CLINICAL STUDY PROTOCOL

Understanding the factors contributing to perioperative morbidity in older perioperative patients in Ireland: The Irish Perioperative OutcomeS (IPOS) Study

Study protocol version 2.1

Date: 14/08/2026

Steering Committee
John Laffey
David Cosgrave
Donal Buggy
Michelle Duggan
Gabriella Iohom
Pádraig Ó Scanaill
Ger Curley

Statistician: Prof Andrew Simpkin, University of Galway.

Chief investigator's contact details: John Laffey, Chair, Outcomes Research Committee, College of Anaesthesiologists, 22 Merrion Square North, Dublin 2.
e-mail: jlaffey@universityofgalway.ie Telephone: 091-544074

Funders: College of Anaesthesiologists of Ireland

Signature:

Date: 14/08/2026

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BACKGROUND AND RATIONALE

Advances in perioperative medicine and surgical techniques have expanded the range of procedures feasible for older patients with multiple comorbidities. However, these same patients remain at significantly increased risk of adverse postoperative outcomes, particularly when presenting for major urgent or elective surgery. Our healthcare system in Ireland therefore faces the dual challenge of providing safe perioperative care for ever more complex procedures to an ageing and increasingly comorbid patient population.

Large epidemiological studies from multiple international groups consistently identify a high-risk subpopulation comprising approximately 10–15% of patients undergoing major inpatient surgery (1-4). Within this group, the predominant contributors to poor outcomes are not directly related to the surgical procedure or anaesthetic technique, but rather the development of serious postoperative medical complications (5). These include pneumonia, cardiac failure (6, 7), myocardial infarction (6, 7), sepsis, and thromboembolic events, which arise in the days following anaesthesia and surgery (5). Postoperative Delirium in older adults undergoing noncardiac surgery has been shown to be strongly associated with poor outcome (8). These complications often occur in patients with diminished physiological reserve, compounding the impact of pre-existing illness and limiting recovery potential (5).

Several modifiable factors have been linked to worse perioperative outcomes in this high-risk group. For example, preoperative anaemia (9) and abnormal serum sodium concentrations (10) are associated with increased postoperative morbidity and mortality. System-level factors may further influence outcomes, particularly for urgent, emergent, and out-of-hours procedures, where constraints in operating theatre access and limited availability of postoperative critical care facilities may delay timely intervention and compromise optimal management (11, 12). Access to comprehensive geriatric assessment for older patients undergoing surgery may improve outcomes, but is limited in Ireland (13).

Despite this growing evidence base internationally, there are limited high-quality data describing perioperative risk, complications, and resource utilisation in Ireland. Given demographic trends, with an ageing population and rising multimorbidity, the absolute number of high-risk patients presenting for major surgery will continue to increase. Without a clear understanding of the determinants of poor perioperative outcomes in our context, health service planning and targeted quality improvement programmes cannot be optimally informed.

We propose a collaborative, multicentre observational study of perioperative outcomes older adults presenting for major urgent and elective surgery in Ireland. The study will: a) assess the incidence of postoperative morbidity and relationship to patient clinical complexity and risk; b) determine the incidence of major perioperative adverse outcomes; c) identify modifiable factors contributing to suboptimal perioperative outcomes, including patient-related, treatment-related, and system-related factors; and d) assess national capacity to deliver optimal perioperative care, including access to critical care facilities and timely surgical intervention.

Our primary outcome measure will be the Postoperative Morbidity Survey (POMS) score. Multiple studies shows that the POMS is both a reliable and valid measure of short-term postoperative morbidity in patients undergoing major abdominal surgery (14, 15), with high degrees of inter-rater reliability demonstrated (16).
Findings from this study will establish a robust baseline for perioperative outcomes in Ireland, and the relationship between clinical complexity, resource availability and perioperative morbidity. It will provide an evidence platform to inform national policy, guide resource allocation, and underpin targeted quality improvement initiatives. Ultimately, this work aims to improve surgical outcomes and deliver safer, more equitable perioperative care for high-risk patients across the country.

