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Editor's Corner

In today's digital communications, institutions and individuals alike are taking extra efforts to protect the confidentiality and privacy of their records. This behavior, however, is not restricted to the digital era. Well before the arrival of what we now know as digital communications, existed the era of analog communications. The desire to conceal or to cipher records became globally notorious from the ***electro-mechanical Enigma cipher machine***. Its unique code system is illustrated on the cover page of this issue. Developed at the end of World War I, and commercialized in the early 1920s, it was adopted by military and government services – most notably, those of Nazi Germany before and during World War II (https://www.cryptomuseum.com/crypto/enigma/hist.htm).

Upon the release of the 2014 Oscar-nominated film, The Imitation Game, our society became familiar with the name and work of the brilliant mathematician, Alan Turing. Alan cracked the Enigma code at the beginning of World War II (https://www.iwm.org.uk/history/how-alan-turing-cracked-the-enigma-code) and helped decipher the military codes used by Germany and its allies. His impact on computer science has been widely acknowledged and revered. Throughout the ages, our society has gone to great lengths to protect certain records. On the contrary, here at the Global Clinical Engineering Journal, we aim to collect and share records and information by publishing them, and broadcasting this knowledge to all four corners of the healthcare world.

For a long time now, I have heard clinical engineers express that they feel underrepresented. In some way we countered that, by establishing the American College of Clinical Engineering Association (https://accenet.org); and by reviving the IFMBE/CED (http://cedglobal.org). After that, several people mentioned the need for a clinical engineering recognition/awards program… and now we have a program to do it (http://cedglobal.org/awards). Following that, others voiced their opinion about our field lacking focused general conference…and now we have a very successful International Clinical Engineering and Health Technology Management Congress (http://www.icehtmc.com). Last but not least, we have now also the newly created Global CE Journal https://www.globalce.org.

It is the duty of clinical engineers all over the world to improve patient care, and one effective way to move toward that goal is by publishing quality manuscripts that teach, increase the visibility, and contributions of our professional practice. A recent international survey by WHO suggests that there are more than 800,000 practitioners in our field. But where are the submissions?

Contrary to the Enigma machine, the Global Clinical Engineering Editorial Board and myself intend to initiate workshops and training to teach clinical engineers how to write papers that will be successfully reviewed and published – hopefully in our Global Clinical Engineering Journal. Let's open up pathways to information, encourage authors to submit, and dissolve one of clinical engineering's disreputable attributes: being fearful of publishing.

Help me to break that cycle by deciphering and sharing the knowledge our clinical engineers have to offer!

Together we will make it the best it can be!

Dr. Yadin David

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Evaluation of Medical Equipment Technology Management Performance Outcomes Related with Patient Safety: A Mathematical Analysis of Advanced Clinical Engineer

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ABSTRACT

With the rapid development of medical equipment technology, the quality of patient care becomes under the spotlight of clinical engineering management of medical equipment since the past 4 decades and it is continually. Researchers give in-depth attention to minimize undesired incidents which are associated with medical and surgical equipment such as patients' unnatural deaths and injuries. This proposed research work investigates the relationship between performance outcomes of medical equipment technology management/patient-care technology and the reduction in undesired events like injury and even unnatural deaths. This proposed research work investigates the effect of varying levels of performance on quality of patient care and uses an indicator such as patient safety (PS) and cost-effective care by applying mathematical modeling of clinical engineering approach methodology to medical equipment technology management. In this study the quality model of Clinical Engineering Departments is determined by educational qualification, Clinical Engineering (CE) certification, training, and duration of experiences in this field. The standard performance of patient-care technology management is determined by the parameters of medical devices and the outcomes performance of medical equipment is determined. Data for this study was collected from 18 countries including from high, upper and lower-middle income regions. We were able to collect and analyze data of different performance levels of CE and biomedical engineering programs. The analysts' report measures the performance outcomes of Medical Equipment Technology Management System (METMS) and its impact on patient-care outcomes specifically impact on the reduction of patient risk factors associated with medical and surgical equipment. The findings should encourage researchers and healthcare stakeholders to better integrate the clinical engineering professionals in a hospital in order to achieve a safe functional condition of medical equipment to keep its scheduled life span in compliance with recommended span declared by manufactures. Cost-effective Clinical Engineering Department (CED) model can be designed and monitored through the methodology of this study. We hope that this study will motivate the deployment of senescence methodology for conventional electro-medical assets, by biomedical engineering and medical professionals, healthcare policymakers, equipment users, and vendors to improve outcomes as proposed by the research work described in this paper.

Keywords – *clinical engineer, Clinical Engineering Department, medical equipment technology, hospital, quality of patient care*

INTRODUCTION

Ensuring the quality of patient care when medical equipment is deployed becomes a global issue and must be addressed in order to avoid unintended patient outcomes. Qualified clinical engineer's knowledge and methodologies are used as an approach to reduce risk factors associated with the use of medical and surgical equipment.[1,2] This proposed research work investigates the relationship between performance outcomes of medical equipment technology management/patient-care technology and the reduction in undesired events like injury and even unnatural deaths. Despite the continuous necessity to ensure the quality performance and impact on patient outcomes of medical equipment technology the establishment of the standardized ratio of Clinical Engineering Department (CED) in hospitals under public healthcare system, many countries could not fully accept it. As a result, every year, many patients have been subjected to serious risks and even unnatural death which was not reported to agencies in many countries. For lower- and middle-income counties, this data is often hidden and frequently, both the doctors and patients were not aware of the cause.[3–5]

This proposed research work investigates the effect of varying levels of performance on quality of patient care and uses indicators such as patient safety (PS) and cost-effective care by applying mathematical modeling of the CE approach methodology to medical equipment technology management. In this study quality model of CED's is determined by educational qualification, CE certification, training and duration of experiences in this field. The standard performance of patient-care technology management is determined by the parameters of medical devices and the outcomes performance of medical equipment is determined.[6–8] Data for this study were collected from 18 countries including from high, upper and lower-middle income regions.[9]

While technology reliant patient-care services can vary widely in their dependency, the ratio of clinical engineering professionals serving the population can be one indicator that is common to many regions. One Clinical Engineering Professional (CEP) can adequately service technologies supporting a population of 10,000 persons, and one CED can manage CE service program for region with a population of 10,000.[9] Quality performance of CEP and Medical Equipment Technology Management System (METMS) can be standardized by adopting parameters that relate to equipment performance such as unintended incidents, downtime, cancellation of patient examinations due to equipment issue, and similar known indicators.[10,11] By using mathematical analysis, the performance outcomes of METMS can be benchmarked and compared with other facilities.[10] It must be remembered that even a 100-bed modern hospital operation is ensuring the quality and safety of patient-care in any zone of a country.[10] The performance outcomes thus relate to patient-care outcomes and the status of patient safety (PS) can be measured by tools such as laptops, pen drives, Internet modems, cell phones, and testing analyzer use for data collection. This investigation interpreted correctly, can contribute to the development of voluntary guidelines for adopting and improving performance reporting. Similarly, patient-care organizations and groups actively involved in furthering measurement, management and reporting may use this methodology in assessing the impact of work carried out by them in adopting the CED model in hospitals to evaluate and enhance the performance of patient care like P_S and educating them for ensuring the standard performance of MEMTS.[11]

We were able to collect and analyze data of different performance levels of CE and biomedical engineering programs. The analyst's reports measure the performance outcomes of MEMTS and its effect on patient-care outcomes specifically on the reduction of patient risk factors associated with medical and surgical equipment. The findings should encourage researchers and healthcare stakeholders to better integrate the CEPs in their hospitals in order to achieve a safe functional condition of medical equipment and to keep its scheduled lifespan in compliance with those recommended by the manufactures.[12] A cost-effective CED model can be designed and monitored through the methodology of this study.

Despite barriers including low willingness, competing business group interests, and unethical pressure from some personnel within the healthcare system,[13] it is for the benefits of the patients, their relatives, and taught stakeholders that well-managed healthcare technology has a positive impact on care outcomes and on the optimal use of limited healthcare resources. This investigation, if

interpreted correctly, can contribute to the development of voluntary guidelines for adopting and improving performance reporting. Similarly, patient-care organizations and groups actively involved in furthering measurement, management and reporting may use this methodology in assessing the impact of work carried out by them in adopting the CED model in hospitals to evaluate and enhance the performance of patient care like P_S and educating them for ensuring the standard performance of METMS. But, in spite of some challenges, the need for this proposed research work cannot be denied.[13,14] We hope that this study will motivate the deployment of senescence methodology for conventional electro-medical assets, by biomedical engineering and medical professionals, healthcare policymakers, equipment users, and vendors to improve outcomes as proposed by the research work described in this paper. While an analytical approach to P_S and cost-effective care has become the expectations of patients, this topic is starting to be explored in the literature, mostly concluding that additional data is needed.

RELATED DEFINITIONS AND TERMINOLOGIES

While it is unreasonable to assume that clinical engineeThis section uses definitions and terminologies related to the proposed research with subsequent subsections presenting different definitions and terminologies.

Evaluation

Evaluation is a systematic determination of a subject's merit, worth, and significance using criteria governed by a set of standards. It can assist an organization, program, project, or other intervention or initiative to assess any aim, realizable concept/proposal, or alternative that would help in decision-making, or to ascertain the degree of achievement or value in regard to the aim and objectives and results of any such action that has been completed. The primary purpose of evaluation, in addition to gaining insight into prior or existing initiatives, is to enable reflection and assist in the identification of future changes.[15–17] In this study, we evaluate the performance outcomes of METMS to understand the situation of PS.

Medical Equipment Technology Management

Confusion is often seen in research with the use of some of the terminology such as Healthcare Technology (HT), Medical Technology (MT), Medical Devices Technology, Medical Equipment Technology (MET). For better understanding, we submit an explanation in this section. The World Healthcare Organization (WHO) has defined HT as the "application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life.[18]" The International Network of Agencies for Health Technology Assessment has stated that HT includes pharmaceuticals, devices, procedures, and organizational systems used in the healthcare industry, as well as computer-supported information systems.[19] But our proposed study deals with MET which is one of the major elements of HT. In the United States, these technologies involve standardized physical objects, as well as traditional and designed social means and methods to treat or care for patients.[20]

Wikipedia has stated that HTM sometimes referred to as CE, CE management, clinical technology management, HT management, medical equipment management, biomedical maintenance, biomedical equipment management, and biomedical engineering.[21] MT may broadly include medical devices, information technology, biotech, and healthcare services.[21] Alternatives terms have mentioned in 2 statements. Among them, the term "clinical engineering management" is appropriate for the proposed research work. The justification for the selection of MET management for this proposed study has given as the statement in the next paragraph.

