

EXHIBIT 19

Hospital Outpatient Quality Reporting Program

Overview

The Hospital Outpatient Quality Reporting Program (Hospital OQR) is a pay for quality data reporting program implemented by the Centers for Medicare & Medicaid Services (CMS) for outpatient hospital services. The Hospital OQR Program was mandated by the Tax Relief and Health Care Act of 2006, which requires subsection (d) hospitals to submit data on measures on the quality of care furnished by hospitals in outpatient settings. Measures of quality may be of various types, including those of process, structure, outcome, and efficiency.

Under the Hospital OQR Program, hospitals must meet administrative, data collection and submission, validation, and publication requirements, or receive a 2 percentage point reduction in payment for failing to meet these requirements, by applying a reporting factor of 0.980 to the Outpatient Prospective Payment System (OPPS) payments and copayments for all applicable services.

In addition to providing hospitals with a financial incentive to report their quality of care measure data, the Hospital OQR Program provides CMS with data to help Medicare beneficiaries make more informed decisions about their healthcare. Hospital quality of care information gathered through the Hospital OQR Program is available on the *Hospital Compare* Web site.

Outpatient Department Measures

Outpatient care can refer to numerous types of health services, such as emergency department services, observation services, outpatient surgical services, lab tests, and X-rays, provided to those who visit a hospital or other healthcare facility. Outpatient often refers to a patient who leaves the facility after treatment on the same day but may include a patient who spends the night at the hospital for whom a doctor has not written an order for inpatient admission.

Hospital Compare provides results on emergency department and outpatient quality measures, which evaluate the quality of care provided to patients. A quality measure converts medical information from patient records into a rate or time that allows facilities to assess their performance and consumers to compare how well patients are being cared for at their local hospitals.

The outpatient measures evaluate the regularity with which a healthcare provider administers the outpatient treatment known to provide the best

results for most patients with a particular condition. An example includes patients receiving appropriate fibrinolytic therapy within 30 minutes of arrival to the emergency department.

The Hospital OQR measures include data collected from various methods to measure patient care outcomes, process of care, imaging efficiency patterns, care transitions, ED-throughput efficiency, Health Information Technology use (HIT), care coordination, and patient safety. Data may be collected through chart abstraction, claims volumes, or reporting on a hospital process. Specialty areas were identified by CMS as having common and frequent procedures in the hospital outpatient setting. These procedures were identified as colonoscopies and outpatient imaging procedures. Other areas of future focus are outpatient surgery and chemotherapy.

Measures for the CY 2021 Payment Determination

- OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
- OP-8: MRI Lumbar Spine for Low Back Pain
- OP-10: Abdomen CT—Use of Contrast Material
- OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
- OP-22: Left Without Being Seen
- OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
- OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
- OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
- OP-33: External Beam Radiotherapy for Bone Metastases
- OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
- OP-36: Hospital Visits after Hospital Outpatient Surgery

* Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OP/ASC final rule with comment period (79 FR 66946 through 66947).

Read more about the Hospital OQR Program in the most recent final rule found [here](#).

More information regarding the Hospital OQR measures can be found on the QualityNet website [here](#).

Public Reporting

Data collected through the Hospital OQR program is publicly reported so people with Medicare and other consumers can find and compare the quality of care provided at ambulatory surgical centers. Publishing these data can improve facility performance by providing benchmarks for selected clinical areas and public view of facility data.

The CMS [Hospital Compare](#) website publishes information on the quality of care provided to patients; this information is made available to inform consumers and to encourage healthcare facilities to make continued improvements in care quality. *Hospital Compare* is generally refreshed bi-annually for the Hospital OQR program. Information on Public Reporting can be found in Section 1833(t)(17)(E) of the Social Security Act and requires that the Secretary establish procedures to make data collected under the Hospital OQR program available to the public.

Contact Us

Submit questions and search for answers on the Hospital OQR Program through the [Quality Question and Answer Tool](#) or call the Hospital OQR Support at **(866) 800-8756** weekdays from 7 a.m. to 6 p.m. Eastern Time.

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EXHIBIT 20

Influential factors on medical equipment maintenance management

In search of a framework

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Abstract

Purpose – Effective maintenance management of medical equipment is one of the major issues for quality of care and cost-effectiveness especially in modern hospitals. An effective medical equipment maintenance management (MEMM) consists of adequate planning, management and implementation. This is essential for providing good health services and saving scarce resources. Considering the importance of the subject, the purpose of this paper is to extract the influential factors on MEMM using a qualitative approach.

Design/methodology/approach – Documents review and interviews were main methods for data collection. Semi structured interviews were conducted with a purposive sample of 14 clinical engineers with different degree of education and job levels. Interviews were voice recorded and transcribed verbatim. Qualitative data were analyzed using a content analysis approach (inductive and deductive) to identify the underlying themes and sub-themes.

Findings – Factors influencing an effective and efficient MEMM system categorized in seven themes and 19 sub-themes emerged. The themes included: “resources,” “quality control,” “information bank,” “education,” “service,” “inspection and preventive maintenance” and “design and implementation.”

Originality/value – The proposed framework provides a basis for a comprehensive and accurate assessment of medical equipment maintenance. The findings of this study could be used to improve the profitability of healthcare facilities and the reliability of medical equipment.

Keywords Maintenance management, Hospital, Medical equipment, Medical devices

Paper type Research paper



Introduction

Medical equipment is extensively utilized for patients' diagnosis and treatment. Nowadays, providing health services through the use of diagnostic and treatment devices is a fundamental part of health services, especially in hospitals (Wang *et al.*, 2008, 2012). Medical devices are assets that directly improve the quality of life for many people (Painter and Baretich, 2011). Medical devices requiring calibration, maintenance, repair, user training and decommissioning activities are usually managed by clinical engineers. Medical equipment

requires scheduled and unscheduled maintenance during its useful life (WHO, 2011). Hospitals should ensure that medical equipment is kept in working condition, and is safe, accurate, and reliable and operates at the required level of performance effectively (Augustýnek *et al.*, 2018). Lack of proper maintenance of medical equipment leads to equipment downtime, reduces the level of device performance, and wastes costs and resources. In this concern, it is essential that hospitals focus on effective and quick maintenance of more critical devices (Bracale and Pepino, 1994; Dyro, 2004; Stiefel, 2009).

Medical equipment maintenance has different types: inspection and preventive maintenance (IPM) and corrective maintenance (WHO, 2011). Effective management of maintenance and repairs (Kinley, 2012) shall be planned and implemented using appropriate maintenance strategies to keep the devices safe and functional according to basic functional specifications (Wang, 2012). In addition to high initial investment, the medical equipment requires continual and costly maintenance during its useful life (Cheng and Dyro, 2004). The maintenance problem is the key discussion point in the management of medical devices (Bracale and Pepino, 1994). Other studies have indicated that the most common cause of medical equipment downtime is poor maintenance, planning, and management (Wang and Levenson, 2000; Wang and Rice, 2003). To solve this problem, it is necessary to establish and regulate a system of proper maintenance and the correct use of medical equipment (Stiefel, 2009). Perfect maintenance is the equation of performance, risk, resource inputs and costs to reach this goal (Campbell and Jardine, 2001).

