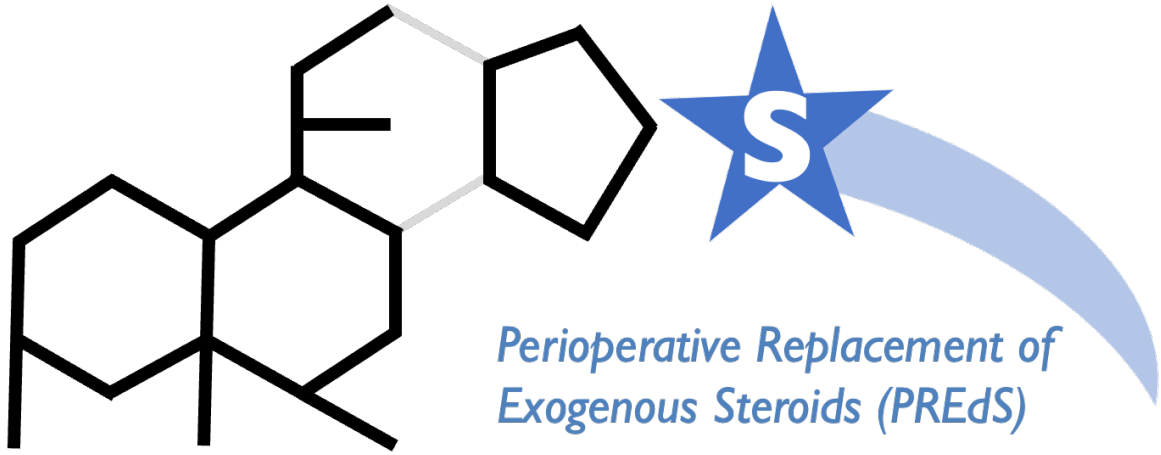
The Perioperative Replacement of Exogenous Steroids (PREdS) Audit: Preliminary data collection of patients presenting for surgery with potential adrenal insufficiency

Phase A1: A multi-centre audit of current practise and collection of patient data for future analysis



Sponsor

University Hospitals Bristol and Weston NHS Foundation Trust
R&D Office
Level 3, Education Centre
Upper Maudlin Street
Bristol BS2 8AE

Severn Trainee Anaesthetic Research Network
Dr Oliver Barker
University Hospitals Bristol and Weston
Email: oliver.barker@doctors.org.uk

Severn Trainee Anaesthetic Research Network
Dr Aravind Ramesh
University of Bristol
Email: ar17163@bristol.ac.uk

Severn Trainee Anaesthetic Research Network
Dr Inthu Kangesan
University Hospitals Bristol and Weston
Email: ikangesan@doctors.org.uk

Severn Trainee Anaesthetic Research Network
Dr Jonathan Barnes
University Hospitals Bristol and Weston
Email: jonathan.barnes77@gmail.com

Chief Investigator
Dr Ben Gibbison
University of Bristol
ben.gibbison@bristol.ac.uk

Methodological Lead
Prof Barnaby Reeves
Bristol Trials Centre
barney.reeves@bristol.ac.uk

Statistical Lead
Dr Jess Harris
Bristol Trials Centre
Jessica.harris@bristol.ac.uk

ABSTRACT

Introduction: **Oral corticosteroids are prescribed to approximately 1% of the UK population. Indications are broadly split into two groups; those deficient in corticosteroid who require replacement, or those taking therapeutic corticosteroid for a range of inflammatory conditions. Therapeutic treatment can induce (tertiary) adrenal insufficiency with the subsequent inability to increase production at times of physiological stress, such as surgery, potentially leading to major complications. Current guidance therefore recommends steroid supplementation in the perioperative period. Replacement therapy for primary and secondary insufficiency will always be required, but the degree of adrenal suppression is not well understood in the therapeutic patient group. Consensus guidelines exist for such patients but are based on limited evidence. This audit of UK practise is designed to assess compliance with current guidelines. The data gained from the audit will then be used to guide design of a randomised clinical trial.**

Methods and analysis: **This prospective audit will invite all 19 Anaesthetic Trainee Research Networks within the United Kingdom to participate, working across more than 150 NHS Acute Trusts. Data will be collected over a two-week period using an electronic case record form (CRF) and stored on a secure database. Descriptive statistics for the use of/compliance with existing guidelines will be performed, with additional data collected for secondary analysis to include the number of patients presenting for surgery receiving therapeutic corticosteroids, diagnoses, demographics and planned procedure.**

Ethics and dissemination: **Ethical approval is not required for this audit as defined by the NHS Health Research Authority Defining Research and Ethics tool. All participating centres will be expected to register their involvement with local audit departments and comply with local data protection policy. Results will be reported to Trainee Research Networks who will in turn disseminate results to individual Trusts. Data will undergo secondary analysis to inform the design of a randomised controlled trial assessing peri-operative corticosteroid supplementation regimens. The results of this audit will be disseminated by peer-reviewed manuscript, conferences, and will inform future guidance.**

1. Introduction

Corticosteroid use is common. Initial 'scoping' work for this project (interrogating the Clinical Practice Research Datalink (CPRD)), showed that around 1% of the UK population, takes oral corticosteroids for ≥28 days each year and there were roughly 8 million prescriptions for oral corticosteroids in 2020.[1] Although individual prescriptions are inexpensive, the volume means corticosteroids are one of the 20 highest prescription costs in the UK.[2] Patients prescribed corticosteroids comprise those:

- Deficient in corticosteroids who require replacement (e.g. primary pituitary or adrenal insufficiency)

- Taking therapeutic corticosteroids for a range of inflammatory conditions (e.g. asthma, autoimmune diseases)

This audit is concerned only with those taking therapeutic corticosteroids, who form by far the largest group. This patient group potentially present more frequently than the general population for surgery with indications related to their diagnosis (e.g. bowel resection for inflammatory bowel disease, joint replacement for inflammatory arthritis), or the consequences of corticosteroid use (e.g. bone fracture due to demineralisation, accelerated coronary artery disease etc). There are currently no data quantifying this relationship.

