THIRLWALL INQUIRY

CLOSING SUBMISSIONS ON BEHALF OF THE CARE QUALITY COMMISSION

Introduction

1. The role and remit of the Care Quality Commission ("CQC") remains as described in its written Opening Statement. As explained in the witness statement of Joyce Frederick [INQ0108378] and confirmed in the oral evidence of Chris Dzikiti [transcript, 14 January 2025], a substantial amount of work is ongoing within CQC to (amongst other matters) make changes to its assessment framework, in response to the review by Dr Penny Dash and the subsequent CQC-commissioned review by Professor Sir Mike Richards. There are also a number of areas on which CQC has reflected, or is reflecting, in light of the evidence examined by this Inquiry. These are addressed further below.

2. These written submissions are structured as follows: A. The February 2016 inspection; B. Events from 30 June 2016 onwards; C. Specific issues that have been raised by the Inquiry (including those identified in the Inquiry's Note of 4 February 2025); D. Areas of reflection; E. The request, made on behalf of the former Countess of Chester Hospital executives, for the Inquiry to be paused.

A. The February 2016 inspection

3. The 2016 inspection was the first which was undertaken by CQC of the Countess of Chester Hospital NHS Foundation Trust ("CoCH") as part of the comprehensive inspection programme which had been introduced in 2014.[1]

[1] There had been an inspection previously in February 2013, in which CoCH was rated as compliant for all six outcomes inspected and no concerns had been subsequently flagged to CQC such as to warrant a responsive inspection [INQ0103620 page 6].

This was the first time that NHS Hospital Trusts had been inspected in this way and used the five key questions[2] and service focused assessment frameworks to complete a programme of comprehensive inspections and ratings. To some extent, therefore, this was a process whereby CQC itself was learning as it went. Improvements and modifications were made to the process and learning applied to strengthen and mature its approach as the programme progressed.

4. This was a routine inspection, rather than one which was triggered by specific concerns. It was an inspection across eight core services, of which Children and Young People was one[3], structured on specific "key lines of enquiry" (including safety [INQ0017286 pages 16-30]).[4]

5. CQC does not repeat the detailed content of the evidence (written and oral) which the Inquiry has received regarding the February 2016 inspection from those directly involved (inspectors,[5] specialist advisors,[6] data analyst[7]).

6. An inspection visit by its very nature is focused and intense and takes place over a fixed period. The observations and interviews the inspection team undertake during that process are of considerable importance to CQC's assessment of the provider, and can help identify poor practice or any issues or areas for improvement,[8] but there exist inevitable limitations on what and

[2] See the first witness statement of Ian Trenholm at paragraphs 61-64 [INQ0012634].
[3] The others being Urgent and emergency services; Medical care (including older people's care); Surgery; Critical care; Maternity and gynaecology; End of life care; and Outpatients and diagnostic imaging.
[4] As Professor Sir Stephen Powis (NHS England) noted in his oral evidence to the Inquiry, *"the CQC inspections at the time were broad whole organisation inspections and the neonatal unit would be only one part of that"* [transcript, 17 January 2025, internal page 145].
[5] See the witness statements of Ann Ford [INQ0107911, INQ0108375, INQ0108674], Helen Cain [INQ0102617] and Julie Hughes [INQ0107914] and the transcripts of their oral evidence on 14 and 15 November 2024.
[6] See the witness statements of Elizabeth Childs [INQ0102368], Mary Potter [INQ0102608] and Benjamin Odeka [INQ0102611] and the transcript of their oral evidence on 14 November 2024.
[7] See the statement of Lyn Andrews [INQ0108743] (and, more broadly on the question of data, the statement of Lisa Annaly [INQ0108742]).
[8] Oral evidence of Chris Dzikiti, transcript, 14 January 2025, internal pages 27-28. This Inquiry's focus is, properly and inevitably, on what happened on the neonatal unit (which CQC did not detect at the inspection), but it is important, by way of context, to consider the entirety of that which was inspected, as recorded in the inspection report [INQ0017433] which shows the range of issues that were considered, analysed and assessed across the core services.

how much can be gleaned as there is a reliance and an expectation that the provider being inspected and those being interviewed will be honest and open in their responses. Inspection and assessment are, therefore, part of a process which requires an NHS trust to be open, transparent and forthcoming with CQC and to share with it actual and emerging risks and trends

7. CQC has made clear that no one, before, during or after the inspection, at any stage up to publication of the report on 29 June 2016, raised with CQC **any** concern about increased neonatal mortality rates,[9] and that no one, before, during or after the inspection, or at any stage prior to May 2017, raised with CQC **any** concern that a nurse might be deliberately harming babies or killing babies on the neonatal unit.[10]

8. Prior to the inspection itself in February 2016, there was ample opportunity for CoCH to inform CQC of any concerns they held regarding neonatal deaths, which were clearly (on the evidence which the Inquiry has received and heard) being discussed internally. They could also have communicated with CQC by phone or email, or utilised the three meetings that took place in the second half of 2015 to do so. There was an engagement meeting between CQC and CoCH[11] on 21 July 2015; a further meeting on 13 October 2015 to

[9] In addition to the evidence referred to elsewhere in these Closing Submissions, see also the witness statement of Deborah Lindley [INQ0107913] at paragraph 11 and the oral evidence of Chris Dzikiti [transcript, 14 January 2025, internal pages 29-30]. CQC observes that NHS England was in a similar position, notwithstanding its commissioning oversight: Professor Sir Stephen Powis told the Inquiry that *"NHS England was not aware of the increase in mortality until July 2016"* [transcript, 17 January 2025, internal page 40].

[10] Oral evidence of Chris Dzikiti [transcript, 14 January 2025, internal pages 30-31], third statement of Ann Ford [INQ0108375, paragraph 7.5], second statement of Ann Ford [INQ0107911 at paragraphs 3.18-3.19], second statement of Chris Dzikiti [INQ0108866, paragraphs 27-33]. CQC notes again the broadly similar position of NHS England, which was not aware that there was suspicion around a particular member of staff until March 2017 [transcript, 17 January 2025, internal page 41]; witness statement of Robert Cornall at paragraph 89 [INQ0107032].

[11] Attended by Ian Harvey, Tony Chambers, Alison Kelly and Ruth Millward for CoCH. Various matters were discussed at the meeting, including a never event, the investigation of complaints and the sepsis outlier, and CoCH were provided with details of the new inspection manager and inspector (Bridget Lees and Deborah Lindley) [INQ0017285].

discuss various incident alerts which had been received[12]; and a pre-inspection engagement meeting on 26 November 2015.[13]

9. CQC's expectation is that serious concerns such as an unexplained increase in patient deaths would be communicated by the hospital Trust to CQC ahead of an inspection, and if not, then during the inspection. See for example:

    a. Witness statement of Elizabeth Childs [INQ0102368] at paragraphs 15, 33 (see in particular Ms Childs' wholly unsurprising observation that *"Across the health service it was widely considered good practice to inform the CQC early with any care concerns arising within a Trust"*) and 67.
    b. Witness statement of Helen Cain [INQ0102617] at paragraphs 22, 67 and 118-119.
    c. Witness statement of Mary Potter [INQ0102608] at paragraph 71.
    d. Oral evidence of Helen Cain [transcript, 14 November 2024, internal pages 22 and 76].
    e. Oral evidence of Dr Odeka [transcript, 14 November 2024, internal page 92].
    f. Oral evidence of Ann Ford [transcript, 15 November 2024, internal pages 54-57].
    g. Oral evidence of Chris Dzikiti, 14 January 2025, internal pages 73-77.

10. There is no credible evidence that anyone within CoCH told CQC about the increased neonatal mortality, still less any suspicion of correlation between neonatal deaths and the presence or involvement of a member of staff. See, for example, the following evidence of those involved in the inspection for CQC:

[12] The meeting was attended by Ruth Millward and others from CoCH, and Bridget Lees and Deborah Lindley from CQC [INQ0106786].
[13] The date of the meeting, and the attendees from CQC (Bridget Lees, Deborah Lindley and Ann Ford) appear on page 12 of INQ0106720. Although (as explained in the second statement of Ian Trenholm at paragraph 17 [INQ0017809]) there is no note of the meeting, there has been no suggestion by anyone that the concerns regarding neonatal mortality were communicated to CQC at this meeting.

a. Witness statement of Elizabeth Childs [INQ0102368] at paragraphs 50, 55-60 and 65.
b. Witness statement of Helen Cain [INQ0102617] at paragraphs 64-66 and 91.
c. Witness statement of Mary Potter [INQ0102608] at paragraphs 38 and 44.
d. Witness statement of Dr Benjamin Odeka [INQ0102611] at paragraphs 53-55.
e. Oral evidence of Helen Cain, transcript 14 November 2024, internal pages 37-38, and internal pages 60-62.