The ultimate goal of maintenance is reliability and safety. It should always be safe for both patients and users (Wang, 2012). Maintenance management has had an extraordinary impact on the ability of organizations to achieve their objectives (Duffuaa *et al.*, 2002). Hospital management has gradually been perfect, but as far as medical equipment maintenance management (MEMM) is concerned, there still exist some problems and hospital MEMM system is too loose. For example, there is no corresponding maintenance personnel composition, degree requirements and even no maintenance access qualification. Maintenance personnel placement is done most often casually, personnel division of labor is not clear, and the maintenance caters to some surface problems and fails to do finishing repair (Wang, 2014).

Today, medical devices and equipment have become increasingly more complex (Jamshidi *et al.*, 2014), and deals with patient care in a hospital may range from simple thermometers to complex systems such as MRIs (Palesh *et al.*, 2010).

In Iran, in accordance with the law on the organization and functions of the Ministry of Health and Medical Education (MoHME), the medical equipment office was established to monitor the production, supply, consumption and use of medical equipment. Medical equipment in hospitals is purchased through two different channels: The MoHME and Board board of trustees in each hospital. Engineer/technician is responsible for the management and maintenance of medical equipment in the hospital and has different responsibilities such as training, improving patient and personnel safety, installation and repairing cycle management and maintenance management.

Why this study: aims

Mahady *et al.* (2002) in his study states, despite the importance of medical equipment maintenance, unfortunately, enough attention has not been paid to this issue, especially in developing countries (Mahady *et al.*, 2002). A number of studies have been conducted on medical equipment until now (Ameriyoon *et al.*, 2006, 2007, 2014). To our best knowledge, no studies have provided a comprehensive framework for MEMM in Iran. This study aimed to explore the views of experts on factors affecting MEMM. This paper presents a framework for MEMM with the purpose of enhancing and improving our understanding of the effective factors in this realm.

Methods

Design

This is a qualitative study based on content analysis approach. Qualitative data were collected through documents review and semi-structured interviews. Qualitative research approaches have an explorative nature and are used to understand people experiences in all its complexity and in all its natural setting (Pope *et al.*, 2000). Health or education policies can be developed using this type of research (Tong *et al.*, 2007). The collected data consisted of the perspectives of medical and biomedical engineers concerning factors influencing MEMM.

Sampling

Purposive sampling was used to conduct this study and was continued until data saturation. Participants were selected from different cities of Iran as the most knowledgeable persons about this subject. The research participants included 14 clinical engineers whose education varied from bachelor to PhD degree. The inclusion criteria for interviewees were having at least bachelor's degree with at least two years of work experience in clinical engineering department of hospitals during the study period, being accessible and being willing to participate in the study. As experts in the medical equipment, an equal number of male and female participants ($n = 14$) took part in this study.

Data collection

Semi-structured interviews and documents review were used for data collection. Related documents were regulations of MEMM, MEMM guidelines and other related regulations or reports developed by MoHME. The time period for data collection was from April to July 2016. The interview questions were asked in an open ended manner. They were based on an interview guide (Boyd, 1989). Interviews lasted approximately 30–90 min and were interviewed in the working place of the participants. The researchers and the participants agreed on an appropriate time before referral. The face-to-face interviews were recorded through voice-recorder and transcribed verbatim. All the research team participated in developing the interview guides (Appendix). Interview guide was lists of demographic questions and questions that covered aims of the study. The interview began with general and simple questions. During the interview, the interviewer added extra questions about unexpected but relevant area that emerged. Data collection continued until saturation was achieved and no new information was discovered in data analysis.

Data analysis

Morse and Field's qualitative content analysis approach (Morse and Field, 1995a) was adopted for data analysis. Content analysis is a widely used qualitative research technique in health studies in recent years and is used to interpret meaning from the content of text data and, hence, adhere to the naturalistic paradigm (Downe-Wamboldt, 1992; Krippendorff, 2004; Sandelowski, 1995) (Hsieh and Shannon, 2005). Content analysis can also be a useful tool for discovering and describing the focus of individual, group, institutional or social attention allowing researchers to test theoretical issues to enhance data understanding. In this study, content analysis approach (inductive and deductive) was used to analyze the data. Data analysis started with the transcription of interviews and repeated reviews until meaningful themes emerged. Then, data were read word by word to derive codes. Next, the first impressions, thoughts, and initial analyses were noted. Afterwards, codes were generated from participants' words. For example, the code "training on general equipment" was generated by the researcher from a participant's comment that "every nurse who graduated from the university should be trained about the general equipment." MAXQDA 12 (qualitative) software was used to analyze the data. Two researchers (LD and RB)

analyzed the data to help minimize bias. All data were transcribed, coded and analyzed by both researchers. The extracted codes, then were sorted into both items and subthemes based on comparisons between similarities and differences. Once the themes had been agreed by the authors, the two researchers read the remaining transcripts. Finally, themes were created as the expression of the hidden content of the text after being identified, reviewed and defined. The member-checking method was used to meet study validity. To address credibility, transcriptions were given to the participants to ensure the accuracy of the transcriptions. Also, the initial codes, subthemes, and major themes were audited by two of the researchers (LD and RB) and the results were confirmed.

Ethical considerations

All of the participants agreed on recording their voice with the exception of one participant who just allowed the researcher to take notes while she was talking. Moreover, all participants were informed about the objectives of the study and their informed consent was taken. Participation in the study was voluntary and the participants were assured on the confidentiality and anonymity of the provided data.

Results

Through data analysis, the factors affecting MEMM were categorized in seven main themes and 22 subthemes (Table I). As follows, the definitions of each theme and subtheme are reported using the participants' direct quotations.

Theme 1: resources

This theme had three categories including "Physical Resources," "Human Resources" and "Financial Resources." In general, the provision of resources is one of the main and effective items in MEMM in this regard. All interviewees underscored the importance of all of the above-cited resources.

Themes	Sub themes
Resources	Physical resources Human resources Financial resources
Quality control	Safety tests Performance tests Adjustment and calibration
Documentation	Providing medical devices ID (Identification) Use of local and global evidence Providing user manual
Education	Recording executive processes Technical and practical training
Service	Corrective maintenance (repair) Decommissioning Outsourcing Reform and improvement system
Inspection and preventive maintenance (IPM)	Reporting adverse events and recall system Periodic, internal, case and practical inspection Management processes to increase the life of the device
Designing and implementation	Knowledge and attitude Process management Purchasing management

Table I.
Themes and sub-themes of factors affecting medical equipment maintenance management

Physical resources

Maintenance management relies on physical resources. These include workspace, tools and test equipment, supplies, replacement parts, and operation and service manuals needed to perform maintenance mechanisms. Workspace is one of the main factors in MEMM. The participants harbored these notions that lack of workspace for repair and maintenance of medical equipment is a great issue. Moreover, they stated that providing a safe and healthy work environment for staff and patients is required. One engineer gave the following explanation:

“I would say that before the user we prepare our environment for the user.” (P9) One of the other participants said: “Now when you go to hospitals, you can see that 90% of hospitals do not have a place for device repair” (P6).

Various tools and test equipment are required to perform maintenance activities, depending on the type of equipment in service. Some participants expressed that the existence of some facilities such as computers, printers and types of software are essential for the unit of biomedical engineering.

Some experts commented on this issue: “Today some companies that work on the preventive maintenance have powerful software, but this software is related to the unit of medical equipment [...] Also, the University of Medical Sciences is required to equip them with the software” (P1):

Medical engineering unit should have direct telephone line, fax and computer, but, none of them is available (P4).

