



GlobalSurg 2 Study

Determining the worldwide epidemiology of surgical site infections after gastrointestinal surgery

Study registration number:

GlobalSurg 2 Study protocol v7.9

30th January 2016



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Abstract

Aim: The primary aim is to determine worldwide surgical site infection (SSI) rates following gastrointestinal surgery.

Primary outcome measure: 30-day surgical site infection rate.

Hospital eligibility: Any hospital in the world performing emergency or elective gastrointestinal surgery is eligible to enter.

Inclusion criteria: Consecutive patients undergoing elective or emergency gastrointestinal resection, cholecystectomy or appendicectomy.

Team: Individual hospital teams with up to three people, collecting data for two weeks. Patients will be identified and data collected on **all** patients during the selected two-week period, with 30-day follow-up. Multiple teams may collect data over different two-week periods.

Time period: 4th January 2016 to 31st July 2016 (with follow-up of the last period to 30th August).

Validation: The quality of methods used to collect data will be assessed through independent evaluators and interviews with collaborators across a representative selection of low, middle and high income country hospitals.

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

Introduction

Building on GlobalSurg 1

The GlobalSurg collaborative is a network of over 3000 clinicians across 67 countries. The GlobalSurg-1 project launched in 2014 and delivered an international cohort study of over 10,000 patients undergoing emergency abdominal surgery[1]. This study identified that mortality after emergency abdominal surgery is two-to-three times higher in low, compared with high human development index (HDI) countries. This difference was not attributable to patients' baseline clinical characteristics alone.

Although mortality is the worst, most extreme outcome after surgery, it only affects 1-3% of patients undergoing surgery. More common markers of outcome are needed that are relevant to the other 97% of patients. Surgical site infection (SSI) is the most common complication following surgery, affecting up to 25% of patients after midline laparotomy in high income settings[2]. Our first study of emergency intra-peritoneal surgery identified that the incidence of SSI more than doubled from high (7.4%), to middle (14.4%), to low (20.0%) HDI countries. The SSI rate was even higher in those undergoing midline laparotomy (approximately 30%).

Antibiotic resistant organisms are now prevalent worldwide and a focus of interest for policy leaders and global health advocates[3]. Some hospitals have no information on the rate of antibiotic resistant SSI. When regular audits of pathogens and antibiotic prescribing are undertaken, redundant antibiotic use is reduced[4, 5]. Patients who contract infections caused by resistant organisms are at higher risk of mortality, morbidity and require more healthcare resources[6].

Globalsurg 1 assessed SSI as a secondary endpoint in only emergency surgery. Elective surgery was not included and no data on organism and antibiotic resistance was collected. GlobalSurg- will allow participating centres to audit their own practice and will inform the design of future trials aimed at reducing the incidence of SSI.

GlobalSurg is run by the SURG Foundation, a registered charity. The international steering group give their time to the charity for free, but we need your help to meet the costs of the 2015 program. You can support the Foundation here: givey.com/SURG_Foundation

Authorship

Participation in GlobalSurg projects results in co-authorship on arising publications, with a PubMed citable ID attributed to all collaborators. Publication will be authored under one main group name (*GlobalSurg Collaborative*) on the authorship by-line underneath the title, recognising every contributors' efforts. All collaborator names will then be listed at the end of the paper. This authorship model has been successfully used for previous collaborative projects, for example:

STARSurG Collaborative. Impact of postoperative non-steroidal anti-inflammatory drugs on adverse events after gastrointestinal surgery. *Br J Surg*. 2014;101(11):1413-23.

<http://www.ncbi.nlm.nih.gov/pubmed/25091299>.

Methods

The 'collaborative' model for 'snapshot' clinical audit is now well established, and has previously been described elsewhere[7]. These networks have now delivered major multicentre projects including cohort studies and multicentre randomised controlled trials. GlobalSurg-II continues to build on these internationally.

Aims

The **primary aim** is to determine SSI rates across low, middle and high Human Development Index (HDI, <http://hdr.undp.org/en/statistics>) countries.