METHODS

Study Design: Fourteen-day, prospective observational national cohort study of older (≥60 years) patients undergoing major in-patient surgery.

Inclusion criteria:

1. Patients ≥60 years
2. Emergency surgery (category I, category II or category III) **AND/OR** Intermediate to Major elective surgery
3. Patient requires an inpatient postoperative stay.
4. ASA grade 2 – 5 (2E to 5E)

Exclusion Criteria:

1. Patients undergoing planned day-case surgery
2. Patients undergoing cardiac surgery, neurosurgery, or radiological or obstetric procedures.

Objectives and Outcomes

Primary Objective: To understand relationship between clinical complexity, risk profile, and capacity to provide care and morbidity profiles in patients presenting for major surgery in Ireland.
Secondary Objectives: To assess adverse outcome rates and identify potentially modifiable factors contributing to adverse outcomes in higher risk patients undergoing major surgical procedures in Ireland.

Primary Outcome: Incidence of major postoperative complications within 7 days of surgery as defined by a Postoperative Morbidity Survey (POMS) score >1.

Secondary Outcomes

- Incidence of major perioperative adverse outcomes (by organ system)
- All-cause in-hospital mortality by Day 7 (or discharge if earlier).
- Need for unplanned ICU/HCU/PACU Admission

- Incidence of Incidence of postoperative delirium (assessed by (assessed by CAM-ICU or 4AT depending of level of care).
- Time from decision for surgery and induction of Anaesthesia for urgent/emergent patients.
- Percentage of requests for postoperative ICU/HDU/PACU care not provided.

Ethical Considerations

This study will be conducted under a waiver of consent because there is clear risk of bias if individual patient consent is required. Patients enrolled will be informed of the study aims and objectives, have the management of their data explained to them, and they will be given the option to 'opt out', i.e. have their data completely removed from the study database.

Where an enrolled patient chooses to opt out, the local investigator must immediately destroy the patient's paper CRF and permanently purge their entry from the REDCap database. If the REDCap file has been completed and submitted, the investigator must contract the Chief Investigator, who will then ensure that the file is deleted.

The justification for this approach is that collecting all consecutive patients is needed to provide an unbiased estimate of the prevalence of complications. If individual patient consent were required, certain – potentially different risk - populations may be over or under-selected, and that this missing data will be non-random, and skewed. This results in a study population that does not represent the typical patient requiring this type of airway management, potentially understating – or overstating - the risk to patients from this procedure.

The impact of bias due to consent requirements are highlighted in studies by Kho et al. (17) and Tu et al. (18). This specific issue was raised following a landmark international study of perioperative outcomes (4) that undermining the scientific validity and impact of the results in Ireland (19).

Overall, the potential benefits of conducting this study outweigh the foreseeable risks to patients. In terms of mitigation of risk to participants, this study is entirely observational with minimal direct risk to participants. The data collected is data generated and collected as part of routine clinical care, and no additional tests or examinations will be performed. The study will be conducted in accordance with Good Clinical Practice guidelines (20) and the Declaration of Helsinki (21). Additionally, the research will be conducted in compliance with local CREC requirements at each centre. All participants will be be visited by a member of the site study team on the day after their surgery and/or before discharge and informed of their enrolment in this study and will be given the option to have their data removed from the database.

Data Management and Data Protection

***Data controller*:** The data controller for this study is the Health Services Executive (HSE). The data controller has overall responsibility for the lawful processing of personal data collected as part of this study, in line with the General Data Protection

Regulation (GDPR), the Data Protection Act 2018, and the Health Research Regulations 2018 (as amended). A Data Protection Impact Assessment (DPIA) covering this study has been completed; where additional detail on data-protection processes is required, the DPIA is the operative document, and the present protocol is consistent with it.

Definitions used in this section

Coordinating study team: The study is coordinated by Galway University Hospital.

Pseudonymised data: Data in which direct identifiers have been replaced by a numeric code, with the linkage between code and identifier held in a separate master key file accessible only to local site investigators.