The synonym of clinical engineering is medical engineering and besides technology is one of the parts of engineering and clinical engineering role is to maintain the management of medical equipment. So according to references and discussions, the term clinical engineering management" can be used as "medical equipment technology management." For the entire proposed research work, the term medical equipment technology management is to be used. METMS can be defined as the mechanisms for interaction and oversight of the medical equipment used in the diagnosis, treatment, and monitoring of patients. The related policies and procedures govern activities from selection and acquisition to incoming inspection and maintenance of medical equipment. The main goal of METMS is to ensure that the equipment used in patient care must

be safe, available, accurate, and affordable. This article deals with the evaluation of the performance outcomes of medical equipment technology management system that are related to patient safety.

ADVANCED CLINICAL ENGINEER'S APPROACH

Although procedures can vary from one field of inquiry to another they are often quite similar. The process of a skilled CE method involves making hypotheses, deriving predictions from them as logical consequences, and then carrying out experiments or empirical observations based on those predictions such as quality of CED models and their contributions for appropriate controlling of MET to ensure the PS.[24]

Methodology

The safe functional condition of medical equipment ensures it reaches its scheduled life span in compliance with manufacturers recommendations. These are the outcomes of HT management and it is actively related to patient satisfaction parameters such as PS, quality, and cost. However, this can not be ensured by many countries due to a lack of a skilled clinical engineer's approach. While the global CE forum has been trying to improve the quality of CEPs in many higher, upper-middle income countries, lower-middle-income countries have not yet implemented the conventional engineering approach for managing the medical equipment in their countries. Authors have stated that a conventional CEP is 14% of the skills on METMS. Investigation reports show that the P_S of these countries has become questionable and it is continually.[25] Subsequent studies provided additional quantitative data. In a landmark report, "To Err is Human: Building a Safer Health System," the Institute of Medicine estimated that medical errors cause 44,000 to 98,000 deaths annually in U.S. hospitals.[26] We did not find any articles regarding MET assessment in lower-middle income countries such as Bangladesh due to a chronic lack of a CE approach. Investigation reports by the WHO in 2017 report that the density of biomedical engineering professionals and density of hospitals with biomedical engineering department unit/service are very poor to negligible in lower-middle income countries like Bangladesh, Bhutan, Pakistan, Nepal, Sri-Lanka and so forth.[9] As a result, the performance outcomes of METMS in these countries have not been good. The investigation report of the World Bank has stated that more than 65% of medical and surgical equipment were not functioning in Bangladesh public hospitals.[27] Functional equipment in the intensive care units of Bangladesh hospitals provided much error-filled data. From the investigation report, we have observed that P_S is very poor in the intensive care units of 6 modern hospitals in Bangladesh due to the absence of hospital CEDs.[28]

Some of the issues are outlined below:

A. The staffing model of the CED could not design and develop to match the workload and activities of the hospitals.
B. The message of modeling a CE approach for evaluating the quality of patient care could not be properly disseminated among healthcare stakeholders properly thus eliminating the conventional engineering approach by the research.
C. The concept regarding the importance of modeling of CEDs and their relation to obtaining safe outcomes performance of METMS as well as its relation with parameters of quality of patient have yet to be unexplored in the literature.
D. Both patients and medical doctors are not yet aware of the benefits of introducing quality CED models in the hospitals.

Objectives of this study are as follows:

1. To define the outcomes of METMS and its impact to ensure PS
2. To investigate the present densities of CEP and CED per 10,000 population
3. To analyze the outcomes of METMS related to CED
4. To specify densities of CEP and CED and their quality related to outcomes of METMS
5. To evaluate the performance outcomes of METMS to P_S
6. To submit a recommendation for improving the present poor conditions

The purpose of this section is to undertake a literature review focusing on P_S by applying the quality model of CED. Shaffer has submitted a statement regarding the selection criteria of one clinical engineer professional based on population and bed numbers of the hospital.[26]

The author stated "the recent history of this sub-discipline is somewhat erratic. In the early 1970s, CE was thought to be a field that would require many new professionals. Estimates for the U.S. ranged as high as 5,000 to 8,000 clinical engineers or 5 to 10 clinical engineers for every 250,000 of the population, or one clinical engineer per 250 hospital bed."[26]

From this statement, it is found that one CEP was needed per 31,250 people in the U.S. The WHO literature has suggested that one CEP is required per 10,000 people in general regions.[9] From this statement, we have observed that the current demand for biomedical engineering professionals has significantly increased more than threefold over the past 48 years. This has been revealed by the earlier publication by Shaffer.[26] Besides the densities of CEP/BEMP and hospital with CED/biomedical engineering unit/service were presented for per 10000 population of WHO enlisted countries respectively. The data are very much helpful for this study.

Pietro et al stated that an HT or MET assessment process is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods.[2] Given the variety of impacts addressed and the range of methods that may be used in an assessment, several types of experts are needed in HTA. Among them, clinical and biomedical engineers are considered the key components for the HTA. ACCE defines, the clinical engineer as a professional, who supports and advances patient care by applying engineering and managerial skills to HT.[23] The performance of METMS is very much important and related to the outcome of patient care and safety.[9] Eighty percent of METMS is maintained by the hospital in-house CED, and clinical departments are responsible for maintaining the remaining 20% of METMS.[23] Hossain et al have stated that a skilled clinical engineer maintains 52% of METMS in the modern hospital and subsequently, a typical METM cycle is represented in Figure 1.[28]

The WHO has stated that introducing quality biomedical/clinical engineering department unit/service is compulsory in modern hospitals to obtain the quality outcomes of METMS.[9] From a comprehensive literature review,[11] it was found that it is very important to develop a model of CED which consists of a skilled clinical engineer, a CE technologist, and a biomedical equipment technician. Their performances can be determined by basic education, accredited certificate on MET, and length of services in this field. Regardless of the necessity to design and introduce a quality CED model to optimize the use of MET, many countries could not yet do so. As a result, the lower performance outcomes of patient-care technology reduced the quality of patient outcomes. A group of search results explored that P_S has been reduced with rapid increases of complex medical devices in lower-middle income countries. This study investigated the quality model of a CED and its performance outcomes related to PS.[6,11] It has also been shown common models of CED for HT management system for the hospitals. For example, a CED model is shown n Figure 2.

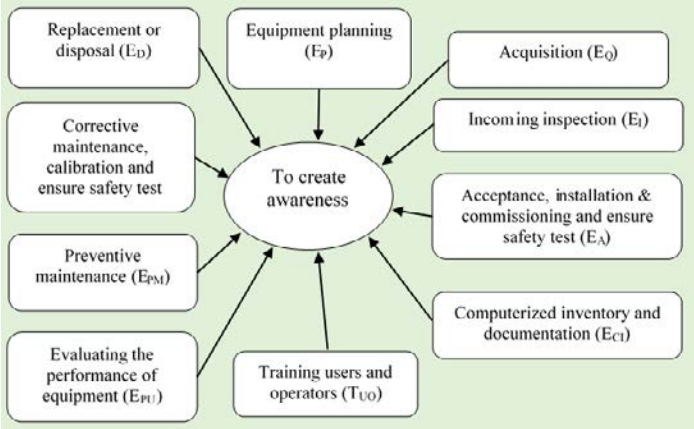

FIGURE 1. Roles of the Clinical Engineering Department to ensure the performance of Medical Equipment Technology Management Systems parameters.

Figure 2. does not include a clinical engineering technologist (CET) to ensure the safe operation of critical equipment such as a heart-lung pump machine. Whereas, a group search results suggested that 3 types of engineering professionals must be considered such as engineers, technologists, and technicians.[29] Other studies (e.g., Japan, Malaysia) have also emphasized this to ensure safe operation and preventive maintenance tasks.[9,23] Recent publications note that CETs are very much important human resources to ensuring the safe operation of life support, therapeutic, and monitoring equipment in the

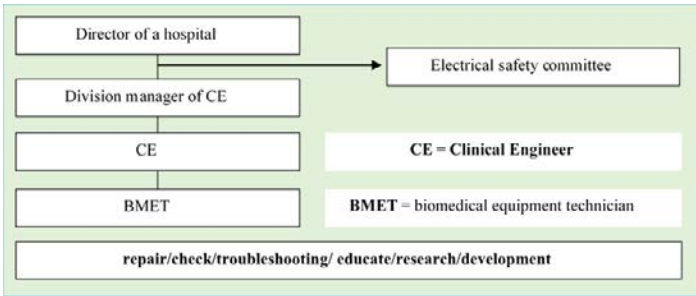

FIGURE 2. Clinical Engineering Department model for a hospital in the U.S.

critical care departments in a hospital.[22] Other studies suggest that CETs are the best operators of life support, therapeutic, and monitoring equipment in the Critical Care Unit, the Intensive Care Unit, the Operating Theatre, and the Dialysis, Anesthesia, and Emergency Departments as well.[29,30] Integration of CEs, CETs, and biomedical equipment technicians (BMETs) are shown in Figure 3.

METMS are very much closed to CEDs for patient care. Certified staff from CEDs are much better than Conventional Engineering Department in hospitals. But, it is not possible to ensure all parameters of METMS by CEs

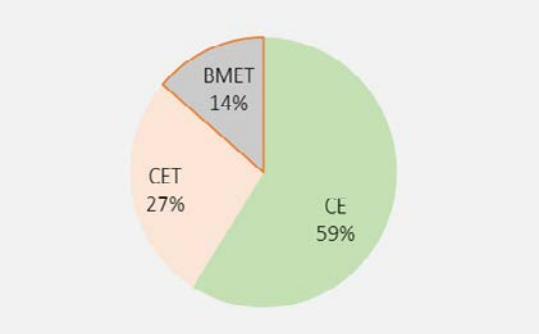

FIGURE 3. A basic model of a Clinical Engineering Department for a hospital.

CE = clinical engineer; CET = clinical engineering technologist; BMET = biomedical equipment technician.

because some parameters of METMS are actively related to CETs and BMETs. The overdependence on the use of technology in every treatment step can result in severe economic burdens for families and individuals. However, the cost can be minimized by ensuring the desired lifecycle of the medical equipment. From literature review results it was observed that the model of a CE approach can ensure the safe use of equipment up to the expected life span.[22] The World Health Organization noted that one CEP can be considered per 10,000 population. From the literature review results,[22] the performance of A_p can be considered as 100% subject to accessibility of the density of CEP=1, per 10,000 people and the performance of G_p can be considered as 100% subject to density of hospital with CED unit/service of 3.00 per 10,000 people to ensure 24-hour services. So, the performance of A_p = 1 @ density of CEP=1, and G_p=100%. @ hospital density with CED unit/service CED= 3 for per 10,000 population in a country.