Human resources

Many of the engineers pointed out that developing human resources is necessary to operate an effective maintenance program, so the first step is to identify the number and type of required staff. All participants reported that the provision of trained and skilled human resources was a main factor behind job satisfaction as illustrated by the following quotes:

Supply of the fixed manpower is one of the factors affecting performance of biomedical engineering unit (P2).

If the human resources are not expert, companies can abuse regulations (P8).

Financial resources

Financial resources for maintenance primarily focus on two tasks: monitoring costs and managing the budget. Furthermore, maintenance program is required for financial planning where the costs and benefits of the current situation and the new proposal can be compared. Therefore, it is better for each medical device in the hospital to have a history of all time and expenses associated with maintaining that device. According to the participants' opinions the budget for the implementation of medical (devices) equipment maintenance program should be estimated and funded. The interviewees commented on this issue:

Maintenance management has preventive role in costs, while the cost of repair is high (P9).

The allocation of funds for maintenance should be from hospital policies. For example, funds have been allocated for providing parts, calibration, maintenance and service (P6).

Theme 2: quality control

This theme emerged from three subthemes: “safety tests,” “performance tests” and “adjustment and calibration.” Generally, the quality control tests include tests of safety, performance and calibration.

Safety tests

Most of the participants reported that safety is the first and most important step in the design, manufacture, installation, utilization and maintenance of medical equipment. There are various safety aspects to consider when implementing a successful and effective maintenance program, such as the safety of technical personnel. These tests are essential for patient and personnel. This ensures that when working on medical equipment it is essential for technical personnel to work safely in hazardous conditions. According to the interviewees:

While quality control is easy in practice, if a simple device is impaired, it compromises patient safety (P14).

Another engineer stated:

If the electrical safety is not guaranteed, the patient may be injured from it and also users can't use the device with confidence (P11).

Performance tests

Performance tests of medical equipment require special training and equipment that include technical, functional, laboratory and clinical tests. Technical testing should be performed by authorized companies and agents, and other tests should be carried out by users. During the interview with the participants, none of them referred to performance tests. The study of documentation including guideline MEMM at health centers showed that performance tests are one of the quality control tests.

Adjustment and calibration

Calibration measures the outputs of device under test by the tester with accuracy at defined conditions and specified ranges. It includes adjusting medical equipment in order to achieve the desired precision and ensuring its operation based on international metrics. All participants believed that calibration is a principal factor in MEMM. One interviewee commented:

I think calibration meaning an understanding of proper working of the device is a key element in maintenance management (P5).

Another interviewee pointed out that:

Calibration is not only to say that a device is calibrated or not [...] calibration is something that says us what is wrong, and it soon returns to standard status (P8).

Theme 3: documentation

Documentation was the most dominant concept in this study. One of the fundamental responsibilities of a clinical engineering manager is the documentation of the maintenance processes and activities. Without proper documentation, maintenance and management of equipment will simply lead to inconsistent implementation and unpredictable outcomes. These data provide the inventory database of every maintenance task performed on the device.

This theme consists of four subthemes: "providing ID for medical devices," "the use of local and global evidence," "provision of user manual" and "recording executive processes."

Providing medical devices ID

Medical equipment ID was expressed by the participants as another important factor in MEMM. Preparing and updating medical equipment ID is required for their proper management. Having the available information about medical equipment specifications is useful for its proper management. ID includes information such as a device specifications,

warranty status, service installations, acceptance tests, preventive maintenance, calibration, etc. An expert commented that:

We have designed an intelligent system for medical devices for the first time in the country that indicates when the device is repaired, when calibrated, when serviced. This is called ID of a device (P7).

One of the factors for improving maintenance management is documentation in the form of computer. In this regard, a computerized ID is designed but has not been implemented yet (P4).

The use of local and global evidence

Constant communication with scientific standard references is required in order to be informed on international standards and be up to date in the field of medical equipment. According to the ever increasing progress of medical equipment, utilization and mapping with the available scientific evidence can help to improve MEMM. One of the interviewees explained this in these terms:

We are not connected with standard references scientifically in the world.

Adequate studies have not been conducted about medical equipment maintenance management in our country (P1).

Providing user manual

Ideally, the maintenance program will have an operation (user) manual for each model of medical equipment. The operation manual is essential and valuable for equipment users and for equipment technicians. Unfortunately, operation manuals are not always available, or may be in a language not spoken or understood by equipment technicians. One engineer expressed that:

After the user training, provision of user manual for equipment is important [...] Also, attachment of the user guide on the device can be regarded as a primary training for users (P9).

Another participant added that:

One of the influencing factors in maintenance management is labeling and provision of user manual which is among the duties of biomedical engineering unit (P5).

Recording executive process

Recording and maintaining information on medical equipment and their classification in the form of an ID according to international standards are essential for hospitals. An archive of related activities is a requisite for the continuity of maintenance program such as: costs associated with repairs, installation, and calibration. These data are typically contained in work order records that provide documentation of every maintenance task performed on the device. For instance, one interviewee commented that:

Through computerized ID, accurate and updated documentation is available (P7).

Another participant stated:

All reports about inspections, preventive maintenance or related forms need to be documented (P11).

Theme 4: education

This theme refers to user and biomedical engineer training that includes “technical and practical training.” For the safety of the patient and the user, proper training is critical for both the user and the technical staff. Engineers or technicians must undergo additional training because medical equipment is highly specialized and if improperly maintained or repaired, it may have adverse consequences on human life.

Technical and practical training

User training means implementation, maintenance and presentation of report on the performance of devices. Technical training implies the principles and methods of maintenance, calibration, initial repairs and medical equipment management concepts. Engineers or technicians need to have proper training because medical equipment is highly specialized and if improperly maintained or repaired, it may have adverse consequences on human life. One of the interviewees commented on this issue:

There are two types of training: ongoing education and training after device installation (P10).

Another participant believed that:

User training plays an important role in medical equipment maintenance because if users don't learn the proper usage of the device, it may destroy the device (P14).

Theme 5: service

This theme emerged from five subthemes which engineers described as factors affecting MEMM: "Repair," "Decommissioning," "Outsourcing," "Reform and improvement system" and "Reporting adverse events and recall system." According to the study documents, it was found that the interviewees did not mention the last two factors.

Service activities refer to report of unpleasant disasters, calling medical devices (equipment), correction or upgrades of medical devices (equipment), repair and maintenance contracts.

Corrective maintenance (repair)

A process is used to restore the physical integrity, safety, and/or performance of a device after a failure. In order to return a device to its full functionality, efficient repair is required to verify the failure and determine its origin. Many of the engineers said that repair work on the most sophisticated medical equipment is only accomplished by highly trained specialists or reliable companies. In this regard, an interviewee stated that:

Whatever more investment in medical equipment maintenance, requirement to repair them becomes less and thereby reduced repair costs (P5).

Nowadays repair is known completely in hospitals, but still there are deficiencies in the field of maintenance.

Another participant mentioned that: "Repair is part of maintenance as maintenance is related to before equipment failure and repair refers to after it" (P4).

