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APPROACHES TO MEDICAL EQUIPMENT LIFE CYCLE

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Medical equipment is the most expensive investment in the healthcare industry that helps ensure the safety, quality and efficiency of the medical care. In the context of the continuous development of technology and the limitation of available resources in the healthcare sector, as well as in order to increase the potential of assets and their technical performance and for optimizing the costs associated with use, advancing robust equipment management is a managerial must for healthcare leaders. This multidisciplinary activity of health technology management is of fundamental importance in the development of the organization and requires an understanding of the life cycle of medical equipment and the associated processes. The current article provides an overview of the stages of equipment life and the interdependent functions of this chain, in order to improve the decision-making process and the rational use of resources.

Keywords: medical equipment; life cycle; lifespan; medical equipment management; efficiency.

Uncertainties caused by the ongoing health care reform, the year-by-year increase in general healthcare costs, the expansion of patients' medical demands, the concern of health units to extend the life of assets and reduce the costs of operating and supporting medical equipment, in order to make the hospital's business profitable, are the main factors that determine the development of a complete management during the life cycle of medical equipment. This involves thoroughgoing and optimizing the stages in the life of equipment, through a systematic approach to their life cycle, continuous monitoring and periodic analysis of each stage, from the identification of the need in the medical market to sales, within the innovation cycle and development, from planning to final disposal, within the operational life cycle, as well as activities necessary to support the lifetime of the equipment.

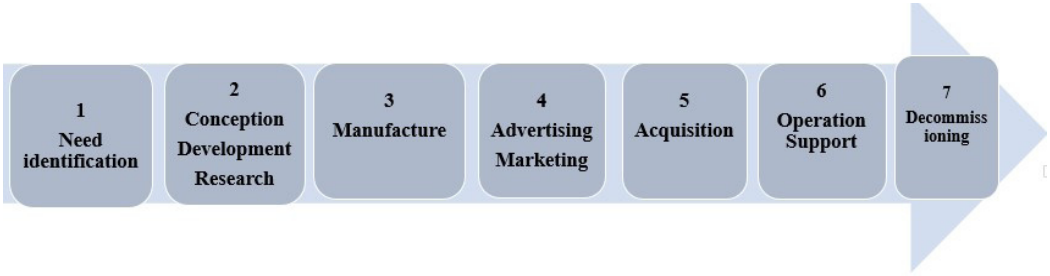

Figure 1 *Phases of the extended life cycle of medical equipment*
Source: Adaptation after [World Health Organization], Medical Device Regulations, *Global overview and guiding principles*, Geneva, 2003, p. 5.

The extended life cycle of a medical equipment (ME), as shown in Figure 1, represents the time frame and the progress of the equipment, from the clarification of its need and utility in healthcare services to the decommissioning. This cycle includes interdependent management activities, corresponding to the two component sequences of ME life – the industrial life cycle (innovation and development sequence) and the operational life cycle (clinical sequence under the responsibility of health units).

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Industrial life cycle

In the first sequence, following the identification of the need in the clinical environment, researchers and medical practitioners seek to develop concepts, through technical methods and scientific conventions to ensure prototypes of safe and high-performance equipment, with low risks and increased effectiveness. After obtaining the prototypes and performing the tests and the verifications of the acceptance parameters, the clinical engineers make corrective modifications to the initial project in order to attest the concept and to carry out the clinical studies.

Official approval in advance of the manufacturing phase (e.g. CE marking in the European Union) for placing on the market is made by notified bodies from the New Approach Notified and Designated Organizations (NANDO[1]) list, and at the end of production, medical devices are assigned unique device identifiers[2] (UDI).

Advertising aims to promote ME and to influence users (medical staff) and final beneficiaries (patients) on the belief in the safety, quality and performance of new technologies, in order to increase future expectations and sales.

The sale of medical technologies overlaps with the acquisition phase of the operational life cycle, representing the intersection of the two sequences in the life of medical technologies and requires the implementation and compliance by providers of international regulations on medical devices, and by medical organizations, good knowledge of ME newly entering the market (performance, parameters, costs).

Lifespan of ME

With the interaction of ME with the clinical environment in the health unit (clinical sequence of life cycle - operational life cycle), we encounter, although not in equipollence, interchangeably, three terms for life[3]: actual life, physical life and useful life.

Actual life is the period of time during which an ME operates at nominal technical parameters and can achieve the expected results in the diagnosis or treatment for which it is recommended and used.

Physical life is determined by the period of time in which an ME is productive and ends when it suffers a severe failure and can no longer be restored to operational status or can no longer fulfill its function and purpose for which it was created.

