

Towards increased global availability of surgical equipment

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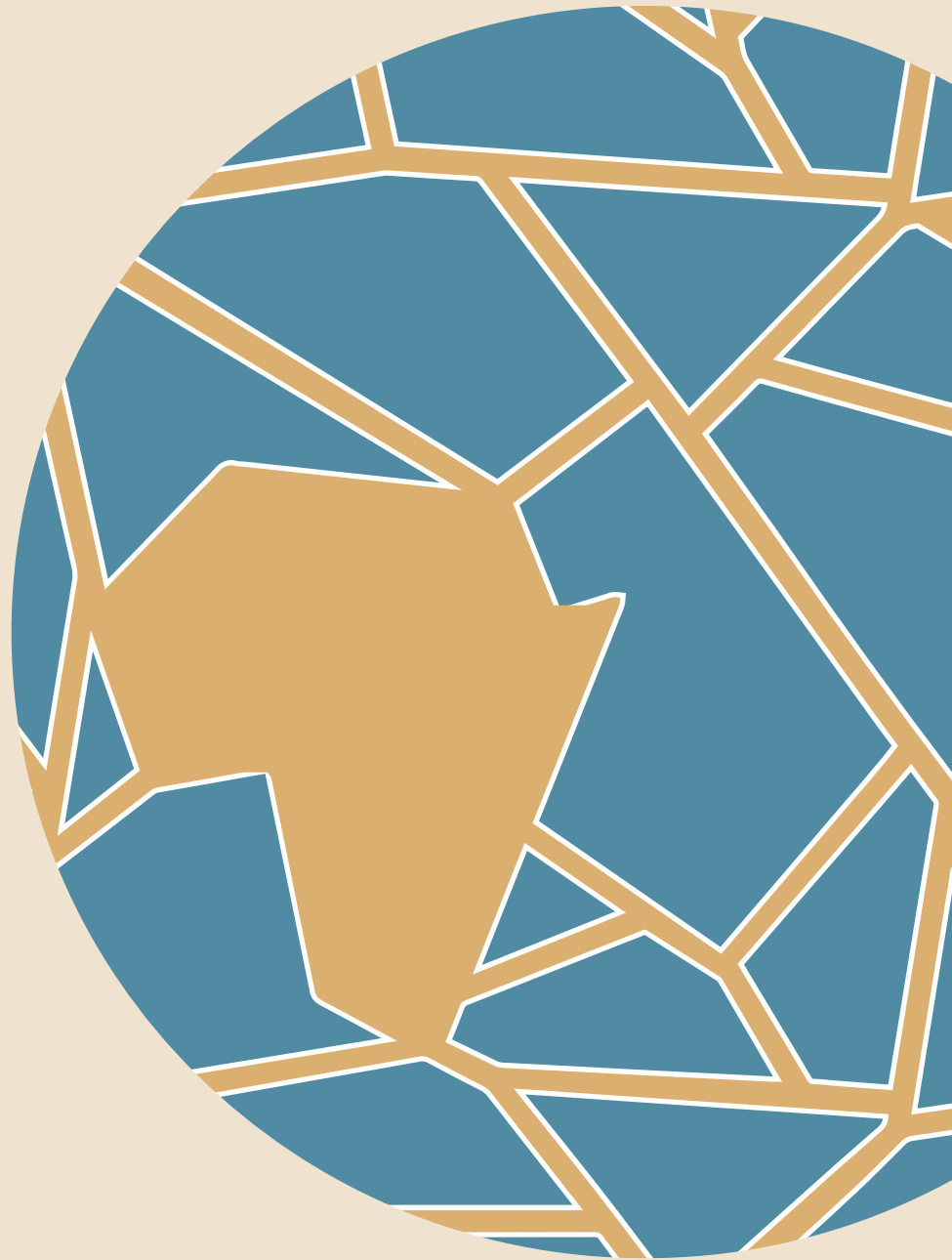
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**TOWARDS INCREASED
GLOBAL AVAILABILITY OF
SURGICAL EQUIPMENT**

ROOS MARIEKE OOSTING

**TOWARDS INCREASED GLOBAL AVAILABILITY
OF SURGICAL EQUIPMENT**

Roos Marieke Oosting

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Towards increased global availability of surgical equipment

Dissertation

for the purpose of obtaining the degree of doctor
at Delft University of Technology
by the authority of the Rector Magnificus prof.dr.ir. T.H.J.J. van der Hagen chair of the
Board for Doctorates
to be defended publicly on
Thursday 12 December 2019 at 15:00 o'clock

by

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GLOSSARY

Essential surgical care: All surgical procedures that promote individual and public health. The Bellwether procedures, caesarean delivery, laparotomy and open fracture treatment, are often used as a proxy for surgical systems that have the ability to provide a broad range of procedures (1).

Surgical equipment: Equipment required to perform surgery. Equipment (that requires a battery or electricity) that is minimally required to perform surgery included in this thesis was selected based on three guidelines of the World Health Organization on infrastructure and supplies for essential surgical care and the Personnel, Infrastructure, Procedures, Equipment and Supply (PIPES) tool (2).

Hospitals in Low-and-Middle Income Countries (LMICs): Hospitals in all countries below 12,055 of Gross National Income/Capita (in US\$) as identified by the World Bank. This thesis focusses on hospitals in these countries that target the low-income group, and not the (expensive) hospitals that focus on the high-income group that are not a representative of the hospitals serving the majority of the population.

Context of use: Collection of spatial-temporal factors that influence daily use of a product (3). In this thesis, we studied aspects influencing the context of use, such as procurement, training, usage, complications, maintenance and infrastructural barriers.

Contextual factor: Specific aspect that influences daily use of surgical equipment.

Context-specific design: Design that is intendedly adapted to fit the context of use.

Context-specific design requirements: Design requirements that are intendedly adapted to fit the context of use.

Design ethnography: Social science research methods (ea., surveys, observations and interviews) to understand more of the user's perception of the object, environment, system, or service the user is engaged with (4).

Consumables: Products that are often used in addition to surgical equipment that are intended to be used up and then replaced.

Spare parts: Interchangeable part that is used to repair or replace failed parts.

Maintenance: Providing repair, planned preventive maintenance or calibration to equipment.

Biomedical Equipment Technicians (BMETs): Technicians trained to perform maintenance on medical equipment.

Biomedical engineers (BMEs): University trained engineers with a background in design and workflow of medical equipment in hospitals.

Medical device company: Company which develops and supplies hospitals with medical equipment, including donation agencies or nongovernmental organizations (NGOs).

End-user: Surgeons, nurse or BMET interacting with equipment on a daily basis.

Electrosurgical unit (ESU): Wave generator used for cutting and coagulation of tissue during surgical procedures.

Monopolar handheld: Accessory required in combination with the electrosurgical unit for cutting and coagulation of tissue during surgical procedures.

Laparoscopic surgery: A surgical procedure that uses small incisions to access the patient's body requiring specific equipment, such as a laparoscope.

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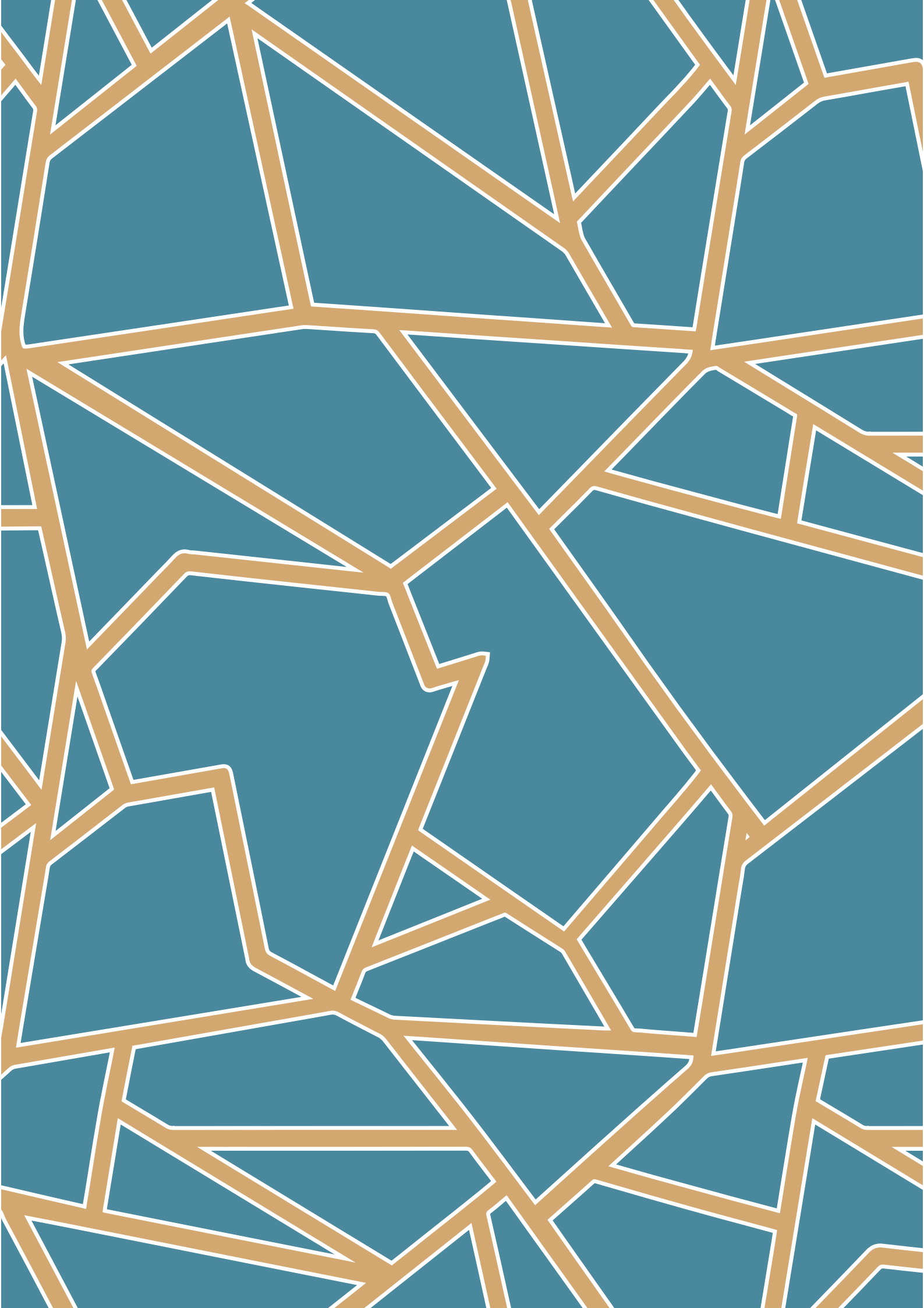
Electrosurgical unit in a large hospital in Kenya with a patient plate sticker.

KENYA



Operating room in a large
hospital in Kenya

KENYA



CHAPTER 1

Introduction

NEED FOR SURGERY

The need for surgery in low- and middle-income countries (LMICs) is tremendous; more people die from treatable surgical conditions than from tuberculosis, malaria and HIV put together (1). Less than 10% of all surgeries performed are received by the poorest one-third of the world's population (1, 2). The need is greatest in Africa and South Asia. In these areas, due to absence of surgical care, easily treatable conditions, such as appendicitis, hernia, fractures, and obstructed labour are fatal (1).

Surgery should be an integral component of national health care services in all countries to reach the goals set for universal health coverage by the World Health Organization (WHO) (1) and sustainable development goal 3: 'Ensure health lives and promote well-being for all at all ages'. This is especially true since the need for surgical care in LMICs will increase even more in the future due to higher incidence of cancer, traffic injuries and cardiovascular diseases (1). The common notion that surgery is too complex and expensive to implement is changing to the realization that surgery is affordable (1, 3). High-burden conditions, such as complications of pregnancy, injuries and surgical emergencies (e.g. appendicitis), are all cost-effective, with most surgical interventions costing \$10-100 per disability-adjusted life year (DALY). This is in the same range as widely accepted global health interventions such as, immunization programs or bed nets for prevention of malaria (2).

In high-income countries (HICs), laparoscopic surgery has become the standard for many surgical conditions. The advantages of laparoscopic surgery compared to open surgeries, which are especially beneficial in LMICs, are decreased risk of infection, decreased blood loss and rapid return to work (4). Diagnostic laparoscopy could function as an effective replacement of expensive modern diagnostic procedures (such as MRI and CT) in LMICs (5). However, there are still major clinical, economic and infrastructural barriers to widespread implementation of laparoscopic surgery in LMICs, for example, because of high incidences of major complications, high start-up-costs and limited availability of trained health care workers (4).

The roots of the surgical system start in the community and primary health centres (Figure 1.1), where health workers refer patients to the first level hospital (district hospitals). District hospitals should provide basic surgical procedures, while more specialized cases should be referred to referral hospitals that also serve as hubs for research and training (6). In many areas, surgical care is provided by both the public (district and referral hospitals) and the private system (private hospitals). Public hospitals fall under the responsibility of the government, in contrast to the private hospitals and for- and not-for-profit providers (e.g., non-governmental organizations (NGOs), mission organizations and traditional healers). The private hospitals are in some areas the largest provider of surgical care (1).

Patients seeking surgical care in LMICs face a series of barriers, including: lack of facilities, government corruption and poor health system infrastructure (7). The largest barrier is the financial concern, including both direct and indirect costs. Direct costs are fees for

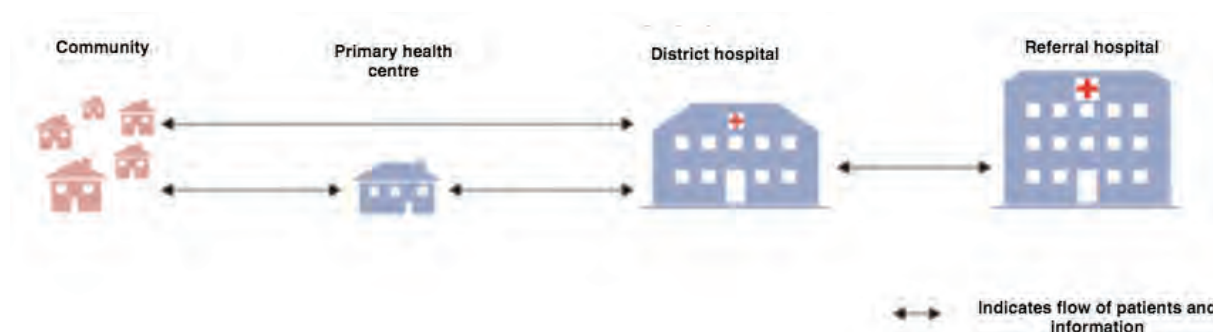


Figure 1.1: The different categories of the surgical system in many LMICs (adapted from Meara et al. (2015)(1)).

surgery, drugs and supplies, transport and costs for hospital-stays. Indirect costs cover bringing a caregiver to the hospital and loss of income. Health insurance is not yet widely implemented in LMICs, or the insurance does not cover all costs, often resulting in out-of-pocket payments directly to the hospital (7).

SURGICAL EQUIPMENT

To perform surgery, health workers, such as surgeons, nurses and medical officers are required. Also, anaesthesia, sterilization, storage and maintenance are needed for the operating theatre to function properly. Tools and surgical equipment are crucial too, as are running water and electricity (8). A crucial barrier to surgical care is the limited availability of surgical equipment in many operating theatres in LMICs, which results in delays and cancellations of surgeries on a daily basis (1, 4, 7). Limited availability of surgical equipment were found by previous studies in Nigeria (9), Cameroon (10), Sierra Leone (11), Somalia (12), Ethiopia (13) and Malawi (14). Accordingly, limited availability of surgical equipment has been reported as a barrier to implementation of laparoscopy in LMICs (4). Barriers to availability of medical equipment in LMICs, include e.g., high costs, lack of consumables and spare parts, and limited access to maintenance (4, 15-26). Medical equipment that is available is often donated from HICs to LMICs (15) or procured by hospitals in LMICs. However, this equipment is often designed for use in HICs (16), which introduces challenges during use in LMICs. The World Health Organization's (WHO) 'Priority Medical Devices Project' confirmed this mismatch between the design of medical devices and their use in LMICs (17).

The barriers to availability of equipment occur during procurement, use, maintenance, and disposal. In order to design successful strategies to increase availability of surgical equipment, the root causes of perceived barriers need to be understood.

DESIGN OF SURGICAL EQUIPMENT

To increase global availability of surgical equipment, we propose that context-specific surgical equipment should be designed for use in LMICs, as was also recognized by the Lancet commission on Global surgery (1, 27, 28). Although the common perception of

equipment being expensive, highly engineered and not essentials in LMICs is changing, this shift came more than 30 years after similar recognition was given to essential medicines (18).

To design context-specific surgical equipment, the context of use of surgical equipment should be considered: because surgical equipment cannot function without sterilization, maintenance and infrastructure (water and electricity), and should be used without complications. In addition, procurement systems and training all influence the context of use.

A large majority, 75%, of the equipment included in the compendium of technologies for low-resource settings issued by the WHO originates from HICs (29). Which is to a large extent caused by a limited number of biomedical engineers and medical device companies in LMICs. This imposes a need for biomedical engineers in HICs to understand the context of use of surgical equipment in the unfamiliar context in LMICs (16, 22). This demands that a significant amount of time and money must be devoted to analysing the context thoroughly, before determining the context-specific design requirements (30).

This thesis focusses on surgical equipment. Surgical equipment is a particularly interesting category of medical equipment, firstly because it has a large influence on the successful outcome of a surgical procedure, and secondly because, surgical equipment has a high turnover rate: the same device is used for multiple procedures on the same day. Therefore, surgical equipment should be reliable under all circumstances and the context of use should be supported by the design. Of the 134 commercially available medical products that are especially designed for LMICs, only 20 address needs other than infectious diseases (20), and only a few (n=2) of the 51 medical products of the WHO compendium on innovative technologies for global health, are categorized as surgical equipment (31). This reveals a large gap in design projects for surgical equipment.

GOAL OF THIS THESIS

The overall goal of this thesis is to study current use of surgical equipment in LMICs, in order to understand how to increase global availability of surgical equipment in the future. One of the strategies that is researched more thoroughly, is the design of context-specific surgical equipment for global surgery.

APPROACH AND OUTLINE

The title of this thesis, 'Towards increased global availability of surgical equipment', represents the research of the use of surgical equipment in hospitals in LMICs and context-specific designs that could impact surgical practice in the future. As many areas in Sub-Saharan Africa feel the burden of limited access to surgery, we have included hospitals in Sub-Saharan Africa as a case study, with a main focus on Kenya. Previous research has shown that most barriers mentioned to the use of medical equipment are overall consistent (4, 15-26) and we expect that findings of this thesis can be translated to other LMICs.

This thesis consists of **two main** parts (Figure 1.2). In the **first part**, the context of use and barriers to surgical equipment in hospitals in Sub-Saharan Africa are studied in order to understand what is required to increase availability. Although, previous studies identified barriers to availability of equipment in LMICs; little is known about the specific types of equipment that cause difficulties and the root causes of these difficulties.

This results in the following research questions:

- 1) What is the availability of surgical equipment in hospitals in Sub-Saharan Africa?
- 2) What are the main barriers to availability and their root causes in hospitals in Sub-Saharan Africa?
- 3) What is required to increase global availability of electrosurgical units (ESUs) and laparoscopic equipment in the future?

In the **second part**, a context-driven design approach is presented that can be used to collect contextual factors when designing context-specific surgical equipment for LMICs. In addition, the use of our design approach during the development of an electrosurgical unit (ESU) and monopolar handheld for hospitals in Sub-Saharan Africa is presented.

This results in the following research question:

- 4) What contextual factors should be collected during a design project to design context-specific surgical equipment for use in LMICs?
- 5) How to increase access to electrosurgery in LMICs by context-driven design?

Part 1 - Understanding the context of use of surgical equipment in hospitals in Sub-Saharan Africa

Chapter 2 presents the availability of and barriers to surgical equipment in hospitals in nine countries in Sub-Saharan Africa. By surveying 42 surgeons, we first identified the availability of 13 essential types of surgical equipment in three different hospital categories (district, referral and private). Secondly, we identified reasons for limited availability of surgical equipment and for its failure. Additionally, possible solutions for context-specific design are presented.

Chapter 3 presents the equipment journey (the journey that surgical equipment goes through during its lifespan) and its phases (procurement, use and disposal). Seventeen Biomedical Equipment Technicians (BMETs) were interviewed and asked to identify barriers that they encounter during procurement, use and disposal. Kenya was used as a case study. We discuss the key role of maintenance in supporting availability of surgical equipment and the root causes of difficulties with spare parts and donated equipment.

In **Chapter 4**, the availability, procurement, training, usage, complications and maintenance of the electrosurgical unit and laparoscopic equipment are detailed for 11 countries in Sub-Saharan Africa to identify gaps in the aspects that influence the context of use of surgical equipment. A total of 80 respondents (59 surgeons and 21 BMETs) were surveyed. Additionally, maintenance records were analysed to identify what type of maintenance is provided.

Part 2 - Context-specific designs to increase availability of surgical equipment in hospitals in Sub-Saharan Africa

We developed a context-driven design approach to guide biomedical engineers in what contextual factors to collect when designing context-specific surgical equipment for use in LMICs, that is presented in **Chapter 5**.

Chapter 6 describes how we used our context-driven design approach in practice during the design of an ESU and monopolar handheld for hospitals in Sub-Saharan Africa. We provide a detailed description of the context of electrosurgery in hospitals in Kenya; in total 19 surgeons were interviewed and 14 surgical procedures were observed. Together with the data collected during the field trips that were done for the first part of this thesis, a comprehensive overview of the context of use is provided. In addition, we provide context-specific design requirements for the ESU and the monopolar handheld for hospitals in Sub-Saharan Africa. Moreover, we present two context-specific designs that comply to the established list of requirements.

Finally, **Chapter 7 discusses** the work presented in this thesis during which we bridged global health research and engineering principles, to show what could be encountered when these fields come together. The context of use of surgical equipment in hospitals in Sub-Saharan Africa, together with how contextual factors can be used to develop context-specific surgical equipment will be described. Finally, we discuss future roles of different actors that should contribute in the process towards increased global availability of surgical equipment.

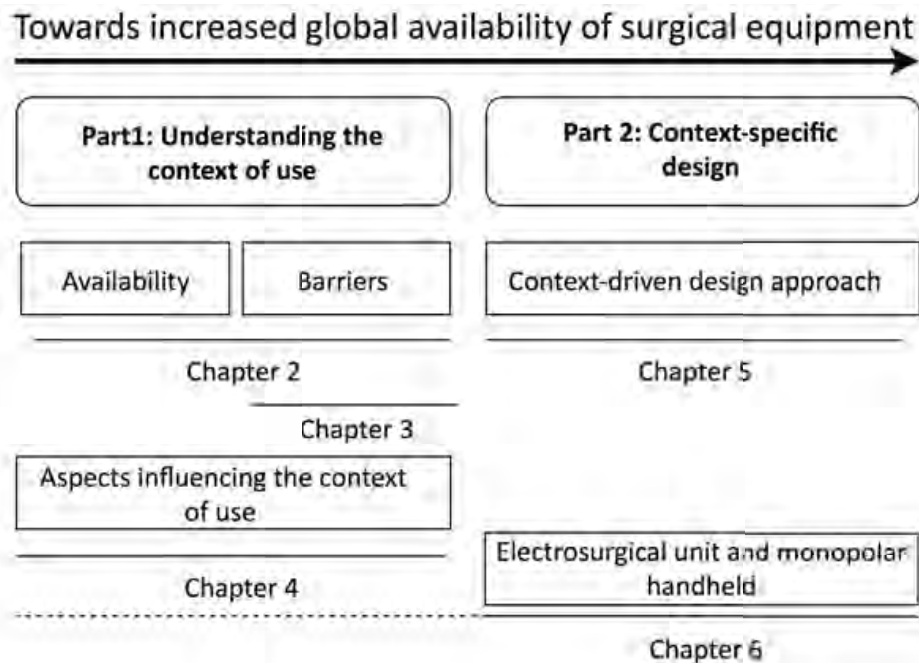
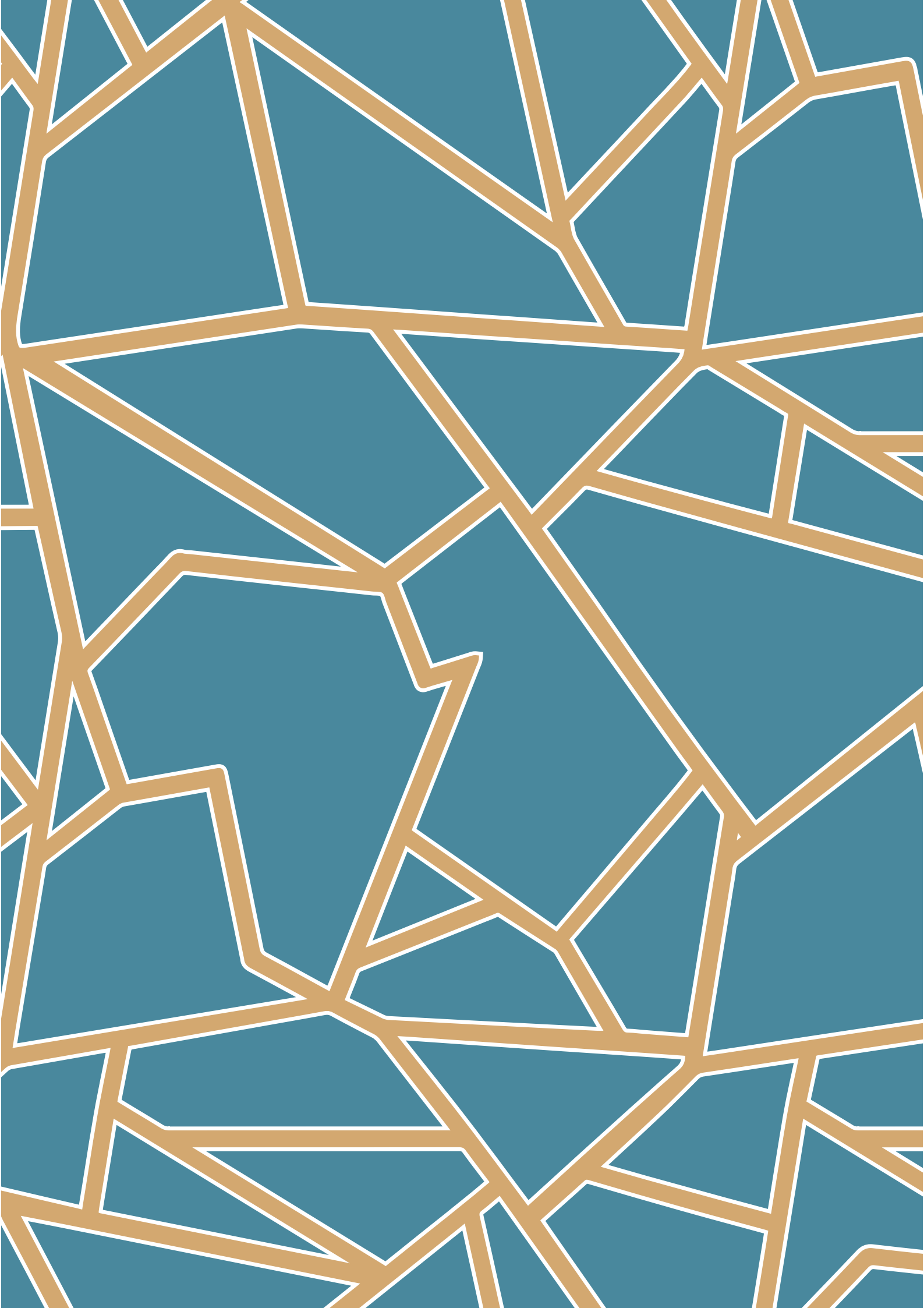


Figure 1.2. : Content of this thesis.

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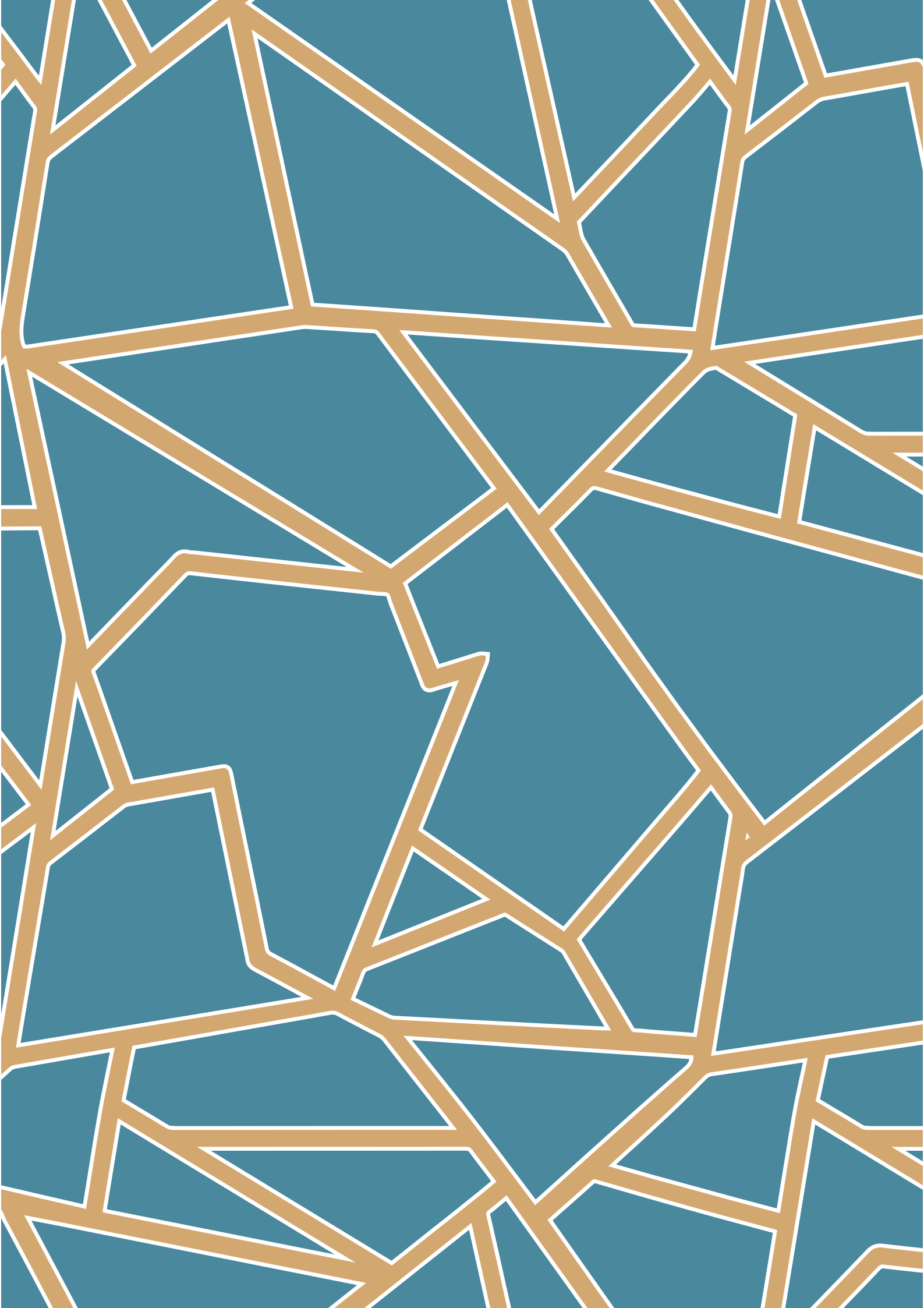
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PART 1

**Understanding the
context of use**



CHAPTER 2

Equipment for essential surgical care in 9 countries in Africa: availability, barriers and need for novel redesign

The aim of this dissertation is to study the current availability of surgical equipment in LMICs, in order to understand how to increase global availability of surgical equipment in the future. Previous research identified barriers to availability of surgical equipment in LMICs; however, little is known about the specific types of equipment that cause difficulties and the root causes of these difficulties. This chapter highlights the current availability of surgical equipment in 9 countries in Sub-Saharan Africa and reasons why equipment is not available. Furthermore, we present a list of equipment that should be redesigned to fit the context of use in LMICs according to the 42 surgeons who participated in this study.

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ABSTRACT

Shortages of medical equipment in low-and-middle income countries (LMICs) have been found by several previous studies that assessed surgical capacity. To increase surgical capacity, there is a need to identify the availability of specific types of surgical equipment on a local, regional and national level.

A survey was conducted among surgeons attending the annual meeting of the College Of Surgeons of East, Central and Southern Africa (COSECSA) in December 2016. General information of the facilities, availability of surgical equipment, reasons for limited availability, daily usage of equipment and equipment that could benefit from redesign were assessed. Forty-two respondents participated in this study, representing 33 individual healthcare facilities (14 public referrals, 9 public district and 10 private (for-profit and non-profit)). The respondents worked in 9 countries in East, Central, Western and Southern Africa.

A deficiency in availability of basic surgical equipment was found, especially in public district hospitals. Electrosurgical units, endoscopes, defibrillators, infusions pumps and electrocardiogram monitors were of limited availability. Reasons indicated for this limited availability were: no need, too costly, no training, no disposables and no repair. Lack of maintenance and old/overused equipment were identified as major reasons for failure of equipment. Equipment that could benefit from redesign were for example: electrosurgical units, laparoscopic equipment and theatre lights.

Availability of surgical equipment should be increased, especially in public district hospitals. Novel context appropriate redesign that is adapted to fit the context in LMICs could decrease the barriers to availability and to failure of surgical equipment.

INTRODUCTION

Global public health initiatives have neglected the necessity for provision of surgery for decades. However, recently surgery is increasingly recognized as an important component of public health (1,2). There is a significant disparity between surgical procedures performed in high-income countries (HICs) and low-and-middle income countries (LMICs), only 3.5 % of the surgeries performed in the world are received by the poorest one third of the worlds' population (2). The common notion that surgery is too complex and too expensive to implement in public health interventions is changing. Surgery, is complex and relies on availability of equipment, however patients can recover from their disease and are less likely to be under continuous surveillance for their disease in contrast to an infectious disease such as HIV (3).

Surgical care across Sub-Saharan Africa is provided by the private and the public healthcare sector, where the public healthcare sector is roughly subdivided in health centres, district and referral hospitals. Based on the guidelines of the World Health Organization (WHO) on essential and emergency surgical care, public district hospitals in LMICs should have adequately equipped major and minor operating theatres (OTs)(4). These public district hospitals should be able to provide short-term treatment of 95-99% of all life-threatening conditions. Public referral hospitals should be equipped with basic intensive care facilities and should be able to provide all treatment that is offered in public district hospitals with the addition of thoracic trauma care, complex eye surgeries and major gynaecological surgeries (4). To achieve the targets of the WHO, increased workforce capacity, but equally important, increased availability of surgical equipment is required. This requires strategic investments from stakeholders, such as local governments, biomedical engineers, biomedical equipment technicians (BMETs) and medical device companies (5).

The role of biomedical engineers, BMETs and medical device companies in increasing availability of surgical equipment is already widely acknowledged (5-7). Barriers unique to usage of medical equipment in LMICs were identified before (8), and the WHO 'Priority Medical Devices Project' identified a mismatch between the design of medical devices and the context in which medical equipment is used in LMICs (6).

Inventories of surgical capacity across sub-Saharan Africa have been made by different authors based on different surgical capacity tools: shortages of equipment were found in Nigeria (9), Cameroon (10), Sierra Leone (11), Somalia (12), Ethiopia (13), and Malawi (14). However, there is a need to identify the mismatch of specific types of surgical equipment on a local, regional and national level to plan future strategic investments. Therefore, the aim of this study is trifold:

- 1) to highlight the current availability of surgical equipment in public (district and referral) and private (for-profit and non-profit) hospitals across Sub-Saharan Africa,
- 2) to indicate the barriers surgeons experience on a daily basis in their efforts to assist in the population's health needs, and
- 3) to identify equipment that could benefit from context appropriate design.

METHOD

Surgical equipment that is essential to be able to perform safe surgery on both district and referral level in public, mission and private hospitals was identified by reviewing the following two guidelines and two tools:

- a. the WHO guideline to infrastructure and supplies at various levels of healthcare facilities (4),
- b. the WHO guideline for generic essential emergency equipment (15),
- c. the WHO tool for situational analysis to assess emergency and essential surgical care (16), and
- d. the PIPES tool (Personnel, Infrastructure, Procedures, Equipment and Supplies tool) to assess surgical capacity (17).

Guidelines a and b were developed by the WHO within their global initiative on emergency and essential surgical care. Tools c and d are the most frequently used tools to assess surgical capacity globally. It was believed that these guidelines and tools form a comprehensive basis for equipment required for essential safe surgery on both district and referral level in public, mission and private hospitals. Essential surgical equipment presented in these guidelines and tools that require batteries or electricity were included in this study.

Based on these four guidelines and tools a list of 13 equipment items essential for surgical care was established consisting of: oxygen concentrator, anaesthesia machine, pulse oximeter, suction pump, blood pressure measurement equipment, sterilizer, theatre light, electrosurgical unit (ESU), endoscope, electrocardiogram (ECG) monitor, infusion pump, defibrillator and laryngoscope.

A survey was developed to assess the availability of equipment required for essential surgical care across Sub-Saharan Africa. The survey consisted of four parts:

- 1) General information of each hospital (name, country, number of beds, number of OTs, availability of surgeons and biomedical equipment technicians (BMETs).
- 2) Availability of surgical equipment and reasons for limited availability (no need, too costly, no training, lack of spare parts, need for repair, lack of disposables or lack of energy or other). Participants were asked to indicate only the main reason for limited availability of equipment in their hospital.
- 3) Daily use of surgical equipment and the implications of malfunctioning equipment to patients (e.g., problems with equipment, reasons for failure of equipment, percentage of times surgeries are delayed or cancelled).
- 4) Maintenance, barriers during usage, and possible solutions and options for redesign of surgical equipment (e.g., what sort of maintenance is available, which equipment should be redesigned for more successful implementation).

The survey was conducted among surgeons working in African based hospitals who attended the annual meeting of the College Of Surgeons of East, Central and Southern Africa (COSECSA) in December 2016.

Hospitals were stratified into self-reported levels of care either public district or public referral or assigned as being private (for-profit or non-profit). No distinction between for-profit and non-profit was made since both categories of private hospitals do not fall under responsibility of the Ministry of Health (MoH) in terms of budget allocations, in contrast to public hospitals.

RESULTS

A total of 42 surgeons attending the conference participated. They represented 33 individual hospitals, 10 private hospitals (for-profit and non-profit), 14 public referral hospitals, and 9 public district hospitals (Table 2.1). Respondents were working in 9 countries in East, Central, Western and Southern Africa: Kenya (19), Zambia (2), Ethiopia (2), Zimbabwe (1), Uganda (1), Malawi (2), Congo (2), Mozambique (3) and Nigeria (1), and 9 surgeons did not specify the country they were working in.

Table 2.1: General information of the respondents

Hospitals category	Private/NGO/Mission (for-profit & non-profit) (n=10)	Public (n=23)	
	Private (n=10)	Public referral (n=14)	Public district (n=9)
Number of respondents	16	16	10
Number of hospital beds (for surgical and medical cases)	1926 (196, 64-380)*	10945 (622, 100-2000)* (n=10)	2470 (200, 50-500)*
Number of operating theatres	43 (4, 2-8)*	139 (8, 4-18)* (n=12)	27 (2, 1-7)*
Number of personnel performing surgery	148 (14, 5-30)*	319 (28, 3-50)* (n=11)	98 (10, 4-30)*
Hospitals with biomedical equipment technicians	8	12	7

*(total (median, range))

AVAILABILITY OF SURGICAL EQUIPMENT

Overall, the availability of surgical equipment was less in public district than in private and public referral hospitals (Figure 2.1). On average, overall equipment availability was indicated by 87.5% of the respondents from private hospitals, by 70% of the respondents from public district and 81% of the respondents from public referral hospitals. Blood pressure measurement equipment and laryngoscopes were available for all respondents. All respondents working in private and public referral hospitals had access to anaesthesia machines, for public district hospitals this was 90%. Endoscopes, defibrillators, infusion pumps and oxygen concentrators were of limited availability in public district hospitals.

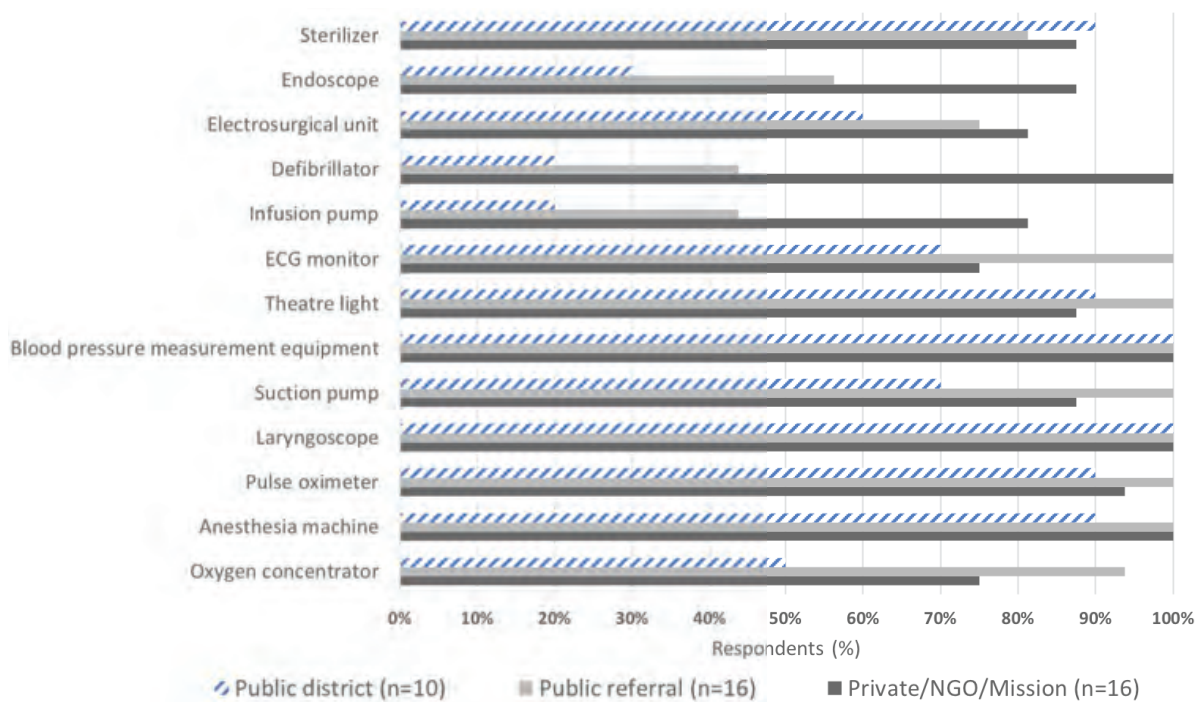


Figure 2.1: Availability of surgical equipment (in percentages) indicated by the respondents (n=42).

Main reasons for limited availability of surgical equipment

Respondents were asked to choose between categories (no need, too costly, no training, lack of spare parts, need for repair, lack of disposables or lack of water/electricity) and indicate the main reason why equipment was of limited availability within their facility. A total number of 86 reasons for limited availability were given by the 42 respondents. Figure 2.2 shows the reasons for limited availability of surgical equipment per hospital category. Too costly was indicated to be the largest reason for limited availability in all three hospital categories (ranging from 33 % to 71%). The second most mentioned reason was lack of repair (21-22%). No training and no disposables were reasons for limited availability mentioned by respondents in public district and public referral hospitals (no training ranging from 26% to 17% and no disposables ranging from 3% to 4%, respectively). Lack of water/electricity was mentioned by respondents from public district hospitals only (3%). Lack of spare parts was not reported as a reason for limited availability by any of the respondents.