Administering exogenous corticosteroids can reduce production of adrenocorticotropic hormone (ACTH) from the pituitary gland due to negative feedback, which in turn can lead to the adrenal gland being unable to produce enough cortisol in response to stressful stimuli such as surgery. Without adequate corticosteroid supplementation, such patients may develop potentially fatal circulatory failure, hypoglycaemia and other metabolic derangements. Patients on therapeutic corticosteroids are often given 'extra' corticosteroids to ensure their physiological needs are met. This action however should be taken after weighting potential benefits against the risks of administering supplementary steroids (e.g. poor wound healing, infection, hyperglycaemia and other morbidity). Our previous work shows that the dose of peri-operative corticosteroid supplementation in current guidelines, is 10x the 'normal' daily production of cortisol on the day of major surgery.[3-4]

In 2012, the Association of Anaesthetists of Great Britain and Ireland (AAGBI), the Society for Endocrinology UK (SfE), the Royal College of Anaesthetists (RCoA) and the Royal College of Physicians (RCP) received a 'Report to Prevent Future Deaths' from HM Coroner expressing concern about care standards for patients with potential adrenal insufficiency undergoing surgery.

The Coroner's notification led to the first national consensus guidelines generated by the joint Royal Colleges.[3] Literature reviews to inform this guidance highlighted a paucity of evidence about which patients taking therapeutic corticosteroids need supplementation around the time of surgery, and how much steroid they should take, if any. This is echoed in the United States, as well as by the Cochrane Collaboration.[5-6] Studies were mechanistic and not powered for robust, clinical endpoints. To gain further information about potential supplementation regimens, we performed an RCoA sponsored survey of >1200 UK anaesthetists shortly after publication of the guidance, which showed no consensus regarding whether patients needed supplementation and if so, which patients and at what dose, frequency and duration.[7] The aim is therefore to audit compliance with the guidelines on an individual basis and use the data gained to inform the design of an RCT that seeks to evaluate the impact of steroid supplementation on clinical outcomes.

2. Aims and scope

Audit objectives

The objectives of this audit are to assess compliance with national clinical guidance governing supplementary steroid use, and estimate the prevalence of patients receiving therapeutic glucocorticoids who present for procedures.

Primary objective

To assess compliance with current glucocorticoid supplementation consensus guidelines.

Secondary objectives

We will also be able to describe patient demographics, indication for glucocorticoid therapy, prescribed dose (to include medication, dose, duration, route, and frequency), planned operation, peri-operative supplementation practices, and the number of patients presenting for procedures who are taking therapeutic glucocorticoids.

3. The PREdS Audit – Multi-centre steroid supplementation evaluation

3.1 Audit design

This is a prospective audit of practise. It will collect data on the number of patients presenting for both planned and unplanned procedures receiving any dose of oral steroids, for any duration, with or without a diagnosis of adrenal insufficiency. Data will be eligible to be collected over a window of two months, with fourteen days of consecutive data recorded, at the discretion of the enrolled Trust.

3.2 Eligibility

All patients under the care of an anaesthetist (including those performed under general anaesthesia, regional anaesthesia, and/or sedation with monitoring), ≥18 years of age, presenting for elective, urgent or emergency procedures performed by any medical or surgical specialty at each centre will be eligible to be included in the audit.

3.3 Identification of procedures

Patients will be identified at each centre by the local team, utilising local systems for theatre list scheduling.

3.4 Projected numbers

We aim to recruit as many NHS Trusts (centres) as possible by utilising Anaesthesia Trainee Research Networks (TRN). Within the Severn Trainee Anaesthetic Research (STAR) Network, seven NHS Trusts will be enrolled in this prospective audit. On average each NHS Trust in the UK performs 1000 operations per week, therefore providing a large population for data collection.[8] Each centre is expected to identify all eligible patients and collect contemporaneous data.

3.5 Data Synthesis

The primary measure of this audit will be whether eligible patients undergoing anaesthesia receive appropriate glucocorticoid therapy(s) in compliance with AAGBI guidelines, defined as those taking therapeutic glucocorticoids for >28 days in the 3 months preceding surgery. The primary output of this audit will be the aggregate number of such patients (and the proportion of the total number audited).

The secondary data measures will include:

1. Details of patients': Age, gender, BMI, ASA and NHS Number

2. Details of patients' diagnoses: Known primary adrenal or pituitary insufficiency, any diagnoses requiring therapeutic steroid therapy, current prescribed steroid regime (including medication, dose, duration, route and frequency).

3. Details of patients' procedures: Procedure performed, elective, urgent or emergency

4. Details of peri-operative steroid supplementation

3.6 Additional guideline sharing

Local leads will be encouraged to submit any peri-operative steroid supplementation guidelines that may be in use by the centre that differ from current national consensus guidance. Assessment of peri-operative supplementation will however be measured against the national guidelines.

