OPTIMIZING DEVICE LIFECYCLE: EFFECTIVE INSPECTION AND MAINTENANCE IN HEALTHCARE SETTINGS

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Annotation: Medical devices are fundamental components of modern health services used for diagnosis, treatment, and monitoring of patients. They are progressively being deployed to increase the capabilities of health diagnostic and treatment services. On the other hand, the potential to manage and maintain medical equipment in most developing countries remain rather weak (World Health Organization). It is required to have practical methods and powerful management strategies to meet the challenges of ever-increasing number and use of medical devices.

Keywords: Medical devices, management, life cycle of medical equipment, preventive maintenance, Computerized Maintenance Management Systems

Basic medical equipment is widely used in the healthcare facilities. This essential equipment is supportive to provide primary healthcare to the public. World Health Organization (WHO) classifies essential medical equipment in four main categories. The list given in each category includes the devices required for a specified health service delivery. The type of equipment is significantly dependent on the local health practice, physical characteristics and culture of the population.

1. Diagnostic imaging equipment

Diagnostic imaging equipment is used to take pictures, which help physicians to diagnose a patient's medical condition.

- Diagnostic X-ray equipment
- Ultra-sound equipment

Ultra-sound equipment may be less frequently used, and is usually added if the budget is available in a hospital.

2. Laboratory equipment

A variety of laboratory equipment is used for analysis or measurement purposes.

- Microscope
- Blood counter
- Analytical balance
- Colorimeter/spectrophotometer
- Centrifuge
- Water bath
- Incubator/oven
- Refrigerator
- Distillation and purification apparatus

3. General electro-medical equipment

- Portable electrocardiograph
- External defibrillator
- Portable anesthesia unit

- Respirator
- Dental chair unit
- Suction pump
- Operating theatre lamp
- Diathermy unit

4. Other support equipment

- Operating theatre table
- Delivery table
- Autoclave- for general sterilization.
- Small sterilizer-for specific services (e.g., dentistry)
- Cold chain and other preventive medical equipment
- Electrical generator
- Electrical power regulator
- Air conditioner, dehumidifier
- Refrigerator
- Ambulance-four-cylinder diesel, four-wheel drive vehicle equipped with medical equipment for emergencies; complete accessories, spare tires and tools
- Gynecological examination table
- Small, inexpensive equipment and instruments

Individual hospital authorities decide which type and what number of these devices are required for their own health service purposes.

Medical Equipment Management

Medical Equipment Management Program (MEMP) is established in hospitals to provide safe and reliable operation of medical equipment and promote its effective utilization. This program defines procedures and policies to manage activities related to medical equipment, from their selection and acquisition to decommission. MEMP ensures that devices can provide reliable and accurate information to clinicians, operate safely for patients, and are used to their fullest capacity.

The life cycle of medical devices should be thoroughly considered for effective management. Deficiencies in managing each stage of the life cycle, especially in the earlier phases can cause more problems in the succeeding stages. For example, if the maintenance capabilities are considered during acquisition stage, it can hinder the challenges that might be faced during the maintenance stage of the equipment.

Life Cycle of Medical Equipment

A typical life cycle of medical equipment has the stages shown in Figure 1.1 (World Health Organization). Proper management of each phase can have a positive impact on the others.

