

THE INTERDISCIPLINARITY OF EFFICIENT MEDICAL EQUIPMENT ACQUISITION PROCESS

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Abstract: *In the context of increasing healthcare demand, as a result of an aging population, and current budgetary constraints, as a result of reduced public resources, the decision to invest in efficient medical equipment is a challenge for most health facilities, constantly concerned with promoting innovative and sustainable solutions, as well as results-based ones, in order to increase the value of health technologies and the overall benefits of patients. In order to achieve the balance between safety, quality, costs and benefits and the realization of the best value of medical equipment, the decision-making process requires a multilateral evaluation of financial, clinical and social impact instruments, represented by relevant profitability, life cycle costs, results delivered and overall productivity. In the case of procurement of medical equipment, the lowest price of an economic offer is not an award criterion that strictly reflects the value or efficiency of the technology and departmental procurement structures must include in the evaluation strategies and complementary factors to the process, to add value to the medical organization.*

Keywords: *medical equipment; acquisition; efficiency; value; cost; life cycle.*

Introduction

Medical equipment is a wide range of devices and technologies, varying in complexity from simple blood pressure monitors to sophisticated surgical robots, used in medical practice, with an essential role in ensuring the diagnosis, monitoring, treatment and recovery of the patients.

The continuous technological evolution of this equipment, through the emergence of new models and innovative clinical applications, which aims to improve the quality of services delivered, by improving the health of the general public (social value), increasing efficiency, reducing waiting times, morbidity and mortality (clinical value) and the extension of healthcare coverage, by increasing the degree of addressability and accessibility (economic value), corroborated with the doctors' permanent requests for new acquisitions, as well as with the limitations of the annual capital budget, represent a reference of decision management in rational use of available resources.

In this context, the promotion of value-based procurement of durable medical equipment must bring to the forefront robust processes for evaluating the medical outcomes delivered, other than the technical requirements in the specifications. Value-based health procurement refers not only to prices and technical characteristics, but also to the social benefits offered by medical equipment or technology, thus including in the list of assessment tools both cost factors and non-cost factors.

The holistic concept of value includes cost elements that exceed the purchase price (total cost of ownership or life cycle cost – direct clinical costs, maintenance and operating costs, administrative costs and fees, training and continuing education costs, decommissioning costs), factors of clinical efficacy, safety in use, performance of results and reliability, as well as indicators of social benefits and environmental effects.

Both the United Nations (UN), by recommending evaluation on the basis of cost-effectiveness (*best value for money*¹), and the European Union (EU), by using *the most economically advantageous offer*² terminology, promote the analysis of value by financial, clinical and social factors, in contrast to the narrow and price-oriented assessment. The

¹ United Nations Office for Project Services, *Procurement Manual*, Organization of Procurement, New York, 2019, p. 4.

² *Directiva 2014/24/UE a Parlamentului European și a Consiliului din 26 februarie 2014 privind achizițiile publice și de abrogare a Directivei 2004/18/CE*, pp. 134-135.

assessment of the value of medical equipment must therefore include data on the vision of the health unit, on the one hand, but also of the taxpayer, on the other hand and on the pace and phases of development of the analyzed technology, as well as substantiated information on solutions, available system that can reduce costs, simplify procedures and expand the area of healthcare services and technical opinions of medical staff and clinical engineering structures.

Traceability of the medical equipment acquisition process

At the national level, there is currently no standardized procedure for planning and carrying out the process of purchasing medical equipment, which, by establishing the technical parameters and selection of equipment in the pre-bidding phase most often by a single doctor and by awarding contracts on *the principle of the lowest price*, lead at the departmental level to the occurrence of difficulties related to delivery times, installation and commissioning, costs associated with the entire life cycle and even the clinical performance of that technology. These dysfunctions thus demonstrate the urgent need to develop multidisciplinary medical technology evaluation groups, right from the period of market evaluation and planning of future investment objectives.

