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REspiratory COmplications after abdomiNal Surgery (RECON): Study protocol for a multi-centre, observational, prospective, international audit of postoperative pulmonary complications following major abdominal surgery

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Introduction

Postoperative pulmonary complications (PPCs) are common following major abdominal surgery, with an estimated incidence of between 9% and 40%[1]. The Standardized Endpoints for Perioperative Medicine: Core Outcome Measures in Perioperative and Anaesthetic Care (StEP-COMPAC) definition of PPCs includes atelectasis, pneumonia, pulmonary aspiration and acute respiratory distress syndrome (ARDS)[1]. Pulmonary complications impact both short- and long-term survival after surgery, and have been recognised as a priority topic in perioperative care research[2].

The Royal College of Anaesthetists (RCOA) Guidelines for the Provision of Anaesthesia Services (GPAS) and Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines provide several recommendations to reduce risk in the pre-, intra- and postoperative periods[3,4]. Enhanced Recovery After Surgery (ERAS) protocols also exist, with a view to minimising postoperative infective complications[5].

The primary aim of the REspiratory COmplications after abdomiNal Surgery (RECON) audit is to describe variability in adherence to risk reduction strategies for PPCs following major abdominal surgery. The secondary aims are to characterise the incidence of PPCs across operation types, validate existing clinical risk scores, and assess the clinical impact of pulmonary complications.

Methods

Study design

Student Audit and Research in Surgery (STARSurg) is a student-led, national research collaborative that empowers medical students and junior doctors to conduct high-quality, protocol-driven audit and research[6]. RECON is a prospective, cross-specialty, multi-centre, international ‘snapshot’ audit that will be conducted across this network.

Centre and patient eligibility

Any centre that performs elective and/or emergency major abdominal surgery and/or anterior abdominal wall hernia repair in the UK, Ireland, and Australasia is eligible to participate. There are no centre-level volume restrictions. Data will be collected on consecutive adult patients (greater than 16 years old) undergoing emergency or elective major abdominal surgery through a transabdominal incision. This includes visceral resection (colorectal, upper gastrointestinal, hepatopancreatobilary, urological or gynaecological), reversal of stoma, open vascular surgery, and anterior abdominal wall hernia repair (incisional or parastomal), using any operative approach. Procedures performed for trauma, planned day-case procedures, and procedures without an abdominal incision (e.g. vaginal hysterectomy, transanal endoscopic microsurgery (TEMS)) are excluded.

Patients will be identified over four consecutive 2-week data collection periods in 2019. This will be conducted by "mini-teams" of 1 to 3 medical students and one junior doctor (pre-consultant/attending grade). All mini-teams will be supervised by consultants in surgery and anaesthesia or critical care. All included patients will be followed up to 30 postoperative days using routinely collected Electronic Health Records; no changes will be made to existing follow-up pathways.

Outcome measures

The primary outcome measure will be adherence to selected RCOA, AAGBI, and ERAS guidelines for prevention of PPCs, spanning the pre-, intra- and postoperative periods (Table 1). Pulmonary complications and their severity will be recorded up to postoperative day 7 and day 30, and defined according to StEP-COMPAC diagnostic criteria[1].

Data collection and governance

Data will be stored online through a secure server running the Research Electronic Data Capture (REDCap) platform (Vanderbilt University, USA) at Birmingham Surgical Trials Consortium (University of Birmingham, UK). Data will be collected on adherence to audit standards, and risk factors for pulmonary complications (using PERISCOPE[7] and

ARISOCAT[8] scores) allowing patient-level risk adjustment of outcomes and national benchmarking. Data quality will be assured through: (1) a detailed on-line study protocol; (2) mandatory online training modules (learning.starsurg.org); (3) supporting infrastructure for data collection, including supervising consultants; (4) data completeness and validation reports. Only centres with >95% data completeness will be included in analysis. No formal sample size calculation was deemed to be required. Based on recruitment data from previous audits, we project 150 centres to contribute a mean of 40 patients each (approximately 6,000 patients in total).

Ethics and dissemination

The full RECON study protocol is available as a **Supplementary File**. The study protocol will be disseminated through the STARSurg network in the UK and Ireland (www.starsurg.org) and TASMAN collaborative in Australasia (www.anzsurgsocs.org). Individual centres will be responsible for obtaining their own audit or institutional approval, or ethical approval in countries where local research ethics committees deemed it a requirement. The South East Scotland Research Ethics Service reviewed this protocol and considered the study to be exempt from formal research registration. RECON will be reported according to STROBE and SAMPL guidelines.

