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THIRLWALL INQUIRY

WITNESS STATEMENT OF LISA ANNALY

I, Lisa Annaly, of the Care Quality Commission ("CQC"), 2 Redman Place London, E20 1JQ , will say as follows:

1. Introduction

1.1 I am currently Deputy Director of Analytic Content at CQC a position I have held since April 2022. I lead one of the functions with the Data and Insight unit at CQC, and my function is responsible for the development and delivery of indicators and risk models derived from a range of datasets, about the quality of care in the services CQC regulates. Between April 2014 and April 2022, I was Head of Provider Analytics for Hospitals and during 2015-2016 my team oversaw the data monitoring and analysis relating to secondary healthcare services, including the provision of data analysis for the inspection of the Countess of Chester Hospital. (I was on I&S at the time of the inspection itself.) I was Head of Quality Risk Profiles (2010 – 2014) and before that Head of Information policy and research (2009 – 2010) at CQC. I worked at the Healthcare Commission, CQC's predecessor, between 2002 and 2007, first in its analytics function before moving into the methods function from 2004 onwards. My professional background has been in analytical and regulatory roles, with a focus on healthcare data analysis.

1.2 The facts in this witness statement are true, complete and accurate to the best of my knowledge and belief. In the course of preparing this statement I have consulted colleagues in my current and former teams in order to conduct checks where that has been necessary. Where I refer to information supplied to me by other people, the source of the information is identified; facts and matters derived from other sources are true to the best of my knowledge and belief.

- 1.3 When referring to documents already disclosed to the Inquiry the relevant reference is given where that is available (eg. [INQ000000])
- 1.4 The purpose of my statement is to assist the Inquiry as to the ability of the CQC to monitor mortality indicators, especially at the time of its inspection of the Countess of Chester Hospital during 2016 and 2017 and to the neonatal department in particular.
- 1.5 It addresses the following topics:
 - 1.5.1 The **available “data tools” and methodology** which the CQC used (and uses) to monitor and analyse mortality data in NHS trusts, and the extent to which these did (and do) include neonatal mortality.
 - 1.5.2 **Professor David Spiegelhalter’s evidence to the Inquiry** concerning the development and use of a “prospective mortality tool” by the CQC.
 - 1.5.3 In respect of the CQC’s **monitoring and inspection of the Countess of Chester Hospital:**
 - 1.5.3.1 The mortality data received in 2015-2016, especially that relating to neonatal mortality, and the sources of that data.
 - 1.5.3.2 Whether any of the CQC’s data tools and statistical analysis highlighted or flagged an increase in neonatal mortality, or any related concerns about neonatal mortality, at the Countess of Chester Hospital during 2015-2016. If so, what this identified and how this was shared with CQC inspection teams.
 - 1.5.3.3 Whether any of the CQC’s data tools highlighted an increase in neonatal mortality after 2016 at the Countess of Chester Hospital. If so, when this data was made available and what it showed.
 - 1.5.4 **Current use and access to neonatal mortality data.** What tools are in use and how the available data is analysed to ensure any increased mortality rates are identified and flagged to the relevant teams within the CQC.

1.5.5 **Reports of deaths to NHS England’s National Reporting and Learning System (“NRLS”) and the Strategic Executive Information System (“STEIS”)**. How NRLS reporting was shared with the CQC generally and made available to an inspection team during inspection, particularly during the time of the 2015/2016 inspection of the Countess of Chester Hospital. What data STEIS would have contained in 2015-2016 and how it was used by the CQC.

2. Available “data tools” and methodology relating to mortality data in NHS trusts

2.1 Overall Approach

2.1.1 Since its establishment in 2009, CQC has had a vision to be intelligence or insight driven in its approach to regulation. To deliver this vision, CQC has committed resources to the acquisition, analysis, dissemination and review of key datasets to inform how it monitors risk and informs its judgements of quality in services.

