Strategic Medical Equipment Incorporation Process: A Proposed Model to be used by the Lebanese Healthcare Organizations

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Doi: 10.19044/esj.2018.v14n6p140 URL:http://dx.doi.org/10.19044/esj.2018.v14n6p140

Abstract

Background: The Improvement in healthcare as provided by new modern equipment is associated with the rise in healthcare cost. Lebanon's economy and its public healthcare sector might be struggling with a crisis stimulated by the absence of any legal limit for the sophisticated medical equipment number per population density. **Purpose:** to assess the current methodology for health technology incorporation used by the Lebanese hospitals, and to propose an incorporation model guiding them in medical devices acquisition. **Methodology**: combination of quantitative and qualitative approaches were used in addition to a proposed incorporation models with an applied case study on it. Questionnaires were distributed among 34 hospitals, with a response rate of 82.35%, and interviews were conducted with five biomedical managers. **Results:** The study shows that only 7% of mangers know what Health Technology Assessment (HTA) means, and none of these hospitals use HTA reports. Additionally, 71% of hospitals don't monitor their incorporation process and only 4% evaluate the purchased devices' utilization. Based on the qualitative analysis, the lack of proper need assessment, market study, and poor supplier evaluation were the main reasons behind poor incorporation processes. **Conclusion:** We found that hospitals lack a proper incorporation process as evident in their poor methodology, hence recommendations were to follow a formalized process for medical device incorporation. However when it comes to the Ministry of Public

Health, the recommendations were to formalize and apply new laws and regulations for the certificate of needs.

Keywords: Medical Equipment, Incorporation Process, Health Technology Management, Health Technology Assessment, Decision Making

Introduction

In recent years, there has been improvement in healthcare, provided by new medicines, a diversity of modern equipment, new tools to support diagnosis, and others. According to the World Health Organization (WHO): "Medical devices are crucial for the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation" (World Health Organization, 2011, p. 2). As stated by Wang, health technology is a tool that has a core value in providing "High-quality care in a cost-effective way if used by the right person(s) at the right time and in the right manner. Therefore, it is mandatory on the health leaders to manage technology properly so there is a balance between the needs and desired benefits on one hand, and the impacts on the other" (Wang, 2009, p. 5).

In this context, where technologies are evolving with great speed, new priorities in the medical device incorporation process are emerging. Medical equipment must correspond to local clinical needs, as well as be accurate and reliable in the environment for which they are used, in order to generate safety and effectiveness for health care (Margotti, Santos, & Garcia, 2013).

Medical device incorporation as defined by Wang "Is the entire process of absorbing technology into a health system or organization through planning, selection, and acquisition, with emphasis on its dependence on technology policies and continuous feedback from technology management" (Wang, 2009, p. 46). Appropriate incorporation process demands information from decision-makers and requires appropriate planning and management, as well as professionals trained for this purpose. Therefore, tools are needed to make it possible for decision-makers to obtain maximum benefits from the limited resources available, and to do so in a legitimate and transparent manner. Between the most commonly used tools are the Health Technology Assessment (HTA) tools that defined by Wang as a "Systematic approach to evaluate the properties, effects, and impacts of health technologies or interventions" (Wang, 2009, p. 45). Accurate incorporation processes lead to a better quality with lower cost of healthcare services, and improvement in access to healthcare services.

Many assessment reports conducted among healthcare organizations showed that inadequate methodology for medical device incorporations often lead to bad outcomes such as: raise in healthcare cost, abusive use, and frustrated health mangers, users and patients (ECRI, 1997). In addition, many

donated medical devices did not bring the desired health benefits and large amounts of medical devices lay idle due to the lack of a proper incorporation process ("*Medical device donations*", 2011).

Many studies proposed different methodologies for medical device incorporation processes. According to Binseng Wang, in his book *Strategic Health Technology Incorporation*, he proposed a methodology for medical device incorporation process in 2009. Wang, defines the incorporation as a process that encompasses two phases: planning and acquisition (Wang, 2009).

Another methodology was proposed and discussed by the WHO in 2011, under the Global Initiatives on Health Technologies (GIHT) project (World Health Organization, 2011). It is important to note that this methodology focuses on the medical device incorporation phase especially procurement process.

