SurgWeek-2: Identifying the global burden of postoperative complications - an international prospective cohort study protocol

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Summary

Background: Surgery is a core component of healthcare, fundamental to delivery of maternity, trauma, and cancer care. Around 313 million people undergo surgery each year. However, postoperative complications place a heavy burden on patients, communities, and health systems; an estimated 50 million adults experience postoperative complications each year. Complications can prolong hospital admissions, increase healthcare costs, result in disability, and lead to 3.5 million postoperative adult deaths each year. Despite the importance of postoperative complications, there is limited high-quality postoperative outcome data in many settings.

Aim: The aim of this international, prospective, multicentre cohort study is to assess global burden and variation of postoperative complications.

Logistics: This investigator-led study will include consecutive patients undergoing surgery across six, 7-day data collection blocks between 31 August 2026 and 11 October 2026. Any hospital that delivers surgery is eligible to participate. Mini-teams of up to three collaborators will collect data for one or multiple specialities, over one or multiple 7-day data collection blocks. To maximise the number of specialties and/or 7-day data collection blocks covered, hospitals can set-up multiple mini-teams. Hospital Leads will coordinate mini-teams at their hospital and ensure that all necessary study approvals are in place before data collection starts.

Methodology: Consecutive adult and/or paediatric patients undergoing elective or emergency surgery will be included. Any hospital worldwide may participate. 30-day follow-up data will be collected from routine hospital records. The primary outcome will be overall 30-day postoperative complications. There will be no changes made to routine patient care pathways, management, or follow-up.

Discussion: This study will provide robust, contemporary global data on the burden and variation of 30-day postoperative complications across diverse healthcare settings. The findings will inform benchmarking, guide quality improvement initiatives, and support strategies to reduce postoperative morbidity and mortality worldwide.

Introduction

Surgery is a core component of healthcare, fundamental to delivery of maternity, trauma, and cancer care. Around 313 million people undergo surgery each year.[1] However, postoperative complications place a heavy burden on patients, communities, and health systems; an estimated 50 million adults experience postoperative complications each year.[2] Complications can prolong hospital admissions, increase healthcare costs, result in disability, and lead to 3.5 million postoperative adult deaths each year.[3-5] Despite a lower risk profile and fewer complications, patients in low- and middle-income countries are twice as likely to die after surgery than patients in high-income countries.[6] Complications are not an inevitable consequence of surgery as data suggests around half of complications are avoidable.[3, 4] Proven interventions, from the WHO Surgical Safety Checklist to multidisciplinary Enhanced Recovery programmes reduce morbidity and cost, yet uptake is patchy and not monitored at scale.[7, 8]

There are emerging threats to compound the problem. Antimicrobial resistance represents a silent pandemic, with rates predicted to continue to rise to 2050; it is already associated with 4.71 million deaths a year.[9] Surgical site infections are the most frequent surgical complications; studies have shown resistant organisms isolated in over half of infected wounds in LMICs.[10] Alongside this, there is a drive for minimally invasive surgery globally, with a growing number of robotic platforms and surgical technologies. Despite the proven benefits to patients of minimally invasive surgery, access globally remains unequal.[11] Additionally, data to support the uptake of robotic surgical technologies in some surgical specialities is lacking.

To maximise the benefits of surgery it needs to be safe and effective. However, there is limited high-quality postoperative outcome data in many settings. The SurgWeek-1 study was the largest-ever prospective study in surgery and captured data on 140,231 patients (116 countries) in 2020 to explore the impact of SARS-CoV-2 on surgical outcomes.[12] Updated global baseline data is needed to explore and define postoperative complication rates in the post-COVID-19 era. Better understanding who experiences postoperative complications and the sequalae of these complications will inform initiatives to make surgery safer.

Methods

Aims

The primary aim of SurgWeek-2 is to assess the global burden and variation of postoperative complications. We will determine the frequency of postoperative complications across low-, middle- and high-income countries, further stratifying by age, sex, and surgical speciality.

The secondary aims are to assess:

- Global variation in postoperative infective complications and antimicrobial resistance.
- Global variation in postoperative mortality and underlying mechanisms
- Global variation in access to and outcomes of minimally invasive and robotic surgery.
- Global variation in the delivery and outcomes of the Bellwether procedures (laparotomy, caesarean section, open fracture surgery).

Participating in SurgWeek-2 will allow hospitals to benchmark their outcomes against national and global data. At the national level, SurgWeek-2 data will help inform priorities for advancing safe surgical care and support policymaking by surgical associations, healthcare systems, and governments. Globally, the study will identify patients at highest risk of postoperative complications and mortality, and this will inform the design of future interventional trials aiming to reduce postoperative complications and mortality. We will not publish identifiable hospital-level data.