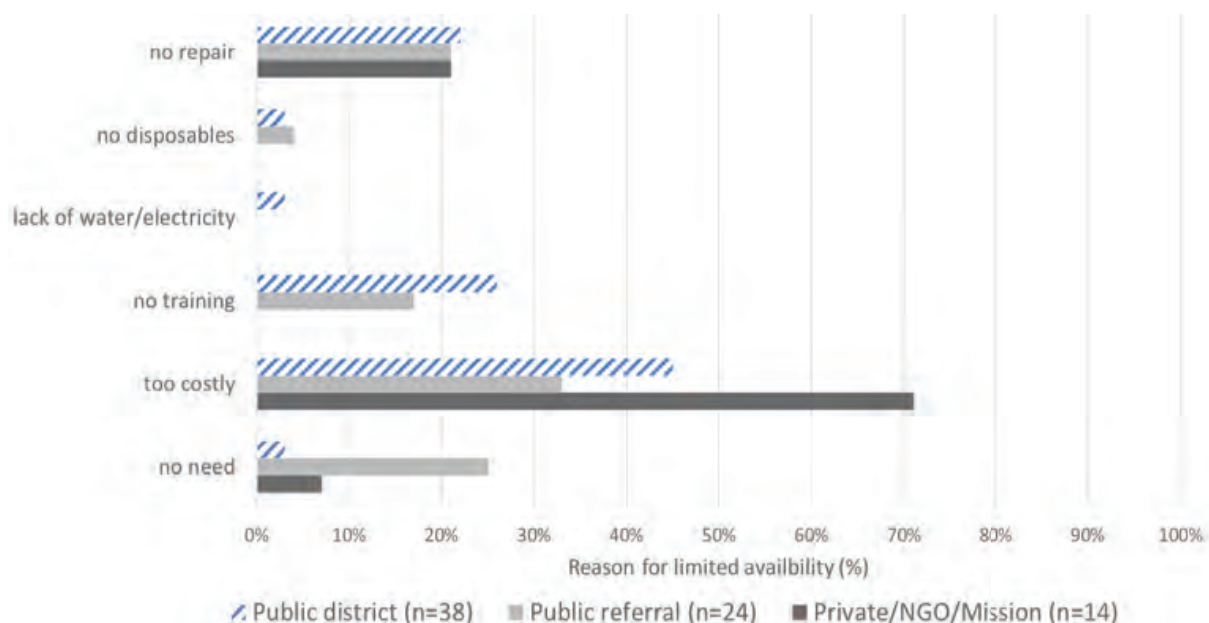


Figure 2.2: Reasons for limited availability of surgical equipment (86 reasons) indicated by the 42 respondents.

Problems regarding equipment and availability of maintenance

Delay and cancellation of surgery due to malfunctioning equipment was self-reported to be lower in private hospitals (delay and cancellation $\leq 8\%$) than in public hospitals (district and referral $\geq 20\%$ delay and cancellation) (Table 2.2).

Table 2.2: Percentage of delayed and cancelled surgeries per hospital category due to malfunctioning equipment.

	Private/NGO/Mission (n=16)	Public district (n=10)	Public referral (n=16)
Delay surgery (%)	8% (1%- 50%)*	20% (5%- 70%)*	25% (1%- 80%)*
Cancel surgery (%)	2% (0%- 10%)*	20% (0%- 50%)*	20% (0%- 50%)*

*median (range)

Sixty eight percent of respondents have access to maintenance facilities within their hospital and 36% of respondents have access to maintenance provided by service contracts. Ten percent of respondents indicated they have no access to maintenance facilities if equipment breaks. Eighty percent of respondents indicated that BMETs are working in their hospital with an average of 2.8 years of training.

All respondents indicated that they experience failure of surgical equipment. In total 53 reasons for equipment failure were self-reported. Lack of maintenance was reported the most as reason for failure (47%), followed by failure due to old or overused equipment (36%). Failure as a result of limited infrastructure facilities (mainly power outages) was reported by 11% of respondents. Finally, 5.5% of respondents reported that lack of finances caused failure of surgical equipment.

Barriers during usage and suggestion for redesign of surgical equipment

Thirty-nine respondents responded to the question if redesign is required for the context they work in. Twenty-five respondents (64%) agreed that redesign of surgical equipment could improve availability of surgical equipment in LMICs. Table 2.3 presents barriers 13 respondents encounter during usage and possible solutions and suggestions for redesign.

Table 2.3: Barriers encountered by 13 respondents during usage and possible solutions

Type of surgical equipment	Barriers for/during usage	Possible solution / Suggestions for redesign
Drills	Reuse of drills between surgery	Sterilize only parts that need to be sterile
Electrosurgical unit handhelds	Designed for single use	Reusable electrodes
Electrosurgical unit Theatre lights	Electrodes breakdown	xx
Electrosurgical unit Theatre lights Staples	Expensive spare parts	Robust devices
Laparoscopic equipment	Limited available	Acquisition of refurbished models
Monitoring device during anaesthesia in rural settings	Lack of trained personnel Lack of manufactures High costs	Partner with private settings
Sterilizers	Limited available Power outages	Autonomous/ portable machines
Suction machine	Frequent break downs	Regular maintenance
Theatre tables	Cannot be altered in height	xx
Water filtration	Hard tap water that is used leaves saline, so machines that use tap water break down.	xx

XX not answered by the respondents

DISCUSSION

Our results show important deficiencies in the availability of basic surgical equipment across Africa. Equipment, such as defibrillators, infusion pumps, endoscopes and oxygen concentrators had limited availability in public district hospitals.

As expected, the results of our survey (Figure 2.1) showed that private and public referral hospitals had more surgical equipment available (88% and 81%, respectively) than public district hospitals (70%). Unfortunately, availability of surgical equipment was only described in literature for 84 public referral and private hospitals in Sierra Leone, Nigeria, Liberia, Ghana, Ivory Coast, Burkina Faso, Guinea, Niger, Senegal, Togo, and Uganda (9, 18, 19). The

results of this survey showed higher availability for endoscopes, ESUs, pulse oximeters and anaesthesia machines than previously published data, especially for private hospitals. Our survey showed that in public district hospitals (n=10), 30% had an endoscope, 60% had an ESU, 90% had an anaesthesia machine. No published data was found on availability of surgical equipment in public district hospitals to compare our survey data to. This indicates a clear need to identify availability of surgical equipment in public district hospitals in future studies.

Respondents in all three hospital categories assigned high costs and no repair as major reasons for limited availability of equipment (Figure 2.2). Additionally, all respondents indicated problems with failing surgical equipment in their hospital, mainly due to lack of maintenance and old and overused equipment. Lack of spare parts was not mentioned as a reason for limited availability by the respondents within this study, probably because surgeons might not be aware of the necessity of spare parts to maintain equipment. The majority of our respondents relied on maintenance within the healthcare facility. Maintenance in hospitals in LMICs relies heavily on the skills and knowledge of the BMETs, and the availability of tools and access to spare parts within the hospitals, in comparison to HICs where maintenance of equipment is often provided by the medical device company. Strategic investments in BMET training could have a significant impact in LMICs. Additionally, a complete toolkit, maintenance budget and access to technical expertise (for example via the internet) are required (20). For example, Bradley et al. (2015) estimated that the useful lifespan of oxygen concentrators in LMICs could reasonably exceed seven years when maintenance, with a low skill and knowledge level, and repairs (for less than 10\$) are in place (21).

The percentages of surgeries that were cancelled or delayed due to malfunctioning equipment was lower in private hospitals than in public hospitals, which might indicate that the quality of the equipment is higher and that the skills and knowledge of the BMETs is better in private hospitals. Future research is required to identify the differences in skills and availability of tools between BMETs in the different hospital categories (private, district or referral) and if they comply to the needs of the equipment required to perform essential surgical care. Additionally, more insight in the procurement process within the different hospital categories across Sub-Saharan Africa is required to design successful implementation strategies of surgical equipment.

One strategy to increase the availability of surgical equipment could be the design and implementation of equipment that is adapted to fit the context in LMICs. The context around surgical equipment in LMICs differs from HICs, mainly in terms of financial resources and access to maintenance, spare parts and consumables (7). The WHO issued a compendium of medical devices especially for LMICs to present an overview of devices that are likely to fit the context (22). Examples of context appropriate designs are the anaesthesia machines that have been brought to the market in LMICs by the companies such as Diamedica and Gradian health systems.

Our survey revealed that 64% of respondents agreed that there is a need for design that is adapted to fit the context in LMICs to increase availability of surgical equipment. Research has shown that equipment does not necessarily need to be simpler, but should be adapted to fit the context in LMICs (6-8). Since, high costs (Figure 2.1) and limited access to maintenance facilities (Figure 2.1 and reasons why equipment fails found within this study) were identified in this study as reasons for limited availability and failure of equipment, redesign should take these aspects into consideration. Suggestions given for redesign of surgical equipment presented in Table 2.3 show that ESUs could benefit from redesign in terms of reducing costs and by providing electrodes for multiple use. Adjustments to enhance functioning of devices during power outages were suggested for ESUs, theatre lights and sterilizers.

Future (re)design should consider that equipment is operated in environments with high temperatures, altitudes, local voltage outlets and humidity (23). Furthermore, manuals should be provided in the major local languages. By using generic parts that are easy to access in LMICs, BMETs can easily replace these parts. This would reduce the need for service contracts with medical device companies that are often based outside of LMICs.

This study has some limitations. Firstly, the survey data included 42 respondents representing 33 individual hospitals. This means that some hospitals were represented by multiple respondents. It is expected that this has influenced the results of the availability of equipment, especially in private hospitals since 10 individual hospitals were represented by 16 respondents. However, no differences in availability of equipment between overlapping respondents were found. Reasons for limited availability did differ between respondents that represented the same hospital. Secondly, it can be assumed that hospitals represented in this study had certain financial resources to let their employees attend the annual meeting of COSECSA in Kenya, which means that the hospitals represented in this study are not representative for all hospitals across Sub-Saharan Africa. This was a survey of surgical academic forum attendees, so the data of rural hospitals was under-represented. Thirdly, all respondents were surgeons who might not be aware of the reason why equipment cannot be repaired. Therefore, this study might underestimate the need for spare parts. The equipment that was found to be limited available, as well as reasons for limited availability and failure indicated in this study, show that there is a large need for future research regarding surgical equipment in LMICs. During our future research, different hospital categories in LMICs will be visited to include facilities that might not be covered in this study. Additionally, BMETs views on reasons to limited availability of surgical equipment and suggestions for (re)design will be researched too. Despite these limitations the gap between hospitals' needs to provide safe surgery and hospitals resources is highlighted by this study. The availability of surgical equipment is vital for hospitals' capacity to provide safe surgery but also vital to work on retaining of surgical and anaesthesia providers by increasing their work satisfaction since their quality of work relies on this equipment.

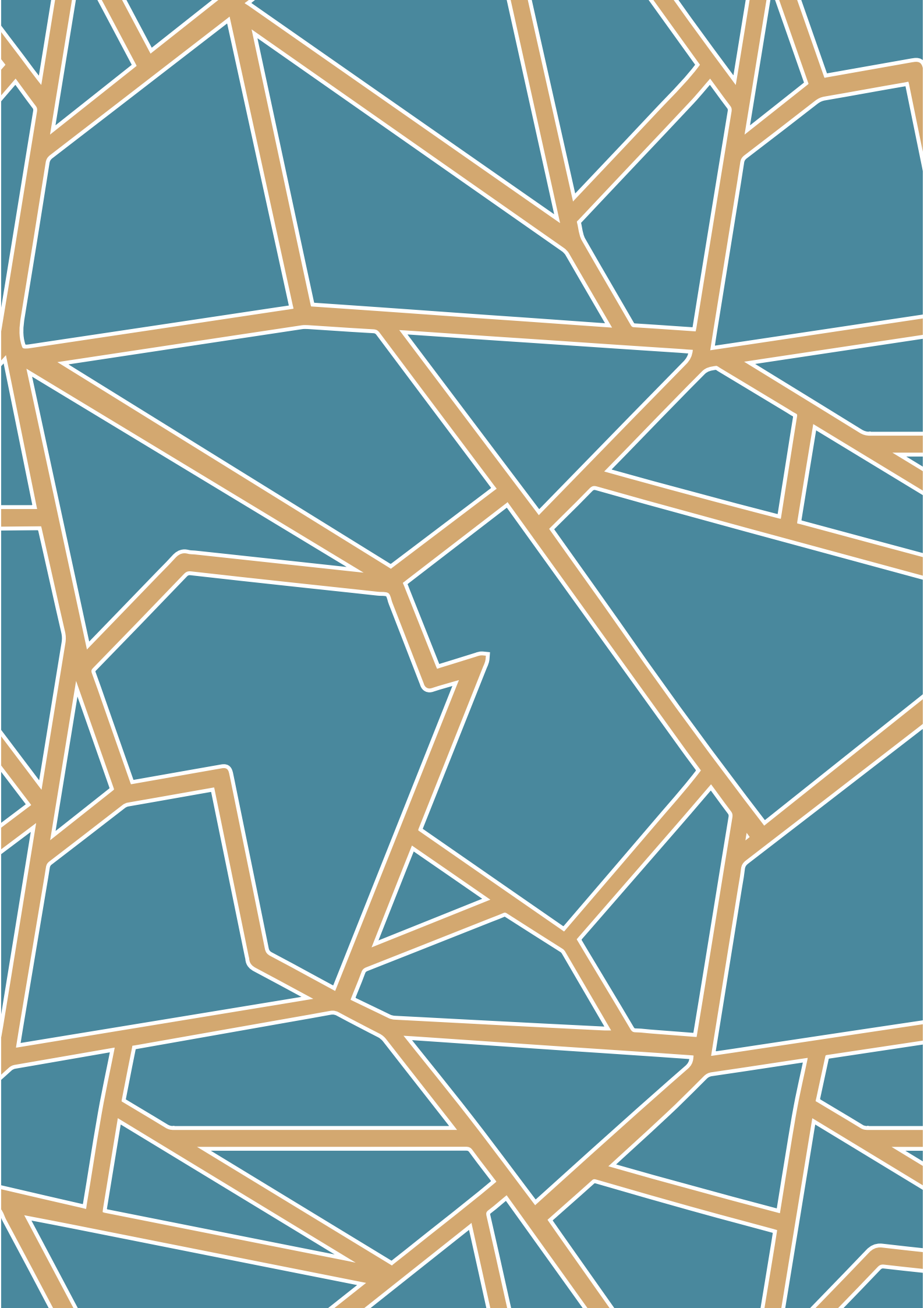
CONCLUSION

This study revealed deficiencies in the availability of basic surgical equipment in nine countries across Sub-Saharan Africa, mainly in public district hospitals. Redesign that is adapted to fit the context in LMICs could decrease the reasons for limited availability and failure of equipment identified within this study. Among other equipment the ESU, laparoscopic equipment, and theatre lights are identified as equipment eligible for redesign to increase availability in LMICs. To increase availability of surgical equipment and increase surgical capacity in LMICs collaboration between surgeons, surgical training programs, biomedical engineers, BMETs and companies is highly recommended.

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CHAPTER 3

Barriers to availability of surgical equipment in Kenya: a surgical equipment journey approach

Chapter 2 identified lack of maintenance, high costs and old and overused equipment as barriers to availability of surgical equipment, such as electrosurgical units, infusion pumps and oxygen concentrators in LMICs. To identify strategies to increase availability of surgical equipment in LMICs, it is important to understand the root causes of these barriers. This chapter analyses the lifespan of surgical equipment based on in-depth interviews with 17 biomedical equipment technicians (BMETs) working in 6 hospitals in Kenya. Three phases (procurement, use and maintenance, and disposal) in the equipment journey of surgical equipment are identified, and the barriers within each phase are described.

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ABSTRACT

The need for surgery is currently not met in Sub-Saharan Africa, requiring both extra workforce and surgical equipment. Currently, there is a gap in the availability of surgical equipment which, among others, limits the provision of safe surgery. To design strategies to increase availability, the use of surgical equipment in this context needs to be understood. This study aims to: 1) identify the different phases surgical equipment goes through during its lifespan (i.e. the surgical equipment journey) in Kenya, and to 2) identify barriers that are perceived by biomedical equipment technicians (BMETs).

Seven semi-structured in-depth interview sessions were conducted with a total of 17 BMETs working in Kenya. Participants worked in six different hospitals (four public, one private and one mission). Interviews were conducted between December 2016 and December 2018. Participants were asked to describe or draw the surgical equipment journey and describe the perceived barriers during this journey.

The surgical equipment journey consists of three phases: procurement, usage, and disposal. Stakeholders involved in the surgical equipment journey are users, BMETs, procurement officers, local distributors and in case of donations, donation agencies. Bureaucracy during procurement, difficulties to obtain consumables and spare parts (especially for donated equipment), cleaning with heavy chemicals, and usage in challenging environments were identified as barriers during the surgical equipment journey.

Sustainable interventions at multiple organizational levels are required to optimize the surgical equipment journey in hospitals in Kenya. Different strategies that can be applied in parallel to increase availability of surgical equipment in Kenya were identified by the participants in this study: policies on donations, procurement of durable equipment, more well-trained BMETs and university-trained biomedical engineers, and designs and business models that fit the local use in Kenya and presumably other countries in Sub-Saharan Africa.

INTRODUCTION

Surgery requires human resources, equipment, medicines, and an organized infrastructure. Several authors have already indicated gaps in the availability of surgical equipment in low- and middle-income countries (LMICs) such as Malawi, Sierra Leone, Nigeria, Cameroon, Somalia, and Ethiopia (1-6). The gap in availability of surgical equipment is a large contributor to the unmet need of surgical care in these countries (7). A large evidence-based study performed by Duke University estimated that for example up to 40% of equipment available in hospitals in LMICs is not usable (8). A report of the World Health Organization, 'Managing the mismatch', identified that consumables, spare parts, and other support systems are often limited in LMICs, resulting in equipment being unavailable (9). The local use is not always considered during donation of equipment. For example, Howie et al. (2008) described a case study in Gambia where the lifespan of donated oxygen concentrators did not exceed 30 minutes (where this could be 5-7 years in HICs) because of the wrong voltage and frequency to match the electricity network in Gambia, leading to overheating (10).

Limited access to maintenance, spare parts, and inappropriate donations have been documented before as barriers to functioning equipment in LMICs (10-13). However, to design successful strategies to increase availability of surgical equipment, the root causes of these problems need to be understood. Installation and maintenance of equipment are often provided by biomedical equipment technicians (BMETs), which makes their perspective on surgical equipment very valuable.

To understand the barriers to availability and functioning surgical equipment in LMICs, the situation in Kenya is used as a case study. This study aims firstly, to identify the surgical equipment journey (the different phases surgical equipment goes through during its lifespan), and secondly, to identify the barriers that are perceived by BMETs during the different phases.

METHOD

Semi-structured in-depth interview sessions were conducted during hospital visits in Kenya with BMETs. Interviews were conducted from December 2016 to December 2018. Participants selection was done by snowball sampling. Participants were instructed that equipment, such as electro surgical units (ESUs), monitors, operating theatre lights, sterilizers and anaesthesia machines were identified as surgical equipment in this study. All interviews were done in English.

Each session consisted of two parts in which participants were asked to describe:

- 1) the different phases surgical equipment goes through during its lifespan within their hospital and which stakeholders are involved in each phase,

- 2) how the following concepts relate to the surgical equipment journey within their hospital: the supply chain, procurement, sterilization/cleaning, donation, policies, disposal, design, maintenance, costs, mis-use, hidden costs, lack of infrastructure, spare parts, usage, management of equipment, training, and disposables.

This study was approved by the human research ethics committee of the Delft University of Technology and informed consent was obtained from all participants.

Table 3.1: Participants' characteristics during each interview session

Session number	Number of BMET during session	Type of hospital#	Gender	Education level*
1	1	Public hospital	Female	Higher level diploma
2	1	Mission hospital	Male	Diploma
3	1	Private hospital	Male	Diploma
4	1	Public hospital	Male	Diploma
5	3	Public hospital	All male	1x Diploma 1x Higher-level diploma 1x Certificate
6	7	Public hospital	1x female, 6x male	3 x Diploma 3 x Higher level diploma
7	3	Public hospital	All male	All diploma

Surgical care in Kenya is provided by public, mission (non-profit) and private hospitals. The public care system consists of four national hospitals (Level 6) that fall under the responsibility of the national government, the county (Level 5) and sub-county hospitals (Level 4) fall under responsibility of the 47 county governments (14).

*Certificate includes 1 year of training, diploma 3 years of training, and higher-level diploma 5 years of training at a technical college in Kenya

Data analysis

The interviews were recorded and transcribed. Data was analysed with MAXQDA 2018. The concepts discussed during the interviews were used for coding the transcripts.

RESULTS

In total, 17 BMETs participated from six different hospitals (Table 3.1). After seven sessions data saturation was reached. Session 4 and 6 were in the same hospital.

Equipment journey

Participants within this study identified three phases within the surgical equipment journey: procurement, use and maintenance, and disposal (Figure 3.1). Stakeholders that were identified in the equipment journey were: the user, the BMET, the procurement officer, local distributors of the medical device company, and in the case of donations, the donation agency. The user refers to the healthcare worker (nurse, surgeon, etc.) who operates

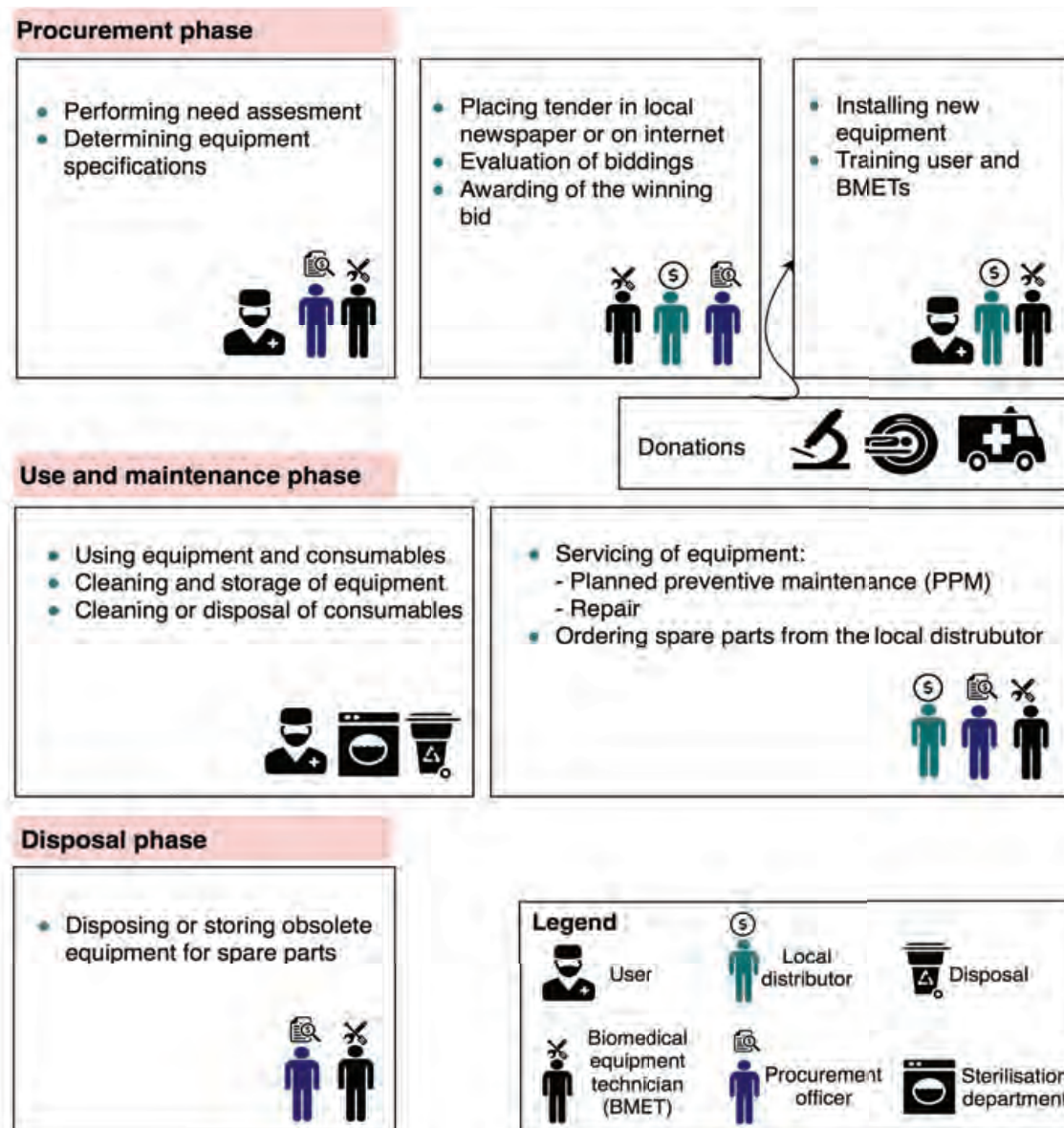


Figure 3.1: The surgical equipment journey according to BMETs in Kenyan hospitals.

- User: healthcare worker (e.g., nurse, surgeon) using the equipment
- Biomedical Equipment Technician (BMET): responsible for maintaining the equipment
- Procurement officer: responsible for procuring the equipment
- Local distributor: local agent of the medical device company

the equipment. BMETs are responsible for maintenance and the procurement officer is responsible for procurement. Donation of equipment to a hospital can be organized by either a foreign hospital, NGOs (e.g. AMREF), or a foreign government.

Procurement phase

All participants indicated the following procurement process: when a health care worker (a user in the equipment journey) requires new equipment, a need assessment is done by the user and the procurement officer. When the need is defined, the BMETs are consulted to define the equipment specifications. Thereafter, a tender request is placed in the local newspaper and on the hospital's website for local distributors or medical device companies to respond. All public hospitals are obliged to procure by tenders. The highest referral level

hospitals (Level 6) can organize their own tender process, all other public hospitals organize this process via the county government. Private and mission hospitals use tenders too, but they can also procure directly from the local distributor or the medical device company. The bureaucracy within the procurement phase, which makes it a very time-consuming process, was mentioned in all 7 interview sessions. The procurement committee comes together to analyse the bidders and will often award the lowest bidder that meets all the specifications.

'To get a new electrosurgical unit took up to 4 months. We have to make a request, set up specifications, this is taken to the supply department who puts it in the local newspaper. The bidders get 2 weeks to respond. After 2 weeks we sit down for an evaluation, after which we write a report to the CEO advising which company to award. Then the award letter is made and then we have to wait for the supplier. Then the problems at importing it into the country starts, delays often happen at customs.' Session 7

'It is often a challenge to know what the market value of equipment is. Sometimes we budgeted for 1000 dollars, but the good equipment is 2000 dollars, that is also why we end up with cheaper inappropriate equipment. The procurement law states that the lowest price that suits the specifications wins. European equipment is often too expensive to win.' Session 6

'We also check what the hospital's history with a company is. If the company did a good training and has good support they are rated higher during the tendering process.' Session 7

'Some equipment is really cheap, but when it breaks it is difficult to repair and then we have to buy new ones' Session 2

Although the system for procurement is in place, a lot of surgical equipment is often received by donations. Donations can either be organized via the county government or are directly sent to the receiving hospital. The private hospital visited during this study did not receive any donations, whereas one of the mission hospitals obtained equipment mostly by donation, often organized by the expat surgeons working in the hospital. The public hospitals' equipment was received by both donation and procurement.

Before the new equipment can be used and maintained (next phase), training is needed. The difficulty to receive appropriate usage and maintenance training by the medical device company was identified as a large barrier too, and was mentioned during 4 of the 7 interview sessions. One participant stated:

'We have received on-site training given by the medical device company. However, information is often quite limited. Often, we cannot open a machine to do troubleshooting because they come in with a new machine. We would recommend

that we can train on models that can be opened up and were we can trouble shoot to learn what to do in case of an error.’ Session 7

Use and Maintenance phase

Equipment is used by various healthcare workers (e.g., surgeons, nurses or medical officers) in the operating theatre (OT). Many types of surgical equipment require accessories to perform surgery; these can either be consumables (one-time use) or reusable parts. Accessories need to be cleaned and sterilized after usage, which is most often done by the sterilization department. However, participants within this study explained that some parts (for example, accessories of the electrosurgical unit) are cleaned in the OT complex with heavy chemicals (e.g. cidex). Equipment, such as, electrosurgical units and anaesthesia devices are often stored in the OT or in the corridors between the OTs. These devices are cleaned by the cleaning staff, often also with heavy chemicals.

Surgical equipment can either be out of service because of a breakdown or because of planned preventative maintenance (PPM). Repairs and PPMs are done by the BMET department within all hospitals in this study. Spare parts, tools, and manuals are required to keep equipment functioning. Spare parts can refer to power boards or displays that need to be replaced when they are broken, but also to filters that need replacement every other month. All hospitals reported their repair orders in hardcopy books, except for two hospitals (1 mission and 1 private) that additionally store a digital copy in a software program.

The difficulty to get spare parts in Kenya was mentioned during all seven interview sessions. The five hospitals that receive donations all have difficulties to obtain both consumables and spare parts required for the equipment.

‘The challenge with donated equipment comes when it breaks, the spare parts are often not available. For example, for the electrosurgical unit a different patient plate is available within the country than the ones that came with the device, so we have to find a way to work around this.’ Session 2

However, also for procured equipment, the supply chain of consumables and spare parts remains a challenge. This is either due to the long bureaucratic procurement process that needs to be followed for each new order, high costs of spare parts and consumables, or delays because parts have to come from outside Kenya or the African continent. Only a small portion of the equipment available in the hospitals is supported by a maintenance service contract, which means that maintenance, spare parts and consumables are provided by the medical device company.

‘If we have imported a machine from overseas, we also have to import the spare parts. Getting the spare parts becomes tricky and takes a lot of time.’ Session 3

One participant mentioned that they do not always get permission to order a spare part required for PPM, that has the potential to increase the lifespan of equipment.

‘Sometimes BMETs only get permission to fix when it the equipment is broken. When it is still functioning but needs to be serviced to keep functioning, this is not understood. At the moment it is obsolete, everyone starts looking for a spare part’. Session 1

Participants in two hospitals also mentioned the breakdown of equipment due to the challenging environment in which equipment is used. Modern sensitive equipment is often not designed to withstand power interruptions, unstable electricity networks, dust, and high temperatures. Additionally, participants working in two hospitals described how the use of heavy chemicals for cleaning shortens the lifespan of equipment too.

‘Power in Kenya is different, also temperatures, altitudes, pressure, and the users are trained differently than in Europe and Asia where equipment comes from’. Session 4

Disposal phase

When equipment is obsolete, it needs to be disposed either by the hospital or via the county government. All participants were involved in the disposal process, but approval often has to be obtained from the disposal committee or from the procurement department. This is a time-consuming procedure and often results in piles of unused equipment at hospitals grounds, as one of the participants from session 5 described:

‘You find we even get used machines and they are most of the time obsolete. Than we only have to worry about the disposal, and that means extra work for us.’ Session 5

DISCUSSION

Surgical equipment is not always available in LMICs, which results in delays of surgeries that are highly required to comply to populations’ need for surgery. Other studies have identified synergies in barriers to medical equipment between different LMICs (10-13). This study offers insights from front-line BMETs providing maintenance on a daily basis on why these barriers exist, by identifying the journey during the life span of surgical equipment. Participants worked in 6 different hospitals in Kenya. In other to ensure theoretical saturation 5 additional hospitals (1 private hospital, 3 public hospitals and 1 mission hospital) were visited.

The identified surgical equipment journey within this study revealed that equipment undergoes three different phases during its lifespan: procurement, use and maintenance, and disposal. Within the procurement phase, a difference between public and private hospitals was found that results in a different procurement route: public hospitals are obliged to procure via tenders, whereas mission and private hospitals can also buy directly from the medical device company. Procurement of equipment was identified as a timely process by all the participants. Besides the tender process being very time-consuming, it does not always result in the most appropriate type of equipment when the lowest bidder wins. Diaconu et al. (2017) identified that equipment costs are often leading in procurement planning in many LMICs, underestimating the true costs of maintenance, servicing and user

training (15). Public hospitals can only buy equipment from respondents to the tender, and those respondents need to provide equipment that fits the specifications of the tender. According to the participants in the public hospitals, this means they can often not buy from large international brands, because they do not respond to the tenders, or are out of scope because of the budgets that are set in the tender specifications. However, training opportunities and companies' track records on spare part delivery and support are becoming more and more important during the tender awarding process according to some of the participants in this study. Diaconu et al. (2017) also identified that careful consideration of the context of use results in the most successful uptake of medical technology in LMICs (15).

Procurement of appropriate equipment is the first step in a good functioning surgical equipment journey, secondly, the use phase should be properly organized. This starts with providing training for both the user and the BMETs (15). The participants in this study have experience with on-site training and overseas factory training at the medical device companies. Participants indicated that some of the on-site training is very short and superficial, especially when the training is done with functioning equipment without the possibility to open up or troubleshoot. By the time maintenance is required, the company has to be consulted for advice again, because it was not covered during the training. Maintenance is now often recorded offline in repair books, which is difficult to consult during procurement of new devices. Computer software for inventory, repair, and maintenance record could increase the amount of information about previous procured or donated equipment and their lifespan within the hospital, which can be helpful information during the procurement process (15).

Previous studies mentioned the lack of consumables and spare parts as a barrier to availability of surgical equipment in LMICs (11, 16). Our study confirmed these barriers within the surgical equipment journey. However, within this study, we also have researched the underlying process to these barriers. We identified that procurement of consumables and spare parts can be a timely and costly process. Firstly, spare parts can become very expensive when they have to be imported from overseas. Secondly, parts for donated equipment are often not manufactured anymore which leads to disposal of equipment. Lastly, participants indicated that they do not always get permission to order a spare part for PPMs because the equipment is still working. When the delivery of consumables is delayed this results in equipment that is out of use. This is one of the reasons why consumables are often reused. The costs of consumables are often paid by the patient, so reuse of these parts will reduce the costs of surgery for the patients.

Participants within this study indicated that although problems arise with donated equipment when maintenance or consumables are required, they still welcome donations because a lot of newer technology will otherwise stay out of their reach due to its high costs. Some medical device companies are starting to lease high-end equipment to hospitals in Kenya. These hospitals have a contract with the medical device company for the consumables and servicing of the equipment. Additionally, the Kenyan government

has recently equipped 98 public national and county hospitals with brand new equipment for intensive care units, diagnostic imaging and operating theatres. Within this program training and servicing is provided for at least seven years (17).

Kenya aims to increase the quality of their health care system, alongside the WHO and the global health community aim to increase access to safe surgery worldwide. Availability of medical equipment is vital for the realization of these goals. The possibility to lease high-end equipment and the implementation of high-end equipment by the Kenyan government are all attempts to increase the availability of equipment in Kenya. However, sustainable interventions at multiple organizational levels are required to optimize the surgical equipment journey in the future. A list of potential interventions to increase availability that were identified by participants is provided in Table 3.2.

This study only included BMETs working in Kenya and the quality of the healthcare system in Kenya (number 73 on the GDP list of the world bank) is expected to be higher than in other countries, such as Uganda or Mozambique (number 106 and number 132, respectively)

Table 3.2: Potential interventions to increase availability of surgical equipment as stated by the participant in this study.

Theme	Potential intervention
Donations	- Policies on donations
Procurement	- Procurement of durable equipment, including training, access to spare parts and consumables
Training	- More university-trained biomedical engineers, more on-site training for users and BMETs - Training by the medical device company on models that can be opened to trouble shoot
Equipment	- Demonstrations before equipment is procured - Robust designs and suitable for the context (able to withstand: eruptive power supply, dust, high temperatures, cleaning detergents etc.)
Medical device companies and manufacturing	- Medical device companies within the country/or continent. - Users and BMETs in contact with R&D departments to give feedback - Adapted strategies for LMICs based hospitals (placement of equipment or leasing equipment).

(18). Kenya has six colleges for BMET training and 2 university programs for biomedical engineers which equips BMET departments with well-trained BMETs. In contrast, other countries have no BMET departments within their hospitals or BMET training available in the country. They have to hire employees with a technical background, but without specific training on medical equipment. Barriers identified in this study could be even larger in these countries. Commonalities and best practices of both medical providers and BMETs

in other countries may therefore provide also other root causes to limited availability of surgical equipment in LMICs. Despite these limitations, we believe that this study can be used as a starting point to design strategies to increase availability of surgical equipment in the future either by academia, medical device companies or policy makers. It also highlights the importance of including local stakeholders' input in design and the development of plans for provision of surgical care.

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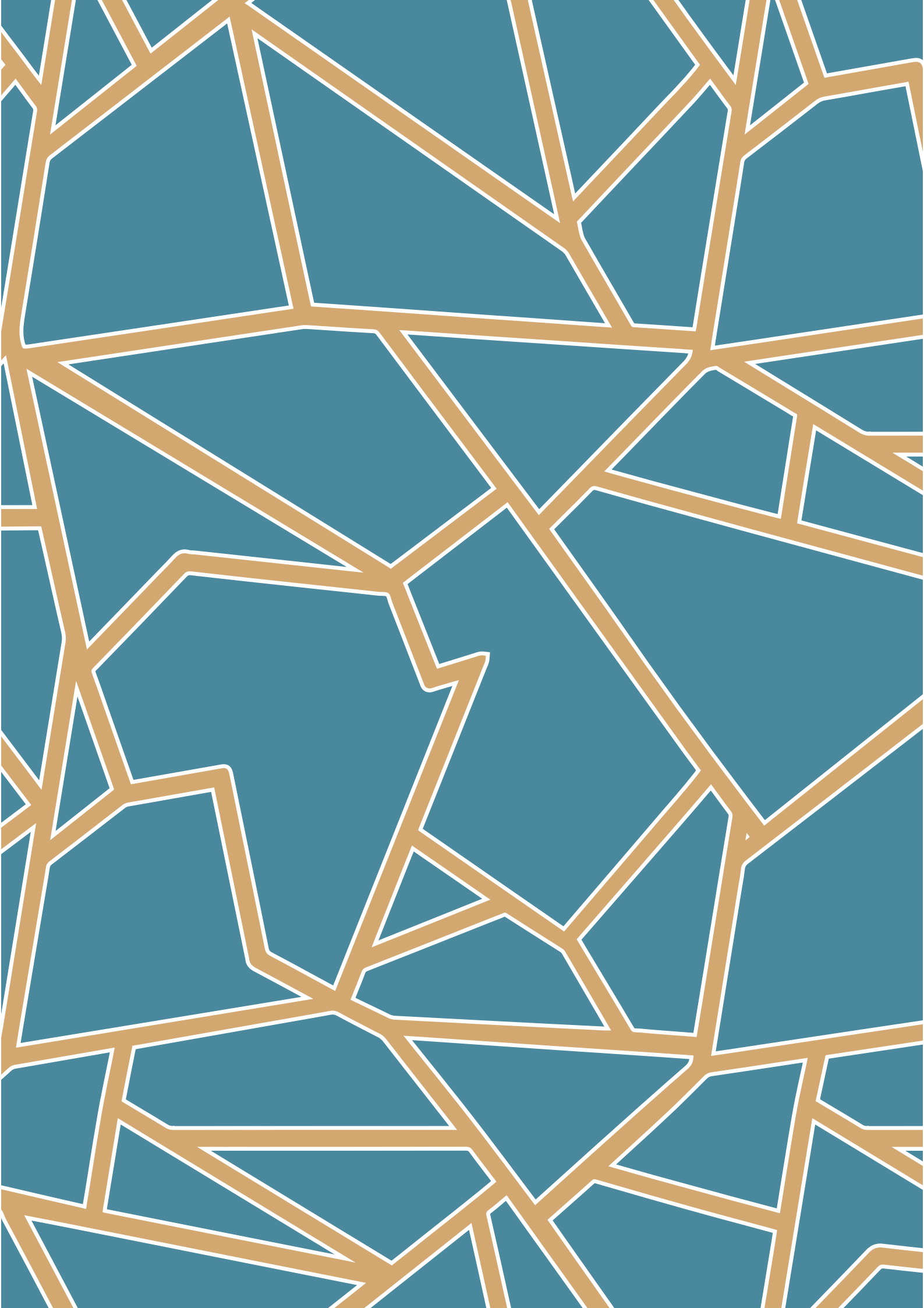
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CHAPTER 4

Towards global implementation of open and laparoscopic surgery: availability, procurement, training, use, complications and maintenance of electrosurgical units and laparoscopic equipment in 11 African countries

Chapter 2 and 3 showed that it is a complex process to ensure availability of surgical equipment in LMICs. Aspects influencing the context of use, such as procurement, training, use, complications and maintenance all influence availability. We therefore, studied availability but additionally these other 5 aspects influencing the context of use of two important types of surgical equipment: the electrosurgical unit (ESU) and laparoscopic equipment, in 11 countries in Sub-Saharan Africa. A total of 80 respondents, 59 surgeons and 21 BMETs, were surveyed. Additionally, maintenance records were analysed to identify what type of maintenance is provided.

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ABSTRACT

To develop strategies to increase availability of surgical equipment in the future, we investigated the current availability, procurement, training, usage, maintenance and complications in low- and middle-income countries (LMICs) of two important types of surgical equipment: the electrosurgical unit (ESU) and laparoscopic equipment.

A survey was conducted among surgeons that attended the annual meeting of the College Of Surgeons of East, Central and Southern Africa (COSECSA) in December 2017 and the annual meeting of the Surgical Society of Kenya (SSK) in March 2018. Additionally, Biomedical Equipment Technicians (BMETs) were surveyed and maintenance records were collected in Kenya between February and March 2018.

Eighty respondents participated: 59 surgeons from 11 different African countries and 21 BMETs working in Kenya. Additionally, 36 maintenance records were collected. ESUs were found to be available for all COSECSA and SSK surgeons who participated. Only half of the surgeons (49%) had access to working laparoscopic equipment. Our findings highlight the reuse of disposable ESU accessories and difficulties to receive CO₂. Seventy-eight percent of the participating surgeons indicated that maintenance on the ESU was available, and 59% indicated that maintenance was available for the laparoscopic equipment in the hospital they represented.

Despite the availability of surgical equipment, reducing gaps in availability of training and access to maintenance together with the implementation of equipment that fits current use in LMICs are important steps in reaching global implementation of open and laparoscopic surgery.

INTRODUCTION

There is an increased need for surgery in low- and middle-income countries (LMIC). An estimated five billion people in LMICs do not have access to safe and affordable surgery. In the future, the need for surgical care will only increase due to higher incidence of cancer, traffic injuries and cardiovascular disease (1, 2). In high-income countries (HICs), laparoscopic surgery has become the standard treatment modality for many surgical conditions. Advantages of laparoscopic surgery compared to open surgery, that are especially beneficial for LMICs, are decreased risks for infection and blood loss, and rapid return to work (3). Additionally, in LMICs diagnostic laparoscopy could effectively replace expensive modern diagnostic devices (such as, MRI and CT) (4). However, there are still major clinical, economic and infrastructural barriers to widespread implementation of laparoscopic surgery in LMICs. These barriers includes e.g., limited access to trained laparoscopic surgeons, high costs of laparoscopic equipment, the need for general anesthesia, and limited resources to handle maintenance issues (3). Despite these barriers, successful implementation of laparoscopic surgery has shown significantly improved outcomes (e.g. limited overall complications) for surgical patients in LMICs (5).

Surgical equipment is vital for provision of safe surgical care; health care workers have to rely on uninterrupted availability and reliable quality of surgical equipment. However, shortages of surgical equipment were found by previous studies in Nigeria, Cameroon, Sierra Leone, Somalia, Ethiopia and Malawi (6-13). To ensure that surgical equipment is available, a system supporting the equipment should be in place: the right equipment should be procured, equipment should be used and maintained as intended, users and technicians need to be trained, and supply chain of consumables needs to be in place.

Reaching global implementation of open and laparoscopic surgery will require implementation of new, or upscaling existing, surgical programs in LMICs. Careful considerations on how to increase availability of surgical equipment in this process is required: firstly, availability of equipment can only be ensured when systems supporting surgical equipment (such as: training and maintenance) are in place (14, 15). Secondly, actors such as academia, medical device companies, biomedical engineers and non-governmental organisations should ensure that equipment that fits the context in LMICs is commercially available on the market (1, 16). Sarvestani et al. 2018 indicated that less than 15% of the commercially available medical devices designed for global health were targeting noncommunicable diseases (cardiovascular diseases, cancer and diabetes), and even less were surgical devices (17). Awareness on the need for high-quality medical equipment that fits the context of use in LMICs is rising, and is acknowledged by the Lancet commission on Global surgery and the World Health Organization (WHO) (1, 18). The need for development of electrosurgery for LMICs was for example highlighted in several publications (13, 19). In addition, several designs of laparoscopic equipment have been recently published that make use of mobile technology to decrease cost and reduce the number of devices required for laparoscopic surgery (20-22).

Difficulties with and barriers to availability of equipment have been described before (19, 23-26). We identified for example the equipment journey (meaning: the different phases surgical equipment goes through during its lifespan) and the barriers that are encountered with surgical equipment in Kenya in a previous study (26). This previous study revealed that barriers exist in the procurement, use and maintenance and disposal phase and that it is a complex process to ensure availability of surgical equipment. Aspects such as procurement, training, usage, complications and maintenance all influence availability. The combination of these different aspects supporting availability and differences between types of surgical equipment are not described in literature before. The aim of this study was therefore to explore the current availability, procurement, training, usage, maintenance and complications encountered during use of two frequently used types of equipment, the electrosurgical unit (ESU) and laparoscopic equipment, in hospitals in Africa. Gaining more information on these devices is an important step when determining what is required to increase availability in the future of these and other types of surgical equipment. We included both surgeons' and BMETs' perspectives in this study, since both have valuable insights.

METHOD

Attendees of the annual meeting of the College Of Surgeons of East, Central and Southern Africa (COSECSA) in Maputo, Mozambique in December 2017 and the annual meeting of the Surgical Society of Kenya (SSK) in Mombasa, Kenya in March 2018 were asked to be surveyed. Data on availability, procurement, training, usage, maintenance and complications encountered during use of the ESU and laparoscopic equipment were collected. Respondents were only asked to fill in the questions if they had access to the equipment in the main hospital they work for.

