

Roadmap for design of surgical equipment for safe surgery worldwide

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Roadmap for Design of Surgical Equipment for Safe Surgery Worldwide

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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, anesthesia 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 roadmap for design of surgical equipment for worldwide use. The roadmap 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 implementation strategy and 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.

Keywords— Surgery, Low-and-Middle Income Countries (LMICs), design, surgical equipment, biomedical engineering

I. 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 labor, breast and cervical cancer [1]. Additionally, surgery can play a role in diagnostics 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, anesthesia 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. (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.

II. 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 roadmap was developed indicating different phases and aspects that should be considered when designing surgical equipment for worldwide use.

To support the roadmap 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’.

III. FINDINGS

The roadmap consists of four phases (Fig. 1). 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 (Fig. 2),

Phase 2: Determining design requirements, and

Phase 3. Act.

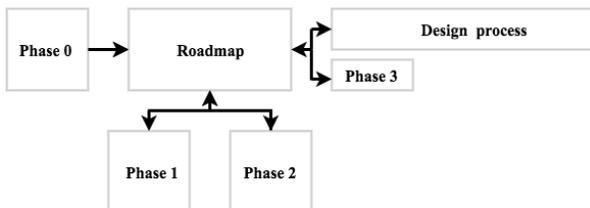


Fig. 1: Overview of the position of the roadmap in the entire design process

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].

A. 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 researched and will be explained in the following section and an overview is given in Fig.2.

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 anesthesia 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].

2) Phase 1.2 Structures of the health care system

The setup of health care systems globally, organization structures can either be public, private or funded by non-governmental organization (NGO's) or missions. Public, private and NGO/mission health care centers 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.

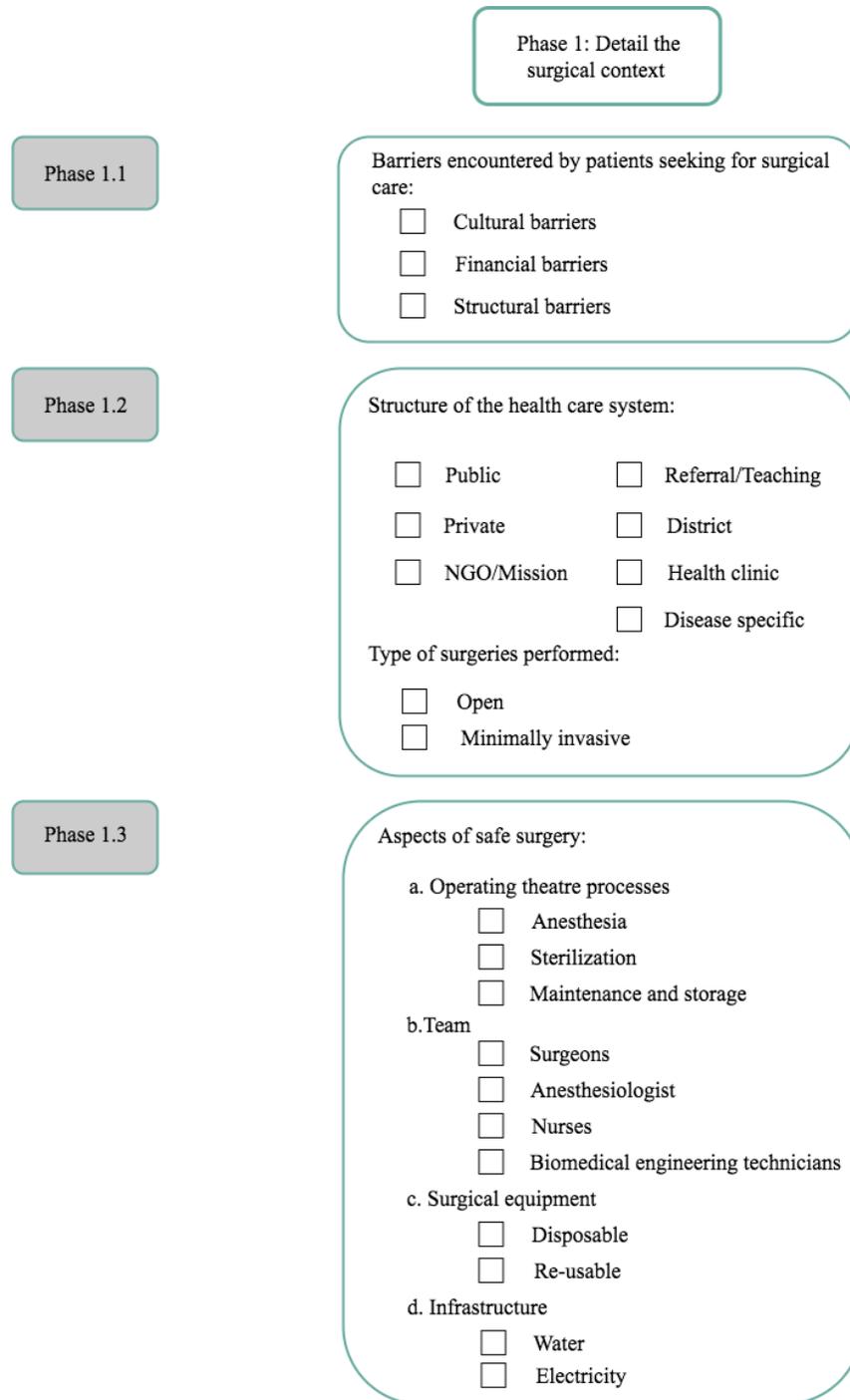


Fig. 2: Overview of all aspects of the context that could be considered during Phase 1.

Besides organization structures, it is important to consider the differences between health care centers, 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 centers should contain a small number of beds and a sparsely equipped operating theatre for minor procedures.
- Health care centers should provide emergency care in 90-95% of trauma and obstetrics cases (excluding Caesarean sections).

- District hospitals should have adequately equipped 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 open or by minimally invasive surgery (MIS) techniques. MIS 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 startup 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.

3) Phase 1.3 Aspects of safe surgery

To provide safe surgery, several complex processes (anesthesia, 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. Anesthesia 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

- Anesthesiologist(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]. Re-usables 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 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

1) 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.

2) 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)

Table 1: Summary of the roadmap 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 the following questions and use the overview given in Fig.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

- Elimination of the necessity of external power sources

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 hemorrhage, 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 sterilizable re-usable drill cover developed by Arbutus Medical that can be used on hardware drills to convert them into orthopedic drills to reduce costs [48]. And the anesthesia 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].

IV. FINAL REMARKS

We presented a detailed roadmap 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 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 roadmap (Table 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 roadmap. 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 roadmap 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 roadmap. 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 roadmap 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 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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