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Editor's Corner

CE Vision 2022 – Year of the Child

Greetings, fellow CEs around the globe. First, I commend and thank each of you for the hard work and enormous contributions you've made to saving lives and conquering this vicious pandemic. It has been – and continues to be – a rewarding and humbling opportunity to work with you this past year to solve the endless waves of HTA and HTM challenges. WORTHY WORK! This is why we chose the CE profession, isn't it?

I would like to share a fresh idea of renewal for us to consider and embrace: creating a "CE Vision 2022 - Year of the Child" action plan. The global COVID-19 pandemic spanning 2020 and 2021 has been terribly hard on children. While the Coronavirus hasn't claimed many young lives directly, birth rates have plunged around the world, children have suffered from loss of parents, grandparents, immense social and school isolation, daily fear, and unemployed parents everywhere have been hard pressed to provide basic food and healthcare for their kids.

Children are our future, our hope, our path to enduring survival! During this pandemic, though, children and their very childhood have been threatened worldwide like no time in recent history.

What can WE do? I think we can focus some of our collective time and energy to improve health and welfare for children a bit at a time in the coming years. How? Well, we might start with ideas and actions that support our CE colleagues in Children's Hospitals, and also supporting pediatricians, family physicians, and midwives, who do the lion's share of medical for children around the world.

A little background: my career begin in 1975 at ECRI, and my first field assignments that year were at Philadelphia's Children's Hospital, testing and servicing the equipment in the Neonatal Intensive Care and Pediatric Intensive Care Units. Those weeks of time working with nurses, physicians, and fellow engineers left an indelible image in my mind's eye: the primal struggle of a tiny life clinging to each breath and heartbeat. Over the decades, in the course of various educational and humanitarian relief efforts I have had the privilege of visiting NICU and PICU units throughout the US, and in China, India, Mongolia, Romania, Slovakia, and elsewhere. Every visit brings back the intense reminder of why I am a Clinical Engineer: to save lives and improve the human condition whenever, wherever, and however I can.

Back in the mid-90s, I had the exciting opportunity to hear Dr. Jonas Salk deliver the opening keynote speech at "Child Health 2000: 2nd World Congress and Exposition" in Vancouver, Canada from May 30-June 3, 1995. Dr Salk died barely a month later, and this, his final public speech, was a clarion call: let us all do everything we can to assure safe and healthy kids by the year 2000!

On behalf of ACCE, I led a panel with Bob Morris titled Global Approach to Appropriate Technology for Maternal and Child Health on Technology Assessment and management at the Congress, which you can still read in two archived ACCE newsletters.[1,2,3] I must admit that I left that conference quite humbled, however. I came to understand that child and mother mortality depended on far more simple things than ventilators and monitors. I was struck by the simplest of ideas presented. For example, one product was a small cereal-box sized kit with a bar of soap, a plastic drape, a clean razor blade, and a length of twine. i.e., a simple baby delivery kit to keep the mom and baby off and dirt floor and provide a modicum of sanitation for mother and child!

During the following decades, during my travels to many bare-bones hospitals and clinics I repeatedly humbled by the heroic efforts to care for children with woefully inadequate resources. Two examples that stick in my mind were 1) seeing three preemies tucked in a broken incubator with the doors wide open to compensate for the failed thermostat, and the oxygen plumbed in through plastic tubing from a welding oxygen tank 40 feet away,

and 2) a heartbreaking discussion with a post-surgical pediatric recovery team which was experiencing nearly 100% mortality despite their best efforts.

Only a few years later, in 2003, my own premature daughter's life was saved by a new medical gas, nitric oxide, that my team had the privilege of introducing to the US in the late 90s. It was only a mere stroke of luck that the hospital had just introduced that technology, or she may not have survived. These many child health technology challenges – and opportunities – have persisted can be found in every corner of the world, as documented by our colleagues like Tom Judd in 2016 in collaboration with WHO.[3]

It is now 26 years since that 2nd Child Health 2000 Congress in Vancouver, and, yes, we have cell phones and apps, and we have access to many training and research resources, but the child and maternal mortality rates are still unacceptably high, even in the US.

As I mentioned at the beginning, we cannot ignore the horrors that this COVID-19 pandemic is creating for newborns and children around the globe. The second Coronavirus surge in India this spring, for example, will leave a huge number of babies and children without one or both of their parents, and the national hospital resources are terribly depleted. This is presenting yet another terrible child health crisis that cannot be overlooked.

I have written this editorial to suggest that we, the Global Clinical Engineering community lean in and lock our shoulders together through GCEA, IFMBE CED, the Healthcare Technology Foundation, and our vast network of global colleagues, friends, and partners like WHO, PAHO, UNICEF, and many others to improve Child Health beginning in 2022 and beyond.

How? Following our upcoming ICEHTMC global congress in Orlando, let's begin holding a monthly "Global Clinical Engineering Year of the Child" collaboration meeting on the first Tuesday of every month with Zoom, during which we can set global and regional priorities. Let's set up a dedicated CE Child Health WhatsApp group to communicate and collaborate, too!

Sanitation and education could be a humble start, but we can do more. Perhaps we can create a global CE resource for children's hospitals, nurses, physicians, and midwives to access training literature. Perhaps we can work with WHO, UNICEF, and others to tackle essential product and training resources that match language and cultural norms. Perhaps we can invent a creative supply chain to source donations, parts, or equipment. Perhaps we can become a CE resource for the many government and faith-based relief agencies who work to save children's lives each and every day. Perhaps, too, we can make a point of inviting one article on Child Health for this Global Clinical Engineering Journal? And why not make this a resounding theme of our upcoming ICEHTMC Conference in Orlando in September, too?

Let's stand up and be counted as a Clinical Engineering community, proclaiming to the public that we can and will make a difference in Child Health. Let us commit to each other to ensure that our Clinical Engineering profession makes meaningful improvements to Child Health by carving out a piece of our time and energy every month in order to make a difference together.

It is not impossible! As the old adage tells us: "A journey of a thousand li begins with a single step."

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CONTENTS

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Compilation About Adverse Events Recorded in FDA/USA and ANVISA/Brazil Databases Through Models Available in the Literature Concerning Analysis and Prioritization of Actions for Medical Devices

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ABSTRACT

The development and application of medical technologies have grown steadily in all health fields, offering numerous benefits to users. However, adverse events, which may cause severe consequences for patients, also have increased. Technical and human factors that provoke dangers are related to the complexity of the devices, quality control in manufacturing, software, maintenance procedures, materials, and mode of use. This work aims to present the main alerts, dangers, and failures and some ways to mitigate them related to the following medical devices: Defibrillators, Infusion Pumps, Physiological Monitors, Pulmonary Ventilators, and Ultrasonic Scalpels. For that, we performed an analysis of adverse events reported in the Food and Drug Administration (FDA/USA) and the Brazilian Health Surveillance Agency (ANVISA) databases since 2016. Finally, we classified the events into different categories, according to their similarity. The results show a total of 3,100 cases registered in the FDA for the six types of medical devices addressed in this work and 75 cases registered in the ANVISA/Brazil for two of them. Based on the top ten health hazards provided by ECRI (2016-2020), this work contributes to understanding the most significant hazards of the previously mentioned devices and the main ways to mitigate these risks. Throughout our research, we found that the risks addressed in this work are common to several medical devices; therefore, there preventative measures to avoid them must be established, for example, training users to use and maintain the equipment, improving their quality, and also reporting adverse events to manufacturers.

Keywords – *Adverse Events, ANVISA, ECRI, FDA, Medical Devices, Manufacturing, Training, Maintenance.*

INTRODUCTION

According to the World Health Organization (WHO), a medical device is an "apparatus, instrument, machine, software, material or another similar article, intended for a medical purpose" as monitor treatments, help people with disabilities, diagnose and treat illnesses[1]. In the current COVID-19 pandemic, measures of prevention and control of health services have been defined by the Brazilian Association of Clinical Engineering, whose guidelines include checking the configuration and availability of Intensive Care Unit (ICU) beds and their primary devices: mechanical ventilator, multi-parameter monitor, defibrillator, and infusion pumps, noting the need for staff training to use them. In addition, it is also necessary to identify defective or unused equipment due to a lack of parts or inadequate maintenance.[2] In this sense, clinical engineers play an essential role in managing fundamental medical devices for treating patients affected by the disease.[3]

Despite the importance and benefits of medical equipment in health care, adverse events are also associated with them. In Brazil, the National Health Surveillance Agency (ANVISA) classifies adverse events like health problems caused to the patient by a device subject to a health surveillance regime, even used under recommendation from the manufacturer.[4] These events can occur because the medical device environment is a complex system of human-machine interaction that requires understanding the environment and identify risk factors.[5]

Every year, the Food and Drug Administration (FDA/USA) receives many thousand reports of suspected medical device-associated injuries, deaths, and malfunctions.[6] The FDA uses these reports to detect potentially related safety issues, monitor device performance, and contribute to benefit-risk assessments of these products.[7] Since 1991, FDA has received more than 4.4 million adverse event reports.[8] In addition, the ECRI/USA publishes the annual top ten of health hazards that assist in understanding risks in health procedures worldwide.

This work addresses risks associated with six pieces of equipment commonly used in ICUs. The first is the Automated External Defibrillator (AED, non-wearable), which uses external electrodes to analyze the patient's electrocardiogram (ECG) and automatically deliver an electrical shock to treat ventricular fibrillation on victims of sudden cardiac arrest.[9] The second, Direct-Current Defibrillator (low energy), delivers an electrical shock of up to 360J through paddles placed either directly across the heart or on the surface of the body, which is used for restoring normal heart rhythm in pediatric defibrillation or cardiac surgery.[10,11]

The third piece of equipment is the Infusion Pump (IP), which perfuses medications or nutrients to the patient at a controlled amount; a health professional programs the rate and duration of fluid delivery using the equipment's software.[5,12] Fourth is the Physiological Monitor (PM), which is a device connected to the patient, able to identify clinical emergencies when vital signs like heart rate, blood pressure, and oxygenation exceed preset thresholds; in this case, alarms are activated.[13]

The fifth is the Pulmonary Ventilator (PV), which involves a breathing tube placed in the patient's windpipe, connected to the mechanical ventilator, which delivers oxygenated air.[14] PV is used during surgeries or treatment for lung disease, essential to treat respiratory failure caused by COVID-19. Sixth is the Ultrasonic Scalpel (US), which generates harmonic vibrations in a metal rod that denatures proteins, cuts tissues, and coagulates them simultaneously.[15]

Unfortunately, there are harms associated with the use of these medical devices. Estimates from 2008 to 2017 have shown alarming results: defective medical devices may have caused more than 1.7 million injured patients and approximately 83000 deaths worldwide.[16] These data denote the importance of identifying types of failures, hazards, and their causes, as what can be done to reduce them. Thus, this work aims to present the main alerts, dangers, and failures related to the use of PV, IP, AED, DC-Defibrillator, PM, and the US. This overview of their main events can guide users for their most appropriate management and best practices when using these medical devices.