In addition, Santos and Gracia proposed a model for medical device incorporation process to be applied in public health centers in 2012 entitled as "*Planning incorporation of health technology into public health center*". This model was based on three main domains: Health Technology Assessment, Medical Equipment Incorporation and Decision Making (Santos & Gracia, 2012).

Based on the reviews of the literatures, we found that the incorporation process still is not yet covered in some of these aspects such as: the planning and decision making process, the proper engagement of input resources such as HTA reports and the organization's mission, vision and goals, appropriate device evaluation and the main selection criteria and tools. Therefore, we will propose a model that will highlight these limitations, to be used as a comprehensive approach.

Lebanon's economy and its public healthcare sector may be struggling with a crisis due to medical device acquisition, but private hospitals and diagnostic centers are operating well. This medical device crises is caused by the absence of legal procedures that help in limiting the number of needed medical equipment per population density, and the absence of the certificate of needs.

The primary purpose of this research is to analyses the decision making process for medical device incorporation among the Lebanese hospitals, as a key component in health technology management, in order to place an "ideal" methodology, wherein hospitals strive to follow for hospital and public benefits.

A secondary purpose is to examine the device evaluation criteria which hospitals depend on to select new medical devices, and to check if any hospital follows key tools such as health technology assessment tools and other. These purposes were addressed through the following research questions:

1. Do Lebanese healthcare facilities follow a proper incorporation process for medical device acquisitions?
2. On what criteria do Lebanese hospitals select their medical equipment?
3. What are the major causes for poor incorporation processes?

Methods

The methodology used in this study; it includes both the proposed incorporation model and the research design of quantitative and qualitative tools as a practical part that will help us in describing both the quantity and the quality of the current health technology incorporation process among Lebanese healthcare organizations.

Proposed model

The proposed incorporation model is made up of many processes that start with health technology planning and need assessment, and ends up in monitoring, as feedback for the incorporation process. It contains many external and internal input resources. Since many gaps had been identified in the literature, this model will highlight the planning, need assessment, device evaluation and selection criteria. This model is mainly depending on the WHO procurement methodology, however, we modified it to be used in the whole incorporation process (World Health Organization, 2011).

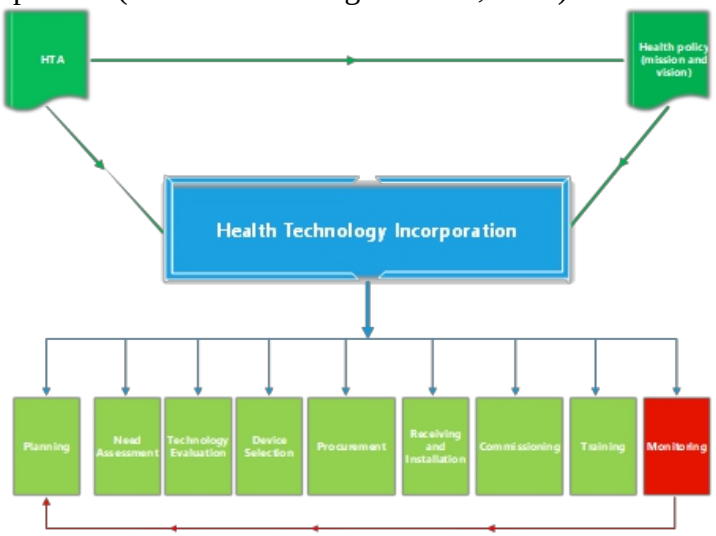

Figure 1: Proposed Health Technology Incorporation Model

As shown in ***Figure 1***, a model depicting the process of health technology incorporation process, particularly medical devices; this model is made up of many processes that have different parameters and criteria. It can applied on national, macro and micro levels, in both public and private

healthcare organizations, especially for expensive assets where resources are limited.

Design

In this study both quantitative and qualitative study was used to collect data that will help for in-depth understanding of hospital performances in the health technology incorporation process, and to have a detailed assessment of every step of this process. In addition a case study was done as an example for a hospital that needs to incorporate an MRI machine by following our proposed model. An official written study approval letter was sent by mail for all hospitals in order to get the approval by their ethical committee to collect data and fill questionnaires and interview with mangers of the biomedical engineer.

Settings

This survey was conducted during June and July 2017 at hospitals in Lebanon. Our target population was Lebanese hospitals, from different six governorates, including both public and private, university and non-university, of all bed capacity.

