Global Outcomes in Surgery

Determining universal markers of quality in emergency abdominal surgery: a global evaluation

A multicentre, international, social media delivered evaluation of midline laparotomy as a as a globally relevant quality marker

Study protocol v4.5

Long version; a short version is available for local investigators.

Registration: www.globalsurg.org/register


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Abstract

Importance: With 1 in 25 people being operated upon across the world and nearly every acute hospital providing surgical services, emergency general surgery represents an internationally important quality target. Best practice treatment practices that are relevant to good patient outcome around the world require validation using patient level data.

Delivery: GlobalSurg proposes a novel approach to a global surgical outcomes project, involving collaborative surgeon-up methodology, including both developed and developing nations, and using 'snap-shot' clinical data collection. The Internet and social media enable international networks to be developed with previously uncontactable doctors. A surgical outcomes study provides an ideal setting to test pan-global networks; inclusion criteria and outcomes are clearly defined with the ability to demonstrate variation. Emergency midline laparotomy is a standard of acute abdominal surgery and the most invasive procedure. Whether variation in mortality following laparotomy represents a method of assessing global surgical performance remains to be determined.

Validation and feasibility assessment: During registration of interest (www.globalsurg.org/register), a brief survey of available resources will be undertaken from participants. This will test feasibility and validate inclusion criteria.

Method: Multicentre, international, prospective cohort study. Centres will be identified through an online dissemination programme, using local, national and multinational organisations and online opinion leaders. This study will audit international variation against accepted standards, stratifying countries by the Human Development Index. The primary standard will be assessment of 30-day in-patient mortality. Any hospital in the world performing acute surgery is eligible to enter. Globally relevant factors influencing outcomes will be explored, including imaging, critical care, pulse oximetry, safety checklists and intra-operative warming.

Timing: Centres will collect observational data on patients for a two-week period during mid-2014. There will only be 30 data-points (GlobalSurg30). This ensures that it is feasible for those with limited resources, and is feasible for the individual practicing surgeon.

Discussion: Acute general surgery may represent an important target for global health improvement that requires standardisation. This methodology may facilitate faster delivery of multicentre studies, including randomised trials, with greater worldwide relevance.

Introduction

Why is this project important?

Surgery has an undeservedly low profile in global health priorities; it was not mentioned in the Millennium Development Goals. This is despite 1 in 25 people undergoing an operation in their lifetime, representing an estimated 234 million surgeries worldwide per year[1, 2]. Most of these operations are restricted to developed populations, meaning there is disparity in access to surgery across the world and unmet surgical need[3]. 70% of countries have no information of the frequency of surgical procedures performed[4].

There is a lack of patient level data in surgical global health. Detecting variation associated in outcome from common emergency general surgical operation, and risk factors for this variation, is likely to act as a surrogate marker for the performance of acute surgical units[5, 6]. Globally relevant risk factors relate to the type of surgeon, the availability of investigations, use of safety checklists, equipment use in operating theatres and access to critical care facilities[4, 7-9].

Emergency general surgery, including emergency laparotomy, appendicectomy and emergency hernia repair is performed in virtually every acute hospital in the world and is likely to be subject to performance variation[6]. It may be able to act as a marker of international surgical epidemiology and quality, across different health settings and levels of economic development. This type of surgery encompasses a wide range of procedures and conditions, meaning that standardised and accurate outcome measures are difficult to determine and compare. Emergency midline laparotomy is a standard of acute abdominal surgery (including trauma), and is the most invasive procedure with the highest side-effect profile[10]. Its post-operative mortality affects up to 15% of patients and morbidity up to 30%[10, 11].

A prospective audit of current practice is underway in the United Kingdom, led by the National Emergency Laparotomy Audit, although initial results will not be presented until 2015. Risk factors from studies based in highly developed nations are likely to lack relevance in global settings. The World Health Organisation (WHO) Global Initiative for Emergency and Essential Surgical Care[12] (GIEESC) is disseminating practice, but only focuses on low and middle income countries (LMIC) and will not produce risk-adjusted patient level outcomes as proposed here.