11. There was more than sufficient opportunity for CoCH to bring these matters to CQC's attention during the inspection and during any of the interviews and observations which are described in Helen Cain's statement at paragraphs 86-109.[14] Dr Odeka conducted a one-to-one interview with Dr Brearey, in which several issues were raised (including staffing levels) but not any concerns regarding increased neonatal mortality: see Dr Odeka's statement at paragraphs 71-73 and paragraph 90 [INQ0102611].[15] Ms Cain explained that at the end of every interview the opportunity would be offered to the staff being interviewed to *"tell us anything that they wanted us to know"*.[16] Ann Ford explained that it was standard practice for interviewers to say to the interview *"Is there anything else that you would like to tell us? Is there anything that we have missed? Is there anything you want to share with us?"*[17] Elizabeth Childs identified the questions that would be asked: *"What are the serious risks? Are there any concerns you have about care? What are you*

[14] See also the third statement of Ann Ford at paragraph 9.4 [INQ0108375]: *"During the inspection in 2016, inspectors were visible and the information about the inspection was made public with posters being put up informing staff at the hospital about the inspection and that CQC would be on site. Anyone spoken with is advised that they can do so in private and in confidence. In the past we have set up meetings off site so that those who do not feel comfortable speaking on site can do so elsewhere."* Mary Potter acknowledged in her statement that it can be difficult to provide these kinds of disclosure in the presence of colleagues or managers *"and we offered the opportunity for one-to-one fact-focussed interviews during the inspection to accommodate for this"* [INQ0102608 at paragraph 71].
[15] The notes of Dr Odeka's one-to-one interview with Dr Brearey are at INQ0017339 at pages 60-64. There was also a meeting with all team leads (including Dr Brearey, Dr Jayaram and Eirian Powell), the notes for which appear at pages 206-214 of INQ0017339.
[16] Transcript, 14 November 2024, internal pages 63-65.
[17] Transcript, 15 November 2024, internal pages 20-21.

doing about those concerns? What are you doing to mitigate those concerns?"[18]

12. It is clear, however, from all the evidence, not least the contemporaneous notes from the interviews undertaken for the Children and Young People inspection, that there was no communication of the concerns regarding increased neonatal mortality during any of those interviews (or at any other stage prior to the publication of CQC's inspection report) [INQ0017339].[19]

13. Insofar as the evidence of staff from CoCH is concerned:

    a. Dr Gibbs did not raise any concerns with CQC. He told the Inquiry that he did not think it would have been appropriate to talk about a particular member of staff (*"There are other ways to deal with that rather than asking the CQC who happen to be visiting the hospital about that"*).[20] In relation to the *"sub optimal care issues"* and the unexplained/unexpected deaths highlighted in the thematic review, he *"would have thought you deal with that within the hospital first and then go to the CQC if it's not been dealt with"*.[21]
    b. Dr Jayaram did not discuss the thematic review with CQC and did not recall discussing the rise in numbers of neonatal deaths.[22]
    c. Dr Brearey did not raise concerns about the deaths with CQC. He told the Inquiry that there was *"a bit of an internal dialogue going on with*

[18] Transcript, 14 November 2024, internal page 152. See also the evidence of Chris Dzikiti, transcript, 14 January 2025, internal pages 77-79.
[19] There was a discussion about neonatal mortality and morbidity meetings and the notes record the numbers of meetings that had been held and were scheduled, but as Helen Cain's statement makes clear *"there was no mention of an increase in deaths. If such an increase had been raised, this would have been recorded in my notes and further enquiries would have been raised"* [INQ0102617 paragraph 93].
[20] Transcript, 1 October 2024, internal page 87. He added *"it is a bit inappropriate to just tell the CQC inspectors when they happen to be visiting if you haven't tried to sort that out within your own Trust management structure. It's almost like telling OFSTED you have got a problem with a teacher and you have never told anyone in the school …"* Transcript, 1 October 2024, internal page 88.
[21] Transcript, 1 October 2024, internal pages 88-89.
[22] Witness statement of Dr Jayaram [INQ0107962, paragraph 332]; transcript, 13 November 2024, internal pages 91-92. Dr Jayaram appeared to acknowledge in his oral evidence that it would have been a safe environment in which to raise concerns *"because there were independent people there"* [transcript, 13 November 2024, internal page 95] but also appeared to say that he did not really know that he could have gone to any of the wider national bodies (including NHS England, CQC, the NMC and the GMC) [transcript, 13 November 2024, pages 255-256].

myself in terms of what – what to say to the inspectors" because *"effectively I would be raising concerns to the CQC before I raised concerns to the Medical Director"*. His position (as communicated in his oral evidence) appears to be that he decided he would talk about it if specifically asked but not otherwise.[23] Whether that is a satisfactory position for a consultant to adopt is ultimately a matter for the Inquiry (CQC would submit that it is not), but in any event it is clear that Dr Brearey did not tell CQC of his concerns.[24]

d. Dr ZA was not present during the February 2016 inspection.[25]
e. Eirian Powell did not tell CQC about the raised mortality rate or unexplained deaths.[26]
f. Yvonne Farmer did not think it was her role to tell CQC and did not do so either during the February visit or when interviewed by Helen Cain on 4 March (2 days after the email circulating the updated thematic review).[27]
g. Ruth Millward, who was responsible for overseeing preparation for the CQC inspection, confirmed that CQC did not, as far as she was aware, see the thematic review.[28]
h. Sian Williams, who also participated in preparation for the inspection, did not share any of the concerns with CQC.[29]

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[23] Transcript, 19 November 2024, internal pages 103-107.
[24] In his witness statement, Dr Brearey suggested that there was no opportunity to talk to an inspector confidentially during the walk around the neonatal unit with inspectors [INQ0103104, paragraph 215], and in his oral evidence he appeared to state that the opportunity for a one-to-one discussion was turned down [transcript, 19 November 2024, internal page 107]. However, Dr Brearey not only participated in the meeting between the inspection team and staff from the paediatric and neonatal services [INQ0017339, pages 206-214], but also had a one-to-one meeting with Dr Odeka [INQ0017339, pages 60-64] and transcript, 19 November 2024, internal page 192.
[25] Transcript, 7 October 2024, internal pages 47-48. She clarified that the references to a CQC visit in her witness statement were to the 2018 inspection. It follows that the assertion in paragraph 75 of Dr Brearey's witness statement [INQ0103104] – that Dr ZA raised patient safety concerns with CQC in February 2016 – is incorrect.
[26] Transcript, 17 October 2024, internal pages 112- 113. She appears to have accepted in her evidence that she should have done (internal page 115, line 21), although she adds, in relation to sharing information about the reviews, *"I did think maybe the Consultants would have done that, maybe Dr Brearey would have done that"* (internal page 116, lines 20-23).
[27] Transcript, 16 October 2024, internal pages 48-49 and 150-151. Anne McGlade also did not say anything – her assumption was that colleagues on the neonatal unit would have said something about the increase in mortality or that CQC would have asked about it: transcript, 16 October 2024, internal pages 214-215.
[28] Transcript, 4 November 2024, internal page 129.
[29] Transcript, 5 November 2024, internal pages 14-20.

i. The only witness who appeared to suggest that matters were shared with CQC was Anne Murphy. However, not only is that not supported by the contemporaneous notes [INQ0017339] (which Ms Murphy thought were accurate[30]) but it is not consistent with Ms Murphy's witness statement.[31] It is clear that Ms Murphy's answers in her oral evidence (*"I mean, we clearly told the CQC, you know, about the raised mortality"*) reflect the fact that the questions to her were put on an incorrect factual basis (CTI having positively suggested to her that the reference to *"5 from NNU last year x4 this year"* in the notes [INQ0017339 page 207] meant that *"it does appear that there is some discussion about the number of deaths at that meeting?"* – a proposition with which Ms Murphy then agreed (*"Yes"*). In fact, as became clear when the Inquiry heard evidence from the CQC inspection team, those notes referred to a discussion about the numbers of mortality and morbidity meetings taking place, and not to a discussion about the numbers, or rates, of deaths.)[32] Ms Murphy's evidence on this point is therefore unreliable, and she acknowledged herself that she *"can't remember what was actually discussed".*

14. Following the main inspection visit, CQC wrote to Tony Chambers on 29 February 2016 providing an overview of its preliminary findings, including that there were no immediate patient safety concerns but that there were nurse staffing issues and particular concerns in relation to numbers of delayed transfers of care [INQ0008007]. This was an accurate reflection of CQC's assessment of the position during its inspection. It should have been evident to CoCH from this letter that CQC was unaware of the concerns regarding neonatal mortality. This provided a further opportunity for CoCH to tell CQC that there were indeed such internal concerns but no such information was shared or forthcoming by CoCH.

[30] Witness statement of Anne Murphy at paragraph 21 [INQ0101325].
[31] In her statement Ms Murphy stated that there was no discussion with anyone about discussing or presenting the thematic review to CQC; that due to the passage of time she could not recall the context of what was discussed during the CQC inspection; and that she did not think that the correlation of Letby's presence and increased mortality was raised during the meeting [INQ0101325, paragraph 21].
[32] Transcript, 21 October 2024, internal pages 63-65. CQC stress this is not intended as any criticism of CTI.

15. Two days before CQC returned to CoCH for a follow up visit on 4 March 2016, Dr Brearey and Ms Powell produced an updated version of the thematic review [INQ0004561, INQ0004538], which was circulated on 2 March 2016 to a number of senior clinical staff within the hospital [INQ0003114]. No such information was shared with CQC regarding the neonatal deaths during the 4 March visit.[33]

16. CQC was not provided with any version of the thematic review, before, during or after the inspection, nor told that it was being, or had been, carried out.[34] The first reference to such a review being undertaken was in Alison Kelly's email of 30 June 2016. CQC notes that:

    a. There is no documentary evidence to suggest that the thematic review was provided to CQC. Whilst CQC accepts the deficiencies in its retention of some of the documents (for which both Ann Ford and Chris Dzikiti have apologised[35] – an apology which CQC formally repeats in these closing submissions), had the thematic review been provided by CoCH to CQC it would be expected that there would be some form of email or audit trail <u>from CoCH</u> but there is none.
    b. The internal CoCH meeting to discuss the thematic review on 8 February 2016 was attended by (amongst others) Dr Brearey, Eirian Powell and Anne Murphy [INQ0003217], all of whom were interviewed by CQC during the inspection visit only a few days later without making any reference at all either to the review or to the concerns which underpinned it.
    c. The draft thematic review was emailed by Dr Brearey to Ian Harvey on 15 February 2016 and by Ian Harvey to Alison Kelly on the same date [INQ0003140]. Ms Kelly did not recall whether she read the review in

[33] Ann Ford agreed in her oral evidence that this (along with *"the whole inspection"*) was an opportunity for CoCH to tell CQC about what was happening: transcript, 15 November 2024, internal pages 67-68.
[34] See the fourth statement of Ann Ford at paragraph 7 [INQ0108674]. Nor, as CQC understands it, was NHS England informed of the thematic review or its findings or the concerns which underpinned it: see the first witness statement of Professor Sir Stephen Powis at paragraph 508 [INQ0017495].
[35] Transcript, 15 November 2024, internal pages 10 and 28; transcript, 14 January 2025, internal pages 30-34.

preparation for her meeting with CQC on 17 February and it is clear from her oral evidence to the Inquiry that she did not bring the review, or the increase in neonatal mortality to the attention of CQC (*"it wasn't a completed report … there was further work to be done in feedback from others so we took that as a draft report … we had only just received it, we hadn't a chance to digest it and in actual fact it wasn't the full report … we didn't have a clear picture when the CQC landed to do their inspection at that time … I don't know why that wasn't discussed with the CQC at that time … I think we needed to understand what the bigger picture was before we shared anything with the CQC"*): see transcript 25 November 2024 internal pages 71-78 and pages 27-271 (*"I don't think from myself and Ian Harvey's perspective we probably hadn't joined all the data together at that time, so we didn't raise anything with the CQC because we needed to look at it ourselves internally"*).

