

## **SurgWeek-2 Appendices**

### **Appendix A: List of excluded procedures**

The SurgWeek-2 study will include all operations (elective or emergency) performed in an operating theatre, excluding minor procedures. All surgical specialties are included. Both day case surgery and inpatient surgery are included. Both children and adults are included. The minor procedures that are excluded are listed below.

<b>Specialty</b>	<b>Excluded procedures</b>
Abdominal surgery	Ascitic drain (drainage of peritoneal cavity)
	Endoscopic ultrasound
	Laparoscopic ultrasound
Breast surgery	Breast biopsy
Cardiac surgery	Insertion of cardiac pacemaker
	PCI: percutaneous coronary intervention
	Transluminal balloon angioplasty of coronary artery
Colorectal surgery	Colonoscopy (diagnostic or therapeutic)
	Flexible sigmoidoscopy (diagnostic or therapeutic)
	Proctoscopy (diagnostic or therapeutic)
Dental procedures	Implantation of tooth
	Insertion of dental prosthesis
	Orthodontic operations
	Restoration of tooth
	Extraction of tooth
Gynaecology	Cervical biopsy
	Colposcopy (diagnostic or therapeutic)
Obstetrics	Any vaginal delivery (normal delivery, breech delivery, forceps delivery, vacuum delivery)
	Repair of obstetric laceration

Ophthalmology	Removal of foreign body from cornea
Orthopaedics	Bone biopsy
	Injection into joint
	Muscle biopsy
Otolaryngology	Nasendoscopy (diagnostic or therapeutic)
	Packing of cavity of nose
Thoracic surgery	Bronchoscopy (diagnostic or therapeutic)
	Chest drain
Upper gastrointestinal surgery	ERCP: endoscopic retrograde cholangiopancreatography (diagnostic or therapeutic)
	Liver biopsy
	OGD: Oesophago-gastro-duodenoscopy (diagnostic or therapeutic)
Urology*	Bladder biopsy
	Extracorporeal shock wave lithotripsy (ESWL)
	Flexible cystoscopy (diagnostic or therapeutic)
	Percutaneous nephrostomy
	Percutaneous nephrolithotomy (PCNL)
Vascular surgery	Transluminal (endovascular) procedures on arteries (diagnostic or therapeutic), including with open cut down to the artery
	Transluminal (endovascular) procedures on veins (diagnostic or therapeutic)
Other	Insertion of central venous catheter/ line (CVC)
	Lumbar (spinal) puncture
	Percutaneous tracheostomy
	Skin biopsy (including shave biopsy of skin)
	Therapeutic epidural injection

\*Note: transurethral resection of the prostate (TURP), transurethral resection of bladder tumour (TURBT), rigid cystoscopy under general anaesthesia, and insertion of ureteric stent should be included.

## Appendix B: Case Report Forms (CRF)

In the CRF the sections in grey will become available via branching logic if triggered by prior data entry.

Demographic and pre-operative data		
1.1	Period operated in	1, Period 1 (00:00 31 <sup>st</sup> August 2026 – 23:59 6 <sup>th</sup> September 2026)   2, Period 2 (00:00 7 <sup>th</sup> September 2026 – 23:59 13 <sup>th</sup> September 2026)   3, Period 3 (00:00 14 <sup>th</sup> September 2026 – 23:59 20 <sup>th</sup> September 2026)   4, Period 4 (00:00 21 <sup>st</sup> September 2026 – 23:59 27 <sup>th</sup> September 2026)   5, Period 5 (00:00 28 <sup>th</sup> September 2026 – 23:59 4 <sup>th</sup> October 2026)   6, Period 6 (00:00 5 <sup>th</sup> October 2026 – 23:59 11 <sup>th</sup> October 2026)
2.1	Sex	1, Female   2, Male
2.2	If female and age 10-59: pregnancy status	1, No   2, Yes – first trimester (<13 weeks)   3, Yes – second trimester (13-28 weeks)   3, Yes – third trimester (>28 weeks)
3.1	Age	1, <52 weeks   2, 1-4 years   3, 5-9 years   4, 10-17 years   5, 18-29 years   6, 30-39 years   7, 40-49 years   8, 50-59 years   9, 60-69 years   10, 70-79 years   11, 80-89 years   12, 90 years or more
4.1	ASA	1, Grade I   2, Grade II   3, Grade III   4, Grade IV   5, Grade V   6, Grade VI
5.1	BMI (Link to calculator: <a href="https://extras.bhf.org.uk/patientinfo/bmi-v1.01/app/index.html">https://extras.bhf.org.uk/patientinfo/bmi-v1.01/app/index.html</a> )	<Integer value>
6.1	Co-morbidities (Please tick all that apply)	1, Ischaemic heart disease   2, Congestive heart failure   3, Cerebrovascular disease   4, Diabetes mellitus – insulin dependent   5, Diabetes mellitus – non-insulin dependent   6, Chronic kidney disease (baseline creatinine >176.8 µmol/L or >2 mg/dL)   7, Human immunodeficiency virus (HIV)   8, Hypertension   9, None of the above
6.2	If HIV: HIV status	1, Untreated HIV   2, HIV with CD4 cell count <200 cells/mm <sup>3</sup>   3, HIV with CD4 cell count 200-500 cells/mm <sup>3</sup>   HIV with CD4 cell count >500 cells/mm <sup>3</sup>   HIV with CD4 cell count unknown
7.1	Clinical frailty score ( <a href="https://www.bgs.org.uk/sites/default/files/content/attachment/2018-07-05/rockwood_cfs.pdf">https://www.bgs.org.uk/sites/default/files/content/attachment/2018-07-05/rockwood_cfs.pdf</a> )	1, 1 – Very fit   2, 2 – Well   3, 3 – Managing well   4, 4 – Vulnerable   5, 5 – Mildly frail   6, 6 – Moderately frail   7, 7 – Severely frail – completely dependent for personal care   8, 8 – Very severely frail   9, 9 – Terminally ill
8.1	Smoking status (Please tick all that apply)	1, No – never smoked   2, No – ex smoker, stopped ≥ 6 weeks ago   3, No – stopped in the last 6 weeks   4, Yes – current smoker   5, No – previously vaped, stopped ≥ 6 weeks ago   6, No – previously vaped, stopped in the last 6 weeks   7, Yes – currently vapes
9.1	Type of admission	1, Elective (surgery on a planned admission)   2, Emergency (surgery on an unplanned admission)
10.1	Indication for surgery	1, Benign   2, Malignant / pre-malignant   3, Trauma   4, Obstetrics
10.2	If malignant: Intent of this operation	1, Curative   2, Palliative
10.3	If malignant: Extent of malignancy	0, Pre-malignant   1, Primary only   2, Nodal metastases   3, Distant metastases   4, Not staged
10.4	If trauma: Mechanism of injury (Please tick all that apply)	1, Fall less than 2 metres   2, Fall more than 2 metres   3, Road traffic collision – occupant   4, Road traffic collision – pedestrian   5, Road traffic collision – cyclist   6, Gunshot   7, Stab   8, Other penetrating injury (not gunshot/stab)   9, Assault – blunt force   10, Blast / explosion   11, Crush injury   12, Industrial / Occupational   13, Animal bite   14, Sport related   15, Burns or thermal injury   16, Self harm   17, Other (specify)
10.5	If trauma: Identify all injuries (Please tick all that apply)	1, Single acute fracture   2, Multiple acute fractures   3, Hand injury   4, Traumatic brain injury   5, Skull fracture   6, Facial fracture   7, Neck injury (vascular/airway)   8, Rib fractures   9, Pneumothorax/Haemothorax   10, Lung contusion   11, Cardiac injury   12, Abdominal solid organ injury   13, Abdominal hollow viscus injury   14, Vertebral fracture   15, Spinal cord injury   16, Upper limb dislocation   17, Upper limb soft tissue injury   18, Lower limb dislocation   19, Lower limb soft tissue injury   20, Vascular injury   21, Nerve injury
11.1	Body region of main operation	1, Head and neck   2, Thorax   3, Abdomen   4, Pelvis   5, Upper limb   6, Lower limb   7, Spine
12.1	Describe the indication for the operation: (For example: perforated duodenal ulcer, symptomatic inguinal hernia, fractured neck of femur, hip replacement for osteoarthritis, obstructing ureteric stone with sepsis, bladder tumour, foetal distress in labour, patient choice for caesarean section etc.)	<Free text>
9.2	If emergency admission: On presentation, was the patient septic?	0, No   1, Yes
9.2a	If sepsis: Duration of time from identification of suspected sepsis to first antibiotics being given	1, <30 minutes   2, 30-59 minutes   3, 60-119 minutes   4, 120 minutes - 24 hours   5, No antibiotics given within 24 hours
9.3	If emergency admission: On presentation were their signs of shock?	0, No   1, Yes
9.4	If emergency admission: Time of symptom onset / injury to presentation to hospital	1, Under 12 hours   2, 12-23 hours   3, 24-47 hours   4, 48-71 hours   5, 72 hours or more
9.5	If emergency admission: Time from presentation to hospital to review by surgical team	1, <1 hour   2, 1-2 hours   3, 3-6 hours   4, 7-12 hours   5, 13-24 hours   6, Over 24 hours   7, Unknown
9.6	If emergency admission: Time from review by surgical team to decision for operation	1, <1 hour   2, 1-2 hours   3, 3-6 hours   4, 7-12 hours   5, 13-24 hours   6, Over 24 hours   7, Unknown
9.7	If emergency admission: Duration of time from decision to operate (booking of theatre case) to patient arrival in theatre	1, <2 hours   2, 2 - 6 hours   3, 7-18 hours   4, >18 hours
9.8	If emergency admission: What was the intended window from booking the case to the operation?	1, <2 hours   2, 2 - 6 hours   3, 7-18 hours   4, >18 hours   5, No window set   6, Unknown
9.9	If emergency admission: Immediately prior to attending this hospital, did patient seek care from anywhere else? (Please tick all that apply)	0, No   1, Yes – Traditional or faith healer   2, Yes - Community health worker   3, Yes - Family/primary care doctor   4, Yes - Another hospital (transferred) this patient to this hospital   5, Yes – Other   6, Unknown
9.9a	If transfer from another hospital: What was the reason for hospital transfer? (Please tick all that apply)	1, For input from a surgical speciality not available at referring hospital   2, No surgeon at referring hospital   3, Anaesthetic requirement   4, No operating theatre   5, HDU or ITU requirements   6, Diagnostics; for example no CT scanner   7, Interventional radiology unavailable   8, Blood product availability   9, Equipment limitations (robot/laparoscopy/stapling devices etc)   10, Complexity requires tertiary

		centre (i.e. patient factors)   11, External disruption; for example power issues, flooding, staff strikes   12, Financial constraints   13, Other, please specify
9.10	If elective admission: How many days passed between the patient being booked for the operation to having the operation?	<Integer value (days)>

