

Witness  
Name: [Professor Richard  
Feltbower, Professor  
Elizabeth Draper, Dr  
Sarah Seaton]  
Statement No.: [XXXX]  
Exhibits: [XXXX]  
Dated: [30/1/2024]

## THIRLWALL INQUIRY

---

### WITNESS STATEMENT OF [The Paediatric Intensive Care Audit Network (“PICANet”)]

---

We, [Professor Richard Feltbower, Professor Elizabeth Draper, Dr Sarah Seaton], will say as follows: -

#### **Purpose of the Paediatric Intensive Care Audit Network, PICANet**

1. The Paediatric Intensive Care Audit Network (PICANet) was established in 2001 and is recognised as the definitive source for paediatric critical care (PCC) data in the UK and Republic of Ireland. The role of PICANet is to collect paediatric critical care data for the primary purposes of clinical audit and service evaluation.
2. Data collected includes any activity which takes place within:
  - “Level 3” Paediatric Intensive Care Units (PICUs) and Specialist Paediatric Transport Teams that transfer to them, from across the United Kingdom and Republic of Ireland. These data have been collected since 2002.
  - “Level 2” High Dependency Care Units in England since 2023. This collection is being rolled out across England following the completion of a pilot study in October 2022 and not all Level 2 units contribute data as yet.
  - Extra Corporeal Membrane Oxygenation (ECMO) treatment administered within any UK ECMO centre since 2023. UK ECMO centres are located within a Paediatric Intensive Care Unit.
3. The aims of PICANet are to support clinical audit, service evaluation and research.

## **Reasons why PICANet was established**

4. The Inquiry into the case of a ten year old boy from Stockport who died in 1995 during a lengthy search for admission to a PICU due to acute bed shortages led to the production of a report in 1996 which instigated an examination of the paediatric intensive care service. A national group was commissioned and the Paediatric Intensive Care: A Framework for the Future was published in 1997. Clinical audit of paediatric intensive care was regarded as a fundamental component of the service and the need for a national central audit database agreed in 2000.
5. In 2000 the Department of Health invited bids to establish a central national paediatric intensive care audit database enabling core information to be collected in a standardised way to support the monitoring of national paediatric intensive care services and the development of the service. Funding was awarded to the Universities of Leeds, Leicester and Sheffield, all of whom had experience of observational research studies in paediatrics.

This comprised expertise in:

- Data handling and analysis.
  - Database management.
  - Data security and confidentiality.
  - Paediatric epidemiology and statistics.
  - Clinical involvement and access to clinical advice.
  - Capacity and ability in conducting and supporting research linking with national professional networks.
  - Establishing and working with groups to oversee establishment and development of projects/databases.
  - Capacity to link with other programmes and datasets and to conform to standards.
6. The Paediatric Intensive Care Audit Network (PICANet) was established in 2001 and data collection commenced in 2002. PICANet has bid for each subsequent tender for the contract to deliver this national clinical audit, covering English NHS paediatric intensive care services. Due to the longstanding and evolving expertise of the PICANet Principal Investigators (PIs) and team, PICANet has been successful in obtaining the contract.
  7. PICANet are also funded to conduct the audit for the devolved nations and the Republic of Ireland which enables wider benchmarking and standardisation of care.

## **Management and governance structure**

8. The PICANet Management Team consists of the Principal Investigators (PIs) and staff from the Universities of Leeds (PI: Professor Richard Feltbower) and Leicester (PI: Dr Sarah Seaton who has recently taken over the role from Professor Emeritus Elizabeth Draper). This team meets monthly to review progress against the programme goals. The PIs and the Senior Project Manager regularly meet with commissioners and funders of the audit to monitor contract deliverables and the financial budget.
  
9. The PICANet Organisational Structure outlining the funding and governance is provided within exhibit PIC/1.

[\[PIC/1: PICANet-Governance-Structure-v3.0-Oct2022.pdf\]](#)

10. The entire project is overseen and guided by the PICANet Steering Group. The Steering Group oversees the wider governance of the project, providing advice and guidance on policy and operation to ensure that PICANet provides a sound evidence-base for audit, service evaluation and research in paediatric critical care. The Steering Group has representatives from a broad range of organisations across the UK and Republic of Ireland with an interest in paediatric critical care and includes lay representation from parents with lived experience, the Paediatric Critical Care Society, and the Royal Colleges of Paediatrics and Child Health, Anaesthetists and Nursing. A full membership list is available within exhibit PIC/2.

