture as part of the single assessment framework, gathering relevant evidence as part of the well-led assessment.

29. In relation to the culture of the Countess of Chester Hospital in particular: CQC notes that, during the 2016 inspection, consultants in a focus group had raised concerns with CQC about staffing levels and complained that the Trust leadership had failed to consider these concerns (see e.g. Ian Trenholm's Second Statement at paragraphs 68-70). These concerns were not specific to the neonatal unit. However no specific concerns were raised regarding excess neonatal mortality and much of what was being considered behind the scenes by the Hospital in late 2015 and early 2016 simply was not shared with CQC. Based on the information available to it, and its inspection team's observations, CQC did not have particular concerns about the culture of the neonatal ward when it inspected in 2016.

30. CQC considers that the Inquiry may wish to explore the culture on the neonatal ward in 2016, focussing in particular on whether staff properly raised concerns they may have had, if not why not, and how management engaged with any concerns of which they were aware.

h. Previous inquiries. *Please see the link to the table of recommendations by previous inquiries. Do you have any further additions or amendments in respect of this? Do you want to add any further comments to the table?*

31. In relation to the Inquiry's very helpful table of recommendations of previous inquiries, CQC has the following general observations:

    a. In some instances, systems, policies and processes within the NHS, or within the regulatory framework applicable to NHS bodies, will have changed in the years since recommendations were made by previous inquiries. By way of example only:

        i. In relation to item 12 on pages 381-382 of the table (Mid-Staffordshire Public Inquiry), the intelligence monitoring system referred to is no longer current (CQC now monitors whether NHS Trusts have declared compliance against the new National Patient Safety Alerts) and the National Reporting and Learning System has recently been replaced by NHS England's Learning from Patient Safety Events.

        ii. In relation to item 27 on page 391 of the table (Mid-Staffordshire Public Inquiry), CQC's approach to enforcement has developed over the years: it has published enforcement policies which describe the position in relation to both civil and criminal enforcement (see also the First Statement of Ian Trenholm, which contains information regarding CQC's use of its enforcement powers).

b. In relation to the Kark Review of the Fit and Proper Person Test (table, item 1, pages 670-671), CQC's role is to ensure that NHS organisations have robust processes in place to perform the Fit and Proper Person Test assessment adequately and to adhere to the requirements of regulation 5. As part of its Well-led reviews, CQC will consider the quality of the processes and controls supporting the Fit and Proper Person Test, the quality of individual assessments, board member references, the collation and quality of data relating to the Fit and Proper Person Test, and the evidence that exists as to whether board members meet the Test. CQC may intervene where there is evidence that proper processes are not in place or have not been followed. CQC does not investigate individual board members but will pass on any information of concern received about the fitness of a board member to the relevant NHS organisation and will review and consider the response received from the NHS organisation. Where CQC finds that the organisation's processes are not robust, or that an unreasonable decision has been made, it will contact the organisation for further discussion, schedule a focused discussion or take regulatory action in line with CQC's enforcement policy if a breach has been identified.

c. More generally, CQC has developed since March 2023 its own system for tracking recommendations. Multiple recommendations are made for CQC every year by external stakeholders, including statutory inquiries. CQC has developed a system for logging and considering CQC's position in relation to recommendations and the actions that are require. It prioritises recommendations from reports published by a parliamentary select committee, government review or public body, reports with recommendations of direct relevance to CQC, serious safeguarding reviews and recommendations which CQC has itself identified through its own listening and learning work.

i. Reflections. *In light of the events at the Countess of Chester hospital between 2015-2016, please explain how your organisation has reflected on how such murders and injuries to babies may have been prevented? What issues do you consider require exploration in oral evidence in respect of any changes?*

16. As set out above CQC has not identified any failures in the inspection methodology or processes in place in 2015-2016. In particular, CQC was not aware of concerns about deaths on the neonatal unit at the time of its visit in 2016 and CQC considers that its 2016 Inspection Report was reasonable given the information available to it at the time (see Ian Trenholm's Second Statement at paragraphs 152-153).