METHODS

The ECRI's top ten health technology hazards ranked annually (from 2016 to 2020) have guided our research regarding the types of equipment that most offer danger

to patients and the main ways to mitigate them. On the other hand, a review of documents published (since 2016) by FDA/USA and ANVISA/Brazil was also analyzed here, which report adverse events related to medical equipment. Several papers from the literature about that subject were analyzed too in our research.

The FDA database contains medical device reports submitted by mandatory reporters, manufacturers, importers, and facilities, in addition to voluntary reports by consumers, health care professionals, and patients.[7] The medical devices addressed in our research (AED - non-wearable and DC-Defibrillator - low energy; IP; Non-Continuous PV; PM - without arrhythmia detection or alarms; and the US) were searched in the FDA database within the period from January 1st, 2016 to April 30th, 2020. The cases from the FDA were classified into six categories defined in this study, which are shown in Table 3. It is worth mentioning that only reports of death and injuries for these devices were considered. The information found on the ANVISA databases is shown in Table 4. The searches for PV and AED were conducted considering the same period, and the alerts found were classified into three categories.

RESULTS

Main causes of failures in medical devices

In their historical development, medical devices have an increasing degree of complexity, with the development of new components and materials. This complexity impacted the maintenance and performance of the devices and their reliability,[17] which is directly related to the increased failure rate (Fig. 1).

The analysis of contributing factors in the appearance of faults demonstrates that causes are varied. Tables 1 and 2 respectively show the classification of incidents according to studies by Amoore using ECRI database and Shepherd.[18,19] In these tables, aspects as "device" are repeated, including manufacturing, materials, and maintenance. Another common factor is the "user" or "operator," i.e., ignorance, inadequate technical training, and staff negligence.[17]

In the scientific literature, it is possible to identify models such as the Swiss cheese, proposed by Orlandella and

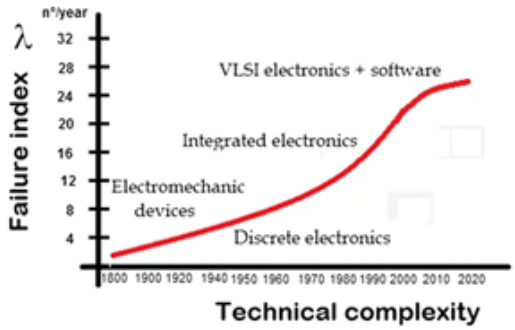

FIGURE 1. Reliability conditioned by technical complexity[17]

TABLE 1. ECRI Classification of medical device incidents[17]

Device	1) Human factor design 2) Parts design unexpected failure 3) Deterioration failure that requires preventive maintenance (e.g., Battery)
Operator	1) Training and use error 2) Diverted attention 3) Criminal intent
Facility	1) Human factor design 2) Parts design; unexpected failure 3) Deterioration that requires preventive maintenance 4) Maintenance error
Patient	1) Active patient action affected the outcome 2) Patient's condition affected the outcome

TABLE 2. Shepherd's Classification of medical device incidents[17]

Device	1) Design error 2) Device or accessory failure 3) Improper maintenance / testing / modification 4) Manufacturing error
User	1) Device miss-assembly 2) Failure in pre-use inspections 3) Improper connection 4) Improper reliance on an automated feature 5) Incorrect clinical use and control settings
External	1) Electromagnetic or radiofrequency interference 2) Power Supplies (including gas)
Support System Failures	1) Error in hospital policy 2) Failure to train 3) Improper storage 4) Lack of competent accident investigation 5) Poor pre-purchase evaluation

Reason, which allow understanding the system failures, which arise when protection measures are overcome (Fig. 2).[20] In that model, the human aspect is highlighted, which occurs when the error originates from inadequate actions from health personnel due to fatigue, stress, inattention, and negligence. Regarding the system, it is possible to standardize the security measures taken from design, quality control, safety testing, maintenance throughout the life cycle, and adequate user training. Each aspect is equivalent to a cheese layer, representing barriers to errors and present fragilities. Therefore, it is crucial to scientifically determine which layers are involved in medical device failures and ensure that these "cheese holes" are not aligned, creating problems.[17]

Another model is Pareto analysis, which shows that many failures occur in critical devices, being possible to determine the causes, allowing focusing professional attention on the most relevant situations and corrective actions. This model showed that misuse, lack of maintenance, and use by untrained personnel are the leading causes of medical equipment failures.[17]

Both models contain promising elements, which were applied in our research, detailed in the sections that follow.

FDA Adverse Events

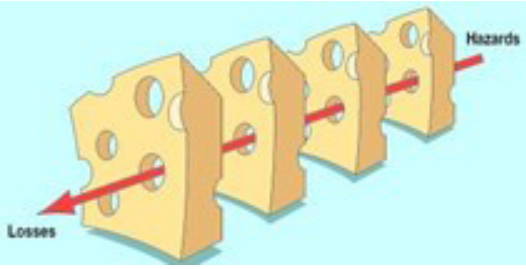

FIGURE 2. The Swiss cheese model for events occurrence[20]

The data in Table 3 shows adverse events related to devices of general clinical use (with important application in ICUs), such as the equipment addressed in our research: PM, IP, AED, and PV. In addition, Table 3 also shows the US equipment used in surgical procedures. Several cases were reported in the USA, totaling 3,100 events between 2016 and 2020. The highlights are the equipment AED and IP, which have 1,382 and more than 1,424 reports. The PV, US, and PM have, in that order, 187, 60, and 40 cases, respectively, whereas the DC-Defibrillator has only 7 cases.

The AED presented 831 cases of operating issues associated with malfunction and shock problems and problems in defibrillation and alarm errors. For this equipment, 77 cases were related to monitoring problems with incorrect messages, and 58 cases of assembly or structural defects due to the defective connection and impedance problems. Cases of incorrect procedures were 59 due to inappropriate actions that lead to burns. Hazards were 20 events of shock and burn to nurses and physicians. Finally, unknown reasons were 337 events. Regarding the DC-Defibrillator, which is activated manually, the seven cases were related to device operating issues generated by inappropriate shock. All events were related to severe cases, with four deaths and three injuries (Fig. 3).

For IP, we analyzed a total of 1,424 events related to injury and death. Most of them were related to device operating issues (913) due to stop working and failure to deliver medication. Still, flow obstruction and alarm error were also reported. The assembly or structural defects had 124 cases reported due to the component disconnection and broken devices. The monitoring problems, with 30 cases, occurred due to incorrect messages on display. Unknown reasons were 306 events.

PV covers 187 events, with 73 being device operating issues that correspond to airway pressure and oxygen saturation defects. The 65 hazard cases were linked to loss of smell sense and respiratory distress. Assembly or structural defects were 43 cases related to broken pieces, connection of tubing problems, and inadequate humidification. The PM comprised 40 cases, ten device operating issues related to alarm problems, software, and electronic motherboard problems. Incorrect procedures were due to inadequate or insufficient training. Seventeen monitoring problems were due to inappropriate electrocardiograms and incorrect display messages. The US had 60 cases, 43 due to device operating issues linked to failure to cut, malfunction during surgery, and energy output problems. The remaining cases were divided into assembly or structural defects and hazards, with 10 and 7 cases, respectively, including disconnecting components and fragmented material.

TABLE 3. Adverse events reported in FDA databases during January 1st 2016 to April 30th 2020[1].

Medical Devices	Assembly or structural defects	Device operating issues	Hazards	Incorrect procedures	Monitoring problems	Unknown reasons	Total
AED (non-wearable)	58 (4%)	831 (60%)	20 (1%)	59 (5%)	77 (6%)	337 (24%)	1,382
DC-Defibrillator	-	7 (100%)	-	-	-		7
IP	124 (9%)	913 (64%)	10 (1%)	41 (3%)	30 (2%)	306 (21%)	1,424+ [1]
PM	-	10 (25%)	10 (25%)	3 (7,5%)	17 (42,5%)	-	40
PV	43 (23%)	73 (39%)	65 (35%)	-	6 (3%)	-	187
US	10 (17%)	43 (72%)	7 (11%)	-	-	-	60
Total	235	1877	112	103	130	643	3,100

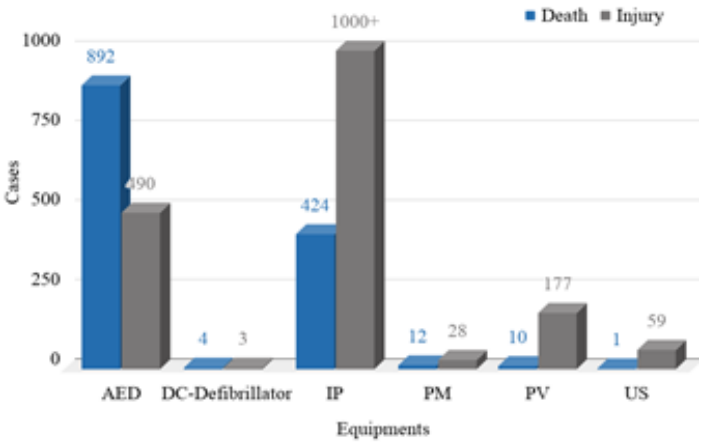

FIGURE 3. Graph of death and injury found in FDA referring to Table 3[1]

The FDA's adverse events are again shown in Fig. 3, but in this case, separating death and injury provoked by the device. Again, the data are alarming for AED, with 892 deaths and 490 injuries related to events. IP has 424 deaths and more than 1,000 injury cases. Injuries were also more common than death for PV, PM, and the US.

ANVISA Adverse Events

The data from ANVISA/Brazil is restricted to national and international events with medical devices used in Brazil. The search on this public agency official page offers gross values, often unrelated to the device. Thus, we identified 38 alerts for PV and 37 alerts for AED (Table 4).

TABLE 4. Adverse events reported in the ANVISA/Brazil databases during January 1st 2016 to April 30th 2020.

Medical devices	Device operating issues	Assembly or structural defects	Manipulation or installation problems	Total
PV	26 (68%)	8 (21%)	4 (11%)	38
AED	29 (78%)	8 (22%)	-	37
Total	55	16	4	75

PV presents most cases of device operating issues, totaling 26. Of these, 24 are related to display and oxygen sensor failure, incorrect ventilation, and stop working; and two cases were caused by problems with equipment alarm, such as sound-related problems. The assembly or structural defects were eight cases due to lack of soldering on the plate, leading to loss of power and short circuit interrupting the ventilation. Manipulation or installation problems (four cases) occurred due to problems in the power panel of the ventilators. For this type of device, three alerts contained records of death and 11 cases of patient hypoxia, which could cause sequelae and lead to death.

