GLOBALSURG 2 VALIDATION PROTOCOL

A multicentre evaluation of prospective observational data and processes to validate a global surgical outcomes study

GlobalSurg Collaborative

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Contents:

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VALIDATION OUTLINE

GlobalSurg 2 is a multicentre international study determining the global epidemiology of surgical site infections (SSIs) after abdominal surgery. Across centres worldwide, teams of up to 3 collaborators will collect data within a two-week period between January and July 2016, with a 30-day follow up.

Validating data and the processes for collecting this are important in establishing the accuracy of submitted data. Given the global nature of this study, validation has logistical and practical limitations. This protocol therefore triangulates data and process validity through three component parts:

A. **CENTRE QUESTIONNAIRE**: Self-reporting of key processes used to identify and follow-up patients
B. **INDEPENDENT DATA VALIDATION**: Quantitative case ascertainment and sampled data accuracy
C. **TEAM INTERVIEWS**: Qualitative and quantitative collaborator process and system assessment

VALIDATION TIMELINE:

Month	Study Period	Part A	Part B	Part C
January				
February				
March				
April				
May				
June				
July				
August				
September	Follow-up			

- **Jan-Jul 2016:** Centre questionnaire built into the GlobalSurg 2 data collection form is completed by each team of collaborators participating (Part A).
- **March 2016:** National Leads begin recruiting an independent validator for each centre.
- **Apr-Aug 2016:** Validators verify number of eligible cases for one data collection period as well as a sample of data points for each of these patients (Part B).
- **July 2016:** Steering Committee sample collaborator teams at random for team interviews (Part C).
- **August 2016:** Skype/Telephone interviews with teams to be held (Part C).

Independent Validator Authorship

All independent validators contributing to the process will be listed as collaborating co-authors on published papers, irrespective of whether the data submitted by the team being assessed is valid or not.

PART A: CENTRE QUESTIONNAIRE

The centre questionnaire will be completed by all collaborator teams uploading data to REDCap. The purpose of this section is to assess the range of processes used to identify patients for inclusion and establish their status at follow-up.

The questions below are embedded into the data collection form on REDCap for completion by all collaborating teams uploading data:

Please select how you identified this patient for inclusion?	☐ Theatre logbook or electronic system review after the operation occurred ☐ Planned theatre lists or diaries before the operation occurred ☐ Handover lists ☐ Memory recall from staff ☐ Review of ward lists (Check all that apply)
How was 30-day follow-up status achieved?	☐ Still inpatient ☐ Clinic review ☐ Telephone review ☐ Community/ home review ☐ Discharged before 30-days and not contacted since (Tick all that apply.)

PART B: INDEPENDENT VALIDATORS

Quantitative data validation will seek to establish case ascertainment (the proportion of cases correctly identified and included in the given data collection time period) and data accuracy (the proportion of data points correctly recorded in the given data collection time period).

Independent validators will be required to confirm all eligible cases in the given time period but, given the workload involved in undertaking Part B, will only be required to check a sample of data points for accuracy in order to avoid replicating the entire data collection process. This sample consists of 8 (31%) data points out of the 26 being recorded in the study; these are chosen to validate core data items without repeating the entire data collection process, and limiting the burden on independent validators.

The time period to be assessed is the first 2-week data collection period undertaken at that centre.

One validator per centre will be recruited by National Leads. They should:

1. Be a qualified doctor or nurse
2. Be independent of the mini-team collecting data
3. Have access to logbooks from all eligible operating theatres (or whichever form of patient identification is used at the centre)
4. Read the GlobalSurg 2 study protocol and complete the associated training modules

Once contact information for the independent validator has been provided by the National Lead to a member of the GlobalSurg steering committee, the independent validator will be issued with a set of instructions and login details to a REDCap account. This account will give them access to the dates during which data was collected by the collaborating teams at their centre, but not the data itself.

The independent validator will have 30 days to complete a separate data collection form:

1. On the REDCap system, what are the start and end dates of the first two-week data collection period at your centre? (*check input dates*)
2. What is the best way to identify eligible patients at your centre? *(checks for correlation with centre questionnaire [Part A])*
3. Using this patient identification method, how many patients were eligible for inclusion in this study between the two dates? (*input number for comparison*)
4. What is the best method of follow-up for this patient? *(checks for correlation with centre questionnaire [Part A])*
5. Sampled data point accuracy (to be filled for each eligible patient identified; an "unable to find this data" option will be available for situations where the data point could not be validated e.g. no hospital records available):
    A. Patient ID (which will be provided, and not be counted as a validated data point)
        1) Age
        2) Gender
        3) Date and Time of Operation
        4) Primary Operation
        5) Urgency
        6) Operative Approach
        7) 30 Day Re-Intervention
        8) 30 Day Mortality

PART C: TEAM INTERVIEWS

Qualitative and quantitative collaborating team interviews will seek to understand adherence to optimal processes for patient identification, data recording and follow-up. In addition, it will seek to identify and quantify external limitations on data validity posed by the local healthcare system (e.g. no patient notes in some low-income hospital settings). Collaborating teams participating in this will be sampled at random globally within each HDI category (high, middle, low) to participate, whilst ensuring adequate representation from each income category.

Interviews will be arranged by a member of the GlobalSurg steering committee, and conducted in-person where possible, or by either telephone or Skype™, lasting approximately 30-minutes. Potential answers detailing the range of expected responses have been provided to help categorise qualitative answers for easy analysis. These will not be provided to interviewees.

The question list is detailed below:

1. How did you gain approval for this study?
2. How did your team identify the patients included in the study?
3. On average, how regularly would your team identify eligible patients to include?
4. How did your team identify any inpatient complications?
5. How did your team identify any complications that happened within 30-days after discharge?
6. How did you collect data on the details of the surgery your patients underwent?
7. How did you collect or check data on laboratory values?
8. How does your hospital routinely store clinical data on their patients?
9. How did your team perceive the overall quality of clinical data used?
10. Were you able to identify if your patients were re-admitted at a different hospital?
11. How easy is it to access clinical data for this study/audit at your local centre?
12. What is the general support for clinical audits/ research projects at your hospital site?
13. How confident was the collaborator group in carrying out research and/or audit activity?
14. How did you hear about GlobalSurg?
15. Did you encounter any problems when completing GlobalSurg?

Analysis of Data Validity Results

Validity assessments will be reported anonymously; no individual surgeon or hospital will be identifiable.

Analysis of responses will allow centres to be grouped on the basis of high or low quality collaborator processes and high or low health system limitations to these processes.

The results of the data validation process will permit the following analysis to be presented:

- Overall case ascertainment
- Overall sampled data accuracy
- Proportion and range of optimal case ascertainment and data collection process compliance
- External health system limitations restricting collaborator compliance with optimal case ascertainment and data collection processes, and their prevalence
- Relation of all above factors to centre HDI

FURTHER INFORMATION

For further questions regarding validation or National/Local Lead identification, please email: enquiry@globalsurg.org

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