

## Global Outcomes in Surgery Collaboration



### **Determining universal processes related to best outcome in emergency abdominal surgery: *An international evaluation***

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A multicentre, international evaluation of emergency abdominal surgery to identify common, modifiable best practice processes

**Registration:** [www.globalsurg.org/register](http://www.globalsurg.org/register)



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GlobalSurg.org

Study protocol v9.1

6<sup>th</sup> June 2014

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## 2. Authorship

GlobalSurg represents an international network of practicing surgeons and other interested clinicians from around the world, which includes you. Your help in delivering this global study will be based on a previously described equal partnership collaborative model, which we have described in the Lancet<sup>1</sup>.

We ask journals to make all co-authors PubMed citable in resulting publications. Papers will be published under one main name (*GlobalSurg*) which represents our group effort. To accommodate this, GlobalSurg will create the following groups to be listed at the end of papers:

- **Protocol development:** collaborators who have actively contributed to setting up the protocol.
- **Dissemination team:** collaborators who have worked to disseminate the protocol across international borders.
- **Country leads:** collaborators who have lead several sites in their country
- **Local collaborators:** collaborators who have collected data at their site. Up to three collaborators per hospital will be listed as PubMed citable co-authors in the planned journal paper reporting the study results. These authors should all have made substantial contributions to audit set-up (including gaining research or audit approval), patient identification, data completion and follow-up for mortality/complications. Author names will be submitted at the same time as the final dataset.
- **Writing Committee:** this will be a group of internationally representative surgeons and trainees who will produce final papers, ensuring they are globally relevant.

This authorship model has previously been successfully used for other collaborative projects <http://www.ncbi.nlm.nih.gov/pubmed/23842836> :

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Br J Surg. 2013 Aug;100(9):1240-52. doi: 10.1002/bjs.9201.

**Multicentre observational study of performance variation in provision and outcome of emergency appendicectomy.**

National Surgical Research Collaborative.

**Collaborators (241)**

Bhangu A, Richardson C, Torrance A, Pinkney T, Battersby C, Beral D, Cornish J, Dent H, Hall N, Palsler T, Panagiotopoulou I, Strong S, Velineni R, Panagiotopoulou I, Chalzizacharias N, Rana M, Rollins K, Eitehadi E, Jha B, Tan Y, Fanous N, Markides G, Tan A, Marshal C, Akhtar S, Mulaserry D, Ismail A, Hitchins C, Sharif S, Osborne L, Sengupta N, Challand C, Pourmaras D, Bevan K, King J, Massey J, Sandhu J, Wells J, Teichmann D, Peckham-Cooper A, Sellers M, Folaranmi S, Davies B, Potter S, Egbear D, Kallaway C, Parsons S, Upchurch E, Lazaridis A, Cocker D, King D, Behar N, Loukogeorgakis S, Kalaiselvan R, Marzouk S, Turner E, Kaptanis S, Kaur V, Shingler G, Bennett A, Shaikh S, Aly M, Coad J, Khong T, Nouman Z, Crawford J, Sztatny P, West H, MacDonald A, Lambert J, Gash K, Hanks K, Griggs E, Humphreys L, Torrance A, Hardman J, Taylor L, Rex D, Bennett J, Crowther N, McAree B, Flexer S, Mistry P, Jain P, Hwang M, Oswald N, Wells A, Newsome H, Martinez P, Alvarez C, Lein J, Carradice D, Gohil R, Mount M, Campbell A, Iype S, Dyson E, Groot-Wassink T, Ross A, Jones C, Charlesworth P, Bavlem N, Voll J, Sian T, Creedon L, Hicks G, Goring J, Ng V, Tiboni S, Palsler T, Rees B, Ravindra P, Neophytou C, Dent H, Lo T, Broom L, O'Connell M, Foulkes R, Griffith D, Butcher K, McLaren O, Tai A, Yano H, Torrance H, Moussa O, Mittapalli D, Watt D, Basson S, Gilliland J, Pilgrim S, Wilkins A, Yee J, Cain H, Wilson M, Pearson J, Turnbull E, Brigg A, Yassin N, Clarke J, Mallappa S, Jackson P, Jones C, Lakshminarayanan B, Sharma A, Velineni R, Fareed K, Yip G, Brown A, Patel N, Ghisel M, Tanner N, Jones H, Witherspoon J, Phillips M, Ho M, Ng S, Mak T, Campain N, Mukhey D, Mitchell W, Amawi F, Dickson E, Aggarwal S, Satherley L, Asprou F, Keys C, Steven M, Johnstone M, Muhschlegel J, Hamilton E, Yin J, Dilworth M, Wright A, Spredborough P, Singh M, Mockford K, Morgan J, Ball W, Royle J, Lacy-Colson J, Lai W, Griffiths S, Mitchell S, Parsons C, Joel A, Mason P, Harrison G, Steinke J, Rafique H, Battersby C, Hawkins W, Gurrum D, Hately C, Penkethman A, Lambden C, Conway A, Dent P, Yacob D, Oshin O, Hargreaves A, Gossedge G, Long J, Walls M, Futaba K, Pinkney T, Puig S, Boddy A, Jones A, Tenucci C, Battersby N, Wilkin R, Lloyd C, Sein E, McEvoy K, Whisker L, Coloni A, Sinclair P, Loughran M, Lawrence A, Horsnell J, Bagenal J, Pisesky A, Mastoridis S, Solanki K, Siddiq I, Merker L, Sarmah P, Richardson C, Hanratty D, Evans L, Mortimer M, Bhalla A, Bartlett D, Beral D, Blencowe N, Cornish J, Haddow J, Hall N, Johnstone M, Pilgrim S, Velineni R.