Intra-operative		
13.1	Was the WHO Safer surgery checklist used in theatre?	0, No   1, Yes
14.1	Grade of the most senior surgeon in theatre	1, Consultant or equivalent   2, Doctor/surgeon with 3 or more years of experience   3, Doctor/surgeon with 1-2 years of experience   4, Non-physician
15.1	Grade of primary surgeon (Defined as performing over 50% of the critical operative steps)	1, Consultant or equivalent   2, Doctor/surgeon with 3 or more years of experience   3, Doctor/surgeon with 1-2 years of experience   4, Non-physician
16.1	Grade of the most senior anaesthetist in theatre	1, Consultant or equivalent   2, Doctor/surgeon with 3 or more years of experience   3, Doctor/surgeon with 1-2 years of experience   4, Non-physician
17.1	Type(s) of anaesthesia (Please tick all that apply)	1, General (gaseous)   2, General (total intravenous)   3, Neuraxial - epidural   4, Neuraxial - spinal   5, Regional nerve block   6, Sedation   7, Local anaesthetic   8, None
18.1	Time of knife to skin (start of operation)	1, 08:00-17:59   2, 18:00-23:59   3, 00:00-07:59
19.1	Main operation	See drop down list
20.1	Planned initial operative approach	1, Open   2, Standard minimally invasive (e.g. laparoscopic, thoracoscopic or equivalent video-assisted technique excluding robotic assisted)   3, Robotic assisted   4, Hybrid minimally invasive / open   5, Endoluminal   6, Natural orifice transluminal
21.1	Final (completion) surgical approach	1, Open   2, Standard minimally invasive (e.g. laparoscopic/thoracoscopic or equivalent video-assisted technique excluding robotic assisted)   3, Robotic assisted   4, Hybrid minimally invasive / open   5, Endoluminal   6, Natural orifice transluminal
22.1	Degree of intra-operative contamination	1, Clean   2, Clean-contaminated   3, Contaminated   4, Dirty
23.1	How was the main surgical wound closed?	1, Primary closure   2, Left to heal by secondary intention
24.1	What dressing was used for the main surgical wound?	1, Antimicrobial (e.g. iodine, silver)   2, Negative pressure (e.g. VAC, PICO)   3, Glue-containing (e.g. Prineo)   4, Simple dressing only   5, No dressing
23.2	If wound healing by secondary intention: Location of the wound left to heal by secondary intention	1, Foot   2, Leg   3, Abdomen   4, Other
25.1	Skin preparation (Please tick all that apply)	1, Chlorhexidine in alcohol   2, Aqueous chlorhexidine   3, Povidone-iodine (aqueous)   4, Povidone-iodine in alcohol   5, Alcohol only   6, Olanexidein   7, Ioban drape or equivalent   8, Other, please specify   9, Unknown
26.1	Were there any power outages during the operation?	0, No   1, Yes, 1-14 minutes total power outage   2, Yes 15-29 minutes total power outage   3, Yes, 30-59 minutes total power outage   4, Yes, > 1-hour total power outage   5, Not sure
26.2	If there was a power outage: Did this result in any change of procedure?	0, No   1, Conversion from minimally invasive to open   2, Abandoned procedure objective   3, Alternative procedure performed   4, Other (please specify)
26.3	If there was a power outage: What was the impact to the patient?	1, No impact   2, Minor complication   3, Moderate complication   4, Life-threatening complications

Post-operative data		
27.1	How was 30-day follow-up completed? (Tick all that apply)	1, In-person clinic follow-up   2, Telephone/video call   3, Hospital record review
27.2	If follow-up in person or telephone/video: On what post-operative day did the patient return to normal activity? (This could include work, care or community roles)  (If the patient has not returned to normal activity, please enter 99)	<Integer value (days)>
28.1	30-day Clavien-Dindo grade	1, Grade I   2, Grade II   3, Grade IIIa   4, Grade IIIb   5, Grade IV a   6, Grade IV b   Grade V   99, No complications
28.2	If 30-day complication: Which post-operative complication(s) did the patient have? (Please tick all that apply)	1, Surgical site infection or fracture-related infection   2, Deep organ space infection   3, Pneumonia   4, Unexpected ventilation   5, Acute respiratory distress syndrome (ARDS)   6, Pulmonary embolism   7, Deep vein thrombosis   8, Myocardial infarction   9, Anastomotic leak   10, Acute kidney injury resulting in dialysis   11, Wound dehiscence   99, None of the above
29.1	30-day reoperation	0, No   1, Yes, planned re-operation   2, Yes, unplanned re-operation   Yes, both planned and unplanned re-operations
30.1	Post-operative length of stay (days) (Day 0 is the day of operation)	<Integer value (days)>
31.1	30-day hospital re-admission	0, No   1, Yes
31.2	If re-admitted: Length of readmission stay (If discharged on the same day as readmission then enter 0)	<Integer value (days)>
32.1	Was the patient admitted to critical care (high dependency unit or intensive care unit)?	0, No - not required   1, No - planned to go to critical care but no bed available   2, Yes - planned from theatre   3, Yes - unplanned from theatre   4, Yes - unplanned from ward
32.2	If critical care admission: Critical care unit length of stay.	<Integer value (days)>
33.1	Did you patient have an enhanced recovery after surgery (ERAS) protocol or equivalent?	0, No   1, Yes
10.6	If malignancy: Was histology performed?	1, Not performed   2, No specimen   3, Yes – benign   4, Yes – malignant with R0 resection margin   5, Yes – malignant with R1 resection margin   6, Yes – malignant with R2 resection margin   7, Yes – malignant but no resection margin provided
34.1	Did the patient receive antibiotics at induction of anaesthesia?	1, Yes, at induction of anaesthesia   2, No, but had a dose within the previous 8 hours   3, No and did not have any antibiotics in the preceding 8 hours.
35.1	On how many postoperative days within 30 days of the operation did the patient receive at least one dose of antibiotics	<Integer value (days)>
36.1	Did the patient have a wound swab sent for microbiology?	0, No   1, Yes, but no growth on any specimens   2, Yes, growth on one or more specimens but organisms with no antimicrobial resistances   3, Yes, growth of organisms in one or more specimens with antimicrobial resistance
36.2	If 36.1 is option 3, which organisms had resistance to antibiotics? (Please tick all that apply):	Enterobacteriales: 1, Escherichia (e.g. E. coli)   2, Klebsiella (e.g. K. pneumoniae)   3, Enterobacter   4, Proteus  Specific resistances: 5, ESBL-producing Enterobacteriales (e.g. E. coli, Klebsiella)   6, Carbapenem-resistant Enterobacteriales (CRE)   7, Pseudomonas aeruginosa (multidrug-resistant)   8, MRSA (Methicillin-resistant Staph aureus)   9, VRE (Vancomycin-resistant Enterococcus)  Anaerobes: 10, Bacteroides fragilis   11, Other Bacteroides spp.   12, Peptostreptococcus   13, Clostridium spp.  Other: 14, Gram negative   15, Enterococcus  16, Other not listed, please specify
37.1	How was the majority of the cost of surgery supported?	1, Insurance provided by the government (national or regional level)   2, Insurance provided by employer (or household members' employer)   3, Insurance that the patient has privately arranged and paid for   4, Insurance but unknown how this was arranged   5, External funds or grants awarded by charities/NGOs   6, Out-of-pocket payments (patient paid the hospital directly)   7, Free at the point of use (e.g. UK National Health Service)
37.2	If option 1-5 from 'how was the majority of the cost of surgery supported: Did the patient pay anything out of pocket?	0, No   1, Yes
37.3	Did an inability to pay result in a delay to the patient having an operation?	0, No   1, Yes

