

Life Cycle Information for the Analysis of the status of a Medical Technology: applying an Integrative Approach*

Información de ciclo de vida para el análisis de la situación de una tecnología médica: aplicando un enfoque integrativa

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ABSTRACT

This paper describes a new definition of the life cycle concept to assess the status of a medical technology. This approach integrates concepts from several sources that study this problem. The model takes into consideration factors related to intensity of use, maintenance, personnel, its social impact and the economics involved, as well as the interrelationships from these factors. The life cycle is divided in diffusion, use and conservation, and final disposal phases. The conditions under which the model of medical technology life cycle can operate are determined. The information obtained for X-Ray and Tomography equipments from this concept lead to prioritize the actions to be taken in order to solve the problems arisen.

Key words: Medical Technology, life cycle, technology management, assessment

RESUMEN

En este trabajo el concepto de ciclo de vida se concibe para evaluar el estado de una tecnología médica y con un enfoque que integra posturas de varias fuentes. El modelo tiene en cuenta factores relacionados con intensidad de uso, mantenimiento, personal, su impacto social y los aspectos económicos involucrados, así como las interrelaciones de estos factores. El ciclo de vida se divide en la difusión, uso y conservación, y las fases de disposición final. Son determinadas las condiciones en las que el modelo de ciclo de vida de la tecnología médica puede operar. La información es obtenida de X-Ray y Equipos de tomografía llevando a priorizar las acciones que deben tomarse para resolver los problemas planteados.

Palabras clave: Tecnología Médica, ciclo de vida, gestión de la tecnología, la evaluación.

1. Introduction

THE term “medical technology” incorporates equipment, devices, programs and systems that, together with drugs and other hospital accessories are indispensable for the prevention, monitoring and treatment of diseases [1]. The extinct U.S. Office for Technology Assessment defines medical technology as the set of medical

supplies, medical and surgical devices use on the healthcare, as well as support and coordinate systems inside of which healthcare is delivered [2]. For the World Health organization this term is related to any instrument, device, tool, reagent or system that is used to prevent, diagnose, monitor and treat a disease, as well as to replace a physiological function in the human body [3].

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Medical technology can also be defined from the integration of different perspectives: a physical point of view that includes devices, systems, equipment and drugs; a knowledge-based perspective that incorporates clinical and surgical procedures as well as the management of processes and strategies that are particular to the health care system; the point of view of information gathering, storage, classification, analysis and recovery, organization modeling, quality systems and other performance measures; and finally the point of view that sees technology as an agent of change that influences processes, system structure workflow in clinical services and even cultural issues. Following this line of reasoning, medical technology can be defined as “any resource that facilitates or enables a health professional to fulfill his job and to reach the goals set by the profession” [4].

One of the most important aspects related to the concept of health technology is the behavior of this technology over time. At present, several countries and organizations have interpreted this aspect differently.

The world health organization proposes a definition of life cycle of technology that includes the concept and development of an idea, manufacturing, packaging and labeling of the product in question. It also includes publicity for the commercialization stage, its use in the hospital setting and its final disposal [3].

In Mexico, the phases of medical technology life cycle start with innovation, development, application, dissemination and disposal. The last three phases are evaluated within the medical facilities [5].

In Colombia the Social Protection Ministry has defined a life cycle definition that includes two general phases: pre and post-commercialization. The first includes the conception, development, fabrication, importation and registration of the technology, while the latter phase includes planning, selection, acquisition, installation, clinical use, maintenance and final disposal [6].

The Institute of Clinical Effectiveness in Argentina proposes a life cycle model that is similar to the others, where the initial phases are research and publicity, while the final phases that are carried out within the hospital facilities are acceptance, use and obsolescence [7].

As it can be seen, the research, development and experimentation phases exist in almost all definitions and refer to the development and application of an idea to a specific problem to satisfy a preexisting need in the health care sector. During these phases, the technologies are validated and evaluated before they are introduced into the hospital setting. Researchers, developers and constructors are involved in order to guarantee the safety and effectiveness of the new systems under development. The final product at this point is a prototype that has been validated and that should be evaluated under several conditions before it can be considered as a possible candidate for introduction as an

alternative technological solution for a specific set of needs in the medical sector. The remaining stages, which are generally implementation, acceptance, use and final disposal take place within the clinical setting; this implies that the previous stages were successfully accomplished and approval was obtained.