Methodology

SurgWeek-2 will be an international, prospective, investigator-led, observational cohort study. All hospitals where surgery is performed are eligible to participate. There will be no changes made to routine patient care pathways, management, or follow-up.

Any hospital worldwide that delivers surgery is eligible to participate on the following conditions:

- They secure all necessary study approvals required by local and national regulations.
- They commit to identifying and following-up all consecutive eligible patients during their selected 7-day data collection block(s) in their selected specialities, ensuring that they achieve >95% data completeness.

Inclusion and exclusion criteria

Inclusion criteria: Any operation (elective or emergency) performed in an operating theatre is eligible for inclusion, except for minor procedures specified in Appendix A. All surgical specialties can participate including acute care surgery, breast surgery, cardiac surgery, colorectal surgery, general surgery, gynaecology, hepatobiliary surgery, neurosurgery, obstetrics, oesophagogastric surgery, ophthalmology, oral and maxillofacial surgery, orthopaedics, otolaryngology, paediatric surgery, plastic surgery, thoracic surgery, transplant surgery, trauma surgery, urology and vascular surgery. Patients undergoing both day case surgery and inpatient surgery should be included.

To ensure consecutive patients are included, mini-teams should employ the following strategies to identify patients:

- Daily review of the theatre logs.

- Daily review of handover sheets, ward, or assessment unit entries.
- Daily discussion with admitting or on-call teams.

Exclusion criteria: The following should be excluded:

- Patients who do not undergo an operation (e.g. planned operations that are cancelled).
- Patients undergoing angiography or minor procedures listed in Appendix A.
- Procedures performed outside of an operating theatre
- Individual participating centres can choose to include children only, adults only, or both children and adults. If including children or adults only, an age cut-off should be selected that is appropriate to the local context.
- Each individual patient should only be included in the study once, based on the first operation they undergo within the data capture window. Therefore, patients who are re-operated within 30-days should only be entered once.

Data collection and follow-up

Patient data will be collected on the following (a full list of data fields and definitions is in Appendix B and C):

- Demographics and presentation.
- Emergency and diagnostic pathways.
- Intraoperative variables.
- Post-operative outcomes.
- Antimicrobial resistance.

If possible, pre-operative and intra-operative data should be collected as soon as possible after the operation to ensure data accuracy and completeness. Follow-up data should be collected as soon as possible after postoperative day 30 (the day of surgery is day zero).

Follow-up data will be collected from routine health records such as medical notes, electronic health records, observation charts, drug charts, microbiology reports, radiology reports, discharge letters, clinic letters, and any other relevant documents. No additional follow-up is required for this study. Dedicated telephone and in-person 30-day follow-up should not be undertaken for this study.

Outcome measures

The primary outcome will be overall 30-day postoperative complications. The secondary outcomes (detailed definitions in Appendix C) will include:

- 30-day Clavien-Dindo complication grade. This is the most widely used complication grading system worldwide and it has been extensively validated.
- 30-day reoperation.
- 30-day readmission.
- 30-day postoperative mortality.
- 30-day surgical site infection.
- 30-day deep organ space infection
- 30-day postoperative pneumonia.
- 30-day acute respiratory distress syndrome
- 30-day unexpected ventilation.

- 30-day pulmonary embolism.
- 30-day deep vein thrombosis.
- 30-day cardiac complications.
- 30-day anastomotic leak.
- Hospital length of stay within 30-days of surgery.
- Days alive out of hospital at postoperative day 30.

Data analysis

Based on previous prospective cohort studies, this study is anticipated to include 1,000 hospitals. We estimate than on average five mini-teams will participate per hospital, each collecting data on an average of 20 patients. Therefore, we anticipate total recruitment will be 100,000 patients.

Categorical variables will be described using frequency tables and percentages. The rates from the surgical outcomes will be presented by income group, and differences between patient, disease, and operative-specific factors will be tested using Student's t-test for continuous data (p-value) and $\chi 2$ for categorical data (reported as $\chi 2$, p-value). The data will be mapped to World Bank country income groups: low-income countries (LICs), lower-middle income countries (LMICs), upper-middle-income countries (UMICs) and high-income countries (HIC).

A multilevel regression with random intercepts for hospital nested within country will be used, which will account for clustering and naturally limits the influence of any single, high-volume site multilevel models (hospital nested in country). A formal statistical analysis plan will be finalised prior to data analysis. All statistical analyses will be performed using R (version 4.0.2). A p-value of less than 0·05 will be deemed statistically significant. Further information can be found in Appendix D.

