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Editor's Corner

The Inaugural Issue!

If you have ever had the good fortune to experience the moment a child is born, then you know that it transforms life as you know it. If you have not experienced this magnificent moment yet, I do hope that one day soon, you will. It is hard to put such a feeling into words, but it is a glorious moment, especially when the newborn is part of your own family.

Our Journal has arrived! In a way, you can think of the Global Clinical Engineering Journal as the child that will foster a sense of pride for clinical engineers all over the world – producing the magnificent aura that new parents delight in as they nurture and rear their beautiful baby.

This baby (the Journal) has older siblings – all members of the profession's family that are working together to be successful. Among the slew of important, recent achievements that makes our family proud, are:

- The ushering of the only Congress dedicated to the Clinical Engineering field – the International Clinical Engineering and Health Technology Management Congress – the third congress slated to take place in Rome, Italy, in October 2019 (www.icehtmc.com).
- The world-wide celebration of the Global Clinical Engineering Day (http://global.icehtmc.com/), this year on October 21st will be initiated from Chengdu, China, recognizing the contributions of CEs to improving healthcare outcomes.
- The initiation of the Clinical Engineering Awards Program (http://cedglobal.org/awards/).
- The free-access posting of Human Factors for Health Technology Safety book (http://cedglobal.org/human-factors-for-health-technology-safety/) on the Clinical Engineering Division Web site (www.globalced.org); and now
- The arrival of our own publication – the Global Clinical Engineering Journal (www.GlobalCE.org).

It is critically important that you feel as though the Journal is your child, since this is going to be your creation, and the outcome will be directly correlated to the level of your personal engagement and investment. We all know that raising a child "takes a village." It is no exception that Global CE Journal needs a village, and that with the proper amount of tender loving care, it will grow and turn into a mature, impactful publication. It will only thrive when and if you (the village) will feed, care for, encourage, and share your knowledge with it.

We do have a few advantages that should make you all proud. For instance, I am so proud of the amazing members of the Editorial Board of our Journal who make up a wide range of disciplinary fields, including clinical engineers, medical doctors, surgeons, anesthesiologist researchers, health informatics, technology evaluation experts, medical device incubator leaders, forensic engineers, academicians, researchers, adult and pediatric hospital engineers, industry, government, World Health Organization (WHO), Federation, associations, non-government organizations, and patient care. They are all established leaders in their areas of expertise, with well-published manuscripts. In addition, they represent expertise from the four corners of the world, ranging from Africa and the Americas, to Europe and Asia. Who can ask for more?

Another advantage we have is the selection and deployment of an open-access platform that facilitates a timely, systematic, and consistent double-blind review process of submissions, online archiving, and secure access to high-quality manuscripts anywhere in the world. The Journal is fortunate to have a dedicated manager, Ms. Stavrianou, who holds a doctorate degree in Biomedical Engineering. What a suitable expert for our high-quality Journal.

Our volunteer-based reviewers represent a wide scope of knowledge in many related topics. These reviewers offer their time and expertise to facilitate and promote

fair, high quality, and a scientifically constructive review process of the submissions, thus supporting the editors' objectives.

As you probably know, raising a child requires resources, and we have an advantage there as well. Through the Clinical Engineering Division (CED) early support, the first few baby steps were taken successfully. Now thanks to the generous support of China Medical Device (CMD) enterprise, these steps have turned into a march.

This is a momentous occasion, where your submissions and scholarly contributions will turn our dream into a reality. The Journal aims to also encourage submissions from young engineers, as well as from senior scientists.

To join as a reviewer, or to submit your manuscript, go the Web site: www.GlobalCE.org and log in. Once you register, you can select the actions you would like to follow – either to become a reader, a reviewer, or to submit your work. I invite you to act and be part of the family. This Journal is for you and your colleagues. You have a unique opportunity to participate in "raising" our profession. Prepare your submission now!

Together we will make it the best it can be!

Dr. Yadin David

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Applying Human Factors Methods in a Clinical Engineering Setting to Reduce Medical Device Risks

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ABSTRACT

This paper describes the ways in which human factors methods can help to enhance the work of established clinical engineering teams by placing a new emphasis on error reduction and patient safety. This approach in many ways represents a natural evolution for departments that are looking to enhance their usefulness and relevance to healthcare. Several examples are given of points at which the introduction of human factors methods can reveal issues related to the safe use of medical devices that are not easily accessible by other means. Adoption and implementation of these methods offers the potential for clinical engineering departments to enhance their role in ensuring optimal patient safety.

Keywords – *Human factors, medical devices, error investigation, patient safety.*

INTRODUCTION

For clinical engineering teams, managing risks associated with medical devices is at the core of their work. Great attention is rightly paid to the effective maintenance of medical devices, to ensure that they are operating within specification and are inspected as required to support continued good performance. An ideal approach to this considers all phases of the medical device lifecycle, from acquisition planning to eventual decommissioning. The objective is that properly selected and maintained devices will help to ensure good patient outcomes during treatment.

In 1999, the Institute of Medicine (IOM) in the United States issued a landmark report titled: *To Err is Human: Building a Safer Healthcare System*,[1] which provided a harsh wakeup call to the healthcare community with an extrapolated estimate that at least 44,000 to 98,000 deaths were occurring each year in the US healthcare system as a result of generally preventable medical errors. This explosive statistic caused much debate and analysis within the healthcare community, both in the US and in other countries, and subsequent studies in other jurisdictions revealed remarkably similar rates of error when normalized for population size.[2] One of the results of this information was to place new emphasis on patient safety, and organizations began to search for methods that would allow them to study their current levels of safety, capture errors, and make improvements that would have a lasting effect on patient safety outcomes.

In the search for methods and approaches that might prove beneficial in healthcare, attention turned to the aviation and nuclear power industries, both of which had experienced significant catastrophic events that led to a clear demand for action. The discipline of human factors

combines principles and methods from psychology and engineering to understand how humans interact with the world around them, examining issues of cognition and the interaction between people and the environment that surrounds them. Leaders in the field, such as James Reason and Jens Rasmussen, have developed models that help to determine whether a system is well designed for safe human use by posing questions such as; Is it clear and logical to operate? Does it behave in a manner that is similar to other systems that the operator encounters? Does it reveal its operating state in a clear and concise manner?

These methods have proved remarkably effective at increasing the safety both in aviation and at nuclear power plants. Commercial aviation has become far safer in the past 40 years as a result of the standardization of various procedures and the use of tools such as checklists and safety interlocks.[3] These methods offer great potential for improving the safety of healthcare as well, but to date, the results have been mixed[4] and it is useful at this point to consider why it is proving so difficult to achieve truly significant reductions in error rates in healthcare. Healthcare providers spend many years of training to deliver the best possible care to their patients and are understandably distressed when errors occur during diagnosis or treatment.

Effective improvements in aviation and nuclear power safety have come about because of the standardization and codification of safe practices, and at first glance it appears that it might be possible to have a similar effect in healthcare, but there are some important differences that come into play which are making it much more difficult to have an impact on error rates.

(1) Healthcare processes are far more varied than the processes followed in an airplane cockpit prior to take off, for example (J Ruiter-Ligeti, MD, personal communication). They cannot necessarily be standardized to the same extent, and many healthcare providers have become expert at improvising in complex situations. The term "workaround" is one that is commonly heard in patient care environments as front-line care providers modify well-intentioned but restrictive protocols to try to provide optimal care for each patient.

(2) In an effort to improve safety, system planners in healthcare often seek to impose a level of standardization which restricts the ability of front-line staff to provide optimal care, leading to frustration and a sense that one must "go it alone" to provide optimal care. This often comes about when systems are imposed on users without a thorough understanding of the specifics of the work being done at the bedside. As an example, it is easier for an administrator to write a policy in response to an earlier error forbidding a particular practice, than to spend time in the care environment understanding why that practice is being used. Everyone wants to do what is best for the patient, but understanding what that looks like requires a very detailed knowledge of the actual environment of care.

(3) Healthcare is not a static entity. Indeed, big changes have occurred in the past 19 years since the IOM report, including the widespread adoption of computerization and the introduction of new types of medical devices. Both of these useful forces add complexity to an already complex environment, making safety an increasing challenge. Further, these systems and devices are often introduced in ways that fail to take into account the environment of care and the skills, abilities, and training levels of the users, leading to new possibilities for error.

Human factors methods can be brought to bear on all of these issues, and there are some early encouraging signs that these are taking hold. Interestingly, the application of human factors methods is not new in healthcare. A remarkable early example is the work of Dr. Jeff Cooper and colleagues in Boston with regard to anesthesia safety.[5] This work was way ahead of its time compared with other areas of healthcare and it had a profoundly positive impact on patient safety during anesthesia. Sadly, this approach did not gain a significant foothold in many other areas of care, and so we are now presented with the challenge of how to accomplish widespread adoption in the complex health environment of today, where devices are often networked together and information is aggregated in complex IT systems.

Clinical engineers and technologists are well-placed to champion the application of human factors methods in healthcare, at least regarding the role that medical

devices play in errors. Jim Keller of ECRI Institute has stated that their data reveal that 75% of errors that occur with medical devices are not due to device failure per se but are as a result of use error.[6] In the next section, a series of ways in which the clinical engineering team can participate in the application of human factors methods in the healthcare process are explained, and it is hoped that we as a profession will seize the opportunities that these tools provide to do our bit to try to ensure that medical devices are used as safely and effectively as possible.

HUMAN FACTORS ROLES FOR CLINICAL ENGINEERING

While it is unreasonable to assume that clinical engineering can solve all of the systemic error problems in healthcare, it is clear that a number of these relate in one way or another to the use of medical devices and IT systems. Medical device support has been the traditional domain of clinical engineering, and in recent years there has been a strong emphasis on clinical engineering becoming much more involved in the deployment of IT-based systems as well, since in many ways the issues posed by these mimic the ones posed by medical devices themselves; issues such as technical specifications, network connectivity, interfaceability, and overall user satisfaction. IT systems are often an extension of patient data collection, much of it initiated by medical devices at the front end, so this extension of activities is logical and sensible.

Clinical engineering is well-placed to bring a systems engineering approach to helping to reduce error, and this has the advantage of moving the approach away from opinion and conjecture and towards measurable parameters and outcomes; the classic tools of quality improvement. A full review of the various ways in which clinical engineering can engage in bringing a human factors approach to healthcare is beyond the scope of this paper, but a comprehensive treatment of this subject can be found online.[7] The following is a brief summary of the key areas where contributions are possible, and further reading is encouraged. There are a small but growing number of teams specializing in these methods in healthcare around the world, and it is hoped that in time, these methods will become widespread and routine, since they offer great potential to improve the level of safety associated with the use of medical devices and IT systems.

