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

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International Neonatal Consortium

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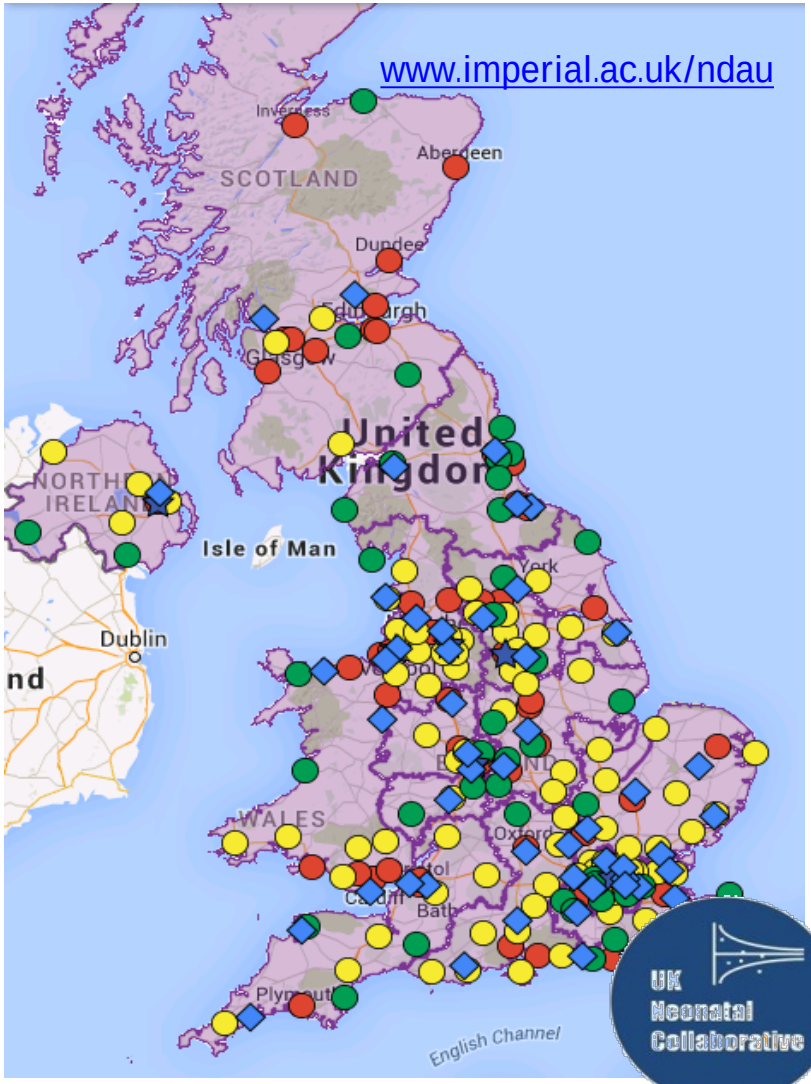
A unique and innovative approach to population data: the UK National Neonatal Research Database

