Review Article

Information technology infrastructure, quality improvement and research: the UK National Neonatal Research Database

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Abstract: Technological developments, coupled with strengthened governance and data security have led to increasing recognition of the potential of real-world health data to benefit patient care and health services. Real-world health data are those captured in the course of routine care. Here I describe a mature source of real-world health data, the UK National Neonatal Research Database and provide examples of the many types of uses it supports.

Keywords: Real-world data; database; neonatal; infant newborn; information technology quality improvement; audit; neonatal research

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Introduction

Researchers, managers and other investigators too often call upon busy clinical teams to collect or record data repeatedly for different purposes. Often, separate data collection systems are put in place for administration, clinical care, quality improvement and research. This is wasteful of time and effort, and increases the likelihood of inconsistencies and errors. We developed the UK National Neonatal Research Database (NNRD) at the Neonatal Data Analysis Unit at Imperial College London (1) to provide a single source of high-quality data that diverse users could use for multiple purposes to improve neonatal care, support neonatal services, facilitate research and develop national policies. The strong collaborative efforts of clinicians, parents, health service managers and data experts were crucial in making this initiative possible. Here I describe the NNRD and the outputs it supports.

The organisation of neonatal care in the UK

Infants admitted for neonatal care are those requiring support in the early neonatal period, for example, following preterm birth or for neonatal conditions that require ongoing medical support or surgical care. In the UK, neonatal units provide care for all babies requiring more than normal care. There are three neonatal unit designations providing intensive care (Neonatal Intensive Care Unit), high dependency care (Local Neonatal Unit) and special care (Special Care Baby Unit) (2). Neonatal care is organised on a regional networked basis with babies transferred to units delivering higher or lower categories of care as necessary. Provision of neonatal care outside National Health Service (NHS) neonatal units is exceptional. There are only two non-NHS maternity hospitals in the UK and they transfer all very preterm babies and neonates with critical care requirements to NHS care.

The National Neonatal Research Database

The NNRD contains a set of defined variables, extracted at quarterly intervals from the Electronic Patient Records (EPR) of all admissions to NHS neonatal units in England, Scotland and Wales (n=181 in 2019). Thus, the NNRD has near-complete population coverage of all very preterm and sick newborn babies. We established the NNRD in 2007 and have since received quarterly data extracts from neonatal EPR since this time. Data are available from 96% of English neonatal units from 2010 and 100% from 2012. Data from all Welsh neonatal units are available from October 2012 and all but one Scottish neonatal unit from May 2018. To date the NNRD contains information on approximately one million infants with approximately 25,000 new patients added each quarter. Neonatal units offer parents the opportunity to opt-out of their baby's data being included in the NNRD but there have been no opt-outs to date.

Healthcare professionals in NHS neonatal units in England, Scotland and Wales record data into an EPR as part of routine clinical care. The data comprise demographic and anthropometric details, daily interventions and treatments throughout the neonatal in-patient stay, diagnoses and outcomes, and follow-up health status at the age of 2 years. The data in the NNRD comprise the Neonatal Data Set, a specified data extract of the data in the EPR. The Neonatal Data Set comprises around 450 variables. The Neonatal Data Set is an NHS Information Standard for England (ISB1595). Identifiers are held only for specific purposes approved by the UK Health Research Authority Confidentiality Advisory Group [reference ECC 8-05(f) 2010].

The NNRD is a dynamic relational database. On receipt of quarterly downloads, we remove all identifiers (NHS number of baby and mother; mother's postcode; date of birth of mother and baby; baby admission and discharge dates) (data on babies admitted to neonatal units in Scotland contain the CHI (Community Health Index) number for mother and baby, not the NHS number). We hold identifiers in a separate file on a secure NHS server. We identify babies in the relational structure of the NNRD using a pseudonymised code. Neonatal length of stay can extend to several months and the EPR system includes facility to document health and development at age 2 years.

We receive the previous 5 years of data at each quarterly download; hence, this ensures that any changes made by clinicians locally are incorporated progressively and available in the most recent version of the NNRD. The point of lock-down of an individual infant's record is 5 years from neonatal unit admission, which provides ample opportunity for changes arising from multiple rounds of data quality assurance to be incorporated into the NNRD, and a generous margin for delays in 2-year assessments and/or their data entry.

Governance

The UK National Research Ethics Service (reference 16/LO/1093) and the Scottish Public Benefit and Privacy Panel (reference 1718-0076) have approved the NNRD as a research database. The Caldicott Guardians and lead neonatal clinicians of all contributing NHS Trusts Approval also provide approval for data from their neonatal units to be included in the NNRD. We request all neonatal units to provide a copy of the General Data Protection Regulation compliant Privacy Notice to parents. This explains the purpose of the NNRD in supporting audit, health service evaluations, quality improvement and research. It also explains how parents can opt-out of inclusion of their baby's data in the NNRD. A poster for parents "*Why your baby's data are important*" and a trainee leaflet providing information about the NNRD, Neonatal Data Set, are also available. Parents have been involved in the development of the NNRD since inception. The NNRD oversight steering board includes parent representation. As a work-stream of a NIHR research programme grant that demonstrated the breadth of impact of the NNRD (3), we conducted a study involving 1,000 parents that showed they trust healthcare professionals with their baby's data and want to see these used to improve care.

A Steering Board with independent co-chairs provides oversight of the NNRD. The Steering Board has wide stakeholder representation including professional organisations (British Association of Perinatal Medicine, Royal College of Paediatrics and Child Health National Neonatal Audit Programme), nurses, parents, trainees, neonatologists, researchers, and the national charity for preterm and sick newborn babies, Bliss.