If operative approach is robotic (branch from question 20.1 and Question 21.1)	
Robotic platform	1, da Vinci Xi   2, da Vinci X   3, da Vinci Si   4, da Vinci 5   5, Versius   6, Hugo RAS   7, Senhance   8, Moon   9, KangDuo/KD-Surgibot   10, Tourmai/Rebo   11, Hinotori   12, ROSA robotic system   13, Sina surgical system   14, Microport   15, Sentire surgical system   16, Mako robotic-arm assisted surgery system   17, Ottava surgical system   18, SSi Mantra   19, Single-port system (please specify)   20, Other ( please specify)
If no robot had been available today, what would have been done for this patient?	1, Cancel this operation   2, Open surgery   3, Laparoscopic or other minimally invasive equivalent surgery
Was team briefing completed, including plans for emergency undocking and system failure?	0, No   1, Yes
Lifetime number of robotic cases for the console surgeon	1, 0   2, 1-10   3, 11-25   4, 26-50   5, 51-100   6, Over 100
Grade of the bedside assistant	1, Consultant or equivalent   2, Doctor/surgeon with 3 or more years of experience   3, Doctor/surgeon with 1-2 years of experience   4, Non-physician
Was a proctor present?	0, No   1, Yes
Was a dual console used?	1, No   2, Yes - Trainee at second console   3, Yes - Consultant at second console   4, Yes - Proctor at second console
Was telepresence (remote input) used?	1, Not available   2, Available, but not used   3, Used - Lead surgeon   4, Used - Second surgeon   5, Used - Proctor   6, Used - Observer
What was the docking time (from start of prep and draping to being fully docked) in minutes?	Free text
What was the console time (from docking to undocking the robot) in minutes?	Free text
What was the overall theatre time (from patient being wheeled into theatre to being wheeled out of theatre) in minutes?	Free text
What was your port configuration?	1, Robotic-specific layout   2, Same as standard laparoscopic/thoracoscopic or equivalent   3, Single-port   4, Other (please specify)
Did you use a wristed stapler?	0, No   1, Yes   99, Unknown
Primary energy source	1, Monopolar and bipolar   2, Advanced bipolar   3, Ultrasonic   4, Combination (please specify)   5, Unknown
Was fluorescence imaging (e.g. ICG - indocyanine green) used?	0, No   1, Yes - No change to procedure   2, Yes - Led to change in procedure
Did you experience failure of any of the following during the operation?	1, Instrument wrist or tool tip   2, Cautery problem   3, Shaft failure   4, Cable failure   5, Housing failure
Was there additional laparoscopic/thoracoscopic or equivalent assistance required beyond what was planned initially?	0, No   1, Yes
If converted: what was the reason for conversion?	1, Bleeding   2, Poor exposure   3, Equipment malfunction   4, Progress too slow   5, Oncological concerns   6, Other (please specify)
How many other major cases are on your list today?	Free text
How many other minor cases are on your list today?	Free text
Compared with the approach you would have otherwise used (laparoscopic or equivalent or open), how did the robotic case affect your musculoskeletal comfort?	1, Much worse than alternative   2, Worse than alternative   3, No difference   4, Better than alternative   5, Much better than alternative   99, Unable to answer
Was there a trainee involved in the operative console in this case?	1, No   2, Yes

<b>If abdominal operation (branch from question 11.1 – excluding caesarean section)</b>	
Has the patient had previous abdominal surgery?	0, No   1, Yes, open surgery   2, Yes, minimally invasive surgery   3, Yes, open and minimally invasive surgery
If open: Incision	1, Vertical midline   2, Paramedian   3, Transverse   4, Oblique (e.g. Kocher / McBurney)   5, Flank   6, Pfannenstiel   7, Chevron/Rooftop   8, Thoraco-abdominal   9, Not applicable
If standard minimally invasive, robotic assisted: – Was there an extraction site?	0, No   1, Yes - Vertical midline   2, Yes - Paramedian   3, Yes - Transverse   4, Yes - Oblique (e.g. Kocher / McBurney)   5, Yes - Flank   6, Yes - Pfannenstiel   7, Yes - Chevron/Rooftop   8, Yes - Thoraco-abdominal   9, Yes - Other
Was a stoma created? (Please tick all that apply)	0, No   1, Yes - end ileostomy   2, Yes - loop ileostomy   3, Yes - double-barrelled ileostomy   4, Yes - end colostomy   5, Yes - loop colostomy   6, Yes - double-barrelled colostomy   7, Yes - urostomy   8, Yes - mucus fistula   9, Other, please specify
Was a bowel anastomosis performed?	1, No   2, Yes - Stapled and intracorporeal   3, Yes - Stapled and extracorporeal   4, Yes - handsewn and intracorporeal   5, Yes - handsewn and extracorporeal
Did any of the following intra-operative complications occur?	1, Operating time >4h   2, Solid organ or ureteric injury   3, Vascular injury   4, Blood transfusion   5, Haemodynamic instability   6, Vasopressor requirement   7, None of the above
Was tranexamic acid used intra-operatively?	0, No   1, Yes - given prophylactically on induction   2, Yes - given in response to bleeding
If colonic resection: Did the patient have mechanical bowel preparation pre-operatively	0, No   1, Yes
If clean-contaminated/ contaminated/ dirty abdominal operation: Were gloves and instruments changed prior to abdominal wall closure?	0, No   1, Yes
If open or extraction site: What suture was used for fascial closure of the incision	1, PDS   2, PDS Plus   3, Prolene   4, Vicryl   5, Vicryl Plus   6, Catgut   7, Maxon   8, Nylon   9, Other   10, Unknown
If open or extraction site: Was the fascial closure technique: (Please tick all that apply)	1, Continuous running suture   2, Interrupted sutures   3, Small bite technique   4, Large bite technique   5, Unknown
If laparoscopic or robotic assisted abdominal operation: Which port sites were closed at fascial level?	0, None   1, All ports sized 5mm and above   2, All ports sized 8mm and above   3, All ports sized 10mm and above
If ports closed: How were these ports closed at fascial level?	1, Vicryl   2, Vicryl plus   3, PDS   4, PDS plus   5, Prolene   6, Maxon   7, Nylon   8, Triclosan impregnated/coated   9, Other, please specify
How was the skin closed	1, Staples   2, Interrupted sutures   3, Subcuticular suture   4, Skin glue   5, Left open or delayed closure
Did the patient experience any of the following post-operative complications? (Please tick all that apply)	1, Stoma complications (high output/prolapse/necrosis)   2, Wound dehiscence   3, Line associated infection   4, Ileus   5, Intra-abdominal collection   6, Fistula (enterocutaneous/enteroenteric)   7, Hernia   8, Stroke   9, Acute Kidney injury   10, Electrolyte disturbance   11, Adhesive small bowel obstruction   12, Reintubation   13, Mechanical ventilation   14, Septic shock   15, Blood transfusion   16, None of the above
<b>If Emergency laparotomy (Branch from Question 9.1, 11.1, 20.1 and 21.1) (excluding appendicectomy or cholecystectomy)</b>	
Was the patient seen by or discussed with a Consultant or equivalent surgeon prior to a decision to operate?	0, Not seen or discussed with a Consultant or equivalent surgeon   1, Patient discussed with a Consultant or equivalent surgeon   2, Patient seen by a Consultant or equivalent surgeon
Was the patient seen by or discussed with a Consultant anaesthetist or equivalent prior to the operation?	0, Not seen or discussed with a Consultant or equivalent anaesthetist   1, Patient discussed with a Consultant or equivalent anaesthetist   2, Patient seen by a Consultant or equivalent anaesthetist
Did the patient have a CT scan pre-operatively?	0, No   1, Yes
Was a risk prediction model used before the operation to predict post-operative mortality?	0, No   1, Yes
Did the patient have a history of active cancer in the last 5 years?	0, No   1, Yes
What was the indication for the laparotomy? (Please tick all that apply)	1, Perforation – Oesophagus   2, Perforation – Stomach   3, Perforation – Duodenum   4, Perforation – Small bowel   5, Perforation – Large bowel   6, Perforation - other  7, Sepsis – perforation   8, Sepsis – anastomotic leak   9, Sepsis – abdominal abscess   10, Sepsis – intestinal fistula   11, Sepsis – iatrogenic injury   12, Sepsis – not specified  13, Obstruction - Tender small bowel obstruction   14, Obstruction - Non-tender small bowel obstruction   15, Obstruction - Tender large bowel obstruction   16, Obstruction - Non-tender large bowel obstruction   17, Obstruction - Gastric outlet obstruction   18, Obstruction - Incarcerated/strangulated hernia   19, Obstruction - Hiatus hernia / para-oesophageal hernia   20, Obstruction - Volvulus   21, Obstruction - Internal hernia   22, Obstruction - Incisional hernia   23, Obstruction - Intussusception   24, Obstruction - Pseudo-obstruction   25, Obstruction - Foreign body    26, Ischaemia – small bowel   27, Ischaemia – large bowel   28, Ischaemia – stomach   29, Ischaemia – oesophagus   30, Ischaemia – other  31, Other – abdominal wall dehiscence   32, Other – bleeding or haemorrhage   33, Other – abdominal compartment syndrome   34, Other - colitis   35, Other – planned re look laparotomy   36, Other-specify
Did the patient have a white cell count and/or CRP tested?	0, No   1, White cell count   2, CRP

(Tick all that apply)	
If WCC above: White cell count (x10 <sup>9</sup> /L) (Please record the value closest to the time of decision to operate/booking patient for theatre)	Free text
If CRP above: C-Reactive Protein (CRP) (mg/L) (Please record the value closest to the time of decision to operate/booking patient for theatre)	Free text
Did the patient have a blood lactate tested?	1, No - cannot measure in our hospital   2, No - can measure in our hospital, but not performed   3, Yes – arterial blood gas   4, Yes- venous blood gas
If blood lactate: What was the blood lactate?	Number
If adult: Estimated blood loss	1, < 100 ml   2, 100-500 ml   3, 501-1000 ml   4, >1000 ml
If child: Estimated blood loss as percentage of estimate blood volume	1, <5%   2, 5-10%   3, 11-20%   4, >20%
Was the abdomen left open at the end of the operation i.e. a damage control laparotomy?	0, No   1, Yes
If the abdomen was left open: how many more re-look laparotomies did the patient undergo?	Free text
If the abdomen was left open: Which technique was used for the open abdomen at the primary operation?	1, Traditional temporary abdominal closure methods, including but not limited to Bogota bag, opsite sandwich etc.   2, Vacuum-assisted or negative pressure therapy device   3, Mesh mediated or dynamic fascial closure techniques   4, Skin-only closure options   7, Other (please specify)
If the abdomen was left open: What was the closure technique for the open abdomen at the final relook laparotomy?	1, Primary fascial closure   2, Mesh mediated or assisted fascial closure   3, Component separation techniques   4, Bridged fascial closure (when midline cannot be closed)   5, Skin only closure   6, Other (please specify)
What was the frequency of post-operative observations for the first 24 hours following the operation? (Observations include blood pressure, heart rate, temperature, oxygen saturations, respiratory rate and conscious level)	0, No observations done in the first 24 hours   1, Observations done between every 0-4 hours   2, More than 4 hours between each set of observations
When were they first reviewed by a Consultant or equivalent surgeon following the operation?	1, Within 6 hours   2, Over 6 hours but less than 12 hours   3, Over 12 hours but less than 24 hours   4, Over 24 hours   5, Not reviewed by a Consultant or equivalent surgeon in the post-operative period