Use in Assessment and Procurement

The assessment and procurement of medical devices has long been recognized as a critical task for clinical engineering since decisions that are taken then have an impact of many years. A poor choice of technology can result in devices that are unreliable or difficult to operate. In most jurisdictions, the demand for new technology outstrips the available funding, so decisions need to be made carefully. Once made, the selected devices are long-term commitments that ideally should satisfy the needs of the healthcare system. Very often, medical device decisions do not involve many, or even any, of the end users who will ultimately have the task of trying to extract good performance from the chosen system. Traditional user assessments in clinical areas are often subjective and haphazard, and subject to bias. Using the human factors methods of work flow analysis and usability testing in a controlled simulated or real environment allows a high measure of objectivity to be brought to an evaluation of competing products from several vendors.

Representative end users are initially observed interacting with comparable technologies if present, to gain a thorough understanding of the ways in which the technology fits within the environment and associated work flows. Users are then recruited into a series of controlled interactions with competing technologies using scenarios that are scripted to represent typical tasks in the observed clinical work flows. The human factors team members passively observe the performance of each participant, paying special attention to areas where users experience confusion interacting with a device, or make errors during use. If multiple participants experience problems at a particular stage of use, that is a strong indication that some aspect of the device being tested is proving problematic for the entire user population, and an assessment should be made of the potential severity of the problem. Could it lead to an incorrect treatment or diagnosis, for example? Can it be bypassed or modified in some fashion?

Mounting tests of this kind requires some effort and knowledge of the evaluation methods used, but the investment of time for a major device acquisition is well worth

this effort. Institutions have to choose which device areas to subject to this rigorous evaluation, and as a general guide, the following filters can be applied; is the device one which has been associated with past incidents and errors? Is the device widely distributed in the organization and thus used by a variety of different people? Is there a major financial investment being made? If the answer to one or more of these questions is yes, then the upfront cost and effort associated with a human factors-based pre-purchase evaluation may well reap dividends over the lifetime of the equipment. One other important issue to consider is that when end users participate directly in this type of evaluation, they come to a better understanding of the capabilities and limitations of the device, and are more vested in the selected product, assuming that their experiences are used to help inform an optimal purchasing decision.

Use in Predicting and Investigating Errors

Even with careful device selections, errors will still periodically occur, and so the next area in which the human factors approach can play an assistive role is in the prediction and investigation of adverse events. Tools such as Failure Mode and Effects Analysis (FMEA) can be used proactively to assess the likelihood of certain events occurring during the use of device or a system. Each potential failure mode is identified and the associated effects from each are categorized, asking what the probability of occurrence is and what the impact will be should it occur. Once these are drawn up, a list of mitigating strategies can be identified and decisions can be made about which of these are realistically implementable. Note that all of this work is prospective. It is done ahead of implementing a particular device or system, and if the analysis is thorough, it offers the potential to significantly reduce the overall error rates associated with a particular system. Clinical engineering teams are often very well-placed to lead this analysis since they are aware of the details of implementation of a technology and also have a good grasp of the potential problem areas associated with its use.

Assuming that an incident has now occurred and that the institution has initiated an investigation, the Root Cause Analysis (RCA) method is a powerful tool grounded in human factors theory that can be used to try to understand the root causes behind the incident. With very rare exceptions, healthcare workers are deeply committed to the welfare of their patients and are traumatized when adverse events occur that compromise their patients' care. Sometimes the initial reaction to an adverse event is to criticize the people involved and ascribe it to poor judgment. This has the double effect of quickly identifying the "culprits" and reassuring the system that this was a one-off event, leading to a false sense of security that the underlying issues have been effectively addressed. The human factors approach helps us to look behind these assumptions to try to understand the root causes involved. Perhaps the healthcare provider was interrupted during a very critical task. Perhaps the system itself is so complicated that many users do not know how to properly operate it. Perhaps a user was presented with information that appeared to confirm that the system was performing as intended and failed to notice that the potential for an adverse event was evolving as a result of their actions. An RCA helps to uncover these issues, and once they are revealed, helps to guide those responsible for the system regarding the changes that are required to the system to try to minimize the likelihood of a recurrence. Again, clinical engineering is well-placed to take a lead role in aspects of this analysis, working with colleagues from other disciplines to uncover these root causes. By identifying and mitigating these issues, systems truly become safer in the long term.

Looking for No Fault Found Repair Reports

As mentioned at the beginning of this paper, clinical engineering departments are rightly charged with the effective maintenance of the medical devices used in their institution. Ask any hands-on service person in clinical engineering whether they have ever received a piece of equipment from a clinical area with a label on it saying "broken" only to find that when they test it on the bench, it is performing to specification. These are often referred to as "no fault found," since no fault was detected by the service team. A recent study[8] pulled data related to no fault found service events and then identified a range of devices that showed higher incidence levels of no fault found reports. When these devices were assessed for usability, a correlation was found between user difficulties and the likelihood of a no fault found event occurring. In

other words, users were experiencing difficulties using a device and some of them were giving up in frustration on the assumption that something must be wrong with the device itself, or simply taking the approach that if I can't get this unit to work, maybe I should get another one and send this one in for "repair." From this it can be seen that no fault found reports in clinical engineering departments are to some degree a proxy for devices that are difficult to operate. Further investigation can reveal whether interventions such as further user training can be effective at helping to reduce operating problems, or are the issues built into the design of the device such that the only effective remediation is replacement of the device altogether.

CONCLUSION

While not all of the approaches described above can be performed solely by the clinical engineering team in an institution, the application of these human factors methods can easily be developed and championed by it. With their technical background, the team is ideally placed to adopt and promote these methods, and will often find allies among clinical staff, administrators and risk managers, all of whom have a strong interest in reducing errors during care as much as possible. As clinical engineering adapts and grows, this area represents a high-impact extension to the work that they currently do, and it can be argued that promoting human factors methods is a challenge not unlike the one faced by clinical engineering 10 years ago regarding their involvement in information technology systems. That debate is largely resolved, and it is hoped that the next 10 years will see a similar outcome regarding the adoption of human factors methods by clinical engineering. To gain this knowledge, users are encouraged to learn more about this topic through reading and through contact with colleagues who have already worked in this area. Industrial Engineering and Psychology departments of nearby universities may have faculty with strong human factors knowledge who are interested in collaborating with people who are working in a live clinical environment. Also, there are an increasing number of labs whose work is focused specifically on the application of human factors methods to healthcare, and these represent expert sources of information and, potentially, collaboration.

In sum, clinical engineering departments have an excellent opportunity to play an important role in helping to make the provision of healthcare safer through the adoption and application of human factors methods in their work. Clinical engineering professionals are encouraged to seize this opportunity and make a contribution. Development of this area of expertise in healthcare will help to elevate clinical engineering from a technical support role to important players in ensuring optimal safety for patients.

CONFLICT OF INTEREST

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

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Spin-off use of adverse events data: why and how. The case of FDA's MAUDE

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ABSTRACT

Objectives: This paper attempts to measure the impact of the second stage exploitation of FDA's MAUDE database on patient safety, technology assessment and other scientific fields.

Methods: Five bibliographic databases have been queried with the terms "Manufacturer and User Facility Device Experience Database" and "FDA AND MAUDE". A number of eligibility criteria where applied on the results, which led to a final group of 117 papers. An extensive study of these publications resulted to a number of interesting findings.

Results: The results concern the evolution of the database exploitation over time, and are examined according to the device groups that the identified papers are referring to, the research goals of these papers, the reasons that led the authors of these papers to use MAUDE data and finally how these data were used within their research methodology.

Conclusions: Patient safety and technology assessment are two of the scientific fields on which MAUDE database has the greatest impact. On average, more than 10 peer-reviewed papers each year involve MAUDE data as a mean to reach their research goals. This proves that MAUDE is an exploitable and valuable data source for research in these scientific fields.

Keywords – *Medical Devices, MAUDE, Adverse Events Reports, Patient Safety, Health Technology Assessment.*

INTRODUCTION

Patient safety, health technology assessment and medical device vigilance are fields that heavily rely on data availability. They need valid data from various sources in order to extract useful information. A significant source of data for medical devices (MDs) appears to come from the medical devices vigilance and post-market surveillance mechanisms that are imposed by the relevant regulatory systems, in most part of the world. The Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database is such a source.

Millions of medical devices are used today in various places (hospitals, clinics, houses, etc.) and thousands of new models enter the market every year. Undoubtedly these MDs have a significant contribution to the improvement of the healthcare services provided. However, medical technology, like any other technology, is not risk free. There are numerous cases where devices have been recalled because of their involvement in adverse incidents compromising patients' health or cases where a "promising" innovative approach has to be withdrawn after a

relatively short period of use, because it is not proven as safe as expected.[1, 2, 3, 4]

The largest MDs markets today (USA, EU, Japan, etc.) are ruled by regulatory frameworks (Regulations, laws, directives, guidelines) according to which a medical device has to comply with specific safety provisions in order to enter these markets[5, 6]. One safety requirement, common to all these frameworks, is the adverse event reporting system or vigilance system that follows the medium and high risk devices, after they have entered the market, in parallel with the post-market surveillance.[5, 6, 7]

A MDs vigilance reporting system aims to increase patient safety by preventing the recurrence of reported adverse events. This is achieved by mandating users and manufacturers of medical devices to report to the health authorities, incidents where a medical device contributes to an adverse event. According to this mechanism, whenever a medical device is potentially contibuted in a death or injury of a patient or user, the manufacturer has to report this event and assess if corrective actions should be taken. In parallel, a user reporting system encourages users to report to the manufacture and/or to authorities any such incident that comes to their attention. The principal purpose of the medical devices vigilance and user reporting systems is to improve the safety of patients, users and others, by reducing the likelihood of reoccurrence of a similar event elsewhere in the future. This is to be achieved by the evaluation of reported incidents and, where appropriate, dissemination of information, which could be used to prevent such repetitions, or to alleviate the consequences of such incidents.

