Witness Name: Karen Luyt
Statement No.1
Exhibits: 6
Dated: 22 February 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF PROFESSOR KAREN LUYT

I, Professor Karen Luyt, will say as follows: -

1. I hold a tenured clinical-academic position in Neonatal Medicine at the University of Bristol. I work as a clinical neonatologist in the Regional Neonatal Intensive Care unit at St. Michael's Hospital, Bristol, with a special interest in brain injury, neuro-intensive care and improving health outcomes in high risk infants.

2. In my academic position as Professor of Neonatal Medicine, University of Bristol, my research has focussed on optimising health outcomes in newborn infants. I have been lead for the neonatal mortality review for University Hospital Bristol NHS Trust from 2010 to 2018 and the academic lead for child death review (University of Bristol) since 2014.

3. I currently hold leadership roles in various organisations specialising in specific aspects of infant care. In particular:
   a) I am the strategic clinical lead for the Perinatal Excellence to Reduce Injury in Premature Birth (PERIPrem) project;
   b) the national clinical lead for the Prevention of Cerebral Palsy in Preterm Labour (PReCePT) programme; and
   c) the Academic Lead for the Child Death Overview Group.

4. I am the programme Director for the National Child Mortality Database (NCMD).

SECTION 1 - BACKGROUND

5. The NCMD is an NHS-funded programme delivered by the University of Bristol which gathers information on all children who die in England, to help improve and save children's lives in the future.

6. The NCMD is a national data collection and analysis system which records comprehensive data, standardised across a whole country (England), on the circumstances of children's deaths. The purpose of collating information nationally is to ensure that deaths are learned from, that the learning is widely shared and that actions are taken, locally and nationally, to reduce the number of children who die.

7. The NCMD programme was established and is delivered by the University of Bristol, in collaboration with the University of Oxford's National Perinatal Epidemiology Unit (NPEU), a health innovation partnership (UCL Partners) and a software company QES. It also includes representation from bereaved families through the NCMD charity partners: Child Bereavement UK, The Lullaby Trust and Sands. The programme is funded by NHS England and was commissioned by the Healthcare Quality Improvement partnership (HQIP).

8. The aims of the NCMD project are to:
   a) Capture, analyse and disseminate appropriate data and learning from child death reviews;
   b) Drive the quality of child death review at every stage through bench-marking and quality improvement (QI) methodology;
   c) Study and analyse the patterns, causes and associated risk factors of child mortality in England, providing information to target preventative health and social care and to assist in policy decisions, and
   d) Develop a sustainable model after the lifetime of the project.

9. The NCMD national data collection and analysis system is the first of its kind anywhere in the world to record comprehensive data, (standardised across a country), on the circumstances of children's deaths.

10. Before NCMD came into existence, all such data in England was held locally. Now, with data shared across England, there is the potential to identify trends and introduce changes that could improve or save the lives of more children than before.

The origins of the NCMD and the current child death review process.

11. In 2003 two mothers were both wrongly convicted of murdering their own children when the infants died unexpectedly. The University of Bristol's Professor Peter Fleming played a key role in highlighting this miscarriage of justice, by presenting evidence based on his investigations of sudden unexplained deaths in infancy.

12. Professor Fleming identified that in both of these cases (and others) that all of the information needed to explain what had happened leading up to the infant death was being obtained within three months of the infant death but the information collected was being held by different agencies (including the police, the health authority and social services), so that it could not be reviewed and understood in full.

13. These tragic cases were the catalyst that led to the establishment of the child death review process. Under this new system, the deaths of all children would be systematically reviewed to identify what could be learned, to improve the lives of young people and their families and to ensure that no further miscarriages of justice occurred.

14. When the child death review process was first set up, responsibility for its delivery was given to the **Local Safeguarding Children Boards (LSCBs)**, under the oversight of what was then the Department of Children, Schools and Families. LSCBs were responsible for improving the overall wellbeing of children in their local authority area, and each board had a statutory duty to review the deaths of all children normally resident in their area who die before their 18th birthday. The process came into being under The Children Act 2004 nationally on 1 April 2008 following a pilot in the South West from 2006.

15. At this time, areas with a population of 500,000 or more were required to set up **a Child Death Overview Panel (CDOP)** and to implement a process for the investigation of children who died suddenly and unexpectedly, then known as a 'rapid response'. Statutory guidance for the process was set out in a document called **Working Together to Safeguard Children** and a set of statutory forms were produced to assist LSCBs with data collection and to give CDOPs as much information as possible to review each death.

16. The next milestone for the process came in 2010 when the Department of Children, Schools and Families was replaced by the Department for Education, and the child death review process and CDOPs then became the responsibility of the new department. At that time, the statutory forms were also reviewed and updated, and a set

of supplementary forms were introduced, designed to ask more detailed questions depending on the cause of death. These were implemented, and local CDOPs began to develop their own amendments to these forms to suit the needs of their individual panels.

