Management of Maintenance/Repair Facilities of Medical Equipment and Patient Safety Management -

An Integrated Clinical Engineering Program

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Abstract

Technology in its own right is now universally recognized as the engine of economic growth. Technological innovation generates increases in productivity, keeps companies competitive, and ultimately enables increases in the nation’s standard of living. It is precisely through doing a better job of managing technology that an improved standard of living can be created for all citizens. Unlike manufacturing companies that produce particular goods, hospitals must offer the highest quality of care possible to their customers, the patients and their families. Although manufacturers must produce high quality products and/or services (to remain in business), the health care industry’s failure to offer quality care, can lead to life threatening consequences.

Repair and PM are important to the success of any clinical engineering program. Since the goal of the clinical engineering department is to provide a safe and effective for delivery of the best health care possible, PM and repair are the first-line activities that guarantee that the medical equipment is calibrated and operational. Clinical engineers are the medical device experts. When it comes to medical devices clinical engineers should profoundly hold the key responsibility of patient safety, i.e., ensuring the safety and efficacy of all these devices.

The present paper seeks to develop a comprehensive program that may be used in the health care system by the decision-makers, such as the administrators, chief executive officers, as well as by the chairmen of the different medical departments, and maybe other physicians, as well as the chief nurses. The usage of that program should enable the team to benefit as much as possible from the available technological resources, and at the
same time solve many of the problems that might confront patient safety inside the hospital.

Analysis of the program reveals that each of its two constituent modules can be applied independently. The two modules represent both fundamental aspects of quality, namely efficacy, reflected in the proper choice of the suitable maintenance/repair organization which the decision-maker trusts that it will render the malfunctioning device operative and at the highest possible level of performance, and safety, reflected in the satisfaction of the basic standards of patient safety. The program with its two modules will serve only as a guideline. Finally, the application of the program to the solution of any technology management problem, regarding performance and safety is affected by other parameters besides the problem itself, namely the hospital’s policy, infrastructure, managerial configuration, and more importantly its technological resources.

Keywords
Clinical engineering, Technology management, Maintenance/repair organization, Healthcare systems, Patient safety

1. Introduction

Biomedical engineers assist in the struggle against illness and disease by providing materials and tools that can be used for research, diagnosis, and treatment by health care professionals. One particular subset of the biomedical engineering community, namely clinical engineers, has become an integral part of the health care delivery team [1].

A clinical engineer may be defined as an engineer who has graduated from an accredited academic program in engineering or who is licensed as a professional engineer or engineer-in-training and is engaged in the
application of scientific and technological knowledge developed through engineering education and subsequent professional experience within the health-care environment in support of clinical activities [1].

A clinical engineering department, through outstanding performance in traditional equipment management, will win its hospital’s support and will be asked to be involved in full range of technology management activities. The department should start an equipment control program that encompasses routine performance testing, inspection, periodic and preventive maintenance (PM), on-demand repair services, incidents investigation, and actions on recalls and hazards. The department should have multidisciplinary involvement in equipment acquisition and replacement decisions, development of new services, and planning of new constructions and major renovations, including intensive participation by clinical engineers, materials managers, and financialists. The department also should initiate programs for training all users of patient care equipment, quality improvement, as it relates to technology use, and technology-related risk management [2].

1.1. Clinical Engineering and Technology Management

Technology in its own right is now universally recognized as the engine of economic growth. Technological innovation generates increases in productivity, keeps companies competitive, and ultimately enables increases in the nation’s standard of living. It is precisely through doing a better job of managing technology that an improved standard of living can be created for all citizens [3].

Management of technology (MOT) is a complicated interaction of people with their strengths, weaknesses, biases, wishes and so on. The
difficulties in exploiting MOT come from a narrow description of the resources of an organization and the specific activities that are assigned to the resources. Resources include more than people, plant and equipment, and money. As an example, intellectual property is a resource. Time is also a vital resource; it cannot be replaced. Information is a resource, but the sources and integrity of the information must be known [4].

Technology as a resource is effective only if it is applied to some specific activity and within the confines of a particular infrastructure. The same is true for every other element of the resources. People without technology, without available time, or without a supporting infrastructure do not enhance performance [4].

