Bulletin of "Carol I" National Defence University
10.12753/2284-9378-20-17

EFFICIENT STRATEGIES IN MEDICAL EQUIPMENT MANAGEMENT

Col.Eng. George UDROIU, PhD Candidate*

Medical equipment is one of the most critical resources of the healthcare system worldwide, used for diagnosing, treating, monitoring and caring for patients, so the management of these vital health technologies, developed as a comprehensive patient-centered process, is aimed towards the performance of health facilities, through rapid accessibility and availability, viability and safety, quality services and satisfaction of final beneficiaries, as well as the control of cost throughout the life cycle, allocation and optimal use of resources and overall profitability of the medical institution. This article presents a series of helpful strategies that healthcare units should use in order to increase the value of medical equipment and the success of the medical act, strategies implemented and monitored by clinical engineering structures.

Keywords: medical equipment; management; efficiency; quality and safety; clinical engineering.

The continuous development of new medical technologies, their variety and interoperability, as well as the increase in the number of patients, representative elements of increasing health costs, lead medical organizations to constantly seek for appropriate solutions for medical equipment management, to increase operational capacity, safety and quality, minimizing lifecycle cost, efficient resource planning, balancing investment expenditures, maximizing the life of medical equipment and substantiating the decision-making process on the basis of quantifiable data.

The efficiency of medical equipment management is the result of the interaction mechanisms created between clinical and administrative structures, the organization and coordination of technical and financial actions, carried out by qualified personnel from clinical engineering (CE) structures, including evaluation, planning, programming and budgeting activities, selection and procurement, records and monitoring, maintenance and training, disposal and decommissioning, as shown in Figure 1.

In the context of these challenges and financial pressures in the healthcare sector, integrated management of health technologies should be based on efficient strategies for each stage of the life cycle of the medical equipment, developed based on the mission and the objectives of the health unit. Deciding leaders in the field of medical equipment investment should understand and be aware of the costs associated with the implementation and use of new technologies before making the final decision on acquisition and operational integration.

Figure 1 *Active management of medical equipment*
Source: Adaptation after [World Health Organization], "WHO Medical devices technical series, Global Atlas of medical devices", *3.4 Health Technology Management,* Geneva, 2017, pp. 44-69.

Medical Equipment Management Group (MEMG)

The interdependence of the processes of strategic planning and operational management of medical equipment, as well as the need to ensure

**„Gl.dr.av. Victor Anastasiu" National Institute of Aeronautical and Space Medicine*
e-mail: *uddy_74@yahoo.com*

quality, safety, cost control during the life cycle and profitability of the medical organization, determine the need to establish multidisciplinary medical equipment management groups at each health unit, for the analysis and evaluation of existing technologies in the hospital, selection of the most appropriate future investments, both adequate to the specifics and requirements of the institution, study of associated cost and the implementation of medical equipment (ME) policy.

In this regard, the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) has issued a recommendation as follows: "healthcare organizations should establish a medical device management group to develop and implement policies across the organization"[1].

The group, which should include members of the Board of Directors (BOD), clinical staff (doctors and nurses), clinical engineering staff, administrative and financial specialists, is usually chaired by the medical director of the hospital or head of the CE structure and has the role of creating relationships and communication on the ME segment within the organization, in order to increase the involvement of users and technicians, to raise awareness and accountability of staff on the concept of technology management, by reporting full costs throughout the life cycle, and to establish and implement governance and policies at the health unit level.

MEMG must analyze the use of ME throughout the life cycle, the risks associated with it and the financial efficiency of the hospital, to assess the support for the strategic objectives of the medical institution. The result of this analysis must be materialized by developing a Medical Equipment Management Plan, subsequently objectified in specific work programs and procedures.

The policy developed by MEMG must include, at strategic level, the requirements of the program of evidence (inventory) – a tool to support the planning of existing ME replacements, procedures for evaluation and selection of new technologies proposed, risk management and incident management, addressing environmental problems, life cycle of ME, proper operation procedures, maintenance and decommissioning of ME, legislative support.

