

Study Summary

iNeo: The International Network for Evaluating Outcomes of Very Low Birth Weight and Very Preterm Neonates: Collaborative Comparisons of International Health Services for Quality Improvement in Neonatal Care

1 Background: Recent comparisons of national population-based data show marked variations in neonatal outcomes between countries. For example, Canada has higher rates of necrotizing enterocolitis, whereas Japan has higher rates of chronic lung disease and retinopathy of prematurity; Australia and New Zealand have lower rates of mortality and several morbidities; however, they report higher air leak and higher resource utilization than Canada. Variations in outcomes may be due to differences in care processes and care delivery between countries. Identification of variation provides potential to improve neonatal outcomes.

2 Aims: The foundation of this research programme is the establishment of the international Network for Evaluating Outcomes (iNeo) in neonates. This will be used to examine and ultimately improve outcomes, care processes, and health care delivery for very low birth weight infants (VLBW) through international collaborative learning. iNeo currently includes collaborators from Australia, New Zealand, Canada, Israel, Japan, Spain, Sweden, Switzerland, and the UK. The overall aims of the iNeo programme are to:

- 1) Compare outcomes at country level for VLBW infants
- 2) Identify country-specific characteristics that may underlie variations in outcomes
- 3) Train and support junior researchers in neonatal-perinatal health services research
- 4) Identify clinical and organizational improvements relevant to Canadian neonatal care
- 5) Implement and continually evaluate the impact of data-informed and evidence-linked clinical and organizational practice changes in Canadian neonatal units

Note: Collaborating countries may choose to adopt aims 4 and 5 for local application

3 Research plan: Individual-level data from each country for the period 2008 to 2015 will be extracted from each national database for infants born between 2008-2015 at $\leq 31^{+6}$ weeks gestation or with a birth weight $< 1500\text{g}$ and admitted to participating neonatal units. For UK neonatal units, data will be extracted from the National Neonatal Research Database. No patient or hospital identifiers will be included. Analysis of the data will take place at the iNeo Coordinating Centre in Toronto. Data will be used solely for the purposes of the iNeo study and subsequently destroyed. All public reporting of data will be aggregated to country level. Data will be analysed to compare mortality and severe morbidities. Country-specific characteristics will be related to variations in outcomes and used to develop international benchmarks.

4 Lead investigators: Dr Prakesh S Shah, Associate Professor and Dr Shoo Lee Paediatrician-in-Chief and Director of the Maternal-Infant Care Research Centre, Department of Paediatrics, Mount Sinai Hospital, Toronto

5 Collaborating investigators: Dr Ross Haslam, Associate Professor of Neonatal Medicine, and Dr Kei Lui, Associate Professor of Neonatology, Sydney Children's Hospital, Australia; Dr Brian Darlow, Professor of Neonatal Medicine, University of Otago, Christchurch, New Zealand;

Dr Satoshi Kusuda, Tokyo Women's Medical University, Dr Rintaro Mori, Department of Health Policy, National Centre for Child Health and Development, Tokyo, Japan; Dr Hans Bucher, University Hospital Zurich; Professor Adolf Valls-i-Soler, Unidad Neonatal Barakaldo, Spain; Dr Stellan Hakansson, Umea University Hospital, Sweden; Dr Gunnar Sjors, Uppsala University, Sweden; Dr Brian Reichman, Sheba Medical Centre, Israel; Professor Neena Modi on behalf of the Neonatal Data Analysis Unit and the UK Neonatal Collaborative

6 Regulatory approval: Research Ethics Board, Mount Sinai Hospital, Toronto, Canada; reference number REB 12-0336-E

7 Research funder: Canadian Institutes of Health Research

8 Research sponsor: Canadian Institutes of Health Research

9 UK sponsor:

10 Study end date: 01/12/2018

11 Research location: The iNeo Coordinating Centre is based at the Maternal-Infant Care Research Centre at the Samuel Lunenfeld Research Institute at Mount Sinai Hospital, Toronto.

12 Publication policy: All publications will have “iNeo Collaboration” as the final author. Publications subsequent to the publication of the primary analyses will be authored by individuals who meet the criteria for authorship as laid out by International Committee of Medical Journal Editors; these names will be followed by “iNeo Collaboration” as final author. The names of all UKNC leads and neonatal units contributing data to the iNeo collaboration will be listed in all iNeo outputs.

13 iNeo website: <http://ineonetwork.org>

14 Data items to be extracted from the National Neonatal Research Database for iNeo

Data will be extracted for infants born between 2008 and 2010 therefore the items are listed as they appear on screens for the Badger3 system.

Screen: General Baby Details

- Birth month and birth year
- Gestation
- Birth weight
- Birth order and total number of babies this pregnancy
- Final neonatal unit outcome

Screen: Parents Details

- Mother's year of birth
- Mother's ethnicity
- Father's ethnicity

Screen: Pregnancy

- Complications of pregnancy
- Problems this pregnancy
- Steroids given, courses given

Screen: Labour and delivery

- Duration of rupture of membranes
- Presentation at delivery
- Mode of delivery
- Resuscitation
- Surfactant given

Screen: Admission details

- Date of admission (minutes from birth)
- Weight on admission
- Head circumference on admission
- Temp on admission
- Principal diagnosis at admission
- Postnatal transfers (determined from episodic details)

Screen: Clinical summary of stay

- Respiratory diagnosis
- Patent Ductus Arteriosus
- Necrotising enterocolitis treatment

Screen: Discharge details

- Date of discharge (minutes from birth)
- Discharge destination
- Principal diagnosis

Screen: Cranial Ultrasound

- Periventricular haemorrhage (right and left)
- Cystic periventricular haemorrhage

Screen: Retinopathy of Prematurity

- Maximal grade (right and left)
- Maximal zone (right and left)

Screen: Abdominal X-ray

- Was laparotomy for necrotising enterocolitis required?
- Confirmed necrotising enterocolitis (visual/histology)
- Peritoneal drain inserted

Screen: Extended daily summary

- Respiratory support
- Mode of Continuous Positive Airway Pressure
- Pneumothorax present today
- Chest drain present today
- Surfactant given today
- Surgery for Patent Ductus Arteriosus today
- Treatment for necrotising enterocolitis today
- Retinopathy of Prematurity surgery today
- Drugs given today