Unlike manufacturing companies that produce particular goods, hospitals must offer the highest quality of care possible to their customers, the patients and their families. Although manufacturers must produce high quality products and/or services (to remain in business), the health care industry’s failure to offer quality care, can lead to life threatening consequences. The health care industry is undergoing a rapid process of reengineering that will lead to an integration of clinical and management technologies. This will require a radical redesign of hospital systems to create powerful health care delivery processes and a leadership with a strong customer orientation. In particular, a process that incorporates a multidisciplinary approach may help overcome the perceived negative feelings regarding management of the hospital’s technology [4].
1.2. The Central Role of Preventive Maintenance and Repair

The design and functional complexity of medical equipment and devices as a major technological resource have tremendously increased during the past 50 years. As device functionality becomes more intricate, concerns arise regarding efficacy, safety, and reliability [5].

Repair and PM are important to the success of any clinical engineering program. Since the goal of the clinical engineering department is to provide a safe and effective for delivery of the best health care possible, PM and repair are the first-line activities that guarantee that the medical equipment is calibrated and operational [6].

By PM we understand all actions performed in an attempt to retain an item in specified condition by providing systematic inspection, detection, and prevention of incipient failures. PM as an activity is only one component of an overall maintenance program also comprising corrective maintenance and spare parts replacement. PM plays an important role in the process of reliability optimization. Wearout failures of medical devices may be eliminated by conducting timely PM on a device, with appropriate replacement of effected components [5].

In most large hospitals there are usually three major divisions within the hospital’s clinical engineering department, a services and maintenance division, an engineering division, and a clerical staff division. The first division is responsible for almost all of the tasks associated with medical equipment once it has arrived and is in the hospital. This includes incoming inspections for safety and performance, user education, PM and repair, with much emphasis put on the last two items. The engineering division, on the other hand, is responsible for finding solutions to longer-range problems,
such as facility planning, medical device acquisition, computer applications, and research [6].

It seems that the PM and repair division in any hospital, no matter how big the hospital is, forms the basic skeleton of clinical engineering in that hospital. Up to twenty individual tasks have been assigned to that division, which depending on the hospital’s infrastructure and resources, should be partly or totally performed to the extent provided by these resources [7]. It also seems that the medical device market is continuously fighting against a growing frustration associated with dealing with companies that are uncooperative with clinical engineers when it comes to problems with the equipment that they “partnered with the hospital” on [8].

Another point has to be considered. Efforts on part of clinical engineers have pushed the manufacturers to supply more reliable devices with more features, because nowadays probably more than half the features on devices are never used. Manufacturers are also pushed to supply more devices with built in diagnostics or self tests. Moreover, engineers do not have to spend as much time doing PM’s nor repairs, as they used to do. In most departments component level troubleshooting is too costly, so board swaps have become more common than ever [9].

So, due to the above mentioned reasons, PM and repair in health care centers embraces extremely complex tasks and a firm infrastructure will have to be provided for practically all hospitals. Service facilities have become excessively intricate regarding scope and resources. A partial list of independent service organizations can be found in [10].
1.3. The Relevance of Patient Safety for Clinical Engineers

Of immediate impact on hospitals and other components of the healthcare delivery system are new patient safety standards promulgated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO, 2001). The new patient safety standards cut across disciplinary boundaries in an attempt to make safety a fundamental principle of patient care. The standards are linked to long-standing safety-related standards regarding infection control, the environment of care, and other disciplines [11].

Clinical engineers are the medical device experts. When it comes to medical devices clinical engineers should profoundly hold the key responsibility of patient safety, i.e., ensuring the safety and efficacy of all these devices [8]. The American College of Clinical Engineers (ACCE) has developed a sharp vision of the role of clinical engineering in enhancing patient safety. Accordingly, clinical engineers, individually and collectively, will continue to work to improve patient safety [11].

1.4. Objectives of the Study

The present paper seeks to develop a comprehensive program that may be used in the health care system by the decision-makers, such as the administrators, chief executive officers, as well as by the chairmen of the different medical departments, and maybe other physicians, as well as the chief nurses. The usage of that program should enable the team to benefit as much as possible from the available technological resources, and at the same time solve many of the problems that might confront patient safety inside the hospital. The program is made up of two principal modules,
which can run independently, a module for the determination of a suitable maintenance/repair facility and one for patient safety.

2. Materials and Methods

The program proposed by the authors consists of two independent modules, a module for making decision about a recommended maintenance/repair organization (MRO) [12], and a patient safety module [13].