[\[PIC/2: Steering Group Membership\\_January 2024.pdf\]](#).

11. In addition, PICANet is overseen by a Clinical Advisory Group (CAG), whose members represent the paediatric critical care teams and specialised transport services that submit data to PICANet. The CAG has the following functions: to provide practical clinical advice to the PICANet team; to act as a forum in which paediatric critical care staff can raise issues about data entry and validation; to contribute to discussions about the long-term strategic development of PICANet; to identify important audit and research questions that the PICANet database could address; and to review the results and interpretation of analyses from a clinical perspective. It also acts as the natural forum for the co-ordination of multi-centre clinical research studies and reviews requests for access to PICANet data to ensure feasibility, prevent duplication of other work and to encourage collaboration. The

CAG has a representative on the Steering Group to give feedback from a clinical perspective. A full membership list is provided within exhibit PIC/3.

[PIC/3: Clinical Advisory Group Membership\_January 2024.pdf].

### **Data collected by PICANet**

12. Information is collected on all paediatric critical care activity taking place within paediatric intensive care units and immediately before/during transport by Specialist Paediatric Transport Teams. This includes three main datasets:

- Admission data contains demographic details of each child including their name, date of birth, NHS/CHI number, address and ethnic group; it also records where children are admitted from, their date of admission and clinical diagnoses, and some clinical information on admission including blood pressure, medical history and ventilation status. Data on specific medical interventions received on each day of admission and the outcome and discharge details are included.
- Referral data for all children where clinicians agree a paediatric intensive care bed and/or paediatric intensive care transport is required includes details of the referring hospital, demographic details of the child, grade of the referring doctor or nurse, the outcome of the referral, the transport team involved and the destination paediatric intensive care unit.
- Transport data for all children who require paediatric intensive care during a transport to PICU or other location (e.g., a hospice). This includes details about the child as well as information about their presenting physiology. Details of the composition of the transport team, journey times, any interventions carried out and critical incidents are also recorded.

13. In addition to these three core datasets, customised data collections are occasionally undertaken which collect additional clinical data items specific to an area of care for the purposes of audit. These collections can be in response to local, national or international clinical requirements. Examples of recent customised data collections include:

- The COVID-19 Customised Data Collection to capture data on admissions to paediatric intensive care with COVID-19, paediatric inflammatory multisystem

syndrome temporally associated with SARS-CoV-2 (known in the UK as PIMS-TS) and potential COVID-19 vaccine-related complications.

- The Extra Corporeal Membrane Oxygenation (ECMO) data collection which began in 2023 to supplement the clinical database of paediatric intensive care activity. The collection comprises an ECMO Referral and ECMO Admission dataset for implementation only by the paediatric intensive care unit teams which undertake ECMO.

14. PICANet data collection was expanded to include care provided in standalone Level 2 paediatric critical care in 2021 in England. This dataset is based on the existing Level 3 paediatric intensive care admission dataset but is tailored for the level of care commonly received in Level 2 units. As of January 2024, 23 units are actively submitting data out of a total of around 50 units.

#### **Uses of PICANet data collection**

15. PICANet data are used to support clinical audit, service evaluation and research in the areas of paediatric critical care, specific conditions affecting children and young people accessing paediatric intensive care services (e.g. cardiac, neurological, infection, trauma), the epidemiology of critical illness, public health including supporting national data requests and national emergencies, e.g. the COVID-19 pandemic and the modelling of PICU bed capacity.

16. Findings from the PICANet clinical audit are used by the paediatric critical care clinical community to improve the quality of care provided to children at local and national levels. The analyses measure quality of care and outcomes against pre-determined standards with benchmarking against other care teams. PICANet's key metrics have been recommended either by the Paediatric Critical Care Society or NHS England, and measure the following items:

- Case ascertainment and timeliness of data submission;
- Transport mobilisation times;
- Emergency readmissions within 48 hours;

- Mortality in PICU;
- Unplanned extubations in PICU.