- 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



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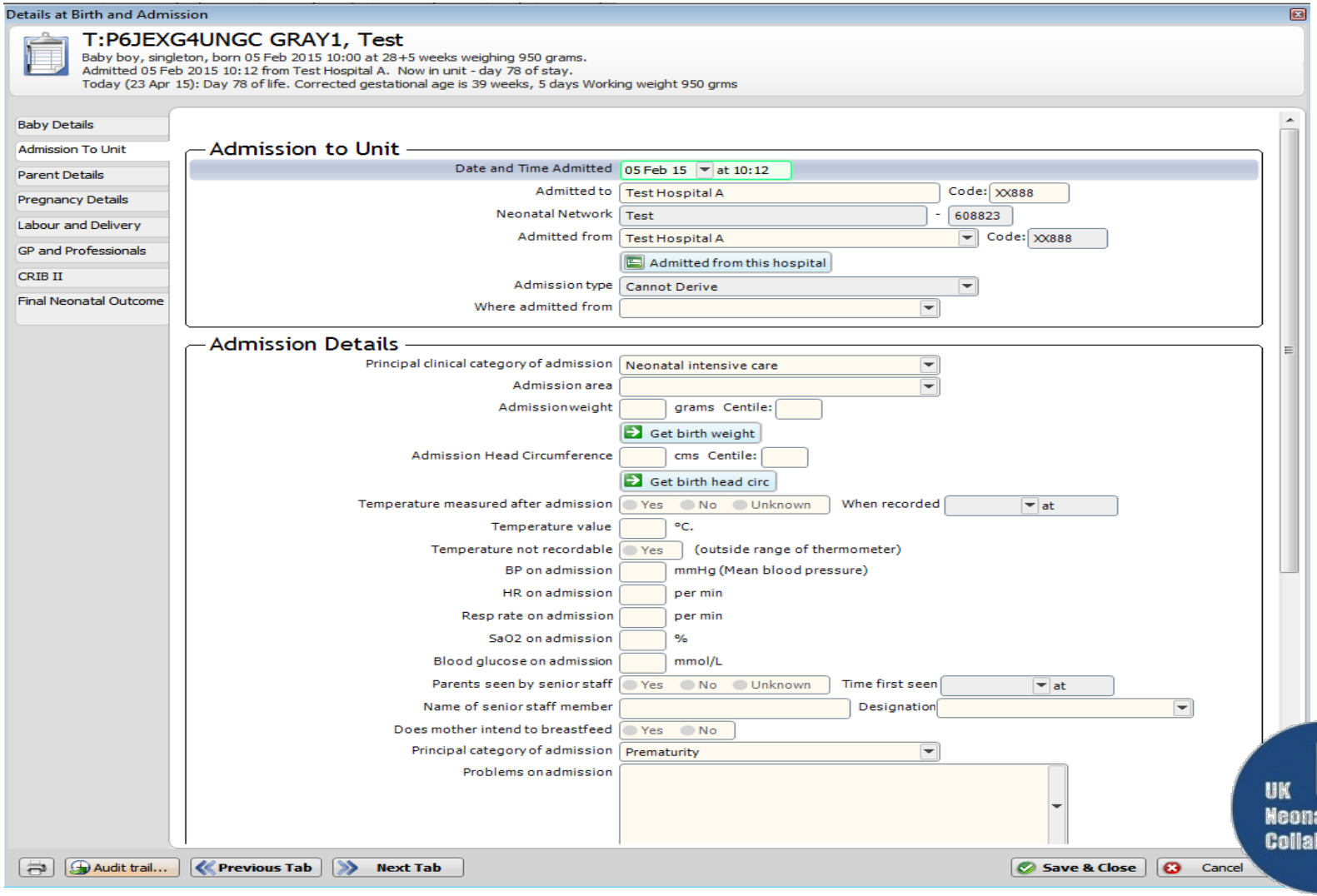
Neonatal Electronic Patient Record: multiple entry screens



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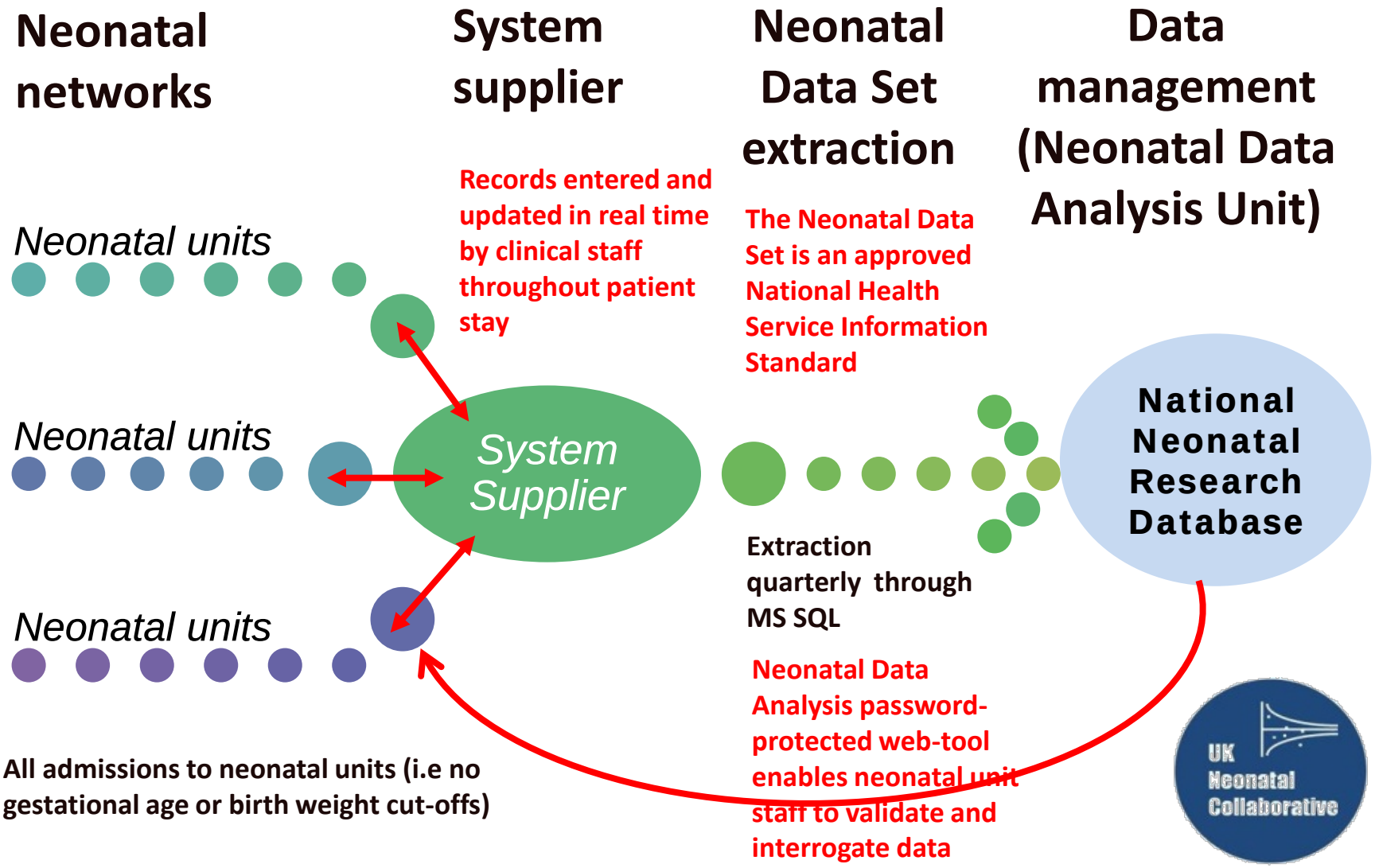
Data flows to the National Neonatal Research Database