In order to support innovation and acquire value from medical equipment purchases, multidisciplinary evaluation teams, consisting of medical staff, biomedical engineers, logisticians, physicists, planners and financiers, must know the image of the health system (treatment and diagnostic methods, cost-effectiveness of interventions, times of physical incapacity and length of hospitalization), to consult the market and to interact with the medical industry in the preliminary phase of the actual acquisition (research offers and opinions in order to increase the value of money invested), to rationally analyze the cost elements and benefits obtained by the organization and patients (collection of clinical information to support the process of evaluating and differentiating the results delivered and the total cost of ownership for each piece of equipment), as well as being able to choose the most appropriate award procedures (pragmatic study of earnings resulting from each competitive or trading option).

In order to optimize the entire procurement process, specialists with responsibilities and skills in the field must address this flow in stages, according to Figure no. 1 and monitor the developed procurement management model, including the mechanisms for generating needs, areas of application and objectives to be achieved through new capital assets, all for the purpose of substantiating and rational using of resources and obtaining value, by incorporating innovation and streamlining health care services.

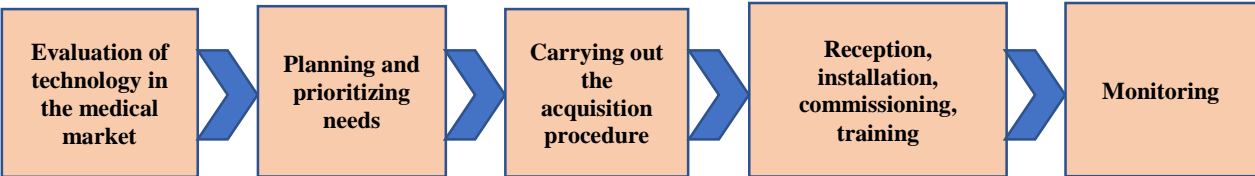


Figure no. 1 - The flow of the medical equipment acquisition process³

The decision-making process in healthcare procurement policy, integrated into a complex health technology management cycle, is based on the importance of innovation and

³ World Health Organization, Medical devices technical series, *Procurement Process Resource Guide*, Geneva, 2011, p. 12.

optimizing the overall cost-effectiveness of healthcare, as key elements of current global health reforms, but also to improve productivity, in order to advance sustainability, by incorporating social and environmental factors.

This complex cycle begins 2-3 years before the initiation of specific public procurement procedures, in the pre-bidding phase, by assessing needs and developing the set of requirements to allow a balanced analysis of market availability, continues with the choice of approach to the procurement procedure focused on value and, after the implementation of the project, with the monitoring of the post-award phase, by collecting data and information throughout the life cycle of medical equipment.

Evaluation of potential acquisition in the pre-bidding phase

Market research and research of medical technology available in the pre-bidding phase, understanding the economic and epidemiological context of the analyzed period, collecting data on clinical performance, risks and costs of equipment, and identifying emerging solutions to the closed procurement system (*captivity or lock-in*)⁴ are tools for elaborating and interpreting comparative decision analysis reports.

In this context, with regard to the overall life cycle of health technologies and conformity assessments and patient safety risks, for the implementation of Regulation (EU) 2017/745 – Medical Device Regulation (MDR) and for the correct understanding and information of health professionals about medical devices placed on the European market, starting with 26 May 2020, the European Database on Medical Devices (EUDAMED)⁵ has been developed and fully operationalized.

In addition, in support of the decision-making process to identify the most sustainable and safe alternatives to the equipment available on the market⁶, healthcare professionals can obtain valuable information about tools, resources and good purchasing practices by accessing specialized platforms such as HCWH Europe Safer Medical Devices Database (<http://safermedicaldevices.org/>) or Global Green and Healthy Hospitals (<https://www.greenhospitals.net/>).

The next step in pre-bidding for a successful acquisition of innovative equipment is to determine the type of technology considered appropriate for the medical organization's mission and future objectives, before analyzing how to obtain it and assessing the costs required to implement the proposed investment project and estimate the financial impact. The strategic perspectives of this determination must identify the correspondence between the evaluated technical solution and the medical practices of the hospital, the difficulties of commissioning and operation of the new technology, but also the eloquent advantages of the health unit and the target public by delivering those healthcare services.

