

# Assessing the need for surgical treatments in Sierra Leone

<b>Submission date</b> 11/10/2019	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/08/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The need for surgical procedures is increasing, especially in developing countries where there is generally more need than availability. Research on the need for different types of surgery is needed to raise awareness of the medical need of people in these countries, to convince donors of the number of people with conditions that can be treated using surgery and to provide policy makers with the data needed to plan interventions. This study aims to investigate the need for surgery in Sierra Leone.

The researchers will conduct a survey on the numbers and types of surgeries needed across Sierra Leone. There are six parts to the study. The first is to repeat the Surgeon Over Seas Surgical Assessment Survey (SOSAS) from 2012, which was piloted in Sierra Leone. The original SOSAS study has already been performed in several other African and Asian countries, but has never been conducted twice in the same country. This will help us to see the differences in 7 years' time. Secondly, they aim to understand how common lower urinary tract symptoms (LUTS) are among men and boys aged 12 years or older, including an evaluation of health-seeking behaviour (what people do to try to resolve their symptoms). In addition, the researchers aim to study groin hernia and associated health-seeking behaviour and wounds and associated health-seeking behaviour. The survey will also investigate the need for surgeries related to women's health and childbirth, including comparing the health of mothers and newborns before, during and after the Ebola outbreak in Sierra Leone. Lastly, the researchers aim to investigate the numbers of surgical procedures performed per year and understand whether the proportion performed under the country's health service or paid for privately.

### Who can participate?

Any person living in a household in the areas of Sierra Leone selected for the survey.

### What does the study involve?

The researchers will go to randomly selected areas of the country and will visit people in their homes. They will conduct interviews with a representative of the household and two people from the household who have been selected randomly by rolling a dice. Depending on whether the selected people are in certain groups (for example, boys or men aged over 12 years), they might be asked additional questions from the survey.

What are the possible benefits and risks of participating?

There is no treatment in this study. It only involves interviews and limited physical examinations, therefore there are no risks expected. People will be asked questions about times when they have been unwell and some people might find this distressing.

Benefits will be mostly long-term. The information gathered will help to improve access to surgical treatment in Sierra Leone.

Where is the study run from?

Masanga Medical Research Unit (Sierra Leone)

When is the study starting and how long is it expected to run for?

September 2018 to December 2019

Who is funding the study?

CapaCare (Norway), Masanga Medical Research Unit (Sierra Leone) and Statistics Sierra Leone (Sierra Leone)

Who is the main contact?

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## Contact information

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
PRESSCO-SL

## **Study information**

**Scientific Title**  
Prevalence Study on Surgical Conditions 2019 in Sierra Leone: PRESSCO-SL.

**Acronym**  
PRESSCO-SL 2019

**Study objectives**  
The need for surgical care is increasing, particularly in low- and lower middle-income countries where the burden of surgical conditions by far outweighs its treatment capacity. Knowledge on

the prevalence of health conditions is needed to raise awareness of the medical need of populations, to convince donors of the magnitude of treatable conditions and to provide policy makers and ministries of health with the requisite data needed to plan interventions. To address these deficiencies for surgical conditions in Sierra Leone, community-level research to quantify the surgical need of the population is needed.

The purpose of this study is to assess the prevalence of surgical conditions in Sierra Leone. The study has six arms, which are interlinked:

1. Repeat the Surgeon Over Seas Surgical Assessment Survey (SOSAS) from 2012, which was piloted in Sierra Leone. The original SOSAS study has already been performed in several other African and Asian countries, but never before conducted twice in the same country.
2. Establish the prevalence of lower urinary tract symptoms (LUTS) among men 12 years or older, including an evaluation of health-seeking behaviour.
3. Establish the prevalence and incidence of groin hernia and health-seeking behaviour.
4. Establish the prevalence of wounds in Sierra Leone and health-seeking behaviour.
5. Establish the need for surgical female and obstetrical care in Sierra Leone, describe maternal and neonatal outcomes and their development in the pre-, during and post- Ebola time frame.
6. Establish the rates of surgical procedures performed per year and determine contributions of the public and private sector.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Current ethics approval as of 12/11/2019:

1. Approved 03/10/2019, Office of the Sierra Leone Ethics and Scientific Review Committee ([SLERC], Directorate of Training and Research, Ministry of Health and Sanitation, 5th Floor, Youyi Building, Brookfields, Freetown; no telephone number; efoday@health.gov.sl), ref: none
2. Approved 28/10/2019, Regional Committee for Medical and Health Research Ethics, Central Norway (post@helseforskning.etikkom.no), ref: 31932

Previous ethics approval:

1. Approved 03/10/2019, Office of the Sierra Leone Ethics and Scientific Review Committee ([SLERC], Directorate of Training and Research, Ministry of Health and Sanitation, 5th Floor, Youyi Building, Brookfields, Freetown; no telephone number; efoday@health.gov.sl), ref: none
2. Pending, REC North - Secretariat (Nordland, Troms and Finnmark) (UiT Norges Arktiske Universitet, Postboks 6050, Langnes, 9037 Tromsø, Norway; +47 77 64 61 40; rek-nord@asp.uit.no)