**Abstract**

**BACKGROUND:** Identification of variation in practice is a key step towards standardization of service and determination of reliable quality markers. This study aimed to investigate variation in provision and outcome of emergency appendicectomy.

**METHODS:** A multicentre, trainee-led, protocol-driven, prospective observational cohort study was performed during May and June

### 3. Abstract

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**Importance:** With over 200 million surgical operations per year worldwide and with nearly every acute care hospital providing surgical services, emergency abdominal surgery represents an internationally important marker of health capacity.

**Delivery:** GlobalSurg proposes a novel approach to a global surgical outcomes project, involving collaborative methodology that uses 'snap-shot' clinical data collection. Emergency abdominal surgery requires invasive operation with a high adverse event rate. Snapshot clinical data collection over a 2-week period will form the basis of the study.

**Validation and feasibility assessment:** During registration of interest ([www.globalsurg.org/register](http://www.globalsurg.org/register)), a survey of available resources and capacity will be undertaken by participants. A pre-starting survey based on the WHO Tool for Situational Analysis will be performed.

**Method:** This is a multicentre, international, prospective cohort study. Any hospital in the world performing acute surgery is eligible to enter. **Any patient undergoing emergency intra-peritoneal surgery is eligible.** Caesarean sections are excluded. The primary aim of this study is to identify internationally relevant, modifiable surgical practices (in terms of modifiable process, equipment and clinical management) associated with best care. The primary outcome measure will be the **24 hour peri-operative mortality**. The secondary outcome will be 30-day peri-operative mortality.

**Timing:** Centres will collect observational data on patients for a 14-day period during July-November 2014. Required data points will be limited to ensure practicality for the individual collecting data.

**Discussion:** Baseline outcome measurement to facilitate future evaluation has not yet been undertaken at an international level and may provide a useful indicator of surgical capacity and the modifiable process, equipment and clinical management that influence this. This novel methodological approach may facilitate faster delivery of multicentre studies at a global level, in addition to building international audit and research capacity in surgery.

## 4. Introduction

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### Why is this project important?

Surgery has an undeservedly low profile in global health priorities. It was not mentioned in the Millennium Development Goals despite at least 1 in 25 people who will require an operation in their lifetime. This figure represents an estimated 234 million surgeries worldwide per year<sup>2, 3</sup>. Most of these operations are restricted to high income countries, meaning there is disparity in access to surgery across the world and considerable unmet surgical need<sup>4</sup>. An estimated 70% of countries have no information on the frequency of surgical procedures performed<sup>5</sup>.

