Received November 18, 2018, accepted March 02, 2019, date of publication March 21, 2019

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

By M. A. Hossain[1], M Ahmad[2], M R Islam[2], and Y David[3]

[1] National Electro- Medical Equipment Maintenance Workshop & Training Center, Dhaka under the Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

[2] Department of Electrical and Electronic Engineering, Khulna University of Engineering & Technology (KUET), Khulna-9203, Bangladesh

[3] Principal, Biomedical Engineering Consultants, LLC, USA

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]

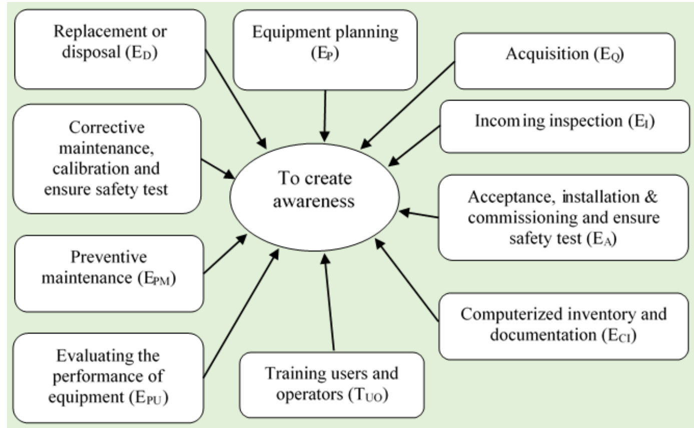

FIGURE 1. Roles of the Clinical Engineering Department to ensure the performance of Medical Equipment Technology Management Systems parameters.

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 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

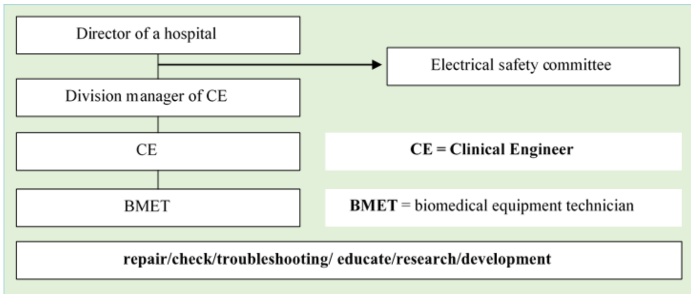

FIGURE 2. Clinical Engineering Department model for a hospital in the U.S.

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 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.

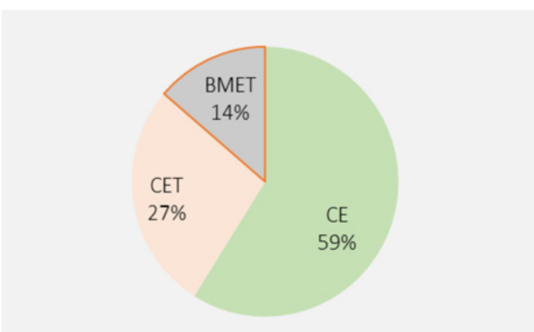

FIGURE 3. A basic model of a Clinical Engineering Department for a hospital.

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

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 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 life-cycle 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]

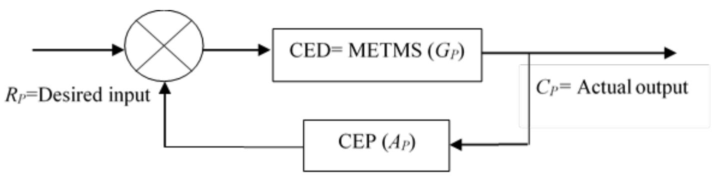

FIGURE 4. Proposed research methodology to evaluate the performance outcomes of METMS that is with patient safety.

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.

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

$$C_P = \left[\frac{G_p}{1+G_p A_p}\right] \times R_P \quad (1)$$

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.

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%.

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

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.

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).

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

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

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 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.

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

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
PAK	52	0.067

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).

$$P_S \alpha C_P \tag{5}$$

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.

ACKNOWLEDGMENTS

We acknowledged this research work to the Ministry of Health & Family Welfare, Government of Bangladesh, Biomedical Engineering Department, Khulna University of Engineering &Technology, Khulna-9203, Bangladesh, NEMEMW& TC, Ministry of Health & Family Welfare, Dhaka, and Global Clinical Engineering Leaders.

