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Editor's Corner

Would you like to know the health state of your brain? Have you ever assessed your intelligence quotient (IQ)? Soon, in addition to measuring your IQ we will also be able to determine your brain's health with quantification just like those used in the assignment of IQ levels. This depends to a large extent on how many resources, including clinical engineers, will focus on the research about the intricacies of the human brain.

In the book "The Tell-Tale Brain," a *New York Times* bestseller, Ramachandran, director of the Center for Brain and Cognition at the University of California in San Diego investigates the working of the mind through malfunctions of the brain. He states that in the 50s we were able to decipher the human genetic code, but by comparison, the science of the mind languishes and that, for most of the 20th-century neuroscience, was still young upstart. "As heady as our progress has been, …we have only discovered a tiny fraction of what there is to know about the human brain."

To help initiate, last October, the celebration of the 2019 Global Clinical Engineering Day, I invited distinguished faculty members to share with me in the program hosted in China. Recognized experts such as Tobey Clark from the University of Vermont, Ilir Kullolli from Stanford/Children's Hospital and currently ACCE President, Dr. Kallirroi Stavrianou from Warwick University in the UK, and Dr. Howard Derman, a neurologist chief of the Concussion Center at the Methodist Hospital in Houston, Texas. Each member of the faculty shared their unique expertise, and all were received with roaring success https://www.youtube.com/watch?time_continue=16&v=yQ1DuSlSfvQ&feature=emb_logo. It was a perfect set-up for the initiation of the global celebration recognizing all that clinical engineers do every day around the world to better patient care outcomes!

Specifically, I wanted to include physician/neurologist to our Global Clinical Engineering program because not too many clinical engineers know of the specific neurology based challenges healthcare practitioners face in the management of brain conditions. Dr. Derman did an excellent job of connecting a wide spectrum of clinical needs with expectation that future technological tools will meet.

Over years of working with neurology based researchers, I personally observed how much they struggled to overcome the inability to quantify changes in the health state of the brain when they were faced with the challenge of managing or diagnosing brain injury, trauma, or diseases. In several studies, where I joined as a clinical engineer with a team that included pediatric neurologists and other scientists, we all experienced firsthand the difficulty of developing and applying experimental technological tools to diagnose and quantify brain functions. Not only such instrumentation was rare but more often the interpretation of the results produced by these tools set a new frontier for wide interpretation of new brain mapping data. These studies included instruments such as near-infrared spectroscopy to measure cerebral blood flow ("Correlation of Near Infrared Spectroscopy Cerebral Blood Flow Estimations and Microsphere Quantitations in Newborn Piglets" https://www.karger.com/Article/Abstract/14056), and scalp temperature sensors that measured and correlated with predicted brain decay ("Rectal-Scalp Temperature Difference Predicts Brain Death in Children, Pediatric Neurology April 1999; 20(4);267–9) https://www.academia.edu/6751649/Rectal-scalp_temperature_difference_predicts_brain_death_in_children, and cortical electrodes in "Computer-Controlled Electrical Stimulation for Quantitative Mapping of Human Cortical Function," https://www.ncbi.nlm.nih.gov/pubmed/19061348.

The pharmaceutical field is in a similar situation. The cover story in *The Scientist*, December 2019, "Markers of Alzheimer's," Michelle Mielke, a neurologist at the Mayo Clinic in Rochester, Minnesota, who studies cognitive decline states, "At this point, I do not think we have the best idea in term of what biomarker is exactly going to be used for what". Essentially suggesting that pharmaceutical industry and the technological solutions are at the same situation.

However, Dr. Derman's presentation directed at clinical engineers described the physiology of injured brain following with observed symptoms from such injuries suffered in combat, motorbike accident, or during contact sport. His message was that engineers need to focus on solving how to equip healthcare providers with tools that help form a quantified diagnosis so that they can know how to better manage the patient condition/progress. As reported in a study by geriatrician Sharon Inouye at Hebrew SeniorLife and Harvard Medical School "20–30% of patients over the age of 70 who have a major surgery will experience delirium that is associated with long-term cognitive decline and increased risk for developing Alzheimer's disease." Again, still a non-quantified condition. (*Wall Street Journal*, December 10, 2019, page A12).

Improving the arrival at the correct diagnosis is a key aspect of good health care. It provides an explanation of a patient's health problem and informs proper subsequent health care decisions, states the Institute of Medicine's report, September 2015, on "*Improving Diagnosis in Health Care.*" One way to achieve that is through closer collaboration between clinical engineers, physicians and researchers to guide and enable the focusing of technological innovation on addressing challenges not only in neurology but in every medical/surgical and rehabilitation discipline.

It is important to insert scientific exchanges such as Dr. Derman's presentation within clinical engineering meetings and this *Journal* will continue to facilitate that as reflected by the membership of the *Global Clinical Engineering Journal* Editorial Board. Having neurologist, orthopedic surgeon and anesthesiologist reviewing submissions together with clinical engineers. What do you think can increase clinical engineers' participation in finding and evaluating tools to quantify the health status of our brains?

Together we can do it better and I am-looking forward to your feedback!

Dr. Yadin David

CONTENTS

WHO Update Column

By Adriana Velazquez Berumen

2020 is now here, I wish you all a healthy, prosperous and joyful New Year! I am very interested to continue the recurring WHO updates and communications with you in this volume of the Global Clinical Engineering Journal. The last half of 2019 proved to be very productive for the medical device team, particularly with respect to health technology management issues.

In my last update, I talked about the national reference lists of medical devices, which are used in countries as a reference to procurement, reimbursement, which includes two components:

First the WHO Essential in Vitro Diagnostic List (EDL), describes the laboratory and point of care tests and related technologies that need to be available to screen, diagnose or monitor priority diseases or health conditions. The Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) is meeting 23rd to 27th of March to review the submissions to update the WHO Model List of Essential In Vitro Diagnostics List (EDL, as well as related policies and strategies on laboratories. Updates on this work can be found here: https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/. On the 23rd of march the session will be open in webex format for those that are interested.

Secondly, with the increase of non-communicable diseases, WHO has been developing lists for priority medical devices for cardiovascular, stroke and diabetes. This work is ongoing and hope to list all that are needed from diagnostics, to treatment , rehabilitation and palliative care for the 3 levels of care, from prehospital to specialized care. This work is expected to be finalized by March 2020.

Last October, the global Clinical Engineering community celebrated Global CE Day on October 21st. With China hosting the in-person event, the celebration of clinical engineers' impact on patient outcomes hit a new level. A link to the Global CE Day video commemorating this event and the importance of the work of clinical engineers in 2019 can be found here: https://www.youtube.com/watch?time_continue=16&v=yQ1DuSlSfvQ&feature=emb_logo. Co-aligned with the Global CE Day, was the 3rd International Clinical Engineering Healthcare Technology Management Congress (ICEHTMC) held in Rome, Italy. With over 1,000 attendees from all six WHO regions, this event showcased what clinical engineers and healthcare technology managers are doing globally to support patient outcomes and typified the global exchange of ideas for the betterment of global standards and outcomes. I was very honored to be invited to share the work that is being done in WHO and to look forward to address countries needs on medical devices including their selection, management and safe use https://ced.ifmbe.org/blog/icehtmc3-presentations.html.

At the end of 2019, WHO published the Decommissioning Medical Devices book as a continuation of the WHO Medical Device Technical Series. Decommissioning is an important part of healthcare technology management in lifecycle management and safe removal and disposal is important to health

for all. The publication can be found here: https://apps.who.int/iris/bitstream/handle/10665/330095/9789241517041-eng.pdf .

While 2019 was a productive year, 2020 already appears to be shaping up to be very fruitful as well. Throughout 2019, you heard me discuss a standard nomenclature and its importance for stronger harmonizing reasons on many occasions. In May of 2019, the 145th WHO Executive Board included a thorough discussion of the standard nomenclature project which can be found here: https://www.who.int/about/governance/executive-board/executive-board-145 (statements from member states is covered from 1:03 to 2:04 in video). In 2020, our work continues to focus on the standard WHO international nomenclature system and its implementation. The next steps include a concept note being published to the executive board as an update and response to the Member State comments in the coming months. Your input into the survey https://extranet.who.int/dataform/614614?newtest=Y will be most welcome. The deadline has been moved to 10th February.

On the horizon in 2020 is also the publication of the WHO technical specifications for automated non-invasive blood pressure measuring devices, Technical specifications for cervical cancer and for the procurement of the essential in vitro technologies to allow the EDL tests.

Finally, we are working on response to Coronavirus, continue with support for Ebola and many other requests from Member States. Please find technical information for Coronavirus here https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance.

As clinical engineers, you play an important role in supporting medical devices and I look forward to the continued work in 2020.

Respectfully,

Adriana

An Addendum

In October of 2019, I had the privilege of serving as a short-term technical advisor at the WHO headquarters in Geneva, Switzerland. While I had known previously about the WHO initiatives in the Clinical Engineering arena, particularly those interfacing with the IFMBE-CED group, I was awestruck at the shear amount of initiatives and breadth of their impact on medical devices globally that are ongoing.

In the halls of WHO headquarters, there are global experts on every healthcare specialty you can imagine. Just as in a hospital, clinical engineers work collaboratively with other groups to advance healthcare priorities globally for the betterment of health for all. In a healthcare organization, a clinical engineer works daily to understand the intent and overarching goals of the organization in support of patient access, outcomes, safety and experience. Additionally, for decades, Clinical Engineering has been talking about how the profession can cohesively bring our individual efforts in our spheres of influence to strengthen the Clinical Engineering profession, regulations and standards globally. Daily, Adriana Velazquez, the Senior Advisor for Medical Devices at the WHO, works tirelessly to bring medical devices to the forefront of global health policy and initiatives. In her role, she interfaces with professionals globally on medical device regulations, health technology assessment and health technology management. In this way, you can see that building capacity and clinical engineers in this space are essential to proper health technology management. As the professionals responsible for the longest portion of a medical device's life – commissioning, sustainment, maintenance and decommissioning- the clinical engineering community is essential to ensure safe and clinically appropriate medical devices are being used across the world to prevent and treat acute and chronic illnesses. It is further important for clinical engineers to understand not only the emerging trends in health technology management, but those in medical device regulations and health technology assessment as well.