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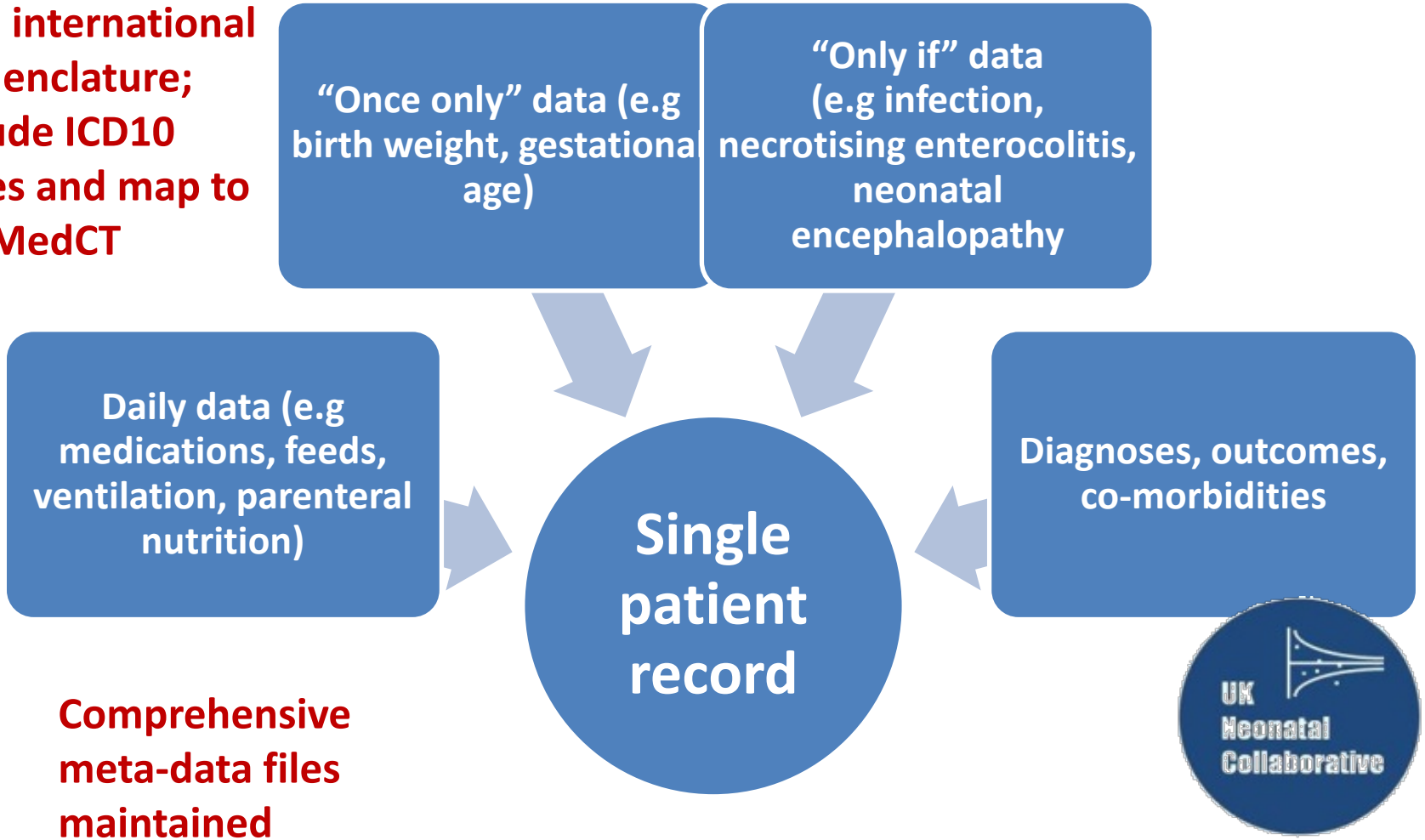
At the Neonatal Data Analysis Unit

