Prevalence Study on surgical conditions 2019

SOSAS Repeat / Lower urinary tract symptoms / Groin hernia / Chronic wounds / Surgical volume / Maternal and perinatal health

Study protocol version 2.3 (final) | 1st September 2019

Håkon A. Bolkan[a,b,c] (Principal investigator)
Martin Grobusch[d,e] (Co-Principal investigator)
Osman Sankoh[f] (Co-Principal investigator)
Jurre van Kesteren[g,h,i]
Mia Nyeng Østensen[a]
Sofie Mack Løvdal[a]
Karel Lindenbergh[g]
Jonathan Vas Nunes[d,e]
Daniël van Leerdam[c,k]
Josien Westendorp[a,c,o]
Hanna Mathéron[d,e]

Collaborators

Alex van Duinen[a,b,c]	Helena Bertilsson[a,b]	Thaim Kamara[n,p,q]
Reinou S. Groen[m,r]	Thomas Ashley[c,n,s]	Jenny Löfgren[l]
Diede van Delft[e]	Frank Bloemers[h]	Jaap Bonjer[h,i]
Dag Halvorsen[a,b,c]	Joyce Browne[o]	Janine Martens[t]
Michael Kamara[c,p]	Marcus Rijken[o]	Daan van Herwaarden[t]
Daniel Boateng[o]	Kerstin Klipstein-Grobusch[o]	N.N[f]
N.N[f]	N.N[f]	N.N

Affiliation / Institute

a. NTNU, Norwegian University of Science and Technology, Trondheim Norway
b. St. Olavs Hospital, Trondheim, Norway
c. CapaCare, Trondheim, Norway
d. Universiteit van Amsterdam, Amsterdam, The Netherlands
e. Masanga Medical Research Unit, Tonkolili district, Sierra Leone
f. Statistics Sierra Leone, Freetown, Sierra Leone
g. Faculty of Medicine, VU Vrije Universiteit, Amsterdam, The Netherlands
h. Department of Surgery, Amsterdam UMC, Amsterdam, The Netherlands
i. Global Surgery Amsterdam, Amsterdam, The Netherlands
k. KIT, Royal Tropical Institute, Amsterdam, The Netherlands
l. Karolinska Institutet, Solna, Sweden
m. Johns Hopkins School of Medicine, Baltimore, USA
n. Ministry of Health and Sanitation, Freetown, Sierra Leone
o. UMC Utrecht, Julius Center, Utrecht, The Netherlands
p. College of Medicine and Allied Health Sciences, University of Sierra Leone, Freetown.
q. Department of Surgery, Connaught Hospital, Freetown, Sierra Leone
r. SOSAS – Surgeons Over Seas, New York, USA
s. Kamakwie Wesleyan Hospital, Sierra Leone
t. Faculty of Medicine, University of Utrecht, Utrecht, The Netherlands

---- Research consortium ----

The prevalence 2019 study is a partnership between three equal organisations: Statistics Sierra Leone, Masanga Medical Research Unit and CapaCare. The survey has been initiated and will be led by the principal investigator Dr. Håkon Bolkan from CapaCare/MMRU. The study will be coordinated by the Masanga Medical Research Unit (co-PI Prof. MP Grobusch), and conducted in close collaboration with Statistics Sierra Leone (co-PI Prof. O Sankoh).

Table of content

1. Executive summary

Background
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.

Purpose
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.

Methods
Cross-sectional study using a national community-based sampling survey to estimate surgical need in Sierra Leone. We will randomly select 1,873 households from 75 nationwide representative clusters. Sampling will be done through a weighted random cluster design, where the probability of cluster choice is proportional to the population size. Sampling of the individuals in the households starts after the determination of the household size/household denominator. A random number calculator will assign two household members to be surveyed using the SOSAS repeat questionnaire. For this study purpose, the SOSAS questionnaire is complemented with additional questions on groin hernia and wounds. Furthermore, if a selected household member is a male over the age of 12 years, or the randomly selected individuals are females in their reproductive years; the SOSAS repeat survey will be further extended with questions regarding LUTS or maternal health respectively. In contrary to the original SOSAS study, all household members of the randomly selected ménage will be asked to participate in the surgical volume arm if they have had a surgical procedure in the past year.

Timelines

Based on the findings from the original SOSAS study, we estimate that the actual data gathering for the population based surgical survey can be done in eight weeks. This is including recruitment and training of personnel.

The following timeline is scheduled:

01. Aug	finalizing the protocol and applying for ethical approval
20. Sept	Planning of fieldwork, finalize data collection handbook and run a pilot trial
06. Oct	Testing equipment and questionnaire, training data-collectors
14. Oct	Start data collection
13. Dec	End of data collection

2. Abbreviations

BPH	Benign Prostate Hyperplasia
CD	Caesarean Delivery
CHO	Community Health Officers
CS	Caesarean Section
DCP	Disease Control Priorities
EA	Enumerator Area
EVD	Ebola Virus Disease
IPSS	International Prostate Symptom Score
LCoGS	Lancet Commission on Global Surgery
LLMICs	Low- and Lower- and Middle-Income Countries
LMICs	Low- and Middle- Income Countries
LUTS	Lower Urinary Tract Symptoms
MD	Medical Doctor
MMRU	Masanga Medical Research Unit
MoHS	Ministry of Health and Sanitation
NGO	Non-Governmental Organisation
NTD	Neglected Tropical Diseases
PHU	Primary Healthcare Unit
QoL	Quality of Life
ROH	Rate of Homogeneity
SDG	Sustainable Development Goals
SOSAS	Surgeons over Seas Assessment of Surgical need
SSA	Sub-Sahara Africa
TEAP	Transurethral Ethanol Ablation of the Prostate
UHC	Universal Health Coverage
UNFPA	United Nations Population Fund
VPSS	Visual Prostate Symptom Score

3. Definitions

Burn	Wound of the skin caused by heat, chemical or electrical exposure
Cluster	The geographic area where the assigned households are located and where the interviews are hold. In this article, cluster and enumerator area have a similar meaning.
Essential Surgical Procedure	One of the 44 surgical procedures that were deemed as essential on the basis that they address substantial needs, are cost-effective, and can feasibly be implemented. Provision of essential surgical procedures would avert an estimated 1.5 million deaths a year, or 6-7% of all avertable deaths in low- and middle-income countries (1).
Groin hernia	A weakness in the muscle and tissue of the groin (2).
Head of household / Household representative	A male or female member of a household recognized as such by the other household members. The head of the household is generally the person who has the economic and social responsibility for the household. All relationships in the household are defined with reference to the head.
Household	Every person who eats from the same pot as the head of household and slept in the household the night before the visit of the enumerator.
Major Surgical Procedure	Surgical procedure that is frequently performed in a first level or referral hospital and usually requires a type of anaesthesia (1).
Met surgical need	The amount of surgeries that are actually performed on yearly basis.
Minor Surgical Procedure	Surgical procedure that is frequently performed, and can be safely done, in a community facility or primary health centre as described by the third edition of the Disease Control Priorities (DCP3) (1).
Primary health care unit	Healthcare facility with overnight beds and 24-hour staff (as would be needed for e.g. normal vaginal delivery) (1).
Private health facility	Collection of heterogeneous facilities; independent hospital or clinic, informal facility or formal for-profit entity, that may include (un)licensed providers, and non-profit, faith-based and non-governmental organizations (3).
Public health facility	Facility where health care is usually provided by the government through national health care systems (3).
Referral and specialized hospital	A facility that has advanced or subspecialized expertise for treatment of one or more surgical conditions, not usually found at lower-level facilities (1).
Surgical Care	The provision of operative, perioperative and non-operative management for all surgical conditions. Surgical care also includes preoperative assessment (including the decision of whether to operate or not), with the provision of safe anaesthesia, and postoperative care (1).

Surgical Condition	Any disease, illness or injury in which surgical care can potentially improve the outcome.
Surgical need	The amount of surgical procedures that should ideally be performed on yearly basis per 100,000 inhabitants for a particular country in order to keep its inhabitants unrestrained from diseases and disabilities and well recovered from trauma occurring on a yearly basis.
Surgical Procedure	Suturing, incision, excision, or manipulation of tissue; or other invasive procedure performed in an operating theatre or procedure area regardless of anaesthesia type or surgical provide.
Traditional Medicine	The knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health and in the prevention, diagnosis, improvement or treatment of physical and mental illness.
Unmet Surgical need	The surgical need, subtracted the met surgical need (4).
Wound	'Open skin', regardless of size or aspect or aetiology.

4. Introduction

Five billion people do not have access to safe, affordable surgical, anaesthetic and obstetric care when needed. Access is worst in low- and lower-middle income countries (LLMICs), where nine out of ten people cannot access basic surgical care (5). As a result, relatively simple surgical conditions lead to premature death. While it is obvious that patients with road traffic injuries, complications of childbirth and abdominal emergencies often need surgery (1), a considerable proportion of the total global burden of disease can actually be attributed to conditions that require surgery. Estimates by the Lancet Commission on Global Surgery (LCoGS) reveal that up to one-third of the global burden of disease consists of medical conditions that require some form of surgical care (5). This publication from 2015 has substantially impacted the perspective on global access to surgical care and paved the way towards the acknowledgement of the existence of the unmet surgical burden. In that same year, the World Health Assembly unanimously endorsed a resolution calling all countries to strengthen essential surgical capacity. This resolution stated that "surgical capacity is an essential part of universal health coverage and the political commitment and programmes must reflect that" (6). It will be impossible to achieve universal health coverage without ensuring that surgical, obstetrical and anaesthetic care is available, accessible, safe, timely, and affordable (6).