Participant

A non-random sampling method was used to select our sample of Lebanese hospitals, from different six governorates, including both public and private, university and non-university, of all bed capacity. We determined our target numbers of hospitals in each Governorates based on its population density. The overall sample was 34 hospitals from 6 different governorate of different bed capacity, public and private, university and non-university hospitals. We got the approval of 28 hospitals, thus, the total response rate was 82.35%.

Data collection procedure and instruments

A study request letter was given to each hospital, explaining the reason behind the study. After hospital approval, for better data collection, an appointment was taken from each hospital biomedical engineer to fill this guided survey in the presence of the researcher. A well-developed research questionnaire in the English language. Was used to collect data for different categories based on our proposed model, in addition to the literature review and previous studies. The questionnaire included 9 categories of structured items: Health Technology Assessment, Planning, Need Assessment, Technology Evaluation, Device Selection, Procurement, Installation, Commissioning and Monitoring. Open-ended questions help us figure out how different hospitals incorporate their medical devices, and what the major

obstacles that challenge their processes are, in addition to some real examples on poor technology incorporation processes. The main tool used to collect the data is a questionnaire. This questionnaire was well-structured by consulting with professionals in HTM and hospital management. Before distributing questionnaires a pilot study was done on a selective group of biomedical managers, where they were asked to complete the questionnaires and write down their comments. After the pilot study, some changes in the questionnaire were done.

Statistical analysis

The data collected was analysed both quantitatively and qualitatively. Summaries were used as a qualitative analyses for open-ended responses. For categorical variables a simple summary of numbers and their percentage was used. The questionnaire included like-rate questions to determine the frequency and the weight of each selected criteria of medical device selection procedure; Statistical Package for Social Sciences (SPSS) version 19 software was used for data analysis.

Results

Quantitative analysis

The quantitative analysis focused on identifying the characteristics of the processes involved in medical device incorporation.

Hospital Bed Capacity

71% of surveyed hospitals have bed capacity less than 200, while 29% are in between 200 and 400 beds.

Health technology assessment

Figure 2 Below represents the percentage of managers who know what HTA is. As shown in this pie chart, 93% of the surveyed managers reported that they did not know what HTA is, while only 7% (2 hospitals) knew what HTA was. Among the hospitals that know what HTA is (7% of the total, 2 hospital managers), both hospitals did not use HTA reports as input for their incorporation process.

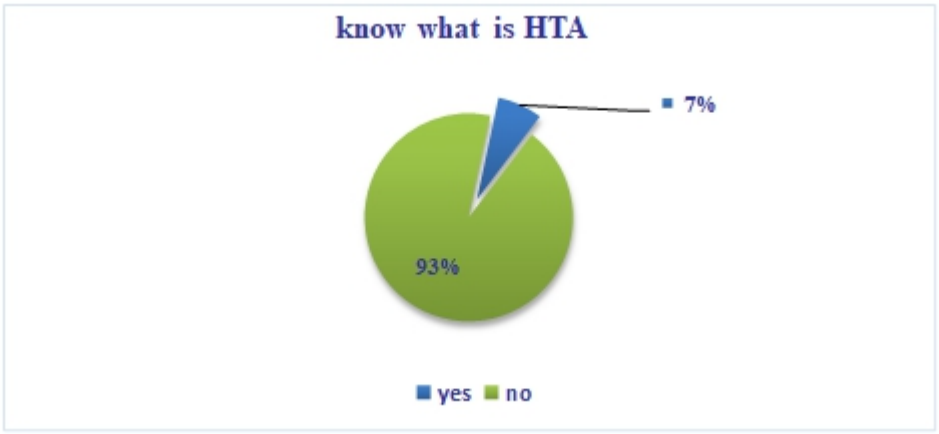

Figure 2 : Knowledge about HTA

Need Assessment

Figure 3 below represents the percentage of hospitals that perform the need assessment step before medical device incorporation. 62% of these hospitals do perform the need assessment step, while 38% of hospitals do not**.**

Figure 3: Percentage of Hospitals that Perform Need Assessment

Technology Evaluation

Figure 4 below shows the sources of information used by hospitals to perform technology evaluation; all the hospitals 100% (26 hospitals) refer to the manufacturer/ vendor and consider it as a primary source of technology evaluation information, the secondary source of information is International organizations such as: WHO, FDA, ECRI, AHRQ, etc., were 84% of hospitals refer to this resource. Medical literature were the lowest possible resource of information at 42% used by these hospitals.