<b>If procedure is Caesarean delivery/section (branch from question 19.1)</b>	
Gravida (number of pregnancies including this pregnancy)	Free text
Parity (number of previous births after 24 weeks gestation)	Free text
Number of previous caesarean deliveries	Free text
Previous uterine surgery (other than caesarean deliveries)	0, No   1, Yes
Current pregnancy (weeks)	Free text
Current pregnancy (days)	Free text
Maternal complications during pregnancy	1, Anaemia   2, Pre-eclampsia   3, Antepartum haemorrhage   4, Diabetes in pregnancy (gestational)   5, Suspected placenta praevia or placenta accreta spectrum   6, None of the above
Was the woman in labour prior to Caesarean delivery?	0, No   1, Yes - 1st stage   2, Yes - 2nd stage
Was the labour induced or spontaneous?	1, Induced   2, Spontaneous
Category of urgency	1, Immediate threat to life   2, Maternal or foetal compromise, but not immediately life threatening   3, Needing early delivery but no compromise   4, Elective
If labour occurred: Maternal complications during labour (Tick all that apply)	1, Failure induction of labour   2, Placental abruption   3, Delay in first stage   4, Delay in second stage   5, PROM >24 hours   6, Infection (e.g. chorioamnionitis)   7, Failed instrumental birth   8, Obstructed labour   9, Suspected uterine rupture   10, None   11, Other (please specify)
Main indication for Caesarean delivery	1, Failure to progress / labour dystocia   2, Failed induction of labour   3, Suspected foetal compromise   4, Malpresentation   5, Twin pregnancy   6, Previous Caesarean delivery with contraindication to VBAC   7, Maternal medical conditions   8, Obstructed labour / cephalopelvic disproportion   9, Placenta Praevia (major) & Placenta Accreta spectrum   10, Placenta abruption   11, Suspected uterine rupture   12, Cord prolapse   13, Maternal request   14, Severe foetal macrosomia   15, Other, please specify
Type of skin incision	1, Transverse (Joel Cohen / Pfannenstiel)   2, Midline vertical
Pre-operative haemoglobin (gram/litre)	Free text
Were uterotonics given to prevent post-partum haemorrhage?	0, No   1, Yes
Intra-operative blood loss (millilitres)	Free text

Was blood loss measured or estimated	1, Measured (quantified)   2, Estimated (visual)   3, Mixed (partly measured, partly estimated)   4, Unknown
Did the patient have a post-partum haemorrhage?	0, No   1, Yes - primary post-partum haemorrhage   2, Yes - secondary post-partum haemorrhage   3, Yes - primary and secondary post-partum haemorrhage
Additional blood loss after surgery (ml) up to 24 hours postpartum	Free text
What measures were taken to treat the post-partum haemorrhage? (Tick all that apply)	1, Additional uterotonics   2, Artery ligation   3, Balloon tamponade   4, Compression suture (e.g. b-lynch)   5, Hysterectomy   6, Blood transfusion   7, None of the above
Was uterine rupture confirmed at caesarean delivery?	0, No   1, Yes
Did any of the following intra-operative complications occur? (Tick all that apply)	1, Uterine angle extension   2, Impacted foetal head   3, Bladder injury   4, Bowel injury   5, Ureteric injury   6, None of the above
Did the woman had post-operative sepsis, if so, what was the source of this?	0, No   1, Yes - surgical site infection   2, Yes - intra-abdominal sepsis   3, Yes - endometritis   4, Yes - urinary tract   5, Yes - chest source   6, Yes - other (please specify)   7, Yes - unknown
Post delivery haemoglobin (gram/litre)	Free text
Did the woman receive a blood transfusion after Caesarean delivery but before discharge?	0, No   1, Yes
If return to theatre: What was the reason for return to theatre?	1, Repair of wound dehiscence   2, Treatment of post-partum haemorrhage   3, Treatment for sepsis   4, Repair of organ injury   5, Other (please specify)
Length of hospital stay following caesarean section	Free text
Number of foetuses in pregnancy?	1, 1   2, 2   3, 3
Presentation of baby at birth	1, Cephalic   2, Breech   3, Shoulder
Apgar score at 1 minute	Free text
Apgar score at 5 minutes	Free text
Was the baby admitted to the neonatal unit?	0, No   1, Yes
Did the baby suffer any of the following complications within 30 days of birth?	1, Birth asphyxia   2, Seizures   3, Skin laceration   4, Cephalohaematoma   5, Skull fracture   6, Brachial plexus injury   7, Neonatal death   8, None   9, Other (please specify)

<b>If the patient had a fracture or hand injury (branch from question 10.5)</b>	
Please identify all the patient's fracture locations. (Tick all that apply)	1, Humerus   2, Radius/Ulna   3, Femur   4, Tibia/Fibula   5, Hand   6, Paediatric nail bed injury (Age ≤16 years)   7, Finger laceration with digital nerve injury   8, Pelvis/Acetabulum   9, Foot   10, Spine   11, Other (please specify)
Was this revision surgery?	0, No   1, Yes
If femoral fracture: What is the location of the femoral fracture?	31, Proximal   32, Diaphyseal   33, Distal
If 31 Proximal: What kind?	31B (Intracapsular)   31A1/A2 (Extracapsular, Peritrochanteric)   31A3 (Intertrochanteric/ Reverse Oblique)
If femoral fracture: Was this an open fracture of the femur?	0, No   1, Yes
If tibia/fibula fracture: What is the location of the tibia/fibula fracture?	41, Proximal   42, Diaphyseal   43, Distal   44, Malleolar segment (Ankle)
If tibia/fibula fracture: Was this an open fracture of the tibia/fibula?	0, No   1, Yes
If hand fracture: What is the location of the hand fracture?	51, Carpal bones   52, Metacarpals   53, Phalanges
If hand fracture: Was this an open fracture of the hand?	0, No   1, Yes
If pelvic fracture: What is the location of the pelvic fracture?	61, Pelvic ring   62, Acetabulum
If pelvic fracture: Was this an open fracture of the pelvis?	0, No   1, Yes
<b>If it is an ankle fracture (Branch from 44)</b>	
Documented peripheral neuropathy?	0, No   1, Yes
Malleolar involvement (tick all that apply)	0, None (isolated syndesmosis injury)   1, Lateral   2, Medial   3, Posterior
Type of definitive fixation	1, Plates and screws   2, Fibular nail   3, Hindfoot nail   4, External fixator (non-circular)   5, Circular / Hexapod frame   6, Cast   7, Other
Was the syndesmosis fixed?	1, No   2, Yes – rigid fixation (screw)   3, Yes – Flexible fixation (tightrope)
If yes: Was the posterior malleolus fixed?	0, No   1, Yes
Total time intended restricted/non-weight bearing from surgery? (days)	Free text
Intended immobilisation once unrestricted weight bearing	0, None   1, Cast   2, Boot   3, Other

<b>If it is an open fracture (Branch from any open fracture above)</b>	
What is the Gustillo-Anderson Classification of the fracture?	1, 1   2, 2   3, 3a   4, 3b   5, 3c
Type of irrigation at debridement	1, Saline only   2, Water   3, Soapy   4, Including betadine   5, Other
What skeletal stabilisation was completed at the time of initial debridement?	1, Definitive stabilisation   2, Provisional stabilisation
Provisional method employed	1, Cast   2, External fixator (non-circular)   3, Circular / Hexapod frame   4, Internal fixation   5, Nothing   6, Removal splint   7, Mono-lateral Exfix + cast
Definitive fixation at initial debridement	1, Amputation   2, Cast   3, External fixator (non-circular)   4, Circular / Hexapod frame   5, Intramedullary nail   6, Plate / screws   7, K wires   8, Mono-lateral ExFix + cast
Definitive method of skeletal stabilisation if not at initial surgery	1, Amputation   2, Cast   3, External fixator (non-circular)   4, Circular / Hexapod frame   5, Intramedullary nail   6, Plate / screws   7, K wires   8, Mono-lateral ExFix + cast
Was a definitive closure achieved at initial debridement?	0, No   1, Yes
If no: what type of wound dressing	1, Negative pressure   2, Standard dressing (not negative pressure)   3, Honey   4, Other (specify)
What was the method employed for definitive closure?	1, Primary closure (at index procedure)   2, Delayed primary closure (i.e. not at index procedure)   3, Skin graft only   4, Local muscle flap (e.g. gastrocnemius, peroneus brevis)   5, Local fasciocutaneous flap (e.g. keystone or propellar)   6, Free flap – fasciocutaneous (ALT, groin flap etc)   7, Free flap – free muscle flap with skin graft (latissimus dorsi, gracilis etc)   8, Left of heal by secondary intention
If primary or delayed closure, was any bone shortening or deformation undertaken	0, No   1, Yes
What was the total number of operations this patient underwent?	Free text
How many days were there between the initial operation and final operation?	Free text
For how long were antibiotics continued following definitive closure (days)	Free text
<b>If hip fracture (Branch from 31B)</b>	
Did the patient receive a hip hemiarthroplasty	0, No   1, Yes
If yes: approach	1. Anterior   2. Anterolateral   3. Posterior   4. Other
If yes: what was the implant	1. Cemented   2. Uncemented
If yes: what was the cement	1. No antibiotic   2. Single antibiotic   3. Dual antibiotic
<b>If hip fracture (Branch from 31A1/2 or 31A3)</b>	
Was the implant	1. Short nail   2. Long nail   3. Sliding hip screw   4. Other
If SHS: was a trochanteric stabilisation plate used?	0, No   1, Yes
<b>If closed tibial fracture (Branch from tib/fib 41, Proximal   42, Diaphyseal   43, Distal and closed)</b>	
Was the fracture fixed with	1, Intramedullary nail   2, Plate / screws   3, External fixator (non-circular)   4, Circular / Hexapod frame   5, K wires   6, Amputation
If external fixator was used: was this	1. A temporary fixator   2. Definitive external fixation
<b>If hand surgery (Branch from fracture locations – 6,7)</b>	
Following repair of the nailbed was the nail plate re-affixed to the nail bed?	0, No   1, Yes
Was the digital nerve directly repaired (with sutures)?	0, No   1, Yes
Following alignment of the digital nerve ends, were microsurgical sutures used to directly repair the nerve?	0, No   1, Yes
<b>If Orthopaedic operation</b>	
Were local antibiotics used during any surgery?	0, No   1, Coated implant   2, Topical powder   3, Local antibiotic carrier e.g. beads, cerament (please specify)   4, Irrigation   5, Other (specify)