Why is this project important to the global health community?

Global surgery is an under-recognised and under-studied area. There have been several projects to address this at national level, including the WHO EESP and the WHO Safe Surgery Save Lives campaign[2]. Studies at local level, engaging individual surgeons and collecting patient level data, are lacking. Since acute general surgery is offered in virtually every acute hospital, it may be able to help standardise future care by acting as a surrogate marker of hospital services and performance. Such markers are needed as the global health community moves beyond the Millennium Development Goals, with an increasing focus on surgical intervention for non-communicable disease.

Why is this project is important to international surgeons?

GlobalSurg will develop a network of surgeons and surgical units that will have the long-term ability to collaborate on further outcome studies, and even randomised trials.

This project will give grass-root surgeons the opportunity to participate in a major project. This project should lack complexity and not require extra resources or funding. It will be easy for local surgeons to execute for the following reasons:

1. It only requires two weeks' worth of patients
2. Patients are easy to identify
3. There are only 30 patient related data-points to collect (GlobalSurg30)
4. Endpoints are largely dependent on in-patient care
5. In most cases it will approved as audit and patient consent is not needed

This will enable surgeons to form networks both locally and across the globe, and prevent academic isolation based on income and expertise.

How is this project different to others?

We propose a novel approach to a global surgical outcomes project, involving collaborative surgeon-up methodology, including both developed and developing nations and using 'snap-shot' clinical data collection[8, 13]. This project be unique through the speed by which it will recruit individual surgeons. By using multiple centres over just a two-week period, high numbers will be maintained and a rapid outcome analysis can be delivered.

One and a half billion people on the planet use social networking and up to 80% of online users interact with social networks regularly[14]. This provides a novel platform from which to contact individual doctors around the world, and changes

the way networks are formed. This may eventually allow more rapid and widespread delivery of trials, in a more cost-effective manner than conventional methods. The potential for development of pan-global networks, developed through social media, requires testing. A surgical outcome study provides an ideal target for such a test; inclusion criteria are easily definable, variation is often present, and outcome measures are clear.

This study will deliver patient level data derived at source, and will not rely on administrative or aggregated data that can be inaccurate. We will also include trauma, which is a leading cause of death in young people around the world[15]. It provides a technically challenging laparotomy and is often excluded from surgical outcome studies.

Validation and feasibility

Throughout the dissemination programme, interested participants will be asked to register their details. At this stage, a brief survey of available resources will be undertaken from participants. This will have two key benefits:

1. It will determine the spread of centres and number of surgeons, testing feasibility.
2. It will ensure validity of inclusion criteria and risk factors being tested, which can be adjusted based on the results.

Aim

This study will identify variation in provision and outcome of emergency midline laparotomy across international settings. This will determine whether globally relevant quality improvement strategies are needed within acute surgical units. Identification of globally relevant risk factors will allow accurate risk adjustment of these outcomes, and will identify best practice measures to disseminate.

Delivery

Rapidly delivered, snapshot, clinician driven surgical outcome studies are feasible[8, 16]. The study's short two-month inclusion period was balanced by the inclusion of multiple sites, leading to inclusion of 3326 patients, and acts as proof of principle that high volume risk-adjusted outcome analysis is feasible.

Social media platforms are accessible via multiple Internet driven devices. Most major national and international organisations engage with social media and disseminate key information to their membership. Many organisations span multiple countries, through developed and developing worlds, and provide a unique opportunity for dissemination of studies. As proof of principle, the social

media driven educational platform SchoolofSurgery.org recently delivered a survey study, and included 6200 surgeons from 70 countries in a month period.

This study will test development of the network with an international audit of surgical outcomes following emergency midline laparotomy. Any surgical unit around the world offering this operation can participate. Successful development of global networks can be transferred to other specialties, and may be able to deliver randomised controlled trials. The breadth of these networks may deliver patient numbers faster than exiting networks, and generalisability would be high.