AED presented 29 cases of operational problems, such as electric shock error, cable failure, attenuated discharge in defibrillation, and alarm error, which could lead to death and injury of the patient. For assembly or structural defects, there were 8 cases of battery drainage and component failures.

[1] Considering up to 1,000 cases for IP related to injuries and all 424 cases related to death

Top Ten Health Hazards of the ECRI

The ECRI is a nonprofit organization, which develops guidance for improving the safety and quality of care across all healthcare environments worldwide. Every year they produce a report of the top 10 health technology hazards, whose items represent hazards that managing technologies can minimize. ECRI's engineers, scientists, and clinicians select topics based on insight gained through investigating, testing, observing operations, reviewing the literature, and speaking with clinicians, clinical engineers, administrators, and device suppliers.[21-25]

Comparing our results to ECRI lists, we noticed a convergence regarding problems and errors presented by the six devices evaluated. Devices alarm problems were present in all five lists considered. For PV and IP, alarm malfunction, overload, and loss of alarms could induce severe consequences in patients. Infusion errors appear in the 2017 and 2019 lists. Problems with device operation by the medical team were listed in 2016 and 2019; however, many other cases were related to inadequate procedures.[21-25] Regarding device cleaning, alerts were on the five lists due to patient infection or technical problems arising from incorrect cleaning. Structural problems appeared in 2020 (such as the risk of loose nuts and bolts to device failures) and 2019 (about device battery charging defects). From 2017 to 2020, cybersecurity risks were emphasized due to system exploitation by hackers, causing health care disruption.[21-25]

DISCUSSION

Nowadays, practically all health specialties need modern technologies, going beyond health establishments to patients' homes. However, the risk of adverse events concerning these technologies is growing rapidly. These events can result from a single cause or the simultaneous occurrence of several factors, with the clinical team generally being held responsible. However, we identified several causes to be considered in all processes: the choice of technology, proper installation, technical maintenance throughout the life cycle, and correct use in relation to the patient.

The results shown in Tables 3 and 4 suggest high reliability. However, it is worth commenting that In this sense, Table 3 shows adverse events recorded at the FDA/USA whereas Table 4 presents alerts from ANVISA/Brazil.

The hazard for patients occurs when: an alarm condition is not detected by a medical device (such as IP, PM, or PV); the condition is detected but not communicated to a staff member, or the condition is communicated but not appropriately addressed.[20] Regarding the PV, injuries occur mainly in the respiratory tract because the patient depends on this equipment for ventilation. Errors in the air supply, if not rectified, can lead to damage like hypoxic brain or lung injury and death, as shown in some records in this study. These devices have alarms that indicate inadequate ventilation, so proper configuration is needed. However, the challenge is to manage the alarms, which are usually missed due to alarm fatigue (when the team is overloaded), lack of sound sensitivity, or failure in the notification of alarms, in which they are not effectively communicated to staff.[26]

Other factors contributing to the inadequate ventilation implementation include insufficient knowledge of the best practices for ventilation and ventilator functionality.[21] Healthcare facilities need policies on setting ventilator alarms and protocols for verifying components. In addition, too often, lung-protective strategies and advanced ventilator tools are not commonly used, and best practices are not adopted.[22,24] Mitigate these problems by verifying that all staff members dealing with mechanical ventilation have a good understanding of how these devices work.[21]

PM is used in physiological monitoring. The improper customization of the alarms could make it more difficult for the operator to understand changes in the patient's physiological conditions or problems with the device. These systems must be configured not to act too many alarms or too few alarms, as this involves settings based on the needs of a care area and the patient's condition. In addition, establishing policies and educating staff about optimal alarm-customization practices can help reduce the risks of loss sounds and harm to the patient.[13,24,27]

A total of 424 deaths and up to 1,000 injuries (Fig. 3) related to IP were recorded in this study. The incorrect programming procedure performed by the medical team occurs even with smart pumps that have a dose error reduction system. In this case, the patient can receive either too much or too little solution. The complex programming display and the absence of procedures to verify the programming can contribute to these errors. Thus, the surest way to eliminate them is to use auto and double-checks programming. Still, the staff needs to notice signs of damage to the IP components to guarantee the correct flow of medication.[22,24]

The AED has high values of death and injury, respectively 892 and 490 cases in FDA. The relationship to the death of patients undergoing resuscitation is mainly linked to the operational failure of the device, for example, not providing an adequate charge or discharge. Successful defibrillation depends on delivering the shock to the myocardium, as the longer brain and heart are deprived of oxygen, the more damage suffers.[10,11]

The US is reported to be quick for the cutting and coagulation of tissue.[28] Studies claim the benefits of this equipment, including allowing faster and safe surgical procedures.[29] However, the alerts show that no device is exempt from technical and human failures; for example, there might be improper cutting.

Achieved results indicate the essential need for better protocols on activity verification and medical equipment quality control, especially for high-risk instruments. It is also necessary to provide medical staff training about the operation and execution parameters of all equipment to get good accuracy.[11]

Another critical point is the medical equipment maintenance carried out by clinical engineers. Thus, the predictive maintenance that accompanies equipment performance parameters, aiming to define the right moment of the intervention, with the maximum use of the asset, proves to be profitable, combining operational safety of the equipment and cost.[30] On the other hand, preventive maintenance, according to NBR 5462-1994, "is carried out at predetermined intervals, or according to prescribed criteria, designed to reduce the probability of failure or degradation of the functioning of an item"[31], therefore offering more safety.

In Brazil, to guarantee the safety and the values measured within the reliability standards of medical equipment and to obtain the Brazilian certification by the National Institute of Metrology, Quality and Technology (INMETRO), the clinical engineering team management performs testing and calibration of equipment following Brazilian standards, such as RDC number 02 and NBR15943.[4,32] The manufacturers and distributors have a great responsibility in producing equipment in compliance with regulations and quality requirements.

On the other hand, health authorities must follow regulations, conduct technological surveillance, and collect information about events. In health establishments, the clinical and biomedical engineers are professionally trained to relate scientifically to devices, being increasingly important in product certification, choosing technologies and training of personnel, and thus helping to avoid serious failures.[17]

To evaluate the events addressed in our research, we used Pareto's analysis to prioritize corrective actions and quantify the causes of problems in medical devices, allowing focusing the professional's attention on the most relevant causes. The Swiss cheese model was used when protective measures of systems were overcome by circumstantial factors that combined them and produced an undesirable result. This model encompasses human aspects, such as faulty actions and the system, which need barriers against errors (cheese layers). The layers represent points in developing and using a device that can have weaknesses, so these layers cannot align.[17]

Finally, the alerts, hazards, and adverse events registered allowed us to identify the best practices to be adopted concerning the highlighted medical devices. This included increasing the training of operators and technicians in maintenance, expanding predictive maintenance, changing the corrective maintenance modus operandi, adapting the infrastructure of the health care establishment (hospital, clinic, polyclinic, etc.), identifying the need

to replace obsolete technologies, providing feedback to manufacturers and suppliers of medical technologies, and suggesting new public policies for the management of medical devices among other actions.

CONCLUSIONS

The common faults in AED, DC-Defibrillator, IP, PM, PV, and US are related to alarm conditions not being issued by the medical device or not being adequately addressed by the team of professionals. In addition, these professionals are often not adequately trained to deal with the devices, the scarcity of system verification protocols, errors in the automatic execution of standard processes, lack of maintenance and programming according to the patient's needs.

All medical devices can fail; however, the failures must be avoided by adequately selecting and maintaining these devices. For that purpose, it is necessary to pay attention to medical devices' clinical and technical needs, perform regular equipment tests and maintenance, and medical team training. In addition, the medical devices must have adequate incorporation with an extensive search for suppliers, involving technical, clinical, budgetary, and infrastructure areas, allowing for a specification that meets the clinical, operational, and cost.

To understand and mitigate adverse events, this work shows that it is essential to apply models to analyze their causes, for example, Pareto's analysis, which prioritizes corrective actions. In addition, it is necessary to stratify the types of adverse events for medical equipment, for example, using the layers of the Swiss cheese model to help understand which stages of development and use of the device contributed to the failures.

Indeed, future research and studies with other international databases are necessary to widen the outcomes obtained in our research. Nevertheless, we believe that all aspects brought through applying models from Pareto's analysis and Swiss cheese can impact the mitigation of these adverse events and, consequently, offer end-users safer medical devices and more effective health care.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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A risk assessment method based on the failure analysis of medical devices in the adult Intensive Care Unit

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ABSTRACT

Backgrounds and Objective: The Intensive Care Unit (ICU) receives patients whose situation demands high complexity tasks. Their recovery depends on medical care, their response to medications and clinical procedures, and the optimal functioning of the medical devices devoted to them. Adverse events in the ICU due to failures in the facilities, particularly medical devices, impact the patients, operators, and all involved in their care. The origins of the technological failures seem to be more oriented to the interaction between the equipment and the operator. Once the medical equipment is functioning, we must guarantee its correct execution to meet both the clinical service's objectives and the expectations of those involved in care, including the patients themselves. We present an approach to quality management based on failure analysis as the source of risk for medical devices' functioning and operation in the ICU. We decided to address it through a systematic approach by using elements from the Failure Mode and Effects Analysis (FMEA) method and the Ishikawa diagrams' support to obtain the causes graphically.

Material and Methods: We used the risk analysis framework as a basis of the methodology. By obtaining the causes and sub causes of technological failures in the ICU for adult patients, we adapted some of the FMEA method and applied the Ishikawa diagrams to analyze the relationship between cause and failure. The ICU devices came from the Official Mexican Standard and the World Health Organization (WHO) information related to the ICU operation and facilities. The data from the causes of failure came from specialized consultation and discussion forums on medical devices where these topics were addressed; we searched for over five years in Spanish forums. We proposed a calculation of the Risk Priority Number based on the information subtracted from the forums. Then, we defined an indicator showing the priority level used to address the issue.

Results: In general, the results showed that most of the medical equipment failure causes have medium and high-risk priority levels and, in some cases, the cause presented as the most prevalent did not match with the reported in official documents such as technical or operation manuals. The most frequent causes found are related to electrical system issues and operation skills. We presented three study cases: defibrillator, vital sign monitor, and volumetric ventilator, to show the risk level designation. The conclusions inferred from these cases are oriented to training strategies and the development of support material in Spanish.

Conclusion: The development of risk management methodologies to monitor and solve potential hazard situations in critical areas is valuable to the health technology management program. The FMEA method showed a solid basis for the risk assessment processes, and its application to the ICU medical technology allowed the creation of the evidence supporting the decision-making process concerning strategic solutions to guarantee patient safety.