3.7 Data collection

All investigators will be required to comply with the requirements of the Data Protection Act 2018 regarding the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Data will be entered by either the clinician delivering care, or local investigators, into Case Report Forms (CRF) on a REDCap database (https://redcap.link/PREDS). This database will be held upon a secure server at University Hospitals Bristol and Weston (UHBW) and be compliant with standards for collection of sensitive data, thus allowing the collection of patient identifiable information in the form of an NHS number.

In addition to the CRF, Hospital Episode Statistics (HES) for each patient will be requested from the respective Business Intelligence Unit (BIU) for each enrolled Trust, identified by use of collected NHS number. This will provide additional demographic information (e.g. gender, ethnicity) plus further information relating to their admission (e.g. length of stay, geographical distribution). This data will facilitate further descriptive analysis of patient demographics, diagnoses and procedures carried out.

3.8 Audit management

The audit will be co-ordinated by anaesthetic trainees who are part of the Severn Trainee Anaesthetic Research Collaborative (STAR; https://www.anaesthesiaresearch.org/), with support from the PREdS Chief Investigator and the UHBW Research & Development Centre.

Data will be collected principally by Junior Doctors and Consultants. Local data will be returned to each hospital for audit purposes.

3.9 Data analysis

Descriptive statistics will be produced. Qualitative assessment of guideline use will be undertaken should numbers allow.

3.10 Patient and public involvement

Patient and public involvement (PPI) is not strictly necessary for audits of practice. The wider package of work however, of which this audit is part, was discussed at the Bristol Musculo-skeletal

PPI group where many patients had previously taken corticosteroids, or were taking them at the time of surgery. They were supportive of the work in general and understood the rationale challenging perceived wisdom.

3.11 Ethical Considerations

The NHS Health Research Authority Defining Research and Ethics tool (http://www.hra-decisiontools.org.uk/research/) confirms this initial data collection is not defined as research, and therefore does not require Research Ethics Committee Approval. No direct patient contact, nor changes to their care, will occur as part of this study and therefore patient consent is not required. Approval from the Caldicott Guardian at the lead site (UHBW), and audit registration at all enrolled centres will be required prior to commencing the project. The Principal Investigator at each site will be trained with protocol details via virtual seminars prior to recruitment commencing, and are expected to disseminate this information amongst local investigators.

3.12 Financing and insurance

We do not anticipate any additional funding requirements for this audit. All investigators shall be present NHS employees covered by their respective Trust indemnity insurance.

3.13 Dissemination and authorship

It is anticipated that this audit and subsequent data analysis will inform the study design of an NIHR grant application for a randomised-controlled trial. It is anticipated the results of this audit will be presented at national/international meetings and published in a peer reviewed journal. Recognition of contribution for authorship will apply to local Principal Investigators and their team where at least 50 CRF are contributed to the study.

4. Study guide and timeframes for collaboratives and centres

June 2022

- STAR
    - Formally invite all TRNs to participate
    - Distribution of protocol, educational materials, advertising information, and CRF guidance

July 2022

- TRN
    - To formally accept invitation to participate in audit
    - Leads to identify an audit lead within each network

- Audit lead to publicise protocol and recruit centres
- Local principal investigator (PI) to be identified at each centre

August 2022

- STAR
  - Organisation of educational webinars and opportunity to answer Q&As
  - Publication of FAQ
  - Protocol revisions (if needed)
- Centre level
  - Local PI to identify team at their centre
  - Local hospital audit department approval must be sought and confirmation of this returned to relevant TRN lead (See Appendix A for example)

September 2022

- TRN
  - TRNs to liaise with local centres and confirm window for data collection
- STAR
  - Repeat educational webinars as necessary

October-November 2022 (Data Collection Window; anytime from 26th September – 4th December)

- Centre level
  - Local lead to identify eligible patients for data collection
  - Local lead to ensure data on all operations performed during audit period is collected and returned via the electronic data collection tool. This will be done by publicising the audit (e.g. via posters, electronic communications, noticeboards, departmental meetings etc) with an anticipation that most data entry will be completed by the responsible anaesthetist.
- STAR/TRN
  - Available for queries, guidance and support throughout

February 2023

- PREdS Study Group
  - Release of provisional data analysis

5. References

1. NHS Business Services Authority. Prescription Cost Analysis – England 2020/21. 2021; https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-202021 (accessed 08/11/2021)
2. Library HoC. Medicine Statistics. In: Library HoC, ed. London, 2015
3. Woodcock T, Barker P, Daniel S et al. Guidelines for the management of glucocorticoids during the peri-operative period for patients with adrenal insufficiency. *Anaesthesia* 2020; **75**: 654-63

4. Gibbison B, Spiga F, Walker JJ et al. Dynamic pituitary-adrenal interactions in response to cardiac surgery. *Critical care medicine* 2015; **43**: 791-800.
5. Liu MM, Reidy AB, Saatee S, Collard CD. Perioperative steroid management: approaches based on current evidence. *Anesthesiology* 2017; **127**: 166-72.
6. Yong SL, Maria, P, Esposito M, Coulthard P. Supplemental perioperative steroids for surgical patients with adrenal insufficiency. *Cochrane Database Syst Rev* 2009: Cd005367.
7. Ramesh AV, Pufulete M, Reeves BC, Fletcher S, Tomlinson JW, Gibbison B. Peri-operative corticosteroid supplementation for patients on therapeutic glucocorticoids: a national survey. *Anaesthesia* 2020; **75**: 1396-8.
8. NHS Digital. Provisional Hospital Monthly Statistics for Admitted Patient Care, Outpatient and Accident and Emergency data April 2019 - March 2020 (M13). 2020; https://digital.nhs.uk/data-and-information/publications/statistical/hospital-episode-statistics-for-admitted-patient-care-outpatient-and-accident-and-emergency-data/april-2019---march-2020-m13 (accessed 08/11/2021)

Appendix A. Example Audit Registration Form

University Hospitals Bristol NHS
NHS Foundation Trust

ID No:
(office use only)

CLINICAL AUDIT PROJECT PLAN

All clinical audit projects should be registered before they start.