2.1. The Maintenance/Repair Organization (MRO) Management Module

This module embraces two functional systems:

a. A system dealing with the selection of the level of MRO capability

b. A system dealing with the selection of the Type of MRO

2.1.1. Determination of the Level of Capability of MRO (Fig. 1)

Possible levels of MRO capability include:

• Organizational (O) Level

• Intermediate (I) Level

• Depot (D) Level

The simplest way out would be to try to find out if an O-level would be sufficient to solve the maintenance problem at hand. If this is not the case, an I-level will have to be examined. If an I-level turns out to be also insufficient, then a D-level will become necessary in most cases. If an I-level is even inappropriate (in rather seldom cases), then we have customize our own level of capability.
Next, we have to look for the interpretation of the different symbols appearing in Fig. 1.

**Fig. 1.** Determining the MRO Level of Capability

An O-level may be suitable to accomplish one of the following tasks:

- **O-1**: Determining whether a fault actually exists, or whether an operator error was the cause of an anomaly
- **O-2**: Performing module or equipment substitution to restore the medical capability rapidly
- **O-3**: Performing minor technical tasks that can be carried out by trained non-technical personnel
- **O-4**: Serving as an inventory control point to monitor equipment referred to a higher level
- **O-5**: Keeping records pertaining to equipment maintenance history

An I-level may be suitable to accomplish one of the following tasks:
• I-1: Testing medical equipment to verify performance and adherence to specifications & safety standards

• I-2: Diagnosing & troubleshooting equipment at least to the subassembly level

• I-3: Adjusting, aligning, or harmonizing internal controls not normally available to the operator

A D-level is the level of choice for the following cases:

• D-1: Troubleshooting to the piece-part level

• D-2: Finding and replacing components on the subassembly

2.1.2. Determination of the Type of MRO

The following are the common MRO types:

• Manufacturer’s Service Department

• Commercial MROs

• In-house MROs

• Shared Service MROs

• In-house Contractor MROs

• Part-time Shop

• Single-technician Department
2.1.2.1. Manufacturer’s Service Department

Scope:
It includes those departments owned and operated by the manufacturer

Location:
– At the factory (usually D level)
– Locally (usually I level)

Indications:
– Bad need for Manufacturer’s:
  • competent service
  • better information
  • deeper experience
  • more rapid access to spare parts
– Irrelevance of elevated service expenses
– Irrelevance of possible prolonged response
– Irrelevance of possible inadequate commitment to service

Pitfall:
The promise of local service is sometimes met by placing a single technician in a desk space or his home’s basement.
2.1.2.2. Commercial MROs

Scope:

They are commercial firms that provide service on medical equipment

Indications:

– When best solution for cost-effective maintenance management is looked for Great emphasis put on the following criteria:

• integrity

• reputation

• technical abilities

• depth of spares inventory

• ability to respond to customer demands

– Full trust of the following issues regarding the company’s standpoint:

• sound financial condition

• sufficient coverage by liability insurance

Pitfalls:

– Exaggerated marketing claims often conceal the true company’s capability

– Imprudent can-do attitude on the part of commercial MROs
2.1.2.3. In-house MROs

Scope:

Owned and operated by the organization or hospital it serves

Location:

At the hospital

Indications:

– Equipment emergencies otherwise affecting patient care
– Odd-hour (around the clock, 24/7) service badly needed
– Less consideration given to the increased demand for high salaries and benefits deserved by properly trained and qualified technical staff

Pitfall:

Early departure of excellent personnel as a result of lack of facilities for career growth

2.1.2.4. Shared Service MROs

Scope:

Owned and operated by two or more cooperating institutions, also users of the service

Location:

– D level (on selected systems)
– Full I level (on all systems)
**Indications:**

– Consortium work proves desirable

– High specialization of individual groups

– Cost effectiveness of maintenance for several institutions

– Secure provision for political stability and peace management among the different institutions

**2.1.2.5. Shared Service MROs**

**Scope:**

Cross-fertilization of the in-house and the commercial MRO concepts

**Indication:**

Situations where the management model of medical equipment maintenance is quite similar to housekeeping management

**2.1.2.6. Part-time Shop**

**Scope:**

Small repair organization provides medical equipment maintenance for the local hospital on a part-time basis

**Location:**

I level (minimal capability)

**Indications:**

– First line of defense for remote or rural hospitals

– Full confidence in the biomedical equipment repair capability of the owner of the shop
2.1.2.7. Single-technician Department

Scope:
Smaller hospitals often employ a single repair technician

Location:
I level (minimal capability)

Indication:
Most useful when there is a strong credential support

2.2. The Patient Safety Management Module

The patient safety module consists of six subroutines. Their sequence is quite flexible. Any subroutine can appear before or after another one. Yet, following the order appearing in the reference [13], the following is the outline of the patient safety management cycle:

- Address human factors/communications
- Address human factors/training
- Address human factors/fatigue scheduling
- Study environment and equipment
- Review rules, policies, and procedures
- Consider possible barriers

Let us now analyze each of the above subroutines in more detail.
2.2.1. Addressing Human Factors/Communications (Fig. 2)

**Fig. 2.** Flowchart for the human factors/communications subroutine

The program flow of the subroutine should be clear apart from the fixed and the Type I issues.