USA is the biggest medical device market[8, 9] and FDA, as the relevant organization for market surveillance, is also responsible for medical devices vigilance. FDA has implemented since the 1990s a database called Manufacturer and User Facility Device Experience Database[10] for reporting of medical devices related with adverse events. Nowadays, this database receives more than 800.000 reports annually.[11]

Today, MAUDE contains more than 4 million medical device reports (MDRs)[11] of suspected device-associated deaths, serious injuries and malfunctions as well as other non-conformities such as packaging and labelling problems, unsterilized delivery etc. MAUDE contains MDRs filed by manufacturers and importers from August 1996 to present, all mandatory user facility reports from 1991 to present and voluntary reports filed after June 1993[12]. A portion of the database is open to the public, providing valuable information on MDs safety. It is accessible through the FDA's website (www.fda.gov) and can be queried through a search form. In addition, all main datasets are provided to the public as text files importable to common databases.

After an evaluation process, the high volume MDRS or the ones involved with a death are investigated by FDA and in many cases this investigation leads to corrective actions, with obvious benefits for the safety of both patients and users. At a second stage, this huge amount of data appears to be a valuable source for further research. Retrospective analysis studies, data extraction techniques and other scientific use of these data, offer spin-off benefits to patient safety, medical device technology assessment and other scientific fields[13, 14.]

This study attempts to measure quantitatively and qualitatively the second stage exploitation of MAUDE and the impact of this exploitation on scientific research.

MATERIALS AND METHODS

Five international bibliographic databases (ScienceDirect, Journals@Ovid Full Text, Pubmed, Web of Science and Scopus) have been queried with the terms "Manufacturer and User Facility Device Experience Database" and "FDA AND MAUDE" in order to find all publications that contain these terms. The databases were queried in January 2015. The results of these queries were consolidated through the removal of duplicates, which led to an initial number of 1.016 unique publications. (The results from each database appear in Table 1).

This set of results was filtered according to the publication type, language and publication time so as to keep only peer-reviewed papers, written in English, from 2005 to 2014. Books, editorials, commentaries, letters, comments on a paper, publications in conference proceedings, etc., were excluded from the final selection. After filtration, 381 scientific papers remained.

The next step was to extract out of these 381 papers the ones that have used directly data from MAUDE. This

TABLE 1. Bibliographic Search Results

Bibliographic Database	MAUDE AND FDA	"Manufacturer and User Facility Device Experience Database"
ScienceDirect	322a	269
Journals@Ovid Full Text	196[a]	175
Pubmed	54	42
Web of Science	49	41
Scopus	209[a]	322
Total (without duplicates)	631	604

[a] The search has been performed with proximity indicators (MAUDE w/10 FDA) or (MAUDE ADJ10 FDA)

selection led to a final group of 117 papers. Among these papers, there were 4 where the authors searched the MAUDE database but the results were found to be irrelevant to this work. However, these 4 papers were decided to be included in the final group because, although they finally did not use any data from MAUDE, they took into consideration the content of the database. The list of 117 papers appears in the Reference section (Ref: 14-25, 28, 31, 33-135).

It should be mentioned that among the 264 excluded papers, more than 50 referred to MAUDE data, but this reference was either limited to a single comment about one or two cases or indirect, using the results of other papers that had used the original data.

The last step was to study again in more detail the final group of these 117 papers, focusing on the device groups that these papers referred to, the evolution of the database exploitation with time, the research goals of these papers, the reasons that led the authors of these papers to use MAUDE data, how they finally used these data within their research methodology, etc. The flowchart for the query methodology is shown in Figure 1.

The bibliographic search results were processed initially with the Mendeley desktop references management software and later with Microsoft Excel.

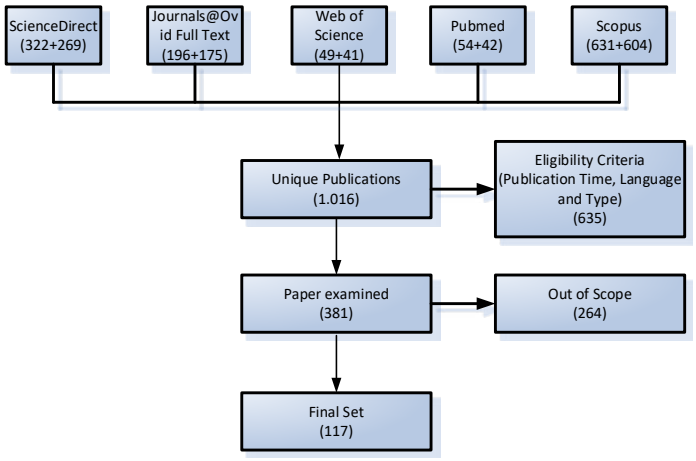

FIGURE 1. PRISMA flow chart for FDA MAUDE system search

RESULTS

The analysis of the final set of 117 papers revealed the following:

A) Since MAUDE is a database containing MDRs, each record is related with a medical device. Hence retrieval of data for the second stage usage is also related with medical devices. The analysis carried out identified the device groups that were used as a reference in the papers. These device groups were grouped, where applicable, into more generic device categories. It should be mentioned that although 24 papers were focused exclusively on a device type rather than on a group as a whole, only the device group was considered for the purposes of this analysis.

TABLE 2. Number of Papers per Device Group

Cardiology Devices	**29**
Stents	9
Implantable Cardioverter-Defibrillators	7
Vena Cava Filters	6
Automated External Defibrillators	2
Angioplasty Catheters	1
Arterial Closure Devices	1
Catheter Introducing Sheaths	1
Catheters	1
Vascular Closure Systems	1

Implantable Devices	**22**
Meshes	6
Septal Occluders	4
Cochlear Implants	4
BMP2 protein	3
Breast Implants	1
Cerebrospinal Fluid Valves	1
Heart Valves	1
Silicone-Polyurethane Copolymers	1
Spinal Cord Stimulator	1
Endoscopy Devices	**14**
Endoscopy-General	4
Endometrial Ablation Devices	3
Endoscopic Stapling	1
ERCP	1
Gastrointestinal Endoscopy	1
Microwave Endometrial Ablation	1
Mucosal Ablation Devices	1
Radiofrequency Ablation	1
Various	1
Laparoscopy Devices	**6**
Hem-o-lok	3
Laparoscopic Morcellator	1
Laparoscopic Trocar	1
Various	1
Infusion Devices -Pumps	**5**
Infusion Devices	2
Insulin Pumps	2
Infusion Pumps	1
Prosthesis	**4**
Artificial Discs	1
Hip Prosthesis	1
Lumbar Total Discs	1
Shoulder Prosthesis	1
Robot Assisted Surgery	**4**
Transcervical Sterilization	**4**
Patient-Controlled Analgesia	**3**
Stone Extraction Balloons And Baskets	**2**
Stone Baskets	1
Stone Extraction Balloons and Baskets	1
Extracorporeal Oxygenation	**2**
Extracorporeal Membrane Oxygenation	1
Oxygenator	1
Lasers – General	**2**
Cosmetic Laser	1
Lasers	1
Ambulance Stretcher	**1**
Bed Rails	**1**
Breast Pumps	**1**
Contact Lenses	**1**
Ethylene vinyl alcohol copolymer	**1**
Feeding Tubes	**1**
Glucose Monitors	**1**
MRI	**1**
Operating Microscopes	**1**
Peritoneal Dialysis	**1**
Piggybacks	**1**
Tanning Units	**1**
Papers referring to Various Device Groups	**8**

According to the analysis performed, the general category of Cardiology Devices was the most frequently referred (29 papers), while Implantable Devices (22 papers) and Endoscopy Devices (14 papers) were the next ones. As regards the device groups, Stents (9 papers), Implantable Cardioverter-Defibrillators (7 papers), Meshes (6 papers), Vena Cava Filters (6 papers), Septal Occluders (4 papers), and Cochlear Implants (4 papers) were the leaders. Finally, there were 8 papers that have not been included in this part of the analysis, since they

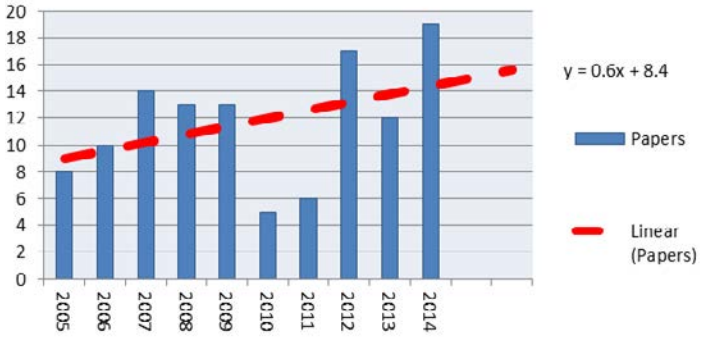

FIGURE 2. Number of papers published each year.

used a combination of data related with various device groups. The number of papers classified under each group is presented in Table 2.

B) As regards the publication time of these papers, 2014, 2012 and 2007 were the years with the most published papers (19, 17 and 14 papers respectively). The linear trend line shows that the number of papers that used the MAUDE data increases with time (slope =0.6). (Figure 2)

C) Although it was difficult and maybe risky to summarize and classify the research objectives of papers covering various scientific areas and subjects, into a few generic objectives' categories, such an attempt was made in order to outline the research orientation of the papers that use data from the MAUDE database.

The most common objectives among these papers were "to review/identify the reported adverse events/complications related with a device group or type" (31 papers), "to evaluate adverse events" (22), "to evaluate design characteristics of a device group or type" (15 papers), "to explain why these events occur" (14 papers), and "to overview a medical technology and/or its performance" (10 papers). Table 3 presents the results of this analysis.

TABLE 3. Research Objectives

Papers' Objectives	Number of papers	Example of Objective
To review/identify reported adverse events/ complications	31	To collate world reports of adverse events (AEs) resulting from lasers used in urology[15]
To evaluate adverse events/complications	22	To raise awareness of the potential hazard of auricular burns associated with operating microscope use during otologic surgery[16]
To examine/evaluate design characteristics of a medical device	15	We sought to determine if perforation rates are related to cannula design[17]
To explain why specific adverse events/ complications occur	14	This study was undertaken to analyze bleeding problems with tension-free vaginal tape (TVT) operations[18]
To overview a medical technology and/or its performance	10	This study sought to determine whether infusion device event logs could support accident investigation[19]
To assess the frequency and/or severity of adverse events/complications	8	The purpose of this study is to use large databases to assess the frequency and severity of such complications and compare them with those of surgical atrial septal defect closure[20]
To evaluate/test a method or a hypothesis	7	The aim of this article is to evaluate a new system and procedure, dedicated to oxygenator change-out[21]
To review a new technology/procedure	7	This document will review the biliary and pancreatic stone extraction devices that are currently commercially available in the United States[22]
To discuss regulatory issues	2	The present analysis aimed to compare the 510(k) and PMA approvals and recalls on the basis of the number of devices approved in each group[23]
To estimate cost	1	To estimate the rates and costs of intravenous patient-controlled analgesia (IV PCA) errors from the hospital or integrated health system perspective[24]

D) Equally difficult was the attempt to examine and classify the purpose for which the MAUDE data were used within those papers. The findings of this analysis were similar with the findings of the analysis of the papers' objectives. In brief, the main reasons for the use of MAUDE data was "to summarize or review adverse events" (53 papers) as well as "to explain why these events occur" (42 papers). Additionally, it was found that 36 papers dealt with the evaluation of adverse events or complications, and 32 papers provided directly suggestions for patient safety measures. Finally, it should be noted that in each paper these data could have been used for more than one purpose. All the findings of this analysis are presented in Table 4.