17. The process remained largely unchanged until in 2016 when Alan Wood MP's review into the role and function of LSCBs was conducted. Alan Wood's review identified a number of challenges with the way CDOPs worked and the organisation of the process, and he made a number of recommendations. These recommendations included:
    a) A change in the government department sponsoring the process from the Department for Education to the then Department of Health (now the Department for Health and Social Care);
    b) recognition of the need for child deaths to be reviewed over a population size that allows a sufficient number of deaths to be analysed for patterns, themes and trends; and
    c) the implementation of a national database to collate the information gathered by CDOPs.

18. Following the publication of Alan Wood's recommendations, the government held a consultation between October and December 2017 to seek views on revisions to their statutory guidance on **Working Together to Safeguard Children**. The consultation asked a number of questions related to the child death review process and the work of CDOPs. The conclusions were then published along with the government's response to the consultation in February 2018. After that, work began on the revised version of **Working Together to Safeguard Children,** which was published in July 2018.

19. The Working Together to Safeguard Children (2018 version) made reference to a new document, **Child Death Reviews (Statutory and Operational Guidance)**, which was published in October 2018. This document provides a huge level of detail for those commissioning and delivering child death review processes, and aimed to reduce some of the variability of practice that had developed between CDOPs over the years to enable a more consistent approach to the review of child deaths. Updates were also made to the statutory forms, new versions of which were published in September 2018. (Exhibited to this statement as KL1). INQ0014505

20. Alongside the above activity, the report of the **Child Death Review Database Development Project** was published in July 2016. This project was commissioned by

the **Healthcare Quality Improvement Partnership (HQIP)** on behalf of NHS England and the Health and Social Care division of the Scottish Government. The purpose of the project was to investigate whether and how it might be possible to create a national database of information collected in the course of child death reviews conducted by CDOPs in England and other Child Death Review agencies. The findings of this project demonstrated overwhelming support, both from parents and professional stakeholders, for the creation of a national child death review database.

21. In April 2018, the NCMD was commissioned by HQIP (on behalf of NHS England) to reduce preventable child mortality in England. Following a procurement process, a contract was awarded to a collaboration led by the University of Bristol and involving University of Oxford's National Perinatal Epidemiology Unit, UCL Partners and QES. The NCMD database was formally launched and it commenced data collection from CDOPs on 1st April 2019.

22. The NCMD received funding for five years in the first instance – from April 2018 to 31st March 2023. During the first year of the contract, the database was designed and built. In July 2023, NCMD was recommissioned for a further 3 years, with a contract in place until 30 June 2026. As part of the current recommissioning, the contract can be extended for a further 2 years, until June 2028.

23. In the first year, the database was developed in consultation with key stakeholders, including the bereaved. In addition to deaths occurring from 1 April 2019, NCMD also collected information on children who died prior to that date where their child death review was still ongoing on that date. By May 2021, the NCMD held two complete years' worth of data on child deaths, it was therefore able to begin reporting on key issues and trends in child mortality. Five academic papers, two data releases, two thematic reports and a briefing were published in 2021, generating significant interest from clinicians, professionals, and the public at large.

NCMD's role and function

24. NCMD's role is to collect and analyse data obtained from CDOPs on all live-born children in England who die before their 18th birthday, regardless of the cause of death. It enables the identification and analysis of the wider social determinants of health including those factors in the child, social environment, parenting capacity and physical environment which may play a part in child death. The purpose is to ensure that lessons

are learned following a child's death and that learning is widely shared, and that actions are taken, locally and nationally, to reduce child mortality.

25. The two documents that cover the statutory function of child death reviews, including the role of NCMD are:

    a) **Working Together to Safeguard Children (2023) (WT 2023)**; (Exhibited to this statement as KL2) and INQ0014506

    b) **The Child Death Review Statutory and Operational Guidance (2018) (CDR Guidance),** Exhibited to this statement as KL3. INQ0014507

    Together these two documents set out the requirement for CDOPs to submit data to NCMD using a standard set of forms.

26. The **CDR Guidance** states that child death review **CDR** partners should instruct their C**DOP** to submit copies of all completed forms associated with the child death review process and the analysis of information about the deaths reviewed (including but not limited to the Notification Form, the Reporting Form, Supplementary Reporting Forms and the Analysis Form) to the National Child Mortality Database.

What agencies does NCMD work with to collect data ?

27. **CDOPs** are the primary stakeholders of NCMD. We work closely with **CDOPs** in terms of providing advice on interpretation of national guidance and on how to conduct the **CDR** process. NCMD provide **CDOPs** with regular reports on their data and interact with them to discuss missing or incomplete data as needed. Most of the interaction is electronic via email, MS Teams and webinars but in addition NCMD also attends regular meetings and conferences in person to discuss its findings and analysis.

28. NCMD has no direct interaction with neonatal units in terms of data collection as the entities that provide the data to NCMD are CDOPs. Neonatal units would interact directly with the local CDOP, providing their information to the CDOP, who in turn provides it to NCMD. NCMD does have some ad hoc contact with neonatal units, in the same ways as with all other CDR stakeholders which would be if they contact us directly by email, if they attend a webinar or conference we are speaking at or if they send us an alert about an issue of concern.

29. NCMD had a data sharing agreement in place with Badgernet (currently pending renewal) who provide the patient care record system used by most neonatal units in the

UK. This enables NCMD to receive patient information on children who have died who have had a stay in a neonatal unit.