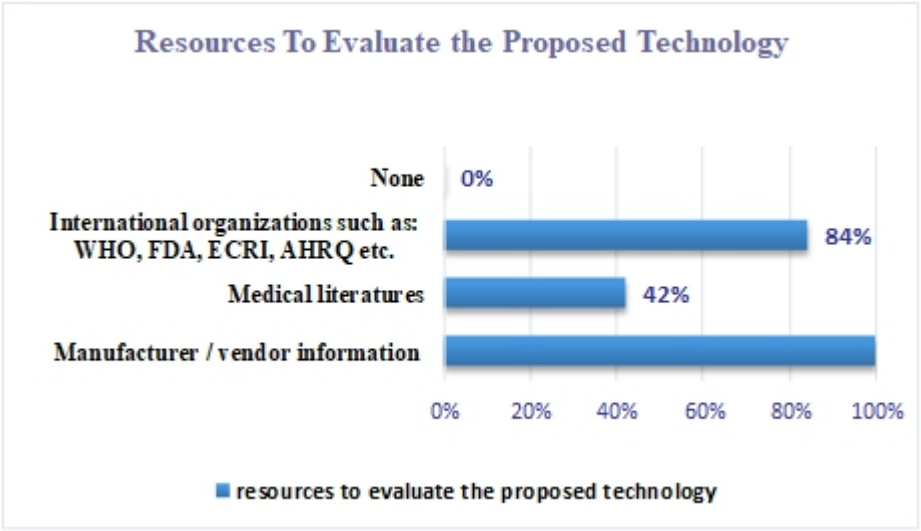

Figure 4 : Sources to Evaluate the Proposed Technology

Device selection

Figure 5 represents the percentage of hospitals that have decision making tools that aid in device selection during the incorporation process. Most hospitals, 75%, do not have any decision making tool such as multiple criteria decision analysis, while 25% hospitals have decision making tools.

Figure 5 : Availability of Decision Making Tool

Table 1: Rating Score of Medical Device Selection Criteria according to Their Weight or Degree of Importance.

Degrees Of Importance	Criteria
Essential	• Technical characteristics • Vendor evaluation • Legal aspect • Safety aspect
Very important	• Current use of technology • Material resources / supplies • Type of qualification / training required
Important	• Costs-effectiveness and economic benefits • Clinical effectiveness • Clinical efficiency
Little important	• Evidence of adverse events, occupational hazards and other risks to users. • Departmental modifications
Irrelevant	• Ethical analysis • Acceptance of technology in institution • Patient and social aspects

Table 1 represent the categorization of different criteria used by hospitals to select a medical device by the degree of importance or the applied weight. In this question we provide 17 criteria from different categories used to evaluate any medical device. The most criteria that rated as being **Essential** are four; these criteria are: **Description and technical characteristics, Vendor evaluation and maintenance support, Legal aspect and safety aspect.** Three criteria were mostly rated as being **very important** during device selection procedure; these criteria are: **Health problem and current use of technology, Material resources / supplies / supplies for the use of technology and the Type of qualification / training required for the use of technology.**

Monitoring

Figure 6 below represents the percentage of hospitals that monitor and evaluate their medical devices and incorporation processes. The majority of the hospitals (71%) do not monitor or evaluate their incorporation processes, while 29% of hospitals monitor and evaluate it.

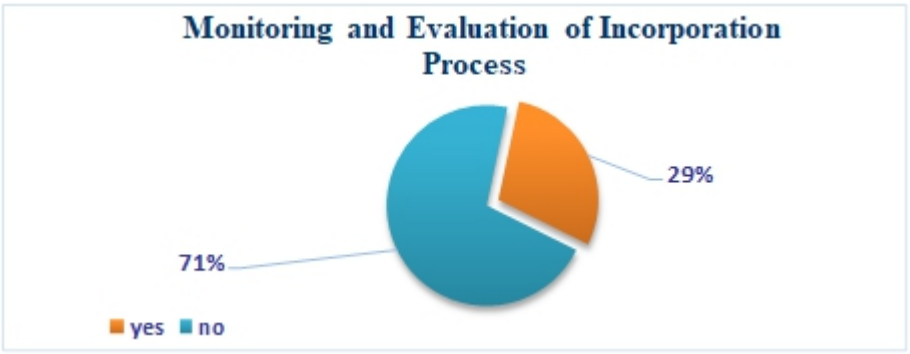

Figure 6 : The Percentage of Hospitals That Monitor and Evaluate Their Medical Device Incorporation Cycle

Figure 7 below represents the percentage of hospitals that evaluates the utilization of all bought features of any medical device by the users after a period of time. As shown below, the majority of the hospitals (96%) don't evaluate these features, while only 4% of hospitals do evaluate the utilization of all features.

