Witness name: Ann Ford

Witness statement number: 3

Exhibits:1 [AF/39]

Dated: 18th October 2024

IN THE THIRLWALL INQUIRY

BEFORE LADY JUSTICE THIRLWALL

THIRD WITNESS STATEMENT OF ANN FORD

ON BEHALF OF THE CARE QUALITY COMMISSION

I, Ann Ford of the Care Quality Commission ("CQC"), Citygate, Gallowgate, Newcastle upon Tyne NE1 4PA, will say as follows:

1. Introduction

1.1 I make this statement to clarify and add detail to certain matters relating to the 2016 CQC inspection of the Countess of Chester Hospital ("CoCH") and issues arising from that inspection. I make this statement in my (then) capacity as the Head of Hospitals Inspections ("HHI"), a position I took up in 2014. Whilst in that role, CoCH fell within my area of responsibility.

1.2 I moved into the Head of Local System Review role within CQC in the autumn of 2016, returning to the North Region as Deputy Chief inspector in 2019.

1.3 I am currently the Director of Operations Network North within the CQC. The CoCH sites fall under Network North, the area for which I am responsible.

2. Background

2.1 As indicated above during 2016 I was HHI.

2.2 This role meant that I was responsible for a team who engaged with and monitored providers of healthcare in the form of hospitals, community health services, and ambulance service providers to ensure consistent application of CQCs regulatory methodologies and compliance with health and social care regulation.

2.3 Each NHS Trust at that time had a Relationship Owner ("RO") who was a CQC inspector. The RO would be supported by an Inspection Manager ("IM"), and the HHI supports the IM and the team as a whole.

2.4 As indicated, CoCH fell within my area of responsibility. The RO for CoCH at that time was Deborah Lindley. The IM at that time was Bridget Lees.

2.5 It is the responsibility of the RO to plan their engagement and monitoring of providers in consultation with their IM and the HHI. The decisions on monitoring and engagement were made considering various sources of information including available national data sets ,information from the public and from the provider themselves.

2.6 One way an RO could gather information was by holding engagement meetings. Engagement meetings were set up at regular intervals by CQC with the providers including NHS trusts - these meetings were an opportunity to discuss performance, challenges and risks and the action the provider is taking to improve performance and manage risk. It was also an opportunity for CQC to update the provider about developments within CQC

2.7 Information such as statutory notifications of incidents from the Trust would also be considered as part of monitoring activity and risk assessment.

2.8 Statutory reporting requirements, such as the notification of incidents would be reviewed by the RO for the service and any follow up action required should then be recorded on CRM – the CQCs case management system used by inspectors.

2.9 CQC set notifications as a high priority data source for monitoring and determining follow up.

2.10 Tracking of notifications submitted to STEIS/NRLS/LFPSE that map to death, serious injury, abuse/allegations of abuse or events that stop service. These notifications were (and are still) flagged to Operations teams at CQC for review and are used to inform decisions regarding regulatory activity including inspections.

2.11 Where necessary, Inspectors can request from the trust, data analysis which would include more detailed analysis of notifications of incidents, information of concern and any whistleblower information that had been reported. These requests can be made pre, post and during an Inspection as well as for ongoing monitoring purposes. All the information gathered is used to support an ongoing view of safety and quality.

2.12 Providers may conduct local analysis of trends, and we would expect them to share any analyses with CQC if a risk was indicated or if requested.

2.13 Those organisations that collect and analyse national data relating to neonates would be expected to publish trends in this data at a national and regional level (e.g. NNAP Data Dashboard) and on some occasions at a local level. CQC monitors trends from these published data sets as part of its usual regulatory activity. All available data is also considered pre inspection to inform and target Inspection activity.

2.14 NHS trusts like all health and social care providers were assessed at inspection over five key questions, those being,

2.14.1 Are they safe?

2.14.2 Are they effective?

2.14.3 Are they responsive?

2.14.4 Are they caring?

2.14.5 Are they well led?

2.15 Each question had specific framework and lines of enquiry to be followed with standard questions and prompts to be used in inspection.