30. NCMD regularly interacts with child death review professionals across the multi-agency landscape including paediatricians, nurses, midwives, police, social care, public health and education professionals. In particular, we have regular interaction with **Designated Doctors for Child Deaths** who have specific responsibilities laid out within the CDR guidance.

31. We also interact with **Integrated Care Boards (ICBs)** via our mortality reports and with **NHS England (NHSE)** and the **Department for Health and Social Care (DHSC)**. We meet with NHSE monthly to escalate any emerging issues or highlight any signals identified in the data. We also discuss any relevant alerts sent to us by CDOPs on specific issues. NCMD also works with a network of charity partners including Sands, Child Bereavement UK and the Lullaby Trust on issues relating to neonatal deaths. NCMD also engages with the All-Party Parliamentary Groups (APPG) particularly the APPG on Baby Loss, which is relevant here.

32. NCMD provides bespoke reporting on neonatal and infant mortality for local and regional improvement projects in reducing child mortality. For example, NCMD contributed to recent work on developing a **Strategic Action Plan for Reducing Mortality in Babies, Children and Young People** in London as led by the **Office for Health Improvement and Disparities (OHID)**.

What data does the NCMD collect and how?

33. All data from the NCMD system is collected in the statutory child death review forms. This includes numerical, categorical and free text information data. The data is only extracted by the NCMD team. The timescales for data extraction depend on the outputs that the data is intended to be used for. As the data is accessible by the NCMD team in real-time, data can be extracted at any point in time. By real-time we mean the data is available to the NCMD team as soon as it is recorded on the online system by the CDOP teams.

34. Quarterly data quality monitoring reports and annual regional reports are distributed to CDOPs which include statistics on data completeness and timeliness. These reports serve as a prompt for CDOPs to check data quality and improve completeness and

facilitate communication between CDOPs and NCMD to ensure data accuracy. In addition, monthly key field data completeness extracts for each CDOP, identifying the exact field (e.g., gestational age) in each case which is incomplete for the CDOP to action.

35. Regular SQL queries are executed to identify any issues with data accuracy, such as checking for duplicate entries or date of birth/date of death errors causing incorrect age calculation. Such errors, along with any ad hoc data quality issues discovered will be fed back to CDOPs to correct the data at the source.

36. Vigilance and scrutiny of all staff processing and analysing data is maintained, and additional data quality checks on specific analysis are conducted. There are validation rules (e.g. these can be embedded into the system rules that check whether the format of the data entered is correct, for instance date of death cannot be before date of birth) within the system at the point of data entry to stop as many errors as possible at the point of data entry (e.g., only valid NHS numbers can be entered) and these continue to be deployed as appropriate.

37. In addition, at the end of each reporting year NCMD contact all CDOPs to confirm the number of deaths in each area to ensure all deaths are accounted for within the national database and in line with local records, with any discrepancies investigated and resolved.

38. Data are collected via CDOPs who enter data into one of two online platforms (eCDOP or NCMD portal), which in turn flows to NCMD. These data are stored within SQL server and are available for extraction from members of the data team within NCMD. Once extracted, data files are processed and analysed on secure University of Bristol secure file store servers, within CSV or excel formatted files. Population or live births data are downloaded from ONS, where these are available, stored in the database, and used appropriately for calculation of mortality rates. Depending on the output required, relevant software is used for analyses, including: SQL Management Studio, Microsoft Excel, STATA, Python, and NVivo. Most descriptive analyses take place using Excel or STATA.

39. Data are processed and analysed for the publication of thematic reports, data releases, academic papers and responding to data requests, in addition to routine reporting to CDOPs/ICBs. All outputs are then quality assured and verified by at least one other

member of the NCMD team before release, and distribution is via secure SharePoint folders or encrypted email, or published on the NCMD website.

How is NCMD data used and with whom is NCMD data shared?

40. NCMD provides a centralised analysis service to maximise system learning from the statutory child death reviews undertaken by the CDOPs. It aims to ensure the learning arising from the data collection and analysis is disseminated to the relevant agencies in a timely, effective and standardised manner. This enables agencies to implement necessary actions with speed. To achieve this, NCMD provides a range of outputs that can be used by key stakeholders, particularly for the purposes of learning from child deaths and implementing actions recommended from the reviews.

41. There are currently no specific arrangements in place for neonatal staff on hospital units to access NCMD data. All published data produced by NCMD is publicly available to everyone through the NCMD website.

42. There are currently no arrangements in place for feedback to be provided to neonatal hospital units about the data held by NCMD.

Regular NCMD published outputs

43. The Annual Child Death Reviews Data Release
    a) This provides a summary of the number of child deaths and the number of reviews of children whose death was reviewed by a CDOP. The data in this report is presented by age groups (including neonatal deaths) and by demographics (sex, ethnicity, deprivation), region in England, place of death (including whether the death was on a neonatal unit), by gestational age, by category and sub-category of death and ICBs.
    b) The annual CDR data release includes basic statistics on when and where deaths occurred, the characteristics of the children, including sex and age groups, and the modifiable factors identified by categories of death for the completed reviews.
    c) NCMD actively seeks feedback from CDOPs and other key audiences (e.g., NHSE national and regional teams, OHID) on the usefulness of the data and implement improvements in agreement with the funder. For instance, we have worked on expanding this reporting to include presenting the data by suspected categories of death and by region and ICB, so that provisional trends in child deaths are timelier.

d) The latest report and data tables including deaths in the period between 1 April 2019 and 31 March 2023 can be accessed from the NCMD website.

