Data for executing the Consortium's research plan: applying regulatory science to neonatal electronic data

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International Neonatal Consortium
A unique and innovative approach to population data: the UK National Neonatal Research Database

- All neonatal units in the UK (n=200; the UK Neonatal Collaborative) use real-time, point-of-care, clinician-entered neonatal electronic patient records

- ~400 defined data items (the Neonatal Data Set) are extracted from the neonatal Electronic Patient Records and held in the National Neonatal Research Database at the Neonatal Data Analysis Unit at Imperial College London

- Cited as an exemplar for making “record once, use multiple times” a reality

- NHS savings estimated at around £6.6M per annum for every 10 “bespoke” data collections

- Data on over 500,000 patients held to date and over 5 million care days (from 2007); 20,000 new patients added each quarter

www.imperial.ac.uk/ndau
Neonatal Electronic Patient Record: multiple entry screens
Data flows to the National Neonatal Research Database

Neonatal networks

System supplier

Records entered and updated in real time by clinical staff throughout patient stay

Neonatal units

Neonatal Data Set extraction

The Neonatal Data Set is an approved National Health Service Information Standard

Extraction quarterly through MS SQL

Neonatal Data Analysis password-protected web-tool enables neonatal unit staff to validate and interrogate data

Data management (Neonatal Data Analysis Unit)

National Neonatal Research Database

All admissions to neonatal units (i.e. no gestational age or birth weight cut-offs)
At the Neonatal Data Analysis Unit

Data are compliant with international nomenclature; include ICD10 codes and map to SnoMedCT

“Once only” data (e.g. birth weight, gestational age)

“Only if” data (e.g. infection, necrotising enterocolitis, neonatal encephalopathy)

Daily data (e.g. medications, feeds, ventilation, parenteral nutrition)

Diagnoses, outcomes, co-morbidities

Comprehensive meta-data files maintained
Creating the National Neonatal Research Database

**Neonatal Data Set extracted from Electronic Patient Record**

**Standard Operating Procedures**

- Separate patient identifiers into a discrete relational database
- Merge data packets to create a single file for each patient for each neonatal unit episode
- Link patient episodes across neonatal units (transfers) to create a single linked episode file for each patient to discharge or death
- Identify and flag missing, inconsistent, and out-of-range data for feedback to Neonatal Units
- Link National Neonatal Research Database to Hospital Episode Statistics and Office for National Statistics data

**National Neonatal Research Database**

**National Neonatal Research Database**

**Link National Neonatal Research Database to Hospital Episode Statistics and Office for National Statistics data**

**Separate patient identifiers into a discrete relational database**

**Merge data packets to create a single file for each patient for each neonatal unit episode**

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**Identify and flag missing, inconsistent, and out-of-range data for feedback to Neonatal Units**

**Link National Neonatal Research Database to Hospital Episode Statistics and Office for National Statistics data**
Source verification: electronic audit trail
The Neonatal Data Analysis Unit: an academic unit of Imperial College London

<table>
<thead>
<tr>
<th>UK Neonatal Collaborative</th>
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<tbody>
<tr>
<td>• All neonatal units in England, Wales and Scotland (n=200)</td>
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<tr>
<td>• All have provided regulatory approval for a defined, detailed extract of data from their neonatal Electronic Patient Records to be held in the National Neonatal Research Database</td>
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<td>• The data items (n=400) extracted from the neonatal Electronic Patient Record</td>
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<td>• Approved in December 2013 as a new NHS Information Standard (ISB1595)</td>
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<td>• A permanent, high quality repository of the data extract from neonatal Electronic Patient Records</td>
</tr>
<tr>
<td>• Regulatory approvals from the National Research Ethics Service, NHS Caldicott Guardians, and the Confidentiality Advisory Group of the UK Health Research Authority</td>
</tr>
<tr>
<td>• Used for multiple purposes</td>
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</table>
A collaborative achievement and national resource

Multi-professional Steering Board including strong parent representation

National Neonatal Research Database

Linkage to other national datasets
- Office of National Statistics
- Hospital Episodes Statistics

National audit and benchmarking
- Quality improvement
- Network and neonatal unit reports
- Research

- Data for baseline rates, natural history of disease, PK, post-marketing and other surveillance, clinical trials, Mendelian randomisation, cohort studies, economic evaluations
- Substantial potential for personalized newborn medicines (e.g. by development pipeline incorporating preliminary GWAS) and for inclusion of ALL sick and preterm newborns
The power of population data

Incidence of NEC surgery/death in England

Time that PN was first given to babies born < 30\textsuperscript{9} weeks by birth year

Exclusive mother's milk
Outputs in multiple formats (note: data are fictitious)

Network: London - North West Neonatal Network
Month(s): All
Discharged: All
Reflection paper on expectations for electronic source data
European Medicines Agency GCP Inspectors Working Group 2010

Transparent audit trail
Accurate, contemporaneous, original, attributable, complete, consistent, enduring, available

Compliant with CPMP/ICH/GCP /135/95 Standards for the use of electronic trial data
Established, strong, parent-professional-academic collaboration

Imperial College London
Data Science Institute
Neonatal Data Analysis Unit (NDAU)

Chelsea and Westminster Hospital
NHS Foundation Trust

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Formal evaluation of National Neonatal Research Database items against trial Clinical Record forms

- Component of a National Institute of Health Research Programme
- Test bed was the recently completed multicentre, randomised controlled trial, the “Probiotic in Preterm babies Study (PiPS)”
- Generally baseline characteristics have consistency and low major discordancy rates in all neonatal units; items that require improved accuracy have been identified
- Tests of concordance in resource use and costs between comparator data sources show relatively high levels of agreement for the majority of categories of resource use or cost and notably for the total cost of neonatal care
- Key next steps include engaging clinicians and testing measures to further optimise data quality and completeness
- Exploration of parent involvement underway
Organisations and research groups supported

• British Association of Perinatal Medicine
• NHS England
• Public Health England
• Office of the Chief Medical Officer
• Royal College of Paediatrics and Child Health
• Royal College of Obstetricians & Gynaecologists
• London Neonatal Nurses Group
• North East Quality Observatory System
• Healthcare Quality Improvement Partnership
• Care Quality Commission
• NHS London
• NHS Manchester
• Information Standards Board
• Health & Social Care Information Centre
• Bliss
• World Health Organisation
• Queen Mary University of London
• Institute of Child Health
• University of Toronto
• University of Leicester
• Bradford NHS Foundation Trust
• University of Oxford
• University of Liverpool
• Peninsula University
• University College London
• St George’s University of London
Recent peer-reviewed publications


- Shah et al The International Network for Evaluating Outcomes of very low birth weight, very preterm neonates (iNeo): a protocol for collaborative comparisons of international health services for quality improvement in neonatal care *BMC Pediatr* 2014 Apr 23; 14:110


- Wong et al and the UK Neonatal Collaborative, Retinopathy of prematurity in English neonatal units: a national population-based analysis utilising NHS operational data *Arch Dis Child Fetal Neonatal Ed* 2014; 99(3):F196-202


- Cole et al on behalf of the Neonatal Data Analysis Unit and the Preterm Growth Investigator Group Birth weight and longitudinal growth in infants below 32 weeks gestation: a UK population study *Arch Dis Child Fetal Neonatal Ed* 2014; 99:F34-40


Within reach: a Neonatal Consortium Data Platform

- Multi-professional Neonatal Data Analysis Unit
- Steering Board
- Oversight Board
- Operational Unit
- National Neonatal Research Database
- National Audit and other NHS Service Support
- Research and Research Support
- European Benchmarking

Neonatal Consortium Data Platform