The previously mentioned definitions establish phases conforming a life cycle as well as the type of evaluations to perform on the technology. Control is still centered on preventive and corrective maintenance as well as to the assurance of a dependable supply of consumables. Other types of studies are taken into consideration, such as economic and technical analyses that are carried out before a new technology is acquired or introduced into a hospital. However, other relevant aspects are overlooked. Productive capacity, functionality, safety, risk and clinical and social impact that are associated to the use of medical technology over time are other factors that contribute importantly to analyze the real behavior of medical equipment in the clinical environment.

Some of the questions that arise regarding the analysis and control of medical technology are related to the phase in the equipment's life cycle under which it is operating: Is there enough evidence to determine at which point in time it is convenient or even necessary to replace the technology? For how long the appropriate use of the technology can be guaranteed? Are the technological resources being used optimally according to the health care policies that have been determined for the hospital?

These types of questions require the analysis of various types of information that should be obtained from the experience gathered from the use of the technology in the clinical environment. In other words: evidence should be obtained that is based on the experience.

The aim of this work is to present a novel life cycle concept that is based on the analysis of the technological, economic and clinical components that are present in different definitions of equipment life cycle, as well as to the performance of the technology once it is introduced into the hospital setting. The information obtained from this concept was used to assess two medical technologies in different kinds of hospitals.

2. Methodology

A retrospective study of the definition and the description of the life-cycle phases of medical technology have been carried out. It incorporates information from different government and non-governmental organizations. Different technical, economic and clinical factors that intervene in each phase have been analyzed.

In order to characterize and define the life cycle phases of technology once it enters the hospital, the following factors involving the technology were deemed necessary for further analysis:

- Intensity of use

- Personnel involved in the use of the technology
- Financial resources invested
- Maintenance requirements
- Social Impact

For each phase in the life cycle the degree of interaction among the aforementioned factors was analyzed individually and in pairs.

3. Results

Based on the study of the life cycle concept, a definition was proposed that is oriented towards describing the behavior of medical technology once it enters a medical institution. Considering that the technology is incorporated progressively into the hospital, it reaches an optimal utilization or maximum point of use in the hospital and at a moment in time its use is discontinued in order to make way for the substitution, the description of the life cycle consists of three phases: Dissemination, Use and conservation, and Final disposal. Figure 1 presents the life cycle phases of medical technology as a function of intensity of use within the hospital.

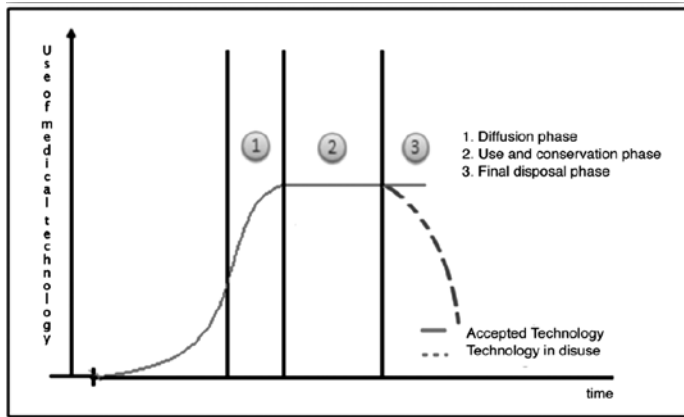


Figure 1. Phases of the life cycle as a function of intensity of use

Fuente: Table modified by the authors from Banta & Luce

Several relational matrices were constructed to analyze the factors of intensity of use, maintenance, costs and social impact for each phase of the proposed life cycle. Table 1 shows the interrelationships among factors for the dissemination phase, while table 2 presents the results for the use and conservation phases, and table 3 shows those of the final disposal phase.