17. CQC was not provided with the Brigham review [INQ0106105] before, during or after the inspection, nor told that it was being, or had been, carried out.[36] It was provided to CQC much later, under cover of an email dated 24 April 2018 [INQ0106103].

18. CQC should have been expressly told by CoCH:
    a. that there were significant concerns within CoCH regarding an increase in neonatal mortality;
    b. that some consultants considered that the increase in neonatal mortality was, or might be, attributable to the deliberate acts of a nurse;[37]
    c. about the internal reviews that were being, or had been, undertaken.[38]

As Ann Ford explained, *"the Trust had a professional obligation and an obligation to patients to be open and transparent with us."*[39]

[36] See the fourth statement of Ann Ford at paragraphs 8-9 [INQ0108674].
[37] See the oral evidence of Ann Ford: transcript, 15 November 2024, internal pages 70-71.
[38] Helen Cain set out her expectation that the thematic review would have been provided by CoCH to CQC, and that the 2 March 2016 updated version of the thematic review would also have been provided prior to the finalisation of the report: transcript, 14 November 2024, internal pages 40-42. See also the oral evidence of Ann Ford: transcript, 15 November 2024, internal page 52.
[39] Transcript, 15 November 2024, internal pages 83-84.

19. In relation to the provision of information regarding reviews, CQC notes that at its routine engagement meeting with CoCH on 21 July 2015 [INQ0017285], the discussions included the fact that CoCH was undertaking an interventional radiology review (following a serious incident 18 months previously), *"looking at the processes, how patients are managed and the interface with other teams"*, and also including *"an organisational development piece of work around the culture"*. CoCH also explained that a review of the breast service was being undertaken, following three incidents of delayed diagnosis, with the Royal College of Surgeons having completed an independent review. This discussion reflected CQC's reasonable expectation that it would be informed of any such significant reviews (internal or external) being undertaken in relation to services at CoCH and reinforced the expectation that CoCH would be forthcoming with such information.

20. Alison Kelly's handwritten diary notes record her call to Bridget Lees at CQC on 29 June 2016 as *"high level reasons expressed"* [INQ0015537 p5]. It is for the Inquiry to determine whether that was, as Counsel to the Inquiry put it, *"a euphemism for saying you did not tell her [Bridget Lees] about the concerns of the Consultants"*, but it is clear from Ms Kelly's response to CTI that she did not tell Ms Lees about the concerns of the consultants regarding Letby and the possibility of deliberate harm: *"We said there was a – there was an increase in mortality at that time. But again we needed to understand before we could communicate more widely what we were dealing with because we didn't know"* [transcript, 25 November 2024, internal pages 82-3].

21. It is apparent too from Alison Kelly's email of 30 June 2016 to Ann Ford [INQ0017411] that there was no communication of the consultants' concerns. What she told CQC was that *"The Trust has identified an increase in the number of deaths of new born babies (different levels of prematurity) on our Neonatal Unit in 2015-16 and now in 2016-17 compared to previous years".* Reference was made to the thematic review, and to a peer review by a consultant from another hospital, followed by the statement that *"the reviews*

have failed to identify any cause or common theme for this increase". The email then went on to set out the actions being taken, including the commissioning of an independent review from the RCPCH and the proposed downgrading of the unit to Level 1.

22. These communications on 29 and 30 June 2016 were the first notification to CQC of the increase in neonatal mortality. CQC notes (from the evidence heard by the Inquiry – see for ease of reference the entries in the Inquiry's Chronology Version 4) that in the days immediately preceding that call there had been a number of meetings and discussions involving consultants and members of the executive team of CoCH in which the consultants' concerns that Letby was deliberately harming babies were squarely raised. Those concerns were not shared with CQC, as Alison Kelly accepted in her oral evidence [transcript, 25 November 2024, internal pages 85-87]. Ms Kelly also accepted that the suggestion in her email of 30 June that the reviews (thematic review/peer review) had been submitted to CQC was in fact incorrect.

23. As to the extent that Tony Chambers and/or Ian Harvey have suggested otherwise, their evidence is purely speculative and lacking in credibility. Tony Chambers asserted that it was *"difficult to be really clear whether that document [the thematic review] should have been shared at that time. But it may well have been. And I think you need to test that conversation with Mr Harvey tomorrow because there isn't any clear record as to whether the CQC had got that report or – or not."* [transcript, 27 November 2024, internal page 212], later asserting *"I do seem to remember that bundles of documents following the review were shared with the CQC … It was my understanding that the Thematic Review, I think, was part of one of those bundles, but I can't be absolutely certain"* [transcript, internal pages 212-4]. CQC suggests that this is inconsistent with Mr Chambers' own witness statement in which he said that he was *"not aware of anyone raising any neonatal related patient safety concerns with the CQC at the time of their visit"*, and that he would have been very surprised if they had as he would have expected this to be fed back to CoCH *"both verbally at the feedback meeting and via the inspection report"*

[INQ0107708 paragraph 156]. It is plain that Mr Chambers could have had no first hand evidence to give on the sharing of this information with CQC, as his evidence is that he only became aware himself of the concerns regarding increasing numbers of neonatal deaths on 29 June 2016 [INQ0107708 at paragraph 163]; he further identifies in his statement (correctly) that CQC was appraised of the concerns in relation to increased number of deaths in June and July 2016 [paragraph 166].[40]

24. Ian Harvey asserted in his oral evidence to the Inquiry [transcript, 28 November 2024, internal page 105] that *"I am confident that I shared and we – we're sort of moving on – the Thematic Review of Dr Brearey with the CQC ahead of them – their visit in February 2016"*, although it appears from later answers [transcript, 29 November 2024, internal pages 220-221] that this was *"simply surmising"* based on the fact that he had asked Dr Brearey for the review with the CQC visit forthcoming. His evidence is, however, inconsistent with the evidence of the CQC witnesses; it is inconsistent with the evidence of Alison Kelly; it is unsupported by any contemporaneous documentary evidence such as an email from Ian Harvey to anyone at CQC providing the review; and it is inconsistent with Ian Harvey's own witness statement. In that statement [INQ0107653] he asserts that the tone and content of Dr Brearey's email attaching the thematic review did not cause him any concern and that he was *"reassured that the events were being appropriately examined"* (paragraph 111). He states that he would have reviewed the report *"in overview"* but would not have taken any immediate action (paragraph 112) and that he would have inferred that the neonatal team were not worried about any correlation with a staff member (paragraph 112). He records that he forwarded the email to Alison Kelly with a comment which indicated he was reassured by the information that Dr Brearey was providing (paragraph 115); and that he was simply sending it to Alison Kelly for information purposes *"and would not have expected her to action anything in relation to*

[40] It may be that Mr Chambers' apparent belief that CQC was provided with the thematic review stems simply from the fact that he was copied into Alison Kelly's email to Ann Ford of 30 June 2016, a fact which he records in his witness statement at paragraph 221. However, Ms Kelly has explained to the Inquiry that the assertion in that email regarding the provision of the thematic review was incorrect.

it" (paragraph 117). Mr Harvey also said in his statement (paragraph 118) that he could not comment on whether CQC was provided with information regarding neonatal deaths and that he had no specific recollection of what was discussed in his meeting with CQC (paragraph 119). He added that if patient safety concerns had been raised, that would have been included in its report (paragraph 120). His written statement is thus flatly inconsistent with any positive assertion in oral evidence that the thematic review was provided by him to CQC.

25. Moreover, a failure by CoCH to provide the thematic review to CQC is, it is submitted, consistent with the overall approach of its executive team to the sharing of information regarding the concerns about the neonatal unit (whether with the families, NHS England, the Coroner, CQC or others).

26. A copy of its draft inspection report was sent by CQC to CoCH on 23 June 2016 [INQ0002652], with notification that the report would be published on CQC's website on 29 June, following the Quality Summit on 27 June. Even at that stage, either in response to the receipt of the draft report or at the Quality Summit, CoCH did not tell CQC of its increased neonatal mortality or of its concerns.

27. That said, if CQC had been provided with information regarding the increase in neonatal deaths, it is unlikely to have led at that time to an investigation by CQC itself into the circumstances of the deaths. CQC would have considered what actions had been or were being taken by the Trust to respond to the increase. As explained in Helen Cain's statement at paragraph 23 [INQ0102617], *"If an increase in neonatal deaths were identified, CQC would want to know what action the Trust was taking in response to this. For example, had each death been reviewed individually and also looked at as part of 'a bigger picture'. Had any commonalities been identified such as similar clinical presentation, or cause of death, and had any themes or trends been identified. Also, what immediate actions had been taken and how were*

any 'lessons learned' being disseminated."[41] In her oral evidence Helen Cain explained that the inspection looks to see *"if there is a process in place to ensure incidents like this are identified, reported, identified, investigated and lessons learnt"*. [42] Ann Ford explained that *"on an inspection like this, we look at how the Trust … the Trust is charged with the responsibility of investigating those incidents … when we look at incidents, we look at them in terms of the process and how they* [the Trust] *are discharging those responsibilities."*[43]

Issues relating to the inspection process that have emerged/been raised during the Inquiry

The role of the Specialist Advisor

28. As explained in the witness statement of Elizabeth Childs [INQ0102368, paragraphs 7 and 11] the involvement of the specialist advisors was for the duration of the inspection. The specialist advisors would not be involved in data collection prior to the inspection visit: see the witness statement of Mary Potter [INQ0102608 at paragraph 8] and the witness statement of Dr Odeka [INQ0102611 at paragraph 13]. The primary role of a specialist advisor is to provide clinical support and expertise during the visit itself: oral evidence of Helen Cain [transcript, 14 November 2024, internal pages 5-6] and oral evidence of Dr Odeka [transcript, 14 November 2024, internal page 81]. CQC did not, and does not, routinely share all the information it holds with the specialist advisor. The data packs would however be provided to the specialist advisors, who would also attend the intelligence presentation on the first day of the inspection.[44] Inspectors can share with the specialist

[41] See also paragraphs 68 and 74 of Helen Cain's statement; paragraph 40 of Mary Potter's statement [INQ0102608]; paragraph 4.8 of Ann Ford's third witness statement [INQ0108375].
[42] She described that there were discussions with staff *"about incident reporting, about what would be reported, how it would be reported, how things were investigated, how lessons were learnt"* and that she reviewed three incident reports as part of that process [transcript 14 November 2024 internal pages 33-36]. Ms Cain explained that *"I asked staff as a matter of course in an inspection: what would you report? How would you report it? What types of incident would you report? Where would you find the policy? Do you know what the policy says? Could you access it?"*
[43] Transcript, 15 November 2024, internal page 47.
[44] See Helen Cain's evidence, transcript 14 November 2024, internal page 51.

advisors any of the material they have access to; likewise specialist advisors can request access to any material from the inspectors.

