

## 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 University College London Great Ormond Street Institute of Child Health.

### 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 any doctor has seen a child with one of these conditions they tick a box on the card and send it back. The BPSU tells the research team who send the doctor a short confidential questionnaire asking for more information from the medical record. 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 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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## Public Information Leaflet Symptomatic glucocorticoid induced Adrenal Suppression in the United Kingdom and Ireland (GLAS study)

This leaflet provides information about a new study to identify children and young people who have adrenal suppression (AS) caused by steroid medicines (glucocorticoids) and have an inability to make the natural stress steroid cortisol in their adrenal glands. This type of adrenal suppression is very rare and potentially very serious. Researchers want to find out why this occurs in some children and not others.

### What is adrenal suppression?

The adrenal glands sit just above the kidneys and are involved in making important steroid hormones needed to keep the body working normally, particularly in times of stress such as injury or illness. Some medicines containing glucocorticoids can prevent our adrenal glands producing natural steroid hormones including cortisol and result in symptoms such as tiredness, decreased appetite and weight loss. When unwell, children with AS may not be able to make the extra cortisol needed to cope with the associated stress and become extremely unwell with nausea and vomiting, low blood pressure and low glucose levels (an adrenal crisis). Patients with AS can develop drowsiness or coma and, if not recognised, this condition can be fatal.

### Why does adrenal suppression secondary to the use of steroid medication develop?

Glucocorticoid medications are used to treat a wide variety of medical conditions and can be used in many different forms such as creams, inhalers or tablets. When large amounts are absorbed by the body, the adrenal gland's ability to produce natural steroid hormones may become reduced. This means that they may not be able to make the extra steroid needed at times of stress.

## **What are the aims of this study?**

We know that steroid medication containing glucocorticoid can cause AS but it is not known how common this is. We aim to find out 1) how frequently children become unwell with symptoms of AS after using steroid medication, 2) which underlying conditions and which medications are involved, 3) whether particular routes of administration and length of use increase the risk of this happening. We hope that this information will allow us to manage the condition better and find a way to stop this happening in future. This study is being supported by the BPSU as well as the British Society for Paediatric Endocrinology and Diabetes.

## **How will the information be collected and used?**

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor and data controller for this research study (project reference 09236) so is responsible for looking after the information and using it properly.

Data will be collected about children with a new diagnosis of AS from the doctors who are looking after them. Doctors will complete questionnaires using medical records. Doctors will not provide names and addresses to the study team but they will provide details like sex, ethnic group and date of birth. The smallest amount of personally identifiable information will be used. After the study finishes, the sponsor will securely store this information

As we cannot identify individual children, we cannot remove, change, withdraw or provide access to personal information used in the study. If you want to find out more about how personal information is used in the study, see the BPSU website: (<https://www.rcpch.ac.uk/bpsu/adrenal-suppression>).

If you want access to the information in your child's medical records, then you should contact your child's NHS hospital or doctor. BPSU researchers do not contact the children or families with the condition. Information on reported cases are sent to the research team without any names or addresses. All information that is collected will be confidential and stored securely.

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

## **Where is this study happening?**

The study will be carried out throughout the UK, and the Republic of Ireland with study teams based in Edinburgh, Newcastle and Nottingham.

## **How long will the study go on for and who is funding this study?**

The study surveillance will go on for a two-year period commencing in September 2020 with a further year to analyse and present the information obtained.

## **Who is funding and supporting this study?**

The study is funded through a grant from the Joint Research Executive Scientific Committee at Newcastle upon Tyne Hospitals NHS Charity and the Newcastle Healthcare Charity, and from a grant from Nottingham Hospitals Charity.

## **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/adrenal-suppression>.

## **Who has reviewed this study?**

This study has been approved by North West - Preston Research Ethics Committee (reference: 19/NW/0627); HRA Confidentiality Advisory Group (reference: 19/CAG/0191); and Public Benefit and Privacy Panel for Health and Social Care (reference: 1819-0336).

## **Who to contact if you have any questions**

Dr Tim Cheetham, University Reader and Honorary Paediatric Consultant, The Great North Children's Hospital, Newcastle-upon-Tyne NE1 4LP **Email:** [tim.cheetham@nhs.net](mailto:tim.cheetham@nhs.net)

## How will we use information about you?

We will need to use information from you / your child's medical records for this research project.

This information will include your:

- NHS number
- Date of birth (not if you live in Scotland).
- Postcode

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

## What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

## Where can you find out more about how your information is used?

You can find out more about how we use your information

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- our leaflet available from the BPSU and BSPED websites
- by asking one of the research team
- by sending an email to [tim.cheetham@nhs.net](mailto:tim.cheetham@nhs.net)

- by ringing us on 0191 282 9562

*This leaflet will become obsolete in 2022.*