2.1.2 This has been achieved in three ways:

2.1.3 *(i) Provision of a suite of dashboards enabling ongoing access to indicators of quality and risk for each of the services CQC regulates.*

2.1.3.1 These dashboards (see paragraph 2.2 below) have evolved in line with changes in CQC’s model of regulation, and as datasets have evolved about the quality of care. Dashboards are refreshed in line with the availability of dataset updates – as determined by the processes for each dataset. Some of these may be updated on a weekly or monthly timeline, others are annual or biennial datasets. A suite of mortality indicators has been one of the datasets incorporated into these dashboards.

2.1.4 *(ii) Programmes that have tracked a focused set of priority indicators to ensure there is appropriate review and follow up of their results.*

2.1.4.1 CQC ran an outliers’ programme between 2009 and 2020 focusing on a set of mortality indicators for inpatient services and a set of indicators, including mortality, for maternity and perinatal (including neonates) services. This programme was initiated by the Healthcare Commission, one of CQC’s predecessor bodies, and continued by CQC. Briefly, outliers are indicators, metrics or other observed data that

deviate in a statistically significant way from that expected in the context of a particular setting or sometimes in comparison: with national trends or statistics, for example. Outliers are used as a prompt to raise questions rather than provide judgements about a service. The outliers programme followed a consistent process up until 2020 but, due to COVID-19, changes were made to both the scope of the programme and the processes followed in order to enable services to focus on responding to COVID-19. In effect all non-urgent programmes were stood down. These changes were maintained during 2020-2022. Further changes have been made from 2022 as part of CQC's more recent transformation programme. In addition, from 2018, CQC added outliers from the National Clinical Audit and Patient Outcomes Programme— commissioned and managed on behalf of NHS England by the Healthcare Quality Improvement Partnership (HQIP) - to its programme.

2.1.5 *(iii) Provision of analysis to support inspections*

2.1.5.1 CQC put in place analytical services to support CQC's processes for inspection, particularly from 2013 onwards when the new ratings approach was introduced at CQC. The analytical teams have developed specific briefing reports and supporting analysis for inspection teams, particularly in the planning of inspections. The reports and supporting analysis incorporated mortality indicators from the monitoring processes described above. The approach for inspection briefings was to focus on findings of note, for example where the indicators were statistically tested as above or below average.

2.1.6 CQC's access and use of Hospital Episode Statistics (HES) to support mortality analysis

2.1.6.1 Ahead of providing more detail on 2.1.3- 2.1.5 above, I have set out CQC's access and use of the HES dataset as it is a key data source for the analysis of mortality for services provided in NHS hospitals (as well as for a wider range of quality indicators about care). HES is a dataset about admissions, outpatient appointments and historical accident and emergency attendances at NHS hospitals in England. It features as a data source for the mortality analysis described in sections 2-3 of this statement.

2.1.6.2 CQC is a secondary user of the dataset and has access to the dataset arranged through the Data Sharing Request Service (DARS) now run by NHS England

(previously run by NHS Digital). CQC's use of the data, is set out in a data sharing agreement, signed between NHS England and CQC. This agreement includes, for example, how we manage and store the data, ensuring the data is restricted to only those processing it for any identifiable fields. In addition, CQC publishes appropriate descriptors where its analysis results in low numbers that could lead to identification of individuals (e.g. results between 1 and 7).

2.1.6.3 The dataset is transferred to CQC through a series of tables every month. CQC then carries out a range of data engineering processes to set up the tables and queries ready for CQC to then run its analytical methods on the data. CQC does not provide HES data, that is the remit of NHSE.

2.2 Dashboards providing access to indicators of quality and risk

2.2.1 CQC has iterated its monitoring approaches and associated tools over time to support its changing regulatory models. There have been four main development periods:

2.2.2 *2009-2013*: CQC developed a *Quality and Risk Profile* for each service it regulated. Bringing together indicators mapped to each essential standard to support inspectors to monitor quality and plan inspections.