Registration

Interested participants should register at: www.globalsurg.org/register

If you have the motivation and ability to act as a local lead for your country (either alone or as part of a team of your colleagues), please email us directly at: enquiry@globalsurg.org

Methods

01
Summary
Prospective observational study of consecutive patients undergoing emergency midline laparotomy over a 14-day period at your hospital.

02
Aim
The **primary aim** is to determine worldwide variation in risk-adjusted 30-day in-patient mortality following emergency midline laparotomy, The secondary aims are to:

- Determine variation in risk-adjusted morbidity.
- Determine best practice equipment and management associated with good outcome.
- Describe the epidemiology of indication for emergency midline laparotomy.
- Assess the feasibility of a study protocol disseminated globally via social media.

03
Outcome Measures
Primary outcome measure
In a surgical global health setting, the primary outcome measure needs to be simple, widely applicable, relevant and have positive effects when variation is shown. For this project in which local surgeons are collecting data, it needs to be easy to determine, clear, and due to differences in follow-up practices, should be related primarily to inpatient stay. Using an inpatient measure prevents biases due to losses to follow-up, which are frequent across different health settings. Due to the short study period and the low number of patients at each individual centre, the nature of the statistic also needs to be applicable across the four HDI levels and at country level, to provide high enough patient numbers for meaningful analysis. Analysing at HDI and country level will also prevent any penalties associated with identifiable hospital or surgeon performance, which will *not* be performed. Mortality will be related to day-of-surgery death ratio and postoperative in-hospital death ratio.

The primary outcome measure is the 30-day in-patient mortality rate. The main secondary outcomes will be the 30-day serious complication rate. These serious complications can be expected within the index hospital stay, and so biases due to lack of follow-up or readmission to other centres are minimised.

These endpoints represent grade III and V of the internationally standardised and validated Clavien-Dindo classification[17]. Although not all centres have critical care facilities (grade IV complication), this will provide a measure of the re-intervention rate. However the endpoints chosen are based on this widely accepted system, and are in keeping with those recommended by WHO Safe Surgery Saves Live Measurement and Study Groups[2].

04

Audit standard

This study will measure current practice, and requires no change in patient care. It is thus considered as an audit (section 11). The primary audit standard will be that 30-day mortality should not exceed 15%[6, 10, 11]. The secondary audit standard will be that the rate of serious complications should not exceed 30%[10, 18]. International variation in these rates will be assessed stratifying countries by the four levels of the 2012 Human Development Indicators (HDI, http://hdr.undp.org/en/statistics/). Data will not be analysed at the level of individual surgeon or hospital.

05

Structure and quality assurance of participants

Protocol development and Advisory teams

These teams have experience in delivering and publishing multicentre surgical outcome studies. They will be responsible for overall organisation, dissemination and for production of the protocol.

Quality assurance of participants

It is financially unviable and carbon-footprint heavy to have a central investigators meeting, which will also act as a barrier to participation for LMIC. To ensure that participants are quality assured, registration emails will be required from an affiliated institution (e.g. hospital, university or other health organisation email address).

Country leads

Where possible, one or more leads for each country are encouraged, to disseminate the protocol to local centres. Each lead is expected to deliver a minimum of 10 centres. In larger countries multiple leads are possible, to deliver a minimum of 10 centres each. If you have the motivation and ability to act as a local lead for your country (either alone or as part of a team of your colleagues), please email us directly at: enquiry@globalsurg.org

Local investigators

Each hospital will have a local investigator who will be a doctor. Each local investigator will be required to register centrally for updates. At each centre, local investigators can form a team of two people (including themselves) to accurately perform patient identification and data collection. Local investigators will be specifically responsible for:

- Gaining local audit approval.
- Ideally forming a team of 2-3 people (including themselves) to identify patients and collect data.
- Creating clear mechanisms to identify and include eligible patients.
- Identify clear pathways to establish mortality and complications by 30 days.

Language and summary protocol

A short summary protocol will be produced for local investigators. English is the main language of this study. Where possible, leads and local investigators may wish to translate the protocol into local languages.