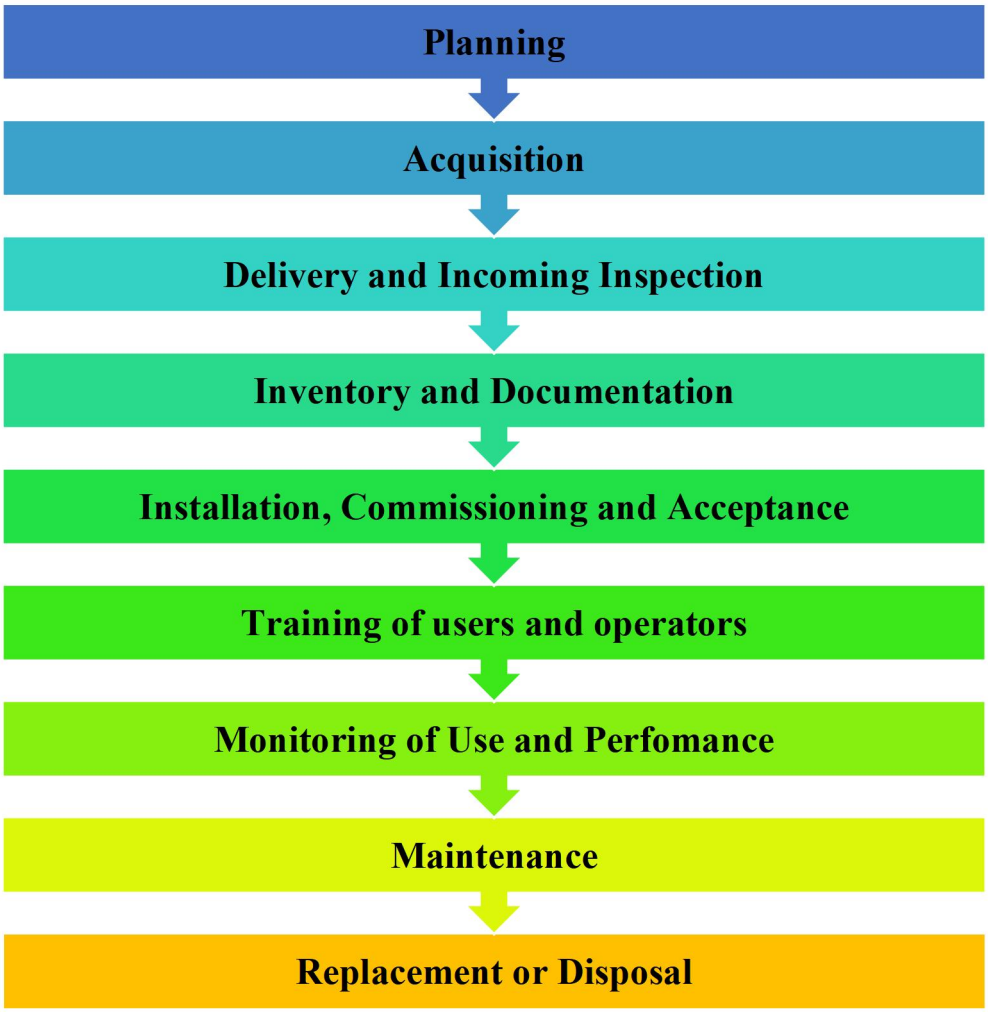


Figure 1.1. A typical life cycle of medical equipment

In the planning stage, distinct policies on acquisition, utilization and maintenance of medical equipment are clearly outlined. This can significantly minimize the problems arising from the contracts, spare parts and maintenance of the equipment. For example, considering the skill level of operators, ensure that only appropriate technology is acquired. Most costs incurred during the life cycle of a device are hidden from view (Figure 1.2). For proper planning of a large number of devices, a full consideration of all elements in the equipment's life cycle is required.

Evaluation and procurement are two main aspects of the acquisition phase. Evaluation process includes safety, performance and maintainability assessment of devices. Moreover, the models and manufacturers of equipment are standardized. In the procurement process, it is emphasized that the supplier must supply operating and service manuals, and must provide operation and service training and essential spare parts.

Incoming devices should be checked carefully for possible damages in the shipment process, conformity with the purchase order, and all required accessories, spares, and documents. Inventory and documentation are important aspects of equipment management and standardization. Inventory entries should include all accessories, spares, and manuals of each device. In-house technical staff or the suppliers can perform installation and commissioning stage. In the latter, in-house staff should monitor the process and record it in the equipment service history. Proper training of users and operators assures effectiveness and safety of medical devices and decreases maintenance errors. In-house

technical staff should act as a link between user and supplier and monitor the supplier's technical services. Medical equipment must always be maintained in working condition and calibrated periodically for safety and accuracy. When a medical device is old and its spares run out of supplies, it should be replaced and disposed according to the safety procedures. The management of each stage mentioned above can be enriched if the resources are available. For example, in addition to corrective maintenance, preventive maintenance can be added to enrich the maintenance element of the management plan.

