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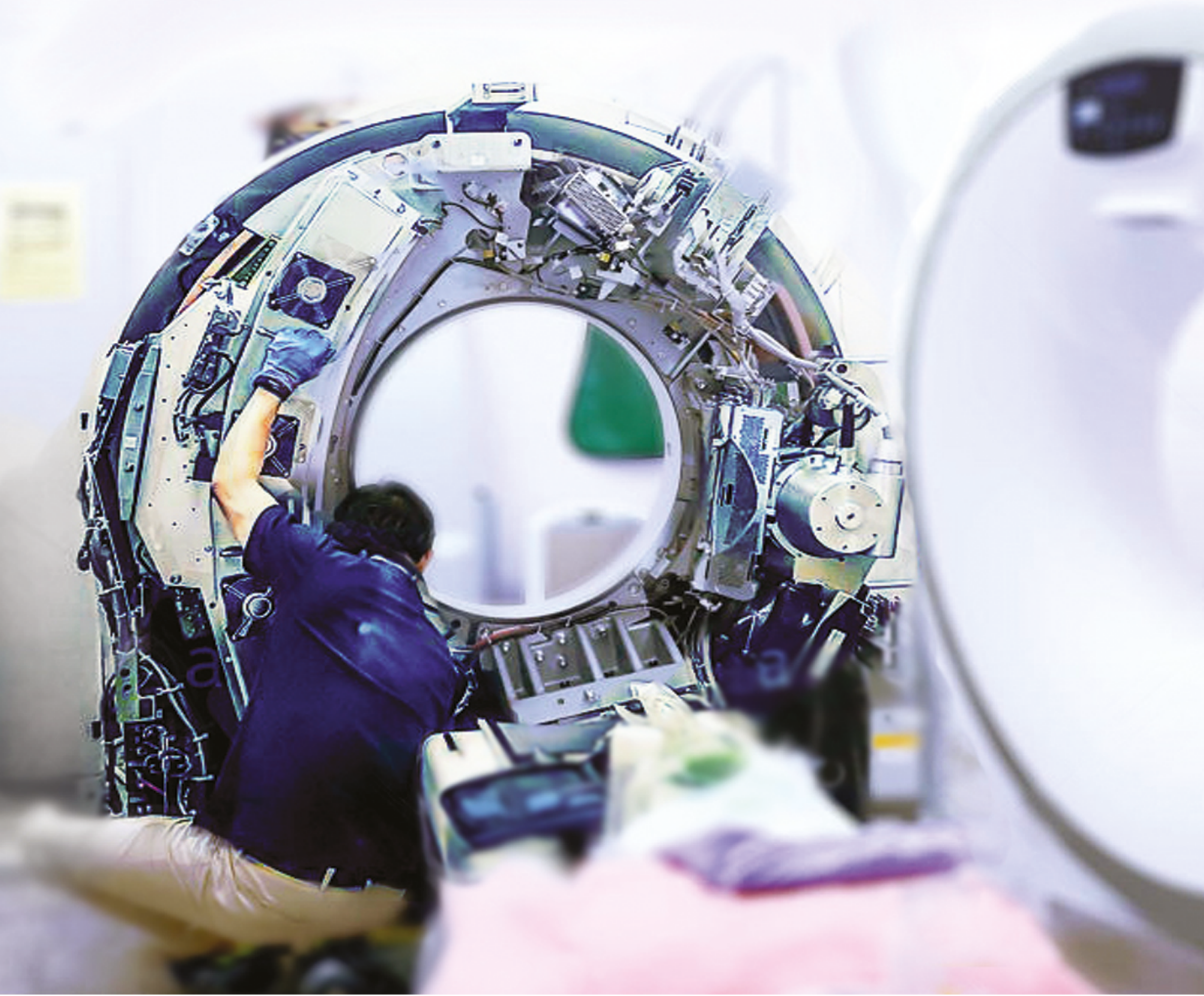

Editor's Corner

What Should Clinical Engineering Professionals Know?

As the year comes to an end (thank god), to say that 2020 was a devastating year would be an understatement. All over the world, the virus-causing pandemic kept the infection spreading, mutating, and pounding everything without relief and leading to the loss of precious lives, devastated economies, forced social isolation, and misery we never knew was possible. We are experiencing a changing world, and perhaps never did we need to support each other more than we do now. We each do it in our own way within groups of families and friends and by further backing colleagues as members of the clinical engineering community. Will, how, or what impact the pandemic will have on future clinical engineers (CEs) and technologists is not yet known. The question now is, how should future CEs be better prepared for what is to come?

One lesson learned from this abnormal pandemic era is the need for better technology lifecycle management methodology and tools. In healthcare past, the timeline separating discovery and innovation, from use to benefits, was measured in multiples of years. However, the success of Operation Warp Speed[1] has demonstrated how rapidly accelerated development and approval for the COVID-19 vaccine can be completed. We are ready to meet similar growing challenges such as the lack of mechanical ventilators, oxygen generators, personal protective gear, and isolated care spaces within similar accelerated timelines. These timelines have been shortened from years to months and, in some instances, even less. Through interdisciplinary collaboration (such as automotive and medical product manufacturing) and international research cooperation (such as the UK, Germany, and USA) we have seen multiple medical triumphs, technological advances, and engineering solutions (public-private alliances) that have forever altered previous conventional approaches.

The medical device industry has changed forever, and the forces that currently shape it will drive rethinking and expectations into the future. Product innovation and development will become processes that are much closer to a specific patient's needs, demographics, and experiences. Modifying hospitals to also act as medical technology laboratories. The number of people in the world age 60 years and over is expected to grow by 56%, reaching nearly 1.5 billion by 2030.[2] This suggests that care expectations will increase. In response, further demand will be placed on personalized care that is already being supported by extended reality (both virtual and augmented) tools and creative wearable products with embedded intelligence that can modify their function in response to the data collected.

As I touch on lessons learned from the past year and on the anticipation for the creative future that has already begun to impact the healthcare industry, it begs the question: what about clinical engineering practitioners and members of the front-line healthcare team heroes? What is in-store for them? The demand for better access to and future growth in provisioning of healthcare services will undoubtedly magnify the system's dependence on technological tools, their performance, and integration. This will translate into stronger demand for competent clinical engineering education and expertise. However, if everything around us is changing, and we chose to stay statically stationed, the opportunity will fade and perhaps be picked up by others. It is critically significant, therefore, that clinical engineering practitioners demonstrate the pursue of the following E.S.P. attributes that will deliver an advantage to their ability to successfully fulfill their future duties and to reach greater on-the-job satisfaction:

Education – Increase your knowledge and expand your expertise to include subjects like artificial intelligence, digital health (telehealth/telemedicine/eHealth), extended reality, robotics, cybersecurity, wireless communications, and big data that are all part of the coming fields in need of engineering champions at the point-of-care.

Stewardship – Understand your role expectations, learn to communicate clearly and rapidly, be reliant and provide update/follow-ups on projects assigned to you, do not avoid responsibility, and always be passionate about keeping equipment safe and patient-ready supporting the quality-of-care outcomes. Remember, patients cannot fend for themselves. They depend on you to carry out your responsibilities.

Professionalism – Members of healthcare teams are educated, credentialed in their field, engage with their society's activities, collaborate with peers, read, and publish in their field's literature. CEs need to embrace such attributes and do it now to ensure you gain a seat at the table.

Specific examples in our own field provide evidence supporting the need for more international collaboration and stronger professional knowledge exchange as they are going to be part of our future. The Call for Papers for the 4th International Clinical Engineering and Health Technology Management Congress, scheduled to be held in Orlando, Florida, USA coming September 2021, is still open; however, it already broke the record established last year in Rome for the number of abstracts submitted (reaching almost 350). Further, this past October's inauguration of the new Global Clinical Engineering Alliance[3] is yet more evidence that as healthcare and technology are changing so are the needs in our field. These changes magnify the increasing dependency between CEs, educators, practitioners and the persistent ensuring that goal for the intended care outcomes. As this is becoming more evident it mandates clinical engineering practitioners to declare their professional boundaries and become stewards for patient safety and care quality by updating their expertise and building opportunities for growing their professional competencies through training, reading, and networking. As CEs, your ability to use knowledge for solving system problems reliably, safely, and quickly should be the navigating lights leading all of us into a brighter, happier future.

The Global Clinical Engineering Journal and its Editorial Board experts will back you up and focus on sharing knowledge internationally, identifying best practices, communicating lessons learned, and highlighting innovations to make sure you are in the best position and are prepared to claim your seat at the table.

We send you our very best wishes for fewer air hugs and more bear hugs in the coming new year!

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Together we are making it better!

Dr. Yadin David

CONTENTS

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A Multi-platform Information Management System of the Total Life Cycle for Medical Equipment

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ABSTRACT

Objective: To establish a total life cycle information management system for medical equipment based on our hospital's actual situation.

Methods: Per the definition of the total life cycle for the particular item of medical equipment, the function modules were designed and distributed according to different staff postings and then implemented on the WeChat public account-a series of API and services to develop custom features, a mobile app, and a computer web browser.

Results: After implementation, the system can cover a series of management stages of the entire life cycle for medical equipment and the information exchanged among various stages. The relevant staff in different posts can operate the medical equipment management information on any of the three platforms.

Conclusion: The improvement and efficiency aid staff in various settings in managing medical equipment and medical behaviors and patient safety is increased..

Keywords – *Medical equipment, Information system, Multi-platform.*

INTRODUCTION

Large-scale hospitals have a wide variety of scientific and medical equipment which requires efficient information management systems. Traditional management methods cannot cover and connect the devices at various stages effectively while they are in hospital circulation. Traditional medical device management methods have the following drawbacks**:**

- Data are not interconnected. There is an information island between the functional modules of medical device information management because each function module has different application sequences, different software vendor solutions, and different technical levels in different periods. There is also a failure of unification in planning and construction leading to differences in system architecture, data formats, protocol standards, and network environment among functional modules. The system function modules are independent of each other, making it impossible to implement or partially implement data sharing.

- Data management is not integrated. Traditional management methods focus on bidding procurement, contract management, installation and acceptance, fixed asset files, maintenance and measurement, and scrapping. Therefore, traditional management systems are generally established in these areas. However, for planning and budgeting, market research and inquiry, usage evaluation, routine maintenance, inspections and preventive maintenance, adverse event monitoring and recalls are usually underestimated leading to a relative lack of management information modules for the devices.
- The data processing error rate is high. As data in device management modules cannot share or partially share information, and if the device management information among the modules is inconsistent, data will not be accurately provided. For example, a device in a Chinese hospital management system has four ledgers: (1) Financial management department general ledger; (2) Fixed assets management department ledger; (3) Procurement ledger; and (4) Medical equipment maintenance unit account. Since the four ledgers' management information is not entirely interconnected, it may cause data discrepancies if login is on different systems and may also cause management information inconsistency with the physical object. The management information of the equipment may be lost due to poor management, mostly when recorded in paper format.
- Data processing is not timely. For traditional equipment, information management at various stages is stored in different system modules and storage media, such as Client/Server architecture mode database, Excel spreadsheet, or paper files. Accessing and updating real-time information on devices requires operating on different systems at different times. Also, equipment maintenance, inspections, measurements, etc., need to be executed regularly, but traditional management methods cannot achieve dynamic setting plans and automatic expiration reminders effectively.
- Data statistics and reporting functions are imperfect. The statistical data of various devices are fuzzy, and muti-latitude measurement and comparison data are scarce. Monitoring of the running status of equipment is not clear or intuitive.

With the needs of modernization and the intelligent refinement development of hospitals and the need to review China's 3A grade and Healthcare Information and Management Systems Society (HIMMS), medical equipment management urgently needs an integrated information management system to break the barriers among the original modules and realize information interconnection among modules and systems. The total product life cycle (TPLC) method is a holistic approach that considers all of the steps and processes in the evolution of a device from conception to obsolescence and integrates information and knowledge across pre-market and post-market activities. David W. Feigal proposed that TPLC of a medical product included phases such as concept, prototype, preclinical, clinical, manufacturing, marketing, commercial use, and obsolescence. Combining the perspectives from different science disciplines was widely accepted in the medical devices field.[1] According to the characteristics of equipment management in China's medical institutions and the medical technology management of our hospital, we divided the total life cycle information management system for medical equipment (TLCIMSME) in the hospital into the following stages: (1) Equipment demand, planning, and budget as the starting point; (2) Market research, bidding procurement, and contract management as the initial stage of equipment life; (3) Receiving, installation, and acceptance, personnel training, fixed asset file management, use management, application evaluation, daily maintenance, inspection and preventive maintenance, metering maintenance, and monitoring and analysis of adverse events are used as application stages; and (4) Recalls, scraps, and updates as the later stages. According to the four stages, the medical equipment life cycle information management system should be fully covered and all stages can be interconnected. Each user of the system can log in to the system to manage medical equipment information at any time or place and get statistics and report information intuitively.

