Witness Name: Edile Mohammed Nur Murdoch
Statement No.: 1
Exhibits: EM/1 – EM/9
Dated: 10 July 2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF EDILE MOHAMMED NUR MURDOCH

I, Edile Mohammed Nur Murdoch, will say as follows: -

1. I am a Consultant Neonatologist at the Royal Infirmary of Edinburgh, NHS Lothian (Scotland). I am also currently the Chair of the NHS England Maternity and Neonatal Outcomes Group, having been appointed to this role in April 2023 following a competitive process arranged by NHS England. I hold various other external roles which are set out in the CV exhibited [**EM/1, INQ0098312**] to this statement.

2. This statement seeks to address the issues set out in the Rule 9 request sent to me by the Inquiry on 18 January 2024. I have sought to respond to the Inquiry's questions as best as I am able, noting that some of the questions asked relate to issues falling outside of my specific roles or knowledge. This statement was drafted on my behalf by the external solicitors acting for NHS England in respect of the Inquiry, with my oversight and input. It is the product of drafting after communications between those external solicitors and me, in writing and by video conference.

3. I have structured my response to the Inquiry's questions by first making some general points about this statement before explaining the following:

    a. The tasks that were assigned to the Maternity and Neonatal Outcomes Group from Recommendation 1 of the "Reading the Signals" report into maternity care at East Kent ("the Kirkup Report");

    b. The role of the Maternity and Neonatal Outcomes Group;

c. The role and key principles of safety signal systems in improving outcomes;

d. The methodology that the Maternity and Neonatal Outcomes Group has used to develop MOSS and looking in particular at:

I. What to measure – outcomes; and

II. Validation of the measurement tool;

e. How the established "MBRRACE-UK real time data monitoring tool" is relevant to and will be used with MOSS;

f. What the Perinatal Quality Surveillance Model is and how this relates to MOSS;

g. What is needed to establish a maternity safety signal system;

h. The purpose and intended operation of MOSS;

i. Whether the MOSS can be used to examine data relating to the neonatal mortality events at the Countess of Chester Hospital between 2014 and 2017 and if so, what the conclusions of this analysis tell us; and

j. Next steps in the development of the MOSS and the overall governance intended to apply to the use of both MOSS and the MBRRACE-UK real time monitoring tools.

4. In short, what I will say is:

a. The work arising from the Reading the Signals Report is ongoing and MOSS, which is primarily aimed at identifying potential critical safety issues in maternity care, is still in the development stage. The intention is for this data analysis tool to be used at Trust level, although we are also looking at how it could be used for others such as regulators remotely in the future. In relation to how the tool operates, the intention is for signal data to be entered by trusts as soon as possible, so as to give as close to "real time" data as they can get. This is something that will form part of the testing as we move towards implementation.

b. Safety signal systems such as MOSS improve safety culture, listening and responding to concerns and communication at all levels in a Trust, including the Board. If MOSS was in place in 2015-2016 it is likely to have supported a more responsive, accountable safety culture. However, MOSS only analyses events at term, including term neonatal deaths.

c. The MBRRACE-UK real time monitoring tool does identify changes in frequency of preterm and term neonatal deaths. However, this tool only gathers mortality data up to 28 days after birth, and my understanding is that the some of the crimes committed by LL related to the deaths of babies who had been in the unit longer than this.

d. It has been agreed that the Perinatal Quality Surveillance Model will provide mandated governance in relation to both MOSS and the MBRRACE-UK real time monitoring tool, ensuring Trust to national oversight.

5. A draft of this statement was submitted on 18 March 2024. Following that, the Inquiry confirmed that it would like me to run the analysis I had said that the Maternity and Neonatal Outcomes Group was willing to undertake, looking at data from the Countess of Chester in the period between 2014-2017. This updated and final version of my statement incorporates the conclusions of this analysis and updates on progress of the work.

6. In the course of finalising my statement, I have also made some amendments to the draft previously submitted. The purpose of these amendments is to:

a. apply the current terminology that is now being used to describe the MOSS to ensure consistency;

b. ensure that the work of the Maternity and Neonatal Outcomes Group described in this statement is as up to date as possible, noting that the work to develop the signalling tool described in this statement remains active and iterative; and

c. respond to a further query from the Inquiry in relation to how my team triangulated the data set we received for the Countess of Chester with publicly available information to ensure that the correct month was assigned for each event

Key Terms

7. I have sought to avoid the use of acronyms and technical terms as much as possible in this statement. Some, however, are unavoidable. For ease, I have listed below the key terms used in this statement and the definition of each in this context.

Key Term	**Definition**	**Paragraph reference**
CUSUM	Cumulative Sum. This is a statistical analysis that plots changes in cumulative outcomes over time.	75
Critical Safety	Processes and measures that ensure systems avoid high impact outcomes or adverse outcomes.	16, 28, 31, 34, 35, 78, 84
Hypoxic-ischaemic encephalopathy ("HIE")	Brain injury that is caused by oxygen deprivation to the brain. It can happen before, during, or shortly after birth and can lead to developmental delay and neurodisability.	40, 42, 65
Intrapartum care	This term is used to describe care given to women during labour.	62
Neonatal	This term is explained in more detail in the body of my statement. In short, it describes the time from a live birth up to 28 days following birth. It includes both preterm and term babies.	8-13
MBRRACE-UK real time data monitoring tool	The tool developed by MBRRACE-UK for real time monitoring of perinatal mortality including neonatal deaths. This tool has been operational since August 2019.	17, 25, 51, 54, 55, 62, 85, 90
MOSS	Maternity Outcomes Signal System; the name of the tool that is being developed by the Maternity and Neonatal Outcomes Group to provide a method to identify potential critical safety issues in maternity care that may lead to adverse outcomes.	17, 21, 41-49, 55, 58, 62-64, 69, 73-88, 90