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



Comprehensive meta-data files maintained

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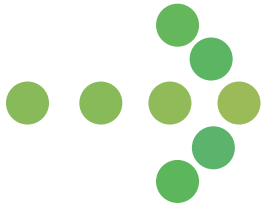
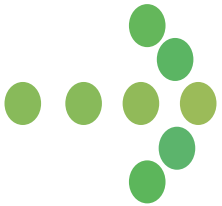
Creating the National Neonatal Research Database

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 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

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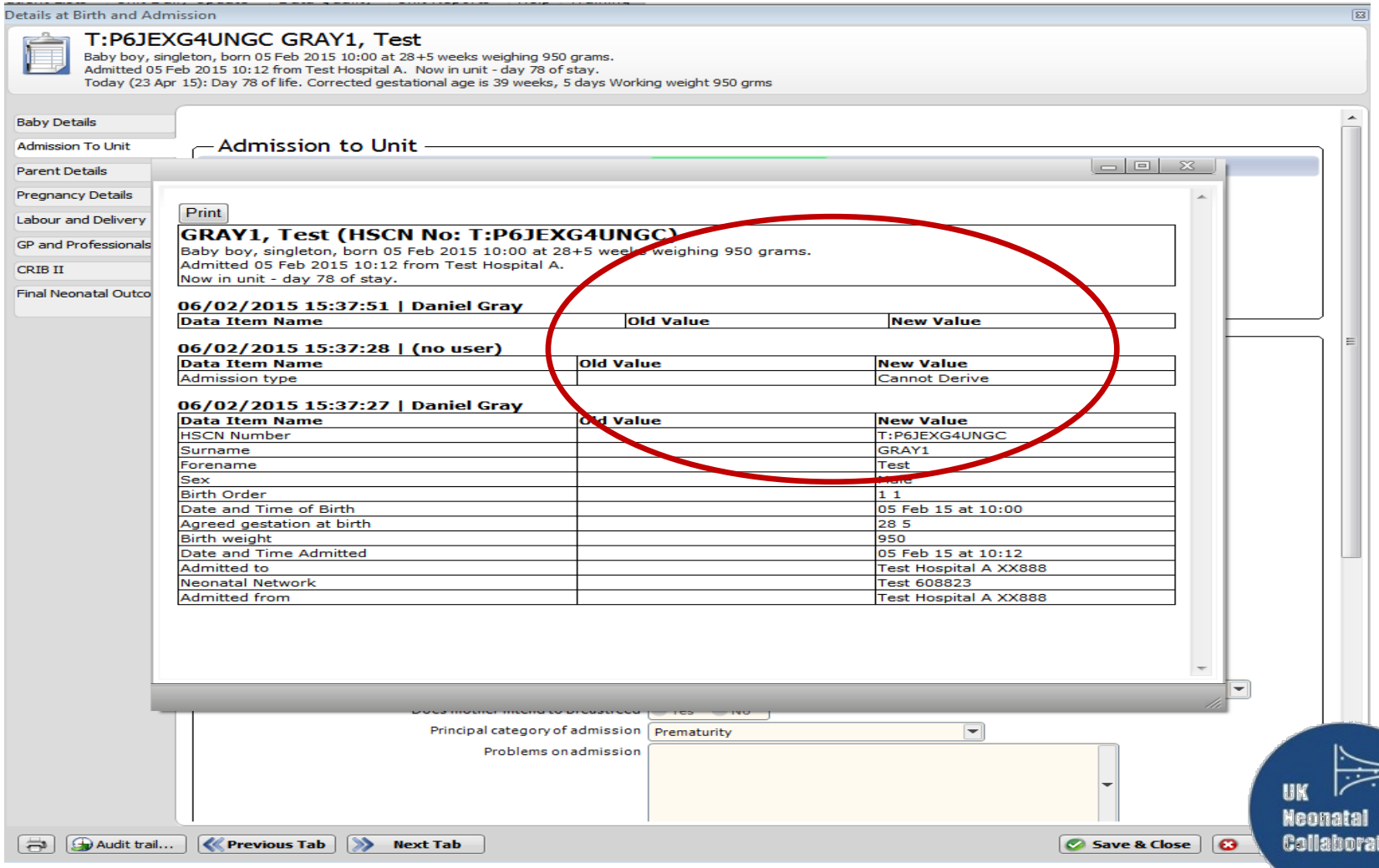
Source verification: electronic audit trail



