Received April 24, 2019, accepted June 6, 2019, date of publication June 29, 2019

Barriers to Availability of Surgical Equipment in Kenya: A Surgical Equipment Journey Approach

By R.M. Oosting[1], L.S.G.L Wauben[2], S.W. Mwaura[3], J.K. Madete[4], R.S. Groen[5], J. Dankelman[1]

[1]Dept. Biomechanical Engineering, Delft University of Technology, The Netherlands

[2]Research Centre Innovations in Care, Rotterdam University of Applied Sciences, Rotterdam, The Netherlands

[3]Association of Medical Engineering of Kenya, Nairobi , Kenya

[4]Dept. of Electrical and Electronic Engineering, School of Engineering and Technology, Kenyatta University, Nairobi, Kenya

[5]Dept. Gynecology and Obstetrics, Johns Hopkins University, Baltimore, USA

ABSTRACT

Background and Objective

The need for surgery is currently not being met in Sub-Saharan Africa, requiring both extra workers and surgical equipment. Currently, there is a gap in the availability of surgical equipment which 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).

Material and Methods

Seven semi-structured in-depth interview sessions were conducted with a total of 17 BMETs working in Kenya. Participants worked in 6 different hospitals (4 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.

Results

The surgical equipment journey consists of 3 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.

Conclusion

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.

Keywords – *Surgery, Surgical equipment, Sub-Saharan Africa, Kenya, Biomedical Equipment Technicians (BMETs), Maintenance.*

INTRODUCTION

Surgery requires human resources, equipment, medicines, and 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 the availability of surgical equipment is a large contributor to the unmet needs 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] Local use is not always considered during the donation of equipment. For example, Howie et al. described a case study in Gambia where the lifespan of donated oxygen concentrators did not exceed 30 minutes (as opposed to 5–7 years in high- and middle-income countries [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 for increasing the 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.

METHODS

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 electrosurgical units, monitors, operating theatre lights, sterilizers, and anesthesia machines were identified as surgical equipment in this study. All interviews were done in English.

Each session consisted of 2 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, and**
2. **how the following concepts are related to the surgical equipment journey within their hospital: the supply chain, procurement, sterilization/cleaning, donation, policies, disposal, design, maintenance, costs, misuse, 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.

DATA ANALYSIS

The interviews were recorded and transcribed. Data were analyzed with MASDAQ 2018. The concepts discussed during the interviews were used for coding the transcripts.

RESULTS

In total, 17 BMETs participated from 6 different hospitals (Table 1). After 7 sessions data saturation was reached. Session 4 and 6 were in the same hospital.

Table footnote:

BMETs = biomedical equipment technicians.

 # Surgical care in Kenya is provided by public, mission (non-profit) and private hospitals. The public care system consists of 4 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 the 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*

TABLE 3. Participants' Characteristics During Each Interview Session

Session Number	BMETs 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	1× Diploma
5	3	Public hospital	All male	1× Diploma, 1× Higher-level diploma, 1× Certificate
6	7	Public hospital	1× female, 6×male	3× Diploma, 3× Higher level diploma
7	3	Public hospital	All male	All diploma

EQUIPMENT JOURNEY

Participants within this study identified 3 phases within the surgical equipment journey: procurement, use and maintenance, and disposal (Figure 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 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, non-governmental organizations (NGOs [e.g. AMREF]), or a foreign government.

PROCUREMENT PHASE

All participants indicated the following procurement process: when a healthcare 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

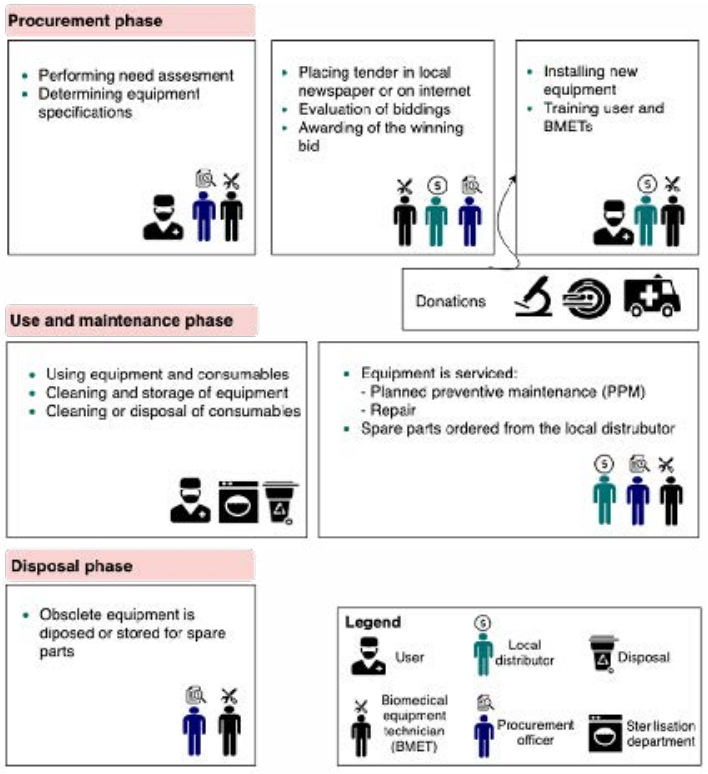

FIGURE 1. The surgical equipment journey according to BMETs in Kenyan hospitals.