METHODS

The TLCIMSME had to be designed to interconnect functional modules and other relevant information

systems in the hospital. The TLCIMSME was designed and implemented from multiple perspectives, including logical general view, hierarchical system structure, life cycle timing diagram, functional module diagram, and three-platform operation diagram.

CONNECTING MEDICAL EQUIPMENT MANAGEMENT SYSTEMS AND OTHER RELATED INFORMATION SYSTEMS IN THE HOSPITAL

The information systems related with medical equipment management system in our hospital have are Office Automation (OA) system, medical equipment preliminary marketing research system, third-party tender evaluation system, intensive care system, Laboratory Information System (LIS, Picture Archiving and Communication Systems [PACS]), outpatient and inpatient electronic medical record system, fixed asset management system and finance system. The medical equipment information management system should interconnect with these related systems (Figure 1).

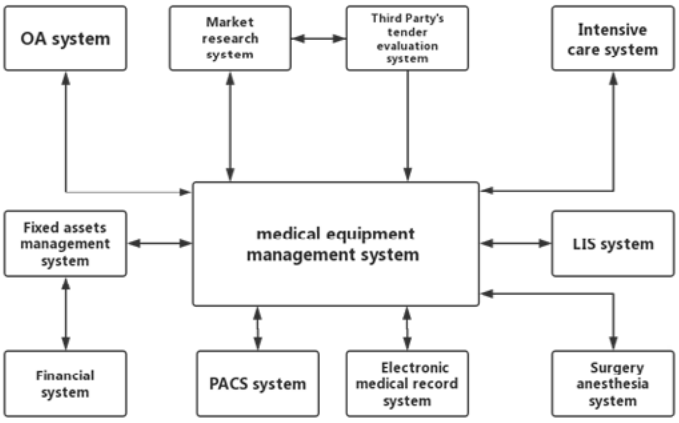

FIGURE 1. Connecting medical equipment management systems and other related information systems in the hospital.

MEDICAL EQUIPMENT MANAGEMENT SYSTEM LAYERED STRUCTURE

1. User interface layer. This layer, containing all user pages, is responsible for interacting with the outside world, receives business requests from the Application Programming Interface (API), forwards the request to the business logic layer for processing, and returns the final result.
2. Business logic layer. This layer is responsible for processing requests submitted by users. The requests are submitted to the data access layer and the results are passed back to the user interface layer. Windows Communication Foundation (WCF) is used to pass messages between the user interface layer and the business logic layer.
3. Data access layer. This is a bridge between the business logic layer and the database. Pass the request to the database and return the results to the business logic layer[2] (Figure 2).

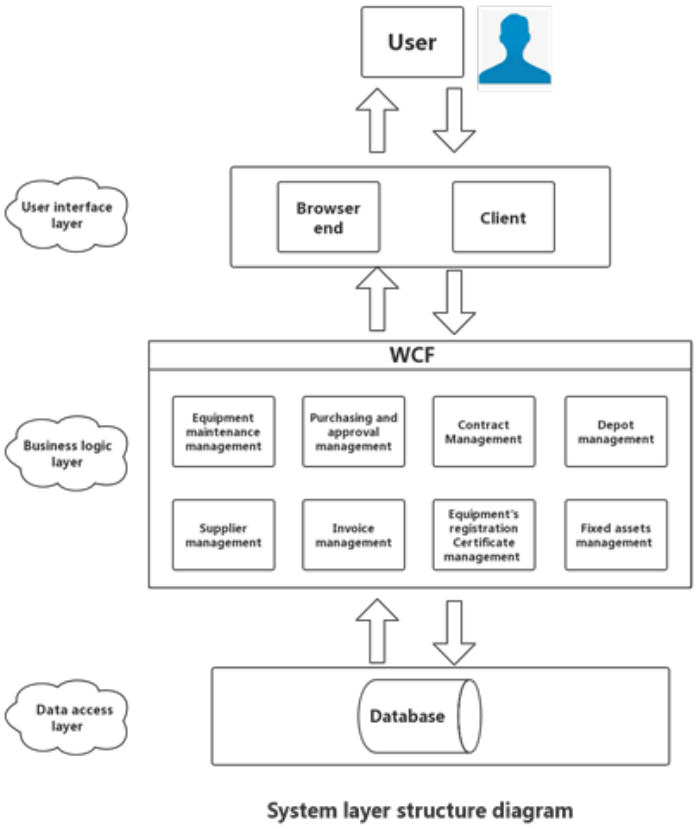

FIGURE 2. Medical equipment management system layered structure.

FUNCTIONAL ORGANIZATION STRUCTURE

1. The starting point of the lifeline. When the medical equipment demand departments fill in the application form and submit the demands, a serial number

is generated to track the equipment. Information such as the application department, equipment name, quantity, budget, and basic equipment configuration and functional requirements are transmitted to the tendering stage.

2. Initial stage of equipment. The hospital generally entrusts a third-party bidding company to tender according to a hospital's needs (refer to the provisions of the national bidding documents) and determines the bid supplier, equipment brand, model, quantity, and price. This information is transmitted to the hospital procurement stage. Our hospital and the winning supplier sign the purchase and sale contract following the winning bid information.
3. Equipment application stage. Then the clinical medical engineer, the manufacturer engineer, department staff, and the fixed asset manager install, test, and accept the medical equipment together according to the contract. After acceptance, the fixed asset administrator will file the equipment information into the assets system. After training medical engineers and equipment operators, the equipment can be used. Clinical medical engineers then conduct risk assessment of the equipment in the system, develop preventive maintenance measures and content and cycle, inspection plans and daily maintenance plans and later execution, additional measurement plans and a measurement equipment file are prepared for the metering equipment and executed later. If the equipment fails, the equipment user can initiate application by two-dimensional code of the fixed assets which is created during the acceptance. Medical engineers also receive the repair information through the system to execute and fill in the maintenance report form. When an adverse event occurs, both the equipment users and the clinical engineers can report through the system, and the fixed asset administrator also counts the medical device by scanning the two-dimensional code.
4. Late stage of the equipment. When a medical device recall occurs, all the models and batch numbers of the equipment involved are queried in the system, and the recall procedure is executed. When the medical device is scrapped, the device user, the fixed asset administrator, and the clinical medical engineer operate and record the event together in the system. When updating the equipment, the system can be used to check and analyze the medical equipment repair, inspection, and maintenance data records and determine whether the equipment needs to be updated. In this way, a medical device completes the closed-loop management of the entire life cycle[3] (Figure 3).

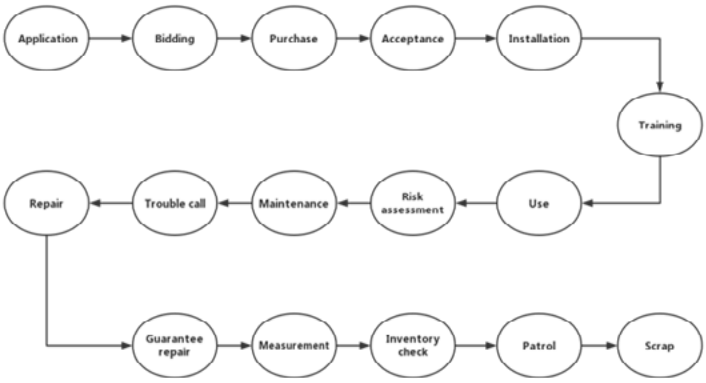

FIGURE 3. Equipment lifeline sequence diagram.

PERSONNEL POSITIONS FOR MEDICAL EQUIPMENT MANAGEMENT

Medical equipment personnel positions are divided into equipment section chiefs, equipment operators, purchasers, fixed asset administrators, gaugers, and clinical medical engineers[4] (Figure 4). The medical equipment department chief mainly obtains statistics and reports on various types of equipment management information from a macroscopic perspective. The requirements include statistics on the hospital's entire assets, statistics on the asset distribution in various hospital departments, the proportion of risk levels and another 16 asset statistical analysis charts such as usage rate and asset brand statistics.

The equipment operators use the system for routine maintenance and inquiry to repair.

The purchaser mainly uses the procurement management module, including summary demanding application and approvals, procurement demonstration and plan, entrusting the third-party tendering company, signing purchase and sales contracts and conducting contract management and invoice management.

The fixed asset manager is responsible for equipment acceptance, documentation, asset label printing, asset allocation, borrowing, inventory, and scrapping.

The gauger is responsible for the metering of medical equipment in the hospital according to annual plans, including compiling the inventory of the metering instruments, drawing up the annual metering plan for the instruments, recording the metering files, and ensuring consistency between accounting books and physical inventory.

Clinical medical engineers utilize three modules: repair, maintenance, and quality control management.[5] Functions of the repair module include online receipt of repair orders, online dispatch, repair stations, online work orders, online approval, warranty management, equipment faults library, spare parts inventory management, and maintenance invoice management. The maintenance module includes inspection and preventive maintenance, as well as daily maintenance. The quality control management module includes medical device risk assessment, medical device performance testing and planning, measurement management, and adverse event management. After logging on to the system, personnel in different positions can set the corresponding function modules' operation rights, and the information between each function module can be interconnected.

THREE PLATFORM TERMINALS

The system makes full use of the popular mobile app technology and computer network technology to provide three kinds of platform for user interaction: a public WeChat account, a mobile app, and PC web pages.[6] The underlying data of the three platforms are interactive and interoperable.

Public WeChat Account

WeChat is a multi-purpose messaging and social networking app developed by Tencent. It has been called China's "app for everything" and a "Super App" because of a wide range of functions and platforms. Almost every Chinese person has a WeChat account.[7] WeChat supports developers registering a public account, which can interact with users and provide them with services. This system has developed a public account named "gzfezx" as the interaction ports and equipment operators can register user account through the public account and then scan two-dimensional code on the assets to record daily maintenance information and submit a repair application of medical equipment.

Mobile App

A mobile app is a computer program designed to run on a mobile device such as a phone/tablet or watch. The

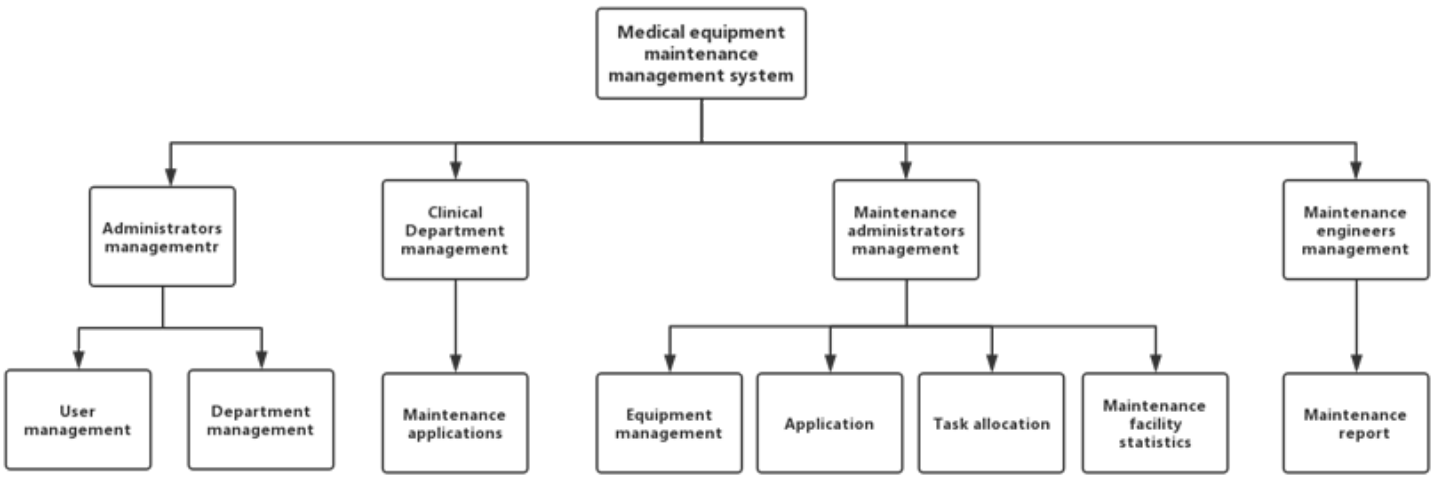

FIGURE 4. The personnel positions for medical equipment management.

system is specially developed named Medical Equipment Information System（MEIS）App. Equipment operators, fixed asset managers, gaugers, clinical medical engineers, and equipment chiefs can log in on the MEIS App to implement the modules in their rights distributed. It will not be detailed here.

