Witness Name: Marian Knight
Statement No.: 1
Exhibits: 10
Dated: 10 January 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF PROFESSOR MARIAN KNIGHT

I, Marian Knight, will say as follows: -

Section 1

Background

1. Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK) is the collaboration appointed by the Healthcare Quality Improvement Partnership to run the Maternal, Newborn and Infant Clinical Outcome Review Programme. The collaboration is led from the National Perinatal Epidemiology Unit based at the University of Oxford with additional collaborations at the Universities of Leicester and Birmingham, Newcastle-upon-Tyne Hospitals NHS Foundation Trust, Chelsea and Westminster Hospital NHS Foundation Trust and the stillbirth and neonatal death charity, Sands. The National Perinatal Epidemiology Unit is a multi-disciplinary research unit established in 1978 for the purpose of conducting clinical and epidemiological research to improve the care and services provided to women, babies and families during pregnancy, childbirth, the newborn period and early childhood.
2. The Maternal, Newborn and Infant Clinical Outcome Review Programme is commissioned as part of the National Clinical Audit and Patient Outcomes Programme. The National Clinical Audit and Patient Outcomes Programme includes around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The Maternal, Newborn and Infant Clinical Outcome Review Programme is one of several National Clinical Audit and Patient Outcomes Programmes, which are designed to help assess the quality of healthcare, and stimulate improvement in safety and effectiveness by systematically enabling clinicians, managers, and policy makers to learn from adverse events and other relevant data. The Maternal, Newborn and Infant Clinical Outcome Review Programme is funded by NHS England, the Welsh Government, the Health and Social Care division of the Scottish government, The Northern Ireland Department of Health, and the States of Jersey, Guernsey, and the Isle of Man.

3. The MBRRACE-UK collaboration investigates the deaths of women during pregnancy and up to one year after the end of pregnancy, and selected cases of severe maternal morbidity during or after pregnancy through routine surveillance and confidential enquiries. The collaboration also undertakes surveillance of all stillbirths, late fetal losses and neonatal deaths (deaths up to 28 days of age) in the UK, alongside confidential enquiries into the care of specific samples of babies who die or have serious morbidities. The specific samples of babies for the topic-based confidential enquiries are chosen by an Independent Advisory Group established to oversee the Maternal, Newborn and Infant Clinical Outcome Review Programme. Data on maternal and perinatal deaths are provided to MBRRACE-UK through a variety of sources including directly from trusts/health boards through the MBRRACE-UK web-based reporting system, and through cross-linking with routine data sources such as the Office for National Statistics and National Records of Scotland.
4. The Perinatal Mortality Review Tool was developed during 2017 and released in January 2018. The tool is provided free to all UK NHS maternity and neonatal units to support high quality standardised perinatal reviews on the principle of 'review once, review well'. The tool provides maternity and neonatal units with a series of questions to enable units to:
    a. Conduct systematic, multidisciplinary, high-quality reviews of the circumstances and care leading up to and surrounding each late fetal loss (late miscarriage at 22-23 weeks' gestation), stillbirth (from 24 weeks gestation) and neonatal death (babies who are born alive and die up to and including 28 days after birth), and the deaths of babies who die in the post-neonatal period (babies who die after 28 days after birth) having received neonatal care.
    b. Undertake active communication with parents to ensure they are told that a review of their care and that of their baby will be carried out and how they can contribute to the process.
    c. Conduct a structured process of review, learning, reporting and actions to improve future care.
    d. Come to a clear understanding of why each baby died, accepting that this may not always be possible even when full clinical investigations have been undertaken; this involves a grading of the care provided.
    e. Produce of a clinical report for inclusion in the medical notes.
    f. Produce a report for parents which includes a meaningful, plain English explanation of why their baby died and whether, with different actions, the death of their baby might have been prevented.
    g. To identify broader learning to improve care for the future including preventing

future perinatal deaths.