Keywords – *Risk Assessment, Failure analysis, FMEA, ICU medical equipment, Health Technology Management.*

INTRODUCTION

The patients in the Intensive Care Unit (ICU) are under unique circumstances. This situation is due to the requirement of specialized multi-organ support actions needed to restore their health, including medical devices.[1] Furthermore, the ICU patients' complexity makes them depend on medical care, their response to medications and clinical procedures, and the optimal functioning of the medical devices devoted to them. Studies carried out in this regard have shown the impact of failures related to technology and its applications in the analysis of adverse events at ICU,[2] and the importance of safety improvement in using medical devices in this area to have greater control of incidents.[3]

Technological failure is defined in the hospital environment as an event in which medical equipment has stopped working correctly, which is associated with a probability of harming the patient or the operator.[4] The origin of technological failures can be approached from different perspectives; some of the most relevant has to do with the negative effect on the patient or the context of medical devices' operation. Some sources of failure that have been identified in this regard are[5]:

- The wrong dynamic range of measurement
- A lack of training in the operation of the equipment
- A lack of quality control in measurements
- A lack of quality control in pre-installations
- The wrong design

The origins of the technological failures mentioned are more oriented to the interaction between the equipment and the operator. Once the equipment is in operation, we must guarantee its correct execution to meet both the clinical service's objectives and the expectations of those involved in care, including the patients themselves. In this sense, technological failure becomes a reference point for developing plans and strategies that help improve quality. Within this frame of reference, aspects related to the medical device's operation will be taken as a quality feature so that the failure analysis approaches from a strictly technological perspective. Furthermore, it implies that the factors associated with its operation and functioning, including infrastructure, device design, and human resources, will be analyzed around the medical device and not as independent causes. Thus, we can design strategies for the containment and eventual elimination of the fault.

As for the ICU, analyzing the causes of medical devices' failures will make it possible to develop plans for risk management and control of related incidents. This kind of management process is particularly relevant, given the vulnerable condition of the patients treated in ICU demands actions that guarantee their safety and those who interact with them. We must address two considerations: a failure may be due to more than one factor, and in ICU, the potential factors involved increase the difficulty of the analysis. We decided to address the issue through a systematic approach, so we chose to take the Failure Mode and Effects Analysis (FMEA) method.

FMEA method is a systematic process that identifies the potential product or process design failures before they occur to eliminate them or minimize the associated risk.[6] Although this method has been used more frequently in the automotive industry; it can detect and contain potential failures in various natures' products and processes. Therefore, its application to the medical field has been growing.[7] It includes improving patient safety,[8] the analysis of risk points in the implementation of smart devices,[9] its application in radiotherapy,[10] or quality management in the clinical laboratory.[11] FMEA method integrates two stages for its implementation: identifying the failure and its evaluation.[12]

The identification stage includes the following: the process' phases list to be analyzed, the potential failure modes, the identification of the effects, if the failure mode occurred, the causes that could have originated them, and the discovery of the controls that the process has to prevent failures from happening, that is, prevention and detection. The evaluation stage evaluates the severity, occurrence, and detection of the failure and identifies the points to apply corrective and improvement actions. Finally, the stage is complemented by assigning risk through an indicator and prioritizing failure modes to take action.

Tools such as Pareto diagrams or cause-effect diagrams are common to identify the causes of failures. In this case, we selected the Ishikawa diagram because it facilitates analyzing problems and solutions in aspects such as quality of processes, products, and services. The Ishikawa diagrams rely on a logical order to structure the information and take the form of a fishbone; the multiple cause

and effect relationships of the variables that intervene in the processes are presented.[13]

We present an approach to quality management that starts from analyzing failures as sources of risk for medical devices' functioning and operation in the ICU. From the FMEA, we used the first stage, identification of the failure. Then, with the Ishikawa diagrams' support, we obtained graphic displays of its causes and origins where created, which, together with a numerical indicator, allowed determining the prioritization of corrective actions.

METHODS

The methodology we used was founded on the risk analysis framework. By considering the technological failures that occur in the ICU for adult patients, we identified their causes and sub-causes. We adapted some elements from the FMEA method with the support of Ishikawa diagrams to analyze the relationship between cause and failure.

We obtained the ICU medical devices' identification to be analyzed from the Official Mexican Standard NOM-025-SSA3-2013 for the organization and operation of intensive care units[14] and the central medical equipment section of the World Health Organization (WHO).[15] Then, for each piece of medical equipment, the causes of failure were classified into the following five categories[13] and incorporated into an Ishikawa diagram:

- Human resources that are involved in the operation
- Environment or conditions under which medical equipment operates
- Materials used for its operation
- Methods for the development of functions for its operation
- Machines or any equipment or tools required to perform the work

We obtained the information to identify the possible causes of failures associated with using the equipment from the search in specialized consultation and discussion forums on medical devices where these topics were addressed; we searched for over five years in Spanish forums. Among the platforms consulted are yoreparo.com, ayudabiomedica.com, forumsdeelectronica.com, sefh.es, and elhospital.com. The information was completed by consulting the equipment's technical and operation manuals. We identified the possible causes of a failure for each medical equipment and, based on the number of mentions found in the forums consulted, their priority level. We determined to evaluate the quality of operation of each piece of equipment by defining the following metric based on the Risk Priority Number (RPN) that, according to the FMEA evaluation stage, is defined by

$$RPN = Severity * Occurrence * Detection \quad (1)$$

Each of the terms included in (1) were adapted to the forum information context, so:

- Severity is computed by taking the number of found mentions per specific cause divided by the highest value of mentions per any cause in the medical device.
- Occurrence is calculated by taking the number of mentions per specific cause divided by the total number of mentions in the medical device.
- For Detection we proposed to assign three levels of impact of the failure, 1 to low, 2 to medium, and 3 to high, according to the information reported in the equipment's medical manuals. We carried out the assignment by searching the troubleshooting sections for the frequency of reported failures and solutions, assigning a higher level to the most frequent.

Then, we defined an indicator that shows a level of priority that can be used to address the issue. First, we normalized the RPN for each failure cause in the equipment (RPNn); then, we classified it into low, medium, and high categories based on the proportion of the RPNn failure cause within the related equipment. In general, high class was assigned to RPNn > 0.5, low priority to RPNn < 0.1, and medium priority to RPNn between these two values. Following, we proposed a priority level percentage indicator that shows the general situation of the equipment as:

%_Priority_Level = (Number of mentions per RPN class/ number of total mentions per equipment)*100

We determined each medical equipment's risk level based on the percentage of failures with high and medium priority levels obtained from the priority indicator. These results enabled us to focus on specific issues to develop action plans to address them.

RESULTS

The ICU medical equipment included in the analysis were:

- Apnea monitor
- Central monitoring
- Defibrillator
- Hospitalization bed
- Infusion pump
- Portable X-ray system
- Vital sign monitor
- Volumetric ventilator

The numbers of causes found, total mentions identified, and percentages of priority levels for each one are shown in Table 1.

We present below the Defibrillator, Vital Signs Monitor, and Volumetric Ventilator cases to illustrate the results.

TABLE 1. Causes, Mentions, Priority Levels (PL) Percentage Found in ICU Medical Devices

Medical Device	Causes	Total Mentions	% High PL.	% Medium PL.	% Low PL.
Apnea Monitor	11	24	50	33.33	16.67
Central Monitoring	10	24	62.50	25	12.50
Defibrillator	14	39	53.85	33.33	12.82
Hospitalization Bed	13	34	26.47	44.12	29.41
Infusion Pump	14	55	49.09	21.82	29.09
Portable X-ray	17	69	39.13	23.19	37.68
Vital Signs Monitor	15	39	46.15	38.46	15.38
Volumetric Ventilator	13	38	28.95	44.74	26.32

Case 1: Defibrillator.

Table 2 shows the causes found, the number of mentions, the values of severity, occurrence, and detection obtained, and the computed normalized RPN. The cause with the highest number of mentions was the suspension of the electrical system with 5. In contrast, the causes with the lowest number of mentions were related to the equipment's documentation. The prioritization was carried out as follows:

- Low priority: $0.01 \leq RPN_n \leq 0.1$
- Medium priority: $0.16 \leq RPN_n \leq 0.24$
- High priority: $0.43 \leq RPN_n \leq 1$

The last column's color corresponds to the priority class assigned, green to low, yellow to medium, and red to high priority level.

To illustrate obtaining the Severity, Occurrence, Detection and RPN_n values, we will take the failure cause "Insufficient battery charge" (ibc).

Then, we get the RPN_n :

The Max_RPNdefibrillator was obtained from computing severity, occurrence, and detection of the failure cause

$$Severity_{ibc} = \frac{Mentions_{ibc}}{Highest\ Mention\ Number_{defibrillator}} = \frac{4}{5} = 0.8$$

$$Occurrence_{ibc} = \frac{Mentions_{ibc}}{Total\ Mention\ Number_{defibrillator}} = \frac{4}{39} = 0.102$$

$$Detection_{ibc} = 3\ (It\ was\ found\ in\ all\ the\ manuals\ consulted)$$

with most mentions (Emergency electrical system). Since

$$RPN_{n\_ibc} = \frac{Severity_{ibc} * Occurence_{ibc} * Detection_{ibc}}{Max\_RPN_{defibrillato\ r}} = \frac{0.8 * 0.102 * 3}{0.3846} = 0.6365 \approx 0.64$$

TABLE 2. Causes, Mentions, RPNn Data, and Priority Classes Found in the Defibrillator

Cause found	No. Mentions	Severity	Occurrence	Detection	RPNn
Emergency electrical system	5	1	0.128	3	**1**
Suspension of electrical service	4	0.8	0.102	3	**0.64**
Insufficient battery charge	4	0.8	0.102	3	**0.64**
Difficulty using the defibrillator	4	0.8	0.102	3	**0.64**
Broken electrode cables	4	0.8	0.102	2	**0.43**
Transients caused by other loads with the same supply	3	0.6	0.076	2	**0.24**
Voltage fluctuations	3	0.6	0.076	2	**0.24**
Power cord	3	0.6	0.076	1	**0.12**
Poor electrode cleaning or incorrect application	2	0.4	0.051	3	**0.16**
Battery life	2	0.4	0.051	2	**0.11**
Faulty electrodes	2	0.4	0.051	3	**0.16**
Incorrect electrode placement	1	0.2	0.025	2	**0.03**
Lack of manuals and/or guides	1	0.2	0.025	1	**0.01**
Difficulty with the documents' language	1	0.2	0.025	1	**0.01**

$RPN_{n\_ibc} > 0.5$, the priority for this failure cause is high, so it gets the red color.

