

Clinical Governance Registration Template

The structural and organisational impacts of perioperative enhanced care services in the UK:
A Retrospective Evaluation of Post-operative Alternatives to Critical Care (REPACC)

What is the project title?

The structural and organisational impacts of perioperative enhanced care services in the UK: A Retrospective Evaluation of Post-operative Alternatives to Critical Care (REPACC)

What type of project is this?

This project will form part of a national research project of enhanced perioperative care services in the UK.

What is the estimated start date?

Please submit your date of submission to the clinical governance team in answer to this question.

What is the estimated completion date?

It would be reasonable to set a date 4 months away to allow extra time for any clarifications, should they be necessary, once the data is submitted. This is likely far more time than will be required to complete the project at your site.

Which service or care group will lead this project?

Anaesthetics and critical care.

What is the scientific justification for this project and what standards are being measured against?

Delivery of post-operative critical care for high-risk surgical patients represents a significant challenge within the NHS due in part to high bed occupancy rates [1]. Rates of on-the-day cancellation of elective procedures, and deferral of treatment until outside of the recommended 28-day window post-cancellation, due to absence of an appropriate post-operative destination are high, at a time when surgical waiting list pressures are at unprecedented levels [2-3]. Accounting for inevitable circumstantial variability, all NHS Trusts are expected to adhere to the standard of minimising the number of cancelled operations, and if operations are cancelled, to provide a binding alternative date [4].

The requirement for a post-operative critical care bed is independently predictive of on-the-day cancellation of elective surgery in the UK [5]. In order to reduce unnecessary cancellation, and relieve pressure on critical care beds, new models of care such as Post-Anaesthetic Care (PACU) and Overnight Intensive Recovery (OIR) units have evolved [6-7].

The faculty of intensive care medicine has advocated for funding of these facilities, collating an evidence base comprised of a heterogeneous sample of facilities whose introduction have led, in single centre cohorts, to improvements in organisational efficiency and certain clinical outcomes [8-9]. In 2015, approximately 55% of surveyed organisations in the UK had some form of intermediate enhanced care facility, such as PACU or OIR, for the care of high-risk post-operative patients [10]. These were predominantly anaesthetist led, caring for a median of 4 patients, with just less than 30% of institutions having ring-fenced bedspaces for this purpose.

Whilst intuitively these models of care stand to improve organisational efficiency, there is speculation that reduced clinical and risk score thresholds for admission to these intermediate units may serve to increase the likelihood of on-the-day cancellation if these services are over-burdened. The finding that institutions with an operational PACU or OIR demonstrate significantly higher rates of on-the-day cancellation adds weight to this concern [5].

Presently, there are no resources that describe the current status of enhanced care services operational within the UK. Furthermore, whilst these models of care are increasingly prevalent [6], there is a paucity of literature addressing the organisational impacts of their introduction, or indeed which models of care are most effective in reducing systemic pressure.

What are the aims & objectives of this project?

The data collection at this site will contribute to a national research project. The objectives of this evaluation are:

1. To describe the current models of enhanced care operational within the UK.
2. To identify the structural and organisational factors associated with rate of on-the-day cancellation due to lack of an enhanced care bed space.
3. To evaluate the effect of different models of enhanced care on wider measures of organisational efficiency.

What is the proposed methodology of this project?

This project has two main components:

1. A retrospective analysis of on-the-day cancellation rates, and several other measures of organisational efficiency, in patients referred to enhanced care facilities for post-operative care between 01/09/23 and 30/11/23.
2. A qualitative appraisal of the structure of enhanced care services at participating centres.

Our site has been sent a survey that will describe the structure of enhanced care at our institution. Our team will also collect data, from routine documentation covering a 3 month period, to quantify the total number of surgeries of different types (emergency, elective etc.) performed per day, the number of on-the-day surgical cancellations, and referrals & admissions to each level of care including enhanced care (PACU/OIR, level 1), high dependency care (HDU, level 2), and intensive care (ICU, level 3).

To further understand the patient journey, we will also follow up on what happens to each person who was referred to levels 1-3 care for post-operative management. We will collect information regarding their referral to enhanced care, their procedure, details of any cancellations that occur, and changes in planned post-operative destination. We will also collect basic demographic information (age, gender and ethnicity) and details of their past medical history. The cohort we follow up will be exclusively made up of adults undergoing elective surgery.

The protocol for this project has been distributed via regional trainee research networks. Regional leads have commissioned for volunteers to run the data collection process at each hospital. All team members at this site are clinicians that form part of the direct care team. Once data from our site is collected, we will submit strictly anonymised data to the lead site for analysis. Data from our institution will be compared to other hospitals, working from the null hypothesis that similar sized hospitals will perform similarly in the measures of organisational efficiency that we record. The results of this

analysis will be published in an academic journal and may be presented at relevant conferences.