Full details can be found in exhibit PIC/4

[\[PIC/4: PICANet-Key-Metric-Definitions\\_v6-Oct-2022.pdf\]](#)

17. Routine outputs and examples of use in relation to the Level 3 data collection include:

- Annual 'State of the Nation' Reports comprising summary infographics and comprehensive tables and figures for exploration of the data for information and to support local quality improvement initiatives. The reports include up to five national recommendations which are targeted at specific national bodies who have the power to effect change.
- In 2023, a new public-facing online interactive PICANet Data Dashboard was established. This provides an overview of paediatric intensive care unit activity and an indication of performance against PICANet's clinically agreed key metrics. This Data Dashboard will be updated more frequently than the annual State of the Nation Reports.

These analytical outputs are primarily shared with:

- Stakeholders (funders and commissioners of the data collection and paediatric critical care services): NHS England via the Healthcare Quality Improvement Partnership, NHS Scotland, Welsh Government, Health and Social Care Northern Ireland, National Office of Clinical Audit (NOCA) Republic of Ireland.
- Participating organisations.
- The general public.

18. PICANet Key Metrics are reported to the Care Quality Commission annually to inform inspection planning and for inclusion in the National Clinical Audit Benchmarking online portal which provides national audit performance data.

19. PICANet data informs the development of the Paediatric Critical Care Society's Quality Standards (QS).

20. Data downloads and reports are available to all participating organisations for clinical audit and service evaluation. Uses of these include:

- Data downloads enable the units to obtain their data to support local quality improvement projects and routine reporting. For example, the medical interventions received on each day by each child enable NHS organisations in England to supply information on the cost of their activity.
  
- Monitoring of risk-adjusted mortality in paediatric intensive care units using risk-adjusted Resetting Sequential Probability Ratio Test (RSPRT) plots for every unit to review internally. These plots are available in 'real-time' to assess each unit's performance related to in-PICU mortality over a period of time. The plots show the odds of mortality over time alongside two thresholds, one less stringent than the other. RSPRT plots can be accessed at any time by each paediatric intensive care unit and PICANet, and can be customised to focus on a specific time period if required. PICANet reviews the plots quarterly and disseminates these to units with an associated categorisation based on the following thresholds:
  1. satisfactory (does not cross either threshold during the period of interest or does not cross the less stringent threshold for three consecutive months);
  2. cause for close monitoring (crosses the less stringent threshold for three or more consecutive months but does not breach the more stringent threshold); or,
  3. cause for concern indicating internal review (the more stringent threshold is breached in relation to the odds of mortality doubling).

These plots are supported by guidance to assist paediatric intensive care units in identifying and responding to potential issues with the quality of care in a time-sensitive fashion. While these plots are "real-time" in the sense that they are based on data as it is recorded on PICANet and are updated immediately if new data are inputted, the quality and accuracy ultimately depends on how up-to-date the unit's data is on PICANet. The Paediatric Critical Care Society Quality Standards require data to be submitted to PICANet within 2 months of discharge from PICU or death. However, this target is not always met by every unit.

Further details of RSPRT plots, their interpretation, categorisation and guidance for units based on this categorisation can be found in the PICANet RSPRT Guidance for Units in exhibit PIC/5.

[\[PIC/5: RSPRT-Guide-for-units-v1.1-Nov-2023.pdf\]](#).

21. Although PICANet is primarily a clinical audit database, a research database has been established which enables the data collected to also be used for research purposes subject to ongoing Research Ethics Committee approval. Under this approval, research can be carried out either by the PICANet team or by sharing de-identified data with other researchers.
22. Data can be requested from PICANet following formalised data request and data access processes. Examples of the use of data or information recently requested includes:
- Provision of patient numbers to determine trial feasibility.
  - Provision of data to support pilot clinical trials.
  - Provision of data for national cohort studies using data linkage.
  - Provision of key data for the Getting It Right First Time (GIRFT) national programme to inform service development around national paediatric critical care.
  - Customised data downloads of routinely collected PICANet data can also be instated to enable observational and randomised controlled trials in paediatric critical care. Downloads are readily available to participating trials sites to then submit to the clinical trial unit, reducing the burden of trial-specific data collection for paediatric intensive care unit staff and allowing them to collect the data once and use it many times.
  - The general public.