Expanding this to the global community, one of the key ways a Clinical Engineer can understand the WHO's global health objectives is to familiarize themselves with the WHO Sustainable Development Goals (SDGs), particularly SDG3 "Good Health and Well-Being," and the Triple Billion targets of "1 billion people enjoying better health and well-being, 1 billion people benefiting from universal health coverage and 1 billion more people better protected from health emergencies." In this way, clinical engineers can leverage the strategic framework outlined by the WHO to align priorities and efforts globally. IFMBE and its Clinical Engineering Division work tirelessly to align their work with the overarching global priorities set forth by the WHO.

As we kickoff 2020, I can't think of a more exciting time for the global ethos of Clinical Engineering. On the heels of the 3rd ICEHTMC in Rome, Italy, over 1,000 clinical engineering professionals from 6 continents got together to share information, vision and passion for building capacity in clinical engineering to improve patient safety, support access and spur innovation for medical devices and health technology management globally; clinical engineering professionals are well-positioned to use 2020 as a springboard that will bring a new depth of international standards, information sharing

and understanding of our profession to the world. Additionally, we are being led by courageous and passionate leaders in Adriana Velazquez at the WHO and Tom Judd the IFMBE CED Chair who have an in-depth understanding of the healthcare landscape and how clinical engineering plays a role in bringing healthcare to all.

So what can you do next to stay tapped into the WHO and IFMBE efforts? Check out the IFMBE CED "News and Blog" at https://ced.ifmbe.org/blog.html where Adriana posts the most up-to-date and agile information about WHO initiatives, and happenings as it relates to medical devices and health technology management. Also, ensure you visit the main WHO medical devices website at https://www.who.int/medical_devices/en/. Within this site, you will find information and resources on regulations, health technology assessment (HTA) and health technology management (HTM). Additionally, IFMBE/CED is working on several exciting projects and initiatives that will be bringing even more resources to the global clinical engineering landscape. Pertinent information on these can be found on the IFMBE CED site at https://ced.ifmbe.org/projects.html.

Cheers to a 2020 filled with advances in Clinical Engineering and health and well-being globally.

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Is There Sufficient Evidence to Support the Use of Temporal Artery and Non-contact Infrared Thermometers in Clinical Practice? A Literature Review

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ABSTRACT

Background and Objective

Accurate measurement of body temperature is a key part of patient observations and can influence important decisions regarding tests, diagnosis, and treatment. For routine measurements in hospitals, non-invasive thermometers such as tympanic infrared ear thermometers are very widely used even though non-invasive thermometers are not as accurate as core thermometry. However, there are known issues regarding the accuracy of these thermometers due to user errors including dirty probe covers and not straightening the ear canal. We were therefore keen to understand if there was evidence to support the use of alternative non-tympanic, non-invasive thermometer that could be easily and widely deployed across Nottingham University Hospitals NHS Trust.

Material and Methods

A search of the published literature via the NICE HDAS was undertaken to identify the evidence on the use of temporal artery (TAT) or non-contact infrared forehead (NCIT) thermometers compared to a core body temperature thermometer in a clinical setting. The relevant literature was identified, appraised and summarized.

Results

Fifteen papers described the use of TAT but only 5 reported results that were considered within clinically acceptable limits of which 2 included febrile patients. Nine of the 10 studies where TAT was considered not to be within acceptable limits included febrile patients. For the NCIT, 3 studies were identified but only 1 reported results within acceptable limits and this did not include febrile patients.

Conclusion

A review of the literature for both TAT and NCIT has indicated that in their current form neither is suitable as a replacement for oral or tympanic thermometers in clinical practice. In particular, the evidence suggests that they are not acceptable methods for detecting temperatures outside the normothermic range and do not detect fever accurately. Known user errors with both TAT and tympanic infrared ear thermometers (IRET) could be detracting from the usefulness of the technology.

Keywords – *Thermometer, infrared, temporal artery, non-contact, forehead, tympanic, oral, core, virus.*

INTRODUCTION

Body temperature measurement is a key part of routine patient observations in all healthcare settings including secondary care and it is one of the 6 components of the national early warning score (NEWS) system developed by the Royal College of Physicians (https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news-2) to standardize the assessment and response to acute illness. Temperature monitoring can influence important decisions regarding tests, diagnosis, and treatment. It is therefore crucial that thermometers are accurate, reliable and easy to use since inaccurate results may lead to a failure in identifying patient deterioration and compromise patient safety. The most accurate measure of body temperature comes from invasive "core" thermometry options such as pulmonary artery (considered gold standard[1]) but also bladder, nasopharynx or esophageal thermistors.[2] However, these methods are invasive, potentially high risk and restricted to patients undergoing specific procedures and not suitable for everyday use in all care settings. There is a range of non-invasive thermometers for obtaining temperatures from peripheral body sites including the tympanic membrane, the mouth or the axilla.

Electronic contact non-disposable thermometers that incorporate probes specific for use in either the oral cavity (sublingual), axilla or rectum, are commonly used in many different healthcare settings, particularly the oral cavity. Infrared sensing thermometers such as IRET or tympanic, which measure the temperature at the tympanic membrane, are also very commonly used across all healthcare settings as well as in a domestic setting. Other infrared thermometers include the non-contact infrared forehead thermometers (NCIT) and the temporal artery thermometers (TAT). There are several chemical thermometry options such as chemical dots or phase change strips though these are generally not as widely used as the electronic thermometry options.

While peripheral body sites are convenient for rapid and easy temperature monitoring, not all thermometers have clinically acceptable accuracy and published studies comparing them to core or oral electronic temperature measurements show substantial variability in the methodologies, outcomes and patient populations. In particular, the use of peripheral thermometers to detect temperatures outside of the normal range (36–38°C) is crucial to identify patients who are either hyper- or hypothermic and to make the necessary treatment decisions. The wide range of often conflicting data has made drawing firm conclusions from these studies difficult but there have been various systematic reviews and meta-analysis[2–5] which overall conclude that not all peripheral thermometry options are clinically acceptable. Of all the thermometry options, non-disposable electronic oral thermometers are considered by many to be the most accurate reflection of core body temperature[3] and can be considered as the "gold standard" of non-invasive temperature monitoring.[6]

The Royal Marsden Manual of Clinical Nursing Procedures (ninth edition, chapter 11: Observations[7]) includes recommendations on the use of different thermometry devices to determine patient temperature including the use of tympanic thermometers as an acceptable method to measure body temperature. Within the NHS, tympanic thermometers are widely used non-invasive thermometry devices. However, there are issues associated with tympanic thermometers which have been previously described[8] and by the Marsden Guidelines[7], such as dirty probe covers and user error (not straightening the ear canal) as factors that could contribute to inaccurate readings being recorded by these devices. In addition, the MHRA also published a Medical Device Alert in May 2003[9] that highlighted these 2 issues as contributing to low-temperature readings.

Measuring body temperature at peripheral sites, therefore, represents a compromise between patient acceptance, ease, and speed of recording over temperature accuracy. The Clinical Engineering department at Nottingham University Hospitals NHS Trust (NUH) are responsible for the medical equipment that is used across the Trust including tympanic ear thermometers for patient monitoring. Many of the devices are returned to the department for cleaning and maintenance due to the issues described above. We were therefore keen to understand if there was evidence to support the use of alternative non-tympanic, non-invasive thermometer that could be easily and widely deployed across the Trust to measure body temperature in patients. There have been 2 horizon scanning/technical scoping articles published covering

infrared thermometer use in both children (NCIT[10]) and adults (TAT[11]). The overall conclusions of these 2 reports were that the evidence is somewhat equivocal but that NCIT could be useful in clinical practice but more research is needed. The 2 types of thermometer considered here were the TAT and the NCIT.

MATERIALS AND METHOD

Literature Search Strategy

All searches were performed using the NICE HDAS (Healthcare Databases Advanced Search) and included Pubmed (including Cochrane database), Medline, Embase and Cinahl. Searches were restricted to the English language and in the last 10 years (2008 onwards).

Search terms were as follows: Thermometer; Forehead; Non-contact; Temporal artery; Thermometer AND non-contact; Thermometer AND temporal artery; Non-contact infrared thermometer.

The output was downloaded to Excel and the output reviewed with references being selected according to the inclusion/exclusion criteria and availability (see Table 1).

TABLE 1. Inclusion/Exclusion Criteria for Infrared Non-contact Thermometer Search

Inclusion	Exclusion
Non-contact infrared forehead thermometer (NCIT)	Measurement of temperature in other body locations e.g., skin, corneal, umbilicus
Temporal artery thermometer (TAT)	No comparison to other thermometers
Clinical or professional use in humans	Non-clinical studies i.e., animals or scientific studies, exercise studies
Any age group	Large population scanning studies e.g., traveller studies
Comparison to core or oral thermometers	Use of mercury-in-glass thermometers
Original research published since 2008	

DATA REVIEW

Each paper that was considered to be in scope according to the criteria in Table 1 was reviewed and summarized in terms of populations, setting, devices used, outcomes and detection of hypo/hyperthermia (febrile) patients. The conclusion of the authors regarding whether the device was clinically acceptable or not was also recorded where it was explicitly stated.

FUNDING

No funding was sought for this study.

RESULTS

Literature Search

For the literature search and review, no age groups apart from neonates were excluded to review the widest range of literature. The literature search identified 161 references of which only 16 were considered to be in scope. The 16 original clinical research papers were very varied in their populations, interventions, comparator (or standard reference thermometer), study design, primary outcomes, how the data was analyzed and how the results were reported. However, all papers compared the test devices to a standard reference method (which was presumed to be the most accurate) and most (though not all) concluded whether the test devices returned results within defined clinically acceptable limits. Most papers discussed the limitation of the study which included whether febrile patients were included, whether the study included any device-specific training and whether user technique was considered. Reference methods included invasive core measurements such as pulmonary artery, esophageal and bladder thermometers as well as non-invasive thermometers such as oral or rectal electronic thermometers. As anticipated, no test devices were found to be superior to the standard reference device. Some studies included a range of devices, not just infrared non-contact devices and these were included in the analysis for completeness. The key question we asked of the papers was whether the evidence supported the use of infrared non-contact thermometers in the population being studied and this is summarized in Table 2.