Equipment inventory management during its life cycle

The record of medical equipment or their inventory is the fundamental tool in the activity of clinical engineering, that permanently reflects the level of equipment endowment with by types of medical devices and the current state of existing technologies, in order to ensure their safety and efficiency in use, an integrated system of data and information useful for the informed decision-making process. The system is basically a constantly updated document, which serves as a guide for the projection and elaboration of future budgets – both in terms of capital expenditures (procurement planning based on factors such as life cycle, condition, risks and associated costs as well as operating and support (planned maintenance and calibration costs, spare parts, consumables), determining the training and education needs of medical and technical staff, establishing the need for testing and calibration equipment.

With this tool, healthcare units actually manage the entire life cycle of medical equipment, assess and analyze its technical condition at any time, monitor existing risks, schedule inspection and preventive maintenance (IPM) operations, record repair history and breakdowns, control stocks of parts and consumables, account for all life cycle costs and plan for human, material and financial resources for future periods.

Depending on the size and mission of the health facility, as well as the fleet of medical equipment, IC structures should determine the equipment that will be included in such a computerized inventory program, following an evaluation, preferably based on equipment function, risks associated with use, incident history and maintenance requirements[2]. Small medical units, such as specialized outpatient clinics, with few equipment, can include all devices in this program (up to the level of tensiometers and stethoscopes), while hospitals with developed infrastructure can focus, in particular, on nuclear equipment and facilities, magnetic resonance imaging (MRI), computed tomography (CT), radiotherapy, laboratory units, anesthesia equipment or other complex and expensive installations.

Such a program should at least include information on: the type, series and identification number of the equipment; manufacturer and year of manufacture; date of commissioning; management

documents and the value of the acquisition; the operational condition of the equipment, the necessary preventive maintenance operations, the scheduled time and the cost of maintenance operations, including spare parts and consumables; corrective maintenance interventions, supporting documents and costs (own or outsourced regime); operational maintenance procedures; operating fees and licenses; calibration data and risks during operation; due dates and warranties; normal service life as well as estimated service life; monitoring the performance of service contracts. The program may generate reports on maintenance costs, periods of inactivity of equipment, the type of most common failures or spare parts used throughout the life cycle and may be a quantifiable justification in the procedure for demonstrating the opportunity for new investments, planned as replacements of existing equipment.

The more complete the inventory, the more efficient and performing the management of medical equipment is, therefore it is mandatory that the program should be continuously updated, monitored and improved, as well as audited and reviewed annually.

Prioritization, selection, and acquisition of medical equipment

The aspirations of medical staff and their continued desire to use the latest equipment or to update existing technologies, in order to increase the safety, quality and efficiency of the medical act, driving substantial annual investment needs, on the one hand, and budgetary allocations and the outcome of the identified needs analysis, on the other hand, represent a challenge for hospital boards and lead, in a balanced prioritization and justified replacement of ME, to an interactive and complex process that seeks both rational and timely use of available resources. Investments in medical technology, the driving force of expensive health services[3], must be prioritized, planned and substantiated in order to give clinical, and operational value to the medical institution.

In this regard, health facilities should be aware of their equipment needs and the availability of financial resources for a period of at least 3-5 years, in order to develop well-planned investment plans, but also be able to react quickly through revisions of plans or reprioritizations, to counter effect of changing technologies and sometimes of health regulations that may change or prohibit the use of ME.

The need to purchase new ME is identified in the following cases: replacement of obsolete existing medical devices that are no longer reliable and safe or have become too expensive to maintain and operate; the introduction of new medical technologies to serve healthcare services of the organization or to reduce the total costs of the hospital; reducing the risks associated with use by standardization and interoperability; compliance with regulatory policies in the field of medical devices.

Medical institutions must analyze and evaluate the solution for the implementation of new technologies, aiming for increasing quality, reducing costs, covering a wide range of services and, of course, in accordance with the mission and strategic objectives of the medical organization. The evaluation of medical technology must be based on the principle of value, in the light of competing demands of medical departments, by understanding the life cycle of ME and by knowing and analyzing objective factors such as: hospital *vision*, technology *efficiency*, *value* of investment in relation to market price, possible *savings* of the chosen solution, full acquisition *cost*, installation commissioning, operation, support and disposal, *maintenance* requirements and existing availabilities, in order to optimize the operation of ME and associated costs throughout the estimated life.