Visits to hospitals in Kenya were conducted to survey BMETs between February and April 2018. Data on training and maintenance of the ESU and laparoscopic equipment were collected.

Informed consent was obtained from all respondents. No personal details of the respondents were recorded (therefore approval by an institutional review board was not required). Furthermore, all data were anonymously processed and archived to ensure privacy of the respondents.

All respondents were instructed that 'laparoscopic equipment' included the laparoscope, light source and insufflators. 'The ESU' included the ESU generator and the accessories (the patient plate, a monopolar electrode, a bipolar handheld or foot pedal) that are required to use the ESU. The ESU is also frequently used during laparoscopic surgery in addition to laparoscopic equipment.

In addition to the surveys, we collected maintenance records on the repair of the ESU and laparoscopic equipment to detail what type of maintenance is required and what maintenance issues BMETs are able to repair. Maintenance records report the date, type of device, cause of failure and what repair was required. Maintenance records of the time

period of October 2015 and January 2018 were collected in three hospitals in Kenya. Each original maintenance record was photocopied and stratified to type of surgical equipment and analyzed to indicate if the BMETs were able to solve the maintenance issue.

RESULTS

A total of 80 respondents were surveyed, 59 surgeons and 21 BMETs (Figure 4.1). Thirty-one surgeons represented hospitals in Burundi (1), Ethiopia (1), Kenya (6), Malawi (3), Mozambique (3), Namibia (3), Rwanda (3), Tanzania (3), Uganda (1), Zambia (4), Zimbabwe (1), Swaziland (1) and 1 unknown. Twenty-eight surgeons who attended SSK 2018, represented hospitals in Kenya.

During the field visits conducted in Kenya, 21 BMETs were surveyed, and additionally, 36 maintenance records on the ESU were collected.

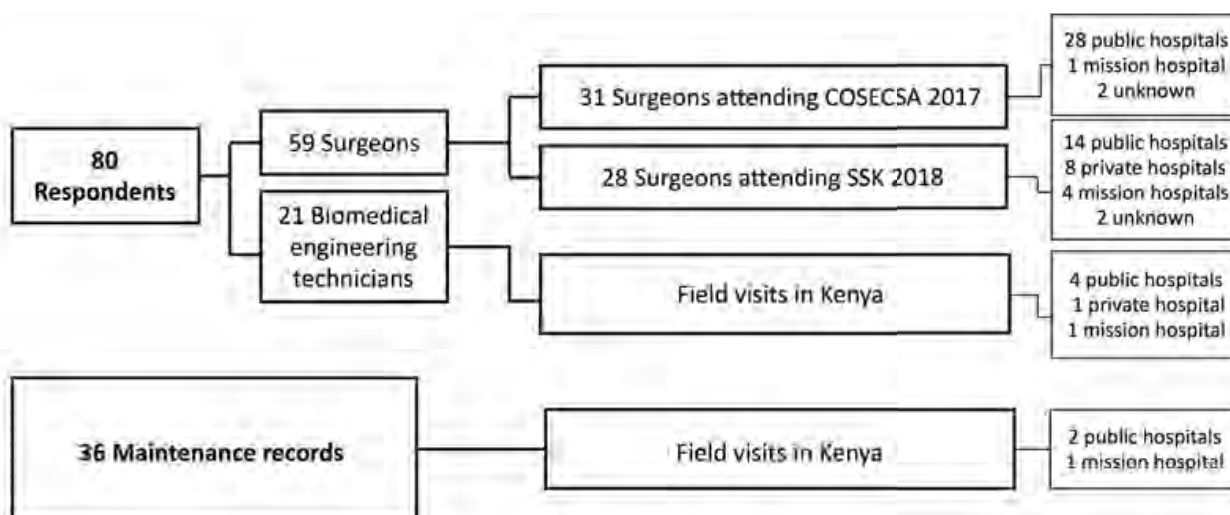


Figure 4.1: Overview of the respondents (surgeons and biomedical equipment technicians (BMETs) and the 36 maintenance records.

Use of the ESU according to the surgeons

Table 4.1 presents an overview of the current availability, procurement, training, usage, maintenance and complications of ESUs according to the 59 surgeons. ESUs were widely available; 100% had access to an ESU that were all used and 44% were trained in electrosurgery during medical school. Fourteen surgeons (24%) indicated that disposable accessories are cleaned in heavy chemicals (such as CIDEX or glutaraldehyde) and were reused.

Table 4.2 provides an overview of how electrosurgical equipment is procured in relation to reuse of accessories, access to in-house maintenance, and complications. It shows that relatively more complications were encountered and more disposable accessories were reused when having donated ESUs compared to purchased ESUs. One surgeon that had purchased equipment indicated there is no access to in-house maintenance, but that maintenance is provided by an external party such as the medical device company.

Table 4.1: Availability, procurement, training, usage, maintenance and complications of the electrosurgical unit (ESU) according to 59 surgeons.

Category		Percentages (%)	Number
Availability	Access to an ESU	100	59
Procurement	Purchased	46	27
	Donated	14	8
	Both purchased and donated	37	22
	Unknown	2	2
Training	Trained during medical school	45	26*
	Trained by medical device company	14	8
Usage	Used ESU in bipolar and monopolar mode	68	39**
	Used ESU in monopolar mode only	26	15**
	Used ESU in bipolar mode only	5	3**
	Used coagulation	100	59
	Used cut	97	57
	Used fulgurate	11	7
	Used blend	27	16
	Reused disposable accessories	24	14
Maintenance	Available	78	46*
	+Performed by BMETs	36	21
	+Outsourced (service contract, donation agency, partners abroad etc.)	8	5
Complications	Encountered complications during use	59	29
	+Burns	27	16
	+Electrical shocks	12	7

Answered by *58, **57 of the 59 respondents, respectively.

*These categories were not specified by all respondents that answered the question.

Table 4.2: Overview of how electrosurgical units were procured within the hospitals in relation to the reuse of disposable accessories, access to inhouse-maintenance and complications.

Category	Reuse of disposable accessories (n=14)	No access to inhouse-maintenance (n=11)	Complications (n=29)
Purchased (n=27)	5	8	10
Donated (n=8)	3	2	7
Both donated and purchased (n=22)	6	1	11
Unknown (n=2)	x	x	1

Maintenance of the ESU performed by BMETs

All 21 BMET participants had access to an ESU and performed maintenance on these ESUs. Almost half of the BMETs (48%, n=10) were trained during medical school and 29% of BMETs (n=6) were trained by the medical device company on maintenance of the ESU.

Out of the 36 collected maintenance records, 23 described repairs on the accessories of the ESU (Table 4.3). All 23 issues with accessories were successfully repaired. Nine (out of 13) issues on the ESU generator were successfully repaired. In four situations ESU generators were sent back to the manufacturer for further inspection. These devices were for example not able to regulate the voltage level of cutting and coagulation. In addition, all 21 BMETs that were surveyed indicated that accessories (cables, connectors, patient plate and electrodes) were prone to breaking and required maintenance frequently. Moreover, 57% of BMETs (n=12) mentioned that power modules are prone to breakage.

Table 4.3: Maintenance records (n=36) for the electrosurgical unit in three hospitals in Kenya.

Part	Total	Repaired	Excerpt
Patient plate	14	14	Replacement of the plate (n=12) Soldering parts together (n=2)
Monopolar electrode	6	6	Replacement (n=1) Soldering new cables or other components (n=5)
Foot pedal	3	3	Replacement of the entire pedal (n=1) Replacement of a faulty part (n=2)
Generator	13	9	Replaced the display board (n=1) Fitted a new input filter (n=3) Replaced a faulty part by taking a spare from an old machine (n=1) Other repairs (n=4) <i>Unsolved repairs were outsourced to the medical device company</i>

Use of laparoscopic equipment according to the surgeons

Table 4.4 presents an overview of the current availability, procurement, training, usage, maintenance and complications of laparoscopic equipment according to the 29 surgeons, that had access to laparoscopic equipment. This is almost half (49%) of the 59 surgeons that participated in this study. Complications during use were indicated by 52% of the respondents and included: fogging of the camera head, air leaks, inappropriate focus and instrument pairing, poor resolution and conversion to open surgery because of limited experience. Besides, 32% (n=9) of surgeons indicated that they had difficulties obtaining CO₂.

Table 4.4: Availability, procurement, training, usage, maintenance and complications of laparoscopic equipment according to the 29 surgeons who had access to laparoscopic equipment.

Category		Percentages (%)	Number
Availability	Access to laparoscopic equipment	49	29 (n=59)
Procurement	Purchased	38	11
	Donated	28	8
	Leased	3	1
	Both purchased and donated	24	7
	Unknown	7	2
Training	Trained during medical school	45	13
	Trained by medical device company	46	13*
Maintenance	Available	59	16**
	+Performed by BMETs	17	5
	+Performed by service contracts	17	5
Complications	Encountered complications during use	52	13***
	Encountered difficulties obtaining CO ₂	32	9*

*Answered by *28, ** 27 and *** 25 of the 59 respondents, respectively.

+ These categories were not specified by all respondents that answered the question

Table 4.5 provides an overview of how laparoscopic equipment is procured in relation to access to in-house maintenance, complications and difficulties obtaining CO₂. It shows that participants that have access to donated laparoscopic equipment have less access to inhouse-maintenance and more difficulties obtaining CO₂ than participants with procured laparoscopic equipment.

Table 4.5: Overview of procurement of laparoscopic equipment in relation to access to inhouse-maintenance, complications and difficulties obtaining CO₂.

Category	No access to inhouse-maintenance (n=11)	Complications (n=16)	Difficulties obtaining CO ₂ (n=10)
Purchased (n=11)	3	6	2
Donated (n=8)	5	4	3
Both donated and purchased (n=7)	3	3	4
Leased (n=1)	1	1	1
Unknown (n=2)	x	1	x

Maintenance of laparoscopic equipment performed by BMETs

Most BMETs (76%, n=16) had access to laparoscopic equipment and 48% of BMETs (n=10) indicated that they can maintain laparoscopic equipment. Eight BMETs (38%) were trained by the medical device company on maintenance of laparoscopic equipment. Out of the 16 BMETs that had access to laparoscopic equipment, most BMETs indicated that the light source and camera are most prone to breaking (56% (n=9) and 50% (n=8), respectively), followed by the insufflator (25%, n=4), ESU accessories (25%, n=4) and the CO2 seal (6%, n=1).

We were not able to analyze maintenance records of laparoscopic equipment because they were either not available due to the availability of service contracts or due to unavailability of laparoscopic equipment in the hospitals we visited.

DISCUSSION

By exploring the current availability, procurement, training, usage, maintenance and complications of the ESU and laparoscopic equipment, we detailed the current situation in clinical practice in various LMICs settings to identify gaps. This study revealed that despite their availability (which was larger for ESUs than for laparoscopic equipment), access to maintenance, training and consumables are not always in place.

ESUs were for example available for all surgeons and BMETs that participated in this study. However, complications during electrosurgery, such as burns and shocks, were indicated by respectively 27% and 12% of the surgeons. Burns can occur due to improper attachment of the patient plate (27), which can easily happen when disposable patient plate stickers are reused. Furthermore, electrical shocks can occur due to insulation failure of the electrodes, which for example can be caused by deteriorating of the material of the electrodes due to the heavy chemicals used during the cleaning process. Reuse of consumables in various LMICs settings have been reported before (1, 19, 28), our findings highlight the reuse of disposable ESU accessories that are cleaned in heavy chemicals. In addition, most maintenance records reported repair on the ESU accessories, parts were for example soldered back together to use them as long as possible.

Almost 80% of the responding surgeons had access to maintenance and 100% of the BMETs performed maintenance on the ESU. The analysed maintenance records for the ESU revealed that maintenance often demanded small repair work on ESU accessories, but also included larger issues, such as the replacement of a display board. These repairs were all done successfully by the BMETs. This study showed that the repairs done by BMETs are a valuable asset in keeping the ESUs available in clinical practice by solving small repair issues. However, large repairs on the ESU generator were outsourced to the medical device supplier, donation agencies or other partners abroad. It is unknown if this is due to lack of skills, tools or because of the design of the ESUs that limits the performance of inhouse-maintenance.

Laparoscopic equipment was available for almost half of the surgeons and three quarter of the BMETs that participated in this study. Our findings highlight complications during usage, for example: fogging of the camera, and difficulties to receive CO₂. Gasless laparoscopic procedures have been proposed as an alternative to the use of CO₂ (29). In addition, BMETs indicated that both the camera and the light source are prone to breaking. Maintenance was available for 60% of the 29 responding surgeons that had access to laparoscopic equipment and 50% of the BMETs provided maintenance on laparoscopic equipment. It was indicated by three of the surgeons that did not have access to maintenance that this was due to lack of trained BMETs within the hospital they represent.

Careful considerations of procurement, training, usage, maintenance and complications are required to increase availability of surgical equipment in the future, and this study highlights that not all of these aspects are currently 100% covered in the hospitals represented in this study. This results in the precarious situation in which equipment is available, but this availability is difficult to sustain on the long term, for example, when a new set of consumables or repair is required.

Within this paper we aimed to create awareness on what aspects influence availability of surgical equipment and should therefore be considered during the implementation of surgical equipment. When equipment is implemented in a specific setting, firstly, the financial resources of hospitals should be considered, half of the available equipment in this study was purchased. This study showed that hospitals still rely on donations, which could be due to high purchasing costs of equipment that were identified before as a barrier to implementation of laparoscopic equipment in LMICs (3). Difficulties with donations have been described before, for example when equipment remains unavailable because the total cost of ownership (e.g. cost for consumables or maintenance) is not considered during the donation process (30). These difficulties were also indicated by the participating surgeons in this study. Therefore, a next step is to develop strategies so that before equipment is donated, it is ascertained that that equipment can be maintained and that the hospital has access to accessories. These strategies are as important as the donated equipment itself. Secondly, this study revealed the reuse of ESU accessories and difficulties to obtain CO₂ in hospitals represented in this study, showing that the supply chain of consumables introduces a barrier to availability. The need for consumables asks for the establishment of a well-functioning supply chain and enough financial resources to sustain this. Procurement of reusable ESU accessories and using local available non-medical gasses via local soft drink manufacturers (31) or implementation of gasless laparoscopy (29), are ways to tackle these barriers. Thirdly, our data showed that 40% of the surgeons that had laparoscopic equipment, did not have access to maintenance, which can be a barrier to ensuring equipment's availability (14). In-house maintenance is of great value to ensure availability of equipment, strategic investments in BMET training during implementation of technology is therefore beneficial to increase availability of equipment (14). Besides investments in in-house maintenance done by BMETs, we highly encourage a strong communication link between the hospital and the medical device company, since, their help is required for complex specialised cases, as shown in this study by analysing the

maintenance records of the ESU.

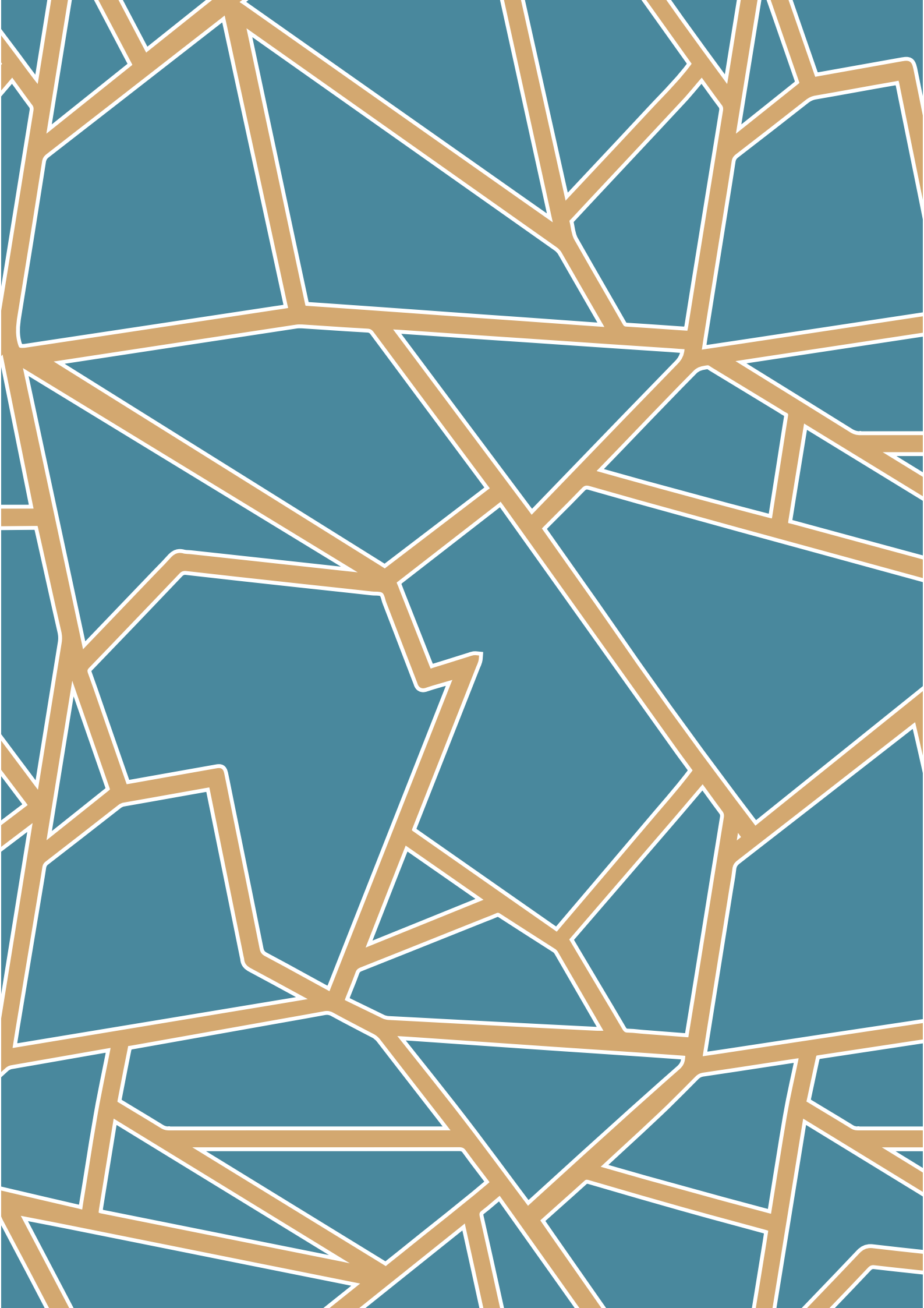
Besides awareness for the need for training and access to maintenance when implementing surgical equipment, equipment that fits the local infrastructure, available financial resources and skills and tools of both surgeons and BMETs should become commercially available on the market. Implementation of surgical equipment in LMICs presents different challenges than encountered in HICs, including; irregular power supplies, dust, high temperatures and medical device companies being outside the country (1, 2, 14, 19, 32, 33). Our data revealed for example, that not all surgeons and BMETs are trained to handle ESUs or laparoscopic equipment, which should be considered during the design of the interface and manuals. The fact that disposable accessories are reused and parts are prone to breaking could be helpful input during the design of robust and reliable equipment for this context. We hope this study encourages and provides fundamentals for future designs of surgical equipment for LMICs, to increase the number of surgical equipment that is fit-for-use in LMICs. In addition, we hope to encourage multi-disciplinary partnerships between surgical associations (such as COSECSA), medical device companies, academia, hospitals, BMETs and healthcare workers to ensure that all aspects influencing availability of surgical equipment are considered during implementation.

This study has some limitations. The majority of the participants (34 of 59 participating surgeons and the 21 BMETs) worked in Kenya, which is a country with more financial resources than countries, such as Mozambique, Zimbabwe, Ethiopia and other countries that are underrepresented in this study. Additionally, all surgeons that participated attended a scientific conference which might have led to under representatives of rural hospitals that did not have the financial resources to let their employees attend these events. Future studies should include data from these missing categories of hospitals where surgery is performed (whether this is done by qualified surgeons or not) with data that is for example collected by side visits. The lack of rural hospitals and hospitals from countries with less financial resources influenced the availability of ESUs and laparoscopic equipment found in this study, which is expected to be less in these facilities. The BMETs that participated in the survey and the hospitals from which the maintenance records were collected represented large urban hospitals in Kenya. The available skills and tools for maintenance might not be a representative for more rural facilities in Kenya and hospitals in other LMICs. Additionally, only 36 maintenance records in a time span of 3 years were collected on the ESU in three large hospitals, which is most likely to be an underestimate of the number of maintenance issues with this device. We expect, that not all small maintenance issues involving ESU accessories are always reported. Also, maintenance records are currently collected in hard copy, which are difficult to analyse and results in a loss of valuable information on equipment. Digital copy maintenance reporting systems for BMET departments could increase access to maintenance data. Despite these limitations, data on two types of surgical equipment in clinical practice in LMICs were presented, indicating that ESUs are widely available, however, to increase availability of laparoscopic equipment strategic investments in the future are required.

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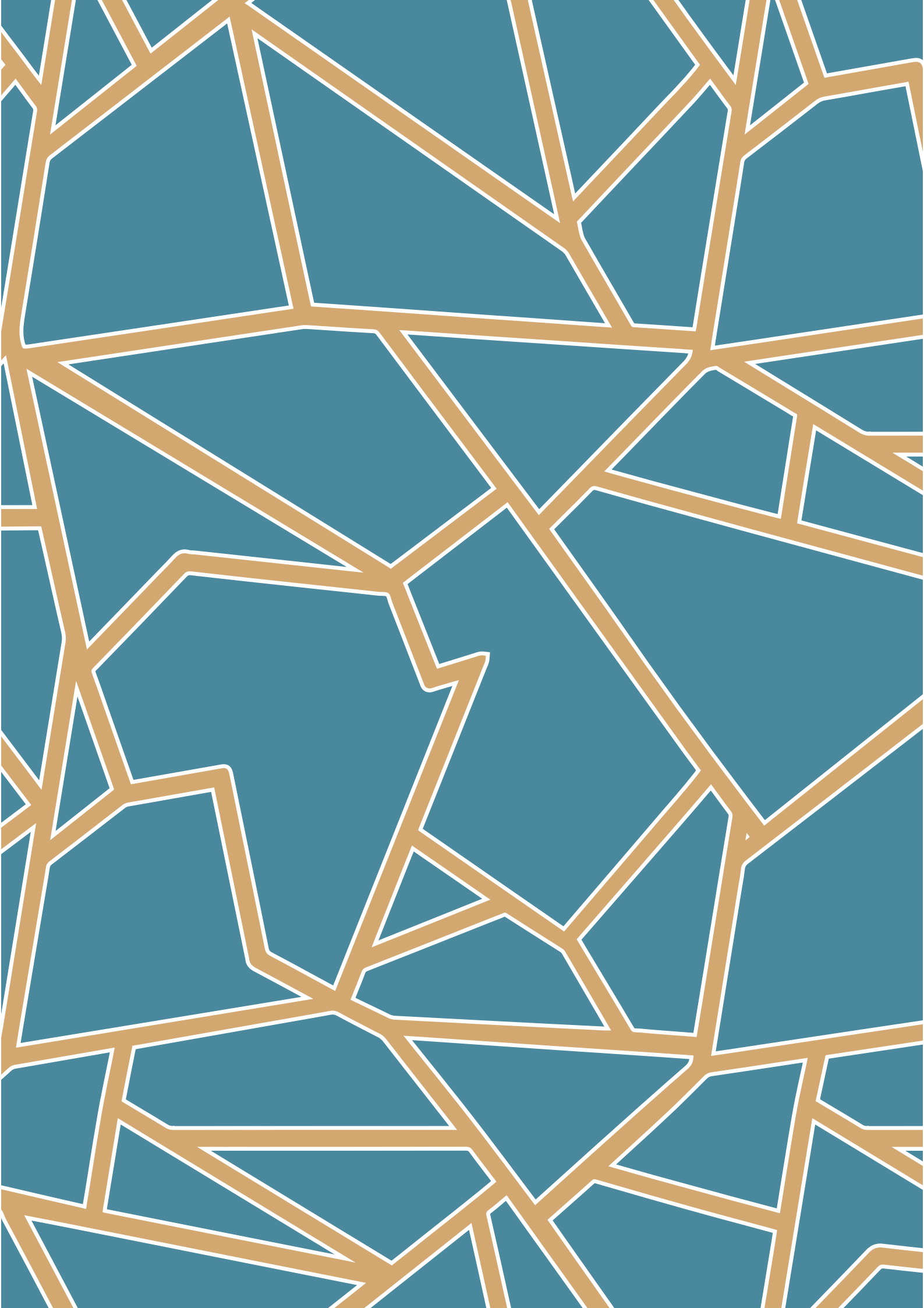
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PART 2

**Context-specific designs to
increase availability of surgical
equipment in hospitals in
Sub-Saharan Africa**



CHAPTER 5

Context-driven design approach for surgical equipment to increase global availability of surgical equipment

Barriers to availability of surgical equipment exists, as described in Part 1. These have several root causes, including differences in the infrastructure (such as eruptive power supply, dust, high temperatures and difficult roads), difficulties in the supply chain of spare parts and consumables, and limited access to financial resources (Chapter 3). These are all factors that should be considered during the design process of context-specific surgical equipment for use in LMICs. This chapter presents a context-driven design approach for designers to understand which contextual factors should be identified, after which they can be translated into context-specific design requirements and built into prototypes.

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ABSTRACT

Safe and affordable surgery is not accessible for five billion people when they need it. Multiple surgical capacity studies have shown that hospitals in low-and-middle income countries do not have complete coverage of basic surgical equipment such as, theatre lights, anaesthesia machines and electro surgical units.

Currently, almost all equipment is designed and manufactured with a main focus on the context in high income countries. The context in low-and-middle income countries in which surgical equipment is used, differs from high income countries, especially in terms of financial resources and access to maintenance, spare parts and consumables.

The aim of this study is to present a context-driven design approach for surgical equipment to increase global availability of surgical equipment. The context-driven design approach consists of four phases: before the start of a design project a clear need for certain surgical equipment should be identified (Phase 0). During Phase 1 the context should be researched thoroughly by determining the barriers encountered by patients to surgical care, the structure of the health care system and if the aspects required for safe surgery are in place. In Phase 2 the context-driven design requirements should be determined and in phase 3 prototyping starts in close interaction with local end-users.

We believe that designers should strive for design that is of the same quality and complies with the same safety regulations as equipment designed for HICs. In this way user and patient safety can be assured in any setting worldwide. And we advocate for surgical equipment that fits the context optimally and that will be applicable in comparable settings globally.

INTRODUCTION

Five billion people do not have access to safe, affordable surgical care when they need it. Due to the absence in surgical care, patients die of easily treatable conditions including appendicitis, hernia, fractures, obstructed labour, breast and cervical cancer (1). Additionally, surgery can play a role in diagnosis of various diseases (2).

Multiple surgical capacity studies have shown that hospitals in low- and middle-income countries (LMICs) do not have a full coverage of basic surgical equipment such as, theatre lights, anaesthesia machines and electro surgical units (ESUs) (3-10). Additionally, Perry & Malkin et al. (2011) estimated that 40% of the equipment that is available in hospitals in LMICs is not working (11). The health impact of the limited availability of surgical equipment in LMICs is unknown, but is expected to result in delayed surgeries and complications for patients.

Currently, almost all surgical equipment is designed and manufactured with a main focus on the context in High Income Countries (HICs). The context in which surgical equipment is used in LMICs differs from HICs, especially in terms of financial resources and access to maintenance, spare parts and consumables (12). Neighbour & Eltringham et al.(2010) state that equipment in LMICs not only needs to operate safely, it also needs to do so in more challenging conditions (high temperatures, dust, interrupted electrical supplies and limited consumables) than in HICs (13). Equipment for global surgery should not necessarily be simpler than other surgical equipment, and no compromises on safety and basic functionalities of equipment should be made (14).

Howitt et al. (2012) describe that although implementation of technology can improve global health, technology alone is not enough; it should be combined with innovation in processes (15). For example, surgical equipment requires besides an optimal design a working system of appropriate training, supply of consumables and financial resources. Design of surgical equipment that uses the input of local end-users and considers the local context has the opportunity to increase access to surgical equipment globally. A design team based in India designed a portable Electro Cardio Gram (ECG) system for General Electric for the Indian market at 20% of the price of high-end models, using the same analysis software but featuring a more compact design. The portable ECG system is nowadays widely used by physicians in Germany (15). This example shows that high quality and robust surgical equipment designed for a LMIC setting has the potential to gain health benefits globally and can also help mitigate health care costs in HICs.

When introducing surgical equipment globally, careful consideration should be given to both the required technology and the implementation in the clinical context, to enable effective usage. The aim of this paper is, therefore, to provide biomedical engineers and medical device companies with a detailed overview of different aspects to consider during the design process of surgical equipment for worldwide use. In which we strive for high quality equipment that has a potential to be used in HICs as well.

METHOD

During several brainstorm sessions with a total of 15 different industrial designers, health care professionals, biomedical engineers and people working for Non-Governmental Organizations (NGOs) a context-driven design approach was developed indicating different phases and aspects that should be considered when designing surgical equipment for worldwide use.

To support the context-driven design approach a literature search was done in PubMed and Google scholar using the keywords: 'medical or surgical equipment', 'surgery', 'biomedical engineering/clinical engineering' and 'low-and-middle income countries or low resource settings or developing countries'.

FINDINGS

The context-driven design approach consists of four phases. Before the start of a design project, a clear need for certain surgical equipment should be identified (Phase 0). Medical needs identified by scientific research, NGOs or local end-user could all act as a starting point for a design project (16). Additionally, a guideline on how to identify gaps in medical devices globally was given in the document 'Managing the Mismatch' issued by the WHO (16, 17). When a need is identified and a design team is formed, three phases should be completed when designing surgical equipment for worldwide use:

- Phase 1: Understanding the context (Figure 5.1),
- Phase 2: Determining design requirements, and
- Phase 3. Act.

Functioning surgical equipment requires a good understanding of the context. Therefore, Phase 1 is required as input to determine equipment requirements that will fit the context during Phase 2. Within Phase 3 a design will be made and prototypes will be built. This is an iterative process in which contact with the local end-users is highly recommended (18).

Phase 1: understand the context of global surgery

Mapping the context of global surgery can be conducted in various ways. Examples are using the Capability Driven Design method developed by A. Mink (19) or qualitative research methods like surveys, semi-structured interviews and site visits. Surgical barriers, the structure of the health care system and aspects of safe surgery should be studied and will be explained in the following section and an overview is given in Figure 5.1.

Phase 1.1 Surgical barriers for patients in LMICs

It is difficult to determine the exact impact that barriers to seeking surgical care have on patients in LMICs. However, several studies describe the cultural, financial and structural barriers to surgical care in different LMICs (3-10).

Cultural barriers are the fear of undergoing surgery and in many cultures the family and social supportive networks play a crucial role in deciding whether to undergo surgery (20). The study by Groen et al. (2013) in Sierra Leone has shown that common fears were: becoming half human after surgery, complications, stigma from having a scar and financial burden after surgery (21).

Financial barriers are large and indicated by many independent studies in different areas in the world (21-24). Direct costs to surgical care are fees for surgery, supplies, drugs, hospital stay, food and transport. Indirect costs are the loss of income and the cost of bringing a care giver to the hospital. Health insurances are often not available in many LMICs or they do not cover all costs, resulting in out of pockets payments done by patients directly to the hospital (20).

Structural barriers result in delays of getting the required surgery, which are caused by limited provision of transport for patients between referral facilities. Provision of surgical care is often at a significant distance away of rural areas in LMICs (20). Different surgical capacity studies by e.g., Groen et al. (2012) in Sierra Leone (9) and Henry et al.(2012) in Nigeria (4) have indicated that facilities lack many types of equipment required to provide surgery such as anaesthesia machines, oximeters, running water and electricity. Nwanna-Nzewunwa et al. (2016) have identified that the Region Referral hospital in Uganda experienced overbooked wards at least two-thirds of the time which resulted in patients sharing hospital bed, sleeping on the floor and outside the ward. Workforce limitations and unavailability of medical equipment were the leading causes of delays in surgical interventions (25).

Phase 1.2 Structures of the health care system

The setup of health care systems differs globally, organization structures can either be public, private or funded by NGOs or missions. Public, private and NGO/mission health care centres differ in organization structures, availability of staff, training and equipment. Local differences between private and public care can be large. Some countries work with disease specific hospitals, for example, for spinal injuries, maternal care or laparoscopic surgery.

Besides organization structures, it is important to consider the differences between health care centres, district hospitals and large referral and teaching hospitals (26). The WHO compiled a guide for infrastructure and supplies at various levels of health care facilities based on the WHO manual for surgical care at district hospitals in 2003 (27).

- Rural hospitals or health care centres should contain a small number of beds and a sparsely equipped operating theatre for minor procedures.
- Health care centres should provide emergency care in 90-95% of trauma and obstetrics cases (excluding Caesarean sections).
- District hospitals should have adequately equipment major and minor operating theatres and be able to provide short term treatment of 95-99% of

- the major life threatening conditions.
- Referral hospitals should provide the same treatment as district hospitals with the addition of basic intensive care facilities (27, 28).

Despite these guidelines there is a large discrepancy between what care facilities across LMICs should offer and what they do in practice, due to limited budgets, training and staff (3-10). Depending on the type of health care facility, surgery in different specialties can be performed either by open or laparoscopy surgery. Laparoscopic surgery has advantages for patients because it reduces recovery time, especially in LMICs where hospital beds are often limited and households depend on one income (29). However, laparoscopic surgery requires different training and equipment than open surgeries. Chao et al. (2016) described the benefits and challenges regarding laparoscopic surgery in LMICs (29). Although they identified that laparoscopic surgery is cost-effective in LMICs, it is not widely available yet because it requires high start-up costs. For example, equipment is expensive and therefore often donated. Other barriers included limited availability of trained staff and maintenance (29).

When designing surgical equipment for worldwide use, it is important to consider the barriers that patients encounter when seeking surgical care. Moreover, the type of hospital and type of procedures will impact the design requirements of the surgical equipment. For example, surgical equipment that will be used during very specific minimally invasive procedures will require a different design than a general tool that needs to be available during every surgery. Furthermore, costs for consumables are often paid by the patient directly to the hospital. Patients visiting a large private facility are more likely to be able to pay this than patients seeking care at public district hospitals.

Phase 1.3 Aspects of safe surgery

To provide safe surgery, several complex processes (anaesthesia, sterilization and maintenance), an experienced team, surgical equipment, and well-functioning infrastructure are required. During the design process an inventory of the available aspects can be used to determine design requirements which will increase the change of successful implementation in LMICs.

a) Operating theatre processes

To provide surgery there should be more processes in place than just the surgery itself. Anaesthesia should be provided. For safe usage of equipment, a sterilization department and a supply chain of consumables should be available. Equipment requires maintenance (repair and planned preventive maintenance) and appropriated storage to stay in service.

b) Team

The team responsible for the clinical work regarding surgery should consists of:

- Surgeon(s), or other personnel trained to perform surgery
- Anaesthesiologist(s)
- Nurses (9, 30)

The number of surgeons in Sub Saharan Africa is less than 1% of the number of surgeons in the United States of America, although the population is three times larger (31). There is a large need to expand human workforce in these areas. Chilopora et al. (2007) studied the post-operative outcomes of clinical officers, non-doctors trained locally to perform surgical procedures, in Malawi and they have found comparable outcomes to fully trained surgeons (32).

To support the processes surrounding the actual surgery, equipment should be cleaned and maintained to make sure that they can be used during the procedure. The sterilization department is responsible for cleaning and sterilization of the equipment used during surgery. Maintenance is often provided by BioMedical Equipment Technicians (BMETs) (14, 33). Equipment requires planned preventive maintenance that contains for example bi-monthly replacement of a filter, replacement of batteries, or calibration (34). Moreover, equipment can stop functioning and will require repair. Equipment used in operating theatre can either be serviced (both planned preventive maintenance and repairs) outside the hospital by a service contract with the local distributor or by a medical device company. When these service contracts are not available, inhouse servicing is often done within the department of medical engineering (also called clinical engineering), by BMETs (35). Previous studies have shown that the largest barrier to maintenance of equipment is the availability of spare parts (14, 35). Spare parts require an equipment maintenance budget and a relatively reliable supply chain with strong manufacturing relationships. However, in addition to replacing spare parts, BMETs should also be able to maintain the equipment, so manuals and tools should be available. Since, in the absence of service contracts maintenance relies on the skills and knowledge of the BMETs within the hospitals, strategic investments in BMET training can have significant impact. For example, Bradley et al. (2015) estimated that the useful lifespan of oxygen concentrators in LMICs could reasonably exceed 7 years when maintenance with a low experience level and repairs for less than 10\$ are in place (33). Mullaly et al. (2008) identified that hospitals in LMICs had difficulties finding qualified maintenance staff, this was especially the case in Africa (37). Recently, more and more BMET programs are established globally. For example, Malkin et al. (2014) described a unique evidence-based curriculum that was developed by the GE foundation, Duke University and Engineering World Health (EWH) that focusses on non-equipment specific skills such as: finding leaks, cleaning of tubes and rewiring battery packs (38). Within their study in Rwanda they have found that BMETs trained by their curriculum increased their productivity. Beside appropriate pre-education BMET, service training for specific devices should be provided to ensure that the required skills and competences are available within the hospital.

Currently a limited number of university-trained Biomedical Engineers (BMEs) are working in hospitals in LMICs, and management boards that determine procurement of equipment are often not equipped with BMETs or BMEs. This results often in procurement of low-quality equipment that is bought because of its cheap price, without considering the total cost of ownership (35).

c) Surgical equipment

Surgical equipment is required to perform surgery and can either contain disposable or re-usable parts. Disposables are for example one-time-use electro surgical knives (39). Reusables are surgical scissors or graspers that are sterilized after each surgery. Many types of surgical equipment require electricity, maintenance and spare parts to keep functioning.

A basic set of surgical equipment is required for each procedure, however there is also equipment (like microscopes) that are used during specific procedures. Surgical equipment can enter hospitals via different routes: equipment can be donated (new or used), purchased or leased from medical device companies (39). In several parts of the world, large quantities of equipment are donated by either donation agencies, overseas hospitals, governments or individuals. When equipment is donated the total cost of ownership, such as: spare parts, accessories, technicians training, planned preventive maintenance etc. is often not considered. Donations often result in piles of unused equipment. The WHO and THET issued guidelines on sustainable donations to prevent donated equipment ending up useless on hospitals grounds in LMICs (40-42). Emmerling et al. (2017) have shown that leased equipment results in higher numbers of functioning equipment than purchasing and donation of equipment in three different LMICs (39). Maintenance and consumables supply chains can be established by service contracts between the medical device company, local distributor and the hospitals (42, 43). Equipment is often not bought directly from the medical device company, but sold via local distributors within the country (44). Depending on the organizational structure, procurement can be done via tenders, or quotes are asked directly from local distributors or the medical device company itself. Decisions on procurement can be made at regional, country or individual health facility level, often depending on if facilities belong to the public, private, or NGO healthcare system within LMICs.

To ensure quality and safety of surgical equipment, equipment should comply to international safety regulations for medical devices for which the WHO guideline on medical device regulations can be used as a guideline (45). International safety regulations often not consider the context of LMICs. For example, regulations state that batteries should still function at temperature of -10 degrees Celsius. This is not applicable in tropical areas where temperatures of 40 degrees Celsius should easily be tolerated by the equipment (13, 17, 44).

d) Infrastructure

To use equipment during surgery and sterilization, electricity is required. Sterilization also requires clean water. In many LMICs power outages are common and often prolonged. When electricity is available this is often not as stable as in HICs, this requires incorporation of voltage stabilizations and battery backup support for surgical equipment. Furthermore, In LMICs temperatures can easily rise above 40 degrees Celsius and humidity can be above

Phase 1.1

Barriers encountered by patients seeking for surgical care:

- Cultural barriers
- Financial barriers
- Structural barriers

Phase 1.2

Structure of the health care system:

- Public
- Private
- NGO/Mission
- Referral/Teaching
- District
- Health clinic
- Disease specific

Type of surgeries performed:

- Open
- Minimally invasive

Phase 1.3

Aspects of safe surgery:

- a. Operating theatre processes
 - Anesthesia
 - Sterilization
 - Maintenance and storage
- b. Team
 - Surgeons
 - Anesthesiologist
 - Nurses
 - Biomedical engineering technicians
- c. Surgical equipment
 - Disposable
 - Re-usable
- d. Infrastructure
 - Water
 - Electricity

Figure 5.1: Contextual factors that should be researched to detail the context of use.

95% which can be harmful for modern sensitive surgical equipment. Finally, hospitals can be situated in very rural areas that need to be reached by difficult roads, so equipment should be robust and withstand this journey of delivery (13).

The combination of the types of surgeries that are performed, the available team, surgical equipment and infrastructure will play a huge factor in determining design requirements for surgical equipment for global usage. When no maintenance facility is available, efforts to design durable equipment should be made extensively and in absence of a stable electricity network backup batteries could be incorporated. A surgical team with limited training on specialized equipment could benefit from additional explanations of settings in the interface or manual of the equipment.

B. Phase 2: Determine the implementation strategy and the design requirements

Phase 2.1 Implementation strategy

To implement surgical equipment for global use innovative implementation strategies are required. For some equipment donation (based on the guidelines by the WHO) or lease of equipment could be an optimal solution. Within lease contracts, equipment can for example be donated, but contracts between the supplier and the hospital are established in which they agree upon a period during which the hospital buys consumables from the company and all servicing is covered. Emmerling et al. (2017) suggested a pay-per-use (opposed to pay-per-month, that often counts for service contracts) system during which the leasing company is only paid when the equipment is used (no matter what the interval time is) (39). This strategy might give both parties involved (the hospital and the leasing company) an incentive that the equipment is in service and used on patients.

Since the implementation strategy and the design influence each other, it is important to think about the implementation strategy already during the design process.

Phase 2.2 Design requirements

After understanding the context and choosing an implementation strategy, a list of design requirements can be drawn up. There are some requirements that are common for many LMICs settings such as (13, 16, 39, 46):

- Low costs
- Easy to use and maintain (low training needs)
- Compact and portable
- Flexible in terms of required accessories (option to use different brands of accessories/types of monitors)
- Robust (able to withstand high temperatures, humidity, power fluctuations)

For each type of surgical equipment certain requirements will have different priorities based on the context and implementation strategy.

C. Phase 3: Act

When the need, the context, the implementation strategy and the design requirements, are established, the design team can start to design, prototype and test the equipment. Examples of context specific surgical equipment used in clinical practice globally that can be used as inspiration are: the Hemafuse developed by SISU global health (47) that employs a novel technique to mechanically transfuse blood intraoperatively from internal haemorrhage, to augment donor blood in emergency situations. This replaces the use of a ladle to collect the blood, where after the blood is filtered through a gauze and stored in a blood transfusion bag before it is given back to the same patient again. The sterilisable re-usable drill cover developed by Arbutus Medical that can be used on hardware drills to convert them into orthopaedic drills to reduce costs (48). And the anaesthesia devices developed by Diamedica and Gradian health that do not require compressed oxygen and continue working during power cuts (49, 50).

As described by Ploss et al. (2017), it should be recognized that co-creative design processes involving local stakeholders generate the most effective global health solutions. Context specific medical device design often requires resourcefulness and creativity rather than technical sophistication (51). Involvement of end-users during the design process can be highly beneficial for the applicability of the design (18). For example; Cremer et al. (2017) held three focus groups with key stakeholders and potential users of the adapted CryoPen they worked on, which resulted in modifications to the prototype in terms of portability, durability, ease-of-use and efficacy (52).

One way of involving local stakeholders could be by establishing partnerships with local universities, NGOs, or local hospitals. Examples of partnerships in global health technologies are: ‘the innovation in Global Health Technologies lab’ at Northwestern University that established a consortium with the University of Cape Town, and two Nigerian Universities (The University of Ibadan (UI) and the University of Lagos (UL). Duke University established a program together with Makerere University where BME students work collaboratively on global health design projects (51). The UBORA project is a Euro-African open biomedical engineering e-Platform for innovation through education projects, bringing together European and African universities. The platform aims to share ideas on concepts, design files, documentation, source codes and test results with other medical device designers. The designers are taken through a stepwise approach that follows European safety regulations (53). Additionally, there are several summer schools and design competitions on medical device design for global use organized in different parts of the world: UBORA (54), Rice360 (55), BMEIdea (56) amongst others (44).

Final remarks

We presented a detailed context-driven design approach for biomedical engineers and medical device companies that aim to increase the availability of high-quality surgical equipment globally. Since almost all surgical equipment is designed for usage in HICs, there is a large need for equipment to fill the gap in LMICs. We believe that designers should

Table 5.3: Summary of the context-driven design approach to design surgical equipment for worldwide use.