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The Neonatal Data Analysis Unit: an academic unit of Imperial College London

UK Neonatal Collaborative

- All neonatal units in England, Wales and Scotland (n=200)
- 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

Neonatal Data Set

- The data items (n=400) extracted from the neonatal Electronic Patient Record
- Approved in December 2013 as a new NHS Information Standard (ISB1595)

National Neonatal Research Database

- A permanent, high quality repository of the data extract from neonatal Electronic Patient Records
- Regulatory approvals from the National Research Ethics Service, NHS Caldicott Guardians, and the Confidentiality Advisory Group of the UK Health Research Authority
- Used for multiple purposes

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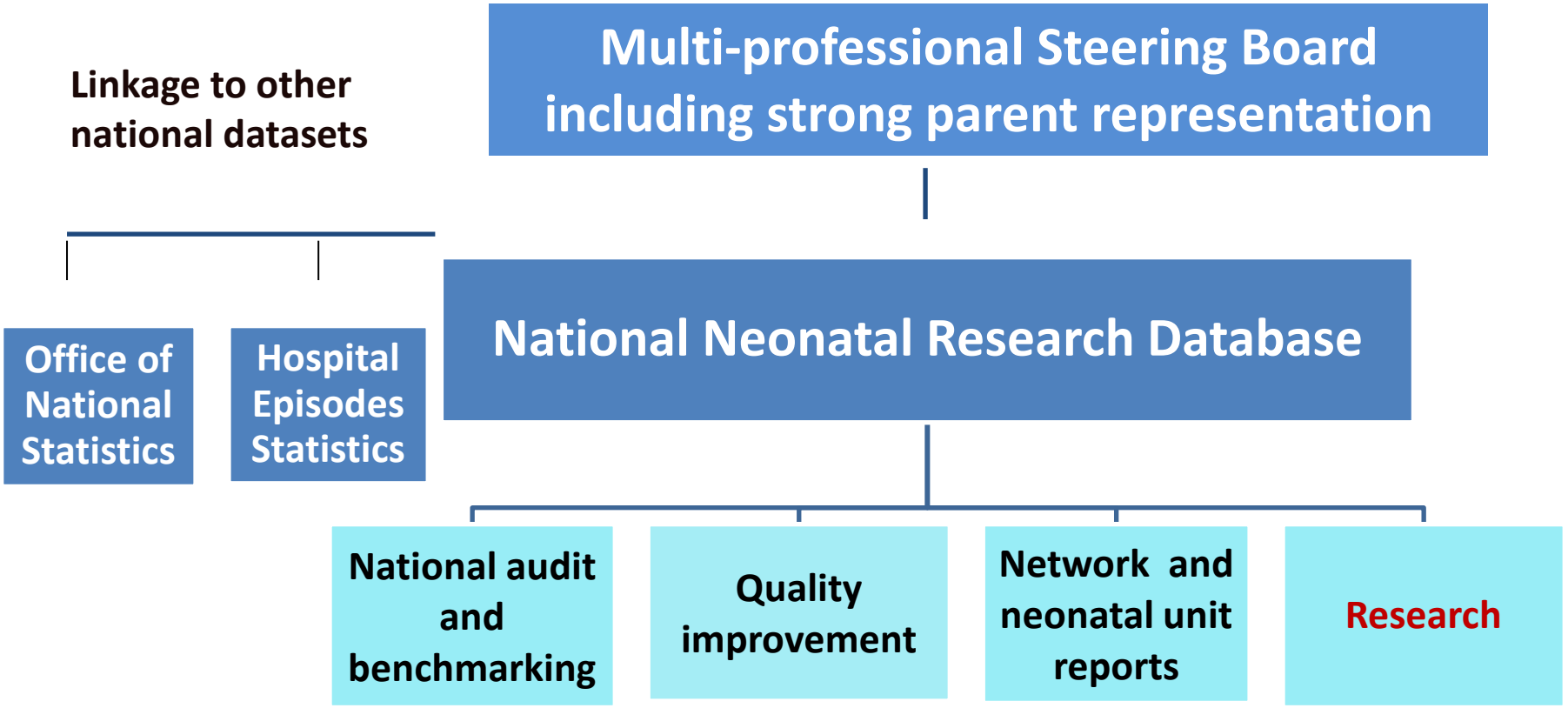
A collaborative achievement and national resource