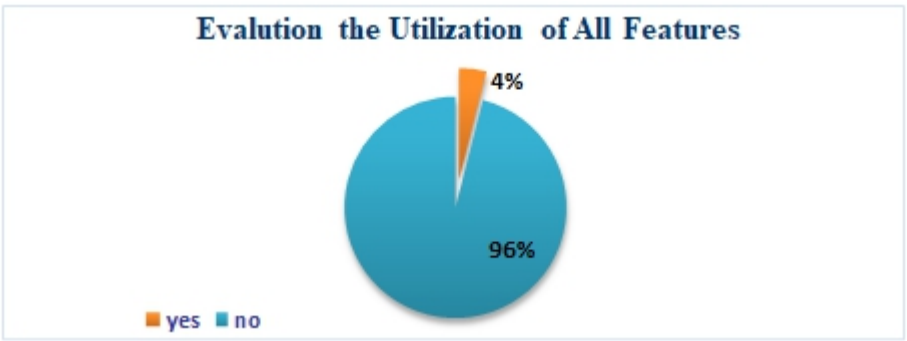

Figure 7 : The percentage of hospitals that evaluates the utilization of all features of any bought medical devices.

QualitatuiveAnalysis

The qualitative analysis showed that the majority of the interviewed hospitals have a formal process for incorporation process and some have an incorporation committee. The lack of qualified personnel and financial resources were the main obstacles for medical device incorporation. The main reasons behind poor incorporation process were the lack of a proper need assessment, market study, poor supplier evaluation and donation.

Discussion

Health technology assessment

7% of managers (2 hospitals) know what HTA means, while 93% don't know. This can be explained by the lack of awareness, regulations, and guidelines from the ministry of public health regarding the importance of HTA

although the ministry did a project entitled as the "*National Strategy for Regulation Assessment and Management of Medical Technologies in Lebanon*" (World Health Organization, 2017). However this project hasn't been implemented yet. Thus, no hospital in Lebanon considers any HTA reports for incorporation process. Among the hospitals that know what HTA means, none of them use HTA reports as input for their incorporation processes, in addition, they don't evaluate the evidence of these reports and none of these hospitals highlight any criteria from these HTA reports. Furthermore, none of the hospitals that know what HTA is have access to any international HTA agency database. 36% of all surveyed hospitals refer to Evidence-Based Medicine as an input resource for the incorporation process, while the majority do not. This can be explained wherein most of the hospitals in Lebanon, specifically the biomedical departments, don't work as HTM, which is a prerequisite for HTA.

Planning

89% of surveyed hospitals have a formal health technology incorporation process, and 93% have a committee for technology incorporation. This can be explained by the presence of effective planning role. However, only 31% of hospitals plan strategic basis and consistent with organization's mission, vision and goals**.** The absence of strategic vision for medical device planning is explained by the lack of strategic planning that aim to determine the expected changes in health care services that can be forecasted by future technology acquisition. 42% of hospitals perform market studies during the planning phase and 97% set priorities for needed medical technologies. This a good indicator, that most of the hospitals set priorities through planning phase faced by budget constraints. However, 34% of hospital's medical devices investment drivers (the highest driver) are requested due to physician needs. This can be explained as most hospitals don't plan by multidisciplinary functions through a committee, but rather only look at physician's needs since they represent the main drivers of hospital profits and don't look for the end-users needs. This result was consistent with the study conducted by Mukherjee, Al Rahahleh, & Lane entitled as "*Capital Budgeting Process of Healthcare Firms*" (Mukherjee, Al Rahahleh, & Lane, 2015)**.**

Need assessment

62% of hospitals perform need assessment, 88.8% of these hospitals collect data to determine their health service requirements by considering data on target population density, epidemiological data, catchment area, disease burden, and the available health care service providers. All hospitals consider the budget constraints, while 85% of all hospitals perform a *feasibility study*

for starting new health services, results consisting with the study conducted by Mukherjee et al (Mukherjee, Al Rahahleh, & Lane, 2015). This indicates a limit that some hospitals in Lebanon that perform need assessment procedure, consider the most important pillars: the required health service by the population, the available health services and the needed medical technologies to fill the gap between the current and the expected future situation.