There is a shortage of patient-level data in surgical global health<sup>6</sup>. Detecting variation associated with outcomes of common emergency abdominal surgical operations, and modifiable practices associated with this variation, is likely to act as a surrogate marker for best performance of acute surgical units<sup>7, 8</sup>. Globally relevant risk factors relate to the experience of operating surgeon, the availability of investigations, use of safety checklists, equipment use in operating theatres and access to critical care facilities<sup>5, 9, 10</sup>.

Emergency abdominal surgery, including laparotomy, appendicectomy and hernia repair is performed in virtually every acute hospital in the world and is likely to be subject to performance variation<sup>8</sup>. Emergency laparotomy is a standard of acute abdominal surgery (including trauma), and is the most invasive procedure with the highest side-effect profile<sup>11</sup>. Post-operative mortality affects up to 15% of patients and morbidity up to 30%<sup>11, 12</sup>.

A prospective audit of current practice is underway in the United Kingdom (National Emergency Laparotomy Audit, [www.nela.org.uk](http://www.nela.org.uk)), in high-income countries (HICs) may lack relevance and comparability in low-and middle income countries (LMICs). GlobalSurg will supplement the World Health Organisation (WHO) Global Initiative for Emergency and Essential Surgical Care<sup>13</sup> (GIEESC) by providing frequency of surgery and risk-adjusted patient level outcome data.

### Future of GlobalSurg

GlobalSurg will develop a network of surgeons, surgical departments and other interested groups that will have a long-term ability to collaborate on further outcome studies, including randomised trials. Widespread provision of the protocol and supporting educational materials will empower individual

practitioners to participate and will facilitate audit and research capacity-building in regions that currently lack local opportunities for development. Successful development of global networks can be transferred to other specialties, and may be able to deliver randomised controlled trials.

## **Participation**

GlobalSurg will develop a network of surgeons, trainees, surgical departments and other interested groups that will have a long-term ability to collaborate on further outcome studies, including randomised trials. Widespread provision of the protocol and supporting educational materials will empower individual practitioners to participate and will facilitate audit and research capacity-building in regions that currently lack local opportunities for development.

This global research project will allow surgeons from across the world to contribute data, without need for extra resources or funding. It will be achievable for practicing surgeons because:

- Patients who undergo emergency abdominal surgery are easily identified
- The number of required data points is minimal to simplify data collection
- The primary endpoint relies only on 24-hours of follow-up data
- The secondary endpoint relies on inpatient care
- Data collection is limited to 14-days' worth of patient data

Surgeons and other clinicians will be able to form networks both locally and internationally, preventing clinical and academic isolation secondary to either income or experience.

## **How is this project different to others?**

We propose a novel approach to a global surgical outcomes project, involving collaborative methodology, including institutions in HIC and LMIC settings, and using 'snapshot' clinical data collection<sup>10, 14</sup>. By using multiple centers over a 2-week period, sufficient patient numbers will be achieved whilst minimizing resource requirements in each centre.

This study will deliver patient-level data derived at source, and will not rely on administrative or aggregated data, which, when analysed retrospectively, can be inaccurate. Trauma data, which is a leading cause of death in young people around the world<sup>15</sup>, will also be included. Trauma may result in a technically challenging laparotomy but is often excluded from surgical outcome studies.

We will endeavour to make the outcomes of this project available to all irrespective of access to academic resources. Depending on the availability of funding or fees waiver, we aim to publish the eventual results in an open-access journal. Additionally, anonymised raw data will be deposited in an open-access online repository (e.g. <http://figshare.com/>) for others to analyse. Open-access data will be modified to ensure that individual patients, hospitals or surgeons cannot be recognised.

## **Feasibility**

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

- Determining the spread of centres and number of surgeons, testing feasibility.
- Ensuring validity of inclusion criteria and risk factors being tested, which can be adjusted based on the results.