Essential surgical care

It is essential to know the rate of conditions in patients in need for surgical care to raise awareness in the population, to convince donors of the magnitude of treatable conditions and to provide policy makers for allocation of resources and planning training for expanding capacity (7). A shortage of health system data covering surgical and anaesthesia care in low-resource countries has made it challenging to monitor the provision of surgical health services. As a

benchmark and to achieve most of the population-wide benefits of surgery, an estimated surgical need for LLMICs was set at 5,000 operations per 100,000 population per year (5). As mentioned by the LCoGS, this target should be regarded as the utmost minimum threshold for the provision of essential surgical care in LLMICs. Initially, for most LLMICs it makes sense to focus on essential surgical care as the surgical conditions have the highest health burden. Thereby, alleviating this burden will lead to substantial improvements in health (1). Provision of essential surgical procedures can avert an estimated 1.5 million deaths a year, or 6-7 % of all avertable deaths in LLMICs (1). Furthermore, these procedures rank among the most cost-effective health interventions and are feasible to promote and organize globally (1). To address the deficiencies for surgical conditions and show the need for access to essential surgical care, community-level research to quantify the surgical need of populations is needed (7).

5. Sierra Leone

Sierra Leone is a country on the southwest coast of West Africa. In the west, the country borders the Atlantic Ocean, Liberia in the southeast, and Guinea in the northeast. According to the latest census (2015) the population is slightly more than 7 million people (8). The country is ranked 184 out of 189 at the Human Development Index, which makes it one of the poorest in the world (9). Life expectancy at birth is 52.2 years and infant mortality and maternal mortality remain high. The mean years of schooling is 3.5 years and the literacy rate among adults (ages 15 and over) is 32.4 (9). According to the 2015 census, over 60% of the population is under the age of 25, while less than 3.5% is older than 65 years. It is predicted that the elderly population will increase drastically the next decades (8).

After the civil war in the 1990's, recovery has been on-going but hampered by low economic progress, limited governmental support and most recently by a devastating outbreak of Ebola. Between 2014-2016, Sierra Leone experienced a devastating outbreak of Ebola Virus Disease (EVD), where close to 7% of all the health care workers perished (10). Already before the EVD outbreak, one in four inhabitants in Sierra Leone had an untreated surgical condition needing medical attention (7).

6. Study overview

In 2012 the American organization Surgeons over Seas, together with the Ministry of Health and Sanitation (MoHS) of Sierra Leone performed the Surgeons Overseas Surgical Needs Assessment (SOSAS) (7). Two years after the conduction of this study, the Sierra Leonean health care system was severely affected by the West African EVD outbreak. During and after the outbreak, several major health system interventions have taken place, such as the start of a surgical task-sharing program (11), employment of regionally hired medical doctors to support first level hospitals (12), establishment of national ambulance service and national emergency medical services, as well as mobilising of non-governmental organisations (NGOs) to support the healthcare system after the Ebola outbreak.

We will repeat the original 2012 SOSAS study to measure the effect of the 2014-2016 Ebola outbreak and subsequently also health system interventions aiming to strengthen surgical services in Sierra Leone. In this *Prevalence Study on Surgical Conditions 2019*, we will apply the same methodology as the SOSAS 2012 to measure the current surgical need. In addition to the original questionnaire we have selected five areas where we extend the survey. These five study arms were added to develop a better understanding of the needs and possibly provide support to health systems approaches that may deal with high burden of these specific surgical conditions. The six different arms of the *Prevalence Study on Surgical Conditions 2019* study are:

1. SOSAS Repeat
2. Lower Urinary Tract Symptoms (LUTS) (for male participants older than 12 y/o)
3. Groin Hernias
4. Wounds
5. Maternal and Perinatal Health (for female participants in their reproductive age)
6. Surgical Volume

6.1 SOSAS Repeat

Several forthcoming publications from the SOSAS performed in Sierra Leone in 2012 revealed a large unmet need for surgical consultations. This initial Sierra Leonean study was followed by studies undertaken in multiple other countries across Africa and Asia. The awareness within public health as well as ministries about these data, have led to the aforementioned surgical resolution and investigations into the surgical system and enhancing delivery of surgical care by expanding capacity or referral systems.

In the case of Sierra Leone and the 2012 SOSAS study, the health care system has been severely affected afterward by the 2014-2016 Ebola Virus Disease (EVD) outbreak in West Africa. Up to 7% of the healthcare workers lost their lives in Sierra Leone (10), including 2 of the 10 surgeons who were employed by the MoHS. In addition to the effect on the healthcare workforce, the EVD epidemic severely impacted the provision of healthcare services and caused setbacks in the health seeking behaviour, treatment and control of surgical conditions as well as other diseases (13).

6.1.1 Aim of the SOSAS repeat arm

It is the aim of the SOSAS repeat arm to establish the countrywide prevalence of surgically treatable conditions and potentially preventable deaths. Data gathered from this repeated survey will be compared against data from 2012. Both the EVD outbreak and health system-strengthening projects are expected to impact the prevalence of major surgical morbidity and mortality. One of the health strengthening projects has been the expansion of a task sharing surgical training program by the Norwegian NGO CapaCare. At the beginning of 2018, thirty-four students were partaking in the surgical training program and since the start of the programme the MoHS had posted 20 graduates in (district) hospitals (47). Since the start of the programme in 2011, the students and graduates combined have performed more than 47,000 surgeries (47). Only 24,152 surgical procedures were identified in the country in 2012, corresponding to a

national rate of 400 surgeries per 100,000 inhabitants (4). The extent to which these barriers and enablers affect the provision of health care is part of the aim of the SOSAS repeat survey

6.2. Lower urinary tract symptoms

From 2004 to 2015 the elderly population (>65 years) in Sierra Leone increased from 125,038 to 246,284, a doubling in just over a decade. This population is projected to further increase to 632,300 in 2050 (8). Lower Urinary Tract Symptoms (LUTS) are recognized as a common condition in men aged ≥40 years, and its prevalence increases with age. As the prevalence of LUTS increases with age, the burden on the healthcare system and society is also expected to increase tremendously in Sierra Leone (14).

Global estimates indicate that 2.3 billion individuals worldwide will suffer from at least one lower urinary tract symptom by 2018 (15). Although the prevalence of LUTS is estimated as being greater in women than men, still 44.7% of affected patients are men (15.) Estimates suggest that Africa will be one of the continents with the highest increase in LUTS, but direct measures of this condition from the African continent are scarce (16).

Symptoms associated with LUTS include urgency, frequency, nocturia, incomplete urination, and weak urinary stream. Causes creating LUTS in LLMIC are a broad spectrum of conditions, including benign prostatic hyperplasia, bladder stones, cancer of the bladder and prostate, detrusor muscle weakness and/or instability, diabetes, side effects of drugs, neurological conditions; for example, multiple sclerosis, spinal cord injury, cauda equina syndrome and inflammation of the prostate (prostatitis), including IgG4-related prostatitis. If left untreated, complications such as urinary retention, renal insufficiency and bladder stone can occur, requiring surgical intervention (17). LUTS is associated with high personal and societal costs, both in direct medical costs and indirect losses in daily functioning, and through its negative impact on quality of life for patients and partners (18). While nonsurgical therapy for LUTS is becoming more available globally, barriers continue to limit patient access to all therapies for LUTS in low resource environments. Illness from infectious disease, distance from clinics and lack of resources are examples of potential reasons why care seeking patterns in high resource settings may not be reflected among a rural African population (18).

6.2.1. Aim of the Lower Urinary Tract Symptoms arm

The main objective is to determine the prevalence of severe LUTS among men 12 years or older in Sierra Leone. In addition, this study will also be able:

1. To quantify how LUTS affects Quality of Life among the study population.
2. To understand barriers towards health seeking behaviour for LUTS
3. To estimate the need for treatment of LUTS in Sierra Leone.

A potential implication of more knowledge of LUTS in Sierra Leone is the possible introduction of transurethral ethanol ablation of the prostate (TEAP). This low-cost therapy has been developed as a minimally invasive procedure for the treatment of patients with symptomatic benign prostatic hyperplasia (BPH) (45). Dehydrated ethanol is injected directly into the prostate, via the transurethral route. Dehydrated alcohol (ethanol) is inexpensive and easily accessible which makes TEAP a good alternative for treatment of severe LUTS in low-resource countries.

Depending on the outcomes of this study, it might be relevant to further investigate the feasibility of offering TEAP in Sierra Leone.

6.3 Groin hernias

The surgical need of groin hernia repairs in SSA is largely unmet. Estimates demonstrate that approximately 30 inguinal hernias per 100,000 people per year are repaired in SSA (19). However, the minimum number of inguinal hernia repairs should be in the order of 200 repairs per 100,000 people per year (19). This number is more in line with figures from the United States, where 200-275 inguinal hernia repairs per 100,000 people per year are performed (20). Besides the unmet need for groin hernia repair in SSA, the (economic) burden of groin hernia is higher in SSA than in Western countries (21). In comparison with the United Kingdom, patients with groin hernias in SSA are younger of age on average, have larger hernias and there is more delay between onset of symptoms and the first presentation in a hospital (21). Appropriate management is needed to reduce the pool of groin hernias. Lowering the burden of groin hernia in SSA is desirable and can be achieved by scaling up the number of groin hernia repairs. With detailed information on the prevalence of groin hernia and the health seeking behaviour towards this condition, policy makers in SSA will be in a better position to plan the strengthening of this essential surgical service. So far, publications on the prevalence of groin hernias in SSA have major limitations, as they tend to focus on men and do physical examination is rarely performed (22-26).