Please discuss your proposal with the appropriate Clinical Audit Facilitator. Contact details and guidance on completing this form are available via relevant workspace http://connect/governanceandquality/clinicalaudit/Pages/default.aspx

Title: see note 1
Perioperative Replacement of Exogenous Steroids

Your Details: Audit lead					
Name	Ben Gibbison	**Division**	Specialised Services		
Position/Job Title	Consultant	**Specialty**	Cardiac Anaesthesia		
Email	ben.gibbison@bristol.ac.uk	**Tel**	07931568135	**Bleep**	

Project Team: see note 2			
Name	**Job Title**	**Specialty**	**Role within Project (data collection, Supervisor etc)**
Oliver Barker	Doctor	Anaesthesia	Audit Design
Jon Barnes	Doctor	Anaesthesia	Audit Team
Inthu Kangesan	Doctor	Anaesthesia	Audit Team
Aravind Ramesh	Doctor	Anaesthesia	Audit Team

Participation details: see note 2			
What areas will this audit impact on? (e.g. another profession/specialty/Trust)	Who in this area have you discussed and agreed this audit with?		
	Name	**Job Title**	**Date Agreed**
Theatres	Joe Bloggs	Matron, Theatres	XX/XX

Background: see note 3

Corticosteroid use is common in the UK. In England alone in 2020 over 50 million corticosteroid prescriptions were dispensed, of which over 22 million were inhaled formulations, and around 8 million oral, with use rising in the last decade [1]. Clinical indications for corticosteroid can broadly be divided into two groups; those with endogenous corticosteroid deficiency who require replacement, and therapeutic corticosteroid for a range of diagnoses including inflammatory and malignant conditions, as well as after organ transplantation. Endogenous deficiency may be further classified; primary due to diseases of the adrenal gland, secondary due to reduced pituitary action, or tertiary from reduced hypothalamic release of CRH. Importantly long-term exogenous steroids can result in iatrogenic tertiary adrenal insufficiency in people with previously normal function, and ultimately adrenal atrophy over time. Any patient prescribed equivalent oral daily doses of prednisolone greater than 5mg in adults, or 10-15mg/m^2 in children, when administered for greater than 1 month, may result in tertiary insufficiency [2,3]. When assessed by a short synacthen test, up to a third of patients receiving glucocorticoid therapy can show evidence of adrenal insufficiency when well, but whether this translates into clinical changes is not known [4].

Physiological stresses such as surgery or acute illness induce the hypothalamic-pituitary-adrenal(HPA) axis and daily cortisol production may quadruple in major surgery, with levels typically returning to normal at 24-48 hours [5]. Insufficient production may precipitate metabolic derangements, hypoglycaemia and ultimately life threatening circulatory failure termed an adrenal crisis, mitigated clinically by the concept of supplementary corticosteroids. In theory, a significant proportion of those receiving therapeutic glucocorticoids are at risk of this, and therefore recent consensus guidelines published in the UK by a collaborative of the Association of Anaesthetists, the Society for Endocrinology and the Royal College of Physicians advise additional supplementation for both patient groups in the peri-operative period [6]. The authors acknowledge the paucity of evidence for supplementation in the therapeutic patient group, and the guidelines specifically highlight the need for high-quality studies to inform future guidance. Glucocorticoids have a plethora of side effects including poor wound healing, susceptibility to infections and hyperglycaemia; unnecessary doses peri-operatively may increase the risk of potentially avoidable complications [6].

A survey on behalf of the RCOA in 2019 demonstrated, prior to the present consensus statement, significant heterogeneity in UK anaesthetic practice [7]. This included the dose threshold of routinely prescribed glucocorticoids that triggered supplementation, nature of surgical procedure, and the actual supplementary dose to prescribe. Importantly the majority of respondents would not administer supplementation in those receiving topical or inhaled glucocorticoids, and had an oral dose threshold of 10mg prednisolone, a clear discrepancy from the latest guidelines.

There is no question that those who are glucocorticoid deficient need an increased dose in the peri-operative period. There remains substantial uncertainties however for those patients receiving therapeutic glucocorticoids, including exactly who should receive supplemental dosing, as well as the most appropriate dose and timing. Understanding the number of patients on therapeutic glucocorticoids presenting for surgery who are at risk of adrenal insufficiency, and the true peri-operative consequences, is clearly desirable. Prior to the COVID-19 pandemic greater than 12 million operations were performed in England alone per year, and therefore this presents a potentially very large cohort of patients requiring peri-operative steroid supplementation [8].

