The Perioperative Replacement of Exogenous Steroids

The PREdS Study – Phase 1a:

A multicentre snapshot audit

***How to run the PREdS audit at your site….***

Many thanks for choosing to take part in PREdS!

Please find below some important instructions on how to run this audit at your site. **We also recommend that you review the FAQs document on the study website.**

Before you begin, please ensure that you register the audit with your local clinical governance and audit department.

**This is essential before data collection can commence at your site!**

**When you receive clinical governance approval, please forward it to the main project team on predsstudy@gmail.com.**

Please see the website for further information sheets, training videos and posters which can be used to run PREdS at your site.

**The Project:**

PREdS is a study designed to run in two distinct phases. The first phase is planned to run in Autumn/Winter 2022 and will be covered by this document. The second phase will involve more detailed analysis of the data collected and will follow pending ethical approval.

PREdS Phase 1a is a multicentre snapshot audit that may take place over any 14 consecutive days within the audit window. It aims to assess the number of patients presenting for elective, urgent and emergency procedures who are taking any dose of oral steroids for a period of greater than 1 month from the date of their procedure, and how perioperative steroid replacement is currently being managed.

**ALL patients undergoing procedures during this period should be included, regardless of whether they are taking long term steroids or not.**

**Timeframe:**

The 14 consecutive day period may take place at any time within the audit window, and this should be co-ordinated locally. The PREdS team recommend that it should start at 08:00 on a Monday morning and finish at 07:59 on the following Monday 14 days later.

**The audit window runs from 26/09/2022 to 04/12/2022**

**Inclusion/Exclusion criteria**

***Inclusion criteria***

* Aged 18 years or above
* Undergoing any surgical, interventional radiology or medical procedure with involvement of an anaesthetist. This may include:
* General Anaesthesia
* Regional or neuraxial anaesthesia
* Deep or minimal/conscious sedation techniques

***Exclusion criteria***

* Paediatric patients (< 18 years of age)
* Patients undergoing anaesthesia for reasons relating to critical illness (e.g. cardiac arrest, respiratory failure, low GCS etc.) who are NOT undergoing a surgical, medical or radiological procedure.

**Running the Study**

Due to the large amount of data collection involved, we would anticipate that several local investigators will be required per site. The aims of the audit, inclusion criteria and how to use the online data collection form (REDCaP) will need to be publicised widely within the anaesthetic department, and the two week data collection period agreed locally.

You will need to identify all patients that meet the inclusion criteria. The exact process will depend how operating lists in your centre are co-ordinated and published, but as an example:

1. Review printed or digital operating lists each day during the data collection period, to identify theatres, procedure rooms, endoscopy suites, cath labs etc. in which procedures are taking place.
2. Brief anaesthetist(s) running lists including demonstrating completion of REDCaP - <https://redcap.link/PREDS>. Sites should aim to have a local investigator available each day to answer queries and support completion of the data collection form by the anaesthetist involved in each case. Login information will not be required.

For out of hours procedures, unless a member of the investigating team is immediately available, we recommend that you brief the on-call team and follow-up at handover to ensure these cases are included.

1. Submit a **daily total of eligible cases** (not the number captured) on the appropriate REDCaP form.

**Support**

Following registration of the project with your local audit department, and confirmation of this with the PREdS project team (predsstudy@gmail.com) you will be invited to a formal Q&A for completion of the data collection form using REDCap. In addition Training Videos and further documents will be available on the website.

If you have any problems, please let us know by email to predsstudy@gmail.com

All data must be uploaded to the online data collection system before the end of the study window on 04/12/2022 at 23.59. Data uploaded after this time will not be included.

**What comes next?**

After the audit is complete, we will write up and aim to publish our findings. Following this, we will aim to perform more detailed statistical analysis of collected data. All appropriate ethical approvals will be obtained prior to this second phase of the project.

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).**

If your local audit department has concerns regarding the storage, handling and transfer of collected data during this phase, we can provide a comprehensive **data sharing agreement** which covers this in more depth. Please contact the study team for more information.

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.

Local investigators from every site will be credited in any publication that ensues from either the first (audit) phase, or the second phase of the study.

All sites will be given access to their own data for local audit/quality improvement work once PREdS is complete.

If you have any further queries, **please consult the FAQs document** on the website, or email the study team on predsstudy@gmail.com.