44. Two thematic reports per year

a) A topic selection process was specifically designed and implemented for the NCMD thematic reports, as approved with the funder. It includes a set of principles such as: proposals should be evidence based using complete and quality assured dataset, the strategic short and long term aims and objectives in government and the national healthcare system policies related to child health and wellbeing, the current gaps in understanding and knowledge and quality improvement focus.

b) NCMD proactively plans and manages this process using its governance structure and directly engaging with the funders and key stakeholders. Topic selections are approved by the funder. Working groups are set up for each thematic report at the start of the planning process to input with their expertise into the topic proposal and analytical plan outlining the dataset, definitions, methods and report structure.

c) The thematic reports include quantitative and qualitative analysis with a focus on contributory and modifiable factors and learning. Personal stories and best practice case studies are also included to illustrate the data and better engage audiences with the findings. Recommendations and line of sight table are included in line with the commissioning requirements.

d) The themes for these reports vary but usually focus on modifiable and contributory factors. The Contribution of Newborn Health to Child Mortality across England thematic report related to neonatal deaths was published in July 2022 and can be accessed from the NCMD website.

45. Monthly and ad hoc exception reporting

a) Based on real-time surveillance for NHS England to facilitate the monitoring of all child deaths.

b) Routine reports, aggregate data tables and benchmarked child mortality statistics are provided to CDOPS, Integrated Care Boards (ICBs) and Operational Delivery Networks upon request.

c) NCMD provides routine reports of aggregate data tables and benchmarked child mortality data to:

i) **CDOPs** - quarterly data quality monitoring reports and annual regional reports;

ii) **ICBs** – with scope and frequency as agreed with NHS England and ICB executive leads for children and young people;

iii) the Learning from Lives and Deaths programme team **(LeDeR);**

iv) **NHS trusts** – we are working with relevant stakeholders at NHS England to develop a plan (scope, metrics, priority areas, frequency) for reporting of aggregate data by NHS Trusts.

d) Monthly and ad-hoc reports are provided to **NHSE**, based on the real-time surveillance of death notifications, and they are analysed by region of England and by ICB.

e) These reports provide ongoing monitoring of the trends in deaths and risks. In addition, targeted analyses are carried out as informed by triangulation of areas of concern raised from other sources of information (e.g., an increase of infections or near-drownings).

f) An alert function is included providing a mechanism for flagging up concerns from the national analysis and the alerts raised by CDOPs and CDR professionals.

46. NCMD provides evidence for the assessment and further development of existing national standards and processes. This includes our ongoing work on supporting the development of the CDR and medical examiner processes, informed by NCMD data.

47. We plan to continue our collaboration with the Maternity and Newborn Safety Investigations (**MNSI**) and engage and scope a collaboration with the Special Health Authority for independent maternity investigations. We continue to align our outputs with the relevant national initiatives such as national policies, government commitments and NHS standards and guidelines (e.g., NHS Long Term Plan, Saving Babies Lives Care Bundles, NHSE CORE20PLUS5 on reducing health inequalities, OHID initiatives on reducing child mortality).

48. We use relevant evidence from the data to support Paediatric Early Warning Score (PEWS) implementation and data linkages/information sharing to support other national initiatives such as the National Asthma and COPD Audit Programme and National Confidential Inquiry into Suicide and Safety in Mental Health. Findings and intelligence from the NCMD data are also used to support the work of national charities as the agents of change and government agencies responsible for safety and standards (e.g., the Office for Product Safety and Standards).

49. We collaborate, for instance, with ROSPA (The Royal Society for the Prevention of Accidents) and the National Home Safety Committee and provide them with information on accident-related deaths (e.g. blind cord strangulations) and the work led by OHID

(The Office for Health Improvement and Disparities) on new emerging methods of suicide.

50. Additional outputs include versions of reports written in an easy access format for bereaved families as the primary audience and extended outputs from published data for professional and academic audiences.

Data Access Requests

51. NCMD data is also shared in response to specific data access requests. These data access requests follow the HQIP data access request procedure as HQIP is the NCMD data controller. There are 2 types of data requests –

    a) requests for fully anonymised aggregated data (with small numbers suppressed), or

    b) requests for record level data (or aggregate data) that is identifiable (or potentially identifiable) with small numbers non-suppressed.

52. Different approval processes are in place for each type of request. More details on the data access requests processes are available on the HQIP website.

How data is analysed by the NCMD

53. NCMD continuously develops its outputs and their availability and accessibility. The NCMD team use relevant software for the analyses and outputs, such as: SQL Management Studio, Microsoft Excel, STATA, Python, as well as Power BI for interactive visualisation of data using graphs, summary tables of aggregate data and infographics. Statistical analysis of quantitative data is performed using the statistical software for data science, STATA. The methodology used depends on the output required.