The Steering Committee will make the final decision on which outcome measure(s) will be included in the first publication. Remaining outcome measures and sub study findings will be reported in subsequent papers. Further secondary analyses may be performed at the steering committee's discretion.

Study approvals

It is the responsibility of the Hospital Lead to ensure that all necessary study approvals required by local and national regulations are secured. Data collection should only start once necessary written approvals for data collections are received. Access to online data entry will only be granted once the Hospital Lead has confirmed that they have secured all necessary approvals. The Hospital Lead will be required to submit a copy of the approval(s) to the steering committee.

Study registration in the UK

In the UK, SurgWeek-2 should **NOT** be registered as research (see Appendix E for a printout of result from the Health Research Authority *'Is my study research'*) The study must be registered as an audit or service evaluation. The study is registered as clinical audit at the lead centre, University Hospitals Birmingham NHS Foundation Trust (reference CARMS-24253 – see Appendix E).

The audit standards that SurgWeek-2 (see Appendix E for further detail) will assess are:

- World Health Organisation (WHO) Safer Surgery Checklist use.
- Time to antibiotics in patients with sepsis.
- Time to emergency surgery, by NCEPOD classification.

In addition, SurgWeek-2 incorporates a service evaluation of the uptake of robotic surgery in the UK and will benchmark the safety of robotic surgery against the accepted standards of care; minimally invasive surgery (e.g. laparoscopic, thoracoscopic) and open surgery, by comparing complications, mortality and reoperation in each group (see Appendix E for further detail).

When registering the study as a clinical audit, it must be emphasised that:

- All data collected will measure current practice.
- There will be no changes to normal patient pathways or treatment.
- There are no additional tests or follow-up required.
- Only anonymised data will be uploaded to the online database.

Study registration outside of the UK

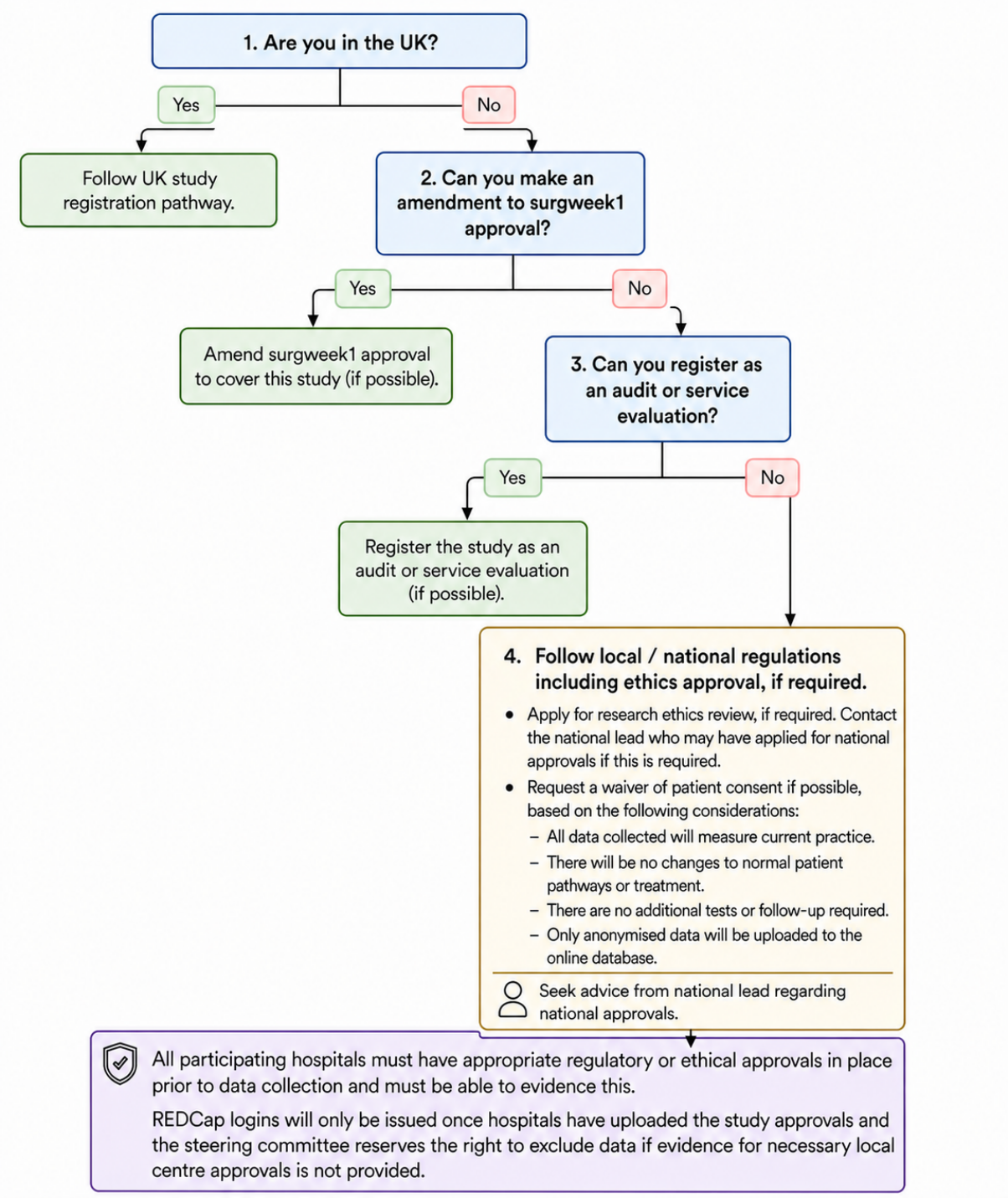
If possible, the study should be registered as an audit or service evaluation (please see above for advice). If your hospital participated in SurgWeek-1 in 2020, consider whether an amendment is possible to the SurgWeek-1 approval to cover this study (documents to support this process can be found on the SurgWeek-2 website). Please see below for a flowchart of suggested local approval processes.