Master key: The site-held file linking patient numeric codes to identifiable patient records, used solely to allow follow-up of clinical outcomes and resolution of missing data within the study window.

Irrevocable anonymisation: The point at which the master key is destroyed, and no remaining file, mapping, or record permits a numeric code in the dataset to be re-linked to an identifiable individual. After this point the dataset is no longer personal data within the meaning of GDPR.

End of study: Defined as the point at which the full dataset has been cleaned, validated, and irrevocably anonymised. All subsequent statistical analysis, reporting, and publication activity occurs post-study and is conducted on the irrevocably anonymised dataset.

Data Collection and Collation

The study/source data is collected from the patient's medical electronic and paper hospital records. Data will be collected at each participating centre using standardised paper case record forms (CRFs). Personal data will be recorded only to the extent necessary for participant identification, clinical follow-up, and validation of study data, and will remain at the local site at all times. Paper CRFs and the local enrolment log, which constitutes the master key linking participant identities to coded study records, will be stored securely in locked offices with access restricted to authorised study personnel. Each participating centre and each participant will be assigned a unique numeric code, and local investigators will transcribe pseudonymised data into a secure, internet-based electronic CRF hosted on REDCap.

The coordinating study team and data controller will have access only to the pseudonymised dataset and will not be able to re-identify individual participants from the central database. Access to the electronic data capture system will be protected by individual username and password credentials issued during investigator registration, and all data transfers between sites and the coordinating centre will be conducted over secure, encrypted, password-protected channels. Each site will maintain a trial file containing the study protocol, delegation log, and relevant ethics or waiver documentation. Data accuracy and completeness will be supported by cross-referencing recruited cases with HIPE data. All processing will be undertaken in accordance with the principles of lawfulness, fairness and transparency, purpose

limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality, with appropriate technical and organisational measures implemented to safeguard personal data throughout the study.

Data Management and Anonymization process

Retention paper CRFs: Paper CRFs are retained securely in a locked office at each participating centre for a period of 10 years from the end of study, in line with institutional research records retention policy, HSE policy, and the Health Research Regulations. Retention is the responsibility of the local site lead investigator. After 10 years the paper CRFs are securely destroyed by shredding or incineration, in accordance with the local institution's confidential waste policy.

***Irrevocable anonymisation Process*:** The master key linking numeric codes to identifiable patient records is held only at the participating site and only for the duration of active data collection and follow-up. The expected timeline is as follows: data collection completion by the end of 2026; database cleaning and query resolution within 12 - 18 months thereafter. Once the steering committee has confirmed that the dataset is cleaned and locked, the chief investigator (Prof John Laffey, on behalf of the HSE) issues written instruction to all participating sites to destroy their master keys. Destruction is performed by the local site lead investigator and confirmed in writing to the coordinating centre. The point at which all participating sites have confirmed master key destruction is the point of irrevocable anonymisation and is defined as the end of study.

Non-reidentification of Data: The chief investigator (Prof John Laffey) on behalf of the HSE formally undertakes that no member of the site or coordinating study team will attempt to re-identify data once the database has been closed.

Site identifiability in the final dataset: Following irrevocable anonymisation, specific participating institutions are identifiable in the analysis dataset. Each site is referred to only by a study code that indicates the hospital and its level (e.g. model 3/4). Given that this information will only be used for structural level analysis, and the study investigators have undertaken not to attempt to re-identify patients once the database has been locked and the site key destroyed, this satisfies the criteria that a hospital code does not make individual patient re-identification 'reasonably likely'.

Fate of the electronic dataset: Once the dataset has been irrevocably anonymised, the electronic dataset will be retained indefinitely for the purposes of secondary analysis, scientific reproducibility, and meta-analytic contribution. Data retention will follow the HSE policy on archiving electronic research data and with the access controls applicable to the data controller. Because the dataset is irrevocably anonymised before transfer to long-term archive, retained electronic data are no longer personal data within the meaning of GDPR.