1. NHS Business Services Authority. Prescription Cost Analysis – England 2020/21. 2021; https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-202021 (accessed 08/11/2021)
2. Woods CP, Argese N, Chapman M, *et al.* Adrenal suppression in patients taking inhaled glucocorticoids is highly prevalent and management can be guided by morning cortisol. *European Journal of Endocrinology* 2015; **173**(5): 633-642
3. Husebye ES,Allolio B,Arlt W, *et al.* Consensus statement on the diagnosis, treatment and follow-up of patients with primary adrenal insufficiency. *Journal of Internal Medicine* 2014; **275**: 104–15.
4. Bancos I, Hahner S, Tomlinson J, Arlt W. Diagnosis and management of adrenal insufficiency. *Lancet Diabetes and Endocrinology* **2015**; 3: 216–26.
5. Prete A, Yan Q, Al-Tarrah K, *et al.* The cortisol stress response induced by surgery: A systematic review and meta-analysis. *Clinical Endocrinology* 2018; **89**: 554–67.
6. Woodcock T, Barker P, Daniel S *et al.* Guidelines for the management of glucocorticoids during the peri-operative period for patients with adrenal insufficiency. *Anaesthesia* 2020; **75**(5): 654-663
7. Ramesh AV, Pufulete M, Reeves BC, *et al.* Peri-operative corticosteroid supplementation for patients on therapeutic glucocorticoids: a national survey. *Anaesthesia* 2020; **75**: 1394-1397
8. NHS Digital. Provisional Hospital Monthly Statistics for Admitted Patient Care, Outpatient and Accident and Emergency data April 2019 - March 2020 (M13). 2020; https://digital.nhs.uk/data-and-information/publications/statistical/hospital-episode-statistics-for-admitted-patient-care-outpatient-and-accident-and-emergency-data/april-2019---march-2020-m13 (accessed 08/11/2021)

Aim: see note 4
The objectives of this audit are to assess compliance with national clinical guidance governing supplementary steroid use, and estimate the prevalence of patients receiving therapeutic glucocorticoids who present for procedures.
Objectives: see note 4. You may find it is unnecessary to use the "Objectives" section i.e. "**Aim**" and "**Criteria**" may cover all the essential information.

Primary objective

To assess compliance with current glucocorticoid supplementation consensus guidelines.

Secondary objectives

We will also be able to describe patient demographics, indication for glucocorticoid therapy, prescribed dose (to include medication, dose, duration, route, and frequency), planned operation, peri-operative supplementation practices, and the number of patients presenting for procedures who are taking therapeutic glucocorticoids.

STANDARDS

List standards as per example in first row. Be sure data you plan to collect will measure performance against listed standards.

Provide full information on source of standards – Title, website reference etc.

	Criteria	Target (%)	Exceptions	Source & Strength* of Evidence		Instructions for where to find data
E.G.	*At initial assessment urinary incontinence should be categorised as stress/mixed/urge*	*100%*		*NICE Guideline-CG 40* *http://guidance.nice.org.uk/CG40*	*C*	*Medical notes*
1	Assessment of whether patients having surgery are taking exogenous corticosteroids.	100%	Patients receiving replacement corticosteroid therapy			Patients and medical notes

2	Assessment of whether patients on therapeutic corticosteroids are supplemented in the peri-operative periods.	100%		AAGBI Guidance http://dx.doi.org/10.1111/anae.14963	C	Anaesthetic record, patient drug chart and medical notes

***Strength of Evidence**

A At least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation
B Availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation
C Expert committee reports or opinions and/or clinical experience of respected authorities. Absence of directly applicable clinical studies of good quality
D Recommended good practice based on clinical experience (local consensus)

Data Collection Methodology (see note 5)	
Prospective data collection with Clinician-led data entry into a secure REDCap database.	
Further details or other method	UHBW R&D REDCap database with support from Mai Baquedano. REDCap database link: https://redcap.link/PREDS
Please give details of how this has been/will be piloted:	Test database created and pilot data collection by organisers of the audit.
▪ **You must include your data collection form/spreadsheet with this proposed Audit Plan.** ▪ **Be sure the data items you're collecting match the standards set**	

Audit Sample: see note 6	
Sample selection criteria	All patients under the care of an anaesthetist (including general anaesthesia, regional anaesthesia, and/or sedation with monitoring), ≥18 years of age, presenting for elective, urgent or emergency operations.
Time period audited *(i.e. Oct 12- Jan 13)*	14 day period within the **October/November 2022 (26/9/22 – 4/12/22)**
Estimated number of cases	>100
Who will provide list of patient (NB – need appropriate hospital / NHS numbers)	Theatre co-ordinators at respective site will provide elective theatre lists for the duration of the audit. Emergency/unscheduled patients will be identified by the local team.
If you are requesting notes through the CA team, where would you like them delivered	N/A

Timescale/Deadlines: see note 6	
Proposed start of data collection	01/09/2022
Proposed date for presentation of results	January 2023
Forum	Divisional audit meeting, national/international meetings, peer-reviewed journal
Proposed finish date *i.e. after report and action plan produced*	Spring 2023

Will you be leaving your current post in the near future?	No
If Yes, please give leaving date	
If your project will not be finished by then, please identify and provide the name and job title of another member of staff who is willing to take over when you go	
Are there any other deadlines you need to take into consideration?	No

You need an appropriate senior clinician / manager to support the project. List below. Helpful to discuss with clinical audit team before seeking approval from senior colleague.

Project Lead: I agree to ensure that this project is completed, the results disseminated, and a report given to my clinical audit facilitator. I understand that non-anonymised (staff/patient) audit data must not be taken outside the Trust. I understand that audit results belong to the Trust and that the project report may be made available to anyone who requests it.