A minimum value of zero was assigned to those factors with a null correlation, while 1 corresponded to a low intensity relationship, 2 corresponded to a relationship of medium importance and 3 represented a complete (strong) interrelationship among the factors under consideration.

Table 1. Correlation matrix among factors for the diffusion phase.

Factors	Diffusion phase			
	Intensity	Maint	Costs	Impact
Intensity		1	0	1
Maint	1		1	0
Costs	0	1		0
Impact	1	0	0	

Table 2. Correlation matrix for factors for the use and conservation phase.

Factors	Use and conservation phase.			
	Intensity	Maint.	Costs	Impact
Intensity		3	2	3
Maint	3		3	2
Costs	2	3		2
Impact	3	2	2	

Table 3. Correlation matrix for factors for the final disposal phase.

Factors	Final disposal phase			
	Intensity	Maint	Costs	Impact
Intensity		3	3	3
Maint	2		2	2
Costs	2	3		2
Impact	3	2	3	

Source: Table modified by the authors from Satty Method for Priorities in Hierarchical Structures.

The phases of the proposed life cycle are described as follows

A. Dissemination phase:

In this phase, medical technology is introduced into the hospital environment and starts to be used in some areas or specific clinical services. Aspects such as effectiveness, usefulness and the clinical consequences that the technology produces on the organization are taken into consideration to evaluate its acceptance in the hospital environment. This way the conditions, mechanisms and strategies for the dissemination of the technology are determined.

The personnel that are involved in this phase include the equipment provider, the operators, the administration and the conservation/biomedical engineering department. The provider is in charge of assuring that the medical equipment complies

with the different regulatory aspects in each country; providing adequate training and support for the user on operation and conservation of the system and help in the installation of the technology in the service that will be operating it. Direct and indirect operators of the technology (both physicians and technicians) are responsible for the use of the system and thus should be aware of indications and counter-indications for the use of the technology, as well as the operating procedures that are recommended by the manufacturers. The administration is responsible for the verification of warranty conditions and periods stated in the purchase contract as well as to provide administrative support to all involved during the acquisition and installation of the equipment. Finally, the conservation/biomedical engineering department is responsible for the verification of installation, startup and functioning of the technology as well as for the assurance of adequate maintenance during this and all subsequent phases of the equipment's life cycle.

The intensity of use of the technology during this phase is low, as it is just starting to be used in the clinical setting, and it has not been incorporated yet as a part of the standard operating procedures in all the clinical services that might require its use.

Additionally the expenses and maintenance during this phase are minimal as technology costs, consumables, installations, preventive and corrective maintenance procedures are included in the warranty agreements of the providers.

B. Utilization and conservation phase:

During this phase, the medical technology is incorporated into the general clinical practice and is accepted as part of the standardized procedures at the institution.

Technical and medical personnel requirements are reduced during this phase as full knowledge (within the parameters specified by the equipment provider) about the operation of this technology has been acquired. Biomedical engineering personnel play a fundamental role in the conservation of this technology as the different warranty periods start to expire.

During this phase, operating costs start to increase, as different corrective and preventive maintenance procedures are required. When a good previous analysis has been done, financial requirements and the types of service to provide can be planned in advance in order to guarantee optimal performance of the technology at the institution.

The social impact that the proper use of the technology provides is defined in terms of the number of patients that have been tended to. During this phase constant and intense use of the technology is to be expected and this should have an impact on the quality of health care provided to the general population. As it is not possible to separate this impact from the economic

point of view, this component is evaluated through a cost/benefit, cost/effectiveness, and cost/utility analysis.

C. Final Disposal Phase

During this phase, the technology currently being used or its applications do not fulfill the requirements and clinical objectives for which it had been purchased and employed.

Thus its use is discontinued and the technology is substituted by a more adequate option. The personnel involved in the final disposal phase include the operators, the administration and the technical staff. All of them are involved in the process of discontinuing the use of this obsolete technology and its substitution by an updated system. The social impact of this technology is significantly diminished as the use of the system is reduced until it is replaced completely.