5. Note that the Perinatal Mortality Review Tool programme does not conduct surveillance. Data are used as described in paragraph 4 and by units to produce summary reports to identify emerging themes across a number of deaths to support learning and changes in the delivery and commissioning of care to improve future care and prevent the future deaths which are avoidable. As part of Safety Action 1 of the NHS Resolution Maternity Incentive Scheme, Trusts in England are required to present quarterly reports to the Trust Executive Board reporting findings from Perinatal Mortality Review Tool reviews of perinatal deaths; the basis of these reports can be generated from the summary reports available from the Perinatal Mortality Review Tool system. The collaboration also uses the data to produce an annual report summarizing learning from Perinatal Mortality Review Tool reviews conducted across the UK.
6. The collaboration monitors compliance with safety action 1 of the NHS Resolution Maternity Incentive Scheme. Trust submissions received by NHS Resolution are cross-checked to verify compliance using data from MBRRACE-UK and the Perinatal Mortality Review Tool.

Identification and reporting of stillbirths and neonatal deaths

7. Deaths reported to MBRRACE-UK since 1 January 2013 are: late fetal losses (a baby delivered between 22 and 23 completed weeks' gestational age showing no signs of life, irrespective of when the death occurred), stillbirths (a baby delivered at or after 24 completed weeks' gestational age showing no signs of life, irrespective of when the death occurred), and neonatal deaths (a liveborn baby born at 20 completed weeks' gestational age or later who died before 28 completed days after birth). These definitions also include any late fetal loss, stillbirth, or neonatal death resulting from a termination of pregnancy.
8. To ensure complete data collection and to facilitate international comparisons, the eligibility criteria for MBRRACE-UK are based on gestational age at birth irrespective of when the death occurred. Therefore, all births from 22 completed weeks' gestational age showing no signs of life must be reported, irrespective of when the death occurred; the date of birth and date of confirmation of death are both reported for these deaths. For all deaths, where an accurate estimate of gestation is not available, a minimum birthweight of 400g is used to determine eligibility. For multiple pregnancies, where there is more likely to be a longer gap between an in utero death and the subsequent birth, deaths are excluded where the death is confirmed before 20 completed weeks' gestational age.
9. The MBRRACE-UK collaboration operates a secure online reporting system which can

be accessed by all UK Trusts and Health Boards providing maternity and neonatal care. Responsibility for reporting a death and for the completeness and the quality of the data reported to MBRRACE-UK lies with the Trust or Health Board where the death occurred. Since 1st September 2021 timely reporting and review of deaths has been included as a requirement of the Maternity Incentive Scheme in England. English Trusts are required to notify all stillbirths, late fetal losses and neonatal deaths within seven days of the death occurring and to complete surveillance information within 30 working days. MBRRACE-UK warns Trusts after late notification. Each Trust and Health Board has identified a small number of MBRRACE-UK Lead Reporters who act as key points of contact between their organisation and MBRRACE-UK. Data are not extracted directly from any medical records by MBRRACE-UK; all data are extracted by hospital staff. In order to check for any relevant deaths that have not been reported to MBRRACE-UK, details of statutorily registered deaths are obtained from the Office for National Statistics (England and Wales), National Records of Scotland (Scotland), Northern Ireland Maternity System and Northern Ireland Statistics and Research Agency (Northern Ireland), Health Intelligence Unit (Bailiwick of Jersey) and Health and Social Services Department (Bailiwick of Guernsey).

Information collected

10. Comprehensive information about each death is requested from Trusts and Health Boards to allow detailed examination of the risk factors for perinatal mortality in the UK. Data items are collected with the aims of, first, offering more appropriate adjustment of the crude mortality rates than had previously been possible and, second, providing a clearer insight into the health, social and lifestyle factors most commonly associated with stillbirth or neonatal death. The data relating to each death consists of information about the following: mother's and baby's identifying information (to permit the cross-checking of each death against other national databases and to facilitate the identification of duplicate records), mother's health, lifestyle and previous pregnancy history, mother's antenatal care, labour and delivery, cause of death and post-mortem examination. Approvals have been obtained from all relevant authorities for identifiable data to be collected without consent and to access statutory birth and death information. Further details of data items are provided in **document MK/1**

[**INQ0006746**].

