

Witness Name: Professor Neena Modi

Statement No.: 1

Exhibits: NM1 The Neonatal Data Set

Dated: 05-12-23

## THIRLWALL INQUIRY

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### WITNESS STATEMENT OF PROFESSOR NEENA MODI

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I, Neena Modi, will say as follows:

#### **Section 1 Background**

1.1 I am a clinician and Professor Neonatal Medicine at Imperial College London and Chelsea and Westminster NHS Foundation Trust. I hold the following professional degrees: MB; ChB; MD; FRCP; FRCPCH; FFPM; FMedSci. I lead a multidisciplinary neonatal medicine research group focussed on improving the health and life-long wellbeing of infants born preterm or sick. I have published over 350 peer reviewed original research papers, chapters in textbooks, reports, and other publications. I lead the UK National Neonatal Research Database (NNRD), an International Neonatal Research Database (eNewborn), and the current National Institute for Health Research, Imperial Biomedical Research Centre “*Pregnancy and Prematurity*” theme. The Thirlwall Inquiry has asked me to provide a Witness Statement with particular reference to national clinical data in preventing or identifying unusual occurrences and changes, if any, that could be made in respect of the use of neonatal data to improve the quality of care and safety of newborn babies.

1.2 The NNRD is a National Information Asset, a dynamic relational database containing around 450 variables many recorded daily, that flow from the Electronic Patient Records of admissions to NHS neonatal units. NNRD data include demographics, diagnoses, outcomes, treatments and care processes many of which clinical staff record daily during the neonatal in-patient stay. A version curated for artificial intelligence and other data science applications, the NNRD-AI, is also available.

1.3 My team and I led the establishment of the NNRD in 2007 at our research unit, the Neonatal Data Analysis Unit, at Imperial College London and Chelsea and Westminster NHS Foundation Trust, in collaboration with a wide range of stakeholders. These include representatives of the British Association of Perinatal Medicine and Bliss, the national newborn charity, clinicians, researchers, and others involved in newborn care. We continue to manage and develop the NNRD. A Steering Board with an independent chair and extensive stakeholder representation provides oversight. The NNRD received a small amount of start-up funding from the Department of Health but subsequently no core funding from any source. Hence, a self-sustaining model based upon grants, and provision of support to external researchers, supports NNRD maintenance and development.

1.4 The purpose of the NNRD is to provide a source of high-quality data for diverse secondary purposes to improve care and outcomes across the neonatal patient benefit pathway e.g. audit and quality improvement, surveillance, health services research, epidemiological studies, surveillance, clinical trials, and policy development

1.5 The data extract held in the NNRD comprise the items in The Neonatal Data Set, DAPB1595, which is an NHS Information Standard for England (Document NM1).

1.6 The Neonatal Data Analysis Unit team update the NNRD quarterly through a feed from NHS Electronic Patient Record systems managed by an authorised NHS hosting company Clevermed (acquired by System C in February 2023). To date the NNRD contains clinical information on over approximately 1.3 million infants. We add data on around 100,000 new infants each year.

1.7 The NNRD represents collaborative effort across the UK neonatal healthcare community as all 181 NHS neonatal units in England, Wales and Scotland submit data under approval by the Caldicott Guardian of each contributing NHS Trust. Northern Ireland neonatal units are currently working through regulatory requirements to join as soon as possible. The UK Health Research Authority and the Scottish Public Benefit and Privacy Panel have approved the NNRD as a research database.

1.8 Only the items listed in the National Neonatal Data set are transmitted to the Neonatal Data Analysis Unit at Imperial College London. Clevermed/System C transmit these data items each quarter. Mortality and major morbidities are available in the NNRD.

1.9 The NNRD does not hold physiological monitoring data (e.g., heart rate, respiratory rate, pulse oximetry). Neonatal unit staff continuously monitor these data in many patients and

view these on cot side monitors. Some neonatal units have ability to store and download such data but this is not universal.

1.10 Neonatal unit staff do not have direct access to the NNRD. Neonatal unit staff only have direct access to data in their patients' Electronic Patient Records.

1.11 Prior to incorporation into the NNRD, the Neonatal Data Analysis Unit team undertake quality assurance procedures following Standard Operating Procedures. They notify contributing neonatal units of potentially erroneous or missing entries each quarter, to facilitate local checking of entries in the Electronic Patient Records.

## **Section 2 Data origination**

2.1 During the period 4th January 2012 to 19th October 2023, the Neonatal Data Analysis Unit received data from neonatal units in England, Wales and Scotland. We made these data available for secondary research under the terms of our regulatory approvals and utilised the data for own research. The Health Data Research UK Gateway lists publications relating to this research here: <https://web.www.healthdatagateway.org/dataset/67020745-9def-4c6e-b5ac-bb273bd0a20e>

2.2 During the period June 2015 and October 2016 all neonatal units in England and Wales, and the majority in Scotland, contributed data to the NNRD in the same way as they do currently. Clinical staff in neonatal units enter data into the infant's Electronic Patient Record. An authorised NHS hosting company, Clevermed/ System C manage these data. The data covers the entire neonatal unit stay for each baby. Staff using the Clevermed system are able to view all episodes of a baby's care across multiple neonatal units.

2.3 During this period, and as at present, my research group utilised data in the NNRD for our own research under the terms of my National Research Ethics approval. In addition, we granted and grant access to external researchers that fulfil predefined requirements, including that a National Research Ethics Committee, or other relevant authority, has approved the study and that it should be of public/patient benefit.