Data access and ownership

On behalf of the steering committee, the Health Services Executive will act as custodian of the data. The Steering committee will retain the right to use all pooled

data for scientific and other purposes. Members of the IPOS study group will have the right to access the pooled data for research purposes provided the research proposal has been reviewed and deemed satisfactory by the Steering committee. The primary consideration for such decisions will be the quality and validity of any proposed analysis. Only summary data will be presented publicly, and all institutions will be anonymised except in the individualised report provided to each institution at the end of the study. Individual patient data provided by participating sites remain the property of the respective institution.

Sample Size

An event rate of POMS score >1 of approx. 50% on Day 7 has been reported in prior studies in the UK (14). Using 10 events per predictor variable as a rule of thumb, this allows us to investigate the effect of 30+ predictors if we have a sample size of 750, i.e. 375 expected to have POMS>1.

Statistical Analysis

Descriptive statistics will be used to describe the patient characteristics. Continuous data will be expressed as mean and standard deviation or median and interquartile range depending on distribution, and categorical data as number and percentage. Bivariate analyses will be conducted using $\chi 2$ or Fisher exact test for categorical variables, and the Mann-Whitney or t-test for continuous variables (as appropriate). A complete case analysis (with no assumptions made for missing data) will be performed. For the primary objective, the incidence and degree of major postoperative complications (POMS score >1, with 95% confidence interval) will be estimated overall, and within clinically relevant strata (e.g., sex, age, urgent versus emergency procedures, post-procedure care in ward vs. ICU, low vs. high-risk patients, comorbidities, indication for surgery, etc.). A Cox proportional hazards model will be used for time to major complications (POMS score > 1), to investigate clinical predictors of the primary outcome. A frailty term for centres will be added to allow clustering by setting.

For secondary objectives, (1) to assess unmet need regarding level of postoperative care delivered versus optimal care requirement; (2) Identify modifiable factors contributing to suboptimal outcomes, including Unmet care (e.g. % high risk patients not receiving critical care), delayed care (e.g. Out of hours Category II – III surgery), and suboptimal care (staffing ratios; ancillary services e.g. Physiotherapy), multivariable models (which may include logistic regression, Poisson regression, negative binomial regression, according to the nature of the data) adjusting for patient and surgical characteristics will be conducted. Kaplan-Meier curves and Cox regression may be implemented to analyse survival data, if appropriate. Exploratory analysis will be conducted to understand the risk profiles and provision of perioperative care. Given the multicentre enrolment, all analyses will be performed using multi-level models (e.g. model 3 versus model 4 hospitals). All tests will be 2-sided and a p-value less than 0.05 will be considered statistically significant. Statistical analysis will be

performed using R software (R Foundation for Statistical Computing, Vienna, Austria).

Publication plan

Data will be presented and disseminated in a timely manner. In discussion with the funder(s), the steering committee will appoint a writing committee to draft the scientific report(s) of this investigation. Specific funding is requested to allow publication of data on an open access basis. On request, centres will be provided with an individual report allowing comparison of their individual centre's summary data to that of their national cohort and the overall dataset. In line with the principles of data preservation and sharing, the steering committee will, after publication of the overall dataset, consider all reasonable requests to make the dataset available in whole or part for secondary analyses and scientific publication. The steering committee will consider the scientific validity of requests prior to granting any such requests. Where appropriate, a prior written agreement will set out the terms of such collaborations. The steering committee will consider proposals for secondary analyses on the basis of the scientific quality of the proposal. Hospital groups may wish to perform secondary analyses specifically of their dataset. Such proposals are generally encouraged, and the Steering committee will make the group datasets available to national co-ordinators on receipt of a hospital group study proposal. However, the steering committee must approve the final version of all manuscripts prior to submission for publication, whether they relate to part or all the IPOS dataset.

Deliverables

The main deliverables will be scientific reports of preliminary findings for general and specialty journals, abstracts for presentation to national and international meetings including those of the supporting societies and a final report summarising the overall findings.