Reporting of mortality rates

11. Rates of stillbirth, neonatal death and extended perinatal death are presented for births from 1 January to 31 December in the reference year; thus, neonatal deaths of babies

born in December 2021 which occurred in January 2022 are included in the report for 2021 births. The reporting of mortality for a birth cohort contrasts with statutory publications (such as those produced by the Office for National Statistics), which are based on deaths in a calendar year. This method of reporting allows more accurate estimates of mortality rates to be produced, as appropriate denominators are available.

12. To facilitate the comparability of mortality rates between organisations, and unless stated otherwise, births less than 24 completed weeks' gestational age and terminations of pregnancy are excluded from the mortality rates reported. This avoids the influence of the wide disparity in the classification of babies born before 24 completed weeks' gestational age as a neonatal death or a fetal loss, as well as the known variation in the rate of termination of pregnancy for congenital anomaly across the UK. The mortality rates reported include all eligible deaths, including deaths due to congenital anomalies, unless stated otherwise.
13. The number of deaths of babies born in the UK in the reference year as described by MBRRACE-UK differs from that of statutorily registered deaths published by the Office for National Statistics (England and Wales), National Records of Scotland and the Northern Ireland Statistics and Research Agency because of the exclusion criteria used to ensure standardisation of mortality rates. It is important to recognise that data sources from statutorily registered births and deaths include both birth and death registrations following termination of pregnancy from 24 completed weeks' gestational age and variable inclusion of births at 23 completed weeks' gestational age and below, depending on whether they were reported as being liveborn or not. MBRRACE-UK receives stillbirth and neonatal death registrations from statutory sources. These data are matched to the detailed MBRRACE-UK death notifications. Of these registered deaths, neonatal deaths are excluded if birth was before 24 completed weeks' gestational age or they were a termination of pregnancy (deaths are classified as resulting from a termination of pregnancy based on the detailed MBRRACE-UK data).

Organisations for which mortality rates are reported

14. Rates of stillbirth, neonatal death, and extended perinatal death are reported for four groups of clinical and administrative organisations.
15. Organisations responsible for population-based care commissioning based on postcode of mother's residence at time of delivery: Integrated Care Boards and sub-Integrated Care Board Locations in England, National and Health Boards in Scotland and Wales, National and Local Commissioning Groups in Northern Ireland and for each Crown Dependency (Isle of Man, Bailiwick of Guernsey, and Bailiwick of Jersey).
16. Service delivery organisations based on place of birth: NHS Trusts in England, Health

Boards in Scotland and Wales, Health and Social Care Trusts in Northern Ireland and for each Crown Dependency (Isle of Man, Bailiwick of Guernsey, and Bailiwick of Jersey).

17. UK Neonatal Networks based on place of birth.
18. Local government areas based on postcode of mother's residence at time of childbirth: single tier authorities, upper tier authorities and London boroughs in England, unitary authorities in Scotland, local authorities in Wales, local government districts in Northern Ireland and for each Crown Dependency (Isle of Man, Bailiwick of Guernsey, and Bailiwick of Jersey).