54. For death notifications, we initially report the demographics (including sex, ethnicity, deprivation, and region). Decile of deprivation is calculated using 7 main domains (income, employment, education, health, crime, access to housing and services, and living environment) and is calculated from the child's postcode to a granularity of around 1500 people (with 1 being most deprived and 10 least deprived). Rates for overall deaths and for each category, are presented by year of death using statistical methods.

55. Trends are compared using statistical models for random effects, clustered by month of death to reduce the effect of seasonal variation, with counts of death collapsed to number per day.

56. Trends and changes across the time period are assessed using appropriate distributions and predictions (e.g., allowing variation of predictions at key-points across the past 4 years). Interaction p-values are derived to test if trends or profiles of mortality differ by each characteristic (e.g., sex).

57. For ad-hoc or thematic reports, we use statistical methods appropriate for the research questions. For most outputs, counts, percentages, and risks are presented. Where more in-depth analysis is required a statistical analysis plan is developed with a-priori objectives and any exploratory analysis labelled as such.

58. Risks are derived by using population estimates and live births data from ONS, with numerators converted to measures of risk for any underlying population. Adjustments are performed for all population measures available at that level of granularity from national or local population data. Unadjusted and adjusted results are presented to aid interpretation.

60. Qualitative data are analysed using a thematic approach in identifying key themes and developing appropriate coding schema. NCMD data is stored in a SQL database, this contains all information from all cases that have been submitted to NCMD. Microsoft Access is a piece of software which is used by the NCMD team to review specific fields from our dataset. For example, in SQL we have a series of free text fields which are populated if a factor contributed to the death of a child. Using Microsoft Access, we review these fields to apply pre-defined codes, from a categorisation schema, to make the qualitative information quantifiable. For example, we may review the contributory field free text that states the 'father smoked in the house' to which we would apply the code 'Parent/carer smoked tobacco/e-cigarettes in the household'. This enables us to say 'Parent/carer smoked tobacco/e-cigarettes in the household' was a contributory factor in the death of X number of children, thus making the information quantifiable. This data has been interpreted and coded by the NCMD team using Microsoft Access, we then import it back into the SQL database to incorporate all information relating to the child, for analysis.

59. Themes relating to what is recorded in the record and to underpinning ideas, patterns and assumptions are reviewed with clinical expert input where required. An inductive approach to the analysis is undertaken, and the themes identified as being most important are those that provide a deep understanding of the issue, not just those that occur most frequently.

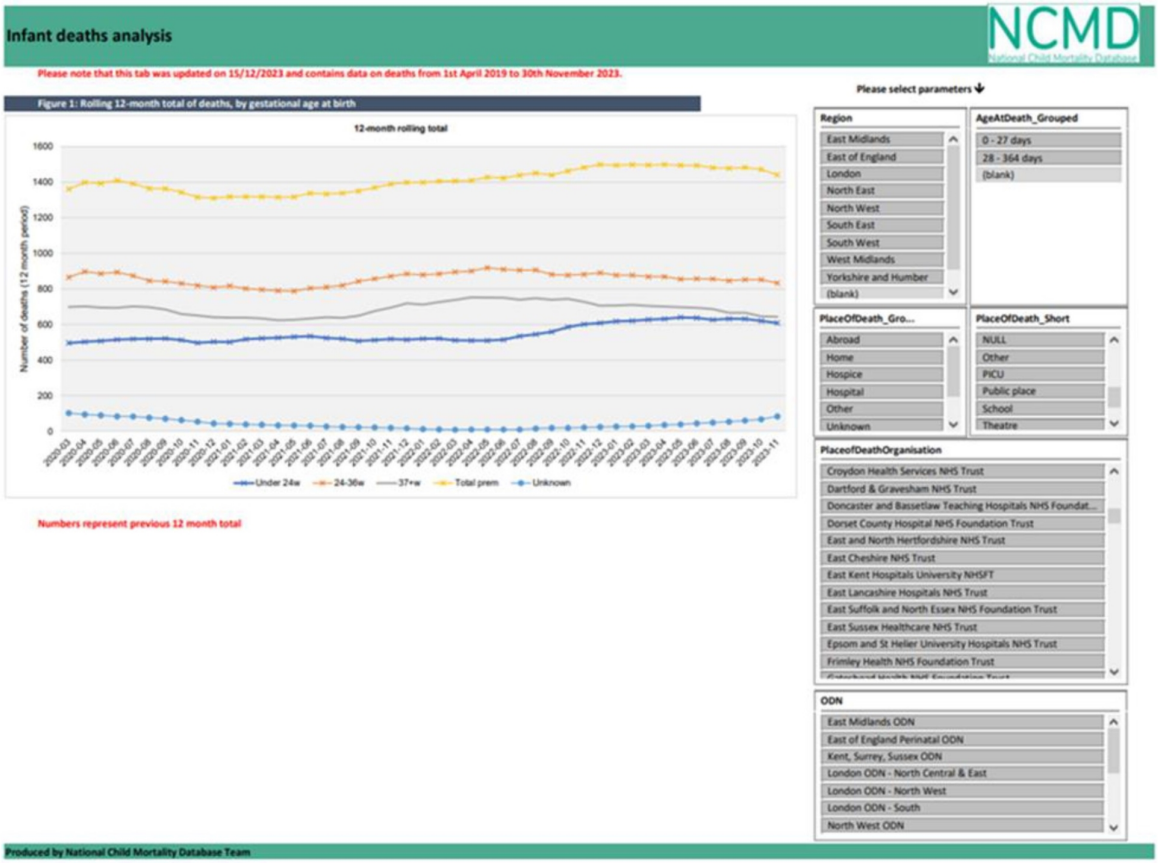
60. The NCMD real-time surveillance system has shown reproducibility, validity, and utility over the last 5 years. It uses initial notification information where suspected cause of death is coded by 3 NCMD paediatricians. In addition, alerts from CDOPs, clinicians and key stakeholders lead to specific rapid analysis and reporting to clarify peaks or signals. These additional analyses are provided in ad-hoc addendums to the monthly report sent to NHS England, and to other key stakeholders where appropriate. Further work is developed after discussions where additional data or time is needed to guide advice or policy.