In order to achieve this desideratum and for the selection of the most sustainable medical technology, I consider that the specialists from the evaluation group must analyze a series of non-cost factors of the future possible acquisition, according to Figure no. 2, with an impact on the mission and profile of the hospital, taking into account aspects related to quality, safety, interoperability, maintainability, patient satisfaction (always located in the center of the evaluation system), clinical acceptability and environmental conditions.

⁴ “*Captivity is a notion of marketing and is the phenomenon of a contracting authority's long-term dependence on a particular supplier or distributor*” – Consiliul Concurenței, STUDIUL PRIVIND EFECTUL DE CAPTIVITATE (LOCK-IN) ÎN SECTOARELE SENSIBILE ÎN DOMENIUL ACHIZIȚIILOR PUBLICE, IT ȘI ECHIPAMENTE / APARATURĂ MEDICALĂ, București, 2019, pp. 12-16, 35-43.

⁵ <https://ec.europa.eu/tools/eudamed/#/screen/home>, accessed on 11.12.2020

⁶ Arianna Gamba, Dorota Napierska and Maja Milkowska, *Guidelines for the procurement of safer medical devices*, Healthcare Without Harm Europe, Brussels, Belgium, 2020.

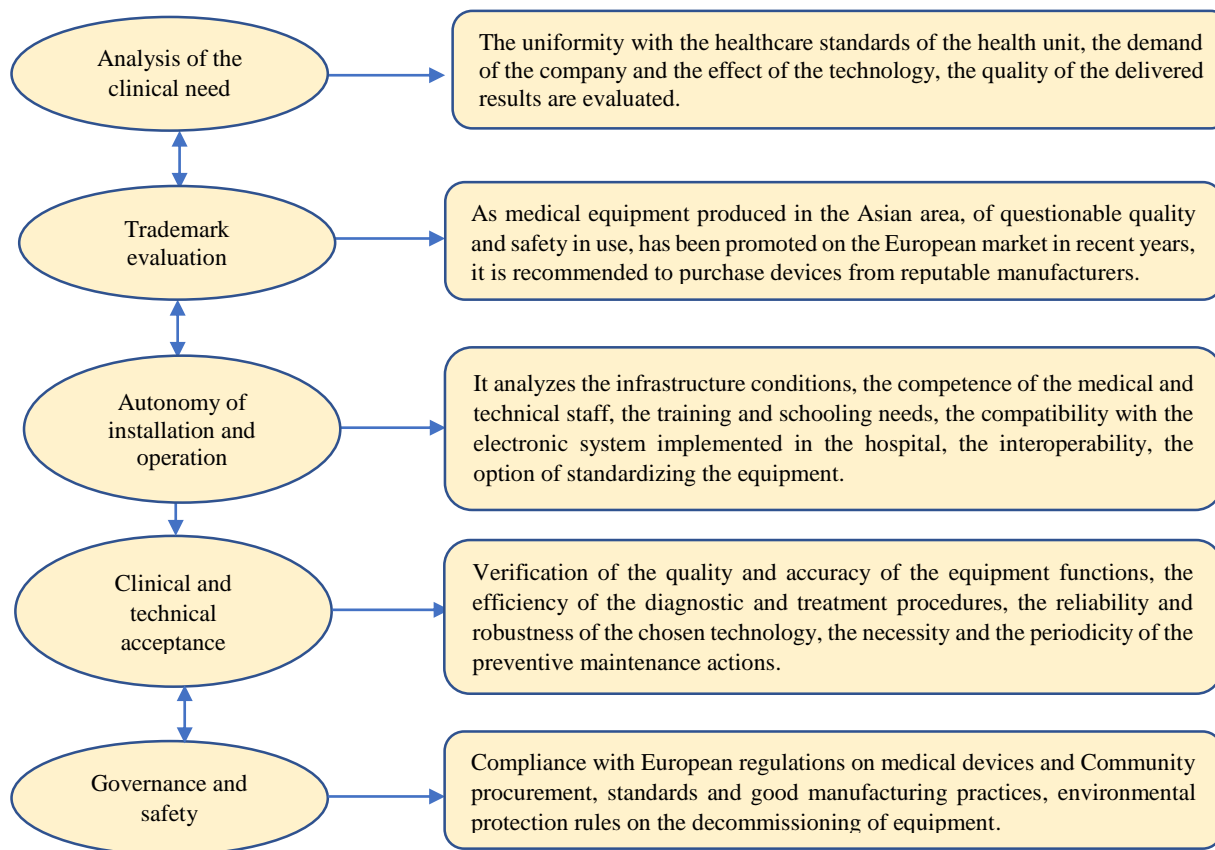


Figure no. 2 - List of factors evaluated in the pre-bidding phase of medical equipment