### **Monitoring mortality in paediatric intensive care units using PICANet data**

23. PICANet has an established Outlier Policy for in-PICU mortality, described in exhibit PIC/6. [\[PIC/6: PICANet\\_Outlier\\_Policy\\_v3.0\\_2023-07-10.pdf\]](#)

PICANet undertakes outlier analysis of risk-adjusted excess mortality compared to the expected mortality based on disease severity at the time of admission using funnel plots. The outlier analysis is based on all admissions to paediatric intensive care for children aged 0-15 years within the previous three-year reporting period (e.g. for the 2023 PICANet State of the Nation report, the period of analysis was 2020-2022). Any provider that falls above the upper line of the funnel plot is considered a potential negative outlier and triggers the management process detailed in Appendix C of the above Outlier Policy.

24. To help paediatric intensive care units understand the reasons why they have been identified as a potential outlier, PICANet also provides additional analyses broken down



over the most recent year of reported data, including all admissions regardless of age and in various clinical subsets. These are detailed in the Section 5.2.5 of the PICANet Statistical Analysis Plan, exhibit PIC/7.

[PIC/7: [PICANet-Statistical-Analysis-Plan-2023\\_v1.1\\_2023-10-31.pdf](#)].

### **Identifying best clinical practice and outcomes of treatment using PICANet data**

25. PICANet present data annually in the State of the Nation Report and this includes detailed information on outcomes in terms of in-PICU mortality, length of stay, unplanned extubations and emergency re-admission to PICU within 48 hours of discharge. These tables can be accessed in the 2023 State of the Nation Report Summary Report in exhibit PIC/8.

[PIC/8: [PICANet-State-of-the-Nation-Report-2023\\_v1.0-14Dec2023.pdf](#)]

PICANet also provides further detailed information on outcomes of treatment by paediatric intensive care unit or Specialised Transport Service in the associated Tables and Figures which are available within exhibit PIC/9.

[PIC/9: [PICANet Tables and Figures via https://www.picanet.org.uk/annual-reporting-and-publications](https://www.picanet.org.uk/annual-reporting-and-publications)]

26. One PICANet key metric focuses on data quality, specifically completeness and timeliness which assesses how quickly each paediatric intensive care unit submits complete data for all admissions within two months of discharge. This is then documented in the annual State of the National Report published on the PICANet website and available within exhibit PIC/8.

[PIC/8: [PICANet-State-of-the-Nation-Report-2023\\_v1.0-14Dec2023.pdf](#)]

27. To identify best clinical practice, PICANet focuses on in-PICU mortality including the identification of positive (i.e. lower observed mortality compared to what would be expected based on each child's risk of death at the time of admission) as well as negative outliers (i.e. higher observed mortality compared to the expected mortality). When a unit is identified as an outlier for in-PICU mortality there is a clearly established process to

follow, outlined in exhibit PIC/6. This includes steps to ensure the quality and completeness of the data. This enables all paediatric intensive care units to learn from those units demonstrating best practice. Details of how positive outliers are identified are described in the PICANet outlier policy, within exhibit PIC/6.

[\[PIC/6: PICANet\\_Outlier\\_Policy\\_v3.0\\_2023-07-10.pdf\]](#).

### **PICANet Data Collection Obstacles**

28. There are a number of challenges in collecting high quality national paediatric critical care activity data. These include:

- Ensuring optimal case ascertainment. This is achieved through virtual validation meetings (when notes and logs are compared with PICANet data to ensure completeness) and quarterly emails to all units and transport teams to validate data entry numbers by the PICANet Research Nurse and team. 100% case ascertainment has been achieved following permission from the Health Research Authority Confidentiality Advisory Group for England and Wales not to apply the National Data Opt-Out to clinical audit data received from English paediatric critical care services. Permission was granted because the absence of even one child's data can lead to inaccurate conclusions.
- Ensuring optimal data quality. This is achieved through virtual validation meetings with each individual paediatric intensive care unit and transport team every 12-18 months to ascertain data collection processes, understanding of definitions, communication of new variables and any changes within PICANet and the unit. Six-weekly routine validation emails are also disseminated to units and transport team to ensure compliance with agreed national Paediatric Critical Care Society Quality Standards. PICANet also have clearly established data validation rules as part of the preparation for the State of the Nation report where clinical colleagues are contacted to correct any errors, see exhibit PIC/6.
- Ensuring in-PICU mortality is carefully monitored. This is achieved through the use of quarterly cumulative mortality risk plots known as "Risk-adjusted Resetting Sequential Probability Ratio Test (RSPRT) plots". These are sent to all units and transport teams.
- Ensuring all information governance and research ethical approvals are in place and up-to-date, e.g. Health Research Authority Confidentiality Advisory Group (Section 251).