Decommissioning

Decommissioning process is important for decision-making in providing alternative and obtaining the necessary funds. In the process of scrapping, it is essential to report involved costs, future necessary costs, affordable repairs to ensure the safety and performance of the device during use, funding for replacement, the importance of devices, measure of device downtime and disruption created in performance of the medical center and patient's dissatisfaction. One of the engineers stated:

We found the new equipment in outdated devices stock of hospitals which is a waste of resources (P8).

Another interviewee indicated that: "Clinical engineers should be aware of the decommissioning process [...] when residual value of a device is less than 20%, one can scrap it" (P13).

Outsourcing

Service contracts and maintenance are not necessary; however, they are recommended to increase the setup time of devices (up time) and decrease their downtime. In this regard, third-party companies play an important role. One interviewee commented:

Usually service and maintenance contracts are for vital and capital devices (P12).

Also two of the interviewees mentioned: "In order to repair and complete quality control tests, there should be contracts with a company that is qualified and provide exclusive services for the device" (P1, 2).

Reform and improvement system

"According to the maintenance guideline, the process of upgrading and reforming the medical device in the treatment center needs to be done under the supervision of the medical engineering unit and by the manufacturer of the device or its legal representative. This factor is applicable through hardware and software by adding new smithereens and tools and through software updating" (Doc2).

Reporting adverse events and recall system

"An adverse event is an incident that results in death or serious injury to the patient, the user of the devices or any other person. According to the participants, observing the criteria for reporting incidents and recalling medical equipment are required. Adverse events should be reported to the manufacturer of the medical device or their legal representatives as well as to the medical equipment department. This report should be prepared in written format and according to the framework set by the medical equipment department. The producing company or its legal representative is required to design and implement the supervision system for quality and the performance of medical devices. The users should be made aware of the problem occurrence in the medical equipment in terms of performance, safety, effectiveness and/or non-compliance with the requirements" (Doc 2).

Theme 6: inspection and preventive maintenance

This theme comprises three subthemes: "management processes to increase the life of the device" and "periodic, internal, case and practical inspection." Inspection refers to the evaluation and monitoring of all operations that include a variety of quality control tests of medical equipment, study facilities and ancillary facilities related to equipment, different inspections and assessment of the performance of technical personnel. Management processes to increase the life of a device involves maintenance performed to extend its life and prevent failure. These processes are sometimes referred to as "planned maintenance" or "scheduled maintenance." The most appropriate method for scheduling maintenance in a particular health-care facility should be chosen.

Periodic, internal, case and practical inspection

Generally, there are two types of inspections, including equipment inspection and practical inspection. Equipment inspection is divided into three types of inspections: periodic, internal and case inspections. Practical inspection includes inspection of space and environment, the use of a medical device, and its storage and transportation. The use of inspection can make the difference between having reliable and properly functioning equipment or not. Almost all participants mentioned the importance of proper inspection,

but most of them had inadequate information about types of inspections. For example, one interviewee commented that:

When you do not have a guideline [...] a person who inspects biomedical engineering unit will inspect personalization in fact (P1).

We utilize inspection from self-made and accredited checklists (P2).

Management processes to increase the life of the device (preventive maintenance)

Preventive maintenance is performed to extend the life of the device and prevent failure. These processes are usually scheduled at specific intervals and include specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts. Almost all participants noted the importance of this item, for example: “preventive maintenance must be performed properly. “Unfortunately, we can’t implement preventive maintenance fully because we don’t have adequate knowledge about it” (P3).

Another interviewee added that: “If preventive maintenance is not well monitored in a hospital, patients’ lives are in grave danger” (P7).

Theme 7: designing and implementation

This concept refers to several management aspects. This theme is composed of three sub-themes: “processes management,” “knowledge and attitude” and “purchasing management.” Each sub-theme is explained in the following section.

Process management

A good number of the participants emphasized various aspects of the activities and management of the processes. In this context, from the perspective of research participants, these are very important items such as specification of access level to medical equipment, development and determination of policy, weakness in management infrastructure, long bureaucratic processes and codification of action plan. According to the interviewees:

We spent about 20% for maintaining our devices because we do not have appropriate management and planning (P8).

Another participant said: “Heavy workload and long administrative procedures are other factors that they make. Thus, we assign the second priority to maintenance” (P4).

Knowledge and attitude

Level of knowledge and attitudes of managers and clinical engineers are significant in decision-making and in the implementation of the processes and maintenance of activities. In fact, all the taken measures reflect the attitude of the owners of the processes. In this regard, an interviewee stated that:

Clinical engineers and users do not have sufficient knowledge with the term maintenance management (P8).

Another interviewee argued that:

Maintenance and repair are analogous to prevention and treatment in that treatment is more costly [...] Most medical facilities do not take maintenance seriously (P13).

Purchasing management

Effective management in the clinical engineering department primarily requires a correct selection of medical devices. Therefore, purchasing medical equipment must occur following a specific procedure. The purchasing management objective is buying devices and

equipment of the right quality, in the right quantity, at the right time, at the right price, and from the right source. One of the interviewees stated that:

One of the objectives of maintenance is to purchase from reliable companies that there are on IMED website and this prevents the contraband (P2).

Another participant mentioned:

Purchase of medical equipment should be based on hospital's need (P3).

Our findings showed all the influential factors (mentioned in this study) on MEMM are interrelated to each other Figure 1.

Three factors including quality control, inspection and service are complementary to each other, indicating a mutual relationship among them. As can be observed, inspection includes monitoring quality control tests. Education is relevant to human resource factor, which includes user and clinical engineer training. Preventive maintenance and repair are two types of complementary maintenance programs. Preventive maintenance includes management processes to increase durability of a device and prevent its failure. Repair includes management processes to restore physical conditions, safety, and performance of the systems after failure. Documentation is associated with each factor, meaning that all maintenance administrative processes should be documented and saved. Design and implementation are the setting for this framework. This indicates that all six factors are developed and implemented through design and implementation.

Discussion

This study provided an in-depth and rich description of the influential factors on maintenance management. Our findings directly pointed out the importance of factors on affecting maintenance management and the related concepts were extracted. One of the studies concluded in developing countries reported that the useful life of the equipment under regular maintenance programs were on average double the useful life of the equipment that was not covered through this program (Hallwachs, 2000). This study showed that consideration of influential factors on maintenance management results increased patient satisfaction and cost reduction. Our findings are consistent with those of Hasper (1991) who reported that the implementation of medical equipment management program boosts customer satisfaction while minimizing costs (Hasper, 1991).

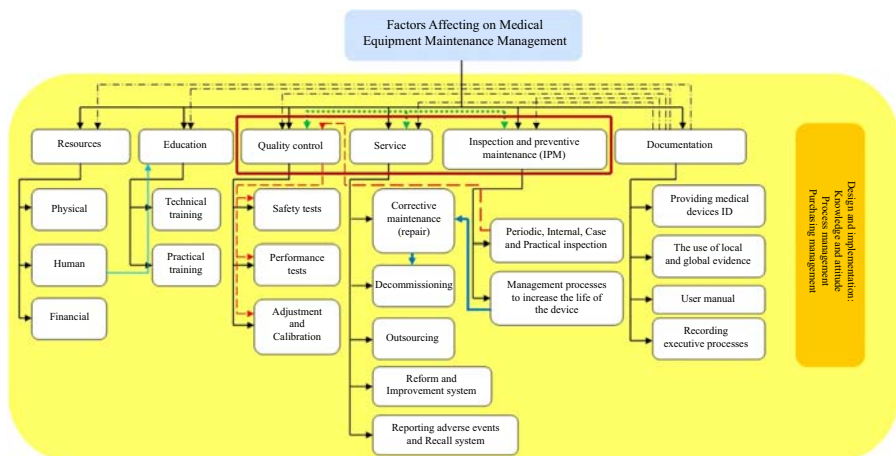


Figure 1.
Framework of medical
equipment
maintenance
management (MEMM)

Almost all participants stated that complete and correct implementation of preventive maintenance is effective in reducing medical device failure. In the study about the influence of maintenance on the survival medical equipment, concluded that preventive maintenance implementation is effective in increasing device longevity (Khalaf *et al.*, 2013).