Perinatal	The period covering pregnancy from 24 weeks gestation up until the first 28 days following the birth of a baby.	25, 50, 51, 53, 54, 59, 89
PDS	Data from the Person Demographics Service (PDS) contains information on birth and death notifications, which indicate occurrences of stillbirth and neonatal death.	83
Pre-term	In the context of what I describe in my statement, this means babies born before 37 weeks gestation.	68, 73, 79
PMRT	The MBRRACE-UK perinatal mortality review tool, which has been in operation since 2019. The NHS England Maternity and Neonatal Outcomes Group was not involved in the development of the PMRT.	25, 50, 51, 52, 65
PQSM	This is the NHS England Perinatal Quality Surveillance Model, which was published in 2020 and has been in operation since 2020. It provides the governance and assurance around investigation, reporting and assurance of perinatal quality issues (with regional and national escalation and reporting).	56-58, 61, 78, 85
Term	Babies born on or after the 37th completed week of pregnancy.	8-13, 29, 40, 42, 45, 68, 73, 75, 79
Time between events analysis	The time between events chart shows the number of days between each event. For example, if an event occurred on 1st January 2014 and another on 3rd January 2014 a point would be plotted on 03/01/2014 with a value of 2 days. NHS England Statistical Process Control rules have been applied to this chart to identify variation in the number of days between events that is unusual.	69
VLAD	Variable Life Adjusted Display. A VLAD chart shows the cumulative number of excess events over time compared to what would be	77

	expected if the trust had the same rate as the national event reference rate.	

What can the term "neonatal" mean?

8. The term neonatal is used in different ways. It variously describes:

   a. the time period after the birth of a baby;

   b. clinical conditions and outcomes (for example "neonatal seizures");

   c. services (for example "neonatal unit"); and

   d. professional roles (for example, "neonatal nurse" or, in my case, "neonatologist").

9. The neonatal period is the time from a live birth up to 28 days following birth. This includes babies born preterm and at term.

10. Neonatal outcome data refers to a wide range of recognised measures that can be used to assess the safety and quality of neonatal care and understand the natural history of clinical conditions. Outcome data can be measured at birth, during inpatient admission, at discharge from hospital and during longer term neurodevelopment follow up into childhood.

11. Most babies born at term are healthy and are not admitted to a neonatal unit, but some can be e.g., if there is an infection or where respiratory support is required. The majority of preterm babies are admitted to a neonatal unit.

12. Most neonatal deaths are preterm. Term neonatal deaths are rare.

13. Term neonatal deaths may be caused by sub optimal maternity care. Preterm neonatal deaths are more likely to be caused by known complications of prematurity.

Tasks assigned from the "Reading the Signals" report recommendations

14. The "Reading the Signals" Report of the independent investigation led by Dr Bill Kirkup into maternity and neonatal services in East Kent was published in October 2022. The report found that adverse outcomes for mothers and babies in East Kent were caused by suboptimal maternity care. It did not find evidence of suboptimal neonatal care.

15. The "Reading the Signals" Report had 4 recommendations. One of these, Recommendation 1, was for "the prompt establishment of a Task Force with appropriate membership to drive the introduction of valid maternity and neonatal outcome measures capable of differentiating signals among noise to display significant trends and outliers, for mandatory national use." Recommendation 1 reflects the problem that, despite the availability of sizeable and high quality data, there is not a system that can use this data to promptly alert maternity services about potential safety issues that could lead to adverse outcomes.

16. The task set in Recommendation 1 was therefore to develop a tool that could identify signals about potential critical safety issues in maternity care that could lead to adverse outcomes. The tool should prompt effective and timely maternity critical safety assessments to determine the cause of the signal and any actions required. The tool should use existing data that is routinely collected and not make recommendations for new data collection (recognising the volume of data already collected). NHS England was asked to take Recommendation 1 forward and implement it, as described below.

17. In the "Reading the Signals" Report sub optimal neonatal care was not found to have significantly contributed to the adverse outcomes. Standardised reviews of preterm deaths have not shown significant contributions of poor maternity or neonatal care. While there may be benefit in a neonatal outcome signal system, this was not part of Recommendation 1 and based on our current knowledge, there is a good tool already available (the MBRRACE-UK real time data monitoring tool). However, the learning from the methodology and approach we have used to develop the MOSS could be applied if another neonatal-specific tool would be of benefit.

Establishment of the maternity and neonatal outcomes group

18. In order to action Recommendation 1, NHS England established a stakeholder group to be known as the Maternity and Neonatal Outcomes Group [**Exhibit EM/2, INQ0098311**]. As noted above, I was appointed Chair of this group in April 2023. My role is to build consensus across the maternity and neonatal clinical community and provide advice, scrutiny and challenge to drive the delivery of the recommendation. I report to the Chief Nursing Officer for England.

19. The Maternity and Neonatal Outcomes Group contains a range of stakeholders from across the NHS and its partner organisations. It also includes service user voice representation to ensure users of maternity and neonatal services are involved in national policy and decision-making. **Exhibited** [**EM/3, INQ0098314**] to this statement is a list of the Group's current members.

20. The group receives external specialist advice from Dr Bill Kirkup and Professor David Spiegelhalter (Emeritus Professor of Statistics in the Centre for Mathematical Sciences, University of Cambridge) who both have extensive experience from their work on national safety enquiries and safety signal systems. Dr Kirkup was, as described above, the author of the East Kent report, which contained Recommendation 1.

21. Two sub groups were established to progress specific pieces of work on (i) developing the signal measurement tool and (ii) the outcome measures to be used for the tool. Dr Bill Kirkup and Professor David Spiegelhalter are part of the former group, which has responsibility for agreeing and validating the statistical methodology required for MOSS.

Identifying the value of safety signal systems, benefits and limitations

22. The Inquiry has asked me to describe the value of early warning systems, the benefits and limitations of such systems.

23. The definition of a safety signal system we have adopted is as follows:

> "A safety signal system refers to a structured method for identifying, monitoring, and responding to potential safety issues, especially in contexts where risks to

human health or safety are involved. These systems are designed to detect early signs of potential problems, allowing for timely interventions to prevent harm."

24. Safety signal systems are known to improve outcomes in health care and non-health care settings (for example in transport, military and sport). There are other clinical services that are using safety signal systems tools, such as Understanding Children's Heart Surgery Outcomes and PICANet for paediatric intensive care services. My understanding is that these systems have contributed to improved outcomes.

25. In a neonatal context, there is already a monitoring tool available. This is the MBRRACE-UK real time data monitoring tool, which is available to individual neonatal and maternity units. This signal system monitors real time changes in perinatal mortality. This tool is different from the PMRT, which I have described below.