06
Inclusion Criteria

- **Consecutive patients undergoing emergency midline laparotomy for a general surgical indication, including trauma.**
- Consecutive means that all sequential patients operated in the hospital undergoing an emergency laparotomy should be included.
- Emergency (unplanned, non-elective, same admission) procedures only.
- Midline incision. Laparoscopic converted cases with a subsequent midline incision can be included if the midline incision was used to explore or access deeper structures.
- 18 years of age or above.

07
Exclusion Criteria

- Elective (planned) or semi-elective (emergency admission, planned discharge prior to surgery) procedures.
- Complete laparoscopic cases and laparoscopic assisted procedures where midline incision is made only to deliver specimen.
- Patients with para-median or any other incisions other than midline longitudinal. Inclusion of these cases will lead to a large volume of heterogenous data.
- Gynaecological, urological or vascular primary indication (bowel ischaemia is however an includable indication).

The final inclusion and exclusion criteria will be modified based upon the feasibility and validation process during registration.

08
Methods to identify consecutive patients include:

1. Daily review of theatre lists
2. Daily review of team handover sheets/ emergency admission lists/ ward lists
3. Daily review of theatre logbooks

09
Timeline
The study will run over a 14-day, consecutive time period in mid-2014.

10
Centres

- Any acute surgical unit worldwide that performs emergency surgery is eligible to enter.
- All participating centres will be required to register their details, complete an online training module, and complete a pilot audit prior to commencing.
- Centres must ensure that they can include consecutive patients and provide >95% data completeness.

11
Local approval
There will be various mechanisms in worldwide hospitals to gain permission for this study. All data collected will measure current practice, and no changes of normal

management are required. Local investigators are expected to gain approval from one of the following:

- Clinical Audit Department – as either audit or service evaluation
- Research Departments/ Institutional Review Boards – as either observational research, or as service evaluation.

It is likely that some hospitals will not have these departments, in which case written permission should be provided from the next best available source. This may include the Chief of Surgery or a supervising consultant. Local investigators will be solely responsible for ensuring they have followed correct mechanisms, and will asked to confirm this.

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Data Collation and Governance

Data will be collected via a secure online webpage, which will be developed during the registration period.

A Microsoft Excel spreadsheet, due to its relatively greater availability compared to other methods worldwide, will also be available. This will be compatible with the freely available OpenOffice (http://www.openoffice.org/download/) where Microsoft software is not available. The local Excel file will be password protected (encypted). Data should be collected and held on local hospital computers with patient identifiers to facilitate follow-up. Data will then be submitted centrally with all patient identifiers removed (including removal of patient ID, Column A). This totally anonymous data will be re-submitted centrally via email. Files will be encrypted and cleaned to ensure anonymity, being held centrally on password protected computer systems.

All patient data will be transmitted and held anonymously; the data will not be analysed at hospital or surgeon level.

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Pilot and quality assurance

A quality assurance strategy has been developed to maximise identification of eligible patients, and prevent missing or inaccurate data. A post-collection quality assurance check is unfeasible, as many centres are unlikely to have access to immediately available administrative or other corroborative data (including the UK).

The validation survey, sent out at the time of the registration questionnaire, will act as a pilot for suitability of the 30-data points. Use of hospital/university/research affiliated email addresses will help validate local investigators, whilst allowing free internet services for those without formal email addresses.

In order to overcome a learning curve in identifying patients and relevant data, all participating centres will be asked to complete patient identification and the initial stages of the data collection form for one ‘pilot’ day in the month leading up to the main starting date. This will also familiarise local teams with hospital pathways and data systems. In order to maximise data completion and to emphasise its importance to collaborators, contributing centres with <95% data completeness will be excluded from the study. Regular reminders will be sent to participating centres. An additional regression model using a multiple imputation dataset will be used to

test the effect of remaining missing data. Any problems encountered will be addressed through email (enquiry@globalsurg.org) with the steering committee and teleconferencing where appropriate.

14
Dataset
30 data points (GlobalSurg30) related to the patient, surgeon, operation, hospital, operative method and postoperative period will be collected. A complete list of data fields and corresponding definitions is provided below. In order to maximise completion of data, the minimum required dataset has been designed to be brief and to test only those factors that are likely to be relevant.