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Appendix 1: Case Report Form

Irish Perioperative Outcomes Study (IPOS)

Case Report Form

Version 1.0

CONFIDENTIAL

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Site Code:	
Patient ID:	

Form 0 – Site Information

Complete once per site. All fields mandatory.

Site Details	
Hospital Name	
Hospital Code	
Site Lead Name	
Hospital Level	Model 1 ☐ Model 2 ☐ Model 3 ☐ Model 4 ☐
Number of Operating Rooms	
Post-op Care Options Available	Ward ☐ Enhanced Ward ☐ PACU Level 1 ☐ HDU Level 2 ☐ ICU Level 3 ☐
Number of ICU/HDU Beds	
Key Resources Available	
Physiotherapy	Weekday ☐ Weekend ☐ OOH ☐
ICU/HDU Availability	24/7 ☐ Limited ☐

Form 1 – Participant Screening

Tick all that apply. Patient must meet inclusion criteria AND not meet any exclusion criteria.

Inclusion Criteria (tick all that apply)	
Age > 60 years	Yes ☐
Emergency surgery	Cat I ☐ Cat II ☐ Cat III ☐
OR	
Major elective surgery (inpatient)	Yes ☐
ASA Grade 2–5 (2E–5E)	Yes ☐
Exclusion Criteria (tick any that apply)	
Planned day-case surgery	Yes ☐
Neurosurgery	Yes ☐
Radiology procedure	Yes ☐
Obstetric procedure	Yes ☐

Form 2 – Preoperative Risk Assessment

Record all fields. Use dd/mm/yyyy for dates. Units specified alongside fields.

Patient Number (linked to hospital)	

A. Demographics	
Age (years)	
Sex	Male ☐ Female ☐
Height (cm)	
Weight (kg)	
Ethnicity (tick one)	White – Irish ☐ White – Irish Traveller ☐ White – Other ☐
	Black or Black Irish – African ☐ Black or Black Irish – Other ☐
	Asian or Asian Irish – Chinese ☐ Asian or Asian Irish – Other ☐
Socio-economic Group (tick one)	Other (specify): _____
	Professional ☐ Managerial/technical ☐ Non-manual ☐
	Skilled manual ☐ Semi-skilled ☐ Unskilled ☐
	Own account/Self-employed ☐ Farmer ☐ Unknown/Not stated ☐
Date of Admission (dd/mm/yyyy)	
Preoperative Assessment (tick one)	Virtual PAC – Anaesthetist ☐ Virtual PAC – Nurse led ☐
	In-person PAC – Anaesthetist ☐ In-person PAC – Nurse led ☐
	During current admission ☐ Day of Surgery ☐

Record if available within 6 months prior to surgery.

Preoperative Labs	
Hb (g/dL)	
WCC (×10⁹/L)	
Creatinine (µmol/L)	
Na (mmol/L)	
K (mmol/L)	

Preoperative Vital Signs	
HR (bpm)	
BP (mmHg)	_____ / _____
SpO_2 (%)	
Temp (°C)	

B. Comorbidities / Frailty / Function	
Clinical Frailty Scale (1–9)	
Known Cognitive Decline (last 6 months)	Y ☐ N ☐
Functional Status: Independent in ADLs	Y ☐ N ☐
Charlson Comorbidity Index	
Myocardial Infarction	Y ☐ N ☐
Congestive Heart Failure	Y ☐ N ☐
Peripheral Vascular Disease	Y ☐ N ☐
CVA or TIA	Y ☐ N ☐
Dementia	Y ☐ N ☐
Chronic Pulmonary Disease	Y ☐ N ☐
Connective Tissue Disease	Y ☐ N ☐
Peptic Ulcer Disease	Y ☐ N ☐
Liver Disease	None ☐ Mild ☐ Mod–Severe ☐
Diabetes	None ☐ Uncomplicated ☐ End-organ damage ☐
Hemiplegia	Y ☐ N ☐
Moderate to Severe CKD	Y ☐ N ☐
Solid Tumour	None ☐ Localised ☐ Metastatic ☐
Leukaemia	Y ☐ N ☐
Lymphoma	Y ☐ N ☐
AIDS	Y ☐ N ☐
Other Comorbidities	
Hypertension	Y ☐ N ☐
Asthma	Y ☐ N ☐
Other (specify)	