After assessing the non-cost factors and restricting the selection of medical equipment appropriate to the mission and objectives of the medical organization, the multidisciplinary team initiates the procedure of financial analysis of potential acquisitions to determine the feasibility of the proposed investment and long-term financial implications, based on collected data about the fixed and variable life cycle costs of the capital asset, added revenue or budget losses incurred by introducing new clinical procedures⁷ (estimated the number of newly attracted patients, those who will go to other hospitals, but also the number of procedures and investigations to be performed with the new technology). The evaluation ends with the determination of the overall profitability ratio (the percentage of net gains or losses, with reference to a certain time interval and related to the average profitability indicator in the European Union of 10.6⁸), in order to project the amortization period.

In order to outline an integral financial evolution, I can state on the basis of personal experience in the field of material and financial resources management that health units usually take into account 80% of the total cost of ownership as recurring costs (a lifetime average is 10 years), represented by costs and fees of accreditation, authorization and operation, operating and maintenance costs (usually planned for an annual full service maintenance contract as 10% of the initial purchase price), training costs and technical assistance, decommissioning and

⁷ *Procurement of medical equipment for the 21st century*, <https://www.ebme.co.uk/articles/management/procurement-of-medical-equipment-for-the-21st-century>, accessed on 11.12.2020.

⁸ European Commission, Directorate General for Regional and Urban Policy, *Guide to Cost-Benefit Analysis of Investment Projects*, Brussels, 2015, pp. 116-122.

decommissioning costs (in the case of complex radiology and medical imaging equipment, up to 6-8% of the initial purchase price).

A final aspect to be considered before initiating the procurement procedure is the use of the medical equipment fleet standardization tool, as the most advantageous economic model in terms of life cycle costs (ensuring interoperability, negotiating prices with suppliers or manufacturers). for consumables or service contracts, reduction of staff training costs, already familiar with medical technology), but *the conflict between standardization and innovation*⁹ must be managed in a balanced way, through the flexibility of the procurement process and the periodic revision of standard models, in case of large scale fleet replacements or to the existence on the market of models with an important advance in technology.

All this data, clinical, technical, economic and social information, used as analysis and evaluation tools for the selection of the most valuable and innovative medical equipment available in the medical market and support elements for formulating realistic purchasing strategies, adapted and appropriate to the requirements, capacity and resources of the medical organization, requires time for collection and permanent consultation with the medical industry and other health units in the national or departmental health network.

The selection and definition of priorities, in the context of efficient allocation of resources, is based on management programs or standard replacement procedures developed at the level of each health unit, in relation to the mission and objectives of the institution, after assessing inventory status, technology level, costs lifecycle support and operating conditions¹⁰.

Design of technical specifications and selection of evaluation factors

Once the capacity and size of the pre-tender medical market are known, multidisciplinary hospital teams can also obtain, before the development of the final technical specifications, through *the market consultation*¹¹ tool provided by the new EU regulations, other valuable technical and cost information, both in order to strengthen the requirements of the contracting authority and to promote transparency and equal treatment.

The development of specifications, with the aim of acquiring the value of the purchased equipment, must aim at maintaining the balance between intelligibility and flexibility, by combining the arguments of clinical efficiency (safety and efficacy) and economic profitability (life cycle costs and revenues), along with innovation and social and ethical relevance, thus focusing rather on the results obtained, not just on the description and satisfaction of minimum technical requirements.

The technical specifications (TS) can be drafted according to two globally recognized models, according to Figure no. 3, but in both cases, they must contain at least the following requirements: details of the purpose and destination of the equipment; required reference documents; minimum technical and performance requirements; terms of service and warranty; conditions of delivery, installation, commissioning and training; additional durability requirements (such as – personal protection, quality, reliability, ergonomics, interchangeability)¹².