17. More generally, however, CQC notes that concerns were not identified (or were not shared) quickly enough:

    a. No relevant concerns had been raised with CQC about neonatal services at the Countess of Chester Hospital prior to the 2016 inspection - despite it now appearing that Countess of Chester staff had concerns about this prior to (and indeed during) the 2016 inspection process. Had concerns about excess mortality been raised with CQC, CQC expects that its inspection team would (and should) have given proper attention to this issue.[37] CQC has continued to encourage and facilitate whistleblowing. This is now more common and a significant number of CQC inspections now follow the raising of concerns. CQC considers it more likely that concerns about an increase in mortality similar to that which took place in the Countess of Chester Hospital would now be raised directly with CQC.

    b. CQC was not in a position to identify outlier mortality data sooner as there is a significant delay in the delay in the provision of national statistical data. *Mothers and Babies: Reducing Risk Through Audits* ['MBRRACE'] is a perinatal data mortality data stream produced by the University of Oxford's Population Health Unit that enables CQC to identify perinatal mortality outliers. MBRRACE data is not, however, provided in real time and can be provided with an 18/24-month delay. CQC also analyses Hospital Episode Statistics ['HES'] for mortality outliers. But, again, this data is benchmarked nationally and has to be collected at a central point and quality controlled after the material events. In 2015/2016 a four-to-five-month time lag was typical. The Dr Foster Data (addressed in Ian Trenholm's First Witness Statement at paragraphs 205-207) suffered from similar delays (five-six months) and is no longer received.

    c. CQC understands that Countess of Chester Hospital had concerns about increased deaths in the neonatal unit prior to the 2016 Inspection. This information was not shared with CQC. CQC is of the view that this information should have been shared and it remains unclear why it was not.

    d. CQC reviews unexpected deaths on a monthly basis. This process, however, relies on Trusts to properly report unexpected deaths. The babies who were murdered at the Countess of Chester were not reported in this way and so no CQC review took place. Clearer guidance as to what constitutes an "unexpected death" is now in place; CQC samples relevant reports; and all Trusts are expected to have transitioned from the

[37] CQC recognises that there is evidence before the Inquiry from Dr ZA which describes attempts to inform CQC at its 2018 inspection about doctors' experience of raising concerns which, according to Dr ZA's statement, was not followed up [INQ0099097 paragraph 28]; see also the statement of Dr V [INQ0102068 paragraph 169] and the statement of Dr Brearey [INQ0103104 paragraph 75]. These matters may need to be explored in oral evidence.

NHSE Serious Incident Framework to the NHSE's Patient Safety Incident Response Framework – all of which strengthen the reporting process (see Ian Trenholm's First Statement at paragraph 139-140).

18. Furthermore, and as set out above, CQC accepts that its approach was not sufficiently pro-active following the communication that the matter had been referred to the police:

    a. CQC did not run investigations in parallel with the police investigation. It is likely that it would now adopt a different approach.

        i. Should CQC be made aware of an 'incident of concern', it will apply the Specific Incident Guidance [INQ0010482] Insofar as is material CQC will establish whether the service user has been exposed to a significant risk of avoidable harm and, if so, whether the specific incident raises concerns about ongoing risk of harm to other service users or to that service user which the CQC should inspect.

        ii. CQC will also consider whether the specific incident suggests the harm was avoidable and may have resulted from a prosecutable breach of fundamental standards. If so CQC will gather information for a potential prosecution. The first version of CQC's Specific Incident Guidance was published in 2018.

        iii. In 2020 CQC published CCAPP guidance [INQ0107927], referring to the Criminal Cases Assessment Progression Panel. Where inspectors believe there has been a prosecutable breach of standards, the case will be presented to the CCAPP to decide if there is sufficient evidence to progress the matter to a formal criminal investigation, in which event the case is directed to the National Enforcement Team who investigate the suspected offences.

        iv. Care clearly needs to be taken in relation to parallel investigations, but CQC will not generally pause investigations or decide not to start them merely because other agencies are investigating.