15
Follow-up
The primary and secondary outcome measures will be recorded if they occurred at any point during the day of surgery up to and including the 30th post-operative day. Most of these events are expected to occur during the patient's index stay and have been recommended for use[4]. Because this is an audit of current practice, no changes to normal follow-up should be made. However, centres should be proactive in identifying post-operative events (or an absence of them), within the limits of normal follow-up. Local arrangements may include:

- Daily review of the patient and notes during admission and before discharge to identify in-hospital complications.
- Review the patient in outpatient clinic or via telephone at 30 days (if this is normal practice).
- Check hospital records (electronic or paper) or handover lists for re-attendances or re-admissions.
- Check for Emergency Department re-attendances.

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Statistical analysis
At an estimated rate of 7 emergency bowel resections in a 14-day period from 200 centres, this study should include a minimum of 1400 patients; 500 centres will result in 3500 patients. A minimum participation of 40 countries is expected, to ideally represent a spread of at least 10 countries per HDI level. At this split, 800 patients per group will provide adequate power to detect a difference in 5% serious adverse event rate between the lowest and highest group (alpha 0.05, P1 7.5%, P2 12.5%, power =91.6%). The feasibility questionnaire will enable either validation of the expected numbers, or alteration during development.

Differences between demographic groups will be tested with the χ^2 test. Multivariable binary logistic regression will be used to test the influence of variables on the outcome measures. Variables entered into these models will be those that may have directly affected the event, were clinically plausible and that occurred before the outcome event. They will be pre-defined, and used to adjust the main explanatory variables irrespective of statistical outcome. To confirm the validity of models, taking into account the random variation of different hospitals and the potential for missing data, the following models will be created and compared:

- A multilevel model, including the hospital as a random effect at the second level. Variables included in the fixed part of the model will be those judged to be clinically relevant, and will include country and/or HDI level.
- A single level, fixed effect regression model using complete case analysis.
- To test for the impact of missing data, the single level model will be repeated using a multiply imputed dataset.

The 2012 Human Development Indicators (HDI, http://hdr.undp.org/en/statistics/) is a composite statistic of life expectancy, education, and income indices used to rank countries into four tiers of human development. It will be used as the key variable to test variation of outcome measures.

Model fit and calibration will be tested. Data will be analysed using SPSS version 19.0 and the R Foundation Statistical Programme 3.0.0. The authors are experienced in this type of statistics will perform the analysis (AB and EW).

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Delivery
Planned pathways for global dissemination will be created. These will include using multiple national and international organisations, and social media. Each country in the six populated continents will be searched for structures and organisations through which dissemination will be promoted. The protocol is available in English language as a written version, and as a YouTube video.

National coordinators are encouraged to spread the protocol further to interested colleagues. Each coordinator is asked to deliver at least 10 participating centres. Multiple coordinators per country working together, each delivering at least 10 centres, are also encouraged, especially in larger countries. Coordinators are allowed to translate the protocol for dissemination where appropriate. The extra efforts of these people will be clearly identified in a separate section of the final manuscript.

20
Authorship
Three collaborators per hospital will be listed as 'Pubmed' citable co-authors. These authors should all have made substantial contributions to set-up (including gaining research or audit approval), patient identification, data completion and follow-up for mortality/complications. Submitting centres with >5% missing data will result in exclusion of that centre from analysis; this includes authorship.

Appendix A: Key steps for successful inclusion of your centre

1. Register yourself and your hospital: www.globalsurg.org/register

2. Consider forming a team of two to three people, to help identify patients, collect data, and look for post-operative complications. Any grade of doctor is eligible to be part of the team. Medical students on electives are also eligible, although they must form a team with a responsible local doctor.

3. Ensure that you gain **formal approval** from your hospital using the most suitable mechanism. This may involve Clinical Audit Departments, Research and Development Offices, Institutional Review Boards, or responsible individuals (e.g. Head of Department of Surgery). You should use this protocol to complete and support your application. You should begin this process soon, as it can take time. You are responsible for ensuring this has been done in using the most suitable mechanism; we will ask for your confirmation at the time of data submission.

