

Project Management for Clinical Engineering – Considerations in the evaluation and acquisition of medical equipment for health services in Brazil

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Abstract— The public health system in Brazil must provide the population, comprehensive care and with wide availability of resources. However, the actual conditions demonstrate that available resources are not sufficient to give full attention to required health. With regard to medical devices, it is observed that its acquisition is often done without adhesion to technical criteria aiming to support the technology throughout its life cycle. The project management processes enables the clinical engineer to join the assessment team of technology to be acquired proactively analyzing the acquisition of medical equipment throughout its life cycle. The research presented involved the search for articles that deal with the project management in state of the art applied to the evaluation of medical devices focused on the incorporation of these technologies in the health care environment, addressing an adapted model of the project management processes proposed by the Project Management Institute to the activities of clinical engineer.

Keywords— project management, clinical engineering, technology assessment, medical equipment.

I. INTRODUCTION

In Brazil, the public health system, must be, by law, moved by the principles of universality, fairness and integrity. In other words, the Brazilian public health system should have a wide coverage of pathologies, affordable and equally to the entire population. In this regard, in a country where health needs are measured in continental dimensions, as the resources to treat them are strictly limited should be mandatory to think that the demand for health services is far beyond the resources available to achieve their goals. With this, the country is faced with problems such as the destocking of hospitals, obsolete equipment in use, equipment out of operation, lack of services rendered to the population compared to the huge existing technological advancement.

Increasing innovation and technological dependence on health systems have led to a continuous growth of expenses on health and has pressed managers to adopt evaluation processes more systematic and rational for incorporating technology [1]. The acquisition and incorporation of healthcare technologies is a complex activity because it involves the creation of multidisciplinary teams in order to

achieve a common goal. For the clinical engineer criteria such as increased availability and increased equipment life, ability to customize and upgrade technology must be glimpsed during the technology development project phase.

Medical equipment are devices that require calibration, maintenance, repair, user training, infrastructure, accessories, supplies, proper storage, waste management and, in addition, proper disposal when they are out of operation [1, 2]. These activities should usually be managed by a clinical engineer. Purchasing medical equipment and making them available for use without prior planning materialized in a sustainability plan would thus subject them to the possibility of early deterioration, malfunction or improper operation and even expansion of cargo risks inherent in the use of this equipment.

Thus, acquire and incorporate medical technology in health care, involve drawing up a medical equipment sustainability plan, which, in turn, can be constructed as the product of a project prepared using the most appropriate methodology for each case. Project can be thus defined as a temporary endeavor undertaken to create a product, service or single result, with the use of limited organizational resources [3, 4, 5]. When the clinical engineer, makes use of the tools and the project management processes, expands the possibilities of generating the required focus to that cope with the challenges of new tasks often required during the process of incorporating technologies [6], before an activity complex than that is to incorporate medical equipment to health services.

II. MATERIALS AND METHODS

A. Research stages

The study was divided into two phases. The first phase of the research will include a review of articles written for the purpose of verifying the state of the art project management applied to clinical engineering, specifically in the evaluation of medical equipment for its incorporation to health services. The second phase involves the analysis of adaptation of project management methodology proposed by the Project Management Institute (PMI) for the processes and procedures of analysis and incorporation of medical technologies in health care facilities.

B. Search strategy

Search for articles that deal with the subject, was carried out on the basis of periodic data of Higher Education Personnel Training Coordination (CAPES), which refers to a collection of over 36 thousand full text, references 130 bases, 12 bases dedicated exclusively to patents, as well as books, encyclopedias and reference works, technical standards, statistics and audiovisual content [7]. With regard to Biomedical Engineering, the search for articles was performed in 25 different journals such as IEEE Xplore, ACS Journals Search, ScienceDirect.

The terms used for peer reviewed research articles were "project management", "clinical engineering", "technology assessment" and "medical equipment". Quantitatively, the results obtained after the search, including the crossing of the terms, are listed in Table 1.