6.3.1 Aim of the groin hernia arm

The main aim of the groin arm is to determine the prevalence of groin hernia among children, women and men in Sierra Leone. The prevalence will be determined based on a combination of responses to the questionnaire and a physical examination. Hernia repairs are the most commonly general surgical procedure performed in Sierra Leone (4). Non-emergent surgical procedures decreased dramatically during EVD outbreak (46). This may have contributed to an increased backlog of hernia repairs performed, thus contributing to an increased prevalence compared with before the outbreak. We have chosen to include a physical examination of the groin area if household members mention to have a solid/firm and or soft/reducible mass in that area. In the SOSAS 2015 study from Nepal, a groin exam was not done, and that may be a reason for the lower-than-expected reported prevalence of inguinal hernias (27). Furthermore, we will investigate the health seeking behaviour of patients with groin hernias and estimate the recurrence rates.

6.4. Wounds

Severe wounds cause considerable morbidity, mortality and an (socio) economic burden worldwide. Therefore, severe wounds are identified as one of the fifteen categories of essential surgical conditions requiring global attention (28). Although data on the prevalence of wounds in West Africa (e.g. Sierra Leone) is scarce, Wong *et al*. found that 301 of their 496 household survey respondents required some kind of surgical interventions (29). In 17% of the cases this was because of a wound (including trauma) and in 6,8% because of a burn wound. The same research group demonstrated that up to 4.8% of the 230 deceased elderly household members died as the result of a neglected wound during the past year (29).

Besides the prevalence, little is known about the aetiology of the most common wounds in Sierra Leone, let alone on the spectrum of bacterial (super-) infection and resistance pattern. A previous study by Kollie *et al*. described 21 patients with a wound due to *Mycobacterium ulcerans* in neighbouring Liberia in 2012 (30). Although Buruli ulcers would need goal directed therapy with rifampicin/streptomycin and or surgical debridement and skin grafting, most ulcers are treated with over-the-counter available antibiotics. A study from Lai et al, who provided care on a ship, anchoring at six coastal West African countries, showed considerable resistance to common antibiotics (31). From clinical experiences at Masanga Hospital, a referral centre for patients with large wounds, it is known that most patients visited a traditional healer – and have started treatment (herbs and or antibiotics) – before seeking care in this rural hospital in Sierra Leone. In Sierra Leone the estimated 45.000 traditional healers (32), by far outweigh the 323 physicians in the country (33). Little is known on the type of wound treatment provided by traditional healers and the perception and health seeking behaviour of wound patients in Sierra Leone. Mallet et al described that traditional healers played a role in the West African 2014-2016 Ebola outbreak, no data was found on a potential impact the outbreak may have had on this wound treatment and health seeking behaviour (33).

6.4.1. Aim of the wound arm

We believe that a large proportion of severe wounds, burns, injuries, amputations, contractures and deaths are preventable by improving knowledge on the perception and usage of modern and traditional medicine for wounds. This study aims to describe the current prevalence of wounds and the status of wound care in Sierra Leone.

The aims are:

1. To describe the prevalence of wounds in Sierra Leone
2. To study the aetiology of wounds (traumatic, infectious, snake bites, burns, vascular)
3. To describe the health seeking behaviour of patients with wounds
4. To describe the surgical need in treatment of wounds
5. To describe the impact of wounds on daily life
6. To assess the level of hypertension in Sierra Leone, together with health seeking behaviour for the hypertension.

Hypertension is an important risk factor for cardiovascular diseases (CVDs) in Africa, with rising frequency of hypertension related complications like stroke and heart failure (48,49). The rising prevalence of hypertension in SSA could lead to an upsurge in CVDs in this region if not controlled. Yet to date, detection, management and control of high blood pressure are insufficient and haphazard (50). Renewed commitment to improved surveillance and the prevention and control of hypertension of high blood pressure in Africa is critical.

6.5. Maternal and Perinatal health

Sierra Leone is one of the most challenging countries to be pregnant and to give birth (35). The estimated maternal mortality of 1360 women per 100.000 live births is one of the world's highest (9). Approximately one in seventeen women die from pregnancy or childbirth-related causes, with similar high rates of neonatal mortality (36). The poor access to surgical care is regarded as one of the major causes of these poor health parameters (37,38).

This health determinant is in line with other low-income countries (LICs), where half of the pregnant and labouring women have no access to emergency obstetric surgical care (1). This means that certain emergency obstetrical situations cannot be relieved with an assisted vaginal delivery with vacuum, forceps, or a Caesarean Delivery (CD).

Countries with CD rates of less than 10% have an increased maternal and neonatal mortality (39). The 2012 SOSAS reported that only 1,9% of the total births was by CD (40). This is much lower than the threshold recommended by the WHO (38). An even lower percentage (0,4%) were delivered by assisted vaginal delivery; of all the recalled 2316 deliveries, 59% took place outside a healthcare facility (39).

To make Sierra Leone a safer place for mothers and their children, many actions have been taken. Promotion of universal access to CDs is considered as one of the key prerequisites to improve maternal and perinatal outcomes and is an integral part of WHO's comprehensive emergency obstetric care package (40).

6.5.1 Aims of the maternal and perinatal health arm

This arm will provide a status update on the access and need for female and obstetrical care for women and mothers in Sierra Leone from a community perspective in the pre, during and post Ebola time frame. This study aims to describe the general status of women's health and more specific need for surgical care and family planning methods used in women in their reproductive years at the moment of the interview.

We provide a description of the amount and outcomes of pregnancies as established by this household survey of total women of reproductive age (12-50 years old) interviewed. For all deliveries we describe the actual and preferred place of delivery and means and availability of transportation (including the new ambulance transportation system) in the pre- during and post Ebola time frame. We will be able to estimate a foetal and neonatal death rate (of total births of women interviewed) and we aim to estimate a CD and assisted vaginal delivery prevalence (of total deliveries of women interviewed). Lastly the results of this study can be compared with the findings of the maternal health section of the SOSAS study in 2012. This information may help us to understand the consequences for female and maternal health during a large Ebola epidemic and it will assist us in appropriate allocation planning in the post Ebola period.

6.6. Surgical volume

Before the EVD outbreak, there were ten consultant surgeons in the public government hospitals and an estimated twenty-six in private non-profit hospitals in Sierra Leone (41, 42). The LCoGS demonstrated that a surgical workforce density of less than 20 per 100,000 specialist surgeons, anaesthesiologists, and obstetricians correlates with lower rates of maternal survival (5). Based on this reported workforce density model, there should be an estimated minimum of 1,400 specialist surgeons, anaesthesiologists, and obstetricians for the 7 million inhabitants of Sierra Leone.

In 2012, a nationwide facility survey found that all surgical providers combined, performed 400 surgical procedures per 100,000 inhabitants in Sierra Leone. Private, non-profit facilities performed 54.0% of the surgical 'met need', compared with 39.6% by public and 6.4% by private

for-profit facilities. More than 90% of the estimated surgical need in Sierra Leone was unmet in 2012 (4).

Quantifying the national surgical volume by conducting a comprehensive household survey is a novel approach. Minor and major surgical procedures will be included and classified according to the essential surgical package (DCP3 volume 1) (1). These will provide an indication of the status of delivering surgical services in light of the universal health coverage. The suggested population perspective can help identifying post-operative outcomes and provide a broad overview of the contributions of the public and the private surgical providers.

6.6.1. Aim of the surgical volume arm

The main aim of the study is to determine the annual volume of surgical procedures conducted in Sierra Leone from a population-based perspective. Surgical procedures will be classified using the DCP3 essential surgical package. The contributions of the public and private surgical sectors will be assessed. In addition, 7- and 30 days perioperative mortality will be measured.

7. Methods

7.1. Study design

This is a population-based, cross-sectional household survey of surgical, urological and maternal health conditions. This study will investigate the prevalence of untreated and treated surgical conditions in Sierra Leone. Participants will be recruited nationwide. The methodology is based on a cross-sectional household survey evaluating the prevalence of surgical conditions, known as the SOSAS survey (7). In addition, five topics will be investigated more in-depth to complement the previously designed SOSAS survey.

Arms Prevalence study	**Lead/Co-Lead**	**Target population**
SOSAS Repeat	Jurre van Kesteren	Two randomly selected household individuals
Lower Urinary Tract Symptoms	Mia Nyeng Østensen Sofie Mack Løvdal	All men > 12 years among the two randomly selected household individuals
Groin Hernia	Karel Lindenbergh	Two randomly selected household individuals
Wound	Jonathan Vas Nunes	Two randomly selected household individuals
Maternal and perinatal health	Josien Westendorp Hanna Mathéron	All females >12 years <50 years among the two randomly selected household individuals
Surgical volume	Daniel van Leerdam	All household members who have had a surgical procedure in past year

7.2. Sample size and sampling

The extended SOSAS Repeat survey consists of two parts. The first part is established to identify the number of household members and to quantify the household members that have undergone a surgical procedure in the previous year. In the second part of the survey two randomly selected household members undergo a head-to-toe (verbal) examination.

The sample size for the first part of the survey is based on the surgical volume arm. For the surgical volume research arm, all household members who have undergone a surgical procedure in the previous year will be included in the study. The selection of the household members will not be done randomly in this study arm, but all the household members of the randomly selected households will take part and serve as the denominator. In the second part of the survey only two randomly selected household members will be included.