Next, we elaborated the Ishikawa diagram, shown in Figure 1, where the causes of failures were located in the established categories based on their failure impact, the most significant impact near the fishbone. The colors indicate the assigned priority level: red-high, yellow-medium, and green-low.

Case 2: Vital Signs Monitor.

Table 3 shows the causes found, the number of mentions, the values of severity, occurrence, and detection obtained, and the computed normalized RPN. For example, the cause

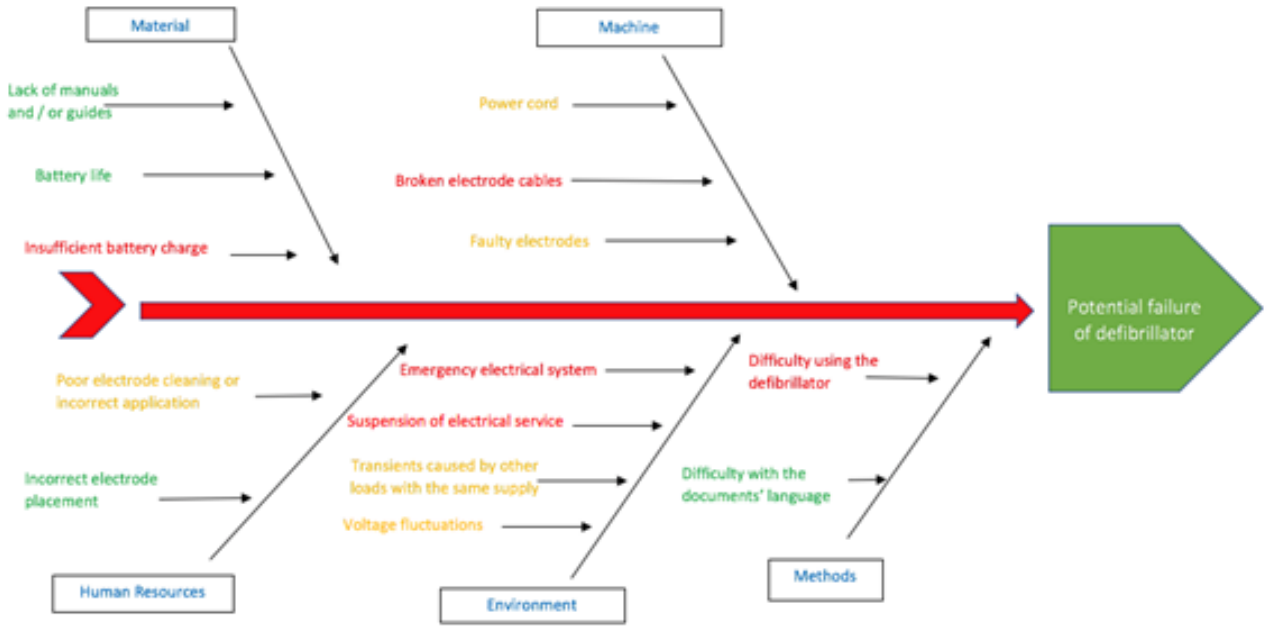

FIGURE 1. Ishikawa diagram for the defibrillator failure analysis.

with the highest number of mentions was related to the emergency electrical system with 6. On the other hand, the causes with the lowest number of mentions included electrical supply and equipment documentation issues. In this case, the prioritization was carried out as follows:

- Low priority: $0.03 \leq RPN_n \leq 0.06$
- Medium priority: $0.11 \leq RPN_n \leq 0.25$
- High priority: $0.35 \leq RPN_n \leq 1$

As in the previous case, the last column's color corresponds to the priority class assigned, green to low, yellow to medium, and red to high priority. We elaborated the Ishikawa diagram corresponding to this medical equipment, shown in Figure 2, using the same settings for the previous case of the failure location and the color assigned according to the priority.

We elaborated the Ishikawa diagram corresponding to this medical equipment, shown in Figure 2, using the same settings for the previous case of the failure location and the color assigned according to the priority.

Table 4 shows the causes found, the number of mentions, the values of severity, occurrence, and detection obtained, and the computed normalized RPN. In this equipment, the cause with the highest number of mentions was related to the power cord with 6. On the other hand, there were only two causes with the lowest number of mentions, including electrical transients and pneumatic systems. In this case, the prioritization was carried out as follows:

- Low priority: $0.01 \leq RPN_n \leq 0.17$
- Medium priority: $0.22 \leq RPN_n \leq 0.38$
- High priority: $0.69 \leq RPN_n \leq 1$

The last column shows the priority class assigned: green to low, yellow to medium, and red to high priority level following the color agreement.

In the same way, we elaborated the Ishikawa diagram corresponding to this medical equipment, shown in Figure

TABLE 3. Causes, Mentions, RPN Data and Priority Classes Found in the Vital Signs Monitor

Cause found	No. Mentions	Severity	Occurrence	Detection	Norm. RPN
Emergency electrical system	6	1	0.153	2	**1**
Suspension of electrical service	5	0.833	0.128	1	**0.35**
Power cord	4	0.666	0.102	3	**0.67**
Difficulty using the monitor	3	0.5	0.076	3	**0.38**
Insufficient backup batteries	3	0.5	0.076	2	**0.25**
Communication with the non-invasive pressure module sensor	3	0.5	0.076	2	**0.25**
Battery charge timeout	3	0.5	0.076	1	**0.13**
Lack of knowledge of the use of the control console for calibration and adjustment (software)	2	0.333	0.051	3	**0.17**
Communication with the heart rate module	2	0.333	0.051	3	**0.17**
Communication with the pulse oximetry module	2	0.333	0.051	2	**0.11**
Communication with the temperature module	2	0.333	0.051	1	**0.06**
Voltage fluctuations	1	0.166	0.025	3	**0.04**
Lack of manuals and / or guides	1	0.166	0.025	3	**0.04**
Transients caused by other loads with the same supply	1	0.166	0.025	2	**0.03**
Difficulty with the documents' language	1	0.166	0.025	2	**0.03**

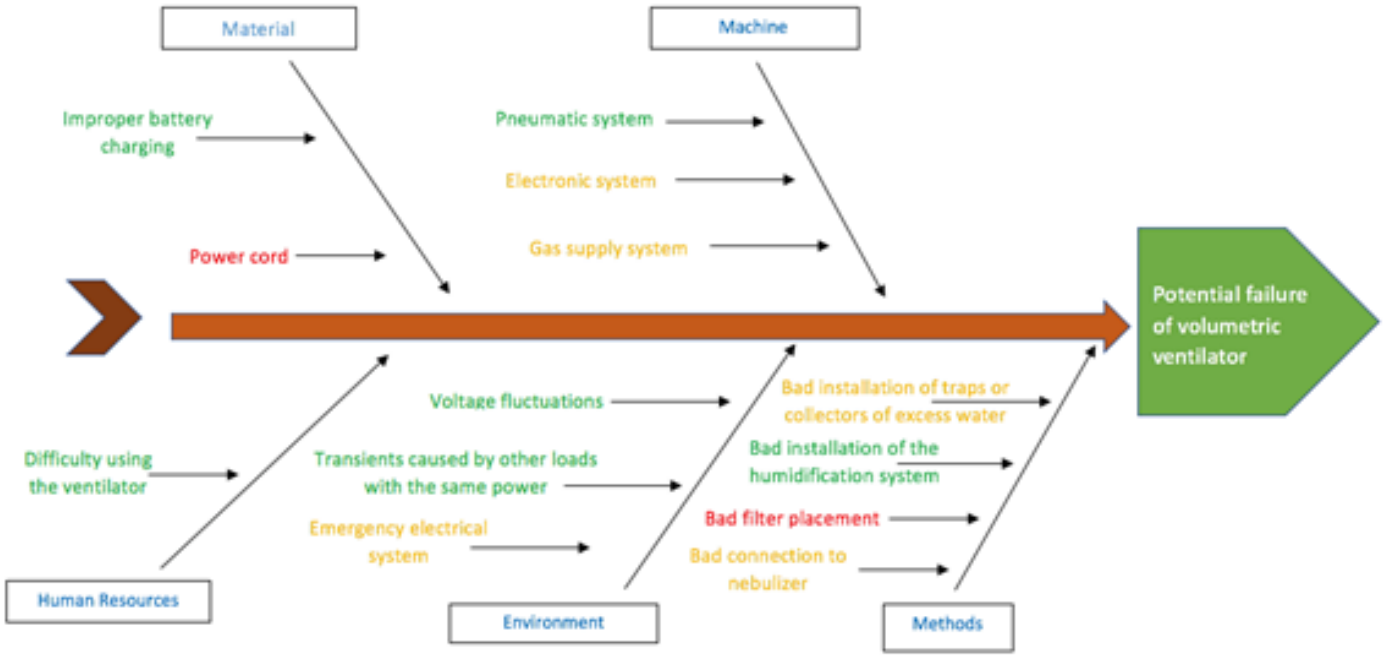

FIGURE 2. Volumetric Ventilator

TABLE 4. Causes, Mentions, RPNn Data and Priority Classes Found in the Volumetric Ventilator

Cause found	No. Mentions	Severity	Occurrence	Detection	Norm. RPN
Power cord	6	1	0.157	2	**1**
Bad filter placement	5	0.833	0.131	2	**0.69**
Bad connection to nebulizer	4	0.666	0.105	1	**0.22**
Emergency electrical system	4	0.666	0.105	1	**0.22**
Bad installation of traps or collectors of excess water	3	0.5	0.078	3	**0.38**
Gas supply system	3	0.5	0.078	3	**0.38**
Electronic system	3	0.5	0.078	2	**0.25**
Bad installation of the humidification system	2	0.333	0.052	3	**0.17**
Improper battery charging	2	0.333	0.052	3	**0.17**
Voltage fluctuations	2	0.333	0.052	2	**0.11**
Difficulty using the ventilator	2	0.333	0.052	2	**0.11**
Transients caused by other loads with the same power	1	0.166	0.026	3	**0.04**
Pneumatic system	1	0.166	0.026	1	**0.01**

3, using the same priority color assignment of the other cases.

Table 5 shows the failures that occurred most frequently in the remaining ICU medical equipment's consultation forums and Table 6 shows the risk level assigned after considering the priority levels obtained from the analysis.