<b>If Ventriculoperitoneal shunt (branch from question 19.1)</b>	
Hydrocephalus aetiology	1, Malformations (e.g., Spina bifida, Chiari)   2, Aqueduct stenosis   3, Post-haemorrhagic (e.g., SAH in adults, neonatal IVH)   4, Tumour – benign   5, Tumour – malignant   6, Trauma   7, Infection   8, Cyst (e.g., colloid, arachnoid, pineal)   9, Idiopathic intracranial hypertension (IIH)   10, Idiopathic Normal Pressure Hydrocephalus (iNPH)   11, Other (specify)
Birth status (up to 18 years old)	1, Pre-term   2, Term   3, Not known
Does this patient have a concurrent CNS infection or within the last 3 months	0, No   1, Yes
Primary shunt insertion	0, No   1, Yes

If primary shunt insertion is 'No' – revision shunt insertion (components revised)	1, Ventricular catheter   2, Peritoneal catheter   3, Both   4, Neither (just valve)
What shunt catheters are available in your hospital?	1, Antibiotic only   2, Plain only   3, Both antibiotic and plain
Catheters used for shunt surgery	1, Antibiotic   2, Plain
Shunt infection (30-days)	0, No   1, Yes
Postoperative day shunt infection confirmed (Date of operation is day 0)	
Shunt infection within 12 months  (Are you happy to be contacted at 12 months to assess for 12-month shunt infection?)  By ticking yes, you agree to ensure you have the appropriate ethical or regulatory approvals in place and keep the data secure at your hospital (including operation date) and the team running this study module will be in touch closer to the time to assess for 12-month shunt infection)	0, No   1, Yes

<b>If Clavien-Dindo V i.e. mortality (branch from question 28.1)</b>	
On what post-operative day did the patient die? (day 0 is the day of operation)	Free text
Where did the patient die?	1, In hospital which they underwent the index operation   2, In a different hospital to that where they underwent their index operation   3, Out-of-hospital (i.e. at home or in the community)   4, Hospice or equivalent
Was a formal autopsy performed for this patient, and the results available to you?	0, No autopsy performed   1, Autopsy performed, but results not available to me   2, Autopsy performed and results available
Was the case formally reviewed at a departmental Morbidity and Mortality (M&M) meeting or equivalent?	0, No   1, Yes, but the results are not available to me   2, Yes and results available
Cause of death	1, Primary (from the disease)   2, Secondary (complications of an operation)
Please outline the cause of death  If available, please include the cause(s) of death recorded on the death certificate.	Free text
Failure of which organ system using the Advanced Life Support algorithm (ABCDE) predominantly led to this patient's death?	1, Airway, including airway obstruction   2, Breathing, including hypoxia and primary respiratory failure   3, Circulation, including distributive, hypovolaemic, obstructive, cardiogenic and neurogenic shock   4, Disability and exposure, including neurological events, hypo/hyperthermia, toxins, metabolic or electrolyte disturbance   5, Not able to identify a cause of death
Based on the information you have available, was this death preventable?	1, Not preventable   2, Possibly preventable (< 50% likelihood)   3, Probably preventable (>50% likelihood)
Before presentation to hospital, what opportunities or changes in this patient's care may have prevented death? (Tick all that apply)	1, Earlier diagnosis/recognition of disease   2, Better access / affordability of primary assessment   3, Better health seeking behaviours   4, More appropriate triage into secondary care or hospital   5, Optimisation of existing long-term conditions   6, Improved physiological reserve at baseline (prehabilitation)   7, Other (please specify)   8, None of the above
In the pre-operative, but while the patient is in hospital, what opportunities or changes in this patient's care that may have prevented death? (Tick all that apply)	1, Earlier diagnosis / recognition of disease   2, Better access or affordability of assessment   3, Improved communication between staff members or teams in the hospital   4, Improved monitoring / recognition of deterioration   5, Improved access to diagnostic tests and imaging   6, Earlier initial resuscitative treatment   7, Better availability of resuscitative products (e.g., blood, fluids, drugs)   8, Prompt escalation to senior clinician(s)   9, Earlier decision for surgical intervention   10, More operating theatre capacity or better access to operating theatre   11, Admission under the correct speciality team   12, Incorrect decision for surgery – e.g. patient should have been offered a less invasive treatment or non-surgical management or surgery was futile   13, Suboptimal preoperative optimisation; for example lack of recognition of comorbidities, inadequate resuscitation   14, Availability of a higher care environment e.g., high dependency unit or intensive care   15, Improved capacity for non-operative strategies (interventional radiology / endoluminal)   16, Other (please specify)   17, None of the above
In the intra-operative phase, what opportunities or changes in this patient's care may have prevented death? (Tick all that apply)	1, Improved communication between staff members or teams in the hospital   2, More experienced surgeon present in theatre   3, More experienced anaesthetist present in theatre   4, Improved availability of surgeons from other specialities   5, Better availability of resuscitative products (e.g., blood, fluids, drugs)   6, Avoid surgical technical errors   7, Improved surgical decision making   8, Higher quality equipment / avoid equipment failure   9, More stable supply of electricity   10, Wrong operative decision – e.g. colonic anastomosis when should have had stoma   11, Wrong operative approach – open when should be done laparoscopically or reverse   12, Delay in conversion to a different operative approach e.g. laparoscopic converted to open   13, Escalation to senior surgeon   14, Other (please specify)   15, None of the above

<p>Following the operation, but whilst the patient is still in hospital, what opportunities or changes in this patient's care may have prevented death?</p> <p>(Tick all that apply)</p>	<p>1, Availability of a higher care environment e.g., high dependency unit or intensive care unit   2, Earlier diagnosis / recognition of post-operative complication   3, Improved monitoring / recognition of deterioration   4, Improved access to diagnostic tests and imaging   5, Better availability of resuscitative products (e.g., blood, fluids, drugs)   6, Prompt escalation to senior clinician(s)   7, Earlier decision for surgical / endoscopic / radiological / re-intervention   8, More operating theatre capacity or improved access to operating theatre   9, Improved capacity for non-operative rescue strategies (interventional radiology / endoluminal)   10, Improved communication between staff members or teams in the hospital   11, Improved access to rehabilitation   12, Improved symptom relief (pain control, nausea and vomiting)   13, Better access to supplementary nutrition   14, Appropriate VTE prophylaxis or anticoagulation   15, Affordability of treatment or care   16, Incorrect decision for reoperation e.g. should have been offered conservative management or less invasive treatment or surgery was futile   17, Other (please specify)   18, None of the above</p>
<p>Following the operation, after the patient had been discharged from hospital, what opportunities or changes in this patient's care may have prevented death?</p> <p>(Tick all that apply)</p>	<p>1, Earlier diagnosis / recognition of post-operative complication   2, Improved monitoring / recognition of deterioration   3, Better access / affordability of assessment   4, Better health seeking behaviours   5, More appropriate triage back into secondary care/hospital   6, More regular follow-up with the clinical team   7, Improved access to rehabilitation   8, Improved symptom relief (pain control, nausea and vomiting)   9, Better access to supplementary nutrition   10, Appropriate venous thromboembolic prophylaxis or anticoagulation   11, Affordability of treatment or care   12, Other (please specify)   13, None of the above</p>
<p>Advanced presentation of the disease requiring surgery (e.g. advanced cancer, massive hernia)</p>	<p>1, Not present   2, Present, but did not contribute   3, Contributed slightly   4, Contributed moderately   5, Contributed significantly</p>
<p>Unstable physiology at the time of presentation (e.g. shock, hypoxia)</p>	<p>1, Not present   2, Present, but did not contribute   3, Contributed slightly   4, Contributed moderately   5, Contributed significantly</p>
<p>Underlying frailty</p>	<p>1, Not present   2, Present, but did not contribute   3, Contributed slightly   4, Contributed moderately   5, Contributed significantly</p>
<p>Underlying long-term health conditions</p>	<p>1, Not present   2, Present, but did not contribute   3, Contributed slightly   4, Contributed moderately   5, Contributed significantly</p>
<p>What is the source of the above information?</p> <p>(We would recommend using the outcomes of a morbidity and mortality meeting or two independent senior clinician opinions on the case)</p> <p>(Tick all that apply)</p>	<p>0, Data inputter only (including grade)   1, Morbidity and Mortality meeting   2, Two independent senior clinician opinions   3, Other, please specify</p>

## Appendix C: Definitions with referenced question number

### 4.1 ASA Classification of physical status<sup>1</sup>

Class	Definition	Examples
1	Normal health	Healthy, non-smoking, no or minimal alcohol use
2	Mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, 30 < BMI < 40, well-controlled DM/HTN, mild lung disease
3	Severe systemic disease	Substantive functional limitations. One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled M or HTN, COPD, morbid obesity (BMI ≥ 40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction in ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (> 3 months) of MI, CVA, TIA or CAD/stents
4	Severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA or CAD/stents, ongoing cardiac ischaemia or severe valve dysfunction, severe reduction in ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
5	Moribund: survival not expected without surgery	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischaemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
6	Brain-dead organ donor	

BMI, body mass index; DM, diabetes mellitus; ESRD, end-stage renal disease; HTN, hypertension; PCA, post conceptual age; MI, myocardial infarction; CVA, cerebrovascular accident; TIA, transient cerebral ischaemic attack; CAD, coronary artery disease; DIC, disseminated intravascular coagulation; ARD, acute respiratory distress.