The lead site analyse the data by comparing hospitals of similar size to each other on the parameters that we collect. For example, they will compare on-the-day cancellation rates in each participating centre after adjusting for how busy the hospital is, it's size, and the number of critical care beds available. The team are interested to see if there are any differences in these measures of efficiency when different models of enhanced care employed, such as those that rely on on-the day referral rather than admissions that are scheduled following surgical pre-assessment clinic.

How will potential participants be identified?

Local systems of referral to these units such as physical diaries, secure email inboxes, electronic health record data, and bespoke databases will be searched to identify the cohort of patients referred to each area. In addition, the hospital numbers of patients undergoing surgery, who had a procedure cancelled, or those that were admitted to levels 1-3 of care will be sought from the clinical informatics team. This will be used to quantify the number of patients per day that experienced said outcome, as well as cross-reference with the referrals to each unit in order to identify those that were referred verbally. Members of the direct care team will therefore use routine hospital documentation, linked to the hospital numbers provided, to identify participants that fit into each category.

How will data be recorded?

Hospital IDs will be recorded in two case report forms. Firstly, a case report form in the format of a time-series of operations, cancellations and critical care referrals/admissions will be created as described previously. In order for the direct care team to appraise the notes of each service user identified hospital numbers will be retained at this stage. Once referrals to levels 1-3 care have been identified the hospital numbers will be entered into a second case report form of per-patient data. Here, basic demographic information (age, gender and ethnicity) will be recorded alongside clinical pathways information concerning each patient's index admission. Once again, in order to collect data - such as reason for enhanced care referral - hospital numbers will be retained by the direct care team. No personally identifiable information will be recorded beyond basic demographics and hospital numbers. These will all be stored on encrypted flash drives as specified in the protocol which can be made available on request.

The case report forms automatically anonymise hospital numbers in separate sheets. Only anonymised data will be submitted to the lead site. Information linking study to hospital IDs will be retained by the our team should clarification or amendments be

necessary. Anonymised data will be collated and analysed in the UK only. This will be performed by the lead site, Kingston Hospital.

We will delete data linking study and hospital IDs after publication of the findings of the project. Anonymised data will be retained for 10 years post-publication to permit scrutiny of our findings. These data will be stored on 256-bit encrypted, password-protected USB Flash Drives and will only be accessible to members of the lead site unless further permissions are obtained to permit post-hoc analyses. Documentation providing the link between study and hospital IDs will not be shared outside of the direct care team.

How will data be stored, shared and archived?

All documents will be stored on 256-bit encrypted, password-protected USB Flash Drives. Several encrypted copies of the documents will be created in order to provide a back-up in the eventuality of loss of this data (e.g. to inadvertent destruction of the USB Flash Drive). Data will only be made available to the sponsor for monitoring purposes.

Data, all of which will be anonymised prior to transfer between local investigators and the lead site, will only be transferred electronically between NHS.net e-mail accounts, all of which are password protected and require multi-factor authentication. Data will only be transferred directly between local teams of investigators and the lead site with no intermediate. Archiving arrangements will include the secure storage of flash drives containing study documentation by our team. No external database or additional archiving systems will be utilised. Documents will be kept for 10 years post-publication, after which they will be destroyed.

Will patients be contacted about their involvement?

No. The proposed use of this data is not considered sufficiently intrusive nor representative of sufficient risk to participants to justify making contact, or seeking consent.

What support do you require from the clinical governance team?

Registration of project only.

Will be shared outside the Trust? Will it be anonymised?

Data generated during this the conduct of this project will contribute to a wider national research project. Data will therefore have to be shared outside of the Trust. Potentially sensitive information that will be collected includes generic demographic information (age, gender and ethnicity) and hospital identification numbers for each participant identified. This will all be collected by members of the direct care team, all of which will have access to this data on a routine basis, and recorded in case report forms that will be stored on 256-byt encrypted, password-protected USB Flash Drives. Hospital numbers will be automatically anonymised by the case report forms by code written directly into the files, thus anonymising the data, before sharing with the lead site. Only anonymised data will be received outside of the context it is already stored at our site.

How will the results of this project be presented?

The results of this project will be published in an academic journal and may be presented at relevant conferences. Publication and presentation of this data will include only summary statistics and comparative analyses, no individual patient data will be made available. Our team may contribute this data to quality improvement and audit work to improve local services. As a part of this process, we may present this at departmental or trust-wide governance meetings.

References

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- [10] Appendix 1: Enhanced Care Guidance – Methodology. Provision of Enhanced Care Services in the Acute Hospital Setting. Faculty of Intensive Care Medicine (2020). https://www.ficm.ac.uk/sites/ficm/files/documents/2021-10/enhanced_care_guidance_appendices_-_methodology_survey_summary_data.pdf - accessed 26/08/23