

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 epidemiological surveillance. Doctors can also gather information about all the cases of a particular rare condition so they can begin to understand what might have caused it and how to diagnose and treat. BPSU studies can benefit future patients with rare conditions.

How does the BPSU work?

Each month the BPSU sends an e-card to over 4,000 consultant paediatricians and specialists; the card lists the rare conditions currently being studied. If any doctor has seen a child affected by one of these conditions they tick a box on the card and send it back. The BPSU informs the research team who send the doctor a short confidential questionnaire asking for more information. Researchers are not told the names and addresses of patients, and families are not contacted.

What has the BPSU achieved?

The BPSU has now helped to undertake surveys of over 120 rare conditions, which may affect children. These have helped to increase understanding of why the conditions occur and can help to provide better diagnoses and treatments.

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British Paediatric Surveillance Unit Public Information Leaflet

Herpes Simplex Virus (HSV) Disease in infants younger than 90 days of age

This leaflet provides information about a new study of Herpes Simplex Virus (HSV) disease in young infants. 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 the researchers undertaking the study and a link to the website where the results will be published.

What is HSV?

Herpes simplex (HSV) is a virus. It causes different types of infections and illnesses. It is a very common infection in adults often causing only cold sores. Neonatal HSV disease is when the virus makes a baby sick in their first few days or weeks of life. Babies can be affected if their mother has the infection during her pregnancy or at the time the baby is born, or if an individual with the infection comes into very close contact with the baby in the baby's first weeks of life.

Why is this study important?

Neonatal HSV disease is a rare but devastating disease. Many of the babies affected will die or will suffer from long-term neurological problems.

We are trying to reduce the number of babies who become sick from this disease by identifying those who are at greatest risk and taking steps to prevent them from becoming infected.

At the moment we do not have enough information about the number of cases of this disease, which babies are most at risk, ways we might be able to reduce those risks, and whether the treatment and prophylaxis we are using is reducing long-term problems and later relapses.

In the decade since the last national UK surveillance study, there have been significant changes in the way we detect the virus, how common the

virus is in the adult population, and how we manage both pregnant women and babies who are affected.

What are the aims of this study?

In the short-term we aim to establish the current number of cases of HSV disease occurring in babies younger than three months of age, in the UK and Republic of Ireland. We aim to find out detailed information about those cases from pregnancy through to admission to hospital, outcome and follow-up at 12 months of age, including relapse rate and neurodevelopmental outcome at one year if they survive.

Data collected on infants with HSV infections will help us to improve our understanding of the current burden of infection and its risk factors. This will help target future strategies to prevent infections.

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

This study will last for a total of 4.5 years (30-months surveillance with 2 year follow-up) from March 2019 and will be taking place across the United Kingdom and Ireland. The study is being led by investigators based at St George's, University of London (SGUL) and Brighton and Sussex Medical School / Brighton and Sussex University Hospitals Trust in collaboration with investigators from Public Health England; Health Protection Scotland; Health Protection Surveillance Centre, Ireland; Department of Health, Social Services and Public Safety, Northern Ireland; Public Health Agency Northern Ireland; Edinburgh Royal Infirmary and Royal Hospital for Sick Children, Edinburgh.

How will the information be collected and used?

Brighton and Sussex Medical School (University of Sussex) is the sponsor for this research study and Brighton University Hospitals NHS Trust (BSUHT) is the data controller for this research study so is responsible for looking after the information and using it properly. BSUHT's privacy notice can be accessed at <https://www.bsuh.nhs.uk/your-visit/your-information-and-rights/information-we-hold-about-you/>. The Data Protection Officer at BSUHT can be contacted on 07900 736. We will collect information about children with a new diagnosis of HSV disease 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 date of birth. They will complete questionnaires using information from medical records.

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. Brighton and Sussex Medical School 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 <http://www.rcpch.ac.uk/bpsu/hsv>

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 my child to be involved?

Hospitals will record if parents do not want their child's notes to be used for audit or research so you must tell your doctor if you do not want your child's notes used. If you do this, then your child's notes will not be used in any BPSU study.

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 <https://www.nhs.uk/your-nhs-data-matters/>

Who is funding and supporting this study?

The Kit Tarka Foundation (<https://www.kittarkafoundation.org>) and Rockinghorse Children's Charity (<https://www.rockinghorse.org.uk>) are supporting this study.

Where will the results be published?

Once the study is completed, you will be able to find the results on the BPSU website: <https://www.rcpch.ac.uk/bpsu/hsv>

Who has reviewed this study?

The study was approved by: Wales Research Ethics Committee 7, the Health Research Authority Confidentiality Advisory Group (England and Wales) and the Public Benefit and Privacy Panel (Scotland).

Who to contact if you have any questions

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