Global Outcomes in Surgery Collaboration

GlobalSurg II: Determining the worldwide epidemiology of surgical site infections after gastrointestinal surgery

Data Collection Help Sheet

Introduction

This document will help you in the process of data collection. It explains the data fields you will need to enter into the REDCap data server.

You may use to use this data collection help sheet alongside the **1-page paper data collection form** (found separately on the GlobalSurg website). It is not necessary to use this paper form, but it may assist you if internet access is not immediately available. Please be aware that if you use paper forms, these must be stored and disposed of securely since they contain sensitive, patient-identifiable information. Alternatively, you can upload data **immediately onto REDCap**. Remember that **only data uploaded to REDCap** will be included in analysis, so we encourage you to upload all data as soon as possible. We cannot accept data submissions by email, or by post.

Please try to avoid using the "unknown" option. Make every effort to give definitive entries for the data points where possible. Data with high levels of 'unknown' fields will be excluded from analysis, and subsequent authorship.

Other Resources

Please complete the **training modules** on our website:

1. GlobalSurg-II protocol module: http://globalsurg.org/globalsurg-2-training-module/
2. Surgical site infection training module: http://globalsurg.org/globalsurg-2-training-module/
3. REDCap data server module: http://globalsurg.org/data-collection/

Data Dictionary

REDCap Form 1:
Patient Demographics

Record ID_____

(Automatically generated, do not change.)
> You can't change this field

Hospital ID_____
> Enter a unique identifier for this patient. Hospital identification numbers should only be entered if you have received permission to do so from your hospital's Caldicott Guardian, or equivalent data governance body.

Age: Over 2 years old/Under 2 years old
> If age is >2 years, you will be prompted to enter the patient's age in years. If under 2 years old, you will be prompted to enter in months.

American Society of Anesthesiologists (ASA) score: 1/2/3/4/5/Missing or cannot be calculated

ASA means the American Society of Anaesthesiologists physical status classification score. This is a clinically defined measure of pre-operative risk defined as follows:

1. **"Normal healthy patient"**: *no significant organic, physiological or psychiatric health problems, good exercise tolerance; <u>excludes</u> extremes of age.*
2. **"Patient with mild systemic disease"**: *Well-controlled disease with no functional limitations- such as diabetes mellitus without complications; cigarette smoking without complications; mild obesity; pregnancy.*
3. **"Patient with severe systemic disease"**: D*isease with no immediate threat to life, such as stable angina, chronic renal failure, poorly-controlled hypertension.*
4. **"Patient with severe systemic disease that is a constant threat to life"**: *At least one severe poorly controlled disease- such as severe emphysema, symptomatic heart failure or unstable angina.*
5. **"Moribund patient not expected to survive without the operation"**: *Examples: haemodynamically unstable due to trauma or sepsis; multiorgan failure.*

<u>Immunosuppression</u>

Does the patient have HIV?:　　　Yes/ No/ Unknown

If you enter Yes, you will be asked the following question…

Has the patient had a CD4 count done in the past 12 months?: Yes/ No/ Unknown

If you enter Yes, you will be asked the following question…

Last CD4 count within 12 months, if HIV positive: ___

Measured in number of CD4 cells per mL

Does the patient have an active malarial infection?:　　　Yes/ No/ Unknown

Does the patient have Diabetes?: Yes/ No/ Unknown

If you enter Yes, you will be asked the following question…

How is diabetes controlled? (need to choose one only): Diet-controlled/ Medication (non-insulin)/ Insulin controlled

This question should be answered according to the patient's status before their surgery (i.e. if they were started on insulin after their surgery but were previously on oral medication alone, choose "Medication").

If the patient was taking insulin before their surgery, the option of "Insulin controlled" should be chosen even if also on oral medication.

If the patient is not on insulin, and is taking oral medication as well as modifying their diet, then choose the option of "Medication".

<u>Drugs causing immunosuppression</u>

Please note that these questions refer to use of drugs **<u>preceding</u>** surgical intervention.

Is the patient taking steroids?:　　　Yes/ No/ Unknown

Please note that if the patient is only on topical steroids (e.g. steroid inhaler, steroid creams) then this question should be answered as "No". Only answer as "Yes" if receiving oral or intravenous steroids.

Is the patient taking immunosuppressants?:　　　Yes/ No/ Unknown

Examples: methotrexate, azathioprine, mycophenolate mofetil, anti-TNF alpha antibiodies.

Is the patient receiving chemotherapy for cancer?:　　　Yes/ No/ Unknown

This would include drugs such as capecitabine, oxaliplatin, fluorouracil. It would NOT include hormone-modifying drugs such as tamoxifen, anastrozole or goserelin.

Smoking status: Never smoked/ Ex-smoker/ Current smoker/ Unknown
> Please try to obtain an accurate history and avoid using "unknown" unless necessary. If a patient has only very recently stopped smoking (a week or less from the time of admission), answer them to be a "current" smoker.

Date and time of admission: _____
> DD-MM-YYYY date format and time in 24 hour clock, e.g. 20-01-2016, 17:30. If exact time not available, please provide a best estimate.

Please select how you identified this patient for inclusion: Theatre logbook review/ From planned theatres lists or diaries (i.e. before the surgery had occurred)/ Handover lists/ Memory recall from staff/ Review of ward lists
> Select all that apply.

REDCap Form 2:
Operative details

Time (and date) operation started (time of knife-to-skin):
> DD-MM-YYYY date format and time in 24 hour clock, e.g. 20-01-2016, 17:30. If exact time not available, please provide a best estimate.