2.2.3 *2013-2015*: CQC developed an *Intelligent Monitoring tool*, which tracked a set of key indicators about a service to inform the prioritisation of services for inspections. This analysis was also published, and the Intelligent Monitoring reports have been disclosed to the Inquiry by CQC. For example, the Countess of Chester Hospital Intelligent monitoring report May 2015 [INQ0007866]. This was during the period that CQC introduced ratings across the services it regulates.

2.2.4 *2016-2023*: CQC developed a profile "*CQC Insight*" for all NHS trusts, bringing together a wider set of indicators to support inspectors to monitor quality of care in services. The profiles were intended to be a "one stop dashboard" for Hospital inspection teams to access routinely available analysis about the services CQC assesses. There was one profile per NHS Trust providing acute services, incorporating insight about all acute services provided, including maternity and children and young people. The profiles were shared with NHS Trusts as well as used by internal CQC teams, which they could decide to use to support their own

reviews of quality. For example, the Countess of Chester Hospital Insight profile dated February 2021 (Exhibit LAN/01). [INQ0108766]

- 2.2.5 *2023 - present*: move away from CQC Insight to a set of *dashboards aligned to the new Single Assessment Framework*, but again mapping indicators about quality to support Operations in planning and conducting assessments. 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 for clinical services).
- 2.3 For acute and specialist hospitals the above dashboards have all included a range of mortality indicators, covering the following:
- 2.3.1 *Trust level mortality indicators*: Summary Hospital-level Mortality Indicator (NHS England), Hospital Standardised Mortality Ratio (HSMR) Hospital Standardised Mortality Ratio (Weekday), Hospital Standardised Mortality Ratio (Weekend) and Telstra Health UK (previously Dr Foster).
- 2.3.2 *Condition specific indicators*: mortality indicators for a hospital speciality (e.g. infectious diseases, haematology, respiratory medicine), mortality outlier alerts for either conditions or a procedure relevant to the speciality (e.g. operations on jejunum, non-infectious gastroenteritis mortality outliers were mapped to gastroenterology).
- 2.3.3 From 2017, we have increasingly incorporated more outcome measures, including mortality indicators from the National Clinical Audit and Patient Outcomes Programme (NCAPOP) run by the Health Quality Improvement Partnership. This programme covers a wide range of clinical audits that track the extent to which national standards have been achieved. The patient outcomes programmes covered by NCAPOP look to examine the quality of care for deaths for specific patient groups or pathways of care.
- 2.3.4 From the mortality datasets and analysis set out in 2.3.1 – 2.3.3 we incorporated analysis of two main sources of data pertaining to perinatal mortality: outlier alerts developed by CQC using HES as the data source for the analysis (neonatal and perinatal mortality indicators) and neonatal indicators from the National Perinatal Epidemiology Unit (Oxford) which runs Mothers and Babies: Reducing Risk through

Audits and Confidential Enquiries across the UK (MBRRACE-UK). The latter source is part of NCAPOP, described in 2.3.3.

2.3.5 We continue to update the current suite of dashboards used in CQC with this range of indicators. However, we no longer have the suite of mortality outliers for adult inpatient activity (for reasons outlined in 2.6.2). There are a range of data refresh processes that CQC follows to keep these indicators as up to date as possible. The timetable for the refresh processes is set by the frequency with which the datasets are updated by external data owners, which are tracked to ensure updates are completed close to when the data becomes available. The data sources often include a lag between data collected and the resulting analysis, for example, the MBRRACE-UK data sets were available annually to CQC with the analysis and findings relating to care from two years before publication. Some datasets require CQC to carry out data processing ahead of being able to run indicator analysis – for example, we have a set of routines that have to be run when the dataset for Hospital Episode Statistics is updated. If the structure of the data set, or the measures have changed in the source data, this requires changes to CQC's core systems to reflect these changes.