7.2.1 Sample size survey first part

Based on the found surgical met need by Bolkan *et al.*, the expected period prevalence of major surgical procedures is 0.4% in Sierra Leone (4). This means that approximately 400 major surgeries per 100,000 population per year are performed in Sierra Leone. In the surgical volume arm, we estimate that at least twice as many minor procedures are performed. This results in an estimated prevalence (P) of major and minor surgical procedures combined of ± 1% per year. The level of precision is suggested within the range of 20% of the estimated prevalence, which allow us to apply an expected range (L) of (20% x 1% =) 0.002%.

Calculation

$n = Z^2\ p\ (1\text{-}p) / L^2$

n = sample size

Z = Confidence Interval (95% - Z is 1.96)

p = Estimated proportion of the prevalence of the condition looked for

L = Range excepted

$n= (1.96)^2 \times 0.01 \times (1 - 0.01) / (0.002)^2 = 9702$

Under the assumption that some household representatives will not consent to partake in the survey to elucidate on the surgical conditions of the other household members, we have chosen to add a margin of 5% to the sample size. Hereby we will be able to estimate the population prevalence with a reasonable precision.

7.2.2 Sample size survey second part

The sample size is based on the original SOSAS study protocol (7). A randomly selection of 1873 households will provide sufficient power to all of the six arms of the Prevalence Study on Surgical Conditions 2019. For the current power calculation we have applied the original estimated prevalence of 7.3% surgical morbidity as used by Groen et al (33). We are aware that the original SOSAS study revealed that of the 3,645 respondents, 1,352 (37%; 95% CI 34·8–39·4) people indicated that they had a wound, burn, mass, growth, deformity, or other surgical condition at the time of interview and 896 (25%; 22·9–26·2) indicated that they needed surgical care (7). This found prevalence is much higher than the prevalence used originally for the power calculation. Hereby it might seem that we are over calculating the needed power if we use the 7.3% estimated prevalence.

However, as we are repeating the SOSAS study from 2012, we have chosen to use the original prevalence of 7.3% for surgical conditions in order to be able to compare our outcomes with the original study without the need to adjust for different sample sizes afterwards. Furthermore, this current SOSAS repeat study has additional arms on LUTS, severe wounds and maternal and perinatal health. The estimated prevalence for these conditions are ± 6%, ±1.9% and 2%

respectively (15, 40). As we are anticipating for lower prevalence of morbidity within three of the six sub-study arms we have calculated that an overall estimated prevalence of 7.3% will provide the needed power for all the arms within this study.

The sample size calculation is based on: Kelsey 1996 'Methods in observational Epidemiology' (43). The estimated proportion of the prevalence (p) of a surgical condition is set at 7.3%. The prevalence of 7.3% is based on a pilot study of the original SOSAS research group (44). The accepted range (L) around the estimated prevalence of the disorder is set at 1%. Letter Z is CI (95%–Z is 1·96). In the pilot study from August 2011, 95% of the targeted population was eligible, and the same proportion responded (44). This provides a response rate (95%) and eligible rate (95%) needed for the sample size correction. The sample size is further corrected for the population size and is multiplied by a design-effect (DEFF) of 1.3, assuming that surgical conditions are not very clustered. The estimated population of Sierra Leone was 7,09 million in in 2015 (8)

Calculation
$n = Z^2\ p\ (1-p) / L^2$
n = sample size
Z = Confidence Interval (95% - Z is 1.96)
p = Estimated proportion of the prevalence of the condition looked for
L = Range excepted
$n= (1.96)^2 \times 0.073 \times (1 – 0.073) / (0.01)^2 = 2599.6$

Corrected sample = sample size x effect of population size Sierra Leone x DEFF x (1/response rate) x (1/eligible rate)

n x (1 + (n-1)/ 7,090,000) x DEFF x (1/response rate) x (1/eligible rate)

2599.6 x 1.00 x 1.3 x 1/0.95 x 1/0.95 = 3744.6 = 3745

For this section of the household study, we aim to include 3,745 individuals. In total 1,873 household visits will be needed as we are including two randomly selected individuals per household.

7.3. Sample size and sampling total

For the first part of the household survey, we need to include 10,187 individuals. The average household consists of 5.5 members; resulting in 1,852 household visits. For the second part of the survey we need less household visits as we have calculated to include 3745 individuals. These individuals are clustered as 2 per household, resulting in 1,873 household visits. Due to time and financial constraints we will maximize the household visits at 1,873. This should be sufficient for the first and second part of the survey.

A pilot study will be conducted to assess the appropriateness and utility of the design and investigate the response rate, eligible rate and use of the current small design-factor. We will also monitor the time it takes to perform the extended SOSAS repeat questionnaire. The original SOSAS questionnaire took about 30-45 minutes. In order to be successful, the new extended

questionnaire should depend on the findings of the demographics of the respondent and their surgical history and current comorbidities not last longer than 60 minutes on average.

7.2.1. Sampling method for the clusters

Sierra Leone is divided in four provinces, further divided into 16 districts, and 190 chiefdoms, which are further divided into 9,671 enumeration areas, the smallest administrative units in Sierra Leone. Sampling will be done through a weighted random cluster design, where the probability of cluster choice is proportional to the population size. From this moment onwards, a cluster and an enumeration area are the same. For Sierra Leone, the clusters will be randomly chosen in a two-stage sampling process starting with the Chiefdoms and selecting the number of clusters needed out of the Chiefdoms proportional to the population size in the chiefdoms to further select, the Enumerator Areas (EA's) out of the Chiefdoms. This process of sampling will be led by Statistics Sierra Leone, who will also provide maps and coordinates for the assigned clusters.

7.2.2. Assignment of the households within the cluster

If maps of structures of the randomly selected EAs are available, those are used for randomly designing the first household to approach. Thereafter every fifth structure at the right side of the interviewed household while standing with the back to the front door is approached for the survey. In case of more households per structure an on-site listing is made and random assignment of the household is facilitated by the use of the random calculator (that will be available on the tablet). If maps of structures are not available or out-dated an onsite structure count is made and random assignment of structures is given, by utilizing a random calculator.

To be able to have a weighted cluster sample, each cluster should have the same household numbers interviewed. Therefore, if a structure randomly chosen appears to be empty or the household does not give informed consent the next structure will be approached to be interviewed. Records will be kept on households' and individuals' refusal to participate, for the analysis of the results.

7.2.3. Sampling of the individuals for the six arms

There are six different arms in the prevalence 2019 study. Three arms have a similar selection model and three arms only include household members under certain conditions.

3xarm (SOSAS Repeat, Hernia, Wounds)	= Two randomly selected household members
1xarm (LUTS)	= Only men over the age of 12 years
1xarm (Maternal)	= Only female(s) >12 years < 50 years
1xarm (Surgical Volume)	= All household members that had a surgical procedure in the last year

Inclusion of the household individuals will be according to the 'rolling the dice once rule'. Sampling of the two individuals out of the 1,873 households starts after the determination of the household size. A random number calculator will assign two household members to be surveyed. We have chosen not to include a minimum age, as this will not give a good demographic comparison with the District Health System (DHS). 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. The two selected individuals receive the SOSAS Repeat questionnaire including additional questions on groin hernia and wounds. If a randomly selected male is > 12 years of age, he will receive the additional LUTS questionnaire. If the selected household members are no men or men less than 12 years of age, in that household no additional LUTS questionnaire will be used. If a randomly selected individual is a female >12 years <50 years she will receive the additional Maternal and Perinatal health questionnaire. Additionally, the household representative will receive questions about all of the household members that had a surgical operation in the last year. These questions may be about the two randomly selected household members and/or for any additional persons residing within the ménage that underwent surgery in the last year.

If a person is selected but not available for the interview, an appointment is made for later that day or the following day (each cluster has a minimum of two interview days). If by the third appointment the person is still not available, this person will be excluded from the analysis. When the (randomly assigned) household member does not provide consent no replacement is sought. If neither household member is available, or do not give consent, the next household will be approached to maintain the weighted sample size of households per cluster (e.g. ~25 households in each cluster).

7.3. Data collection – SOSAS Repeat

The data will be collected via individual face-to-face interviews using a national community-based sampling survey at the houses of the respondent. This fall the recruited students/nurses/medical staff will be trained to become enumerators. These enumerators will collect data with handheld tablets provided by the Prevalence 2019 research team. The recruited drivers will use a Global Positioning System to get the enumerators to the exact location and enumerators familiar with working with maps will be recruited.

The SOSAS repeat survey consists of two parts.
The first part is administered to a household representative to establish the number of household members, identify deaths in the household during the previous year, and establish whether any of the deceased household members had any of the following conditions in the week before their death: abdominal distension or pain; bleeding or illness during childbirth; injury; mass, growth, or swelling; acquired deformity; or a wound not due to injury or congenital deformity.

The second section consists of structured interviews of two randomly selected household members who undergo a head-to-toe verbal examination covering six anatomical regions: face, head, and neck; chest and breast; abdomen; groin, genitals, and buttocks; back; and arms and hands and legs and feet. The need for surgical care was recorded on the basis of an individual's response to whether they had a wound, burn, mass, deformity, or other condition needing surgical assessment or care—i.e., the respondent decided whether or not they felt they needed surgical care. A surgical procedure was defined as: wound care, suturing, incision, excision, or other manipulation of tissue, in a safe and painless way. Procedures were deemed major if they required regional or general anaesthesia and minor if they required local anaesthetics or none.