In order to evaluate the accuracy of the concept for obtaining the status of a medical technology, the set of parameters that forms each phase was investigated on several radiological technologies of four different healthcare institutions in Mexico and Colombia; two studio cases are presented.

Case study 1.

This is a private institution of high complexity on the Northeast of Colombia; it has 160 beds and 360 medical equipments distributed on 14 services. The Radiology service manages 5 X ray and 1 CT equipments that attend a demand of 5750 radiological and 525 CT studios according to the 2008 records. These systems are about 15 years old on average and do not have technical support from the supplier nor a maintenance program; only repairs on demand are carried out. Thus, the functionality is suboptimal and the service exhibits a high failure and dead-time indices, the documentation is incomplete and not accessible. Three X ray systems were evaluated and the results show that although their physical conditions are acceptable, the clinical performance is optimal, the results are satisfactory, and the quality criteria and the safety issues are correct (including radiological safety), the problems presented cause the interruption of the service making the productivity deficient. The service has a preventive maintenance program, but there is a lack of documentation of the inactivity of the equipment; it also has a post warranty service contract that is unable to solve the problems in less than 48 hours. The last year's investment costs began to reflect the conditions of early obsolescence, so the X ray technology is located on the first half of the final disposal phase and its replacement must be considered.

Case study 2.

This is a National Specialties Institute belonging to the Mexican Health System with a Radiological service that performs 54750 studios on average, between simple and specialized, and 2999 CT studios according to the 2009 records. It has a Biomedical Engineering Department that manages the preventive and

corrective maintenance programs of the installed equipment; it has an integral service that is devoted to perform the visual inspection, calibration, maintenance and disposal supply of the high complexity technologies including the 7 X ray and the CT equipments. In general the radiological technology is about 12 years old and in good conditions. At present a digital replacement of the conventional X ray and a PACS installation are under consideration. The results of the evaluation were similar to the previous case, thus the technology is located in the final disposal phase. In this case the information obtained from particular parameters of impact and intensity of use can be useful to justify the substitution by a digital technology. For example there is a set of questions regarding the clinical service management situations where a staff absenteeism problem and a deficient design of the patient datasheet were found. Since the evidence began to be documented, reliable planning can be developed in order to obtain the solution that best matches the needs of the service.

4. Discussion

In order to have a clear idea of the situation of the health services with regard to their technological resources, it is necessary to have access to information regarding their performance from different perspectives once it is operating regularly in a hospital. The concept of life cycle allows us to organize this information in different phases that describe the conditions at several points in time. This concept incorporates technical and economic information that is integrated with clinical data in order to provide a clearer vision regarding the performance of different technologies that can complement cost/effectiveness analyses that are used for evaluation purposes.

Some of the requirements that should be taken into consideration in order for the life cycle concept to be valid are related to the evaluation and acquisition/purchasing procedures. Both should be carried out to the client's satisfaction, which means that they should fulfill the initial requirements and should take into account the service and financial agreements correctly. This will provide the knowledge of the starting point or the initial conditions for the economic, technical and clinical factors that will be used to initiate the analyses.

The life cycle concept for medical technology is a proposal that can help analyze different aspects of technology use at different times and can be useful for planning of equipment substitution and resource optimization. At present work is being carried out in order to evaluate the different contributing factors in each phase.

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6. Conclusion

The concept of life cycle allows us to analyze the behavior of medical technology while it provides information that is useful

for decision-making. Within a hospital, the use of the concept of equipment or technology life cycles will reveal the tendencies regarding the performance of these technologies and will allow the development of control systems that are better suited to real-life situations. This definition incorporates different points of view from different types of personnel involved in the procedures regarding the use of medical technology and thus can provide better information for the decision-making processes around medical technology.

The characterization of the defined parameters in each phase of the life-cycle can be used in order to evaluate the performance of technology within a hospital, to identify potential difficulties regarding the use and conservation of said technologies and to provide information that can assist the decision making process when replacement must be carried out. Present work is being performed on a technology management system that will incorporate these concepts.

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