	Action	How?
Phase 0	Identify a clear need for certain surgical equipment in a specific context	Use input of scientific research, NGOs or local end-users
Phase 1	Ensure a proper understanding of the context of global surgery	<p>Answer for example, the following questions and use the overview given in Figure 5.1:</p> <ul style="list-style-type: none"> • What barriers are encountered by patients seeking for surgical care? • What type of health care facilities are targeted? • What surgical procedures are performed? • Is anaesthesia, sterilization and maintenance provided and how is it organized? • Who is involved during procurement and usage of equipment? • Who is part of the team providing surgery, and how are they trained? • Is the infrastructure working properly (water, electricity, etc.)? • What equipment is available and used? If unavailable: What is the reason why equipment is unavailable? Etc.
Phase 2	Determine the implementation strategy and design requirements	<p>Determine for example, based on Phase 1:</p> <ul style="list-style-type: none"> • Will equipment be bought, donated or leased by the hospital? • How will the relationship between the provider of the equipment and the hospital be during usage and disposal of equipment? • What costs are feasible? • What is required to make the device durable (to withstand high temp, humidity, power fluctuations?) • What type of accessories are required (consumables or re-usable)? • How will maintenance and repair be organized?
Phase 3	Act	<ul style="list-style-type: none"> • Design and built and test prototypes in close interaction with local end users • Establish partnerships

strive for design that is of the same quality and complies with the same safety regulations as equipment designed for HICs. In this way user and patient safety can be assured in any setting worldwide.

As shown in the summary of the context-driven design approach (Table 5.1), design of surgical equipment for global use requires more than technical solutions, because it needs to fit the entire context. Besides a deeper understanding of the context in which surgical equipment is used in LMICs, this study advocates for solutions for problems that are identified on ‘the ground’. We advocate for surgical equipment that fits the context optimally and that will be applicable in comparable settings globally. A limited number of papers

has been published regarding the information required to fill in our context-driven design approach. When financial resources are available for innovation, it is often not enough to perform an entire context study. However, information about the context is needed to determine the implementation strategy and design requirements. We, therefore, suggest to work in multi-disciplinary teams and establish partnerships with local universities, NGOs and/or end-users. We strongly encourage academia to publish their findings about the use and design of medical equipment for LMICs settings, so this information can be used globally during future design processes. Finally, the design of surgical equipment for a global context could benefit from learning from enterprises that are presently involved in this market and acquired a lot of experience through working in this setting.

We aim to spread this context-driven design approach throughout our network of biomedical engineers, medical device companies, academia and NGOs globally to enhance global usage. We feel that interest in the field of global biomedical engineering has been rising in the past couple of years. However, it will be challenging to make everyone working in this field aware of this context-driven design approach. However, by publishing open access, presenting our work at different international conferences and making additional information available through our website we hope to reach out to design teams working for this context.

Biomedical engineers and medical device companies can have a larger impact by playing a more participative role in the context of global surgery. Future research should focus on collaborations between local medical providers, biomedical engineers, and medical device companies. Projects that go beyond finding innovative solutions for complex medical problems, but focus on medical technology with a potentially large global impact, should be globally supported. Academia can play a key role by bridging knowledge between all different stakeholders.

Based on this context-driven design approach the department of Biomechanical Engineering of the Delft University of Technology is working on the design of an electrosurgical unit, video laryngoscope and laparoscopic equipment to enhance safe surgery worldwide. This equipment was chosen based on context studies that were performed in several locations in Sub-Saharan Africa to identify current needs and end-user wishes. Designs are adapted to reduce costs, provide possibilities to continue working during power cuts and make use of re-usable accessories.

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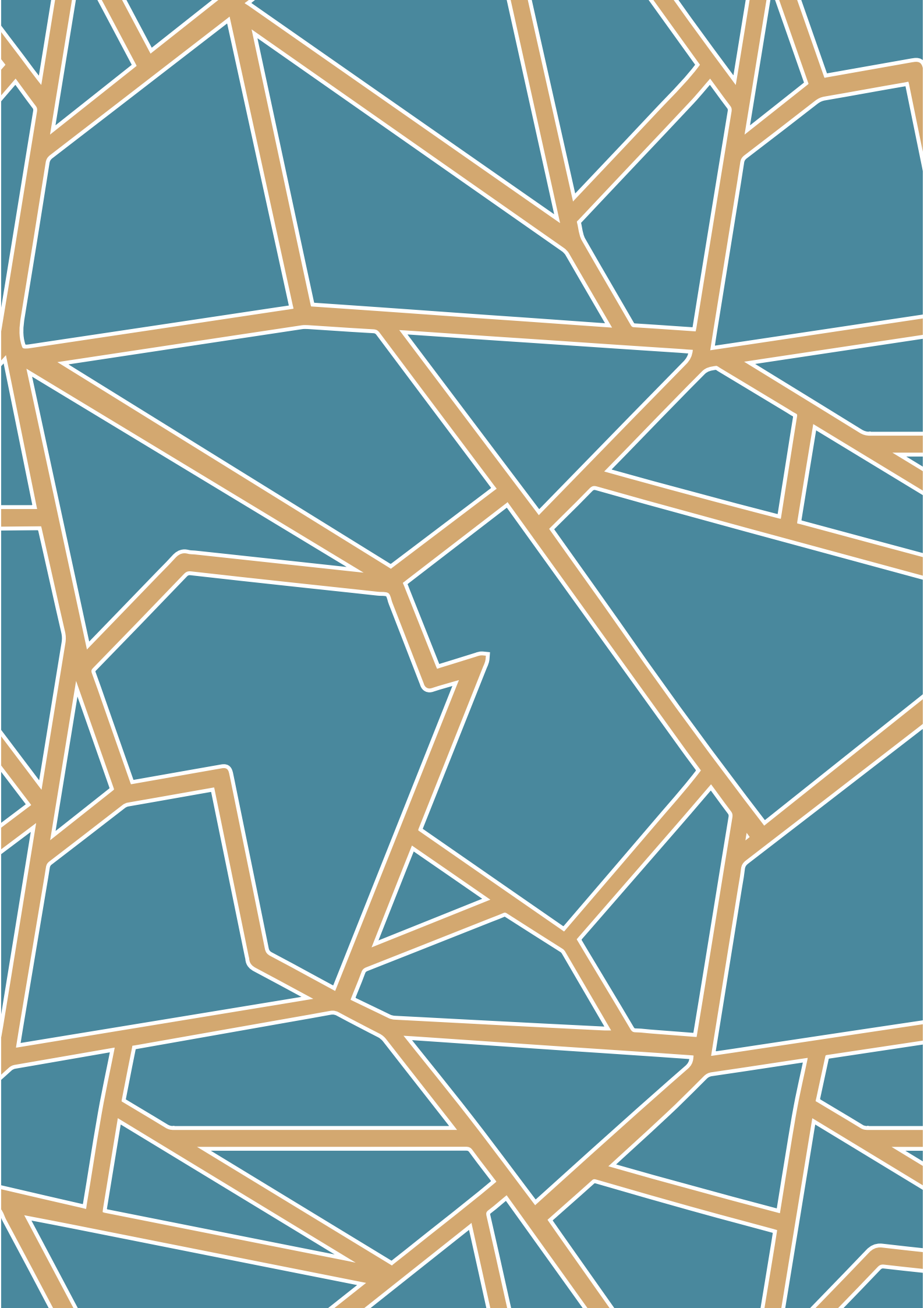
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CHAPTER 6

Context-specific design of an electrosurgical unit and monopolar handheld to enhance global access to surgical care: a design approach based on contextual factors

The need to improve electrosurgery in LMICs was identified in Chapters 2 and Chapter 4. This chapter uses the context-driven design approach presented in Chapter 5 to detail all contextual factors that should be considered during the design of context-specific surgical equipment. Data on contextual factors were collected during five field studies, mostly in Kenya. These contextual findings were translated into context-specific design requirements. Concepts for the prototypes of an affordable electrosurgical unit (that is compact and battery powered) and a robust reusable monopolar handheld are presented. User acceptance of these prototypes were later assessed by 51 surgeons working in 12 African countries.

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ABSTRACT

To comply to the large global need for surgery, surgical equipment that fits the challenging environment in low- and middle-income countries (LMICs) should be designed. The aim of this study is to present a context-specific design of an electrosurgical unit (ESU) and a monopolar handheld to improve global access to surgery.

This chapter presents both a detailed description of electrosurgery in clinical practice in LMICs and the design of an ESU generator and monopolar handheld for this specific setting. Extensive fieldwork (by means of surveys, interviews, observations and collection of maintenance records) was done by authors RO, KO and LH. Feedback from users working in Kenya on the first demonstrator designs was obtained, after which the designs were adapted into conceptual prototypes. These were further evaluated by surveying respondents who attended the annual meeting of the College Of Surgeons of East, Central and Southern Africa (COSECSA) in Kigali, Rwanda in December 2018.

Conceptual prototypes were developed for a) an affordable ESU that is compact and battery powered and b) a robust reusable monopolar handheld, that can be cleaned in the autoclave and by chemicals (e.g., glutaraldehyde solution). The conceptual prototypes were positively received by the 51 respondents of the survey.

The findings from the field work and the feedback from users during the design phase has led to a clear understanding of the specific needs and potential solutions. The presented conceptual prototypes need to be further developed into functional prototypes, which could be implemented in Kenya and other settings for further evaluation.

INTRODUCTION

There is a large need for surgery in low- and middle-income countries (LMICs), as five billion people do not have access to safe and affordable surgical care for conditions, such as appendicitis, hernia, fractures, obstructed labor, breast and cervical cancer (1). To increase global access to surgical care, increased workforce capacity is required. However, the availability of surgical equipment is equally important to achieve these targets. Shortages of equipment for essential surgical care were identified by previous surgical capacity studies conducted in Sub-Saharan Africa (2-8). To increase availability, medical device companies, non-governmental organizations (NGOs) and academia are addressed in various publications to work on innovations to improve access to surgical care and medical equipment in LMICs (9, 10). Sarvestani et al. 2018 indicated that less than 15% of the commercially available medical devices designed for global health were targeting noncommunicable diseases (cardiovascular diseases, cancer and diabetes), and even less were surgical devices (11). This shows an urgent need for innovations targeting the large global need for surgery.

The context in which surgical equipment is used in LMICs differs from high-income countries (HICs). For example, the higher temperatures, eruptive power supplies, and dust demand that equipment can withstand these more challenging environments in LMICs (12). Additionally, factors, such as lack of spare parts and consumables, limited access to maintenance, bad roads to reach rural hospitals, complex procurement systems, and limited financial resources all contribute to the complexity of using surgical equipment (1, 13, 14).

Design in the domain of biomedical engineering is traditionally done from a technical perspective, with a limited focus on the context of use. The context in which surgical equipment is used in LMICs is unfamiliar for the majority of biomedical engineers (BMEs) originating from HICs. What differs from traditional biomedical engineering design projects is that an extensive use of qualitative context research is required to gather and to analyze information of the context (15).

Aim of this study is to present a multidisciplinary project that the Delft University of Technology started in 2016 to design an electrosurgical unit (ESU) and a monopolar handheld to improve global access to electrosurgery by using a context-driven design approach (16). We developed this design approach to guide biomedical engineering design teams when designing equipment for global surgery, to ensure that this equipment fits the context of use in LMICs. Additionally, design teams are encouraged to involve users during the design process to receive feedback in an early stage. The rationale to focus on electrosurgery, is because it is used during almost all general surgeries. Electrosurgery is time efficient, reduces blood loss and facilitates wound healing (17). Moreover, the need for developments of electrosurgery for LMICs is highlighted in several publications (13, 18). Electrosurgery requires a generator, an electrosurgical unit (ESU), and either a combination of a monopolar handheld and patient plate, or a bipolar handheld. In this study we present the process of applying this context-driven design approach during the development of ESU equipment for LMICs.

METHOD

This study contains of three parts: 1) a field study of the surgical context in LMICs by the use of our context-driven design approach (16), 2) the translation of the collected information into a list of design requirements that were used to design an ESU generator and monopolar handheld. And 3) an evaluation of the designs by surgeons working in Sub Saharan Africa.

1. Study of the surgical context

A context-driven design approach for surgical equipment for safe surgery worldwide (16) that we developed was used to collect contextual factors to determine context-specific design requirements for the ESU and monopolar handheld. The contextual factors included in the context-driven design approach are: A) type of hospitals and type of surgeries performed, B) availability of equipment, C) procurement, D) infrastructure (water, electricity, etc.), E) team composition and availability of training, F) maintenance, G) sterilization, H) storage, and I) daily usage (settings, modes, etc.).

Fieldwork

Qualitative and quantitative research methods were used to identify contextual factors of electrosurgery in Kenya and other African countries. Extensive fieldwork (by means of interviews, observations, collection of maintenance records) was done by the main researcher (RO, Study 1,2, and 3, Table 6.1).

Complimentary, industrial design engineering master student KO conducted interviews with surgeons during hospital site visits in Kenya, gaining feedback on the demonstrator designs of the ESU and monopolar handheld (Study 4, Table 6.1). Industrial design engineering master student LH observed the practice of electrosurgery during 14 surgical procedures in Kenya to detail the 'equipment journey', meaning that every step involving electrosurgery during daily use was observed and recorded in detail (Study 5, Table 6.1). All data such as transcripts of interviews, notes, pictures and survey data was analyzed using MAXQDA 2018.

2. Design of an ESU generator and a monopolar handheld

The contextual factors that were studied based on the context-driven design approach were translated into a set of context-specific design requirements for both the ESU and the monopolar handheld. After the ideation phase, demonstrator designs (Figure 6.1) of the ESU and the monopolar handheld were taken on a field trip to Kenya (Study 4, Table 6.1) to receive feedback from surgeons in the early stage of the design trajectory. After receiving the feedback, the designs of the ESU and monopolar handheld were further developed into non-functional concepts prototypes for further evaluation (Figure 6.2). Calculations on the design and of the electrical hardware of the ESU were done in Jupyter Notebook and simulations were done in LTspice.

3. Evaluation

Respondents who attended the annual meeting of the College Of Surgeons of East, Central and Southern Africa (COSECSA) in Kigali, Rwanda in December 2018 were surveyed (Table 6.1, Study 6). Respondents were asked to indicate if they currently had access to an ESU

Table 6.1: Fieldwork conducted to identify contextual factors that influence design of the electrosurgical unit and monopolar handheld.

	Type of study	Country	Dates	Type of hospital	Number of participants	Published
1	Survey COSECSA* in Mombasa, Kenya (conducted by RO)	9 African countries	December 2016	10 private hospitals 14 public referral hospitals 9 public district hospitals	42 surgeons	Yes (18)
2	a) Survey COSECSA* in Maputo, Mozambique	11 African countries	December 2016	28 public hospitals 1 mission hospital 2 unknown	31 surgeons	Submitted
	b) Survey Society of Surgeons of Kenya, Mombasa, Kenya		April 2017	14 public hospitals 8 private hospitals 4 mission hospitals 2 unknown	28 surgeons	
2	c) Survey of 21 biomedical equipment technicians (BMETs)	11 African countries	February - April 2018	4 public hospitals 1 private hospital 1 mission hospital	21 BMETs+	Submitted
	d) Collection of 36 maintenance records in Kenya (conducted by RO)		February - April 2018	2 public hospitals 1 mission hospital		
3	Semi-structured in-depth interviews (conducted by RO)	Kenya	December 2016- December 2018	5 public hospitals 1 private hospital 1 mission hospital	17 BMETs+	Yes (19)
4	a) Semi-structured in-depth interviews	Kenya	June 2018	9 Public hospitals 2 Private hospitals	19 surgeons 2 BMETs+	No
	b) Feedback on the demonstrator designs (Conducted by KO)					
5	Observation of 14 surgical procedures (Conducted by LH)	Kenya	October 2018	1 Public hospital		No
6	Survey COSECSA* in Kigali, Rwanda (conducted by RO)	12 countries in Sub Saharan Africa	December 2018	35 referral hospitals 5 district hospitals 2 private hospitals 9 mission hospitals	51 surgeons	No

* COSECSA: College of Surgeons of East, Central And Southern Africa

+ BMET: Biomedical Equipment Technician

and to score the following aspects of the redesigned ESU and monopolar handheld from 0 (lowest score) to 5 (highest score): dimensions, portability, the three different pre-settings for low, medium or high voltage settings and the reusable monopolar handheld. In addition, they were asked if they will use the battery, if the provided modes (cut and coagulation) are sufficient, and if they expect this device to improve their surgical practice. Additionally, respondents were asked if they would prefer these devices over the current ESUs and monopolar handhelds currently available in their hospital and if they had additionally feedback that should be included in the design of the devices.

RESULTS

To ensure that the designs of the ESU generator and monopolar handheld comply to the context of use in LMICs this study was divided into three parts: 1) study of the surgical context, 2) design of the ESU generator and monopolar handheld and 3) evaluation by surgeons working in LMICs (Figure 6.1). A total number of 120 surgeons and 40 BMETs working in 11 different countries in Sub Saharan Africa were surveyed or interviewed to detail the surgical context, that led to a list of engineering specifications for both the ESU generator and monopolar handheld. Fourteen surgical procedures were observed in one large hospital in Kenya. Another 51 surgeons working in Sub Saharan Africa evaluated the designs in part 3 of this study.

1. Surgical context study

The data collected during the five different field studies (Table 6.1) that were conducted to study the context of use of electrosurgery in LMICs were combined. Resulting in the following insights per contextual factor of the context-driven design approach.

A. Type of hospital & type of surgery

We conducted our fieldwork in Kenya in public and private (for- or not-for profit) hospitals where they had at least one operating theatre (Table 6.1). Two surgeons mentioned different aspects concerning their daily practice that we should be aware of in our design process:

'Most of the surgeries that I do are paediatric surgery which is around 40% of all my surgeries. This involves a lot of child surgery. From my experience each child in Africa by the age of 16 has had a surgery wherein the ESU was needed. The awareness on child surgery should therefore be highly visible in the design.' Surgeon 22, Study 4

'Think about laparoscopic surgery as well. Within five years this will be more and more available. So, make your design flexible to make the product more sustainable and not obsolete within five years.' Surgeon 11, Study 4

B. Equipment availability

Study 1 (Table 6.1) revealed that 60% of district hospitals, 75% of public referral hospitals and 82% of private hospitals had access to an ESU. Study 2 (Table 6.1) showed that there

was at least one working and one used ESU per hospital for all surgeons that participated. Also, all 21 BMETs that participated had access to an ESU (Study 2, Table 6.1). This in contrast to laparoscopic equipment, which was only available for 49% of surgeons included in Study 2 (Table 6.1).

Despite the large availability that we found, ESUs and (disposable) accessories were not always sufficiently available for every operating theatre:

‘Not every theatre has an ESU, so we cannot always use the ESU for each surgery, sometimes it is already used by someone else.’ Surgeon 1, Study 4

‘Mostly we just had one handheld to use for the entire day.’ Surgeon 15, Study 4

‘Most times, the handheld can be used several times by cleaning them in chemicals but after a while the buttons start to break. As a solution we changed the attachment point so that we can use the same handheld by using the pedal to be able to use them a bit longer.’ Surgeon 22, Study 5

At places where split-patient plate stickers were available, they were reused (Study 5, Table 6.1). Other hospitals (Study 3 and Study 4, Table 6.1) had patient plates without a monitoring system indicating if the patient plate is not properly attached, often made from rubber or aluminum.

C. Procurement

Study 2 (Table 6.1) revealed that almost half of the surgeons had ESUs that were procured by the hospitals and 37% relied on a combination of both donations and procured equipment. In Study 1 (Table 6.1) high costs were identified as one of the main barriers why equipment was unavailable. The use of disposable accessories has to be paid by the patient on top of other costs for surgery, which can result in financial difficulties for many patient groups since surgeries are often out of pocket payments (Study 4, 5, Table 6.1). In addition, it is expensive for hospitals to obtain consumables from outside Kenya (Study 3, Table 6.1).

During our hospital visits we encountered ESUs developed by large European, American and Chinese brands. Most Chinese brands were procured by the hospital itself, large European and American brands are often too expensive and mostly obtained by donation (Study 3, 4 and 5, Table 6.1).

D. Infrastructure

Kenya has, like other LMICs, an instable electricity network. Hospitals in Kenya often have a generator to provide electricity during power cuts. However, this does not mean in practice that the generator provides electricity for the entire hospital, often only for a few areas (for example, the intensive care unit and large operating theatres). In addition, voltage peaks often occur when the power goes back on, which can cause damage to equipment (Study 2, 3, Table 6.1).

'The power goes off frequently in rural areas so it is important to have a reset button for the last setting used. This will take away a lot of frustration of the surgeon and will reduce unnecessary damage on the tissue.' Surgeon 15, Study 4

In some areas the electricity network is not stable enough to run all equipment, so other energy sources are used:

'The autoclave that we use is not powered on electricity but by fire. This can result in a fluctuating temperature range.' Surgeon 19, Study 4

Donated equipment does not always match with the local power supply rating, resulting in damaged equipment:

'For example, the user can put it in a 240 V which is supposed to run by a 110 V. As such, the power supply gets burned, when this happens the machine is not working.' BMET 2, Study 3

E, Team & training

In most of the large hospitals the surgical team consists of the following members:

'The surgery staff consists of the surgeon, one or two surgical assistants, one or two circulation assistants (nurses) and one anesthetist.' Surgeon 13, Study 4

However, in some rural areas it is difficult to find health care staff. As a result, medical officers are often performing small general surgical procedures in these areas.

Limited training on electrosurgery is provided during medical school for surgeons, 45% of 59 surgeons that were included in Study 2 (Table 6.1) were trained during their medical education. Those not receiving training learned about electrosurgery practice on the job:

'Currently all surgeons just follow what they have learned from their supervisory surgeon. In the rural areas there is no supervisor so guidelines can create confidence and will prevent that the ESU will not be used as consequence of a lack of confidence or control.' Surgeon 22, Study 4

'During the study we just learn some basic theory and one or two practical examples. This means we are not acquainted with what power settings to use for a certain surgery.' Surgeon 6, Study 4

The nurses that worked in the operating theatre explained that they do not learn about electrosurgery during their education.

'We do not learn a lot about electrosurgery at school, more on the job. The BMETs can teach us a lot because they know more. But I know that one needs to place the return electrode on vascularized mass and close as possible to the surgical site.' Nurse 2, Study 5

Two surgeons explained that the provision of guidelines on safe electrosurgery could be helpful:

'Guidelines should be positioned on the wall of the theatre, because while preparing the surgery room and the machines, we always look at the posters on the wall.' Surgeon 8, Study 4

'I would decide to put the guidelines attached with a chain to the ESU and put the guidelines on the cart that is used. In case they want to be sure they can take the guidelines and check them. If you would attach them to the top of the ESU they will break or eventually fall of. A pamphlet in the surgery room will also always help. So, this is a thing that you can do additionally!' Surgeon 23, Study 4

F. Maintenance

Eighty percent of the in total 101 surgeons we surveyed had access to maintenance within their facility (Study 1, 2, Table 6.1). In addition, all interviewed and surveyed BMETs performed maintenance on the ESU. Half of the 21 BMETs learned about electrosurgery during their education (Study 2, Table 1). Additionally, we noticed during our field visits that BMETs have a lot of knowledge about the working principles of the devices. When new equipment is procured they sometimes get additional training from the medical device company. However, this does not always mean that BMETs can practice maintenance work on models that can be opened up to learn how to trouble shoot in case of an error or how to replace parts (Study 3, Table 6.1).

Based on the 36 maintenance records that we collected in three large hospitals in Kenya (Study 2, Table 6.1) we identified that most of the maintenance was related to the soldering of parts of the accessories (7 out of 20 maintenance records on the accessories). However, when the ESU generator required repair this sometimes (4 out of 13 cases) could not be repaired by the BMETs themselves. In addition, all 21 BMETs (Study 2, Table 6.1) indicated that accessories (cables, connectors, patient plates and monopolar handhelds) break easily. Additionally, more than half (57%) of 21 surveyed BMETs indicated that power boards of the ESU generator are prone to breaking. We found that BMETs perform relatively more in-house repairs on the ESU than for example on laparoscopic equipment. Laparoscopic equipment is often too delicate and requires a servicing contract with the medical device company. An electrical analyzer can be used to evaluate the functioning of the ESU, for example to measure the current leakage. However, there are no electrical analyzer in most of the hospitals in Kenya, only one large hospital that we visited had access to one.

Suggestions for the design of a new ESU generator given by the 21 BMETs that we surveyed included:

- Prevention of insulation failure of the handhelds
- Reduce the number of printed circuit boards in the generator
- Separate power supply boards for easy diagnosing. Power filters should be easy to procure from local stores.
- Install power stabilizers into the equipment for protection during large power peaks

G. Sterilization

The ESU accessories that are in contact with tissue need to be sterile. Many hospitals in HICs use disposable one-time use ESU accessories. However, 24% of 59 surgeons in our survey mentioned that they reuse these disposable accessories as much as possible (Study 2, Table 6.1), mostly because of financially and structural barriers. It is difficult to get the ESU accessories in some countries (Study 2, 3, Table 6.1). We noticed during our field trips that only a small number of hospitals had reusable accessories. The disposable accessories cannot withstand the high temperatures in the autoclave and are therefore cleaned by heavy chemicals (including cidex).

'We use the autoclave during the whole day, but when you quickly need a handheld, we always use cidex detergent.' Surgeon 1, Study 4

'There are some problems with getting the cidex out after usage because there is not a long drying time. They normally shake the handheld to get the water out.' Surgeon 10, Study 4

'The sterilization room is far from the theatres, so in a lot of cases the accessories are cleaned quickly to reuse a handheld that has been used in the surgery prior to the new surgery. This is a fast method to sterilize the handheld (10 min). However, there are problems with electricity and the liquid that stays in the handheld. The risk of this is that the high-power settings can cause insulation failure in the cables as well as the exterior of the handheld. It happened that a hole was blown in the exterior after frequent sterilization.' Surgeon 1, Study 4

H. Storage

During our field visits we noticed that equipment was placed on the floor, chairs, tables or in the windowsill. The patient plate was frequently kept close to the ESU; however, the cables were often still on the floor and hospital beds were moved over these cables frequently.

Two surgeons described why the ESU should be compact:

'The ESU should be as small as possible because we do not always have a good table for this.' Surgeon 19, Study 4

'The ESU is moved a lot from place to place so it should be small, light and have a handgrip.' Surgeon 15, Study 4

I. Daily usage (settings, modes, etc.)

The 59 surgeons that participated in Study 2 (Table 6.1) mostly used coagulation (100%) and cut (97%) as settings to perform their surgeries. Twenty-six percent only used the ESU in monopolar mode, 5% only in bipolar and 68% used both modes. Sixty percent indicated that they experience complications during use, burns were encountered by 27% and electrical shocks by 12% (Study 3, Table 6.1). During our conversations with surgeons and observations we noticed that the most frequently used settings were between 20W-50W. Also a few surgeons used higher settings (more than 70W) to perform certain procedures (Study 4 and Study 5, Table 6.1). Most surgeons were aware that they should use the lowest settings as possible and adjust the settings according to the tissue response.

Coagulation and cut are more than sufficient for the surgeries in Africa.' Surgeon 4, Study 4

'The surgeon checks the power setting by seeing the reaction on the tissue. When the cut function does not do much, they will increase. When there is too much smoke they will decrease. Most times, the power setting will stay the same for the rest of the surgery.' Surgeon 23, Study 4

'Most times when I use high power is when the machine is not working properly. I can see this within this hospital that I use way more higher power settings than in the other hospital where I work. The power setting for a surgery should always start as low as possible.' Surgeon 5, Study 4

'You should only focus on the spatula electrode because this electrode is mainly used and is multifunctional. Normally we do not like to change electrodes during the surgery so if you focus on one please focus on the spatula electrode.' Surgeon 23, Study 4

When the power needs to be adjusted during surgery this is often done by the circulation assistant (nurse). Two surgeons explained why a clear display is important:

'Sometimes the ESU is positioned on a chair lower than the bed, which makes it harder to see the ESU interface and the power setting. So, it is highly important that this is properly visible.' Surgeon 5, Study 4

'The display should be visible from at least two meters away, I want to check if the power setting has changed.' Surgeon 8, Study 4

We described in detail the equipment use during each step when electrosurgery was used, based on 14 observations in Kenya (Study 5, Table 6.1). This resulted in 84 steps

Table 6.2: Context-specific design requirements for the ESU generator

Consumer requirements generator	Engineering specifications	Rationale
Portable	<ul style="list-style-type: none"> • Contain a handle • <8Kg⁺ 	<p>The ESU generator must be easy to move between operating theatres due to insufficient numbers of devices per hospital (<i>contextual factor B, H</i>)</p>
Durable	<ul style="list-style-type: none"> • Lifetime of the device >5years • Casing made from 100% non-absorbent material • Able to operate at temperatures between 10°- 45°C and 0%-90% relative humidity⁺⁺ • Resistant against high ambient dust in rural operation theatres and a possible drop of water on the exterior (IP54) 	<p>The ESU generator must function in operating theatres that do not have temperature or humidity control systems (<i>contextual factor D and F</i>)</p> <p>The ESU generators must withstand cleaning with water and chemical solutions that are used to clean the device in between surgeries or at the end of the day (<i>contextual factor I</i>)</p>
Safe and efficient use	<ul style="list-style-type: none"> • Power 0W-70W • Cut and coagulate • Monopolar and bipolar mode • Power stabilizer (AC/DC converter)⁺⁺⁺ • Audible alarm when patient plate is not properly attached • Audible indication when activated • Clear interface that can be read from 3m distance of the device • Consistent power delivery with changing tissue impedance[^] • High quality components of manufacturers that are ISO9001 certified or have a history of CE marking 	<p>The ESU should operate with a power up to 70W, since this is the maximum power used in clinical practice according to our participants (<i>contextual factor I</i>)</p> <p>The ESU generator must operate in cut and coagulation mode, since these are sufficient to perform majority of surgeries according to our participants (<i>contextual factor I</i>)</p> <p>The ESU generator must be able to withstand large power fluctuations since the electricity infrastructure in many LMICs is unstable (<i>contextual factor D and F</i>)</p> <p>The ESU generator must contain an interface that enhances intuitive use since not all staff are properly trained on installation and use of the ESU generator (<i>contextual factor E an I</i>)</p> <p>The ESU generator must comply with CE marking regulation (<i>contextual factor C</i>)</p>

Battery powered	<ul style="list-style-type: none"> • Battery required for 90 min inactive use, 5 minutes of active use at largest power setting (70W)++++ • Compatible with 100-240 VAC and 50-60 Hz^^ • Compatible with airplane regulations on batteries 	<p>The ESU generator must accommodate the variety of electricity infrastructures from LMICs that can contain large electricity peaks (<i>contextual factor D</i>)</p> <p>The ESU generator must be enable use during power interruptions (<i>contextual factor D and I</i>)</p>
Easy to maintain	<ul style="list-style-type: none"> • Easily replaceable power board • Clear error codes for maintenance issues 	<p>BMETs must be able to provide in-house maintenance on the ESU generator avoiding timely out sourced repairs (<i>contextual factor F</i>)</p>
Low costs	<ul style="list-style-type: none"> • 0-1500 US dollar^^^ 	<p>The ESU generator must be affordable and should not cost more than competing models from China (<i>contextual factor C</i>)</p>

+The dimensions and weight of a Valleylab Force Fx were chosen as benchmark values, participants indicated that they were able to carry this device from one operating theatre to the other, but larger than this will become difficult for one person (20).

++ Chosen according to publication of Neighbour et al. (2012)(12)and Forrester et al.(2019) (21)and the World Federation of

Societies of Anaesthesiologists (WFSA) performance standards for anesthesia equipment for LMICs (22)

+++ Chosen according to our own data supported by the publication of Neighbour et al(2012)(12)

++++Meeuwssen et al (2017)(23)indicated a mean activation time of 2.5 min of the ESU during laparoscopic cholecystectomies performed by experience surgeons during procedures with an average time of 44 minutes. According to the WFSA performance standards procedures should be able to continue for at least 90 minutes.

^ The resistance in the human body can differ from 25 to 4 k and full power should be delivered over the entire resistance span. During use of the ESU the resistance will vary a lot when different type of tissue is cut. It is preferred to keep the power that is delivered to the load (tissue in this case) as constant as possible to enhance optimal use. The voltage needs to be regulated according to the Ohm's law in order to keep the output power, the same, by a changing resistance (17).

^^According to the publication of Forrester et al.(2019) (21)

^^^ This amount was specified based on experience of our participants that indicated that this is the price range of equipment that is currently procured and is manageable by the hospitals (Study 4, Table 6.1)

Table 6.3: Context-specific design requirements for the monopolar handheld

Design requirements monopolar handheld	Engineering specifications	Rationale
<p>Compatibility should be ensured with different ESU brands that are currently on the market</p>	<ul style="list-style-type: none"> • Standard 3 plug for monopolar handheld • Monopolar handheld should be button activated and compatible to work with a foot pedal 	<p>The monopolar handheld must contain a standard 3 x 4mm banana plug connector that is used by large international brands, since hospitals have various brands of ESU generators (<i>contextual factor B, C, and I</i>)</p> <p>The monopolar handheld must be activated by a button because it is mostly preferred by the participating surgeons, but in case of failure of the buttons, compatibility with a foot pedal is desirable (<i>contextual factor B and I</i>)</p>
<p>Reusability</p>	<ul style="list-style-type: none"> • Scapula electrode • 100% non-corrosive material • Compatible with heavy chemical cleaning solutions (such as, glutaraldehyde solution and chlorine) • Withstand temperature of the autoclave >150°C • Watertight design of the handpiece to prevent corrosion of internal components 	<p>The monopolar handheld must contain a scapula electrode is sufficient for most general surgeries (<i>contextual factor I</i>)</p> <p>The monopolar handheld must withstand cleaning by sterilizers, and for when accessories or sterilizers are of limited availability they must withstand cleaning by heavy chemicals (<i>contextual factor B, F, G and I</i>)</p>
<p>Durability</p>	<ul style="list-style-type: none"> • Cables with at least two isolation mantels • Strain relief between the connections of the handheld and the cable and the connector to the ESU • Tip of the instrument can be replaced when contaminated with eschar 	<p>The monopolar handheld must withstand the fact that hospital beds are moved over cables (<i>contextual factor H and I</i>)</p> <p>The monopolar handheld should be designed as such that repair of the connection points between the handheld and the cable is not necessary (<i>contextual factor H</i>)</p>
<p>Low costs</p>	<ul style="list-style-type: none"> • 0-50/100 US dollar* 	<p>The monopolar handheld must be affordable and should not cost more than competing models from China (<i>contextual factor C</i>)</p>

*This amount was specified based on experience of our participants that indicated that this is the price range of equipment that is currently procured and is manageable by the hospitals (Study 4, Table 6.1)

(during procurement, pre-surgical treatment, surgical treatment, post-surgical treatment, maintenance, repair and disposal) revealing details of electrosurgery in clinical practice. The entire equipment journey can be accessed via: <https://projects.invisionapp.com/share/7DQ2GTEQGJB#/screens/342674421>.

Overall, detailing the equipment journey revealed that the nurses are mostly responsible for the installation of the ESU and the accessories prior to surgery, and it revealed the following issues: improper placement of the patient plate, a missed alarm sound given by the ESU, the cleaning of monopolar handhelds in chemicals that are not properly dried, delays during surgery because a monopolar handheld suddenly does not function anymore, and reuse of the patient plate sticker. Although these aspects were also identified during studies 1-4; the equipment journey provides information on the specific phase during use of electrosurgery during which they occur, and revealed which users are involved during each phase of the equipment journey.

2. Designs of the ESU generator and a monopolar handheld

We developed a context-specific set of design requirements based on the surgical context study for the ESU (Table 6.2) and the monopolar handheld (Table 6.3).



Figure 6.1: Demonstrator designs of the ESU interface and the monopolar handheld that were evaluated by 19 surgeons and 2 BMETs working in Kenya (Study 4, Table 6.1).

Demonstrator Designs

After establishing the context-specific set of design requirements, the following two design directions were chosen:

- An affordable ESU generator that is compact, has a clear user interface and is battery powered and can be operated in both cut and coagulation mode, and
- A robust reusable monopolar handheld that can be cleaned in the autoclave and by chemicals.

During the ideation phase several demonstrator designs for the ESU and the monopolar handheld were generated (Figure 6.1). Two rotating buttons to control the power levels for both cut and coagulation, together with a division of the power between 0-70 W in three different levels (micro, moderate and macro), were chosen as a base for the interface of the ESU generator. For the monopolar handheld a pen shaped design with two different buttons, both in terms of color and orientation, were chosen as a base for the design of the monopolar handheld. Several mock up models were developed and evaluated with 19 surgeons and 2 BMETs working in Kenya (Table 6.1, Study 4).

Evaluation demonstrator designs

ESU generator interface

Comments given on the two rotating buttons to adjust the settings, included:

+ 'Having a limited bandwidth within a subgroup will be a great safety precaution for wrong power setting by the circulation assistance.' Surgeon 13, Study 4

+ 'There will be more awareness and attention when moving to another sub-group.' Surgeon 15, Study 4

+/- 'The maximum macro power that you used is rarely used. For adults I go maximum up to 70 W if I need to cauterize the liver (a lot of blood). Normally I will not go higher than 50 W. Macro is now according to your design a generic setting that is normal to use. Create more precaution for this sub group to avoid for it to become normal to use.' Surgeon 22, Study 4

+/- 'Creating a distinction between the cut and coagulation mode by adding color will make it easier to see what mode has been changed and can be better understood by the surgical assistance.' Surgeon 8, Study 4

Monopolar handheld

Comments given on the pen shaped monopolar handheld included:

+ 'The pen shaped grip in the handheld will maintain grip when activating the handheld and when the rubber gloves are wet. Most handhelds will start to slide away when the rubber gloves are wet which increases the risk to drop them and does not give the feeling of confidence and precise examination of for instance a cut.' Surgeon 23, Study 4

+ 'I really like to hold the handheld like this with this design. It is actually really comfortable and gives me good grip when I hold it as a pen. It makes me feel more secure that the handheld will not drop.' Surgeon 13, Study 4

+ 'It is very nice that your buttons have a different sensation that means that when my fingers are used to the difference I will not have to check the button colors and I can keep my focus on the surgery. This will ensure less checks.' Surgeon 14, Study 4



Figure 6.2: Final designs of the ESU and monopolar handheld.

+ ‘What is a really important advantage of your handheld is that you have a controlled feeling in the hand. During the surgery my gloves often get wet and with the smoother surfaces’ handheld, for instance rounded once they often slide out of the hand so I will have to dry my hands a couple of time during the surgery.’ Surgeon 19, study 4

Conceptual prototypes of the ESU generator and the monopolar handheld

The demonstrator designs were further finalized into conceptual prototypes of both the ESU and the monopolar handheld (Figure 6.2), incorporating the feedback obtained from surgeons working in Kenya.

ESU

The design of the ESU consists of an interface with two large rotating buttons, which can be used to adjust the power for both cut (left in yellow) and coagulation (right in blue). Two LED screens provide the currently used power setting of the device and in case of failure, error codes will be displayed to assist health care staff and BMETs. These LED screens are bright enough to be read from a distance of three meters and a view angle of 30 degrees. On the left side of the interface, the user can choose between three different pre-settings for the output power, low (5-25W), medium (30-50W) or high (50-70W). The rotating buttons can be used to adjust the setting of cut and coagulation within this bandwidth of the three different pre-settings of the output power (low, medium or high) in steps of 1W. When the device is switched on, it will always be set to the lowest setting (5W), the reset button in the middle of the two LED displays can be used to set the device back to the previous used setting. The rotation button has no maximum rotation angle as seen in potentiometers. Consequently, this enables software to start at to the lowest power setting when the device has been switched off.

The connections for the patient plate, both monopolar and bipolar electrodes and the foot pedal are placed on the bottom of the device. Prior to the surgery, the interface will instruct the surgical team when connecting the accessories by blinking LEDs above the ports. Once the accessories are appropriately attached, for instance in case of monopolar electrosurgery, the return electrode and the monopolar handheld, the sub-group LEDs will start blinking.

The ESU is designed for cutting and coagulation, so the wave generator used in the design provides two different alternating currents: a continuous waveform for cutting and an intermitted waveform for coagulation. For both modes the maximum output voltage is set to 70W. The electrical hardware (Figure 6.3) consists of two parts: the power supply board and the main board (with the wave generator and microcontroller). The two boards can be replaced separately, when maintenance is required. The power supply board includes a power stabilizer that is compatible between 85-164 VAC (and for 15s at 300 VAC) and 45-65Hz. The 2 x 12V 0.8 Ah lithium batteries provide enough energy to continue working for 90 minutes, including at least 9 minutes of activation on the highest power setting of 70W. The main part of the electrical hardware consists of a microcontroller and custom-built wave generator. Transformers will be used to control the power output with changing impedances of tissue. The microcontroller will be programmed to control: the output of the wave generator (cutting or coagulation), LED lights, alarms during activation and in case of an error and the rotating buttons. In addition, the temperature, the current leakage between the source and the load (to prevent unintended burns because of direct coupling) and the resistance between both sides of the split patient plate, will be measured and the ESU will stop functioning when an unwanted situation occurs. A heat sink is used for cooling of the device. Also, all components are able to operate between temperatures of 0 to 60°C. All components, except the custom-built wave generator, are made by high quality manufactures with ISO9001 certification and a history with CE marking, that have distributors in Kenya and other African countries.

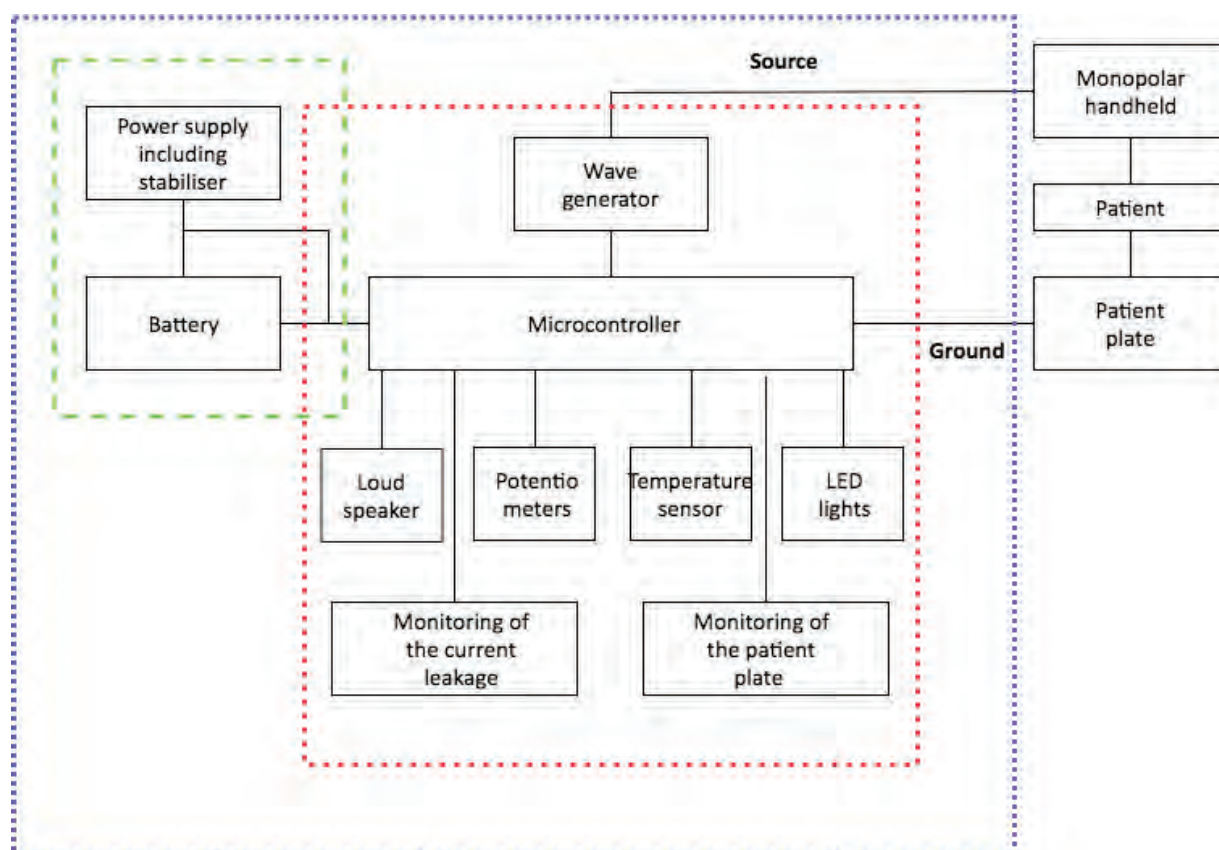


Figure 6.3: Flowchart of the electrical hardware of the ESU (in the blue square) containing the power supply board (green square) and the main board (red square).

The heaviest part of the internal hardware are the power stabilizers, the batteries and the heat sink: with a combined weight of approximately 4 kg. The dimensions of the device including a handle to tilt the device that is placed on the backside (Figure 6.2) will allow for transport between operating theatres. A raster to provide cooling to the device is placed inside the handle to prevent water and dust getting in. The exterior is made from ABS and stainless steel which are 100% non-absorbent and therefore able to withstand cleaning by chemicals (24). The interface made of a polycarbonate foil is highly reliable and resistant against the cleaning detergents that are used for cleaning. All ink of the symbols and text is applied on the back of the polycarbonate sticker and cannot be harmed by excessive use. Besides, the sticker ensures a dust free seal since the buttons are integrated in the foil.