Table 1 Terms searched and results obtained

Terms searched	Results obtained
Project management	12.367
Clinical engineering	385
Technology assessment	10.819
Medical equipment	17.165
Project management & clinical engineering	4
Technology assessment & clinical engineering	19
Medical equipment & clinical engineering	25
Project management & technology assessment	18
Project management & medical equipment	11
Technology assessment & medical equipment	68

As noted, were located only 4 articles dealing with the theme clinical engineering & project management, and after analysis, it was found that none of them referred to technology assessment or medical equipment, a fact that led to their exclusion from this study. Similarly, when crossing "technology assessment" and "clinical engineering" between 19 obtained articles, no articles were found related to project management. The large number of items individually deals with "clinical engineering," "project management," "technology assessment" and "medical equipment" was not enough when these terms were associated to the acquisition of reference articles.

III. RESULTS

As noted, the search for relevant articles dealing with project management in clinical engineering with a focus on evaluation of medical equipment was not productive. This fact requires attention and can be seen as an underdeveloped area, or as an opportunity for project managers turn their attention to this field of work.

Develop studies to assess the incorporation of medical equipment involves the evaluation of comprehensive needs, including the potential impact on the performance of users of medical equipment, and the provision of services within the health system resources beyond the provision of priorities services. This assessment takes into account the overall objectives of the health institution, its existing facilities and infrastructure and, similarly, the changing needs. Also considers the long-term strategic planning and the proper management of human resources including its development long before setting off to buy medical equipment [8].

The challenge is to reconcile these actions with the project management processes distributed among the project management knowledge areas involving the management of integration, scope, time, cost, quality, human resources management, communications, risk, procurement and stakeholders. The implementation of the project life cycle consists of the stages of initiation, planning, execution, monitoring and control and closure, should be thought to be accommodated in other activities of the clinical engineer within the healthcare organization. This is due to the fact that during the planning period and execution of the project, the clinical engineer often remains involved with other activities related to their expertise with the health service.

The project management processes [3] listed in Table 2 should be performed taking into consideration all existing organizational environment, culture and style, communication processes, organizational process assets and strategic maturity. The tools and techniques to be used in project management processes must be adapted to the reality of the institution since the health services in Brazil are in different situations, considering the continental dimensions of Brazil.

Table 2 Actions to be developed by the clinical engineer

# Process	Process	Actions to be developed by the clinical engineer
01	Develop project charter	The clinical engineer is replaced aware of his participation in the project team
02	Identify stakeholders	Identifies potential users of the health system, managers and equipment operators
03	Develop project management plan	Plan how to coordinate all subsidiary plans in an integrated manner

# Process	Process	Actions to be developed by the clinical engineer
04	Plan scope management	Managing the scope and define how the scope will be defined, validated and managed
05	Collect requirements	Collection of the needs and demands of users and employees of the health service
06	Define scope	Defines the scope based on technological solutions available on the market
07	Create WBS	Create WBS subdividing the work to be performed to the achievement of the objectives of the project
08	Plan schedule management	It documents how will run the project schedule
09	Define activities	Define the project activities, the work contained in the WBS package
10	Sequence activities	Documents the relationship between the project activities
11	Estimate activity resources	Qualitative and quantitative estimate of the resources needed to carry out the project activities
12	Estimate activity durations	Estimates the time required to execute the project activities
13	Develop schedule	Create the project schedule model taking into account all the resource constraints imposed on the project
14	Plan cost management	Plan expenditure management and control of project costs
15	Estimate costs	Analysis of the cost of ownership of identified technological solutions considering the acquisition value, inputs, guarantees, insurance and maintenance
16	Determine budget	Aggregates the individual costs of the work packages. Provides the clinical engineer the ability to analyze the total cost of ownership of the identified technology solutions
17	Plan quality management	Identifies the project requirements and quality standards and deliveries and also documents how will be demonstrated compliance with the requirements. Short description, need and enough of the technology to be aligned to the health service needs, including the assessment of the adequacy of the needs of the health service environment to accommodate the equipment serving the legal and regulatory requisites
18	Plan human resource management	Needs assessment of human resources needed to support technology involving their roles, responsibilities, required skills
19	Plan communications management	Planning a correct approach to communication, considering the characteristics of each identified stakeholder
20	Plan risk management	Defines how project risk management activities will be conducted
21	Identify risks	Identification of the main risks involved in the acquisition of the equipment in question, as well as the risks of the technology to be not promote the expected results
22	Perform qualitative risk analysis	Identify risks from a qualitative aspect
23	Perform quantitative risk analysis	Identifies the probabilities of occurrence of identified risks
24	Plan risk responses	Plan the actions and responses to case any of the generating events of the risks identified
25	Plan procurement management	Plans acquisitions necessary to undertake the introduction of technology
26	Plan stakeholder management	Plan how you will manage the relationship with stakeholders
27	Direct and manage project work	The clinical engineer to lead and participate in the completion of the work defined in the project management plan
28	Perform quality assurance	Measures and compares the quality required and achieved in order to verify adherence to established standards
29	Acquire project team	Mobilizes the team during the design phase. During execution allocates resources to perform their activities throughout the project
30	Develop project team	Facilitates the integration of the project team
31	Manage project team	Monitors the performance of the project team, participating proactively in conflict management
32	Manage communications	Collects and distributes the fashion design information as planned
33	Conduct procurements	Obtaining response process of potential suppliers, selection and implementation of acquisition
34	Manage stakeholder	Maintain active communication with stakeholders to meet their demands