2.16 The Well led key question relates to governance and leadership, workforce, as well as assurance about service quality and the management of risks, and how these processes work from 'board to ward'

2.17 As well as managing the team, it was my responsibility to agree and sign off inspection programmes as well as lead and manage individual inspections as required.

2.18 It was my responsibility as HHI to be ultimately in charge of the inspection activity. It was not always the case that I would attend every inspection, however I did attend the inspection of CoCH in 2016.

2.19 As HHI it was also my responsibility to lead all enforcement activity in my geographical area and had final decision-making authority for any enforcement, however final decision on ratings of the Trust after an inspection fell to a Deputy Chief Inspector.

3. 2016 inspection – Planning

3.1 In February 2016 CQC planned an inspection of CoCH. This was a routine planned announced inspection. The inspection itself took place between 16th -19th February and 4th March 2016. There was also an out of hours unannounced visit on 26th February 2016.

3.2 As I said above, I was not always present at every inspection, however I did attend the inspection of CoCH.

3.3 Prior to the inspection I worked closely with the RO and IM to plan the inspection.

3.4 The PIR was sent to the Trust as was usual process. As explained above, the PIR is a standard set of questions and in addition there may be other questions asked or

information requested. The data was then analysed by the data analysts. For this inspection they were Lyn Andrews – senior data analyst and John Cunningham.

3.5 Hospitals inspections will often involve the use of Specialist Advisors ("SpA") in addition to CQC inspectors. This is because of the specialist areas that are being inspected, it is important that those inspecting have sufficient knowledge and experience to support a robust judgement of service quality. During the 2016 inspection the SpA's used were Dr Odeka, Mary Potter and Elizabeth Childs. Elizabeth Childs was also the inspection chair. This is an important role in ensuring that our inspections are rigorous and fair and that the judgements made are proportionate and accurate. The purpose of the Inspection Chair is to provide leadership to the inspection team, expert advice and support to the CQC Inspection Lead (a Head of Hospital Inspection or Inspection Manager) and to contribute, where appropriate, to the inspection report.

4. The other members of the Inspection team were CQC Inspectors Helen Cain Julie Hughes and Deborah Lindley. Deborah Lindley was also the Relationship Owner for the Trust. I also attended the Inspection in 2016 as did Bridget Lees. There were other inspectors also in attendance – a full list is at pages 7-10 of INQ0017286.

4.1 Prior to going on site, we prepared the inspection team for the inspection by holding briefing meetings. I led these meetings and shared the material included in the briefing packs. The briefing pack used for this inspection is at INQ0017286.

4.2 The briefing pack was a comparative analysis of a trust's performance using a standard set of indicators. This included available metrics on mortality and "outliers" and other contextual data about the service. During the preparation for the inspection of CoCH in 2016, the Statistical analysis of Healthcare Episode Statistics ("HES") by CQC as part of the "outliers" programme did not flag CoCH as an outlier for higher-than-expected rates of perinatal or late neonatal mortality for the period April 2015 to December 2015. This means that the data did not show a statistically significant difference between the actual number of deaths and expected number of deaths over this period. This is because the data for neonatal mortality was and still is published retrospectively and the data for 2015-16 was not available at the time of the inspection.

4.3 I think it is important to note that NHS providers did not and do not report all deaths to NRLS (or to STEIS) but focus on unexpected or avoidable deaths.

4.4 The National Archives do have the numbers of deaths reported for the trust – however the numbers are at trust level – e.g. April-end September 2016 has number of reports with level of harm as death, however they are for the whole trust and not specific to neonatal services.

4.5 Outliers in relation to puerperal sepsis were identified [INQ0002650]. The Outlier's programme was established by the Healthcare Commission (one of three

predecessors to CQC) in 2007 and initially included mortality indicators only. Maternity outliers were introduced in 2009 under the CQC. The programme routinely monitored patient level maternity and mortality data (HES referred to above) to identify statistical outliers at individual NHS acute trusts which may reflect concerns about quality of care.

4.6 If an outlier was identified an internal process was followed to ensure outliers were reviewed and the trust took remedial action. This included further analysis and review by clinical advisors and regional colleagues within CQC

4.7 Following publication of MBRRACE_UK report in 2017 (for births in 2015) a process was put in place where trusts reported to have mortality rate of more than 10% higher than average were logged on CQC case management and available to all inspectors via the Acute Insight report at the time.