The **secondary aims** are to:

- Assess variation in use of prophylactic antibiotics.
- Determine the rate of antibiotic resistant SSI.
- To assess the interaction between SSI, HDI and mortality.
- Assess how 30-day follow-up is completed across an international network.

Audit Standards

Some centres require an 'audit standard' in order to register the study as clinical audit. GlobalSurg 2 will use the audit standards for surgical site infection established by the UK National Institute for Health and Clinical Excellence (NICE)[8].

- **Surveillance:** People having surgery are cared for by healthcare providers that monitor surgical site infection rates (including post-discharge infections) and provide feedback to relevant staff and stakeholders for continuous improvement through adjustment of clinical practice (Quality Statement 7).
- **Treatment of surgical site infection:** People with a surgical site infection are offered treatment with an antibiotic that covers the likely causative organisms and is selected based on local resistance patterns and the results of microbiological tests (Quality Statement 6).

Time period

The study window will run from 4th January 2016 to 31st July 2016 (with follow-up for the last period ending 30th August 2016). Each local team may select a convenient consecutive two-week time period. **Multiple teams covering different time periods from a single institution are encouraged, and the same team can continue for more than two weeks.**

Hospital inclusion criteria

- Hospitals performing elective or emergency gastrointestinal surgery anywhere in the world may participate.
- All centres are required to register their details and all collaborators must complete an online training module prior to commencing data collection.
- For inclusion in the study, centres must include consecutive (i.e. one after the other) patients. There is no minimum number of patients per centre, so long as all eligible patients during the study period are included.

Patient eligibility

Inclusion Criteria

- All consecutive patients undergoing **elective or emergency gastrointestinal resection, cholecystectomy, or appendectomy**.
- Open, laparoscopic, laparoscopic-assisted, laparoscopic-converted and robotic cases should be included.
- Patients of any age should be included.
- Note that a primary trauma indication should be included.

Exclusion criteria

- Operations with a primary indication that is vascular, gynaecological, urological (including ileal conduit) or transplant.
- Caesarean section should be excluded
- Whipple's procedure should be excluded
Simple hernia repair (although a hernia repair with a bowel resection **should not be excluded**).

Gastrointestinal resection is defined as complete transection and removal of a segment of the oesophagus, stomach, small bowel, colon or rectum.

Emergency procedures are defined as unplanned, non-elective operations and include reoperations after previous procedures.

Each individual patient should only be included in the study once. Patients returning to theatre due to complications following earlier surgery can be included, as long as their indexed procedure has not already been included.

Outcome Measures

Primary outcome measure

The primary outcome measure is superficial or deep incisional surgical site infection (SSI) within 30 days of surgery. This involves any of the operative incisions made. This measure uses the definitions within the 2008 Centre for Disease Control[9] definitions of SSI.

This requires the patient to have **at least one of the following**:

- Purulent drainage from the superficial or deep (fascia or muscle) incision but not from within the organ/space component of the surgical site.
- At least one of: pain or tenderness; localised swelling; redness; heat; fever; **AND** the incision is opened deliberately or spontaneously dehisces.
- Abscess within the wound (clinically or radiologically detected)

SSI will be measured at **30-days** after surgery either in person or by computer record/chart review. If 30-day follow up is not possible, SSI will be measured at the point of discharge.

We strongly encourage teams to assess patients at 30-days (in-person or via telephone), as this is the only way to audit practice properly.

Secondary outcome measures at 30-days:

- 30-day postoperative mortality rate (POMR), defined as death any time after skin incision until 30th day after surgery. If the patient is discharged alive but not seen again by day 30, this is equivalent to the in-patient mortality rate [10].
- Administration of perioperative antibiotics.
- Rate of antibiotic resistant SSI.
- Method of 30-day follow-up.

Local approval/ethical considerations

The proposed study observes normal patient management and will not affect or change standard clinical care. In many centres this study will not require formal ethical approval and can be classified as an audit. However, each country and hospital will have differing regulations for gaining permission to undertake this study. All data collected will measure current practice. Data will not be presented at the level of individual surgeon, hospital or country.