TABLE 4. Purposes of MAUDE data use

The MAUDE data have been used:	**Number of Papers**
To summarize the adverse events related with a device group or type	53
To explain why specific adverse events occur	42
To evaluate adverse events or complications	36
To suggest patient safety measures	32
To assess a device group or type	30
To estimate how frequent is the occurrence of an adverse event or to calculate trends	30
To assess the safety of a technology or of a medical procedure	24
To assess the severity of adverse events/complications	15

DISCUSSION

The final number of 117 papers that were found to have used MAUDE data cannot be considered as covering the whole spectrum of the respective research activities. The actual range of MAUDE data usage must be considered even greater if it is taken into account that among the publications that were excluded by the present study, there were many papers that a) refer to a unique case from MAUDE, b) use partially or complementarily data from it or c) refer to other papers based on MAUDE data analysis. In addition, it was also found that there were many other kinds of publications, such as books, editorials, and publications in conference proceedings, which were used on MAUDE data.

The device groups that the papers focused on were mainly cardiology devices (Stents and Implantable Cardioverter-Defibrillator), implantable devices (Meshes and Cochlear implants), endoscopy and laparoscopy devices. It is surprising that high risk device groups that are used widely in hospitals, such as Respirators, Anesthesia Machines, ECG, etc., were not among the devices of this list. One possible reason for this fact is that the researchers have directed their attention to devices that had entered the market within or near the period under examination (drug eluted stents, robot assisted surgery, transcervical sterilization, etc.) or to device groups containing products which have been involved in serious recalls (Stents, Occluders, Cardioverter, Defibrillators etc.)[1].

The number of papers that use data from MAUDE appears to increase with time, having a time trend with a rate of 0.6 (Figure 1). It is expected that in the near future the second stage exploitation of MAUDE data will further increase given that FDA makes a constant effort to improve the quality of data and their accessibility (Unique Device Identifier, Total Product Life Cycle, Open FDA etc.)[2, 3, 11 25, 26] in combination with the fact that new or improved management and analysis techniques of big data emerge.

The examination of the papers' research objectives clearly shows that the majority of the papers under consideration contributes directly or indirectly to patient safety by reviewing or summarizing the adverse events/complications related with a specific device group or type (31 papers), by evaluating adverse events/complications (22 papers), by explaining why these events occur (15 papers) or by assessing the frequency or severity of adverse events (8 papers). Additionally, the contribution to technology assessment is also significant through the evaluation of the devices' design characteristics (14 papers), the overview of a medical technology and its performance (10 papers) and the review of new technology and/or medical procedures (7 papers). Finally, the papers in question have a contribution in other fields too. For example, 7 papers used MAUDE data in order to test or evaluate a method and 2 papers discussed the regulatory issues for medical devices.

The fact that the MAUDE database is a useful source for patient safety purposes is further supported by the examination of the manner in which these data are used in the papers. It was found that MAUDE data have been used among others to summarize the adverse events related to a device or a medical procedure, to explain why adverse events occur and to suggest specific measures. The ultimate goal of the above-mentioned uses was to inform the medical community as well as MD designers and manufactures about the problems that could arise, the likelihood for them to occur, the underlying mechanisms that lead to these complications, the ways to avoid or to deal with these events and the measures to eliminate their consequences. Besides, MAUDE appears to be a useful tool as regards technology assessment too, since its data have been used in order to assess the use of medical technologies and medical devices, as well as to estimate the risk of the utilization of a device or procedure. It is also worth mentioning that from this analysis, it was found that 14 of the papers used the MAUDE database as a source in order to test or evaluate a method, a procedure or a hypothesis. For example, MAUDE data were used to evaluate the role of human factors in acute care equipment decisions[27] and to examine whether the log files could assist in an accident investigation[19].

During the papers' analysis, other useful information was also gathered, pertaining to research limitations inserted by the use of MAUDE data as well as to the quality and integrity of these data. In many papers it is mentioned that the MAUDE data and the use of adverse event reports data in general, inserted certain limitations dealing with the reporting rate and the denominator issue[28]. As regards the reporting rate, there is a general belief that not only adverse events are under-reported but there is also a lack of information about the ratio representing the number of adverse events reported versus the number of real events that have occurred. Similarly, there is a lack of baseline numbers (e.g. total number of surgical procedures relevant to a product, total number of specific devices used, etc.) that could be used as denominators. Both these limitations make the data unsuitable for determining rates[29, 30].

Moreover, there was criticism as regards the consistence and quality of the MAUDE data. Some researchers have doubts about their quality, stating that the data provided by FDA are not structured in a common way, are not complete and their accuracy is debatable, thus obstructing the analysis procedures. Others commented that the information and degree of detail contained within these reports are highly variable, making interpretation of the reports difficult and causality often uncertain[29, 31].

During the period 2005-2014, MAUDE data could be searched either by an online search form provided by the FDAs' web site or by downloading them in txt formatted files. The majority of the studies have used the online search form. There were only a few that have used the MAUDE data provided in txt format. This is probably because the insertion of these txt files into a relational database is not an easy task given the amount of data (some tables have more than 3 million rows) and because the txt files need some technical preparatory actions in order to be ready for insertion. It is expected that the openFDA web site (https://open.fda.gov/) which provides capabilities for easier and more comprehensive access to the data in addition with the further use of the database with contemporary big data analysis tools or data mining techniques will lead to a more intense exploitation of MAUDE database.

Finally, it is worth mentioning the positive impact of the transparency of MAUDE database comparing it with

the European Databank on Medical Devices (EUDAMED). In the EU, legislative changes imposed stricter and more detailed monitoring and enforcement requirements for both notified bodies and national competent authorities, in response to increasing safety concerns. Recently, the enforcement of a more rigorous new legislation in the form of two Regulations[136, 137] has been voted by the European Parliament. The use of the European Databank on Medical Devices (EUDAMED), containing regulatory information on MDs available on the EU market, including recalls, is also reinforced. However, regarding the EU user reporting system for medical devices adverse events, there is not an overall collection of the reports submitted to the national competent authorities. This is due to the decentralised structure of the EU regulatory system, in combination with the fact that there is no provision for a centralised collection into the EUDAMED. Additionally, the EU policy that does not allow the public access to all these data, including the recalls, prohibits their analysis by independent researchers.

A research comparing the impact of the transparency of EU vigilance system with the one of FDA for the period 2004-2015, found that there are no papers or reports, even from a central EU body, based on the EUDAMED data[138]. However it is a fact that EUDAMED can provide similar information. As an example, Bliznakov et.al[139] performed a survey on medical device recalls, concerning only devices using software, based on FDA data for the period 1995-2002. It was found that about 25% of the recalls studied, were caused by software failures. As might be expected, the proportion of these recalls due to software problems increased, from 17% in 1995 to 34% in 2002. Follow up studies[140, 141] revealed that this proportion went up to 40% in year 2012. These authors, performed in parallel a survey on recalls caused by software failures using EUDAMED data, and found very similar results. Unfortunately, those results could not be published due to the restrictions on the use of EUDAMED data.

CONCLUSIONS

FDA provides public access to a portion of its post-market surveillance database, thus allowing researchers outside FDA to carry out analyses and studies based on the raw data, with a consequent spin-off benefit for public health. The fact that, in spite of the limitations, more than 10 peer-reviewed papers each year use MAUDE data shows that MAUDE is an exploitable and valuable data source.

According to the analysis of the papers, MAUDE database is used mainly for research works related to patient safety and technology assessment compared to other scientific areas. It is also observed that the MAUDE data are mainly used to evaluate devices that are relatively new to the market, or to investigate issues related with these devices. Additionally, it was found that MAUDE is a useful data source when it is required to summarize adverse events related with a device as well as when the reasons that could lead to an adverse event have to be examined. Finally, MAUDE data exploitation increases with time and is expected to be even more intensive in the future.

Undoubtedly, there are improvements that could increase the exploitation of MAUDE database. However, despite limitations, restrictions and criticism, it is a common conclusion among the majority of the papers studied, that the MAUDE database is a useful and valuable tool for patient safety and technology assessment. The benefits resulting from the MAUDE use should be taken into consideration by the EU, so as to move in the direction of enhancing and improving the data collection procedures from the vigilance system as well as to increase the transparency of EUDAMED as explicitly stated in the regulations[136, 137]: "..vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding medical devices should be introduced, to improve health and safety … The objectives of the database are to enhance overall transparency, including through better access to information for the public and healthcare professionals …". Additionally individual researchers should be allowed to have access to relevant data, in order to be able to perform similar studies that significantly contribute to equipment improvement and patient safety.

CONFLICT OF INTEREST

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

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Making a Difference – Global Health Technology Success Stories: Overview of over 400 submissions from 125 Countries

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ABSTRACT

Health Technology (HT) is vital to global health care. The dependence of health, rehabilitation, and wellness programs on technology for the delivery of services has never been greater. It is essential therefore, that HT be optimally managed. Clinical and biomedical engineers have been recognized by World Health Organization (WHO) as essential to providing this critical management.

At the 1st International Clinical Engineering and HT Management Congress and Summit held in China in 2015, a resolution was adopted by the global Clinical Engineering (CE) country participants to identify and promote CE unique qualifications, and to record the CE contributions to the improvement of world health status. Review of published literature and submissions of case studies resulted in the first group of CE success stories. The review captured 150 stories from 90 countries – spanning over a period from the prior 10 years and the results were presented to health leaders at the WHO World Health Assembly in 2016. Last year, in 2017, additional 250 case studies from a total of 125 countries were added from the 2016-2017 period. This paper describes the evidence identified during the review, their sources and the 6 major categories they represent.