4.8 Had the information regarding increased unexpected neonatal deaths been available at the time or prior to CQC inspection in 2016 this would have led to CQC exploring these with the trust. CQC would have sought assurance from the trust that the increase in unexpected deaths was being investigated and would have expected the trust to follow their morbidity and mortality process. CQC would expect the trust to consider whether there were any causal factors and if CQC was not satisfied that the risk to patient safety was being mitigated CQC would have followed up and appropriate regulatory action taken. Unfortunately, there were no indications that there was a significant increase in unexpected neonatal mortality and consequently it was not a line of inquiry followed at the 2016 inspection.

5. 2016 Inspection

5.1 On the first day of the inspection, I led a presentation for all the inspection team. This included a presentation by Lyn Andrews of the available data. At that meeting I set out what the plan was for each team in terms of where they were going and what they would inspect.

5.2 During the inspection itself CQC inspectors and SpA's observe practice at the hospital, seek feedback from staff and patients by speaking to them and holding focus group meetings, and observe the wider operation of the hospital. CQC placed posters around the hospital and provided comment boxes to ensure that people were aware the CQC were on site and that feedback could be provided to the inspectors should anyone wish to provide such feedback.

5.3 In addition to this the above, interviews were held with a range of staff members. The planned interviews are at INQ0017287. Unfortunately, CQC is unable to locate the notes from the meetings with Duncan Nichol, Ruth Milward, meeting with staff side representative, the safeguarding lead, the non-executive director for quality and safety

Alison Kelly, Lorraine Burnett Ian Harvey or the complaints lead. I am therefore reliant on my recollection of events. I cannot say with certainty that these meetings took place, but I don't recall there being any changes to the planned meetings. CQC has undertaken extensive searches to locate material held that may be relevant to the Inquiry. This is covered in my first two statements.

5.4 The inspection plan indicates that I was scheduled to interview Sir Duncan Nichol, Hayley Cooper, Sue Hodkinson, Tony Chambers and Ian Harvey.

5.5 The well led key question had a set of standard prompts so whilst I cannot recall all that was discussed in the interviews, I am confident that I would have explored leadership, management and governance of the trust and how the trust assures itself that it is delivering high quality care, how it supports learning and innovation and how it promotes an open and fair culture. These were and remain elements of the Well Led key question.

5.6 In addition to the questions above, in the interview with Ian Harvey we also would have asked questions regarding any challenges in the medical workforce, medical staff engagement, whether there were any risks regarding medical workforce and how such risks were mitigated.

5.7 In relation to staff side interviews, we would have asked how staff viewed and perceived the trusts leadership team and how leaders interacted with staff representatives and how they responded to concerns. We also asked about relationships between staff representatives and senior leaders and whether the relationship was open and productive.

5.8 Although I cannot find any notes from these meetings despite colleagues at CQC undertaking extensive searches, I have been asked to consider INQ0017319. This I understand is a note made by Julie Hughes during one of the focus groups attended by consultants across a range of services and not just Children and Young People. It is noted that some staff raised concerns regarding staffing levels, bullying culture, lack of support, these matters were raised with the medical director Ian Harvey on the same day – 17th February 2016. They were also discussed at the corroboration sessions the inspection team held at least daily. In addition, the issues regarding lack of responsiveness from leadership, and related cultural issues, coupled with nurse staffing concerns on the neonatal unit were shared with the trust during the feedback session and were included in the CQC inspection report.

5.9 I understand that in the early hours of **PD** February 2016 Lucy Letby attempted to murder child K. The CQC were undertaking an inspection of CoCH during the 16th and 17th of February 2016 however I understand that this criminal act was committed by Lucy Letby **I&S** at which time inspectors would not have been on site. From

the information available I understand that Lucy Letby committed the acts of murder and attempted murder when she was not in view of others.

5.10 Although CQC do observe one on one care it is not possible to observe all care delivered.

5.11 Each day during the inspection a corroboration meeting was held. At these meetings we discuss as an inspection team what we had observed. I chaired these sessions along with the inspection chair. The sessions were used to consider the evidence and highlight immediate risk or quality issues and consider whether there had been any regulatory breaches.