Monopolar handheld

The monopolar handheld has a pen shaped design with two buttons, one in the front for cutting (yellow) and one behind for coagulation (blue) that are placed in a different orientation. The handheld consists of two parts, the pen and the tip. The tip can be replaced, for example when too much eschar has built up. The monopolar handheld is designed as such that when the handheld is laid down the tip will not come into contact with the surface, in case the ESU is accidentally activated. The monopolar handheld has a watertight design, allowing it to be cleaned in one piece for reuse. The tip is made from stainless steel. It was chosen to use a strain relief connection made from polymers between the handheld and the cable to ensure durability and to make the design watertight.

Materials used for the pen should be highly resistant against chemicals and high temperatures, as for example Polysulfone (PSU). The monopolar handheld has a connection with 3 x 4 mm banana plugs, similar to the design of commonly used international brands.



Figure 6.4: Non-functional concept prototypes of the ESU and monopolar handheld that were used for further evaluation of the designs. * A redel connector was used for this prototype because it was easily accessible during the manufacturing of this prototype, the 3x 4mm banana plug will be used for future prototypes.

Concept prototypes

We have developed the designed into non-functional conceptual prototypes with working LED lights to demonstrate what we envision for the design in the future (Figure 6.4). Due to budget constraints it was not possible yet to build full functioning prototypes including the electrical hardware.

3. Evaluation of the ESU and monopolar handheld by surgeons working in Sub-Saharan Africa

A total number of 51 surgeons participated in our survey to evaluate the design of the ESU generator and the reusable monopolar handheld (Table 6.1, Study 6). Surgeons represented hospitals in Angola (1), Botswana (1), Cameroon (1), Congo (2), Ethiopia (4), Kenya (20), Malawi (2), Uganda (3), Rwanda (10), Tanzania (2), Zambia (4), Zimbabwe (1) and one surgeon specified to work in various countries.

More than half (n=35) of the surgeons worked in referral hospitals, 5 in district hospitals, 2 in private hospitals and 9 in NGO/mission hospitals.

Table 6.4: Average ratings and comments on the concept prototypes given by 51 surgeons participants in this study.

Comment on the device	Average rating by the participants (0=lowest, 5=highest ranking)
I like the dimensions of the prototype	4.3
I like the portability of the prototype	4.5
I will use the option to operate the device on a battery	3.8
I believe that cut and coagulation (both monopolar and bipolar) are enough to perform most of the surgeries	4.3
The three different pre-settings for minor, moderate and major surgery will help me to select the right setting	4.0
I would like to use reusable accessories (that are intended to be reused)	4.6
I believe the device could improve the way I perform surgery on a daily basis	4.3

Comments on the devices	Excerpt
Back-up power	<i>'It is portable & can be used in rural areas without electricity, perhaps look into incorporating solar for remote areas without stable power.'</i> Participant 16
Reusability	<i>'The reusable aspect of the cautery tips is the main appealing component'</i> Participant 32
Back-up power	<i>'Battery mode is a game changer'</i> Participant 39
Robust	<i>'Will it stand when dropped by 1 m?'</i> Participant 41
Portability	<i>'Can it come with a portable light weight foldable stand?'</i> Participant 7

Forty-seven (94%) of the participants currently had access to an ESU in the hospital they work in, three respondents had no access and one did not respond to this question. Of the 46 participants that responded to the question if they would prefer this prototype over the current ESU they have in their hospitals, 40 participants (87%) responded with yes. Table 6.4 shows the rating participants gave to different aspects of the conceptual prototypes. The participants indicated to especially like the use of reusable accessories (score of 4.6 out of 5), followed by the portability of the device (4.5 out of 5).

DISCUSSION

Despite the large global need for surgery, only a few efforts have been made to develop surgical equipment specifically targeting this specific need for surgery in challenging environments in LMICs. The goal of this paper was to design a context-specific ESU and monopolar handheld to increase global access to electrosurgery. To ensure that the newly designed ESU and monopolar handheld comply to the context of use in LMICs, we used the context-driven design approach, that we developed (16). By the use of quantitative and qualitative research methods (surveys, interviews and observations) in Kenya, and other African countries we collected contextual factors influencing use. We translated these findings into context-specific design requirements and into new designs of both the ESU and the monopolar handheld. The conceptual prototypes were evaluated by surgeons attending a large surgical conference in Rwanda in December 2018.

Within this project adaptations to conventional designs of the ESU and monopolar handheld were made to design context-specific surgical equipment that complies to the context of use in LMICs. To overcome current barriers to use, we have designed: 1) an ESU that is portable, has a clear user interface and a backup battery for at least 90 minutes of usage and 2) a robust reusable pen shaped monopolar handheld and that can be cleaned in the autoclave and by heavy chemicals. Current ESUs available on the market are expensive, difficult to maintain and have complex interfaces. In addition, there are, to our knowledge, no ESUs on the market that are battery powered. Chawla et al. (2018) reported that in 21 LMICs, less than two-thirds of the hospitals had access to a continuous electricity source or a generator, demonstrating the wide impact that battery powered surgical equipment might have (25).

As reported before (1, 13, 26), we also identified the reuse of disposable monopolar handhelds during our fieldwork. Reusable monopolar handhelds are available on the market, often with a disposable tip. These reusable monopolar handhelds are expensive, prone to breaking (especially the cables) and do not, based on the experiences of our participants, withstand cleaning by heavy chemicals. Reuse of both, disposable and reusable, monopolar handhelds by cleaning with heavy chemicals, can lead to insulation failure possibly leading to unintended burns (17) or electrical shocks. Some commercially available reusable monopolar handhelds have to be dismantled before cleaning, resulting in parts that get lost, leading to unavailability of the equipment. We have chosen to focus on durability for the design of the monopolar handheld rather than its reparability, because

to support maintenance, adaptations had to be made that would reduce its durability. We have, therefore, chosen to focus on a durable design that when overused or broken, will need to be replaced in total.

Besides, the introduction of a battery and the design of a durable reusable monopolar handheld, other features to increase global accessibility of electrosurgery were introduced as well. Firstly, an interface with two rotating buttons and three different pre-settings for the power output was designed, ensuring that the power can only be adjusted within the bandwidth of the selected category (low, medium or high). The use of the pre-settings, will ensure that users are more aware of using higher power settings, because they actively have to move to the higher pre-setting. Secondly, the interface aims to provide guidance for the users during installation of the ESU, by the blinking LED lights on the interface. Thirdly, to enhance inhouse maintenance performed by BMETs, it is easy to dismantle the ESU and the power board is a separate component that is accessible if replacement is required. Maintenance will be supported by error codes that are displayed in the LED screens and will be explained in the manual of the ESU. Previously described adaptations, can be especially helpful for users with limited training on how to use electrosurgery. Additionally, a pen shaped monopolar handheld was designed, that provides more grip while holding the handheld with wet gloves and prevents contact with tissue or other materials when laying down, while not in use. Lastly, the different orientation of the two buttons on the monopolar handheld provides feedback to the user during activation of cut or coagulation. These adaptations, could be useful in any setting worldwide. The use of a power stabilizer, battery and the choice for materials that can withstand cleaning by heavy chemicals are features that are probably not valuable in HICs, but can have a large impact in LMICs.



Figure 6.5: Reusable patient plate including a safety monitoring system.

In addition to the designs presented in this paper, we are working on the development of a reusable patient plate that supports safety monitoring system in ESU generators that are currently available on the market (Figure 6.5), guidelines for use and installation that can be placed on top of the ESU, a poster with safety instructions for use in the operating theatre (Figure 6.6), and a manual that explains the error coding displayed on the LED-screens. Future projects will involve the design of a cart to store and easily transport the ESU between operating theatres and a drying tripod for the monopolar handholds after cleaning by chemicals.

The next step is to build the designs presented in this study into working prototypes for further evaluation. The design requirements seem technically feasible and we also expect to stay below the maximum costs for the device. However, working prototypes that can be evaluated in a lab setting and clinical practice are required to ensure that all context-specific design requirements are met. Heat simulations should, for example, be conducted to determine whether a heat sink provides sufficient cooling for the temperatures reached in LMICs, or if a carbon heat pad should be included. Additionally, the number of times that the monopolar handholds can be safely reused and if a battery backup time of 90 min is sufficient enough to bridge power interruptions should be tested in clinical practice. In addition, acceptance by users and if the device can be maintained by BMETs should be evaluated. Future steps will include certification and we will have to look for a commercial partner that is willing to bring the designs on the market. We envision these designs as a set of surgical equipment that is bought by the hospitals with a certain number of reusable accessories, depending on the number of operating theatres and surgeries performed on a daily basis. A strong relationship between the user and the medical device company must



Figure 6.6: Poster with instructions for use and guidelines on safe electrosurgery that are developed in addition to the ESU and monopolar handheld.

be established to ensure the supply chain of the accessories. Additionally, BMETs should be able to contact the device company for large repairs. Calibration devices that are required to check for example, if the voltage of the ESU is still in range, were not available in the hospitals that we visited. An affordable calibration device should be developed and, in the meantime, the medical device company should ensure that these checks will be done on a six monthly or yearly basis.

This was the first design project that used the context-driven design approach to research contextual factors influencing context-specific surgical equipment. Sarvestani et al.(2018) showed that engaging end users in the design process is essential to ensure successful adoption (11). Mohedas et al.(2015)also showed that a combination of different qualitative research methods is valuable to collect contextual factors during design projects (27). We provided a practical example of the context-driven design approach and the contextual factors that we studied in this design project through surveys, observations and interviews in Kenya, and other African countries. The data collected during the first three field studies (Table 6.1) led to the preliminary list of context-specific design requirements, this was a solid base to develop the demonstrator designs of the ESU and monopolar handheld. These were used to get feedback from surgeons working in Kenya (Study 4, Table 6.1) in the early stage of the design. Study 4 and 5 (Table 6.1), were used to finalize the context-specific design requirements that were used for the conceptual prototypes. The first evaluation of the conceptual prototypes by the 51 surgeons, showed that 87% preferred the redesigned ESU and monopolar handheld over the equipment they currently have in the hospital they worked in. The portability of the ESU and the reusable monopolar handhelds received the highest scores of the respondents (4.6 and 4.5, respectively). This indicates that the ESU and monopolar handheld are expected to be adopted by end-users. However, this needs further evaluation by implementation of working prototypes in hospitals in different LMICs.

The high front-end costs for the developments of the prototypes was an important barrier during the design project described in this study. This barrier needs to be overcome to move to next phases of manufacturing, testing and widespread implementation. We hope that the designs of the ESU and monopolar handheld, will eventually be adopted by surgical organizations such as COSECSA and SSK and will be included in the compendium of technologies for low resource settings that is issued by the World Health Organization.

Despite the assumption that all context-specific design requirements presented in Table 6.2 and 3 are technically feasible, it is a limitation of this study that we were not able to build full functioning prototypes of the designs. In the future, users and BMETs should evaluate the design while using them in clinical practice. Contextual factors were collected in areas where ESUs are already implemented, and the use of our designs in locations without previous experience with ESUs should be evaluated, to indicate how successful translation between different settings in LMICs is.

We hope that this paper can provide an example to other design teams that are working on innovations for surgical, or other medical equipment, for LMICs. Within the Biomechanical Engineering department of the Delft University in the Netherlands, other projects have

started on the design of a video laryngoscope and equipment for laparoscopic surgery, using a similar approach. We hope that successful implementation of the presented designs in this study, marks the start of increased global access to electrosurgery, and paves a path for the implementation of context-specific designs of surgical equipment.

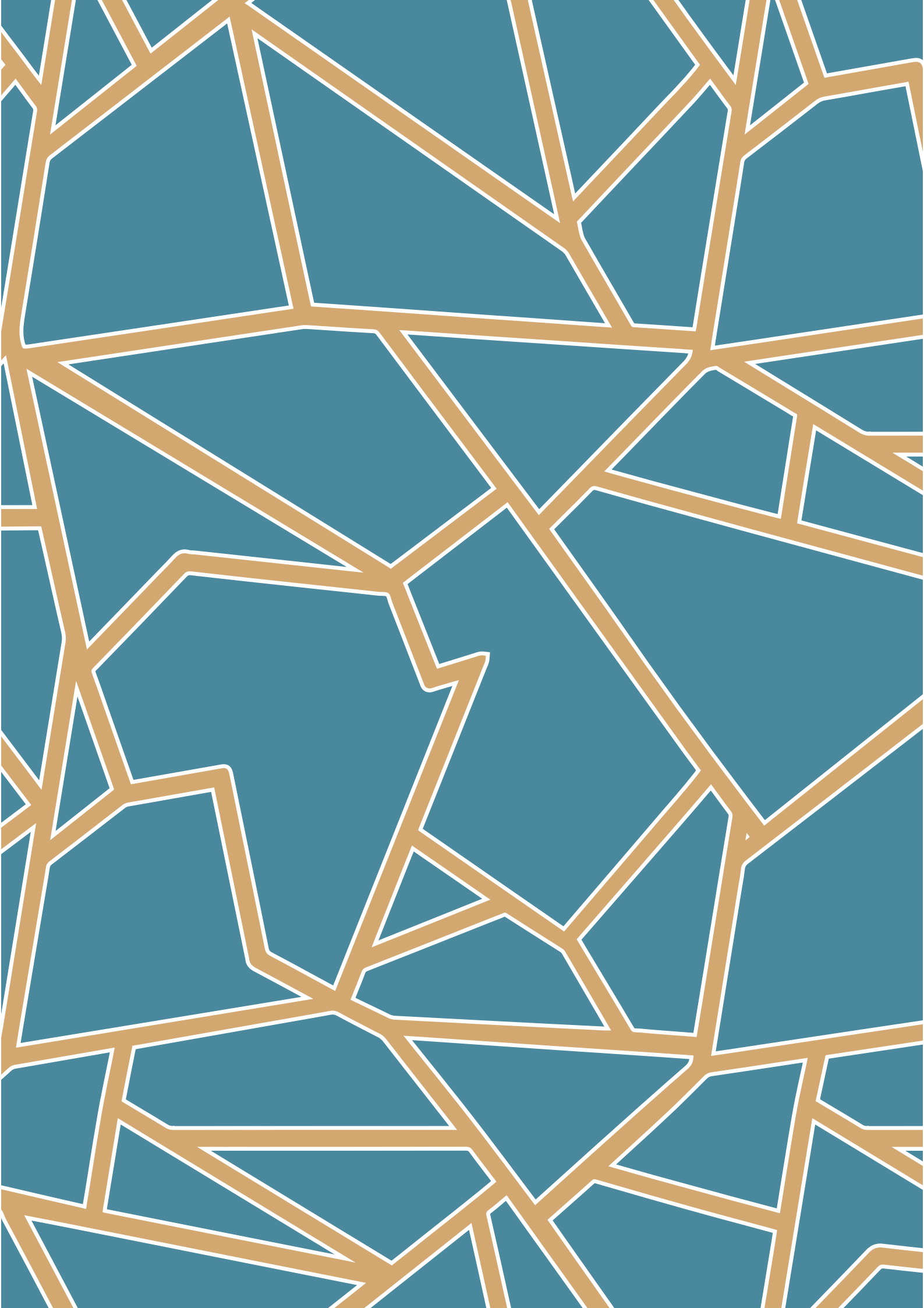
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CHAPTER 7

Discussion

The title of this thesis, 'Towards increased global availability of surgical equipment', represents the research of the use of surgical equipment in hospitals in LMICs and context-specific designs that could impact surgical practice in the future. In the first part, the context of use and barriers to surgical equipment in African hospitals were described in order to understand what is required to increase availability. In the second part, a context-driven design approach was presented that can be used to collect contextual factors when designing context-specific surgical equipment for LMICs. In addition, the use of our design approach in practice during the design of a context-specific ESU and monopolar handheld for use in hospitals in Sub-Saharan Africa was presented.

MAIN FINDINGS

The context of use of surgical equipment in hospitals in Sub-Saharan Africa

The availability and the main barriers to availability of surgical equipment were studied in hospitals in different countries in Sub-Saharan Africa, with a main focus on Kenya. A survey among 42 surgeons working in 9 African countries, revealed that 70% of the district hospitals represented in our study had basic surgical equipment required for essential surgery, compared to 88% of private and 81% of public referral hospitals (Figure 2.1). This means that still a portion of equipment remains not available for hospitals. When equipment is unavailable, this can either mean that equipment is not present within the hospital, or equipment is present but not in use, and therefore also not available. Throughout our studies, both surgeons and BMETs, indicated high costs, limited training, lack of consumables, water, energy or repair, and old and overused equipment as barriers to availability of surgical equipment. We detailed the surgical equipment journey, based on experiences of BMETs in Kenya, to understand the root cause of these barriers. High costs were identified as a barrier during the procurement phase of the equipment journey, resulting in procurement of inexpensive equipment that fits the tender specifications, but are not fitting the challenging context of use. The costs and accessibility of consumables or spare parts (especially, but not limited, for donated equipment), together with the challenging infrastructure, during the use and maintenance phase results in barriers to availability. When equipment is available, it still remains a precarious situation to sustain this availability when consumables and spare parts are not accessible or when access to maintenance is missing. Access to maintenance for surgeons that participated in our studies (n=101), varied from 60-80%, revealing that 20-40% of the hospitals had no access to repair when required. Additional barriers encountered by BMETs (n=38) included: unawareness of management staff on planned preventive maintenance or inadequate skills or tools to provide large maintenance issues on complex equipment, such as the electrosurgical unit (ESU) or laparoscopic equipment. The need for consumables, for example accessories required for electrosurgery, are a barrier because consumables are costly and prone to breakage, resulting in unintended reuse and frequent maintenance issues. In addition, donated equipment that is already obsolete when arriving at the receiving hospitals only results in extra work for the BMETs, when they have to organize the (bureaucratic and timely) disposal phase, instead of increasing the number of available equipment.

In the first three chapters of this thesis, we identified that it is a complex process to ensure availability of surgical equipment and that this depends on more than the equipment itself. Aspects influencing the context of use, such as procurement, training, usage, complications and maintenance all influence availability. Therefore, additional data on procurement, training, use, complications and maintenance were collected while studying the availability of electrosurgical units (ESUs) and laparoscopic equipment in 11 African countries. This revealed that despite their availability (which was larger for ESUs than for laparoscopic equipment), access to maintenance, training and consumables were not always in place. This results in the precarious situation in which equipment is available, but this availability is difficult to sustain in the long term, for example, when a new set of consumables or repair is required. Within this thesis we aimed to create awareness on what aspects influence the context of use of surgical equipment and should, therefore, be considered during the implementation of new equipment or research to availability.

Besides our aim to increase the understanding of barriers to availability of equipment, we identified potential interventions to increase availability in the future, that are for example: more policies on donations, procurement of durable context-specific equipment, more university-trained biomedical engineers, and more on-site training for BMETs and end-users (e.g., surgeons and nurses), robust design of equipment and a more active role of medical device companies. These interventions call for action from different actors related to the field of medical equipment, from policy makers, to academia, biomedical engineers and medical device companies. Design of context-specific equipment for use in LMICs, as a solution to overcome barriers to availability was acknowledged by 64% of the surgeons in Chapter 2 and by publications of the WHO and the Lancet commission on Global health (1-3).

Context-specific designs to increase availability of surgical equipment in African hospitals. Barriers to availability are reported (3-13), and in Part 1 of this thesis, and the need for context-specific medical equipment for global health is widely acknowledged (1-3). There is little information to be found on successfully accepted designs of surgical equipment for this context. While the importance of understanding the context of use during design of medical devices is rising (8, 14, 15), limited practical guidance for biomedical engineering design projects is available. We developed a context-driven design approach for surgical equipment based on design ethnography (16). Our context-driven approach consists of four phases:

- Phase 0: the identification of a clear need,
- Phase 1: research of the context of use by identifying contextual factors,
- Phase 2: formulating a set of context-specific design requirements,
- Phase 3: translation of the context-specific design requirements into prototypes by an iterative process in close interaction with end-users (e.g., surgeons, BMETs, nurses).

Detailing contextual factors is an important part of the context-driven design approach resulting in valuable information to determine context-specific design requirements, that eventually can be used to develop prototypes. We advocate for close interaction during each phase of the design process with end-users to ensure acceptance of the final design.

Suggestions for which surgical equipment should be redesigned were given by the 41 surgeons that participated in our study presented in Chapter 2 and included: reusable electrodes, robust ESUs and the need for portable sterilizers (Table 2.3). These suggestions, together with the fact that ESUs were only available for 60% of the district hospitals, and the suggestion in literature to improve electrosurgery (12), made us decide to use the ESU as a case to test our context-driven design approach. Additionally, the ESU is an important type of equipment used during both open and laparoscopic surgery.

We used the context-driven design approach to redesign the ESU and the monopolar handheld for use in hospitals in Sub-Saharan Africa. In order to collect the contextual factors and to receive feedback on the designs we conducted several field trips to hospitals in Kenya. The following conclusions were drawn from the contextual factors:

- 1) ESUs are often not available for each operating theatre and are transported between operating theatres, and should therefore be small and portable;
- 2) Not all settings (such as blend and fulgurate) of the high-end ESU generators are used, cut and coagulation are enough for most surgeries;
- 3) Hospitals receiving power from the national grid and backup generators suffer from power interruptions a few times per week, ranging from several minutes to longer, therefore devices should withstand power interruptions;
- 4) Accessories are insufficient available, and therefore reused and cleaned in CIDEX in between surgeries;
- 5) Training for users (especially nurses) on electrosurgery is limited and more guidance on installation and safe use should be provided on the machine or in the operating theatre;
- 6) Faulty ESU accessories use results in delays that can be easily prevented by clearer error coding on the ESU to guide user in finding a solution.

We, therefore, designed (Figure 6.3):

- An affordable ESU generator that is compact, has a clear user interface and is battery powered and;
- a reusable monopolar handheld, that can be cleaned in the autoclave and by CIDEX.

We evaluated the initial designs of the ESU and the reusable monopolar handheld with 51 surgeons working in 12 African countries, 87% of surgeons indicated that this design could improve the way they perform electrosurgery in clinical practice. Despite the successful response of future end-users, this study also revealed challenges that occur while designing equipment for LMICs. While we aimed for low-cost equipment, the front-end development

costs of this design were still high and resulted in a barrier to develop a full functioning prototype. In addition, we decided to use cables for the monopolar handheld that are more robust and can withstand chemical cleaning processes, which were a slightly more expensive option compared to other cables made from cheaper materials. The use of local available materials, for complex equipment (such as the ESU), remains a challenge especially when aiming for ISO 9001 or CE marked equipment. The newly designed ESU requires mostly of the shelf components, and will give guidance by error codes if maintenance is required. But without an electrical analyser and enough background in electrical engineering, close interaction with the medical device company will still be required to enhance sustainable use. Additionally, electrosurgery will always depend on the use of accessories, that although being robust still need a part (the tip) that will require replacement every once in a while. Furthermore, the number of times that our design of the monopolar handheld can be reused still has to be tested.

SOCIETAL IMPLICATIONS

Global surgery

To increase worldwide access to safe surgery, strategic investments from different actors are required in the near future (1). Although patients do not differ globally; late diagnosis, due to limited awareness or inadequate health care systems, influences the complexity of surgical treatments. All surgeries require, functioning high quality equipment on which the professionals can rely and all patients want to be treated in the best possible way. Organizations (such as the College of Surgeons of East Central and Southern Africa (COSECSA)) work hard to increase workforce capacity of district hospitals in Sub-Saharan Africa. In some countries clinical officers are trained to perform surgical procedures, showing comparable clinical outcomes to surgeries performed by fully trained surgeons (17). The availability of reliable surgical equipment in district hospitals should increase simultaneously to an increase in workforce capacity, to keep patients as close as possible to their homes for basic surgical treatment, and avoid overly crowded referral facilities (18).

Gap & mismatch

This thesis revealed that there is a gap in availability of essential equipment for surgical care. However, this gap will not be reduced by supplying hospitals with large numbers of surgical equipment that were originally developed for the setting in HICs. In the past, huge numbers of surgical equipment (and many other types of medical devices) have been donated by western parties to hospitals in LMICs (9, 19). Some of this equipment was well received and highly appreciated by partners in LMICs to establish surgery programs. However, a lot of this equipment was already broken when it reached the hospitals or stopped working at the point spare parts or a new stock of consumables were required, resulting in piles of unused equipment (Figure 7.1). Besides, the fact that there is a gap in availability, it can also be concluded that there is a mismatch between the equipment that is available on the market and the needs in LMICs, as was also concluded by the WHO in 'Managing the mismatch' for medical technology in LMICs in general (3). Context-specific equipment that is designed for the specific needs in LMICs needs to become commercially



Figure 7.1: Obsolete equipment that is waiting for disposal. Part of it was already obsolete when it was received as a donation by the hospital.

available on the market to resolve this mismatch. This is a responsibility of medical device companies, that can be supported in this process by academia and funding from NGO's or the WHO. Academia and the WHO should support in identifying the needs and directions of design project. Additionally, they should support medical device companies in their attempts to tackle the markets in LMICs. Once, context-specific equipment is on the market it should also reach the target group and be accepted (meaning: used to its purpose), to translate designs into innovations (19).

Context-specific design

While currently many basic supplies are lacking in hospitals in LMICs, it might seem a bridge too far to design complex high-end technology for this context. However, we believe that design projects should also evolve around more complex technology for, for example, laparoscopic surgery. Surgical residents from COSECSA are trained in performing laparoscopic surgery and the willingness to implement this type of surgery globally is large. Benefits for patients and cost-effectiveness of implementation of laparoscopic surgery have been reported (20). However, barriers to laparoscopic equipment still exist, including the high costs of equipment (21).

The design of context-specific equipment asks for designers that understand the context they design for. This is challenging, because the context of use in LMICs is unfamiliar for the large proportion of biomedical engineers and medical device companies that develop medical equipment that originate from high-income countries (HICs). The medical device

company D-rev, published a blog about what they learned from a phototherapy device for rural clinics in LMICs, that in the end did not meet the context of use they designed it for (22). This practical example, highlights again the importance on understanding the context of use. Now with the rising recognition of the need for health technologies for LMICs, traditional biomedical engineering design projects should be supported by guidelines to identify needs and context-specific design requirements to ensure the development of context-specific designs that are fit for use in LMICs. Perosky et al. (2012), Mohedas et al. (2015) and Sarvestani et al. (2013) published context-specific designs of medical equipment designed for this context based on ethnographic research to determine contextual factors (8, 14, 23). These studies provide a template for the use of design ethnography in the design of medical devices for LMICs. However, they do not provide a step-by-step approach, nor did they give a comprehensive overview of contextual factors to consider during design projects for LMICs.

Aranda-jan et al. (2016) provide a comprehensive overview of contextual factors to consider during a design project of medical technologies for LMICs (6). Although, this study provides a good starting point towards a context-specific design approach, we decided to develop our own approach specifically for the design of surgical equipment that focusses on the entire design process. We advocate, for the identification of a clear need before the start of a design project. Based on for example, the guidelines of the WHO Managing the mismatch document, scientific research, or a request from an NGO or end-users. Our approach does not focus on how to identify this need, but aims to provide guidance in the phases that result after the need-identification phase (Phase 0 in our design approach). The context-driven design approach gives guidance to biomedical engineering design projects, showing which contextual factors should be identified that should be translated into context-specific design requirements and eventually into prototypes. We focused on specific contextual factors in our design approach and we included therefore less contextual factors compared to the framework that was developed by Aranda-jan et al. (2016) (6) that remains broad in terms of the number of contextual factors they included, as they target all medical technology that is developed for LMICs. The medical technology they included can also be for example target point-of care diagnostics that are directly used by patients (6). Contextual factors that were included by Aranda-jan et al. (2016) are for example, the capacity of hospitals to follow-up patient treatment, the communication between patient and hospital or the religions or cultural beliefs. These contextual factors might be valuable when designing technology for point-of-care diagnosis, but will to a lesser extent influence the context-design requirement of surgical equipment and were therefore not included in our overview of contextual factors. Additionally, we also advocate in our context-driven design approach for consideration of the eventually envisioned implementation strategy, since this can influence the design requirements. In addition, we advocate for close interaction with end-users during each phase of the context-driven design approach.

Both our design approach, as the framework developed by Aranda-jan et al. (2016), require field research to explore contextual factors that influence design choices. For the department of Biomechanical Engineering of the Delft University of Technology, this

meant that we had to extend our traditional research practice in the field of Biomedical Engineering, to an ethnographic approach to understand not only the clinical use of surgical equipment, but also how equipment is procured, maintained and if and how users are trained. We collected data on these contextual factors through both quantitative (surveys) and qualitative research (interviews and observations) methods. A combination of those research methods was used to ensure triangulation of our research findings.

We see the development of the context-driven design approach as an incremental process, that will improve by implementing experiences of future design projects. Each design project will eventually lead to new insights on the design approach. By pursuing the design project presented in Chapter 6 based on the context-driven design approach we identified that most of the context-specific design requirements are determined in Phase 1.3, where contextual factors such as: the operating theatre processes (anaesthesia, sterilization, maintenance and storage), the available team, equipment and infrastructure were identified. Despite, the fact that most of the context-specific design requirements resulted from Phase 1.3, we obtained very valuable information from other phases. For example, by detailing the surgical equipment journey to understand when, where and why barriers during use occur. This is a research tool that we adopted from current patient journey mapping (24) and rapid rural appraisal methods (25), and has shown to be helpful during a design project, but also during research to understand current handling of medical technology (shown in Chapter 3).

After the first application of the context-driven design approach (Chapter 6), we identified that the design approach should emphasize that the current daily use of equipment (for example, which setting and mode) can reveal important information. Daily use is a contextual factor that should be added to the design approach in a future iteration. Additionally, the design approach presented in Chapter 5 does currently not include categories such as, clinical evaluation, manufacturing and implementation, which are important steps of the innovation cycle (19). We advocate for the development of equipment according to the same standards as equipment developed for HICs, and by a lack of local medical device regulations, equipment should comply to CE or FDA regulations. However, as described by Neighbour et al. (2012) several requirements are in direct conflict with the conditions in LMICs (7). How and if, this is a barrier that is encountered during design projects during the clinical evaluation and implementation phase requires future research. We hope that design projects will publish their good and bad experiences regarding certification processes in different LMICs, as this is an important category to include in the design approach. To guide these attempts, Table 7.1 presents categories that we envision to be added to the context-driven design method presented in Chapter 5 in the future.

In general, we believe that the use of the context-driven design approach within this study has shown that it is a good basis to use during design projects on context-specific surgical equipment. However, more research to validate our context-driven approach is required. We currently use the design approach to develop a video laryngoscope for LMICs, to study how useful the context-driven approach is when applied to a different type of

Table 7.1: The context-driven design method presented in Chapter 5 including additional categories that we envision to be added in the future.

	Action	How?
Phase 0	Identify a clear need for certain surgical equipment in a specific context	Use input of scientific research, NGOs or local end-users
Phase 1	Ensure a proper understanding of the context of global surgery	<p>Answer the following questions and use the overview given in Fig.5.2:</p> <ul style="list-style-type: none"> • What barriers are encountered by patients seeking for surgical care? • What type of health care facilities are targeted? • What surgical procedures are performed? • Is anesthesia, sterilization and maintenance provided and how is it organized? • Who is involved during procurement and usage of equipment? • Who is part of the team providing surgery, and how are they trained? • Is the infrastructure working properly (water, electricity, etc.)? • What equipment is available and used? If unavailable: What is the reason why equipment is unavailable? Etc.
Phase 2	Determine the implementation strategy and design requirements	<p>Determine based on Phase 1:</p> <ul style="list-style-type: none"> • Will equipment be bought, donated or leased by the hospital? • How will the relationship between the provider of the equipment and the hospital be during usage and disposal of equipment? • What costs are feasible? • What is required to make the device durable (to withstand high temp, humidity, power fluctuations?) • What type of accessories are required (consumables or re-usable)? • How will maintenance and repair be organized?
Phase 3	Act	<ul style="list-style-type: none"> • Design and built and test prototypes in close interaction with local end users • Establish partnerships
Phase 4	Testing and CE or FDA certification	<ul style="list-style-type: none"> • Perform functionality test and clinical trials • Obtain CE or FDA approval
Phase 5	Manufacturing	<ul style="list-style-type: none"> • Determine the required manufacturing techniques and at which location this should be performed
Phase 6	Implementation and evaluation	<ul style="list-style-type: none"> • Assess the wide spread implementation of the context-driven design

medical equipment. To study its ability to be translated to other design projects, we highly encourage other biomedical engineering design teams to use the context-driven design approach and reflect on its practicality. Additionally, we hope that this will result in more publications on contextual information (as our publications of Chapter 2-4 and Chapter 6) to increase the amount of data that is available for other design projects in this field. We do not believe that this is a replacement for collaboration with local partners, but it can be a contribution to the body of knowledge regarding this type of research.

Translation of technology between HICs and LMICs has shown to not always lead to optimal results, but translation between LMICs and different settings with LMICs should be researched further to understand how design should tackle these differences. When the design of the ESU that we propose in Chapter 6 will be built into a working prototype in the future, implementation in various clinical settings in LMICs can result in data if these designs actually improved surgical practice. Data on for example, how often the equipment is used, what type of maintenance is required (and if inhouse maintenance was sufficient) and if extra training of end-users was required, should be collected. This is useful information to validate if the context-driven design approach results in surgical equipment that fits the context of use in LMICs.

Designs should become commercially available to reach the target population, which is a process that often encounters many barriers (26). There are different routes that could be explored. Diamedica, Arbutus, Lifebox and SISU Global Health are enterprises that developed equipment for medical needs in LMICs. Large medical device companies (such as, Philips, General Electrics and WISAP) have a few products that are specifically targeting LMICs. Other medical device companies are currently leasing equipment to hospitals in LMICs, where they provide servicing and have contracts whereby hospitals buy a fixed number of consumables on a yearly basis. Emmerling et al. (2018) propose a pay-per-use model to ensure that both the medical device company and the hospital share responsibility in that equipment is used (9). This is, to our knowledge, currently not done by any medical device company and could be an interesting test case. Some medical device companies directly sell equipment to hospitals; however, the role of distributors cannot be neglected when aiming to implement equipment in LMICs. More literature on dissemination of context-specific medical technology in various LMICs by medical device companies, will be a valuable asset to the body of knowledge regarding implementation of context-specific design.

BME for LMICs

For the last four years, we have been expanding our network in Kenya and surrounding countries. Our partners such as, Kenyatta University and COSECSA had a massive contribution to this research. We cannot highlight enough how important these local partners are in the development of context-specific surgical equipment. It has been an investment in terms of both time and money to establish fruitful relationships with mutual benefits. However,, to ensure mutual benefits in design projects (as presented in Chapter 6), is easier said than done. Despite our good intentions, we cannot assure that the innovations we work on will

eventually reach the participants of our studies. Our efforts in establishing relationships with local partners resulted in various shared authorship of papers included as chapters in this thesis. We hope that future projects from the Delft University of Technology (and others) in this field will continue to support the development of biomechanical engineering in both LMICs and HICs.

We provided a list of context-specific design requirements for the ESU, that can hopefully be used in other design projects as an example. This list, together with the list published by Forrester et al. (2019)(27), could be a starting point of a general list of design requirements for surgical equipment in LMICs to guide both procurement, design and implementation. The World Federation of Societies of Anaesthesiologists (WFSA) published a general list of performance standards for anaesthetic equipment in LMICs for the same purposes (28). Organization such as the WHO or COSECSA, together with biomedical engineers, should take the lead in establishing of standards for surgical equipment for safe surgery worldwide. Research on the implementation of our designs and the surgical head light of Life box could support in the developments of these standards.

Mohedas et al. (2014) have described design ethnography as an engineering tool and advocated for implementing this type of design into biomedical engineering education to enhance the design of context-specific equipment (29). On the other hand, biomedical engineering is still a small research field in LMICs with limited focus on design. Local design expertise should be supported by collaborative programs between universities. Existing programs are for example: ‘the innovation in Global Health Technologies lab’ at Northwestern University in cooperation with the University of Cape Town, and two Nigerian Universities (The University of Ibadan (UI) and the University of Lagos (UL)). Duke University developed an education program with Makerere University in Uganda, where BME students from both universities work collaboratively on global health design projects (30). The UBORA project is a Euro-African open biomedical engineering e-Platform for innovation through education projects, bringing together European and African universities(31). The platform aims to share ideas on concepts, design files, documentation, source codes and results with other engineers. The program takes design teams through a stepwise approach that follows European safety regulations. Another example is the makerspace of the University of Nairobi collaborates with Kenyatta National Hospital on the development of medical equipment, which is supported by the Philips foundation and UNICEF. Additionally to education, support systems in terms of funding, incubators and local manufacturing are required. Johnson and Johnson launched their second Africa innovation challenge that supports novel ideas and start-ups with \$50 000 and training to support innovation in healthcare solutions in the region.

BME in LMICs

The field of global surgery has changed drastically in a few years. First, there was limited recognition, then it started with surgical missions by expatriate surgeons, followed by the establishment of local education systems and many surgeons that went abroad to receive their specialist training. Recently, more local surgical training and specialist programs are

established (for example, by COSECSA in several African countries), including training on laparoscopic surgery (32). Lately, the biomedical engineering community has also gained more attention for the subject. Biomedical engineering conferences, such as the International Society for Medical Innovation and Technology, are focusing within their conference program also on technology for global health, the same holds for journal such as the Journal of Biomedical Engineering that are about to publish a special issue on technologies for LMICs. The role of biomedical engineers in increasing availability of surgical equipment goes beyond that of the design of context-specific equipment. In 2010, the GE foundation, Duke University and Engineering World Health Organization developed a BMET curriculum that was implemented in Rwanda that resulted in more productive BMETs resulting in less equipment being out of service. Engineering World Health has developed together with the Developing World Healthcare Technology Laboratory of Duke University, a BMET library with open-source books, manuals and publications relevant to BMET training, particularly in LMICs.

Equipment in other global health projects

Computerised Maintenance Management Software (CMMS)

In this thesis we identified, the complex process to ensure availability of surgical equipment, showing that this depends on more than the equipment itself. Understanding the context of use is not only required when designing context-specific surgical equipment, but is also valuable during the development of other technologies supporting medical equipment in LMICs. We used a similar approach, as described in Chapter 5 and 6, for the development of a Computerized Maintenance Management System (CMMS) presented in Appendix A, that we developed together with the MOI Teaching and Referral Hospital (MTRH) in Eldoret, Kenya. In Chapters 3 and 4, of this thesis, the need for a context-specific CMMS software was identified to keep track of hospitals inventory, maintenance and planned preventive maintenance schedules. CMMS software that is currently available is often too complex and demands a high-level of computer skills. The context-specific CMMS software was developed by Biomechanical Engineering students of Delft University of Technology in close collaboration with the BMET department of MTRH, ensuring that the software would comply to their needs and level of computer skills. The software is currently implemented by the MTRH ICT department. Now, we are exploring ways to make it available open source and flexible so other hospitals in the region can implement it too.

Treatment of cervical cancer

When we, for example, in the future aim to extend the current version of the context-driven design approach for medical technologies used in health clinics it is important to understand barriers to medical equipment use in this context. The research that we conducted together with the Female Cancer Foundation to increase availability of equipment required for treatment of cervical cancer in rural areas in LMICs provided us the opportunity to learn about equipment use in rural health clinics and limitedly equipped hospitals.

Barriers to the use of equipment for treatment of cervical cancer were identified during the evaluation of screen-and-treat programs of cervical cancer in rural areas in LMICs (33, 34), that are implemented in various regions by the Dutch NGO the Female Cancer Foundation. These barriers include: difficulties with the CO₂ supply chain, sensitivity of the equipment and limited access to maintenance resulting in delay of treatment, because the medical device company in HICs need to be consulted. With a multidisciplinary team of tropical doctors, gynaecologists, program managers and biomedical engineers we looked for possible alternatives to the currently used equipment for cryotherapy (Appendix B). Cryotherapy is a treatment method that uses cold to destroy premalignant cervical lesions. An alternative treatment method is thermal coagulation. Equipment to treat premalignant cervical lesions with thermal coagulation (by heating) has been commercially available for years, however, it received limited attention of the global community. The equipment for thermal coagulation is small, lightweight and does not require a supply chain of CO₂ or other medical gasses.

Cryotherapy is widely endorsed by the WHO for treatment of precancerous cervical lesions in LMIC, however, barriers to implementation in clinical practice in LMICs are underreported in literature. Additionally, a small surgical procedure (loop-electrosurgical excision procedure (LEEP)), has become the common treatment modality in HICs, eliminating the demand for research into other treatment modalities. The high incidence of cervical cancer in LMICs results in a large need for screen-and-treat programs in this setting. It is, therefore, highly beneficial to research the differences between cryotherapy and thermal coagulation in terms of treatment effectiveness and how they fit into the context of use during screen-and-treat programs.

Thermal coagulation has been recently implemented in several LMICs and the Female Cancer Foundation suggested, in close consultation with the WHO, that more data is required to support widespread implementation of this treatment modality. A meta-analysis was conducted (Appendix B) to assess the effectiveness of thermal coagulation and cryotherapy in LMICs. The meta-analysis revealed that both treatment modalities are effective for treatment of premalignant cervical lesions in LMICs. This finding has supported the start of a randomized control trial in three African countries, to compare these two treatment modalities in clinical practice. Besides treatment effectiveness, patient satisfaction, acceptance of the equipment by the health care workers, maintenance and how the equipment handles the challenging infrastructure will all be assessed during this study.

PRACTICAL IMPLICATIONS

The main findings of this thesis are relevant for all actors that aim to increase global availability of surgical equipment to enhance access to safe surgery worldwide. Generally, this thesis showed that it is a complex process to ensure availability of surgical equipment and that this depends on more than the technology itself. Barriers to availability are

encountered at different moments during the lifespan of surgical equipment, accordingly design projects for context-specific equipment should consider contextual factors during design. Based on the findings of this thesis, practical implications for different actors are formulated, with a main focus on hospitals in Kenya, which are expected to be for a large extend translatable for other LMICs in Africa and Asia.

Universities and training institutions in both HICs and LMICs should contribute in terms of facilitating research, innovation and training. As shown in this thesis, detailing the context of use in LMICs requires investments in both time and money, which is not available for every design project working on innovations. By publishing relevant findings (open access), design requirements and their rationale, academia could contribute to the amount of data that is available in literature. Collaboration, with medical device companies and NGOs to ensure implementation of developed solutions is highly recommended. The field of BMET and BME education is growing in many LMICs and could be supported by efforts from educational programs in HICs.

Medical device companies should become more active and more aware of the use of their medical equipment in LMICs in order to reduce barriers involving spare parts, consumables and training. Additionally, they could be a large contributor to innovations in this field. There is a large market for medical equipment that is currently underexploited, but it will require investments in terms of both time and money to ensure a headway in the market in LMICs. Several international medical device companies are expanding their markets in the regions by collaborations with governments and training institutions, and will hopefully be followed by others.

Funding agencies and investors should give innovation a push by funding research, innovations and enterprises developing innovations for global health. Not only in the developing phase, but equally important during the commercialization and implementation phase.

Local governments should support hospitals in sustainable use of surgical equipment by developing guidelines on donations, requirements during the tendering process and certification of medical equipment. The Kenyan government has taken a leading role in this field by implementing a program in 98 public hospitals, where they implement brand new equipment for intensive care units, diagnostic imaging and operating theatres.

Governments can be supported in their attempts by the WHO, that published several compendia on health technologies for low-resource settings to provide an overview of technologies that can have a large impact on global access to medical treatment.

Hospitals, NGOs and surgical organizations (such as COSECSA and the Surgical Society of Kenya) should share best-practices and lessons learned regarding equipment procurement and equipment use. The establishment of a general list of performance standards for surgical equipment for LMICs could be a good starting point for this.

Users (surgeons, BMETs, nurses etc.) should become aware of the increasing number of attempts to develop equipment that fits their needs and could push for their implementation in clinical practice, so it can improve their daily attempts to treat patients globally. Additionally, they should play an active role in identifying the needs and the design requirements for equipment that is developed in the future.

Despite the unique roles of the actors that we addressed in the previous paragraphs, we believe that increasing availability of surgical equipment requires a multidisciplinary approach and we advocate for collaborations between different actors as much as possible.