In the United Kingdom, ethical review by the South East Scotland Research Ethics Service and the NHS Health Research Authority has confirmed GlobalSurg 2 does not require formal ethical approval (see appendix), and it can be registered at participating UK hospitals as a clinical audit.

Local investigators must gain approval from one of the following, guided by local policy:

- 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 or emailed permission should be provided to the local investigator 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 the correct mechanisms for this as a condition of participation, and will be asked to confirm local approval when their data is submitted.

Governance

Data will be collected via a secure online webpage, provided by the University of Edinburgh, UK, using the REDCap system (<http://project-redcap.org/>). REDCap is used around the world to securely gather research data[11]. All patient data will be transmitted and held anonymously; data will not be published with hospital identifiers.

All collaborators will be asked to agree to a data handling and storage Code of Conduct prior to participating in GlobalSurg 2. Our formal policy on data governance can be found online (www.globalsurg.org).

Validation study

Validation will be performed in two parts across a randomly selected group of representative centres:

- I. Validation of case completeness. After data submission, independent evaluators will be asked to count the number of eligible patients between two dates at participating

sites. This will be cross-checked against the actual number of cases submitted, and the capture rate calculated across all validation centres. Independent validators should be selected by local teams (e.g. doctors or students from the same hospital, but not involved in the primary study).

- II. Data capture methodology. This will include interviews (combination of face-to-face, telephone and/or Skype) with collaborators to assess data collection methods, against pre-set quality criteria for each methodological domain.

Quality improvement and re-audit

After a site has completed data submission, we will feedback baseline SSI rates to supervising surgeons in each centre. Subsequently, we will create an online evidence based SSI education package. Centres that complete the package will be invited to re-audit their practice and outcomes approximately 12 months later. A lead surgeon will need to be identified at each site in order to take part in the quality improvement cycle.

Methods to identify consecutive eligible patients

Primary method

- Daily review of theatre logbooks or operating lists, from all appropriate operating rooms – **this is the primary method we expect collaborators to use to reliably identify all eligible patients.**

Other/supplementary methods include:

- Daily review of handover sheets/ emergency admission and ward lists.

Collecting Data

Local Collaborators: Each hospital will have local investigators. Each local investigator will be required to register themselves centrally for updates (www.globalsurg.org/register). At each centre, a team of **up to three** investigators can be formed to identify patients and collect baseline and follow-up data. Local investigators will be responsible for:

- Gaining local audit, service evaluation, or research ethics approval.
- Creating clear mechanisms to identify and include all eligible patients.
- Identifying clear pathways to accurately collect baseline and follow-up data.
- Submit data to the online REDCap system, including names of their team members.

Follow-up

All investigators are encouraged to actively monitor patients to identify SSI to 30-days. This is part of standard practice as recommended by many hospitals and national organisations (e.g. NICE). Centres should be proactive in identifying SSI. We will ask how patients were followed up to 30-days. Local arrangements should include:

- Daily review of patient and their notes during admission.
- Reviewing the patient status in outpatient clinic or via telephone at 30 days.

- Checking hospital records (electronic or paper), discharge summaries and handover lists for re-attendances or re-admissions.
- Checking for Emergency Department re-attendances.

Analysis

The possibility of outcome variations across different contexts will be tested by a variety of explanatory variables, including the 2014 Human Developmental Index (HDI[12]); a composite statistic of life expectancy, education, and income indices. Data will not be analysed or reported at an individual surgeon, hospital or country level. SSI rates fed back to individual centres will be done so automatically and anonymously via REDCap.

Differences between demographic groups will be tested with the X^2 (Chi-squared) test. We will report outcomes either split by or stratified by procedure type. Multivariable logistic regression will be used to test the influence of variables on the outcome measures. Hierarchical models accounting for hospital and country will also be used. Bayesian methods with uninformative priors may also be employed. Variables entered into these models will be clinically plausible and occurred prior to the outcome event. They will be pre-defined and used to adjust the main explanatory variable. Model fit and calibration will be tested. Data will be analysed using the R Foundation Statistical Programme.