5.12 At the end of the inspection, I facilitated the initial feedback to the trust. The feedback sessions were in order to raise any immediate patient safety concerns to ensure that any urgent action that may be required was taken immediately. No indication of rating was given.

6. Post Inspection and preparation and publication of the inspection report

6.1 After the inspection was complete the inspection report was drafted. It will have been checked by the IM and myself.

6.2 The report would then have been presented to National Quality Assurance Panel. This is an internal CQC panel chaired by the Deputy Chief Inspector (DCI). The RO will present the findings from the inspection and make the recommendation for the ratings. The RO is usually supported by the IM and HHI at these meetings.

6.3 Ultimately the decision for the rating is made by the DCI as it was in this case.

6.4 Decisions on ratings were made based on evidence gathered. The CQC used ratings descriptors to guide decisions on ratings. All data gathered prior to and during the inspection would be used to support judgements on each key question. The ratings would then have been aggregated for an overall rating score for the trust. It should be noted that Neonatal units fall under Children and Young People core service, the concerns raised in relation to the neonatal unit in terms of staffing were therefore a small part of a larger core service and the rating is reflective of this.

6.5 Following the National Quality Assurance Panel the trust received a copy of the report. The trust then had the opportunity then to make representations in relation to matters of factual accuracy only. It was not a forum to challenge ratings.

6.6 If any errors were noted, the CQC would amend the relevant information and re-consider the ratings. The report would then go back in front of the National Quality Assurance Panel for the DCI to make a final determination of the ratings.

6.7 Once this was done the final report was published. The inspection report of CoCH was published on 29th June 2016.

6.8 Around the time of the publication of the report a Quality summit would be held. I cannot recall when the Quality Summit was held following the 2016 inspection of CoCH, it was either shortly after the report was published or on the day the report was published.

6.9 The purpose of the Quality Summit was to develop a plan of action, and recommendations based on the inspection team's findings as set out in the inspection report. This plan would be developed by the trust and where necessary with support from partners from within the health economy and the local authority.

6.10 Every Quality Summit considers –

6.10.1 The inspection findings

6.10.2 Whether there is planned action by the Trust to improve quality and whether that is adequate

6.10.3 Whether support should be made available to the Trust from stakeholders such as commissioners to help them to improve

6.10.4 Any regulatory action that may be required to protect patients is also considered

6.11 It was split into two parts: Part one – The CQC Inspection Team Leader / Head of Hospital Inspection (HHI) / Inspection Chair) chaired this section and summarise the results of the Trust Inspection Report to the Quality Summit. Part Two – was facilitated by a representative from NHS Improvement or the provider and will be focused on agreeing a high-level action plan in response to the findings of the inspection. The summit provided a robust discussion to ensure that actions were not short term and were focused on sustainable change. The actions were agreed by the trust, CQC and other regulators and professional partners.

7. Events of June 2016 onwards

7.1 Alison Kelly contacted me on 30 June 2016 and informed the rise in mortality rates within the neonatal service at CoCH both in 2015-16 and in 2016 -17 this was the first time I had been made aware of the issue.

7.2 I asked the Alison Kelly what actions had been taken, what actions were planned to mitigate the risk to patients. The actions were discussed, and confirmation of the actions being taken by the Trust is detailed in the follow up email I received from Alison Kelly on 30th June 2016 [INQ0017411].

7.3 I was reassured that the trust was commissioning the Royal College Paediatrics and Child Health ("RCPCH") to review the baby deaths, and the unit was being downgraded so the most poorly babies would not be cared for at CoCH. I thought this approach sensible and in the interests of safety until the cause of the issue was identified. This provided some assurance that any ongoing risks to patients were being mitigated.

7.4 CQC was also provided with the Trust communication plan [INQ0014419]. I would expect a document like this to be provided to CQC in such circumstances and for the Trust to inform CQC of plans through its communication lead.

7.5 It was not until May 2017 following engagement with the Trust that CQC was made aware that there was a criminal investigation into the neonatal deaths at CoCH.