TABLE 2. Literature Review of Infrared Non-contact Thermometry

Authors	Population	Febrile Patients	Thermometer type and Devices Used in Study	Conclusions
Allegaert [12]	Pediatric, n=294	Y	**Rectal - Filac 3000, Covidien** Tympanic - Genius 2 TAT - Exergen NCIT - Thermoflash	YES - TAT agreed with rectal but still not optimal
Barringer [13]	Adult patients undergoing elective surgery, n=86	N	**Oral - WelchAlleyn SureTempPlus Model 690** Axilla - WelchAlleyn SureTempPlus Model 690 TAT - Exergen TAT5000	YES - TAT provided temperature readings closer in agreement with oral readings
Bodkin[14]	Adult patients, n=100	Y	**Oral - Dinamap ProCare 400, oral electronic non-disposable** TAT - Exergen TAT5000	NO - TAT gave significantly different readings to oral electronic thermometer
Brosinski [15]	Pediatric <3yrs, n=126 geriatric >65 yrs, n=125 unable to use oral thermometer	Y	TAT - Exergen TAT5000 **Rectal - WelchAlleyn SureTempPlus**	NO - TAT device not accurate enough compared to rectal to be used in the ED
Calonder [16]	Patients undergoing colorectal or gynecology surgery, n=23	N	**Esophageal - ES400-18 Level 1 Acoustascope Esophageal Stethoscope** Oral - WelchAlleyn SureTempPlus Model 678 TAT - Exergen TAT5000	YES - TAT were accurate for temperature assessment but tended to over-estimate temperature compared to esophageal
Counts [17]	Acutely ill patients aged > 18 years old, n=48	Y	**Oral - WelchAlleyn SureTempPlus Model 690** Oral - Disposable digital oral electronic thermometer: Medichoice (Mesure Technology Co, TAT - Exergen TAT5000	NO - TAT was judged to exceed clinically acceptable limits
Forrest [18]	Febrile and afebrile pediatric patients, 36 months and under, n=85	Y	**Rectal - WelchAlleyn SureTempPlus Model 690** Axilla - WelchAlleyn SureTempPlus Model 690 TAT - Exergen TAT5000	NO - TAT cannot be recommended to detect fever in pediatric populations
Gates [19]	Adults, multiple myeloma, inpatient unit bone marrow transplantation.	Y	**Oral - WelchAlleyn SureTempPlus Model 690** Tympanic - Genius 2 TAT - Exergen TAT5000	NO – TAT over-estimates temperature
Hamilton [20]	Adult febrile (n=11) and afebrile (n=8) Pediatric febrile (n=53) and afebrile (n=99)	Y	**Oral - WelchAlleyn SureTempPlus Model 692** Tympanic - Braun Thermoscan 4520 NCIT - Visiomed SAS Thermoflash LX-26 Forehead - Beurer FT 60 infrared contact forehead thermometer TAT - Exergen TAT-2000C Forehead - Chicco Thermo Touch Plus contact forehead thermometer	NO - TAT or NCIT (or other forehead thermometers) not considered acceptable

Authors	Population	Febrile Patients	Thermometer type and Devices Used in Study	Conclusions
Hamilton [21]	Febrile (n=94) and afebrile (n=111) children	Y	**Oral - WelchAlleyn SureTempPlus** Tympanic - ThermoScan® PRO 4000 prewarmed tip ear thermometer TAT - Exergen TAT5000	NO - TAT not acceptable. Compared to reference, TAT gave statistically significantly different readings
Langham [22]	Patients undergoing laparoscopic surgery. Aged 18-80 yrs, n=50	N	**Bladder - Foley catheter (Mon-a-therm Foley-Temp)** Esophageal – esophageal stethoscope with thermistor (Mon-atherm EST) TAT- Exergen TAT-5000 Tympanic - FirstTemp Genius 3000A Skin-surface thermocouple (Monatherm 6130) Skin - Liquid-crystal display strip (Crystaline Moving Line) Oral and Axilla - Electronic thermometer (IVAC TempPlus II 2080A) Deep thermometer (CoreTemp CTM-205 with a PD-51 probe)	NO – TAT only had reasonable correlation to core. Electronic oral thermometry was the most accurate and reliable device compared to the reference
Lunney [23]	Hemodialysis patients	Y	**Thermometer in Fresenius 5008 hemodialysis machine,** TAT - Exergen TAT5000	NO - TAT method exceeds the clinically acceptable reference method
Marable [24]	Adult male patients, critical care unit, n=69	Y	**Oral - WelchAlleyn SureTempPlus Model 692** Axilla - WelchAlleyn SureTempPlus Model 692 TAT - Exergen TAT5000, forehead and ear TAT - Exergen TAT5000, forehead only TAT - Exergen TAT5000, ear only	NO – The results do not favour temporal artery scanning in adult critical care patients
Opersteny [25]	Pediatric patients aged 0–17 years, inpatient surgical units, n=298	Y	**Oral - WelchAlleyn SureTempPlus Model 692** Axilla - WelchAlleyn SureTempPlus Model 692 TAT - Exergen TAT5000	YES - TAT is an acceptable temperature measure that could substitute oral or axillary thermometers
Sollai [26]	Healthy term (n=119) and preterm newborns (n=70) nursed in incubators	N	**Axilla – Sanitas digital thermometer** Tympanic - Thermoscan Pro 4000 NCIT - Thermofocus 800	YES - NCIT is a promising, quick non-invasive and accurate method to measure temperature in newborn and preterm babies

Bold indicates Study reference devices.

The results from all 16 papers were collated and summarized by device including which thermometer was used as a reference standard, whether the TAT or NCIT were considered as the next best compared to the standard (a frequently reported outcome) and whether it was considered to be within clinically accepted limits (which was considered to be +/- 0.5°C [1°F]) unless otherwise stated, though it was not always explicitly stated.

Of the 15 papers that included the TAT, only 5 of these studies[12,13,16,25,27] reported results that were considered to be within clinically acceptable limits or were not statistically significantly different from the reference device and would support the use of TAT in clinical practice. Of these 5 studies, only 2 reported that the TAT could accurately detect fever.[12,25] Of the remaining 3 papers, Stelfox et al.[27] included febrile patients but reported that the TAT was only acceptable for patients within the normal range (36–38°C) as there was less agreement for temperatures below 36°C and temperatures greater than or equal to 38°C. The other 2 papers[13,16] concluded that TAT was acceptable but they did not include febrile patients in their study.

In the 10 studies where TAT was judged to be not acceptable, 9 of the studies included patients with fever indicating that TAT did not perform accurately to identify fever in a wide range of patient populations.

There were only 3 studies that compared NCIT to a reference thermometry measurement. The study by Sollai[26] using the ThermoFocus device reported results that were considered acceptable compared to the reference standard. However, the reference standard was digital axillary in neonates and the study did not include febrile babies. Both studies [13,20] where NCIT devices were not considered acceptable included febrile patients indicating that the NCIT is not acceptable for detecting temperatures outside the normothermic range.

DISCUSSION

A search and review of the published literature was undertaken to determine if there is sufficient evidence to support the use of non-tympanic non-invasive thermometers in a hospital setting (Table 3). Two types of thermometer were considered: TATs and non-contact infrared forehead thermometers. The literature reviewed focused on the studies comparing TAT and NCIT with either invasive core thermometry or standard oral electronic thermometry.

TABLE 3. Literature Review Summary by Device

Thermometer type: Device	Manufacturer	No . of studies	Used as reference standard	Next best to ref device	Outside accepted limits
Oral: SureTempPlus	WelchAlleyn	8	7	1	
Axilla: SureTempPlus	WelchAlleyn	4	1	2	1
Rectal: SureTempPlus	WelchAlleyn	3	2		
Esophageal: Stethoscope with temperature sensor	Mon-a-therm				
Smiths Medical	2	2			
Bladder: Foley catheter	Mon-a-therm				
Smiths Medical	2	2			
Axilla: Sanitas Dx	Sanitas	1	1		
Oral: Dinamap ProCare 400	Dinamap	1	1		
Rectal: Filac 3000	Covidien	1	1		
Dialysis machine, 5008	Fresenius	1	1		
TAT: TAT5000/2000	Exergen	15		5	10
Tympanic:Genius 2	Covidien	3		1	2
Tympanic: Thermoscan PWT	Braun	2		2	

Despite a decent sized body of evidence, including clinical studies for the TAT, the results do not support their use in a clinical setting with many studies reporting that they were inaccurate outside of the normal body temperature range. This conclusion is in agreement with meta-analyses conducted by Geijer[28] and Niven.[2] The evidence for the NCIT was more limited with very few papers meeting the inclusion criteria and also did not support their use in a clinical setting for the same reasons.

One of the key issues was the relatively small number of papers meeting the inclusion/exclusion criteria used in our study which then described a wide range of settings, populations, devices, comparator (standard reference) devices, outcomes including detection of fever and how the results were analyzed and reported. This wide variation in reporting and outcomes was also identified and discussed as a drawback in the meta-analysis.[2–5] There was some variability in standard reference methods in the papers reviewed and none of the studies used an intravascular measure of temperature (gold standard) although one study[23] did use the thermometer incorporated in the dialysis machine. Typical invasive thermometry options included in these studies were either bladder or esophageal thermometers. However, the most common reference method was an electronic non-disposable oral thermometer such as the WelchAlleyn SureTempPlus. The outcomes, analysis, and reporting also differed between the studies and varied from reporting the mean differences to calculated limits of acceptability. Where febrile patients were included, the reporting varied from false negative or positive rates to misclassification percentages. Due to this variability, we chose to record whether the authors would recommend either the TAT or the NCIT device being studied for use in clinical practice.

