What is the British Paediatric Surveillance Unit (BPSU)?

The aim of the BPSU is to encourage the study of rare conditions in children. It was founded in 1986 by the Royal College of Paediatrics and Child Health, Public Health England and Great Ormond Street Institute of Child Health (University College London).

What does the BPSU do?

It allows doctors and researchers to find out how many children in the UK and the Republic of Ireland are affected by the particular disease or condition each year - this is called surveillance. Doctors can also collect information about children with a particular rare condition. This will help them to understand what might have caused the condition and how to manage it better. BPSU studies can help future patients with a similar rare condition.

How does the BPSU work?

Each month the BPSU sends an online e-card to over 4,000 consultant paediatricians and specialist doctors. The card lists any rare conditions currently being studied. If the clinician has seen a child with one of these conditions they tick a box or ticks 'nothing to report' if not. Cases are reported by clicking BPSU "Orange Card" email and taken directly to a questionnaire held within Health Informatics Centre (HIC) at the University of Dundee. The HIC is a Data Safe Haven which supports the collection and management of data and provides secure data access. Clinicians will complete online questionnaires using patient data found in medical records. The research team will only be given access to coded data (with identifiable information removed) within the data safe haven.

What has the BPSU achieved?

The BPSU has now helped to undertake studies of over 120 rare conditions that affect children. These have helped to improve understanding of the rare conditions, such as why they occur and how to improve prevention, treatment and care.

For further information about the BPSU contact:

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Royal Devon University Healthcare NHS Foundation Trust

Public Information Leaflet

NEWBIE Surveillance:

Incidence of Neonatal Diabetes in the United Kingdom and Republic of Ireland

This leaflet provides information about a new study of neonatal diabetes. It aims to provide information about the condition, why this study is important and what we hope to show by doing it. It also provides contact details of researchers undertaking the study and a link to the website where the results will be published.

What is Neonatal Diabetes (NDM)?

NDM is a rare form of diabetes that occurs within the first 6 months of life. Infants with NDM are born with changes in their genes, which affect insulin production. Infants with NDM do not produce enough insulin, increasing the levels of blood sugar in the body to very high levels. Delayed diagnosis of NDM is associated with developmental concerns. At present, infants with NDM often are unrecognised as being seriously ill until their blood sugar is at a high and life-threatening level, which can be very difficult to treat. Some infants die and those that survive may be left with brain damage and need lifelong care.

Why is this study important?



Key to improving treatment and care, reducing the impact of disease on families and NHS costs would be the ability to diagnose NDM as soon as possible, to enable treatment to be started much sooner.

The aim of our research is to develop a glucose test, that can be used as part of the NHS newborn blood spot screening programme.

We are working with health economists to find out whether screening for this condition is suitable and cost effective, however important information is lacking which is not routinely collected.

What are the aims of this study?

This surveillance study aims to collect data on infants that have been diagnosed with NDM. This information will help us to estimate how many infants are diagnosed with NDM per year and to understand how the condition is diagnosed, treated & managed in hospital. We will also collect follow up data 24-36 months after a baby is diagnosed with NDM to understand more about the long-term treatment and outcomes.

How long will the study last and where is it happening?

This study will last for 25 months from [insert start date}] and will be taking place across the United Kingdom and the Republic of Ireland.

How will the information be collected and used?

Royal Devon University Healthcare NHS Foundation Trust is the sponsor and data controller for this research study so is responsible for looking after the information and using it properly.

We will collect information about children with a new diagnosis of neonatal diabetes from the doctors who are looking after them. Doctors will not provide names and addresses to the study team but they will provide details like sex, ethnic group and month and year of birth. Clinicians will complete questionnaires using information from medical records and will include information about how their patient's diabetes has been diagnosed, treated and managed in hospital. A follow-up questionnaire will collect information to understand about the long-term treatment and outcomes for patients diagnosed with neonatal diabetes

The smallest amount of personally identifiable information will be used. We cannot withdraw or remove personal information from the study as this would make the research invalid. When the study finishes, personal information will be deleted or de-personalised.

Royal Devon University Healthcare NHS Foundation Trust will securely store information for at least 20 years.

For more details about how personal information is used in the study, please see the BPSU website: **www.bpsu.org.uk**

If you want access to the information in your child's medical records, then you should contact your child's NHS hospital or doctor.

What if I do not want to be involved?

Hospitals will record if patients do not want their medical records to be used for audit or research. You must tell your doctor or hospital if you do not want your records to be used.

(In addition, individuals living in England can register a national data opt out. Registering an opt out means that none of your child's NHS information relating to care provided in England would be used for research or planning www.nhs.uk/your-nhs-data-matters/)

Who is funding and supporting this study?

This study is funded by the National Institute for Health and Care Research Exeter Biomedical Research Centre (NIHR Exeter BRC). The Exeter Clinical Research Facility and Diabetes UK PPIE groups and The National Rare Diseases Office Ireland are supporting the study.

Where will the results be published?

Once the study is completed, you will be able to find the results on the BPSU website: **www.bpsu.org.uk**

Who has reviewed this study?

The study was approved by South Central - Hampshire B REC (26/SC/0062), the Health Research Authority, Confidentiality Advisory Group (England and Wales) (26/CAG/0035) and the Public Benefit and Privacy Panel (Scotland) (2526-0228 Mcdonald).

Who to contact if you have any questions or concerns?

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