19. CQC considers that the following issues would benefit from further exploration by the Inquiry in oral evidence:

    a. The culture of the neonatal ward, and of senior management, at the Countess of Chester Hospital, in particular whether staff felt empowered to raise concerns and, if not, why not. While these issues will plainly be of central concern to the Inquiry (see

Terms of Reference B(iii)), CQC considers that live examination of these issues is likely to be of particular benefit.

b. Whether staff (both clinical and managerial) appropriately shared information with regulators. CQC has highlighted concerns above that information about increased mortality in the neonatal unit was available to the Countess of Chester clinicians and/or management and that this information was not, in fact, passed to CQC until the day on which it was due to publish its 2016 inspection report. Further, concerns about possible criminal behaviour were not shared with CQC until May 2017. The Inquiry may wish to explore in oral evidence whether it should have been.

j. Recommendations. *What do you wish to contribute by way of oral evidence to the consideration of recommendations on how to help keep babies safe? What is your current position on CCTV observation of neonates in hospitals.*

20. CQC has sought to set out its position in its written evidence (see in particular the first statement of Ian Trenholm). Whilst there is no specific section of this evidence that CQC considers require exploration by way of oral evidence, CQC is keen to consider and reflect on the question of recommendations further, in particular in light of all the evidence which the Inquiry has gathered, from multiple sources, relevant to Part C of the Inquiry's Terms of Reference. Furthermore, the Inquiry may well have particular areas of interest and concern and CQC's witnesses will, of course, assist the Inquiry to address these matters orally to the extent they are able.

21. As to CCTV: CQC considers the question of whether or not to deploy CCTV in neonatal wards to be a complicated and fact specific question and one for individual Trusts to determine.

22. For those Trusts that do wish to deploy CCTV, CQC has published guidance to help ensure that any use of CCTV is safe, appropriate, and in accordance with the law.[38] This explains that the use of CCTV or other forms of surveillance will be checked by CQC against seven principles: (1) the recording equipment has appropriate safeguards; (2) the recording equipment is housed securely and appropriate to the purpose for which it is used; (3) the privacy and dignity of people is at the heart of any considerations when deploying recording equipment; (4) people must be involved in decisions when using recording equipment in private rooms; (5) recording equipment has a specific legal basis for its use and complies with all relevant legislation and codes of practice; (6) staff are trained on the use of the recording equipment; and (7) recording equipment is used in a transparent manner.

[38] https://www.cqc.org.uk/guidance-providers/all-services/how-we-check-use-surveillance. CQC's Guidance and regulation on use of CCTV has been sent to the Inquiry.

23. For completeness CQC notes that it has the power to impose conditions on registration by virtue of sections 12(5) and 15(5) of the 2008 Act. CQC considers that these powers are sufficiently broad in principle to allow CQC to require installation of CCTV (as a means of overt surveillance) as a condition of a grant of registration as a service provider or manager. Such a condition would, however, have to be consistent with the principles outlined above and in particular be Article 8 ECHR compatible (see Ian Trenholm's first witness statement at paragraphs 164-165).

Review of CQC

24. The Inquiry will be aware that on 26 July 2024 the Department of Health and Social Care published a 'Review into the operational effectiveness of the Care Quality Commission: interim report". [39] That review examines the suitability of the Single Assessment Framework introduced by CQC in November 2023. It finds (in summary) "significant failings in the internal workings of CQC" and "a deterioration in the ability of CQC to identify poor performance and support a drive to improved quality". CQC has accepted in full the findings and recommendations in this interim review and work is underway to address the problems identified. Amongst other steps CQC has appointed Professor Sir Mike Richards to conduct a targeted review of how the Single Assessment Framework is currently working for NHS Trusts and where CQC can make improvements. The matters encompassed in the interim report do not directly relate to the issues that are the focus of this Inquiry, but in the event that the reflection being undertaken by CQC, and the measures being introduced, in response to the interim report identify points of relevance to the Inquiry's work, in particular with regard to recommendations, CQC will provide an update to the Inquiry.

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30 August 2024

[39] This is an interim report: the review team intends to publish a more substantive report in autumn 2024.