PC Web Pages

The PC web pages adopt the traditional browser/server（B/S）based architecture mode, and the equipment asset manager, metering staff, equipment chief, and clinical medical engineer can login through Uniform Resource Locator（URL）to access the web server for medical device management information interaction. After login on the URL, modules can be found based on their right, and it will not be expanded. The configuration environment for the PC Web Pages is as follows:

- Database: MySQL database: simple operation, friendly interface, multi-user database management system;
- Development language: PHP language: cross-platform, efficient execution, supports almost all popular databases and operating systems;
- Server operating system: LINUX operating system: occupying small resources, safe and stable.

IMPLEMENTATION RESULTS

Medical Device Life Cycle Line

Selecting either device and clicking allows the user to display the events of the device by time axis. The events include the installation date, the date of repair, routine maintenance, inspections, preventive maintenance date, metering date, and transfer cases. Clicking on each item expands the details of each item. Double-clicking the device name queries the fixed asset details, device pictures and graphically displaying the medical device overview, including normal usage, number of repairs, maintenance costs, and maintenance hours. The users can also analyze maintenance, quality control analysis, and benefits analysis for the device selected.

Equipment Repair Process

The clinical department's equipment manager scans the Quick Response（QR）code of asset management using the smartphone app to apply for repair which is

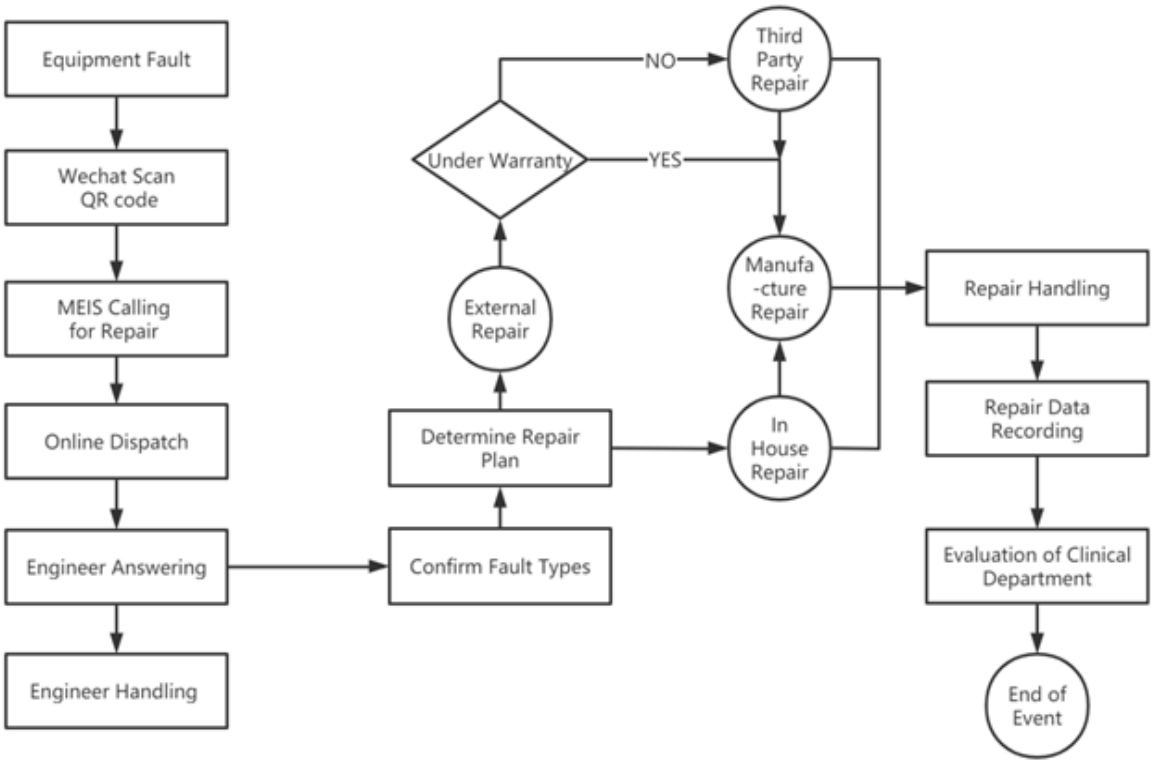

FIGURE 5. Equipment repair process.

transmitted to the server. The team leader who is responsible for repair dispatches engineers according assigned jobs. The engineers will judge the equipment fault type and then carry out an independent repair or inform the manufacturer or a third-party company to repair as needed. After the maintenance is completed, the engineers fill in the maintenance report, the related clinical department scores the maintenance situation, and then finally, the process ends (Figure 5).

Purchasing Module

This management module includes purchase application, purchase review, procurement plan, equipment selection demonstration, procurement announcement, negotiation record, contract management, acceptance, installation, and invoice management. Clicking on each item to allows access specific information. Other modules include maintenance, quality control, maintenance, adverse event management, metering management and equipment benefit analysis. The system also has a distribution map for life support devices that can monitor status such as the amount, type, distribution, fault condition, and intact rate of equipment in the hospital.

THREE INTERFACING PLATFORMS

Public WeChat Account

This port is mainly provided for clinical departments. After clinical department equipment managers log in, the system automatically matches all the department's devices to their accounts. The equipment administrator can perform daily maintenance or submit repair applications for all department equipment by scanning a code. For equipment with a borrowing time of 3 days or less, the borrower can operate through the temporary maintenance menu. For equipment that is not in the department when scanning the code, instructions are given for borrowing or asset transfer procedures before maintenance. Under this interface the system can remind the user of the number of daily maintenance orders. After clicking the reminder, the user can check the detailed information and carry out maintenance. The equipment administrator can also check the number of equipment items in the department that are under repair. Also, the equipment administrator can also perform asset transfer and repair applications after logging in and can perform daily inspections and view inspection records and statistical analysis.

Mobile Phone App

This app supports both Android and Apple operating systems. This port is intended for use by clinical engineers, fixed asset managers, gaugers, and equipment management chiefs. After the clinical engineers log in, they can check the maintenance status of all clinical departments. They can inspect the equipment according to departments. They can also perform preventive maintenance and produce reports in the system for the equipment according to the plan. The clinical engineers can process the repair applications initiated by the clinical departments and record at this interface; the metering staff can perform metering and performance testing management after logging in; the common items can be statistically graphed. Asset administrators can also perform inventory management on the devices with this app.

PC Web Pages

PC Web Pages allow clinical engineers, fixed assets administrators, metering staff, and medical equipment departments to operate and achieve detailed statistics and graphical reports. The computer maintenance and management module has three menus: routine maintenance, inspection, and preventive maintenance. The routine maintenance menu can be queried according to the device name, type of care, the use of the department and templates of routine maintenance can also be set up. The inspection menu can set the inspection task and remind the inspection time. After an inspection, an electronic report form is generated and archived. The preventive maintenance menu can alert devices that are due for expiration, set up preventive maintenance plans, and execute and set up a personalized template and match. The system can also provide abundant graphical reporting features such as the distribution of equipment failure types,[8] statistics of value of equipment assets over time, and the total number of repairs according to the department.

CONCLUSION

The MEIS system comprehensively utilizes the public WeChat public account the mobile phone app and web pages based on the B/S structure to modularize the

design of the medical device life cycle, and the work-flow moves through various staff positions in the equipment department to realize optimal equipment management and interconnect information resources in multiple modules allowing users to share and break the information resources "island" situation. Interconnection between various management modules mutual authentication information ensures accurate information is extracted. The management data also updates to the cloud server, the security of device management information is guaranteed, and the risk of information loss is greatly reduced.

The system uses the two-dimensional code-fixed asset tag as the interactive medium between the staff and the medical devices. All the three platforms can scan the fixed asset two-dimensional code to read and write the device management information in real time.

The system can output a variety of equipment management information statistical charts, including statistical analysis functions of assets from 16 different angles, including value, use department, equipment risk level, normal usage rate, and statistical analysis by asset brand. Also, 23 different statistical analysis functions are available, including maintenance and maintenance costs, fault type, the type of maintenance, repair application departments distribution, Top 20 clinical departments by the number of malfunction statistics, graphical daily maintenance, inspection and preventive maintenance profiles by department, and by type of equipment. The system also enables cost analysis of large medical devices and provides analytical reports and statistical analysis of medical device adverse events and metrology.

DISCUSSION

The MEIS system's promotion and use standardize the workflow in the daily maintenance, inspection, and preventive maintenance of medical equipment. The system platforms can be planned in advance and then implemented according to the plan to ensure the workflow's smooth progress. Simultaneously, the devices can be effectively monitored in real-time on three different platforms to ensure the quantity of maintenance.

The promotion of the MEIS systems has improved user interaction and experience. The combination of the QR code and smartphones enables the user to operate through the scan code login platforms under the 4G mobile network and the WIFI network, which greatly assists the users of each role.

The traditional medical equipment management system is based on a fixed asset management system and a medical equipment maintenance system, paper processing, and Excel form management for the initial stage, application stage, and final medical equipment stage. The MEIS system realizes electronic management of data at each stage of the life cycle, which aligns with the hospital's paperless development process and HIMMS review requirements.

Of course, there are still some issues at present. For example, if the manufacturer does not provide a standardized, unified data interface such as a Digital Imaging and Communications in Medicine (DICOM) protocol port, it will make the device dynamic data collection difficult. Thus, the user cannot analyze the benefit of a single medical device effectively. The hospital environment is complex, equipment is scattered, the network communication conditions can be poor, and the hospital networking infrastructure can be weak. Also, the overall program cost can be high which could delay the use of the MEIS system. However, with the hospital's intelligent development needs, these problems can be solved gradually.

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Evaluation and Optimization of CES Performances: Application of the Pareto Principle to KPIs

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ABSTRACT

In recent times the approach to health care has been mostly influenced by the growing quantity of biomedical equipment used in hospitals, which needs the support of the clinical engineering service (CES).

This work aims to suggest a methodology to improve the performance of a CES through the application of Pareto principle to the leading Key Performance Indicators (KPIs). The methodology is applied by focusing on using KPIs that represent a quantifiable measure of achieving goals set by an organization. In this study, five KPIs are considered: Uptime, MTTR (mean time to repair), PPM (percentage preventive maintenance completion), MTBF (mean time between failures), and the COSR (cost of service ratio). The first three indicators express the measure of CES efficiency in ensuring regular maintenance.

The first step consists of retrieving data related to work orders for 2015-2016 on 6000 installed devices, carried out by management software. The second step is to get the results by using an environment for numerical calculation and statistical analysis.

To identify the main critical issues that may be present, three indicators (Uptime, MTTR and MTBF) are analyzed by applying the Pareto principle (i.e., 20% of the causes produce 80% of the effects). Considering the totality of work orders, it is possible to concentrate on only 20% of them to focus on a small group to understand the correlations between them. Identifying these characteristics means identifying the main critical issues that are present, on which action must be taken, and which affect 80% of the overall behavior. Instead, the COSR and PPM indicators suggest distribution models that focus on the most critical devices.

In conclusion, the way to analyze the results is obtained, when possible, by applying Pareto principle. Therefore, a CES will be able to focus on a few causes of poor performance. The achievement of these results could allow the standardization of the method used, enabling it to be applied to any healthcare system.

Keywords – *CES, KPIs, UPTIME, MTTR, MTBF, COSR, PPM, UCBM.*

INTRODUCTION

- Key Performance Indicators (KPIs) represent a quantifiable measure of achieving goals set by an organization, both operational and strategic. Generally speaking, companies have different KPIs depending on their priority criteria. KPIs can also be established arbitrarily but, to be useful, they must meet the following requirements1:
- Quantifiability - KPIs must be presented in the form of numbers.

- Practicality - they integrate well with current business processes.
- Directionality - they help to determine whether companies are improving.
- Operations - they can be related to the practical context to measure an effective change.