7.3.1 Additional arm specific data collection: LUTS

The randomly selected man or men older than 12 years of age will be asked for consent to participate in the LUTS arm. In addition to the SOSAS repeat, groin hernia and wound questions, they will be interviewed about the presence of lower urinary tract symptoms. The severity of LUTS symptoms will be assessed using the visual prostate symptom score (VPSS) visual questionnaire (Appendix 1). VPSS is the visual analogue to the more commonly used international prostate symptom score (IPSS) questionnaire. IPSS has been validated in several studies in the diagnosis of LUTS and for use in many languages (43). VPSS evaluates patient symptoms with four pictograms. They measure pollakisuria, nocturia, urinary flow rate and life quality. Studies shows that there is significantly less alteration in responses using the VPSS, suggesting that the VPSS is useful in determining LUTS, particularly in patients with low literacy (43).

Uflow meter

VPSS scores are evaluated in three categories, mild, moderate and severe. Only participants with a VPSS score >17, indicating a severe LUTS will be asked to complete a questionnaire related to health seeking behaviour. Also for study participants with VPSS score >17 we aim to measure flow of urine using a portable Uroflow (Uflow) meter. An Uflow meter can measure the peak urine flow rate and detect a weak urinary flow. The peak flow rate can be used as an objective measurement for detection of LUTS. The Uflow meter is a reusable plastic shaped funnel consisting of a cup and a spout divided into three chambers. The spout has a 4.6 mm diameter aperture placed at the bottom. When fluid is poured into the cup it will start to fill the funnel as well as flowing out through the aperture. At the time inflow and outflow are equal, it will maintain a constant maximal fluid level within the funnel. The accuracy and reliability of the device seems adequate for detecting LUTS or voiding dysfunction (46).

Under assumption that the prevalence of severe LUTS is 2 %, the average household size is 5,5 persons and 65 % of the population above 12 years (8,14) we estimate that from 1873 households approximately 67 participants will be asked to use the Uflow meter and complete the questionnaire about health seeking behaviour.

Calculation

1,873 households x 5,5 members per household x 0,5 proportion males x 0,65 proportion >12 years x 0,02 prevalence of severe LUTS = ± 67 people.

7.3.2 Additional arm specific data collection: Groin Hernia

The two household members that are randomly selected will be included in the groin hernia arm after consent. When the questionnaire raises suspicion of a groin hernia (hard or soft mass), the enumerator will request consent to perform a physical examination of the groin area. The enumerator performing the physical examination for the hernia arm is trained to diagnose this medical condition. The enumerator is trained in the different types of groin hernias; inguinal hernia, femoral hernia and scrotal hernia. He/she is able to differentiate between a direct and indirect hernia, based on physical examination and he/she understands and recognizes the differences between a reducible, non-reducible and strangulated hernia. The enumerator will inspect and palpate the groin area of the participant. Privacy of the participant will be kept in

mind and respected by performing the physical examination in a shielded place. Physical examination will be done in a standardized way.

General Inspection
If able, ask the patient to stand (preferable). Throughout the examination, it is important to explain to the patient what you are about to do next

- Inspect the patient from the front and both sides (whilst the patient is standing)
- Note any evidence of pain (e.g. stance/grimacing)
- Note any evidence of abdominal distension (may suggest bowel obstruction)
- Look for asymmetry (left *vs.* right groin)
- Look for scars on the abdomen and in the groin
- Look for obvious lumps protruding from the abdomen or groin
- Look for any testicular lumps or swellings

Assessing a Lump
Site, Size, Shape, Colour, Contour, Consistency, Tenderness, Temperature, Tethering, Cough impulse, Bruit, Lymphadenopathy

Position of Hernia
Above and medial to the pubic tubercle: Inguinal hernia
Below and lateral to the pubic tubercle: Femoral hernia
Below and descending from the pubic tubercle into the scrotum: Scrotal hernia
Swelling in the scrotum only; possible to come above the lump; Hydrocele

Reducibility / Direct *vs.* Indirect Inguinal Hernia / Scrotal Examination

To complete the examination.
Thank the patient / Allow the patient time to get re-dressed / Document the examination directly.

For quality control, this method will be validated internally by evaluating the physical examination of the first 100 selected household members in the groin hernia arm. Hereby we will validate if the verbal responses of the household member (yes or no groin lump) matches the physical examination. Consequently, we do not validate if the enumerator is able to differentiate between a groin hernia and any other palpable mass that may appear in the groin region.

The prevalence of groin hernia is most likely different for adult women, adult men and children. Therefor the results of the study will be reviewed separately for each group.

7.3.3 Additional arm specific data collection: Wounds

The two household members that are randomly selected will be included in the wound arm after having given consent. The wound survey will continue if the participant has a wound at the time of interview. The wound may be of any aetiology, should at least be 5 cm in diameter or at least be one month old. The minimal limit in size is chosen to prevent including participants with minor cuts. To not exclude patients with small but deep wounds, such as those caused by

osteomyelitis, the additional inclusion criteria of a wound existing for at least one month is added. Additional consent will be asked to take four photographs: one close up of the wound, one of the affected area/limbs, one of the whole affected and contra-lateral limb or part of the body and one 3D-photo. All shots will be done in the same manner; outside, in front of a clear background, ruler next to the wound and number on a small sheet of paper in close proximity to the wound. The number on a small sheet of paper is part of a coding system whereby the photo can be traced back to the individual for the health analysis. The enumerator has disposable paper rulers, a new one is used for every examination. Gloves for the enumerator will be provided and he/she is encouraged to use them correctly.

The photographs will be taken by password protected Samsung tablets. The pictures will be shot in a way that the individual cannot be traced back; excluding identifiable body parts and/or tattoos. If inevitable at the time of the photo-shoot, during post processing the photo will be anonomyzed. The photo will be uploaded in the REDCAP software. Where possible, a 3D-photo or short video will be added to the three photographs. Photographs will be transferred and deleted from the tablets to a password-protected computer and password protected and encrypted cloud-based system.

Blood pressure and heart rate

After completing the survey questions we will proceed to do the blood pressure measurements. Explain to the participant that you are going to take blood pressure. You have to be very sensitive in this regard and make sure that you do not offend participants with respect to their traditions and culture.

Take the following aspects into consideration: In case men have to measure women he has to be especially respectful and avoid situations that may be culturally unacceptable. Like the rest of the interview, make sure that you are doing the measurements in a completely private place. Kindly ask the participant to remove excess clothing. Make sure that the left arm is not tightly covered for measuring the blood pressure.

<u>Measurement</u>

Use the provided Blood Pressure Instrument to measure blood pressure and heart rate.

Before starting the measurements explain to the participant that you will take blood pressure 3 times and you will wait 2-3 minutes between measurements.

The participant has to be seated with uncrossed legs and relaxed for 5 minutes before the first blood pressure reading is taken. In case the participant has been seated through the whole interview you can move to the first measurement without waiting those 5 minutes. Place the left arm of the participant slightly bent and with the palm facing upwards. Put the blood pressure cuff around the upper arm of the participant. Assure that the arm does not move and ask the person not to talk while taking the measurement.

Press the start button.
Wait until the machine shows the three results:
DIASTOLIC, SYSTOLIC, RATE

Copy the result in REDCAP
Switch off the blood pressure machine
Wait for 2-3 minutes before taken the second measurement of blood pressure.
Press the START button again.
Take the three numbers again and copy them into REDCAP
Repeat this cycle once more for the third measurement

Refer the participant to a clinic when the second AND the third measurements of blood pressure have either a diastolic (DIA) level that is higher than 90 mmHg or a systolic (SYS) level that is higher than 140 mmHg.

7.3.4 Additional arm specific data collection: Maternal and Perinatal Health

Every female who is among the two randomly selected household members and who is older than 12 years of age and younger than 50 years of age will be included in the Maternal and Perinatal Health arm after consent. The selected household member(s) will undergo a verbal interview. For all women that are currently pregnant, the fundal height will be measured with a tape measure.

7.3.5 Additional arm specific data collection: Surgical Volume

The household representative is the main person responsible for this part of the questionnaire. Due to the nature of the questionnaire, whereby the household representative will be interviewed first, the surgical volume related questions would come before the other arms. The household representative will be asked to provide an overview of the household members that have undergone a surgical procedure in the past year. This accounts for both major and minor procedures. Through this interview, also all household members who passed away after surgery will be identified.

When the household representative identifies a member of the household who underwent a major surgical procedure within the last year, the survey will be extended with additional questions to extracting in depth information concerning the procedure. These questions focus on the type of the surgical problem and the (type of) facility where the surgical procedure was performed. The household representative, and not the specific household member, will be responsible for completing this section of the questionnaire.

It would have been preferable to target the household member who underwent the surgical procedure but it is foreseen that a substantial part of the household members who underwent a surgical procedure in the past year will not be available for interview (e.g. work, travel). The original SOSAS study in Sierra Leone demonstrated that especially male household members are more prone to be absent during the data collection, creating a selection bias (7).

To comprehend if the household representative will be able to answer the in-depth questions reliably on behalf of the household member who had surgery, we will pre-test this approach. For validation purposes, all household members of the first 50 households that had undergone a major surgical procedure in the last year will be asked to fulfil the extended questionnaire themselves as well. The questionnaire will be presented to both the household member and the household representative separately and the answers will be compared in an internal analysis. We will use the found response difference for final analysis of all data. Furthermore, a response

difference up to 10% will be accepted. If the response difference is above the 10%, we will include a second validation pilot study. We would look into the possibility of adding an additional household member to support the household representative. Hereby we will investigate if adding an additional household member will decrease the response difference. This additional household member will be identified by the household representative, but cannot be the member that underwent the surgical procedure.