26. The benefits of a safety signal system are as follows:

    a. improvement is in part achieved from the effects of a team routinely monitoring and responding to potential safety signals in their day-to-day work in a structured mandated way;

    b. improved leadership, team working, communication, resilience, local ownership and accountability;

    c. effective and timely escalation and responses; and

    d. automated mandatory responses to signals that removes the opportunity for personal opinion to change, limit or prevent a response.

27. The limitations of safety signal systems occur if the outcomes being measured are weak signal indicators and/or if the data feed is unreliable, resulting in a signal that cannot be interpreted. Another limitation is if the signal is misunderstood and communicated as a cause for concern or if users do not know how to interpret and respond to a signal.

28. Safety signal systems work through monitoring real time changes in the trends of defined critical safety outcomes. A signal prompts an early critical safety review to understand the causes of the signal change. It is the subsequent assessment and review that will identify

if there are safety issues to be acted upon. Safety signal systems need a governance oversight to ensure that actions are implemented.

29. A safety signal system can measure outcomes such as: the death of a preterm or term baby or other serious adverse baby outcomes, such as brain injury.

30. However, it is important to emphasise that a signal is not an indicator of concern or outlier status. It is also not an investigative tool. The signal is simply a prompt for a rapid assessment to understand what has caused the signal.

31. Although there are many existing maternity data reports, we could not identify a safety signal system that alerts potential critical safety issues in maternity care that could lead to adverse l outcomes (noting that the MBRRACE-UK tool provides signals changes in mortality rates).

32. So, while there is extensive healthcare data in this area (summarised below) there is a gap in the provision of real time data to monitor potential safety issues. Currently, the data collected informs us about different aspects of maternity and neonatal care including:

    a. Assurance of quality and safety of services;

    b. Quality of clinical outcomes;

    c. Quality of patient and staff experience;

    d. Performance of services;

    e. Public health and epidemiology.

33. In each of these cases, retrospective data analysis and periodic reporting (of between 4 months and 2 years) serves the purpose that the data is being collected for.

<u>Summary of agreed learning about signal systems</u>

34. To summarise, the Maternity and Neonatal Outcome Group's agreed learning about signal systems is as follows. Safety signal systems:

a. improve outcomes and should be developed to contribute to the improvement in maternity and neonatal outcomes;

b. are a prompt and do not indicate a concern;

c. remove personal opinion that might otherwise limit or prevent a response to a signal - this is done through having a required mandatory response to a signal; and

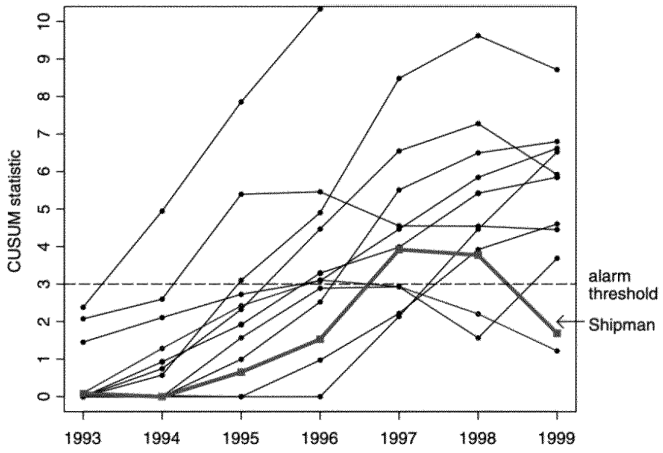
d. important requirements for any signal system are: agreeing the critical safety systems and outcomes to be measured, statistical methodology for measurement, availability of real time data, response to signals, oversight of actions and communication of findings

35. I believe that there is much the NHS can learn from the industries we studied in our initial scoping work and the Maternity and Neonatal Outcomes Group has commenced work with the NHS England Safety Systems Management Group looking at defining maternity critical safety systems and check lists for the user and review guides. This group has representation from other relevant organisations and industries, such as British Airways.

Illustrating what a safety signal system can and can't tell us

36. A safety signal system demonstrates unusual changes in signals but cannot explain why the signal has changed and does not indicate a concern or outlier status. This is identified by the carrying out of the accompanying assessment and escalation process. *Figure 1*, which is a graph from the Shipman Inquiry, illustrates this principle.

Figure 3. CUSUM charts for the 12 GPs (out of 1009 monitored) who signalled (i.e. whose chart statistic crossed the alarm threshold of 3) between 1993 and 1999: Shipman's chart is shown in bold red



37. In this graph, the signals being measured are deaths in an elderly population. A threshold needs to be set to indicate the accepted rate of death in this population (dashed line). 1009 GPs mortality rates were monitored using the safety signal methodology. 12 GPs signalled in the period between 1993 and 1999. This meant that they crossed the signal threshold. The findings of the assessment were that 11 of the 12 GPs worked in areas with higher than average care homes for the elderly, so the increased death rate could be explained. One of these 12 was Dr Shipman and the assessment could not find an explanation for this signal, so this became a true concern. The fact that the signal happened would not have by itself told anyone that Dr Shipman was a murderer, but the assessment would have identified Dr Shipman was an outlier. Based on this analysis this signal would have alerted us to Dr Shipman's mortality rates around 18 months before concerns were actually raised.

Choosing the measures to be monitored

38. A safety signal system measures critical outcomes or metrics. Typically, these are rare events and only a small number of measures are required. In order to determine what outcome measures to include we established the following 4 criteria against which all of the possible outcomes were tested:

    a. There should be a high potential of causation from care and service delivery issues (Duty of candour, avoidable harm, sub optimal care)

    b. There should be a low index of causation from known clinical conditions

c. The outcomes should be defined consistently by clinicians

d. The outcome data should be entered into a national standardised data entry system.

39. There were a number of metrics tested by the outcome sub group before a decision was taken by the Maternity and Neonatal Outcomes Group about which of these potential outcome measures were available for testing in the context of a maternity and neonatal outcomes safety signal system.

40. Since the draft statement, the outcome measures have been further defined to better reflect safety signals. For example, the neonatal death outcome change is based on updated information that maternity care can contribute to why term babies die within the first 28 days of life (rather than the initial 7 day period proposed). The HIE change is aimed at reducing potential "gaming" of the system, i.e. the ability of a healthcare professional to influence data entry by choosing one form of treatment rather than another. The updated HIE outcome now reflects HIE grade 2 and 3 with or without cooling (rather than as initially proposed as being only those who were cooled).