LIMITATIONS

During this entire thesis we used triangulation to ensure data saturation was reached. However, our data on surgical equipment availability is based on self-reported data by attendees of large surgical conferences (the annual meetings of COSECSA and SSK). The main data sources used in Chapters 2 and 4, were data that we collected by surveying respondents of multiple African countries that visited these conferences. This has shown to be an efficient way of data collection, but leads to data that is less reliable than when availability was determined by side visits of hospitals in different countries, including countries outside of the COSECSA region with less established surgical systems. Accordingly, we asked for availability of surgical equipment, this does not necessarily mean that equipment is also used in clinical practice. If equipment is available, but not used (which can occur due to various reasons, as described in this thesis), we can still consider the equipment as unavailable because it is not used to treat patients. This is something that future research regarding availability must consider, for example, by identifying how often equipment is used (every day, only by specialist, etc.). Secondly, by collecting data by surveying attendees of these large conferences, rural clinics are underrepresented in our data. The interviews that were conducted during side visits in Chapter 3, and the BMETs that were surveyed during side visits in Chapter 6 were conducted to ensure that findings from our conference survey data were confirmed. However, we did not include non-users in our study and all hospitals that we visited were on a travel distance of Nairobi or Mombasa in Kenya, introducing spatial-biases by underrepresentation of rural hospitals as in our survey data. This has most likely led to higher numbers of equipment availability in Chapters 2 and 4. In addition, the surgical equipment journey that was identified in Chapter 3 might underrepresent barriers perceived in rural hospitals. The issues regarding maintenance will probably be larger when no BMETs are available or sterilization might be organized differently without access to sterilizers. Within Chapter 6, data on contextual factors influencing the designs for electrosurgery for global surgery were collected by the use of different research methods (surveys, interviews and observations) by three researchers. Design choices were based on triangulation of these three data sources. Despite being based on experiences of current users of electrosurgery, we are confident that the designs will match settings that currently not use electrosurgery, but will do so in the future. A large number of our participants had experience with working in rural, less equipped facilities, so they could relate to working environments in these settings,

that were indirectly included in the contextual factors that we collected. We aimed to accurately detail equipment usage and barriers to availability in this thesis by the research methods that are reported in Chapter 2-4 and 6. Additionally, during the five months that we spend in Kenya a lot of knowledge on the field was gathered in a non-structural matter by informal conversations with surgeons, medical providers, medical device companies, distributors of medical equipment, BMETs, staff of universities and NGOs, that was not reported in this thesis.

The design of the electrosurgical unit and the monopolar handheld presented in Chapter 6 could not be built into working prototypes because of budget constraints, showing that high front-end development costs pursue a barrier to development of context-specific equipment. We hope that increased awareness of the need for context-specific equipment will result in more funding opportunities to overcome this barrier.

The title of this thesis 'towards increased global availability of surgical equipment for surgical care' was chosen because we are aware that we included the first phases of introducing innovations of surgical equipment in LMICs. However, the steps following the finalization of the designs (manufacturing, certification and implementation) were not included in the design approach that we presented in Chapter 5. Accordingly, these steps were not included in Chapter 6 for the designs of the ESU and monopolar handheld, despite their importance. By pursuing these future steps and implementation in various LMICs, translation of the designs to other settings can be researched and this can be used to improve the context-specific design approach presented in Chapter 5 and Table 7.1.

Despite these limitations, insights in current gaps in hospitals' needs to provide surgery and the available resources, barriers to availability of surgical equipment and how context-specific surgical equipment should be designed are provided in this thesis. These are of value for the global health community, policy makers, health workers, the global community of biomedical engineers and medical companies to assist in their efforts to increase surgical capacity worldwide. The research presented in this thesis is one of the first research projects focussing on surgical equipment in LMICs. Despite, the presence of surgical capacity studies and a few papers on barriers to use of medical equipment in LMICs, we identified a gap in literature regarding data on availability of specific types of surgical equipment, perceived barriers specifically for surgical equipment and attempts to increase availability, for example by context-specific design. To ensure that our attempts to increase global availability of surgical equipment fills existing clinical gaps, we started by researching the context of use thoroughly, after which we in a later phase started a context-specific design project.

By publishing our findings (open access) we hope that more data on for example, what type of surgical equipment could benefit from context specific design and what contextual factors to study, is available for similar projects in this field. Additionally, although we started this project without any contacts in LMICs, the fieldwork that was conducted resulted in a solid network in various LMICs that is expected to be very useful in future projects.

Future research directions

Increased global availability of surgical equipment is required to increase global access to surgery, and therefore, an important aspect of reaching the goals set for universal health coverage and sustainable development goal 3. The increasing awareness for the need for global surgery, and the role of health technologies and biomedical engineering in this field is promising for the future. The department of Biomechanical Engineering of the Delft University of Technology aims to work on various technologies for global surgery in the upcoming years. One of the future goals is the development of low-cost robust laparoscopic equipment, to enhance widespread implementation of laparoscopic surgery. Additionally, we aim to further develop the context-driven design approach. We believe that the first steps in achieving these goals were taken during the work presented within this thesis. By combining research in global surgery, biomedical engineering, and design we aimed to provide insights in current practices and how design for the context of use in LMICs should look like. We aimed to prevent the implementation of inappropriate medical technology that does not align with the context of use in LMICs hospitals. We established a large network of surgeons, NGOs, universities and organizations working in various countries in Sub-Saharan Africa and hope that the developed context-driven design approach will be used as a basis to work towards increased global availability of surgical equipment.

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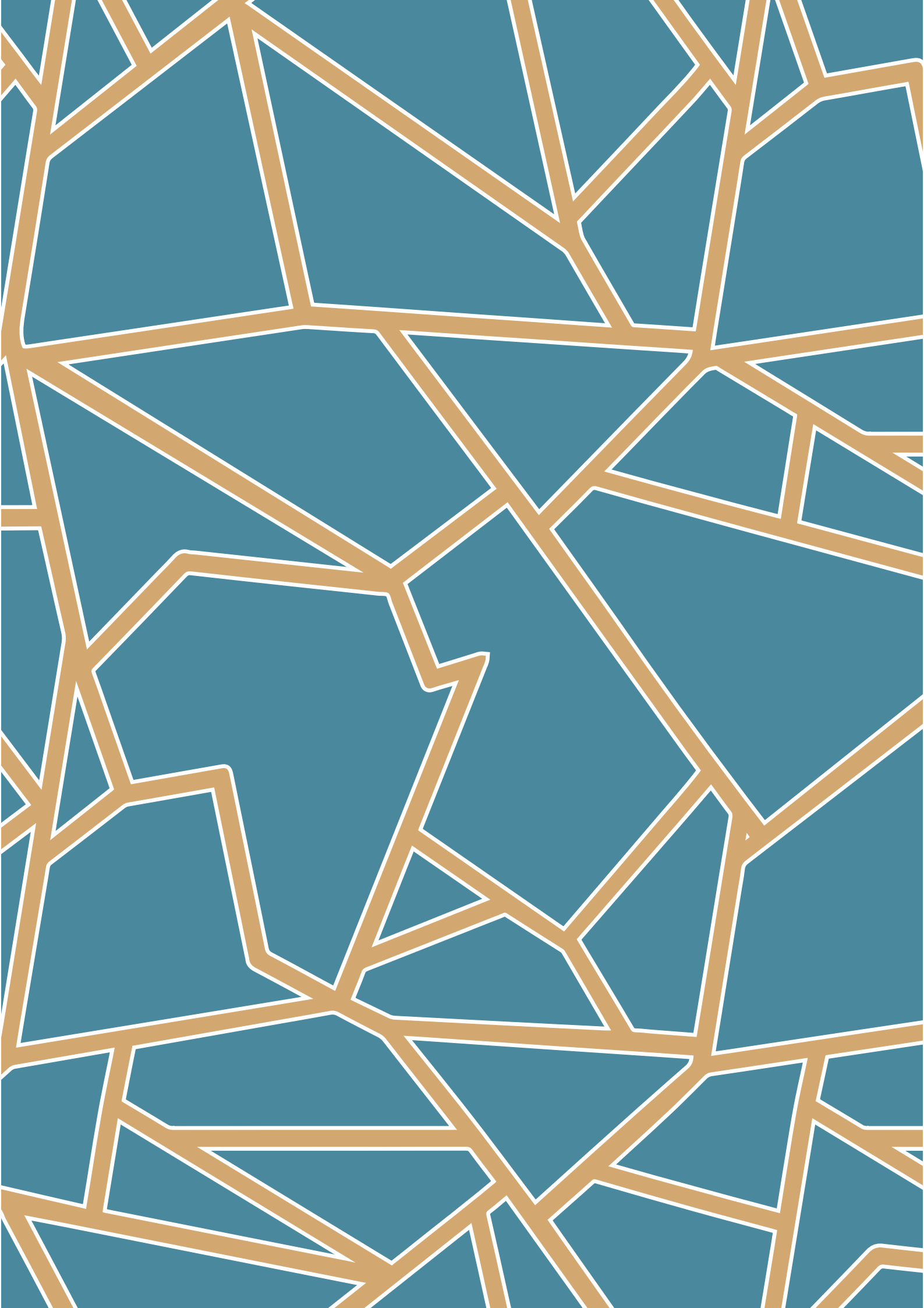
Biomedical engineering equipment technicians workplace in a large hospital in Kenya.

KENYA



Surgeon working in Kenya providing feedback on one of the initial designs of the context-specific electro-surgical unit.

KENYA



APPENDIX A

Computerized maintenance management system (CMMS) for hospitals in low-resource settings - a case in a large national referral hospital in Kenya

Submitted for publication (2019):

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ABSTRACT

Despite its relevance in improving the quality of healthcare systems, healthcare technology management in low- and middle-income countries (LMICs) has received little attention of governments and international organizations. Up-to-date and reliable information concerning medical equipment enables both the hospital management staff and biomedical equipment technicians (BMETs) to carry out their tasks, but also supports procurement decisions. Computerized Maintenance Management Systems (CMMS) have been successfully implemented in high-income countries (HICs) to easily access this type of information. However, modern CMMS software systems require skills and computer specifications that are not available in LMIC hospitals.

The aim of this paper is to present a context-specific CMMS that we co-created together with BMETs of Moi Teaching and Referral hospital (MTRH) in Eldoret, Kenya using Google Drive. We only included the functions that the staff of MTRH will use to reduce the complexity of the software. A combination of Sheets and Forms within Google Drive has proven to be a good starting point for a context-specific CMMS.

INTRODUCTION

The quality of healthcare in low- and middle-income countries (LMICs) is limited by the lack of functional healthcare equipment. A number of barriers that are consistent for various LMICs have been reported, including lack of finances, lack of spare parts, the need for consumables and a lack of trained biomedical equipment technicians (BMETs)(1-3). In an attempt to solve this shortage, large amounts of medical equipment have been donated from high-income countries (HICs) to LMICs, but these donation often come without manuals, spare parts and consumables (4). Inventory and maintenance records in LMICs are mostly paper-based, making them hard to access and analyze. The combination of these types of donations and paper-based record-keeping systems leads to high rates of non-functional equipment. Up-to-date and reliable information concerning medical equipment enables both hospital management and BMETs to carry out their tasks, but also supports procurement decisions (5).

Computerized Maintenance Management Systems (CMMS) have been successfully implemented in HICs to easily access this information. Despite its relevance in improving the quality of healthcare systems, healthcare technology management has received little attention of governments and international organizations in LMICs. Also, modern CMMS software requires skills and computer specifications that are not available in LMIC hospitals. Smartphone based applications can offer user-friendly systems for healthcare technology management, but expensive data rates combined with lack of WiFi and incompatibility with older phones make them unfeasible solutions.

A context-specific CMMS tailored to the needs and capacity of hospitals in LMICS could provide a solution. Therefore, the aim of this project is to co-create CMMS software in a collaboration between biomedical engineering students from the Netherlands and BMETs in a large Kenyan hospital.

METHOD

Authors DD, FG, RvR and GP all spent a period of 10 weeks in the Moi Teaching and Referral Hospital (MTRH) in Eldoret, Kenya between September 2018 and April 2019 to co-create CMMS software together with BMETs in MTRH. The hospital has 2000 beds, one main BMET department, and six sub-departments at different locations within the hospital (e.g., ICU and operating theatres). All BMETs departments have access to a desktop computer that is connected to the internet.

First, the requirements of the software were detailed, to ensure that all functions that the BMETs and management staff required were included. Next, based on these requirements a first version of the software was created in Google Drive. In the third phase an equipment registration system was created and both BMETS and equipment users were trained to use the software.

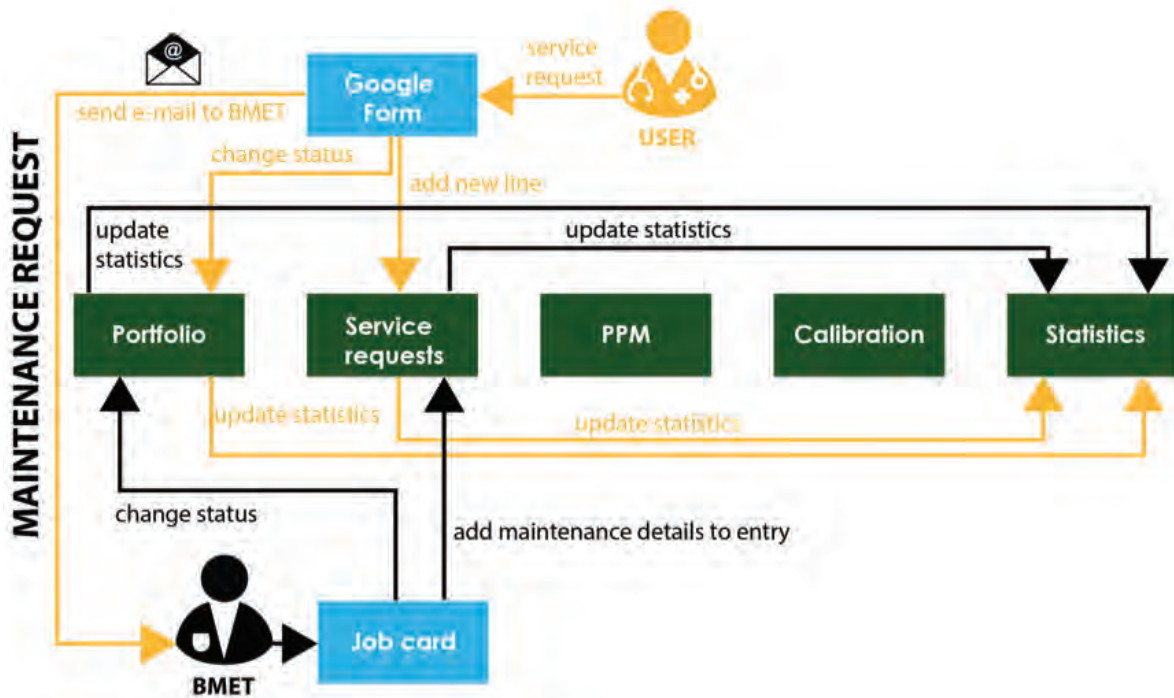
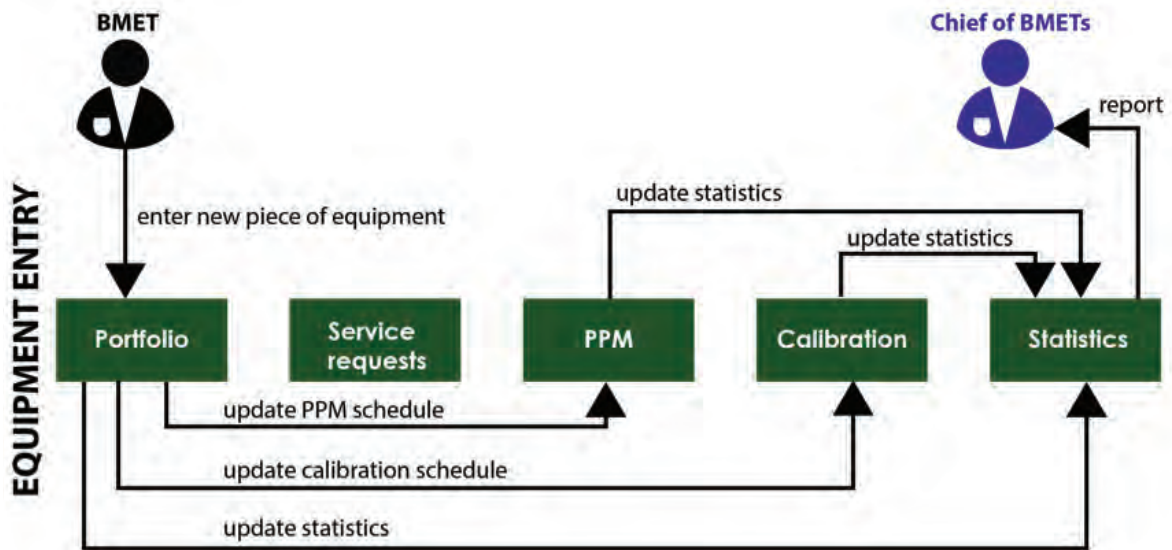


Figure A.1 Workflows of equipment entry (top) and maintenance request (bottom) in Google Drive CMMS. Green blocks represent Google Sheets and blue blocks are Google Forms. BMET = biomedical equipment technician, PPM = planned preventative maintenance

RESULTS

Requirements

The software should be compatible with locally available computers, software and networks. Also, it should match the experience and skills of healthcare staff, BMETs and management staff.

We found that a context-specific CMMS for clinical practice in LMICs should provide the following functionalities

- An inventory of the available equipment
- An inventory of maintenance reports and the ability to analyze these
- Enhancement of easy communication between healthcare staff and the maintenance staff (BMETs)
- Overview of maintenance required per type of equipment to optimize procurement strategies
- Creation of planned preventative maintenance (PPM) and calibration schedules as well as recording its execution

Software development

These requirements were incorporated into five sheets in Google Drive, which are discussed below. These sheets are combined with a general Google Form to request equipment maintenance and Google Forms for each piece of equipment that serve as job cards. Figure A.1 provides an overview of how these elements interact for two workflows; entry of new equipment and maintenance of existing equipment.

Portfolio

An overview of all equipment available within the hospital is provided, including their actual status (in use, need for repair, need for PPM, need for calibration, disposal), their location, the responsible engineer and the links to the maintenance records for specific pieces of equipment. For each piece of equipment there is also a link to a job card based on a Google Form that can be printed as a hard copy file when required.

Maintenance history

An overview of all work done by BMETs (repairs, PPM and calibration) and the costs is stored in the maintenance history. Additionally, the down time per piece of equipment and an overview of the work done by each BMET is provided. A search function is provided to filter the maintenance history for example on, specific types of equipment, departments asking for a service request, and BMETs.

Planned preventive maintenance (PPM) and calibration

The PPM schedule include all medical equipment that is included in the portfolio of the hospital and provides an overview of the tasks per BMET.

Calibration

In this sheet, an overview of tasks per BMET is provided as well as the required elements and results of the calibration for each piece of equipment.

Statistics

Based on data from the Portfolio and Maintenance history an overview of the following information is provided:

- Number of functional equipment
- Number of service requests
- Number of equipment that is obsolete
- Number of equipment waiting for parts, approval on disposal etc.
- Overview of equipment status
- Costs for procurement and repair

Implementation

Both BMETs and equipment users were trained to use the software. Waterproof stickers with a unique code for reference in the software were created. In a 10-month period 1595 pieces of equipment were registered in the software and 322 maintenance requests were made.

CONCLUSION

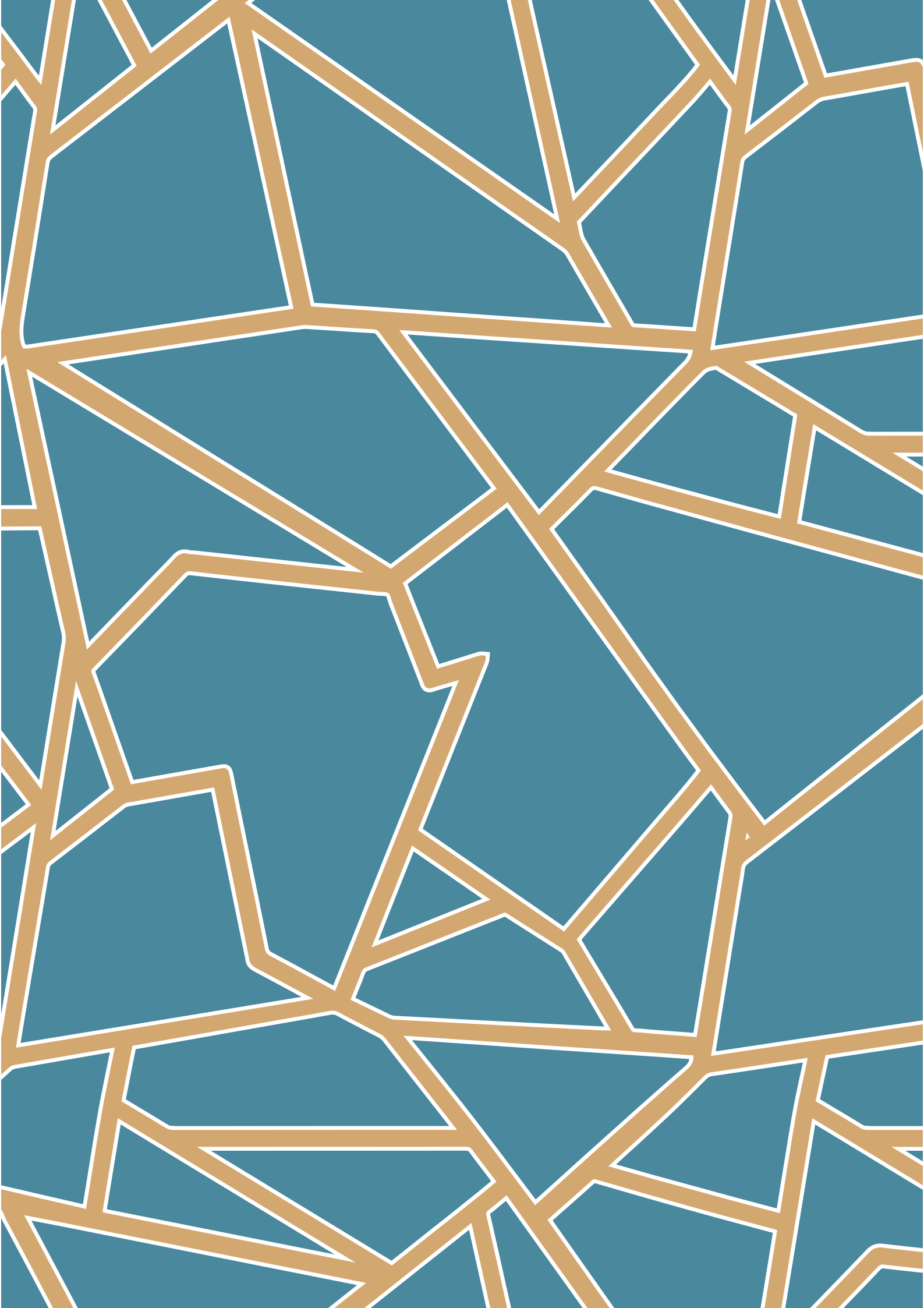
Many hospitals in LMICs do not have access to CMMS software, due to a current mismatch between available commercial or open source software and the resources in these hospitals. The aim of this paper was to present a context-specific CMMS that was co-created by students from Delft University of Technology and BMET staff of MTRH in Google Drive. We only included the functions that the staff of MTRH will use, to reduce the complexity of the software. The software is used regularly by MTRH employees and therefore using Google Drive has proven to be a good starting point for a context-specific CMMS.

One of the requests of the hospitals is to include an option to use text messages to do a service request and to notify BMETs on repair, maintenance or calibration issues. The use of Google Drive has limitations in terms of robustness, privacy and guaranteed functionality with updates, and the hospital has therefore decided to implement the software into their own ICT system. However, this is not an optimal solution for widespread implementation in LMICs. We are currently looking for a commercial partner or NGO to support future developments of the context-specific CMMS to ensure it will be accessible on the long term for other hospitals in the region.

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APPENDIX B

A systematic review and meta-analysis of thermal coagulation compared with cryotherapy to treat precancerous cervical lesions in low- and middle-income countries

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ABSTRACT

Thermal coagulation is gaining popularity for treating cervical intraepithelial neoplasia (CIN) in screening programs in low- and middle-income countries (LMICs) due to unavailability of cryotherapy. The objective of this study is to assess the effectiveness of thermal coagulation for treatment of CIN lesions compared with cryotherapy, with a focus on LMICs.

Papers were identified from previous reviews and electronic literature search in February 2018 with publication date after 2010. Publications with original data evaluating cryotherapy or thermal coagulation with proportion of cure as outcome, assessed by colposcopy, biopsy, cytology, and/or visual inspection with acetic acid (VIA), and minimum 6 months follow-up. Pooled proportions of cure are presented stratified per treatment modality, type of lesion, and region.

Pooled cure proportions for cryotherapy and thermal coagulation, respectively, were 93.8% (95% CI, 88.5-97.7) and 91.4% (95% CI, 84.9-96.4) for CIN 1; 82.6% (95% CI, 77.4-87.3) and 91.6% (95% CI, 88.2-94.5) for CIN 2-3; and 92.8% (95% CI, 85.6-97.7) and 90.1% (95% CI, 87.0-92.8) for VIA-positive lesions. For thermal coagulation of CIN 2-3 lesions in LMICs 82.4% (95% CI, 75.4-88.6).

We could conclude based on these results that both cryotherapy and thermal coagulation are effective treatment modalities for CIN lesions in LMICs.

INTRODUCTION

Thermal coagulation is gaining popularity for treating cervical intraepithelial neoplasia (CIN) in cervical cancer screening programs in low- and middle-income countries (LMICs) due to unavailability of gas and high maintenance for cryotherapy.

Cervical cancer is one of the leading cancers among women worldwide, with an estimated 528 000 new cases and 266 000 deaths each year (1). The burden of cervical cancer disproportionately affects LMICs, where 85% of cases occur (1). Screening programs aim to prevent cervical cancer by timely treatment of precancerous cervical lesions. In resource-constrained settings, the WHO recommends see-and-treat screening programs where women are screened and treated in a single visit with the loop-electrosurgical excision procedure (LEEP) or cryotherapy (2).

The number of LMICs with national screening programs has increased over the years, but coverage remains low (3). There are numerous factors influencing uptake of screening programs, including lack of skilled healthcare workers, lack of equipment, and other health system challenges. An important logistical constraint for the sustainability of see-and-treat programs is maintenance of cryotherapy devices and the lack of availability of refrigerated gas, owing to its high importation and purchase costs and large-size cylinders needed for transport to treatment sites (4,5). This affects the availability of treatment during screening, and thus the success of screen-and-treat programs.

Thermal coagulation is an alternative ablative technique using electricity to destroy the premalignant cervical lesions by heating. The device is small and lightweight, making it practical for use in an outpatient setting with minimal complications. These advantages are particularly important in rural and outreach settings (4,5).

In 2013 and 2014, Sauvaget et al. (6) and Dolman et al. (7) published separate meta-analyses analyzing the efficacy of cryotherapy and thermal coagulation to treat CIN lesions in mainly high-income countries, demonstrating cure proportions of 94.0% (CIN 1), 92.0% (CIN 2), and 85.0% (CIN 3) for cryotherapy, and 96% (CIN 1) and 95% (CIN 2-3) for thermal coagulation. However, data from LMICs included in previous meta-analyses of thermal coagulation were limited to one paper from Singapore and one from India (8,9). To assess the efficacy of thermal coagulation in LMICs, more data from these settings should be reviewed. LMICs differ from high-income countries in terms of healthcare structures and patient population, therefore efficacy may not be equal; for example, HIV-positivity rates are higher in LMICs than in Europe and Northern America, consequently with higher prevalence and recurrence of CIN lesions (2).

The aim of the present systematic review and meta-analysis was to assess the effectiveness of thermal coagulation to treat CIN lesions compared with cryotherapy, with focus on LMICs.

MATERIALS AND METHODS

Papers were identified using two strategies: (1) identified papers from the previous meta-analyses (6,7), which included papers until 2011 and 2013, respectively, were reviewed according to the inclusion and exclusion criteria described below; and (2) an electronic literature search was conducted to identify new relevant papers published after 2010.

Search strategy

An electronic literature search (February 2018) was performed in PubMed, Embase, Web of Science, Cochrane Library, regional databases, and Google Scholar with assistance from a medical librarian. A wide range of definitions are used in the literature, therefore different keywords were included to cover all related publications (supplementary information S1) (S1 seems specific to the search performed in PubMed. Please clarify if these keywords were used across all databases). Papers with a publication date before 2010 were excluded to avoid overlap with the existing meta-analyses. In Google Scholar, no date limitation was used because this database had not been searched in the meta-analyses of Sauvaget et al. (6) and Dolman et al. (7).

Eligibility criteria

Titles and abstracts of all papers were reviewed by three researchers (MF, AR, RO) for relevance and presence of original data. The remaining papers were reviewed by three researchers (AR, RO, MF) and retained if the following criteria were met: cure proportion was the outcome measure and was defined by colposcopy, biopsy, cytology, and/or visual inspection with acetic acid (VIA)/visual inspection with Lugol iodine (VILI). Cytology and pathology are not always available to measure treatment outcome in LMICs; instead, screening is frequently performed by VIA or VILI. As such, papers defining cure proportion with VIA- or VILI technique were considered.

Papers not based on original data or with insufficient data on cure proportion and follow-up were excluded. Follow-up duration had to be 6 months or more after initial treatment, sample size more than 25 patients, and loss of patients attending follow-up not more than 50%. Cryotherapy for CIN 2-3 had to be provided with the double-freeze method, and the treatment procedure had to be performed for no other reason than for treating CIN, nor be provided simultaneously with other treatment. In case of discordant results, consensus was reached among four researchers (AR, RO, MF, JB).

Risk of bias assessment

Study quality was assessed using a component approach (10). Unknown HIV status of screening participants and loss to follow-up of greater than 25% were considered high risk of bias. Studies using cytology or histology to assess outcome were considered low risk of bias compared with VIA-based outcomes. The eligibility criteria described above aimed to eliminate studies with very poor study quality.

Data extraction

For all relevant identified papers, a data extraction sheet was completed in Excel (Microsoft; Richmond, WA, USA). All extracted data were verified independently by two researchers (MF and AM or RO). The following items were collected: author; year of publication; country; study year; study setting; study design; age of patients; case definition (CIN grade or VIA/VILI); case confirmed by biopsy; endocervical involvement; HIV status of patients; treatment provider; treatment procedure (single/double freeze for cryotherapy; temperature, duration, and number of applications for thermal coagulation); number of patients treated; number of patients attending follow-up; number of patients cured; follow-up duration; definition of cure (negative VIA/VILI, cytology, colposcopy, or biopsy); single visit see-and-treat approach; pain; adverse effects; and fertility outcome. Cure rates were defined as a proportion with the number of women with negative VIA/VILI, negative cytology, negative colposcopy, or negative biopsy at a minimum of 6 months' follow-up duration divided by the number of women attending follow-up. Therefore, the terminology "proportion cured" or "cure proportion" was used instead of "cure rate".

Statistical analysis

Pooled cure proportions with 95% confidence intervals were the primary outcome. Cure proportions were pooled in a random effects model. Analyses were stratified by treatment modality (cryotherapy versus thermal coagulation). If both 6- and 12-months' follow-up data were available, 12-months' follow-up data were used as this is the recommended follow-up duration for detection of persistent disease after initial treatment (2). Studies were stratified per CIN grade (CIN 1, CIN 2-3, or VIA/VILI outcome) and region (Europe, North America, South America, Africa, and Asia). In a sensitivity analysis, the effect of follow-up attendance on cure rates was assessed comparing studies with 50%-75% and more than 75% follow-up attendance.

The degree of heterogeneity among studies was assessed by calculating I² statistic values: 0%-25% represented mild heterogeneity, 25%-50% moderate heterogeneity, and more than 50% large heterogeneity. Publication bias was assessed by means of visual assessment plotting cure proportions against sample size. Because the number of studies was small, testing on publication bias was not indicated. Forest plots were created using STATA version 14.0 (Stata Corp LLP, College Station, TX, USA).

RESULTS

Papers identified via literature search

The electronic search yielded a total of 445 unique references from PubMed (n=154), Embase (n=111), Web of Science (n=21), Cochrane Library (n=0), regional databases (n=129), and Google Scholar (n=30). An additional search in clinical trial registers and journal databases yielded no additional publications.

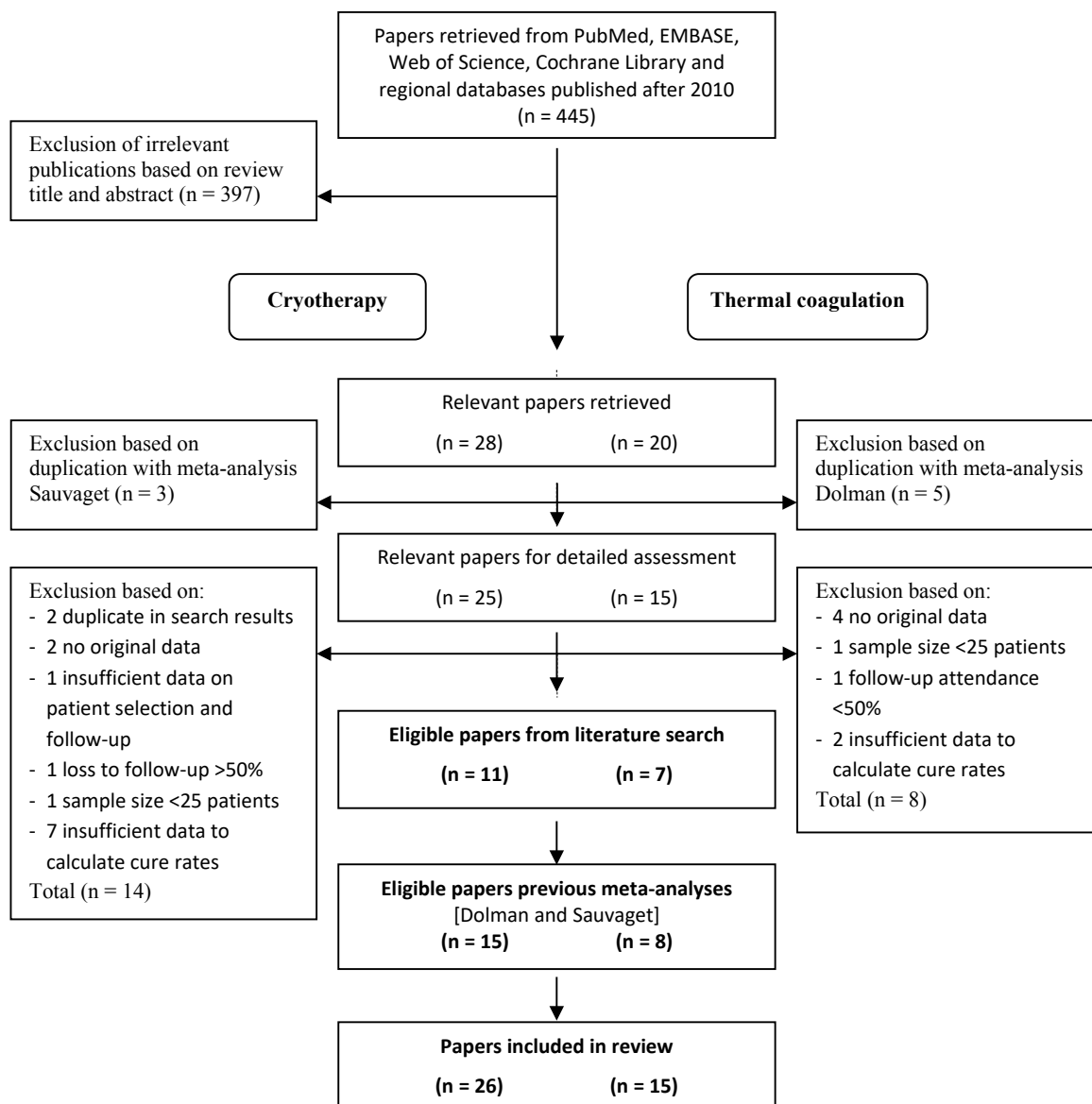


Figure 1: Flowchart summarizing literature search and inclusion of studies

After reviewing the title and abstract of all papers, 28 relevant papers were identified on cryotherapy and 16 on thermal coagulation. After full-text review, 11 papers on cryotherapy and seven on thermal coagulation were eligible for inclusion.

Since publication of the meta-analysis by Sauvaget et al. (6), no new papers on cryotherapy from North America or Europe have been published, therefore these regions were excluded from further analysis for cryotherapy.

Papers from previous meta-analyses

Sauvaget et al. (6) included 20 studies from Asia, Africa, or South America in their meta-analysis on cryotherapy. In the present review, five of these studies were excluded owing to sample size of less than 25 patients, recurrence not specified per CIN grade, single-freeze technique for CIN 2-3 lesions, or no original data (11-15). The remaining 15 studies conducted in Africa (n=5), Asia (n=7), and South America (n=3) were included in the present review.

<i>Table 2: Summary of included studies</i>	Cryotherapy	Thermal Coagulation
Nr of studies, total	26	15
Nr of studies from LMIC (n,%)	26 (100)	6 (40)
Nr of studies with single-visit (n,%)	9 (35)	6 (40)
Nr of studies with data on HIV-positive patients (n,%)	6 (23)	3 (20)
Nr of patients with follow-up data	12915	4501
• CIN 1 (n, %)	9815 (76.0)	788 (17.5)
• CIN 2-3 (n, %)	955 (7.4)	3302 (73.4)
• VIA-positive (n, %)	2145 (16.6)	411 (9.1)
Follow-up attendance (median %, range)	86.7 (55.3- 100)	96.2 (52.3- 100)
• CIN 1	89.0 (55.3- 100)	100.0 (56.4- 100)
• CIN 2-3	86.7 (65.4- 100)	98.0 (52.3- 100)
• VIA-positive	76.6 (68.1- 92.1)	64.5 (61.4- 67.6)
Follow-up duration (n, %)		
• 6 months	5 (19.2)	4 (26.7)
• 12 months	20 (76.9)	11 (73.3)
• Missing	1 (3.8)	-

Dolman et al. (7) included 13 studies in their meta-analysis on thermal coagulation. For the present review, five of these studies were excluded owing to follow-up duration of less than 6 months, insufficient data to calculate cure rates, and cure rates not differentiated per CIN grade (16-20). The remaining eight studies conducted in Asia (n=2), North America (n=1), and Europe (n=5) were included in the present review.

Figure 1 provides an overview of the included papers from the literature search and previous meta-analyses. Table 1 provides the details and references of the 41 included papers (8,9,21-59). An overview of the excluded studies is provided as supplementary information S2 (11-20).

Data from included papers

In total, data from 26 studies of 14 355 patients treated with cryotherapy and 15 studies of 4864 patients treated with thermal coagulation were included. Most papers were published in the last 10 years and described treatment by cryotherapy. Table 2 provides a summary of the papers. The distribution of patients with CIN 1, CIN 2-3, and VIA-positive lesions between studies on cryotherapy and thermal coagulation was unequal. Most papers on cryotherapy treated patients with CIN 1 lesions, whereas most papers on thermal coagulation treated patients with CIN 2-3 lesions. Follow-up attendance was similar, however, studies using the VIA-approach had lower follow-up attendance compared with studies with biopsy- or cytology-based follow-up methods.

3.4. Risk of bias assessment

Of the 26 included papers on cryotherapy, 6 (23%) provided data on the HIV status of participants. Twenty (77%) papers reported a follow-up attendance of more than 75%. Tai et al. (46) (Add this reference chronologically to the list and renumber accordingly) defined cure at follow-up as absence of CIN 3 lesions and did not include recurrence or persistence of CIN 1 and CIN 2 lesions. Of the 15 included papers on thermal coagulation, HIV status was reported for 3 (20%) papers. Eleven (73%) papers had a follow-up attendance of more than 75%. Visual assessment of cure rates in order of sample size did not suggest publication bias.

3.5. Efficacy of treating CIN lesions

Figure 2 and supplementary information S3 and S4 demonstrate the pooled cure proportions for cryotherapy in LMICs: 93.8% (95% CI, 88.5-97.7) for CIN 1, 82.6% (95% CI, 77.4-87.3) for CIN 2-3, and 92.8% (95% CI, 85.6-97.7) for VIA-positive lesions. Figure 3 and supplementary information S5 and S6 show the pooled cure proportions for thermal coagulation: 91.4% (95% CI, 84.9-96.4) for CIN 1, 91.6% (95% CI, 88.2-94.5) for CIN 2-3, and 90.1% (95% CI, 87.0-92.8) for VIA-positive lesions. The pooled cure proportion for thermal coagulation in LMICs only was 82.4% (95% CI, 75.4-88.6) for CIN 2-3 lesions (supplementary information S7).

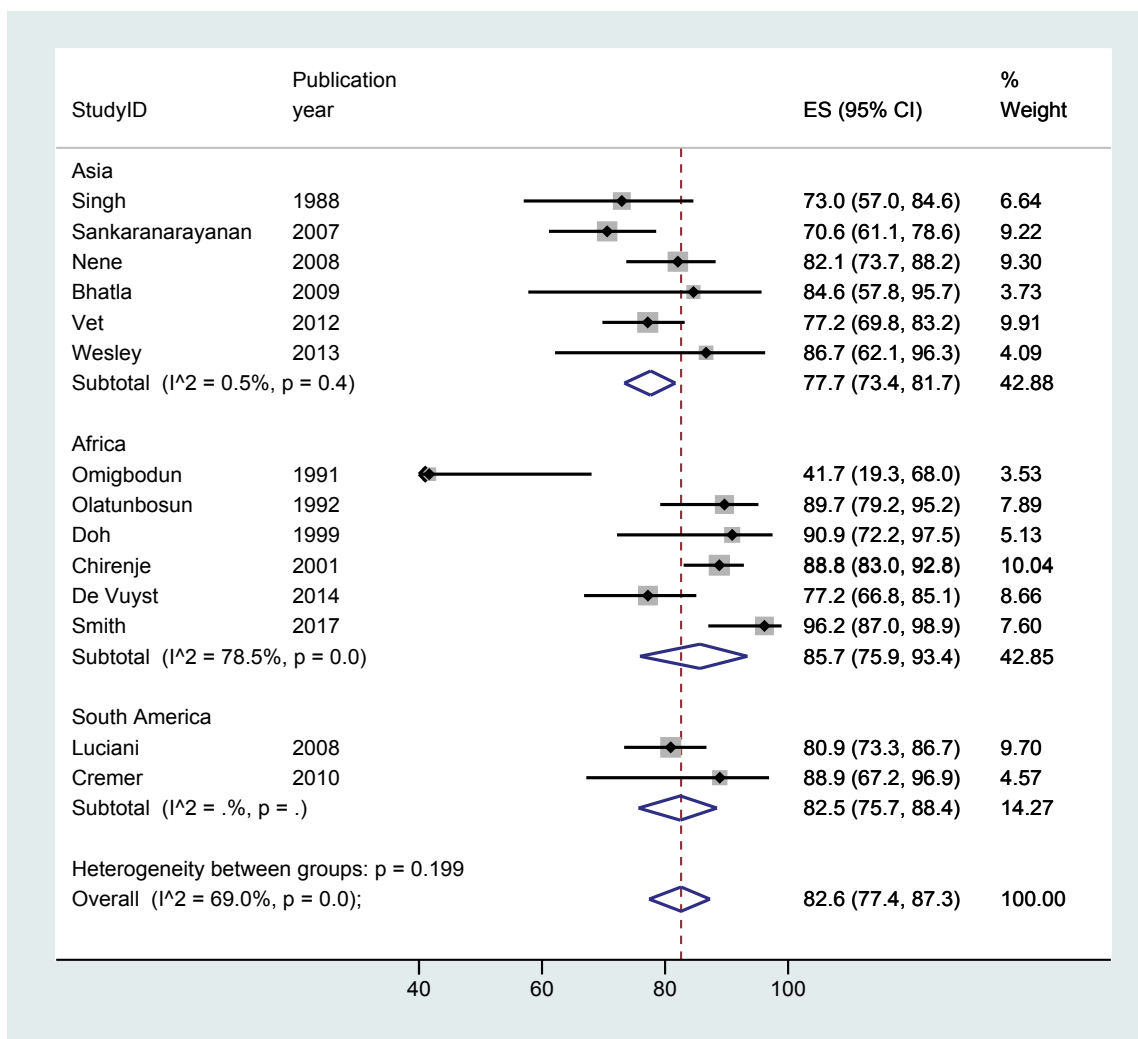


Figure 2: Cure proportions for CIN 2-3 lesions treated with cryotherapy grouped by region.