Patients should only be consented for inclusion in the study if this is required by a research ethics committee. If you must apply for research ethics review, consider requesting a waiver for patient consent based on the following considerations:

- All data collected will measure current practice.
- There will be no changes to normal patient pathways or treatment.
- There are no additional tests or follow-up required.
- Only anonymised data will be uploaded to the online database.

All participating hospitals must have appropriate regulatory or ethical approvals in place prior to data collection and must be able to evidence this. REDCap logins will only be issued once they have uploaded the study approvals and the steering committee reserves the right to exclude data if evidence for necessary local centre approvals is not provided.

Flowchart of proposed approval processes



Data sharing agreements

Some hospitals may need a data-sharing agreement (DSA). If this is required, the Hospital Lead should request a DSA from the steering committee. A template DSA approved by the University of Birmingham will be available. DSA terms will not be negotiated with individual hospitals, due to the volume of DSAs required globally. The deadline to request a DSA will be 30 June 2026.

Data governance

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. Each collaborator will be provided with an individual login, allowing them to securely submit data. Each collaborator will only have access to data entered by their own mini-team. REDCap has previously been successfully used for the CovidSurg and GlobalSurg studies. The REDCap server is managed by the University of Birmingham, UK. Further information can be found in Appendix F.

No patient identifiable data will be collected on the REDCap server. All data should be handled in accordance with local data governance policies. All paper data collection sheets should be destroyed as confidential waste once data are uploaded to REDCap.

The study will be carried out in accordance with national and international guidelines, as well as the basic principles of the protection of the rights and dignity of Human Beings, as set out in the Helsinki Declaration (64th Assembly Fortaleza, Brazil, in October 2013), and according to locally applicable legislation.

Project Timeline

The overall data collection window will be from 31 August 2026 to 11 October 2026, but this can be extended by the steering committee if there are substantial delays to the study set-up and delivery.

Mini-teams will be able to collect data in one or more of the 7-day blocks outlined below. All times should be based on local time. Patients should be included if the time of ‘knife to skin’ (start of the operation) falls within the selected 7-day data collection block.