## 7.1 Clinical Frailty Scale<sup>2,3</sup>

### Clinical Frailty Scale\*



**1 Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.



**2 Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.



**3 Managing Well** – People whose **medical problems are well controlled**, but are **not regularly active** beyond routine walking.



**4 Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities**. A common complaint is being “slowed up”, and/or being tired during the day.



**5 Mildly Frail** – These people often have **more evident slowing**, and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.



**6 Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.



**7 Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).



**8 Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.



**9. Terminally Ill** - Approaching the end of life. This category applies to people with **a life expectancy <6 months**, who are **not otherwise evidently frail**.

#### Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

\* 1. Canadian Study on Health & Aging, Revised 2008.

2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

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## 9.2. Sepsis

Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. Organ dysfunction can be identified as an acute change in total SOFA (Sequential Organ Failure Assessment) score  $\geq 2$  points consequent to the infection.<sup>4</sup>

## 9.3. Shock

A life-threatening condition of circulatory failure resulting in inadequate tissue perfusion and oxygen delivery, leading to cellular and organ dysfunction. There are 4 types of shock: septic, cardiogenic, hypovolemic and distributive shock. The diagnosis of acute circulatory failure is based on a combination of clinical, hemodynamic and biochemical signs. Clinical findings include hypotension (MAP <65 mmHg), tachycardia, altered mental status, oliguria, and signs of impaired perfusion (e.g., elevated lactate).<sup>5</sup>

**10.1. Malignant disease:** Also referred to as cancer, malignant tumour or neoplasm; disease characterised by abnormal cells that grow uncontrollably, invade nearby tissues, and may spread to other parts of the body (metastasis).<sup>4</sup>

**10.2. Curative surgical procedure:** A surgical intervention performed with the intent to completely remove or eradicate a disease (e.g., cancer), aiming for long-term survival or cure.<sup>5</sup>

**Palliative surgical procedure:** A surgical intervention performed to relieve symptoms, improve quality of life, or manage complications of disease, without the expectation of cure.<sup>5,6</sup>

#### 14.1. Consultant or equivalent

A senior, fully qualified surgeon with independent responsibility for patient care and clinical decision-making, or a clinician of equivalent seniority and authority within the relevant healthcare system. (Adapted from: NHS Employers. “The consultant role and responsibilities”; General Medical Council (GMC) guidance on medical roles and responsibilities.)<sup>9,10</sup>

#### 18.1. Knife to Skin (Start of Operation):

The time point at which the first surgical incision is made in the patient's skin, marking the beginning of the operative procedure.<sup>11,12</sup>

#### 22.1. Contamination levels<sup>13,14,15</sup> :

**Clean:** Respiratory, Genital, GI or GU tracts not entered; no entry into a hollow viscus.

Examples: Hernia repair, elective splenectomy, adhesiolysis, breast surgery, elective hip and knee replacement, abdominal aortic aneurism repair, etc.

**Clean-contaminated:** Respiratory, Genital, GI or GU tracts entered in controlled condition, controlled entry into a hollow viscus; without spillage of contents of GI/GU tract .

Examples: Appendicectomy (non-inflamed), bowel resection, cholecystectomy (no bile spillage), caesarean section, lung resection, etc.

**Contaminated:** Minor spillage of contents of GI/GU tracts, incisions in which acute, nonpurulent inflammation is encountered.

Examples: Appendicectomy (inflamed), cholecystectomy (with bile spillage), necrotic bowel resection (no perforation), penetrating trauma, fresh traumatic wound debridement.

**Dirty:** Gross spillage of contents of GI/GU tracts, peritonitis, established infection.

Examples: Hartmann's procedure for perforated sigmoid colon, laparotomy for perforated gastric ulcer, open fracture, empyema drainage.

### **28.1. Clavien-Dindo Classification System**

Adverse post-operative events may be classified as:

- **Failure of treatment** – This occurs when the original surgery fails to achieve its intended benefits; for example, persistent pain following laparoscopic cholecystectomy or tumour recurrence following cancer surgery.
- **Sequelae**: The recognised consequences of a given procedure; for example, gut malabsorption following a large or small bowel resection or immune deficiency following splenectomy.
- **Complication**: Any deviation from the normal post-operative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

In the Clavien-Dindo classification, the factor determining the severity of a complication is the treatment required<sup>16</sup>. Consequently, a given complication may be graded differently depending on how it has been managed. For example, an anastomotic leak may be managed just with antibiotics if it is contained (grade II) or it may require re-operation under anaesthetic (grade III).

Some other considerations:

- Intra-operative complications are not considered unless they have an adverse effect on the patient post-operatively. The only exception to this is intra-operative death; this is classified as grade V.
- All post-operative adverse events are included, even when there is no direct relationship to the surgery.
- All adverse events within the follow-up period (30 days) are included, including following discharge.
- Diagnostic procedures are not included. For example, a diagnostic oesophagoduodenoscopy (OGD) to look for a source of bleeding without any intervention would not be considered a complication, but a therapeutic OGD with clipping of a bleeding vessel would be considered a grade IIIa complication. Since negative exploratory laparotomies are considered to be diagnostic procedures, they should not be recorded as complications.

Clavien -Dindo Grade	Definition (examples listed in italics)
I	<p>Any deviation from the normal postoperative course without the need for pharmacological (other than “allowed therapeutic regimens”), surgical, endoscopic or radiological intervention.</p> <p>Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics.</p> <p><i>Examples: Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.</i></p>
II	<p>Requiring pharmacological treatment with drugs beyond those allowed for grade I complications; including blood transfusions; total parenteral nutrition.</p> <p><i>Examples: Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia.</i></p>
III	<p>Requiring surgical, endoscopic or radiological intervention</p> <p><i>Examples: Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures; return to theatre for any reason</i></p>
IV	<p>Life-threatening complications requiring critical care management; brain haemorrhage; or ischemic stroke (excluding TIA).</p> <p><i>Examples: Pneumonia with ventilator support, renal failure with filtration; SAH; stroke</i></p>
V	<p>Death of a patient</p>

## 28.2. 30-day Complications:

### Surgical site infections

Surgical site infection is defined at 30 days post-surgery using the Centers for Disease Control (CDC) definition<sup>17</sup> of deep incisional or superficial incisional SSI as follows:

1. The infection must occur within 30 days of the index operation
2. The infection must involve the skin, subcutaneous, muscular, or fascial layers of the incision

3. The patient must have at least one of the following: purulent drainage from the wound; organisms detected by wound swab; diagnosed clinically or at imaging; wound opened spontaneously or by a clinician
4. The patient has at least one of the following: pain, tenderness, localized swelling, redness, heat at the wound site, systemic fever ( $>38^{\circ}\text{C}$ ).

### **Fracture related infection**

A fracture-related infection is an infection arising any time after a fracture. The presence of any one of the following features confirms an FRI (confirmatory criteria):

1. Fistula, sinus or wound breakdown
2. Purulent drainage from the wound or presence of pus during surgery
3. Phenotypically indistinguishable pathogens identified by culture from at least two separate deep tissue/implant specimens
4. Presence of microorganisms in deep tissue taken during an operative intervention, as confirmed by histopathological examination.

Suggestive criteria include: skin redness, fever, radiological signs, new onset joint effusion, elevated serum inflammatory markers, persistent, increasing or new onset wound drainage. If suggestive criteria are identified, the diagnosis of FRI should be considered and confirmatory criteria looked for.

### **Deep organ space infection:**

Infection occurring within 30–90 days of surgery involving organs or spaces manipulated during the procedure (deeper than fascia/muscle), defined by purulent drainage from a drain, positive microbiology, or evidence of infection (e.g., abscess) on imaging or examination, meeting criteria for a specific organ/space infection.<sup>17</sup>

### **Postoperative pulmonary complications**

Postoperative pulmonary complications will be a secondary outcome. This is a composite of postoperative pneumonia, acute respiratory distress syndrome (ARDS) and unexpected ventilation. This outcome was adapted from the PRISM randomised controlled trial.<sup>18</sup>

### **Postoperative pneumonia**

The US Centers for Disease Control (CDC) definition of pneumonia<sup>19</sup> will be used, modified to accommodate limited availability of radiological facilities at some participating centres:

At least **one** of the following:

- Fever ( $>38^{\circ}\text{C}$ ) with no other recognised cause.

- Leucopaenia (white cell count  $<4 \times 10^9$ ) or leucocytosis (white cell count  $>12 \times 10^9$ ).
- For adults  $>70$  years old, altered mental status with no other recognised cause.

AND at least **two** of the following:

- New onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements.
- New onset or worsening cough, or dyspnoea, or tachypnoea.
- Rales, crackles or bronchial breath sounds.
- Worsening gas exchange (hypoxaemia, increased oxygen requirement).

Wherever possible, the diagnosis should be confirmed with a chest radiograph. The following findings confirm pneumonia:

- New or progressive and persistent infiltrates.
- Consolidation.
- Cavitation.

### **Unexpected ventilation**

Unexpected postoperative ventilation was defined as:

- Any episode of non-invasive ventilation, invasive ventilation, or extracorporeal membrane oxygenation after initial extubation after surgery, **or**
- Patient could not be extubated as planned after surgery.