How and by whom data is analysed on a local or national level.

61. Annual regional reports broken down by CDOP enable internal (i.e. within the region) and external (i.e. to regional/national data) benchmarking for CDOPs and CDR professionals to identify local trends. Annual data releases are developed to present mortality rates by area (e.g. CDOPs, ICBs, Trusts) to enable benchmarking across areas. The monthly NCMD surveillance report to NHS England includes specific analysis on infant deaths. This is provided in Excel as a figure presenting the rolling 12-month total of infant deaths, by gestational age at birth.

62. The figure is interactive allowing the user to change it by choosing from the following parameters:
    a) region in England, age at death (grouped as: 0-27 days and 28-364 days)
    b) place of death (grouped as: abroad, home, hospice, hospital, AICU, ED, hospital ward, labour ward / delivery suite, midwifery unit, NICU, PICU, hospital theatre, public place, school, other, unknown),
    c) organisation as place of death (a list of hospital trusts to select from)
    d) Neonatal Operational Delivery Unit (ODN) (a list of all ODNs to select from).

63. The copy screenshot below in included as an example of this output:



64. The NCMD team analyses, monitors and presents trends, on both a local and national level, of all child deaths by age groups, including:

    a) neonatal (0-27 days) mortality;

    b) infant (28-364 days) mortality.

    c) child mortality of children aged 1 to 17 years.

65. Local and national trends are communicated to NHS England in the NCMD monthly surveillance report. This includes presenting the neonatal and infant mortality data as national trends and trends by regions in England, ICBs, Neonatal Operational Delivery Networks and hospital Trusts. Where it is more practicable to present some of the information requested by means of an exhibited table or chart, this is encouraged.

SECTION 2: CHILD DEATH OVERVIEW PANELS (CDOP)

66. The CDR guidance sets out the details of CDOP membership. CDOPs are multi-professional panels whose core membership should include senior representation from the following agencies: public health, Designated Doctor for Child Deaths (and a hospital

clinician if the Designated Doctor is a community doctor or vice versa), social services, police, safeguarding (designated doctor or nurse), primary care (GP or health visitor), nursing and/or midwifery, lay representation and any additional professionals / relevant experts as needed to inform discussions. The specific membership of CDOPs across the country can vary, but where CDOPs hold neonatal themed panels, the expectation would be that obstetric and neonatology expertise would be required in addition to the core midwifery representation.

67. CDOPs are required by statute to review the death of any child normally resident in their area. This includes any liveborn child that dies, of any cause, before their 18th birthday.

68. CDOPs must follow the **Child Death Review Statutory and Operational Guidance (England). (CDR Guidance**) . The current CDR guidance also allows for CDOPs to review the death of any non-resident child who dies in their area. Every death of a neonatal, infant or child should be reviewed following the process set out in the CDR guidance.

Stage 1

69. The first stage is the decision-making and notification that needs to take place immediately after the death of a child. The immediate decision-making is undertaken by senior professionals (usually clinicians) who had responsibility for the child at the end of their life. However, often the decision-making will follow discussions between a number of different professionals depending on the circumstances in which the child died.

70. The initial considerations include:
    a) how best to support the family;
    b) whether the death meets the criteria for a Joint Agency Response (sudden and unexpected deaths);
    c) whether a Medical Certificate of Cause of Death (MCCD) can be issued, or whether a referral to the coroner is required; and
    d) whether the death meets the criteria for an NHS serious incident investigation.

71. A number of notifications should also be made:
    a) to the child's GP and other professionals;
    b) to the Child Health Information System; and
    c) to the relevant CDOP.

72. Notification to the CDOP is made using the statutory **Child Death Notification Form**, exhibited to this statement as KL4. INQ0014508

Stage 2

73. This is the investigation and information gathering stage.

74. After immediate decisions and notifications have been made, a number of investigations may then follow. These include:

    a) Coronial investigation;

    b) Joint Agency Response;

    c) NHS Serious Incident Investigation.

75. A post-mortem examination may be required in a number of cases. Which investigations are necessary will vary depending on the circumstances of the individual case. They may run in parallel, and timeframes will vary greatly from case to case.

76. At this stage, the CDOP will also start the process of requesting information from all professionals who were directly involved in the care of the child during life and their investigation after death.