Overall, from the 15 papers the described the use of TAT devices, the device was in general considered to be outside the clinically acceptable limits. This is also highlighted and discussed in the recently published meta-analysis and reviews published.[2,4,5] The majority of studies that found TAT to be acceptable did not include patients outside the normal range and it was shown that there was less agreement for temperatures below 36°C and temperatures greater than or equal to 38°C. These studies indicate that TAT is acceptable for normothermic patients only as has already been highlighted by the meta-analyses. However, several studies found TAT devices to be more acceptable to patients, especially children, and more likely to record a reading at the first attempt.[13,25]

There were fewer papers involving the NCIT and these devices were specifically excluded from the meta-analysis of Niven.[2] Similar to the TAT, these thermometers performed reasonably well in normothermic ranges but not outside this range and the study where the results were within acceptable limits did not contain any febrile patients. A study by Fletcher[29] looked at 9 NCITs (all unnamed, 3 groups according to specification) which were calibrated using 2 NPL standard blackbody sources with emissivities >0.999. NCITs from 2 of the groups were shown to give large measurement errors with readings falling far outside both the manufacturer's stated uncertainties. A third group of NCIT performed well, with all the results falling within the stated uncertainties. Overall, more evidence needs to be gathered as to the clinical acceptability of the NCIT devices in all settings but there is potential for NCITs to provide a rapid, hygienic and non-invasive means of measuring temperature, particularly in children.

The evidence indicates that the TAT and NCIT in their current form are not well suited to detecting temperatures outside the normal range. Failure to detect fever has significant consequences for patient care if the fever is missed and the patient is not treated accordingly or if fever is falsely detected, it may result in unnecessary clinical interventions. This is more critical in patients with cancer where detection of fever can be an indication of a potentially life-threatening infection.[19]

For both types of thermometer, both calibration and training to reduce user error was discussed as being a key factor in obtaining accurate and consistent readings. Three of the studies[13,19,24] specifically mentioned device training and 7 of the studies[16–20,26,27] documented that the devices were calibrated by the Clinical Engineering department. While there was no specific literature on the usability or training for NCIT, there has been a publication detailing the training and use of TAT in clinical practice. Barry et al.[30] undertook an observational study to look at the impact of user technique on the accuracy of TAT measurements. Despite documented training on the

correct technique, only 39% of users demonstrated the correct technique and returned acceptable temperature measurements. The remaining 61% failed to demonstrate correct technique and recorded statistically significantly lower temperatures. The most common mistake was to scan only the forehead and to miss either the temple or under the ear. Similar user mistakes have also been documented with tympanic thermometers where users fail to straighten the ear canal to direct the IR beam to the correct quadrant of the tympanic membrane.[8,9,31] It is interesting to speculate how the manufacturers could use this information to redesign their products to eliminate the user error issues and thereby improve the intuitive use of the device which would in turn reduce the need for regular training to make sure the device is used appropriately. This would then enable a more accurate evaluation to determine whether, when used easily and correctly, the thermometers can measure body temperature within clinically acceptable limits and could be considered as a long-term option for thermometry.

CONCLUSIONS

A review of the literature for both TAT and NCIT has indicated that in their current form neither is suitable as a replacement for oral or tympanic thermometers in clinical practice. In particular, the evidence suggests that they are not acceptable methods for detecting temperatures outside the normothermic range and do not detect fever accurately. Known user errors with both TAT and tympanic IRET could be detracting from the usefulness of the technology.

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Application of Multiparameter Method as an Assistance to the Evaluation of the Need for Replacement of Medical Equipment

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ABSTRACT

Medical equipment is an increasingly important element in modern medicine and medical and hospital care. For medical equipment to contribute effectively and productively to health organizations, it is necessary to carry out the management of their life cycle. A decisive factor in this life cycle is to know when a piece of equipment must be replaced. It is observed that defined and clear methods must be in place to assist the clinical engineering and hospital management in deciding and prioritizing which medical equipment needs to be replaced and when. This work has a practical application in the management of the medical equipment inventory. As a result, the classification of medical equipment and the prioritization of substitution is obtained concerning variety, quantity, and cost of the equipment to be replaced. The application of this method may contribute to the increased quality of the installed equipment and effective budget planning for hospital investments.

Keywords – *Prioritization replacement, multiparameter method, Biomedical equipment.*

INTRODUCTION

Medical equipment is increasingly important in modern medicine to aid in research, diagnosis, monitoring, therapy, and life support of human beings in need of medical and hospital care. Hospitals, in turn, have become sophisticated centers of technology.[1] The inappropriate use of technology may put users and the effectiveness of health organizations at risk. For medical equipment to contribute effectively and for health organizations to use them more productively, there is a need to manage their life cycle. The equipment's life cycle is divided into phases, in the following sequence: Innovation, Initial Diffusion, Incorporation, Large-Scale Use, and Renouncement/ Substitution.[2]

A key factor in this life cycle is knowing when any medical equipment should be replaced (to avoid inefficiency, unavailability, risks to patients, etc.). Other reasons for replacement need may be high operation cost, obsolescence, or inadequacy in meeting demand.[3] The equipment can be classified into two groups, those with decreasing efficiency and a predictable useful life (with low equity options without replacement, low with replacement by same type equipment, and low with replacement by more efficient equipment), and those with constant efficiency and unpredictable useful life.[3] As there is a historical scarcity of financial resources in healthcare an increasing, rational allocation of this resource is vital. Therefore

studies, methodologies development, and tools to define the cost of a technology's useful life are increasingly valued to avoid those subjective criteria being used in the decision-making process.[4]

For some factors, such as which technologies tend to be cumulative rather than substitutive, it is complex to define obsolescence criteria for medical technology.[5] In view of such complexity, it is observed there is an absence of clear and defined methods in the literature, as well as the application of methods and criteria to assist clinical engineering and hospital management in deciding which medical equipment needs to be replaced.

This study presents an alternative method, practical application and has the main objective to present a classification of medical equipment regarding replacement priorization as a consequence of obsolescence, evaluation of the technological medical equipment in use in the hospital, and to assist with direction in the variety, quantity, and costs of medical equipment needing replacement according to obsolescence criteria. The method used in this practical application was the Multiparameter developed in 1992 and applied for the first time at St. Luke Medical Center to a range of five different types of equipment, such as intra-aortic balloon, ECG, defibrillator, neonatal incubator, and ergometric treadmill, totaling 146 pieces of equipment.[6] The option for this method was to understand that it covers a variety of parameters and attributes, from technical, economic-financial and medical-assistance points of view. In the evaluation of the medical equipment life cycle, the importance of the observation by the prism of manufacturer and medical-care user is relevant.[7] This proposed method has a clear and objective formulation and allows applying to a variety and quantity of medical equipment, which is one of the assumptions of this work. Because it is composed of quantitative and qualitative attributes, and thus a wide coverage of the evaluation criteria, the application becomes attractive in relating practice and experience with actual data.[8] The application of this method can contribute to an increase in the quality of the management of medical equipment installed and with the investment planning of the hospital budget. This demonstrates that the knowledge acquired and developed by frequent research from clinical engineering professionals and the disseminated practical application can contribute to the decisions of health organizations´ management and thus add value in a more meaningful way because well-prepared professionals are essential to guide the decisions of health organizations.[5]

MATERIALS AND METHOD

The applied method considers four groups of parameters to compose the plots of the equation denominated RPV (Replacement Priority Value), being: technical (contributing with 40% in the equation), criticality (contributing 20%), financial-economic (contributing 20%), and clinical parameters (contributing 20%). One of the prerequisites for this application is to have the information about the medical equipment inventory to be analyzed, as well as the maintenance history of each one.

The first group mentioned, shown in Table 1, is composed of four attributes related to equipment: the age, maintenance cost (in this study, the maintenance cost [MC] was adapted to 24% according to the Brazilian reality, since in the original study the MC reference is 15%, considering the last 3 years regarding the purchase value), stopping time, and end of manufacturer support. In the four attributes, if the analyzed medical equipment has a good classification it receives a zero score, otherwise, it receives 1. Limits are described in Table 1.

TABLE 1. Technical Parameters

Criteria	Scoring Rule
Technical Criteria	MAN = Age + MC + ST + MS
Age (Age)	Age ≥ 7 years = 1
	Age < 7 years = 0
Maintenance Cost (MC)	MC ≥ 24% New equipment = 1
	CM < 24% New equipment = 0
Stopping Time (ST)	ST ≥ Average group break time=1
	ST < Average group break time = 0
End of Manufacturer Support (MS)	MS = 1, when spare parts are available on the market
	MS = 0, when spare parts are not

The age of the equipment was considered using data provided by the accounting sector of the institution. The MC and stopping time of the equipment were acquired through the asset management software. For the end of manufacturer support criteria, the formal communication issued by manufacturers was used as a reference.

The second group mentioned, as shown in Table 2, is composed of a single attribute, which is the function of the equipment. In this attribute, the medical equipment is framed in one of four classifications, according to the function, as shown in Table 2. In relation to criticality, the equipment was classified according to its application/ function.

TABLE 2. EM Criticality

Criteria	Scoring Rule
Medical equipment criticality (FUN)	FUN
Life support	FUN = 4
Therapy	FUN = 3
Diagnosis/ monitoring	FUN = 2
Analysis / support / assistant	FUN = 1

The third group, shown in Table 3, is composed of two attributes, one is the increase of billing and the other is the reduction of cost. In the two attributes, if the replacement of the medical equipment analyzed results in increased billing or cost reduction, it receives a score of 1.

TABLE 3. Financial-Economic Parameters

Criteria	Scoring Rule
Financial-Economic Parameters	Cost Benefit (CB) = IB + CR
Increased Billing (IB)	IB = 1, if the replacement equipment provides a higher billing
	IB = 0, if the replacement equipment does not provide a higher billing
Cost Reduction (CR)	CR=1, if the replacement equipment provides a reduction in the cost of operation and/or maintenance
	CR = 0, if the replacement equipment does not provide a reduction in the cost of operation and/or maintenance

To classify or score the equipment in the financial-economic parameter, it was necessary to know by which technology the equipment under analysis could be replaced. And, also be aware whether the replacement could bring cost reduction or increased billing. If positive, the score of each of the two mentioned attributes would be 1 (Table 4).