RESEARCH METHODOLOGY

Goal of the Prospective Research

The main aim of the proposed study is to evaluate the performance outcome of METMS by applying skilled a CE's approach to enhance the present PS. The sub-objectives of this proposed study are explained below:

1. To investigate and standardize the performance of CEPs per 10000 people in a country.
2. To investigate and standardize the performance of CEDs per 10000 people in a country.
3. To control the performance of CEDs by CEPs to obtain a standard output of METMS for ensuring PS.

Research methodology and materials

Let R_p and C_p are the desired input and actual output METM that depends on the standard performance of CED. From the literature review results,[3-5] it has seen that the performance of METMS is dependent on the quality of the performance of the CEDs. The CEPs are the controller or regulator of the CEDs and which control the performance of the CED (i.e., CEP controls the performance of METMS). Here, CEP is defined as the clinical engineering manager who monitors and evaluates the performance output of the CED. According to the basic argument in the literature review results and discussions, the methodology of the proposed study can be presented by Figure 4.[17]

Based on the desired input quantity being improved, and on the actual output condition, the input and output variables can be modeled as safe functionality of medical devices up to their standard life span. According to Fig.4

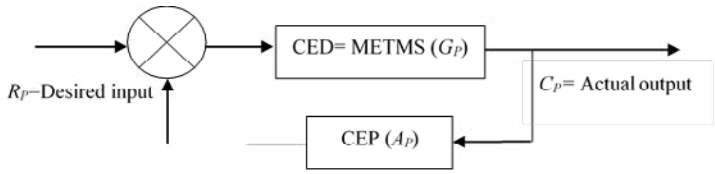

FIGURE 4. Proposed research methodology to evaluate the performance outcomes of METMS that is with patient safety.

Here, R_P= Desired input of METMS which related to standard performance of CED.
C_P= Actual or measured output of METM which related with standard performance of CED.
Let, G_P=Standard performance of METM that depends on the standard performance of CED.
A_P= Standard performance of skilled clinical engineer and which control the input & output of METMS by engineering and managerial skills.

& basic feedback control theory, the output performance of G_P can be measured by the following Eq. (1)

From Eq. (1), it is seen that the value of C_P is dependent on the value of A_P and G_P. So, this is needed to standardize the performance of A_P and G_P and thus from Eq. (1), the value of C_P can be measured.

$$C_P = \left[\frac{G_P}{1+G_P.A_P}\right] \times R_P \quad (1)$$

Basic analysis of the proposed study

The value of C_P is dependent on G_P and A_P. Figure 4 shows that A_P works as a sensor for the system. So, for an enhancing output and stability of the system, the performance of A_P must be kept in a standard setting point. Besides, it is needed to keep the performance of G_P as standard. We can consider the desired input or reference input such as the safe functional condition of medical devices up to their standard life span= R_P=100%. As it is related to the P_S and desired by the patient, 100% can be considered. It is obvious that patients do not expect to suffer unintended outcomes including accident, injury, or other harm from medical devices. For any value of G_P, the value of $(1+A_P.G_P)$ should be greater than G_P and the value of C_P/R_P will be less than 1 or the value of C_P will be less than 100%.

For testing the proposed work methodology, let us consider A_P=1 and G_P=100% and by the calculated of C_P will be 99%. From a group of search results it is found that the sensor's setting point 1 is standard.[8,9,11] To set the standard value of A_{pe}=1, it is needed to standardize the performance of A_P. Besides, the performance of G_P is needed to standardize.

CED = Clinical Engineering Department; METMS = Medical Equipment Technology Management System.

Standardize performance of A_P and G_P

The performance of A_P of G_P can be standardized by the following Eq. (2) and Eq. (3).

From the literature review results, the performance of A_P can be considered as 100% subject to accessibility of density of CEP=1, per 10,000 population and the performance of G_P can be considered as 100% subject to the density of hospital with a CED unit/service of 3.00

$$Density\ of\ CE = \frac{\text{Population in a country}}{\text{Number of CE per 10000 population}} = A_p \quad (2)$$

$$Density\ of\ CED = \frac{\text{Population in a country}}{\text{Number of Hospital with CED per 10000 population}} = G_p \quad (3)$$

per 10,000 population to ensure 24-hour services.[17] So, the performance of A_{pe}= 1@density of CEP=1, and G_P=100%. According to the literature it is observed that the density of a hospital with a CED is 3. 5 per 10,000 people in Japan.[9] It can also be considered that the density of a hospital with a CED service is 1 for 8 hours per 10,000 people. For ensuring 24-hour CED services with a minimum density of a hospital with a CED per 10,000 people can be considered as 3. According to a statement by Hiroki Igeta from the Clinical Engineering Bank,[9,31,32] it was observed in staff for a CE service structure that the quality of patient care was related to the number of the skilled human workforce. For example; the optimal ratio for medical doctors to population are 1:1000. Available statistics show that over 45% of WHO Member States report to have less than 1 physician per 1000 population. CEPs and CEs are not at the same levels. A CEP is defined as a senior skilled CE. So, one CEP can be considered for 10,000 people a standard setting point of A_P. From a group of literature review results, it was observed that 24 hours of equipment services are required to ensure P_S in the Critical Care Unit.[7–9,11] So, the CEDs services are considered as 3 times for 24 hours. Staff duty is considered as 8 hours and regarded as fulltime employ (FTE). Therefore, the density factor has considered as "3". From the discussions, the value of A_P and G_P can consider as A_P=1, to ensure 100% performance and CED= 3 to ensure

the 100% performance of G_P. So, the value of the sensor can be determined by the density of CEP for 10000 population (D1). So, the relation between A_{pe} and D1 is inversely proportional. Standard performance of D_1 is set by D_1=1 and its inverse corresponding values are shown as A_P. Standard performance of D_2 is set by D_2=3 and its proportional values are shown by G_P. For validation, the proposed work methodology the values of C_P are shown. The standard data of A_P and G_P and their corresponding values C_P are shown in Table 1.

Table 1 shows the validity of the prospered research work methodology. Next section uses for data collections and data analysis related to A_P and G_P.

TABLE 1. Standard Data Related to the Proposed Study

Integer	D_1	A_P	D_2	G_in	$C_P = \left[\frac{G_P}{1+G_P A_P}\right] \times R_P$
1.	1	1	3	100%	99%
2.	0.9	1.11	2	66.67%	88.88%
3.	0.8	1.25	1	33.34%	78.12%
4.	0.7	1.43	0.9	30%	68. 34%

Data collection to standardize the performance of A_P and G_P

Data collection has been accomplished by a survey conducted by the WHO in 2017. Global dimensions of biomedical engineers,[9] has submitted a survey report on D_1 and D_2. Based on data and the basic theme, the existing data were analyzed and as A_P and G_P and outlined in Table 2.

TABLE 2. Present Data of A_P and G_P for 18 Countries

Country code	The density of CEP per 10,000 people (D_1)	A_P	Density hospital with CED unit per 10,000 people (D_2)	G_P in%
Any country	1	1	3	100
JPN	1.58	0.64	3.5	116
SVN	0.84	1.2	1.35	45
BEL	0.87	1.5	1.25	42
IRL	0.7	1.42	1.21	41
KIR	0.27	3.7	2.93	97
MYS	0.82	1.2	0.84	28
PAN	0.83	1.22	0.74	25
MNG	0.81	1.18	0.74	25
FIN	2.73	0.37	0.09	3.9
ISR	2.48	0.42	0.09	3.9
ROU	0.64	1.56	0.30	10

Country code	The density of CEP per 10,000 people (D_1)	A_P	Density hospital with CED unit per 10,000 people (D_2)	G_P in%
JOR	0.67	1.49	0.16	5.33
AUS	0.13	7.69	0.43	14.33
IND	0.34	2.94	0.12	4.00
ZAF	0.06	16.67	0.34	11.33
MDS	0.03	33.34	0.037	1.23321
BTN	0.08	12.5	0.047	1.56651
PAK	0.02	50	0.1	3.333

Data collection and statistical analysis

Based on the analysis, the value of C_p can be evaluated using Eq.(4) below.

$$C_P = \frac{100}{1+1\times 100} \times 100\% = 99\% \quad (4)$$

So, the standard value of C_P=99% and it is the output of METMS(G_p). C_p=Safe functional condition of medical equipment to reach its scheduled life span in compliance with the manufacturer's recommendations. But, this factor is related to P_S and thus the values of C_p are proportional to PS. This research methodology can be used as the standard for any country.

The analyst's data in Table 3 regarding A_P & G_P were used to evaluate the values of C_p using Eq.(1) and these values are shown in Table 3.

TABLE 3. Statistical Data Analysis of CP of 18 Countries

Country code	A_P	G_P %	C_p
JPN	0.64	116	178.841
SVN	1.2	45	36.82
BEL	1.5	42	27.60
IRL	1.42	41	28.40
KIR	3.7	97	26.14
MYS	1.2	28	22.62
PAN	1.22	25	19.84
MNG	1.18	25	20.50
FIN	0.37	3.9	6.25
ISR	0.403226	3.9	5.92
ROU	1.5625	9.999	6.01
JOR	1.492537	5.3328	3.18
AUS	7.692308	14.3319	1.85
IND	2.941176	3.9996	1.25
ZAF	16.66667	11.3322	0.68
MDS	33.33333	1.23321	0.037
BTN	12.5	1.56651	0.12
PAK	50	3.333	0.067

Results and discussion

The maximum value of C_p has found as 178.84% in Japan and the minimum value of C_p has found 0.067% in Pakistan. For authentication of the results, we examined the in-house CE models of Japan and Pakistan. According to the standard guideline of the WHO, we have seen that the maximum 12 CEs were necessary for the Aso Hospital in Japan.[28] But Igate and colleagues suggested 63 CEs under the CED in Aso Hospital.[32] He has stated that

improvement to the level of service for patients was a result of standardized clinical techniques ensuring the efficient and safe use of medical equipment.

The performance of the A_p has found as more than 1 and its corresponding sensor setting point of the feedback controller is 0.64 and is shown in Table 2. On the other hand, the value of D_2 is 3.5 and it is more than 3. This indicates that the performance of G_p is higher than 100%. From the data of CEP and CED, we have seen that Japan has introduced more CEs to cover 24-hours of services such as other Intensive Care Unit professionals. Besides, it is found that common medical equipment such as ventilators, defibrillators, hyperbaric oxygen therapy, hemodialysis, cardiac pacemakers, and surgical equipment have been operated by the CETs. Therefore, the performance output value of MEMTS in Japan is (1.80×99%) = 178.84% and that is 1.8-times higher than that of the standard actual value of C_p. From the data, it was found that 10% of hospitals of Pakistan have introduced the biomedical engineering department and the number of biomedical engineers was 0.02 per 10,000 people. Therefore, the measuring feedback sensor setting point of this country was 50. The values of C_p was found as 0.07% which is quite poor.[9,32]

Analysis and discussion

Despite being developed countries, FIN, ISR, and AUS, showed poor values of C_p. The evaluated value of C_p in Japan was found to be much higher than the standard among the 18 countries. Although the performance outcomes of METMS of 7 countries were found to be less than that of the actual standard value of C_p, it can still be considered. The analysts' reports also show that the C_p values of 10 of the 18 countries were much poorer than that of the standard.