## **Aim**

The primary aim of this study is to identify internationally relevant, modifiable surgical processes associated with best care. It will further establish baseline variation of outcomes following emergency surgery across international settings.

In delivering this observational study, it will also provide an assessment of global audit and research capacity together with an educational opportunity to enhance this through study participation.

## **Delivery**

Rapidly delivered, snapshot, clinician-driven surgical outcome studies are feasible<sup>10, 16</sup>. In previous studies, short, 14-day inclusion periods have been balanced by the inclusion of multiple sites, acting as proof-of-principle that high volume, risk-adjusted outcome analysis is feasible.

One-and-a-half-billion people on the planet use social networking and up to 80% of online users interact with social networks regularly<sup>17</sup>. Most major national and international organisations engage with social media and disseminate key information to their membership. This provides a novel platform from which to contact individual doctors around the world. This may eventually allow more rapid

and widespread delivery of trials, in a more cost-effective manner than conventional methods.

All study data will be securely collected and held in the University of Edinburgh's REDCap data collection system.

### **Registration**

Interested participants should register at: [www.globalsurg.org/register](http://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 with your colleagues), please contact: [enquiry@globalsurg.org](mailto:enquiry@globalsurg.org)



## 5. Methods

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01

### Summary

Prospective observational study of consecutive patients undergoing emergency intra-peritoneal surgery (excluding Caesarean section). Collaborators can choose a consecutive 14-day data collection period during a 5-month study window (July-November 2014) in order to best suit their availability and needs; multiple teams covering differing periods from one institution are encouraged.

02

### Aim

The **primary aim** is to identify modifiable surgical practices (in terms of modifiable process, equipment and clinical management) associated with best care.

The **secondary aims** are to:

- Describe the epidemiology of indication for emergency abdominal surgery.
- Determine baseline experience and capacity for local audit in surgical settings.

03

### Outcome Measures

#### *Primary outcome measure*

The **primary outcome measure is the 24-hour peri-operative mortality rate (including intra-operative deaths)**. This is the number of deaths during operation or within 24 hours of operation conclusion, divided by number of operations performed<sup>18</sup>.

To ensure feasibility of this global surgical audit, the primary outcome measure should be simple, widely applicable and relevant when variation is shown. For this project, in which individual 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. Identification of individual hospital or surgeon performance will not be reported.

The main **secondary outcome measure is the 30-day peri-operative mortality rate (POMR-30)**. This is defined as the total number of deaths within 30 days of a surgical operation divided by the total number of emergency abdominal operations performed. We will use a pragmatic definition of POMR-30 which has been refined for applicability in a global setting. Where 30 days of follow-up are unavailable, alive-dead status at the point of final discharge from hospital will be used as a proxy measure for alive-dead status at 30 days. Other secondary outcomes include the 30-day serious complication rate. These serious complications can be expected within the index hospital stay, therefore biases due to lack of follow-up or readmission to other centres are minimised. These

outcomes represent Grade III and V of the internationally standardised and validated Clavien-Dindo classification (see appendix)<sup>19</sup>. Although not all centres have critical care facilities (Grade IV complication), this scale will provide a measure of the re-intervention rate. The outcomes 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<sup>3</sup>.

04

#### **Structure and quality assurance of participants**

**Local Collaborators:** Each hospital will have a local investigator. Each local investigator will be required to register centrally for updates. At each centre, local investigators can form a team of up to 3 people (including themselves) to accurately perform patient identification and data collection. Local investigators will be specifically responsible for:

- Gaining local audit or research approval
- Ideally forming a team of 2-3 people (including themselves) to identify patients and collect data (team names submitted with final data).
- Creating clear mechanisms to identify and include eligible patients
- Identifying clear pathways to establish outcome

#### **Quality assurance of participants**

It is not financially viable to have a central investigators meeting, which would also act as a financial barrier to participation for investigators from LMICs. In order to maximise the legitimacy of local investigators, registration emails from an affiliated institution are encouraged (e.g., hospital, university or other health organisation email address). Where not possible, investigators will be asked to provide other confirmation (e.g., letter of confirmation from department or colleague). Previous experience and knowledge of audit principles will be assessed as part of the initial baseline investigation of local audit capacity. Submitting centres with > 5% missing data will result in exclusion of that centre from analysis.