The four leading indicator typologies are[1]:

1. General indicators - measure the amount of work in the process.
2. Quality indicators - evaluate the quality of the process output based on certain standards.
3. Cost indicators.
4. Service or time indicators - they measure the response time from the start of the process until its conclusion.

Thanks to a set of KPIs, it is possible to evaluate the performance of a clinical engineering service (CES).

This paper discusses the current status of benchmark indicators within the field of clinical engineering. The paper focuses on the evaluation and optimization of the medical equipment repair and maintenance activities of a CES by applying the Pareto principle to KPIs to focus on main critical activities.

STATE OF THE ART

According to Cohen et al., KPIs represent the process of comparing business performance levels to identify opportunities to improve. The results provided an idea of what should be changed and how. However, comparisons have met with limited success due to poor and inconsistent definitions of the parameters measured and lack of quality data available. In the first phase, it was necessary to identify basic indicators that are applied to any healthcare facility. They must be uniquely defined and consequently calculated by the same method so that they can be compared. Afterward, it was possible to start to build other indicators that will be different depending on the specific needs and the technical-economic information that everyone possesses. For this reason, the primary purpose of this paper was to detail some of the quantitative performance and cost benchmark indicators that have been historically used in medical equipment maintenance and repair and to make recommendations on how the clinical engineering profession can develop good quality, useful and meaningful benchmarks. The general characteristics of a useful benchmark indicator are2:

- well defined;
- objective;
- measurable;
- based on current knowledge experience; and
- valid.

The study by Bassem et al. aims to evaluate CES's performance at the University of Cairo, Egypt, using quantitatively measured parameters to allow comparison and improvement objective.3 In addition to the parameters proposed by Cohen et al., considered insufficient, Bassem proposed new indicators. Data were collected by 10 hospitals, corresponding to different healthcare organizations.[2,3] These data were subsequently analyzed by a software tool, providing a score for each CES. The first step was to decide what exactly to evaluate and monitor. Some of the studies reported by Bassem adopted a survey technique as CES directors were asked to select from a list of proposed performance indicators that could be used for performance measurement benchmarking. Their response revealed three mainstream performance indicators. Other indicators had to be added and measured to evaluate the performance of the other services. They used additional essential indicators that should be involved to get an increased accurate evaluation. The results indicated an average gap of 67% between the performance of the CES and the reference they have identified, considered the ideal target.[3]

According to the Tiwari study, service performance on medical equipment serviced by external suppliers is assessed.[4] The performance indicators of CES are first defined according to the needs and benefits required in the specific hospital structure and are then categorized and finally measured as indicated below.

1. The definition of KPIs considering the opinion of experienced staff.
2. The categorization of KPIs into four groups.
3. The measurement of KPIs.

The Tiwari study is an example of an outsourced CES, and the key to success is the measurement of performance to quantify the expected benefits.[4]

METHODOLOGY

This study, conducted by the University Campus Bio-Medico of Rome (UCBM), where there are about 6,000 pieces of biomedical equipment for the year 2016. Before going into the explanation, and then in the calculation of the KPIs, it is vital to understand what type of data have been used. The CES utilizes an equipment management software, in which all the data are collected and related to the inventory number of biomedical equipment: the description, the serial number, the manufacturer, the purchase value, the intervention priority, therefore any information useful to characterize a specific piece of equipment. From the mentioned software, further information can be obtained relating to work orders and the schedule for preventive maintenance. In the first case, the CES takes care of entering all the work orders executed. In the second case, the CES takes care of inserting, within a schedule, all the equipment and the corresponding deadlines for preventive maintenance, in order to record the periodicity with which it is required to carry out maintenance. This approach maximizes effectiveness and efficiency in technical management and ensures economic and technical control of maintenance. It has the objective of providing operational and decision-making support for further optimizing the processes related to registry/inventory management. In this way, from this software, it is possible to obtain categorized data, from which it is possible to calculate the KPIs. Starting from these data, the results are obtained through the use of "Matlab," an environment for numerical calculation and statistical analysis, which also includes the programming language. It allows the calculation of the KPIs considered here. The following paragraph will report the explanation, and the subsequent calculation, of the identified and measurable KPIs.

The following KPIs are used and calculated:

1. **Uptime**. This denotes the time the biomedical equipment has been working for over one year; downtime is its complementary statistic and denotes the state of a not operational system. This may be due to failure, preventive maintenance, or other causes. The measurement is carried out in absolute values or percentage. Uptime is particularly important for all machines where stability and availability are fundamental. Through Uptime, efficiency can be deduced: a high Uptime indicates that the equipment is well configured, while a low Uptime could mean instability of the equipment. To get more evidence on the critical issues, this KPI calculation involves the initial use of data from all the equipment from which one or more work orders have taken place. Also, all devices that have not undergone a work order are then considered and has always been functional; a maximum Uptime value will appear. The Uptime calculation, represented by a percentage, is carried out by first calculating the downtime: the work orders corresponding to each inventory number of the equipment are considered and, consequently, the duration given by the sum of all the work orders for that specific inventory is calculated. It is then divided by the number of days within a year to indicate, the percentage of the number of days that a specific piece of equipment remained inoperative relative to the total period.[4] The formulas used are the following:

$$Downtime(\%) = \frac{n°days_{tot}}{365} * 100$$

$$Uptime(\%) = 100 - Downtime$$

2. **MTTR** (Mean Time To Repair). This denotes the Time to Restore (TTR) expected value, where the TTR is the time interval where the equipment is unavailable due to a failure. The MTTR includes the time for diagnosis, the arrival of the maintenance technician, the arrival of the component(s) to be replaced, and the actual repair. It is a useful parameter for evaluating the effectiveness of the CES in terms of the logistic organization. The calculation of this coefficient involves data from all equipment on which a work order has occurred involving corrective maintenance or functional verification. The MTTR is calculated according to the work orders corresponding to the equipment's inventory and the duration given by the sum of the times to repair in all the work orders, or that specific item is calculated. This is referred to as TTR and it is then

divided by the total number of work orders within a year.[4] The formula used is:

$$MTTR(h) = \frac{\Sigma TTR}{n^{\circ}\ work\ orders}$$

3. **MTBF** (Mean Time Between Failures). This term corresponds to the average time interval between two successive failures (TBF) and indicates the frequency with which a failure can occur. This is mainly a reliability parameter used to indicate the probability that equipment operating under certain conditions will retain, after a predetermined time, the functional capacities for which it was built. The calculation of this coefficient involves data from all equipment on which a work order has occurred that involved corrective maintenance or functional verification. The work orders correspond to each inventory number of the equipment and consequently the total time that elapses between the start date of one work order and the start date of another. This would be the TBF. The TBFs from all work orders are added together and then divided by the total number of work orders within one year.4 The inverse parameter, defined as "frequency of failure," indicates the rate at which technicians must carry out maintenance. The formulas

$$MTBF(h) = \frac{\Sigma TBF}{n^{\circ}\ work\ orders}$$

$$Frequency\ of\ failure(h^{-1}) = \frac{1}{MTBF}$$

used are the following:

4. **COSR** (Cost Of Service Ratio). COSR is an economic parameter that represents the sustainability of costs. It is calculated as the ratio between the overall maintenance cost and the purchase cost, assessed through a percentage measure.4 The calculation of the overall COSR is carried out by proceeding in three phases outlined below.
    1. Equipment with maintenance contracts, to which maintenance cost (if any) has been added the cost of the pieces of spare parts.
    2. Equipment with only spare parts and without maintenance contracts.
    3. Company cost of all the personnel working in the CES.

    The formula used is the following:

$$COSR(\%) = \frac{maintenance\ cost}{purchase\ cost} * 100$$

5. **PPM** (Percentage Preventive Maintenance). This term expresses the overall number of preventive maintenance events or carried out within the deadline, divided by the total planned preventive maintenances within a year expressed as a percentage.[4] This calculation is made for each piece of equipment based on the future expiration date of preventive maintenance and the scheduled maintenance frequency. This makes it possible to derive the previous preventive maintenance expiration date, which is compared with the date of the beginning of the maintenance carried out on each piece of equipment, allowing us to understand if the maintenance has been carried out before or after the deadline. The PPM calculation is also necessary in light of the accreditation manual of the Hospitals of the Joint Commission International.[5] According to this manual, "all medical equipment and technologies are regularly subjected to inspections, maintenances and calibrations and these activities are documented in the appropriate registers. The staff ensure that all medical equipment and technologies operate at acceptable levels and safely for operators." When there is a need to manage the maintenance of many pieces of equipment, it is necessary to adopt criteria allowing priority. The equipment is not all critical in the same way, so it is necessary to distinguish the critical equipment on which the patient's life depends from the less critical ones for which the priority level is lower. There is, therefore, an issue to solve: if the technician receives two maintenance requests at the same time, the technician must be able to evaluate what the priority request is. To do this, a risk assessment is carried out, which is done with objective criteria and not left to free interpretation. In our case, the criticality analysis is carried out based on the assignment of five scores, respectively relating to five categories of equipment criticality (Equipment Management Program Mayo Clinic[6] has taken up this method). According to these criteria, equipment that should be excluded from the

plan can still be included if requested by a certification body or if scheduled by the manufacturer for periodic maintenance or calibrations. The formulas of PPM used are the following:

$$PPM_1(\%) = \frac{maintenance\ carried\ out}{total\ maintenance\ planned} * 100$$

$$PPM_2(\%) = \frac{maintenance\ within\ the\ deadline}{total\ maintenance\ planned} * 100$$

RESULTS AND DISCUSSION

Firstly, the first three indicators are analyzed, where possible, by applying the Pareto principle, one of the most used tools in quality management. The Pareto principle, also known as the 80/20 rule, took its name from Vilfredo Pareto, an Italian engineer who, in 1906, observed that the distribution of wealth in his country had an unequal distribution: 20% of the population owned 80% of the wealth.7 By expanding this idea to other areas and concepts, an empirical theory has been formulated which is respected in the majority of cases (this means that the distribution referred to it must be a very numerous distribution). The Pareto diagram's construction, based on this principle, shows that 20% of the causes produce 80% of the effects.

The advantages that derive from the application of the Pareto principle and diagrams are:

- to help to break down big problems into smaller problems and to establish what are the main factors causing them;
- to help to focus on the most important causes in order to establish priorities, using the available time more effectively;
- to help to link causes with effects; and
- to support in evaluating the improvement based on an analysis of the situation before and after the application of the corrective action.

To identify critical issues, the data relating to the first three indicators, namely Uptime, MTTR and MTBF, are analyzed by applying the Pareto diagrams, showing that, where applicable, 20% of the causes produce 80% of the effects. Considering all the medical equipment, it is possible to concentrate efforts only on 20% of causes to obtain a significantly better result. However, the analysis of data through the Pareto law is not always possible, but to extend its application, it expanded to 30% of causes. However, where the percentage is more than 30%, its application is not considered significant. This analysis makes it possible to focus on a small group of medical devices and understand the correlations between them (type of equipment, manufacturer). Identifying these characteristics allows the discovery of the main critical issues present within the health structure and what action is required. This will pertain to 80% of the overall behavior.

For the construction of the Pareto diagram, a combination of a bar chart can be considered showing the data in order of decreasing KPIs (Uptime, MTTR, MTBF), and of a cumulative curve, constructed by adding the i-th value to the previous values. This allows for immediate identification and effect of the relevant elements.

On the other hand, the COSR and PPM indicators help analyze the data and suggest distribution models that enable focus on the most critical equipment.

The graph of Uptime only considered those devices on which one or more work orders took place, which involved a value of Uptime <100%. It is precisely on these parameters that the analysis of Pareto is carried out. Focusing will be on the downtime rather than on the Uptime to immediately highlight any critical issues. Overall, we note distribution of data mainly concentrated around 100%, while only a smaller percentage corresponds to a value of Uptime less than 100%, mainly distributed between 20% and 30%. Figure 1 shows the average value calculated, which is very high and aligned well with similar measurements noted in the bibliography.

The MTTR graph shows a data distribution mainly concentrated in a range between 0 and 1000 hours (42 days), while only a smaller part, the initial one, shows an increase in the number of hours that goes up to 1800 hours. As shown in Figure 2, this reflects the average value calculated.

Since MTBF is the time between failures, the calculation is performed if there are, for each inventory item, at least two failures, therefore two work orders within a year.