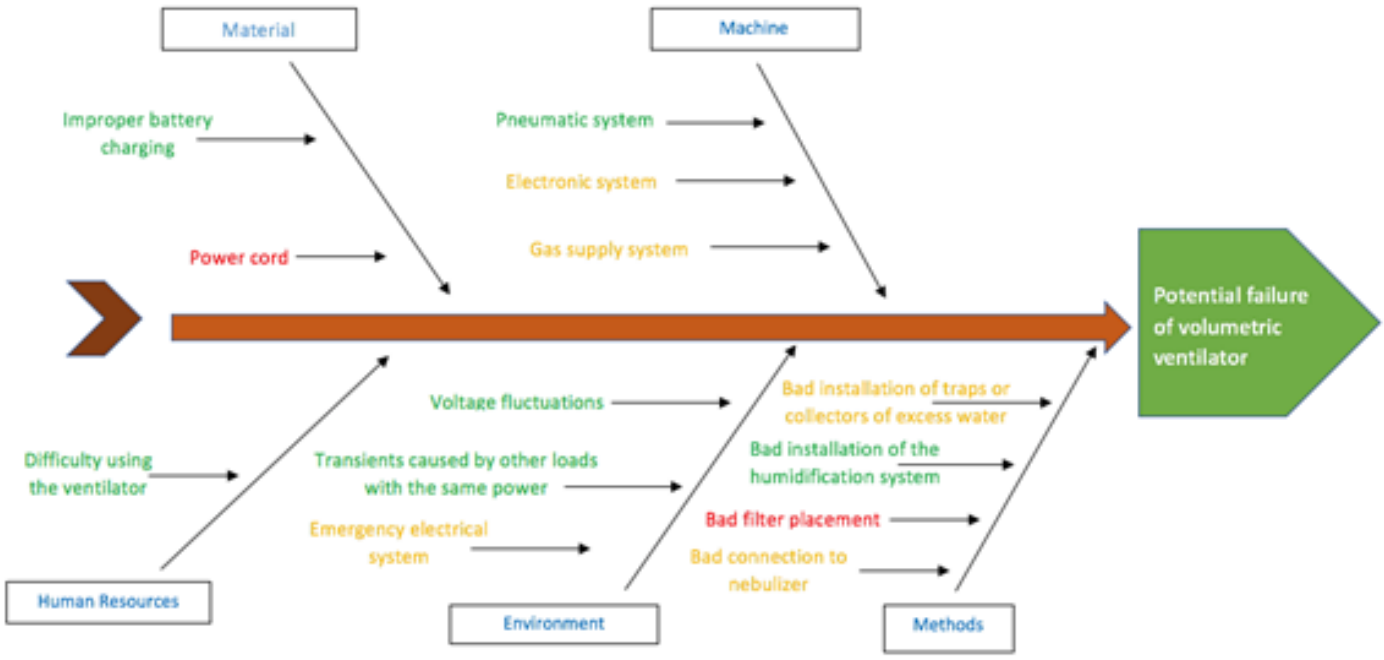

FIGURE 3. Ishikawa diagram for the volumetric ventilator failure analysis. Modified from [19]

The performance of each piece of equipment was obtained from considering the high and medium priority levels. Accordingly, we established the following Risk Levels:

- High: 75≤PL≤100. The equipment's operation presents failures that must be addressed immediately since its impact directly affects the patient's condition. The actions to be taken must be a priority so that the failure does not cause a significant problem.
- Medium: 51≤PL≤74. The equipment generally works as expected, but some elements indicate that a failure could compromise the performance and have consequences for patient care.
- Low: 0≤PL≤50. The equipment works ideally or closely. Care measures should focus on maintaining and improving its functioning to have the level of risk under control.

DISCUSSION

Risk management is a crucial element for the efficient management of medical technology. Unfortunately, its principles and applications in this area have not yet reached a desired level of consolidation, so work on

TABLE 5. Most Frequent Failure Causes in the ICU Medical Equipment

Failure	Medical Equipment
Suspension of electrical service	Apnea Monitor
Emergency electrical system	Apnea Monitor
Suspension of electrical service	Central Monitoring
Emergency electrical system	Central Monitoring
Wear of controls, handles and knobs	Hospitalization Bed
Connections box	Hospitalization Bed
Difficulty using the hospitalization bed	Hospitalization Bed
Lack of knowledge in the use of the control, calibration and adjustment system (software)	Infusion Pump
Emergency electrical system	Infusion Pump
Voltage fluctuations	Infusion Pump
Hold alarm	Infusion Pump
Emergency electrical system	Portable X-ray system
Overheating	Portable X-ray system
Inactivity	Portable X-ray system
Suspension of electrical service	Portable X-ray system
Inefficient equipment placement	Portable X-ray system

TABLE 6. Risk Level Assigned to the ICU Medical Equipment

Medical Device	PL High+ Medium	Risk Level
Apnea Monitor	83.33	High
Central Monitoring	87.5	High
Defibrillator	87.18	High
Hospitalization Bed	70.59	Medium
Infusion Pump	70.91	Medium
Portable X-ray	62.32	Medium
Vital Signs Monitor	84.61	High
Volumetric Ventilator	73.69	Medium

this issue should be promoted. In a critical area, the risk management repercussions impact both the patient and the operator, even reaching the infrastructure due to the complicated relationship these components have for functioning. Failure analysis is an approach to risk management that allows evaluating quality, in this case, reflected in operation, and provides elements that can be integrated with those used to manage medical equipment, such as schedules and maintenance reports, preventive or corrective maintenance documents. These components provide relevant information, but it is their systematic and well-documented integration that adds value for the development of action plans to control these failures.

The FMEA method has proven to be a practical analytical element in different settings. At ICU, it has been applied to evaluate clinical aspects such as pressure injury due to critical illness combined with interventions and therapies.[16] When adapting some of the FMEA components to the information obtained from the ICU's equipment, it is possible to analyze the interaction between the different natures of the causes that generate failures. The Ishikawa diagrams complemented the analysis by contrasting the practical occurrence of the failures reported in the forums, with which they report the technical and operation manuals, which we would consider as more formal and official documentation.

The consultation and discussion forums are a source that may not offer high reliability compared to the information obtained from more official and formal documentation such as technical or operating manuals. However, their presence in the community shows a practical reality of the failures that appear in the engineers' and technicians' daily actions and technicians in charge of attending to the equipment considered; it also represents a need to share and communicate problems and solutions at a higher level of specificity. The quality of this source depends on the seriousness with which the community presents the cases and their responses; we assume this requirement is met given these forums' purpose.

The results show that in practice, ICU medical equipment requires constant and detailed care. None of the equipment was considered obtained at a low-risk level; this implies a constant presence of risk that may come from different sources. Portable X-ray is the device with the lowest risk level; although it is not continuously used, its most prevalent causes are related to infrastructure and operating conditions. In contrast, the monitoring devices are the ones that obtained a higher score in the level of risk; problems associated with the quality of the electrical system are more prevalent as causes of failure. In the case of the vital signs monitor (case 2), it is striking that the difficulty in its use has a high priority. The lack of knowledge of the control console's use for calibration and adjustment (software) has medium priority, and the lack of manuals and documentation has low priority. The location of these causes in the Ishikawa diagram indicates that they have a high impact on the occurrence of potential equipment failure. With this information, a latent training need and the development of support material in Spanish for staff can be inferred.

The defibrillator is another device that scored high risk, and both the level assigned to the high and medium priority causes generally match its location on the Ishikawa diagram. This situation indicates that it is clear what actions must be taken to control this equipment's risk, those related to the electrical supply, its use, the battery's charge, and electrodes. In the case of the volumetric ventilator, the highest priority causes are related to the operator's handling of equipment components, particularly the filter and the power cable. When complementing the Ishikawa diagram analysis, a situation similar to the one presented in the vital signs monitor can be seen, a training and support material problem is detected.

In general, the found results contrast with those of other studies that used the FMEA method in the ICU, where the failures with the highest priority related to alarms of the ventilation device[17] or increased rates of internal

infection due to the inadequate operation of the medical equipment[18] are reported. It is important to note that the FMEA method's application in each case depends on the quantity and quality of the information collected and that the value of the results will be maintained in direct relation to its updating.

The limitations of this article are oriented to the data and its scope. Information from general and non-formal sources was used instead of a specific source such as an ICU of a particular hospital or a health system. Consequently, the results show generalized trends in the community regarding the causes of failures. Therefore, the information obtained from the analysis can be a starting point to develop action plans that can be improved by providing feedback with the particular ICU's specific data under consideration.

The FMEA method is a comprehensive tool for developing risk management programs; what is proposed is to use some of its components to build support elements for these programs, focusing on specific aspects, such as the operation of the medical device. In a previous approach, information was considered to assign priorities related to functioning.[19] Then, using the concepts of severity, occurrence, and detection, an analysis of failures is complemented, attending to the causes and giving them a complete management approach. In this case, we used these concepts as a basis and adapted them by defining them in the context of the information presented in the forums. More advanced work in this field, incorporating information derived from tools such as orders or service logs, is in process.

CONCLUSIONS

The development of risk management methodologies that aim to monitor and solve potential hazard situations in critical areas is valuable to the health technology management program. The FMEA method showed a solid basis for the risk assessment processes, and its application to the ICU medical technology allowed the creation of the evidence supporting the decision-making process concerning strategic solutions to guarantee patient safety.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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Is Clinical Engineering an occupation or profession?

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ABSTRACT

In this paper, we examine the practice level of engineers and discuss whether Clinical Engineering is a profession or an occupation. Many think that occupation and profession are synonyms, but are they? One must explore the difference, if it exists, between these terms, and to accomplish that, clarification of these terms is being offered and established first. We conducted a review of the terms and proceeded to identify if the tenants that are expected to be associated with professional standing are included in applying clinical engineering practices and to what level if it is. Engineering is a profession that improves the quality of living and for the common good. The professional education of engineers requires the education to contain a body of specialized knowledge, problem-solving skills, ethical behavior, and good analytical judgment in the service of all people. The engineering education domains aim to form individuals who are intellectually trained, practically adept, and ethically accountable for their work. Especially within the healthcare delivery system, engineering work engages problem-solving dependent upon sufficient body of knowledge to deal with practical problems by understanding the why, knowing how and identifying the when. There are various levels of the expected body of knowledge within the clinical engineering field ranging from engineers with formal academic training at undergraduate and graduate levels to clinical engineering technologists and technicians having graduated from between 1-4 years of academic training. Engineers may further select to publicly proclaim their adequate preparation and mastering of knowledge to conduct their work through a credentialing process that can confer the term professional, registered, or certified engineer if successfully achieved. Once the differences of working characteristics and obligations between occupation and profession are understood, it is clear that clinical engineers must continuously commit to pursue and fulfill these obligations. Therefore, every professional engineer is called on to achieve a certain degree of intellectual and technical mastery and acquire practical wisdom that brings together the knowledge and skills that best serve a particular purpose for the good of humanity. Clinical engineers and technologists are critical for sustaining the availability of safe, effective, and appropriate technology for patient care. It is as important for their associations to collaborate on compliance with professional obligations that their jobs require.