TABLE 4. Clinical-Safety Parameters

Criteria	Scoring Rule
Clinical Parameters and Safety	Clinical efficacy and preference (CEP) CEP = IT + UP + IS
Improvement in treatment (IT)	IT = 1, if EM offers improvement in the treatment
	MT = 0, if EM doesn´t offer improvement in the treatment
User preference (UP)	UP = 2, if the user preference for exchanging equipment is large
	UP = 1, if the user preference is medium
	UP = 0, if there is no preference for exchange
Increased standardization (IS)	IS = 1, if the replacement equipment provides increased standardization among medical equipment
	IS = 0, if the replacement equipment doesn´t increase standardization among medical equipment

In this parameter group, it was necessary to know if the equipment replacement in the evaluation could be more efficient, to increase the standardization, or to have increased user preference. This classification was conducted

with the support of care managers and doctors from the areas in which the analyzed equipment were allocated.

After completing all the parameters listed, the following formula was applied to obtain a final score, called Replacement Priority Value (RPV). This formula considers a weight or percentage for each group of parameters evaluated.

RPV = 0,4. + 0,2. + 0,2. + 0,2. (1)

To support the classification of Replacement Prioritization there is a decision scale in this method, as shown in Table 5.

TABLE 5. Classification of Replacement Priorization

Criteria	Scoring Rule
Keep in operation	RPV < 1
Reevaluate the condition of the equipment in the next 12 months	1 ≤ RPV ≤ 1,2
Replace in the next 24 months	1,3 ≤ RPV ≤ 1,6
Replace in the next 12 months	RPV ≥ 1,7

A spreadsheet was used as a tool to apply this method in a private, non-profit hospital with approximately 400 beds and an installed base of approximately 4,500 medical equipment.

RESULTS

Through the application of the Multiparametric Method, it was possible to know and visualize an overview of the replacement, which equipment should be kept in operation without any restriction, and how many should be kept in operation but with a reevaluation in the next 12 months (81 pieces of equipment) and 24 months (164 pieces of equipment), as shown in Figure 1.

It was also possible to identify which types and quantities of equipment should be prioritized, visualize the diversity prioritized by cost center, and provide management with an estimate of the financial resources needed to invest in replacements.

FIGURE 1. Overview of the replacement.

Another possible analysis was the verification of the partial classification referring to the groups of clinical, financial, economic, and technical parameters that determined if it was graduated with a partial result. This prism of analysis assists in the understanding of under which parameters certain equipment is worse qualified.

DISCUSSION

Health organizations, through clinical engineering services, need to have effective control of the medical equipment they own. The use of medical equipment life-cycle management software allows us to record all maintenance history. Knowledge of this data and information are a prerequisite for using technology evaluation methods.

The Multiparametric Method, with the range of criteria demonstrated, may be a practical alternative when evaluating the Replacement Prioritization of a wide range of medical equipment types. The continuity of application of this method, adaptations of attributes, and way of applying (mainly subjective ones) are subject to refinement and adjustment. There is also a need to implement the results after modeling, simulation, and resolution of the equations and types of computational tools being used. Both the methods and results of this practical application were fully accepted by senior management, by the managers, coordinators, and the multi-professional team responsible for the evaluation of hospital investments.

The list of medical equipment with a priority of replacement, as a result of the evaluation of obsolescence of the inventory of the technology was the basis of the biomedical equipment investment sheet. Other medical equipment made the list but came from other hospital needs.

CONCLUSION

Clinical engineering services can increase the performance of this evaluation and propose plausible alternatives (appropriate, comprehensive, practical, etc.) to hospitals regarding the use of methods and criteria that allow indicating the appropriate timing and prioritization of equipment replacement. The use of these methods can contribute to the quality, availability, security, and performance of the technologies as well as aid in accounting for the costs related to the life cycle of the hospital medical equipment inventory which would help in the planning of the health institution investment.

Other types of methods also need to be developed, studied, analyzed, and applied in a larger variety of medical equipment (to evaluate which method is best applied to a certain class of equipment) and more widely in the health organizations, to contribute substantially to managing the life cycle of the medical equipment installed.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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IFMBE/CED recognition of certification/registration programs for clinical engineering practitioners

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ABSTRACT

The IFMBE/Clinical Engineering Division (IFMBE/CED) has recently established an International Credentialing Board (ICB) [https://ced.ifmbe.org/projects/ce-htm-credentialing.html] to recognize organizations that certify or register clinical engineering practitioners (CEPs). The ICB has 9 members appointed by the CED Board and these members are experienced Clinical Engineering Practitioners with several certified or registered. The ICB will maintain a list of recognized organizations that certify or register CEPs but will not maintain a list of the individuals certified/registered by these organizations. The National Examining Authority (NEA) that performs national certification/registration can submit information on their program to the ICB and request to be globally recognized. This will include detail information on the program and how it administers their certifying or registering their individuals. Once recognized a program will be subjected to renewal reviews every three years to assure that it is still a valid and compliant operational program.

Since there are yet no specific guidelines for programs to certify/register CEPs, the ICB will have to evaluate each NEA submission in detail. The ICB will need to determine that the individuals certified/registered are qualified practicing CEPs and the program is well managed and fulfills its objectives. To be qualified the NEA must have a set of By-Laws and a Code of Ethics amongst other requirements. Certification programs may be based on credentials only or programs based on exams and credentials. Registration programs may be based on credentials including experience. The recommendations are that certification/registration programs should meet individual countries needs and how clinical engineering is practiced in a country. In lieu of an engineering degree requirement the NEA may substitute experience history since not all clinical engineering practitioners have engineering degrees due to the lack of education opportunities in their local.

The ICB will also aid professional groups that are trying to establish certification/registration programs for CEPs.

Keywords – *Clinical Engineering, Certification, Registration, Practitioner, Board, Clinical Engineer, Education.*

INTRODUCTION

The Credentialing Project Team of the Clinical Engineering Division (CED) of IFMBE https://ced.ifmbe.org/projects/ce-htm-credentialing.html worked for three years on the development and adoption of the framework for recognition of certification or registration programs for clinical engineering practitioners (CEPs). The previous work of the CED was examined. Next existing certification and registration programs for CEPs were reviews to determine if there were any common requirements and operations for the programs. There are major differences between certification and registration programs and significant differences in each of these approaches [link here] https://aamalegaleye.wordpress.com/2017/09/06/registered-vs-certified-a-question-of-terminology/. It was

determined that all of the major certification/registration programs for CEPs appeared to recognize only qualified CEPs. "IFMBE CED White Paper entitled "Certification/ Registration of Clinical Engineering Practitioners" James Wear was submitted 1 September 2017. http://cedglobal.org/wp-content/uploads/2018/06/CED-Certification-White-Paper-with-Annexes.pdf

The team that worked on this project represented different countries and different sections of the world. The present team members are listed here:

- James O. Wear (USA)
- Fabrola Martinez (Mexico)
- Mario Medvede (Croatia)
- Adrian Richards (Australia)
- Ewa Zalewska (Poland)

Since the members were scattered around the world, most of the meetings were by teleconferences. The team submitted the "Proposal for Recognizing Certification/ Registration Programs for Clinical Engineering Practitioners" to the IFMBE CED board in the summer 2019 and it was afterwards approved by this board.

PROGRAM

Clinical Engineering Practitioners perform many technology-related functions in the healthcare field and are called by different names even in the same country. Therefore it was necessary for the team to develop a definition for Clinical Engineering Practitioners for this project. The definition the team developed is:

"A clinical engineering practitioner is a Clinical Engineer, Biomedical Engineer, Healthcare Technology Manager, Clinical Engineering Technologist or Clinical/Biomedical Engineering Technician who practice technology management at a qualified level."

The purpose of the project was to develop a method for recognizing programs that certify or register clinical engineering practitioners and to facilitate evolution of common program elements. It will not be a program to recognize individuals who have been certified or registered as CEPs. The program will only develop a list of recognized programs and will not maintain a list of individuals certified or registered by the recognized programs. To maintain a list of individuals would be time consuming and therefore lead to the need for significant administrative and clerical time. This also would require significant additional funds.

The recognized programs will be expected to have an up-to-date list of individuals they have certified/registered. A requirement for recognition will be that such a list be included and will stimulate individuals to maintain their certification/registration. The program should provide information on the certification/registration of individuals.

Recognized programs will be listed on the IFMBE/CED website with associated contact information. This will be an added benefit of their recognition. This will also provide a method that can be used to determine if an individual is certified/register by a recognized program.

The IFMBE/ CED Board has appointed the first International Credentialing Board (ICB). There are to be 9 members with some members being representative of the IFMBE/CED Board. Their service terms are to be the same as the IFMBE/CED Board members having staggered terms. They also are to be certified/registered or well qualified CEPs and representing the different parts of the world. The members in this first appointment are:

- Fabiola Martinez (Mexico) Co-Chair
- Li Bin (China) Co-Chair
- Ewa Zalwska (Poland)
- Jitender Sharma (India)
- Adrian Richards (Australia)
- Ricardo Silva (USA/Venezuela)
- Ashenafi Hussein (Ethiopia)
- Tomokazu Nagusawa (Japan)
- Riad Farah (Lebanon)

This ICB has representatives from 9 countries and 6 continents. Three or four are from countries that have programs that could seek recognition for their country's certification/registration program of CEPs.

The ICB will have to examine each application in detail to determine if it meets the requirements to be recognized. This will require the application for recognition to be very detailed and in specific format.

The sponsoring organizations of the certification/registration programs do not have to be members of IFMBE

for the program to be able to apply for recognition. Since initially the number of programs applying is expected to be small, there will not be any fee to make application or to be recognized. This will also encourage programs to apply. The program will be administratively supported by the CED Secretariat and ICB board members. The CED may later initiate fees if the administrative costs becomes sufficient to justify it.

The organization that makes the application for recognition must be the one that operates the program and is called the National Examining Authority (NEA). The organization can be a professional organization, a government entity, an academic entity or some other form of a national or regional program. It can also be a for-profit program.

Requirements for a National Examining Authority to make a submission for recognition of their certification/registration program are not as simple as it appears. Existing certification programs are very different and registration programs are very different from certification. Some basic requirements can be made for a submission and these follow in the next section.