77. For neonatal deaths this would also include obtaining information from professionals who cared for the mother during pregnancy.

78. This information is collected by the CDOP using the statutory **Child Death Reporting Form** (exhibited to this statement as KL5) and any supplementary reporting forms INQ0014509 relevant to the baby's death. The CDOP will also obtain a copy of the post-mortem report (if one has been conducted) and the reports of any other investigations e.g. NHS Serious Incident investigation or any other internal agency investigation.

Stage 3

79. The third stage of the process is the convening of the **Child Death Review Meeting (CDRM).**

80. This is a multi-professional meeting attended by professionals across the care pathway and would include hospital or community healthcare staff involved with the child at the end of life and those known to the family prior to the death, pathologists, other professional peers from relevant hospital departments and community services, the patient safety team if a serious incident investigation has taken place, senior

investigating police officer if a Joint Agency Response has taken place and other practitioners for example social work, ambulance and fire services, primary care clinicians, school nurse, head teacher, representatives from voluntary organisations where all matters relating to a baby's death are discussed by the professionals directly involved in the care of that child during life and their investigation after death.

81. For deaths of babies in a midwifery unit, in a delivery suite, labour ward or in a neonatal intensive care unit, the CDRM will often be known as a **Perinatal Mortality Review Group** meeting.

82. It is recommended in the CDR guidance that perinatal mortality review groups use the national **Perinatal Mortality Review Tool (PMRT),** a web-based tool which supports standardised, systematic review of care in perinatal deaths. A draft of the statutory **Child Death Analysis Form** (Exhibited to this statement as KL6) is completed at the CDRM and then sent to the CDOP to be included in their review. INQ0014510

Stage 4

83. The fourth stage of the process is the CDOP review.

84. Section 5.3 of the CDR Guidance sets out the organisations that should be represented on a CDOP panel and specifically states that those attending should be senior representatives from their organisations. In section 5.6 recommendations are made around themed CDOP panels and in appendix 6 the composition of neonatal themed panels specified.

85. The panel should be chaired by someone independent of the key providers in the area. The purpose of CDOPs is to carry out the statutory CDR process on behalf of the CDR partners.

86. Where the CDOPs are convened and operate in compliance with both the CDR guidance and the guidance to follow for a Joint Agency Response in cases of sudden and unexpected deaths, I believe that they are effective in their function. However, not all CDOPs across the country are fully compliant with these two sets of guidance and where they are not compliant, the effectiveness of the CDOPs is reduced.

87. At present there is no national quality assurance of CDOPs or CDR partners and no clear process for parents to follow in the event that they are unhappy with how the CDR process has been conducted for their child. It is also unclear how and by whom CDOPs would be held accountable if they fail to comply with the statutory guidance. I think that consideration should be given as to who should provide oversight and what form that oversight should take.

'Reading the Signals'??

88. The Reading the Signals Group is primarily focusing on mortality and morbidity in Term gestation babies. The Letby trial victims included mainly preterm babies, so the focus appears to be different. A subgroup of the Data Co-ordination group reviewed the NCMD ICB level report on neonatal and infant mortality as this contains up to date data at granular level (ICB).

SECTION 3: DATA ANALYSIS

89. The NCMD national data collection was established on 1st April 2019 with deaths notified to NCMD from that date onwards. Consequently NCMD does not hold any data for infant deaths between June 2015 and June 2016 (inclusive).

90. CDOPs complete the statutory CDR data collection forms and record this data on the NCMD system. NCMD analyses the data which has been recorded on its system by the CDOPs.

91. The purpose of the CDR process is to capture the whole life journey of the baby, including details of their whole clinical stay in each unit that they received care in. That includes the hospital of birth, hospital of death and any other hospital they may have spent time in during their life. There are a set of specific questions asked for each neonatal death and there are a number of free text boxes where a narrative account should be given.

92. The CDOP should request data from all units that have cared for a child. Each trust will provide that data to the CDOP who pull it all together and form the child death review record. This is the data that they review and a subset of what they collect is sent to NCMD for national analysis. In principle, the NCMD data captures the whole clinical stay for each infant, but in reality, what is captured is dependent on how well the forms have been completed.

93. The CDR process uses template statutory forms to collect data on all babies and children who die. There are 3 core forms (child death notification form, child death reporting form and child death analysis form) which are completed for every death including every infant who dies on a neonatal unit. There is then a suite of 21 supplementary reporting forms that are completed for specific deaths. One of these is for deaths on a delivery suite, labour ward or neonatal unit. This would also be completed for every death that occurred in one of those locations. There are a few other supplementary forms that may also be relevant, depending on what the baby died of e.g. supplementary form on chromosomal, genetic and congenital anomalies or the supplementary form for cardiac conditions (congenital or acquired). . The data collection forms are publicly available on the NCMD website.

94. Whether all data is entered or recorded by the clinical staff in neonatal units will vary depending on the form being completed and the local processes adopted in the area where the baby died.

95. The Child Death Notification Form, may be completed by anyone. For babies it is most often completed by a member of the clinical team, however, it is possible that it may also be completed by a ward clerk or administrative person. This will vary depending on the processes in place in each hospital.