The data analysis focuses on the frequency of faults, and it is carried out using Pareto diagrams. The MTBF graph (Figure 3) shows data distribution mainly concentrated in a range between 0 and 832 hours (35 days), while only a smaller part, the initial one, shows an increase in the number of hours that rises to 1354 hours.

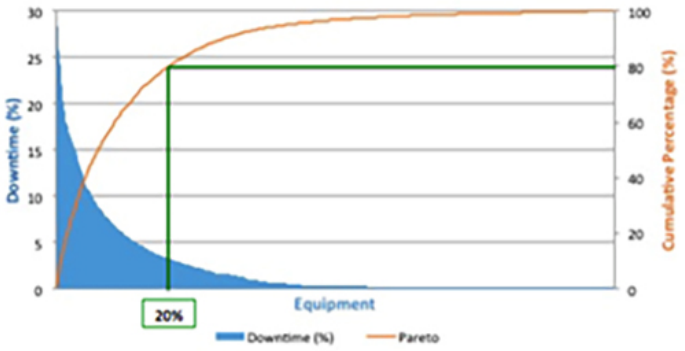

FIGURE 1. Pareto diagram for calculating downtime for equipment in 2015.
x axis = number of devices; y-axis = percentage of time out of service (Downtime).

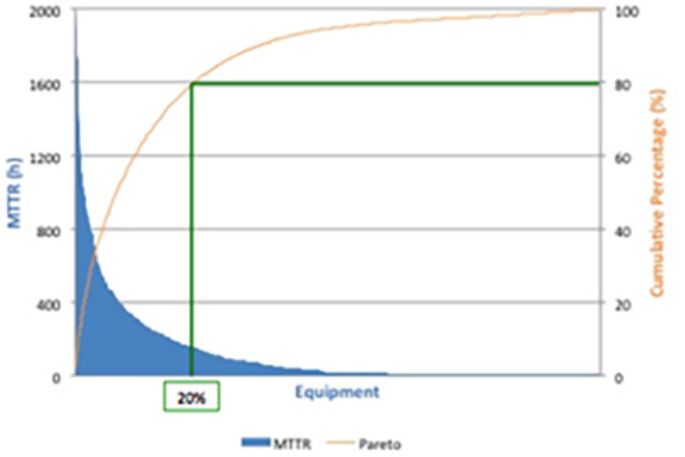

FIGURE 2. Pareto diagram for calculating MTTR for equipment in 2015.

The COSR is calculated by paying attention to equipment with COSR> 0% to highlight any critical issues more efficiently. A histogram has been constructed (Figure 4) from these devices: the COSR trend has been highlighted through 0.5% intervals and the number of devices is then reported, having the corresponding COSR. The COSR trend resembles a Poisson distribution, in fact the data

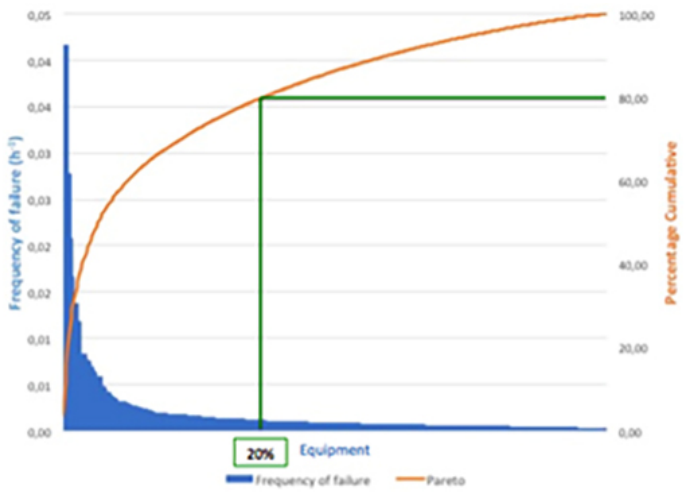

FIGURE 3. Pareto diagram for calculating the frequency of failures for equipment in 2015.

are distributed bell-shaped around a value belonging to the COSR range between 1.5 and 2%, corresponding to which we have 115 devices in 2015 and 124 devices in the year 2016. The trend over the two years is, in fact, the same. However, the highest histogram bar remains the one with COSR> 10% and will be analyzed later in detail for the analysis of critical issues. As can be seen, the COSR values are quite low at around 1%, but personnel costs must be added to this value, so overall it is around 4%.

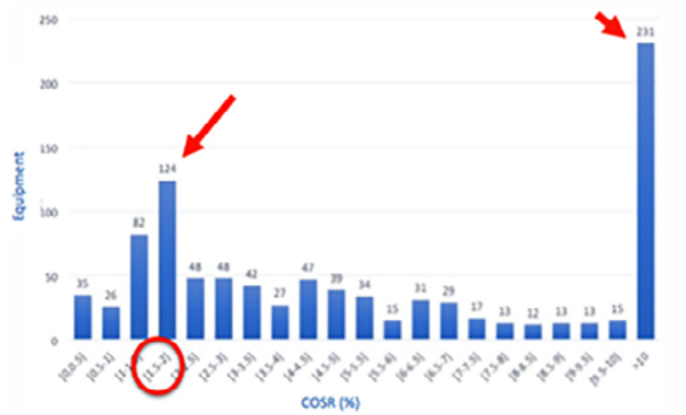

FIGURE 4. Histograms for calculating COSR interspersed by 0.5% in 2016.

The data analysis for the PPM is carried out through the use of histograms (Figure 5) that highlight the equipment on which preventive maintenance took place in advance

(negative numerical value of the days) and late (positive numerical value of the days) concerning the scheduled deadline. If the number of days is 0, the preventive maintenance took place on the same day as the planned date. It should be noted that the maintenance carried out in advance is greater than the delayed since the initial section of the graph is greater than the final one.

FIGURE 5. Histograms of the number of days in advance and delay concerning the scheduled deadline from the next preventive maintenance date.

If we want to summarize in a single value what has just been shown, the value of the Uptime, MTTR, MTBF, COSR, and PPM is reported expressing the measure according to its mean value and standard deviation. Each KPI is calculated for 2015 and 2016, as follows (Equipment that does not have work orders is also included in the Uptime calculation, resulting in 100% Uptime).

As shown earlier, the Tiwari study, which shows numerical calculations and graphs of identified KPIs, assesses the performance of medical equipment serviced by external suppliers; the CES examined in this work, on the other hand, is a predominantly internal CES, so a first difference is immediately apparent. In detail, however, we note that the numerical value of Uptime and COSR obtained from the two studies is comparable; the calculation of MTTR was carried out individually for each month by Tiwari, so it is clear this type of comparison is inconsistent. Also, because some work orders last more than one month; finally, in order to be able to compare the PPM, a clarification is needed, that is, it is necessary to take into account that, in the UCBM Polyclinic, the system revolves around a risk classification that guides the professionals of the CES to act according to different priorities. It is clear that comparing the two numerical values, they are different, but, taking this into account, it would then have been more significant to take as a reference the value of the calculated PPM for priority equipment, at 93.7%. Comparison with the study by Tiwari et al is shown in Table 1.

TABLE 1. Comparison with the Study by Tiwari and Tiwari.

KPIs	TIWARI STUDY	THIS PAPER
UPTIME (%)	98.5 ± 0.5 %	2015→ 98.5 % (6,2) 2016→ 98.5 % (6,1)
MTTR (h)	40 ± 12 min	2015→ 339 h (611) 2016→ 369 h (587)
COSR (%)	4.2 %	4.0 %
PPM (%)	97.3 ± 1.1 %	72.5 % → 93.7%

Starting with the results obtained critical issues are analyzed. In the case of the Uptime, MTTR, and MTBF, this analysis is conducted globally as there is a correlation between them and the level of the numerical calculation performed. They are calculated starting from the durations of the work orders that are carried out during a year. It is therefore important to concentrate on the equipment for which this phenomenon is most evident and this is possible with the analysis carried out using the Pareto diagrams, which are found to be applicable only in those cases where 20% or 30% of the causes have produced 80% of the effects. Therefore, making a detailed analysis for each of these KPIs, a global analysis is deduced, identifying the equipment that more frequently falls into 20% or 30% of the causes. Also, in the case of COSR, the critical issues present are analyzed and made possible by focusing on the equipment for which COSR is more than 10%. Finally, the same reasoning is carried out for the PPM, which, regarding preventive maintenance, focuses on the type of intervention priority, such as equipment of priorities I, II, III.

For example, it is reported as an average across the fleet of pressure such as therapy units for that particular manufacturer of equipment, considered from the criticality analysis of the Uptime, MTTR and MTBF (Table 2).

TABLE 2. Analysis of Critical Issues through the Pareto Diagram for Uptime, MTTR and MTBF: Types of Equipment that Fall Within 20% or 30% of the Causes

Equipment	Downtime(%)
Pressure therapy units	30.0
Scialytic lamps	28.6
Cystoscope	24.1
External cardiostimulator	24.2
Operating table	22.0
Videoduodenoscope	17.9
Electrosurgical units	16.6
Anesthesia device	15.7
Monitor	14.0
Electrocardiograph	12.1
Electro-controlled bed	11.6
Ultrasound probe	10.8

This paper summarizes medical equipment repair and maintenance benchmark indicators that can be used. Therefore, the clinical engineering profession must develop and use indicators that accurately reflect the true costs and quality of medical equipment repair and maintenance.

The way to analyze the results obtained is, when possible, using Pareto diagrams. They help to break down the big problems into smaller problems and to determine which are the main factors that cause them; to help to focus on the most important causes and to set priorities, using the time available more effectively help to link the causes with the effects. This methodology makes it possible to have precise information on the critical equipment that will then be replaced or repaired correctly, which will be taken through work experience and information.

Performance measurement of clinical engineering departments in hospitals using these indicators will get more accurate and fairer performance evaluation. We will be able to find the real reasons for failure and improve performance. Further analysis may be required to better define creating a standard and substantive performance evaluation benchmarks and solve it.

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Lean and Computerized Management System for Non-Hospital-Owned Medical Equipment in Hospital

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ABSTRACT

Many challenges exist in the management of non-hospital-owned medical equipment. This paper proposes implementing a novel kind of lean and computerized management method, including the management policy, procedures, agreement signing, equipment installation, acceptance and maintenance, and exit procedure. The result shows that the Lean and computerized management system can improve oversight and assure the safe integration of non-hospital-owned equipment to reduce liability exposure and increase compliance with regulations.

Keywords – *Non-Hospital-Owned Medical Equipment, Lean Management, computerized management system, Trial Protocol, Medical Safety, assets control.*

INTRODUCTION

With the rapid development of the modern hospital, increasing demand for the medical equipment and technology experienced both in clinical and research environments. Due to the diversity of novel medical equipment, some are supplied for free by the vendors. Vendors have a variety of reasons for bringing in their equipment. They may bring in as a service loaner or as a new model to demonstrate to clinicians. As this equipment may be left for weeks for a clinical trial and evaluation only, the new products' technical parameters and performance can be evaluated and compared in hospitals[1]. We define this kind of equipment as trial equipment in this article. The trial equipment we refer to here is not medical equipment in clinical trials for pre-market approval but equipment already approved for the market. All the indirect hospital purchased equipment are treated as non-hospital owned equipment, including trial equipment, research collaboration equipment, household appliances, among other things.

The state of non-hospital-owned equipment is difficult to judge at times, and some of them may not meet the safety requirements, which can lead to safety problems[2]. Valid concerns about non-hospital owned medical equipment include safety and effectiveness, compliance with applicable accreditation standards and legal requirements, proper integration, and technical support. Therefore, they should be under the oversight of clinical engineering, and

all medical equipment should receive any needed attention regardless of their ownership. In our hospital, all non-hospital-owned equipment is supervised by a Lean and computerized management system. This article takes the trial equipment we defined before as an example and describes the relevant management program.

MATERIALS

Lean management is designed to enhance productivity by improving work efficiency[3]. During the whole procedure, the manager's duty is specified and explicit, and the management process is standardized and systematized. On the one hand, the Lean management's core idea is applied in non-hospital-owned medical equipment, and a strict management policy and procedure ensure its safety. On the other hand, information technology is applied to develop a customized tool for implementing the overall non-hospital owned medical equipment management[4]. Our hospital's medical equipment management system includes the management functions of hospital-wide medical equipment such as testing, reporting for repair, and maintenance, among which the management of non-hospital owned medical equipment is an important module.