SUBMISSION REQUIREMENTS

1. All submissions must be typed in English.
2. The submission must have a single contact person which is the chair person of the NEA or the Secretariat of the NEA. An address, email and phone number must be provided so they can be contacted if there are issues with their submission or administration. The ICB may at any time request additional information on a program through this individual.
3. The date the program was established will be submitted. There are no minimum years of operation since this might discourage new programs from developing. The critical factor is that a NEA is operational and has all the appropriate requirements for consideration of recognition. Also the programs will have a renewal every three years for their recognition. This will allow the ICB to recommend withdrawal of recognition of a program that has not fully developed.
4. The submission must have a sponsoring organization including how the program is involved with the sponsoring organization. This needs for the submission to be very specific for instance one of the major certification programs is sponsored by a national society, but it is independent of the sponsor for operation. The sponsor only provides administration support including budget but not fund raising.
5. The submission must provide all the names and affiliation of the NEA Board Members that are current, their terms, how they were selected and if they are certified/registered and by whom.
6. The submission must include the number of people currently certified/registered as Clinical Engineering Practitioners. The number should show the number in each Clinical Engineering group if there is more than one.
7. The National Examining Authority must be governed by a set of By-Laws included in the submission. If it is a problem for a new program to develop a legal set of By-Laws, the ICB should be able to provide an example of By-Laws to assist in their adoption.
8. Since ethics is a general important issue also for Clinical Engineering, the NEA must have a Code of Ethics that each certified/register person will abide by. The ICB can provide samples of Codes of Ethics to any organization applying.

The major part of the submission shall include a detail of the program including how it is financed. This part of the application can be different for each program and probably will be different for certified programs and registration programs. This shall include at least the following:

- When program started
- Program By-laws
- Forms for individual applications
- Forms for renewal applications
- How applications are reviewed
- If written or oral exams are required
- How many are certified/registered in Clinical Engineering

- Years of experience required including type of experience
- Education requirements including any specific courses
- Fees required

There is no time limit on how long a program has been in operation, but it must be currently operating. No individual practitioner exams are required for a program to be considered for evaluation and some existing programs are based on experience and credentials. Programs like the US and Taiwan started based on experience and credentials and now require both written and oral exams.

If the program has a handbook on how to become certified/registered CEP and renew, a copy must be provided.

A program will normally have a renewal for certification/registration and if so, this must be submitted. This will normally include the completion of continuing education CEUs, experience and professional activity. The renewal time period is usually for 3 to 5 years during which time the person must be practicing in the field.

The submission should include how the program is promoted in general to individuals in the field and to healthcare administrators. This would include how Clinical Engineering Practitioners are informed that the program exists in their area. This might be with presentations at their professional meetings as well as presentations at healthcare providers and administrator meetings. The program should be promoted to other healthcare providers such as administrators, physicians, nurses, technologists and to government agencies. This can be done with their interactions with these individuals. Offering to make presentations to their professional meetings and submitting articles about clinical engineering practitioners certification/registration to their professional journals.

After considering the application and the support documentation the ICB will determine if the application met the requirements and qualified for inclusion in the roster of ICB recognized NEA. The ICB may make specific recommendations for changes to a non-recognized program which can then resubmit an application.

A recognized program will be reviewed periodically to assure that it is still operating and if it has made any changes in operations. The ICB will have to determine how frequently this will occur and what will be required for demonstration of compliance.

CONCLUSION

The newly established International Credentialing Board currently conducts its business through virtual platform that support participation of its members from different parts of the world. It is working to encourage existing certification/registration programs to submit application for their program to be recognized. It is also developing materials and support that can aid in the development of new programs.

The ICB can be contacted through the IFMBE CED.

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Logistics of Medical Devices for Indigenous Health Care Attending in Remote Sites in the Brazilian Amazon Rain Forest

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ABSTRACT

Background and Objective

In Brazil, there are 896,917 Indigenous people with 47% dwelling in the Amazon rainforest region. To avoid expensive displacement of this population, especially for surgeries such as hernias and cataracts, the Expedicionários da Saúde non-governmental organization (NGO) has visited this specific group 3 times per year since 2003. The visit is done through a field hospital (FH) and is supported by clinical engineering (CE). This article outlines the characteristics of logistics as well as the operation of medical and hospital devices in remote sites of the Amazon region. The object of this paper is to describe the transportation processes, installation, operation, and maintenance involved in ensuring the safe use of medical devices in one FH in the Amazon forest and to present solutions to adverse conditions encountered throughout the course of several expeditions.

Material and Methods

Initially, a survey of the processes used for transportation, installation, operation, and maintenance of medical devices was collected from 28 expeditions to the Amazon forest over a period of 10 years since the implementation of CE the team. A task-analysis process was performed to systematically identify the process used during these expeditions. To better understand the complexity and the specifics of each expedition, an evolutive planning process based on a Software Development Spiral Model was used to describe a continuous activity flow that was used to implement and test improvements in each new expedition. Besides continuous improvement, the model also takes in consideration budget solutions once all the voluntary work by the NGO is done. The efficacy of the method was evaluated from indicators of use of medical equipment, the assessment of reported adverse events, and interviews with the professional from the CE team, the users of the medical devices, and the opinion of those responsible for managing of the expedition.

Results

Several improvements were observed specifically in the transporting and installation processes, mainly through the adoption of customized packages and manuals for assembly and disassembly of the medical equipment. Further enhancements were obtained through customizations and adaptations of the devices to the hostile characteristics of the environment. Both physicians and nurses were satisfied with the performance of the devices, and few procedures for repair and calibration were required after the equipment was installed.

Conclusion

The CE team is crucial to the implementation of FHs, being essential in the management of medical technology and in the planning and operation of this type of health structure. The spiral planning method was shown to be very helpful mainly

because it takes into account the experiences and needs of the past expeditions and for allowing the continuous improvement of the already used processes. Given the great complexity of the rainforest environment in which the technologies will be used and the unpredictability of the risks and challenges faced by the EC team the evolutionary work approach presents itself as an applicable solution when planning future expeditions.

Keywords – *clinical engineering, field hospital, medical devices, Amazon Rain Forest, Expedicionarios da Saude.*

INTRODUCTION

In Brazil, there are 896,917 Indigenous people with 47% of them dwelling in a reserve forest in the Amazon region.[1] Basic healthcare for this population is provided through the use of specialized health teams sent to their villages.[2,3]

For cases requiring specialized care, patients are sent to urban regions.[4] However, this involves a significant increase in costs and great discomfort for patients because of the distance and difficulty associated with traveling to the closest specialized medical center.

To reduce displacement of patients, especially for surgeries such as hernias and cataracts (prevalence of 2.1%),[5] the non-governmental organization (NGO) Expedicionários da Saúde (Brazilian Health Expeditions) has attended to this specific population 3 times per year since 2003. There were 44 expeditions with a total of 97,060 nonsurgical patient encounters and 8,773 surgeries.[6] All of the work is done by voluntary professionals who, in addition to the provided care, also assist with the assembling of the field hospital (FH) used for this service. This FH contains a specialized surgical center, sterilized material center, and ophthalmology, pediatrics, odontology, gynecology, and general clinical medicine outpatient facilities.[7] The FH is defined as a mobile, self-contained, self-sufficient health care facility capable of rapid deployment and expansion or contraction to meet immediate emergency requirements for a specified period.[8,9] As with permanent structures, this hospital needs medical devices for patient diagnostics and therapy. According to Finestone, the FH must be equipped appropriately to function independently.[10] Therefore, it should have all necessary external resources needed to function such as medical instruments, operational material, infrastructure, and additional equipment.

Support from the clinical engineering (CE) team is crucial to the implementation of FHs and is essential to the planning, management, and support not only of the structure but also of the facilities and the medical technologies used.[11]

The CE team is composed of 3 engineers who travel one at a time for the expeditions and one engineer who give support to the routine work in maintenance of medical devices.

Among the diverse medical technologies involved, it is necessary to recognize their technological complexities. Consequently, the CE team is in charge of the transportation and assembling of items including electrosurgical units, physiologic monitors, imaging ultrasound, phacoemulsification machines, surgical microscopes, surgical lamps, portable laboratory, autorefractors/keratometers, pulse oximeters, colposcopes, slit lamps, and ocular biometers.

A total of 15 tons of materials and pieces of equipment for the FH are transported to their remote sites in the Amazon.[12] The route includes roads, rivers, and airports with most lacking proper conditions for the landing of big-load aircraft and the transportation of delicate medical devices.

All of the material is vulnerable to weather and local environmental conditions such as high humidity, temperature, sun exposure, dust, strong winds, and impacts related to loading and unloading of boats, trucks, and aircrafts.[13]

The main role of technology management done by CE team is to make sure the medical devices are available and are working properly and safely. This process is done through assembling, installation, maintenance, and very importantly, by the protection of medical devices to avoid damage during transportation.[14]

However, the high complexity transportation of medical devices in the Amazon forest and the lack of available financial resources due to the project's often philanthropic

origin demanded the development of a structured and evolutionary work process aiming for low-cost solutions.

OBJECTIVE

The object of this paper is to describe the transportation installation, operation, and maintenance processes used to ensure the safe use of medical devices in one FH in the Amazon forest and to present proposed solutions to overcome adverse conditions throughout the course of several expeditions.