2.4 CQC's outliers programme

2.4.1 *Overview*

2.4.1.1 Outliers are used as a prompt to raise questions rather than provide judgements about a service. The outliers programme had 3 areas of focus:

2.4.1.2 *Mortality metrics for adult inpatients within acute hospital services*, covering a wide range of mortality indicators for specific conditions (e.g. sepsis/septicaemia) or procedures (operations).

2.4.1.3 *Outcome and safety metrics for maternity and perinatal services* (including neonatal services). The CQC programme focused on the following maternity indicators:

2.4.1.3.1 maternal readmissions,

2.4.1.3.2 puerperal sepsis and other puerperal infection,

2.4.1.3.3 emergency and elective caesarean, and

2.4.1.3.4 the following perinatal indicators: neonatal readmissions, Perinatal mortality, and Neonatal mortality.

2.4.1.4 *Mortality outliers ('alarms') through the National Clinical Audit and Patient Outcomes Programme (NCAPOP)*. In 2017, CQC started to be notified of mortality outliers from NCAPOP audits that were triggered at approximate to 3 standard deviations. In agreement with HQIP and each of the audit programmes, CQC were provided with outliers from across the NCAPOP programme. These outliers were shared with the lead inspection teams for the relevant NHS Trust, and as set out in the HQIP outliers protocol. The protocol sets out that during their routine local engagement with the providers, their inspectors will:

- i) encourage Trusts to identify any learning from their performance and provide the CQC with assurance that the Trust has used the learning to drive quality improvement;
- ii) ask the Trust how they are monitoring or plan to monitor their performance; and
- iii) monitor progress against any action plan if one is provided by the trust. This is set out in NCAPOP's current Outlier Guidance policy¹.

2.4.2 *Outliers analytical approach*

2.4.2.1 The CQC programme looked at changes over time in the metrics, using a cumulative sum (or CUSUM) methodology – which tracked the difference between observed and expected (statistically “expected”) figures for a service. If the result for a service crossed a threshold (3 standard deviations) this “outlier” would then be reviewed by a panel at CQC.

¹ NCAPOP Outlier Guidance - Identification and management of outliers, published by the Healthcare Quality Improvement Partnership (January 2024): [HQIP-NCAPOP-Outlier-Guidance_21022024.pdf](https://www.hqip.org.uk/outlier-management-for-national-clinical-audits/). The previous guidance (January 2011) that was in place at the time of the Countess of Chester Hospital Inspection during 2015-2016 until November 2017 and subsequent updates are available here: <https://www.hqip.org.uk/outlier-management-for-national-clinical-audits/>

2.4.2.2 For adult inpatient mortality many of the outliers were identified by the Dr Foster Unit at Imperial College using data from Hospital Episode Statistics (HES) and shared with CQC (the Unit at Imperial would also alert the affected trust). CQC would also run a CUSUM analysis for a number of conditions not covered by the Dr Foster Unit, from its own source of HES data.

2.4.2.6 For maternity and perinatal services (including neonatal services), CQC carried out the CUSUM analysis rather than the Dr Foster Unit at Imperial College, again using HES as the source data. For these services, the analysis was run on a quarterly schedule.

2.5 Outliers Review processes

2.5.1 Between 2009 and 2020 outliers were reviewed at a panel meeting for adult inpatient mortality indicators and maternity and perinatal (including neonates) services. The panel was made up of teams from across CQC including clinical specialists, analytical specialists and the lead inspection team for the NHS Trust.

2.5.2 The panel could decide to pursue the outlier, which would involve a letter being sent to the NHS Trust's Executive team to request more information pertaining to the specific alert. The panel would often request that the trust carry out an audit to determine if there were any safety and quality concerns relating to the mortality alert. Typically, NHS Trusts would respond with the results of their completed audits, and associated actions.