The first step in the proper management of medical equipment is planning (Aghaei, 2003). According to the findings of this study, poor planning and management infrastructure are the main culprits behind weaknesses in maintenance management.

Conducted in one of the Latin American countries, showed that there is a dire shortage in the number of qualified people to work with medical technical equipment maintenance. He found that 44 percent of medical instruments were lacked even engineering or medical technicians (Maxwell, 1985). Our study showed that inspection and maintenance of medical equipment is effective for its function. Also another study surveyed the medical equipment management systems in developing countries and demonstrated that 60 percent of medical equipment cannot be used for different reasons. In Iran, nearly 60 percent of medical devices in hospitals affiliated to medical sciences universities had not been inspected by the staff (Noori Tajer *et al.*, 2002). Our findings prove that the inspection of medical equipment is essential and a necessary factor for maintenance management. Performance and safety control, activities documentation, using computerized systems for preventive maintenance were among the issues that mentioned in the designing a model of Medical Equipment Management for Iranian hospitals (Nasiripour and Jadidi, 2008). Also, the Walsh's study suggests that by creating an efficient and proper maintenance system, capital equipment can be preserved, and this could improve the effectiveness of hospital facilities (Walsh, 1995). While confirming the above-cited studies, our findings showed that consideration of the factors affecting maintenance management is necessary for reducing costs as well as decreasing amortization and failure of medical devices and disorder in the treatment of patients.

In terms of applicability, repair and maintenance, medical and hospital instruments are not well kept in developing and even developed countries. This negligence leads to waste of resources in the health sector (Boisvert, 1978). The investigated wards in the study failed to meet the expectations and requirements in terms of medical device management. There were not in desirable situations for the usability of devices and use of informational electronic system in these hospitals (Dargahi *et al.*, 2014).

Management of biomedical engineering in hospitals involved experienced and expert staff who takes over the purchase, procurement and distribution of medical and laboratory equipment is instrumental in cost-effectiveness (Rommelzwaal, 1997). In this regard, our findings showed that provision of trained and expert human resources is the first and pivotal step in establishing an effective maintenance program and purchasing management affecting maintenance management. Furthermore, in our findings, most of the participants stated that maintenance is most often ignored. Some of the findings of the present study had already been discussed in the cited studies, but they were striking differences in objectives. Policy makers and managers can provide a context for evidence informed decision making using the results of this study to improve the efficiency of maintenance management in health care system.

Strengths and limitations

In our knowledge, this study is the first comprehensive study of its-kind addressing all of the factors affecting an effective and efficient MEMM. It offers a comprehensive structure for evaluating the status of MEMM.

Although interviewees provided in-depth and convincing information on the issue, but lack of enough information concerning the concept of maintenance management was the most notable challenge. Many of the participants similarly defined the concepts of preventive maintenance and maintenance management.

Recommendations

This study provided insight into which elements of the MEMM the participants found most helpful. The findings demonstrate that implementation of a proper maintenance management depends on resources including financial, human resources, physical, documentation, training and education, IPM, quality control, design and implementation, and service. Moreover, these factors play an important role in developing and adopting the most effective maintenance strategies. A major share of hospital costs is allocated to the procurement of medical equipment annually. However, the related management or maintenance is particularly weak in hospitals. It is essential for any health-care facility to implement a maintenance program for medical equipment. An effective maintenance management of medical devices increases efficiency and productivity of health technology resources, which is especially important when resources are limited. This leads patients to have access to medical equipment that can provide them with an accurate diagnosis, effective treatment or appropriate rehabilitation. The findings of this study underscore the fact that fulfillment of these objectives requires establishing a framework for the development of MEMM. Several factors affect the MEMM considering each of which is important for improving functionality of the devices and providing health care services to the patients. Also, in our context, most medical engineers are less informed about the concept of maintenance management and that explains why there is little attention to maintenance of medical equipment. The extracted factors can help to managers and engineers in evaluating maintenance management systems and offer options and interventions to decision makers or policy makers for the improvement of such systems. This framework provides for the development of national essential health technology programs that will have a positive impact on the burden of disease and ensure effective use of resources. Also, it can help to identify and modify innovative technologies that can have a significant impact on public health. Further research into maintenance management is warranted to improve quality in this field. Themes derived from this study can be subjects for further research in Iran and in other countries.

References

- Aghaei, H.B. (2003), "Study of the state of the maintenance management of medical equipment in NASA hospitals", thesis Master of Health Services Management, Tehran.
- Ameriyooun, A., Hamze Aghaei, B. and Mohebi, H. (2007), "Assessing the medical equipment maintenance management at two hospitals military in contery", *Journal of Military Medicine*, Vol. 9 No. 3, pp. 189-195.
- Ameriyooun, A., Tofighi, S. and Zaboli, R. (2006), "Assessing the medical equipment maintenance management at selected hospitals affiliated with the medical sciences universities in Tehran (2003-2005)", *Journal of Health Administration*, Vol. 9 No. 23, pp. 17-24.
- Ameriyooun, A., Zaboli, R., Shokri, M., Aghighi, A. and Sadeghi, A. (2014), "Study of medical equipment maintenance management in NAJA hospitals", *Journal of Police Medicine*, Vol. 3 No. 2, pp. 107-114.
- Augustýnek, M., Laryš, D., Kubiček, J., Marešová, P. and Kuča, K. (2018), "Use effectiveness of medical devices: a case study on the deployment of ultrasonographic devices", *Therapeutic Innovation & Regulatory Science*, Vol. 52 No. 4, pp. 499-506.
- Boisvert, F.A. (1978), "Considerations in developing an effective biomedical equipment repair program", *Journal of Clinical Engineering*, Vol. 3 No. 1, pp. 61-63.
- Boyd, C.O. (1989), "From practice to grounded theory: qualitative research in Nursing Menlo Park, CA: Addison-Wesley", *Nursing Science Quarterly*, Vol. 2 No. 1, pp. 53-54.
- Bracale, M. and Pepino, A. (1994), "Medical technologies in developing countries: a feasibility study on the maintenance of medical equipment in Ethiopia", *Medical and Biological Engineering and Computing*, Vol. 32 No. 2, pp. 131-137.