CONFLICT OF INTEREST

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

REFERENCES

1. Latin A. Holzmueller CG. et al. Evaluating safety initiatives in healthcare. Cur Anesth Rep 2014;Jun;4(2):100–106. PMID: 24976794
2. Pie Derrico MR, el. al. Clinical Engineering. 2011 DOI: 10.5772/19763. Available at: https://www.intechopen.com/books/applied-biomedical-engineering/clinical-engineering.
3. Keil O, Widmann DE. Assessment of the impact of medical devices on the quality of care, QRB Qual Rev Bull 1984 Sep;10(9):278–80. PMID: 6436769.
4. Kohn L, Corrigan J, Donaldson M. To Err is Human: Building A Safer Health System. Institute of Medicine (U.S.) Committee on Quality of Health Care in America; 2000.
5. Signori MR and Garcia R. Clinical engineering incorporating human factors engineering into risk management. IFMBE Proceedings 2009; WHO Regional Office, Copenhagen, DK-2100, and Denmark 25 (VII):449–52.
6. Nagel JH. Protocol for the training of clinical engineers in Europe. European Alliance for Medical & Biological Engineering & Science (EAMBES), BIOMEDEA 2005;1–17.
7. Subhan A. Clinical Engineering Certification. 2014. Available at: www.24x7mag.com/2014/03/clinical-engineering-certification.
8. American College of Clinical Engineering. A Guide to Clinical Engineering Certification. 2017. Available at: https://accenet.org/CECertification/Pages/Default.aspx.
9. WHO. Global Dimensions of Biomedical Engineers. In: Human resources for medical devices - the role of biomedical engineers, World Health Organization, Geneva, Switzerland; 2017.
10. David Y. Planning hospital medical technology management. IEEE Med Biol Mag 2014;23(3).
11. Joseph D. Clinical Engineering Definition of ACCE 1992. In: The Biomedical Engineering Handbook, Third Edition. CRC Press; 2006.
12. World Health Organization. Life cycle of medical equipment management system. WHO Bull 2014.
13. Hossain MA, Ahmad M, et al. Clinical engineering and healthcare delivery performance measurement: basic module of clinical engineering department for 250 beds hospitals in Bangladesh. Proc Medi Tec 2016.
14. Grinder S, Patient Safety and Quality Improvement Act of 2005 - HHS Guidance Regarding Patient Safety Work Product and Providers' External Obligations. Agen Healthc Res Qual (AHRQ) 2016;32665–60.
15. International Center for Alcohol Policies. What Is Evaluation? Archived from the original on 2012-05-04. Retrieved 13 May 2012.
16. Sarah Del Tufo "WHAT is evaluation?" Evaluation Trust. The Evaluation Trust. Retrieved 13 May 2012.
17. Dorf RC and Bishop RH. Modern Control Systems, 12th Edition, Pearsons, Prentice-Hall, Inc. Upper Saddle River, NJ, USA; 2000.
18. Kraus S. What is Health Tech and how will it evolve?" [Internet] Hot Topics. 2016. Available at: https://www.hottopics.ht/23983/what-is-health-tech/.
19. World Health Organization. Technology, Health. Geneva: AU;. Retrieved 20 March 2015.
20. INAHTA (International Network of Agencies for Health Technology Assessment). HTA Glossary. INAHTA. Archived from the original on May 26, 2009.
21. Temple-Bird. How to Organize a System of Healthcare Technology Management. Healthc Technol Manag WHO 2015.
22. Forum for Asian Clinical Engineering. To Face the Globalization Age of Asian Clinical Engineering. Proc. of First Forum for Asian Clinical Engineering (FFACE), Osaka, Japan, 2012. Available at: http://osaka.jikeigroup.net/face/.
23. Joseph D. Clinical Engineering Definition of ACCE 1992. The Biomedical Engineering Handbook, Third Edition. CRC Press; 2006.
24. Wikipedia. Scientific Method. 2017. Available at: https://en.wikipedia.org/wiki/Approach#Other_uses
25. Kohn LT, Corrigan JM, Donaldson M. To Err is Human: Building a Safer Health System, Institute of Medicine (US) Committee on Quality of Health Care in America; Washington (DC): National Academies Press (US); 2000.PMID: 25077248.
26. Shaffer MJ. Clinical engineering: an in-depth review of its economic potential. Med Care 1977;XV(7)552–67.
27. Clinical Services / Departments. Christian Medical College Clinical Engineering in India. Available at: http://en.wikipedia.org/wiki/Clinical_engineering.
28. Hossain MA, Ahmad M, et al. Clinical engineering and healthcare delivery performance measurement: Basic module of clinical engineering department for 250 beds hospitals in Bangladesh. Proc Med Tec 2016.
29. Hossain MA, Ahmad M, Islam MR, David Y, et al. Clinical Engineering Approach to Improve Healthcare Technology Management for Enhancing Healthcare Delivery System in Middle-Income countries, Proceedings of ICCEHTMC, Brazil; 2017.

30. Gurses AP, Doyle P. Medical Devices in the "Wild". AHRQ Patient Safety Network. 2014. Available at: https://psnet.ahrq.gov/webmm/case/337/Medical-Devices-in-the-Wild.
31. Clinical Engineering Bank. Website: https://www.clinicalengineeringbank.com/cefunctions.htm.
32. Igeta H. The Role of Clinical Engineers in JAPAN - A Case of ASO Iizuka Hospital. Japan Association for Clinical Engineers; 2015.
33. Hossain MA, Ahmad. M, Islam MR, et al. Current status of skilled clinical engineers in developing countries, Science Direct. Proc Soc Behav Sci 2015;195:688–93.
34. Nelson AL, Powell-Cope G, and et al. Technology to promote safe mobility in elderly. Nurs Clin North Am 2004;39:649–71.

AUTHOR'S BIOGRAPHY

Anwar Hossain has completed BSc in Electrical & Electronic Engineering since 1990 from Khulna University of Engineering & Technology (KUET), Bangladesh. He joined as an electro-medical engineer at the National Institute of Cardio-Vascular Disease & Hospital, Dhaka, Bangladesh since 1991 and then was moved to National Electro-Medical Equipment Maintenance Workshop & Training Center, Dhaka under the Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh. as an assistant medical electronics engineer. Currently, he is working in the same organization as the technical manager (repair) cum chief training counselor. He has obtained 10 fellowships such as WHO, JICA, FRG, GOB, World Bank, 2nd FACE. He completed his MSc in Biomedical Engineering from KUET and is a PhD candidate in the Biomedical Engineering Department of KUET, Bangladesh. He has published research articles in different renowned journals and conference proceedings. His research interests include advance clinical engineering management to enhance the quality of healthcare.