29. Following the introduction of CQC's Insight system in October 2016 (i.e. after the date of the CoCH inspection), specialist advisors were expected to familiarise themselves with information held on CQC Insight.[45] At the time of this inspection, the expectation would have been to consider the data packs and intelligence presentation, and to ask for any further information which the specialist advisor considered would be helpful or appropriate to consider. It would not, in CQC's view, be realistic to ask a specialist advisor to go through (for example) all reported serious incidents for a core service, as this would not be the best use of the limited time that the specialist advisors are on site. In the event of there being significant concerns, themes or trends identified by the inspector in planning the inspection, the inspector would be expected to brief the team (including the specialist advisors) about any such concerns, themes or trends so as to allow for a more in-depth exploration where appropriate.

Timing of requests for information

30. It would not be unusual for documents or information to be sought from the Trust during the inspection visit (see, e.g., witness statement of Elizabeth Childs [INQ0102368 paragraph 22]; witness statement of Helen Cain [INQ0102617 paragraphs 15-18]; the guidance in the Intelligence Presentation on 16 February [INQ0103620 at page 35]; the oral evidence of Ann Ford[46]). Whilst, as Chris Dzikiti agreed in his oral evidence, the *"more time with the data, the better"*, CQC does not agree that this is a *"weakness*

[45] This expectation was set out in a handbook for specialist advisors: the most recent handbook (October 2022 – accessible online at https://www.cqc.org.uk/about-us/jobs/information-specialist-advisors) advised specialist advisors of the importance of familiarising themselves with three sources of background information prior to going on inspection (CQC Insight, previous CQC inspection reports, and the inspection framework and guidance) and in relation to CQC Insight advised that *"Prior to going on inspection you can ask the inspection manager to send you this information to enable you to have a better understanding of the background of the Provider".* There is an earlier version of the handbook from 2019 to similar effect. However, as set out in the main text the February 2016 inspection was prior to the introduction of CQC Insight.

[46] Transcript, 15 November 2024, internal page 49.

in the inspection system".[47] Information can be sought and analysed before, during and after the inspection, and it may sometimes only be practicable to seek information shortly before or during or even following the inspection.

Issues raised at Consultants' focus group

31. As the Inquiry knows, there were a number of focus group meetings during the course of the February 2016 inspection visit. These included a consultants' focus group i.e. a meeting for consultants across the hospital, not specific to any department, which took place on 17 February. The recollection of Julie Hughes, the inspector who conducted that focus group, was that perhaps 14-15 consultants attended.[48] The notes of that meeting have not been found, but notes in a diary made by Ms Hughes referred to themes of *"bullying, lack of support, staffing"* [INQ0017319], and she told the Inquiry that it would have been standard practice to inform the medical director of those concerns, *"as he carried overall responsibility for medics across the Trust"*.[49] Ann Ford's understanding too was that these concerns were raised with the medical director.[50] CQC accepts, as did Ms Ford and Mr Dzikiti in their oral evidence, that it should have been followed up and then escalated to the chair of CoCH if a problem remained.[51]

32. CQC notes that other focus group notes, which have been retained and disclosed, show a broadly positive view: see the Admin and Support Workers Focus Group [INQ0017324]; the Registered Nurses and Midwives Focus Group [INQ0017427]; the Matrons Focus Group [INQ0017398]; the Student Nurses Focus Group [INQ0017431]; and the Governors Focus Group [INQ0017292].

Consideration of data

[47] This is how it was characterised in the questions to Mr Dzikiti – transcript, 14 January 2025, internal pages 69-72
[48] Transcript, 15 November 2024, internal page 103.
[49] Transcript, 15 November 2024, internal page 124.
[50] Transcript, 15 November 2024, internal pages 64-65.
[51] Transcript, 15 November 2024, internal pages 91-92

33. The CQC witnesses who gave evidence on 14 and 15 November 2024 were questioned (entirely understandably) on the basis that the intelligence data pack relating to the Children and Young People service [INQ0101422] inaccurately stated that there were no serious incidents reported to NHS England when in fact the death of Child D had been reported on STEIS [INQ0108752]. As is now apparent from the witness statement of CQC data analyst Lyn Andrews [INQ0108743], the STEIS report of the death of Child D is in fact one of the seven serious incidents reported between November 2014 and October 2015 that is included within the Maternity and Gynaecology data pack [INQ0103668, pages 7 and 9]. It was also included within the intelligence presentation given on 16 February 2016 [INQ0103620 at page 26]. This was a presentation provided to all the inspection teams. It gave an overview of data regarding Never Events and Serious Incidents (page 9), Complaints (pages 11-12), Feedback from Stakeholders (page 13) and information from Surveys (page 15). Intelligence findings for the various core services were outlined. For Maternity, the number of serious incidents was provided, with the observation "No themes identified" (page 26): that the Maternity intelligence included the neonatal unit is apparent from the last bullet point on page 26, which expressly identified the staff vacancy rate for that unit.

34. CQC understands the Inquiry's concern (reflected in the questioning of Chris Dzikiti on 14 January 2025) as to the potential for confusion and accepts that the current system, whereby neonatal services are inspected as a standalone service, is a better one.[52] However, it would observe that: it was, at the time, standard practice for all inspections for neonatal care to be dealt with in the maternity and gynaecology data pack; as Lyn Andrews explains, she would expect inspectors and specialist advisors to be aware of that[53]; all data packs would be sent to CoCH ahead of the inspection[54]; inspectors and specialist advisors were sent all the data packs and expected to read them[55]; the inspection team would have access to all the packs (both in hard copy on site

[52] See the oral evidence of Chris Dzikiti, transcript, 14 January 2025, internal page 57.
[53] Witness statement of Lyn Andrews at paragraphs 43 and 46 [INQ0108743].
[54] By email on 2 February 2016 [INQ0108749].
[55] Witness statement of Lyn Andrews at paragraphs 24 and 46 [INQ0108743].

and electronically)[56]; inspectors could review the detail of any serious incidents in the standard data packs[57]; all inspectors and specialist advisors would (as set out above) attend the intelligence presentation; the Maternity and Gynaecology data pack expressly referred to the neonatal unit[58]; and the expectation would be that teams would share and/or flag up significant information as appropriate.[59]

35. In relation to the NRLS reports of the deaths of Children A, C, D, E and I, as again Lyn Andrews' statement explains,[60] the CQC data analyst team would filter out the incidents categorised by the provider as "no harm" or "low harm". This reflects the sheer volume of reports made on NRLS. It is CQC's position that this is not an unreasonable approach to have taken, particularly as CQC has to be able to identify the relevant set of reported incidents in NRLS (now LFPSE) that map to the statutory notifications (including deaths, and serious injury) required from each provider. The definition of what is reportable and grading of incidents is sent out by NHS England, rather than being determined by CQC.[61]

36. When Ann Ford gave evidence, she was questioned on the basis that the CoCH data (if complete) would have met the outlier threshold for mortality

[56] Witness statement of Lyn Andrews at paragraph 46 [INQ0108743].
[57] Witness statement of Lyn Andrews at paragraph 46 [INQ0108743] and [INQ0108753].
[58] See the reference on page 4 to the level of neonatal unit; the description of neonatal critical care provision on page 5; the further references to the neonatal unit (adjacent to the descriptor "Effective") on page 6; and the references to the national neonatal audit programme questions on page 11 [INQ0103668]. Whilst it is right to note also page 18 (which explains that if a new born baby requires treatment in a special baby care unit or neonatal intensive care unit where the care is delivered by a paediatrician, this will be included under the children's care core service), that simply (and correctly) reflects the way in which the inspection is organised (see also page 14 of INQ0017286); the fact remains that data regarding neonatal care is expressly referenced in the maternity and gynaecology pack.
[59] See the oral evidence of Chris Dzikiti, transcript, 14 January 2025, internal pages 56 - 57.
[60] Paragraphs 48-50 [INQ0108743].
[61] See the witness statement of Lisa Annaly at paragraph 5.4 [INQ0108743]. Helen Cain was asked during her oral evidence about testing the system of reporting and categorisation and confirmed that this was tested: *"we talked about incidents with numerous members of staff about incident reporting, about what would be reported, how it would be reported, how things were investigated, how lessons were learnt."* She *"looked at the review reports to ensure that the mortality and morbidity process was being followed, that the appropriate information was included in the report, if there were any lessons learnt, what the actions were, and how they were disseminated to staff, where they would be discussed …"* transcript, 14 November 2024, internal pages 33-36. It would be routine in an inspection at that time to pick a random sample of serious incidents to review and look at those in terms of grading, learning, harm etc. CQC used also to monitor consistency of reporting to NRLS and can track timeliness of reporting to LFPSE.