96. The Child Death Reporting Form and any supplementary reporting forms will be completed by clinical staff and, usually, each member of the team will be asked to complete the same form. So the CDOP would request one from the community midwife, one from the delivery midwife, one from the obstetrician, one from the neonatologist etc.

97. If care was received at more than one hospital, the Child Death Reporting Form would be sent to clinical professionals at each hospital.

98. In some areas, they may submit one form for “maternity services” as opposed to each individual form described above, but these would still be completed by clinical members of staff.

99. For the Child Death Analysis Form, these would be completed by clinical members of staff following the perinatal mortality review. Usually this would be the hospital mortality lead in the hospital where the baby died.

100. A sudden change in a baby's heart rate, respiratory rate and oxygen levels would not be routinely recorded by clinical staff. There is no specific question in the CDR data set that relates to sudden changes in a baby's heart rate and / or oxygen levels.

101. Data relating to sudden changes in a baby's heart rate, respiratory rate and /or oxygen levels could be recorded in the free text box in the Child Death reporting Form or on the Child Death Analysis Form if it is discussed during the review. On request, NCMD would be able to extract such data using a free text search. However, this would mean that NCMD would only know about deaths where this had been mentioned by the reviewing team. If a sudden change in heart rate or oxygen level had occurred, but not been recorded in any of the free text boxes, then that death would not be included in any extract.

102. As regards serious adverse events relating to an infant there is no uniform methodology for capturing this data by the NCMD. The child death reporting form has a specific question that asks "Was there a formal Serious Incident investigation or any other internal agency investigation?" so this question should be answered by everyone who completes that form.

103. If the answer to a Serious Incident investigation question is "Yes" then the CDOPs will then be asked to provide more details. Where the CDOP knows of any serious adverse event they can request any report relating to such an incident. If the CDOP is using the eCDOP case management tool (which most are), then they can upload the report, and this allows NCMD to see it. If, however, it is uploaded as a PDF, then NCMD is not able to extract data from these PDF documents. We therefore ask the CDOPs to cut and paste the learning and recommendations from these reports directly into the child death analysis form so that it can be fed into national analysis.

SECTION 4

This part of the statement focusses on Section C of the Terms of Reference which is focussed upon: "The effectiveness of NHS management and governance structures and processes, external scrutiny and professional regulation in keeping babies in hospital safe and well looked after, whether changes are necessary and, if so, what they should be, including how accountability of senior managers should be strengthened. This section will include a consideration of NHS culture."

104. As set out above there is currently no specific data collection to monitor and prevent unusual patterns in infants or children suffering an unexpected collapse or to monitor and prevent a sudden rise in deaths or persistently high mortality rate.

105. NCMD could add specific questions to the statutory dataset to routinely record instances of unexpected collapse on neonatal units. This would provide a way of collecting this data as part of the statutory process. The statutory process already includes the requirement for a Joint Agency Response for all deaths that occur suddenly and unexpectedly in any setting.

106. NCMD could engage with the **Neonatal Operational Delivery Networks (ODNs)** directly to further develop the reporting of neonatal and infant mortality data to support the function of the ODNs.

107. The analysis of neonatal deaths is now the subject of a number of audits and programmes of work looking at neonatal mortality, covering different aspects of this challenging area.

108. The **National Neonatal Audit Programme (NNAP)** reports neonatal deaths, but is limited to admissions to, and deaths on, NHS neonatal units.

109. **The Perinatal Mortality Review Tool (PMRT)**, launched in January 2018, is used to review the deaths of babies who die within the first 28 days after birth. Use of the PMRT is recommended for neonatal deaths but it can also be used to review post-neonatal deaths.

110. All Trusts use the PMRT to review their perinatal deaths and the vast majority of neonatal deaths (in excess of 95%) are reviewed using the PMRT. For the purposes of the child death review process, the PMRT review is the same thing as the local child death review meeting.

111. **The Maternity and Newborn Safety Investigation programme** (formally known as the Healthcare Safety Investigation Branch (HSIB)) also investigate early neonatal deaths when the baby died within the first week of life (0-6 days) of any cause. Eligible babies include all term babies (at least 37 completed weeks of gestation) born following labour.

112. **MBRRACE-UK: Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries** across the UK surveillance data provide surveillance on babies who die in the first 28 days after birth, as well as stillbirths and late miscarriages.

113. To complement these projects, NCMD collects data on all babies and children who die after birth, and before their 18th birthday. The reporting of deaths is rapid (normally within 48 hours of the event) and a statutory requirement.

114. As you can see from the above processes, neonatal deaths are already subject to a high degree of scrutiny. In addition, the way that neonatal care is delivered across the 4 nations of the UK is complex, particularly cross-country or cross-county movement of mothers and babies between different care settings.

115. It would be worth considering holding a round table discussion to discuss how the currently commissioned programmes can work together better and to share information and improve quality of care and safety in neonatal units. This could include representation from the 4 nations, hospital trusts and all relevant data collection processes to discuss how we can better work together to achieve this goal. This should include those delivering care as they will be best placed to advise on what mechanisms could work.

Statement of Truth

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

Signed: Personal Data

Dated: 22 February 2024