05

#### **Patient Inclusion Criteria**

- **All sequential patients undergoing emergency intra-peritoneal surgery during the chosen 2-week period.**
- Emergency (unplanned, non-elective, same admission) procedures. This includes patients undergoing re-operation after a previous procedure.
- Laparoscopic, laparoscopic converted and open cases can be included.
- Any age patient (adult and paediatric) can be included.

06

#### **Patient Exclusion Criteria**

- **Elective** (planned) or **semi-elective** (where patient initially admitted as an emergency, then discharged from hospital, and re-admitted at later time for surgery) procedures.

- **Caesarean section.** These patients represent a separate operative group, with different priorities and treatment pathways. They have been studied in detailed elsewhere, and their frequency would skew the results of this study.

07

**Methods to identify consecutive patients include:**

- Daily review of operating theatre lists
- Daily review of team handover sheets/ emergency admission lists/ ward lists
- Daily review of theatre logbooks

08

**Time period**

The study will run over a 14-day, consecutive time period of the individual participant's choice in July-November 2014. This wide period was chosen to maximise participation. Each local team should select the most convenient consecutive 14-day period for their needs. Multiple teams covering differing periods from one institution are encouraged.

09

**Hospital inclusion criteria**

- Any acute care surgical unit worldwide 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.
- There is no minimum number of patients per centre, as long as the patient(s) included are consecutive.

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**Local approval/ Ethical considerations**

Different countries and hospitals will have differing mechanisms in place to gain permission for this study. All data collected will measure current practice, and no changes to normal patient management will be required. In the United Kingdom, ethical review has confirmed this project is therefore considered as an audit (see Appendix D), and it will be registered at each participating hospital centre as a clinical audit.

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)

Some hospitals may 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/attending physician.

Local investigators will be solely responsible for ensuring they have followed correct mechanisms, and will be asked to confirm this when data is submitted.

In many centres, this study may be considered as global audit or global service evaluation, and may not require formal ethical approval. In such cases, the primary audit standard will be that the post-operative mortality rate should not exceed 15%<sup>8, 11, 12</sup>. For example, within the United Kingdom, this study has been assessed as a University of Edinburgh audit project by the South East Scotland ethics service (see Appendix D). Data will not be analysed at the level of individual surgeon or hospital.

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#### **Data Collation and Governance**

Data will be collected via a secure online webpage, provided by the University of Edinburgh using the REDCap system (<http://project-redcap.org/>). REDCap is used around the world to securely gather research data. All patient data will be transmitted and held anonymously; the data will not be analysed at identifiable hospital or surgeon level.

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#### **Pilot and quality assurance**

A post-collection quality assurance check is unfeasible because 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 data points. A final pre-starting survey, based on the WHO Tool for Situational Analysis to assess Emergency and Essential Surgical Care, will be performed.

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. Any problems encountered will be addressed through email ([enquiry@globalsurg.org](mailto:enquiry@globalsurg.org)) with the steering committee and teleconferencing where appropriate.

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#### **Data set**

Data points related to the patient, surgeon, operation, hospital, operative method and postoperative period will be collected. In order to maximise completion, the minimum required dataset has been designed to be brief and to test only those factors that are likely to be relevant.

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### **Follow-up**

The primary outcome measure is achievable 24 hours post-surgery. All investigators are encouraged to monitor patients to identify 30-day complications. Most of these events are expected to occur during the patient's index stay and have been recommended for use<sup>5</sup>. 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 patient status and notes during admission and before discharge to identify in-hospital complications
- Reviewing the patient status in outpatient clinic or via telephone at 30 days (if this is normal practice)
- Checking hospital records (electronic or paper) or handover lists for re-attendances or re-admissions
- Checking for Emergency Department re-attendances

In cases where follow-up only occurs at 24 hours, the investigators should indicate 'unknown' for 30-day follow-up measures.