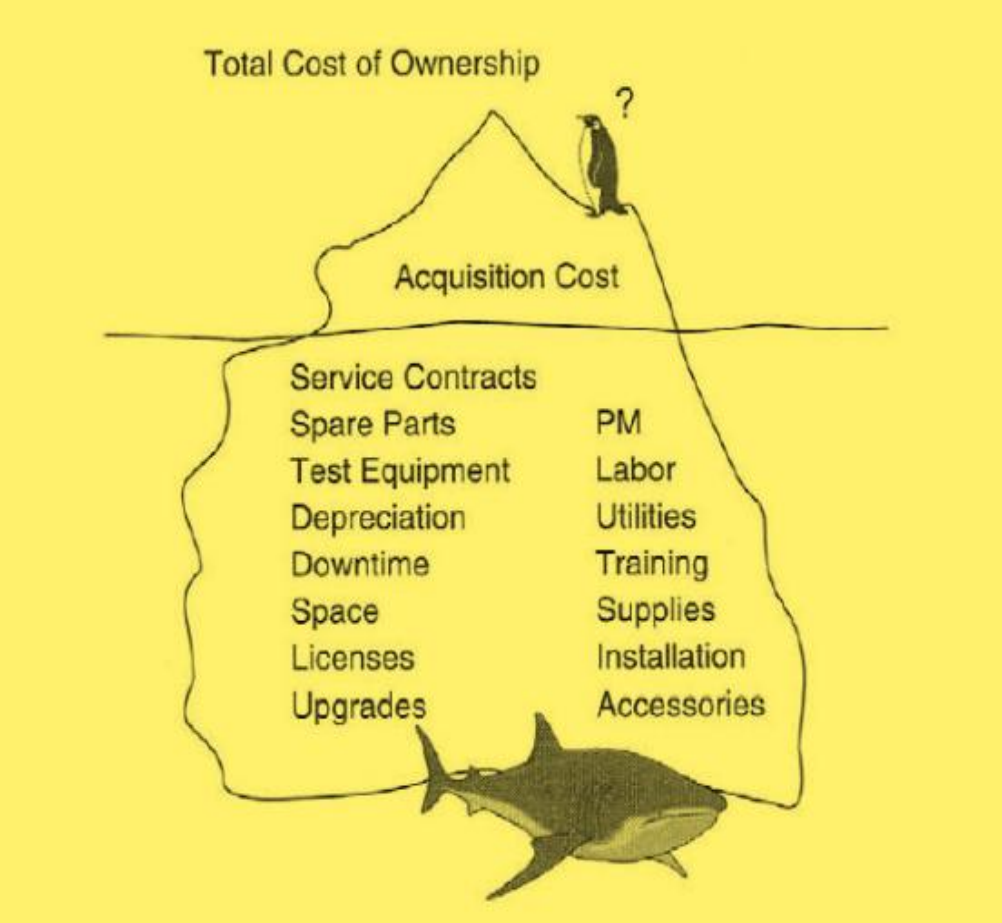


Figure 1.2. Acquisition iceberg

Preventive Maintenance of Medical Equipment

Medical devices are often complex repairable systems consisting of a large number of interacting components, which perform a system's required functions. A repairable system, upon failure, can be restored to satisfactory performance by any method except replacement of the entire system. Medical devices usually undergo several types of tests/inspections during their life cycles as described here:

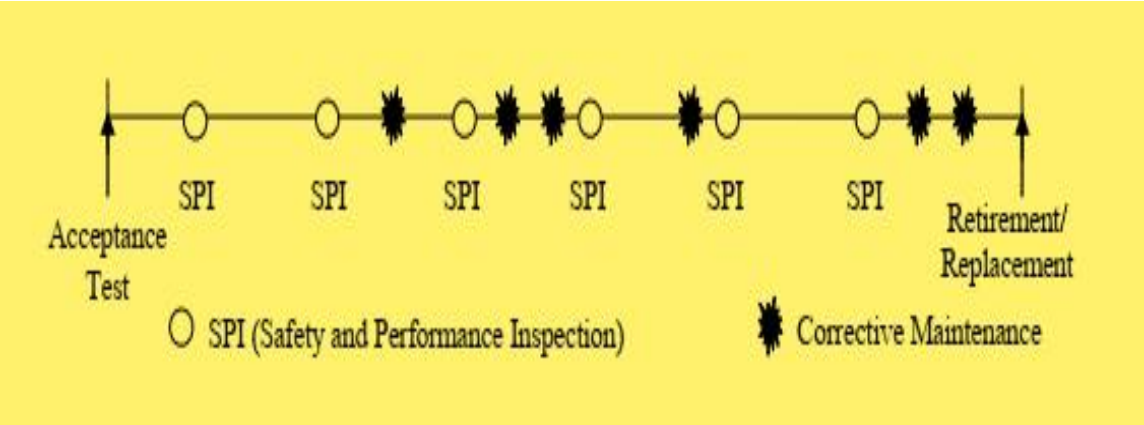
A series of qualitative and quantitative tasks designed to verify the safety and performance of newly received equipment, as well as conformity to applicable codes, regulations and standards.

Visual and operational check of the equipment's safety and functionality typically performed at the beginning of the day or work period, or just before using equipment on a patient.

A set of qualitative and quantitative tasks designed to verify the safety and performance of each piece of equipment by detecting potential and hidden failures and taking appropriate actions. After accomplishing the acceptance test for a newly received device, SPIs are scheduled to be performed

periodically. If any problem is found at inspection, corrective actions are taken to restore the device or its defective parts to an acceptable level. In addition, a set of failure preventive actions may be taken to prevent future failures and/or restore device function; these include part replacement, calibration, lubrication, etc. to address age or usage related deterioration.