Ben Gibbison	31.11.2021
Project Lead	Date

Senior Clinician / Manager: I confirm that this project has been agreed as part of the Specialty audit programme and that I will give my full support to it. I will ensure the dissemination of audit results and lead on the development and implementation of an action plan (if necessary) in order to obtain improvements in the quality of care provided.

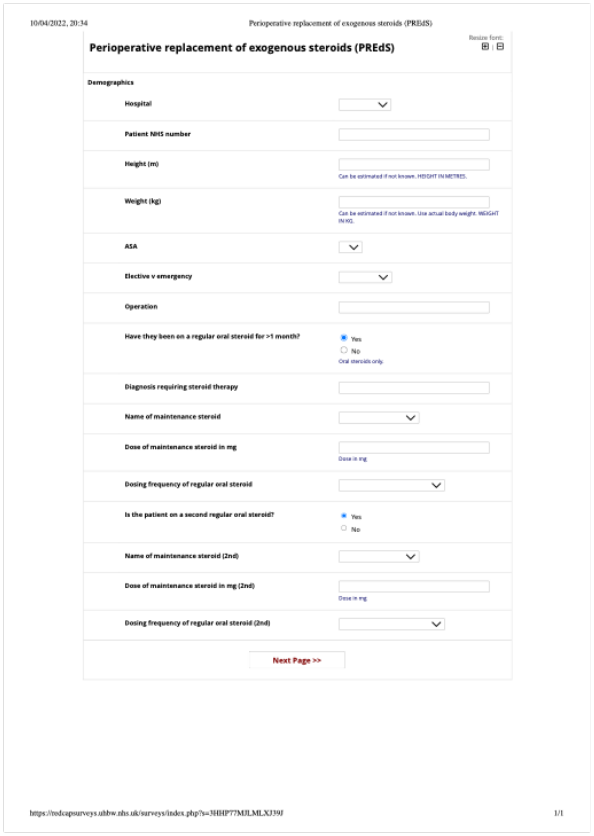
Ben Gibbison	31.11.2021
Senior Clinician/Manager	Date

Clinical Audit Convenor: I approve the project described above and confirm that it has been appropriately reviewed for methodological quality, resource implication and importance to the Trust.

Clinical Audit Convenor Date

- Once you have completed this form, please email it to the relevant Clinical Audit Facilitator, copying in your Senior Clinician / Manager
- If this project is approved, the information on this form will be entered onto the Clinical Audit Project Management database.
- You will be asked to complete a final report and action plan once the results of your audit are known. Detail of these will also be entered on the database.

Appendix B. Example Case Report Form



10/04/2022, 20:34 Perioperative replacement of exogenous steroids (PREdS)

Perioperative replacement of exogenous steroids (PREdS)

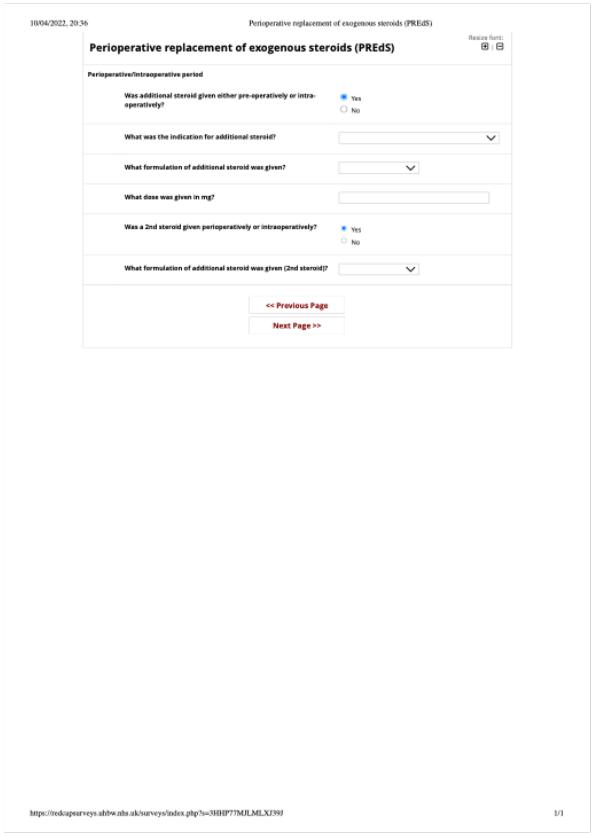
Resize font:

Demographics

- Hospital
- Patient NHS number
- Height (m) — Can be estimated if not known. HEIGHT IN METRES.
- Weight (kg) — Can be estimated if not known. Use actual body weight. WEIGHT IN KG.
- ASA
- Elective v emergency
- Operation
- Have they been on a regular oral steroid for >1 month? — Yes / No — Oral steroids only.
- Diagnosis requiring steroid therapy
- Name of maintenance steroid
- Dose of maintenance steroid in mg — Dose in mg.
- Dosing frequency of regular oral steroid
- Is the patient on a second regular oral steroid? — Yes / No
- Name of maintenance steroid (2nd)
- Dose of maintenance steroid in mg (2nd) — Dose in mg.
- Dosing frequency of regular oral steroid (2nd)

Next Page >>

https://redcapsurveys.uhbw.nhs.uk/surveys/index.php?s=3HHP77MJLMLXJ39J 1/1



10/04/2022, 20:36 Perioperative replacement of exogenous steroids (PREdS)