and answered accordingly.[62] The Inquiry now has the statement of Lisa Annaly, which describes CQC's outliers programme [INQ0108742], and further evidence (written and oral) from Professor Sir David Spiegelhalter.[63] As explained by Professor Spiegelhalter, the outlier detection system that he helped set up was looking for what he described as *"really extreme results"* rather than just *"high"* results, because the latter would be *"completely impractical"*. He also explained that, from a statistical as opposed to a clinical perspective, the increase in deaths in 2015 *"would generally be considered sufficient to trigger an alert signal, someone should look at this locally. But not extreme enough to be considered an outlier … There are about 150 neonatal units in the UK covered by MBRRACE and therefore we would expect one signal of this magnitude to occur each year just by chance alone. Through no underlying cause, nothing special changing at all."* He explained that the data would justify *"an alert, an internal investigation"* within CoCH but from a national level *"is not very surprising at all"*. Thus, even if there had not been the time lag in the submission of data, it would not have been identified as an outlier.[64]

CQC Insight

37. Ian Trenholm's second statement described a tool called CQC Insight, which brought together in one place information about services to support inspectors in monitoring the quality of care [INQ0012634, paragraph 193]. It was put to Chris Dzikiti during his oral evidence that *"it would follow … from the fact that at the inspection in 2016 the CQC were unaware of uncreased mortality at the Countess of Chester, CQC Insight had not identified that increased mortality".*[65] Whilst it is of course correct that CQC was unaware of the increased mortality, CQC Insight was not in fact in place at the time of the February 2016 inspection. It was developed in 2016, but postdated this

[62] Transcript, 15 November 2024, internal pages 41-43.
[63] Second witness statement of Professor Spiegelhalter [INQ0108786] and transcript, 15 January 2025.
[64] By contrast there was a maternity outlier alert for puerperal sepsis and other puerperal infections identified in 2015 [see, for example, INQ0002650].
[65] Transcript, 14 January 2025, internal pages 35-36.

inspection. As at February 2016, the tool used by CQC was an intelligence monitoring tool.[66]

B. Events from 30 June 2016 to the charging of Lucy Letby

38. Alison Kelly followed up her telephone conversation with Ann Ford by email of 30 June 2016 [INQ0017411]. CQC submits that it is striking that she made no mention of there being any concerns about babies having been deliberately harmed at this time. She informed CQC that CoCH had *"commissioned an independent review of the unit from the RCPCH, we anticipate this will be commenced in the next 4 weeks"*. (For the avoidance of doubt, the terms of reference for this review were not provided with this email (see Chris Dzikiti's second witness statement at paragraph 23 [INQ0108866]). The email then went on to detail a comprehensive range of management interventions (including a proposal to limit the neonatal unit to 'Level 1' babies with an action plan to be developed by the following day; a review of incident reporting data; a deep dive into staff rotas; a review of environmental issues; a review of any staff competency/performance issues; a review of PALS/Complaints data; and a review or Coroners' referrals).

39. As is set out above, Ms Kelly's email has incorrectly asserted that the thematic review had previously been provided to CQC. On reflection, CQC considers that it would have been best practice to have requested sight of the review at this stage instead of relying on CoCH's summary of the conclusions, although it is unlikely that this would have led CQC to respond in any different manner, as neither the thematic review nor Dr Brigham's report highlighted potential concerns about staff members harming babies. What these reports did appear to show (taken together with the 30 June 2016 email) was that there was an increase in neonatal mortality at CoCH, that this was being

[66] See the witness statement of Lisa Annaly at paragraphs 2.2.3 to 2.2.4 [INQ0108742]. As she also explains in the statement at paragraphs 2.2.4-2.2.5, since late 2023 there has begun a move away from CQC insight to a set of dashboards aligned to the Single Assessment Framework (although CQC Insight is still available for inspectors to access it is no longer updated). For NHS Trusts, a range of mortality indicators have been incorporated into these dashboards, including indicators developed by CQC as well as by external bodies that also monitor mortality and other outcomes.

investigated in detail, and that appropriate mitigations were in place. (See further Ann Ford's comments in her third witness statement at paragraphs 7.1-7.3 [INQ0108375] and in her oral evidence[67]). CQC notes that this view was shared by NHS England at the time.[68]

40. CQC accepts, nonetheless, that greater professional curiosity was appropriate at this point. This email at least suggested that information which should have been brought to CQC's attention during the February 2016 inspection had not been properly brought to its attention. Having reflected during the course of this inquiry, CQC takes the view that it should have explored with CoCH *why* this information had not been shared earlier. [69]

41. The chronology of CQC's interactions with CoCH after this date are set in detail in Ian Trenholm's second witness statement at paragraphs 78ff [INQ0017809] and is not repeated here. CQC does however draw attention to the matters set out in the following paragraphs.

42. On 7 July 2016, Ruth Millward emailed CQC regarding the *"concerns raised regarding neonatal mortality"*, indicating that an independent review from the RCN and RCPCH review had been requested, and noting her understanding that the neonatal unit's admission criteria had been amended to focus on lower risk babies [INQ0017328]. Again, however, CoCH failed to inform CQC at this stage that concerns had been raised by doctors that babies may have been deliberately harmed.

43. On 24 August 2016 a CQC Inspector and Inspection Manager attended an engagement meeting with CoCH (Ian Harvey, Sian Williams, Ruth Millward) [INQ0017296]**.** The minutes record: *"Key risk areas — Maternity / Neonatal services — external review planned for next week. Copy of report requested once available."* CoCH again failed to take this opportunity to draw concerns

[67] Transcript, 15 November 2024, internal page 69. CQC accepts, as did Ms Ford, that no consideration was given at that time to whether there should be an addendum to the published report: transcript, 15 November 2024, internal pages 72-74.
[68] See the statement of Margaret Kitching at paragraphs 71-72 and 138 [INQ0107036].
[69] See the oral evidence of Chris Dzikiti, transcript, 14 January 2025, internal pages 94-97.

about possible staff involvement in the deaths of babies to the attention of CQC.

44. A further engagement meeting took place on 22 December 2016 [INQ0017298], at which CQC was informed that the RCPCH report was at draft factual accuracy stage and it requested a copy of the final report [INQ0008075]. As CQC now understands, the RCPCH's final report had in fact been sent to CoCH on 28 November 2016, i.e. prior to this engagement meeting, and as Julie Hughes confirmed in her oral evidence, it was CQC's expectation that it would be told that they had the final report and that the report would be provided to CQC in a timely fashion.[70]

45. As set out in Chris Dzikiti's second witness statement at paragraphs 21-26, CQC had previously understood that no request by CQC for the terms of reference for the RCPCH Review had been made. However, having re-reviewed the documents in the course of drafting these closing submissions, it has become clear that CQC did, in fact, request a copy of the terms of reference on 30 January 2017 [INQ0106564].[71] Ms Millward also shared with CQC a letter sent by Alison Kelly to NHS England (dated 21 December 2016).[72] In that letter CoCH explained that it had "*only just received"* the final approved document, that the report found that a further independent case review was required of relevant cases, and that this was being undertaken by a neonatologist who required a secondary pathology review on a small number of cases. CoCH explained that *"As a consequence, we currently do not have a final report of this part of the review and therefore are not comfortable in sharing the Royal College report until we have the details of the case review."* The letter went on to note that *"the safety of our unit is paramount and on the day the review team left the Trust, they assured us that*

[70] Transcript, 15 November 2024, internal pages 127-128. On 17 January 2017, Ruth Millward emailed CQC to explain that CoCH had in fact had a copy of the final RCPCH report as at the date of the December engagement meeting [INQ0106564].
[71] Although what appears to have been provided in response to the request was an "RCPCH review preparation list" [INQ0017281] rather than the terms of reference [INQ0009591].
[72] See Ian Trenholm's second witness statement at paragraph 81 [INQ0017809] and the letter at [INQ0017397].

there were no immediate actions or concerns." CQC considers that it was reasonable to have acted consistently with that assurance.[73]

46. On 17 February 2017, following publication of the RCPCH report, a CQC Inspection Manager and Inspector/Relationship Owner met with CoCH (Tony Chambers, Ian Harvey, Alison Kelly, Sian Williams, Ruth Millward) [INQ0017300]. A strategic update was provided, which again made no reference to any suspicions of deliberate harm – a further missed opportunity to inform CQC about the position.[74]

47. On 22 February 2017, the CQC Inspection Manager followed up this meeting and requested the updated action plan to implement the RCPCH review [INQ0017301].

48. The detailed action plan [INQ0017410] which was then provided to CQC on 22 March 2017 (see Ian Trenholm's second witness statement at paragraph 86 [INQ0017809]) did not directly engage with risks posed by members of staff deliberately harming babies at all. This was despite the fact that, as it now transpires, Ian Harvey informed the NHS England Regional Clinical Director for the North that there was a concern that there was *"a connection between a particular individual and neonatal deaths"* on 29 March 2017 (i.e. a week after the action plan was shared with CQC) (see Professor Sir Stephen Powis' witness statement at paragraph 549 [INQ0017495]). CQC notes that even in this conversation with NHS England, CoCH appears to have been opaque in its explanation. While it cannot be certain, so far as CQC is aware, NHS England did not raise these concerns with CQC at this time (see Chris Dzikiti's second witness statement at paragraph 26 [INQ0108866]).

49. Not only did the action plan not explicitly address the risk of deliberate harm, but there is no suggestion that this matter was raised when that plan was

[73] On 3 February 2017, CoCH provided CQC with background for a media briefing which included the observation from RCPCH that *"…we do know that the Trust acted quickly on the key recommendations"* [INQ0017392].
[74] Oral evidence of Ann Ford, transcript, 15 November 2024, internal page 77.

discussed at the 13 April 2017 engagement meeting with CQC (Alison Kelly and Ian Harvey attending for CoCH) [INQ0017302].

50. It appears from the information available to CQC that CQC first became aware of a criminal investigation into deaths on the neonatal unit at CoCH in May 2017 (see Ian Trenholm's second witness statement at paragraph 94 [INQ0017809] and Lorraine Bolam's email [INQ0017303]).