A secondary aim is to determine the rate of antibiotic resistant SSI. This will allow us to determine how many patients undergo routine wound culture and to map causative pathogens. This information will be split by HDI/anonymised country, building a roadmap for causative organisms around the world and allowing centres to review their own prescribing practice. We will not be standardising laboratory assessment, techniques or definitions used, since it is impractical over so many centres and countries. Thus, this is an exploratory analysis only with full appreciation of the limitations in this measure.

References

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Appendix A: Key steps for successful inclusion of your centre

- Register yourself and your hospital at: www.globalsurg.org
- Form a team at your hospital of **up to three** people for one two-week data collection period. This team will identify all eligible patients, collect data, and capture post-operative complications. Any healthcare professional is eligible to be part of the team. Medical students can participate, but they must form a team with a doctor.
- A **lead surgeon** from each site should be registered to supervise the local collaborators. The lead surgeon will be invited to take part in the quality improvement cycle.
- Your hospital can form multiple teams covering **different** two-week periods (i.e. each individual patient is only included in the study once). Each team can cover longer than two weeks if capable.
- Ensure that you gain **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 a substantial amount of time. You are responsible for ensuring this has been undertaken, and you will be asked to confirm this at the time of data submission.
- Collect complications up to the 30th postoperative day, both during the index admission and any readmissions. Be **proactive** in identifying postoperative complications (e.g. review patients on the ward, daily checking of hospital notes or computer systems, review for readmissions). This will prevent under-estimating the true event rate.
- Identify **all consecutive eligible** patients using the inclusion and exclusion criteria.
- In order to ensure robust and valid results from this study, centres with low data completeness will be excluded from analysis, and not included in authorship.
- After completing data collection, **review** your data with the lead surgeon at your hospital, ensuring the data is of high quality and representative. **Lock** your dataset on the REDCap database to submit this for analysis.

Appendix B: Data fields

Note: Day of surgery is defined as post-operative day 0.

	Patient ID. 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. 01, 02).	
1	Age	If >2 years = whole years, if <2 years, months
2	Gender	Male, Female
3	American Society of Anaesthesiologists (ASA) score	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 Unknown
4	Immunosuppression	>Diabetes: Diet controlled, Tablet controlled, Insulin controlled, No (If a patient is managed with both oral hypoglycaemic drugs (tablets) and insulin, please select 'insulin controlled'.) >HIV: yes-on antiretroviral therapy; yes-not on antiretroviral therapy, no/unknown >Steroids (oral, intravenous or topical, e.g. prednisolone, fludrocortisone, dexamethasone): yes, no >Other immunosuppressive drugs (e.g. azathioprine, methotrexate, biologic agents): yes, no >Chemotherapy (current chemotherapy or if the last cycle was within 12 weeks of operation): yes, no >Active malarial infection: yes – confirmed by blood film or equivalent test, no HIV: yes – most recent preoperative CD4 count
5	Smoking status	Current smoker (including those who stopped smoking within the last 6 weeks), Previous smoker, Never smoked, Unknown
6	Date and time of admission	DD/MM/YYYY HH:MM
7	Date and time operation started (knife to skin time)	DD/MM/YYYY HH:MM
8	Length of operation (knife-to-skin until point of completion).	Minutes
9	Urgency of operation	Emergency (any surgery on the same admission as diagnosis), Elective (any planned admission for surgery)
10	Was a surgical safety checklist used (WHO or an equivalent)?	Yes, No - but available in this centre, No - not available in this centre
11	Initial operative approach	Open midline, Open non-midline, Laparoscopic, Laparoscopic converted to open, Robotic, Robotic converted to open
12	Primary operation performed	Pick from dropdown list; pick single main procedure performed. <i>Appendicectomy</i> – Appearance at surgery: simple (non-perforated), complex (perforated, free pus), normal <i>Appendicectomy</i> – Duration of symptoms (e.g. abdominal pain) prior to surgery (days, 0,1,2,3,4,5,6,7+)
13	Main surgical pathology/indication (The main cause leading to surgery).	Malignant (proven or suspected tumour/cancer), Benign
14	Intra-operative contamination	Clean-Contaminated: GI tract entered but no gross contamination; Contaminated: GI tract entered with gross spillage or major break in sterile technique; Dirty: There is already contamination prior to operation (e.g. with faeces or bile).
15	Antibiotic use:	
	Used for <i>treatment</i> before surgery (e.g. trial of antibiotics to treat diverticular abscess)	Yes (total days), No
	Used for <i>prophylaxis</i> at the point of incision (i.e. standard hospital prophylaxis)	Yes, No
	<i>Continued</i> at the end of surgery (i.e. extended prophylaxis after surgery)	Yes (total days), No
16	Was epidural analgesia inserted on the day of	Yes, No