C. Preoperative Clinical Status (immediately prior to surgery)	
Oxygen Requirement Pre-op	Y ☐ N ☐
Vasopressor/Inotrope Requirement Pre-op	Y ☐ N ☐
Airway: Mallampati Score (1–4)	
Difficult Airway Anticipated?	Y ☐ N ☐

D. Perioperative Planning	
ICU/HDU Bed Needed Post-op?	Y ☐ N ☐
ICU/HDU Bed Requested?	Y ☐ N ☐
ICU/HDU Bed Allocated?	Y ☐ N ☐

Form 3 – Intraoperative Data

A. Surgery Details	
General Surgery	
Upper GI resection (e.g. oesophagotomy, gastrectomy)	☐
Colorectal resection (laparoscopic/open)	☐
Hepatobiliary / pancreatic resection	☐
Emergency laparotomy	☐
Hernia repair (inguinal, incisional, ventral)	☐
Cholecystectomy (laparoscopic/open)	☐
Appendicectomy	☐
Other (general)	☐
Vascular Surgery	
Abdominal aortic aneurysm repair (open/endovascular)	☐
Peripheral vascular bypass / endarterectomy	☐
Carotid endarterectomy	☐
Other (vascular)	☐
Orthopaedics / Trauma	
Hip fracture fixation	☐
Hip arthroplasty (primary/revision)	☐
Knee arthroplasty (primary/revision)	☐
Spinal surgery (decompression, fusion)	☐
Major trauma fixation (pelvis, long bones)	☐
Other (orthopaedic)	☐
Urology	
Prostatectomy (open/robotic/TURP)	☐
Cystectomy	☐
Nephrectomy (partial/total)	☐
Ureteric / bladder reconstruction	☐
Other (urology)	☐
ENT / Head & Neck	
Laryngectomy / pharyngotomy	☐
Thyroidectomy / parathyroidectomy	☐
Neck dissection	☐

Major airway procedure (excl. tracheostomy alone)	☐
Other (ENT)	☐
Plastic / Reconstructive	
Free flap reconstruction (head & neck, limb, breast)	☐
Amputation (major limb)	☐
Other (plastic)	☐
If other surgery, specify	
Urgency Category	1 ☐ 2 ☐ 3 ☐
Time: Decision to Surgery → Induction (hh:mm)	
Start Time (hh:mm, 24hr)	
End Time (hh:mm, 24hr)	
Surgery Timing	In-hours ☐ Out-of-hours ☐
Anaesthesia Type	GA ☐ Regional ☐ Sedation ☐ Combined ☐
Post-op Analgesia Plan	

Anaesthesia Detail	
General Airway	LMA ☐ ETT ☐ Other ☐
Regional Technique	Epidural ☐ Spinal ☐ Peripheral nerve block ☐
	Fascial sheath block ☐ Nerve catheter ☐ Wound catheter ☐
Grade of Surgeon	
Grade of Anaesthetist	

B. Surgical Apgar Score Components	
Lowest MAP (mmHg)	
Highest HR (bpm)	
Estimated Blood Loss (mL)	

C. Other Intraoperative Factors	
Vasoactive Agent Used Intraoperatively	Y ☐ N ☐
Blood Transfusion Given	Y ☐ N ☐
Lowest Core Temperature (°C)	

Form 4 – Postoperative Course (to Day 7

A. Care Location Post-op

Location on Day 1	Ward ☐ Monitored bed ☐ PACU ☐ HDU ☐ ICU ☐
Was Location Same as Planned?	Y ☐ N ☐
Duration of Stay at Higher Level Care (days)	
Duration of Stay in Hospital (days)	

*B. Postoperative Morbidity Survey (POMS) – Tick if morbidity present at each timepoint. Record day of change from previous POMS where applicable. Day 3: skip if discharged earlier. Day 7: or discharge, whichever is first. * Day Δ = day of change from previous POMS.*

