Virtual Research Ethics Board

Canadian Registry of Neonatal Patients

Background

A major weakness in our health research enterprise today is the lack of ability to effectively, efficiently, and rapidly translate knowledge into improved quality of care, better patient outcomes, and reduced health care costs. Failure to translate knowledge into practice and policy is not confined to one therapeutic area. Improved translation of knowledge into practices and policies could potentially improve patient outcomes and reduce costs of health care.

Research Question

There are longitudinal variations in outcomes and practices among Canadian NICUs that can be used for audit, quality improvement and research and ultimately improve outcomes for sick newborns.

Participants (Inclusion/Exclusion Criteria)

Inclusion: Infants admitted to a Canadian NICU between (*two fictional dates for purposes of case study*).

Exclusion: Infants not admitted to a Canadian NICU between (*two fictional dates for purposes of case study*).

Proposed Methodology

This is an on-going database involving data collection from patient charts only. Concurrently, with 30 other NICU's in Canada, all liveborn infants born/admitted to NICU at >22 weeks gestation or >400g will be enrolled. A research assistant will abstract data from patient charts into a computer program. At regular interval, this data will be electronically transferred using secured means to a central database at the Canadian Neonatal Network™ Coordinating Centre. Patient identifiers will be stripped prior to transfer, and a code substituted for each patient. In the event that a child is transferred to another hospital, the unique identifier will be made available to the receiving hospital. Patients will not be contacted during the study, and no consents will be obtained. Only the research assistant collecting the data and the site investigator will have access to the data. Strict confidentiality will be observed. Individual data at each site will be available to site investigators at each site for their own research. Aggregate data at the CNN Coordinating Centre will be available to investigators from other NICUs across Canada, but study sites and patient identity will remain anonymous at all time points.

This case has been adapted from Canadian Neonatal Network Database research proposal submitted to Island Health in 2008 and is used with permission of the Principal Investigator.

Risks

None.

Benefits

There is no direct benefit to the patient. However, the information will be used in aggregate with information from other patients to potentially improve quality of care, treatment and to identify patients at risk of bad outcomes for all future patients admitted to the NICU.

Recruitment

Patients are not approached. No additional patient consents will be obtained other than that routinely obtained by the NICU for recording patient information into a patient chart when the patient is admitted.

Data Security

Trained research assistants will abstract data daily from patient charts directly into laptop computers, using a customized data entry program with build-in error checking and a standard manual of definitions. SSL-encrypted data re electronically transmitted to the Coordinating Centre through a website for verification. Potential data errors are identified and data re-checked by site research assistants. For data analysis and publication, only aggregate data are used. Participating sites will remain anonymous and be identified only by randomly assigned letter codes.

At each site, data will be stored in a secured database in the NICU or alternate secured site used by the NICU to store patient information (.e.g. health records department, computer services department). At the Coordinating Centre, the central database will be stored in a secured computer database located on a server that is maintained and secured by the Information systems department. A back-up database will be located on a server (with firewalls) that is also maintained and secured by the Information Systems department with off-site back-up.

Dissemination

An annual report will be published and distributed to participating hospitals and relevant health authorities. Results are used to publish manuscripts in peer-reviewed journals.