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

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 analyze 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 around importing it into the country start, 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 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 arranged by 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 where we can troubleshoot 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 anesthesia 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 2 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 7 interview sessions. The 5 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, the 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 the 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 2 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 2 hospitals described how the use of heavy chemicals for cleaning shortens the lifespan of the equipment.

'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 of either by the hospital or via the 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 on the hospital 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. Then 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 urgently needed by the population.. Other studies have identified synergies in the barriers to medical equipment between different LMICs.[10–13] This study offers insights from frontline 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 3 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.

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 equipmentthat 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. 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 the 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 the 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 the 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 surgical equipment. Within this program training and servicing is provided for at least 7 years.[17]

Kenya aims to increase the quality of its healthcare 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 2.

Table footnote:

BMETs = biomedical equipment technicians.

LMIC = low- and middle-income countries;

R&D = research and development.

TABLE 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 troubleshoot
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)

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).[18] Kenya has 6 colleges for BMET training and 2 university programs for biomedical engineers which equip 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 the 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 the design and the development of plans for the provision of surgical care.

ACKNOWLEDGMENTS

This research was funded by the Delft Global Initiative of the Delft University of Technology, Delft, The Netherlands (P70357).

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this paper.

ETHICAL STATEMENT

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethical approval was obtained from the Human Research Ethics committee of the Delft University of Technology.

REFERENCES

1. Henry JA, Frenkel E, Borgstein E, Mkandawire N, Goddia C. Surgical and anaesthetic capacity of hospitals in Malawi: key insights. Health Pol Plan 2015;30(8):985–94.
2. Henry JA, Windapo O, Kushner AL, Groen RS, Nwomeh BC. A survey of surgical capacity in rural southern Nigeria: opportunities for change. World J Surgery 2012;36(12):2811–8.
3. Kouo-Ngamby M, Dissak-Delon FN, Feldhaus I, et al. J A cross-sectional survey of emergency and essential surgical care capacity among hospitals with high trauma burden in a Central African country. BMC Health Serv Res 2015;15(1):478.
4. Wong EG, Gupta S, Deckelbaum DL, et al. The International Assessment of Capacity for Trauma (INTACT): an index for trauma capacity in low-income countries. J Surg Res 2014;190(2):522–7.

5. Elkheir N, Sharma A, Cherian M, et al. A cross-sectional survey of essential surgical capacity in Somalia. BMJ Open 2014;4(5):e004360.
6. Chao TE, Burdic M, Ganjawalla K, et al. Survey of surgery and anesthesia infrastructure in Ethiopia. World J Surg 2012;36(11):2545–53.
7. Meara JG, Leather AJ, Hagander L, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. Lancet 2015;386(9993):569–24.
8. Perry L, Malkin R. Effectiveness of medical equipment donations to improve health systems: how much medical equipment is broken in the developing world? Med Biolog Engineer Comput 2011;49(7):719–22.
9. World Health Organization. Medical Devices: Managing The Mismatch: An Outcome Of The Priority Medical Devices Project: Geneva: Author; 2010.
10. Howie SR, Hill SE, Peel D, et al. Beyond good intentions: lessons on equipment donation from an African hospital. Bull World Health Org 2008;86(1):52–6.
11. Malkin RA. Design of health care technologies for the developing world. Annu Rev Biomed Eng 2007;9:567–87.
12. Emmerling D, Dahinten A, Malkin RA. Problems with systems of medical equipment provision: an evaluation in Honduras, Rwanda and Cambodia identifies opportunities to strengthen healthcare systems. Health Technol 2017:1–7.
13. Neighbour R, Eltringham R. The design of medical equipment for low income countries: dual standards or common sense. 7th International Conference on Appropriate Healthcare Technologies for Developing Countries; 2012.
14. Republic of Kenya. Ministry of Health. Kenya Health Policy 2014-2030 2014. Available at: https://www.afidep.org/?wpfb_dl=80. Accessed on April 1st, 2019
15. Diaconu K, Chen Y-F, Cummins C, et al. Methods for medical device and equipment procurement and prioritization within low-and middle-income countries: findings of a systematic literature review. Globaliz Health 2017;13(1):59.
16. Ogembo-Kachieng'a M, Ogara W. Strategic management of technology in public health sector in Kenya and South Africa. East African Med J 2004;81(6):279-86.
17. Republic of Kenya. Ministry of Health. Demystifying the Managed Equipment Services (MES) project in Kenya. Available at: http://publications.universalhealth2030.org/uploads/MES-BROCHURE.pdf. Accessed on April 1st, 2019
18. The World Bank. World Development Indicators. Washington, DC: Author. Accessed on April 1st, 2019