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### **Statistical analysis**

An estimated rate of seven emergency bowel resections in a 14-day period from 200 centres will provide a minimum data collection for 1400 patients. This will provide adequate power to detect a treatment practice associated with a 2.5% 24 hour survival difference (5% to 7.5%,  $\alpha$  0.05, power 80%). The feasibility questionnaire will enable either validation of the expected numbers, or alteration during development.

The possibility of outcome variations across different contexts will be tested by a variety of explanatory variables, including the 2012 Human Developmental Index (HDI) (<http://hdr.undp.org/en/statistics/>) which is a composite statistic of life expectancy, education, and income indices. Other possible explanatory variables will be the availability of specific hospital resources, and healthcare expenditure per capita. Care will be taken to ensure that individual surgeons, hospitals or countries will **not** be identified from the presented data.

Differences between demographic groups will be tested with the  $\chi^2$  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. Model fit and calibration will be tested. Data will be analysed using the R Foundation Statistical Programme.

## 6. Appendix A: Key steps for successful inclusion of your centre

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- Register yourself and your hospital: [www.globalsurg.org/register](http://www.globalsurg.org/register)
- Consider forming a team of 2-3 people, to help identify patients, collect data, and look for post-operative complications. Any healthcare professional is eligible to be part of the team. Medical students are also eligible collaborators, although they must form a team with a local doctor.
- Multiple teams covering differing periods from one institution are encouraged.
- 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 because it can take time. You are responsible for ensuring this has been undertaken via the most suitable mechanism and we will ask for your confirmation at the time of data submission.
- Complete a **practice** audit day: Complete 1 day of audit in your hospital of choice in the month before 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 address any unidentified problems.
- Mortality will be assessed among in-patients. As a minimum, the 24-hour mortality rate should be determined, meaning that the patient must be assessed the day after surgery. The patient should continue to be followed until the time of discharge to assess mortality, and staff involved should provide information on any relevant mortalities. Complications to 30 days, whether as an inpatient 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.**
- Avoid **missing data**; complete all fields. If > 5% of patients at your centre are missing data, your centre and name cannot be included.