Because the data collection is based on self-reporting there are two important biases that can be identified on forehand. Firstly, the household representative will especially be susceptible to the recall bias. It is unclear if the household representative will have sufficient knowledge with regard to the type of surgical problem and the facility where the surgery was performed to be able to answer the questions. To address this, we will pre-test the questionnaire on a number of surgical patients and their 'representatives' separately to observe if the answers compare sufficiently

Secondly, there could be social desirability bias. Patients might think this study aims to identify unlawful surgical practices and might choose to not disclose particular information about surgical entities in order to protect the surgical providers.

8. Data management and collection tool

The data collection is based on the *Prevalence Study on Surgical Conditions 2019* questionnaire (appendix 2). Password secured Samsung tablets with mobile Internet access will be used to collect the data. The software used for the data collection is REDCAP (Research Electronic Data Capture). This is a secure web application for building and managing online surveys and databases. Data will be transferred over the Internet using secured data communication protocols. In case the mobile Internet connection is disrupted, the mobile application of REDCAP is able to store the collected data on the tablet. Once the Internet connection is restored, the collected data will be send to the servers. Databases, web server hosting and technical assistance will be provided by University Medical Center Utrecht, The Netherlands.

Four research teams will perform the data collection. Each team consists of: one driver, one supervisor, three interviewers and one international junior research assistant. This research assistant will provide backup and coordinate the logistical management. The interviewers will be either nurses or medical students. When a translator is needed, one will be recruited on a per day basis from the area. Licensed medical professionals; nurses or Community Health Officers perform all physical examinations. Final responsibility for data collection will be with the supervisor of each research team. In Sierra Leone, Masanga Hospital, Tonkolili district will be the 'home base' for the study and research teams.

After online registration, the individual members of the research team will get a role-based access to the REDCAP application. The role-based access will avoid unauthorized data access and misuse of the data software. Prior to the start of the data collection, all team members will receive training on the use of the application. During the data collection, certain members of the research team that are especially assigned for this task will manage the data.

REDCAP software application employs various methods to prevent security vulnerabilities. For further detail on security vulnerabilities the data management can be found in appendix 3. The data will be made accessible for secondary analysis after the closure of the study. Access to the data can be requested through the principal investigator HAB. The request will be discussed within the research steering committee. AvD and KL will be responsible for the data management. DB of the Julius Centre for Health Sciences and Primary Care will support AvD and KL.

9. Timelines

The following timeline is a guide and includes most of the organizational aspects, but will per definition need adaptation for implementation in the geographic area of interest.

We estimate that the actual data gathering for the population based surgical survey can be done in two months, including recruitment and training of personnel. There are, however, some procedures which need to be done before the survey can take place. Table 2 shows an overview over the planned activities.

Period	Activity
July/August 2019	Finalizing the protocol and applying for SRC clearance and ethical approval
September 2019	Finalize data collection handbook and run a pilot trial
Early October 2019	Testing equipment and questionnaire, training data-collectors
Mid October / December 2019	Data collection

9.1. Project organization and Logistics

The project is organized with representatives from Sierra Leone, the Netherlands, USA, Sweden and Norway; see Chapter 8 for further descriptions of institutions and individuals. A core research group is developed from the Masanga Medical Research Unit (MMRU), CapaCare and individual members from institutions included. The core research group has overseen the development of the methodology and will also develop the logistical details to allow the data collection to proceed as planned.

Representatives of the MMRU with support from Masanga hospital and CapaCare will facilitate logistics. Both Masanga hospital and CapaCare has for more than a decade running large healthcare projects all over Sierra Leone. The study will be implemented and monitored with the help of junior medical doctors and medical students from institutions taking part in the study. Local data collectors and supervisors will be engaged, partly to promote research capacity building, partly to ensure cultural sensitivity when interacting with the local population.

9.2. Financial compensation enumerators

No financial compensation will be offered to international collaborators, study arm leads or PIs. For Sierra Leonean enumerators the following will apply:

All research assistants needed for the project will be hired through the project administration (MMRU - DvD) under the supervision of the PI.

- The need for research assistants will be assessed in advance (number and period)
- Vacancies will be circulated among the Surgical Assistant Community Health Officers and other potential candidates familiar with diagnosing hernia repairs.
- Predefined employment criteria will be defined with the focus on academic benefits and not on financial benefits and published together with the vacancy publication
- Applications letters will be sent before the deadline to HR committee (leaded by MMRU - DvD)
- Recommendation letters attached to the applications can provide better chances
- The HR committee selects and invite candidates for interviews
- Interviews will be conducted in Masanga by the HR committee
- Successful candidates that sign a contract will be invited for the training session.

9.3. Funding

The study will be financed by the Norwegian University of Science and Technology, whom will have no influence on the protocol or the questionnaire. CapaCare and MMRU are offering in-kind contributions such as an international coordinator and lending out vehicles for transportation. Masanga hospital will offer housing for participant in the study. Additional funding will be sought from various sources.

	Cost estimate (Le)
Personnel Salaries and per diem:	155 200 000,00
Transportation:	132 185 000,00
Consumables:	8 700 000,00
Other:	20 309 000,00
Ethical approval submission fee 1,500 dollar	13 050 000,00
Total	**342 494 000,00**

10. Ethical considerations

We will apply for approval from the Masanga Research Unit's Scientific Review Committee and from Sierra Leone Ethics. Introduction letters from the MoHS will be presented to the village chiefs and/or local administrators before interviewing households. All District Medical Officers will be informed about the survey and the visit of enumerators to their district, they will also be contacted at the time of visiting the districts for interviewing.

Informed consent will be obtained from all participants in the study. Individuals' rights for refusal of collaborations will be respected at all times during the study. For individuals under the age of 18 the informed consent will be asked to one of the parents or guardians and the individual her/himself will be asked assent as well.

If surgical problems are identified during the survey, the person or guardian will be informed about possible treatment options. Depending on the urgency, referral to the local health facility is arranged and/or a letter of referral is written. This is the task of the field coordinator. Enumerators can contact their field coordinator in case they meet a very ill person. The field supervisor is the one who will arrange transport if immediate referral is needed.

Privacy and confidentiality of results means that the answers the respondent gives are not shared with anybody. A responder's privacy should be honoured at all times and information concerning the (surgical) condition should not be shared with anyone except persons designated by the responder. This means that the interview needs to be held at a place where it cannot be overheard, although a responder is free to choose someone familiar with him/her at the time of interview. We will not publish any information that is person sensitive.

Confidentiality will be taken care of by a password protected database and encryption where possible.

11. Institutions and individuals

To accomplish the ambitious study goals a strong collaboration between international institutions is a prerequisite. Experts from different fields, local experts and international medical students are attached to this study.

11.1. Institutions

In Sierra Leone, institutions involved in this research proposal include the Ministry of Health and Sanitation, College of Medicine and Allied Health Sciences (COMAHS), CapaCare (a non-profit humanitarian organization dedicated to medical education and training in developing countries) and Masanga Medical Research Unit (established in 2018 as an independent addition to the Masanga Hospital rehabilitation project) in Tonkolili district.

This research project is organized and coordinated from Norway by the Norwegian University of Science and Technology in Trondheim together with the St. Olavs University Hospital.

The other institutions in this partnership are from the Netherlands, Sweden and USA. Participating from the Netherlands are: Amsterdam University Medical Centres (former AMC and VUmc), Global Surgery Amsterdam, Royal Tropical Institute Amsterdam, Utrecht Medical Center / Julius Center. Participating from Sweden is Karolinska Institute and from USA Johns Hopkins School of Medicine, Baltimore, USA Review of the protocol is provided by researchers previously or currently involved in survey projects using SOSAS.

11.2. Individuals

Håkon A. Bolkan, MD, PhD, General and Abdominal Surgeon specialist. (Principal Investigator) Postdoctor, Department of Cancer Research and Molecular Medicine, Norwegian University of

Science and Technology, Norway. Department of surgery, St. Olavs University Hospital, Trondheim, Norway.

Martin P. Grobusch, MD, PhD, FRCP, (Co-PI). Prof. Tropical Medicine and Travel Medicine, Amsterdam University Medical Centre, Amsterdam, The Netherlands.

Osman Sankoh, PhD. Statistician General, Statistics Sierra Leone. Visiting professor College of Medicine and Allied Health Sciences, University of Sierra Leone. Honorary associate professorship, School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa. Honorary professor, Faculty of Public Health, Hanoi Medical University, Hanoi, Vietnam.

Alex van Duinen, MD, GHTM, MIH, Research fellow, (Editor merged protocol) Department of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Norway. Department of surgery, St. Olavs University Hospital, Trondheim, Norway.

Reinou S. Groen MD, MIH, PhD Attending at Alaska Native Medical Center, Obstetrics and Gynecology, Alaska, USA**.** Affiliated Associate Professor, Johns Hopkins Hospital, Department of Gynecology and Obstetrics. Baltimore, MD, USA

Jurre van Kesteren, MD, GHTM. (lead SOSAS Repeat arm & Editor merged protocol) Surgical Resident VU University Medical Center, Department of Surgery, Amsterdam, The Netherlands.

Diede van Delft, Manager Masanga Research Unit, Tonkolili District, Sierra Leone.

Mia N. Østensen, (Co-lead LUTS arm). Medical student Faculty of Medicine, Norwegian University of Science and Technology, Norway.

Sofie M. Løvdal, (Co-lead LUTS arm). Medical student Faculty of Medicine, Norwegian University of Science and Technology, Norway.

Dag Halvorsen, MD, Specialist Urologist. Department of surgery, St. Olavs University Hospital, Trondheim, Norway.