- 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

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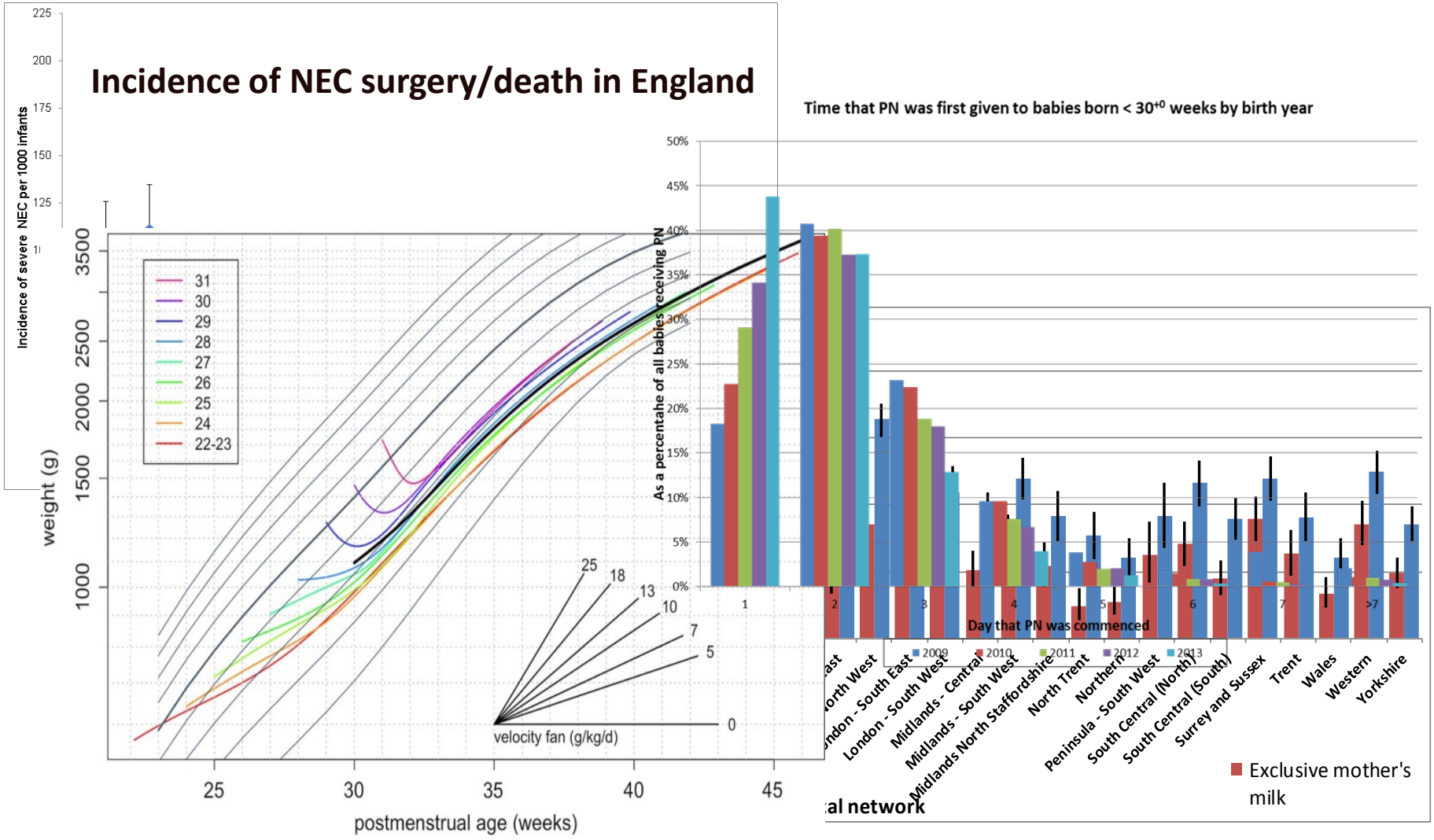
The power of population data