⁹ Keith Wilson, Keith Ison, Slavik Tabakov, *Medical Equipment Management*, CRC Press – Taylor&Francis Group, LLC, USA, 2014, pp. 115-123.

¹⁰ K. Bastidas, O. Bermdez, F.M. Obando, *Process of Acquisition and Renovation of Biomedical Technology*, Revista Ingeria Biomedica, vol 11, 2017, pp. 79-83.

¹¹ Directiva 2014/24/UE a Parlamentului European și a Consiliului din 26 februarie 2014 privind achizițiile publice și de abrogare a Directivei 2004/18/CE, p. 120.

¹² World Health Organization, User Guide, *WHO Technical Specification for Medical Devices*, Geneva, 2014.

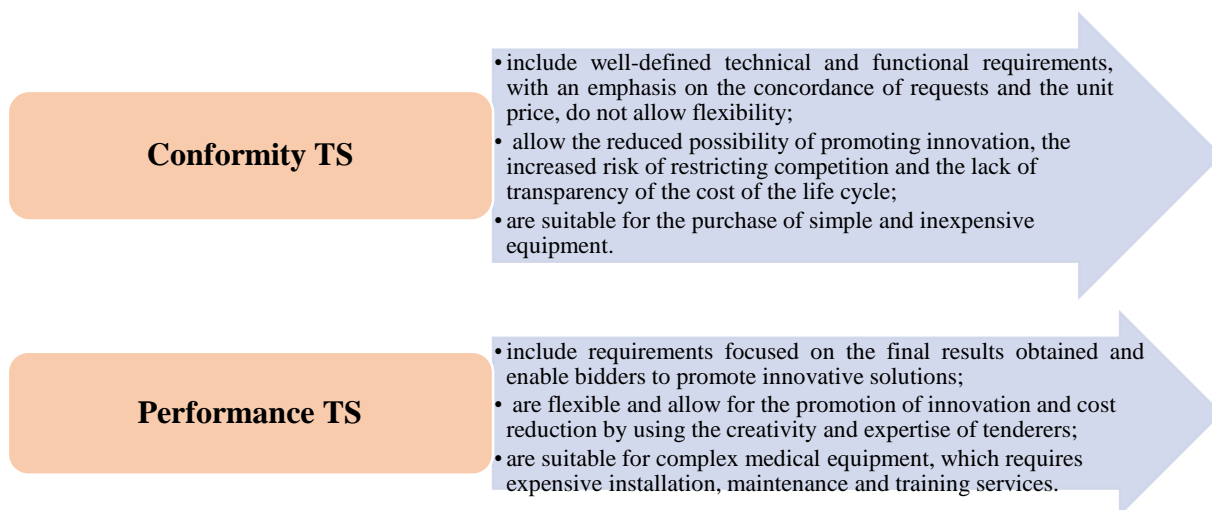


Figure no. 3 - Types of technical specifications

Certainly, in the case of the purchase of medical equipment, the inflexibility of TS compliance and their adequacy with the criterion of awarding *the lowest price*, is not an optimal solution for the visibility of costs associated with the entire life cycle, in contrast to performance TS, which combines innovation with the technical indicators of quality and the costs necessary to support the whole life, the unit price representing only a part of the procedure, in order to implement the most efficient investment solution.

In order to comply with the European legislative framework, in order to obtain *the best value for money*, healthcare units award contracts for the supply of medical equipment on the principle of *the most economically advantageous tender*¹³, using different approaches that include combined economic elements of price, cost and quality.

To promote value and innovation, I recommend the evaluation of combined price/cost factors with non-cost factors, in order to highlight the integrity of the life cycle and analyze all aspects of medical technology, such as: operating cost over the useful life, evaluation quality as a degree of exceeding the requirements, risk reduction criteria, ways to separate solutions that bring favorable cost-effectiveness ratios, as well as sustainability criteria that emphasize economic, environmental and social benefits, adaptable to the evolution of the life cycle of equipment, in the context of rapid technological progress in the healthcare industry.

In addition, there may be other non-cost factors that are part of the evaluation system: integration with electronic medical systems implemented at the hospital level, consumable delivery capacities and availability of service, as well as the level of similar experience.