Time (and date) at end of operation (when wound closed, or time of death if intra-operative death):
> DD-MM-YYYY date format and time in 24 hour clock, e.g. 20-01-2016, 17:30. If exact time not available, please provide a best estimate.

Urgency of operation: Elective/Emergency
> An elective operation is one where it is planned prior to the patient's admission to hospital.

Was a WHO (or equivalent) surgical safety checklist used?: Yes/ No, not available in this centre/ No, but available in this centre/ Unknown
> Usage can be confirmed by direct observation or clinical notes. Please try to obtain a definitive answer and avoid answering "unknown" unless necessary.

Operative approach?: Open/Laparoscopic/Robotic/Laparoscopic converted to open/ Robotic converted to open
> Select one only.

Primary operation performed:
> Select the most appropriate operation title and try to avoid using 'other' unless necessary.

Diagnosis:
> Record the single main cause leading to surgery from the list given. This should be recorded with reference to operative findings; and in some cases in may be necessary to await pathological or other investigations before recording.

Antibiotic use

Used for treatment before surgery (e.g. trial of antibiotics to treat diverticular abscess): Yes/ No/ Unknown
> If you answer "yes", you will be prompted to answer the following question…

Number of days antibiotics prescribed before surgery: _____

Used for prophylaxis at the point of incision: Yes/ No/ Unknown

Continued at the end of surgery? (i.e. extended prophylaxis after surgery) Yes/No/ Unknown

If you answer "yes", you will be prompted to answer the following question…

Number of days antibiotics administered after surgery: _____

    Note this should be the number of days antibiotics were actually administered, which may not be the length of time they were originally prescribed for.

Intra-operative contamination: Clean-contaminated/ Contaminated/ Dirty

    Clean contaminated: GI tract entered but no gross contamination;
    Contaminated: GI tract entered with gross spillage or major break in sterile technique;
    Dirty: Contamination present prior to operation (e.g. with faeces or bile)

Pain control

Were NSAIDs (non-steroidal anti-inflammatory drugs) used post-operatively during the first 5 days after surgery (INCLUDING ibuprofen, naproxen, diclofenac, ketorolac, etoricoxib, but EXCLUDING aspirin)?: Yes/ No/ Unknown

    Includes all routes of administration (IV, oral, suppository). Please note definition above that where aspirin is used alone in the absence of other NSAIDs, this question should be answered as "no". As before, please try to give a definitive Yes or No answer rather than using "unknown" as default.

Was an epidural inserted at the time of surgery for planned post-operative pain relief?: Yes/No/ Unknown

    Use of a single shot of spinal anaesthetic would not count as an epidural – only answer "yes" if an epidural catheter was inserted at the time of surgery. Even if the epidural catheter is only used for a short time, this question should be answered as "yes".

Blood testing

Was serum haemoglobin/haematocrit checked in the first 48 hours post-operatively?: Yes, serum haemoglobin/ Yes, capillary packed cell volume/ No, but tests available in this centre/ No, tests not available in this centre/ Other

    Packed cell volume is also known as haematocrit. If you use "other", you will be prompted to enter the nature of this other test.

Was serum creatinine checked in the first 48 hours post-operatively?: Yes/ No, but available in this centre/ No, not available in this centre

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REDCap Form 3:

30-day outcomes

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Length of post-operative stay (days): ___

    Day of surgery counts as day 0. So if patient was admitted on 4th January, had an operation on 5th January and was discharged on 7th January, this field would be answered as 2 days.

Did the patient have an SSI (surgical site infection) within 30 days of surgery?: No, did not have an SSI/ No, not assessed, Yes, before discharge/ Yes, after discharged.

    This is a crucial field and must be answered with care. Please make every effort to obtain a definitive, accurate answer to this field. It might be appropriate to contact patients by phone or follow them up in clinic; dependent on your local situation. Please make yourself with our definition of surgical site infection (SSI), and ensure that you have completed our training module. SSI in our study means that a patient must have at least one of the following:

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

Were any organisms cultured from the wound or detected by PCR?: Yes/ No, but microbiology services available/ No, microbiology services not available

> PCR = polymerase chain reaction.
> If you answer "yes", some further questions will appear.

Which of the following organisms were isolated from the wound?: Staphylococcus Aureus/ Coliforms/ Anaerobe/ Other (state)

Were any of these organisms found to be resistant to antibiotics?: 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.

Other organisms isolated from wound: _____

Did the patient suffer any other hospital acquired infection?: Yes/ No

> If answered "yes", a further question will appear…

Intra-abdominal or pelvic abscess within 30 days: Yes/ No

> Detected clinically (e.g. at operation), or on imaging (e.g. ultrasound, CT scan).

Re-intervention

Was there unexpected re-intervention within 30 days: Yes/ No

> Could be surgical , endoscopic or radiological interventions. In a case where a plan is made at the time of the original operation for a "re-look" surgery, this is NOT an "unexpected" re-intervention. If you answer "yes", the following question will appear…

30-day unexpected re-intervention: Yes, surgical/ Yes, endoscopic/ Yes, interventional radiology

Mortality

30-day mortality: Alive/ Dead/ Unknown

> The 30-days refers to post-operative days. Please try to answer this field definitively rather than using "unknown". If the patient died, you will be asked…

If died, postoperative day of death: ___

> If the patient died on the day of surgery, this field would be answered "0".

How was 30-day follow-up status achieved (select all that apply): Still in-patient/ Clinic review/ Telephone review/ Community or home review/ Discharged before 30-days and not contacted since