51. A further engagement meeting took place on 31 May 2017 at which CoCH explained that *"…current action plan remains in place with twice daily 'safety huddles' now established. These include lead representatives from the labour ward and neonatal. A greater number of key individuals including consultants join these huddles in times of increased need in the department."* [INQ0017304]

52. A Management Review took place on 9 June 2017. CQC noted that the neonatal unit remained voluntarily downgraded to Level 1 and that a police investigation was currently underway. CQC considered the following options: *"-carrying out a focused or comprehensive inspection -gathering more information -referring the concern or sharing the information of concern with another public body -progressing to Stage 2 of the decision tree and considering what enforcement action to take."* It determined *"No current activity. The concerns were regarding 2015 and assurances have been provided that processes in place to monitor safe care and treatment…"* and noted that it should await the outcome of the police investigation [INQ0017407]. CQC has further reflected on its decision at this point and considers that it may have been too passive in its approach at this time (see further below).

53. CQC continued to maintain regular contact with CoCH see e.g. minutes of meetings on 12 July 2017 [INQ0017306] and 25 August 2017 [INQ0017307]. A further Management Review Meeting took place on 7 November 2017, at which it was noted that the police investigation was ongoing and the meeting recorded that NHS England would co-ordinate and update for all

stakeholders. As recorded at [INQ0017407] CQC considered a number of options *"-Need for a focussed inspection -Continue monitoring at engagement -Contact the police -Contact Margaret Kitchen (NHSE)"* and decided to "*… continue monitoring at engagement to ensure safe processes continue as assurance. Nick Smith (Head of Hospital Inspection) to contact Margaret Kitchen at NHSE for an update To consider including neonatal service at next inspection when presented in RPM document"*. Reasons for not proceeding with the other options were given as *"Need for a focussed inspection discounted as assurances provided that processes in place by the trust to keep patients safe. Not contacting the police as previous agreement with stakeholders that NHSE would co-ordinate…"*[75]

54. In accordance with this approach, CQC and CoCH continued to consider the neonatal unit at engagement meetings (see e.g. the 11 December 2017 meeting [INQ0017309]).

55. Following the arrest of Lucy Letby, CQC was involved in the Incident Coordination call of 4 June 2018 [INQ0017334] and Incident Coordination Panel Meetings of 10 July 2018 [INQ0017335], 22 October 2018

[75] CQC carried out a routine inspection of CoCH in November-December 2018. CQC notes that in her oral evidence on 24 February 2025 Dr Susan Gilby asserted that CQC did not inspect *"Women's and Children's Services" "because of"* the ongoing police investigation which, she said, *"to me, didn't make any sense"* [transcript, internal pages 130-132]. However, by this time CQC's approach to inspection was risk-based. Rather than undertaking a full comprehensive inspection, CQC's approach was to consider the current intelligence held regarding a hospital and the feedback received from stakeholders and to focus on the services which from a risk-based perspective most warranted inspection. Its reasoning in relation to the plan for inspection of CoCH in 2018 is set out in its Inspection Proposal and Regulatory Plan [INQ0017311]. This noted that the neonatal unit was *"on enhanced surveillance due to ongoing police investigation into neonatal deaths"* and that it remained a level 1 unit [page 6]. There was a decision to focus on specific services that were at that time higher risk: in respect of Urgent and Emergency Care there had been *"ten serious incidents, all never events"*; high inpatient mortality rates were reported for Medical Care; and there were a high number of complaints, and whistle blowing, in respect of Surgery [pages 16-17]. The decision not to inspect the Children and Young People, or Maternity Services, thus reflected the relative assessment of risk. Specific concerns highlighted in the PIR and by analysts relating to surgical site infections and staff turnover could be investigated within the Surgery core service and through the well-led assessment: see the second witness statement of Ian Trenholm [INQ0017809] at paragraph 112. Insofar as the neonatal unit was concerned, it was not the fact of the police investigation itself, but the fact that CoCH's response to the increase in neonatal mortality (downgrading the unit, responding to the RCPCH review, increased surveillance) satisfied CQC that risks were being appropriately managed. CQC notes also Dr Gilby's "feeling" that there was *"a bit of an agenda in the terms of that the CQC were more open to finding negative things than perhaps they had been in 2016"* [transcript, 24 February 2025, internal page 34]. CQC rejects this assertion.

[INQ0017332], 28 January 2019 [INQ0017414][76] and 5 April 2019 [INQ0017402].

C. Particular Issues Raised by the Inquiry

56. **CCTV:** CQC's position regarding the use of CCTV in neonatal wards remains as set out in its opening submissions at paragraphs 20-23 and in Ian Trenholm's first witness statement at paragraph 164ff [INQ0012634]**.** CQC acknowledges that the use of CCTV in neonatal care *could* contribute to improving safety, through enhanced monitoring and accountability and the provision of parental reassurance, and notes that anonymous footage could be used for training and learning. However, there are counter-arguments, regarding privacy concerns, legal consent issues, and that the use of footage could make the focus on risk reactive (i.e. after the event).[77] It could also undermine professional trust. CQC considers whether or not it is appropriate for hospitals to deploy CCTV to be a fact-specific question that falls to be addressed by each Trust in light of the specific circumstances at that Trust. In cases where CCTV is appropriate, the CQC has issued guidance to support its lawful use.[78] As set out in its opening statement, CQC has the power to impose conditions on registration by virtue of sections 12(5) and 15(5) of the Health and Social Care Act 2008 and CQC considers that it can (if it were to be judged appropriate) use these powers 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.

[76] CQC notes that at the meeting in January 2019 it was suggested, in response to a query regarding a Regulation 12 investigation, that this would take place following the police investigation and would need to be completed within three years of the allegation. It would, however, have been unlikely at that stage that CQC could complete an investigation (which requires significant resource and time) and bring a prosecution within the statutory time limit. CQC has previously asked the DHSC to consider changes to the statutory framework to extend this period, due to the significant challenges that it can present, but this has not to date been taken forward.

[77] CQC notes the evidence of Professor Sir Stephen Powis on behalf of NHS England that it proposes to undertake a number of pilots with neonatal units regarding the use of CCTV: transcript, 17 January 2025, internal pages 53-4.

[78] A copy of this guidance was disclosed by CQC with its opening submissions but does not appear to be on Relativity. However, a near identical version of the guidance, disclosed by DHSC, is at INQ0107938.

57. **Management of Controlled Drugs:** CQC expects that Trusts will meet the CQC's fundamental standards, including the safe management of controlled drugs. Regulation 12 of the 2014 Regulations requires that registered persons ensure "the proper and safe use of medicines". NHS Trusts, as "designated bodies" under regulation 7 of the Controlled Drugs (Supervision of Management and Use) Regulations 2013, are also required to appoint a Controlled Drugs Accountable Officer. CQC publishes a register of Accountable Officers and assesses applications to be included on this register against the requirements of the 2013 Regulations. The 2013 Regulations are supported by guidance, which CQC expects Accountable Officers to follow (see Ian Trenholm's first witness statement at paragraphs 166-187 [INQ0012634]).

58. CQC does not have a position on whether in any particular case electronic access to drug-storage cupboards is required and/or whether particular protections regarding access to insulin is required (see the oral evidence of Chris Dzikiti, transcript 14 January 2025, internal pages 113 to 115) and does not provide specific guidance relating to security arrangements for the storage or administration of medicines on neonatal units. Trusts are expected to follow national guidance and relevant professional guidance. CQC will, however, reflect on any recommendations regarding the storage of drugs as made by the Inquiry.

59. **Accountability of senior NHS Managers:** as set out in Ian Trenholm's first witness statement at paragraphs 33-47 [INQ0012634], the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 provide the current regulatory framework. Of particular relevance to the question of whether senior NHS managers are sufficiently accountable are the following:

    a. Regulation 5 of the 2014 Regulations, which applies to directors/those performing equivalent functions and requires that such people be "fit and proper persons". The 2014 Regulations make detailed provision for how that requirement should be applied. The Regulations are supported by CQC's *Guidance for providers on meeting the regulations*

[INQ0010466].[79] As the Inquiry knows, NHS England published in August 2023 a fit and proper person test ("FPPT") framework for board members.[80] This is being used by CQC on well-led inspections. There is now an expectation that the chair of an NHS organisation can show evidence that appropriate systems and processes are in place to ensure compliance with the FPPT framework. When undertaking well-led reviews, CQC inspectors will consider the quality of processes and controls supporting the FPPT, the quality of individual FPPT assessments, board member references and the collation and quality of data held by the NHS organisation relevant to the FPPT process. Whilst it is not for CQC itself to determine whether individuals meet the FPPT, CQC will interview the chair to ensure that they have the necessary assurance regarding directors and will look at *"the quality of the information"* held.[81]

b. Regulation 19 of the 2014 Regulations, which applies to employed persons carrying on a regulated activity (as defined in Schedule 1) and also requires that they be "fit and proper persons" – which by Regulation 19(1)(a) includes a good character requirement.

c. Regulation 20 of the 2014 Regulations, which imposes a duty of candour on registered persons in relation to care and treatment provided to service users.

60. CQC notes further that how effectively NHS Trusts are managed is considered by CQC as part of the Single Assessment Framework and that this affords a degree of accountability (see Ian Trenholm's first witness statement at paragraph 226 [INQ0012634])

61. As to the question of whether further regulation of NHS managers as a profession is required, CQC takes the view that serious consideration should

[79] CQC's current well-led guidance is under review.
[80] CQC understands that the framework will be reviewed after 18 months.
[81] Oral evidence of Tom Kark, transcript 17 January 2025, internal page 17.

be given to such a proposal, but it has no settled view on the manner in which such regulation should be implemented (see the oral evidence of Chris Dzikiti, transcript, 14 January 2024 internal page 128). It has recently submitted a detailed formal response to the DHSC's consultation on this issue (which can be provided to the Inquiry if it wishes to see it).

a. CQC agrees with the principle of regulation of NHS managers but takes the view that this needs form part of a wider cultural change within the NHS. CQC considers that the introduction of any such regulation should be phased so as to prevent over-burdensome processes and resource time.

b. CQC agrees that there should be a mandatory professional register of NHS managers (and that there may be a benefit in having a voluntary or mandatory register for health and social care managers in the independent sector).

c. CQC considers that there should be a process for ensuring that managers who have committed serious misconduct are permanently excluded from NHS management roles in future.

d. CQC considers that a system of regulation should apply to chairpersons, non-executive directors, senior strategic level managers and leaders or very senior managers, all NHS staff aspiring to be board level directors, and senior managers and leaders.

e. CQC considers that a system of regulation should also apply to appropriate arms-length body board members (e.g. NHS England), board level members in all CQC registered settings, managers in the independent sector delivering NHS contracts and managers in social care settings; and

f. CQC has no settled position on the issue of dual registration but recognises that it carries a risk of duplication, increased time/costs and ambiguity of responsibility.