7.6 During the course of the Lucy Letby trial, I was in regular contact with the CQC media engagement team. It is usual practice that media engagement colleagues at CQC prepare a draft press release which is reviewed by the Head of Inspection and signed off. There are usually therefore multiple versions before the final one is released. This is because of time constraints, once the information is available it needs to be released to the press as soon as possible. I have been asked to consider INQ0105344, INQ0017392, INQ0017716, INQ0105320 which are emails relating to the media briefings containing various versions of the briefings. One of the initial media briefings included a sentence that CQC inspectors were made aware of the increased mortality rates during the inspection of CoCH. This was not accurate and therefore removed from later drafts. I understand that a separate statement is being made by Kirsten Hanniford of CQC media engagement team who can provide greater detail regarding the media briefings.

7.7 I became aware and was concerned that CQC colleagues had entered into agreement with NHSE/I to be the sole holder of the records of CoCH related meetings and that the notes would not be shared more widely. I was concerned that CQC had entered into this agreement without legal advice or reference to our normal processes. I had not been involved in making that agreement. CQC has its own independent regulatory role and should carry this out without deference. I believe the “secret MOU” referred to in the email INQ0104509 is a term adopted by the emails author in referencing the agreement with NHSE/I. I am unaware of any secret MOU.

8. Dr Penny Dash review of the Care Quality Commission

8.1 The independent review into the operational effectiveness of the CQC by Dr Penny Dash provides criticism of CQC in general terms regarding poor operational performance, challenges with the Provider Portal, loss of credibility in the health and care system due to loss of sector expertise, concerns around the Single Assessment Framework (“SAF”) and lack of clarity regarding how ratings are calculated.

8.2 The majority of the criticisms relate to changes that took place more recently within the CQC and as a result of the implementation of the SAF rather than how the CQC was as an organisation in 2016

8.3 The methodology used in 2016 had been evaluated by researchers from Manchester Business School and The Kings Fund. It was commissioned as part of the CQCs 'learning by doing' approach. That report covered inspections carried out in 18 hospital trusts between September 2013 and April 2014. Exhibit AF39 **[INQ0108374]**
The authors found that the approach (used at the time of the 2016 inspection) had strong credibility, in particular through the use of specialists to inform assessments, and the granular detail of ratings within services rather than at provider level, with the report stating: "Overall CQC's new acute regulatory model receives more or less universal endorsement from stakeholders, not least from the hospitals themselves, and is seen as transformative in comparison with the form of regulation it replaces. It is regarded as much more credible, authoritative, rigorous and in-depth and much less likely to miss any issues of significant concern."

8.4 Many changes were made to the inspection process during and since the evaluation, areas where the report suggested further consideration included; preparatory work leading up to the inspection visit, training and deployment of inspection teams, the level of detail in the assessment framework of lines of enquiry and rating descriptors, how we ensure consistency of ratings and report our findings in the quality summit process which takes place after the inspection.

8.5 During the 2016 inspection there was work ongoing in all the areas mentioned above, for example we were allowing more time in the build up to inspections, revised the data packs used by inspectors, made reports clearer and were carrying out a review of post-inspection arrangements for quality assurance of reports and quality summits.

8.6 The SAF is currently under review following the Dash report

9. Reflections

9.1 I have reflected on areas in which CQC could have improved.

9.2 I am of the view that once the police investigation was launched CQC was deferential to the police. We understood that the police investigation was extraordinarily complex, and we did not wish to muddy the waters or interfere with this important investigation. In addition, the CQC consideration of the level of risk was reduced by the fact that there was a police investigation, and that Lucy Letby had been removed. However, I consider that this is an area where the CQC could potentially have been more professionally curious.

9.3 If such an incident occurred now, the CQC would consider the incident under its own regulatory functions including the possibility of taking parallel criminal investigation or civil enforcement.

9.4 Unfortunately, there was no whistleblowing or other communication of concerns to the CQC in relation to these deaths. I cannot say why this was. 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. I am certain we would have spoken to staff outside focus groups should they have asked for that, and that we would have acted on any concerns raised.

Statement of Truth

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

Name: Ann Ford

Signature:

Personal Data