Limitation of data collection and analysis

It is complex to get the data of CED models including staff numbers and hence we consider only the data of hospital with a CED. Our proposal was to skilled CE's approach and for this reasons CET and BMET data could not be collected due to a lack of secondary data in the literature. And thus, we evaluated the C_p on combined data. But Hossain et al stated that a skilled CE is responsible for ensuring 52% of the outcomes of the METM cycle.[33]

Based on data, the standard C_p and actual evaluated C_p are shown in Table 4.

TABLE 4. Standard and Evaluated Performance of Outcomes of Medical Equipment Technology Management Systems in 18 Countries

Country code	Standard C_p as published	Evaluated C_p according to present data
SVN	52	36.82
BEL	52	27.60
IRL	52	28.40
KIR	52	26.14
MYS	52	22.62
PAN	52	19.84
MNG	52	20.50
FIN	52	6.25
ISR	52	5.92
ROU	52	6.01
JOR	52	3.18
AUS	52	1.85
IND	52	1.25
ZAF	52	0.68
MDS	52	0.037
BTN	52	0.12

Table 4 shows a comparative statement between standard and evaluate C_p according to skilled CE's approach and the data was validated by the secondary research method.[9,30]

Patient safety and outcomes of METMS

Summary of the literature review results confirms that patient safety is proportional to the outcomes of METMS.[34]

We note patient safety as P_S and the outcomes of METMS as C_P. So, the relation between P_S and C_P can be explained by the relationship below in Eq.(5).

$$P_S \alpha C_P \quad (5)$$

The data from Table 4 shows that P_S is very much negligible in lower-middle income countries although the P_S of some higher income countries was found to be poor as well. Also, employing an outsourced CED is very expensive and risky for the patient.

CONCLUSION

The goal of this paper was to understand the current performance outcomes of METM that are related to P_S in 18 high, upper and lower-middle income countries. Most of the developed countries have introduced a BMED service unit for their hospitals without studies which has led to overstaffing and understaffing models of CED/BMED that are not what is best for the patients. Overstaffing can be expensive while understaffing models of CED are very inefficient when it comes to ensuring outcomes performance of METM and puts the patient at risk.

While high and upper middle-income countries have been aware of CE issues, healthcare stakeholders in lower-middle income countries are generally not aware of this subject. This study brings effective results to raise the awareness of the present healthcare stakeholders to introduce one CED in the modern hospitals according to the workload and complexity of the MET. This will improve the present undesired outcomes of METM and the associated patient risks. Necessary recommendations to improve the present undesired conditions are included below.

RECOMMENDATIONS

Based on results and discussions, the following suggestions/recommendations have submitted to improve the present undesired conditions.

1. It is necessary to establish a CE association in each country under the umbrella of the Global Clinical Engineering Forum to disseminate the Global Clinical Engineering Issue.
2. It is necessary to evaluate the performance of METM by utilisation of an advanced CE as the representative in countries that have not yet introduced models of CED in their hospitals.
3. The assigned advanced CE in a position to measure the performance outcomes of METM and publish reports in a yearly "Health System Review" of their concerns to motivate and to raise awareness among healthcare stakeholders. Online course can be started to ensure certified globally CEPs are available.
4. The local office of WHO in each country can invite workshop/seminar/national conference/quarterly meetings with healthcare stakeholders by lead by an advanced CE.
5. A member or country ambassador should be selected by the CED of the International Federation of Medical and Biological Engineering to further and share updated enhancements in CE.
6. More case studies should be published in GCEJ to promote the advantages and benefits of having an in-house CED such as the reduction of patient risks and the reduction in healthcare operating costs associated with medical and surgical equipment management.
7. It is necessary to invite academic biomedical engineering departments from lower and middle-income countries to submit of research articles in this field.
8. There should be an effort to encourage the representatives from the WHO, JICA, World Bank, CIDA, USAID, and UNICEF to help in disseminating the message of "Global Clinical Engineering" in their respective countries.

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CONFLICT OF INTEREST

The author declares that there is no conflict of interest regarding the publication of this paper.

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Identification of Health Technology Management departments in Mexico's State Health Services

By R. Ayala, E. Orencio

CENETEC-Salud, México

ABSTRACT

Due to a lack of verifiable, reliable, and up-to-date official information, the National Center for Health Technology Excellence (CENETEC) carried out a survey of information to identify the organizational areas in charge of the verification and the development of Health Technology Management (HTM) that the State Health Services in Mexico are obliged to perform within each of the 32 States. It was determined that not all States had a department with a specific designation for HTM. Also, it seems the vast majority of existing areas are led by a biomedical engineering professional who responds to infrastructure planning area directives. These findings seek to promote a discussion on the need to standardize this type of service from State Health Services across the country.

Keywords – *biomedical engineering, health technology management, public health services.*

INTRODUCTION

The Mexican health system is composed of public and private sectors. The public sector includes social security institutions such as Instituto Mexicano del Seguro Social (IMSS), Institute of Security and Social Services of State Workers (ISSSTE), the health services of federal agencies Petróleos Mexicanos (PEMEX), the Secretary of National Defense (SEDENA), and the Secretary of Navy (SEMAR). On the other hand, there are health services for people who are not insured by any of the institutions previously mentioned. These people are cared for by health organizations under the control of the Federal Health Ministry and the 32 State Health Services. This is done with financial support from the Health Social Protection System known as Seguro Popular.[1]

Any organization that offers health services must carry out health technology management (HTM) which is defined as the "set of systematic procedures to provide and evaluate the appropriate, safe, effective, and cost-effective technology in health care establishments, with the aim of ensuring the care and good use of the medical equipment by verifying its functionality, security, and availability to ensure effective access to health services."[2] These processes fall into various operational, medical, or administrative departments but Biomedical Engineering

(BME) services are considered to be the most appropriate for coordinating these tasks.

In Mexico, there is no formal or updated census of BME departments in hospitals. According to the Information Base of Health Establishments (CLUES[3], a government information system), there is a register of 85 BME departments in hospitals from the State Health Ministries which represents only 12% of total coverage. Given this circumstance, the strategy has been to encourage the creation of central areas in the offices of each State to meet the needs of the HTM for all hospitals under its jurisprudence. However, there has been no formal register for those either.

Therefore, in 2018, the National Center for Health Technology Excellence (CENETEC), a Ministry of Health agency, through its BME department, undertook the task of running a situational diagnosis of the areas responsible for HTM in the 32 State Health Services. The goal was to identify the existing areas of opportunity related to the execution of the processes and the corresponding activities of the personnel in charge.

As this was the first time that an exercise of this nature had been carried out at the State Health Services, it was important to be able to have updated data to make an analysis of the situation and determine which areas were the responsibility of the HTMs. This would allow the further development of strategies to improve these processes in an efficient and responsible way.

METHODS

A questionnaire was prepared to identify the existence of areas or departments where HTM processes are involved in the State Health Services, their position within the organizational structure, as well as the human resources and materials they have available to them to carry out their tasks. The general items requested were as follows:

1. The State they are located
2. The data from their BME Department
3. The information regarding the person in charge of their BME Department
4. The area of the HTM processes they are part of
5. The infrastructure they have available to carry out their HTM processes

The questionnaire was given to personnel identified as possibly responsible for one or more HTM processes within the 32 State Health Services and the following relevant data obtained is outlined below.

The answers revealed:

- The organizational structure of the areas responsible for HTM.
- The name designation for each area responsible for HTM by State.
- The number of areas falling under the term "Biomedical Engineering."
- The profession of the person identified as being responsible for HTM and their duties.
- The identification of the areas that carry out HTM processes.

RESULTS

Organizational Structure

The 32 States responded with the information requested and it was possible to carry out the analysis to obtain the following results outlined below.

Twenty-four State Health Services (SESA) had an area using the term BME or something similar. In 8 SESAs an area with a similar designation could not be identified (Figure 1).

FIGURE 1. States with a department or area responsible for Health Technology Management.

It was found that 20 different groups or departments had incorporated variations of the title "Biomedical Engineering." These included Director of Biomedical Engineering, Deputy Director of Biomedical Engineering, Department of Biomedical Engineering, Biomedical Engineering Coordination, Biomedical Services Coordination, and Biomedical Area. Other similar names used were Department of Technological Support to Hospitals, Department of Electromechanics, Department of Maintenance to Medical and Electromechanical Equipment, Department of Recovery of Medical Equipment, Department of Maintenance to Medical and Electromechanical Equipment, and Technology and Supplies Coordination. These designations suggest these people/departments have one or more HTM processes as part of their responsibilities.

FIGURE 2. State Health Services that have an area that is responsible for HTM within their formal structure.

Ten of these departments were found within a formal organizational structure while 14 were not, and as shown in Figure 1, 8 did not have an area responsible for HTM. Figure 2 shows the States where the areas responsible for the HTM in the formal organizational structure existed within the State Health Services.

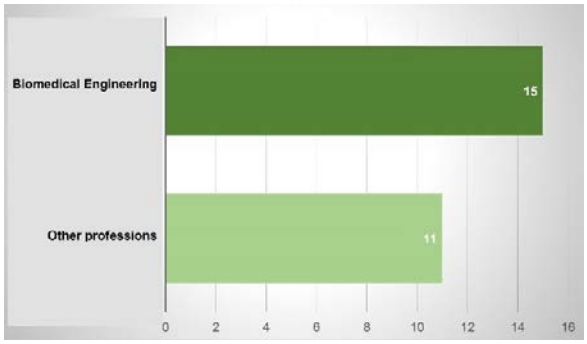
Data regarding which area (administrative, medical or planning) provided direction to the HTM are outlined below.

In 12 States, the HTM area depended on direction from a planning or infrastructure group; 6 States depended on direction from a medical department; 4 States depended on direction from an administrative branch; and 2 States have 2 HTMs being directed by 2 different groups (Figure 3).

FIGURE 3. Health Technology Departments line of command.

Human Resources

The results shown in the graphs below include data from States that have the area responsible for HTM. Graph 1 shows the professions of those responsible for the areas reported. Please note the prevalence of the BME profession.

