

## neoWONDER study

### **Neonatal Whole Population Data Linkage Improving lifelong health and wellbeing of pre-term babies**

#### **Information for parents and carers of preterm children born earlier than 32 weeks**

#### **Why is this research important?**

Each year in the United Kingdom around 8,000 babies are born prematurely, before 32 weeks of the normal 40-week pregnancy cycle. These babies require specialised care in neonatal units.

At present, we do not fully understand the longer term impact of all the neonatal care and interventions (like feeding and breathing support) or of social and environmental factors following hospital discharge.

Better understanding of the longer-term impact would help improve neonatal care. However, this requires following up these children's development, which can be complex and costly.

#### **neoWonder plans to address the problem**

We plan to link health, and education data, to inform a more practical solution. Linking the National Neonatal Research Database (NNRD), which holds information from neonatal units, to other existing health and education data for over 100,000 pre-term babies born in the last 14 years, is our initial ambitious aim.

This combined information will inform us how these babies progress through their childhood. From this we could learn what neonatal unit interventions and/or post-hospital social/environmental factors, may have impacted on their development.

#### **How data will be linked**

Linkage will be carried out by a trusted third parties NHS Digital, NHS Wales Informatic Service (NWIS) and the Department for Education, who already hold personal information like names, dates of birth, postcodes and NHS numbers (NHS Digital and NWIS).

Personal information will be transferred to the trusted third parties who already hold these data. They will not be given any new data not already held.

NHS numbers will be used to link health records.

Names, postcodes, and dates of births will be used to link education data.

All personal information will be removed secure transfer to researchers.

#### **Why we use personal identifiers**

NHS numbers alone can be used to link NNRD to other health data.

Linking health to education data is more problematic because there is no common identifier. The NNRD does not hold names, and educational records do not hold NHS numbers.

To overcome this, a trusted third party, already holding personal information will link both records.

### **Can researchers access personal information?**

No. Researchers only have access to anonymous 'de-identified' information.

After linkage, all personal information is removed and replaced with a unique code (only of use to the secure linkage unit already holding personal information), before being transferred to researchers.

### **Is consent required if I'm happy for neoWonder to use de-identified data?**

For parents of preterm babies born before 32 weeks, between 2007 and 2020 who support data linkage for neoWonder, there is nothing you need to do.

Seeking permission from over 100,000 families would be time consuming, costly and impractical. Therefore, we gained approval from the Confidential Advisory Group (CAG), to enable temporary use of secure identifiers for accurate linkage, without need for explicit consent.

Data linkage is legally permitted by the Health Research Authority under Section 251 of the NHS Act 2006. For more information go to CAG:

[www.hra.nhs.uk/aboutus/committees-and-services/confidentiality-advisory-group/](http://www.hra.nhs.uk/aboutus/committees-and-services/confidentiality-advisory-group/)

### **If you don't want your child's data included, you can opt-out**

Including information on early pre-term babies helps ensure data are representative and research findings are informative and helpful. If you would rather your baby's data are not included, just inform a staff member at any unit where your baby received care. They will contact us on your behalf to 'opt-out'. The study website has more information on 'opt-out' that neonatal units and parents may find helpful [www.neowonder.org.uk](http://www.neowonder.org.uk).

Choosing not to contribute data will not impact on subsequent care in any way.

### **What will happen to me or my child if we take part?**

Nothing different will happen to you or your child. Only your data will be used. It is not possible for the researchers to identify individuals in

the study and therefore you will not be contacted at any point of the study. The study will end in 2025, and data will be kept for another 10 years to ensure the research is completed.

### **How are data protected?**

After data linkage, a de-identified database (containing no personal information) is created. It will be held on a secure Imperial College server in accordance with the General Data Protection Regulations (GDPR). Information in the research database is protected by strict information security rules. The database cannot be accessed or taken outside of the server in any form. NHS numbers are stored separately on the secure NHS server of Chelsea and Westminster NHS Foundation Trust and are not available to researchers. Data included in this study will never be sold or accessed for commercial use.

### **Who manages the NNRD?**

Imperial College (National Data Analysis Unit) are the data controller of the NNRD. They are responsible for managing and protecting your data.

Visit the NNRD website for the privacy notice and further information:

[www.imperial.ac.uk/neonatal-data-analysis-unit](http://www.imperial.ac.uk/neonatal-data-analysis-unit)

### **What are the advantages of taking part?**

Findings from this research may be of benefit in the following ways:

- Understanding long-term outcomes and needs will help inform national health and educational policy and practice to better support affected children and their families.
- Understanding the longer-term impact of interventions in the neonatal unit will help parents and health professionals make informed decisions to improve care.

### **What are the disadvantages of taking part?**

There are no disadvantages for taking part; only data will be used for the study. It will not be possible for the researchers to identify individuals from the anonymised data.

### **What will happen to the results?**

The study results will be presented at conferences, published in scientific journals and publicised via the neoWONDER, Imperial College, BLISS charity and Neonatal Data Analysis Unit websites. The results will be shared with organisations responsible for the health and education, health professionals involved in

neurodevelopmental care, teachers and parents. The findings will be used on neonatal units to help counsel parents about what the future may be like for their children born preterm or with a condition requiring surgery.

The study will also contribute towards the doctorate qualification (PhD) for doctors who are undertaking research training. Dr Emily Blankenstein and Dr Sun Sunjuri will be designing the studies and analysing data. You can find more information about other researchers on the study website here [www.neowonder.org.uk/about-us/collaborators/](http://www.neowonder.org.uk/about-us/collaborators/).

Who has reviewed this study?

This study has been reviewed and granted favourable opinion by the Leicester South Research Ethic Committee.

### **Transparency**

Please visit the Health Research Authority website that explains how data can be used for research.

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

### **Find out more or get involved in neoWONDER**

We welcome parents and patients wishing to get involved.

To find out more or receive our regular newsletters, sign up on our website:

[www.neowonder.org.uk](http://www.neowonder.org.uk)

Email: [info@neowonder.org.uk](mailto:info@neowonder.org.uk)

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