41. The Maternity and Neonatal Outcomes Group was also asked to extend the analysis to all neonatal deaths, including preterm deaths by members of the group and from feedback at presentations. However, in the end, this analysis has not been progressed. This is because as a Group, we now have a better understanding of the MBRRACE-UK real time monitoring tool. The MBRRACE-UK team are also part of the Maternity and Neonatal Outcomes Group data sub group. What we now know is that the MBRRACE-UK real time monitoring tool already provides data on trends for all neonatal deaths. However, currently, this data is available to individual units only. What we concluded was that it would be better to propose using both MOSS and the MBRRACE-UK real time monitoring tool together, to enhance safety signal system use and interpretation. We also concluded that the same guidelines and governance should apply to both tools.

42. In summary, as a result of our work on what outcomes should be monitored, the current agreed outcomes for MOSS are:

a. Babies born at term with HIE grade 2 or 3 with or without therapeutic hypothermia ("cooling")

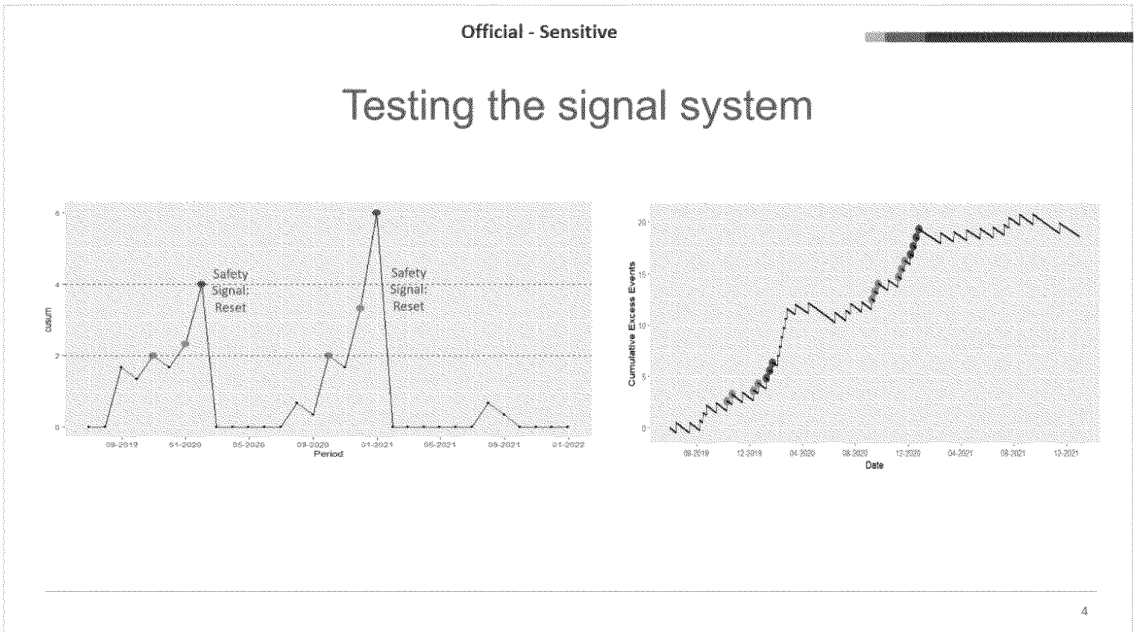
b. Term stillbirths

c. Term neonatal deaths within 28 days after birth.

d. I have described later in my statement what the next stages of testing the MOSS will involve.

Building the MOSS

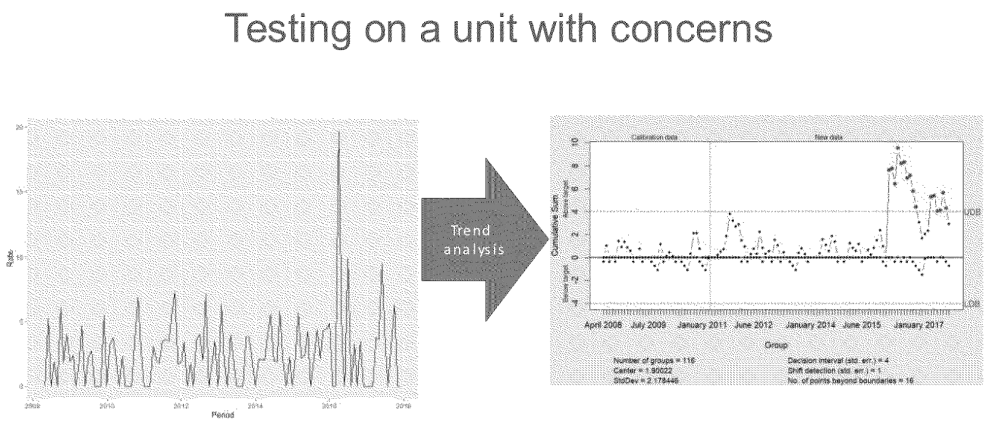
43. *Figure 2: Testing the signal system* shows the two different visual representations of the signals that will be tested when we proceed to live-testing (see paragraph 49 for further information about this stage). The data shown in *Figure 2* was generated through testing on all 120 maternity units in England. We will be seeking feedback from test users at that stage on how they interpret the different visualisations and how each is understood.



44. In the left-hand picture, the lower horizontal dotted line is the local signal threshold level, while the upper line is the national signal threshold. Once the signal line is reached, action will be triggered. I have described below how we intend to mandate and structure this action.

45. The signal thresholds are calculated based on a doubling of the number of predicted events in the trust, compared to the national reference rate. The lower signal threshold represents a 95% confidence that the doubling of adverse events is not due to chance alone. If this threshold is crossed, a local signal is generated. The upper signal level represents a 99% confidence that the doubling of adverse events is not due to chance alone. If this threshold is crossed, a national signal is generated. To be clear, the term local and national does not relate to whether the steps required once the signal is generated are local or national. Each threshold simply represents a different level of statistical confidence.