62. **Safeguarding:** in its *Further Note on Written Closing Submissions*, the Inquiry requested Core Participants to address a number of key issues where applicable, including safeguarding.

63. As to Query A(a): CQC has safeguarding responsibilities. These include identifying safeguarding concerns in information provided to CQC and, where appropriate, making referrals to the relevant local authority or police for further investigation.

64. While CQC does not itself investigate safeguarding incidents (that is a matter for the local authority), it does seek assurance that providers have safeguarding systems, processes, and policies in place, that these are followed by staff, and that providers have the training, supervision, and governance to ensure staff are identifying, responding to, and reporting safeguarding concerns appropriately. CQC's assessment framework focuses on five key questions (safe, effective, caring, responsive to people's needs, well-led). Safeguarding is one component of the safety question and CQC's expectations of providers[82] include the following: that there is a strong understanding of safeguarding and how to take appropriate action; there are effective systems, processes and practices to make sure people are protected from abuse and neglect; and that there is a commitment to take immediate action to keep people safe from abuse and neglect. CQC expects providers to be aware of and following relevant best practice guidance.[83]

65. As to Query A(b): CQC considers that safeguarding obligations apply to all the Core Participants listed by the Inquiry, although the way in which such obligations fall to be discharged will vary and depend on the role, responsibilities and remit of the particular organisation.

[82] These can be found on CQC's website here: https://www.cqc.org.uk/guidance-regulation/providers/assessment/single-assessment-framework/safe/safeguarding.
[83] CQC's website identifies key best practice guidance and includes the *Working together to safeguard children* guidance.

66. As to Query A(f): CQC discharges its safeguarding obligations via its inspectors and employees in a number of ways as described above and below. CQC's safeguarding and closed cultures team came into place in April 2023 and committed to reviewing and updating safeguarding training. Its initial focus was on adult safeguarding training, as the last roll-out of training in adult safeguarding had been in 2019 and CQC had identified a need for this to be reviewed and redelivered. Bespoke adults safeguarding training has been rolled out through late 2023 and 2024.[84] In terms of children's safeguarding training, there was a large roll out within CQC of training between 2021 and 2022. In 2024 this training was reviewed, expanded and updated[85] and the intention is to develop the safeguarding children's training so that it aligns with the safeguarding adults training now in place, including delivery by subject matter experts.

67. Most information other than that received in assessments is provided to CQC by way of its National Customer Service Centre. This information is screened for safeguarding concerns. If CQC is the first to receive safeguarding information, this will be referred to the relevant local authority. Should inspectors identify a new safeguarding concern on assessment (or in any other way), they are expected to take steps to ensure a safeguarding referral is made, including making the referral directly if necessary.

68. Should inspectors identify failings in a provider's safeguarding arrangements, inspectors are expected to consider what regulatory action (including enforcement action where required) is appropriate. Conversely, inspectors are also expected to identify and report on positive practice.

69. As to Query A(k): CQC does not have a direct role in the identification and/or reporting of a sudden and unexpected death. Deaths reported through the Learn from Patient Safety Events (LFPSE) service are available for CQC

[84] Operations staff have always received safeguarding training, but level 1 training is now mandatory for all CQC staff regardless of role and level 2 and 3 training is mandatory for all staffing handling information of concern or working within operations. To date over 1200 employees have finished all three levels and sessions continue to be made available with increased monitoring of uptake.
[85] Initially for use in the induction of new staff.

operations teams to review through a weekly feed of LFPSE data provided to CQC. NHS England leads the LFPSE service and provides guidance on which events (including deaths) should be reported.[86]

70. CQC considers Trust-wide processes for safeguarding as part of the well-led assessment and as part of the assessment of core services will check on levels of training for staff and speak with staff to check their understanding of how to raise a safeguarding referral. CQC's published core service framework for the assessment of Children and Young People services shows the breadth of safety issues that may arise for consideration by inspectors: although this was based on CQC's previous inspection framework, it is still used to support inspections under the single assessment framework.[87] Under the heading Safeguarding, it includes a number of prompts, including *"How are safety and safeguarding systems, processes and practices developed, implemented and communicated to staff?", "Do staff receive effective training in safety systems, processes and practices?", "Do staff identify adults and children at risk of, or suffering, significant harm? How do they work in partnership with other agencies to ensure the are helped, supported and protected?"* The *Working together* guidance is specifically referenced as one of a number of relevant professional standards. CQC cannot, however, confidently state that adherence to the SUDIC process/Joint Agency Review is specifically assessed on each assessment.

71. Queries A(c)-(e), (g)-(j); B; C and D are not applicable to CQC.

D. Reflections

[86] See Lisa Annaly's witness statement at paragraphs 5.1-5.5 [INQ0108742].

[87] https://www.cqc.org.uk/sites/default/files/20200317_NHS_Acute_Core_service_framework_for_CYP_v7.pdf

72. As the Inquiry is aware, following criticism of the operational effectiveness of CQC by Dr Penny Dash, CQC is carrying out a review of how the Single Assessment Framework is working for NHS Trusts and how improvements can be made. CQC has set out its priorities for improvement and continues to publish updates on the progress it has made in improving the way it works.[88] As CQC has not fully or holistically completed this process, it is not in a position yet to set out its definitive view on where it needs to improve and how those improvements can best be given effect.

73. CQC has, however, reflected on the events that are the subject of this Inquiry and makes the following observations:

74. **Parallel Investigation:** as set out above, CQC first became aware of a police investigation into the events in question in May 2017. Lucy Letby was arrested in July 2018. CQC was aware that this was likely to be an extremely complex investigation and did not wish to interfere with or prejudice it. Given that the police were investigating and that Ms Letby was not working in the neonatal unit, CQC considered the risk level to be reduced to a safe level. As a result, CQC did not carry out its own investigations. On reflection CQC takes the view that it was a little deferential to the fact of the police investigation and that it should have carried out its own investigations into criminal/regulatory breaches. Were CQC to be presented with a similar scenario now, it would consider the matter under its own functions (see Ann Ford's third witness statement at paragraphs 9.1-9.3 [INQ0108375], the Specific Incident Guidance August 2023 at pages 9 and 17 [INQ0010482], and Ms Ford's oral evidence to the Inquiry, where she explained that whilst the police had primacy, *"we should have considered earlier whether or not we could have done something in tandem with the police … what we could have done is considered that earlier in case there was an opportunity for us to carry out our own investigation"*, in particular given the time limits on the exercise of CQC's powers[89]).

[88] https://www.cqc.org.uk/about-us/improving-how-we-work/latest-news
[89] Transcript, 15 November 2024, internal pages 78-84.

75. **Speaking Up:** CQC is committed to encouraging a "speaking up" culture in which NHS staff do not feel inhibited from reporting concerns. CQC expects all trusts to incorporate Freedom to Speak up in their policies and to encourage employers to raise concerns where appropriate. This is assessed under the well-led domain. (See Ian Trenholm's first witness statement at paragraphs 208-221 [INQ0012634]). As Chris Dzikiti confirmed in his oral evidence, CQC is increasingly seeing more people "speaking up" and this informs CQC's approach to inspections.[90]

76. **Invited Reviews:** CQC has reflected on the fact that CoCH commissioned reviews into its neonatal care and yet did not provide these reviews to CQC. CQC takes the view that that all external reviews into NHS services should be brought to its attention and is considering how this policy position can best be given effect. The Inquiry will note that CQC's approach is consistent with Recommendation 42 of the Morecambe Bay Investigation: *"We further recommend that all external reviews of suspected service failures be registered with the Care Quality Commission...and that the Care Quality Commission develops a system to collate learning from reviews and disseminate it to other Trusts"* [INQ0002385].

77. **Data:** obtaining accurate and timely data is plainly critical to CQC's ability to properly carry out its functions. CQC obtains data from a wide range of sources. It sets out its reflections below on issues that it understands to be of particular relevance to the Inquiry.

78. Statistical perinatal and neonatal mortality analysis , at the time of the 2016 CoCH inspection, was run by CQC using HES as the source data and MBRRACE-UK (which receives reports of deaths directly from NHS Trusts). CQC carried out an outlier analysis of perinatal deaths, which did not flag CoCH as an outlier (if it had, then CQC would have carried out specific follow up with CoCH as it did in relation to puerperal sepsis). Results from

[90] Transcript, 14 November 2024, internal pages 80 and 125-126.

MBRRACE's analysis of neonatal mortality relevant to the period of the inspection were only released in 2017 and 2018, i.e. after the inspection (see Lisa Annaly's witness statement at paragraphs 4.2.2.1 and 4.2.1.1 [INQ0108742] and Ann Ford's second witness statement at paragraphs 3.9-3.13 [INQ0107911]).

79. CQC understands that MBRRACE is now providing a tool to enable Trusts to analyse and identify changes in patterns of perinatal deaths within their own Trusts. CQC does not, however, have access to the surveillance data reported to MBRRACE nor to the tools, which are being used by Trusts for improvement purposes rather than as a focus for regulation. It is not currently clear that the dataset or the tool will be made available for CQC's use.

80. Similarly, CQC is aware of the new maternity outcomes signal system (MOSS) which is being developed by NHS England, to highlight safety issues in services. It remains unclear at this stage how frequently data will be available to CQC, and over what timescale the decision regarding access will be confirmed.

81. CQC is currently developing a standard set of outcomes to support its NHS well-led assessment process. CQC will consider these outcome measures, including mortality rates, as part of its planning, inspection and judgments for each Trust's well-led assessment. CQC has identified a draft set of key measures or metrics, from existing national data collections, that will be refined and developed. This approach will also take into account the different services that each NHS Trust provides and the availability of outcome measures nationally.