POMS Domain	Day 1	Day Δ	Day 3*	Day Δ	Day 7*
1. Pulmonary – new O_2 therapy, resp. support, or abnormal CXR	☐		☐		☐
2. Infectious – fever >38°C, positive cultures, receiving antibiotics	☐		☐		☐
3. Renal – oliguria (<500 mL/day) or creatinine >177 µmol/L	☐		☐		☐
4. GI – unable to tolerate oral intake, vomiting, NG tube, distension	☐		☐		☐
5. Cardiac – MI, arrhythmia requiring Rx, hypotension needing therapy	☐		☐		☐
6. Neurological – new focal deficit, confusion, delirium, GCS <15	☐		☐		☐
7. Haematological – Hb <8 g/dL or transfusion required	☐		☐		☐
8. Wound – dehiscence, purulent drainage, erythema	☐		☐		☐
9. Pain – pain limiting mobilisation despite analgesia	☐		☐		☐

C. Delirium and Sedation Assessment (RASS / CAM-ICU / 4AT) – Record care location first, then complete the matching row: ICU/HDU patients get RASS + CAM-ICU (CAM-ICU only valid if RASS ≥ -3; code P = Positive, N = Negative, NA = Not Assessable if RASS ≤ -4); Ward/Other patients get the 4AT. Day 3: skip if discharged earlier. Day 7: or discharge, whichever is first.

Delirium / Sedation Assessment	Day 1	Day Δ	Day 3*	Day Δ	Day 7*
Care Location (I = ICU/HDU, W = Ward/Other)					
RASS score (-5 to +4) – if ICU					
CAM-ICU result (P/N/NA) – if ICU					
4AT score (0–12) – if Ward					

D. qSOFA Score – Day 1 (worst values)

RR ≥ 22	Y ☐ N ☐
SBP ≤ 100 mmHg	Y ☐ N ☐
GCS < 15	Y ☐ N ☐
Total qSOFA (0–3)	

E. Other Major Outcomes

ICU Admission	Y ☐ N ☐
Unplanned ICU Admission	Y ☐ N ☐
Reoperation	Y ☐ N ☐
Death by Day 7	Y ☐ N ☐

Form 5 – Critical Care Data

Complete only for patients admitted to critical care. Skip sections if patient discharged from critical care before that timepoint.

Admission Details	
Time from End of Surgery to CC Admission (hh:mm)	
CC Admission (within 24h of surgery)	Planned ☐ Unplanned ☐
If Unplanned, Source	Theatre ☐ Ward ☐
Intensive Care Measures (first 24 hours)	
Invasive Ventilation	No ☐ Yes – Planned ☐ Yes – Unplanned ☐
Non-invasive Ventilation	No ☐ Yes – Planned ☐ Yes – Unplanned ☐
Inotrope / Vasopressor Use	No ☐ Yes – Planned ☐ Yes – Unplanned ☐
Airway at Critical Care Admission	
Invasive	Endotracheal Tube ☐ Supraglottic Airway ☐ Tracheostomy ☐
Non-invasive	Yes ☐
Ventilatory Support at CC Admission	
Type	Invasive ventilation ☐ NIV/CPAP ☐ HFNO ☐
	Other supplementary O_2 ☐ None ☐
Events Prior to Critical Care	
Respiratory Arrest Prior to CC	Y ☐ N ☐
Cardiac Arrest Prior to CC	Y ☐ N ☐
Renal Replacement Therapy	No ☐ Yes – Planned ☐ Yes – Unplanned ☐

SOFA – Day 1 *(highest derangement in preceding 24h)*

Component	Value
Respiratory (PaO_2/FiO_2 ratio, mmHg) Coagulation (Platelets ×10⁹/L) Liver (Bilirubin µmol/L)	
Cardiovascular (MAP / vasopressors, specify agent + dose)	
Central Nervous System (GCS) Renal (Creatinine µmol/L or urine output mL/day)	