Analysis of mortality rates

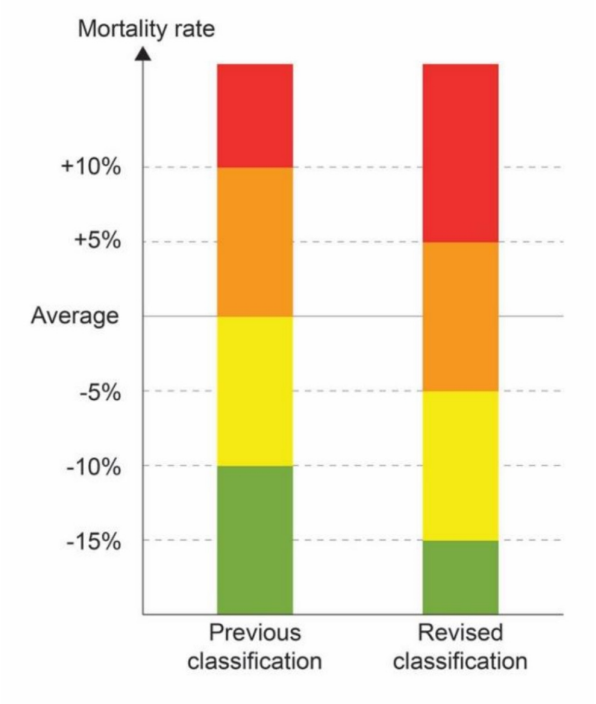
19. Three mortality outcomes are calculated by the MBRRACE-UK perinatal team based at the University of Leicester and reported for each organisation: stillbirth, neonatal death, and extended perinatal death. These mortality rates are presented in several different ways: as a 'crude' mortality rate and as either a 'stabilised' mortality rate or a 'stabilised and adjusted' mortality rate. Stabilisation reduces the effect of high year-on-year random variation, and adjustment takes into account the prevalence of risk factors in the local population. Further explanation of the different rates presented is provided in **document MK/2 [INQ0006748].**
20. It is important to recognise that the mortality rates reported are not definitive measures of the quality of care received by any individual or group. Some of the variation in mortality rates shown in the report might be the result of differences in the proportion of high-risk pregnancies that cannot be accounted for in the analyses due to a lack of routinely collected detailed clinical information for all births.

Presentation of mortality rates

21. The 'crude', 'stabilised' and 'stabilised and adjusted' mortality rates are presented as both tables and maps. Reports including mortality rates for 2015 and 2016 are provided as **documents MK/3 [INQ0006749] and MK/4 [INQ0006750].** Maps have been available in an interactive data viewer since October 2021 (https://timms.le.ac.uk/mbrrace-uk-perinatal-mortality/data-viewer/). In the maps, each organisation is colour coded based on the extent to which their particular mortality rate is above or below the overall national mortality rate. For the organisations based on the postcodes of the mothers' residences at time of delivery, and for Neonatal Networks, this average is the overall observed mortality rate for the whole of the UK and the Crown Dependencies.
22. However, it is known that service delivery organisations based on the place of birth

vary widely in the risk profile of pregnancies referred to their service; therefore, it is reasonable to anticipate variation in their expected mortality rates. To help account for the variation due to the risk profile, all Trusts and Health Boards are classified into five mutually exclusive comparator groups based on their level of service provision and are compared to the overall national mortality rate within their comparator group. The five comparator groups are: Trusts and Health Boards with level 3 Neonatal Intensive Care Unit (NICU) with neonatal surgery, Trusts and Health Boards with level 3 NICU without neonatal surgery, Trusts and Health Boards with 4,000 or more births per annum at 22 weeks or later (no level 3 NICU or neonatal surgery), Trusts and Health Boards with 2,000-3,999 births per annum at 22 weeks or later (no level 3 NICU or neonatal surgery), Trusts and Health Boards or neonatal surgery), units with under 2,000 births per annum at 22 weeks or later (no level 3 NICU or neonatal surgery).

Figure 1: Revised colour coding used to represent mortality rates in MBRRACE-UK perinatal reports since 2017



23. Organisations are then categorised according to whether their mortality rates are above, similar to or below the overall rates for organisations providing similar levels of care. We use colour coding to represent mortality rates in the data viewer and in the reports issued to Trusts and Health Boards. The colour coding used is illustrated in Figure 1. The coding used since 2017 is as follows: green (more than 15% lower than

the average), yellow (more than 5% and up to 15% lower than the average), amber (up to 5% higher or up to 5% lower than the average), red (more than 5% higher than the average). The coding was revised in 2017 in recognition of the fact that the overall UK national mortality rates are higher than in comparable countries and therefore units should only be coded green with rates substantially below the overall national rate.