## 7. Appendix B: Required data fields

Patient ID	Local hospital field
Age	
Gender	Male, Female
ASA score (see glossary of terms).	I, II, III, IV, V, not recorded
History of diabetes	No, diet, controlled, tablet controlled, insulin controlled
HIV status	Positive, negative, unknown
Smoking status	Current, Previous, Never, Unknown
Pre-operative computed tomography performed?	Yes/ No – but CT would be available if needed/ No - CT not available for this patient
If computed tomography (CT) was unavailable for this patient, what was the main reason?	No CT scanner in this hospital/ CT scanner present but electrical supply unavailable/ CT scanner present but not working/ CT scanner present but no reporting service available/ CT scanner present but patient unable to pay for CT/ Other reason/ Not applicable
Date of operation	DD/MM/YY
Time of start of operation (knife to skin)	24 hour clock
Time from hospital admission to start of operation	<3 hours, 3-5 hours, 6-11 hours, 12-23 hours, 24-47 hours, 48-71 hours, 72+ hours
Was a surgical safety checklist (WHO or equivalent) used?	Yes – fully used, Yes – used in part, No
Most senior surgeon present: training	medically-qualified surgical specialist; medically-qualified non-specialist; non-doctor surgical specialist; non-doctor and non-specialist.
Most senior surgeon present: experience since qualification (* or equivalent undergraduate/training course if non-doctor).	<5 years since finishing medical school*; ≥5 years since finishing medical school*
Most senior anaesthetist present: training	medically-qualified anaesthetic specialist; medically-qualified non-specialist; non-doctor anaesthetic specialist; non-doctor and non-specialist; not applicable: no anaesthetist
Most senior anaesthetist present: experience (* or equivalent undergraduate/training course if non-doctor).	<5 years since finishing medical school*; ≥5 years since finishing medical school* not applicable: no anaesthetist
Anaesthetic type	general anaesthetic, spinal anaesthetic, local anaesthetic sedation only (e.g. ketamine)
Supplementary oxygen	Yes- via bottle or mains supply; Yes- via oxygen concentrator; No – but oxygen available, No – oxygen not available
Incision	Midline, paramedian, transverse, gridiron, Lanz, groin, rooftop, Kocher's, Laparoscopic (+/- open specimen extraction), laparoscopic converted to open
Primary operation performed	Fixed fields, other (free text)
Was bowel resection performed?	Yes – hand-sewn anastomosis, Yes – stapled anastomosis, Yes – stoma without anastomosis, No
Stoma formation	Loop ileostomy, loop colostomy, end ileostomy, end colostomy, other, none.
Main pathology/ indication	Fixed fields, other (free text)
Was a pulse oximeter used throughout surgery?	Yes, No but available, No not available
Were antibiotics given?	Yes, No but available, No not available
Whole blood or blood product(s) used?	Yes – whole blood, Yes – blood products (e.g. packed red cells, FFP, plasma, platelets), No - but available at this hospital, No blood products available at this hospital.
Thromboembolic prophylaxis (drug = heparin etc, mechanical = stockings/pneumatic boots etc).	1. Yes – drug and mechanical, 2. Yes- drug only, 3. Yes-mechanical only, 4. Yes-other, 5. None
Intra-operative/24 hours mortality	Alive, Dead
Was there an intra-operative or post-operative complication that led to an unplanned 30-day critical care admission?	Yes, No - but available if needed, No - critical care not available at this hospital, unknown.
30-day re-intervention (tick-box)	Yes – surgical, Yes-endoscopic, Yes-interventional radiology, No, unknown.
30-day mortality (if alive at the point of discharge and no follow-up information available, indicate Alive)	Died-day of surgery, Died-inpatient after day of surgery, Died-outpatient, Alive, Unknown.
Length of stay following surgery (day of surgery is day 0). Leaving blank indicates unknown. If stay was 30 days or longer, indicate 30 days.	Days
Other complication(s) not resulting in critical care, re-intervention or mortality?	Yes/no
Anastomotic leak	Yes/no
Wound infection	Yes/no
Intra-abdominal/pelvic abscess	Yes/no

## 8. Appendix C: Required data fields - Glossary of Terms

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This section provides a data dictionary for key terms in the required data fields 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 be collected after becoming familiar with the system. Some of it may be supported by input from the junior doctor(s) in your mini-team.

- **Your patient ID** (*notes*): Enter your patient ID here. Only you will have access to this secure field. If you don't have hospital IDs at your centre, enter an identifying number here that you can match to the patient (e.g. 1, 2, 3).
- **Patient age** (*notes*): The completed number of years and months should be entered. For paediatric patients <12 months, a field for the number of months will be available.
- **American Society of Anaesthesiologists score** (*take from anaesthetic chart, filed in notes*):
  - I: Normal healthy patient
  - II: Patient with mild systemic disease
  - III: Patient with severe systemic disease
  - IV: Patient with severe systemic disease that is a constant threat to life
  - V: 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.
- **Was a surgical safety checklist used?** (*direct observation, clinical notes*): This related to the WHO surgical safety checklist (or an equivalent team based surgical safety checklist).
- **Most senior surgeon present in operating room** (*direct observation, operation note*): Details entered here should relate to the most qualified or experienced surgeon who was physically present within the operating room (scrubbed or unscrubbed) for part or all of the operation.
- **Most senior anaesthetist present in operating room** (*direct observation, anaesthetic chart note*): In different parts of the world, many different professionals can give an anaesthetic and in some settings the operating surgeon may also administer the anaesthetic. Details entered here should relate to the most qualified or experienced anaesthetist who was physically present within the operating room for part or all of the operation. If the surgeon administered the anaesthetic, state "no anaesthetist",
- **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 (hand-sewn anastomosis, stapled anastomosis, stoma) should be recorded. A stapled anastomosis that is reinforced with hand-sewn 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.
- **Main pathology/indication** (*clinical notes, or operation note, filed in notes or on computer*): This should record the main cause leading to surgery.
- **Was a pulse oximeter used throughout surgery?** (*direct observation, anaesthetist, clinical notes*): If a pulse oximeter is used by anaesthetist or 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).
- **Whole blood or blood product(s) used?** (*direct observation, operation note, drug chart, anaesthetic chart*): This question relates to use at any point in this hospital stay (pre-operatively on this admission, or intra-operatively or post-operatively on this admission). Whole blood use indicates transfusion of all (unseparated) blood components, often from an on-site donor. "Blood product(s)" refers to use of a separated blood component (e.g., packed red cells, fresh frozen plasma). Where both whole blood and blood products are used, state "whole blood".
- **Thromboembolic prophylaxis** (*drug chart, notes, direct observation*): Drug prophylaxis includes unfractionated heparin and low-weight molecular heparin. Mechanical prophylaxis includes use of stockings and intermittent pneumatic compression stockings intra-operatively.
- **24-hour peri-operative mortality** (*patient review*): This includes **intra-operative deaths**. This is the primary endpoint, investigators are expected to go to the ward and review each patient 24 hours after surgery to determine whether they are dead or alive. This must be completed for every patient.
- **30-day critical care admission** (*direct observation, notes*): A complication requiring unplanned critical care admission could be an intra-operative or post-operative complication. 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. However, local definitions of critical care settings, which differ from this, are acceptable.