Helena Bertilsson, MD, PhD, Specialist Urologist. Researcher, Department of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Norway. Department of surgery, St. Olavs University Hospital, Trondheim, Norway.

T. B. Kamara, MD, Specialist Urologist. Ministry of Health and Sanitation, Sierra Leone

P. M. George, MD, Surgical registrar. Ministry of Health and Sanitation, Sierra Leone.

Karel C. Lindenbergh, medical student (lead hernia arm), VUmc School of Medical Sciences, Amsterdam, The Netherlands

Thomas Ashley, MD. Kamakwie Wesleyan Hospital, Makeni, Sierra Leone. CapaCare, Masanga Hospital, Tonkolili District, Sierra Leone. Ministry of Health and Sanitation, Freetown, Sierra Leone.

Jenny Löfgren, MD, PhD. Department of Molecular Medicine and Surgery, Karolinska Institutet, Stockholm, Sweden

H. Jaap Bonjer, MD PhD, FRCSC, FACS, FASCRS. Professor of Surgery Amsterdam UMC, location VUmc. Chair Department of Surgery

Frank W Bloemers, MD, PhD, Prof., Amsterdam University Medical Center, location VUmc, Department of Trauma surgery, Amsterdam, The Netherlands

Jonathan H. Vas Nunes, MD, GHTM (lead wound arm). Masanga Hospital, Tonkolili District, Sierra Leone.

Hanna Mathéron, MD, GHTM (co-lead maternal and perinatal health arm). Masanga Hospital, Tonkolili District, Sierra Leone.

Daniël van Leerdam, MD, GHTM. (lead surgical volume arm). Royal Tropical Institute, Amsterdam, the Netherlands

Janine Martens 6th year medical student University Medical Center, Utrecht, the Netherlands. Julius Center Global Health, Utrecht, the Netherlands.

Josien Westendorp, MD, GHTM, (lead maternal and perinatal health arm). Research fellow, NTNU, Norway. Registrar in department of Obstetrics and Gynaecology, University Medical Center, Utrecht, the Netherlands.

Michael M Kamara, MD. CapaCare, Masanga Hospital, Tonkolili District, Sierra Leone. Ministry of Health and Sanitation, Freetown, Sierra Leone. College of Medicine and Allied Health Sciences, University of Sierra Leone, Freetown, Sierra Leone.

Joyce Browne, PhD, Epidemiologist, MD and Assistant professor in Global Health. The Julius Center Global Health department.

Marcus Rijken, PhD, MD. Assistant professor in Global Health and obstetrician/gynaecologist. The Julius Center Global Health department.

Daan van Herwaarden, 4th year medical student University Medical Center, Utrecht, the Netherlands. Julius Center Global Health, Utrecht, the Netherlands.

Daniel Boateng, PhD. Assistant professor Julius Global Health, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht University, Utrecht, The Netherlands. School of Public Health, Kwame Nkrumah University of Science and Technology, Kumasi, Ghana

Kerstin Klipstein-Grobusch, PhD. Associate Professor of Global Health at the University Medical Center Utrecht, The Netherlands / Visiting Professor of Epidemiology at the School of Public Health, University of the Witwatersrand, South Africa.

N.N (collaborators from Statistics Sierra Leone)

N.N (collaborators not listed)

12. References

1. Debas, H.T., Donkor P., Gawande A., Jamison D.T., Kruk M.E., and Mock C.N., editors. 2015. *Essential Surgery. Disease Control Priorities*, third edition, volume 1. Washington, DC: World Bank.

2. Hewitt D.B. *Groin Hernia*. JAMA. 2017;317(24):2560

3. Basu S., Andrews J., Kishore S., Panjabi R. and Stuckler D. *Comparative performance of private and public healthcare systems in low- and middle-income countries: A systematic review.* PLoS Med, 2012;9(6):19.

4. Bolkan, Von Schreeb, Samai, Bash-Taqi, Kamara, Salvesen, Ystgaard and Wibe. *Met and unmet needs for surgery in Sierra Leone: A comprehensive, retrospective, countrywide survey formal health care facilities performing operations in 2012*. Surgery. 2015;157(6):992-1001

5. Meara, Leather and Hagander et al. *Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development*. Lancet. 2015; 386(9993):569–624.

6. 68th World Health Assembly, 2015 May 26th https://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R15-en.pdf [website: date of access 14th July 2019]

7. Groen R.S., Samai M., Stewart K.A., Cassidy L.D., Kamara T.B., Yambasu S.E., Kingham T.P. and Kushner A.L. *Untreated surgical conditions in Sierra Leone: A cluster randomised, cross-sectional, countrywide survey.* Lancet. 2012;380(9847):1082-1087

8. Togoh, G.P.Y., Turay, A.B., and Komba A. *Sierra Leone 2015 Population and Housing Census Thematic Report on Population Projections*. Statistics Sierra Leone, 2018.

9. United Nations Development Programme. Human Development Reports. http://hdr.undp.org/en/countries/profiles/SLE [website: date of access 14th July 2019]

10. Evans D.K., Goldstein M., and Popova A., *Health-care worker mortality and the legacy of the Ebola epidemic*. Lancet Global Health. 2015;3(8):439-440.

11. Bolkan H,A., van Duinen A., Waalewijn B., Elhassein M., Kamara T.B., Deen G.F., Bundu I., Ystgaard B., von Schreeb J and Wibe A. *Safety, productivity and predicted contribution of a surgical task-sharing programme in Sierra Leone.* Br J Surg. 2017;104(10):1315-1326

12. Wurie H.R. and Witter S., In depth interviews of health workers in Sierra Leone report. https://assets.publishing.service.gov.uk/media/57a089cded915d3cfd00042c/IDIreport-SL-final-230614.pdf [website: date of access 14th July 2019]

13. Alyssa S., Parpia, M., Martial L. Ndeffo-Mbah, P., Natasha S. Wenzel, M., and Alison P. Galvani, P. *Impact of the 2014-2015 Ebola Outbreak on Malaria, HIV, and Tuberculosis in West Africa*. Emerging Infectious Diseases (in press).

14. Kamara, J., Allieu-Kekura I., Kanu A., *Sierra Leone 2015 Population and Housing Census Thematic Report on Elderly Population*. Statistics Sierra Leone, 2018.

15. Irwin, D.E., Kopp Z.S., Agatep B., Milsom I and Abrams P., *Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction.* BJU Int, 2011;108(7):1132-1138.

16. Stothers, L., et al., *Associations between the severity of obstructive lower urinary tract symptoms and care-seeking behavior in rural Africa: A cross-sectional survey from Uganda.* PLoS One. 2017;12(3):e0173631.

17. Emberton, M. and J.M. Fitzpatrick J.M., *The Reten-World survey of the management of acute urinary retention: preliminary results.* BJU Int. 2008;101(3): 27-32.

18. Speakman, M., et al. *Burden of male lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) - focus on the UK.* BJU Int. 2015;115(4):508-519.

19. Grimes C.E., Law R.S.L., Borgstein E.S., Mkandawire N.C., Lavy C.B.D. *Systematic review of met and unmet need of surgical disease in rural sub-saharan Africa.*
World J Surg. 2012;36(1):8-23.

20. Zendejas B., Ramirez T, Jones T., et al. *Incidence of Inguinal Hernia Repairs in Olmsted County, MN.* Ann Surg. 2012;257(3):520-526.

21. Sanders, D.L., Porter, C.S., Mitchell, K.C.D. et al. *A prospective cohort study comparing the African and European hernia*. Hernia 2008;12:527

22. Löfgren J., Makumbi F., Galiwango E., Nordin P., Ibingira C., Forsberg B.C., and Wladis A., Prevalence of treated and untreated groin hernia in eastern Uganda. Br J Surg. 2014 May;101(6):728-34

23. Beard J.H., Oresanya L.B., Akoko L., Mwanga A., Dicker R.A. and Harris H.W. An estimation of inguinal hernia epidemiology adjusted for population age structure in Tanzania. Hernia. 2014 Apr;18(2):289-95

24. Ohene-Yeboah M., Beard J.H., Frimpong-Twumasi B., Koranteng A. and Mensah S. *Prevalence of Inguinal Hernia in Adult Men in the Ashanti Region of Ghana.* World J Surg. 2016 Apr;40(4):806-12

25. Patel, H.D., Groen, R.S., Kamara, T.B. et al. *An estimate of hernia prevalence in Sierra Leone from a nationwide community survey.* Hernia (2014) 18: 297

26. Beard, J.H., Oresanya, L.B., Ohene-Yeboah, M. et al. *Characterizing the Global Burden of Surgical Disease: A Method to Estimate Inguinal Hernia Epidemiology in Ghana.* World J Surg (2013) 37: 498

27. Stewart B., Pathak J., Gupta S., Shrestha S., Groen R.S., Nwomeh B.C., Kushner A.L. and McIntyre T., An estimate of hernia prevalence in Nepal from a countrywide community survey. Int Journal of Surgery. 2015:(13):111-114

28. Botman, M., Meester R.J., Voorhoeve R., Mothes H., Henry J.A., Cotton M.H., Lane R.H.S., Pankaj G. Jani P.G., Hugo A. Heij H.A., Ismail E. A. *The Amsterdam Declaration on Essential Surgical Care.* World J Surg. 2015:39:1335

29. Wong EG, Kamara TB, Groen RS, Zogg CK, Zenilman ME, Kushner AL. Prevalence of surgical conditions in individuals aged more than 50 years:A cluster-based household survey in sierra leone. World J Surg. 2015;39(1):55–61.