Keywords – *Healthcare, Clinical Engineering, Technology Management, Safety, Efficacy, Outcomes, Innovation, Success Stories*

INTRODUCTION

Health Technology (HT) is vital to health and the dependence of health, rehabilitation and wellness programs on HT for the delivery of their services has never been greater. Therefore, it essential that competent and trained professionals manage in an optimal and safe way for better response to the burden of diseases and resources. Trained clinical engineers are academically prepared and appropriately responsible for HT life-cycle management, fulfilling a critical role as members of the healthcare team focusing on availability and reliability of safe and effective technologies and outcomes.

Over the past 50 years growing concerns among Clinical Engineering (CE) professionals about lack of knowledge of government agencies and key stakeholders, coupled with the mute recognition for their vast contributions to the safe and effective creation and deployment of HT, led to programs that address these concerns. Knowledge about

IFMBE-CED is the International Federation for Medical and Biological Engineering (IFMBE)-Clinical Engineering Division (CED), currently representing clinical engineers (hospital-based biomedical engineers) in these roles in 165 countries. See more information about CED at ***cedglobal.org/organization-and-teams/***

and recognition for the professionals of CE community who provide critical services will help recruit students and future practitioners into this needed field. Is CE practice important for health, rehabilitation, and wellness programs and are their contributions recognized? This paper shares the methodology and the findings identified following a three-year examination of published evidence.

Following the international congress on CE and HT management in Hangzhou, China in 2015, a Global CE Summit took place to determine whether regional issues are shared across the world and present common international challenges requiring global strategy for optimal addressing of the critical issues. After order ranking of the issues that identified at the end of the Global CE Summit, the attending members voted that there were 2 major concerns: (1) a lack of understanding of and recognition for the CE contribution to improvements in healthcare delivery. (2) a lack of sufficient education and training for both those who would like to enter the field and for ongoing professional development. An action plan was devised to address these and other issues raised at the summit. At the second global CE summit in Sao Paulo, Brazil, in 2017, these challenges were reviewed and confirmed with attendees adopting resolutions seeking to continue to address these concerns. The action plans from the summit focused first on data collection identifying if CE contributions qualify as improvement to world health and wellness and can they be substantiated through evidence-based records. Addressing the second issue, an international survey of Body of Practice and Body of Knowledge was initiated and has been now completed.

METHODS

Rationale

A task force consisting of senior certified clinical engineers from IFMBE/CED issued a global call for submissions of evidence-supported case studies of CE contributions to the improvement of delivery of healthcare services or of patient outcomes. In addition, literature survey was performed in 2016, and of both sources, the literature and the submitted studies, an aggregate volume of 150 responses from 90 countries was examined and qualified as evidence-based contributions, (see http://global.icehtmc.com/publication/healthteachnology).

Results were rated and tabulated into categories (Innovation, Improved Access, Health Systems, HT Management, Safety & Quality, and e-Technology) and incorporated into document http://global.icehtmc.com/publication/globalsuccess that was submitted to WHO's World Health Assembly in May 2016.

We expanded our review in 2017, as submissions and publications continued to be collected, to include conference-accepted data that was presented and published at IFMBE sponsored events. Our examination methodology identified 250 additional stories from 35 more countries – now raising the total volume over 2 years to 400 publications from 125 countries. These CE success stories point to improved outcomes with benefit from HT, and present overall demonstration of complex integrated systems that must be effectively managed for their optimal and safe clinical and business impact to be realized. Clinical outcomes included change in human life quality, care management decisions support, improving 365×24×7 readiness, and improving operational efficiency.

Definitions

For the present study, we classified the collected database into 6 categories with definitions:

- **Innovation**

Through provision of new HT solutions, adaptation of existing, or a combination to address several issues.

- **Improved Access**

Ease in reaching HT-related health services or facilities in terms of location, time, and ease of approach.

- **Health Systems**

Positive impact from more efficient and effective deployment of HT at national or policy level.

- **Safety & Quality**

HT's positive impact on health services safety or quality outcomes, or through HT human resource development.

- **Healthcare Technology Management (HTM)**

Establishing or improving HTM methodology resulting in improved population health or wellness.

- **e-Technology**

Improvements achieved due to deployment of Internet-based HT tools.

Measures

During the first Global Clinical Engineering Summit in 2015 the question was raised whether evidence of successful HT innovation, management, accessibility, e-technology applications, safety, and quality outcomes can be identified. To accomplish this, a successful project (or submission) was defined as satisfying 2 objective measures developed by the sponsors. These measures included timeliness, cost saving, deployment or adoption by care providers, impact on services, and overall projection for success. Each success metric was evaluated using 3-point scale against a statement representing the success construct (1= strongly disagree; 3=strongly agree).

- Timeliness refers to whether the project/submission was implemented in timely manner. This was measure by the statement "The submission will impact outcomes on present time."
- The cost measure was evaluated by whether the submission's overall costs were within budget constraints and reasonable for the conditions in the region. This was assessed by the statement, "The submission cost objectives can be met in the region."
- The next 2 metrics were combined into the statements "The submission will be deployed by its intended users" and "The submission will have a positive impact on those who will adopt it."
- Finally, overall submission success expectations were assessed with the statement "All things considered, the submission will be a success."

Innovation is the beginning of the technology life cycle where new ideas offer solutions to current problems faced by healthcare providers or their patients. Clinical engineers are well positioned to understand the current problems and guide different or new approaches to resolve them. Innovation, in our category, means to demonstrate the team approach to solving problems all the way from the concept and building of a prototype, to continuing with clinical trials, and a demonstration of compliance with standards, regulations, and intended outcomes. Improved Access to services follows the innovation stage the same as the Safety and Quality category, e-Technology category, and HTM. Products and applications that are considered in successful deployment were rated high and included in the total count for the evidence-based category.

RESULTS

Summaries of the 6 categories of submissions database are described below. They come from the CED's 2016 Health Technologies Resources[1] document provided to the World Health Assembly, WHO's May 2017, 3rd Global Forum on Medical Devices[2]; (3), the CED's September 2017 Sao Paulo II ICEHTMC[3] (S), and others[4] from 2016-2017 IFMBE published sources (O):

A new resource summary document of the findings – with links below – demonstrates that a benefit was registered in the 6 categories from every region around the world. Overall this review identified evidence from 400 case studies received from 125 countries where management of medical devices (main component of health technologies) made a positive difference over the past 12 years.

The 2007 WHO WHA Resolution 60.29 urges Member States to create national HT management plans in collaboration with biomedical engineers. WHO further clarified the definition of these personnel in 2017- 2018 as part of a global survey[5] (http://www.who.int/medical_devices/support/en/) in coordination with IFMBE CED.

"Trained and qualified biomedical engineering professionals are required to design, evaluate, regulate, maintain and manage medical devices, and train on their safe use in health systems around the world.[5]" These occupations have various names in different countries like clinical engineers, medical engineers, … and related professionals and technicians. [WHO and IFMBE CED surveys have identified over 800,000 of these global professionals in 2018.]

The case studies – grouped in 6 categories – aim to formulate national strategies and plans to improve use of health technologies and better manage costs. In several countries, this has best been achieved by developing a HT unit at the Ministry of Health level with CE leadership. The studies provide clear evidence that HT is beneficial; at times, presenting complex systems that must be effectively guided and managed for optimal impact to be realized.

- **Innovation**
- **Access**
- **Management**
- **Health Systems**
- **e-Technology**
- **Quality & Safety**

The case studies are actually Health Technology Success Stories demonstrating, in a limited resource environment, that it is desirable to include professional HT expertise, such as clinical engineers, in national decision-making in order to maximize health systems' services. Case studies from the links on the following pages demonstrate these benefits:

- **Access:** The Ministry of Health HT Unit-led project in Albania that doubled access to critical diagnostic services, such as computed tomography scanners, magnetic resonance and angiography imaging, while reducing equipment downtime to zero, and significantly reducing cost.
- **Health Systems:** Improved coordination between multiple stakeholders in the National Laboratory and its satellites in Colombia, led by the Ministry of Health and clinical engineers who partner with experts from academia and industry.
- **Quality & Safety:** A clinical engineer-led 122-hospital program in the Shanghai region that cooperates with officials, industry, and academic entities, resulting in improved device user satisfaction, tracking of emerging technologies, and closer partnerships with industry.

CONCLUSIONS

HT is vital to health and the dependence of health, rehabilitation, and wellness programs that rely on HT for the delivery of their services has never been greater. Beyond the ongoing healthcare burdens of population growth, political and economic instability, disease management, disasters, the refugee crisis, accidents, and terror attacks, world healthcare technological systems are facing enormous challenges to be innovative and optimally managed. The transition into health programs for the 21st century requires the employment of trained competent CE professionals. Disease prevention, treatment, and rehabilitation is more efficient and effective when health services are provided with appropriate tools. Along with World Health Organization (WHO), the International Federation for Medical and Biological Engineering (IFMBE) Clinical Engineering Division (CED) recognizes and emphasizes how important the use of appropriate, integrated, and safe health technologies (HT) is to successful outcomes for every healthcare delivery systems. In the May 2016 HT resource document that was prepared for the World Health Assembly (WHA), a recommendation was made: Health technologies must be managed to ensure full clinical benefit and expected financial return on investment.

It is critical, therefore, that with limited resources, HT must be professionally managed and its deployment over its life cycle be appropriately guided. This paper describes the extensive study of published data on the vast contributions by CE that positively impact patient outcomes. This study shows that every region of the world including low-resource regions face a challenge of improving health services while facing varied levels of infrastructure and human resources capacity challenges. CEs play vital roles in all stages of healthcare technology life-cycle management. From creation to planning, and from commissioning to utilization and integration; technology-based systems must and can be managed for optimal performance. In each of the technology life-cycle stages the requirement for trained and competent CE input makes critical difference as shown in the analyzed evidence reviewed here. It is our hope that government agencies and other interested parties will have better understanding of CEs role and thus will support their inclusion in the healthcare team of professionals.