82. In terms of incident reporting, at the time of the 2016 Inspection CQC had access to NRLS and STEIS data. NHS England would provide a weekly feed of the data by way of Excel CSV file.[91] NHS England was responsible for setting reporting requirements. As described above, given the volume of NRLS reports, and for the purposes of the analysis presented for the

[91] Not all Trusts uploaded their data on a weekly basis, however.

inspection, CQC's analysts filtered out incidents marked "no" and "low" harm so that the CQC can focus on incidents where the harm is recorded as "moderate", "severe", or "death". The Inquiry will be aware that NRLS has now been replaced by the Learn from Patient Safety Events Service ['LFPSE'] where the same approach applies.

83. CQC has considered this issue and remains of the view that carrying out a detailed review of low and no-harm incidents would be disproportionate and that it is appropriate for CQC to limit its investigations to medium and high-harm incidents (save where it has reason to act otherwise). CQC would expect Trusts to have their own processes to identify and review themes and trends in any event.

84. Finally, CQC recognises the importance of maintaining relationships with Trusts so as to ensure the effective exchange of information. When CQC launched the Single Assessment Framework, it was decided that the role of relationship owner was no longer required. However, CQC has since launched a "Provider Engagement" pilot to test a new relationship-owner type role to run from September 2024 to February 2025 (results of the pilot are currently awaited). The pilot introduced the role of "oversight lead" with responsibility for undertaking specific review of performance data, board papers, recent cases, and incidents; leading on specific incident initial reviews; identifying headline findings, risks and areas of good practice for the engagement meeting preparation session; preparing routine engagement meeting agenda; and supporting engagement meeting preparation sessions. The role is not identical to the previous relationship owner role but the oversight leads will have a direct line of communication with the NHS trust.

85. **Curiosity**: fundamentally CQC considers that it should have been more professionally curious once it was informed of the increase in deaths. On reflection, on 30 June 2016, when CQC was first informed that there had been an increase in neonatal mortality at CoCH and that CoCH had carried out reviews into this, it should have asked to be provided with those reviews and

should have questioned CoCH as to why that information had not been made available during the course of the February 2016 Inspection. For the reasons set out above, CQC does not consider that asking that question would have led to a different approach on the facts of this case, but it does take the view that this would have been best practice.

86. CQC has learned from this. As such, when planning an inspection an MBRRACE outlier for neonatal mortality in 2022 was identified, CQC asked the following questions:
    - *What are the plans for covering the clinical director in the interim and longer term?*
    - *How often do consultant ward rounds take place on neonates?*
    - *How are gaps in middle grade doctors mitigated for neonates to comply with BAPM standards?*
    - *How many neonatal deaths have there been in the past 12 months?*
    - *Have there been any clusters of neonatal deaths and if so, have you identified any themes, trends or commonalities?*
    - *Were these deaths expected or unexpected?*
    - *What is the process for referring neonatal deaths to the coroner?*
    - *How many neonatal deaths have been referred to the coroner in the last 12 months?*
    - *Are you assured that safeguarding processes when there have been safeguarding concerns raised are robust?*
    - *How many neonatal deaths have been referred to the Child Death Overview Panel in the last 12 months and what were the outcomes of these?*
    - *The reason the fetal medicine review by _____ was requested and the Terms of Reference for this*
    - *Following the publication of the Clothier report, are there any concerns that neonatal deaths were as a result of avoidable harm?*

87. This approach was adopted in recognition of the importance of curiosity in these situations.

88. Further, CQC now has *Specific Incident Guidance* (originally introduced in 2018) that requires it to undertake initial assessment of incidents where services users (including neonates, children and young people) have sustained avoidable harm or have been exposed to a significant risk of avoidable harm. That initial assessment requires the decision maker to consider (i) whether the information about the specific incident raises concerns about ongoing risk of harm to users of the service which CQC should inspect and (ii) whether the information about the specific incident suggests the harm sustained was avoidable and may have resulted from a breach of a prosecutable fundamental standard. Following internal review, CQC may instigate a criminal investigation which may in turn, result in criminal enforcement action being taken. CQC has exercised these powers: see for example East Kent Hospitals University Foundation NHS Trust (prosecuted in 2021 for failure to provide safe care and treatment for mother and baby) and Rotherham NHS Foundation Trust (prosecuted in 2022 for failing to provide safe care and treatment for four babies).

89. **Memorandum of Understanding:** CQC is a signatory to the multi-agency Memorandum of Understanding ("MOU") published on 17 December 2024 [INQ0108740].[92] This provides guidance on the investigation of healthcare incidents where suspected criminal activity may have contributed to death or serious life-changing harm and explains that where a reasonable suspicion of a criminal offence of this nature is identified, an Incident Coordination Group ("ICG") will meet as soon as practical. The MOU requires that CQC be informed *"so that it can consider whether to carry out a parallel, but separate, monitoring, assessment and/or investigation of the healthcare provider to determine the impact of wider systems at the time of the incident"*. The MOU explains that CQC will most likely attend the incident coordination group meetings *"where the possibility of wider systems failures, including those that might give rise to provider level failure to provider safe care, are*

[92] See also the fourth witness statement of William Vineall on behalf of DHSC [INQ0108867] at paragraphs 3-6.

under consideration".[93] Where the police refer a case to the CPS, they must inform CQC within 7 working days so that CQC can consider whether to undertake monitoring, inspection and/or civil enforcement functions regarding any ongoing risk of harm to patients or service users, and/or whether to carry out a parallel, but separate, investigation of the healthcare provider to determine if it has breached any relevant regulations, including a failure to meet regulations 12, 13, 14 or 22 of the 2014 Regulations.[94]

E. The request to pause the Inquiry

90. By email dated 23 February 2025 the Inquiry invited Core Participants to comment on the formal request to pause the Inquiry, including the applicable law. CQC's comments below relate only to the law. It does not seek to make submissions as to what the Chair should do in response to this request.

91. CQC notes that, in addition to requesting the Chair to pause the Inquiry under section 17(3) of the Inquiries Act 2005, a request has been made in parallel to the Secretary of State for Health and Social Care to suspend the proceedings of the Inquiry under section 13 of the Act. Section 13 has recently been considered by the Supreme Court in the case of *In re JR 222* [2024] 1 WLR 4877 where, at paragraph 62, Lord Stephens observed that *"not only is there no prohibition in the Act on an inquiry proceeding if there are criminal proceedings but the Act expressly envisages that in the exercise of discretion an inquiry can continue if there are such proceedings."* Lord Stephens further added (judgment, paragraph 85) that it would be contrary to the statutory purpose of an inquiry (*"which is to address public concerns"*) *"if an inquiry were to be suspended unless it was necessary to do so for one of*

[93] Paragraphs 5.6 to 5.8 of the MOU. Where the incident falls within the remit of the Maternity and Newborn Safety Investigations ("MNSI") programme, MNSI will also be informed so that it can ensure it is able to discharge its functions: paragraph 5.10 of the MOU. There is also a formal information sharing agreement between CQC (which now hosts MNSI) and MNSI: this sets out the circumstances in which the MNSI team must share relevant information from its investigation with CQC's regulatory and enforcement teams to support CQC's work as regulator; it also sets out the circumstances in which CQC's regulatory and enforcement teams share concerns and information with MNSI: https://www.mnsi.org.uk/for-nhs/information-sharing-between-mnsi-and-cqc/.

[94] Paragraph 5.19 of the MOU. Paragraph 5.21 outlines the arrangements as between CQC and the police where CQC decides to carry out a parallel investigation.

the stated purposes". The Supreme Court thus read section 13 as imposing a high bar (namely a strict test of necessity for one of the statutory reasons specified) before suspension of a public inquiry by the minister would be appropriate, and considered that the mere fact of parallel criminal proceedings would not, without more, be sufficient to satisfy this hurdle.[95] The exercise of the power in section 13 is a matter for the Secretary of State (subject to a mandatory duty of consultation with the Chair), but the nature of that power (as construed by the Supreme Court) may be relevant to the Chair's consideration of the request to pause the Inquiry under section 17(3) of the Act.

92. Section 17 contains no express power to "pause" an inquiry, but provides that the procedure and conduct of an inquiry *"are to be such as the chairman of the inquiry may direct"* (section 17(1)) and that *"In making any decision as to the procedure or conduct of an inquiry, the chairman must act with fairness and with regard also to the need to avoid any unnecessary cost (whether to public funds or to witnesses or others)"* (section 17(3)). It may be arguable that section 17 empowers a chair to "pause" an inquiry where it would be unfair to continue.

93. Having regard to both sections 13 and 17, CQC suggests that:

    a. Halting an inquiry is principally a matter for the minister under section 13 (which expressly provides for suspension).
    b. The minister's powers under section 13 are highly circumscribed and can only be exercised, following consultation with the chair, where it is *necessary* for one of the statutory purposes.
    c. That a ministerial decision to suspend is subject to such a high bar suggests that a similar decision by an inquiry chair should be similarly constrained.
    d. If the fact that parallel investigations are ongoing does not, without more, require a minister to suspend an inquiry, it follows that the mere fact of

[95] *A fortiori*, it might be thought, in the present case where there are no parallel criminal proceedings but an undetermined application to the CCRC.

parallel proceedings would not, without more, require the chair to do so on grounds of fairness.

e. Assuming that section 17 does empower the Chair to "pause" the Inquiry, this would require the Chair to consider whether it would be fair to all the participants in the Inquiry to suspend it for an indefinite period pending a decision by the CCRC as to whether the case should be referred to the Court of Appeal, in circumstances where (as things stand) there is a conviction and matters have proceeded no further than a reference to the CCRC.[96]

Conclusion

94. CQC recognises that this Inquiry has been examining a wide range of issues that are of importance to its role as the regulator of NHS Trusts. It has no doubt that the findings and recommendations of the Inquiry will merit careful consideration and is committed to ensuring that, alongside the work which it is already undertaking in response to the Dash and Richards' reviews, it continues to reflect on the lessons to be learned from the tragic events at CoCH.

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4 March 2025

[96] Section 17(3) refers also to the need to avoid any unnecessary cost. However, section 17(3) requires the chair to have regard to this factor, rather than requiring the chair to act so as to avoid unnecessary cost. In other words, it is a relevant consideration, but no more.