30. Kollie K, Amoako YA, Ake J, Mulbah T, Zaizay F, Abass M, et al. Buruli ulcer in Liberia, 2012. Emerg Infect Dis. 2014;20(3):494–6.

31. Lai P.S., Bebell L.M., Meney C., Valeri L. and White M.C. Epidemiology of antibiotic-resistant wound infections from six countries in Africa. *BMJ Glob Health.* 2018;2:e000475

32. [Online] Ebola, How traditional healers helped defeat. Dariusz Dziewanski. https://www.aljazeera.com/indepth/features/2015/10/traditional-healers-helped-defeat-ebola-151028114811599.html (website: date of acces 14th july 2019)

33. Groen R.S., Samai M., Petroze R.T., Kamara T.B., Yambasu S.E., Calland J.F., Kingham T.P., Guterbock T.M., Choo B. and Kushner A.L. Pilot testing of a population-based surgical survey tool in Sierra Leone. World J Surg. 2012 36(4):771-4

34. [Online] Government of Sierra Leone Ministry of Health and Sanitation. *Summary Report of the 2017 SARA Plus in Sierra Leone: Service availability and Readiness Assessment (SARA), Quality of Care Survey, and Data Quality Review.* Freetown, Sierra Leone. 2017. https://mohs2017.files.wordpress.com/2018/05/mohs-sierra-leone_sara-report_final.pdf (website: date of access 14th july 2019)

35. [Online] Sierra Leonean Ministry of Health and Sanitation | *Maternal Death Surveillance & Response Annual Report.* 2016. https://sierraleone.unfpa.org/en/publications/maternal-death-surveillance-and-response-annual-report (website: date of acces 14th july 2019)

36. [Online] WHO Country Office Sierra Leone. *WHO Annual Report Sierra Leone 2017.* https://www.afro.who.int/publications/world-health-organization-sierra-leone-annual-report-2017 (website: date of acces 14th july 2019)

37. Treacy L., Bolkan H.A., Sagbakken M. *Distance, accessibility and costs. Decision-making during childbirth in rural Sierra Leone: A qualitative study.* PLoS One. 2018;13(2).

38. Betran A., Torloni M., Zhang J. and Gülmezoglu A. *WHO Statement on Caesarean Section Rates.* BJOG An Int J Obstet Gynaecol, 2016;123(5):667–670.

39. Molina *et al*. *Relationship Between Cesarean Delivery Rate and Maternal and Neonatal Mortality.* JAMA. 2015. 314(21):2263-70

40. Groen R.S., Solomon J., Samai M., Kamara T.B., Cassidy L.D., Blok L, Kushner A.L., Dhanaraj M. and Stekelenburg J. *Female health and family planning in Sierra Leone.* Obstet Gynecol 2013;122(3):525–531

41. Vaughan E, Sesay F, Chima A, Mehes M, Lee B, Dordunoo D, et al. An assessment of surgical and anesthesia staff at 10 government hospitals in Sierra Leone. JAMA Surg. 2015;150(3):237–

42. Bolkan HA, Hagander L, Von Schreeb J, Bash-Taqi D, Kamara TB, Salvesen Ø, et al. The Surgical Workforce and Surgical Provider Productivity in Sierra Leone: A Countrywide Inventory. World J Surg. 2016;40(6):1344–51.

43. Kelsey, J.L. (2008). Observational Epidemiology. International Encyclopedia of Public Health. 609-620. 10.1016/B978-012373960-5.00193-3.

42. Kwon S., Groen R.S., Kamara T.B., Cassidy L.D., Samai M., Yambasu S.E. and Kushner A.l., *Nationally Representative Household Survey of Surgery and Mortality in Sierra Leone*. World J Surg. 2013 Aug;37(8):1829-1835

43. Selekman R.E., Harris C.R., Filippou P., Chi T., Alwaal A., Blaschko S.D. and Breyer B.N., *Validation of a Visual Prostate Symptom Score in Men With Lower Urinary Tract Symptoms in a Health Safety Net Hospital*. Urology. 2015;86(2):354–358

44. Chun, K., S.J. Kim, and S.T. Cho. *Noninvasive Medical Tools for Evaluating Voiding*. Int Neurourol J. 2017; 21(1):10-16

45. Goya, N. and H. Toma. *Ethanol injection therapy of the prostate for benign prostatic hyperplasia.* s.l. : Nihon Rinsho, 2002, Vols. 60 Suppl 11: p. 402-7.

46. Bolkan HA, van Duinen A, Samai M, Bash-Taqi DA, Gassama I, Waalewijn B, et al. Admissions and surgery as indicators of hospital functions in Sierra Leone during the west-African Ebola outbreak. BMC Health Serv Res. 2018;18(1):846.

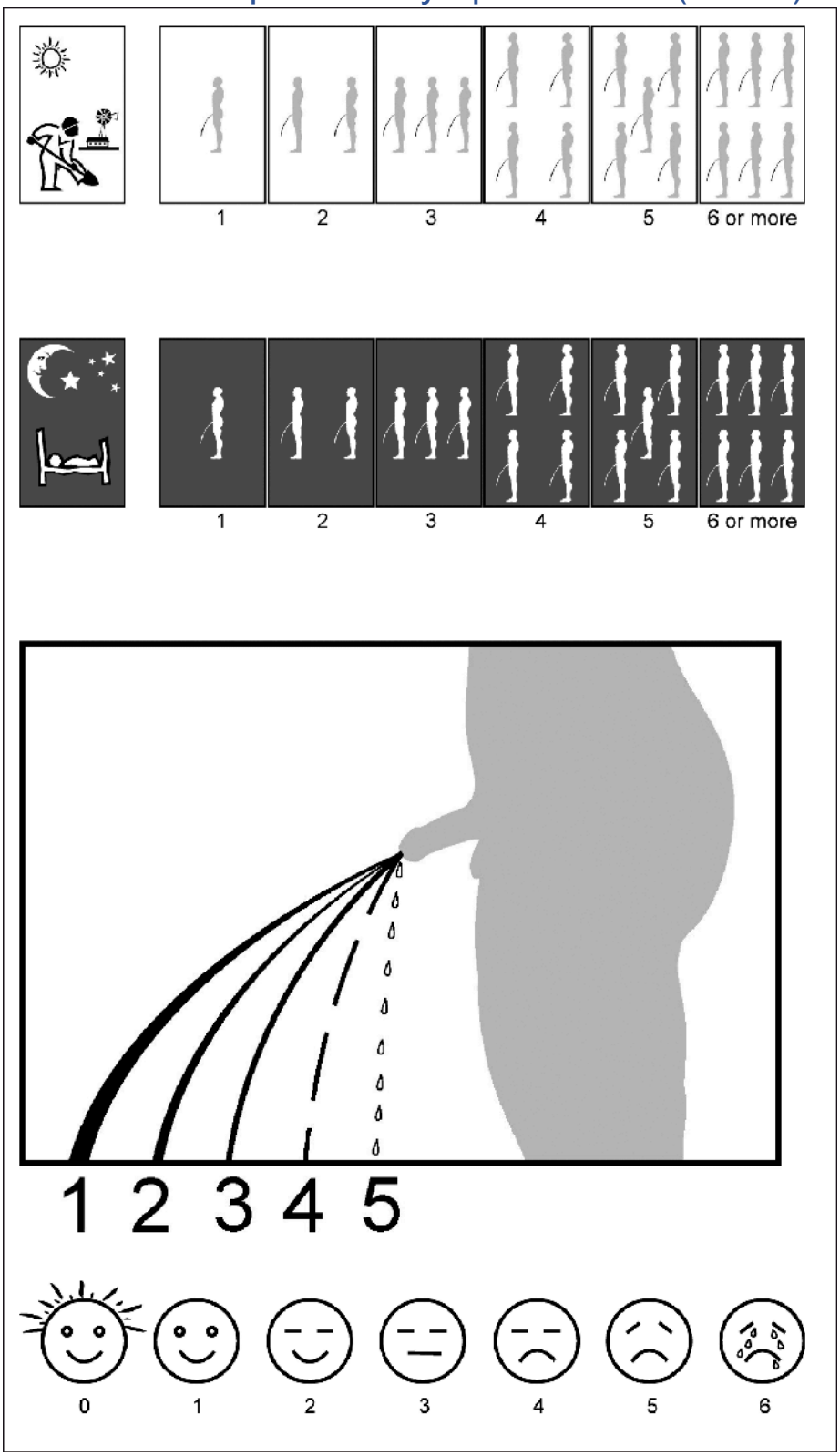
47. [Online] CapaCare Year report 2018. https://capacare.org/wp-content/uploads/2016/12/Annual-report-surgery-sierra-leone_2018_LR-1.pdf (website: date of access 18th July)

48. Mensah GA. Epidemiology of stroke and high blood pressure in Africa. *Heart* 2008;94(6):697 705. doi:10.1136/hrt.2007.127753

49. van de Vijver S, Akinyi H, Oti S, et al. Status report on hypertension in Africa - Consultative review for the 6th Session of the African Union Conference of Ministers of Health on NCD'ss. *Pan Afr Med J*. 2013;16. doi:10.11604/pamj.2013.16.38.3100

50. Cappuccio FP, Miller MA. Cardiovascular disease and hypertension in sub-Saharan Africa: burden, risk and interventions. *Intern Emerg Med*. 2016;11(3):299-305. doi:10.1007/s11739-016-1423-9

Appendix 1 – Visual prostate symptom score (VPSS)



Appendix 2 – Questionnaire

See other document.