Keywords – *Profession, Occupation, Vocation, Engineering, Clinical Engineering, credentialing, certification, Healthcare job, Qualification, Alliance, Engineer.*

INTRODUCTION

To answer the question is Clinical Engineering an occupation or profession, one must explore the difference, if it exists, between these terms. An excellent point to begin is with a practical understanding of the task at hand, i.e., terminology. When humans spend time trying to achieve something, especially when this involves using some effort, it is called **work**.[1] There are many different types of work. **Occupation**[2] is one of many types of work which one occupies oneself with; usually refers to productive activity, task, service, trade, or craft for which one is paid. It is of a long term, perhaps as long as a lifetime, and is a path one embarks upon to fulfill goals, passions, and or ambitions. Such a path is a career that requires a certain level of education or training preparation to achieve the goals and ambitions successfully. The benefits of pursuing a career are often associated with monetary, work satisfaction, personal pride, economic independence, become part of the community, and self-worth, to name a few of them. Throughout a person's career, they will probably hold several jobs[3] or tasks identified as work performed to earn money to support basic needs and also help create relationships or develop a working network to advance one's career.

Many think that occupation and profession are synonyms, but the fact is that they are different. An Occupation is a work activity undertaken by a person to earn a living. It can be business, profession, or employment that a person undertakes to increase their wealth. Occupation refers to the kind of economic activity endeavored by a person regularly for earning money. When someone engages or occupies themselves in any economic activity, that activity is known as their occupation. An occupation does not necessarily require specialized schooling in a particular area and applies to any category of work that is consistently performed. An occupation includes jobs involving both physical work and mental effort. An occupation is a job that may include a profession which leads to most official forms using the term occupation when asking for an applicant's job or profession.

Examples of occupations include jobs such as vehicle drivers, shopkeepers, civil servants, clerks, bookkeepers. Occupations can be further divided into subcategories like:

- Business: A person engaged in any trade, commerce, or manufacturing activities, is assumed to be doing business.
- Employment: A type of occupation in which a person works for others, is being supervised, and gets a fixed and regular income.
- Profession: The type of occupation in which a person renders services to others and holds themselves out as an expert by applying his specific knowledge and skills is a profession.

The line of demarcation between occupation and profession exists but is blurred when given insufficient attention to the attributes that clarify the difference between these terms. For example, when a professional is paid for his skill or talent, it is known as an occupation. However, this represents more specific and different types of occupation when independent creative thinking, based on long and specific training, and compliance with achieving professional credentialing show the public achievement of practice competency we call a profession. Therefore, a profession is an occupation for which a person undergoes specialized training or internship to get a higher degree of education and expertise in the concerned area.

Profession[4] is an activity that requires specialized training, knowledge, qualification, and skills. It implies membership in a professional body, credentialing, and certificate of practice. The individuals who undertake a profession of rendering personalized services are called professionals, guided by a specific professional body code of conduct. A profession refers to specific categories of occupations that typically require advanced education or training and acquisition of the previous knowledge[5] pertains to the research and practice of the field of study.

The main objective of the profession is to render services to those who need them. A professional body or statute governs the profession. To be called a professional, a person has to pursue higher studies and qualify for an exam conducted by the governing body. Typically, a professional is said to be an expert in the field. In addition, the professional body develops ethical codes that the professionals must follow to ensure uniformity in their work.

The primary feature of any profession is the special relationship between the profession and the society and the commitment to serve responsibly, selflessly, and wisely. At times, this can create tension between the two elements of professional responsibility: the duty to serve the interests of one's immediate client and the obligation one has to society. Examples for profession include jobs like medical doctors, architects, lawyers, chartered accountant, clergy, nursing, and engineers, "At present, few would dispute the claim that physicians, lawyers, architects, accountants, engineers, and clergy are professionals."[6]

It is helpful at this juncture to point to what are the major differences between occupation and profession.

1. Unlike an occupation, a profession has an expected code of conduct.
2. An occupation does not require lengthy training in a particular field, but a profession requires specialized training in a specific area.
3. In general, the practice in a profession is regulated by a particular or professional body statute while an occupation is not.
4. A person with an occupation is paid for what he produces. Whereas in a profession, one gets paid according to his knowledge and expertise.
5. The profession is also an occupation when the person is paid for utilizing his skills and expertise.
6. A professional is independent, and any external force does not influence their work. However, conversely, there is a lack of independence in an occupation because the person performing it has to follow the commands of his supervisors.
7. Some conduct responsibilities are associated with the practice of a profession. However, an occupation does not have such responsibilities.
8. The basic pay in a profession usually is higher than in an occupation.
9. Professionals are usually respected more by people and have a higher status in society than those in an occupation.

EVOLUTION OF OTHER PROFESSIONS

Few practice fields are accepted as professions.[7] Some more than others. These include, for example, medicine, law, and nursing. The nursing field went through a developmental evolution of its profession following the challenge such as described in an article published by the *New York Medical Journal* stating that nursing is not a profession since "… it is not primarily designed to contribute to the sum of human knowledge or the advancement of science."[8] The response from the nursing field was clear: "With all due respect to the *New York Medical Journal,* nursing today does require, not only skill and intelligence but education. It is true that there are many mechanical duties in a nurse's life which require only skill but to be an efficient nurse demands also special knowledge and attainments. We have only to look backward a little over a century to notice how education, special knowledge and attainments in nursing affairs have changed the whole system of nursing."[8] The medical profession today is also facing a challenge with the extent of the regulatory nature of the profession, which is critical to the consideration of its professional standing.[9] In medicine, the regulation is practiced at several levels: medical schools must adhere to a standard, licensure as a process at the state level. At the same time, certification is administered through national organizations adopting a minimal level of professional practice requirements and standards. "Most doctors will find a way round this new regime, but short-term petty-minded bosses are beginning to view doctors as factory workers. Their limited vision considers doctors to be dangerously independent, malfunctioning cogs in their wobbly healthcare machine, a species to be controlled and beaten into the shape of the appropriate widget."[10]

The medical profession: "A vocation characterized by a specialized body of knowledge of medicine that its members must teach and expand, by a code of ethics and a duty of service that put patient care above self-interest, and by the privilege of self-regulation granted by society."[11] This establishes a career in medicine as one of the oldest and most respected professions; it affords the potential to impact human life genuinely and is usually associated with a high level of job satisfaction.

ENGINEERING AND ENGINEERS

Like medicine, in engineering, public health, safety, and welfare tasks are expected to be protected from unintended consequences. As shown in a public survey following the fatality caused by an UBER autonomous car accident, public distrust follows public harm. The survey showed that trust in such vehicles dropped by 27%[12] following increased perception of insufficient harm control. Other disasters show a similar trust impact, for example, following the space shuttle explosion after lift-off.[13]

Under the practice of engineering's obligation to public health, safety, and welfare, it is critical to understand what engineering is. Engineering is defined as the "application of science and mathematics to solve problems useful to people."[14] The practice of engineering is defined as "any service or creative work requiring engineering education, training, and experience in the application of engineering principles and the interpretation of engineering data to engineering activities that potentially impact the health, safety, and welfare of the public."[15] Engineers are practitioners of material products of human making just as physicians are practitioners of medicine.[16] An engineer is defined as "an individual who is qualified to practice engineering by reason of engineering education, training, and experience in the application of engineering principles and the interpretation of engineering data."[17] And Professional Engineer means "an individual who has been duly licensed as a professional engineer by the board. The board may designate a professional engineer, on the basis of education, experience, and examination, as being licensed in a specific discipline or branch of engineering signifying the area in which the engineer has demonstrated competence."[17]

Professions lay claim to a theoretical knowledge base such as a body of research, conceptions, and experience thresholds for its services. Whether that knowledge base is a body of biomedical or clinical research and theory, a collection of published manuscripts, or a body of laws, regulations, and legal decisions, professions rest much of their authority on the knowledge accumulated during the practice of the profession. This is one of the challenges clinical engineering faces—a lack of sufficient academic preparation programs and uniformity of public expectations from practicing engineers.

One of the fundamental pillars on which a profession stands is the mastery of a domain of practice. The technical skills of analysis and presentation of a solution or treatment, the practice of diagnosis, action, and interaction are all features of any profession. A profession is identifiable by the very practices in which its members engage. Professions rest much of their authority on the knowledge that their domain develops together with the profession's practice and higher education academic programs. During professional education and through the engineer's career, the practicing professional is expected to remain current with the growth and changes in that knowledge base and establish a threshold for demonstration of competent practice.[18]

Professional practice can be routine at times. However, challenges during professional practice are the need to make complex judgments and decisions leading to skilled actions, sometimes under uncertain conditions. This means that professional practice is frequently pursued at or beyond the margins of previously learned performances. Therefore, professionals must be appropriately trained to operate at the uncertain limits of their previous experience and must also be prepared to learn from the consequences of their actions to develop new understandings and better routines. Hand in hand, professional engineers must engage in exchanging those understandings with other professionals so the entire professional community benefits from their insight. Such an engagement is another deficiency in clinical engineering practitioners lacking the motivation and the available opportunities to publish their lessons learned. This is one of the profession's characteristics of learning from one's experience to improve future outcomes and create better-skilled practitioners. The conditions of professional practice and professional learning demand the establishment of and cross-functioning between professional communities. In addition to knowledge, the engineering profession should also teach their practitioners how to be a member of a professional community, with obligation for establishing and renewing thresholds for both practice and professional education, for critically reviewing new ideas, methods, and techniques, and disseminating it within the community of practice, for overseeing the quality of performances at all stages of engineer's career, and for contributing back to the community where they live.

CLINICAL ENGINEERING PRACTICE

Engineering is, at its core, problem-solving. Being an engineer means being a problem solver, capable of diagnosing, analyzing a situation, and finding a solution within a set of constraints even if it is not optimal. Similarly, one of the most required skills to be a clinical engineer is to solve problems quickly.[19] Also needed is the capacity to formulate the problem in technical and non-technical ways and partition the problem into subparts to achieve a satisfactory and safe resolution., Clinical engineers are uniquely prepared to accomplish this task[20] and determine the requirements and constraints while applying varied knowledge and experience to reach a timely, optimal resolution. Such an approach depends on knowledge and analysis of the state of specific phases in the technology lifecycle, non-compliance issues, risk tolerance management, user's competence, system integration impact, or financial analysis, all in a short duration. Perhaps faster than in the other professions we discussed earlier, the knowledge that a clinical engineer draws from is continually expanding and evolving because of the technological evolution and clinical practice itself. As outlined in the article *The Professional Clinical Engineer,*[21] there are common characteristic considered stewardship of all professions: a commitment to serve in the interests of specific clients and the general welfare of humankind; a body of knowledge and principles; a required specialized set of skills, practices, and performances unique to the profession; the capacity to render judgments ethically and with integrity under uncertain conditions; a commitment to engage in continuing education and learning attitude to absorb new knowledge from the contexts of practice; and the development of a professional community responsible for the oversight and monitoring of quality in both practice and professional education. Clinical engineers are mostly reflective, alert, and methodical as they carry out their clinical engineering projects, hopefully making their wider professional community better practitioners at the end of the project. A recent international survey[22] about the body of knowledge (BoK) and body of practice (BoP) practiced by clinical engineering practitioners demonstrate international variability in the definition of the practice domain with new knowledge subjects added during the last 25 years, such as technology assessment and forensic analysis. The majority of the clinical engineers who responded to the survey were employed within the healthcare delivery system. This population demonstrated that common domain elements across the world exist both in the BoK required to practice and in the BoP performed. Having identifiable domain boundaries is an essential characteristic of a profession, and this survey and others[23] support compliance of the clinical engineering field with this requirement.