METHODS

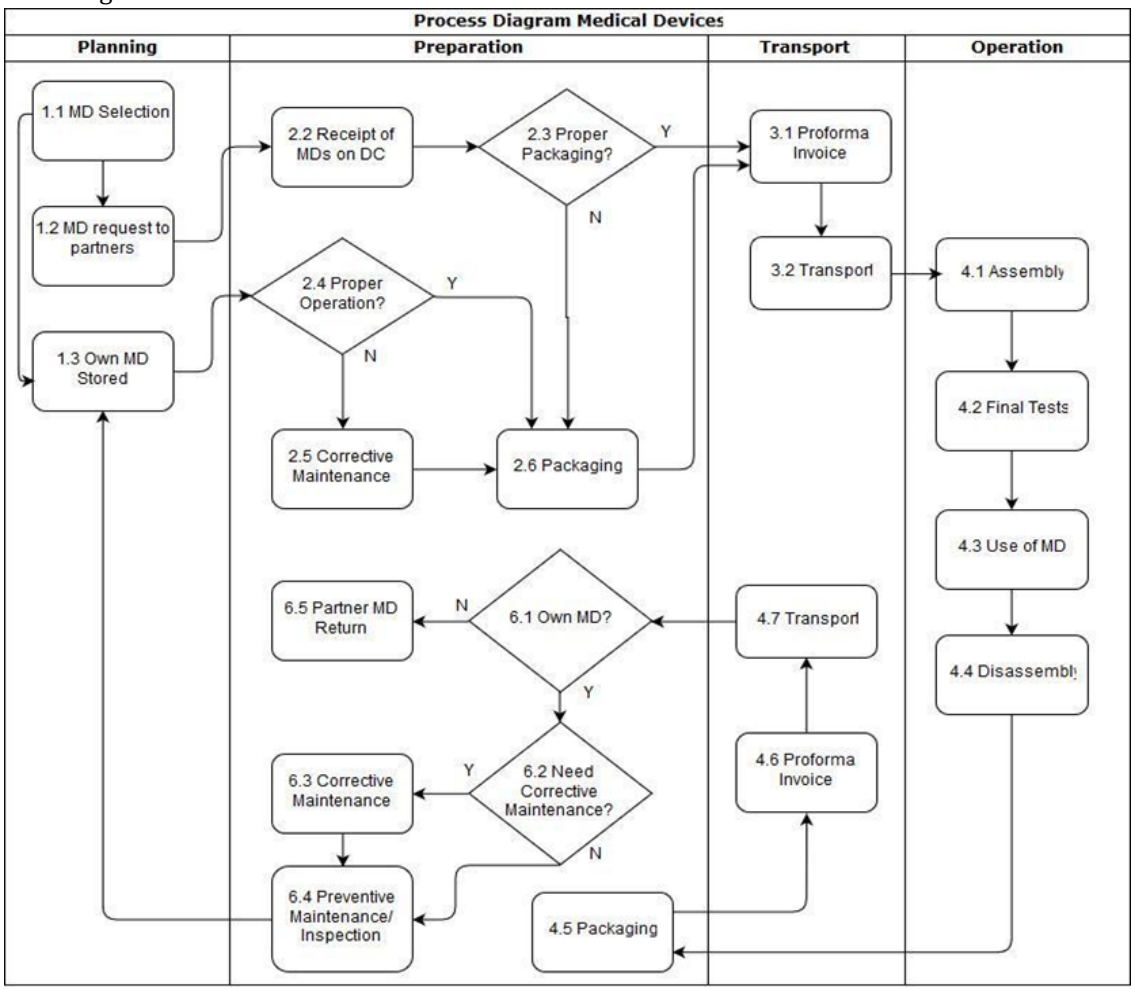
Task Analysis

Initially, a survey of the processes used for transportation, installation, operation and maintenance of medical devices was done using the method called Task Analysis.15 Data from planning, preparation, transport, and operation of medical devices were collected from 28 expeditions to the Amazon forest over a period of 10 years since the implementation of the CE team. To facilitate the visualization of these process, see Figure 1 and the survey of processes and description of stages.

Description of the stages of processes:

1.1 MD Selection: The amount, type and characteristics of the required medical devices depend on their estimated demand and on the types of patients and procedures that will need them. A contingency plan to have a 25 to 50% higher stock of medical devices is established. The corrective maintenance has a low chance of success in case of failures due to the lack of resources, such as spare parts, test equipment, tools, training, and more.

FIGURE 1. Process diagram of medical devices.



1.2 MD Request to Partners: Partner companies provide equipment that is lacking. The number of devices requested is based on demand and the number of devices currently available.

1.3 Own MD Stored: Owned MD equipment is stored in the distribution center (DC) in the southeast of Brazil. This location was selected because of better availability of companies to perform maintenance, access to better storage conditions, and easy access to equipment by the team. The management of expiration dates of accessories and materials is done at this stage.

2.2 Receipt of MDs on DC: Equipment lent by partners is delivered to the DC where it is checked after being previously tested by their providers.

2.4 Proper Operation: Before the packing stage, the NGO's equipment and accessories undergoe functional testing.

2.3 Proper Packaging: Equipment provided by partners is inspected to ensure quality and viability of the packaging and is placed in a 180-liter standardized container as necessary.

2.5 and 6.2 Corrective Maintenance: 30% of corrective maintenance is done in house and managed by the CE team. However, the loaned MDs are repaired by MD's partners.

2.6 and 4.5 Packaging: The equipment is preferably packed in foam, cut in its own format, sealed with plastic bags, and put inside the 180-liter standardized containers. The container has a weight limit of 30 kg (66.1 lb) to allow manual loading. Packages are recycled on their return.

3.1 and 4.6 Proforma Invoice: This is a checklist of the bill or goods (or items) to be included with the FH. All items receive numeric identification, sealing, and external identification with colored codes.

3.2 and 4.7 Transport: The equipment is transported by road, air, and on water (e.g., by river). Transportation from Campinas (southeast region) to Manaus (north region) can be by road or air, go through roads and high-level airports with infrastructure, and via resources such as forklifts and warehouses. After Manaus, the load is carried by military aircraft, ferry boats, wooden boats adapted to the rain forest rivers, and sometimes on unpaved roads which are subject to quagmires and dust. During transportation, the load can be exposed to rain. For this reason, it is protected by plastic tarps. When a load is delivered to the indigenous community or small towns that do not have proper infrastructure the unloading is manually conducted at the riverbank.

4.1 Assembly: There is a visual inspection of each MD for integrity before assembly. Assembling procedures often differ from the original manuals as they are simplified to reduce assembling errors and the limited availability of trained manual labor.

4.2 Final Tests: Before use, MDs are tested and kept working in shifts of 2 hours. This testing ensures the functioning of equipment and the generator when fully loaded.

4.3 Use of MD: The use regimen for MDs is that they will be available 13 hours a day for 6 days with the device operation monitored and controlled by the CE team.

4.4 Disassembly: The equipment is disassembled following the same procedures used in the assembly process.

6.1 and 6.5 Own MD: The partners' pieces of equipment are returned without going through internal maintenance procedures.

6.2, 6.3. and 6.4 Corrective Maintenance, Preventive and Inspection: Before storage, owned pieces of equipment go through corrective maintenance when defects have been identified; after this, equipment goes through post-repair inspection or pre-storage preventive maintenance for devices not requiring repair.

Evolutionary Planning Cycle of Expeditions

We estimated through the 28 expeditions the equipment was transported for more than 163,000 km (approx. 101,000 mi). Due to the highly complex environment and great diversity of problems faced in each expedition, an evolutionary and cyclic work process was developed based on the software development in the spiral (Figure 2). This model, widely used in software engineering for the development of prototypes, describes a continuous activity flow, which allows for improvements for each new expedition.[16] The spiral method is similar to the PDSA (Plan, Do, Study and Act) method of continuous improvement, being chosen by the team involved in this study due to its familiarity with the method. The evolutionary cyclic work process is divided into 4 stages and

always restarts from the last expedition where problems relating to transportation, installation, operation, and maintenance are identified.

In Stage 1 the identified problems are classified into 3 groups: technological, operational, and environmental.

After classification, each problem is analyzed, and possible solutions are proposed based on its classification in Stage 2. The proposed solutions are evaluated and chosen according to their cost × benefit × effectiveness (Stage 3). This decision is influenced by limited financial resources and voluntary labor. In Stage 4, the chosen solutions are implemented and tested; if successful, they are incorporated into future expeditions.

Identification of Problems Found in Expeditions

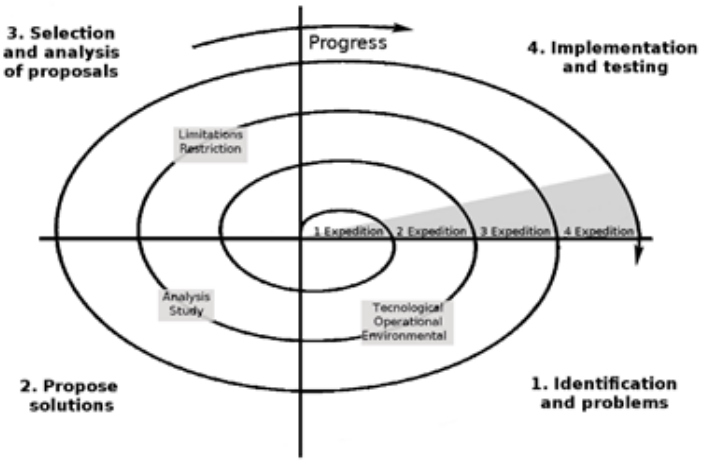
According to the process presented previously, after each expedition, several problems are identified and registered for the improvement of future expeditions. Problems may be related to some of the following:

- Technological factors: related to the limitations of technology, the technology not being designed to the environment where it is used, such as the type of the material used in the equipment, design (size, weight, etc.), or device circuits not being compatible to the quality of energy available.[17]
- Environmental factors: related to the natural characteristics of the environment which impacts both the use[16] or transportation of devices, such as temperature, humidity, and condensation.
- Operational factors: related to the use of the device, such as operational, installation, transport, assembly, and disassembly errors.

Different processes of study and analysis were used to propose solutions for problems previously presented. Solutions to technology- and environment-related problems are proposed after studying device operation manuals and information from the manufacturer's websites. This study aims to identify the technical characteristics of device functioning and which critical elements can be modified and which protective measures must be implemented.

Protective measures can be implemented by improving procedures. Operational problems are studied after task analysis and solutions are implemented with improvement of work processes and by modifying actual device-related protocols.

FIGURE 2. Representation of the evolutionary planning cycle of expeditions.



RESULTS

In the first stage of the spiral cycle of evolutionary planning, problems were identified according to their characteristics.

In Table 1 it is possible to see the problems identified during a series of expeditions regarding the lack of documentation. This indicates the temporal relation between the cycle and the solution.