- **30-day peri-operative mortality** (*direct observation, computer, notes*): Defined as the number of all-cause deaths during operation or within 30 days of operation, or at the point of final discharge if out-patient mortality status unknown.
- **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.
- **Length of stay following surgery** (*notes*): The day of surgery counts as Day 0, and the day of discharge as a whole day, (e.g., staying from Monday to Friday counts as a 4-day length of stay and “4” should be entered).
- **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, up to 30-days. 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 diagnosed clinically/symptomatically, radiologically, and/or intra-operatively. Enter **no** if an anastomoses was not performed.
- **Wound infection** (*direct observation, computer, notes, outpatients*): We advise adherence to the Centre for Disease Control’s definition of surgical site infection<sup>20</sup>, 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
- **Intra-abdominal/Pelvic abscess** (*direct observation, computer, notes, radiology systems, outpatients*): Detected clinically/symptomatically, radiologically, or intra-operatively.

## 10. Appendix D: UK ethics review

### South East Scotland Research Ethics Service

Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG



Name: Stuart Fergusson

Date: 22/04/2014  
Your Ref:  
Our Ref: NR/1404AB12  
Enquiries to: Alex Bailey  
Direct Line: 0131 465 5679  
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Stuart,

**Project Title: Determining universal processes related to best outcome in emergency abdominal surgery: an international evaluation**

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (email correspondence, completed IRAS form - version 1.pdf, globalstudy\_protocol\_v6\_0.pdf), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition).

The advice is based on the following:

- *The project is an audit limited to using data obtained as part of usual care, but note the requirement for Caldicott Guardian approval for the use or transfer of person-identifiable information within or from an organisation*

**If the project is considered to be health-related research you will require a sponsor and ethical approval as outlined in The Research Governance Framework for Health and Community Care. You may wish to contact your employer or professional body to arrange this. You may also require NHS management permission (R&D approval). You should contact the relevant NHS R&D departments to organise this.**

**For projects that are not research and will be conducted within the NHS you should contact the relevant local clinical governance team who will inform you of the relevant governance procedures required before the project commences.**

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that NHS ethical approval is not required. However, if you, your sponsor/funder feels that the project requires ethical review by an NHS REC, please write setting out your reasons and we will be pleased to consider further. You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

Alex Bailey  
Scientific Officer  
South East Scotland Research Ethics Service



1 Headquarters  
Waverley Gate, 2-4 Waterloo Place, Edinburgh EH1 3EG

Chair: Mr Brian Houston  
Chief Executive: Tim Davison  
*Lothian NHS Board is the common name of Lothian Health Board*

## 11. Appendix E: References

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