24. Accompanying tables show stillbirth, neonatal death, and extended perinatal death rates for each organisation.
25. NHS Trusts and Health Boards are provided with a report detailing their own mortality rates and accompanying information to enable them to interpret their results. A sample report is provided as **document MK/5 [INQ0006751]**.
26. Since the analysis of deaths of babies born in 2021 onwards, concerning trends in mortality rates have been highlighted in the individual Trust and Health Board report. Rates of potential concern are highlighted if any of the mortality rates presented (stillbirths, neonatal deaths or extended perinatal deaths) meet any of the following conditions: red in the latest year, consistent decline in colour category over 3 years, red in the latest year and red in both of the two preceding years, or a decline by at least colour categories in the latest year. The letter sent to Trusts and Health Boards explaining this is provided as **document MK/6 [INQ0006752]**.

Data Sharing

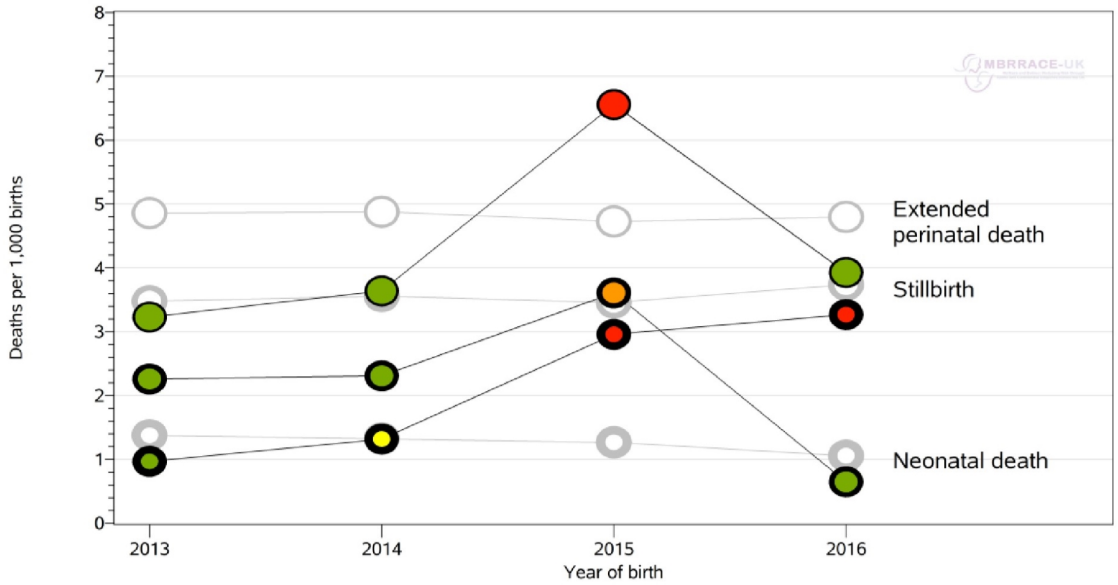
27. Data are shared with external organisations on request after approval by the Healthcare Quality Improvement Partnership Data Access Request Group. We respond to requests from Trusts and Health Boards about their own data without requiring them to go through this data access process. A list of data sharing agreements operating over the time period covered by the Inquiry are supplied as **document MK/7 [INQ0006753]**.