At the same time, in the case of complex medical equipment (laboratory equipment, anesthesia systems, radiology facilities, computed tomography and magnetic resonance imaging), which requires complex commissioning procedures, repeated training sessions and specialized maintenance contracts, the relative weights of evaluation factors associated with the cost component should not exceed 50% of the value for money system. A balanced approach to evaluation should apply a calculation algorithm based on the following maximum weight distribution:

- Price or cost component (fixed price or life cycle cost) – 50%;
- Quality component (technical and functional characteristics, accessibility, social and environmental conditions, design vision, innovative conditions) – 20%.
- Services component (contract management, associated risks, staff skills or experience) – 30%.

¹³ *Legea nr. 98/2016 privind achizițiile publice*, Monitorul Oficial nr. 390 / 23 mai 2016, București, 2016, pp. 61-63.

Regarding the distribution of relative weights in the case of awarding using *the best value for money* criterion, I present a personal approach applied in the case of purchasing sterilization equipment, where the cost component was assessed through the consumption of consumables used during the cycle and the quality component, through the commercial warranty period, as follows:

- Total cost of a sterilization cycle - 35%;
- Unit price of the equipment - 35%;
- Technical performances - 20%;
- Warranty granted to the product - 10%.

When the healthcare unit uses factors associated with marketing and delivery conditions, special attention should be paid to the weight of *the warranty factor*, as this becomes irrelevant when purchasing high-tech medical equipment, which is usually available on the market in a *closed system*, and the consumables used for operation and the spare parts and accessories necessary for maintenance and repair are made only by the manufacturer of the delivered equipment (OEM - Original Equipment Manufacturer).

The practice of the last years in Romanian hospitals to emphasize the extension of the warranty period beyond the 2 standard years offered by the manufacturer¹⁴ (most often, this requirement is offered by a simple declaration of the supplier, unverifiable at the manufacturer), the terms (unless this factor is reflected in an economic or clinical advantage), time limits for intervention in the event of equipment failure (usually the shortest time is offered, without real proof) and certain technical characteristics that do not lead to better clinical results or increase in value, should be replaced by additional consideration and scoring of the *equipment performance*, given that the lifespan of complex technologies is relatively extended, *the costs of consumables and spare parts in the post-warranty period or annual maintenance contracts*, thus representing an assessment based on the cost of the cycle life and awarding the most economically advantageous tender.

To promote the sustainability of medical equipment procurement, it is recommended that hospitals use environmental impact assessments that can address areas of interest, such as energy consumption, water or gas consumption, the nature of cleaning chemicals, sterilization and disinfection, as well as the method of decommissioning and disposal at the end of the life cycle. In this sense, we present some suggestions of ecological evaluation factors and the maximum weights that could be allocated to them, for the most relevant categories of equipment:

- Daily electricity consumption for a radiology device, according to an examination plan provided by the hospital (maximum score for the lowest consumption) – 20%;
- Water consumption necessary to carry out a treatment act for a hemodialysis installation – 10%;
- Gas consumption required for an intervention (scenario prepared by the health unit) for an anesthesia system – 5%;
- Management of the decommissioning process, following decommissioning, dismantling, packaging, storage/transport of components or hazardous waste (radiology equipment, laboratory analyzers, anesthesia systems, sterilization equipment) – 5%.

The smart growth in the value of medical equipment purchases can be further promoted by including conditions with an impact on social characteristics, which are consistent with the purpose of the procurement procedure, such as the employment of certain categories of disadvantaged people or the recruitment of a number of people with disabilities, in order to implement the contract or evaluation factors of the nature of social responsibility, such as the contribution to the improvement of the community in the field of health, as a contract value dedicated to social investments (a weight of 5-10%).

¹⁴ <http://anap.gov.ro/web/biblioteca-de-spete/>, accessed on 17.12.2020.

In the case of the use of such calculation algorithms or scoring systems, for the sake of clarity and good understanding, the technical requirements referred to in certain evaluation factors in the breakdown criterion should be explained in a narrative section of the specification, specifying the elements that will be appreciated and the methods of confirmation (documents, reports, certificates, studies, protocols, etc.)¹⁵.