4. Complete a **practice** audit day: Complete 1 day of audit in your hospital of choice in the month prior to the main start day, and record the relevant information on the designated data collection form. This will allow you to become familiar with the best way to identify patients, and data collection methodology. Contact us with any queries from the day. This will allow the steering committee to iron-out any unidentified problems.

5. Mortality will be assessed as an in-patient. You should keep checking on the patient until the time of discharge to assess this, and you should ask you staff to let you know of any relevant mortalities. Complications to 30 days, whether as an in-patient or during readmission, will also be collected. You should be active in identifying these (review notes, admission lists, other reporting systems).

   Be proactive in identifying post-operative complications (e.g. review patients on the ward, daily checking of hospital notes, review for readmissions etc.). This will prevent under-estimating the true rates.

6. Avoid **missing data**; complete all fields. If more than 5% of patients at your centre are missing data, your centre and name cannot be included. Don't add or remove any columns from the spreadsheet.

7. **Anonymise** your final dataset before sending it: Data protection is essential. **Please delete column A** (the first column, patient ID number) before emailing your dataset back to us.

Appendix B: Required data fields

A	Patient ID	Local hospital field; delete before transmission
1	Patient age (completed whole years)	Years
2	Patient gender	Male, Female
3	ASA score	I, II, III, IV, V
4	History of diabetes	No, diet, controlled, tablet controlled, insulin controlled
5	Smoking status	Current, Previous, Never
6	Pre-operative computed tomography performed?	Yes/ No - but available if needed/ No – patient did not pay/ No - CT unavailable at this hospital
7	Date of operation	DD/MM/YY
8	Time of start of operation (knife to skin)	24 hour clock
9	Time of hospital admission to start of operation	<6 hours, 6-11 hours, 12-23 hours, 24-47 hours, 48+ hours
10	Was the WHO surgical safety checklist (or equivalent) used?	Yes, No but available, Not used at this hospital
11	Consultant/attending SURGEON present in theatre?	Yes- qualified surgeon, Yes-general doctor who provides surgical services, Not present
12	Consultant/attending ANAESTHETIST present in theatre?	Yes- qualified anaesthetist, Yes-general doctor or surgeon who provides anaestheisa, Not present
13	Primary operation performed	Appendicectomy, perforated duodenal ulcer, Hartmanns procedure, left hemicolectomy, right hemicolectomy, subtotal colectomy, panproctocolectomy, anterior resection, abdominoperineal resection, small bowel resection, complete gastrectomy, partial gastrectomy, oesophagectomy, splenectomy, hepatectomy, abdominal packing, washout+/-drain, exploration, excision Meckel's diverticulum, strictuoplasty, bypass procedure, other (free text)
14	Was bowel resection performed?	Yes – handsewn anastomosis, Yes – stapled anastomosis, Yes - stoma, No
15	Stoma formation	Loop ileostomy, loop colostomy, temporary end ileostomy, temporary end colostomy, other, none.
16	Underlying pathology/ indication	Appendicitis, diverticular disease, hernia, malignancy, ischaemic bowel, adhesional obstruction, faecal perforation, ulcerative colitis, Crohn's disease, penetrating trauma, blunt trauma, iatrogenic trauma, other haemorrhage, other (free text)
17	Was a pulse oximeter used during surgery?	Yes, No but available, No not available
18	Were prophylactic antibiotics given?	Yes, No but available, No not available
19	Was active intra-operative warming used (e.g. warming blankets or fluid warmers)?	Yes, No but available, No not available
20	Peri-operative blood transfusion	Yes, No but available, No blood products available at this hospital.
21	Highest post-operative glycaemic reading within 72 hours of surgery using finger prick, blood gas or laboratory value (mmol/L – convert from mg/dl at http://www.diabetes.co.uk/blood-sugar-converter.html or divide mg/dl by 18 to give mmol/L). Leaving this blanks indicates it was not done.	Value (mmol/L)
22	Thromboembolic prophylaxis	1. Yes – chemical+mechanical, 2. Yes-chemical only, 3. Yes-mechanical only, 4. Yes-other, 5. None
23	Total length of stay (whole days; day of surgery is day 1)	Days
24	30-day critical care admission?	Planned from theatre, unplanned from theatre, unplanned from ward, none but available, no critical care available at this hospital
25	30-day re-intervention	Yes – theatre, general anaesthetic, Yes- theatre, local anaesthetic, Yes-endoscopic, Yes-interventional radiology, No
26	30-day mortality	Yes-day of surgery, Yes-inpatient after day of surgery, yes-outpatient, Alive
27	Other complications not resulting in critical care, re-intervention or mortality?	Yes/no
28	Anastomotic leak	Yes/no
29	Wound infection	Yes/no
30	Intra-abdominal/pelvic abscess	Yes/no

