

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.

For further information contact:

British Paediatric Surveillance Unit, Royal College of Paediatrics and Child Health, 5-11 Theobalds Road, London, WC1X 8SH,

T: +44 (0) 207 092 6173/4

Email: bpsu@rcpch.ac.uk **Website:** www.rcpch.ac.uk/bpsu/fpies



Public Information Leaflet

Food Protein Induced Enterocolitis Syndrome (FPIES)

This leaflet provides information about a new study of FPIES. 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 FPIES?

Food Protein Induced Enterocolitis Syndrome (FPIES – pronounced F-pies) is a type of food allergy which leads to repeated vomiting and other gastrointestinal symptoms up to several hours after a problem food (or baby formula) is eaten.

Delays in diagnosis are frequent, since many frontline healthcare providers are not aware of the condition, and presenting symptoms can mimic other serious childhood illnesses, such as septic shock from infection and bowel obstruction.

Why does FPIES develop?

FPIES is a type of food allergy. It is called non IgE-mediated food allergy because validated allergy tests (skin prick tests or specific IgE) are normally negative in FPIES. In other food allergies such as peanut allergy, these tests will be positive. Other parts of the immune system are involved in FPIES, which we can't test for. Very little is known about the underlying cause of FPIES, or why some children develop it and others do not. It is a rare condition, and part of the problem limiting our understanding is that specialists will only see a handful of cases.

What are the aims of this study?

This is the first nationwide study of FPIES in the UK. This study will tell us how common FPIES is in the UK, what foods can cause it and the range of symptoms that children exhibit during a reaction. It will also improve awareness of FPIES amongst paediatricians' as every consultant paediatrician in the country will be told about FPIES through the BPSU. This has the potential to benefit future patients and families through improved recognition leading to quicker diagnosis of FPIES. We hope the results of this study will encourage further research, including ways to help to cure FPIES.

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

This study will last for 13 months from January 2019 and will be taking place across the United Kingdom, the Republic of Ireland and the Channel Islands.

How will the information be collected and used?

University Hospitals of Leicester NHS Trust (UHL) 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 FPIES 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. Doctors will complete questionnaires using information from medical records. If you want access to the information in your child's medical records, then you should contact your child's NHS hospital or doctor. We cannot withdraw or remove personal information from the study as this would make the research invalid. After the study finishes, UHL will securely store information for 20 years, then anonymise or destroy it.

For more details about how personal information is used in the study, please see the BPSU website www.rcpch.ac.uk/bpsu/fpies

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 www.nhs.uk/your-nhs-data-matters/

Who is funding and supporting this study?

The Midlands Asthma and Allergy Research Association (MAARA) are funding this study. Allergy UK (www.allergyuk.org) and FPIES UK (www.fpiesuk.org) 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.rcpch.ac.uk/bpsu/fpies

Who has reviewed this study?

The study was approved by: London-Stanmore Research and Ethics Committee, 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

Dr Gary Stiefel
Consultant in Paediatric Allergy
Respiratory Office, Ward 28 (Windsor building level 4)
Leicester Royal Infirmary,
Infirmary Square,
Leicester LE1 5WW
Email: gary.ghs.stiefel@uhl-tr.nhs.uk
Tel: 0116 258 6694