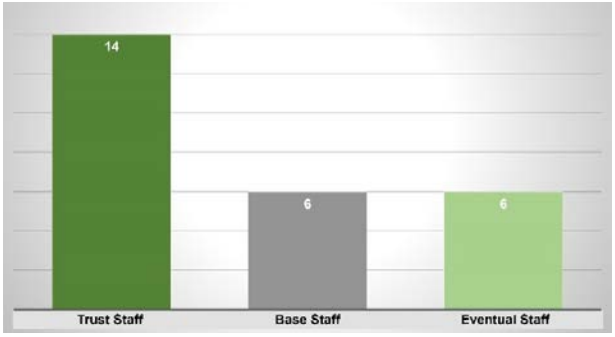


GRAPH 1. Profession of those responsible for Health Technology Management in State Health Services.

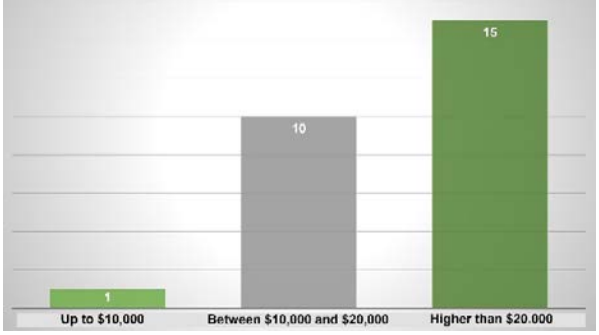
Graph 2 illustrates the type of job contract held by the person responsible for HTM. "Trust Staff" are those who have a formal contract, "Base Staff" are those who have a permanent contract, and "Eventual Staff" are those who have a short-period contract that may or may not be renewable.

Graph 3 presents the monthly salary for those responsible for HTM according to the level of position where the prevalence is higher than $20.000 Mexican pesos.

HTM Processes Attended

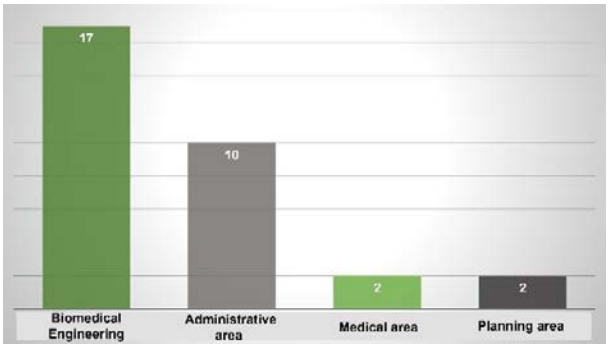


GRAPH 2. The type of job contract held by the person responsible for Health Technology Management.



GRAPH 3. Salary level of the person responsible for Health Technology Management in State Health Services.

Graph 4 outlines the prevelence of tasks involving the the HTM processes and the execution of these processes and which areas in State Health Services carry them out. In 17 States the BME-related areas were the groups who executed most of the HTM processes, while in 10 other States this work was carried out by administrative areas.



GRAPH 4. Prevalence in the execution of the Health Technology Management process in State Health Services.

CONCLUSION

In accordance with the results obtained it can be observed that even when 24 of 32 States have an area related to BME to carry out HTM functions, only 42% are positioned within the formal structure of the SESA and also their department name is often not consistent with other similar groups which can cause confusion.

Taking into consideration the reported areas, 57% have a professionally educated BME as the person in charge. This indicates that this profession should be at the forefront for coordination of the HTM processes. In the same way, according to the data provided, (53% of the cases), there is a high likelihood that the BME area has been designated as the group that should be responsible for carrying out the HTM processes. This was followed by the administrative area that had been designated in 31% of cases.

It could be said that the numbers are promising, but challenges still exist towards achieving effective coordination of the HTM processes in the public health sector.

The next step could be an analysis of the efficiency and effectiveness in the HTM processes when they are carried out by the specific areas chosen. Meanwhile, the material presented in this paper will allow a focused effort to continue formulating strategies associated with HTM that can promote safe, quality, efficient, and cost-effective access to health services.

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Medical Device Donation Practices in Canada: A Survey of Donor and Recipient Perspectives

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ABSTRACT

Background and Objective: Although developing countries have been receiving donations of medical equipment for many years, a number of studies have indicated that a high percentage of donated equipment is never put into use.[1,3,4] Many of the reasons for this can be traced back to inadequate donation practices on the part of donor organizations. The objective of this study was to gain an improved understanding of the practices and challenges associated with medical equipment donations by Canadian charitable organizations.

Material and Methods: Forty-one organizations (registered and non-registered charities, non-governmental organizations (NGOs), non-profit organizations, medical clinics, and hospitals) completed an online survey, and 16 respondents were interviewed via telephone or in person. In addition, representatives from 28 hospitals in Ghana were interviewed in person to gain an understanding of the recipient experience.

Results: We observed that for many Canadian donor organizations there is room for improvement in formalizing procedures, testing to verify equipment functionality before shipping, providing additional support for recipients in the form of manuals, spare parts and training, and long-term monitoring of donated items to measure effectiveness. For recipients, the most common challenges faced were lack of spare parts, and lack of operating or service manuals. Despite these challenges, all of the Ghanaian survey respondents said that donated medical equipment benefited their hospitals.

Conclusion: We concluded that because of staffing limitations in smaller donor organizations, and in order to better meet the needs of recipients, it would be beneficial for Canadian organizations to communicate and collaborate with one another to share resources and expertise when planning donations overseas.

Keywords – *Medical equipment donations, Low resource settings, Canada, Ghana, Best practices.*

INTRODUCTION

Previous reports have estimated that as much as 40% to 70% of medical equipment in developing countries is out of service or never put into use. [1,3,4] The reasons for this include a lack of infrastructure and resources (including spare parts and accessories), poor health technology management, and lack of training. [3] Given that so many developing countries rely on medical equipment donations, donations that meet recipient needs are crucial to mitigating these challenges and reducing the burden of non-functional equipment.

In the past two decades, numerous guidelines for the donation of medical equipment to low resource countries have been published. [2,4,11,12] Despite the existence of these guidelines, recent studies suggest that equipment donation practices are a continuing problem. For example, a study in Tanzania found that 78% of surveyed staff in a national hospital were dissatisfied with the quality of donated medical equipment, citing lack of supporting manuals and training, poor communication between the donor and the hospital, lack of clear equipment specifications, unneeded equipment, and poor donor planning as reasons for their dissatisfaction. [5] A case study about a donation of oxygen concentrators to The Gambia demonstrates how something as simple as a mismatch in electrical requirements can lead to unusable equipment, not to mention wasted effort. [6]

While many organizations across Canada donate medical equipment and supplies to developing countries, no previous study has explored the donation practices of these organizations. The objectives of this study were: (a) to determine the scope of medical equipment donations by Canadian charitable organizations, and better understand their specific donation practices and challenges; (b) to interview representatives of recipient health facilities in Ghana, and learn from their experiences; and (c) to disseminate good practice guidance to donating organizations in Canada and around the world. This study was initiated by the International Outreach Committee of the Canadian Medical and Biological Engineering Society (CMBES), which has had a long-standing partnership with the Ghana Biomedical Engineering Association to support clinical engineering capacity in Ghana. [7]

METHODS

Canadian study

Canadian organizations actively engaged in the donation of medical equipment and/or supplies to developing countries were surveyed using an online survey tool. Follow-up interviews were conducted with a subset of surveyed organizations. The list of prospective study participants was compiled through project partner connections and networks, Internet search, and through Canada's registered charity search engine. [8] This phase of research resulted in a database of approximately 80 registered and non-registered charities, non-governmental organizations (NGOs), non-profit organizations, medical clinics, and hospitals.

Organizations were then contacted by telephone and informed of our study and survey. Organizations that were actively donating medical equipment were sent a link to a survey in a follow-up email. The online survey consisted of 20 multiple choice and short answer questions, grouped into the following categories: (a) general organization information; (b) process for determining recipient needs; (c) communication involved in planning donations; (d) sources of equipment; (e) process for verifying quality and safety before shipping equipment; and (f) follow-up methods for evaluating success of the donations. Forty-one organizations completed the survey.

From the organizations that participated in the survey, a list of 16 organizations was identified for follow-up interviews. The short list of organizations was strategically selected to cover a wide geographic range across Canada, as well as a range in size of operations. The goal of the interviews was to gain a deeper understanding of different organizational processes. Sixteen interviews of approximately one hour duration were conducted. Interviews were conducted in person when possible, and by phone otherwise. The breakdown by province (in-person; phone) was as follows: British Columbia (3; 1), Saskatchewan (0; 1), Ontario (2; 2), Quebec (2; 0), Maritime provinces (4; 1). The research protocol, survey tool and interview question guide were approved by the Office of Research Ethics at the University of Toronto.

Ghanaian study

A second survey, consisting of 35 questions, was developed to gather information from Ghanaian hospitals about their experiences receiving medical equipment donations. Four questions collected information about the respondent. The remaining questions were a mix of multiple choice questions and open-ended long answer questions on topics such as: types of medical equipment received, communication with the donor before and after the donation, discussion of equipment needs, level of support from donors in terms of provision of training, manuals and supplies, maintenance and availability of spare parts for donated equipment, logistics such as shipping and customs, and common challenges encountered with donations.

A geographically representative sample of 28 health facilities was chosen for the survey; at least two facilities were visited in each of Ghana's ten regions. We also sought to ensure that facilities receiving donations from Canadian organizations were well represented in the sample (14 out of 28), and that a range of different hospital types was chosen (government, teaching, mission, etc.). Since many hospitals did not have reliable access to the Internet, surveys were administered in person and on paper by a research assistant ("surveyor") rather than online. In some cases, the surveyor waited for respondents to complete the survey, while in other cases the survey was administered as an interview with the surveyor filling in responses.

The research assistant in Ghana was supervised by the Deputy Director, Clinical Engineering Department, Ghana Health Service. Before conducting the survey, all respondents were given an introductory letter explaining the project.

FINDINGS

The types of Canadian organizations that donate equipment include NGOs, registered charities, and healthcare institutions. Some donor organizations have been in operation for over 25 years (one for almost five decades), others are much newer (five years or less) or are just receiving charitable status. To date, these organizations have provided critical medical equipment to 48 countries around the world (Fig. 1). The most common recipient countries were Haiti, Cuba, Guatemala, and the Philippines.

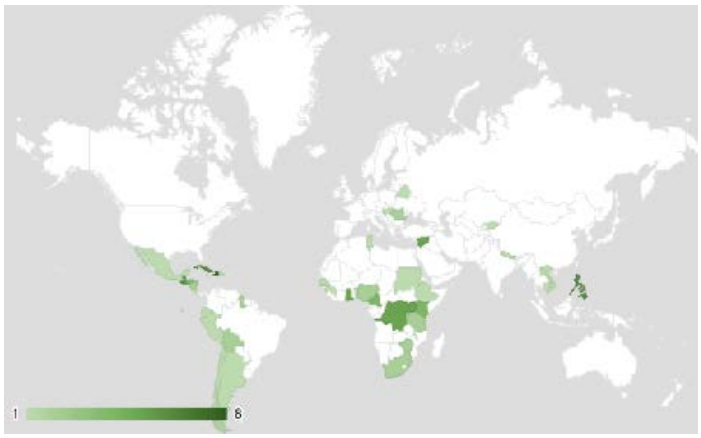

FIGURE 1. Global distribution of recipient countries. Shading indicates number of surveyed Canadian organizations that send equipment to these countries.