The existing ME replacement plan must be the result of an assessment by the CE structures, based on prioritization coefficients, a process in which various factors are analyzed, such as: equipment condition and downtime, age, operational support requirements during the lifecycle time, the EOL – end of life – granted by the manufacturer for some spare parts or consumables required for operation, annual maintenance cost in relation to the purchase value of the equipment, the degree of use within the medical organization and in the context of future objectives, the degree of acceptability of the operating medical staff (physicians' satisfaction) and the function or criticality of the ME within the health unit. Most of the analytical factors are quantifiable elements contained in the ME life cycle monitoring inventory program or database,

and a small part represent subjective opinions of clinical staff, such as medical device users and final beneficiaries (patients).

A number of other factors need to be considered in evaluating the process of selecting and acquiring new ME, such as: the need to update or modernize software applications; compatibility with the electronic health system implemented at the level of the health unit; novelty or topicality of the ME standard; availability of consumables on the medical market; the availability and development of the service network at national or local level, as well as the response times to intervention requests; lifecycle training skills and ways of professional development of own staff; expected life of the technology; additional needs for equipment or plants for installation, commissioning or use.

Globally, there is no standard process of prioritization or selection, but every medical institution should, through the BOD, MEMG and CE structures, look for ways to substantiate and demonstrate the opportunity to acquire ME based and improvement. In this regard, health facilities must develop MS maintenance programs, analyze and decide, taking into account a number of critical factors, as shown in Figure 2, how to perform maintenance operations, but also MS that will be included in the program and the periodicity of IMP operations, based on risk-based assessments, in order to obtain a good cost-effectiveness ratio.

Depending on the complexity of the medical technology, the skills, testing and calibration equipment required to perform the maintenance work, as well as the number and training of qualified technical specialists, the health unit must decide which ME will be provided with outsourced maintenance support or combined support. The trend of the last decade worldwide is the development of own CE teams, trained and informed by participating in various training conferences or training programs, increasing ME warranty periods and eliminating *full service* contracts, in order to reduce costs and increase the availability of medical equipment. Unfortunately, this process

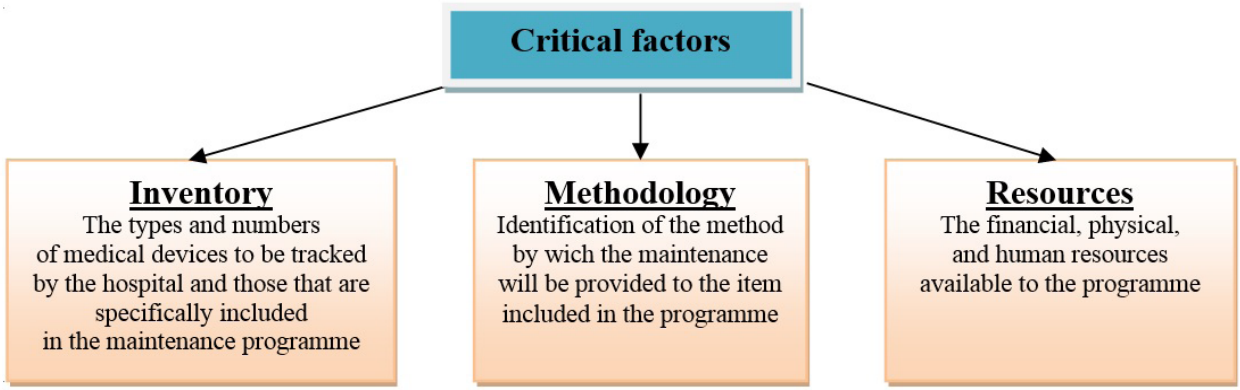

Figure 2 *Critical factors in maintenance planning*[4]

on increasing clinical and economic value of the medical organization, in the context of the constant appearance on the market of new technologies and budgetary constraints in the healthcare sector.

Management of the medical equipment maintenance program

The reliability of EM, equivalent to the safety and availability of the equipment, is the result of the effectiveness of medical technology maintenance activities, activities that require good planning, implementation, monitoring, evaluation of employing with technical and management staff of health technologies at the level of state health units in Romania is slow and difficult, due to the small number of biomedical engineers trained, but also lower salary policies compared to the private sector.