- Campbell, J.D. and Jardine, A.K. (2001), *Maintenance Excellence: Optimizing Equipment Life-Cycle Decisions*, CRC Press, Boca Raton, FL.
- Cheng, M. and Dyro, J.F. (2004), "Good management practice for medical equipment", in Dyro, J.F. (Ed.), *Handbook of Clinical Engineering*, Chapter 31, Elsevier Academic Press, Cambridge, MA, pp. 108-110.
- Dargahi, H., Forouzanfar, F., Bakhtiari, M. and Rajabnejad, Z. (2014), "Study of medical devices management with the approach of evaluation of usability in Tehran University of Medical Sciences Hospitals", *Journal of Hospital*, Vol. 13 No. 1, pp. 43-51.
- Downe-Wamboldt, B. (1992), "Content analysis: method, applications, and issues", *Health Care for Women International*, Vol. 13 No. 3, pp. 313-321.
- Duffuaa, S., Al-ghamdi, A. and Al-amer, A. (2002), "Quality function deployment in maintenance work planning process", *Proceedings of the 6th Saudi Engineering Conference KFUPM, Vol. 4, Dhahran, Kingdom of Saudi Arabia, December*, pp. 503-512.
- Dyro, J.F. (Ed.) (2004), "Equipment control and asset management, computerized maintenance management systems", *Clinical Engineering Handbook*, Chapter 35, Vol. 1, Elsevier Academic Press, Cambridge, MA, pp. 122-130.
- Halbwachs, H. (2000), "Maintenance and the life expectancy of healthcare equipment in developing economies", *Health Estate*, Vol. 54 No. 2, pp. 26-31.
- Hasper, J.R.K. (1991), "Centralized maintenance responsibilities: a case study", *Journal of Clinical Engineering*, Vol. 16 No. 3, pp. 191-206.
- Hsieh, H.-F. and Shannon, S.E. (2005), "Three approaches to qualitative content analysis", *Qualitative Health Research*, Vol. 15 No. 9, pp. 1277-1288.
- Jamshidi, A., Rahimi, S.A., Ait-kadi, D. and Bartolome, A.R. (2014), "Medical devices inspection and maintenance; a literature review", *IIE Annual Conference. Proceedings, Institute of Industrial and Systems Engineers (IISE)*, p. 3895.
- Khalaf, A., Hamam, Y., Alayli, Y. and Djouani, K. (2013), "The effect of maintenance on the survival of medical equipment", *Journal of Engineering, Design and Technology*, Vol. 11 No. 2, pp. 142-157.
- Kinley, C.A. (2012), *Healthcare Technology: A Strategic Approach to Medical Device Management*, East Tennessee State University, Johnson City.
- Krippendorff, K. (2004), *Content Analysis: An Introduction to its Methodology*, Sage, New York, NY.
- Mahady, J., McCullagh, J., Grainger, P.B. and Kinsella, R. (2002), "Equipment management systems for use in developing countries", *IEE Seminar on Appropriate Medical Technology for Developing Countries IEE, London, February 6*.
- Maxwell, R.J. (1985), "Resource constraints and the quality", *Lancet*, Vol. 34 No. 2, pp. 936-939.
- Morse, J.M. and Field, P.A. (1995a), *Qualitative Research Methods for Health Professionals*, Vol. 2, Sage Publications, Thousand Oaks, CA.
- Nasiripour, A.A. and Jadidi, R. (2008), "Designing a model of medical equipment management for Iranian hospitals, 2007", *Arak Medical University Journal*, Vol. 11 No. 1, pp. 97-108.
- Noori Tajer, M., Dabaghi, F., Mohamadi, R. and Haghani, H. (2002), "A survey of maintenance and cost of medical equipment in hospitals associated of Iran university of medical sciences and health services (2000-2001)", *Razi Journal of Medical Sciences*, Vol. 9 No. 30, pp. 445-454.
- Painter, F. and Baretich, M. (2011), *Medical Equipment Maintenance Programme Overview*, World Health Organization Press, Geneva.
- Palesh, M., Tishelman, C., Fredrikson, S., Jamshidi, H., Tomson, G. and Emami, A. (2010), "We noticed that suddenly the country has become full of MRI. Policy makers' views on diffusion and use of health technologies in Iran", *Health Research Policy and Systems*, Vol. 8 No. 9, pp. 1-10.
- Pope, C., Ziebland, S. and Mays, N. (2000), "Qualitative research in health care: analysing qualitative data", *British Medical Journal*, Vol. 320 No. 7227, pp. 114-116.

- Remmelzwaal, B.L. (1997), "The effective management of medical equipment in developing countries", *FAKT-Consult for Management, Training and Technologies GmbH, Project (390)*, available at: [www.faktconsult.de/healthcare_tech\(1997\)](http://www.faktconsult.de/healthcare_tech(1997)) (accessed March 29, 2008).
- Sandelowski, M. (1995), "Qualitative analysis: what it is and how to begin", *Research in Nursing & Health*, Vol. 18 No. 4, pp. 371-375.
- Stiefel, R.H. (2009), *Medical Equipment Management Manual*, 7th ed., AAMI, Annapolis Junction, MD.
- Tong, A., Sainsbury, P. and Craig, J. (2007), "Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups", *International Journal for Quality in Health Care*, Vol. 19 No. 6, pp. 349-357.
- Walsh, T.J. (1995), "Total quality management, the ISO 9002 protocol and reconditioned diagnostic imaging equipment", *Proceedings of the National Forum: Military Telemedicine On-Line Today Research, Practice, and Opportunities, IEEE*, pp. 173-177.
- Wang, B. (2012), "Medical equipment maintenance: management and oversight", *Synthesis Lectures on Biomedical Engineering*, Vol. 7 No. 2, pp. 1-85.
- Wang, B. and Levenson, A. (2000), "PEER REVIEW PAPER: equipment inclusion criteria-a new interpretation of JCAHO's medical equipment management standard", *Journal of Clinical Engineering*, Vol. 25 No. 1, pp. 26-35.
- Wang, B. and Rice, W.P. (2003), "JCAHO's equipment inclusion criteria revisited-application of statistical sampling technique", *Journal of Clinical Engineering*, Vol. 28 No. 1, pp. 37-48.
- Wang, B., Eliason, R.W., Richards, S.M., Hertzler, L.W. and Koenigshof, S. (2008), "Clinical engineering benchmarking: an analysis of American acute care hospitals", *Journal of Clinical Engineering*, Vol. 33 No. 1, pp. 24-27.
- Wang, B., Rui, T., Fedele, J., Balar, S., Alba, T., Hertzler, L.W. and Poplin, B. (2012), "Clinical engineering productivity and staffing revisited: how should it be measured and used?", *Journal of Clinical Engineering*, Vol. 37 No. 4, pp. 135-145.
- Wang, Z.H. (2014), "Application research on the internet in the management of medical equipment maintenance", *Applied Mechanics and Materials*, Vols 651-653, pp. 1535-1538.
- WHO (2011), "Medical equipment maintenance programme overview", World Health Organization Press, Geneva, available at: www.who.int

Further reading

- Miles, M.B. and Huberman, A.M. (1994), *Qualitative Data Analysis: An Expanded Sourcebook*, Sage, New York, NY.
- Morgan, D.L. (1993), "Qualitative content analysis: a guide to paths not taken", *Qualitative Health Research*, Vol. 3 No. 1, pp. 112-121.
- Morse, J.M. and Field, P.-A. (1995b), *Nursing Research: The Application of Qualitative Approaches*, Nelson Thornes, Cheltenham.
- National Medical Device Directorate (2009), "N. M. D. medical equipment maintenance management criteria of the Ministry of Health and Medical Education of Iran", available at: www.fda.gov.ir/uploads/59654f7fc6bc314a8be0776c15f08fe.pdf

Appendix. Interview guide

Number of Interviewee:

Date and venue:

Position of interviewee:

1. Please introduce yourself and briefly describe your work experience.
2. Please explain your general perception of medical equipment maintenance management.
3. Please explain the role of medical equipment maintenance management in hospitals?
4. What is the process of medical equipment maintenance in your hospital?
5. How is the medical equipment maintenance management in hospitals currently evaluated? What are the bottlenecks and shortcomings? Is there an instruction for evaluation?
6. What factors affect the assessment of medical equipment maintenance management in hospitals?
7. What do you know about the most important activities and responsibilities associated with the repair and maintenance of medical equipment?
8. Do the clinical engineers and medical equipment users have the necessary training in this area?
9. What are the challenges and obstacles to implementation of the medical equipment maintenance in health centers, in special hospitals?
10. What are your suggestions for improving medical equipment maintenance management?
11. As a final question, is there anything else you would like to say about medical equipment maintenance management?