From simple frontline equipment (e.g. thermometers, blood pressure monitors, pulse oximeters) to more complex and larger devices (e.g. x-ray, ultrasound machines) Canadian donations help address everything from basic healthcare to supporting a healthy community. Medical devices and consumables are the most commonly donated items, although clinical laboratory and dental equipment, and other items including pharmaceuticals, vehicles and computers, have also been provided as part of donation activities (Fig. 2a). Supplies and small, low complexity equipment are more commonly donated than large, highly complex devices (Fig. 2b). The survey presented the categories as options for the respondents, with examples for each category. The respondents decided which category their equipment fell in to.

The scale of operations varied considerably across organizations in terms of the frequency and size of shipments. There were also considerable differences in organizational structures and human resources. Most relied entirely on volunteers for day-to-day operations, with no paid staff. For example, one organization has a team of about 50 volunteers, with about half in the recipient country who receive small monthly stipends, and the rest in Canada or elsewhere. On the other hand, a minority of organizations have a mix of paid and volunteer staff

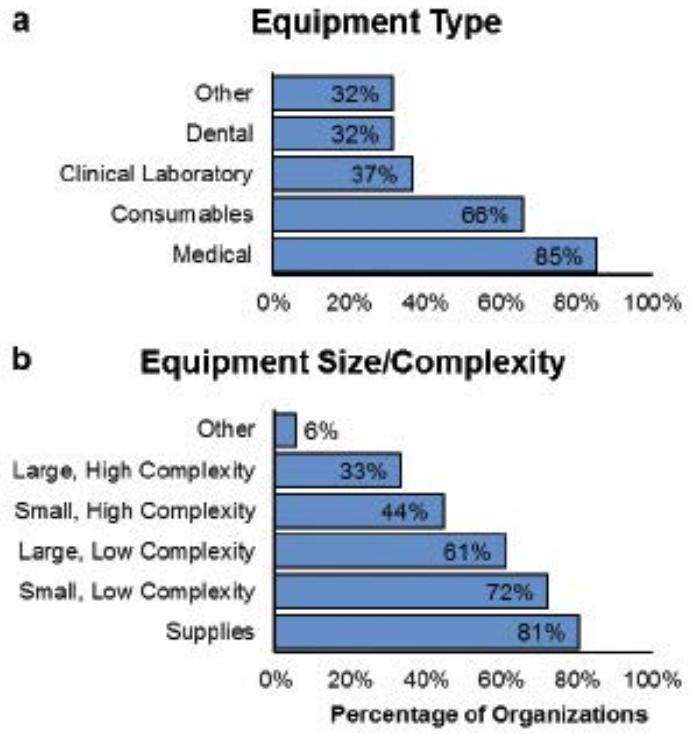

FIGURE 2. Percentage of organizations that reported donating (a) different types and (b) different sizes/complexity of equipment. In (a), the Other category includes mobility aids, pharmaceutical supplies and medicines, school supplies, vehicles (buses, ambulances), office furniture, computers, and funding (to support other organizations that donate equipment) (n = 41). In (b), the Other category includes medicines, vitamins and wound care supplies (n = 36).

(e.g., one having ten paid full-time employees and about 40 volunteers, and another having one paid staff and a volunteer board of directors.

The next three sections summarize survey results on donor experiences related to three main phases of the donation process: consultation and communication with recipients, planning the donation process, and follow-up and monitoring.

Consultation

How Recipients are Chosen

Most organizations chose recipient countries organically, through personal connections or member suggestions. For example, two interviewees told stories of having visited a certain country where they noticed a great need. In one case, this experience led to the inception and founding of the organization. In many other cases, the recipient country reached out to an organization because of having heard about their charitable work. Another model that emerged for recipient selection (at least three organizations) was the existence of a 'sister organization' in the recipient country that could act as a partner for the donation initiative. In one case, the recipient cannot always be controlled because the organization relies on volunteers to bring supplies overseas and to find a suitable recipient upon arrival. Unfortunately, when relationships are formed informally, they can also easily dissolve. For example, one organization said that they will no longer work with certain countries due to poor experiences that made them not want to go back.

Communication

Another key element of a donation initiative is communication between all stakeholders involved. Fifty eight percent of 38 survey respondents said they communicate directly with the recipient hospital or clinic when planning a donation. With these cases of direct communication, the recipient contact person varied and included people involved in receiving/distribution, medical directors, and Ministry of Health representatives. One organization has local volunteers in the recipient country (1 to 3 per hospital) that help coordinate the donations and provide training to healthcare staff at the recipient hospitals.

For those Canadian organizations that do not communicate directly with the recipient hospital, their main point of contact was often another NGO working locally to coordinate the donation, or a sister or satellite branch of their own organization. Forty-seven percent reported communicating with a sister charity or organization and 44% with an independent organization in the recipient country. Only 31% reported they correspond with government officials in the recipient country. Other stakeholders included sister organizations in the US, religious groups, and equipment providers in the US. Sixty-one percent of organizations communicated with multiple stakeholder groups.

The most common mode of communication was email (94% of 35 responses), however in-person communication

was also common (71%). Telephone was used more than Skype (54% versus 20%), which could be indicative of widespread use of cellphones in low-resource settings and poor internet connections. One organization said they use shared file systems as a mode of communication (e.g., Dropbox and Google Drive) when planning a donation. Seventy-four percent of organizations rely on more than one mode of communication.

Meeting Recipient Needs

One of the most important stages in planning a donation is determining the needs of the recipient. Our interviews revealed many different needs assessment strategies employed by donor organizations. One organization has a system in place where potential recipients can submit a 'wish list' that the organization will try to fill. Another said they perform a thorough needs assessment and impact assessment in person every three months at each of the hospitals they work with; the organization's founder speaks directly with the health care staff (doctors and nurses) in every ward and asks what they think they need more than anything else. From this feedback, they produce a list of the most needed pieces of equipment. Other organizations tend to respond to requests from recipients; one stated the needs assessment process is a long email exchange with potential partners in which they determine whether the partner is serious, credible, and capable of receiving a container and getting the equipment to work; another said that they identify needs through a doctor that has actually travelled to the country.

Two of the organizations interviewed deal exclusively in mobility devices. In one case, an advocate in the recipient community (typically a school principal, mayor, doctor) prepares applications for each potential wheelchair recipient - hip size, length, what type of leg support is needed, etc. along with photos. The donor organization then works with the advocate who receives the shipment and coordinates getting the chairs to the right recipients. Another organization mentioned that they are not always able to match needs directly and, based on the available supply, will send a standard set of equipment in their shipments, whether the recipient country has indicated a specific need or not.

Planning and the Donation Process

While many individuals and organizations are highly motivated to provide aid where needed, all donors face significant challenges with the logistics of the donation process. Unfortunately, for many donors, these challenges can prevent donations from reaching their intended recipients.

Equipment Sources

Most organizations (62% of 37 responses) rely on several different sources for the equipment they donate to developing countries. For example, one organization stated in their interview that they collect equipment from hospitals, seniors' homes, private homes, and group homes. Another said about 75% of the equipment they send overseas is sourced from the US, some of it brand new but acquired at a considerable discount. Based on the survey responses, medical clinics and hospitals were the most common source of equipment (about half of the organizations sourced equipment from such places), however manufacturers, second-hand equipment vendors, seniors homes, other non-profit organizations, institutions such as universities and colleges, and individuals (mainly from home care situations) were also listed as sources of equipment. Pharmaceutical and drugstore companies also donate surplus pharmaceutical products such as pain killers, flu medication and burn gauze that are fully FDA regulated, newly packaged and have six months or more until expiration.

Equipment Testing

Once the equipment has been procured from their respective sources, some of the surveyed organizations conduct technical quality control and repairs before shipping to the recipient (Fig. 3a). The most common check was for power compatibility (63% of 27 responses) and the least common was equipment calibration (30%). Fifteen per cent of organizations performed no testing at all on the equipment they donate. Only 13 organizations (43% of 30 responses) reported having a volunteer or staff biomedical engineer available, which may have implications for the level of technical testing that is possible before equipment is shipped overseas. For example, two

organizations shared in their interviews that they get volunteer technologists or engineers to inspect equipment as a quality control measure before it is shipped. One international organization relied on a workshop in their US location for repairs; they also partnered with a repair shop in the recipient country so that repairs could be done locally. Due to limited time, resources, and capacity some organizations reported that they are simply unable to perform any equipment testing.

Shipping

Most organizations surveyed (72% of 32 responses) send shipments in 20' or 40' foot containers by sea. The next most common form of shipping was via checked baggage of volunteers traveling to the recipient country (25%) followed by air freight (19%). Some organizations are able to send containers overseas monthly or every two months, while others send shipments annually. One organization estimated that they send 35 containers per year. It is also common that shipments are sent irregularly, for example, whenever a container is filled or when volunteers are traveling overseas and are able to take donations with them.