Section 2

Analyses specific to the Countess of Chester Hospital NHS Foundation Trust

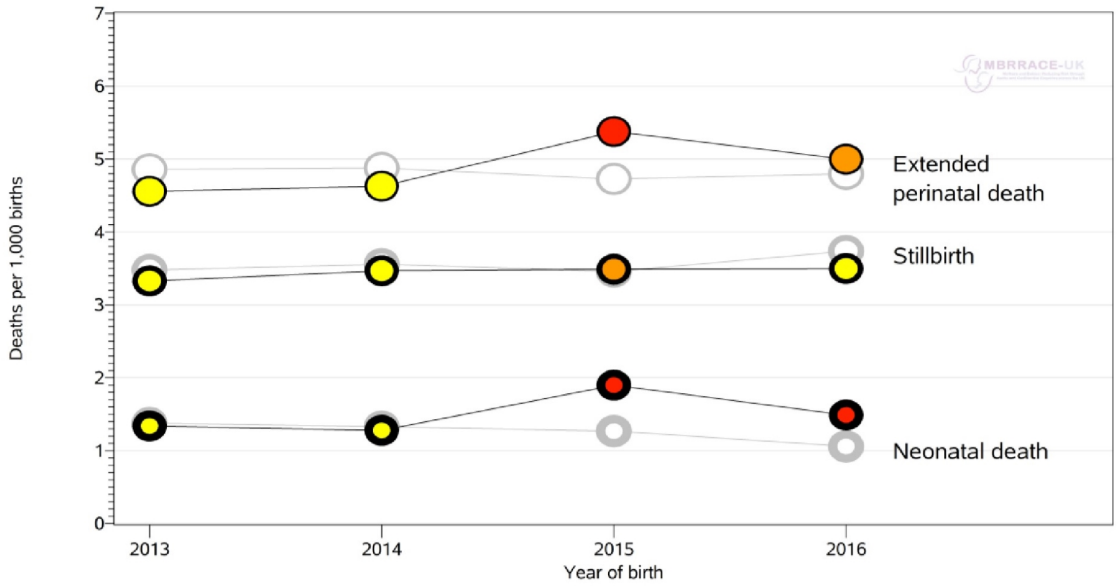
28. Figure 2 illustrates the colour-coded crude mortality rates produced by MBRRACE-UK for babies born at Countess of Chester Hospital NHS Foundation Trust at 24 weeks or later gestational age 2013-2016. The report with data for trends up to and including 2015 was released to the Trust on 15th June 2017 and the report with trends up to and including 2016 was released to the Trust on 8th June 2018.

Figure 2: Crude mortality rates for babies born at Countess of Chester Hospital NHS Foundation Trust at 24 weeks or later gestational age 2013-2016



29. Figure 3 illustrates the colour-coded 'stabilised and adjusted' mortality rates produced by MBRRACE-UK for babies born at Countess of Chester Hospital NHS Foundation Trust at 24 weeks or later gestational age 2013-2016.
30. These trends were identified in the report published on 15th June 2018.

Figure 3: 'Stabilised and adjusted' mortality rates for babies born at Countess of Chester Hospital NHS Foundation Trust at 24 weeks or later gestational age 2013-2016



31. Up to 2016 these colour-coded rates were only published for extended perinatal deaths

in the national report and not for stillbirths and neonatal deaths separately. Separate colour-coded rates were provided in individual Trust and Health Board reports.

32. The following points should be borne in mind when interpreting these mortality rates. MBRRACE-UK reports neonatal mortality based on place of birth, not place of death. Thus, rates of neonatal mortality reported are for babies who were born at Countess of Chester, and they may not have died at Countess of Chester. Similarly, these rates do not include babies who died at Countess of Chester if they were born elsewhere. Neonatal deaths are deaths within 28 days of birth, and may include babies who died on the labour ward shortly after birth and who were not admitted to the neonatal unit. Deaths of babies born before 24 weeks are not included in these rates. Deaths of babies older than 28 days are not included in these rates, even if they died on the neonatal unit.
33. Although mortality rates are presented by place of birth alone, data are collected and reported to each NHS Trust by MBRRACE-UK both on the number of extended perinatal deaths among babies born at that Trust and also on the number of extended perinatal deaths that occurred at the Trust, regardless of the place of babies' birth. Mortality rates are presented by place of birth alone for several reasons but primarily because there are no clear denominator data that can be used to calculate a mortality rate by place of death. Location and occurrence of postnatal transfers will be influenced by factors including events before and during birth, baby illness and neonatal care network pathways. Deaths among babies transferred to a unit after birth are therefore less likely to reflect variation in care received at that particular unit and hence rates including these deaths are much less easy to interpret.
34. Mortality rates by NHS region were not reported by MBRRACE-UK until 2020. In 2015 and 2016 the highest level organisation MBRRACE-UK reported rates for were Sustainability and Transformation Partnerships. These have now been replaced by Integrated Care Boards. Trends were not examined at the level of Sustainability and Transformation Partnerships. Maps and data are provided in **documents MK/3 [INQ0006749] and MK/4 [INQ0006750]**.
35. No MBRRACE-UK data appear in electronic patient records and MBRRACE-UK do not extract any data directly from electronic patient records. MBRRACE-UK do not collect information on Serious Adverse Events which babies experience.