2.2.1.1. Human Factors/Communications (Fixed Issues)
• Correct identification of patient
• Inclusion of the patient and his family in the assessment of treatment planning
• Early warnings from staff about risky situations and risk reduction
• Adequate communications across organizational barriers

2.2.1.2. Human Factors/Communications (Type I Issues)
• Sharing of patient info by team members
• Clear documentation about treatment plan regarding
  – assessments
  – consultations
  – orders
  – treatment team notes
  – progress notes
  – medication administration record
  – x-ray
  – lab reports
  – others
• Adequacy of staff communication monitoring techniques, especially regarding:
  - "read back”
  - confirmation messages
  - debriefs
  - others
• Free communication of potential risk availability
• Management provision of adequate hands-on training
2.2.2. Addressing Human Factors/Training (Fig. 3)

Once again, we have to know about the Type I and Type II issues pertaining to the human factors/training subprogram. The definition of the root/cause contributing factors will be given in Sec. 2.2.7.
2.2.2.1. Human Factors/Training (Type I Issues)

- Was there a program to identify the actual needs for staff training?
- Was training provided prior to the start of the work process?
- Were the results of training monitored over time?
- Were staff training programs designed perfectly?

2.2.2.2. Human Factors/Training (Type II Issues)

- Supervisory responsibility
- Procedure omission
- Flawed training

2.2.3. Addressing Human Factors/Fatigue Scheduling (Fig. 4)

Fig. 4. Flowchart for the human factors/fatigue scheduling subroutine

For this subroutine there are only fixed issues that have to be considered.
2.2.3.1. Human Factors/Fatigue Scheduling (Fixed Issues)

- Appropriate levels of vibration, noise, or other environmental conditions
- Adequate sleep for personnel
- Proper anticipation of fatigue
- Distraction-free environment

2.2.4. Addressing of Equipment and Environment (Fig. 5)

![Flowchart](image)

**Fig. 5.** Flowchart for the addressing of environment and equipment subroutine. For this subroutine there are only fixed issues to be considered.
2.2.4.1. Addressing of Equipment and Environment (Fixed Issues)

- Work area/environment designed to support intended function
- Appropriate safety evaluations and disaster drills conducted
- Work area/environment should meet current codes, specifications, and regulations
- Equipment designed to accomplish intended function
- Equipment involved should meet current codes, specifications, and regulations
- Equipment involved should follow a documented safety review
- Recommendations for service/recall/maintenance should be completed in a timely manner
- Adequate time and resources allowed for physical plant and equipment upgrades
- Adequate equipment to perform the work process
- Emergency provisions and back-up systems available in case of equipment failure
- Supportive history of correct working and appropriate usage of equipment in the past
- Minimization of the occurrence of equipment usage mistakes through good design
- Adherence to specifications and proper operation of equipment
- Equipment design should enable detection of problems and make them obvious to the operator in a timely manner
- Corrective actions should minimize/eliminate any undesirable outcome
- Displays and controls working properly & interpreted correctly
- Medical equipment should be reusable
2.2.5. Review of Rules, Policies, and Procedures (Fig. 6)

![Flowchart for the review of rules, policies, and procedures subroutine](image)

Once again, only the fixed issues are of interest here.

### 2.2.5.1. Reviewing Rules, Policies, and Procedures (Fixed Issues)
- Overall management plan for addressing risk and assigning responsibility for risk
- Possession of audit or quality control system by the management
- Previous audit done for similar events with identified causes and with effective interventions developed and implemented on time
- Would problems have gone unidentified/uncorrected after review
- Required patient care within scope of the facility’s mission and available resources
- Staff involved in adverse event properly qualified and trained
- Staff involved oriented to the job, facility, and unit policies regarding safety, security, etc.
- Up-to-date policies and procedures addressing work processes related to adverse event
• Policies/procedures consistent with relevant policies, standards & regulations
• Relevant policies and procedures used on a day-to-day basis
• If policies and procedures were not used:
  - What objections to their usefulness to the staff
  - What positive and negative incentives were absent

2.2.6. Consideration of Possible Barriers (Fig. 7)

Fig. 7. Flowchart for the consideration of possible barriers subroutine

For that subroutine we have to address fixed, as well as Type I issues.