2.5.3 The panel would review the response, and if the response was satisfactory (in that it covered all the findings of the audit and questions set out in the initial letter), the panel would close the case and responsibility for tracking completion of the action plan would be passed to the lead operations team at CQC. If the response was not deemed satisfactory, the panel could write for further information from the trust, which would again be reviewed at a later panel. There was one panel set up to manage mortality alerts, and a separate panel for maternity and neonatal outliers. They met at regular points across the year, influenced by the volume of outliers.

2.5.4 Outliers generated through National Clinical Audits were not presented to a panel, as these were highlighted directly to the lead Inspection teams for the NHS Trust. The actions were for CQC to review the actions and learning points the trust had identified as part of their relationship management approach.

2.6 Outliers process: impact of COVID-19

2.6.1 In March 2020 CQC reviewed all its programmes given the impact of COVID-19 on services. The following changes were made:

2.6.2 The adult inpatient mortality alerts and review processes were paused and have not been reinstated. In 2020 the decision was made to pause given the pressures on services and given the impact of COVID-19 on mortality rates, and consequently on the analytical methodology used to identify outliers. Discussions between CQC and the Dr Foster Unit at Imperial College in 2020/early 2021 confirmed that the analytical methodology would need to be amended to reflect the impact of COVID-19 on the outliers, given the impact of COVID on mortality rates. However, in October 2021 the Unit at Imperial College confirmed that they were no longer able to generate outliers to NHS Trusts due to changes in their funding arrangements.

2.6.3 For the maternity and perinatal outliers, CQC paused the panel process for reviewing outliers from March 2020. However, the analysis continued to be run on approximately a quarterly timetable over 2020 and 2021, or as close to quarterly as HES data availability allowed. If any outliers were identified these were then highlighted to the lead inspection team for the NHS Trust, who could raise them directly with the Trust as part of their relationship management meetings.

2.6.4 In respect of mortality outliers, derived from NCAPOP, data submission from NHS Trusts to the Programme was paused from March 2020 given the impact of COVID-19. However, once the data collections were restarted in the last quarter of 2020, CQC was notified of any outliers, which continued to be shared directly with lead inspection teams for the NHS Trust. Outliers from NCAPOP were recorded as enquiries on the internal CRM system, which was used by CQC until April 2024 to track many of its regulatory activities.

- 2.7 Current arrangements for tracking outliers (including use and access to neonatal mortality data).
- 2.7.1 CQC continues to run outlier analysis for the maternity and perinatal outliers. We had some challenges with access to the data from May 2022, and with our systems and processes for running this analysis. These issues have now been resolved and we were able to run the analysis in July 2023 and highlight the outliers to the inspection teams. As part of CQC's Transformation programme we have been developing a new way to flag and track outliers, through a "D&I Alerts" module on CQC's new regulatory platform (new computer system for recording and tracking CQC's regulatory activities). If there are any identified outliers from the analysis these will be flagged to the relevant Operations' team. In addition, an analyst team has been assigned to ensure the outliers have been noted by the operations team and to provide any analytical support requested by the receiving Operations' teams. The analytical teams identify lead inspectors for each NHS trust with an alert, and email them to let them know that an alert has been identified.
- 2.7.2 CQC also continues to receive outliers from NCAPOP which are also flagged to Operations teams through the Regulatory Platform. We have redeveloped the processes for doing this, as part of CQC's wider transformation programme, and recognising changes in our Operations teams' ways of working.
- 2.7.3 To date, we have not reinstated an adult inpatient mortality outlier programme.

2.8 Provision of analysis to support inspections

- 2.8.1 To support the comprehensive inspection programme of NHS Trusts 2013-2016 all CQC inspectors of NHS Trusts were provided with a data pack by CQC's analytics teams before the inspection visit. Typically this was supplied 2-4 weeks prior to an inspection. The data pack was also shared with the NHS Trust to provide them with an opportunity to comment on the analysis ahead of the inspection. On the first day of every inspection a member of the analytics team would present the data to the inspection team, including the Specialist advisors, offering them an opportunity to ask any questions. This was true for the inspection of the Countess of Chester Hospital. I have been shown the Intelligence Presentation document dated 16

February 2016 and which I understand was discussed with that inspection team [INQ0103620]. Data packs were based on an 'exception reporting' approach, so included data and metrics showing either above average or below average data of note. This included available metrics on mortality and 'outliers'.