A. Design a Rigorous Management Policy and Procedure

Before its first clinical use, all non-hospital-owned medical equipment providers need to sign an agreement or protocol with the hospital represented by the clinical engineering department. Any unauthorized or disapproval use of non-hospital-owned medical equipment is strictly forbidden. Hence, the recommended procedure is shown in Figure 1.

Step 1: Trial application. The corresponding department is asked to complete the medical device clinical trials' application form, with a description of application reasons, device name, brand and model, quantity, regulation registration certificate number, vendor name.

Step 2: Legal compliance examination and verification. All the necessary documents are reviewed by the department of clinical engineering, including the medical device registration certificate issued by the China Food and Drug Administration (CFDA), production enterprise license, business certificate business license, factory authorization letter, operation manuals. The copies of these documents are saved for future reference.

Step 3: Approving or comments by the related functional departments such as the medical administration department and finance department.

Step 4: Submission to hospital medical equipment management committee for consideration.

Step 5: Signing a protocol of authorized usage for the non-hospital owned medical equipment.

Step 6: Labeling the device and informed users.

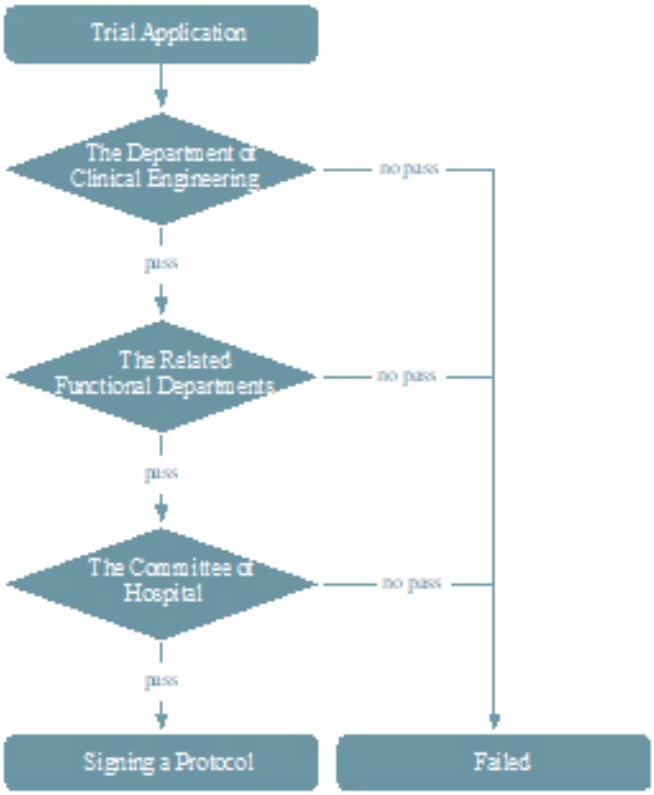

FIGURE 1. The access protocol for non-hospital owned medical equipment.

B. Sign Medical Equipment Trial Protocol

The trial protocol is signed by the hospital (Party A) and the vendors such as the sales company or manufacturer (Party B), in which the duties and obligations for both sides and the agreed usage duration (usually no

more than 3 months) are specified. According to the trial protocol, Party B's equipment should be conforming to all the regulations made by CFDA. Also, Party B should provide valid certificates, installation procedures, and user training. When the trial period ends up, the equipment should return to Party B in time. Party A should take good care of the devices during the trial period. If the device breaks due to the user's carelessness or abuse, the hospital (Party A) will be responsible for the compensation.

C. Standardization of Installation and Acceptance Process

When the medical equipment trial protocol is implemented, the supplier shall be responsible for the trial equipment installation, and the engineers of the department of clinical engineering at the hospital will make an acceptance check to ensure the safety of the equipment.

After the completion of the acceptance process, the supplier needs to conduct training for potential users. Some of the non-hospital-owned equipment is surgical instruments in the operating room. Such instruments may be used already many times in different hospitals. Therefore, it might cause potential surgical infection if sterilization protocol is not carried out strictly or adequately[5]. For example, in orthopedic implant surgery, if the bacteria contaminate the implant, it will be quite challenging to tackle this problem since a layer of protective film is generated in the implant surface, which makes the antibiotics useless and brings about great pain for the patients[6]. Hence, additional precautions should be taken, and relevant measures should be taken according to hospital infection control policy if the trial device is the surgical instrument[7,8]. The corresponding training, assembly, and disassembly demonstration should be provided for the central sterile supply department staff to ensure that all the operations conform to the disinfection and sterilization requirements[9,10] and make sure that the instruments are used in a safe situation[11].

D. The Application of Non-Hospital Owned Medical Equipment Management Module

After completion of the acceptance and training procedures, the trial equipment is commissioned. Simultaneously, all the useful information will be loaded into the computerized management system by the clinical engineering department staff, including basic info, clinical department, maintenance record, and the trial's validity period. Besides, a QR code label containing affiliation, equipment name, brand and model, serial number, and the clinical department is labeled on each piece of trial equipment (Figure 2).

In this paper, a lean and computerized management system is proposed and implemented in the hospital, in which non-hospital owned equipment is subject to oversight and control in a standardized framework, especially in terms of the following several aspects.

FIGURE 2. The QR code label.

1. Based on the strict management policy and procedure, some unnecessary and less prominent medical devices are filtered in the approval process. The quantity of external medical equipment is better controlled and quality is better guaranteed. There are no more than 10 cases of trial medical equipment in our hospital every year in recent years.
2. QR code label. More detailed information is obtained following the scanning of the QR code. It contains device type, serial number, registration certificate information. Besides, repair and maintenance records can be documented in the computerized management system. The registration certificate period for

non-hospital-owned equipment will be monitored by the clinical engineering department's computerized management system. If the clinical department applies for extending the trial time, its validity period must be reviewed and confirmed. Hence, the working efficiency is enhanced since the validity of the registration certificate and trial period validity can be checked by scanning the QR code.

3. Planned maintenance. The computerized management system alerts the need for any maintenance due three days in advance, at which time the department of clinical engineering will contact the vendors for a timely inspection and maintenance. The maintenance task and its record can be easily accessed and carried out by scanning the QR code. All the corresponding information can be reviewed by logging in the system.
4. End of the trial. The computerized management system reminds the trial ending time three days in advance. The clinical engineering department is responsible for reminding and contacting the vendors to remove the trial equipment from the hospital. Also, it is recorded in the information system.

CONCLUSIONS

The lean management system we described takes key management elements of non-hospital owned medical equipment into consideration. Combined with the government requirements of rules and regulations with hospital real-practice scenarios, the department of clinical engineering has designed and implemented an effective lean management system for non-hospital-owned medical equipment. Furthermore, the whole management process is carried out with the support of an information system, in which all the corresponding information and certificates, and quality control activities are recorded and is reviewed together conveniently. By doing so, the management efficiency and performance improves. The risks and potential damages from non-hospital-owned medical equipment are effectively mitigated; medical safety for hospitals and patients is enhanced; compliance with regulations increases.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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Quality Assessment of Emergency Corrective Maintenance of Critical Care Ventilators within the Context of COVID-19 in São Paulo, Brazil

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ABSTRACT

This technical report presents the quality assessment process for the emergency corrective maintenance of critical care ventilators in a node, IPT-POLI, of a voluntary network that is part of the initiative +Maintenance of Ventilators, led by the National Service of Industrial Training (SENAI) and its Integrated Manufacturing and Technology Center (CIMATEC) to perform maintenance on unused mechanical ventilators in the context of the COVID-19 pandemic in Brazil. A procedure was established for the quality assessment of equipment subjected to corrective emergency maintenance, covering the essential aspects of the three primary standards (ABNT NBR IEC 60601-1: 2010+A1:2016, ABNT NBR ISO IEC 62353: 2019, and ABNT NBR ISO 80601-2-12:2014) for performance and safety assessment. A set of nine critical care ventilators was evaluated considering the following parameters: leakage current, protective ground resistance, control accuracy, delivered oxygen test, and alarms. The evaluated ventilators underwent corrective emergency maintenance before performance and safety assessments. In the electrical safety tests, all equipment presented values prescribed for the standard. However, the assessment of ventilator parameters revealed that their performance was below the standard. Finally, quality assessment reports were sent to the clinical engineering departments at hospitals. Thus, it can be concluded that criteria selection for the quality assessment in critical care ventilators is crucial and of great significance for future pandemic scenarios, such as the situation experienced during the COVID-19 pandemic.

Keywords – *Quality assessment, critical care ventilators, standards, corrective maintenance, ventilation modes, COVID-19.*

INTRODUCTION

Faced with the pandemic due to the novel coronavirus (SARS-CoV-2), the Brazilian health system experienced limitations in the number of critical care ventilators due to the increased demand. These ventilators were fundamental for the treatment of patients suffering from the most severe levels of the disease. The number of beds in intensive care units at hospitals was monitored as the disease progressed, and it was observed that certain regions had insufficient capacity.[1]

The Institute of Technological Research (IPT) and the Escola Politecnica (POLI) of the University of São Paulo set up a laboratory (IPT-POLI) to perform maintenance, inspection, electrical safety tests, and quality assessment

of mechanical ventilators to provide support to public hospitals in São Paulo, Brazil. Medical devices that were unusable due to technical failures were repaired and returned to hospitals. There was a voluntary network of 39 maintenance points in all Brazilian states, that are part of the national initiative (+Maintenance of Ventilators) led by the National Service of Industrial Training and its Integrated Manufacturing and Technology Center.

The maintenance and quality assessment processes were based on ABNT NBR 77, ABNT NBR ISO IEC 62353: 2019, and ABNT NBR ISO 80601-2-12:2014. This technical report addresses the quality assessment process conducted during the first months of activity and the set of critical tests selected as criteria for quality assessment after the maintenance process.

Specific electrical safety tests were conducted per ABNT NBR IEC 60601-1: 2010+A1:2016 (general requirements for basic safety and essential performance). The selected tests were leakage current to earth, to the patient, and in the medical device enclosure, considering the manufacturer's classification in accompanying documents.[2]

Another essential standard used for evaluation was ABNT NBR ISO IEC 62353: 2019 (recurrent test and test after repair of medical electrical equipment) that presents the requirements to be analyzed before the medical device is put into service, during maintenance and inspection, and after repair.[3]

The ABNT NBR ISO 80601-2-12:2014 (particular requirements for basic safety and essential performance of critical care ventilators) provides tests to evaluate ventilation modes, analyzed according to the pressure, volume, breath rate, inspiratory time, and oxygen concentration measurements. Also, the standard prescribes testing to describe several failure conditions and alarm verification, emphasizing alarm priorities.[4]

Critical care ventilators are medical life support devices, and the maintenance and calibration processes must be evaluated carefully to guarantee electrical safety and essential performance in ventilation. However, in the crisis scenario, it was not possible to thoroughly conduct all recommended tests; hence, there was a need for a study to select the points considered critical within a set of standards.

A procedure for quality assessment of equipment subjected to corrective emergency maintenance was developed, covering the main aspects of the three standards for performance and safety assessment. This procedure was applied to a small set of critical care ventilators, and the results are presented and discussed.

METHODS

The Electrical and Optical Equipment Laboratory of IPT and the Testing and Calibration Division of POLI were used to regularly conduct electrical safety tests on medical equipment before the COVID-19 pandemic and joined skilled labor metrology systems for this endeavor. IPT-POLI organized four areas inside the IPT campus (São Paulo, Brazil) to conduct maintenance and quality assessment procedures. A brief description of these areas is presented below. The medical devices were registered and disinfected in a reception area. After 12 h, critical care ventilators were transferred to the waiting area, which is also utilized to store devices that were not compliant with the requirements. Then, maintenance and quality assessment procedures were performed in the service area. This two-room area had four workbenches, two for electrical safety evaluation and two for ventilation assessment. Two oxygen gas cylinders, medical oxygen (99 %) and high-purity oxygen (99.995 %), of 10 m^3 with two-stage regulators (from 4–6 bar) (PRG-108, Prostar, Brazil) and an air compressor (1201BF, SCHULZ, Brazil) were connected to a delivery system in the service area to supply oxygen and air. Compressed air and oxygen lines were installed to supply an adjustable pressure between 4.5–5.5 bar on each workbench to accommodate critical care ventilators. Finally, compliant medical devices are stored in the dispatch area.