SOFA – Day 3 *(skip if discharged earlier)*

Component	Value
Respiratory (PaO_2/FiO_2 ratio, mmHg) Coagulation (Platelets ×10⁹/L) Liver (Bilirubin µmol/L)	

Cardiovascular (MAP / vasopressors, specify agent + dose) Central Nervous System (GCS)	
Renal (Creatinine µmol/L or urine output mL/day)	

SOFA – Day 7 or Discharge *(whichever is first; record new values compared with Day 3)*	
Component	**Value**
Respiratory (PaO_2/FiO_2 ratio, mmHg) Coagulation (Platelets ×10^9/L) Liver (Bilirubin µmol/L) Cardiovascular (MAP / vasopressors, specify agent + dose) Central Nervous System (GCS)	
Renal (Creatinine µmol/L or urine output mL/day)	

Data Collection Sign-off	
Data Collector Name	
Signature	
Date (dd/mm/yyyy)	
Investigator Name	
Investigator Signature	
Date (dd/mm/yyyy)	

Appendix 2: Data Dictionary

Anaesthetic technique

General anaesthesia: Pharmacologically induced state of unconsciousness in order to facilitate surgical procedure

Sedation: Pharmacologically induced reduced level of consciousness during which verbal contact is maintained

Regional anaesthesia: injection or infusion of a clinically effective dose of local anaesthetic and / or opioid drugs in order to provide clinically effective anaesthesia

Severity of surgery

Minor: Procedure of less than 30 minutes duration performed in a dedicated operating room which would often involve extremities or body surface or brief diagnostic and therapeutic procedures.
Examples include: arthroscopy without intervention, removal of small cutaneous tumour, diagnostic proctology procedures, biopsy or excision biopsy of small lesions, etc

Intermediate: More prolonged or complex procedure performed in a dedicated operating room that may pose the risk of significant complications or tissue injury.
Examples include: laparoscopic cholecystectomy, arthroscopy with intervention, bilateral varicose vein removal, tonsillectomy, inguinal hernia repair, breast lump resection, haemorrhoidectomy, appendicectomy, partial thyroidectomy, cataract surgery, uvuloplasty, minimally invasive repair of vaginal prolapse, vaginal hysterectomy, tendon repair of hand, fixation of mandibular fracture, etc

Major: Any surgical procedure that requires anaesthesia, performed in a dedicated operating room and is expected to last more than 90 minutes.
Examples include: major gut resection, major joint replacement, mastectomy, extensive head and neck tumour resection, abdominal aortic aneurysm repair, major vascular bypass procedure, procedures involving free flap to repair tissue defect, amputation, total thyroidectomy, cystectomy, trans-urethral resection of prostate, resection of liver tumour, carotid endarterectomy, nephrectomy, total abdominal hysterectomy, spinal discectomy, etc Urgency of surgery

Elective: Not immediately life-saving; planned within months or weeks
Non-elective: As soon as possible after resuscitation and ideally within 24 hours

American Society of Anesthesiologists (ASA) score:

I A normal healthy patient
II A patient with mild systemic disease which does not limit physical activity
III A patient with severe systemic disease which limits physical activity
IV A patient with severe systemic disease that is a constant threat to life

V A patient who is not expected to survive for 24 hours without the operation

Duration of surgery
Time in minutes from induction of anaesthesia to patient being ready to leave the operating room

Post-anaesthetic recovery unit
A post-anaesthetic recovery unit is dedicated facility for the care of all patients following surgery under anaesthesia. This does not include units which routinely care for invasively ventilated patients overnight. Duration of stay is the time from arrival to departure measured in minutes.

Post-operative Critical Care
For this study, a critical care unit is defined as a facility routinely capable of admitting patients who require invasive ventilation overnight. This differs from a post-anaesthetic recovery unit which has a primary purpose to provide care for all patients after anaesthesia regardless of dependency. Duration of stay is the time from arrival to departure measured in hours (part hours to count as one whole hour).

Duration of hospital stay
Time in days from the day of surgery to the day the patient leaves hospital. This will not be adjusted for delays relating to provision of social care in the community.