Thus, the relative weights of the evaluation factors must respect the value-based procurement policy, and the health units in the Ministry of National Defense's own network should avoid purchasing medical equipment based on *the lowest price* criterion and develop competitive dialogue procedures and solutions competition, to better understand the market potential and match the clinical needs and mission of the hospital with the availability of the healthcare industry, in order to streamline procurement and promote the value and innovation of medical technology.

Contract management

For the successful implementation of investment projects, consisting in the delivery, installation and commissioning of medical equipment, the quality and performance parameters offered, within the established contractual term and at the assigned price, as well as ensuring adequate clinical and technical training, Clinical Engineering in hospitals manages the development of contracts through actions of *planning, execution, monitoring and systematic evaluation*¹⁶. The development of TSs based on the value and innovation of medical technology must be accompanied by robust contractual clauses to verify requirements, manage malfunctions and resolve them transparently and equitably, but also apply sanctions in case of non-compliance with legal commitments.

The development of reception plans, including the balanced distribution of actions, resources and time, roles and responsibilities, requires proactive management and, subsequently, continuous monitoring of performance and progress from the time of delivery to the end use of medical equipment, as well as a rational control of the necessary allocated costs, elements that can be managed using the Gantt chart¹⁷.

The whole multidisciplinary team must work together to analyze the risks of contract implementation, potential emerging difficulties and optimize supply process operations and installation logistics, covering issues related to installation site preparation, such as: maximum allowable load, connecting to existing utility networks, shielding workspaces, interoperability with other categories of equipment in the integrated medical information system at the hospital level, as well as obtaining legal compliance documents for the use of the purchased technology.

Thus, value for money can best be leveraged from contract monitoring by developing management plans, drawing clear responsibilities, key information and precise delivery and installation deadlines, financial benchmarks about costs and payments, and explicit registration requirements of actions and resources records.

Conclusions

Purchases of medical equipment assigned by evaluating factors other than the lowest price, minimum technical characteristics or delivery time, are the pillar of sustainability, quality and accessibility of the health system, by increasing the value and efficiency of healthcare services delivered to the general public.

This extensive process of obtaining value and innovation is initiated from the pre-bidding phase, started 2-3 years before the actual procurement procedure, by correctly

¹⁵ Hotărâre nr. 395/2016 din 2 iunie 2016 pentru aprobarea *Normelor metodologice de aplicare a prevederilor referitoare la atribuirea contractului de achiziție publică/acordului-cadru din Legea nr. 98/2016 privind achizițiile publice*, publicată în Monitorul Oficial nr. 423 din 16 iunie 2016, Guvernul României, București, 2016, pp. 22-25.

¹⁶ The World Bank, *Procurement Guidance, Medical Diagnostic Imaging (MDI) Equipment – Understanding how to procure Medical Diagnostic Imaging equipment*, Washington, 2019, p. 100.

¹⁷ GE Healthcare, *Project Implementation Guide for CT, PET/CT, X-Ray, and Nuclear Systems*, USA, 2017, pp. 26-27.

informing on the current technological level of availability in the industry, data collection about the quality, performance, risks and costs of the life cycle, in order to adapt the requirements of the medical organization, its mission and objectives to the potential of the medical market and to write the most flexible technical specifications, with an emphasis on increasing efficiency and improving results.

Multidisciplinary process evaluation teams should identify options for awarding procurement of medical technology to pursue the cost-effectiveness of the solution adopted, not to purchase medical equipment as a simple product, using evaluation criteria and factors that combine clinical and performing factors with cost of supporting technologies throughout the life cycle. In addition to the standard elements for assessing quality and performance, risks and costs, this range of options may include assessment factors of an ecological nature (energy efficiency requirements and efficient use of water or gas), commercial (warranty, delivery time, after-sales services) or social (encouraging employment opportunities for disadvantaged or disabled people), but in any quality-price breakdown algorithm, with an emphasis on the value and innovation of complex medical technology, the cost component would have not to exceed 50% of the allotted weight.

The concept of such acquisitions aims to deliver to patients the most effective methods of treatment, increase the degree of clinical addressability, maximize the value of health care services and reduce the total cost of ownership associated with medical equipment, a financial pressure instrument on our hospital budgets.

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