TABLE 1. Relation of Problems Identified According to Characteristics

Technological Factor Problems
Break of the fairing of the external part, premature break of the optic fiber, breaking of connectors during disassembly, assembly errors, bad internal contacts, equipment without battery backups, and external damage to the manufacturer's packaging.
Environmental Factor Problems
Fungi in lenses, oxidation of parts, equipment not working in ambient temperature, incompatibility of power grids, burned out equipment due to lightning, wet equipment, condensation due to excess humidity.

Operational Factor Problems
Operational errors, equipment lacking software configuration, lack of localization of accessories/errors in checklists, lack of contingency accessories, partner equipment not working (not previously tested), lost parts during transportation, damage during transportation (error in optical measurements).

In some cases, there was uncertainty about how to classify a problem. For example, an MD that was damaged during transportation could have been classified as a technological problem for not being protected before being transported (technological) or as an operational problem for not being properly protected during transportation. Table 2 presents solutions related to problems identified in Table 1.

TABLE 2. Solutions Presented According to Problems Identified

Technology-Related Solutions
Spare accessories, corrective maintenance, change to error-free connectors, improvements in the process of corrective maintenance, acquisition of uninterruptible power supply and change to original packages.
Environment-Related Solutions
Change in preventive maintenance protocols, equipment climate control, equipment replacement, packaging improvement, avoiding taking equipment out of climate-controlled areas, and implementation of lightning protection.
Operational Solutions
Improvement of processes (below).

Improvements that were part of an operational problem solution are:

1.1 MD Selection: Inclusion of required MD specifications, assessment, and field tests.

1.2 MD Request to Partners: Increase in quantity of contingency equipment, accessories, and inputs.

1.3 Owned MDs Stored: Increase in quantity of strategic equipment (essential equipment for the operation of the FH or where there are loaning difficulties between the partners).

2.3 Proper Packaging: Inclusion of provider's packaging assessment. In some cases, the provider's packaging is not the most appropriate for the type of transportation used for the FHs. For example, cardboard packages that come without plastic protection, pieces of equipment without any packaging, wooden boxes without proper protection against storms.

2.4 Proper Operation: Inclusion of the testing criteria.

2.5 and 6.2 Corrective Maintenance: Inclusion of criteria for selection of maintenance providers and beginning of in-house maintenance.

2.6 and 4.5 Packaging: Improvements in the processes and packaging of materials. Some pieces of equipment have to be disassembled to fit standardized plastic boxes and for those which disassembly was not possible, waterproof wooden boxes with external protection were made with key locks and handles for manual transportation. At the bottom of the containers, 8 cm of foam is used to protect against impacts and water infiltration. Internal protection is achieved with medium-density foams and bubble wrap.

3.1 and 4.6 Proforma Invoice: Computerization in the process of packing lists with double checking and logistical team training in the computer system.

4.1 Assembly: Increase in instructions and assembly training, simplification of the assembly procedures, use of devices with only one option for assembly, and standardization of electrical outlets.

4.2 Final Tests: More detailed tests such as the use of an eye phantom and testing of the generators with all equipment on.

4.3 Use of MD: In loco instructions to users and infrastructure improvement for generators and electrical facilities, such improvement and standardization of power distribution boards, standardization of AC cables, exchange of single-phase generators with three-phase generators with automatic voltage control

4.4 Disassembly: More training of staff on disassembly and improvement to disassembly instructions.

6.4 Preventive Maintenance and Inspection: Inclusion of annual preventive maintenance and obligatory inspection for every expedition.

6.5 Partner MD Return: Inclusion of the checklist of MDs that are returned along with information of any intra-expedition failures.

DISCUSSION

It can be observed that the spiral method aided the improvement of the work processes involving the management of the MDs, allowing the implementation of solutions for each new expedition cycle. However, each new proposed solution still needed to be evaluated before being added as part of the work process. And, due to the characteristics of the use of temporary FHs, this process of improvement can be very slow. One way to reduce the time needed to evaluate the proposed improvements is to apply the proposed enhancements in simulated environments. Once validated and tested they can safely be applied in the new expeditions cycle. The use of methods for risk assessment and risk mitigation during the selection and analysis of the proposals can also accelerate the process of adopting the improvements. Performing the risk analysis processes for the proposed improvements while taking into account the existing financial criteria of the expedition, the physical characteristics of the load (volume and weight), and the composition of the team at hand would considerably increase the success of the improvement proposals.

Still, some difficulties need to be assessed in each cycle, with the main difficulties being, scarce resources, continuous change of team members due to the voluntary nature of the work, and the continuous need for training, documentation, labeling, and warnings.

A critical part of the actual work process is the simplified documentation of the meetings themselves and the execution of improvements. Efforts have been made to improve the environmental conditions of the FHs, improve electrical generators, and use energy stabilizers for those more critical cases.

CONCLUSIONS

The use of the spiral method has shown positive results in the improvement of the work process, mainly within the assessment stages for every expedition, the implementation of modifications, and the posterior assessment as a continuous improvement process. The CE action done outside the boundaries of the perennial health structure is necessary for environments where patients need healthcare, with the proper support of the technology available so that such care be provided with safety and efficacy.

This support has been crucial in the attending of the isolated population in the hostile and isolated environment of the Amazon forest. Concerning the FH, the CE is responsible for transport planning and for providing the proper conditions for storage, transportation, installation, operation, and equipment disassembly, even in environments with low availability of resources.

The planning related to MD must be careful, for both supplies and accessories and also for necessary contingencies such as having a sufficient supply of replacement parts, spare pieces of equipment, and other equipment due to the geographical isolation. This isolation makes it difficult to search for solutions outside of the workplace.

Considering the unique characteristics of the FHs and the costs involved in the acquisition of specific MDs for this implementation, equipment acquisition must include the equipment standardization criteria and a reduction of device volume and weight, without any reduction in functionality.

This continuous improvement process is required because the variability found in remote sites in the Amazon challenges both transportation and implementation of FHs.

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APPENDIX

Examples of Transportation in the Rain Forest

Equipment packaging examples

Field hospital

Cataract surgery

General surgery

EC Team

Rogerio Ulbrich, João Galdino, Ryan Ferreira and Tiago Rodrigues

Book Review

By Y. David
Editor-in-Chief, GlobalCE Journal

Global Clinical Engineering Journal has been dedicated to encourage the sharing of knowledge and the publication of engineering and scientific work in the clinical engineering field. In our continuous efforts we are initiating a new section of our Global Clinical Engineering journal www.GlobalCE.org we call *Book Review*. We hope that you will professionally gain from it and at the same time promote the submission of such reviews for the benefit of all our readers.

Clinical Engineering Handbook
Second Edition
Editor-in-Chief: Ernesto Iadanza
ISBN 978-0-12-813467-2
Academic Press, Elsevier
Published 2020

Our first book review is about the Elsevier Academic Press newly published Clinical Engineering Handbook second edition with Ernesto Iadanza as editor-in-chief. Mr. Iadanza is Adjunct Professor in the University of Florence, Italy. He is currently also the IFMBE Health Technology Assessment Division chairman. Following the reach of the first edition of this handbook, the second edition provides expanded coverage of the wide spectrum of technology-related responsibilities that the modern clinical engineering field is tasked with. This handbook contains over 900 pages of content that, while it may range in its importance level, is all pertinent to every practitioner in the clinical engineering and healthcare technology management field. The handbook consists of 13 sections and 127 chapters. The long list of section editors and chapter contributors made up of academicians and practitioners, that together, represents an authoritative view of the current state of subject matter that each of them covered.

As noted in the Foreword written by Adriana Velazquez, Senior Advisor on Medical Devices, World Health Organization (WHO) "This book is a major contribution to the evolution of the profession itself, and serves as a call to institutional leaders to look to clinical engineering to expand the professional capabilities that healthcare systems need worldwide as they grapple with the often overwhelming complexities, always keeping the end-user perspectives of patients, and healthcare workers' needs globally."

The purpose of this handbook is noted in the introduction as "to provide a body of knowledge to all clinical engineers who intend to practice their profession." Indeed, the extended coverage of the handbook provides well for the many phases of the technology life cycle and for the professional practice guidelines. These subjects are fundamental for those who already manage the healthcare technology and a 'must read' for those who enter the field. For those who are at their mid-career practice, they stand to benefit from reading this handbook in preparation for their next career step.

Handbook organization that covers such a large scope of many career roles and tasks within the clinical engineering discipline can be structured in different styles. The style selected here could have been improved upon if, for example, Section 1 on Clinical Engineering would have been restructured so that chapters on Open-source medical devices and the RFID technology been reassigned into Section 7 on Medical devices, allowing for more logical grouping of a single subject matter. Few other similar restructurings of chapters' subject location should have been considered. Also regarding the style, some of chapters offer the benefit of "further reading"

segment that is very useful, but unfortunately, it is not uniformly incorporated throughout the book.

As one of the authors within the long list of colleagues who contributed material for this handbook, I personally witnessed the great deal of effort and burden that the editor-in-chief lived with over the couple of years that it took to make this second edition a reality. It is significant accomplishment and can easily serves as the main "go to" source about the clinical engineering field and be part of every library and healthcare related academic programs resource. Everyone that will examine the list of experts that contributed material for the handbook is surely to be overwhelmed with their knowledge of the subject matter, with their ability to present clear and easy to read content, and of the many locations around the world they represent. The contribution of so many well-known experts is making this handbook unique.

It is a challenge to produce a resource that can encompasses the vast volume of information like that which is contained with an encyclopedia and simultaneously keep the depth of each of the individual subjects being addressed at reasonable level. This handbook is successful in its ability to offer expansive coverage of subject matters while at the same time reaching sufficient depth to help educate the reader. In my review I found this characteristic of the handbook to be uniquely and properly done.

You can find the handbook at https://www.elsevier.com/books/clinical-engineering-handbook/iadanza/978-0-12-813467-2 at the current discounted price of US $170.00. It is unfortunate since this cost is considered a far reach by many in the low resources' regions of the world where such a handbook stands to make the most impact. I hope that the publisher will take this dilemma into consideration.