- 2.8.2 Following the completion of the comprehensive inspection programme, CQC made some changes to its analytical services for inspections carried out from October 2016 to March 2020. Although the specific outputs were redesigned there was consistency in approach. For example, an analytical briefing was presented as part of the planning process for each inspection. In addition, a set of appendices, prepopulated with key findings were provided as part of the inspection report. Mortality indicators were routinely included in both these outputs where there were statistically notable results, for example results worse than expected.
- 2.8.3 CQC's inspection approach changed from March 2020, due to the impact of COVID-19. Inspections were carried out on a responsive basis only. As a consequence, CQC paused the production of a regular set of analytical briefings. Analysis continued to be provided, but in response to inspection team requests. This has continued to be the model since March 2020.

3. Professor David Spiegelhalter's evidence to the Inquiry

- 3.1 In his statement to the Inquiry Professor Spiegelhalter stated (p.5):

"The Care Quality Commission (CQC) had a prospective mortality monitoring tool that I helped set up in 2007, which used sophisticated statistical methods to monitor thousands of mortality indicators and automatically alert a human when a possible outlier was detected (the design issues were covered in an academic paper² in 2012, which has become a standard reference for health-care surveillance). I understand that neonatal metrics were included, but that the system was paused at the start of the Covid pandemic and has not been resumed, but this requires further investigation. The Dr Foster unit at Imperial College ran a similar system, but I understand that this has also now ceased operation." [INQ0008966]

² *Statistical methods for healthcare regulation: rating, screening and surveillance*, J. R. Statist. Soc. A (2012) 175, Part 1, pp. 1–47. Copy enclosed.

- 3.2 Counsel to the Inquiry (CTI) referred to Professor Spiegelhalter's evidence in opening submissions³:

“The Care Quality Commission, an organisation we have already mentioned in the context of inspections which took place at the hospital during 2016 and 2017, monitors data gathered by other organisations. In terms of real time data monitoring, according to Professor Spiegelhalter, during the period of the Inquiry's focus, the CQC utilised a sophisticated statistical method to monitor thousands of mortality indicators, including neonatal metrics. Sir David was involved in setting this tool up in 2007 [INQ0008966 p.5]. He believes this tool is no longer in use. Is that the case? If so, why is it no longer in use and with what has it been replaced, if anything? This is something we will be exploring further with the CQC.”

- 3.3 Although I was employed by the Healthcare Commission in 2007 and aware of Sir David's participation in the development of CQC methods and tools around that time I was not personally involved.
- 3.4 I have set out the approach and details of the data and tools that CQC has used since then to monitor mortality indicators, including neonatal metrics, in section 2 above.
- 3.4 The intent of the approach is to identify services with a greater risk of quality issues, that we prioritise for regulatory activity. The intention was to use mortality indicators to identify potential issues in care. As already mentioned, CQC monitors neonatal mortality metrics (see paragraph 2.4.1.3 above).
- 3.5 We did not set out an intent relating to “real-time” which would normally be required for operational responses. To deliver a CUSUM analysis the methodology tracks the statistics over time. (The CUSUM analysis, set out above in paragraph 2.4.2, looked at changes over time in the metrics we tracked from a variety of sources.)
- 3.6 I would not myself describe the tools that CQC used as typically employing data available to CQC at the point of data collection. Although CQC has processes in place to bring in new data and keep data sources up to date there is often a lag

³ [Thirlwall 11 Sept-0911.ecl](#) P.197

between the point of data collection and its availability to CQC for analysis. So, I would not characterise our tools as operating in “real time”.