Appendix C: Data definitions

This section provides a data dictionary for key terms above, where not self-explanatory. It also provides information on where will be best to find this data, shown in italics. Much of this data you can collect yourself once you know how and have access. Some of it, you may need help from one of the junior doctors in your mini-team.

- **Patient ID** *(notes)* **–** this is the local patient identifier, to be used to track patients. This column must be deleted prior to transmission of the final dataset.
- **Patient age** *(notes)* **–** in completed whole years
- **American Society of Anaesthesiologists score** *(take from anaesthetic chart, filed in notes)*

  I – a normal healthy patient
  II – a patient with mild systemic disease
  III – a patient with severe systemic disease
  IV – a patient with severe systemic disease that is a constant threat to life
  V – a moribund patient not expected to survive without the operation

- **Time of hospital admission** *(direct observation, clinical notes, admission records)* – this refers to the patient's first contact with hospital, whether that was through an Emergency Department or directly with surgical services.

- **WHO surgical safety checklist** *(direct observation, clinical notes)* – any attempt made to complete the WHO surgical safety checklist (or an equivalent team based surgical safety checklist), whether in part or whole, should be documented as **yes**.

- **Consultant/attending surgeon presence in theatre** *(direct observation, operation note)* – the consultant/ attending grade represents the post-training,

independent doctor, typically known as the consultant or attending. This field will detect whether a fully qualified, full time surgeon was available in theatre, whether a non/partially-qualified surgeon was performing operations (i.e. a general doctor who also provides surgical services), or whether surgery was left to a junior doctor (e.g. trainee, non-consultant grade).

- **Consultant/attending anaesthetist presence in theatre** *(direct observation, anaesthetic chart note)* – whether the consultant/ attending anaesthetist was present in theatre (for any duration) or not should be recorded.
- **Primary operation performed** *(operation note, filed in notes or on computer)* – this should record the main procedure performed.
- **Was bowel resection performed?** *(direct observation, operation note, filed in notes or on computer)* – if a complete portion of bowel (from oesophagus to rectum) was resected and the subsequent management (handsewn anastomosis, stapled anastomosis, stoma) should be recorded. A stapled anastomosis which is reinforced with handsewn sutures should be recorded as stapled. If no resection was performed, this should be coded as 'no'.
- **Stoma formation?** *(direct observation, operation note, filed in notes or on computer)* – these are categorised in the main groups. If a mucous fistula type stoma is made in addition to any category, this does not need to be recorded.
- **Underlying pathology/indication** *(clinical notes, or operation note, filed in notes or on computer)* – this should record the main cause leading to surgery.
- **Pulse oximeter use during surgery** *(direct observation, anaesthetist, clinical notes)* – if a pulse oximeter is used by anaesthetist of surgeon during the entire

procedure, this should be recorded as yes. If not used, or used for only part of the procedure, this should be recorded as no.

- **Were prophylactic antibiotics used** *(direct observation, operation note, drug chart, anaesthetic chart)* – prophylactic refers to antibiotics given either at induction, or during surgery but before opening of a contaminated space (e.g. before bowel resection).