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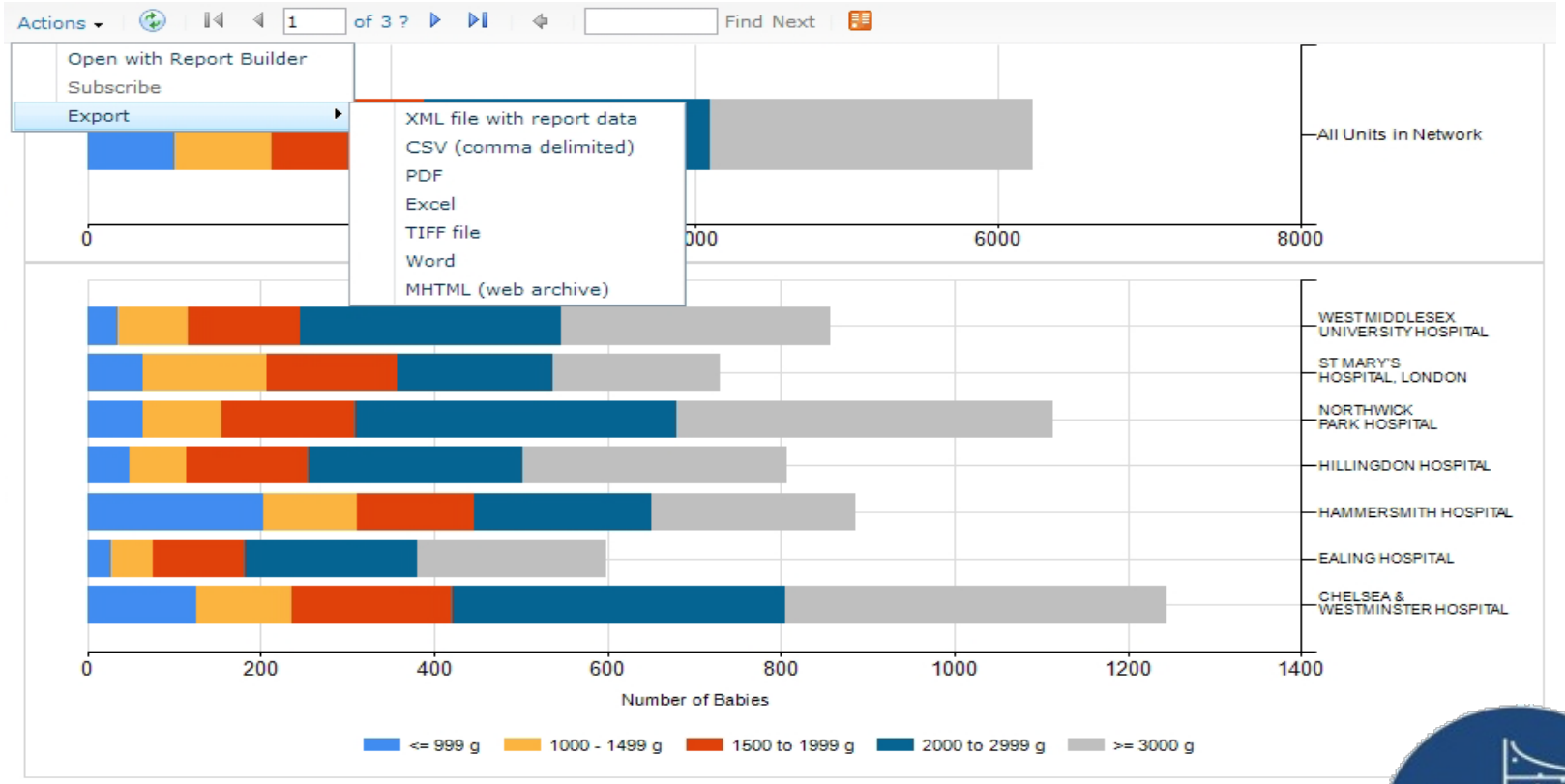
Outputs in multiple formats (note: data are fictitious)