Perioperative replacement of exogenous steroids (PREdS)

Resize font:

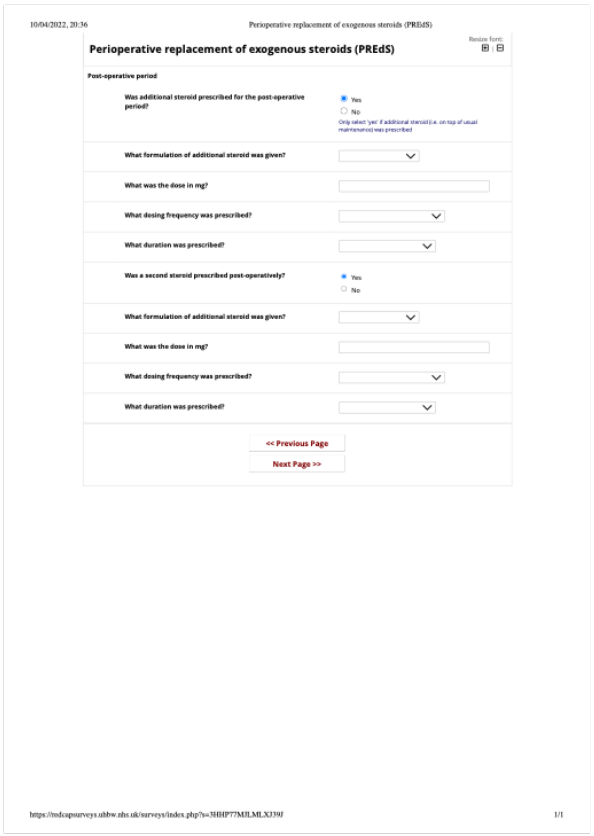
Perioperative/intraoperative period

- Was additional steroid given either pre-operatively or intra-operatively? — Yes / No
- What was the indication for additional steroid?
- What formulation of additional steroid was given?
- What dose was given in mg?
- Was a 2nd steroid given perioperatively or intraoperatively? — Yes / No
- What formulation of additional steroid was given (2nd steroid)?

<< Previous Page

Next Page >>

https://redcapsurveys.uhbw.nhs.uk/surveys/index.php?s=3HHP77MJLMLXJ39J 1/1



10/04/2022, 20:36 Perioperative replacement of exogenous steroids (PREdS)

Perioperative replacement of exogenous steroids (PREdS)

Resize font:

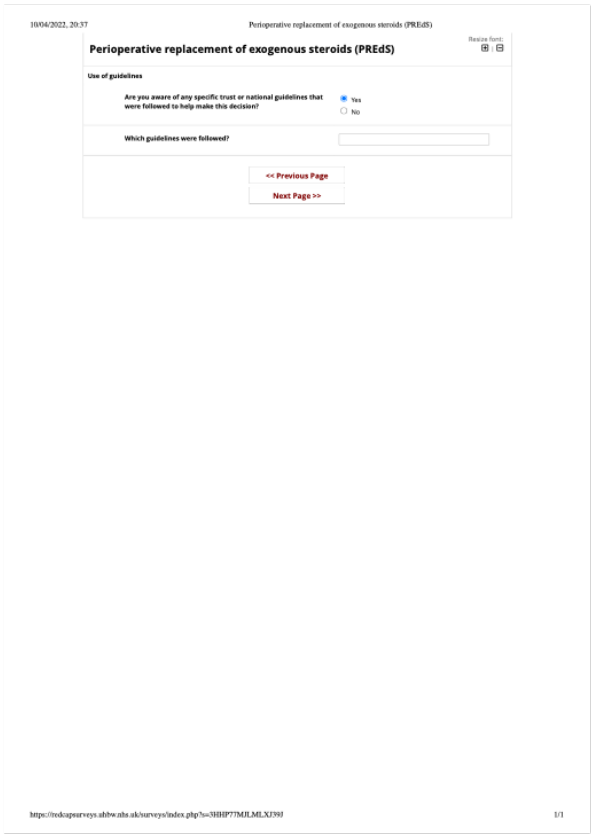
Post-operative period

- Was additional steroid prescribed for the post-operative period? — Yes / No — Only select 'yes' if additional steroid (i.e. on top of usual maintenance) was prescribed
- What formulation of additional steroid was given?
- What was the dose in mg?
- What dosing frequency was prescribed?
- What duration was prescribed?
- Was a second steroid prescribed post-operatively? — Yes / No
- What formulation of additional steroid was given?
- What was the dose in mg?
- What dosing frequency was prescribed?
- What duration was prescribed?