Shipping costs represent a major challenge for donor organizations when planning donations overseas. The surveyed organizations have reported shipping costs ranging from $4,000 - $12,000 CAD per shipment. These large sums of money are mostly gathered through fundraising efforts and sometimes through grant applications. In other cases, organizations have negotiated agreements with shipping companies to waive fees, arranged for embassies of the recipient countries to cover the costs of shipping, or even used connections to arrange for free transport between warehouses. One organization reported that in their case the recipient assumes the cost of shipping and that it depends on the organization whether they organize the shipping details or not. In an effort to help reduce overall shipping costs, it was reported in an interview that a Canadian shipping company offers complimentary domestic shipping of wheelchairs from any Canadian city to Vancouver (to then ship internationally). Unfortunately, donors often cannot transport the wheelchairs to the shipping company itself, so this service remains heavily underutilized. Another organization was able to

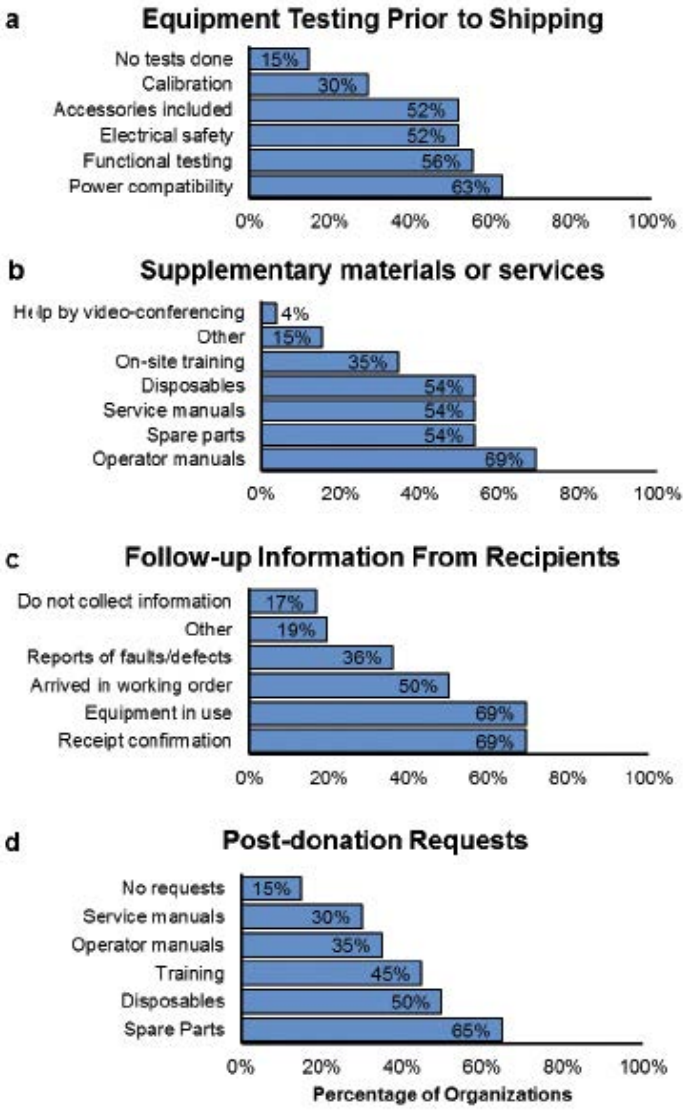

FIGURE 3. Percentage of surveyed organizations providing different types of support (a & b) before and (c & d) after shipping a donation. (a) Technical quality control prior to shipping, including compatibility with line voltage/frequency of destination country, functionality, electrical safety, completeness of accessories, and checking calibration against manufacturer specifications (n = 27). (b) Supplementary materials or services provided with donated equipment (n = 27). Other includes packaged goods, donations, clothing, funding to support sustainable projects, and biomedical engineer visitations. (c) Information collected from recipients after the donated equipment has been delivered (n = 36). Other includes installation, follow-up onsite visitations, ongoing usage reports, and patient data. (d) Post-donation requests from recipients for additional support (n = 20).

arrange free air cargo transport of donations through a Canadian airline.

Customs

Once the equipment has successfully been shipped outside of Canada, the next major challenge is getting through customs. In addition to paying duties, differences in culture and infrastructure of the recipient country need to be considered. While some organizations prefer not to donate to countries if they are charged duty fees, others have partner organizations based in the recipient country who can negotiate the receipt of the equipment. Organizations that deal directly with customs have reported incidences of port officials expecting bribes or additional payment. For example, in one case an entire shipment had to be abandoned at the port because the cost of storage was greater than the value of the goods being shipped.

Donating organizations have found that shipping items that are available in the local market, such as clothing, can introduce difficulties with customs clearance due to the impact these products can have on the local economy. One organization said they try to purchase goods locally whenever possible in an attempt to provide cash flow to the recipient country, helping the local economy in a different way and avoiding custom fees and shipping.

Regulatory and policy considerations

Another challenge organizations face is deciding how to interpret Canadian Medical Device regulations drafted by Health Canada.[9] As a result, some organizations have stopped donating altogether to avoid the issues of perceived liability. Others have created their own legal documents and have the recipients sign a medical release waiver when they accept the donated equipment.

Support for Recipients

In addition to donating medical equipment, many organizations provide additional support materials and services in order to ensure successful equipment usage. Operator manuals are the most common resource provided to recipients, but only about half of the organizations surveyed provide service manuals, spare parts, and disposables (Fig. 3b). One organization told us since not all manuals are available online, it is difficult for recipients to find them, further exacerbated by downloading issues due to poor network connections. This could also explain why so few organizations (4% of 27 responses) make use of video-conferencing as an additional mode of support.

Sending people overseas to help with the arrival, installation, and training of donated equipment is a challenge for many organizations due to the cost and time commitment involved, but some (35%) are able to provide this extra support by one of the following ways:

- returning to the same country year-after-year and has established a three-week camp where they repair and help fit users to wheelchairs;
- providing training programs on how to use the equipment once it has been donated, and has contacts affiliated with their organization in the recipient country that play an ongoing role with equipment use and support;
- sending a team of biomedical technicians overseas around four to five times a year along with service manuals, and ensures that the equipment is fully serviced before shipping it out;
- sending volunteers overseas to help set up equipment (volunteers pay their own way).

Follow-up and Monitoring

The final stage in the donation process is long-term monitoring in order to measure the effectiveness of the donation. We asked organizations about the information they gather from recipients after a donation has been made, and whether or not they receive any follow-up requests from the recipients. Most of the surveyed organizations (70% of 36 responses) request confirmation that the equipment was received and put into service, but only 50% verify that it arrived in good working condition (Fig. 3c). Even fewer (36%) collect reports of equipment faults or failures after it is put into service. Seventeen per cent of survey respondents said they do not collect any information at all.

We learned from the interviews that while some organizations request formal documentation or reports confirming receipt and/or functionality of equipment, in general the feedback that many receive is informal (e.g.,

thank you notes, pictures of the equipment at its final destination) and sometimes indirect (e.g., newsletters of recipient organizations). One organization we interviewed was particularly committed to monitoring their effectiveness. They had a public health specialist conduct a program evaluation, identifying what their organization was doing well and where they were weak. Their commitment to data collection and transparency has helped them to improve their effectiveness as an organization. Another said they track each item they donate in case there is a manufacturer recall, in which case they are able to notify the recipient country.

Another measure of the effectiveness of a donation is the extent to which the recipient requests additional support and/or materials (Fig. 3d). The most common follow-up request is for spare parts (which is consistent with our findings from the survey of recipients in Ghana summarized in 3.2 Recipient Perspective) followed by disposables and training. As discussed above, not all organizations include operator and user manuals with their donations, and so it is perhaps not a surprise that these manuals are often requested. Only three surveyed organizations (15% of 20 responses) reported that they did not receive any additional requests from recipients.

Recipient Perspective

Surveys with stakeholders at 28 hospitals in Ghana provided valuable insight into the recipient perspective with respect to medical equipment donations. Note that not all of these hospitals necessarily received donations from Canadian organizations.

Consultation

Communication

An important element of the equipment donation process that we wanted to learn about was communication between donors and recipients, particularly when it came to the identification of equipment needs. When asked about the last donation received, 96% of respondents reported that there was communication with the donor agency before the donation was shipped, and 86% reported that the donor discussed their needs or asked what their greatest needs were in advance. Equipment needs were requested or identified in several different ways, either through a form or survey given by the donor (18%), a wish list submitted in advance by the recipient hospital (18%), or simply via direct communication between the donor and hospital administrators (11%). In a couple of cases (7%), a representative of the donor organization came to the hospital to discuss the needs of the hospital in person.

Meeting Recipient Needs

Two-way communication between the donor and recipient to identify needs prior to delivery is extremely important for a donation to be effective. 7% of respondents added that this communication enabled them to make additional requests, some for very specific parts (e.g. fuses), allowing them to better operate medical devices they already had. The communication of equipment needs, however, did not always result in needs being met. One hospital mentioned that despite supplying a list of needed equipment, those items were not included in the shipment. 11% said they were not consulted at all about the equipment they needed, and one hospital commented that they had received a "surprise package"

Planning and the Donation Process

Equipment Testing

All recipient hospitals reported that donated equipment typically arrives in working condition, however 25% said they had received donations in the past that were missing accessories essential to the operation of the device, and 18% had received equipment that was faulty. For equipment that does arrive in working condition, 61% of respondents estimated that it lasts less than two years before breaking down. Although 46% of hospitals said they can often repair broken equipment, repairs can take weeks or even months depending on the parts and or expertise required.

Support for Recipients

Upon receipt of donated medical equipment, most donor organizations provide on-site installation of equipment, verification of functionality, and user training. On-site service training was less commonly provided (Fig. 4). The types of support provided were installation, verification, user training and service training with service training

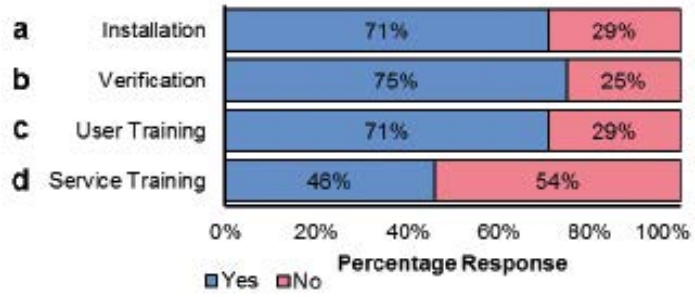

FIGURE 4. On-site support for donated equipment – Recipient facilities (n = 28) were asked if donor organizations provided (a) installation assistance, and (b) verification of functionality. They were also asked if donor organizations provided (c) user training, and (d) service training. Yes = blue, No = red. Recipient responses are given as a percentage.

providing the least support (Fig. 4d) and verification the greatest support (Fig 4b).

When asked about common problems encountered with medical equipment donations, the most common problem mentioned was a lack of spare parts (57%), followed by lack of operating and/or service manuals (32%) and issues with consumables, either lacking or expired (21%). These percentages are based on responses to an open-ended question. For example, Figure 5 shows the

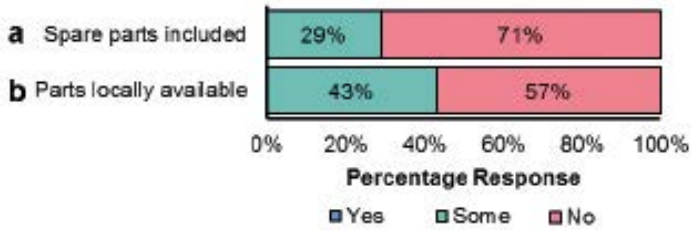

FIGURE 5. Availability of spare parts. Percentage of surveyed recipient hospitals (n = 28) that reported (a) donations included spare parts, and (b) spare parts were locally available. Yes = blue, Some but not all = green, No = red.

percentage of recipients who reported that the received donations included spare parts, and whether spare parts were available locally. All responses were either some or none (Fig. 5).