Discussion

The RECON audit represents a large, international, multi-centre audit of adherence to perioperative guidelines for reducing the risk of pulmonary complications after major abdominal surgery. RECON will highlight areas of practice variation and variability in outcomes and complement ongoing initiatives in perioperative care, for example the Perioperative Quality Improvement Project (PQIP) and the UK National Emergency Laparotomy audit (NELA). It will also provide contemporaneous rates of PPCs across several specialty groups, supporting sample size calculations for future randomised studies. Risk adjustment variables have been selected from existing clinical risk scores and published systematic reviews, allowing external validation of stratification tools within

a large, international cohort. By validating risk nomograms, RECON will facilitate targeted interventions reduce pulmonary complications rates towards highest risk patient groups.

RECON is the first study to incorporate the StEP-COMPAC standardised definitions of postoperative pulmonary complications. This definition includes four pulmonary complications sharing a common pathophysiological mechanism (pulmonary collapse and airway contamination)[1] and grades severity of these complications (mild, moderate, severe). RECON will validate the StEP-COMPAC definitions of disease severity and their clinical impact in abdominal surgery.

RECON will be delivered through a student collaborative network; this methodology has been validated across several international datasets demonstrating good data accuracy and case ascertainment[6]. However, there are several inherent limitations. Firstly, the complexity of data points must be balanced with pragmatic delivery alongside routine clinical practice; this limits the number of variables and standards that RECON is able to include. As the study is conducted in an eight week 'snapshot', there is a risk of seasonal bias in the estimates of pulmonary complication rates. Finally, the observational nature of this study limits causal inference between adherence to specific measures and subsequent PPCs.

RECON will play an essential role in defining targets for future international quality improvement programmes, and map uptake of evidence based perioperative practice.

Authors' contributions: The Writing / Steering Committee (KAM, RAK, WURA, MA, DMB, AB, SKK, EM, VM, RT, IY, JCG) were responsible for project conception, design, and initial drafting of the manuscript as well as project level steering, national coordination. JCG acts as overall guarantor. The Data Management Group (KAM, WURA, AB, IY) had specific responsibility to design, test, and support the data collection process via REDCap. The External Advisory Group (ME, BC, RP, AB, EMH, MJL, DN, TP, NS, RV) provided critical feedback on the design and conduct of the project. All members of the authorship group read and approved the final manuscript, offering critical feedback.

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Table 1. RECON Audit Standards

Relevant audit standards from Royal College of Anaesthetists (RCOA) and Enhanced Recovery After Surgery (ERAS) guidelines:

Pre-operative Standards:	
1. Weight and BMI should be recorded.	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Pre-operative Assessment and Preparation Recommendation 3.23:** Operating lists should include the patients' weight and body mass index (BMI).
2. Cardiopulmonary exercise testing for high-risk patients	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Pre-operative Assessment and Preparation Recommendation 5.16**: Cardiopulmonary exercise testing or functional assessment for high-risk patients should be carried out.

Intra-operative Standards:	
1. WHO Surgical Safety Checklist should be used for all procedures.	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Pre-operative Assessment and Preparation Recommendation 5.8**: The WHO's Surgical Safety Checklist should be used and is fully endorsed by the RCoA as the instrument for promoting team working and patient safety.
2. Operative long-acting NMBA should not be used routinely.	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Neuromuscular blockade (NMB) and neuromuscular monitoring**: Long-acting Neuromuscular blocking agents (NMBA) should be avoided. At the end of surgery, it is important to restore neuromuscular function to preoperative levels and avoid residual muscle paralysis.
3. Dexamethasone should be administered at induction (unless contraindicated).	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Preventing and treating postoperative nausea and vomiting (PONV)**: Dexamethasone 4–5 mg IV after induction of anaesthesia has also been shown to be effective, but its immunosuppressive effects on long-term oncological outcome are unknown. It should not be used in diabetic patients requiring insulin.
4. Patients at risk of PONV should receive at least two intraoperative antiemetic agents.	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Preventing and treating postoperative nausea and vomiting (PONV)**: Aggressive PONV prevention strategy should be included. All patients with 1 – 2 risk factors should receive a combination of two antiemetics. Patients with 3 – 4 risk factors should receive 2– 3 antiemetics.

Post-operative Standards:	
Opioid-sparing analgesic strategies should be used.	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Pain management**: Opioid-sparing analgesic strategies, including regional analgesia techniques, should be implemented in a context of a multimodal analgesic regimen.
Routine nasogastric decompression should be avoided in elective surgery	**ERAS for gastrointestinal surgery: consensus statement for anaesthesia practice** [28] • **Nasogastric (NG) intubation**: Routine nasogastric decompression following elective laparotomy should be avoided.
Early recognition of patients needing specialist postoperative input	**Royal College of Anaesthetists: Guidelines for the Provision of Anaesthesia Services 2018** • **Provision of Postoperative Care Recommendation 3.23:** Mechanisms for the early recognition of patients requiring specialist postoperative input from geriatrician-led services and/or critical care should be developed. These should include patients at risk of or presenting with delirium, multiple medical complications, functional decline or complex discharge planning.