Section 3

More effective use of neonatal data collected by MBRRACE-UK

36. Since May 2019, MBRRACE-UK has provided all Trusts and Health Boards with a real-

time data viewer which enables immediate and ongoing monitoring of all stillbirths and neonatal deaths reported to MBRRACE-UK. An illustrative screenshot of a demonstration version of the viewer is provided as **document MK/8 [INQ0006755]**. This provides a means of responding immediately to any concerning trends. This tool is reliant on timely data being provided by each Trust or Health Board on all baby deaths and therefore actions to ensure timely data provision will make it more responsive. All Trusts in England are required to provide data as part of Quality Accounts. The timeline of data provision is to notify the death within seven days as part of the Maternity Incentive Scheme and we constantly monitor this. Trusts are notified when a death is reported after more than seven working days and when we identify missing cases in routine data. We can only advise Trusts that they have notified a death after more than seven days once they have notified it or after we have identified it from routine data (i.e. we cannot pre-emptively advise them, before the 7 day deadline, that a death is yet to be notified), because we only know about deaths when Trusts report them or they appear in the routine data. Additionally, the data viewer requires a fuller surveillance dataset and these data items are not always provided in a complete or timely manner. Tables 20 and 21 in **document MK/9 [INQ0006756]** provide figures for data completeness and timeliness of notification in 2021. For 2021, 93% of neonatal deaths in England were notified within 7 days, and 97% of stillbirths.

37. In order for the real-time data viewer to be used more effectively I consider that an individual or individuals within each unit should be given responsibility for regular monitoring of the data. The individual will need to receive training on how to interpret the data, when and how to escalate concerns. MBRRACE-UK already plan to add a process control function in the first quarter of 2024 (dependent on staff capacity, user consultation) to automatically identify and flag unusual clusters of deaths. As this function will be built into the existing real-time data viewer, no additional input is required from Trusts and Health Boards, beyond their engagement with the viewer and response to any flags. MBRRACE-UK already provides recommendations around monitoring and response to the data in the Trust and Health Board specific reports (**see document MK/5 [INQ0006751]**). All Trusts and Health Boards have at least two lead reporters nominated by the Trust or Health Board, and one of the roles of the lead reporter is reviewing their Trust or Health Board's data, but we have no means of identifying whether or how this occurs.
38. I consider that there should be an established escalation route to senior management level to ensure that any concerns are taken seriously, and an appropriate action plan put in place. The information considered to generate an action plan should include the summary executive board level report of the issues identified after review of baby

deaths using the PMRT.

39. Additional monitoring of, and responding to, the data in the real-time data viewer at a higher administrative level, such as at the level of an ICB, would add a further layer of assurance that concerning trends are acted upon. There are currently information governance barriers which prevent access at a higher level.

Section 4

Press comments

40. Members of the MBRRACE-UK perinatal team provided factual information on the MBRRACE-UK methodology to Kat Lay, Health Editor at The Times, on 27 July 2023 for the purposes of informing an article relevant to the Inquiry's Terms of Reference. This information is supplied as **document MK/10 [INQ0006747]**.

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: PD

Dated: 10th January 2024