RECOMMENDATION

To encourage the availability, recognition, and increased participation of clinical engineers as part of the health workforce in your national healthcare delivery programs.[2]

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4. IFMBE. [Internet]. Other related CE papers. Available at: CEDGlobal.org.
5. World Health Organization. [Internet]. Medical devices: Biomedical engineering resources. Available at: http://www.who.int/medical_devices/support/en/

ADDITIONAL LINKS AND RESOURCES

- WHO HQ: http://www.who.int/medical_devices/en/
- WHO EMRO: http://www.emro.who.int
- WHO AMRO: http://www.who.int/about/regions/amro/en/
- WHO Digital Health: http://www.who.int/medical_devices/global_forum/Thedigitalhealthaltas.pdf
- WHO Assistive Devices-GATE: https://mednet-communities.net/gate/
- WHO Emergency: www.who.int/medical_devices/global_forum/Essentialresourcesemergencycare.pdf
- WHO NCD Kit Refugees: http://www.who.int/medical_devices/global_forum/NCDkitrefugees.pdf
- IFMBE, CED, HTA: http://ifmbe.org/, http://cedglobal.org/ http://htad.ifmbe.org/
- PATH: https://www.path.org/ (Belgium, China, DRC, Ethiopia, Ghana, India, Kenya, Malawi, Mozambique, Myanmar, Peru, Senegal, RSA, Switzerland, Tanzania, Uganda, Ukraine, Vietnam, Zambia)
- AWHP: www.ahwp.info; Asian Harmonization Working Party - 30 countries, 3/17 Regulatory Authorities
- HTAi: https://www.htai.org/

RESOURCES REVIEWED

Focus Area	***Title,*** authors, with active links
Afghanistan, Iraq, Libya, Occupied Palestinian Territory, Somalia, Sudan, Syria, and Yemen	***Medical Devices for Emergency Kits (NCD Kit)***, Laura Alejandra Velez, Slim Slama
Australia	***Phototherapy to Reduce Exchange Transfusions,*** Luciano Moccia, Gaston Arnolda, Daniele Trevisanuto
Australia	***FREO2 oxygen solutions: the Low-Pressure Oxygen Storage system and FREO2 Siphon,*** Roger Rassool, Jim Black
Australia	***BME development of non-electric portable blood/fluid warmer for roadside trauma,*** Anne-Louise Smith, Mark McEwen
Bangladesh	***Health Technology enhancing rural Primary Care and eHealth***, Ahmed Raihan Abir
Brazil	***Dynamical Orthostatic Chair Development of a new method of lifting and locomotion for physically disabled people***, Walef Robert Ivo Carvalho
Brazil	***A multiband reflectance photometric device for reveal gestational age at birth***, Rodney Guimaraes, Zilma Reis
Brazil	***Prematurity detection by light***, Zilma Reis, Rodney Nascimento Guimarães, Gabriela Luíza Nogueira Vitral, Maria Albertina Santiago Rego, Ingrid Michelle Fonseca
Brazil	***Actions travelling ECG for Telemedicine - a partnership of academic and public service***, Kleber Teixeira de Souza et al
Brazil	***Flow Analyzer for Blood Pump***, L.R. Rodrigo, A.M. Marcelo and S. Anderson
Brazil	***Principal Component Analysis usage in Biomedical Engineering to aid at diagnosing pathologies***, E.F. Esmanhoto
Brazil	***Digital Storage and System Management for Video surgery Records in a Network Platform***, Benedito Fernandes De Lima et al
Brazil	***Early stage strategic effectiveness evaluation of high flow nasal therapy (OPTIFLOW®) in the treatment of Acute Pediatric Respiratory Failure***, Graziela de Araujo Costa et al
Brazil	***Location of electromedical equipment in closed environment using wi-fi technology***, William Knob de Souza
Brazil	***Remote Equipment Monitoring System***, A. Ricardo Maranho
Brazil	***Model fitting and simulation of the respiratory control system under incremental exercise and altitude in healthy subjects***, C. A. Sarmiento, A. M. Hernández, L. Y. Serna
Canada	***Provincial Respiratory Outreach Program in the Province of British Columbia (BC)***, Anthony Chan, Esther Khor
Chile	***Clinical Simulations using actors as a patients as part of a strategic plan to reduce risks associated to a "big bang" opening of a new hospital in Santiago***, Francisco Acevedo
China	***A novel automatic method of renal segmentation in GRF estimation***, Xu Lei
Colombia	***Modeling and simulation of ciprofloxacin pharmacokinetics: Electric circuits approach***, J. D. Otálvaro, A. F. Zuluaga, A. M. Hernández

Focus Area	***Title,*** authors, with active links
Colombia	***Autoregressive models of electrocardiographic signal contaminated with motion artifacts: Benchmark for biomedical signal processing studies***, F. A. Castaño, A. M. Hernández
Colombia	***Parametric modeling of kinetic-kinematic polycentric mechanical knee***, A. M. Cárdenas, J. Uribe, A. M. Hernández
Colombia	***Motion artifacts recognition in electrocardiographic signals through artificial neural networks and support vector machines for personalized health monitoring***, A. Castaño, A. Hernández
Colombia	***Learning tool for mechanical ventilation during spontaneous breathing test on patients intoxicated with pesticides***, M. B. Salazar Sánchez et al
Colombia	***Optimization of spectral analysis of electrophysiological recordings of the subthalamic nucleus in Parkinson' s disease: A retrospective study***, S. E. Valderrama-Hincapié et al
Colombia	***Three dimensional reconstruction and airflow simulation in a realistic model of the human respiratory airways***, A. E. Ruiz, J. K. Aristizábal
Colombia	***Permanent magnets to enable highly-targeted drug delivery applications: A computational and experimental study***, M. Mercado-M et al
Colombia	***Brain functional connectivity in Parkinsons disease – EEG resting analysis***, J. Carmona, J. Suarez, J. Ochoa
Colombia	***Business Opportunities in HT Projects***, Mario Castañeda
Croatia	***Supporting Diabetic Patients with a Remote Patient Monitoring Systems***, S. Zulj et al
Denmark, Norway	***Impedance-based monitoring for tissue engineering applications***, C. Canali et al
Ethiopia	***Producing Oxygen Concentrators for Low Resource Settings***, Mekdes Seyoum
Global	***Development of an Innovative regulated Affordable Uterine Balloon Tamponade for the Management of Post-partum Hemorrhage***, Elizabeth Abu-Haydar, Chris de Villiers
Global	***How we drive innovation within medical devices***, Kristoffer Gandrup-Marino, UNICEF
Global	***A new handheld cordless thermal coagulator,*** W. Prendiville, S. Rengaswamy, B. Partha, P. Groesbeck, Wallace Dean, Pickett Tim, Riddle Mike, Juan Felix
Global	***Safer medication administration for labor/delivery***, Beth Kolko; Bradley Younggren
Global	***Enabling and scaling early detection of breast cancer in lmics***, Mihir Shah, et al
Global	***Ultra-low-cost endoscopy for gastroesophageal cancer screening in low-income countries***, Pietro Valdastri, Joseph Norton, Simone Calo', Beatriz Plaza, Andrew Durkin, et al
Global	***Unsupervised electronic stethoscope for childhood pneumonia diagnostic***, Mohamed-Rida Benissa, J. Solà, F.Hugon,P.Starkov, F.Braun, S.Manzano, C.Verjus, A.Gervaix
Global	***Field testing a neonatal phototherapy device: a novel approach***, Donna Brezinski, et al
Global	***Test for management of preeclampsia***, Wendy Davis, et al
Global	***Device to save postpartum-hemorrhaging women in advanced shock***, M Guha, et al

Focus Area	***Title*,** authors, with active links
Global	***Validity of a device for jaundice screening,*** Anne Cc Lee, et al
Global	***CE-IT Innovation: How to Make Health Care Right***, Mario Castañeda, Tom Judd
Global	***WHO Priority Medical Devices***, Adriana Velazquez Berumen; Gabriela Jimenez Moyao, Antonio Migliori & Natalia Rodriguez, Adham Ismael Abdel, Alejandra Velez
Global	***Appropriate digital X-ray system with eHealth services***, Romain Sahli
Global	***Role of biomedical engineer in assessing medical devices***, Leandro Pecchia
Global	***Challenges in TB Diagnostics***, Christopher Gilpin
Global	***The Digital Health Atlas for Inventories and Routine Registration of Digital Health Investments***, Garrett Mehl
Global	***Global Cooperation on Assistive Technology: WHO Priority Assistive Products List***, Emma Tebbutt
Global	***Essential Resources for (Emergencies and) emergency care***, Teri Reynolds & Ian Norton
Global	***The role of biomedical engineers***, James Goh
Global	***Innovative appropriate technologies for low resource settings***, Adriana Velazquez
Global	***Access to medical devices for Universal Health Coverage and SDGs,*** Adriana Velazquez
Global	***2014: WHO medical device list for Ebola care***, Adriana Velazquez
Global	***WHO Technical Specifications for Oxygen Concentrators, 2015***, Adriana Velazquez
Global	***Quick $2 test reveals if you caught a superbug in hospital,*** Hakho Lee, BME MGH, Boston
India	***GANDHI: global affordable need driven health innovations***, Prashant Jha
India	***Hypothermia alert device: saving newborn lives***, Ratul Narain; Gini Morgan
India	***Novel Technology Policy: Integrating Service Delivery to Industry Promotion***, Jitendar Sharma
India	***Preventing apneas of prematurity***, Ratul Narain; Gini Morgan
India	***Remote monitoring for critical infants***, Ratul Narain; Gini Morgan
India	***MoH "Andhra Med Tech Zone" administering new medical devices manufacturing park***, Jitendar Sharma
India	***MoH Innovations project***, WHO 2GFMD, Jitendar Sharma, 2013
Italy	***Current and Future Trends in the HTA of Medical Devices***, Oriana Ciani et al

Focus Area	***Title,*** authors, with active links
Italy	***HTA of a Large Tablet System in Digital Pathology***, Daniele Giansanti et al
Italy	***Rapid Clinical Evaluation of Robotic Surgery***, Stefano Gidaro & Luca Radice, 2016
Macedonia, Haiti, China	***CED Role in Linking Global HT Innovation and Standards: From the Research Lab to the Bedside***, Yadin David, Fred Hosea, Tom Judd
Malaysia	***Biomechanics of Long Distance Cycling of a Transtibial Amputee***, Azman Hamid
Mexico	***Semi Active Hand Orthosis***, R. Itzel Flores-Luna, Ruben Valenzuela-Montes, David De-Jesus-Cruz, Hanna Garcia-Guerra, Alvaro Ayala Ruiz, Mariano Garcia del Gállego
Peru	***Heavy-Metals Point of Care Detection HT to improve care***, Herb Voigt, Fred Hosea
Senegal	***Oxygen generators type PSA: solution for the supply of oxygen in Senegal***, Awa Ndiaye Ep Diouf
Senegal	***Innovative Diagnostics for Infectious Diseases***, Catharina Boehme
South Africa	***Medical device innovation–Local production of medical devices in Africa: characterizing the landscape and assessing feasibility***, Mladen Poluta
Tanzania	***Maternal Child Health medical devices: potential impact of disruptive technology in rural Tanzania***, Mbuyita, Mbaruku, et al,
Uganda, India	***Cross Border Learning: Catalyzing Medical Technology Innovation with LMICs***, Alexis Steel, Molly Ward
UK	***Automating the diagnosis of Childhood Pneumonia, Elina Naydenova, Climent Casals-Pascual***, Thanasis Tsanas, Maarten De Vos
UNICEF	***Medical Devices for Maternal, Neonatal and Child Care***, Paul LaBarre
Uruguay	***Clinical Engineering driving new public hospital design & construction***, Franco Simini, 2016
WHO	***WHO HT Innovations for Low Resource Countries***, Adriana Velazquez
Africa	***Medical Devices Situation in the Africa Region***, Stanislav Kniazkov