The useful life is the estimated available resource of an equipment, recommended by the manufacturer, usually expressed in operating hours, number of exposures, number of procedures performed or number of diagnoses.

Estimating the actual life of the ME is a crucial parameter in the life cycle planning phase, and the operation is strictly dependent on the following elements of influence: the attention paid by operators to the mode of operation, the periodicity and quality of preventive maintenance operations, usage frequency and environment, the cost of operational support, the availability of software updates, and regulatory changes in the area of regulation.

As part of the ME management and life cycle projection process, clinical engineering (CE) departments around the world use an average ME life of 10 years, with the exception of radiology and imaging equipment, which is extended to 15 years. This period is different from the normal duration of operation legislated at the level of each state and periodically reviewed by the specialized internal bodies. In the United States of America (USA), for example, regulations on the lifespan of ME are renewed cyclically, at 5-year intervals, based on data collected through technical structures in hospitals, by the American Hospital Association (AHA)[4].

Operational life cycle

Analyzed in terms of operational life, the life cycle of ME includes four main phases, as shown in Figure 2, each phase comprising a wide range of actions and activities, components of medical equipment management during the life cycle of competence and the responsibility of the medical organization, such as: needs assessment; technical consultancy; scheduling and cost planning; supply chain management; contract management; records of stocks and spare parts; human and material resources management; hazardous materials management and safety protocols.

The planning stage, initiated by the tool of identifying and demonstrating the need, is an essential period in the management decision-making process, providing the correlation of requests for replacement or additional ME with the vision and strategy of the medical institution, in

terms of future objectives management, regarding the health care services provided or the resources forecast to be allocated.

During this stage, medical equipment management groups must consider a number of aspects and conditions for the viability of projects to invest in medical equipment, as follows:

• Justification of the choice made to demonstrate the opportunity for future investment.

Planning is a dynamic element in the management decision-making chain of ME, with the role of optimizing the allocation and use of resources, thus based on three pillars of health unit development: management policy and strategy, the

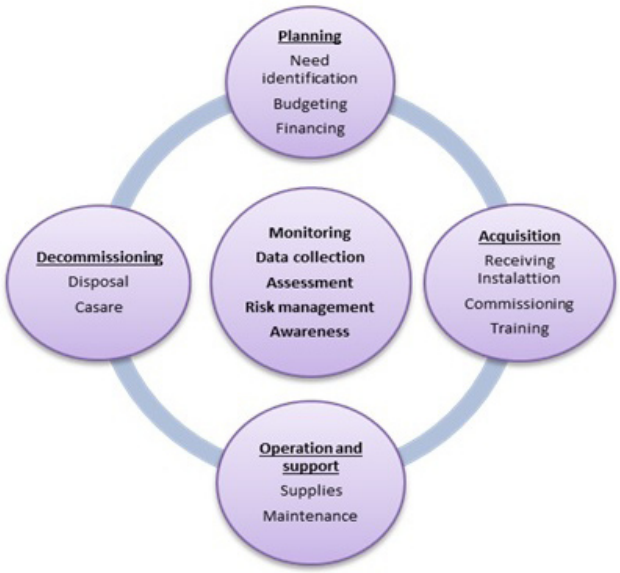

Figure 2 *Phases of the life cycle of medical equipment (operational sequence)*

Source: Adaptation after Joseph F. Dyro, *Clinical Engineering Handbook*, Good Management Practice for Medical Equipment, *Steps in the life cycle of a medical device*, Elsevier Academic Press, Burlington, 2004, p. 130.

• Substantiation and prioritization of the equipment needs, benefits (qualitative, financial, performance) brought to the medical organization by adopting new technologies;

• Identifying the financial feasibility of possible solutions: new acquisition, modernization (reconfiguration/software update) of existing technologies, operation of existing equipment over a well-defined time horizon;

• The capacity and compatibility of the current infrastructure and of the electronic system adopted for the new technology;

• Qualification and competence of the medical and technical staff of the medical organization;

• The degree of development of the service network at national or local level;

• The additional costs necessary for the works and services necessary for the installation and commissioning;

• The costs necessary to operate and maintain the equipment during the life cycle;

• Verification and compliance with the regulations governing medical services;

quality and safety of the health care services and the profitability of the organization, in relation to the costs of the life cycle of the ME.

Internationally, the recommendation for the annual budget allocation for investments is 10% of the total replacement value of the equipment fleet[5], but in recent years, the allocation of resources is based on cost analyzes - efficiency, reliability and operational support.