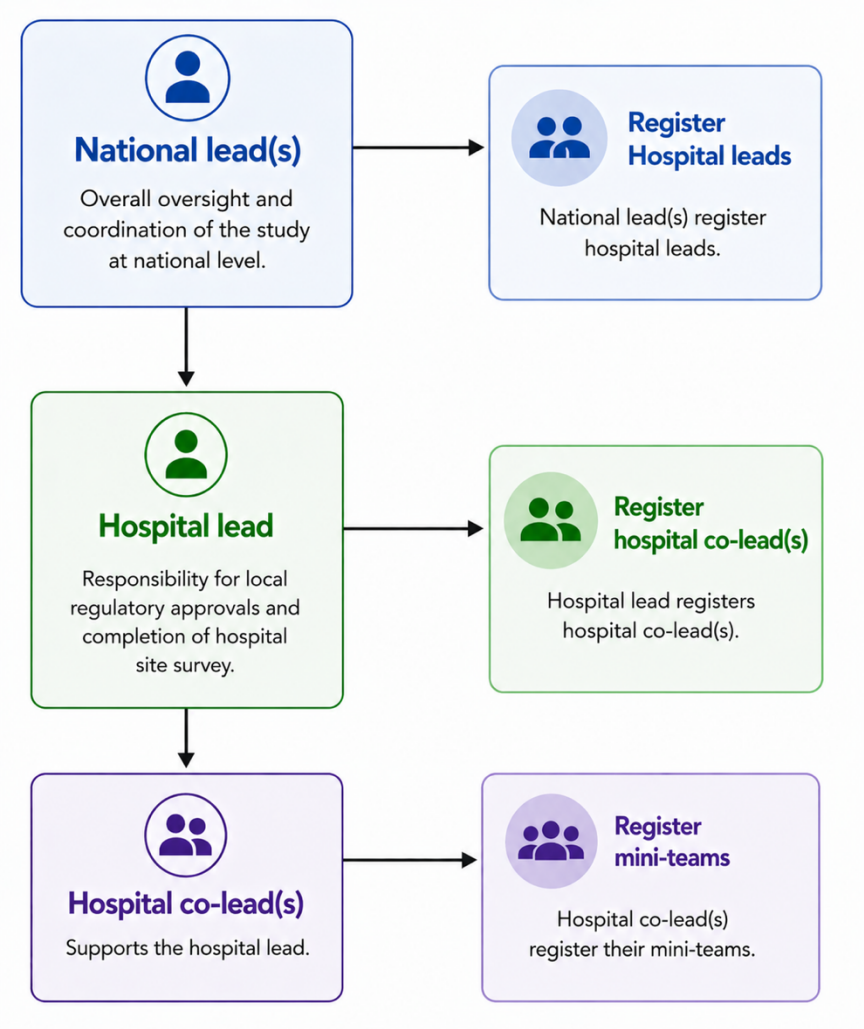
Block	Inclusion starts	Inclusion ends	30-day follow-up ends
Block 1	00:00 31 August 2026	23:59 6 September 2026	6 October 2026
Block 2	00:00 7 September 2026	23:59 13 September 2026	13 October 2026
Block 3	00:00 14 September 2026	23:59 20 September 2026	20 October 2026
Block 4	00:00 21 September 2026	23:59 27 September 2026	27 October 2026
Block 5	00:00 28 September 2026	23:59 4 October 2026	3 November 2026
Block 6	00:00 5 October 2026	23:59 11 October 2026	10 November 2026

Study logistics

A Hospital Lead will coordinate the study within each hospital. The Hospital Lead should be a senior surgeon or anaesthetist (usually consultant / attending or equivalent). The Hospital Lead will be responsible for securing appropriate regulatory approvals in their hospital, completing the site survey and organising and registering co-leads in their hospital. The hospital lead and co-leads will identify, co-ordinate and register the mini-teams that will collect data for each speciality. Any member of hospital staff or student can participate as part of a mini-team, but we suggest that for each participating specialty, at least one senior

surgeon is involved in the study either as a co-lead or as a mini-team collaborator. Mini-teams can include up to three individuals.

Flowchart of study logistics



All surgical specialties are eligible to participate in SurgWeek-2, but it is not mandatory for all specialties to participate at each hospital (e.g. just a few specialties can participate if there is not interest across all specialties). Each mini-team can collect data for one or multiple specialities, and for one or multiple 7-day data collection blocks. Multiple mini-teams can participate in a hospital, so long as there is no overlap in data collection between mini-teams. Clinicians can only participate in one hospital and should not register for multiple hospitals in the study. Further information on the operational delivery can be found in Appendix G.

Hospital-level survey

In addition to patient-level data, participating centres will complete a hospital-level survey to capture hospital characteristics. This will include:

- Hospital resources (e.g. number of hospital beds; operating theatres; surgical, obstetric, and anaesthetic staff).
- Access to technology (e.g. robotic surgery, diagnostic imaging).
- Hospital activity (e.g. total operations performed by each specialty annually).
- Hospital financing (e.g. facility-level funding models – public, private, etc).
- Robotic surgery learning curve data.

Authorship

All National Leads, Hospital Leads, Hospital co-leads and mini-team collaborators who contribute data reported in a publication will be included as PubMed-citable co-authors on that particular publication. Each mini-team may include up to three collaborators. The Principal Investigator is Dr Dmitri Nepogodiev, Associate Professor at the University of Birmingham, UK.

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