The Perioperative Replacement of Exogenous Steroids

The PREdS Study – Phase 1a:

A multicentre snapshot audit

Frequently Asked Questions

**Q. Who is running PREdS?**

A. PREds was designed by a team from the Severn Trainee Anaesthetic Research Network (STAR), a trainee research network based in the Severn Deanery. The lead hospital is the Bristol Royal Infirmary, University Hospitals Bristol and Weston NHS Trust, Upper Maudlin Street, Bristol.

**Q. When will it take place?**

A. The audit window will run from **26/09/20022 to 04/12/2022.** Data collection may take place over **any two consecutive weeks** within this timeframe. This was designed to allow maximum flexibility for each site to choose a data collection period that suits them.

**Q. What is the aim of PREdS?**

A. PREdS is designed to run in two phases.

**Phase 1a: September – December 2022**

A multicentre snapshot audit aiming to determine the number of patients presenting for procedures in the UK who are on long term steroid therapy, and whether their perioperative management is in line with current national guidelines *(Guidelines for the management of glucocorticoids during the peri-operative period for patients with adrenal insufficiency. Woodcock T et al. Anaesthesia 2020;****75:*** *654-663.* [*https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1111/anae.14963*](https://associationofanaesthetists-publications.onlinelibrary.wiley.com/doi/full/10.1111/anae.14963)*).*

This is the part of the study that we need your help with!

**Phase 1b: Winter 2022 – Spring 2023**

Secondary analysis of patient data, including demographics, indication for steroids, type of surgery and spectrum of practice when administering supplementary steroids in patients on long term steroid therapy. **This phase will undergo appropriate ethical approval.**

**Phase 2: Summer 2023 onwards**

Design and submission for funding for an RCT exploring perioperative supplementation in those at risk of adrenal insufficiency.

**Q. How do I get involved?**

A. We hope that each local trainee research network (TRN) will contact sites within their area to encourage participation. They should also be able to provide support in organising and running the audit locally. If you haven’t heard from your TRN however, you can still get involved. Contact the study team on predsstudy@gmail.com and we can help! We would also recommend that you review all the documents available on our website to help you run the study at your site.

**Q. Will I receive acknowledgement of my involvement?**

A. Absolutely! You will receive a certificate of participation for your portfolio and will be listed as a collaborative author for any publications that follow.

**Q. How many people need to be involved at each site?**

A. We would recommend that each site has a lead consultant, at least one lead trainee investigator, and two or more local trainee investigators depending on the size of the site.

**Q. Is patient consent required to collect the data?**

A. No, as this first phase will be registered as an audit, and all information is anonymised, patient consent is not required, and local investigators are not required to have completed Good Clinical Practice (GCP) certification.

**Q. Is ethical approval required at my site?**

A. No, PREdS should be registered with your site as an audit, which does not require ethical approval.

**Q. How is the data uploaded?**

A. Data should be uploaded directly by the anaesthetist involved with each case, to our PREdS specific online data collection form via the link <https://redcap.link/PREDS>. No login details are required.

In addition to this, local investigators should also upload a daily total of eligible cases from their site.

A paper copy of the data collection form is available on request for any sites who are unable to utilise the online form. Please contact the PREdS Study team for more information.

**Q. When is the deadline for uploading data?**

A. All data should be uploaded by midnight on 04/12/2022.

**Q. What about cases taking place out of hours?**

A. We hope to include all emergency and out of hours cases at each site. On call teams should receive appropriate guidance by local investigators on which patients are eligible for inclusion and how data can be uploaded onto the online data collection form via the weblink.

**Q. How do you define “long term steroids”?**

A. Any patient who has been on **any dose of oral steroids** for a period of **one month or more prior to the date of their procedure,** should be classed as on long term steroids for the purposes of this audit.

**Q. Will inhaled or topical steroids count as long-term steroid therapy?**

A. No, only oral or iv steroids should be included as long-term steroid therapy.

**Q. What if I routinely use dexamethasone as an anti-emetic?**

A. This will be captured appropriately by the online data collection form, in addition to steroid given with the intention of steroid supplementation.

**Q. We have participated In data collection for PREdS. What comes next?**

A. Many thanks for your contribution! We plan for PREdS to run in two phases. The first is the multicentre snapshot audit of current practice, to which you have contributed. The second phase will involve more detailed analysis of the collected data. As this will fall under the umbrella of ‘research’, appropriate ethical approval will be sought before proceeding with this stage.

For this part we plan to use Commissioning Returns Data which is requested from the Business Intelligence Unit (BIU) at each participating local trust. This will provide demographic and episode information for all patients included in Phase 1a.

A list of NHS numbers will be returned to each site once their data collection window is complete. **Please then request the Commissioning Returns Data from your local Business Intelligence Unit, and store this securely (may be best kept by Consultant Lead).**

Once ethical approval is in place, the PREdS Chief Investigator will request this data from each local site. We anticipate that this will happen in early 2023.

**Q. Our audit department has concerns regarding the handling of collected data prior to Phase 1b, as this will contain patient identifiable information.**

A. In collaboration with the Information Governance team at our lead hospital, we have designed a **Data Sharing Agreement** to address these concerns. Please contact the PREdS Study team for more information, and a copy of the document.