	surgery?	
17	Were NSAIDs used postoperatively during the first 5 days of after surgery? (including ibuprofen, naproxen, diclofenac, ketorolac, etoricoxib, EXCLUDING aspirin).	Yes, No
18	Was serum haemoglobin/haematocrit checked in the first 48hrs postoperatively?	Yes, serum haemoglobin; Yes, capillary packed cell volume (PCV), No – but tests available in this centre. No – tests not available in this centre.
19	Was serum creatinine checked in the first 48hrs postoperatively?	Yes, No - but available in this centre, No - not available in this centre
20	Length of postoperative stay	Days
21	Surgical site infection:	
	Prior to discharge	Yes, No
	At 30 days after surgery	Yes, No, Not assessed after discharge
		<i>If yes: Was a wound swab sent for microbiological culture: Yes, No - but available in this centre, No - not available in this centre</i>
		<i>If yes: How was this treated: operative drainage, wound opened outside of operating theatre, antibiotics (tick all that apply)</i>
	What bacteria, if any, were identified?	None, S. Aureus, Coliform, Anaerobe, Other (5 tick boxes).
		<i>If yes: Sensitivity: sensitive to antibiotic prophylaxis given; resistant to antibiotic prophylaxis given; sensitivities not tested – but available in this centre; sensitivities not tested – not available in this centre</i>
22	30-day unexpected re-intervention. Record the most serious re-intervention, i.e. if patient undergoes an endoscopic, and then a surgical re-intervention within 30 days, please check the surgical box.	Yes - surgical, Yes - endoscopic, Yes - interventional radiology, No
23	30-day mortality	Dead, Alive, Unknown. <i>If died: post-operative day of death</i>
24	30-day intra-abdominal/pelvic abscess (CT, ultrasound, or clinical (including reoperation) evidence of intra-abdominal or pelvic abscess)	Yes, No
25	Other hospital acquired infection (treated with or without antibiotics)	Yes - urinary tract infection, Yes - pneumonia, Yes - central venous line infection, Yes – peripheral line infection, Yes-other, No
26	How was 30-day follow-up status achieved? (tick all that apply)	Still an inpatient, Clinic review, Telephone review, Community/home review, Discharged before 30 days and not contacted again




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Appendix C: NHS Health Research Authority assessment



Health Research Authority



Is my study research?

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

Title of your research:

Determining the worldwide epidemiology of surgical site infections after gastrointestinal surgery

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?
- 'No' - Are your findings going to be generalisable?


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 HRA.Queries@nhs.net.



Health Research Authority



Do I need NHS REC approval?

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

Title of your research:

Determining the worldwide epidemiology of surgical site infections after gastrointestinal surgery

IRAS Project ID (if available):

You have answered 'No' to the question "Is your study research" which indicates that **you do not need NHS approval.**

Appendix D: NHS Health Research Authority assessment

South East Scotland Research Ethics Service

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG



Name: Stuart Fergusson
Address: 2/2 Boat Green
Edinburgh
EH3 5LL

Date: 16/10/2015
Your Ref:
Our Ref: NR/1510AB5
Enquiries to: Alex Bailey
Direct Line: 0131 465 5679
Email: alex.bailey@nhslothian.scot.nhs.uk

Dear Stuart,

Project Title: Determining the worldwide epidemiology of surgical site infections after gastrointestinal surgery

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 and GS2 protocol v7_4_SJF), 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 feel 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