### **Acute Respiratory Distress Syndrome**

Acute Respiratory Distress Syndrome (ARDS) is an acute diffuse, inflammatory lung injury, leading to increased pulmonary vascular permeability, increased lung weight, and loss of aerated lung tissue with hypoxemia and bilateral radiographic opacities. The Berlin consensus definition<sup>20</sup> will be used:

<b>Acute Respiratory Distress Syndrome criteria - ALL 4 CRITERIA REQUIRED</b>	
<b>1. Timing</b>	Within 1 week of known clinical insult or worsening respiratory symptoms
<b>2. Chest imaging</b>	Bilateral opacities (not fully explained by effusions / collapse / nodules).
<b>3. Origin</b>	Respiratory failure (not fully explained by cardiac failure / fluid overload).
<b>4. Oxygenation</b>	<p>Mild: <math>200\text{mmHg} &lt; \text{PaO}_2/\text{FIO}_2 \leq 300\text{mmHg}</math> with PEEP or CPAP <math>\geq 5\text{cm H}_2\text{O}</math></p> <p>Moderate: <math>100\text{mmHg} &lt; \text{PaO}_2/\text{FIO}_2 \leq 200\text{mmHg}</math> with PEEP <math>\geq 5\text{cm H}_2\text{O}</math></p> <p>Severe: <math>\text{PaO}_2/\text{FIO}_2 \leq 100\text{mmHg}</math> with PEEP <math>\geq 5\text{cm H}_2\text{O}</math></p> <p><i>CPAP: continuous positive airway pressure; FIO<sub>2</sub>: fraction of inspired oxygen; PaO<sub>2</sub>: partial pressure of arterial oxygen; PEEP: positive end-expiratory pressure.</i></p>

### **Pulmonary embolism (PE)**

Pulmonary embolism (PE)<sup>21</sup> is defined as:

- Symptomatic PE confirmed by imaging (computed tomography pulmonary angiogram (CTPA) demonstrating new intraluminal filling defect in a subsegmental or greater sized pulmonary artery; or ventilation/perfusion scanning with a high probability of PE; or pulmonary angiograph demonstrating PE), **or**
- Fatal PE discovered at autopsy or as judged by the clinical team.

### **Deep vein thrombosis**

Deep vein thrombosis (DVT)<sup>22</sup> is defined as lower limb deep vein thrombosis with or without symptoms, proven by:

- Lower extremity ultrasonography revealing non-compressibility at the trifurcation of the popliteal vein or above, **or**
- Computed tomography (CT) venography demonstrating a constant intraluminal filling defect above the trifurcation of the popliteal vein.

### **Postoperative cardiac complications**

#### **Acute Myocardial Infarction**

Myocardial Infarction (type 1, 2 and 3) as defined by the Fourth Universal Definition of Myocardial Infarction (2018) when ‘there is acute myocardial injury with clinical evidence of acute myocardial ischaemia and with detection of a rise and/or fall in cTn values with at least 1 value above the 99<sup>th</sup> percentile URL and at least one of the following:

- Symptoms of myocardial ischaemia;
- New ischaemic ECG changes;
- Development of pathological Q waves;
- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormalities in a pattern consistent with an ischemic aetiology;
- Identification of a coronary thrombus by angiography or autopsy (not for types 2 or 3 MIs)
- Postmortem demonstration of acute atherothrombosis in the artery supplying the infarcted myocardium meets criteria for *type 1 MI*. Evidence of an imbalance between myocardial oxygen supply and demand unrelated to acute atherothrombosis meets criteria for *type 2 MI*. Cardiac death in patients with symptoms suggestive of myocardial ischaemic and presumed new ischaemic ECG changes before cTN values become available or abnormal meets criteria for *type 3 MI*<sup>23</sup>.

### **Anastomotic leak**

The defect of the integrity of a surgical join/anastomosis between two hollow viscera, leading to communication between the intra- and extraluminal compartments.<sup>24</sup>

### **Acute kidney injury**

Acute Kidney injury is defined as any of the following.<sup>25</sup>

- Increase in serum creatinine (SCr) by 0.3mg/dl or more within 48 hours; or
- Increase in SCr to 1.5 times or more of baseline, which is known or presumed to have occurred within the prior 7 days; or
- Urine volume <0.5ml/kg/h for 6 hours

**33.1. ERAS (Enhanced Recovery After Surgery):** A multimodal, evidence-based perioperative care pathway designed to reduce surgical stress, maintain physiological function, and accelerate recovery after surgery.<sup>26</sup>

**Robotics module:**

- Robotics Minor and Major Procedures:

Specialty	Minor	Major
<b>General Surgery</b>	Cholecystectomy Inguinal hernia repair	Colectomy Gastrectomy Pancreaticoduodenectomy
<b>Urology</b>	Pyeloplasty Cyst Decortication	Nephrectomy Prostatectomy
<b>Gynaecology</b>	Salpingo-oophorectomy Endometriosis excision	Hysterectomy Sacrocolpopexy
<b>Cardiothoracic</b>	Thymectomy Lung wedge resection	Mitral valve repair CABG Lobectomy
<b>Neurosurgery</b>	Stereotactic brain biopsy SEEG electrode placement	Brain tumour resection Spinal pedicle screw placement
<b>Orthopaedics</b>	Arthroscopy Ligament reconstruction	Total knee arthroplasty Total hip arthroplasty Spinal pedicle screw placement
<b>ENT</b>	Tonsillectomy	Transoral robotic surgery for oropharyngeal tumours Thyroidectomy
<b>Breast</b>	Lumpectomy Sentinel lymph node biopsy	Mastectomy Latissimus dorsi flap breast reconstruction
<b>Plastics</b>	Carpal tunnel release Nerve repair	Lympho-venous anastomosis or another microsurgery procedure Free flap reconstruction
<b>Paediatric</b>	Orchiopexy Pyloromyotomy	Pyeloplasty Fundoplication
<b>Vascular</b>	Varicose vein surgery Venous thrombectomy	Abdominal aortic aneurysm repair Aorto-iliac bypass

The above list is not exhaustive and is intended to provide a small number of examples only.

#### **Abdominal operation module:**

- **Gloves and instruments change:** Change of sterile gloves (or outer gloves if double gloved) for the operating surgeons, assistant surgeons, and scrub staff, and instruments including needle holder, forceps and scissors, after completion of the abdominal component of the operation but before handling the wound edges and abdominal closure.<sup>27</sup>
- **Ileus:** Ileus is defined as the “intolerance of oral intake due to inhibition of the gastrointestinal propulsion without signs of mechanical obstruction”. This normally begins three to five days post-operatively and lasts two to three days before resolving.<sup>28</sup>

#### **Emergency Laparotomy module:**

- **Laparotomy:** surgical procedure involving an incision through the abdominal wall to gain access to the abdominal cavity. The incision can be made in various locations, including midline, paramedian, transverse and others, depending on the clinical scenario, anatomical site of interest and surgeon’s preference. In the case of emergency settings, laparotomy incisions allow rapid and easy access to the peritoneal cavity.<sup>29</sup>

#### **Caesarean delivery module:**

- **Post Partum haemorrhage:** Primary postpartum haemorrhage (PPH)<sup>30</sup> is the most common form of major obstetric haemorrhage. The traditional definition of primary PPH is the loss of 500 ml or more of blood from the genital tract within 24 hours of the birth of a baby after vaginal birth and 1000 ml after caesarean delivery. PPH can be minor (500–1000 ml) or major (more than 1000 ml). Major can be further subdivided into moderate (1001–2000 ml) and severe (more than 2000 ml). Secondary PPH is defined as abnormal or excessive bleeding from the birth canal between 24 hours and 12 weeks postnatally.

- **Apgar Score**

The Apgar score is a standardised assessment of the clinical status of a newborn immediately after birth, based on five components (colour, heart rate, reflexes, muscle tone, and respiration) each scored from 0 to 2, resulting in a total score ranging from 0 to 10, and reported at 1 and 5 minutes after birth.<sup>31</sup>

Score	0	1	2
Colour	Blue or Pale	Acrocyanotic	Completely Pink
Heart rate	Absent	<100 bpm	>100 bpm
Reflex irritability	No Response	Grimace	Cry or Active Withdrawal
Muscle tone	Limp	Some Flexion	Active Motion
Respiration	Absent	Weak Cry; Hypoventilation	Good, Crying

### **Fracture module:**

#### **- Gustillo-Anderson Classification**

System used to categorise open fractures based on the mechanism of injury, extent of soft tissue damage, and presence of contamination or vascular injury.<sup>32</sup>

The classification divides open fractures into three main types:

- Type I: Clean wound, <1 cm, minimal soft tissue damage.
- Type II: Wound >1 cm, moderate soft tissue injury, no extensive damage, flaps, or avulsions.
- Type III: Extensive soft tissue damage, high-energy trauma, or severe contamination, subdivided into:
  - IIIA: Adequate soft tissue coverage despite extensive injury.
  - IIIB: Extensive soft tissue loss with periosteal stripping and bone exposure, usually requiring flap coverage.
  - IIIC: Associated with arterial injury requiring emergent repair.

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## Appendix D: Statistical Analysis Plan

The primary aim of SurgWeek-2 is to assess complications measured by Clavien-Dindo grade at 30-days following surgery. The secondary outcomes will include 30-day postoperative mortality, 30-day surgical site infection, 30-day postoperative pneumonia, 30-day postoperative pulmonary embolism and deep vein thrombosis, 30-day postoperative cardiac complications, days alive out of hospital at postoperative day 30. Appendix C includes detailed definitions for these outcomes. The analysis will be based on a comparison of complication rates between patients between income status, emergency and elective operating and across specialities.

The study will be conducted according to STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) and SAMPL guidelines (Statistical Analyses and Methods in the Published Literature). Non-parametric data will be summarised with medians and interquartile ranges and differences between groups tested using the Mann-Whitney U test. The  $\chi^2$  test will be used for categorical data. Missing data will be included in flowcharts and summary tables, allowing denominators to remain consistent in calculations.

Hierarchical multivariable, mixed-effects logistic regression will be used to explore the associations with the primary and secondary outcome measure, summarised as odds ratios and 95% confidence intervals (C.I.). Clinically plausible patient, disease, operation and location specific factors have been selected a priori for inclusion in adjusted analyses, in order to identify independent predictors of adverse outcomes after surgery.