Goodman argued that clinical engineering is a profession embarking on an identified path of: "The progress of an occupation toward professionalization involves: the

TABLE 1. Comparison between job characteristics.

Basis for Comparison	Occupation	Profession	Clinical Engineering
Meaning	Occupation refers to the regular activity performed by a person to earn a living	A profession is an occupation or vocation which requires academic preparation for knowledge and expertise in the specific field	Requires a degree of knowledge and expertise in the specific field
Code of Conduct	No	Yes	Partial
Training	Not necessary	Compulsory	Necessary
Regulated by Statute	No	Mostly yes	Country Dependent
Basis of pay	Produce	Skill and Knowledge	Skill and Knowledge
Higher Education	Not compulsory	Yes	Not compulsory
Degree of Independence	Usually there is no independence	A profession is completely independent	Some degree of independence
Responsibilities	Very limited	Yes	Yes
Respect and status	Low	Very high	Partially

appearance of training schools; establishment of university educational programs; licensure or certification; a formal code of ethics; and establishment of one or more national professional associations."[24] He further supports his argument by showing a BoK, a structured educational system, and professional organization representing them in the healthcare field.

DISCUSSION

The U.S. Department of Labor describes engineering as applying "the theory and principles of science and mathematics to research and develop economical solutions to technical programs. [This work] is the link between perceived social needs and commercial applications."[25] This site continues to identify that "Engineering fields can be practiced at the associate degree level include electrical and electronics drafters, civil engineering technicians, and aerospace operations technicians. However, a bachelor's degree is needed for civil, electrical, and mechanical engineering, as well as the less commonly known engineering fields in aerospace, biochemical, energy, industrial, robotics, marine engineering, and naval architecture." In furthering narrowing the career's focus this source reports on bioengineers and biomedical engineers jobs (there is no category to be found for clinical engineers) as required to "Apply knowledge of engineering, biology, chemistry, computer science, and biomechanical principles to the design, development, and evaluation of biological, agricultural, and health systems and products, such as artificial organs, prostheses, instrumentation, medical information systems, and health management and care delivery systems."[26] Having typical job duties that are, in most part, similar to yet not the same as clinical engineer's job.

- Conduct research, along with life scientists, chemists, and medical scientists on the engineering aspects of the biological systems of humans and animals.
- Adapt or design computer hardware or software for medical science use.
- Evaluate the safety, efficiency, and effectiveness of biomedical equipment.
- Develop models or computer simulations of human biobehavioral systems to obtain data for measuring or controlling life processes.
- Research new materials to be used for products, such as implanted artificial organs.
- Write documents describing protocols, policies, standards for use, maintenance, and repair of medical equipment.
- Conduct training or in-services to educate clinicians and other personnel on the proper use of equipment.
- Analyze new medical procedures to forecast likely outcomes.
- Advise hospital administrators on the planning, acquisition, and use of medical equipment.

Table 2 below, articulate few of the shared as well as the different duties between Biomedical Engineer and Clinical Engineer professions.

On the other hand, in addressing the question "What is engineering practice?" in a less detailed and more generalized picture of the work, we also need to consider whose point of view is expressed in the answer. One group is individuals and organizations engaged in engineering work based on, for example, surveys and interviews of practicing engineers. Alternatively, there is the view offered by researchers observing the work of engineers, then synthesize these observations into patterns and a more generalized understanding of the nature of engineering practice. Alternatively, yet still, there is the view that may be offered by those engaged in engineering education, namely engineering faculty and students. These view angles will produce the following answers: engineering is problem-solving, considering the systematic processes that engineers use to define and resolve problems; engineering is knowledge, considering the specialized knowledge that enables or fuels the process; engineering is the integration of process and knowledge. All are acceptable descriptions for the practice of engineering.

Critical differentiators between an occupation and a profession are whether or not members of the field, in our case clinical engineers, having attributes such as:

(1) a BoK with high degree of systematic continuous training,

(2) mastery of their domain,

(3) commitment to selflessly and ethically serve,

(4) ability to render professional judgement, and

(5) Self-governance by monitoring the quality-of-service members provide through a credentialing program. According to the US National Society of Professional Engineers (NSPE),[27] the practice of engineering is a professional service regulated by each of the States' governments that in the USA is governed by the first engineering licensure law[28] enacted in 1907 "to ensure public safety by granting only Professional Engineers (PEs) the authority to sign and seal engineering plans and offer their services to the public." This is an example of one of the profession's attributes, self-governance of service quality through a credentialing program. Following licensure as a professional engineer, individuals may voluntarily have their expertise in a specified field of engineering recognized through an appropriate specialty certification program. Such certification does not imply that other licensed professional engineers are less qualified for practice in their particular field of specialty.

TABLE 2. Comparison of job duties between Biomadical and Clinical Engineer.

Biomedical Engineer	Clinical Engineer
Conduct research, along with life scientists, chemists, and other medical scientists, on the engineering aspects of the biological systems of humans and animals	-
Evaluate the safety, efficiency, and effectiveness of biomedical equipment	Evaluate the safety, efficiency, and effectiveness of biomedical equipment
Research new materials to be deployed in products, such as implanted artificial organs	-
Conduct training or in-services to educate clinicians and other personnel on proper use of equipment	Conduct training or in-services to educate clinicians and other personnel on proper use of equipment.
Advise hospital administrators on the planning, acquisition, and use of medical equipment	Advise hospital administrators on the planning, acquisition, and use of medical equipment.
Adapt or design computer hardware or software for application in medical science uses	Adapt or design computer hardware or software for application in medical science uses
Develop models or computer simulations of human biobehavioural systems to obtain data for measuring or controlling life processes	-
Create guidelines, documents describing protocols, policies, standards for use, maintenance, testing and repair of medical equipment	Create guidelines, documents describing protocols, policies, standards for use, maintenance, testing and repair of medical equipment
Analyse new technology-based medical procedures to forecast likely outcomes	Analyse new technology-based medical procedures to forecast likely outcomes
-	Manage Medical devices performance assurance program (i.e. Maintenance)
-	Design, Implement, monitor, and manage healthcare technology Safety Program
-	Design, Implement, and monitor a Service Contract Management System
Most job duties performed in research laboratories	Most job duties are performed at the point of care
-	Apply Forensic Engineering, Health Technology Assessment, Disaster Preparedness, and Human Factor Engineering principles
-	Operate at the point of care complex healthcare systems in selected countries

Professional engineering licensure, in several countries, is the only qualification for engineering practice. A less successful example but yet crucial for the clinical engineering profession debate was documented by the World Health Organization (WHO) summarizing the work of a task force on *Manpower Development for a Health Care Technical Service*[29] where the minimum qualifications for a Clinical Engineer I states "Must be willing to work towards becoming a Certified Clinical Engineer." Moreover, Clinical Engineer II states, "Clinical Engineering certification and/or professional engineering registration are required." So far, these recommendations have not shown significant impact on the concept of adopting self-governance for clinical engineering practitioners. More substantial adoption will lead to more robust compliance with professional characteristics. It may now be better to initiate a new internationally coordinated effort to achieve broad adoption of this crucial professional trait. While credentialing is a program administered by a third party and is proof of an individual's qualification in a given subject, a certification program[30] is a process that recognizes and validates an individual's qualification that is usually administered by the profession itself. Clinical engineering as a professional field will gain recognition through a better definition for practicing clinical engineers' minimum academic preparation requirements, increase compliance with a public declaration of practice proficiency (certification), commitment to continuing education, and adoption of expected ethical behavior. All of these cannons are already integral parts of the present Clinical Engineers' practice. It will gain further recognition when an international uniformity is adopted.

CONCLUSION

Following the above discussion, it can be said that the occupation is a broader term, and it includes profession. All work deserves respect, and while occupation includes ordinary jobs and hence does not receive high recognition from society, professionals are mainly known by the knowledge base required to provide their service and professional judgment as part of their jobs. They were perhaps suggesting that such contribution to society draws a higher level of respect and recognition.

A profession is usually a higher-order occupation or a calling, especially involving a high level of education, career long continuous training, formal credentialing, mastered knowledge domain, adoption of rules for ethical behavior, and self-governance monitoring program of its members. In general, we found that engineering education programs attempt to prepare graduates for professional engineering practice. The programs include elements that illustrate and teach engineering problem-solving skills, provide engineering graduates with competent technical and managerial skills, and provide cultural education in the humanities and social sciences. Societies of Professional engineers support the notion that engineering curricula must incorporate instruction designed to instill in engineering students the concepts of professionalism and the ethical practice of engineering. Engineering education is and should be a lifelong learning experience. The depth of engineering knowledge continues to expand rapidly, and practicing engineers must renew their knowledge to remain effective and competent. The portion of the lifelong learning experience that follows formal engineering education is referred to as continuing professional development and is one factor that establishes that one's occupation is a profession. However, to fully meet such a mandate, clinical engineers need to demonstrate more comprehensive global compliance. Academic institutions can support this by offering clinical engineering curricula and continuing education training opportunities for their graduates. At all of the engineering branches, the US NSPE supports the premise that, "the public interest is best served by the licensure of all qualified individuals within the engineering profession." Credentialing has many forms, and clinical engineering should be no exception.

Clinical engineers also need to recognize, like other professions that when establishing defined requirements to enter the professional practice, there needs to be consensus about and adopting clinical engineering practice criteria. This includes domain boundaries, establishing a minimum qualifications criterion for entering clinical engineering practice in healthcare, a commitment for compliance with life-long continuing education, adherence to ethical behavior, service stewardship to their communities, and rules for self-governing. Adoption of these cannons will gain wider recognition and elevate the professional standing they desire. We recommend that the Global Clinical Engineering alliance will best serve as a leader for collaboration between stakeholders such

as academia, industry, healthcare providers, and government agencies. Working together to facilitate that clinical engineering practitioners deserve - be the engineering and technology professionals within the healthcare team.

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