Leakage current measurement

An electrical safety analyzer (601 Pro Series, Fluke, USA) was used to perform the tests. Briefly, the test consisted of supplying the medical device with 110 % of the rated electrical voltage, measuring the leakage current under normal conditions for all parts indicated by the ABNT NBR IEC 60601-1: 2010+A1:2016 (leakage current to

earth, to the patient, and the enclosure). The test must be repeated by applying the electrical failures prescribed for the standard and measuring the corresponding leakage current. Critical care ventilators in this study, per the manufacturer, were classified as Class I. This classification refers to medical equipment that has basic insulation and grounding protection against electrical shock. The standard also provides the permitted limits for Class I equipment: leakage current (<5 mA), patient leakage current (<10μA), and enclosure leakage current (<100μA).

Resistance of protective ground

An electrical safety analyzer (19032, CHROMA, Germany) was used to perform the tests. The test consisted of circulating an alternating current of 25 A through the medical device. The ABNT NBR IEC 62353: 2019 standard was used for this test. The resistance of the protective ground was measured with an electrical safety analyzer and must be less than or equal to 300mΩ for equipment with a detachable power-supply cord.

Accuracy of control: Volume control and Pressure control inflation type

The prescriptions related to volume control and pressure control inflation type correspond to items 201.12.1.101 and 201.12.1.102 of ABNT NBR ISO IEC 80601-2-12: 2014. To test the volume control inflation type, it is necessary to measure the volume (mL), inspiratory time (s), positive end expiratory pressure (*PEEP*) (hPa), respiratory rate (breaths/min), and fraction of inspiratory oxygen (FiO_2) (%). For the pressure control inflation type, it is necessary to measure pressure (hPa), inspiratory time (s), *PEEP* (hPa), respiratory rate (breaths/min), and FiO_2(%).

During the first month (April), to verify the accuracy of control, the setup was adopted as described in items 201.12.1.101 and 201.12.1.102 with modifications in resistance and compliance values, as shown in Figure 1. A ventilator tester (AVM100, NÉOS, Brazil) was used for data acquisition. An adult test lung (SmartLung Adult 2000, IMTMedical, Switzerland), an air compressor, and gas cylinders of medical oxygen (99 %), and high-purity oxygen (99.995 %) were applied to vary some parameters, such as compliance (mL/hPa), resistance (hPa/L/s), airflow (L/min), pressure (hPa), and FiO_2 (%).

Tables 1 and 2 list the parameters set for the critical care ventilators and test lungs. Dark gray columns represent the parameters adjusted in the test lung, and light gray columns denote the parameters configured in the critical care ventilator.

In May, IPT-POLI acquired another test lung simulator (Dual Adult TTL, Michigan, USA). The instrument made it possible for the laboratory to verify the control's accuracy (items 201.12.1.101 and 201.12.1.102) of critical care ventilators without any modification of resistance and compliance (Tables 3 and 4). Also, the capability of the test lung simulator increased the number of tests from six to eight. Figure 2 illustrates the experimental setup with the test lung simulator and the ventilator tester for this case.

Based on the ABNT NBR ISO IEC 80601-2-12:2014, all critical care ventilators must declare in their instructions for use the maximum error to expiratory volume, airway pressure (P_{aw}), *PEEP*, respiratory rate, inspiratory time, and oxygen concentration.

Delivered oxygen test

A ventilator tester (AVM100, NÉOS, Brazil) and the lung test were used, as shown in Figures 1 and 2 to check the oxygen sensor on the critical care ventilator. The test lung (SmartLung Adult 2000, IMTMedical, Switzerland) was adjusted to a resistance of 5 hPA/L/s and compliance of 60 mL/hPA; in the case of the test lung simulator (Dual Adult TTL, Michigan, USA), it was configured with a resistance of 5 hPA/L/s and compliance of 50 mL/hPA. The critical care ventilator was configured for control pressure mode, inspiratory time (1 s), pressure (10 hPA), frequency (20 breaths/min), and *PEEP* (5 hPA). The inspiratory oxygen concentration (FiO_2) was measured as 25 %, 50 %, 75 %, and 100 %.

Alarm verification

A set of alarms were analyzed based on item 201.4.3, which was prescribed for ABNT NBR ISO IEC 80601-2-12:2014. Alarm conditions were generated according to the indications for each sub-item. The evaluated alarms are listed in Table 5.

Calibration and verification

Calibrated instruments are mandatory to perform maintenance and quality assessment procedures. The ventilator tester parameters were calibrated according to Table 6 with requirements based on the ABNT NBR IEC 60601-2-12:2014 and the International System of Units. The ventilator tester was calibrated following the available laboratory standard (LMR Metrologia, certificate number L613420, 2020-04-23).

The electrical safety analyzer was calibrated for current, voltage, frequency, and resistance (IPT-Laboratorio de Metrologia Eletrica/CTMetro, certificate number 173117-101, 2019-05-16).

The IPT-POLI acquired a certified oxygen cylinder with a purity of 99.995 % (Air Products Brazil Ltda, certificate number 256461, 2018-11-19) to verify the ventilator's galvanic cell tester that needs to be verified every day before the first use. A nitrogen gas sample was used to emulate the absence of oxygen for verification of the tester.

Uncertainty of measurement (U)

For the ventilator parameters, pressure (hPa), volume (mL), FiO_2 (%), *PEEP* (hPa), and respiratory rate (breaths/min), three measurements were carried out and, consequently, the conventional quantity value and the measurement uncertainties were calculated.

To calculate measurement uncertainties, type A evaluation of measurement uncertainty, derived from a statistical source, and type B evaluation of measurement uncertainty, which is the information from the accuracy of the verification certificate and information from the instrument's manual, were used.

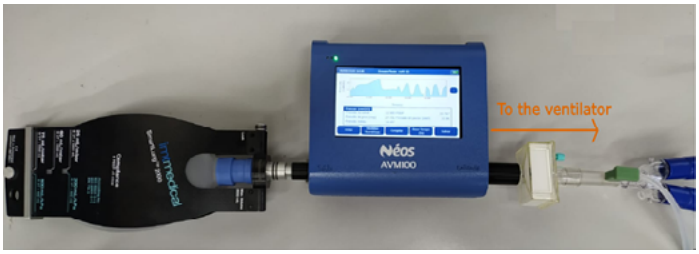

FIGURE 1. Experimental setup with the adult test lung and the ventilator tester. The orange arrow indicates the direction of the ventilator.

Type A and B uncertainties were integrated to provide a combined standard measurement uncertainty.[5]

For each test, leakage current, and resistance of the protective ground, only one measurement was taken, and type B uncertainties were adopted.

The uncertainties were calculated using combined and expanded uncertainties with a coverage factor (k = 2 and 95.45 %) as prescribed in the ISO GUM series - Guide to the expression of uncertainty in measurement.[6]

Assessed critical care ventilators

In total, nine critical care ventilators from two large public hospitals in São Paulo were assessed. Seven critical care ventilators (Vela, Carefusion, USA) were evaluated in April (Tables 1 and 2). In May, two critical care ventilators (Inter 5 Plus, Intermed, Brazil) were assessed, as shown

TABLE 1. Adaptation of volume control inflation-type testing from item 201.12.1.101 of the ABNT NBR ISO IEC 80601-2-12: 2014

Test Number	Test lung parameters		Ventilator Parameters				
	Compliance* (mL/bar)	Linear Resistance* (hPa/L/s)	Volume (ml)	Inspiratory Time (s)	Set rate (breaths/min)	FiO_2 (%)	PEEP (hPa)
1	60	5	500	1	20	21	5
2	60	20	500	1	20	21	10
3	25	5	500	1	20	21	5
4	25	20	500	1	20	21	10
5	25	20	300	1	20	21	5
6	25	50	300	1	20	21	10

(*) Modified values of compliance and resistance.

TABLE 2. Adaptation of pressure control inflation-type testing from item 201.12.1.102 of the ABNT NBR ISO IEC 80601-2-12: 2014

Test Number	Test lung parameters		Ventilator Parameters				
	Compliance* (mL/bar)	Linear Resistance* (hPa/L/s)	Pressure** (hPa)	Inspiratory Time (s)	Set rate (breaths/min)	FiO_2 (%)	PEEP (hPa)
1	60	5	10	1	20	21	5
2	60	20	15	1	20	21	10
3	25	5	25	1	20	21	5
4	25	20	25	1	20	21	10
5	25	20	15	1	20	21	5
6	25	50	25	1	20	21	10

(*) Modified values of compliance and resistance.

(**) Set pressure above PEEP level.

in Tables 3 and 4. The medical devices were named A, B, C, D, E, F, G, H, and I in this study.

The maximum errors for evaluating the first seven ventilators (A, B, C, D, E, F, and G) (Vela, Carefusion, USA) were obtained from its instruction for use and should be per the listed values: expiratory volume ±10 % of the monitored volume, respiratory rate ±2 bpm, airway pressure ±5 hPa, *PEEP* ±2 hPa, inspiratory time ±0.05 s, and oxygen percentage ±2 %.

For the last two ventilators (H and I) (Inter 5 Plus, Intermed, Brazil), the maximum errors were: expiratory volume ±10 % of the monitored volume, airway pressure ±0.05 cmH_2O, *PEEP* ±5 cmH_2O, inspiratory time ±0.05 s, and oxygen percentage ±5 %.

FIGURE 2. Test setup using test lung simulator (Dual Adult TTL, Michigan, USA). The orange arrow indicates the direction of the ventilator.

TABLE 3. Volume control inflation-type testing of item 201.12.1.101 of the ABNT NBR ISO IEC 80601-2-12: 2014

Test Number	Test lung parameters		Ventilator Parameters				
	Compliance (mL/bar)	Linear Resistance*(hPa/L/s)	Volume (ml)	Inspiratory Time (s)	Set rate (breaths/min)	FiO_2 (%)	PEEP (hPa)
1	50	5	500	1	20	21	5
2	50	20	500	1	20	21	10
3	20	5	500	1	20	21	5
4	20	20	500	1	20	21	10
5	20	20	300	1	20	21	5
6	20	50	300	1	20	21	10
7	10	50	300	1	20	21	10
8	10	20	200	1	20	21	5

TABLE 4. Pressure control inflation-type testing of item 201.12.1.102 of the ABNT NBR ISO IEC 80601-2-12: 2014

Test Number	Test lung parameters		Ventilator Parameters				
	Compliance* (mL/bar)	Linear Resistance* (hPa/L/s)	Pressure* (hPa)	Inspiratory Time (s)	Set rate (breaths/min)	FiO_2 (%)	PEEP (hPa)
1	50	5	10	1	20	21	5
2	50	20	15	1	20	21	10
3	20	5	25	1	20	21	5
4	20	20	25	1	20	21	10
5	20	20	15	1	20	21	5
6	20	50	25	1	20	21	10
7	10	50	30	1	20	21	5
8	10	20	25	1	20	21	10

(*) Set pressure above PEEP level.

Volume control inflation type and pressure control inflation type were evaluated for the ventilators using preset modes: continuous mandatory ventilation pressure control (CMV-PC) and continuous mandatory ventilation volume control (CMV-VC).

RESULTS

All ventilators passed electrical safety tests for protective ground resistance, leakage current, patient leakage current, and enclosure leakage current.

Tables 7 and 8 summarize the measurement results for ventilators that did not comply with the stipulated limits.

Because of the ventilators' problems, alarm verification was performed only on ventilators A, H, and I. All ventilators were not compliant with the oxygen level alarm.

DISCUSSION

The IPT-POLI adopted some of the essential performance requirements prescribed by item 201.4.3 ABNT NBR ISO IEC 80601-2-12:2014 to evaluate critical care ventilators. Tables 201.103 and 201.104 of items 201.12.1.101 and 201.12.1.102 of ABNT NBR ISO IEC 80601-2-12: 2014 were taken into consideration; however, within the first weeks, due to the limitations of the available test lung at IPT-POLI, the values of resistance and compliance were adapted according to the nearest values of resistance and compliance, as these configuration scenarios were shown in Tables 1 and 2. Another point was the time to carry out all 21 items in Tables 201.103 and 201.104. As hospitals urgently needed critical care ventilators due to COVID-19,

TABLE 5. List of alarms

Test Number	Item	Test
1	201.11.8.101.1	Technical alarm condition for power-supply failure
2	201.11.8.101.2	Internal power supply
3	201.12.4.101	Oxygen monitor
4	201.12.4.104	Maximum limited pressure protective device
5	201.12.4.103.1	Ventilators intended to provide a tidal volume > 50 mL
6	201.12.4.105	High airway pressure alarm condition and protective device
7	201.12.4.106	PEEP alarm conditions
8	201.12.4.107	Obstruction alarm condition
9	201.12.101	Disconnection alarm condition
10	201.13.102	Failure of one gas supply

only the first six test numbers were performed. All tests were performed with FiO_2 adjusted to 21 % (atmospheric concentration) to evaluate the accuracy of the control and the oxygen concentrations were evaluated separately.