### **Study design**

Cross-sectional study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Need for surgery in Sierra Leone

## **Interventions**

The household will be selected from the randomly selected enumeration areas. In the household the head of household will be informed about the study and informed consent will be asked and written consent obtained if applicable. The first part of the questionnaire (Parts A to D) will be taken if informed consent is given from the household representative. Parts E to N from the questionnaire are answered by two randomly selected household members. They will be asked for separate informed consent. It is estimated that 1 h will be needed for interview time per randomly selected person. They will be asked questions about health problems they have had and the treatment they received. If specific conditions are identified, there is a referral and transport protocol for the participants.

If one of the selected household members is under the age of 12 years, that person needs a chaperone to assist. This can be any of the present and available household members over the age of 18 years.

## **Intervention Type**

Other

## **Primary outcome(s)**

SOSAS Repeat sub-study:

1. Demographic data including age, gender, level of education, occupation and ethnic background
2. Medical information, including health status, medical history, current complaints and clinical symptoms, complete head-to-toe verbal examination, health seeking behaviour, pregnancy history

Lower Urinary Tract Syndrome (LUTS) sub-study:

3. Medical information, including medical history, current complaints and clinical symptoms, health-seeking behaviour, outcome of Uflow meter

Groin Hernia sub-study:

4. Medical information, including medical history, current complaints and clinical symptoms, health-seeking behaviour, findings of physical examination

Wounds sub-study:

5. Medical information, including medical history, lifestyle, current illnesses and medication, clinical symptoms, health seeking behaviour, photograph of wound

Women's Health sub-study:

6. Medical information, including medical history, current complaints and clinical symptoms, health-seeking behaviour, family planning, pregnancy history, perinatal death, symphyseal-fundal height measured with tape measure

Surgical Volume sub-study:

7. Medical information, including medical history of deceased household members, medical history, visits to health care facilities in the past, health-seeking behaviour

## **Key secondary outcome(s)**

SOSAS Repeat sub-study:

Demographic data including age, gender, level of education, occupation and ethnic background

**Completion date**

20/12/2019

## Eligibility

**Key inclusion criteria**

SOSAS Repeat sub-study:

Two randomly selected household individuals who give informed consent

Lower Urinary Tract Syndrome (LUTS) sub-study:

Men and boys aged >12 years among the two randomly selected household individuals

Groin Hernia sub-study:

Two randomly selected household individuals

Wounds sub-study:

Two randomly selected household individuals

Women's Health sub-study:

Females aged 12-50 years among the two randomly selected household individuals

Surgical Volume sub-study:

All household members who have had a surgical procedure in past year

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

All

**Sex**

All

**Total final enrolment**

3618

**Key exclusion criteria**

1. No informed consent given
2. Does not meet inclusion criteria of sub-study

**Date of first enrolment**

16/10/2019

**Date of final enrolment**

07/03/2020

## Locations

**Countries of recruitment**

Sierra Leone

**Study participating centre****Masanga Medical Research Unit**

Masanga Hospital,  
Masanga, Tonkolili district  
Masanga  
Sierra Leone

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**Sponsor information****Organisation**

CapaCare

**Organisation**

Masanga Medical Research Unit

**Funder(s)****Funder type**

Charity

**Funder Name**

CapaCare

**Funder Name**

Masanga Medical Research Unit

**Funder Name**

Statistics Sierra Leone

**Results and Publications**

## Individual participant data (IPD) sharing plan

A managed access procedure will be developed to allow access to other researchers that wish to use the study data for secondary analysis after the closure of the study. These data will not be made openly accessible in line with national, European and international legal, ethical and privacy concerns. Access to the data will be controlled by principal investigator Håkon A. Bolkan and the senior board of PSSC'19. After the study has been completed and the main study paper published, then researchers can apply to principal investigator Håkon A. Bolkan with proposals to access the study data set for future studies. Access to the data set requires approval from the Steering Committee, which comprises representatives from each consortium partner and is chaired by Håkon A. Bolkan. Researchers will additionally need to sign a Data Sharing Agreement to protect the integrity and confidentiality of the requested data. Any shared data will be further minimised and anonymised as much as possible for the requested purpose.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	CVD arm results	18/08/2021	17/01/2022	Yes	No
<a href="#">Results article</a>		06/09/2022	07/09/2022	Yes	No
<a href="#">Results article</a>		01/02/2023	17/11/2023	Yes	No
<a href="#">Other publications</a>	Surgical Volume in Sierra Leone: A Comparison Between Population and Facility-Based Data Collection	15/08/2025	18/08/2025	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version v2.3	01/09/2019	16/10/2019	No	No