When a device fails while it is in use, the operator reports the problem, and again appropriate actions (corrective maintenance) are taken. When the repair of a device is no longer technically feasible or cost effective, replacement becomes the best or the only option. Figure 1.3 describes major



tests and actions performed during a device's life cycle.

Figure 1.3. Major tests and actions performed during a device's life cycle

Computerized Maintenance Management Systems

Computerized Maintenance Management Systems (CMMS) are database applications in an organization that assist in planning and management functions required for effective maintenance. A CMMS to a medical device is similar to an electronic medical record to a patient. It provides the information required for assets management, resource management, financial management, workload, workflow management and regulatory compliance. A CMMS is essential in most healthcare organizations due to the Joint Commission for the Accreditation of Healthcare Organization requirements under the Environment of Care Standards.

One of the most important steps in implementing either a computerized or noncomputerized equipment management system in a hospital, is to have a complete and accurate inventory of all equipment in the MEMP. The inventory should also include the devices that are serviced by other organizations, but they still must be tracked. Each device must have an equipment control number, which is labeled to the device. Equipment control number can be the hospital asset or property number, or can be an independent number assigned to the device. The inventory should be frequently updated as new devices are added. Without an accurate inventory system, tracking equipment maintenance and repair, alerts and recalls is almost impossible.

The core functionalities of a CMMS consist of the modules shown in Figure 1.4.

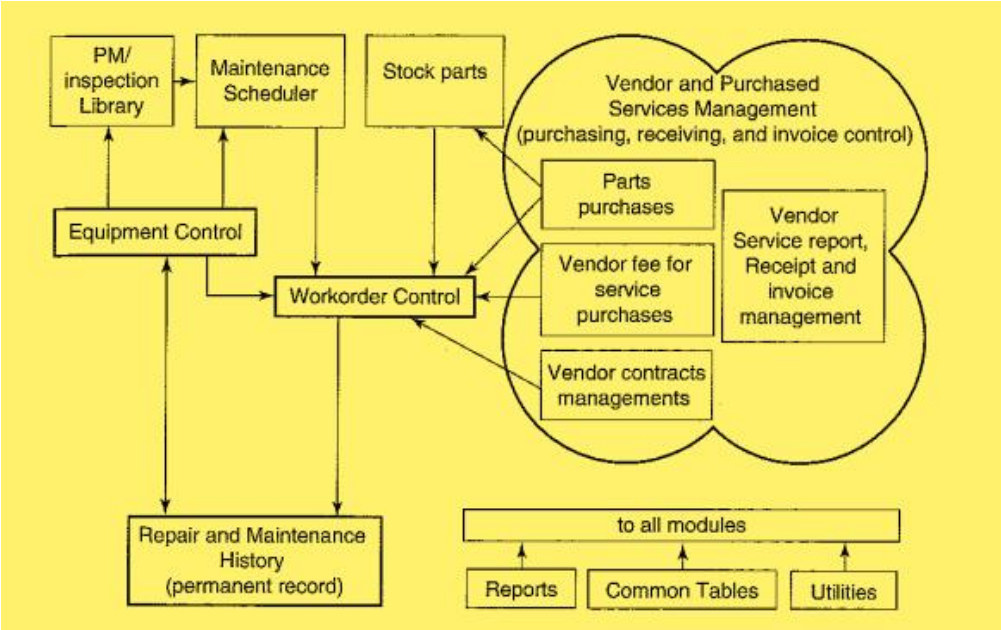


Figure 1.4. CMMS overview

CMMS Core Modules

Inventory control is the core module of a CMMS. It allows an operator to track the inventory movement, i.e., moving in and out of an item from the inventory or from a location to another. To proper planning of service and repair/replacement of each device, healthcare organizations should know the quantity, type, age and the other information related to the device.

Work order or work request is an electronic document used to schedule routine inspection and maintenance. Work order management system is the heart of the CMMS. Using this module, a work order can be created, followed up and completed. It stores all corrective and preventive maintenance requests. It keeps track of the initial customer request, device information, requestor information, date and time of the request, nature of the problem, its urgency, and a summary of the assistance provided so far. All activities performed to a work order should be clearly documented and go into the device's repair and maintenance history. If the CMMS is equipped with an invoice system, a bill is issued and documented for the work order. The work, which is performed, by vendors or external service providers should be also tracked to have a complete history of all devices.