For a balanced budgeting and funding, the planning must cover all hidden costs of ME life (human resources costs, training, maintenance, consumables and spare parts, fees for accreditation and operation, administrative costs, decommissioning and disposal costs), by designing a realistic budget, based on availability and applicability, prioritizing needs and making financial allocations more flexible. Budgets must be planned for the entire life cycle of the equipment, usually with an annual maintenance cost for a full service contract[6] of 10% of the acquisition cost, each sometimes reaching up to 14% in the case of complex equipment (CT, MRI) or, compared to

the total budget of a hospital, of 1% per year, for maintenance support provided to all MEs[7].

The acquisition of medical equipment is a complex and difficult task in their life cycle, requiring good collaboration and communication between all the structures involved in the health unit, in order to procure good quality devices, both safe to operate and accurate in delivering results, cost-effective for life and in line with internationally accepted standards.

The most popular ME purchasing options are:

- New ME from world-renowned manufacturers – advantages: superior quality, operational safety, lifelong logistical support, multiple clinical functions; disadvantages: high life cycle cost and complexity in operation;
- Used or reconditioned ME from globally recognized manufacturers – advantages: attractive quality / price ratio, availability of consumables; disadvantages: low clinical acceptability (medical staff prefer new technologies), short warranty period;
- New, cheap and low-reliability ME, usually made in China – advantages: low life cycle cost; disadvantages: lower quality, lack of compliance with European standards, short service life, low availability for logistical support;

At this stage, the evaluation and selection of existing technologies play a key role in the procurement of appropriate equipment, and specialists must take into account certain factors, such as:

- exchanging information with other medical units about the reliability and results of ME;
- identifying potential suppliers and verifying their ability to support the technology throughout the life cycle (references);
- availability of consumables and checking their price;
- complexity of existing equipment;
- interoperability of identified medical devices;
- standardization of equipment in order to reduce costs during the life cycle;
- choosing the best solutions in relation to the total life cycle costs;
- centralization of needs at national or departmental level (centralized procurement).

The profile of the technical specifications, after which the offers are evaluated from a clinical, technical and financial perspective, must aim at the acquisition of qualitative and high-performance ME, the reduction of risks to patients and operating personnel, logistical assurance issues, technology life, as well as achieving cost efficiency.

In this regard, the World Health Organization (WHO) has drafted a general template of technical specifications for medical devices, which should cover at least the following aspects[8]: the name of the ME and the purpose of its use; technical and physical parameters; usage requirements; requests for consumables and spare parts (accessories); environmental requirements; installation / commissioning rules and initial training; minimum warranty period; maintenance and decommissioning rules; compliance standards.

The award criteria used to determine the most economically advantageous tender may address three economic elements[9]: price only; cost only or the best ratio between quality and price or cost, but for the profitability of procurement processes it is advisable to use as evaluation factors parameters or characteristics that streamline the cost over the life cycle of the ME.

ME reception is based on a detailed planning, developed on a set of tools related to the required documentation, test reports, manuals, instructions, data sheets confirming the required quality and safety performance, as well as compliance conditions and standards.

In order to carry out the ME installation and commissioning procedure in the best possible conditions, all acceptance needs must be assessed in advance, such as: the availability of electricity and water networks in the facility; maximum permissible floor load; the dimensions of the access and storage spaces; coordination and supervision of operations; availability of test equipment and qualified technical staff. The medical and technical staff involved in the use and the maintenance of the equipment must be trained during the commissioning (mandatory request of the specifications - number of persons and duration) to increase skills and professional development, as well as to avoid operating errors or maintenance, the cause of most ME failures.

Operation and support require increased technical attention over the lifetime, during which time the CE is the link between the user medical staff and the provider or service operator of the

equipment, a stage in which patient safety and the validity of the results, the availability of ME and the provision of consumables necessary for operation are paramount.

To this end, medical organizations should:

- plan all control and verification operations;
- develop plans for the training and improvement of medical and technical staff for the training and development of skills;
- promote and respect protocols of good practice adopted at the level of the institution;
- establish procedures for cleaning, disinfection and sterilization;
- estimate, ensure and monitor the need for consumables on stock levels and on shelf life, as well as certified and compliant spare parts for preventive maintenance (based on the manufacturer's recommendations or on a statistical basis);
- develops preventive maintenance, calibration and testing programs, with the role of extending the life of medical technology;
- properly monitor and manage the costs necessary for operation and maintenance;
- assess the risks of equipment not included in maintenance programs;
- hold all staff accountable for the proper operation of ME and the rational use of consumables.

ME maintenance is performed as planned, following a maintenance program that includes two categories of procedures[10]: inspection and preventive maintenance (IPM) and corrective maintenance (CM).

IPM aims at the timely execution of technical actions necessary to reduce the failure rate of ME and increase their availability or to identify and regulate problems hidden or undetected by user medical staff.