Focus Area	***Title,*** authors, with active links
Albania	***HTM improves high technology diagnostics access***, Ledina Picari
Argentina	***HT improving Provincial Access***, 2015, German Giles
Australia & Canada	***Using Telehealth to improve Diabetes care***, E. Sloane, N. Wickramasinghe, S. Goldberg
Brazil	***Evaluation of production capacity, the healthcare coverage and the access of computerized tomography imaging in the Brazilian Public Health System***, Diana Lima et al
Brazil	***Distribution of mammographs by macroregion of Brazil***, Ana Claudia Patrocinio
Brazil	***The Role of Clinical Engineers for the Management of Healthcare Technologies in a Hospital Network***, Eduardo Jorge
China	***Survey of Prolonged Mechanical Ventilation in Intensive Care Units in Mainland China,*** Li J et al
Cuba	***A Telemedicine System to follow-up the Evolution of Chronic Diseases in the Community***, R.I. Gonzalez-Fernandez et al
Denmark	***The mobile laboratory: bringing high-quality testing, to the patient***, Susanne Andresen
Global	***Market Dynamics: Supporting Country Decision- Making on Medical Devices***, Ray Cummings
Global	***Equipment Planning, Safety and Maintenance: Planning of Medical Imaging Services in Rural Health Centers***, Cari Borrás, Mario Forjaz Secca, Yadin David, (***part2***)
Global	***Surgery: indispensable interventions are not readily available***, Walt Johnson
Global	***International Atomic Energy Agency: Roadmap to Cancer-Free World***, Rajiv R Prasad
Global	***The importance of laboratory and pathology for a good diagnosis and treatment, need for recognition and availability***, Jagdish Butany
Global	***The Rise of Telehealth***, Yadin David et al
Global	***Linear Accelerators Case Studies***, Marcos Martins
India	***Prioritisation of medical devices and diagnostics in India***, Yogita Kumar, Gupta Madhur, Ameel Mohammed
India	***Ministry of Health (MoH) Mobile Medical Units***, Jitendar Sharma
India	***MoH Free Diagnostics Service Initiative***, Jitendar Sharma
India	***MoH National Dialysis Program***, Jitendar Sharma
India	***Telemedicine Reducing Blindness in South India***, Niranjan Khambete
Kenya	***Improving Universal Health Coverage Kenya PPP example***, Gisela Abbam, Farid Fezoua

Focus Area	***Title,*** authors, with active links
Mexico	***CENETEC - National inventory of high-tech medical equipment as HTM tool for strategy planning***, Roberto Ayala
Mozambique, Tanzania, Malawi, Togo, DR Congo	***Global Healthcare Telemedicine***, Michelangelo Bartolo
Paraguay	***Innovative telediagnosis technology for universal coverage in remote locations without access to specialists***, Pedro Galvin
Romania	***Telemonitoring Systems and Technologies for Independent Life of Elderly***, S. B. Sebesi
Slovakia	***Telemedicine and mHealth System for Complex Management in T1DM and T2DM Patients: Results of 6 Months Study***, Fedor Lehocki, Tomas Bacigal
Sudan, Egypt, Lebanon, Somalia, Afghanistan and Iraq	***Strengthening Health Technologies & Medical Devices Management in EMRO***, Adham R Ismail
Syria	***Hemodialysis in Syria: a BME Approach,*** Lana Almohamad
WHO	***WHO Cancer Care Initiative 2015-2016***, Adriana Velazquez et al

Focus Area	***Title,*** authors, with active links
Benin, Burkina Faso, Burundi, Cameroon, DRC, Ethiopia, the Gambia, Ghana, Ivory Coast, Kenya, Nigeria, South Africa, Tanzania, Uganda, Zambia	***THET NGO & South Africa enhancing 15 African HTM societies***, Anna Worm & Mladen Poluta
Australia	***In-house Endoscopy support, 2016,*** Anne-Louise Smith
Bangladesh	***Clinical Engineering Approach to Improve Healthcare Technology Management for Enhancing Healthcare Delivery System in Middle Income Countries,*** A. Hossain et al
Benin	***Evaluation of medical devices in Benin,*** Charles Pascal Soroheye, Adjaratou Seidou Maliki, Marc Myszkowski
Benin	***Maintenance management of medical devices in Benin: The case of Papané Hospital,*** Charles Pascal Soroheye et al
Bhutan	***Bhutan Health Technology Management (HTM) and HTA 2015***, Tashi Penjore
Bosnia & Herzegovina	***Testing of dialysis machines in healthcare institutions in Bosnia and Herzegovina,*** Lejla Gurbeta, Berina Alic, Zijad Dzemic, Almir Badnjevic
Botswana	***Using HTM to improve care delivery***, Bonnie Tlhomelang
Brazil	***Impact of clinical engineering in primary healthcare***, Priscila Avelar, Renato Garcia, Carlos Alberto Silva
Brazil	***Logistics of medical devices for indigenous health care attending in remote sites at Brazilian amazon rain forest,*** Ryan Ferriera et al
Brazil	***GETS System on CE-HTM***, Jose Bassani
Brazil	***Medical device manuals analysis using heuristic evaluation***, J.C. Carneiro et al
Brazil	***Proposed Calibration of Apheresis Equipment***, A.S. Anderson et al
Brazil	***Maternal Fetal Simulator***, L.R. Rodrigo et al
Brazil	***Evaluation of Sphygmomanometers: comparison between manual and digital measurement***, Sousa et al
Brazil	***Hospital Maintenance Management***, A.S. Forte, J.E.Neto
Brazil	***Study involving X-Ray Tube Life spam in Computed Tomography Equipment***, Petrick Marcellus de Victorio et al
Brazil	***HTA Applied to HTM through Clinical Engineering***, Santos
Burkina Faso	***The problem of acquisition and maintenance of biomedical equipment in Burkina Faso***, Zida Ouambi Emmanuel
Chile	***Activities of Clinical Engineering in the University of Valparaiso***, Guillermo Avendano
Chile	***The Chilean Navy Hospitals 15 years of CE***, Francisco Acevedo

Focus Area	***Title,*** authors, with active links
China	***Preventive Maintenance of Fetal Monitors***, LE He-qing
China	***The Survey of 3 Departments in Guangdong Province Under New Regulations***, Yang Shaozhou
China	***Impact of national CE Certification on Health Technology***, Zhou Dan
Colombia	***CE and impact on financial management of the hospital***, Paula Berrio
Colombia	***Estimation of the optimal maintenance frequency of medical devices: A Monte Carlo simulation approach,*** Antonio Miguel Cruz et al
Colombia	***Teaching maintenance of medical devices in simulation centers: a pilot study,*** Daniel Alejandro Quiroga Torres et al
Costa Rica	***Clinical Engineering - Health Technology Management (HTM) key areas of challenge and progress in Costa Rica***, Gabriela Murillo
Costa Rica	***HTM in Costa Rica,*** G Murillo, M. Ingeana, (***part2***)
Cuba	***Cuba Health Technology Management,*** Jorge Castro Medina
Dominica	***Health Technology Management in Dominica,*** R. Williams
Ecuador	***Development of Biomedical Engineering in the Honorable Junta de Beneficencia of Guayaquil***, Freddy Matamoros
El Salvador	***Health Technology Management in El Salvador,*** Juarez S.
Ethiopia	***Managing Successful Medical Device Warranty Period Maintenance,*** Demeru Yeshitla Desta, Tegbar Yigzaw Sendeke, Sharon Kibwana, Mihereteab Teshome Tebeje
Ethiopia	***Strengthening Utility and Maintenance of Medical Devices***, Demeru Yeshitla Desta, Sharon Kibwana, Firew Ayalew, Ismael Cordero
Ghana	***CMBES HTM Donations Study,*** 2015, Bradley, Yoon, Zahedi, Adusei-poku, Bill Gentles
Global	***Medical device ownership models and maintenance contracting approaches,*** Lisa Smith, Michael Ruffo
Global	***The Missing Link: The Role of BMETs Throughout the HTM Lifecycle,*** Anna Worm, THET; Ismael Cordero, Gradian
Global	***Global HTM Update 2011,*** Binseng Wang et al
Global	***Global HTM Update 2015***, T. Judd, S. Calil, A. Hernandez, B. Gentles
Global	***IFMBE CED Development of e-Courses for HTM training 2015-2016***, Ernesto Iadanza
Global	***Orbis International Global HTM Training,*** Ismael Cordero, (***part2***)
Global	***ACCE Global HTM Seminars,*** 2013 2GFMD, Antonio Hernandez et al
Haiti	***Using HTM to improve care delivery,*** Monette Valliere, Jean Chery, (***part2***)