Maintenance activities and their periodicity can be planned according to the manufacturers' recommendations or based on individual strategies that respect the good practice standards of the ME field[5], as recommended by the MHRA in the UK. However, it is not considered effective to use the

same maintenance planning strategies for both old and new or state-of-the-art ME (high technology).

Through the data collected through the inventory program, CE structures can analyze all ME, in terms of the specific needs of the health unit and based on three fundamental elements of the role of technology in health: patient safety (represents the risk of ME failure, with effect on patient injury), the maintenance needs of ME (periodicity of IPM operations) and the role of ME in fulfilling the basic mission of the health unit (impact of failure or its consequences on patient outcomes / satisfaction, as well as the institution's budget).

This prioritization process, developed over the years according to several models (Fenningkoh and Smith – 1989, Wang and Levenson – 2000, ECRI – 2012)[6], shows that ME with the highest maintenance needs are not the most critical in terms of patient safety, and those with the highest degree of patient safety hazard often do not require the most complex IPM activities. The EME identified as critical for the medical institution, following the analysis of the CE structure, will be included in the maintenance program and will respect the periodicity of the execution of IPM operations, according to the manufacturers' recommendations.

The Fenningkoh and Smith model[7], approaches ME prioritization for inclusion in the maintenance program, based on an algorithm for evaluating three factors, as follows: equipment function (between 2 and 10 points), associated risk (between 1 and 5 points) and maintenance needs (between 1 and 5 points), and obtaining a total score (TS) by summing the resulting values for each factor, as follows:

TS= Function + Risk + Maintenance needs (1)

ME with TS≥12 will be included in the maintenance program.

Although there are still many government policies that recommend the implementation of IMP operations according to manufacturers, international studies have shown that most manufacturers' recommendations are exaggerated either in frequency and activities to be performed or parts / consumables to be replaced, so in order to save resources, in the context of budgetary constraints and the reduction of intervention and equipment downtime, in recent decades alternative maintenance plans for low-risk ME (considered routine ME) have been practiced, based on maintenance strategies, developed by professionals in the CE structure.

These strategies must not decrease safety, must be fully accepted at the level of the healthcare organization and represent the result of the CE experience, based on two principles: IPM performed according to the manufacturer's recommendations does not further increase patient safety; the same type of equipment, used in different conditions of time and space, requires different ways of performing IPM[8].

It should be noted that experts believe that alternative maintenance programs will not include new ME under warranty, imaging and radiology (CT, MRI, X-ray) or surgical lasers and that all ME, both those with increased risk, as well as routine ones, regardless of the maintenance program in which they will be included, must go through all planned maintenance operations, in order to increase the value of health technologies.

In other words, high-tech and new ME will be included in predictive maintenance programs, and older ME will be included in alternative preventive maintenance programs[9]. In both cases, the maintenance program is the instrument for allocating resources to fulfill the mission of the health unit and to ensure efficient and safe ME in use.

Another difficult decision that the CE has to make in order to achieve a balance between costs and benefits is the choice of the type of maintenance contract awarded to external providers, for ME that will be prioritized for the execution of outsourced service work. Contracts can be full maintenance commitments (full service 24x7) covering all maintenance operations, repairs, calibrations, spare parts, training, planned maintenance commitments and technical diagnostics in the event of a fall or maintenance only commitments.

Conclusions

In order to maximize the value of ME and increase the quality of medical care, any health unit must be guided in its management of ME by its own policies and strategies, specific to the size of the organization, medical mission and clinical and financial objectives, to generate strategic plans, developed, monitored and constantly updated and evaluated by MEMG. The key element of the

group's activity is to ensure that any purchase of equipment is made only with group's approval, respecting the principles of best practices, rules and requirements of standardization and interoperability at the level of the medical organization.

Proactive management of ME, based on the concept of collecting and capitalizing on data from the life cycle of ME, is achieved through an inventory program as complete and accurate as possible, which is the basis of the quality and cost management programs of medical units, developed of CE structures, and the most eloquent element in the decision-making process to prioritize equipment purchases, whether they are the subject of replacements of existing medical equipment, physically or morally worn out, or investments in new high-performance technologies. The analysis and substantiation of capital expenditures in medical organizations must be based on factors that have a direct impact on the full costs associated with the use of ME throughout the life cycle, quality and safety of healthcare services, in order to achieve a balance between clinical and financial performance.