We anticipate recruitment from approximately 1000 hospitals around the world with a median of 100 patients per hospital (average five mini-teams per hospital and 20 patients collected per mini-team), providing a sample size estimate of 100,000 patients. This is based on previous studies performed by the NIHR Global Health Research Unit on Global Surgery.<sup>(1-4)</sup> Analyses will be performed using the R Foundation Statistical Program version 3.1.1 (packages: finalfit, tidyverse).

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## Appendix E: Study approvals processes – UK Audit standards

In the UK we would suggest the study is registered as an audit or service evaluation. Within the UK the audit standards we will assess against are the following:

1. World Health Organisation (WHO) Safer Surgery Checklist use
  - a. The WHO Safer Surgery Checklist is one of the only interventions that has been proven to reduce mortality across surgical specialities and in a global context. As such we will assess the use of this in all operations in the UK.<sup>(1)</sup>
  - b. Audit standard: 100%
2. Time to antibiotics in those with sepsis
  - a. Many post-operative deaths can be attributed to sepsis or bleeding.<sup>(2)</sup> In-hospital mortality for those with septic shock approaches 40-60%. Surgical patients presenting with sepsis is common and they will often require source control with surgical interventions.<sup>(3)</sup> However, prior to this the Sepsis 6 bundle advises antibiotics are given within an hour of recognition of sepsis.<sup>(4)</sup> National Emergency Laparotomy Audit (NELA) data suggests only 15.4% of patients receive antibiotics within an hour, however we do not have UK wide data for all specialities.<sup>(5)</sup>
  - b. Therefore, we will assess in those presenting with sepsis who receives intravenous antibiotics within 1 hour of presentation.
  - c. Audit standard: 100%
3. NCEPOD classification of intervention
  - a. The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was established to in response to concerns about perioperative death. Subsequently they have published numerous reports on this topic. They have created a framework regarding the timing of operative interventions as it is recognised delays in surgery, particularly out of hours is linked with increased morbidity and mortality.<sup>(6)</sup>
  - b. We will therefore compare emergency admissions time to theatre against the NCEPOD classification entered at the time of booking the patient for theatre.
  - c. Audit standard: 100%

The service evaluation component will describe current clinical practice and assess the uptake and outcomes of robotic surgery in the NHS and describe:

- The availability and use of robotic surgical platforms across participating hospitals
- Characterise patients undergoing robotic surgery
- Compare outcomes (postoperative mortality, complications and reoperation) between surgical approaches (robotic vs open vs other minimally invasive techniques)

This analysis is intended to describe current patterns of practice and benchmark outcomes across surgical approaches, rather than test a new intervention or introduce changes to clinical care.

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## NHS Health Research Authority 'is my study research?' tool outcome


07/01/2026, 11:26

Result - NOT Research

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**i To print your result with title and IRAS Project ID please enter your details below:**

Title of your research:

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

IRAS Project ID (if available):

You selected:

- 'No' - Are the participants in your study randomised to different groups?
- 'No' - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
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**Your study would NOT be considered Research by the NHS.**

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the [HRA](#) to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at [Queries@hra.nhs.uk](mailto:Queries@hra.nhs.uk).

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## **University Hospitals Birmingham NHS Foundation Trust Audit approval (CARMS)**

**Audit title** Surgical outcomes and national/international surgical benchmarks  
**Audit Code** CARMS-24253

Your audit has now been registered with the Clinical Audit Team and will appear on the [Clinical Audit Registration and Management System](#) (CARMS).

Please ensure that you log on to the system to update it with any progress made. Once your audit is completed you will need to log in to the system and update your audit status to complete. You will also be required to input your 'key' findings and any recommendations (if applicable) that may have come out of the audit.

Please note that all recommendations will be monitored and you be required to update the progress made on each recommendation (action). Also the person nominated for the action will be alerted so ensure you liaise with them appropriately.

This audit code must be quoted to the Medical Records department (ext 8171/8172) or Health Informatics (<http://charon/Requests/>) if you wish to use their services in connection with this audit.

Please only request notes if you will definitely need to view them, as the Medical Records department have limited space and capacity. If you request patient identifiable data from Informatics, this can only be sent to UHB (@uhb.nhs.uk) or nhs.net email accounts.

If you have any queries please contact [ClinicalAudit@uhb.nhs.uk](mailto:ClinicalAudit@uhb.nhs.uk).

Thank You

C.A.R.M.S.

Clinical Audit & Registration Management System

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## Appendix F: REDCap online data collection

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. The REDCap server is managed by the University of Birmingham, UK. Only anonymised data will be uploaded to the database. No patient identifiable data will be collected.

REDCap databases at the University of Birmingham have been successfully used for a number of international studies, including:

- CovidSurg Study (1,040 participating sites across 85 countries), reference: COVIDSurg Collaborative. *Mortality and pulmonary complications in patients undergoing surgery with perioperative SARS-CoV-2 infection: an international cohort study*. Lancet. 2020;396(10243):27-38. doi:10.1016/S0140-6736(20)31182-X.
- European Society of Coloproctology 2017 Left Colon and Rectal Resection Study (335 participating sites across 49 countries), reference: 2017 European Society of Coloproctology (ESCP) Collaborating Group. *The 2017 European Society of Coloproctology (ESCP) international snapshot audit of left colon, sigmoid and rectal resections - Executive Summary*. Colorectal Dis. 2018;20.
- Right Iliac Fossa Treatment Study (290 participating sites across 5 countries), reference: RIFT Study Group on behalf of the West Midlands Research Collaborative. *Identifying children at low-risk of appendicitis: systematic review and prospective, multicentre validation of risk prediction models in children presenting with right iliac fossa pain*. Lancet Child Adolesc Health 2020; 4: 271–80.

The REDCap database used for the SurgWeek-2 study is run by the NIHR Global Health Research Unit on Global Surgery, within the University of Birmingham Virtual Machine architecture which is physically secured. The architecture is the responsibility of the Storage and Virtualisation Team at the University of Birmingham, Edgbaston, Birmingham, B15 2TT. “At rest” encryption is in place on the database server. Raw data will be stored and will remain at the Birmingham site; it will not be offshored to any other location. The site is physically secure. The virtual hosting service is designed to have no single point of failure with physical redundancy deployed for server, network and storage infrastructure. The virtual server software supports live migration of virtual machines between the physical servers called hosts. Live migration is automatically performed to balance the server load across available infrastructure. On physical server failure the virtual machine is automatically restarted on another host. During host maintenance or intrusive maintenance of the virtual server software, virtual machines are manually migrated to prevent any interruption to service. All physical infrastructure is monitored and automatic alerts generated to systems staff on any failure. All virtual machines are not installed on a single physical server but a range of hosts on which virtual machines automatically live migrate on. Therefore, since there is no one physical location for our machine, it can be considered physically

secure. All physical infrastructure and the virtual server software are maintained by the University of Birmingham IT Services. All physical infrastructure is monitored and automatic alerts generated to systems staff on any failure.

The security of the study REDCap database system is governed by the policies of the University of Birmingham UK, in accordance with the requirements of the General Data Protection Regulations (GDPR). The study will be conducted at collaborating sites in accordance with the country-specific data protection requirements. Once data collection is complete, the electronic research files containing anonymised data will be stored on secure non-networked desktop computers for up to 25 years, in line with current regulations. Access will be restricted to the researchers themselves. Personal data will remain securely at local hospitals.

No sensitive or identifiable data will be collected on the database; the patient's clinical team will only upload anonymised data. Access to data will be restricted, each individual collaborator entering data for SurgWeek-2 will have their own username and password. Each patient will be allocated a unique study number at entry. The central research team will not have any access to patient identifiable data. All communication will use this as the identifier. All data will be analysed and reported in summary format. No hospital level data will be reported. No individual will be identifiable. The anonymised data generated by the study will be held centrally at the University of Birmingham UK, and be analysed by Omar Omar (Senior Statistician, University of Birmingham).

## Appendix G: Operational Delivery

**National leads:** This will comprise a network of surgeons and anaesthetists established with previous GlobalSurg and CovidSurg studies. They are responsible for national coordination of the study. Their specific roles will include

- Acting as a link between mini-teams / Hospital Leads, and the steering committee
- Active engagement with dissemination of the study and other NIHR Unit on Global Surgery Collaborative activities in their country.
- Effective and responsive communication with the steering committee, and with local collaborators
- Recruitment of hospitals within their country
- Registering hospital leads and their teams
- Securing national ethical or regulatory approvals if required

**Hospital Lead:** This will be a single lead point of contact for data collection at each site who has overall responsibility for site governance registration and coordinating handover between local collaborator teams. They should be a consultant or senior clinician. Minimum requirements for authorship on this study as a Hospital Lead include

- Obtaining local approvals for conduct of the study (e.g. registration of the audit, seeking Caldicott guardian permission to upload data to REDCap, submitting the protocol to Ethics Commission where applicable)
- Coordination of handover between all local collaborator teams at the centre
- Identifying Hospital co-leads
- Involvement in local dissemination and presentation of local results at their centre from the study (or otherwise arranges another collaborator to present on their behalf)

**Hospital co-leads:** This will be a lead point of contact for data collection in each hospital. They will support the Hospital lead to identify local collaborators to be in the mini-teams and support the mini-teams to identify patients and collect data. The minimum requirements for authorship on outputs of this cohort study include:

- Compliance with local audit approval processes and data governance policies.
- Active involvement in mini-team recruitment and engagement
- Collaboration with the hospital lead to ensure that the results are reported back to the audit office / clinical

**Local Collaborators (Data Collectors):** This will comprise a team of up to 3 people responsible for data collection over a week period within a single or multiple specialities within their hospital. The ideal team would be a heterogeneous group at different levels of clinical training (e.g. medical students, trainees, consultants). The minimum requirements for authorship on outputs of this cohort study include:

- Compliance with local audit approval processes and data governance policies.
- Active involvement in data collection and uploading it to REDCap
- Collaboration with the regional / local lead to ensure that the results are reported back to the audit office / clinical