After the test lung simulator (Dual Adult TTL, Michigan, USA) was acquired, all tests to verify the control's accuracy were conducted using Tables 3 and 4. It was not possible to fully assess ventilators according to Tables 201.103 and 201.104 because the test lung did not attend the prescribed compliance values (0.5, 1, and 3 hPa/L/s) for neonatal ventilators; nevertheless, the setup made it possible to assess critical care ventilators for adult configuration.

TABLE 6. Calibration points for the ventilator tester

Parameters	Calibration points
Flow (L/min)	0.05, 0.1, 0.25, 0.5, 1, 10, 25, 50, 100
Low pressure (mbar)	0, 5, 10, 15, 20, 30, 60, 120
High pressure (bar)	0, 2, 4, 5, 8, 9.5
Barometric pressure (mbar)	650, 700, 750, 800, 850, 900
Volume (mL)	0.005, 0.01, 0.02, 0.03, 0.05, 0.2, 0.3, 0.5, 1, 1.5
Inspiratory time (s)	0.2, 0.4, 0.6, 1, 2
Respiratory rate (breaths/min)	10, 15, 20, 25, 30, 60, 80
FiO_2 (%)	21, 30, 60, 80, 90, 100

The purchased equipment (test lung and ventilator tester) to assess the volume and pressure control inflation-type modes were those with the shortest delivery time. The equipment was not the most capable; they lacked some features, such as external trigger input and well-sampled data; however, they met the quick application criteria.

Tables 7 and 8 indicate ventilators that did not comply with the delivered oxygen, volume, and pressure control inflation-type tests. This was expected because ventilators were out of use for more than two years and received only emergency maintenance without replacing the maintenance kit.

The FiO_2 The measurement test was essential to evaluate the delivered oxygen; as shown in Tables 7 and 8, eight ventilators did not comply with the prescribed limits due to problems with internal leakages and control valves. External blenders controlled the percentage of oxygen in the ventilators (Inter 5 Plus, Intermed, Brazil); the blenders presented leakages in all configurations (21–100%). Critical care ventilators commonly use galvanic cells to measure oxygen concentration, and those cells, depending on the manufacturer, have a life span of approximately 1–2 years. Also, eight ventilators did not monitor oxygen concentration correctly because of problems related to the galvanic cell or its absence.

Leakages in the ventilator breathing system (devices E and I) were observed during the tests.

One significant issue was noticed during tests with high medical oxygen concentrations, and the two ventilators presented inconsistent results. The results were double-checked with a high-purity oxygen delivery system, and there were improvements in the performance of both ventilators. Therefore, we noticed that the pressure loss in the delivery system of medical gas during high flow occurred due to particle debris in the pipes, which were removed.

Even though pressure setup in critical care ventilators was performed extensively using pressure values in mbar or cmH_2O by the clinicians, the ABNT NBR ISO 80601-2-12:2014 indicated pressure values in hPa. Even these units of measurement present a slight difference between them.

At the end of each critical ventilator quality assessment, all evaluated parameters were summarized in a quality assessment report and forwarded to the hospital's equipment control staff. Therefore, the quality assessment report could play an important role in hospital equipment usage decisions during the pandemic period.

CONCLUSION

Although all medical devices underwent corrective maintenance, eight out of nine failed the delivered oxygen test. Moreover, eight ventilators did not monitor oxygen, and four ventilators were not compliant with volume control and pressure inflation tests. The results are summarized in Tables 7 and 8.

Notwithstanding the urgent requirement of critical care ventilators for COVID-19, the performed tests revealed the necessity of conducting quality assessment after the maintenance of critical care ventilators to avoid risk to patients.

Justified by the fact that severe COVID-19 cases required safe delivery of ventilation oxygen support,[7,8] the tests listed in this study aimed to cover the basis of ventilation assessment to guarantee the accuracy of the critical care ventilator's performance.

The minimum infrastructure and instrument requirements to perform a quality assessment of emergency corrective maintenance of critical care ventilators during the beginning of COVID-19 in Brazil are presented herein.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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TABLE 7. Results of the critical care ventilators (Vela, Carefusion, USA) assessment

Continuous mandatory ventilation volume control (CMV-VC)			
Ventilator	**Test number**	**Results (mL)**	
		Tidal volume	**Uncertainty of measurement (U)**
C	1	570	13
E	1	96.4	7.2
Continuous mandatory ventilation pressure control (CMV-PC)			
Ventilator	**Test number**	**Results (mL)**	
		Pressure	**Uncertainty of measurement (U)**
E	1	37.1	1.5
F	4	33.22	0.47

Oxygen concentration (%)				
Ventilator	**Set value**	**Measured Value***	**Uncertainty of measurement (U)**	**Monitored value**
A	50	52.20	0.68	52
B	75	71.07	0.86	133
	100	82.97	0.90	155
D	25	29.27	0.41	24
	50	46.47	0.59	30
	75	68.57	0.84	38
	100	94.8	1.3	48
E	25	25.57	0.34	**
	50	47.40	0.56	**
	75	68.40	0.80	**
	100	87.6	1.2	**
F	25	27.00	0.33	**
	50	62.03	0.76	**
	75	89.8	1.1	**
	100	99.9	1.2	**
G	50	54.50	0.81	63
	75	82.83	0.97	100

(*) This refers to the monitored O_2 % value displayed on the ventilator..

(**) The monitored O_2 % value is not shown because the galvanic cell was not installed.

TABLE 8. Results of the critical care ventilators (Inter 5 Plus, Intermed, Brazil) assessment

Continuous mandatory ventilation volume control (CMV-VC)			
Ventilator	**Test number**	**Results (mL)**	
		Tidal volume	**Uncertainty of measurement (U)**
H	2	392	10
	3	407.1	9.8
	4	447	11
	6	261.8	6.7
	7	265.6	8.0
	8	170.5	4.3
I	2	395.3	12
	3	421	10
	6	262.4	6.1
	8	168.1	4.0

Continuous mandatory ventilation pressure control (CMV-PC)			
Ventilator	**Test number**	**Results (mL)**	
		Pressure	**Uncertainty of measurement (U)**
H	1	15.8	0.7
	3	32.1	0.8
	8	35.0	0.5
I	1	17.4	0.9
	3	32.7	0.9
	8	37.0	0.7

Oxygen concentration (%)				
Ventilator	**Set value**	**Measured Value***	**Uncertainty of measurement (U)**	**Monitored value**
H	25	22.6	0.3	**
	50	44.4	0.6	**
	75	69.7	1.7	**
I	25	28.9	3.7	**
	75	69.2	0.5	**
	100	93.9	1.1	**

(*) This refers to the monitored O_2 % value displayed on the ventilator..

(**) The monitored O_2 % value is not shown because the galvanic cell was not installed.

Book Review

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

In our continuous efforts to encourage sharing of knowledge and publication of engineering and scientific work related to the clinical engineering field, we have initiated a new section of our Global Clinical Engineering journal www.GlobalCE.org named Book Review. We hope that you will find it helpful to your career and at the same time promote the submission of other books for our review serving the benefit of all our readers.

Introduction to Clinical Engineering

Samantha Jacques & Barbara Christe

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This book review is about the Elsevier Academic Press newly published ***Introduction to Clinical Engineering*** by two authors Samantha Jacques, Ph.D., FACHE, and Barbara Christe, Ph.D. with Foreword by Lawrence (Larry) W. Hertzler, C.C.E., fAAMI. In addition to the Forward, the book contains six chapters, an appendix, and an index for a total of 270 pages. Dr. Jacques (or "Sam" as her colleagues call her) has served as Director/VP of clinical engineering program in several healthcare systems, and her writings express her expertise in healthcare technology management from the applied side. This style adequately complements Dr. Christe's writing that draws from her academic background and pedagogical experience. Together, the two styles combine into a single book that both practitioners and students will find interesting.

True to its title, the book provides a concise introduction to the conventional clinical engineering field that sometimes struggles with identity and recognition. The authors clarify this issue straight up in Chapter 1, the Profession. It starts with an introduction to healthcare technology management (HTM) and argues that clinical engineers are part of HTM. It is an exciting proposition that falls short of the notion that the clinical engineering profession as a learned life science engineering discipline contains a broader scope where HTM is one of its competencies, including consulting, design, informatics, and marketing. In their attempt to clarify a conventional clinical engineering practice, the authors partially achieve their goal; however, they left some confusion with readers, suggesting that technicians and technologists who specifically support medical equipment often function in a biomedical engineer position. Chapter 1 suggests that AAMI in 1973 developed a certification program for clinical engineers but neglected to recognize that this program was discontinued by AAMI and re-initiated through the America College of Clinical Engineering as correctly described few pages later.

The book generally describes the structure of a healthcare system and clinical engineering's role within it from a US point of view. For example, according to Japan's clinical engineering association, over 20,000 certified clinical engineers are licensed to service and to operate complex heart-lung bypass machines as well as dialysis systems. Chapter 2, Healthcare Technology Basics, provides an overview of how medical products enter into commerce and the roles of regulations and FDA function in protecting public safety. I found the scenarios described in section Devices Throughout the Healthcare System and Relationship to Patient care a good topic and practical reference for educating readers about the intersection between care processes and medical technology. Chapter 3 on Healthcare Technology Management introduces the crucial concepts of system

thinking and system engineering. The chapter then follows a short cover of human factors issues and jumps into computerized maintenance management systems (CMMS). It provides an excellent introduction to CMMS with well-organized material.

Chapter 4 on Safety and Systems Safety effectively covers a wide range of subjects that include regulations, standards, safety, risk management, quality, and adverse event investigation. The material is a well organized, easy read; however, the subjects on industry standards and infection control provide limited education for the readers about related international standards bodies and infection control. This is especially notable regarding care areas airway infection management where chapter 6 adds to this content but neglects to connect the readers to it. Furthermore, new air disinfecting tools, which became an increasingly vital component of patient care, both for patients and staff, lacked cover yet are essential during this pandemic era, we all are fighting. Chapter 5 on Information Technology delivers a useful description of the closer relationship between clinical engineering and the Health IT field with an effective comparison between life cycle management that the engineers/technicians follow and the ITIL practice that the IT practitioners do.

Further description of the data flow between medical devices and the EHR is written with clarity and includes content about cybersecurity's evolving importance. This chapter, in my opinion, is one of the best in this book. The final two chapters, chapter 6 on Facilities Management and chapter 7 on Human Resources Management, cover areas that will be most helpful for hospital-based practitioners who were not exposed to these topics previously.

Finally, the most extensive section of the book, almost 100 pages, Appendix: Additional Readings provides, as its name suggests, additional reading that incorporates throughout the various subjects of the Appendix an interesting section of questions to consider, acronyms, and abbreviations. It would have been helpful for the readers to add a table of content. Readers will be able to satisfy their curiosity by continuing further reading in the Appendix subjects related to chapters of the book they are reading at that moment.

The book accomplishes its purpose of providing readers with a clear introduction to the body of knowledge that all novices to the field of clinical engineering must understand. It delivers the reader an appreciation for the vast knowledge one should be competent in and the benefit from realizing how to prepare for their next step in their career.

You can find the handbook at https://www.elsevier.com/books/introduction-to-clinical-engineering/jacques/978-0-12-818103-4?countrycode=US&format=print&utm_source=google_ads&utm_medium=paid_search&utm_campaign=usashoppinglr&gclid=Cj0KCQiAuJb_BRDJARIsAKkycUkC0L0WdkS5fayxfOap78E0KX1HQG-BBolT32tBEMUo-lTxKn_KqitYaAk_pEALw_wcB&gclsrc=aw.ds where it is sold, after discount, for US $74.96.

In this field, recently published books were more extensive in scope, suffering format variation due to their multiple contributors, and were more expensive. As this book is aimed at students, novices, and practitioners ready to advance in their career, it will be very useful to this community and anyone else who explores and is curious about clinical engineering as a future career.