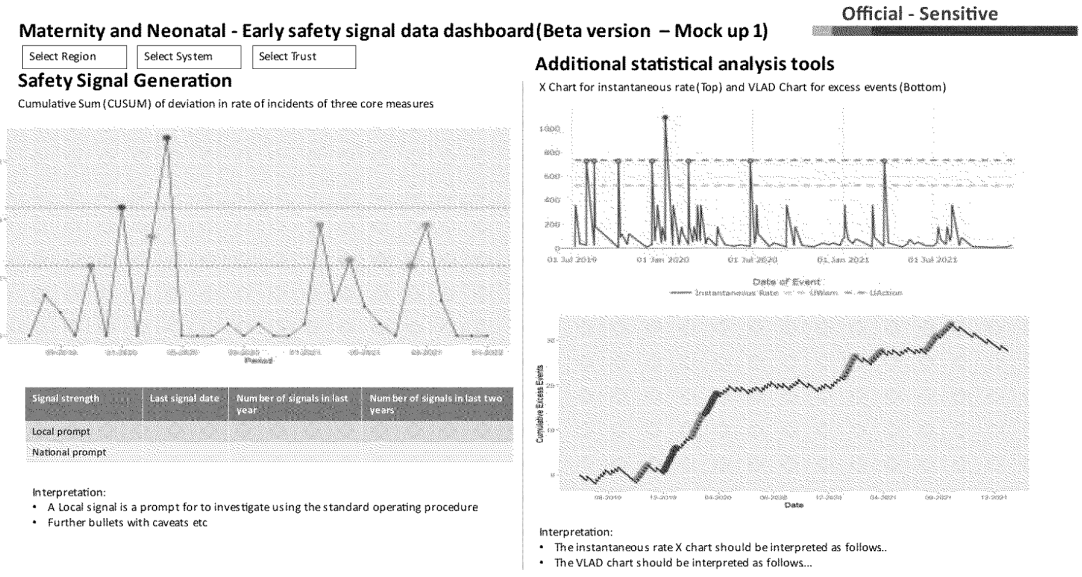
46. *Figure 3: Testing on a unit with concerns* shows the application of the MOSS to East Kent data. What this shows us is that there was a signal in early 2016 through to late 2017(with the index case that raised concerns being November 2017). The data reached the threshold in 2011. However, we cannot say what this means because the necessary interrogation has not taken place. What it does represent, however, is an opportunity when a signal could have been investigated and action taken as appropriate.



47. The MOSS has been tested using retrospective data from 2019-2021 for each NHS Trust in England [**Exhibit EM/4, INQ0102044**]. This included a review of the data from the Countess of Chester and the results of this testing are **exhibited** [**Exhibit EM/8, INQ0102054**] to this statement. Some of the trusts that had signals were either on or subsequently referred to the MSSP. However other trusts that signalled were not. This

confirmed the important principle that a signal is a prompt for review and not an indicator of outlier status.

48. At this stage in the project the MOSS has been validated for testing. This technically, therefore, enables us to meet the requirements of the "Reading the Signals" Report Recommendation 1. The current dashboard is designed as set out in *Figure 4* below.



49. However, what the Maternity and Neonatal Group has learnt is that safety signal systems require further processes to test, validate and achieve operational reliability. The Maternity and Neonatal Group's learning to date, its risks and opportunities, as well as our proposed workplan for 2024 was set out in an update I provided to the Chief Nursing Officer for England in the Autumn of 2023 and which I have **exhibited** [**EM/3, INQ0098314**] to this statement. In summary, however, the processes we have identified as being needed to accompany the MOSS are a user guide, assessment and response guide and a nationally recognised assurance and governance system. I have described this further later in my statement.

MBRRACE-UK perinatal mortality reporting

50. The Inquiry has asked me to explain when perinatal morality review tools were introduced and to comment on their effectiveness. I have addressed this below as best I can. However, I would like to emphasise that I was not personally involved in the development

or introduction of these tools. In my clinical practice I have used the PMRT and annual reports and found them to be effective.

51. There are 3 key outputs from MBRRACE-UK that inform maternity and neonatal services on perinatal mortality:

    a. a tool for standardised perinatal mortality review of individual cases for services and families, the PMRT;

    b. annual reporting of perinatal mortality with 3 year trend changes; and

    c. a perinatal mortality real time data monitoring tool for individual units.

52. The PMRT, delivered by the MBRRACE-UK/PMRT collaboration, is commissioned by the Healthcare Quality Improvement Partnership (HQIP) on behalf of the Department of Health and Social Care (England), NHS Wales, the Health and Social Care Division of the Scottish Government and the Northern Ireland Department of Health. It was designed to support the review of baby deaths, from 22 weeks' gestation onwards, including late miscarriages, stillbirths and the deaths of babies who die in the post-neonatal period having received neonatal care. I believe the review tool has been available since 2019.

53. In addition, MBRRACE-UK publish an annual perinatal mortality report for all maternity and neonatal units in the UK. This reports retrospective data with 3-year trends.

54. MBRRACE-UK also provide a real time data monitoring tool, which facilitates Trust-level data monitoring of changes in frequency of perinatal mortality rates. This tool demonstrates changes in frequency in perinatal mortality and allows such changes to be monitored. In relation to the Inquiry's specific question, I believe the MBRRACE-UK real time data monitoring tool was introduced around 2019 and there was no real time perinatal mortality monitoring in place during the 2015-2016 to monitor trends or patterns in real time.

55. The MBRRACE-UK real time data monitoring tool operates on a similar basis as the safety signal systems described earlier in my statement and allows the detection of a change of frequency of deaths on a real time basis. It can therefore be used to identify changes in trends. However, using, responding to and governance oversight of the real time

monitoring tool is not currently mandated and I consider this is a limitation. I have exhibited and described below the agreed plan between NHS England and MBRRACE-UK to develop a mandated user and response guide with the Perinatal Quality Surveillance Model national surveillance model providing governance oversight for both MOSS and the MBBRACE-UK real time monitoring tool. [**Exhibit, EM/6, INQ0102043**].

Perinatal Quality Surveillance Model and National perinatal surveillance group

56. The Inquiry has asked me to explain the purpose of the PQSM, how it works and who has access to data collected as part of the PQSM.

57. In December 2020, NHS England established a revised Perinatal Quality Surveillance Model, with a National Perinatal Surveillance Group providing oversight and governance. I was not involved in this work and so cannot speak to its establishment. However, I have become familiar with the PQSM through my work as Chair of the Maternity and Neonatal Outcomes Group and attended some of the national surveillance meetings. My understanding is that the purpose of the revised PQSM was (and remains) to provide a consistent and methodical oversight of all maternity services safety so as to target support to trusts in greatest need. I understand that NHS England are currently in the process of updating the model. I also understand that no similar surveillance model exists in Scotland, Northern Ireland and Wales (and I can confirm this from personal experience for Scotland, which is where my clinical neonatology work is carried out).