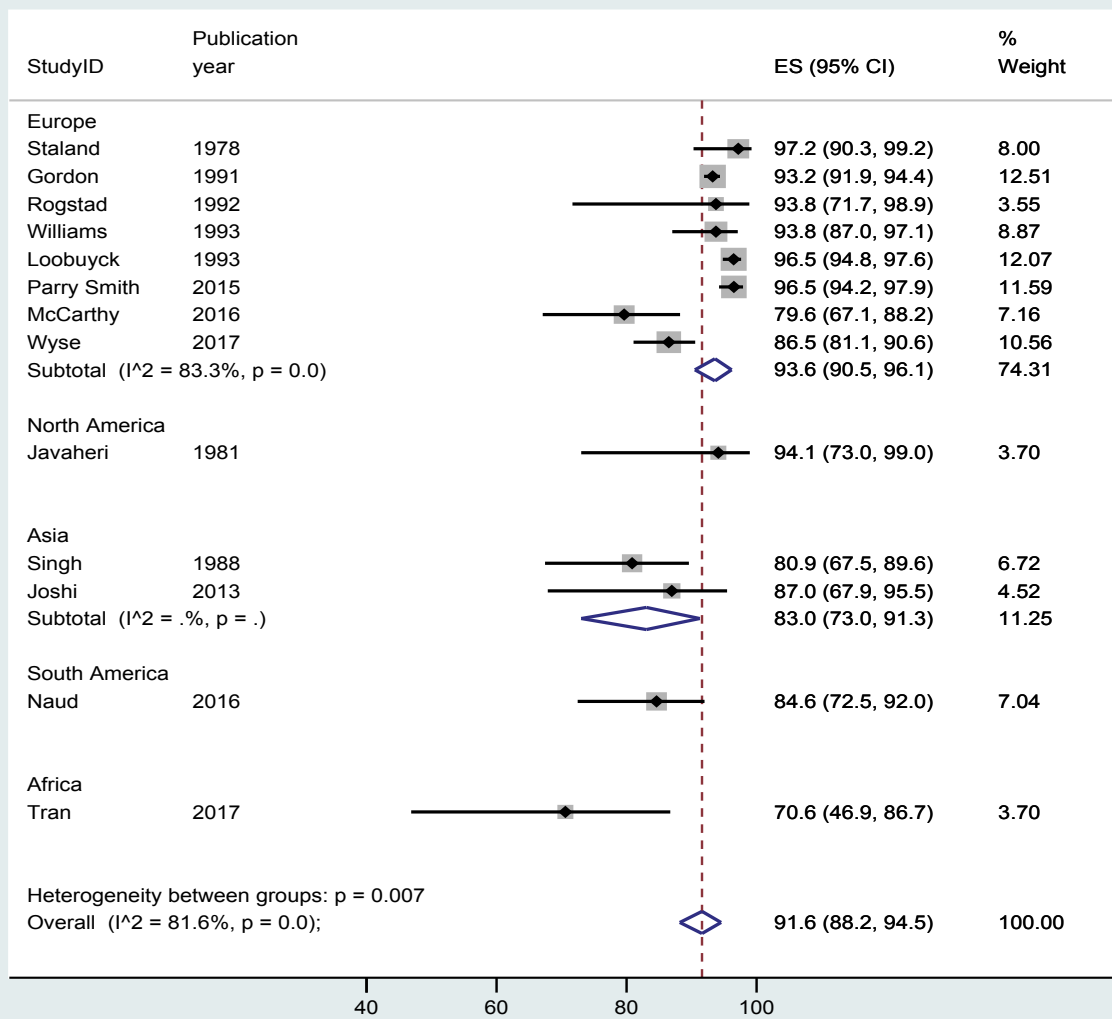


Figure 3: Cure proportions for CIN 2-3 lesions treated with thermal coagulation grouped by region

Sensitivity analysis showed higher proportions of cure for cryotherapy papers with follow-up attendance of more than 75% for both CIN 1 and CIN 2-3 lesions (supplementary information S8).

HIV status

For both treatment modalities, only two studies published cure proportions for HIV-positive patients specifically. Supplementary information S9 presents all studies with cure rates for HIV-positive patients. Data on outcome of HIV-positive patients specifically was too limited to allow statistical testing.

Treatment technique and provider

In contrast to cryotherapy studies conducted in the 1970s and 1980s that make up most of the papers in the review by Sauvaget et al. (6), almost all cryotherapy papers used the internationally recommended double-freeze technique. Three papers did not specify the

treatment procedure.

For thermal coagulation, treatment procedures varied with temperatures ranging from 100-120°C and treatment duration from 20-60 seconds. All studies used repeated treatment cycles with a maximum of four cycles per patient. Due to the heterogeneity in treatment procedures and patient populations, there were insufficient data for statistical testing of the effect of treatment protocol on cure rate.

In 12 out of 15 papers on thermal coagulation, treatment was provided by physicians. Cryotherapy was more frequently provided by nurses (n=5) or by nurses and physicians (n=4).

Pain, adverse effects, and fertility

Pain during and after treatment was discussed in seven papers (47%) on thermal coagulation. Three papers (38%) reported mild cramps or pain in 21%, 25%, and 79% of patients. In contrast, Rogstad et al. (50) stated treatment is painful without further details. Parry-Smith et al. (53) reported routine use of local anesthesia for thermal coagulation. Naud et al. (56) reported a heat sensation in the vagina for 1 in 4 patients during treatment.

Twelve papers (46%) on cryotherapy reported pain, varying from 1.0%-30.0% of patients complaining of mild pain and cramps during treatment to less than 1% experiencing severe pain or cramps. Vet et al. (37) reported routine use of oral analgesics after cryotherapy in Indonesia.

Adverse reactions and complications were reported inconsistently and rarely for both treatment modalities. Supplementary information S10 shows the adverse reactions reported in 6 (40%) thermal coagulation and 15 (58%) cryotherapy papers. Fertility outcomes and pregnancy outcomes were also rarely reported. For each treatment modality, three papers mentioned subsequent pregnancies in treated patients, and three of these papers reported normal outcomes.

DISCUSSION

Main findings

The present review aimed to compare the effectiveness of thermal coagulation versus cryotherapy with focus on LMICs because the sustainability of cervical cancer screening programs in LMICs is impaired by practical and technical challenges with cryotherapy. According to our findings, both cryotherapy and thermal coagulation are effective treatments for CIN lesions based on cure proportions, ranging from 90.1% to 92.8% for VIA-positive lesions, 91.4% to 93.8% for CIN 1, and 82.6% to 91.6% for CIN 2-3 lesions.

Our findings suggest a difference between the treatment effectiveness for CIN 2-3 lesions in favour of thermal coagulation. However, when comparing the effectiveness of both treatment modalities in LMICs only, the proportion of cure was similar: 82.6% for cryotherapy and 82.4% for thermal coagulation.

Cure proportions in HIV-positive patients did not suggest a higher risk of treatment failure compared with the overall target population, but data on this topic were limited and previous studies have shown increased risk of treatment failure (57,60). Patients' experiences of pain, adverse effects, and obstetric outcomes were inconsistently reported. For both treatment modalities, patient acceptability appeared to be good without routine use of local anaesthesia, and both treatment modalities were reportedly safe. Treatment modalities should be selected based on local available resources in LMICs to achieve high uptake of direct treatment in a single-visit approach.

Interpretation

The cure proportions were comparable to previous reviews of cryotherapy (94.0% for CIN 1, 92.0% for CIN 2, 85.0% for CIN 3 lesions, and 89.9%-91.9% for all CIN grades), although they were slightly lower compared with a previous meta-analysis of thermal coagulation (96.0% for CIN 1 and 95.0% for CIN 2-3 lesions) (6,7,61). The lower proportions of cure found for thermal coagulation can be explained by an increased number of papers from LMICs in the present review (7). A retrospective analysis of thermal coagulation in Bangladesh, Brazil, and India by Nessa et al. (62) found cure proportions ranging from 83% to 88% for CIN 1-3 lesions. This paper was not included in the present review owing to more than 50% loss to follow-up.

Furthermore, we employed a different strategy to assess study quality and used stricter inclusion criteria, excluding studies with follow-up duration of less than 6 months and sample size smaller than 25 patients. It is unlikely though that the stricter inclusion criteria explained the difference in pooled cure proportions. The studies excluded from the previous meta-analysis, Hussein et al. (17) and de Cristofaro et al. (18), represented 53 patients with CIN 1 and 128 patients with CIN 3 lesions.

In contrast to previous reviews, we included outcomes of VIA-based programs. The presented pooled proportion of cure for VIA-based programs might be an overestimation of the actual proportion of cure at follow-up due to over-diagnosis of precancerous lesions with VIA-assessment and thus overtreatment of patients without cytological- or histological-proven CIN lesions (34,63). Most single-visit programs in LMICs are based on VIA screening. The follow-up attendance for VIA-based programs included in this review was 65%-77% and is likely even lower in programs not involved in research. The cure proportions reported underline the importance of follow-up attendance to detect persistent or recurrent lesions as early as possible.

Across the studies, reported cure proportions in Africa, Asia, and South America were low compared with Europe and North America. Most studies in Europe and North America are conducted in tertiary hospitals, with physicians and specialists providing diagnosis and treatment in well-controlled screening programs, where bigger lesions are frequently treated with ablative techniques such as LEEP. Another explanation is the higher prevalence of HIV infection in parts of Africa, Asia, and South America. Most studies did not detail the

HIV-positivity rate of their patients, nor did they provide details on their proportion of cure. This is a shortcoming in the currently available data and an important field of research because HIV-positive patients are at increased risk of cervical cancer and treatment failure (2,60,61,42). Besides HIV infection, HPV infection is more prevalent in LMICs (64). In Sub-Saharan Africa and South America, the prevalence of HPV in women with normal cytological findings was 24% and 16.1%, respectively, compared with 14.2% in Europe. The higher prevalence of HPV in the general population, in Sub-Saharan Africa especially, might lead to a lower HPV clearance and higher reinfection rate after treatment (33,64,65).

The present review included papers with cure proportion as the primary outcome and is not representative of all literature published on pain, adverse effects, fertility outcomes, and obstetric outcomes. A systematic review of the adverse effects and benefits of cryotherapy found that complications such as major bleeding and organ damage are extremely rare ($RR < 0.05$) but had low-quality evidence (66). There are currently no reviews on the adverse effects of thermal coagulation. Viviano et al. (67) reported, in a study in Cameroon, a mean visual analogue score of 3.0 ± 1.6 during treatment.

A Cochrane review (68) found an increased risk of premature delivery in women with CIN lesions, with a lower relative risk for ablative techniques ($RR\ 1.35$; 95% CI, 1.20-1.52) compared with excisional techniques ($RR\ 1.87$; 95% CI, 1.64-2.12). However, evidence is of low quality and mainly based on retrospective studies. Ongoing documentation of adverse effects and pregnancy outcomes is important but difficult to achieve in practice.

Limitations

We attempted to identify all papers published on cryotherapy and thermal coagulation for treatment of CIN lesions, with focus on LMICs. However, there are limitations to the data and findings presented. Papers published before 2010 on cryotherapy in LMICs might have been missed because Sauvaget et al. (6) used less inclusive keywords in their literature search (“cervical intraepithelial neoplasia,” “CIN,” and “cryotherapy”) and regional databases were not included. We believe this difference will be minimal, based on our literature search with 129 unique references identified in regional databases, of which only one abstract was found to be relevant and the full article did not meet the inclusion criteria. Despite recent publications on thermal coagulation from Asia, Africa, and South America, most studies have been conducted in Europe and North America. Data on cryotherapy from LMICs exceed that of thermal coagulation, both in number of studies and sample size.

The studies show great heterogeneity in terms of sample size, treatment protocol, and follow-up duration. Additionally, not all papers detailed the achieved follow-up duration, loss to follow-up, or included only patients attending follow-up visits in their data. This might lead to misinterpretation of cure proportions. Sensitivity analysis found higher cure proportions for cryotherapy papers with greater than 75% follow-up attendance, demonstrating the impact of follow-up on reported cure proportions. We found few

studies with nonphysician clinicians as treatment providers. It is important that more data are collected from programs with nonphysician clinicians because this will be the reality for most women screened in low-resource settings.

Future recommendations

In future, more HPV-based screening programs will be implemented in LMICs, with higher treatment rates expected due to higher sensitivity of HPV testing compared with VIA/VILI and cytology (63). This approach will yield greater health benefits than VIA-based programs in low-resource settings where cervical cancer incidence is high (69). A widely available, acceptable, and effective treatment method is necessary. Thermal coagulation is a promising alternative to cryotherapy with comparable proportions of cure, which will enhance the sustainability of screening programs in LMICs and make a significant contribution to the fight against the burden of cervical cancer worldwide. We recommend that more studies including randomized controlled trials are conducted to compare thermal coagulation and cryotherapy in LMICs to assess efficacy, safety, and provider and patient experience. For practical implications, future studies should focus on the risk of treatment failure in HIV-positive patients for both treatment modalities, the effect of different treatment protocols for thermal coagulation on proportions of cure, and report pain and adverse effects consistently.

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Table 1.
Studies included in this meta-analysis for cryotherapy and thermal coagulation.

Author and reference ^a	Publication year	Country	Study year	Setting	Study design	Single visit approach	Age of participants, y	Case definition	Confirmed by biopsy	HIV-status known	Treatment provider	Duration of follow-up	Number of women treated	Cure definition
Cryotherapy														
Singh [8]	1988	Singapore	1983–1988	Hospital (II)	RCT	No	Mean 35 (20–50)	CIN 1–3	Yes	No	Colposcopist	3 months–4 years (79.4% for >1 year)	68	Negative colposcopy, cytology and biopsy
Omigbodun [21]	1991	Nigeria	1984–1988	Hospital (II)	Clinical report	No	Mean 35.4/38.8 (SD 10.0/10.2)	CIN 1–2	Yes	No	Gynecologist	Median 15 months (3–48)	33	Negative cytology
Olatubosun [22]	1992	Nigeria	1982–1984	Hospital (II)	Clinical report	No	Mean 28 (18–56)	CIN 1–3	Yes	No	Gynecologist	12 months	70	No evidence of CIN
Doh [23]	1999	Cameroun	1994–1996	Hospital (II)	Clinical report	No	20 to >60 (88.3% 30–49)	CIN 1–3	Yes	No	Gynecologist	12 months or more	100	No persistent CIN
Chirenje [24]	2001	Zimbabwe	1997–1998	Hospital (II)	RCT	No	Mean 32.5 (SD 6.1)	HSIL	Yes	No	Gynecologist	12 months	161	Negative colposcopy, cytology or biopsy
Chirenje [25]	2003	Zimbabwe	1997–1998	Hospital (II)	RCT	No	Mean 31 (SD 5.2)	CIN 2–3	Yes	Yes	Gynecologist	12 months	61	Negative cytology
Sankaranarayanan [26]	2007	India	2000–2003	Hospital (I)	Clinical report	Yes	30–59	CIN 1–3	Yes	No	Nurse	12 months	1026	Absence of CIN
Aerissens [27]	2008	Nicaragua	2001–2005	Hospital (I)	Clinical report	No	Mean 33.6	CIN 1	Yes	No	Gynecologist	Mean 622 days (14–1240 days)	55	Negative colposcopy, cytology or biopsy
Chumworathayi [28]	2008	Thailand	2001	Hospital (II)	Clinical report	Yes	Mean 38 (31–46)	VIA+	No	No	Nurse	12 months	648	Negative VIA, colposcopy and biopsy
Luciani [29]	2008	Peru	2000–2004	Hospital (I)	Clinical report	Yes	25–49 (84% 25–39)	CIN 1–3	Yes	No	Primary care physician	12 months	472	Negative VIA and cytology, if found positive cured if negative biopsy
Nene [30]	2008	India	Not documented	Hospital (I)	RCT	No	30–59	CIN 1–3	Yes	No	Nurse	Mean 30 months (8–36 or more)	574	Absence of CIN
Bhatla [31]	2009	India	2004–2005	Hospital (I)	Clinical report	No	25–59 (82.7% 25–44)	CIN 1–3	Yes	No	Physician	12 months	31	No evidence of disease (no details given)
Poomtavorn [32]	2009	Thailand	2004–2008	Hospital (II)	Clinical report	No	Mean 36.2 (SD 9.4)	CIN 1	Yes	No	Gynecologist	12 months	26	Absence of CIN
Chumworathayi [33]	2010	Thailand	2007–2009	Hospital (II)	RCT	No	Mean 42 (SD 7.86)	LSIL, HPV+ and >30	Yes	Yes	Not documented	6 and 12 months	29	Negative colposcopy, cytology and biopsy
Cremner [34]	2010	Salvador	2006–2007	Hospital (I)	Clinical report	No	Mean 34.1 (SD 9.7)	VIA+	Yes	No	Gynecologist	Up to 3 years	18	Absence of CIN 2
Denny [35]	2010	South Africa	2000–2002	Hospital (I)	Clinical report	Yes	Mean 43.3 (35–65)	HPV+ and VIA+	No	No	Nurse	36 months	4388	Absence of CIN 2
Phongsavan [36]	2011	Laos	2009–2010	Hospital (II)	Clinical report	Yes	Mean 34 (25–45)	VIA+	No	No	Nurse and Gynecologist	12 months	75	Absence of VIA+
Vet [37]	2012	Indonesia	2004–2006	Mobile clinics	Clinical report	Yes	Mean 37.5 (12–70)	VIA+	Yes	No	Nurse and physician	6 months	918	Absence of VIA and normal cytology
Levinson [38]	2013	Peru	2009	Health clinics	Clinical report	No	Mean 36 and 37 (in 2 regions)	hrHPV+ and VIA+	No	No	Not documented	6 months	57	Negative colposcopy, biopsy and HPV test
Wesley [39]	2013	India	2001–2008	Regional cancer center	Clinical report	No	57.8% <40	CIN 1–3	Yes	No	Nurse and physician	12 months or more	211	Absence of CIN

Chigbu [40]	2014	Nigeria	2011–2012	Not documented	Clinical report	Yes	Mean 36 (SD 2.3)	VIA+	No	No	Gynecologist	6 months	205	Absence of VIA+
Starks [41]	2014	Mexico	2008–2009	HPV-self screening	Clinical report	Not documented	Median 38.8 (30–53)	hr-HPV+ and VIA+	Yes	No	Not documented	6 months	291	Absence of CIN
De Vuyst [42]	2014	Kenya	2009	Hospital	Clinical report	No	Median 41 (IQR 35–45)	CIN 2–3	Yes	Yes	Not documented	6 months	101	Absence of CIN 2–3
Chigbu [43]	2017	Nigeria	2011–2014	Health clinics (rural)	Clinical report	Yes	Mean 43.6 (SD 6.3)	VIA+	Yes	No	Nurse and physician	12 months	64	Absence of VIA+ and CIN
Firnhaber [44]	2017	South Africa	2012–2015	Hospital HIV-clinic	RCT	Yes	Mean 37.2 (32.7–43.5)	CIN 1 and HIV+	Yes	Yes	Nurse	12 months	112	Absence of CIN 2–3
Smith [45]	2017	South Africa	2010–2014	Hospital (III)	RCT	No	Mean 37.5 (26–52)	CIN 2–3 and HIV+	Yes	Yes	Not documented	6 and 12 months	80	Absence of CIN 2–3
Tai [46]	2017	Taiwan	2004–2007	National registry	Retrospective cohort study	Not documented	Not documented	LSIL	No	No	Not documented	35574 person years	7352	Absence of CIN 3

Author and reference ^b	Publication year	Country	Study year	Setting	Study design	Single visit approach	Age of participants, y	Case definition	Confirmed by biopsy	HIV-status known	Treatment provider	Duration of follow-up	Number of women treated	Cure definition
Thermal coagulation														
Staland [47]	1978	Sweden	1971-?	Hospital (III)	Clinical report	No	Not documented	CIN 2-3	No	No	Gynecologist	80% >2 years	71	Negative colposcopy and cytology
Javaheri [48]	1981	USA	1974-1979	Hospital (III)	Clinical report	No	15 to >50 (>80% 20-40)	CIN 1-2	Yes	No	Physician	1-5 years	43	Absence of CIN (defined by cytology)
Singh [8]	1988	Singapore	1983-1988	Hospital (III)	RCT	No	Mean 35.2 (SD 7.2)	CIN 1-3	Yes	No	Colposcopist	3 months-4 years (79.4% for >1 year)	89	Negative colposcopy, cytology and biopsy
Gordon [49]	1991	UK	1975-1989	Hospital (III)	Clinical report	Yes	15 to >50 (75% <35)	CIN 3	Yes	No	Colposcopist	4 months (98%) - 10 years (87%)	1661	Negative cytology
Roestad [50]	1992	UK	1988-1989	Hospital (III)	Clinical report	No	Not documented	CIN 1-2	Yes	No	Physician	6-12 months	60	Negative cytology
Loobuyck [51]	1993	UK	1978-1990	Hospital (III)	Clinical report	Yes	Not documented	CIN 1-2	Yes	No	Colposcopist	6 months-11 years	1204	Negative cytology
Williams [52]	1993	UK	1988-1989	Hospital (III)	Clinical report	No	Mean 24.5 (range 16-46)	CIN 2-3	Yes	No	Physician	12-18 months	125	Negative colposcopy and cytology
Joshi [9]	2013	India	2012-2013	Screening clinic	Clinical report	Yes	21-57 (mean not given)	CIN 1-3	Yes	Yes	Physician	6-9 months	83	No evidence of disease (not detailed)
Parry-Smith [53]	2015	UK	2001-2011	Hospital (non-university)	Clinical report	No	Median 27 (18-57)	CIN 1-3	Yes	No	Colposcopist	1 year (median 406 days)	614	Negative cytology
Campbell [54]	2016	Malawi	2013-2015	Rural hospital and health centers	Clinical report	Yes	16-86 (mean not given)	VIA+	No	Yes	Non-physician	3-6 months	381	Absence of VIA+
McCarthy [55]	2016	Ireland	2009-2010	Hospital (III)	Clinical report	No	Mean 29.2 (SD 5.5)	CIN 1-3	Yes	No	Physician	3 years	93	Negative cytology
Naud [56]	2016	Brazil	2012-2013	Hospital (III)	Clinical report	No	Median 31 (27-40)	CIN 2-3	Yes	No	Physician	1 year	52	Negative VIA and cytology or colposcopy or biopsy
Oga [57]	2016	Nigeria	2010-2014	Hospital (different levels)	Clinical report	Yes	Mean 34.9 (SD 7.4)	VIA+ or VILI+	No	Yes	Nurse	6 months (median 531 days)	262	Negative VIA or VILI
Tran [58]	2017	Cameroon	2015	Mobile clinics	Clinical report	Yes	Mean 38.7 (SD 5.3)	HPV+ and VIA+	Yes	No	Not documented	6-12 months (median 8.4 and 14.5 months)	121	Absence of HSIL at cytology or CIN 2 at biopsy
Wyse [59]	2017	Ireland	2014-2015	Hospital (non-university)	Clinical report	No	Mean 31 (SD 6.37)	CIN 1-3	Yes	No	Colposcopist	6 months	200	Negative cytology

Abbreviations: RCT, randomized controlled trial; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; HPV, human papillomavirus (hr=high risk); VIA, visual inspection with acetic acid; VILI, visual inspection with Lugol iodine; SD, standard deviation; CIN, cervical intraepithelial neoplasia.

^aChirenje et al. (2003) [25] is used for data specific on HIV-positive patients; the paper describes the same population as Chirenje et al. (2001) [24].

SUPPLEMENTARY INFORMATION

Supplementary information S1. Keywords used in the PubMed literature search. In other databases the same keywords were used, commands were adjusted to the specific database.

((("Cervical Intraepithelial Neoplasia"[Mesh] OR "cervical intraepithelial neoplasia"[tw] OR "cervical intraepithelial"[tw] OR "cervical intra-epithelial"[tw] OR "CIN"[tw] OR ((("Uterine Cervical Neoplasms"[Mesh] OR "cervical malignancies"[tw] OR "cervical malignancy"[tw] OR "cervical neoplasia"[tw] OR "cervical neoplasm"[tw] OR "cervical neoplasms"[tw] OR "cervical tumor"[tw] OR "cervical tumour"[tw] OR "cervical tumors"[tw] OR "cervical tumours"[tw] OR "Cervical Neoplasms"[tw] OR "Cervical Neoplasm"[tw] OR "Cervical Neoplasia"[tw] OR "cervical cancer"[tw] OR "cervical carcinoma"[tw] OR "cervical cancers"[tw] OR "cervical carcinomas"[tw])) AND ("Intraepithelial"[tw] OR "Intra-epithelial"[tw] OR intraepitheli*[tw] OR Intra-epitheli*[tw])))

AND

("thermocoagulation"[tw] OR thermocoagulat*[tw] OR thermo-coagulat*[tw] OR "thermal coagulation"[tw] OR thermal coagulat*[tw] OR "thermal ablation"[tw] OR thermal ablat*[tw] OR "Electrocoagulation"[Mesh:noexp] OR "electrocoagulation"[tw] OR electrocoagulat*[tw] OR electro-coagulat*[tw] OR "thermosurgery"[tw] OR thermosurg*[tw] OR "electrocautery"[tw] OR electrocauter*[tw] OR "semm"[tw] OR "cold coagulation"[tw] OR cold coagulati*[tw] OR "ablative"[tw]

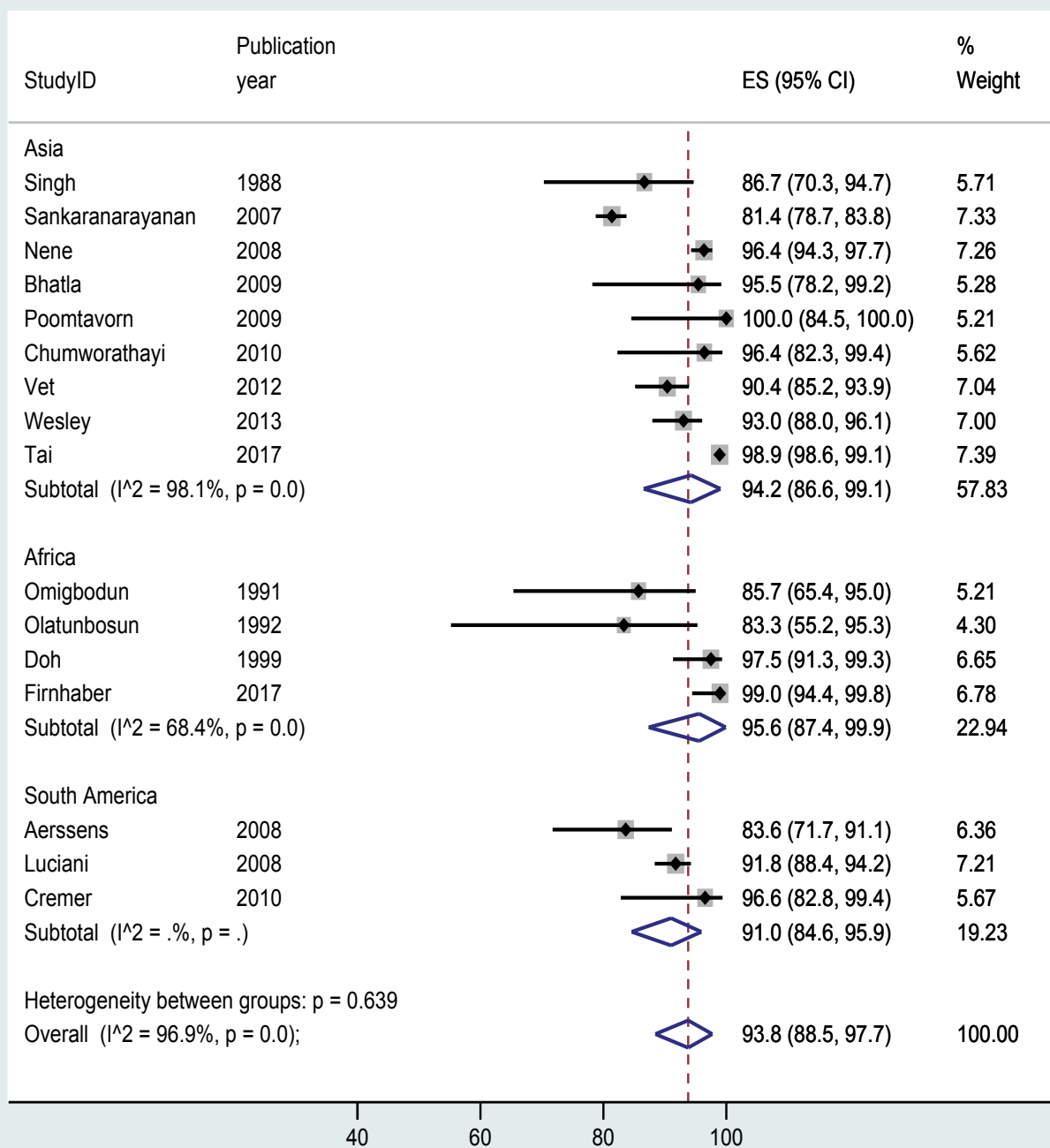
OR

"Cryotherapy"[Mesh] OR "cryotherapy"[tw] OR cryotherap*[tw] OR "cold therapy"[tw] OR "Cryosurgery"[Mesh] OR "cryosurgery"[tw] OR cryosurg*[tw])

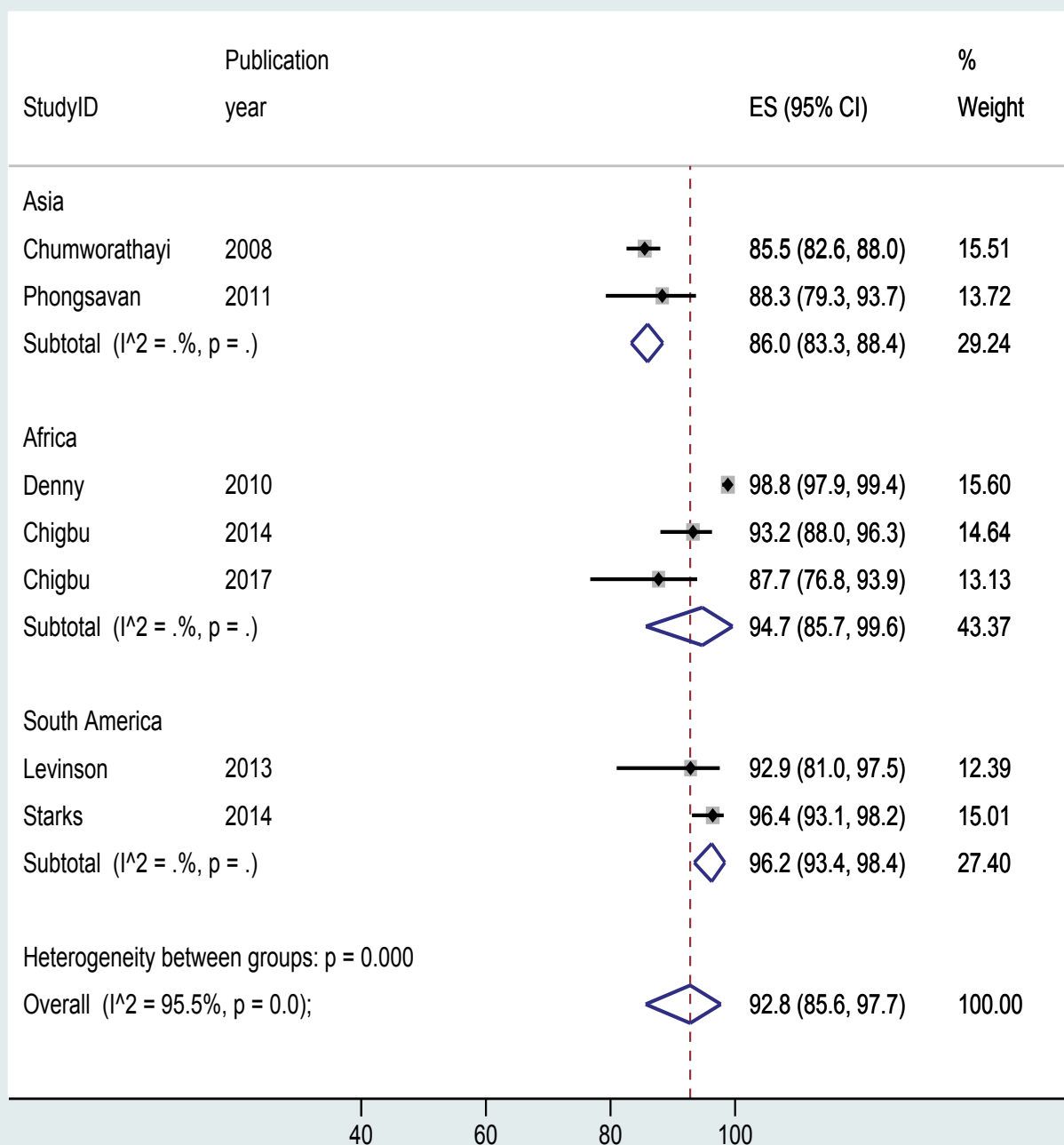
Supplementary information S2. Overview of studies included in previous meta-analyses but excluded from the present study

Treatment	Region	Study	Reason for exclusion
Cryotherapy	Africa	Leiman, 1980	Single freeze technique, insufficient data to calculate cure proportion
		Adewole, 1998	Sample size <25 patients, cure proportion not specified per CIN-grade
		Chirenje, 2003	Same study population as Chirenje 2001
		Blumenthal, 2007	No original data
		Lewis, 2011	Sample size <25 patients at follow-up
Thermal coagulation	Europe	Hussein, 1985	Follow-up duration <6 months
		Cassidy, 1987	Insufficient data available to assess quality and cure proportion
		De Cristofaro, 1990	Insufficient data available to assess quality and cure proportion
		Goodman, 1991	Follow-up duration <6 months
			Cure proportion not specified per CIN-grade

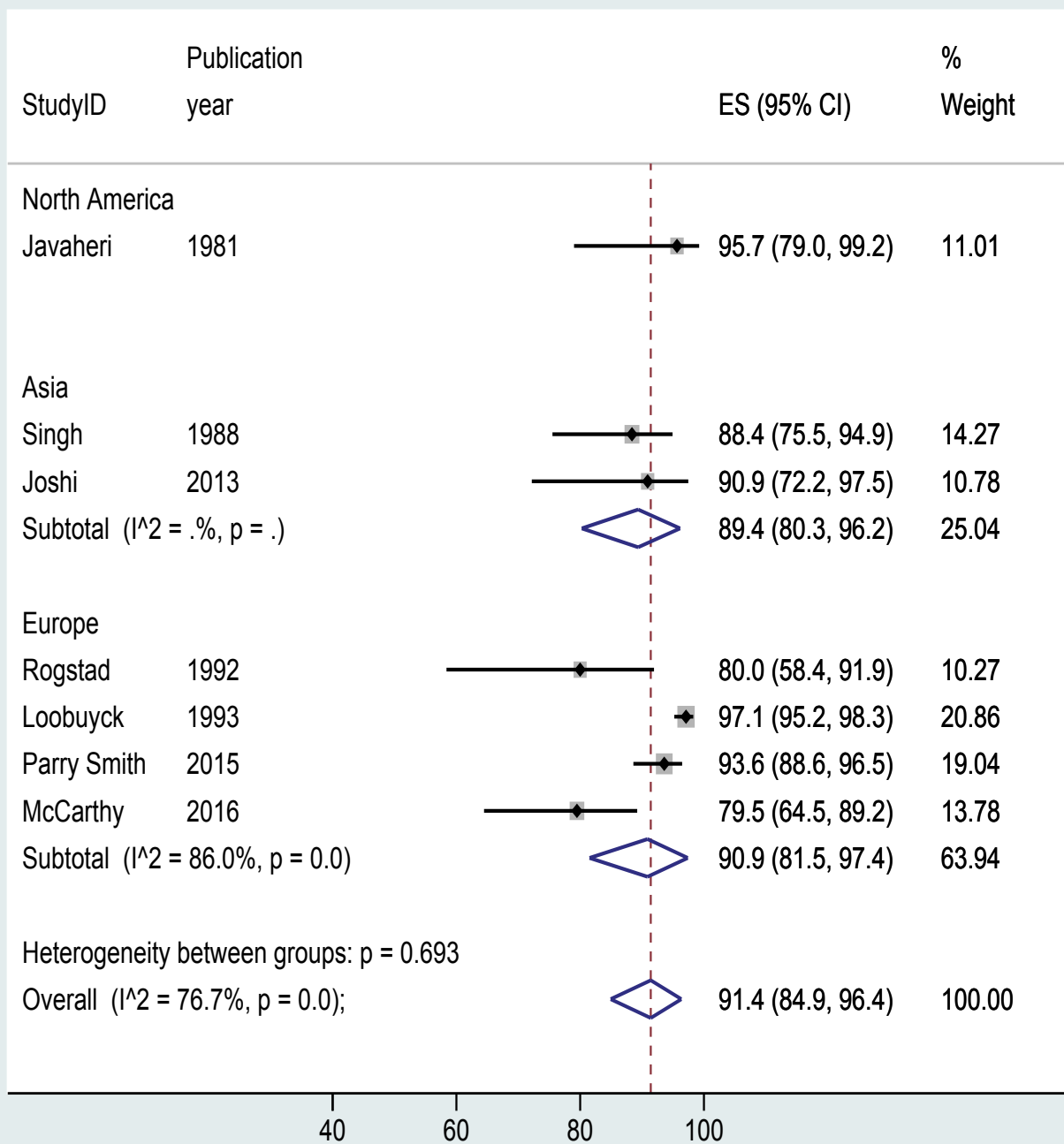
Supplementary information S3. Cure proportions for CIN 1 lesions treated with cryotherapy grouped by region.



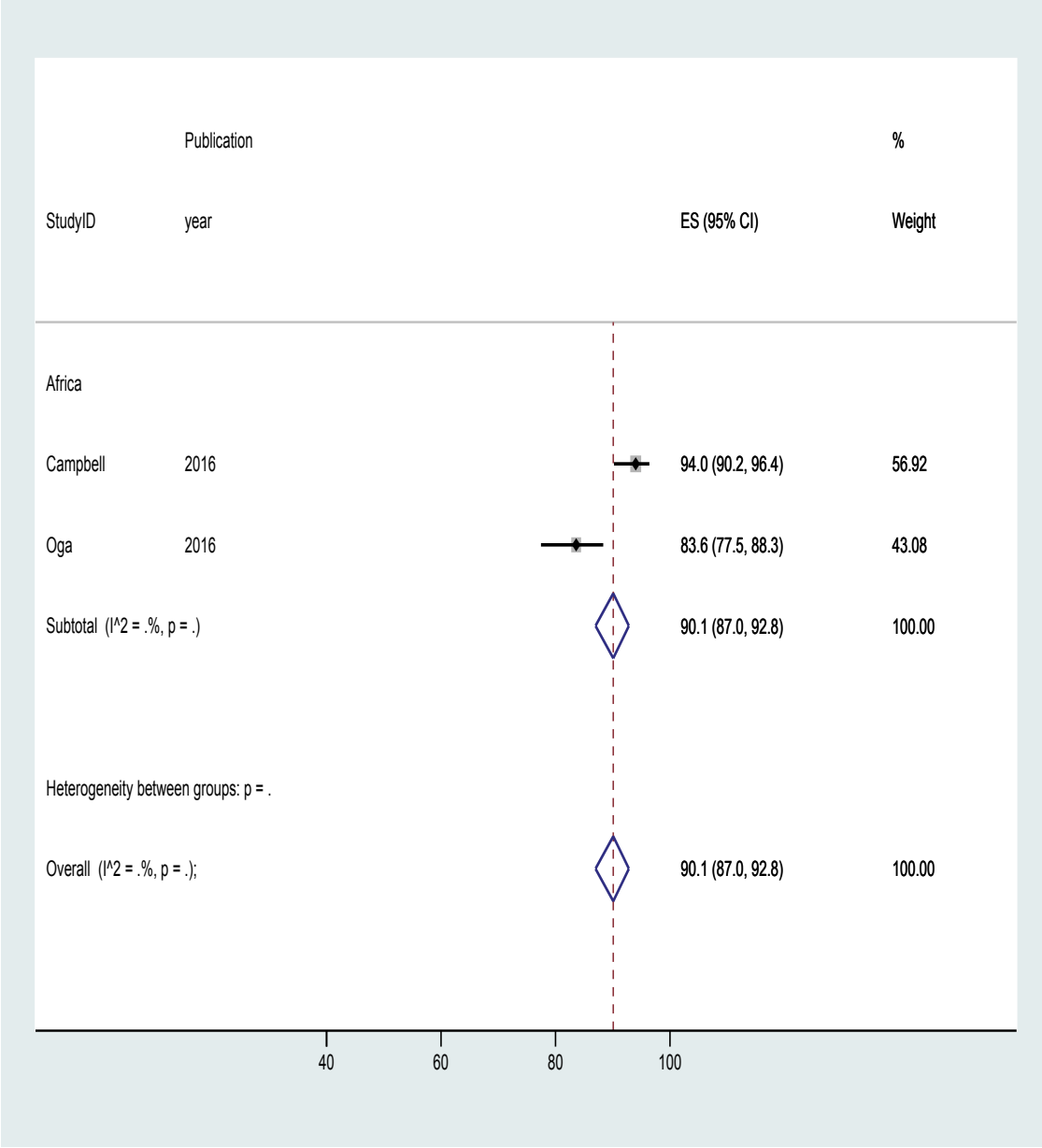
Supplementary information S4. Cure proportions for VIA-positive lesions treated with cryotherapy grouped by region.



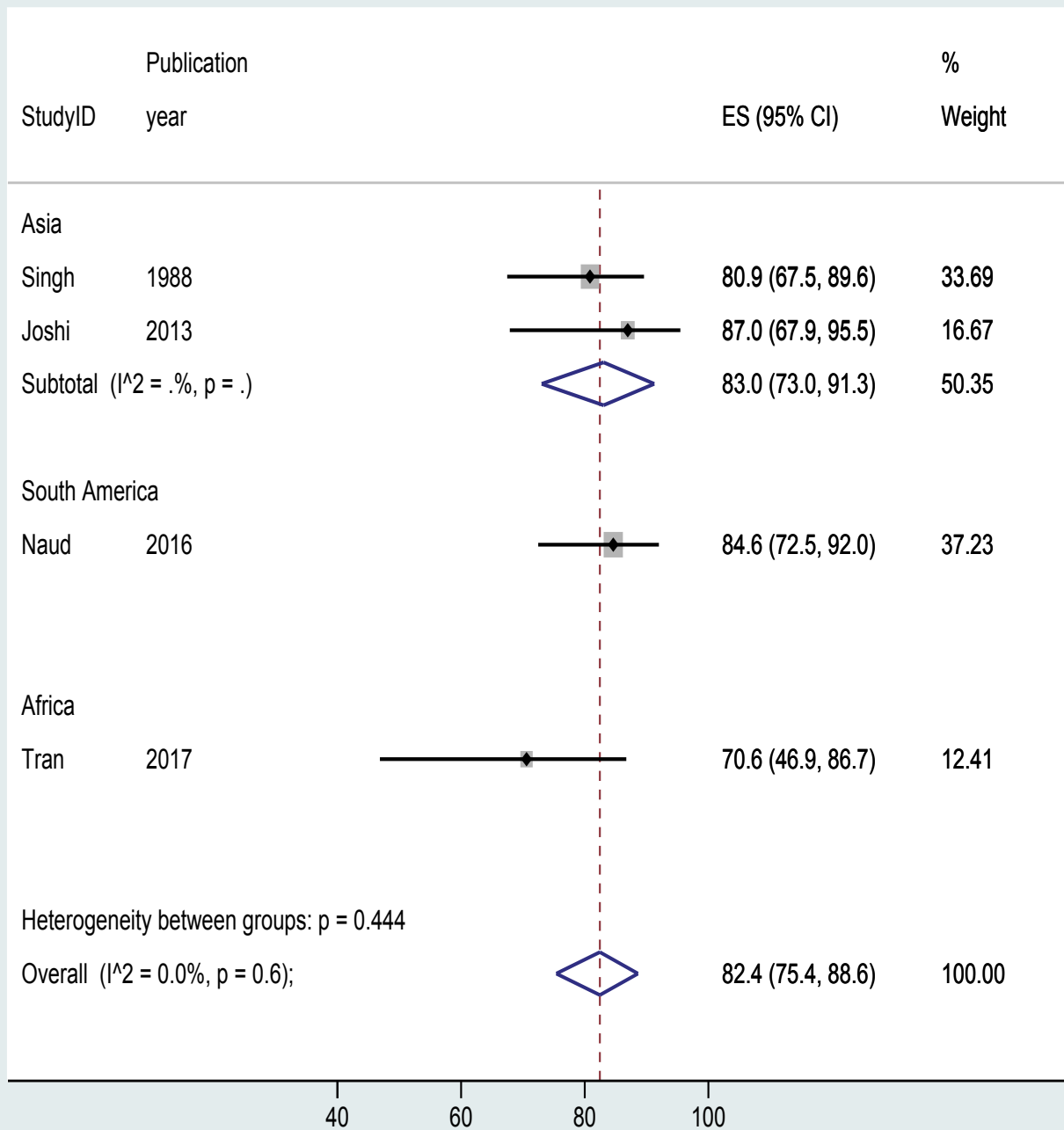
Supplementary information S5. Cure proportions for CIN 1 lesions treated with thermal coagulation grouped by region.



Supplementary information S6. Cure proportions for VIA-positive lesions treated with thermal coagulation grouped by region.



Supplementary information S7. Cure proportions for CIN 2-3 lesions treated with thermal coagulation in low- and middle-income countries.



Supplementary information S8. Sensitivity analysis of cure proportions for studies with follow-up attendance of 50%-75% and greater than 75%.