- **Intra-operative active rewarming used?** *(direct observation, operation note, filed in notes or on computer)* – this should record whether active intraoperative re-warming systems were used (including but not limited to forced-air convection systems, heating blankets, radiant warmers, warmed humidified inspired oxygen and warmed fluid infusion).

- **Peri-operative blood transfusion** *(direct observation, operation note, drug chart, anaesthetic chart)* **–** either pre-operatively on this admission, intra-operatively or post-operatively. Blood transfusion refers to either whole blood or blood products (e.g. packed red cells, fresh frozen plasma).

- **Highest post-operative glycaemic reading within 72 hours of surgery** *(anaesthetic/recovery chart filed in notes; ITU charts, nursing notes at the end of the bed)* – this optional field can be completed if a reading was made as part of normal care. The highest value in the first 72 hours should be recorded, and may either be by finger-prick method, by serum analysis (either blood gas analysis or laboratory). The value should be given in mmol/l (convert from mg/dl at http://www.diabetes.co.uk/blood-sugar-converter.html ; alternatively, divide mg/dl by 18, e.g. 130mg/dl ÷ 18 = 7.2 mmol/l). If this field is left blank, it means no reading was taken. (Blank fields will not contribute to data completeness).

- **Thomoboembolic prophylaxis** (drug chart, notes, direct observation) – the highest level used (1=highest), irrespective of duration and dose, should be recorded. Chemical prophylaxis includes unfractionated heparin and low-weight molecular heparin. Mechanical prophylaxis includes TED stockings and intermitted pneumatic compression stockings intra-operatively.
- **Length of stay** *(computers/ notes)* **–** calculated from the day of admission to the day of discharge. The day of admission counts as day 1, and the day of discharge as a whole day. Thus staying from Monday to Friday counts as a 5-day length of stay ("5" should be entered).
- **Post-operative critical care admission** *(direct observation, notes)* – a planned admission is when the decision is made pre-operatively for a planned post-operative admission to critical care. An unplanned admission occurs when the patient returned to the ward after theatre and was subsequently transferred to critical care, or due to intra-operative incident mandating critical care. If no critical care admission was made, this should be entered as "none." For this study, critical care refers to high dependency or intensive care units. High dependency care is typically for detailed observation, single organ support and carries a 1:2 nursing: patient ratio. Intensive care typically describes multiple organ support and a 1:1 nursing ratio. Local definitions of critical care settings, which differ from this, are acceptable.
- **30-day mortality** *(direct observation, computer, notes)* **–** related to all-cause mortality that occurs up to and including the post-operative Day 30. Whether that mortality was inpatient or outpatient should be noted within this field.
- **30-day re-intervention** *(direct observation, computer, notes)* **–** this relates to surgical, endoscopic or radiological re-intervention, by day 30. The entry field

allows which method used to be specified. If more than one was used, the surgical intervention should be recorded.

- **Other complications** *(direct observation, computer, notes)* **–** the occurrence any complication without the need for re-intervention, critical care admission or death should be recorded here. These will be considered as minor complications and for their simplicity, a yes/no entry will be recorded. Examples include (but are not limited to): Surgical site infection treated with antibiotics, myocardial infarction treated medically, deep venous thrombosis treated with clexane, pneumonia or urinary tract infection treated with antibiotics, ileus, thrombophlebitis.
- **Anastomotic leak** *(direct observation, computer, notes, radiology systems, outpatients)* **–** an anastomotic leak detected clinically/symptomatically, radiologically, and/or intra-operatively. Enter no if an anastomoses was not performed.
- **Pelvic abscess** *(direct observation, computer, notes, radiology systems, outpatients)* **–** detected clinically/ symptomatically, radiologically, or intra-operatively.
- **Wound infection** *(direct observation, computer, notes, outpatients)*– We advise adherence to the Centre for Disease Control's definition of surgical site infection[19], which is any one of:

  (1) Purulent drainage from the incision

  (2) At least two of: pain or tenderness; localised swelling; redness; heat; fever;

  AND The incision is opened deliberately to manage infection or the clinician diagnoses a surgical site infection

  (3) Wound organisms AND pus cells from aspirate/ swab

Appendix D: References

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