This module determines the work required to be performed to satisfy a request. It specifies the most efficient way to perform the work, the schedules and the required resources. Several scheduling procedures are usually considered in the CMMS. It includes periodic or fixed scheduling, floating scheduling, and synchronized scheduling by feature such as device type, location, specialty, and others. Periodic scheduling is scheduling of an activity, such as preventive maintenance periodically, regardless the time of the last action. Floating is scheduling of an activity based on the last time the action has been completed for the device, and the conditions of the device. Synchronized scheduling by feature allows to schedule actions according to a technician's expertise, type of the device, department, etc.

In some hospitals, the most sophisticated equipment such as MRI, scanner, analyzers, etc., are maintained and services by the original equipment manufacturer (OEM). A good CMMS should integrate the vendor and in-house work to have complete histories of all equipment Vendor management system should also include the contracts and purchase management subsystems to allow for recording the contracts with the external service providers and purchase transactions made from the vendor.

Most organization uses a just-in-time process for ordering repair parts. Parts usually are divided into three categories: stock parts, contract parts, and noncontracted parts. Stock parts are those, which are purchased and kept in stock by an organization to be used when needed. They are not usually immediately assigned to a specific work order. Contract parts are those included in a prepaid contract. Prepaid contracts are made with external service providers for a certain period. Noncontracted parts are those, which are purchased usually just in time for a specific work order or maintenance action.

Preventive maintenance is a fundamental module of a CMMS. It generates PM work orders, prioritizes them based on some given criteria, and manipulates them until they are accomplished.

Tracking labor resources can be performed using this module. It includes the information of all maintenance personnel and their expertise.

Purchasing module is to initiate the requisition of parts and materials against a work order and track the delivery and cost data of the item when the part or material arrives.

Budgeting module is integrated with the planned resources (labor hours, parts and materials) usage on the work orders. It includes the labor, parts and materials rates to calculate or estimate the costs associated with a work order.

Scheduled and Non-Scheduled Work Orders

The maintenance and inspection data are usually available in the CMMS of a hospital stored in either scheduled or non-scheduled work orders. Scheduled work orders are used for routine tests (SPIs); however, when a device fails or has a defective part, a non-scheduled work order is requested to fix the problem. Both scheduled and non-scheduled work orders include the basic information of a device and a test checklist designed for a particular class of device. The checklist contains qualitative and quantitative tests; technicians or clinical engineers should use this list to ensure that all necessary tests and checks are accomplished. Qualitative tests mainly consist of visual inspection of the main parts/components of a device. For example, for a general infusion pump, these include testing its chassis/housing, line cord, battery/charger, etc. Quantitative tests include measuring parameters of a device to check whether the parameters are in control. Grounding resistance and maximum leakage currents are among the quantitative tests for a general infusion pump. A work order presents all PM checks and actions, such as cleaning, lubricating or replacement of a device or its parts. A work order is also created for an acceptance test of a newly received device.

“P” (pass), “F” (failed), or “N” (not applicable) are the possible results of each qualitative or quantitative test on the work order. When a test is performed on a component, and it is found to be non-defective, the result is “P”; however, in the case of failure of a part, the result is shown as “F”. Since a general test checklist is designed for a class of equipment, some qualitative or quantitative tests may not be applicable to particular devices in that class; for these devices, the test result is given as “N”. Quantitative and qualitative tests are specifically performed for components/features of a device, but PM checks show the actions performed at the device level.

Currently, most hospitals merely follow manufacturers’ recommended intervals for periodic SPI of devices. SPI intervals differ from 6 to 12 months depending on the device type and risk level (U.S. FDA/CDRH, 2005). Class III (high risk) devices such as defibrillators should be inspected every 6 months, and class II (medium risk) devices like ECGs should be inspected annually. However, the optimality and even the necessity of these recommended intervals are questionable. It is essential to establish an evidence-based inspection or maintenance regimen derived from analysis of field data.

Concluding Remarks

According to standard EC.02.04.01 for Medical Equipment (see Section 2.2.2), healthcare organizations must identify maintenance activities to maintain, inspect, and test all medical equipment on the inventory. They must employ appropriate strategies, including the intervals for maintenance

activities. However, not much research has been presented in the literature to address proper strategies and the methods for implementing them. In the research reported in this dissertation, we propose several strategies, which can be used to meet some requirements of standard EC.02.04.01. We propose a model to decide on inclusion of medical devices in the MEMP, methods for trend analysis of maintenance data, and finally several models to find the optimal periodic inspection interval for a repairable system such as a medical device. The proposed models and methods are discussed in the rest of the thesis.

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