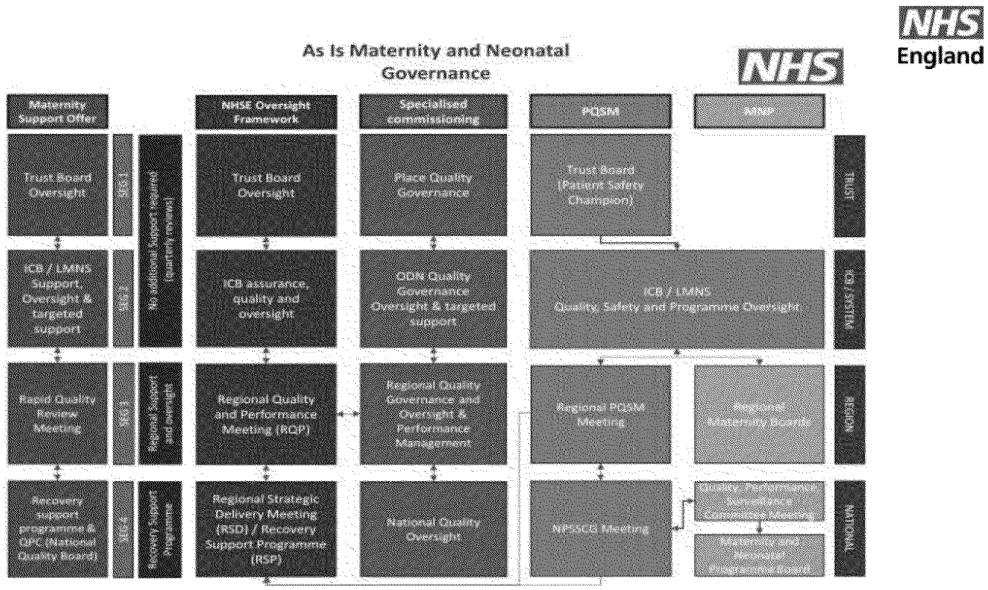
58. I had no personal involvement in the development of this model but have exhibited to this statement the guidance published by NHS England which explains the purpose of the model and how quality oversight should be implemented at a local, regional and national level [**Exhibit EM/7, INQ0018013**]. The intention is for the MOSS to be included in the data that maternity units submit through the PQSM for local, regional and national surveillance.

59. One of the five key principles of the model is national oversight of perinatal safety and quality. This includes aligning national governance with the perinatal clinical quality model. At national level, the current highest level of maternity-specific response involves the National perinatal surveillance group placing trusts on the Maternity Safety Support Programme if required. Maternity services are formally entered onto the programme if they

are rated 'requires improvement' or 'inadequate' in the well led and/or the safe domains by the Care Quality Commission.

60. In my personal view, this appears to be a very effective governance model for monitoring the safety and quality of maternity services by achieving regular national review of all maternity units safety and improvement status and the need for additional support. I am unable to comment specifically on whether the safety of maternity services has improved as a direct result of the model. In response to the Inquiry's specific question, I am not aware of any concerns regarding the sharing of data under the model.

61. *Figure 5: Maternity and Neonatal Governance – current state* sets out the governance arrangements currently in place. The right-hand side of the diagram shows the PQSM governance.



Events at the Countess of Chester Hospital

62. As set out above, as part of testing the MOSS we have carried out a review of data from 2019-2021, including the Countess of Chester Hospital. It is important to note again that, as explained above, the MOSS monitors safety signals in maternity care, in particular where intrapartum care is delivered. It is monitoring safety signals for potential adverse outcomes associated with that care. As a result, MOSS will not identify signal changes relating to preterm neonatal deaths on a neonatal unit where neonatal care is the key contributor but the MBRRACE-UK real time data monitoring tool can (and does is those units currently using it).

63. In my draft statement, I confirmed that the Maternity and Neonatal Outcomes Group would be willing to test the MOSS with data from the Countess of Chester between 2014 and 2017. I understand that MBRRACE-UK are also willing to use its real time monitoring tool in this regard.

64. In order to carry out this analysis, I asked the Inquiry to provide me with this relevant data and confirmed that I would then arrange for the analysts supporting the development of the MOSS to do the modelling.

65. In order to run this analysis, the Inquiry supported me in obtaining the following data from MBRRACE-UK and from NDAU (rather than directly from the Countess of Chester):

    a. MBRRACE-PMRT death data for the Countess of Chester for the period 1 January 2014-21 December 2017 (the data received from MBRRACE also included data from 2013 to ensure that it would include any deaths that occurred in early 2014 for the reasons I explain below at paragraph 69); and

    b. Brain injury data from the Neonatal Data Analysis Unit at Imperial College Healthcare NHS Trust and, specifically, the month of birth of all babies born in the Countess of Chester Hospital and all other maternity units in England who were subsequently admitted to a neonatal unit with a diagnosis of HIE 2 or 3. With this data to cover the period 1 January 2014-21 December 2017.

66. This analysis has now been done and the full results are exhibited to this statement in the report prepared by my team ("the MOSS Report"). I have also set out below the key conclusions reached. [**EM/5, INQ0102051**].

67. Before setting this out, I would like to explain some limitations and how to read the graphs contained in the MOSS Report.

68. First, the data contained in the MOSS Report does not cover deaths occurring in pre-term babies and deaths of term babies after 28 days.

69. Second, in contrast to how MOSS will be used by hospitals when it is operational, the retrospective data we received from MBRRACE-UK did not include the actual date of each

baby's death. This was due to the information governance requirements that MBRRACE-UK have in place to protect patient confidentiality when sending data to third parties. Instead, the data is provided using a sequential timeline commencing on a "Reference Day", which is a date within a 120 day period of the start date. Each event reported after that is identified in accordance with the number of days that have passed since the reference day. This is known as "pseudonymisation" because it means that the data is less able to be linked to a specific identifiable individual. The fact that the data is provided in this way does not affect the trend analysis done by MOSS as the data range between incidents remains the same and the overall conclusions discussed further below at paragraphs 75-80 would be the same regardless of whether we were provided with the actual dates of each death.

