Plan Overview

A Data Management Plan created using DMPonline

Title: Global Surgery Stockholm

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Funder: Swedish Research Council

Template: Swedish Research Council Template

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Project abstract:

Purpose
The purpose is to strengthen the global surgery research group at Karolinska Institutet. Pressing scientific questions will be answered and researchers of the future will be trained.

The aims of the project are to:
1) Expand on the research relating to groin hernia - including surgical techniques, task sharing, surgical training and health economics.
2) Continue the work relating to breast cancer focusing on genetics and artificial intelligence.
3) Introduce and build research relating to trauma which will bridge my clinical work as a reconstructive plastic surgeon with my global surgery research.

Project organisation, time plan and scientific methods
The project consists of several studies, currently involving 6 PhD students. The group has a large number of collaborators in Sub-Saharan Africa, Europe and the US. The studies outlined in the application are a mix of ongoing research that will be completed early during the grant period, studies that will be initiated and a new field of interest that is being developed. The core of the research is randomised, clinical trials. Other methods include epidemiology, qualitative research, genetics, and health economics.

What is important about the planned research
Surgery has long been a neglected field within global health. 5 billion people lack access to surgical services of quality. The planned research will further move the needle for global surgery, aiming at providing evidence for best practices and policy making.

ID: 117476

Start date: 01-01-2023

End date: 31-12-2025

Last modified: 14-06-2023

Grant number / URL: 2022-01924

Copyright information:

Global Surgery Stockholm

General Information

Project Title

Global Surgery Stockholm

Project Leader

Jenny Löfgren

Registration number/corresponding, date and version of the data management plan

14 February 2023

Version

1

Date

14 February 2023

Description of data – reuse of existing data and/or production of new data

How will data be collected, created or reused?

Global Surgery Stockholm is a project that consists of several individual research projects.
Data are collected through
1. Epidemiological research projects where study subjects participate in interviews and physical examination
2. Clinical research including prospective cohort studies and randomised clinical trials. Data are collected through interviews and physical examination and in adjunction with surgical procedures.
3. Clinical research on tissue samples collected from study participants in a clinical setting.
4. Qualitative research, collected through interviews.
5. Health economical research using data on patient outcomes from point 2 above combined with hospital data including end-of-year reports and pay rolls as well as publicly available data.
6. Hospital based data - operation registers in individual hospitals.

What types of data will be created and/or collected, in terms of data format and amount/volume of data?

1. Two studies competed, others may be planned in the future. Together, they have included around 2000 patients. Data consists of information from interviews with study participants and results form physical examination carried out by medical doctors in a study team.
2. Three randomised controlled trials and one prospective cohort study on groin hernia including a total of around 1000 patients. Data consists of information from repeated interviews with the study participants and physical examinations by medical doctors in the study teams. Long term follow up of the patients has been completed in one of the studies and is planned for two of the studies.
Two new RCTs are planned with a total of around 800 patients. The same type of data as described above will be collected.
3. In a study on breast cancer in Ethiopia we offer screening for genetic mutations in blood and tumour tissue. Tumour blocks are

analysed for histopathological diagnosis and receptor status. We assess is artificial intelligence can be used for diagnosis. The data consists of results from genetic investigations, tumour biology and AI data. Patients are also interviewed and information about their disease are collected and forms the data.

4. 3 research projects have been completed. Data consists of audio material and the transcribed version of the audio recordings.

5. Health economical research using data on patient outcomes from point 2 above combined with hospital data including end-of-year reports and pay rolls as well as publicly available data.

6. Data consists of information about surgical procedures carried out in 29 hospitals in Uganda. It includes age and sex of the patients, the indication for surgery and the surgical procedure carried out, the surgeon, the assistant and the person administering anaesthesia.

Documentation and data quality

How will the material be documented and described, with associated metadata relating to structure, standards and format for descriptions of the content, collection method, etc.?

This has not been applicable yet as the ethical approvals that I/we currently have do not allow for sharing of data outside the research team.

In the future, we will include in the ethical applications that data (all or some) will be shared in an open repository or similar. When that is the case, I can make data collection tools available and brief overview of the data collection methodology. The clinical research shall be registered in ISRCTN where further details will be available.

Also documentation will include an easy to use folder structure, codebooks (metadata about the data), analysis plans, input and output files from databases and statistical software

How will data quality be safeguarded and documented (for example repeated measurements, validation of data input, etc.)?

Data are cross checked on several occasions including at the time of data collection, data entry and analysis. Errors are usually detected as data appears conflicting at the time of the quality control and/or data entry. Errors are corrected when possible (most of the time).

Storage and backup

How is storage and backup of data and metadata safeguarded during the research process?

Paper format is used for all of the clinical research carried out abroad. These are stored according to routines in the study countries. The data are also entered in excel spread sheets for data analysis.

Most data will be stored on the KI ELN system.

Alternative places for storing data are Onedrive and a KI server.

How is data security and controlled access to data safeguarded, in relation to the handling of sensitive data and personal data, for example?

Data will be deidentified from names and other identificators.

Legal and ethical aspects

How is data handling according to legal requirements safeguarded, e.g. in terms of handling of personal data, confidentiality and intellectual property rights?

Study participants will be asked to consent to preserve and share the data. In previous studies, we have not obtained consent to

share data. In new projects, study participants will be asked to consent for certain (de-identified) data to be shared for research purposes.
The identity of study participants will never be shared outside the research team. Data sets with very few study participants where those can potentially be identified, will not be shared.
Data will be stored on the KI ELN system where I as PI can decide who has access to what, and for how long.

How is correct data handling according to ethical aspects safeguarded?

Up to now, no data is publicly available, as this has not been part of our ethical approvals and patients have not consented to sharing data outside the research team.
This will be added to future studies so that sharing of all/some data is possible.
Only metadata will published openly, underlying de-identified data will be made available upon request after ensuring compliance with relevant legislation and KI guidelines.
Data will be stored on the KI ELN system where I as PI can decide who has access to what, and for how long.

Accessibility and long-term storage

How, when and where will research data or information about data (metadata) be made accessible? Are there any conditions, embargoes and limitations on the access to and reuse of data to be considered?

Raw data in paper format are stored in the different study countries, according to local routines and laws.
Soft copies, usually in excel format, SPSS or similar, are used for storage of data in Sweden.
All data will be stored in the KI ELN system. Most projects are carried out within PhD training. The individual PhD students can upload their data. The PI is responsible to ensure that this is done.
Only metadata will published openly, underlying de-identified data will be made available upon request after ensuring compliance with relevant legislation and KI guidelines.

In what way is long-term storage safeguarded, and by whom? How will the selection of data for long-term storage be made?

Raw data in paper format are stored in the different study countries, according to local routines and laws.
We intend to store all data for at least 10 years, possibly longer, as reuse of data and long term follow up may be done in the future.

Will specific systems, software, source code or other types of services be necessary in order to understand, partake of or use/analyse data in the long term?

Not according to current plans.

How will the use of unique and persistent identifiers, such as a Digital Object Identifier (DOI), be safeguarded?

Not applicable

Responsibility and resources

Who is responsible for data management and (possibly) supports the work with this while the research project is in progress? Who is responsible for data management, ongoing management and long-term storage after the research project has ended?

The PI has the overall responsibility.

What resources (costs, labour input or other) will be required for data management (including storage, back-up, provision of access and processing for long-term storage)? What resources will be needed to ensure that data fulfil the FAIR principles?

The resources required for data management are mainly time. The ELN system will be used for storage, back-up, and long-term storage.