Network: London - North West Neonatal Network
Month(s): All
Discharged: All

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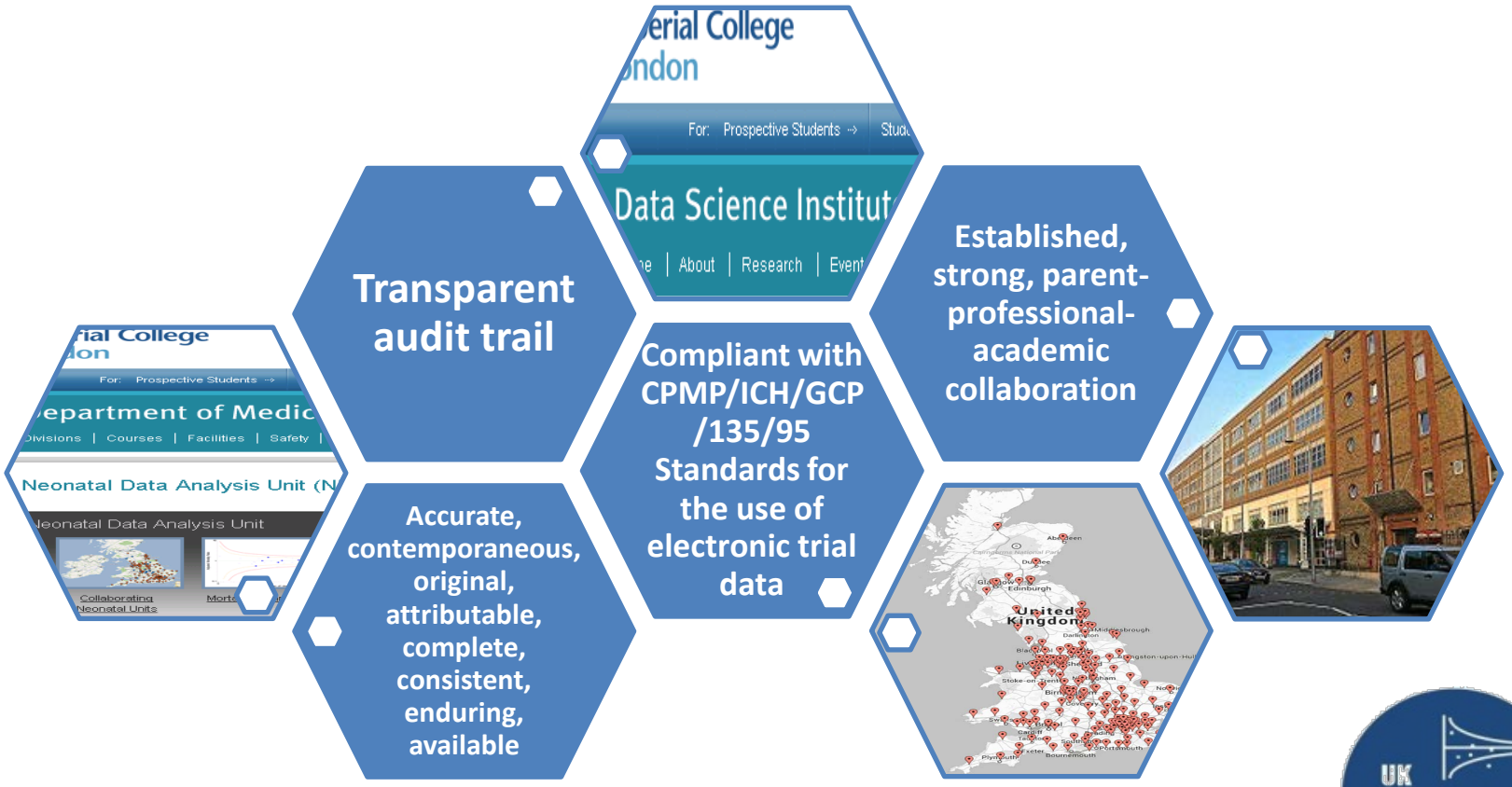
Reflection paper on expectations for electronic source data

European Medicines Agency GCP Inspectors Working Group 2010



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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**

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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

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Recent peer-reviewed publications

- Watson et al on behalf of the Neonatal Data Analysis Unit and the NESCOP Group, The effects of designation and volume of neonatal care on mortality and morbidity outcomes of very preterm infants in England: Retrospective, population-based, cohort study, **BMJ Open 2014**; 4(7):e004856
- 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
- Murray et al and the Medicines for Neonates Investigator Group. Risk Factors for Hospital Admission with RSV Bronchiolitis in England: A Population-Based Birth Cohort Study **PLoS One 2014** Feb 26; 9(2):e89186
- 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
- Battersby et al on behalf of the East of England Perinatal Networks, the UK Neonatal Collaborative and the Neonatal Data Analysis Unit Impact of a regional care bundle on maternal breast milk use in preterm infants: outcomes of the East of England Quality Improvement Programme **Arch Dis Child Fetal Neonatal Ed 2014**; 99(5):F395-401
- 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
- Blencowe et al Beyond newborn survival: Preterm birth associated impairment estimates at regional and global level for 2010. **Pediatr Res 2013**; 74: 17-34
- Murray et al A Quality of routine hospital birth records and the feasibility of their use for creating birth cohorts J Public Health (Oxf) 2013; 35:298-307 Foster et al The use of routinely collected patient data for research: a critical review **Health (London) 2012**; 16:448-63
- Gale C, Santhakumaran S, Nagarajan S, Statnikov Y, Modi N on behalf of the Neonatal Data Analysis Unit and the Medicines for Neonates Investigator Group The impact of introducing managed clinical networks on neonatal care in England: a population-based study **BMJ 2012** Apr 3; 344:e2105

Within reach: a Neonatal Consortium Data Platform