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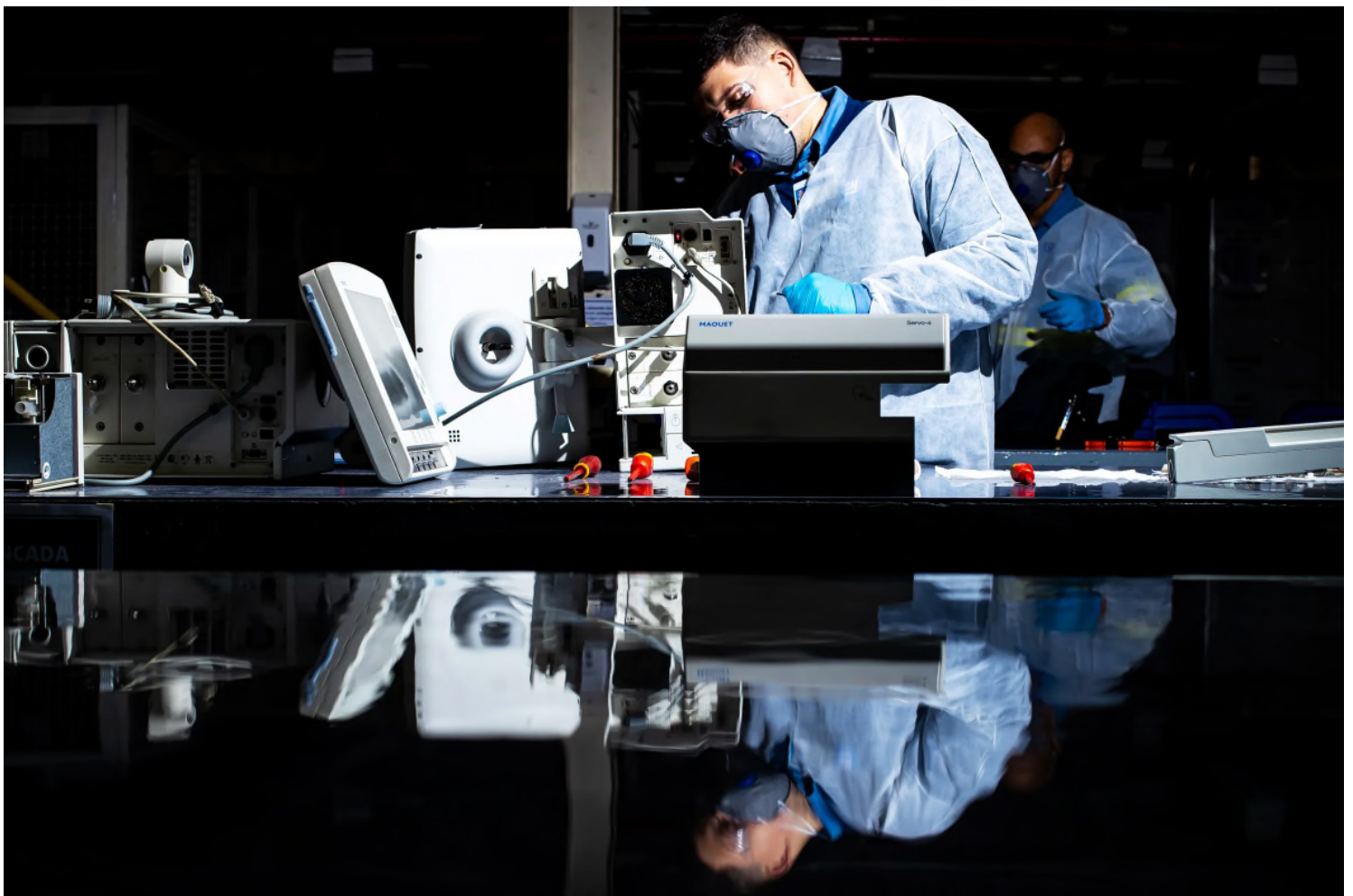
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EXHIBIT 21

LAUREN GOODE GEAR 05.19.2020 12:00 PM

Right-to-Repair Groups Fire Shots at Medical Device Manufacturers

A robust resource for DIY smartphone repairs is focusing next on ventilators and other critical medical equipment.



PHOTOGRAPH: BUDA MENDES/GETTY IMAGES

THE WEBSITE IFIXIT has long been known for its electronics repair kits and for its very public stance that repair manuals should be accessible to everyone. That's one of the foundational arguments of the broader right-to-repair movement, which lobbies that regular consumers should be able to repair the products they've purchased—everything from smartphones to washing machines to farming equipment—without violating a warranty. Now, in the time of Covid-19, iFixit and a prominent consumer interest group are tackling a more immediate concern: access to repair manuals for medical devices.

The company said today it's releasing what it calls the “most comprehensive medical equipment service database in the world.” The collection of thousands of files is supposed to help biomedical engineering technicians—the techs who update or fix medical equipment on site at health care facilities—repair everything from imaging equipment to EKG monitors to ventilators. iFixit founder and CEO Kyle Wiens (who also contributes to WIRED's Ideas section) called it an “absolutely massive” undertaking for iFixit, a project that took more than two months to coordinate and required help from 200 volunteers.

The rollout of the iFixit database is also coming on the heels of a letter sent to state legislators by Calpirg, the California arm of the US Public Interest Research Group, with more than 300 signatures from hospital repair experts. In the letter, the group calls for loosened restrictions on repairs of medical equipment and more cooperation from makers of medical devices.

“Covid-19 is putting incredible stress on our medical system, including the work of hospital biomedical repair technicians,” says Emily Rusch, Calpirg's executive director. Repair and maintenance issues have increased on devices like ventilators, she said, which are being used around the clock. “While some manufacturers provide service information, other manufacturers make it hard to access manuals, read error logs, or run diagnostics tests.”

Many of the arguments that Calpirg and iFixit make are similar to the right-to-repair arguments that have been made against giant tech companies like Apple and Microsoft—and they're likely to rankle medical device makers as much as they have electronics makers. If you own an iPhone or an Xbox, you should be able to repair it yourself or get it repaired by a technician of your choice, goes the thinking of right-to-repair groups; while lobbyists on

behalf of the tech giants maintain that allowing anyone and everyone to tinker with their electronics could pose serious safety and security concerns.