In order to optimize operating and support costs, CE structures need to develop ME maintenance programs based on risk and cost assessments and prioritizations, thus developing alternative plans for non-critical equipment, considering the complexity and amount of existing equipment, the skills of its own specialists and their number, the technical means of calibration and control, as well as the budgetary resources available.

The role of CE in the medical organization is not only to ensure the safety of use and reliability of equipment, but also to direct the entire management process of medical technologies in the health unit.

NOTES:

1 [Managing Medical Devices], *Guidance for healthcare and social services organizations*, Medicines&Healthcare Products Regulatory Agency, UK, 2015, p. 7.

2 [Association for the Advancement of Medical Instrumentation], *Recommended practice for a medical equipment management program,* American National Standards Institute, Inc., 2013, pp. 8-13.

3 Vivian Ho, Jerome Dugan and Meei-Hsiang Ku-Goto, "Why Are Hospital Prices Rising?", *Health Management, Policy and Innovation,* 2013, 1(4), pp. 1-16.

4 [World Health Organization], "WHO Medical devices technical series", *Medical equipment maintenance programme overview,* Geneva, 2011, p. 14.

5 [Managing Medical Devices], *op.cit.*, pp. 33-42.

6 Binseng Wang, *Medical Equipment Maintenance: Management and Oversight*, Morgan&Claypool Publishers series, Connecticut, 2012, p. 24.

7 Joseph F. Dyro, *Clinical Engineering Handbook*, Elsevier Academic Press, Burlington, USA, 2004, p. 123.

8 Binseng Wang, Emanuel Furst, Ted Cohen, Ode R. Keil, Malcolm Ridgway, and Robert Stiefel, *Medical Equipment Management Strategies*, Biomedical Instrumentation & Technology, May 2006, Vol. 40, No. 3, pp. 233-237.

9 Mana Sezdi, *Two different maintenance strategies in the hospital environment: preventive maintenance for older technology and predictive maintenance for newer high-tech devices*, Journal of Healthcare Engineering, Volume March 2016, pp. 1-16.

REFERENCES

[Association for the Advancement of Medical Instrumentation], *Recommended practice for a medical equipment management program,* American National Standards Institute, Inc., 2013.

[European Commission], *Medical Devices*, https://ec.europa.eu/growth/sectors/medical-devices_en

[World Health Organization], WHO Medical devices technical series, *Medical equipment maintenance programme overview*, Geneva, 2011.

[Managing Medical Devices], *Guidance for healthcare and social services organizations*, Medicines & Healthcare Products Regulatory Agency, UK, 2015.

Dyro F. Joseph, *Clinical Engineering Handbook*, Elsevier Academic Press, Burlington, USA, 2004.

Ho Vivian, Dugan Jerome, Ku-Goto Meei-Hsiang, "Why Are Hospital Prices Rising?", *Health Management, Policy and Innovation*, 1 (4) 2013.

Purcărea Victor Lorin, *Medical Technology and equipment*, University Publishing House "Carol Davila", Bucharest, 2008.

Rivas Rosanna, Vilcahuaman Luis, *Health Technology Management Systems*, Elsevier Academic Press, Burlington, USA, 2017.

Sezdi Mana, "Two different maintenance strategies in the hospital environment: preventive maintenance for older technology and predictive maintenance for newer high-tech devices", *Journal of Healthcare Engineering*, March 2016.

Wang Binseng, *Clinical Engineering Financial Management and Benchmarking: Essential Tools to Manage Finances and Remain Competitive for Clinical Engineering/Healthcare Technology*

Management Professionals, Independently Published, USA, 2018.

Wang Binseng, Furst Emanuel, Cohen Ted, Keil R. Ode, Ridgway Malcolm, Stiefel Robert, "Medical Equipment Management Strategies", *Biomedical Instrumentation & Technology*, vol. 40, no. 3, May 2006.

Wang Binseng, *Medical Equipment Maintenance Management and Oversight*, Morgan & Claypool Publishers series, University of Connecticut, 2012.