70. Nevertheless, I was conscious that the Inquiry was specifically interested in the deaths that occurred as a result of LL's actions during the Indictment Period and I wanted to ensure that it was able to see as closely as possible what would have likely been the results had the tool been run by the Countess of Chester at the time of the events (instead of using retrospective MBRRACE-UK data that had been pseudonymised). In order to provide the Inquiry with the most useful information, we wanted to make sure that the correct month had been assigned to each event. In order to do this, we triangulated the data we had obtained from MBRRACE-UK with information that was publicly available about the date of death and gestational age for each baby on the indictment.

71. The Inquiry has specifically asked me to identify the publicly available information concerning each baby's murder used as part of this triangulation exercise and how it was used in the work done. The data provided by MBRRACE-UK gave gestational age, whether it was an early or late neonatal death and the number of days between the actual date of birth and the Reference Day. This data showed that there were two births on day PD (PD days from the Reference Day) and that the outcome for both was early neonatal death. The deaths of babies born on the same day is highly unusual. In the case of the two births on day 1228, this was the only instance in the MBRRACE-UK data set within a 120 day range of June 2016. By looking at the Sentencing Remarks, we were able to see that the actual date of birth of the twin babies "L" and "M" was PD June 2016. The team concluded that the two babies born on day PD were very likely babies "L" and "M".

72. Since my team now knew the probable date on which babies "L" and "M" were born it could establish the date of the Reference Day by counting back PD days until it reached PD February 2013. The team then used data from the sentencing remarks regarding babies A, C, D and E to further validate the accuracy of the Reference Day. This enabled the team to identify more accurately the month that each event occurred and generate data that would be more akin to what would have been achieved had the tool been run by the Countess of Chester at the time. This process is what was referred to as "triangulation" in the MOSS Report.

73. To answer the Inquiry's specific question, I can confirm that whilst some pre-term deaths were used to determine the Reference Day (ie the deaths of babies A, C, E, L and M), no pre-term baby deaths were included in the modelling set out in the MOSS Report for the reasons explained above at paragraph 42. Whilst we cannot confirm the position for certain, it appears that there was only one early term death of a baby on the Indictment (Baby D) that has been identified in the signal generated by MOSS.

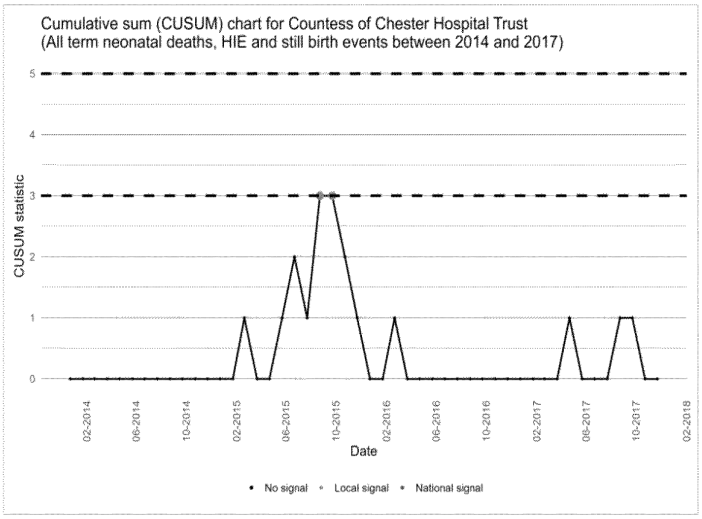
74. It is important that I emphasise again that the triangulation done in this case would not normally be necessary and will not be done when MOSS becomes operational. It was done specifically in this case because:

    a. Pseudonymised data was obtained from MBRRACE-UK, rather than raw data from the Countess of Chester directly; and

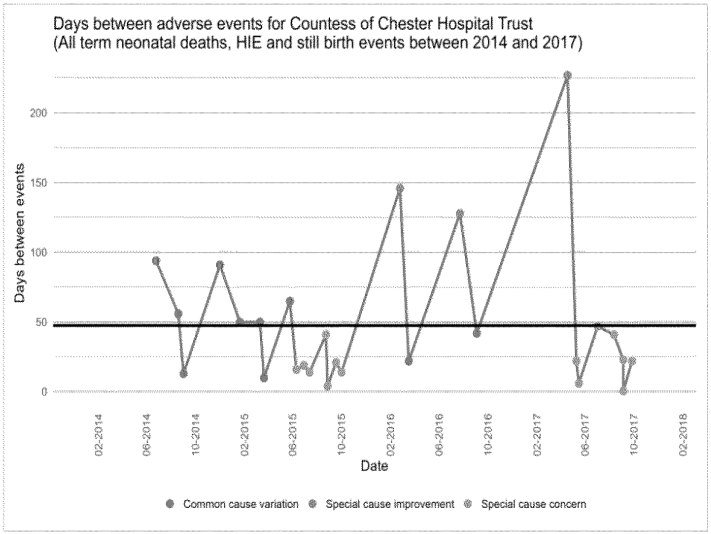
    b. I wanted to ensure that the Inquiry could see as closely as possible using retrospective data how the tool would have operated if it had been used by the Countess of Chester at the time of the events.

<u>The results</u>

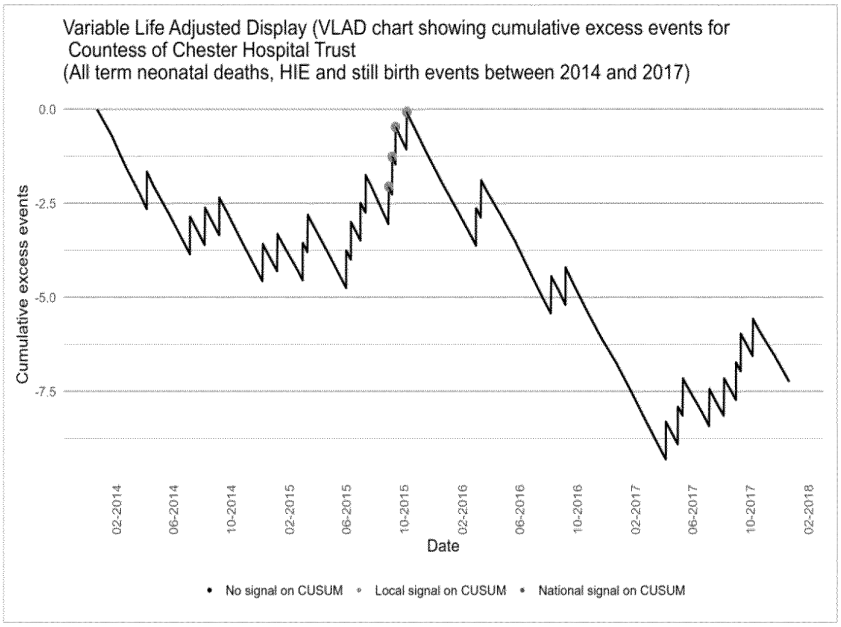
75. *Figure 6: MOSS using CUSUM* this is a chart using the CUSUM analysis, showing the signals that would have been raised for the Countess of Chester data in the period 2014-2017. It shows that there were 2 occasions in 2015 when the local threshold would have been met and a signal would have been raised. These are shown with yellow dots. The national reference rate is calculated as the total number of events, divided by the total number of term births for England between 2014 and 2017.