Access

Researchers, clinicians, managers, commissioners, and others are welcome to use the NNRD. Research utilising the NNRD must have received specific UK Research Ethics Committee approval, and the agreement of each contributing neonatal unit. We provide information on accessing the NNRD on the Neonatal Data Analysis Unit website (1). We maintain the NNRD by cost recovery through work supported. We ask users to make a standard acknowledgement recognising the source of the data and the contribution of the UK Neonatal Collaborative (neonatal units contributing data) and the names of their Lead Clinicians.

Strengths and weaknesses of the NNRD

NNRD data undergo quality and completeness checks. These checks include identification of duplicate, internally inconsistent and out-of-range entries. We relay information on potentially erroneous and missing core data items to clinical teams. Clinical teams make any corrections into the baby's EPR, which we then receive, in our next download. This means that our quality assurance processes also improve the baby's clinical EPR. We have demonstrated data held in the NNRD to be complete and accurate for key data items; for example an evaluation of data completeness and quality of data items held in the NNRD compared to data independently collected as part of a parallel multi-centre randomised controlled trial show excellent agreement (4). To-date the NNRD contains information on around one million infants with approximately 25,000 new patients added quarterly. The NNRD holds near population-level data for infants receiving neonatal care in England, Scotland, Wales and the Isle of Man. Researchers can link the NNRD to other data using probabilistic and deterministic approaches; the use of identifiers for this purpose requires specific permissions. Today, the NNRD provides a common source of high-quality neonatal data, is a recognised national and international resource for studies involving pregnancy and the newborn, and has a strong record of impact. In a systematic review of world literature, we identified 82 neonatal databases and showed the NNRD to be globally unique (5). It covers three complete populations (England, Scotland and Wales), includes every newborn baby requiring over and above normal care with no gestational age, birth weight, insurance cover, or other restrictions, is formed from defined extracts from point-of-care, clinician-entered EPR, hence imposes no additional data collection burden on neonatal staff, and undergoes multiple quality assurance procedures. Neonatal units offer parents opportunity to opt-out of the inclusion of their baby's data in the NNRD but to date none has done so.

The NNRD does not currently hold data for deaths that occur in the delivery room and contains incomplete data on stillbirths and infants receiving transitional care (care that is more than normal but where the baby has not been admitted to a neonatal unit). The NNRD does not currently hold laboratory or genetic data. Data undergo quality checks, but reliance on clinician entry at the point of care places constraints upon the inferences that can be made regarding accuracy. Clinicians usually only record age 2-year follow-up data for infants <30 weeks gestation at birth as these are required for the UK National Neonatal Audit Programme, but though improving, these data currently have a high level of incompleteness (37.4% in 2017).

Work supported by the NNRD

The NNRD is the sole source of clinical data for the UK Royal College of Paediatrics and Child Heath National Neonatal Audit Programme (6), and supports the Royal College of Obstetricians and Gynaecologists National Maternity and Perinatal Audit (7). Other health services evaluations include analyses for the Department of Health national ambition to reduce perinatal brain injuries (8), and work by NHS Improvement to reduce admissions of full term babies to neonatal specialised care (9). The NNRD supports regional and national Quality Improvement programmes. In the East of England Neonatal Networks regional care bundle to improve maternal breast milk use in preterm infants the NNRD was used to provide data for national comparison (10). "Each Baby Counts" is a national quality improvement programme led by the Royal College of Obstetricians and Gynaecologists to reduce the number of babies who die or are left severely disabled as a result of incidents occurring during term labour (11). PReCePT is a national quality improvement programme that aims to reduce cerebral palsy through improving uptake of magnesium sulphate in preterm deliveries (12) in which progress is being measured using data from the NNRD. The NNRD is also widely used for research studies. These include health services research (13-17), health economics (18) and epidemiological studies (19-21). The NNRD is used to provide clinical decision support analyses, for example in relation to gestational age specific mortality (22), length of stay (23), development of a gestational case definition for necrotising enterocolitis (24), care of preterm babies with Downs Syndrome (25) and comparative evaluation of preterm growth (26). The NNRD is being used to support guideline development (27). The NNRD is also the UK data source for international collaborations. The International Network for Evaluation of Outcomes of Neonates (iNeo) is a quality improvement project based on collaborative comparisons of population-based international healthcare for neonates led by the University of Toronto (http://ineonetwork.org) (28) that has produced a number of outputs (29-38). eNewborn is a pan-European preterm benchmarking platform (39).

Future developments

In addition to these wide uses (40,41), we aim to extend the utility of the NNRD further as the use of routine, real-world health data in research is set to grow rapidly. We are linking the NNRD to other heath datasets such as the UK NHS Hospital Episodes Statistics, Office for National Statistics data, and National Maternity Dataset. This will enable long-term infant follow-up into adulthood following interventions in pregnancy (42). We are involved in collaborative work to harmonise definitions and adhere to international standards for electronic nomenclatures (43). We also aim to incorporate physiological monitoring, imaging and genomics data into the NNRD. This will speed progress in newborn research at a pace not previously achieved.

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Footnote

Conflicts of Interest: In the last 5 years N Modi has received conference travel and accommodation from Chiesi, Nestle and Prolacta Life Sciences, speaker honoraria from Chiesi and research grants from the UK Medical Research Council, National Institute for Health Research, March of Dimes, British Heart Foundation, Westminster Medical School Research Trust, HCA International, Chiesi, Nestle, Prolacta Life Sciences, Shire Pharmaceuticals, Collaboration for Leadership in Applied Health Research and Care for Northwest London, Healthcare Quality Improvement Partnership, Bliss, NHS England and Department of Health. N Modi is a member of the Nestle International Scientific Advisory Board; she accepts no personal financial remuneration for this role.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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