But the debate over medical device repairs is different in that both proponents of the right to repair and the trade groups that argue for stricter repair regulations are ultimately sounding the same alarm: They're concerned about patient safety. Biomedical engineers say they want easier access to repair manuals so that they can better and more quickly fix the medical equipment needed to save lives. Conversely, organizations like the Medical Imaging and Technology Alliance say they want to see more quality control and regulatory requirements put in place around the work medical technicians do because that, they believe, will save lives.

“If the iPhone isn't fixed, you're not going to have a phone,” says Nader Hammoud, manager of biomedical engineering at John Muir Health in Walnut Creek, California, and a supporter of the Calpirg initiative to reduce repair restrictions. “If you don't fix a vent, the patient is dead.”

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Wiens said he had been aware of the needs of biomedical repair technicians for years but had decided not to post anything publicly about it, whether that meant issuing statements or publishing a repair guide on iFixit.com. His thinking changed in mid-March, when scattered stories about the coronavirus suddenly morphed into a full-fledged global pandemic.

“It all crystallized for me when we were seeing ventilators in Italy fail, and a [startup group] was 3D-printing valves for them,” Wiens says. “And we started thinking, OK, if ventilators are being used more than normal, they might fail more than normal, and the biomed technicians are going to be on the front lines alongside everyone else.”

On March 18, Wiens put out a call to fixers, medical professionals, and biomedical technicians. He asked them to submit model numbers for critical equipment like ventilators, BiPAP machines, and anesthesia machines, as well as fallibility estimates and ideas for what parts might need to be replaced. Essentially, he wanted to crowdsource one of the biggest databases ever for medical-device repair information.

Wiens' efforts were not unprecedented. For several years now, a biomedical engineer in Tanzania named Frank Weithoner has maintained a website for medical-device repair manuals, called [Frank's Hospital Workshop](#). But that site was created to support his colleagues in developing countries, Weithoner said in an email to WIRED. It hosts about 4,500 device manuals. In some cases, file downloads have been prohibited by device makers. Frank is also just one guy. Wiens wanted to go bigger.

“There are these apocryphal hard drives floating around the biomed community, filled with PDFs that they’ve collected over the years,” Wiens says. “And they’re only as good at doing their job as that folder filled with PDFs is.”

Files started flooding into iFixit, with one particular folder containing as many as 50,000 files. Two weeks into the project, iFixit was overwhelmed. The company reached out to researchers at [the Maintainers](#) and the [American Library Association](#) and solicited volunteers. After two months of work, and with the help of more than 200 archivists and librarians, iFixit launched its searchable collection. The database was deduplicated and consolidated, and it contains more than 13,000 files—repair instruction manuals for everything from ventilators to ultrasound machines to X-ray equipment to anesthesia systems. Wiens says most of the files were shared with iFixit anonymously, but that he believes they were acquired legitimately and that hosting them is legal under the US Copyright Act.



Everything You Need to Know About the Coronavirus

Here's all the WIRED coverage in one place, from how to keep your children entertained to how this outbreak is affecting the economy.

Of course, Covid-19 has exposed not only our biological vulnerabilities but also our structural, society, and political shortcomings. Producing, procuring, and distributing all kinds of medical equipment is a complicated labyrinth outside of a pandemic; within the context of a global pandemic, every move or maneuver has the potential for more dire consequences.

The US medical device industry, the largest in the world, is also a multibillion-dollar business and a highly regulated industry, one that is protective of its proprietary equipment. That means repairing a medical device isn't always a simple process of asking a biomedical technician to do a quick fix during surgery, or to run the device down to the lab in the hospital's basement to replace a part. It requires navigating each device's specific requirements for repair, a process that can take days.

Weins tends to position iFixit as a renegade outfit that distances itself from the broader device industry and its trade groups, and has said that preventing access to this kind of information is "particularly morally fraught during a pandemic." Many biomedical technicians agree. And in

April, five US state treasurers penned a letter to ventilator manufacturers asking them to make their repair manuals more accessible.

“It’s not that it *could* mean life or death—it’s definitely life or death, especially during a pandemic,” John Muir Health's Hammoud said during a virtual briefing on Monday. “I had situations in the past, before Covid-19, where we had to come into the hospital in the middle of the night and try to pull parts from different devices, different sources, because a patient was waiting on a device. We’ve had to do this multiple times throughout my career.”

Hammoud recalled an instance where he sought out a replacement part that would typically cost around \$80, only to be told by the original device maker that the manufacturer would have to come in and fix the device at a cost of around \$4,000.

Paul Kelley, the director of biomedical engineering at Washington Hospital in Fremont, California, says that in the 40 years he’s been in the field, he’s seen a notable change. “It’s getting more and more frustrating,” he says. “We can do less and less work on equipment. We’re getting less and less documentation. Training is getting harder, and parts are getting scarcer.”

Hammoud, Kelley, and others in support of the Calpirg letter declined to name the specific device manufacturers they believe are the most restrictive when it comes to repairs.

Hammoud said that’s because he doesn’t see their group as “fighting” the device makers, but rather asking for cooperation. Wiens is more candid: He says giants like Medtronic and GE tend to be more restrictive, while other companies, like China-based Mindray, are doing a better job than others in terms of public availability of repair information.

Peter Weems, senior director of strategic operations and policy at the Medical Imaging and Technology Alliance (MITA), made a remark that was eerily similar to Hammoud’s: “With other goods, if something like a cell phone is improperly repaired and then it fails to perform, the worst-case scenario is that you have to replace the device. Whereas if a medical device is improperly repaired, there’s the risk of injury to the patient or the operator, or death.” But Weems is making this case on behalf of the medical device industry, particularly the medical imaging segment, and not the right-to-repair movement. MITA has around 50 member companies, ranging from large multinational companies such as GE, Siemens, and Philips, to smaller companies that make components or singular devices.

There are some key distinctions between other right-to-repair initiatives and this one, Weems pointed out. This includes the fact that in the US, manufacturers of medical devices are regulated by the Food and Drug Administration and have to report deaths, serious injuries, or other major malfunctions to a governing body. Third-party repair services aren't necessarily held to the same safety or regulatory requirements.

“What we've been working on with the FDA and Congress is applying consistent requirements for everybody who services a medical device, and these are common sense things such as making yourself known to the FDA via registration,” Weems says. Right now the FDA estimates there's anywhere from 16,000 to 20,000 biomedical engineers working in the US. By getting a firmer grasp on how many technicians there are, the agency can start to implement a quality-management system.

It's an effort that goes back to 2016, when MITA lobbied Robert Califf, who was then the FDA's commissioner, for tighter restrictions around third-party repairs of medical devices. It even sought to redefine terms like “repair,” “refurbish,” or “remanufacture,” as the terms were allowing for a gray area in which repair technicians—those who didn't work directly for the device manufacturers—could operate. There's the risk of direct bodily harm to patients if a medical imaging device isn't functioning properly, the alliance argued; but also, there's the risk that device makers would face liabilities or suffer “diminished brand value.” Follow-up reports issued by MITA in 2018 and 2019 underscored that inadequate repair services, in some cases described as “remanufacturing,” could result in “unsafe environments for patients and users of equipment.”

In other words, right-to-repair advocates continue to clamor for looser restrictions and fewer roadblocks around the repair of personal devices, large appliances, and medical equipment; while representatives for the businesses that make these devices will continue to urge lawmakers to put standards and regulations in place that would protect their products. If there's one thing these groups seem to agree on though, it's that the stakes are now suddenly much higher.

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