Australian and New Zealand Neonatal Network (ANZNN)

Terms of Reference

The purpose of these terms is to set out the principles under which the Australian and New Zealand dataset is formulated and the conditions that apply to the use of these data and release to parties internal and external to the Australian and New Zealand Neonatal Network (ANZNN).

BACKGROUND
In 1993 the National Health and Medical Research Council’s (NHMRC) Expert Panel on Perinatal Morbidity (chaired by Professor David Henderson-Smart) recommended that “The Australian Institute of Health and Welfare National Perinatal Statistics Unit, in collaboration with the directors and staff of all neonatal intensive care units, should develop a national minimum data set and implement a data collection to monitor mortality and morbidity of infants admitted to such units”.

Data collection began in January 1994 and from January 1995 all level III NICUs in both Australia and New Zealand contributed to the audit. In 1998, all level II NICUs in New Zealand joined the Network as did the one level II NICU from Tasmania in 1999.

Until 2008 the Network was hosted by the Centre for Perinatal Health Services Research at the University of Sydney. In 2008, the Network moved to be under the umbrella of the Perinatal and Reproductive Epidemiology Research Unit (PRERU) at the University of New South Wales.

The relationship between the ANZNN and PRERU is set out in a Memorandum of Understanding between the parties, which is effective from 1st January 2008 until 31st December 2012.

REGISTRATION CRITERIA
The scope of the dataset specifications is to provide national unit record data on live born babies meeting specified criteria that have been admitted to Neonatal Intensive Care Units, or affiliated nurseries, in Australia and New Zealand. These registration criteria are;

- born at less than 32 completed weeks gestation; or
- a birth weight less than 1500 grams; or
- received assisted ventilation - assisted ventilation via an endotracheal tube (IPPR), nasal continuous positive airways pressure, (nCPAP) or nasal high flow blended air/oxygen (since 2009) for four or more consecutive hours, or died while receiving assisted ventilation prior to four hours of age; or
- received major surgery (surgery involving opening a body cavity) or
- received therapeutic hypothermia (since 2007)
AIMS: The ANZNN aims to improve the care of high-risk newborn infants and their families in Australia and New Zealand through collaborative audit and research.

OBJECTIVES: The objectives of the ANZNN are:
1. To provide a core data set that will
   - Identify trends and variations in morbidity or mortality warranting further study.
   - Enhance the ability to carry out multicentre studies and randomised controlled trials.
   - Provide information on neonatal outcomes adjusted for case mix and disease severity to participating neonatal units to assist with quality improvement.

2. Monitor the use of new technologies, e.g. surfactant usage by patient type and outcome.

3. Monitor the clinical indicators for perinatal care and improve clinical practice.

STRUCTURE of the ANZNN:
1. Advisory Committee
   The governing body of the ANZNN is the Advisory Committee.

   The Advisory Committee consists of the Directors of each participating level III unit, Director of PRERU, holders of a Chair in Perinatal/Neonatal medicine or nursing, and any persons elected to the Management Committee not in the previous two categories. Directors of level III units may send a nominee in their place to meetings of the Advisory Committee.

   The Advisory Committee will meet at least once annually, usually at the time of the PSANZ annual scientific meeting.

2. Management Committee
   Day to day running of the ANZNN is by the Management Committee (successor to the Executive Committee), with the exception of operational matters relating to the data collection which will be handled by the DCOC (see below).

   Composition of the Management Committee:
   - Six “general” members from level III NICUs (at least one of whom should be from a New Zealand Level III NICU).
   - One member from a Level II NICU participating in ANZNN.
   - One Data Manager representative.
   - One NICU Nurse Manager representative.

   Ex-officio – two members from PRERU.
   In attendance- ANZNN Coordinator

   Members of the Management Committee will hold office for three years initially with an option of standing for two further terms. Elections will be staggered so that each year
three members will stand down or be eligible for re-election. Members of the ANZNN can self-nominate for election. If an election is required, each level III NICU will have one vote for general members and the NZ member; directors of affiliated level II NICUs will have one vote for the level II member; the data manager representative will be nominated by the audit officers and data managers group and the Nurse Manager position will be selected from the Nurse Managers group.

The Management Committee will elect its Chair for a three year term with an option for one further term. The chairperson must be an active member of ANZNN and currently working within the clinical and/or perinatal research area.

The Management Committee will meet three monthly by teleconference (except that this may be face-to-face at the time of the AGM).

3. **Data Collection Operating Committee (DCOC)**

The DCOC will manage the operations of the data collection. The DCOC reports to the Advisory Committee through the Management Committee.

The members of the DCOC will be:
- Three members appointed by the Advisory Committee
- One member nominated by the ANZNN Audit Officers Group
- Two members appointed by PRERU
- The ANZNN coordinator and/or data manager.

The Chair of the DCOC will be appointed by the Management Committee.

**ANNUAL REPORT**

The ANZNN is the original owner of the dataset but under the terms of the MOU with PRERU, both the ANZNN and PRERU will share in equal measure all intellectual property arising from the dataset, including the Annual Report and any other subsequent reports.

Data must be submitted to the ANZNN coordinator at PRERU by 31st August of the following year to be included in the Annual Report.

It is expected that all participating Neonatal Units will collect an agreed upon minimum data set in a standardised format. Data entry on hard-copy data forms or into an electronic data form will be performed by the respective member neonatal unit. The Microsoft Office Access data base system is being used for data processing and all data sent to the coordinating centre will be in the form of Access data files, a Microsoft Office Excel spreadsheet, or on the appropriate forms.
Outline data on key indicators in the forthcoming report are presented at the AGM by the ANZNN Coordinator. It has been agreed by the Advisory Committee that these data will identify Neonatal units by name.

The Annual Report will only publish data in summary form, free from identifying characteristics of a personal, institutional, State or Territory nature.

Three months after publication of the Annual Report, aggregated data will also be released to each Director in an electronic form with their own unit data identified, and the remainder of the data will be completely de-identified.

CONFIDENTIALITY GUIDELINES

All members of the ANZNN and PRERU may apply to use the dataset for further analysis. A statement on the proposal, usually of one page length, will be submitted to the Advisory Committee for approval. Any requests for data that could potentially identify a unit, state or territory will be referred to the advisory committee. All projects require approval from 75% of the Advisory Committee to proceed. If members of the Advisory Committee have not given any response one month after the request, despite a reminder, they will be deemed to have given approval.

Separate ethical approval is required for each approved project and a confidentiality agreement must be signed by the person requesting the data prior to release of that data.

Manuscripts arising from the dataset must include the statement “on behalf of the Australian and New Zealand Neonatal Network” following the named authors. Completed papers must be submitted to the Advisory Committee for approval including to ensure factual and technical accuracy (with the same approval conditions as above) before submission for publication. The authors will inform the Advisory Committee when publication of the article is imminent.

CONDITIONS FOR DATA SECURITY

The ANZNN Data Collection will be housed at PRERU. It will be managed according to existing data security procedures as for other data collections at PRERU.

Patient-identifiable data should not leave the site of PRERU. The electronic version of this data will be maintained on a single central server protected by password. All hard copy patient identifiable data and electronic backup files will be kept in locked cabinets. Master lists of code material will be kept in a separate locked area. All rooms and offices used by ANZNN are locked when not in use. Filing cabinets containing data are locked when not in use. Computerised data are protected by passwords known only to each person who has access to computerised data. Security disposal of data is available through use of designated bags or a shredding machine and must be witnessed by at least two staff members and a destruction certificate stating name of data and date on which it was destroyed is to be issued and retained in the records.