76. *Figure 7: MOSS using time* applies the same data as for Figure 6 but in this analysis we were testing for time intervals between events. As can be seen, this shows two periods where there was a cluster of events (in 2015 and in 2017). These are shown with yellow dots. The line on the chart represents the average (mean) number of days between events for the Countess of Chester between 2014-2017.



77. *Figure 8: Presentation of the MOSS data using VLAD* this is again applying the same data as for Figure 6 but this is a recognised way of displaying the results and uses a widely used visualisation method known as Variable Life Adjusted Display ("VLAD"). The yellow dots show the 2015 signal change. VLAD is the display used by PICANet, for example.



78. If MOSS were in place at the time, the signals would have prompted a standardised critical safety assessment to understand why the signal occurred. The findings and recommendations of the assessment should/would have been escalated through the Board, the local maternity system, regional and ultimately to the National Perinatal Surveillance Group using the PQSM. The PQSM ensures that data from all maternity units is reviewed each month. If there were underlying maternity critical safety issues these should have been identified through this assessment and surveillance system.

79. However, to reiterate, MOSS only analyses term neonatal deaths. I have run the analysis based only on the data that was requested from MBRRACE-UK and NDAU, i.e. term data. If any of the term LL deaths were in this data set then the cases would have formed part of the early assessment and escalation summarised above. Pre-term deaths would not be signalled on this tool and are not on the graph.

80. More generally, safety signal systems improve safety culture, listening and responding to concerns and communication at all levels in a Trust, including the Board. If MOSS was in place at the time, it is likely to have supported a more responsive, accountable safety culture.

Next steps

81. There are three key areas of work to complete the development of MOSS and prepare for implementation. These are:

    a. Putting in place the arrangements for live data feed into the MOSS;

    b. Developing guidance to accompany use of the MOSS;

    c. Developing a plan for effective and supportive implementation.

82. I have briefly described each of these areas in more detail below.

Live data feed

83. The plan is that the MOSS will be "fed" data reported into the Submit Perinatal Event Notification ("SPEN"). The SPEN is being developed as a joint venture between the Maternity and Newborn Safety Investigation Programme at the Care Quality Commission, NHS Resolution, MBRRACE-UK and NHS England. However, the SPEN is not yet operational and our current estimate is that work to enable this to go-live will be completed by the end of the current financial year. MOSS is unable to go fully-live until the SPEN is also ready to be operationalised. However, interim measures are being developed to allow live testing of the MOSS while work is ongoing to put in place arrangements for the SPEN. The Maternity and Neonatal Outcomes Group are exploring use of data obtained from the PDS. Use of PDS data for this purpose remains subject to Information Governance and quality assurance processes.

Guidance for use

84. As I have explained, the work of the Maternity and Neonatal Outcomes Group to date has work has highlighted an important and essential opportunity to define an improved understanding of maternity critical safety systems and develop the critical safety system infrastructure required to support the routine use of the MOSS to drive reduction in avoidable harm. There is an opportunity for a professional and service cultural change to achieve standardised, reliable responses to critical safety signals.

85. To support this, we intend to develop guidance that sets out a mandated way of assessing, responding and escalating changes in signals. We will be working in partnership with MBRRACE-UK to ensure that this applies to both the MBRRACE-UK real time data monitoring tool and the MOSS. Currently, we envisage this guidance to consist of a user guide, review guide and assurance framework, all of which would be embedded in the PQSM.

Planning for implementation

86. Testing of the MOSS and guidance is due to be conducted in the Autumn of 2024 with the East of England region. Feedback from this testing will determine the timeline, resourcing and requirements for a national roll out with a possible start in 2025 (all of which is subject to the development and operational deployment of the SPEN).

87. A specific approach to team working, leadership, training and culture will be needed to support the embedding of the MOSS at local, regional and national level. There are good examples of this infrastructure from other services and organisations that use safety signal systems. As part of planning for effective implementation, we intend that the guidance described above will be accompanied by training. It will be important for staff to understand and perceive the MOSS as a positive and supportive tool. Implementation will also take time as it involves cultural change, as well as the adoption of new ways of working.

88. I am confident that these are challenges we can overcome as further work is undertaken and there is greater understanding about the purpose and benefits of the tool. However, it will be important to recognise that effective implementation of MOSS will take time and require ongoing support and commitment from the partners who have been involved in the development so far. This reflects the experience from other monitoring tools (such as children's cardiac surgery and PICANet), which have taken at least 18 months to become familiar with the audit system and have a national team to provide ongoing support and feedback.

89. I have recently started to present on the work of the Maternity and Neonatal Outcomes Group to NHS England regional perinatal teams, and have **exhibited** [**EM/9, INQ0098310**] the presentation I gave to North East Yorkshire on 11 March 2024 as an example. Together with Dr Bill Kirkup, we have also presented to the East Kent Board and family

representative oversight Board. My impression of these sessions is that there is a lot of positivity and engagement.

Concluding remarks

90. A concerning theme from the LL case and from previous national maternity reviews is that staff concerns were not heard or acted on. I am pleased to have this opportunity to help develop a system that will introduce objective measures of outcomes and trigger mandatory responses when potential safety issues are signalled. The MOSS and MBRRACE-UK real time data monitoring signal systems are planned to have common escalation, with local to national oversight. Sustained resourcing with expert and paced implementation will be required for this new way of working. I am hopeful this initiative with contribute to helping to prevent tragic events like this recurring

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: 10/07/24