- Paediatric intensive care units having sufficient resource to submit data to PICANet and respond to validation queries in a timely manner. The PICANet team support the staff in paediatric critical care by answering queries about data entries and supporting new team members.
- Ensuring the PICANet Data Management and Storage platform meets appropriate levels of data security and resilience whilst remaining accessible to units to upload data 24 hours a day, 365 days a year.

### **Potential extension of PICANet's role to cover data from neonatal units**

29. We are not aware of any consideration being given to extend the role of PICANet to include neonatal data. As we understand it, there would be considerable overlap with the existing National Neonatal Audit Programme (NNAP) which monitors the quality of care in all neonatal units throughout England, Wales and Scotland and is delivered by the Royal College of Paediatrics and Child Health.
30. We believe that the collection of high-quality neonatal data with robust analysis is vital to keep babies within neonatal care safe. However, it is unclear what a new data system would add beyond that captured within BadgerNet, the maternity and neonatal data capture system which underpins the National Neonatal Audit Programme. It would therefore be prudent that any planned enhancements to the scope of BadgerNet and the NNAP for safety monitoring around mortality are discussed with these expert teams directly to ensure these are fit for purpose and make use of carefully validated risk adjustment methodology appropriate within a neonatal setting, which is unlikely to be the same as paediatric critical care. All audits, including those in neonatal and paediatric settings, fundamentally rely on high quality, complete and accurate data collection from all healthcare providers, key principles which are fundamental to any effective clinical audit and surveillance platform.
31. Neonatal mortality data is also collected, reviewed and monitored by the Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK) programme. MBRRACE-UK encompasses all babies who die in the UK within the first 28 days following birth irrespective of where the death occurs (i.e. labour ward, home, in transit or on a neonatal unit or other hospital setting). The MBRRACE-UK programme monitors all units providing maternity and neonatal care using appropriate statistical analysis to identify potential 'outlier' units. In addition, each neonatal death is reviewed as part of the Child Death Overview Panel process.

## **Effective collection and analysis of neonatal data**

32. In relation to analysis, the role of appropriate risk adjustment via validated risk prediction models or other adequate adjustment methods to account for the severity of illness at the time of admission is vital to allow for fair comparison and benchmarking of units.
33. However risk adjustment, whilst crucial, is also not trivial. Within heterogeneous populations such as those within paediatric and neonatal intensive care, developing a robust risk adjustment method which works well for all children can be complex. Risk adjustment is reliant on high quality, accurate and complete data to ensure any predicted risk is as accurate as possible. Where data are not available, often imputed values are used in the calculation of risk which can negatively impact on the adequacy of risk adjustment. PICANet have a number of measures in place to ensure high quality data collection including database validation and virtual validation visits for paediatric intensive care units with experienced research staff. Even when risk-adjustment is conducted with appropriate expertise and care, it is not without limitations (e.g., the role of statistical chance), and therefore clinical and statistical experts should be involved at every stage.
34. Examples of appropriate outlier policies and processes which could be applied to the collection and analysis of neonatal data include those currently in place for the PICANet clinical audit as described in the PICANet outlier policy in exhibit PIC/6.

[\[PIC/6: PICANet\\_Outlier\\_Policy\\_v3.0\\_2023-07-10.pdf\]](#)

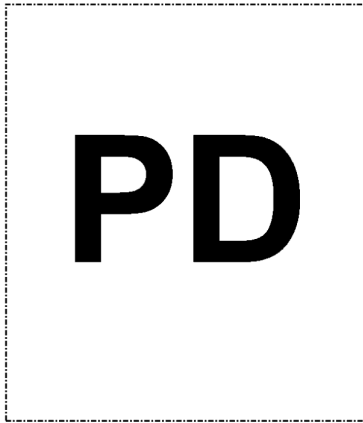
and as described in the National Neonatal Audit Programme in exhibit PIC/10.

[\[PIC/10: NNAP\\_outlier\\_management\\_2022\\_v1.2.pdf\]](#).

**Statement of Truth**

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

**Signed:** \_\_



**PD**

**Dated:** 30/1/2024