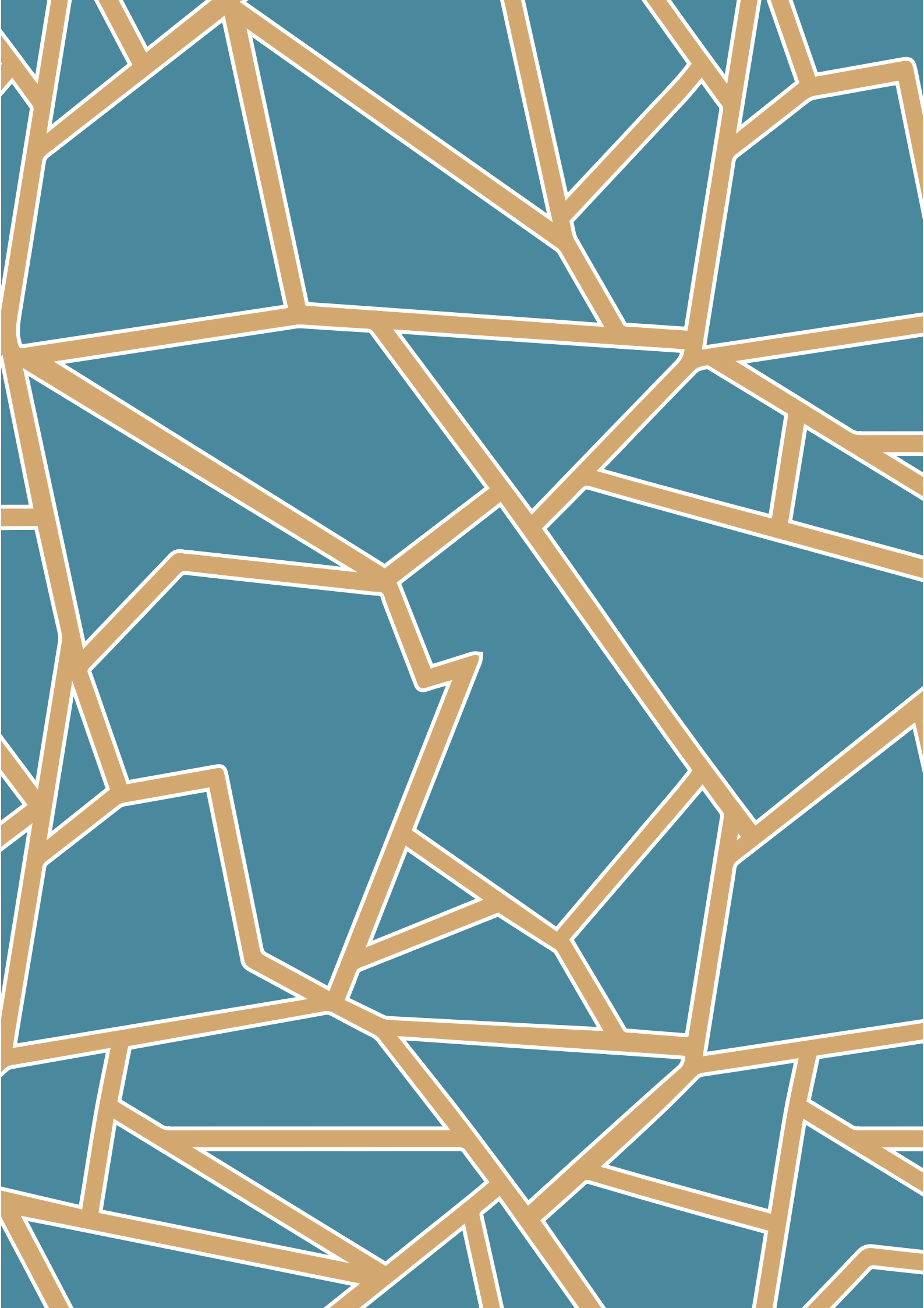
		Follow-up attendance 50-75% Cure proportion (95% CI)	Follow-up attendance >75% Cure proportion (95% CI)
Cryotherapy	CIN 1	0.826 (0.802 – 0.847)	0.973 (0.968 – 0.977)
	CIN 2-3	0.744 (0.686 – 0.794)	0.827 (0.795 – 0.854)
	VIA	0.915 (0.874 – 0.943)	0.898 (0.879 – 0.914)
Thermal coagulation	CIN 1	0.848 (0.699 – 0.930)	0.937 (0.914 – 0.954)
	CIN 2-3	0.925 (0.915 – 0.934)	0.892 (0.745 – 0.959)

Supplementary information S9. Cure proportions stratified per lesion and treatment modality for HIV-positive patients.

	Cryotherapy		Thermal coagulation		
	CIN 1	CIN 2-3	CIN 1	CIN 2-3	VIA
Chumworathayi, 2010 <i>Asia, nr of patients = 2</i>	0.83 (0.19 – 0.99)	-	-	-	-
Firnhaber, 2017 <i>Africa, nr of patients = 99</i>	0.98 (0.92 – 0.995)	-	-	-	-
Chirenje, 2001 <i>Africa, nr of patients = 42</i>	-	0.60 (0.44 – 0.73)	-	-	-
De Vuyst, 2014 <i>Africa, nr of patients = 79</i>	-	0.77 (0.67 – 0.85)	-	-	-
Smith, 2017 <i>Africa, nr of patients = 73</i>	-	0.69 (0.57 – 0.78)	-	-	-
Joshi, 2013 <i>Asia, nr of patients CIN 1 = 22; CIN 2-3 = 23</i>	-	-	0.91 (0.70 – 0.98)	0.87 (0.67 – 0.96)	-
Campbell, 2016 <i>Africa, nr of patients = 12</i>	-	-	-	-	0.96 (0.60 – 1.00)
Oga, 2016 <i>Africa, nr of patients = 120</i>	-	-	-	-	0.82 (0.74 – 0.88)

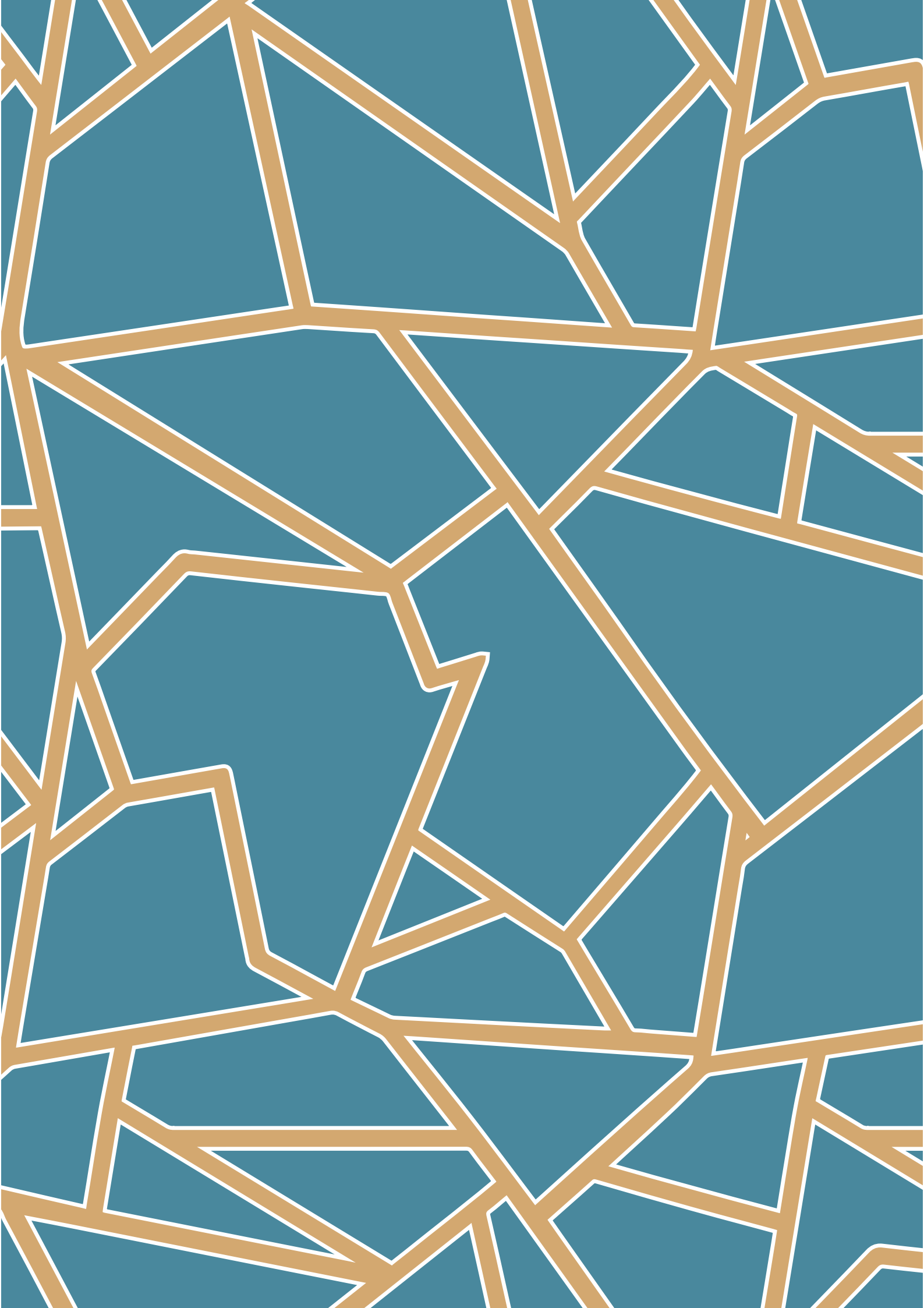
Supplementary information S10. Reported adverse effects and complications, specified by number of studies reporting and percentage of patients affected.

	Cryotherapy		Thermal Coagulation	
	<i>Nr of studies</i>	<i>% of patients</i>	<i>Nr of studies</i>	<i>% of patients</i>
Watery vaginal discharge	4	29 – 92.4	1	16
Heavy/malodorous vaginal discharge	7	<1 – 9.3	3	<1 – 2.4
Purulent/offensive discharge	2	17.3 – 68.2	-	-
Mild vaginal bleeding	7	<1 – 4.7	3	<1 – 2
Prolonged bleeding after treatment	1	40	-	-
Cervical infection	5	<1 – 2	1	1
Cervical stenosis	1	<1	1	1
Fever	3	<1	-	-
PID	-	-	1	1
Vasovagal reaction	1	<1	2	<1





ADDENDUM



SUMMARY

The need for surgery in low- and middle-income countries (LMICs) is tremendous; more people die from treatable surgical conditions than from tuberculosis, malaria and HIV put together. Despite the large need in LMICs, less than 10% of all surgeries are received by the poorest one-third of the world's population. To perform surgery, health workers, such as surgeons, nurses and medical officers are essential. Tools and surgical equipment are crucial too, as are running water and electricity. Also, anesthesia, sterilization, storage and maintenance are needed for a functioning operating theatre. A crucial barrier to surgical care in LMICs is the limited availability of surgical equipment, which results in delays and cancellations of surgeries on a daily basis. Also, limited availability has been reported as a barrier to implementation of basic surgery as well as laparoscopy in LMICs. Barriers to availability of medical equipment in LMICs include e.g., high costs, lack of consumables and spare parts, and limited access to maintenance. Medical equipment that is available is often donated from high-income countries (HICs) to LMICs or procured by hospitals in LMICs. However, this equipment is often designed for use in HICs and does not fit the context of LMICs, which introduces challenges during use in LMICs.

The overall aim of this thesis is to study the current use of surgical equipment in LMICs, in order to understand how to increase global availability of surgical equipment in the future. One of the strategies that is studied more thoroughly, is the design of context-specific surgical equipment. As many areas in Africa feel the burden of limited access to surgery, we have used hospitals in Afrika as a case, with a main focus on Kenya.

This thesis consists of two main parts. In the first part, the context of use and barriers to availability of surgical equipment in hospitals in Sub-Saharan Africa are studied in order to understand what is required to increase availability. Although previous studies have identified barriers to availability of equipment in LMICs, little is known about the specific types of surgical equipment that cause difficulties and the root causes of these difficulties. In the second part of this thesis, a context-driven design approach is presented that can be used to collect contextual factors when designing context-specific surgical equipment for LMICs. In addition, the use of our design approach during the development of an electrosurgical unit (ESU) and monopolar handheld for hospitals in Sub-Saharan Africa is presented.

The availability and the main barriers to availability of surgical equipment were studied in hospitals in different countries in Sub-Saharan Africa, with a main focus on Kenya. A survey among 42 surgeons working in 9 African countries, revealed that 70% of district hospitals represented in our study had basic surgical equipment required for essential surgery, compared to 88% of private and 81% of public referral hospitals. This means that still a part of the available equipment remains unavailable for all types of hospitals. When equipment is unavailable, this can either mean that equipment is not present within the hospital, or equipment is available but not in use, and therefore also unavailable. Throughout our studies, both surgeons and biomedical equipment technicians (BMETs), indicated high costs, limited training, lack of consumables, water, energy or repair, and

old and overused equipment as barriers to availability of surgical equipment. Even when equipment is available, it still remains a precarious situation to sustain this availability when consumables and spare parts are not accessible or when access to maintenance is missing. Access to maintenance for surgeons that participated in our studies (n=101) varied from 60-80%, revealing that 20-40% of hospitals had no access to repair when required. Additional barriers encountered by BMETs (n=38) included: unawareness of management staff on planned preventive maintenance or inadequate skills or tools to provide large maintenance issues on complex equipment, such as the electrosurgical unit (ESU) or laparoscopic equipment. The need for consumables (for example accessories required for electrosurgery) are a barrier because they are costly and prone to breakage, resulting in unintended reuse and frequent maintenance issues. In addition, donated equipment that is already obsolete when arriving at the receiving hospitals only results in extra work for the BMETs, when they have to organize the (bureaucratic and timely) disposal process, instead of increasing the number of available equipment.

In the first two chapters we identified that it is a complex process to ensure availability of surgical equipment and that availability depends on more than the equipment itself. Therefore, additional data on procurement, training, use, complications and maintenance were collected while studying the availability of electrosurgical units (ESUs) and laparoscopic equipment in 11 African countries. This revealed that despite their availability (which was larger for ESUs than for laparoscopic equipment), access to maintenance, training and consumables were not always in place. This results in the precarious situation in which equipment is momentarily available, but its availability is difficult to sustain in the long term, for example, when a new set of consumables or repair is required.

Besides increasing the understanding of barriers to availability of surgical equipment, we identified potential interventions to increase availability in the future, such as: more policies on donations, procurement of durable context-specific equipment, more university-trained biomedical engineers, and more on-site training for BMETs and end-users (e.g., surgeons and nurses), increased availability of robust equipment, and a more active role of medical device companies in LMICs. These interventions call for action from different actors related to the field of medical equipment, from policy makers, to academia, biomedical engineers and medical device companies.

In the second part, a context-driven design approach is presented that can be used to collect contextual factors when designing context-specific surgical equipment for LMICs. In addition, the use of our design approach during the development of an electrosurgical unit (ESU) and monopolar handheld for hospitals in Sub-Saharan Africa is presented. The need for context-specific medical equipment for global health is widely acknowledged. However, not much information on successfully accepted designs of surgical equipment for this context is available. While the importance of understanding the context of use during design of medical devices is rising, only limited practical guidance for biomedical engineering design projects is available. We developed a context-driven design approach for surgical equipment based on design ethnography. Our context-driven approach consists

of four phases: 1) the identification of a clear need, 2) research of the context of use by identifying contextual factors, that result in 3) a set of context-specific design requirements, and 4) that should be translated into prototypes by an iterative process in close interaction with end-users (e.g., surgeons, BMETs, nurses). Detailing contextual factors is an important part of the context-driven design approach resulting in valuable information to determine context-specific design requirements, that eventually can be used to develop prototypes. We advocate for close interaction during each phase of the design process with end-users to ensure acceptance of the final designs.

Suggestions for which surgical equipment should be redesigned were given by surgeons (n=42) that participated in our studies included for example: reusable ESU accessories, robust ESUs, and the need for portable sterilizers. These suggestions together with the fact that ESUs were only available for 60% of the district hospitals made us decide to use the ESU as a case to test our context-driven design approach. Additionally, the ESU is an important type of equipment used during both open and laparoscopic surgery.

We used the context-driven design approach to redesign the ESU and monopolar handheld for use in hospitals in Sub-Saharan Africa. In order to collect the contextual factors and to receive feedback on the designs we conducted several field trips to hospitals in Kenya. The following conclusions were drawn from identifying the contextual factors:

- 1) ESUs are often unavailable for each operating theatre and are transported between operating theatres, and should therefore be small and portable;
- 2) Not all settings (such as blend and fulgurate) of the high-end ESU generators are used; cut and coagulation are enough for most surgeries;
- 3) Hospitals receiving power from the national grid and backup generators suffer from power interruptions a few times per week, ranging from several minutes to longer, devices should withstand this and preferably, interact with this situation in a proper manner;
- 4) Accessories are insufficient available and therefore reused and cleaned in CIDEX in between surgeries;
- 5) Training for users (especially nurses) on electrosurgery is limited and more guidance on installation and safe use should be provided on the machine or in the operating theatre;
- 6) Faulty use of ESU accessories results in delays that can be easily prevented by clearer error coding on the ESU to guide users in finding an appropriate solution.

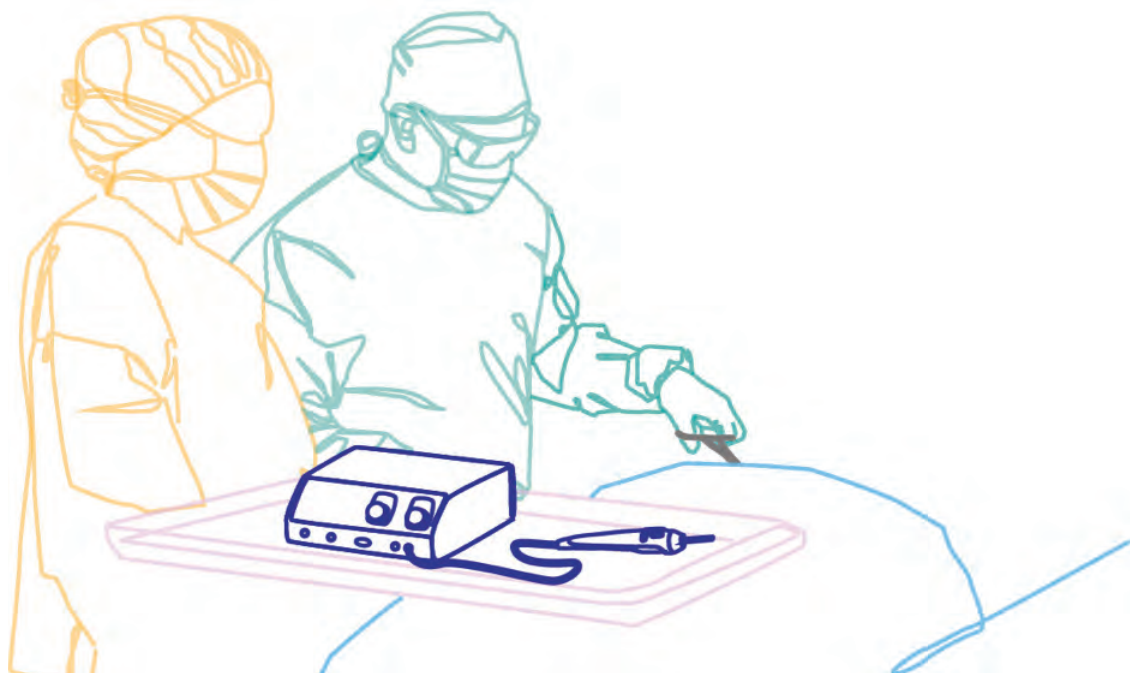
We, therefore, designed:

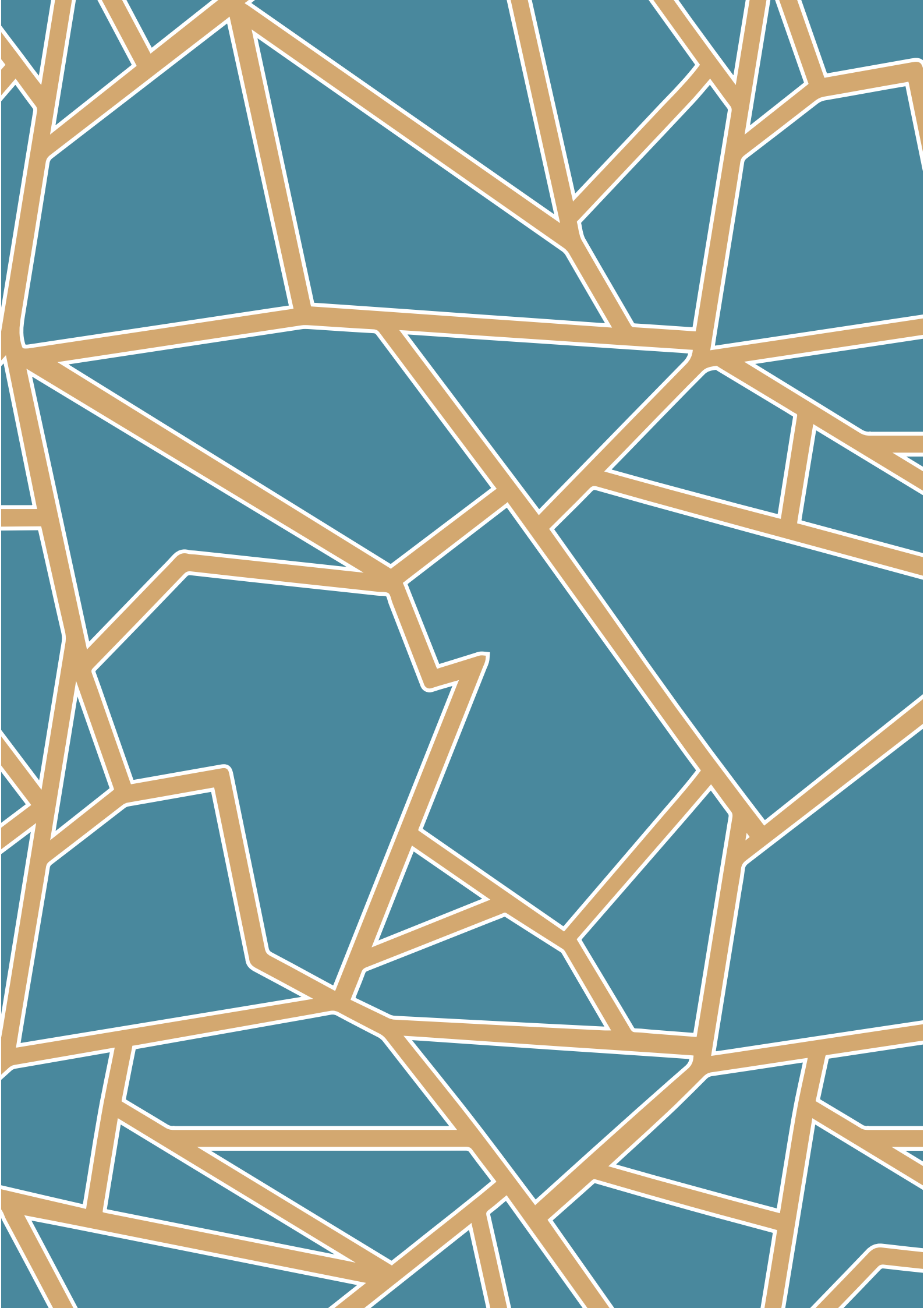
- An affordable ESU generator that is compact, has a clear user interface and is battery powered and;
- a reusable monopolar handheld, that can be cleaned in the autoclave and by CIDEX.

We evaluated the initial designs of the ESU and the reusable monopolar handheld with 51 surgeons working in 12 African countries and 87% of surgeons indicated that these

designs could improve the way they perform electrosurgery in clinical practice. We see the development of the context-driven design approach as an incremental process, which will improve by implementing experiences of future design projects. Each design project will eventually lead to new insights on the design approach.

Based on the findings of this thesis, practical implications for different actors are formulated, with a main focus on hospitals in Kenya, which are expected to be for a large extend translatable for other LMICs in e.g. Africa and Asia. Insights in current gaps in hospitals' needs, barriers to availability of surgical equipment and how context-specific surgical equipment should be designed are provided in this thesis. These are of value for the global health community, policy makers, health workers, the global community of biomedical engineers and medical companies to assist in their efforts to increase surgical capacity worldwide.





SAMENVATTING

De vraag naar chirurgie in lage-en middeninkomenslanden (LMICs: low- and middle-income countries) is groot. Meer mensen overlijden door ziektes die chirurgisch te behandelen zijn dan door tuberculose, malaria en aids bij elkaar. Ondanks de grote vraag, komt maar 10% van het totaal aantal wereldwijd uitgevoerde operaties ten behoeve van de armste groep van de wereldpopulatie. Om operaties te verrichten is medisch personeel noodzakelijk, zoals bijvoorbeeld chirurgen, anesthesiologen en verpleegkundigen. Daarnaast zijn instrumenten, chirurgische apparatuur, water en elektriciteit nodig. Maar ook anesthesie, sterilisatie, opslag en onderhoud dienen beschikbaar te zijn. Een grote barrière voor het bieden van chirurgische zorg is de geringe beschikbaarheid van chirurgische apparatuur in LMICs wat dagelijks leidt tot uitstel en vertraging van operaties. Barrières die aan de geringe beschikbaarheid van chirurgische apparatuur ten grondslag liggen zijn onder andere: hoge kosten, geringe aanwezigheid van gebruiksartikelen en reserveonderdelen en weinig mogelijkheden tot het uitvoeren van onderhoud. Chirurgische apparatuur die wel aanwezig is, is vaak gedoneerd door hoge-inkomenslanden of zelf aangeschaft door ziekenhuizen in LMICs. Nadeel van deze apparatuur is dat deze ontworpen is voor hoge-inkomenslanden en vaak niet past bij de gebruikscontext in LMICs, wat gebruiksuitdagingen oplevert.

Het doel van dit proefschrift is om te analyseren hoe chirurgische apparatuur momenteel gebruikt wordt in LMICs om zo in kaart te brengen hoe de wereldwijde beschikbaarheid in de toekomst verbeterd kan worden. Om dit doel te bereiken zijn de huidige beschikbaarheid van essentiële chirurgische apparatuur en de barrières tot het gebruik hiervan geanalyseerd op basis van vragenlijsten en semigestructureerde interviews onder chirurgen en technische staf werkzaam in verscheiden ziekenhuizen in Afrika. Daarnaast wordt onderzocht hoe een 'context-gedreven design aanpak' bijdraagt aan het ontwerpen van chirurgische apparatuur die beter aansluit bij de context in LMICs. Grote delen van Afrika ondervinden de nadelige gevolgen van de geringe toegang tot chirurgische zorg, daarom stelt dit proefschrift ziekenhuizen in Afrika centraal, waarbij de focus ligt op Kenia.

Dit proefschrift bestaat uit twee delen. Het eerste deel richt zich op het gebruik en de barrières ten opzichte van chirurgische apparatuur in ziekenhuizen in Afrika om te begrijpen wat er nodig is om de beschikbaarheid te verhogen. Hoewel eerder onderzoek de globale barrières ten opzichte van gebruik van medische apparatuur in deze context beschrijft, zijn de achterliggende redenen die resulteren in barrières voor specifieke soorten chirurgische apparatuur onderbelicht. Data verzameld onder 42 chirurgen die werkzaam zijn in 9 verschillende Afrikaanse landen laat zien dat op regionaal niveau 70% van de essentiële chirurgische apparatuur aanwezig is. In privé- en academische ziekenhuizen lag dit aantal op respectievelijk 88% en 81%. Dit betekent dat een deel van de essentiële chirurgische apparatuur niet beschikbaar is in de verscheidene categorieën van ziekenhuizen in deze landen. Redenen hiervoor zijn dat apparatuur simpelweg niet aanwezig is in het ziekenhuis, of dat apparatuur ondanks dat het aanwezig is niet gebruikt wordt (of gebruikt kan worden). Redenen gegeven door zowel chirurgen als door de technische staf betreffen: hoge kosten, weinig tot geen training over gebruik en onderhoud, gebrek aan gebruiks-

en reserveonderdelen en de veelal oude apparatuur. Ook als chirurgische apparatuur wel aanwezig is in het ziekenhuis, is het moeilijk om deze voor operaties beschikbaar te houden als gebruiks- en reserveonderdelen of onderhoud niet beschikbaar zijn. Ook zijn gebruiksartikelen duur, waardoor ze vaak hergebruikt worden ondanks dat ze daar niet voor ontworpen zijn. Dit kan leiden tot onveilige situaties voor zowel de chirurg als de patiënt.

In onze verschillende studies lag de beschikbaarheid van onderhoudsmogelijkheden voor apparatuur voor de respondenten tussen de 60-80%, wat aantoont dat voor 20-40% geen onderhoudsmogelijkheden had als apparatuur dit behoeft. Daarnaast is veel gedoneerde apparatuur al stuk op het moment dat het arriveert, wat resulteert in extra werk voor de technische staf omdat het ontmantelen van deze producten een tijdrovende en dure klus is.

Dit proefschrift laat zien dat het beschikbaar houden van chirurgische apparatuur een complex proces is. Beschikbaarheid behelst meer dan alleen de aanwezigheid van de apparatuur omdat verschillende aspecten dit beïnvloeden. Aspecten zoals bijvoorbeeld welke apparatuur er wordt aangeschaft, training, gebruik, complicaties en beschikbaarheid van onderhoud. Om deze aspecten in kaart te brengen voor twee belangrijke typen chirurgische apparatuur in ziekenhuizen in 11 Afrikaanse landen is data verzameld onder 80 respondenten, zowel onder chirurgen als technische staf. Uit deze data bleek dat de beschikbaarheid van elektrochirurgie hoger ligt dan van laparoscopische apparatuur, en dat belangrijke aspecten zoals onderhoud, training en gebruiksonderdelen niet overal aanwezig zijn. Dit leidt tot de situatie dat apparatuur wel aanwezig is, maar de beschikbaarheid op de lange termijn niet gegarandeerd kan worden omdat deze in sterke mate afhangt van al deze aspecten. Een van de doelen die we beogen met dit proefschrift is dat men zich ervan bewust wordt dat beschikbaarheid van chirurgische apparatuur van vele aspecten afhankelijk is, die allen meegenomen dienen te worden tijdens het implementatie proces.

Daarnaast, zijn binnen dit onderzoek verschillende strategieën in kaart gebracht die kunnen bijdragen aan het verhogen van de wereldwijde beschikbaarheid van chirurgische apparatuur. Zoals het invoeren van regelgeving voor donaties van hoge-inkomenslanden naar LMICs, het aanschaffen van chirurgische apparatuur die beter aansluit bij de context van gebruik in LMICs, het opleiden van universitair getrainde biomedische technologen en meer training voor de technische staf werkzaam in ziekenhuizen, robuuster ontwerp van apparatuur en een actievere rol van medische bedrijven in deze context. Dit vraagt om actie van verschillende actoren werkzaam in en gerelateerd aan de medische sector zoals beleidsmakers, universiteiten, biomedische technologen en medische bedrijven.

Het tweede deel van dit proefschrift presenteert een 'context-gedreven ontwerp aanpak' waarbij contextfactoren geanalyseerd worden alvorens de context-specifieke apparatuur ontworpen wordt. Daarnaast presenteren we een voorbeeld van het gebruik van deze aanpak tijdens het ontwerp van een elektro chirurgisch apparaat en een herbruikbaar gebruiksvoorwerp dat hiervoor noodzakelijk is, een elektrisch mes, voor ziekenhuizen in Afrika.

De bewustwording dat het begrip van de context tijdens het ontwerpen van context-specifiek apparatuur voor LMICs noodzakelijk is neemt toe onder biomedische technologen en medische bedrijven, al is er nog weinig over beschreven in de literatuur. Er zijn daardoor ook weinig praktische leidraden voor ontwerpprojecten beschikbaar. In dit proefschrift presenteren wij een context gedreven ontwerp aanpak bestaande uit vier fasen gebaseerd op etnografische onderzoeksmethoden: 1) identificeren van de vraag, 2) het analyseren van de verschillende contextfactoren, 3) het opstellen van een lijst van eisen en dan 4) het maken en testen van prototypes. De nadruk binnen deze methode ligt sterk op het meenemen van de eindgebruiker tijdens elke fase van het ontwerpproces, om te zorgen dat het uiteindelijke ontwerp goed aansluit bij de gebruikerscontext.

De respondenten tijdens onze studies in Afrika gaven verschillende suggesties voor het herontwerp van chirurgische apparatuur voor deze context waaronder: robuuste elektro chirurgische apparatuur, herbruikbare gebruiksartikelen met name voor elektrochirurgie, makkelijk te vervoeren sterilisatieapparatuur en betaalbare apparatuur voor laparoscopische chirurgie. Deze suggesties en de geringe beschikbaarheid van elektrochirurgie in regionale ziekenhuizen heeft de grondslag gelegd voor een ontwerpproject rondom het vergroten van de toegang tot elektrochirurgie voor ziekenhuizen in Afrika. Electrochirurgie is daarnaast een belangrijk toepassing tijdens laparoscopische chirurgie.

We hebben op basis van de context gedreven ontwerp aanpak context factoren geanalyseerd en daarnaast hebben we op verschillende momenten tijdens het ontwerpproces feedback van eindgebruikers werkzaam in Kenia gekregen.

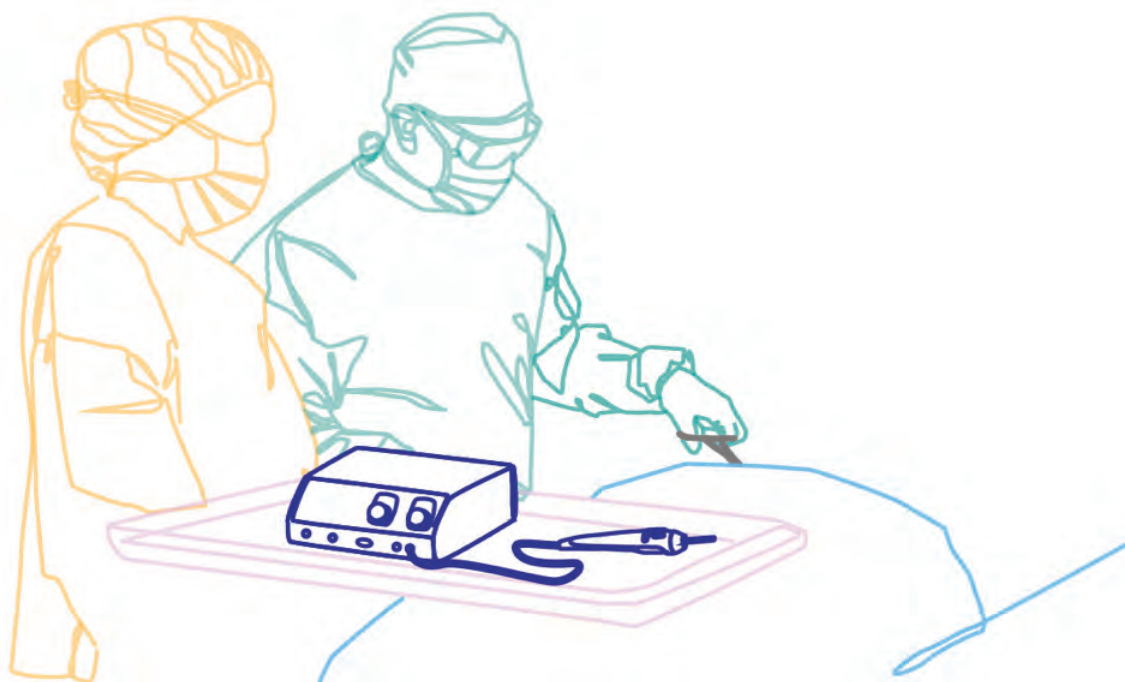
- 1) Elektrochirurgie is niet altijd beschikbaar voor elke operatiekamer, de apparatuur wordt daardoor vaak van de ene kamer naar de andere vervoert, en moet daarvoor klein en compact zijn;
- 2) Niet alle opties van moderne apparatuur wordt gebruikt, de functies om te snijden en te coaguleren zijn de meest gebruikte instellingen en daardoor voldoende;
- 3) Er komen vaak onderbrekingen op het elektriciteit netwerk voor, apparatuur moet hier bestand tegen zijn, en daarnaast op de juiste manier met deze situaties omgaan;
- 4) Gebruiksartikelen zijn niet overal voldoende aanwezig en worden daardoor hergebruikt en schoongemaakt in chemische middelen;
- 5) Medisch personeel wordt weinig getraind in het gebruik van elektrochirurgie en handleidingen voor veilig gebruik moet daarom duidelijk zichtbaar zijn op het apparaat;
- 6) Medisch personeel moet ondersteund worden in het oplossen van veelvoorkomende fouten om vertraging en gevaarlijke situaties te voorkomen.

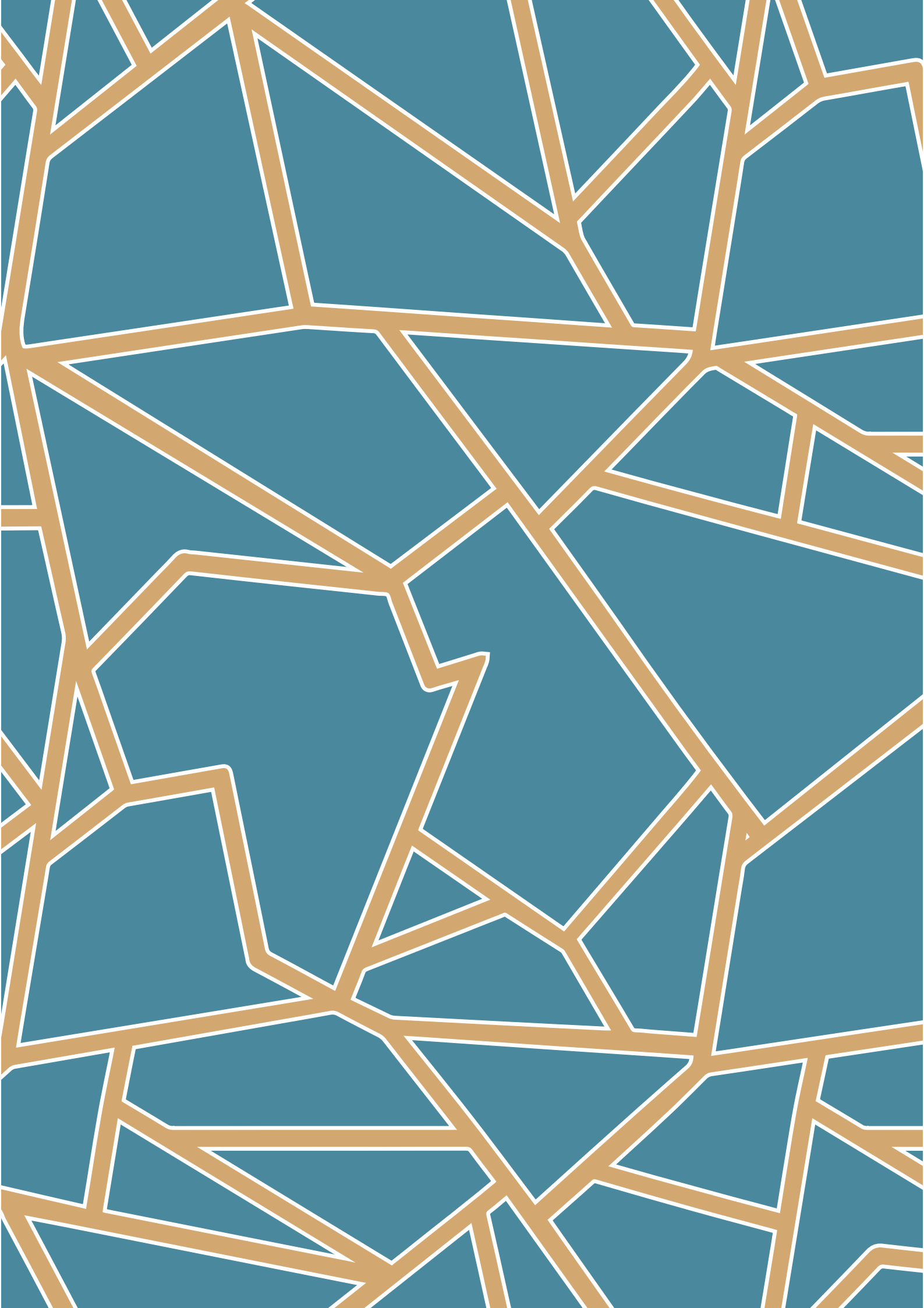
Deze conclusies hebben geleid tot een set van context specifieke ontwerp eisen waarna ontwerpen voor de volgende producten zijn gemaakt:

- Een betaalbaar elektro chirurgisch apparaat, met een duidelijke interface dat tijdens stroomuitval werkt op een batterij
- Een herbruikbaar gebruiksartikel, het elektrisch mes, dat bestand is tegen het schoonmaken met stoom en met chemische middelen.

Deze ontwerpen hebben we geëvalueerd met 51 chirurgen werkzaam in 12 Afrikaanse landen, waarbij 87% verwacht dat deze ontwerpen een positieve invloed op hun mogelijkheden om chirurgische zorg te verlenen kunnen hebben in de toekomst. We zien het ontwikkelen van deze ontwerp aanpak als een incrementeel proces waarbij de elk project weer tot nieuwe inzichten in het gebruik van de methode zal opleveren.

Dat het een complex proces is om beschikbaarheid te garanderen van chirurgische apparatuur en dat dit meer behelst dan alleen de aanwezigheid van apparatuur is een van de belangrijkste conclusies van dit proefschrift. Barrières voor het gebruik van chirurgische apparatuur worden ondervonden op verschillende momenten tijdens de levensduur. Het is daardoor van groot belang dat verschillende contextfactoren worden meegenomen als chirurgische apparatuur specifiek voor deze context ontworpen wordt. In dit proefschrift zijn verschillende strategieën uitgediept om beschikbaarheid van chirurgische apparatuur wereldwijd te verhogen, in de meeste gevallen gefocust op Kenia, maar de verwachting is dat deze voor een groot deel overgenomen kunnen worden voor andere lage- en middeninkomens landen in Afrika en Azië. De verschillende inzichten die worden gepresenteerd, naast het voorbeeld van context specifiek ontwerpen voor deze context zijn van waarde voor de global health community, beleidsmakers, medische personeel, biomedische technologen en medische bedrijven om hen te ondersteunen in het verhogen van de wereldwijde beschikbaarheid van chirurgische apparatuur. .





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June, Asante Sana! Your input on my work has been great and the introductions to your network of BMETs in Kenya has been so helpfull. It is truly amazing what you are doing for the field of biomedical engineering in Kenya, keep up the good work. Looking forward to hopefully a lot more coffees at Java in the future!

Additionally, I would like to thank the defence committee for making time to read my dissertation and making time to come all the way to Delft to be part of the defence.

Reinou, wat een geluk dat ik jouw thesis online vond en jij met veel enthousiasme reageerde op mijn mail of je eens met mij zou willen praten over mijn onderzoek. Dank voor alle input!

JC, wat heb ik met veel plezier met jou gewerkt de afgelopen tijd, ik kom niet vaak mensen tegen die nog meer en nog sneller praten dan ik, maar aan jou moet ik toch een meerdere laten. Je ervaringen in Afrika, kennis over ontwerpen, hoe jij met veel energie en enthousiasme projecten opzet en studenten begeleid, ik heb alles als een spons opgezogen en enorm veel van je geleerd.

I would like to thank all the people I met during my travels to Kenya, Rwanda and Mozambique, without whom this research would not have been possible. Thank you so much for making time for me, showing me around, filling in my surveys and inspiring me

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CV

Roos Marieke Oosting was born August 10 1990 in Wageningen, the Netherlands, where she grew up with two younger brothers. Before starting primary school, she moved for one year with her family to Lethbridge in Canada and during primary school for one year to Bodø in Norway. She graduated from het Pantarijn in Wageningen in 2008. She obtained a BSc degree in Life, Science and Technology (major: biomedical engineering) from the University of Groningen (2013) and a MSc in Biomedical Engineering (2016) from Delft University of Technology. In February 2016, she started as a PhD researcher in the Department of BioMechanical Engineering of Delft University of Technology and as a research fellow of the Delft Global initiative. During her research she worked and lived in Nairobi for a total of 5 months, published in international journals, presented her work at various conferences and meetings, organized group field trips to Kenya and organised a symposium on Global Surgery.

SCIENTIFIC OUTPUT

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TOWARDS INCREASED GLOBAL AVAILABILITY OF SURGICAL EQUIPMENT

ROOS MARIEKE OOSTING

The need for surgery in low- and middle-income countries (LMICs) is tremendous; more people die from treatable surgical conditions than from tuberculosis, malaria and HIV put together. A crucial barrier to surgical care in LMICs is the limited availability of surgical equipment, which results in delays and cancellations of surgeries on a daily basis. The overall aim of this thesis is to study the use of surgical equipment in LMICs, in order to understand how to increase global availability of surgical equipment in the future. One of the strategies that is researched more thoroughly, is the design of context-specific surgical equipment. As many areas in Africa feel the burden of limited access to surgery, we have used hospitals in Africa as a case study, with a main focus on Kenya.