2.2.6.1. Considering Possible Barriers (Fixed Issues)

• Barriers and controls involved in adverse events or close calls
• Design of barriers to protect patients, staff, equipment, and environment
  • What patient risk was considered in the barriers & controls design
• Barriers and controls in place before hazard occurrence?
• Prior evaluation of barriers and controls for reliability
• Other barriers and controls for work processes not related to the hazard
• Concept of “Fault Tolerance” applied in system design
• Would the hazard be prevented if existing Barriers & controls had functioned correctly?
• System or processes tested before implementation of barriers and controls

2.2.6.2. Considering Possible Barriers (Type I Issues)
• Relevant barriers and controls maintained & checked on a routine basis
  by responsible staff
• Reviews related to barriers include evaluation of plans, designs, installation, maintenance,. . .etc.
  • Management anticipation for the results of system changes before implementation

2.2.7. Root Cause/ Contributing Factors - The Five Rules of Causation
• Causal statements must clearly reflect the cause-effect relationship. Description of how and why at the level of every stage and subsystem must be given.
• Negative and vague descriptors (e.g., poorly, inadequate) intended to replace accurate & clear descriptions should not be used in causal statements.
  • Each human error must have a preceding cause.
  • Each procedural violation must have a preceding cause.
  • Failure to act is only causal, if there was a prescribed duty to act.
3. Discussion

From the analysis of the above program, it is clear that each of its two constituent modules can work independently, although it turns out that both modules may be extremely helpful for the decision-maker inside any of the healthcare systems. The decision-maker might during a certain phase of his work look after the most suitable MRO regarding the servicing of one or more pieces of medical equipment or an entire medical system whether for a diagnostic, therapeutic, or monitoring application. At that time a safety problem might not have to be urgently addressed. Conversely, a decision-maker in a hospital, e.g., an administrator may have to deal with a rather disturbing hazard, such as a hospital-borne infection or a radiation hazard, without needing to assume the hazard has been caused by a malfunctioning equipment. Performance and safety are two closely interrelated facets of quality, especially when specifications and standards are considered. However, they do not have interchangeable roles.

The application of the program to the solution of any technology management problem, regarding performance and safety is affected by other parameters besides the problem itself, namely the hospital’s policy, infrastructure, managerial configuration, and more importantly its technological resources.

The reader might ask: Why did we select these two modules from the literature, and combine them into a functional clinical engineering program? After all, we did not invent the modules, did we? The answer is rather simple. From the authors’ point of view, the program with its two modules will serve only as a guideline. Its application in the clinical setting is not mandatory to the decision-maker. It helps him with the complex decision making process by just giving him a useful advice.
4. Conclusions

When the authors sought to develop an integrated model based on both maintenance management and patient safety, they were really tackling both fundamental aspects of quality, namely efficacy, reflected in the proper choice of the suitable MRO which the decision-maker trusts that it will render the malfunctioning device operative and at the highest possible level of performance, and safety, reflected in the satisfaction of the basic standards of patient safety. It should be understood at this point that the achievement of a certain level of patient safety implies the application of the principles of all disciplines of safety in a hospital, ranging from electrical to biological safety.

It is true that the entire scientific and technical material on which the program is based appears in the literature [12, 13], yet the usefulness of the program lies in its interactive behavior. The decision-maker will no more have to consult a reference or search for a website. He only has to define his problem, operate the program and get the advice. This concept is not entirely new. It dates back to the early days of expert systems [14].

Only the program structure as given by the flowcharts has been outlined in this paper. The flowcharts enable even a decision-maker of little programming knowledge to modify or restructure the program aided by a suitable programmer for the reformulation of the code. A quite obvious reason for such kind of reformulation is that although the reliability of medical devices may be high, it doesn’t mean that their components, circuits, and manufacturing cannot be improved. The process is dynamic [15]. The authors have implemented the program in Visual Basic 6.0, although any other programming language will serve the same purpose.
5. Recommendations and Future Work

The program has to be tested and operated as soon as possible in a number of hospitals of different sizes and infrastructures with expected feedback from hospital administrators and physicians. This is the only way to carry on with the research and continue fine tuning the program to fit as many healthcare systems as might be feasible.

Furthermore, expanding the program to include another module, such as a risk assessment module may be very helpful, so that in the near future such a program might become of both commercial and technical value [16].

References


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