BPSU surveillance of Symptomatic glucocorticoid induced adrenal suppression in the United Kingdom and Ireland (GLAS study) Commences in September 2020

Outline of the study: Glucocorticoid (GC) medication is used to treat a wide variety of medical conditions and comes in many different forms such as creams, inhalers, tablets or injections. When large amounts of GC are absorbed by the body, the adrenal glands (that normally manufacture the major GC, cortisol) can become suppressed and unable to manufacture GC in the normal way. Unfortunately adrenal suppression (AS) is not always spotted early enough and if unrecognised or if not managed appropriately it can result in a life threatening adrenal crisis. We intend to undertake a 25-month surveillance study to determine the incidence of symptomatic AS arising because of current or previous GC therapy. We intend to define the characteristics of patients developing symptomatic AS in terms of their age and primary underlying diagnosis. We also intend to look at their GC regimen and their management. We hope that this information will allow us to improve the way in which AS is identified and managed in the future. Deaths from adrenal crises in patients with AS should be preventable provided education is comprehensive and access to appropriate medical treatment is rapid.

Hospital episode statistics (HES) and the Scottish SMR01 database will be used to check case ascertainment in England and Scotland respectively.

Duration: BPSU surveillance will be undertaken for 25-months, commencing in September 2020.

Case definition: Any patient under 16 years of age whose symptoms or signs* partly or entirely reflect abnormally low adrenal cortisol production arising because of recent or ongoing glucocorticoid administration (adrenal suppression). The inadequate cortisol production may result in symptoms on a regular basis or be manifest acutely in association with a stressful event or illness.

> *Signs/symptoms could include hypotension, shock, unexplained hypoglycaemia or hyponatraemia, seizure, lethargy, decreased level or loss of consciousness, anorexia, fatigue, lethargy, myalgia, gastrointestinal symptoms (nausea, vomiting, abdominal pain), growth failure, death (Goldbloom et al. 2017).

Excluding: Cases of primary adrenal failure arising because of intrinsic adrenal pathology such as autoimmune Addison's disease or secondary adrenal insufficiency in patients with pituitary hormone deficiency, including those with combined pituitary hormone deficiency and isolated ACTH deficiency who are normally on GC replacement.

Also excluded are infants who are less than 6 months of age and **who were also** born preterm (<37 weeks gestation).

Reporting Instructions: Please report any child seen in the last month who meets the case definition. If the diagnosis is awaiting confirmation; the child should still be reported.

How will we use information about you? We will need to use information submitted by you for this research project. This information will include your (reporting doctors) name and

contact details. People will use this information to undertake the research and to thank you for your contribution.

People who do not need to know who you are will not be able to see your name or contact details.

We will keep all information about you safe and secure.

What are your choices about how your information is used? You do not have to take part in this study and do not have to give a reason.

Where can you find out more about how your information is used? You can find out more about how we use your details:

- by asking one of the research team
- by sending an email to tim.cheetham@nhs.net
- by ringing us on 0191 282 9562

Website: www.rcpch.ac.uk/bpsu/adrenal-suppression

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Ethical approval: 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).

Further information:

If you would like any advice regarding the eligibility of a particular case for inclusion in the study please contact:

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