# Process	Process	Actions to be developed by the clinical engineer
	engagement	
35	Monitor and control project work	Considers the project as a whole, and observe the progress of the work and the degree of adherence to what was previously planned
36	Perform integrated project control	Analyzes and reviews all requests for changes evident during the execution of the project, considering the impact of changes on the timetable and project costs
37	Validate scope	Process which uses the clinical engineer to control the execution and delivery of the packages listed in the WBS
38	Control scope	Process used to monitor the implementation of what was planned for the baseline of the project scope
39	Control schedule	Monitors the progress of project activities and their adherence to the initial planning
40	Control costs	Monitors the progress of the project as regards the implementation of its initial budget
41	Control quality	Monitors and records the results achieved with the implementation of the project
42	Control communications	Monitors and controls communications during the project life cycle
43	Control risks	Implements the plans of risk responses, accompanies the identified risks, monitoring residual risks and also evaluates the effectiveness of the risk management process
44	Control procurements	Monitor the relations of acquisitions and performance of contracts
45	Control stakeholder engagement	Monitor the relationship between stakeholders and the project
46	Close project or phase	Process that formalizes the close of the project, involving the receipt and accepted by the applicant
47	Close procurements	Closing of the acquisition with the issuance of the contract termination term

IV. CONCLUSIONS

The challenge of reconciling the implementation of the project management processes along with the evaluation activities and procurement of medical equipment is rewarded by the benefits to clinical engineer to participate in the steps of this procedure provided with appropriate tools to achieve their goals. The use of project management tools extends the opportunity to exercise greater control over the limited available resources, whether material, financial and human.

Thus, the clinical engineer expands its vision to all stages of medical equipment life cycle, enabling it to plan the acquisition of equipment bringing incorporated all the requirements to provide this technology the highest possible availability, full use of the equipment in its lifetime and reducing the time out of service, due to the lack of planning.

The effects of this increased availability reflect on the increase of quality of services rendered to the population whereas in the issue of medical equipment, these are now managed in full.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

REFERENCES

1. Assis C, Santos F (2014) Ferramenta metodológica para elaboração de estudos de avaliação para equipamentos médico-assistenciais. In A. Andrade, A. Soares, A. Cardoso, & E. Lamounier (Eds.), *Tecnologias, técnicas e tendências em Engenharia Biomédica* (1st ed., p. 416). Bauru: Canal6 Editora
2. *Health technology assessment of medical devices* (2011) Geneva, Switzerland: World Health Organization
3. *A guide to the Project Management Body of Knowledge (PMBOK guide)*, 5th ed. (2013) Pennsylvania: Project Management Institute.
4. Shirley D (2011) *Project management for healthcare*. Boca Raton: CRC Press
5. Coplan S, Masuda D (2011) *Project management for healthcare information technology*. New York: McGraw-Hill
6. Babler, S (2010) *Pharmaceutical and biomedical project management in a changing global environment*. Hoboken, NJ: Wiley
7. CAPES at www.periodicos.capes.gov.br
8. *Needs assessment for medical devices* (2013) Geneva, Switzerland: World Health Organization

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