CM has the role of restoring the operability of the equipment to nominal technical parameters, through repair, testing and calibration actions.

The management of these procedures is ensured throughout the life cycle by the CE department in hospitals, which should identify, in the context of current budgetary constraints and the complexity of health technology, efficient ways to implement the program[11], by selecting ME that should be included in the maintenance program, both internally (on its own) and outsourced, depending on the human, material and financial resources available, their skills and training, the criticality (function) of the devices within the health unit, the manufacturer's recommendations in regarding the frequency of IPM operations, the history of technical problems and the costs of maintenance operations.

The economic efficiency is largely determined by this financial balance within the maintenance program, found by the CE department, between the identified risks of using the equipment, the maintenance costs and the benefits to the medical organization.

Decommissioning and disposal is the end-of-life stage of the ME life cycle, in which CE structures must identify, following technical and economic analyzes and evaluations, medical devices that have a normal service life, have reached the reported inefficiency point, operating costs, support and benefits to the medical organization, are technologically obsolete and are no longer relevant in the current activity or future strategy of the health unit, have major defects that require unjustified restart costs, the incidence of regulations prohibiting the use of current technology or, simply, unavailability of logistical support on the profile market caused by the lack of production of consumables or spare parts.

Throughout the life cycle, CE structures in healthcare units should monitor the operational trajectory of ME, collect data on the activities and on the costs necessary for their operation and, periodically, analyze and evaluate the results obtained by transforming data into information, in order to understand the management process, confirm progress or stagnation and promote the concept of learning. At the same time, the culture based on data is the essential tool of planning, and the information obtained from the equipment progress reports bring the necessary elements to the analysis of human resource use and medical technology, how to ensure its maintenance and effectiveness, the study of complete costs per life cycle and determination of the efficiency of the usage and the management of medical equipment.

In the same quadrant of monitoring and data collection, the life cycle risk management approach involves monitoring the safety, performance and effectiveness of the equipment, from placing on the market to the end of its life. Adverse events, technical problems, alert criteria, investigation and resolution, as well as safe disposal methods are notions that require their registration and inclusion

in the holistic analysis of medical equipment life cycle management.

Conclusions

Life cycle management of medical equipment is a complex and varied process, initiated with the identification of the need and completed after a period of their interaction with the medical organization (sometimes more than 10 years) with the decommissioning and disposal of devices.

Effective lifespan, which measures the parameters of functionality and reliability, ensuring the quality, safety and clinical performance of the medical act (generally between 8 and 12 years) must be reevaluated, estimated and reviewed periodically, as a complementary factor to support the decision-making process to invest in medical equipment and ensure the availability of support throughout the life cycle.

Life cycle management must be planned and permanent and requires time, physical and budgetary resources and must comply with healthcare-specific regulations and meet the strategic objectives of the healthcare organization, in order to maximize the benefits of both stakeholders (patients and the organization), control costs and reduce the risks associated with the use of health technologies.

The intrinsic relationship between the safe and efficient use of medical equipment and the patient satisfaction determines the full responsibility of all actors involved in the process, with skills and responsibilities in planning, evaluating, purchasing, operating and maintaining medical devices, through an understanding based on data and information, in order to optimize the results of life cycle management. The first elements of streamlining the way of managing the life of medical equipment are the cooperation and communication of the responsible factors: manufacturers, suppliers, service providers, users, patients and government.

NOTES:

1 https://ec.europa.eu/growth/tools-databases/nando/

2 https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en

3 *** *Medical equipment asset management framework*, State of Victoria, Department of Health, Melbourne, 2012, Part C, pp. 14-17.

4 [American Hospital Association], *Estimated Useful Lives of Depreciable Hospital Assets,* Chicago, Health Forum Inc, 2004.

5 Temple-Bird et al., *How to plan and budget for your healthcare technology. How to manage series of health care technology guides no. 2*, St. Albans, Ziken International (Health Partners International), 2005, pp. 119-120.

6 The annual full sevices maintenance contract is a legal commitment by which the service provider covers all the technical expertise necessary for the operation of the equipment, on site and remotely, 24x7, repair and repair of technical problems, software update and modernization, support and in-service training, spare parts and maintenance materials.

7 Binseng Wang, *Medical Equipment Maintenance: Management and Oversight*, Morgan & Claypool Publishers series, University of Connecticut, 2012, pp. 1-2.

8 [World Health Organization], *WHO Medical devices technical series*, Global Atlas of Medical Devices, *3.4 Health Technology Management*, Geneva; 2017, pp. 60-63.

9 *** *Law no. 98/2016 regarding public acquisitions*, Bucharest, May 19th, 2016.

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