Focus Area	***Title,*** authors, with active links
Italy	***Launch of the new WHO Collaborating Centre for Research and Training in CE and HTM,*** Paolo Lago
Italy	***A Novel Approach to Improve the Technical Maintenance of Biomedical Equipment,*** Daniele Bibbo et al
Jamaica	***Health Technology Management in Jamaica,*** 2010, Keith Richards
Kenya	***MoH ophthalmic equipment support,*** Philip Anyango, Mary Nguri & Joseph Rugut
Kenya	***MoH Device HydroCarbon Refrigeration Training BMETs,*** J. Rugut
Kosovo	***HTM in Kosovo,*** 2010, Agron Boshnjaku S. Ramiqi S, K. Hashani, (***part2***)
Kyrgyzstan	***HTM in Kyrgyzstan,*** 2010, Kazbek Agibetov, (***part2***)
Laos	***HTM in Laos,*** 2GFMD 2013, Thanom Insal
Lebanon	***HTM Implementation at Saint George Hospital – Lebanon,*** Riad Farah
Lebanon	***Medical Devices Repair/Replacement Algorithm Model,*** Riah Farah
Mexico	***Decodifying HTM in Mexican Private Hospitals,*** Luis Fernandez
Nigeria	***Key areas of challenge and progress of CE-HTM in Nigeria,*** Bukola Esan
Paraguay	***Health Technology Management in Paraguay,*** Pedro Galvan, (***part2***)
Peru	***Fostering Clinical Engineering & HTM in Developing Countries: Alignment and Effectiveness in Peruvian Health Sector,*** Rossana Rivas
Puerto Rico	***Health Technology Management update in Puerto Rico,*** Oscar Misla, (***part2***)
Romania	***Prioritization of Medical Devices for Maintenance Decisions,*** S. Taghjpour et al
Rwanda	***Medical device technician training,*** A. Worm, Mpamije Tonkin, Mol, Kasaro
Saudi Arabia	***Creation of Health Technology Technical E-Library,*** Salah Alkhallagi
Senegal	***Maintenance of medical devices and quality management in Senegal,*** Dr. Mamadou Sow, Senegal, WHO 2GFMD
Sierra Leone	***Immediate impacts of inventory on procurement,donations,maintenance and use of medical equipment,*** Kabia, Johnson, Ministry of Health, WHO 2GFMD, 2013
South Africa	***Math Model for Reliable Maintenance of Medical Equipment,*** Baset Khalaf, 2015, (***part2***)
Sub-Sharan Africa	***The status of medical equipment in Sub-Sahara Africa,*** Anna Worm, Theogene Namahungu, Harold Chimphepo, Charles P. Soroheye

Focus Area	***Title,*** authors, with active links
Sudan	***Health Technology Management in Sudan,*** Emad Edin Mohamed Hassan, (***part2***)
Taiwan	***Medical Devices Troubleshooting,*** KP Lin
Taiwan	***The Benefit of In-Hospital Clinical Engineer Services for Medical Devices Maintenance,*** Mei-Fen Chenet al
Taiwan	***Taiwan: An IM Strategy for In-House CE Department Based on Equipment Service Life-Cycle Model,*** Chia-Hung Chien et al
Tanzania	***Health Technology Management in Tanzania,*** Y Mkwizu & R Masanja, (***part2***)
Tanzania, Switzerland	***Building management capacities for essential equipment in Tanzania,*** WHO 2GFMD, 2013, Reinhold Werlein, Swiss Tropical and Public Health Institute
The Gambia	***Medical Research Council HTM Unit,*** Anna Kah, Ebrima Nyassi
Togo	***The governance problem in medical equipment donation projects: Case of Togo,*** WHO 2GFMD, 2013, Komi Agbeko Tsolenyanu, NGO Association for Maternal, Neonatal and Child Health
Uganda	***Using HT Policy and HTM to improve MoH care delivery,*** Sitra Mulepo, Kataaha Edward
UK	***Apprenticeship model for clinical engineering workforce development,*** Abdul Basit, Malcolm Birch
USA	***Kaiser Permanente Clinical Engineering Staffing Best Practices 2015,*** Chris Ewing
Zambia	***Medical equipment maintenance personnel and training in Zambia;*** S. Mullally, T. Bbuku, G. Musonda 2012

Focus Area	***Title,*** authors, with active links
Africa	***The potential power of sub-Saharan Africa professional associations for biomedical/ clinical engineering professionals,*** Anna Worm et al
Africa - 18 countries	***The (improved) status of medical equipment in sub-Sahara Africa HTM:*** A. Worm, L. Jones, T. Namahungu, H. Chimphepo, P. Soroheye
Albania	***Regulation, standards and market surveillance of medical devices and systems in Albania,*** Ledina Picari
Albania	***MoH Health Technology (HT) Unit device legislation,*** Ledina Picari, 2016
Argentina	***Present and Future of Clinical Engineering in Argentina,*** German Giles, Marcelo Lencina
Asia Pacific	***Status of Biomedical Engineering education in the Asia Pacific,*** KP Lin et al
Bangladesh	***Biomedical and clinical engineering development,*** Md Ashrafuzzaman et al
Bangladesh	***Necessity of Clinical Engineering to Regulate the Medical Devices in Middle Income Countries,*** Anwar Hossain
Bosnia and Herzegovina	***Medical devices in legal metrology framework,*** Lejla Gurbeta, Almir Badnjevi□
Brazil	***Analysis of the Curriculum of Postgraduate Courses in Clinical Engineering in Brazil,*** Anderson A. Ramos et al
Brazil	***Application of multiparameter method as an assistance to the evaluation of the need for replacement of medical equipment,*** M.A. Marciano, E.K. Souza
Brazil	***Assistant Multi-Parametric Method to the Selection in the Process of Incorporation of Hospital Equipment,*** M.A. Marciano
Brazil	***International Standards for Medical Device and The U.S. Food and Drug Administration,*** R.G. Fernandes
Brazil	***Computed Tomography scanners productivity and examinations times,*** R.P. Santos et al
Brazil	***Defibrillators in locations with a high concentration/movement of people in Bauru/Brazil,*** A.S. de Melo et al
Brazil	***FDA Internationalization Under the Aspect of Medical Device Standards,*** R.G. Fernandes, S.J. Calil
Brazil	***Medical equipment acquisition methodology in public procurement process,*** J. Martins et al
Brazil	***Cost Estimate Methodology in procurement processes of Medical Equipment,*** V. O. Fagundes, R. Zaniboni, R. Garcia
Brazil	***Study of Medical Device Purchasing Cycles through Temporal Series Analysis,*** J. C. Guerrero, J. H. García, A. M. Hernández
Brazil	***RENEM – MoH HT list driving national investment***, Murilo Conto
Cameroon	***Development of the National Healthcare Technology Policy for Cameroon***, J. Riha
Cameroon	***Improvement in the use of medical devices and capitalization of investments in the HT sector in Cameroon,*** 2010, Vincent Ngaleu-Toko
Canada	***Clinical Engineering/HTM in Canada,*** Mario Ramirez

Focus Area	***Title,*** authors, with active links
Chile	***University of Valpariso Health Technology leadership,*** Cristian Diaz
China	***Clinical Engineering in China,*** Bao Jiali, Zhu Chaoyang
China	***HTM as key health planning discipline,*** Guanxin Gao
Colombia	***Integrated model of universities to promote clinical engineering,*** Nelson Escobar, Javier Camacho, Javier García, Juan Barreneche, Beatriz Galeano, Mario Castañeda
Colombia	***Interuniversity model of cooperation for the development of Clinical Engineering in Colombia,*** Beatrix Galeano
Colombia	***Methodology Design for Biomedical Technology Replacement Planning,*** D. M. Torres-Velez
Colombia	***Regional Nodes of Colombian Clinical Engineers,*** Andrea Garcia
Colombia	***Identifying the needs in the integration of disciplines in the hospital infrastructure management in Colombia,*** M. Madroñal Ortiz, B. Galeano Upegui, N. Escobar Mora, L. Cruz Parra, I. Rios Cuartas
Colombia	***HT Regulation, Policy, Management,*** 2015, Andrea García Ibarra, Rojas Morales, (***part2***)
Colombia	***Clinical Engineering for non-engineers: acquisition of medical equipment,*** 2011, Tatiana Molina
Cuba	***Trading barriers in the medical devices industry. Are these barriers hindering the development of this sector in Cuba?*** Y. Chaveco Salabarria, J. C. Rubio Romero, R. M. Guerra Bretaña
Czech Republic	***Hospital Based HTA - Implementation for the Czech Republic***, Ivana Kubátová, Veronika Matlo□ová
Ethiopia	***Using HT Policy and HTM to improve care delivery***, Mulugeta Mideksa, 2015
EU (28 Member States), EFTA/EEA: Norway, Liechtenstein, Iceland; Turkey; Switzerland	***The Regulation of medical devices in the European Union,*** Carlo Pettinelli
Ghana	***Clinical Engineering in Ghana,*** Nicholas Adjabu
Ghana, Canada	***CMBES Donations Project,*** 2015, Nicolas Adjabu, John Zienna, Bill Gentles
Global	***IFMBE/CED and Global CE-HTM Evidence Based Results,*** Yadin David, Ernesto Iadanza
Global	***IFMBE/CED Role in Global BME/CE recognition***, James Goh, Ernesto Iadanza
Global	***Global CE-HTM Success Stories,*** Yadin David, Tom Judd
Global	***Technical characterization of appropriate medical equipment,*** Maurice Page, Matthieu Gani, Mélanie Amrouche, Robin Walz, Blanc-Gonnet & Barbara Comte
Global	***MSF medical equipment framework,*** Gabriela Jimenez Moyao, Oscar Rodriguez, Tom Lauwaert, Jean Claude Tewa, Belgium; Benoit Pierre Ligot, Paul Damien Chateau, MSF, France; Hugues Gaertner, MSF, Spain; Malcom Townsend, MSF, Switzerland; Lizette Van De Kamp, Sean King, MSF, Netherlands

Focus Area	***Title,*** authors, with active links
Global	***Assessment of medical devices in low-income settings,*** L. Pecchia, N. Pallikarakis
Global	***The AHWP Playbook for Implementation of a Health Technology Regulatory Framework, An Overview,*** Ms. Joanna Koh et al
Global	***Global Atlas of Medical Devices,*** Adriana Velazquez
Global	***Medical Devices for universal health coverage and sustainable development,*** Marie-Paule Kieny
Global	***The Book, Human Resources for Medical Devices, the Role of the Biomedical Engineer,*** Adriana Velazquez
Global	***National medical equipment policies and planning for universal health coverage,*** Roberto Ayala
Global	***Improving medical equipment donations: contribution of NGO Humatem,*** Cathy Blanc-Gonnet
Global	***Health Technology Management Initiatives,*** Ernesto Iadanza
Global	***Health Technology Assessment of innovative medical devices***, Iñaki Gutiérrez-Ibarluzea
Global	***IFMBE/Clinical Engineering Division projects for the advancement of the profession of clinical engineering,*** Ernesto Iadanza
Global	***The importance of Technical Specifications,*** Adriana Velazquez
Global	***The Role of HTM to the Universal Health Coverage,*** P. Galvan et al
Global	***2009 WHO database of biomedical/clinical engineering teaching units and associations worldwide,*** Saide Calil
Global	***Global HT Disaster Preparedness,*** Yadin David, Fred Hosea, (***part2***)
Global	***Latin American & Caribbean Health Technology Training,*** 2013, Antonio Hernandez
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