- 3.7 As such I am unable to identify a CQC “prospective mortality monitoring tool” of the sort Sir David defines and gives as an example of real-time monitoring systems. As explained, there is variation across the range of datasets and sources of data collected and available to CQC at any particular time and for a variety of reasons so its monitoring may not necessarily be characterised as “prospective” or “real-time” in nature
- 3.8 Paragraph 2.6 above sets out the impact of COVID-19 on the outliers processes, what we continued to monitor and what we stopped monitoring. Paragraph 2.7 also explains the position relating to the changes we have made to the outliers programme post-pandemic.
- 3.9 Sir David’s 2012 paper sets out details for the methodologies relating to the outliers programme described in section 2 above and also provides details of the development of ‘z-scoring’. CQC continues to apply z-scoring, a statistical method that CQC uses to analyse a range of indicators that are included in its suite of dashboards. Not all indicators use z- scoring, since this is dependent upon the intended use of the data, the specific dataset and measures available, including whether the data supplier has already developed a set of agreed indicators/ statistical analysis of the data (as is the case for NCAPOP audits). The paper also refers to the Annual Healthcheck which was operated by the Healthcare Commission for its assessment of NHS services. This was stopped after CQC’s first year of operation as it was not part of CQC’s regulatory approach.

4. Monitoring and inspection of the Countess of Chester Hospital

- 4.1 The programmes outlined in section 2 above were all applied to the Countess of Chester Hospital, with results presented in the suites of dashboards developed over time for review by our Operations team. In addition, the data pack prepared for the inspection in 2016 reflected the data availability and findings set out below.
- 4.2 Results of analysis relating to perinatal (including neonatal) services at Countess of Chester Hospital

4.2.1 *Results available within CQC's suite of dashboards pertaining to perinatal mortality (as defined in section 2.3.4)*

4.2.1.1 We received analysis from the MBRRACE-UK programme, which identified the trust as higher than average for neonatal mortality indicators for 2015 (more than 10% higher) and 2016 (up to 10% higher). This data was published in 2017 and 2018 respectively, which was after CQC's comprehensive inspection of Countess of Chester. This analysis was included in the CQC Insight reports available for each NHS Trust to consider with other intelligence about the service/trust. The 2017 rate for perinatal mortality was included from September 2017 in CQC Insight reports, and the 2018 results were updated in the September 2018 Insight report.

4.2.1.2 There was a summary page in each Insight report which highlighted significant changes in newly refreshed datasets. In addition, the CQC Insight report was shared with Countess of Chester (this was part of our routine sharing of CQC Insight with all NHS Trusts so they could see the analysis that CQC was producing). The reports were shared with NHS trusts with acute services after each monthly data refresh, which happened most months of the year (there were a couple of months each year when we would not run a refresh, e.g. August and December).

4.2.2 *Findings from the outlier programmes*

4.2.2.1 The measures for neonatal deaths and neonatal non-elective readmissions did not flag as outliers for the Trust in 2015 or 2016. However, looking at all of the indicators that were tracked as part of the outliers programme for *Outcome and safety metrics for maternity and perinatal services* (described in 2.4.1.3) the trust were flagged for two of the maternity indicators. The trust had alerted for the maternal indicators within the maternity and perinatal programme outliers programme for puerperal sepsis in June 2011 and October 2014. In addition, the Trust had flagged as an outlier for the elective caesarean indicator rates in October 2019. These outliers were followed up in line with the panel process described above.

5. Reports of deaths to NHS England's National Reporting and Learning System ("NRLS") and the Strategic Executive Information System ("STEIS").