2.4 Over the period June 2015 to October 2016, the Royal College of Paediatrics and Child Health (RCPCH) commissioned the Neonatal Data Analysis Unit to analyse data for the National Neonatal Audit Programme. The Healthcare Quality Improvement Partnership awarded the tender for this national audit to the RCPCH. The Neonatal Data Analysis Unit sent all outputs to the RCPCH who published these in annual reports and informed neonatal units of any outlier status.

2.5 Over the period 2014 to 2018, the NNRD also supported a national research programme led from the University of Wolverhampton and Royal Wolverhampton Hospitals NHS Trust (OPTI-PREM). The purpose of the research was to assess, for babies born at 27–31 weeks gestation and admitted to a neonatal unit in England, whether care in a Neonatal Intensive Care Unit versus care in a Local Neonatal Unit affected survival and key morbidities. Secondary objectives were to determine if differences in care provided, rather than neonatal unit designation drives gestation-specific outcomes, where care is most cost-effective, and what parents and clinicians' perspectives are on place of care. The Countess of Chester was the only hospital to decline participation. (Pillay T, Modi N, Rivero-Arias O, Manktelow B, Seaton SE, Armstrong N, Draper ES, Dawson K, Paton A, Ismail AQT, Yang M, Boyle EM Optimising neonatal service provision for preterm babies born between 27 and 31 weeks gestation in England (OPTI-PREM), using national data, qualitative research and economic analysis: a study protocol. *BMJ Open* 2019; 22; 9(8):e029421. doi: 10.1136/bmjopen-2019-029421.PMID: 31444186)

### **Section 3 Using NNRD data more effectively to monitor unusual patterns of deaths, safety issues, and quality of care, and the effectiveness of NHS management and governance structures, external scrutiny and professional regulation in keeping children in hospital safe**

3.1 The data held in the NNRD constitute a unique national resource. The data are unique because they are national in scope, detailed, quality-assured, have a high level of completeness, and because a curated version is available, that contains derived variables created using consistently applied criteria. These characteristics make the NNRD well suited to be used for national monitoring of trends and outliers.

3.2 It is important to use consistently applied criteria to derive diagnoses that are based upon multiple variables (examples in neonatal medicine are the major morbidities: bronchopulmonary dysplasia and necrotising enterocolitis). This is because variations in the way in which data analysts derive diagnoses or the way in which clinicians ascribe diagnoses, risks comparing “*apples with pears*”. This will invalidate comparative analyses, reducing the reliability of any conclusions

3.3 The identification of occurrences out-with what might be reasonably possible by chance requires detailed data to enable adjustments to be made for case-mix, large sample sizes to have statistical power to identify non-chance variation, and whole population data, to ensure outputs are not biased. The NNRD meets all these requirements.

3.4 The application of near real-time analytics to the NNRD, using appropriate statistical techniques to ensure inferences are robust and sound, would assist those responsible for NHS

management and governance in making reliable decisions around whether patient safety was at risk, and further investigation warranted.

3.5 The NHS could therefore use the NNRD – with skilled statistical analytical expertise – to monitor neonatal mortality and key morbidities proactively, in near real-time, to identify clusters of occurrences that potentially could not have arisen by chance, outliers, and trends. This was one of the aims underpinning the establishment of the NNRD.

3.6 We are currently working with stakeholders including Health Data Research UK ([www.hdruk.ac.uk](http://www.hdruk.ac.uk)), to try to grow appreciation of the opportunity to use clinical and other data to improve patient care. Health Data Research UK is the national institute for data science and an independent charity. The Health Data Research UK mission is to benefit patients and public health by using large scale data and advanced analytics to facilitate clinical trials and biomedical discovery. This work has involved connecting with UK custodians of data relevant to mother and newborn health, and colleagues from NHS England, with a view to bringing these data together to form a federated, national “*Mother and Baby Data Hub*”. We have also engaged with colleagues in Australia who have developed a successful maternity support platform based upon rapid analysis of clinical data. The intention is that the Mother and Baby Data Hub would be used to support both research and the development of clinical support tools, thus bringing about a convergence of ambition to improve patient care. We are currently at the stage of developing funding proposals for the Hub.

3.7 The current adversarial system of establishing guilt or innocence does not serve patients well and imposes further anguish on families in tragic circumstances. The system would serve families better if the obligation of experts were solely to the court, and not to either prosecution or defence.

3.8 The considerable media and social media discussion regarding the competence of the expert witnesses and the possibility of plausible alternative explanations for the deaths and collapses of babies cared for at the Countess of Chester neonatal unit also does not serve patients and families well.

3.9 Therefore, the endorsement by an appropriate authority, such as the General Medical Council, of the competence of expert witnesses in each relevant area would enhance the confidence of families and professionals in these processes and witness testimonies.

#### **Section 4 Details of press or other public comments made about any matters relevant to the Inquiry's Terms of Reference**

4.1 The Guardian ([Lessons the NHS needs to learn after Lucy Letby case](#)), BBC 5 Live (Monitoring newborn deaths proactively) and LBC (Using routine NHS data to monitor patient

outcomes) have interviewed me about monitoring newborn deaths and morbidities proactively and prospectively.

**Documents**

Document NM1: the Neonatal Data Set

**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:** 05-12-23