<< Previous Page

Next Page >>

https://redcapsurveys.uhbw.nhs.uk/surveys/index.php?s=3HHP77MJLMLXJ39J 1/1



10/04/2022, 20:37 Perioperative replacement of exogenous steroids (PREdS)

Perioperative replacement of exogenous steroids (PREdS)

Resize font:

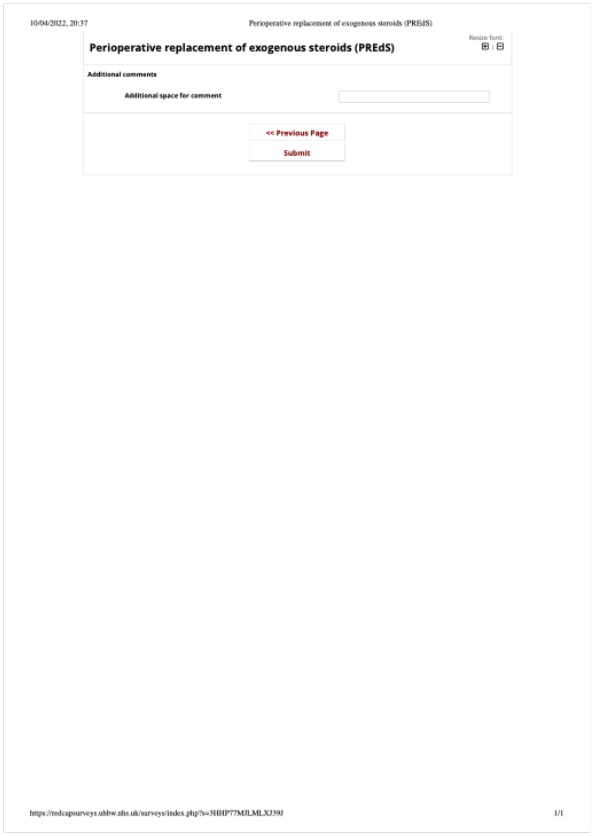
Use of guidelines

- Are you aware of any specific trust or national guidelines that were followed to help make this decision? — Yes / No
- Which guidelines were followed?

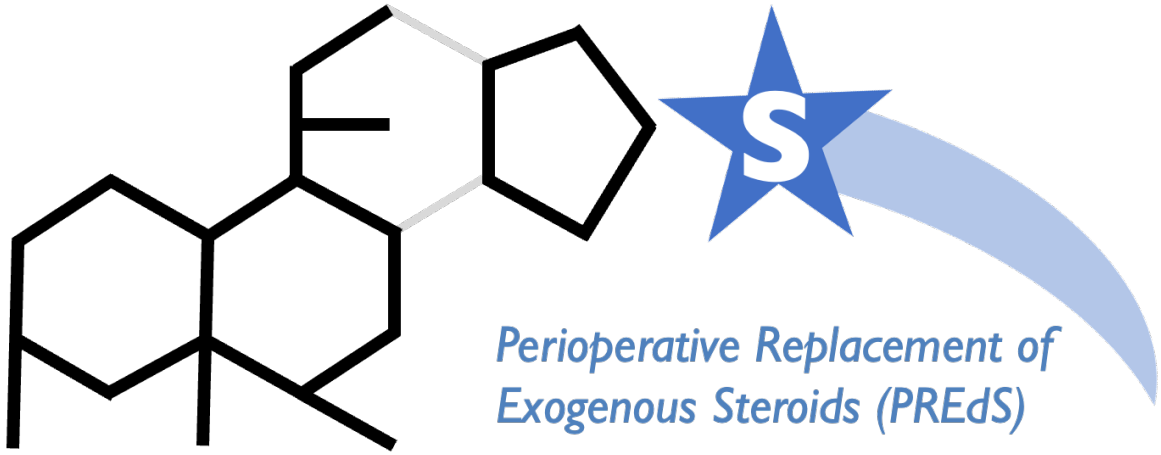
<< Previous Page

Next Page >>

https://redcapsurveys.uhbw.nhs.uk/surveys/index.php?s=3HHP77MJLMLXJ39J 1/1


10/04/2022, 20:37
Perioperative replacement of exogenous steroids (PREdS)
Perioperative replacement of exogenous steroids (PREdS)
Resize font:
Additional comments
Additional space for comment
<< Previous Page
Submit
https://redcapsurveys.uhbw.nhs.uk/surveys/index.php?s=3HHP77MJLMLX239J
1/1

Appendix C. Site Data Capture Form



PREdS Audit - Site Data Capture Form

Site Name:

Trust:

Consultant Lead Investigator:

Name:

Email:

Trainee Lead Investigator:

Name:

Email:

Selected Audit Dates:

Investigators List:

(Continue on additional sheets as necessary)

Name:
Email:
Role:

Appendix D. Protocol Revision History

Status	Version	Date	Contributors	Change Log
	1.0	17/01/2022	Dr Oliver Barker Dr Jonathan Barnes Dr Aravind Ramesh Dr Inthu Kangesan Dr Ben Gibbison Professor Barney Reeves	Pending Final Approval
	1.1	13/04/2022	Dr Oliver Barker Dr Jonathan Barnes Dr Aravind Ramesh Dr Inthu Kangesan Dr Ben Gibbon Professor Barney Reeves	1. Amendments to 3.7, 3.9, 3.10, 3.11 regarding data collection, ethical considerations, and financing. 2. Addition of Appendix B, C, D
	2.0	14/04/2022	Dr Oliver Barker Dr Jonathan Barnes Dr Aravind Ramesh Dr Inthu Kangesan Dr Ben Gibbon Professor Barney Reeves	1. Amendments to formatting and grammatical changes 2. Refined 2.0 aims and scope 3. Updated objectives language in 3.5
Current	3.0	23/05/2022	Dr Oliver Barker Dr Jonathan Barnes Dr Aravind Ramesh Dr Inthu Kangesan Dr Ben Gibbon Professor Barney Reeves	1. Grammatical and formatting adjustments throughout 2. Revision of 2.0 and removal duplicated objectives (previously 3.5) 3. Addition of abstract 4. Addition of 3.10 PPI 5. Updated 4.0