Technology evaluation

96% of hospitals evaluate their proposed medical technology and 55% (15 hospitals) *are always* considering the clinical procedure in every medical incorporation process. All of these hospitals consider medical devices manufacturer/ vendor information as their primary source to evaluate their proposed device and 84% consider data from international organization, while 42% consider medical literatures. This huge variability in the sources of information indicates lack of easy access for information especially for the medical literatures and this can lead to a biased evaluation. In addition, considering manufacture/ vendor as a primary source of information is a weak source. This issue was stated in an article entitled "*Strategies for Success in Purchasing Medical Technology*", were most of the managers only consider vendors as a source of information (Atwood, Larose, & Uttley, 2015).

Furthermore, 31% of hospitals *usually* evaluate their proposed medical device against alternatives in every incorporation process and 39% of hospitals that evaluate their proposed medical device against an alternative one, have formal criteria for the evaluation process. In addition, most hospitals evaluate their medical technologies based primarily on the clinical needs, 87%, followed by 73% for post-sale services criteria. Moreover, 18% of hospitals *always* compare risks and hazards. This can be explained as follows: although most hospitals stated that they do evaluate their proposed device, however, the majority don't have a formal process for a systematic evaluation or the absence of an internal policy for an evaluation process.

Device Selection

25% of hospitals have decision making tools, such as multiple criteria decision analysis, that aid in ranking and selecting the most appropriate device, 60% of these hospitals apply weight for each criterion during multiple evaluation processes. This can be explained by the lack of a systematic process for device selection among managers and the lack of national guidelines that aid in device selection procedure. Moreover, 72% of hospitals ***always*** select internationally approved medical devices. The ability for some hospitals to select non-internationally approved medical devices at any time of an incorporation process indicates the lack of applied laws and regulation by the minister of public health and the strategy followed by some hospitals for

saving the purchasing cost of assets by selecting low quality and unsafe medical devices.

Studying the criteria for medical device selection showed that the most frequent criteria that were rated as being ***essential*** by hospitals are four: description and technical characteristics, vendor evaluation and maintenance support, and legal aspect and safety aspect. Furthermore, Six out of the seventeen criteria rated as being ***important***: cost –effectiveness and economic benefits, ethical analysis, clinical effectiveness, clinical efficiency, pressure by industry, political, patient or by senior physicians and the acceptance of technology in institutions, like health information integration. This result wasn't consistent with the study, entitled "*Hospital Managers' Need for Information in Decision-Making– An Interview Study in Nine European Countries*" this study showed that the essential criteria among European hospital's managers are: ***clinical effectiveness, economic, safety and organizational aspects*** (Kidholm et al., 2015).

Procurement

Most hospitals (82%) ask for 4 and/ or more bids from different vendors. In addition, all hospitals ask bids about technical specifications of the intended devices and consumables that must or should acquire. In addition, most hospitals ask for documentations like service manual, training cost and materials that are available from the vendor, after sale services, cost over the expected lifetime of the technology and options that are mandatory and those that should be considered. However, only 25% of hospitals don't ask for identification of similar clients. This item is important for evaluating any device; it provide hospitals with an input resource of information from previous hospitals that have real experience with the device. This can be explained by the lack of a systematic process for procurement processes among these hospitals. Moreover, 93% of hospitals' primary option as an alternative for procurement is leasing, followed by the donation option, which is chosen by 64% of hospitals. This is a good indicator, especially for low resource hospitals; however, it is important to mention that the donation procedure needs a very careful evaluation process that is lacking by the majority of hospitals in Lebanon, especially since many donated devices weren't feasible clinically and financially. 56% of hospitals ***are always*** considering maintenance support with every procurement procedure of medical device. This low percentage can be explained by the lack of wide vision for device procurement consideration. 96% of hospitals don't share their maintenance expenses by contracting with one maintenance personnel who serve many hospitals together, for the main reason that the majority of the hospital contracts with vendors or suppliers for maintenance support are for sophisticated equipment. Furthermore, around half the hospitals ***are***

always evaluating their bids on financial, technical and supplier aspects. 64% of hospitals consider maintenance support as the most important factor for vendor evaluation. This result showed that the majority of the hospitals in Lebanon need to reevaluate their procurement process.