- 5.1 Providers must report a set of notifiable events to CQC as set out in Regulation 16 of the Care Quality Commission (Registration) Regulations 2009⁴. The Regulations make provision for NHS Trusts to submit four of these notifications, including deaths, through the national incident reporting system, led by NHS England.
- 5.2 CQC receives a weekly data feed of reported incidents from NHSE. This feed includes all reported incidents, of which a subset covers the four notifications (which are deaths, serious injury, abuse/allegations of abuse and events that stop services). The national incident reporting system has recently changed from the National Reporting and Learning System (NRLS) to a new Learn from Patient Safety Events (LFPSE) service. The NRLS was decommissioned at the end of June 2024, although NHS Trusts have transitioned at different times to LFPSE, with some trusts submitting to LFPSE from 2022.
- 5.3 CQC holds the reported incident data for three years, in line with the data sharing agreement CQC has with NHSE. Data from the national archives presents quarterly numbers of reported incidents. In 2016 the number of all reported incidents for all provider types for England was 425,007 (Jan - Mar 2016) and 493,930 (Apr - Jun 2016)⁵. For the last quarter presented this is equivalent to an average of just over 41,000 reported incidents per week shared with CQC. The number of reported incidents has increased since NRLS was first introduced (with the exception of the COVID period). Based on a review of the last two years of data received, CQC has received on average, over 50,000 reported incidents per week (2023) and over 56,000 reported incidents per week (2024) for all submitting organisations.
- 5.4 Reporting requirements for incidents - both for NRLS and LFPSE - are set by NHS England. For each safety incident reported, there is a grading of the level of harm to the patient. Assigning death as the level of harm is applied where *“any unexpected or unintended incident that directly resulted in the death of one or more persons”*⁶.

⁴ See CQC’s Guidance (last updated 10 August 2023): <https://www.cqc.org.uk/guidance-providers/regulations/regulation-16-notification-death-service-user>

⁵ [ARCHIVED CONTENT] [National quarterly data on patient safety incident reports: September 2016 | NHS Improvement](#)

⁶ https://www.england.nhs.uk/wp-content/uploads/2019/10/NRLS_Degree_of_harm_FAQs_-_final_v1.1.pdf

- 5.5 Guidance has been published by NHS England⁷ which confirms that reporting of *“maternity, fetal and neonatal incidents such as intrauterine deaths should be reported to the NRLS, however a degree of harm of death should only be chosen if it is considered that a patient safety incident, such as an omission in care during the antenatal period, has led to or contributed to the death. The degree of harm can be amended and re-uploaded to the NRLS after further investigation.”*
- 5.6 In addition to the weekly feed of incidents reported to NRLS, CQC also has established access to the Strategic Executive Information System (“STEIS”). STEIS is a national system for NHS services to report and monitor the progress of Serious Incident investigations across the NHS. Initially set up by the Department of Health and Social Care (DHSC), responsibility for STEIS was transferred to NHSE in 2018. Where a death is considered to be a serious incident warranting further investigation it is also reported to STEIS. To note, STEIS will be decommissioned as part of the national transition of patient safety reporting to the LFPSE service.
- 5.7 Reports from both STEIS and NRLS (now LFPSE) are made available to Operations teams so that they could review the details of the incidents reported. The dashboards described above (at paragraphs 2.2 and 2.3), also included overviews of reported incidents from NRLS, set out trends in numbers of reported incidents, compared rates of higher harm incidents, tracked consistency of reporting, and broke down the number of reported incidents by graded degree of harm. This analysis was presented at Trust level, which means it summarised the data for all the services within an NHS Trust. To support inspections, the analyst teams assigned to the trust were able to break down the reported incidents to each service – using the grading of the level of harm. For Countess of Chester – during 2016 – the number of incidents reported (for all levels of grading) was hundreds per month (often over 700 a month).
- 5.8 Due to the change to LFPSE, redevelopment of analysis is required to provide equivalent overviews of trends in reporting for use by Operations teams. This has not yet been possible due to the continuing development of the LFPSE dataset nationally.

⁷ https://www.england.nhs.uk/wp-content/uploads/2019/10/NRLS_Degree_of_harm_FAQs_-_final_v1.1.pdf

Statement of Truth

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

Name: Lisa Annaly

Signed:

Personal Data

Dated: 18 December 2024