Figure 6 shows that less than 35% of recipients always receive operating manuals, service manuals, consumables or accessories. Other common problems encountered included: power issues (e.g., the equipment was meant for

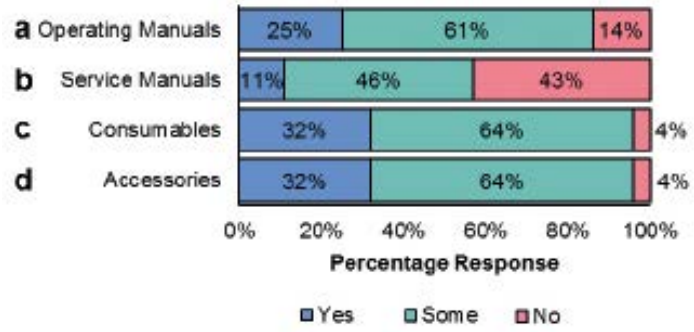

FIGURE 6. Support materials for donated equipment. Percentage of surveyed recipient hospitals (n = 28) that reported receiving (a) operating manuals, (b) service manuals, (c) consumables, and (d) accessories with donated equipment. Yes = blue, Some but not all = green, No = red.

the wrong voltage, or was too sensitive to power fluctuations), or the equipment was not durable or appropriate for the setting (e.g., the climatic conditions impaired the functioning of some equipment).

Recipient Feedback

Recipients were also asked to describe in their own words what they thought could be done to improve the effectiveness of medical equipment donations to Ghana. The following are some illuminating responses:

- "Thorough needs assessments of beneficiary facilities should be done. Equipment donated must meet these needs."
- "All donations must go with initial user trainings and monitoring by the donors as to the functionality of the equipment."
- "Should make available consumables and if possible link users to sources of this items they can be procured by users when it's finished."
- "Tax exemptions on these equipment. Removal of bureaucratic barriers."

Despite the challenges and common problems encountered, when asked whether donated medical equipment benefited their organization 100% responded positively. Donated electronic medical equipment allowed greater efficiency and accuracy for diagnosis, therefore reducing the burden on the nurses and staff, and allowing for better quality of care. 48% of respondents answered that donated equipment helped in cost reduction, with

51% stating that donated supplies either reduced the burden on health care providers or helped with patient management. Furthermore, one of the facilities noted that medical equipment allowed for reduction in premature fetal mortality rates.

DISCUSSION AND NEXT STEPS

Over 40 organizations and hundreds of volunteers across Canada are involved in the donation of medical equipment to developing countries. We have found that these organizations varied considerably in terms of the size of their operation, the types of equipment donated and the processes they follow when carrying out a donation initiative.

There are many resources available to help donor organizations effectively plan and execute all of the phases of a donation activity. [2, 10, 11, 12, 13, 14] These resources cover everything from deciding whether to donate to how to deal with international shipments to putting equipment into service at the recipient institution. A common theme in all the published guidelines on equipment donations is the importance of three core elements (Fig. 7): (a) consultation - ensuring that the needs of the recipient are well understood and have been established through communication with all parties involved; (b) planning and process - having a clear donation plan identified and agreed to in advance by all stakeholders, including comprehensive quality assurance assessments; and (c) monitoring and follow-up - developing a sustained and supportive relationship with the recipient institution, ensuring long-term success and impact We have created a video which clarifies the benefits of including these core elements in the donation process.[10]

FIGURE 7. Three main phases of a medical donation process. Consultation, Planning & Process, and Follow-up & Monitoring.

We have found through this study that many Canadian organizations find it challenging to adhere to such guidance due to limited staff and financial resources.

Donation Strengths and Opportunities for Improvement

Most Canadian organizations appear to be doing well at identifying needs and communicating with a wide range of stakeholders in the recipient country - including healthcare workers, representatives from the Ministry of Health, and sister or local charities - when planning a donation. The recipient survey corroborated this finding as well, with the majority of respondents reporting their needs were discussed with the donor in advance. There is also much evidence of how these different Canadian organizations are having a positive impact on the communities in which they work, for example, providing wheelchairs and other mobility aids to help people to become more active members of their community, or training local staff to repair & maintain wheelchairs. Working with sister organizations in recipient countries helps the sister organization to continue actively working in their communities. Despite these strengths, however, there are still opportunities for improvement (Fig. 8).

In the area of planning and process, we found that donor organizations had limited written policies and procedures to guide and govern their operations (e.g., only one interviewed organization had developed standard operating procedures (SOPs), and very few had systems in place for documentation). Formalizing procedures is a widely accepted practice in well-run organizations. Documenting every step in a process helps maintain quality and ensures that consistent practices are followed. (e.g. one organization uses a computerized inventory system such that boxes leaving a warehouse can be scanned and removed from inventory automatically; another organization uses an online tool, Google Forms, to solicit and track equipment donations.)

Based on our survey, we found a general lack of comprehensive quality assurance testing before equipment is shipped. Recipients reported incompatible voltage, faulty equipment, and missing accessories as common problems, which could have been mitigated with proper inspection and testing. The fact that 57% of organizations did not have a volunteer or staff biomedical engineer to help with testing represents an opportunity for the biomedical engineering community in Canada to become more involved and engage with donor organizations to help improve the effectiveness of donations.

Canadian organizations can also improve when it comes to providing additional support with equipment donations in the form of operator and service manuals, spare parts, accessories and training. Spare parts in particular were the number one follow-up request from recipients (according to donors), and the number one problem encountered by recipients in Ghana.

When it comes to monitoring and evaluation, in general there is a lack of information sharing post-donation about short-term and long-term equipment functionality. This means that most organizations cannot measure the success of their donations or the impact they are having in the recipient countries. It was apparent from our interviews that organizations that have developed a long-term relationship with a particular recipient and return to the same location year after year are better able to monitor progress and identify issues, even without any formal feedback system.

FIGURE 8. Four main areas of improvement for Canadian organizations to focus on: formalizing procedures through documentation, better equipment testing prior to shipping, better long-term support for recipients, and monitoring that includes evaluating donation impact.

Donors should be formally requesting feedback, and recipients should be proactive in communicating how well things are working, so that both parties can mutually track donation effectiveness. This process is facilitated when a long-term partnership is formed between the donor and recipient, and the donation is not a one-off transaction.

The wide range of capabilities among donor organizations suggests an opportunity to share knowledge and best practices, so that they can learn from each other and better address the four areas for improvement as shown in Fig. 8.

Recommendations

Based on the disparities in practices observed in Canadian donor organizations, and the disparities in resources available, it would be beneficial for all donor organizations to communicate and collaborate with one another when planning donations overseas (Fig. 9). There could also be opportunities to economize (e.g., sharing a shipping container), improve the matching of available equipment with known needs, or share resources (e.g., volunteers, engineering expertise), to improve the efficiency of operations. It would also be beneficial for organizations to share their donation experiences and challenges with one another (positive and negative) so that others can

FIGURE 9. Donation Community in Canada. Individuals, groups of volunteers, and small and large organizations across Canada collectively have valuable knowledge and experience that could benefit others engaged in donation work. Better communication, collaboration, and sharing of resources and expertise among these groups could lead to more effective donation practices for everyone and better impact globally.

learn from them, especially if they are doing something innovative. It may be beneficial to create a network for such communication, for example many Internet based tools are available that could facilitate building such a community for the sharing of information.

Lastly, since many organizations do not have the resources or volunteers available to travel to recipient destinations to help with equipment installation, training and maintenance, innovative solutions to the challenge of long-distance equipment support and maintenance are needed. While most organizations are able to use email for basic communications, other tools such as WhatsApp, Viber, or file-sharing applications such as Dropbox or Google Drive, which are not bandwidth-heavy or do not require constant internet connections, could be used more frequently to help plan and support donations and share resources.

CONCLUSION

Thanks to the generous donations of Canadian charities and non-profit organizations, almost 50 countries around the globe have received critical medical equipment to help improve the delivery of healthcare and support healthy communities. Through this study, we found that these donations have provided everything from simple frontline equipment such as blood pressure monitors and pulse oximeters, to MRI and x-ray machines.. The donation process presents challenges to donating organizations, most significantly in shipping equipment, passing customs barriers, ensuring compatibility of equipment, and providing support for recipients. Based on our interviews with hospitals in Ghana, the most prominent recipient challenges include a lack of spare parts, access to service manuals, and replenishment of consumable items. To overcome the challenges for both parties, successful donor practices include consultation with recipient countries to ensure needs are met, careful planning of the entire donation process to provide a clear plan, and finally monitoring and follow-up to facilitate long term success. We strongly believe that more effective collaboration and communication between Canadian donor organizations would reap tremendous benefits for recipient countries, and create opportunities to economize and improve the effectiveness of medical equipment donations.

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COMPLIANCE WITH ETHICAL STANDARDS

Ethical approval

Informed consent was obtained from all individual participants included in the study.

Conflict of interest

The authors declare that they have no conflict of interest.

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

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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

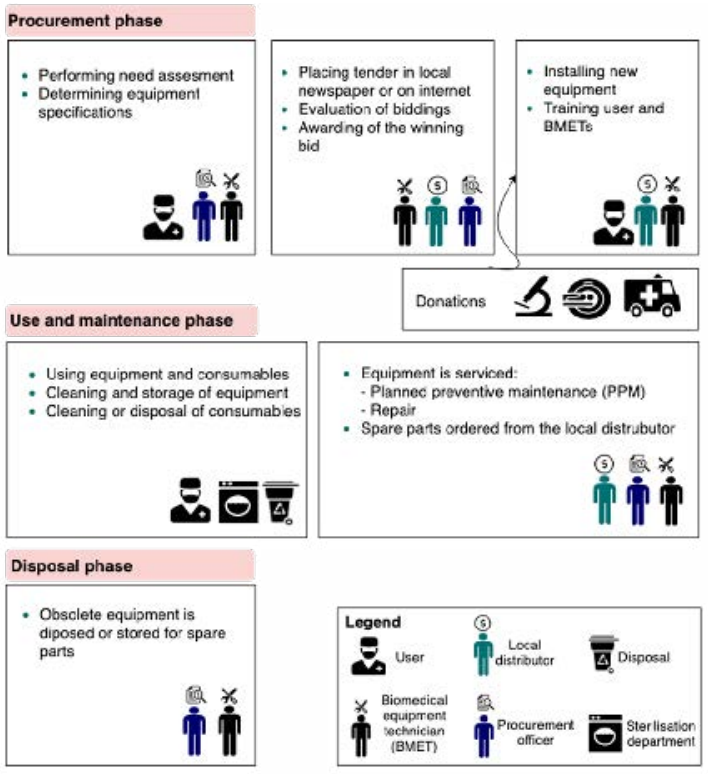

FIGURE 1. The surgical equipment journey according to BMETs in Kenyan hospitals.

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.

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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.

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