Installation

More than half (57%) the hospitals establish a checklist with reference to procurement during the assembly and the construction phase. This can be explained by the lack of a formal policy and procedure for device installation phase. Most of hospitals (96%), check the specifications and the integrity of the new medical device upon arrival.

Commissioning

57% of hospitals ***are always*** performing acceptance, safety calibration and start-up test during any commissioning phase, while 36% of hospitals ***are usually*** performing it. This low percentage indicates that some hospitals do not consider the performance, safety and effectiveness of the new device before it is applied in the service, in addition, the lack of laws and regulations that obligate hospitals to perform these acceptance tests and conformation of the results before application in the health services.

Monitoring

The majority of the hospitals (71 %) don't monitor or evaluate their incorporation process and new medical devices. in addition, out of the hospitals that monitor their incorporation process, 88% have indicators. Moreover, only 26% of the hospitals that monitor their incorporation process and have indicators use it for future feedback.

One of the most important study results was the percentage of hospitals that evaluates the utilization of all bought features of any medical device by the users after a period of time. It showed that only 4% of hospitals do evaluate features utilization. This low percentage of hospitals that monitor their incorporation process and evaluate their medical device's features utilization indicate the lack of a systematic and comprehensive approach for the investment decision in a new medical device, especially since they have a poor methodology for the need assessment and identification.

Limitations

Every study has limitations that will provide an opportunity for new research. Our study limitations were:

1. Lack of hospital commitment to accept our study; some of the major hospitals didn't accept it and this may impact our study results.
2. Limited survey time, only 2 months from June to July.

3. Lack of hospital managers awareness of some of major terms used in the questionnaire.
4. Lack of any international study articles on technology incorporation process as whole, And the Lack of any published similar study, to compare it with our study results.
5. Some of managers were demotivated to share.

Conclusion

In this study we assess the health technology incorporation process among hospitals in Lebanon of varies sizes, types as; private and public, university and non-university. We proposed a model for the incorporation process, based on this model we derived a survey of 9 sections to study all the aspects of comprehensive incorporation processes to come up with results of the current situation. We found that hospital mangers don't use HTA reports as an input for their incorporation process. Although the majority of the hospitals perform need assessment however they don't perform it in appropriate way. Furthermore, the majority of hospitals don't rely on decision aiding tool such as multiple criteria decision analysis (MCDA), that aid in ranking and selecting the most appropriate device during medical technology evaluation. Finally, the majority of hospitals don't monitor or evaluate their incorporation process and a very low percentage of hospitals evaluate the utilization of all bought features of any medical device after a period of time.

Therefore at the hospital level, we recommend hospitals to follow a formalized process for medical device incorporation that include a strategic planning and need assessment as an initial step. To consider the importance of HTA role and Evidence-Based Medicine as an input resource for the incorporation process. Put more effort on their biomedical departments and start considering applying HTM principles.

As an advance stage for hospitals that apply HTM to apply hospital–based HTA for the benefits of proper device evaluation. Encourage hospitals to have a wide vision in prioritizing their medical devices based on the clinical and market needs and not only on physician's needs. To set standard criteria for technology evaluation. To follow a reliable methodology in the decision making process while selecting a medical device such as AHP and MCDA. Put more emphasis on monitoring and evaluating their incorporation process and purchased medical devices by applying general and specific key performance indicators. This will provide a feedback for future incorporation process.

In addition, we recommend for the Ministry of Public Health**,** to initiate and set a methodology for an HTA agency, and raise awareness regarding the importance of HTA reports especially in the medical device incorporation. To set regulations and guidelines in accepting and receiving

donation for hospitals. Include a new standard in the Lebanese accreditation standards, that includes a formalized incorporation process including need assessment and device evaluation criteria so that all hospitals in Lebanon will be requested (by standards) to apply a good incorporation process and engage more in device evaluation. To put more effort in controlling the high number of medical devices such as MRI and CT-Scans by formalizing and applying new laws and regulations for the certificate of the needs and included as a new standard in the Lebanese accreditation standards, so all Lebanese hospitals will be requested to apply for the certificate of the need before purchase any new medical device. Finally, to put more efforts in encouraging biomedical departments of hospitals to work toward HTM.

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