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Planning Incorporation of Health Technology into Public Health Center

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1. Introduction

The incorporation process of Health Technology (HT), particularly, Medical Equipment(s) (ME) encompasses all activities ranging from purchasing, renting, leasing or exchanging, technology assessment, planning and identification of needs, installation, technical rehearsals, calibration, users' training etc. The incorporation process also includes prediction of technology use for ascertaining if what has been planned can be realized, and for aiding future incorporations (World Health Organization [WHO], 2011a).

According to Wang (2009), the incorporation process of ME can be divided into two phases: planning and acquisition. The planning phase includes assessment of needs and impacts, and costs and benefits of ME after auditing the existing resources. The data collected during auditing and assessment should be established and converted into a technology incorporation plan, which might guide future investments. The second phase relies on the selection and acquisition of products that are appropriate to a certain application and environment. Purchasing options, such as leasing, lending and the revenue sharing models, should always be considered.

Health systems must be built in blocks in order to inform the financing policies, human resources, information, service aid, management and health technology. The inter-relations and interactions among these blocks constitute a system. If any of these is lacking, the health system cannot work on the level needed to improve public health. Each block has its own organizational and political challenges. This chapter will discuss the health technology block, considering ME as the essential tool to public health (WHO, 2007; WHO, 2009).

Technology in health service aid is indispensable, even in the most remote and low-resource areas. Drugs, implants, disposable products and medical equipment are the main items that contributed to the progress of health care in the last century, as compared with that during the preceding thousands years. Unfortunately, technology also adds significantly to the fast and ever-growing health costs. Within this context the ME stand for relevant costs to the health system and sometimes under low and limited resources, besides of many medical procedures being totally dependable of technological resources.

Management and administration of this health system technology, which aims at improving the cost-benefit ratio, safety, and reliability, falls within the domain of Biomedical Engineering. Clinical Engineering, which forms part of this domain, incorporates the quality parameters in all phases of the technology life cycle (Raymond, 2004; Moraes & Garcia, 2007).

Therefore, the Clinical Engineer, through ME management and administration, must identify the needs, limitations and factors required to evolve a methodology that leads to appropriate planning of ME incorporation through a systematized and rational structure. Thus, the health system can recommend incorporating just safe and effective ME that has infrastructure, human resources and financial viability. Moreover, it has to observe the legal, social and ethical aspects of the context in which the ME is to be inserted (Centers for Medicare and Medicaid Services, 2000; Cutler & McClellan, 2001; Sônego, 2007; Santos & Garcia, 2010).

Inadequate planning of ME incorporation practices can lower the quality of service aid or of ME's performance. On the other hand, adequate planning can lead to safe, equitable and quality health care. Besides, it also helps in identifying the technology that is appropriate to the Health Care Center (HCC) – not just the cheapest one taken from proposal selection (public bidding) – in terms of well defined and satisfactory parameters, such as deliverance, installation, performance test, training, payment and guarantee. Also, the technology must be so chosen as to encourage the distributors and manufacturers come back with future offerings (Calil, 2007; WHO, 2011a).

These guidelines are to be followed not only in case of purchases, but also in case of the equipments received through donation, renting or borrowing, including the ones replacing the existing ones. Moreover, should be applied to the individual institutions and/or network systems composed of several hospitals in various levels, health centers and community clinics, although the complexity and deadlines are very different from one case to another (Wang, 2009).

This chapter deals with identifying and recommending the main factors that must be considered for ME incorporation. The Clinical Engineer can help the actors involved, as a process facilitator, in identifying these factors and in deciding if incorporation is a real necessity. Thus, the performance of the Clinical Engineer strengthens not just the ME incorporation, but the whole health system and thus the public health.

2. Incorporation process of medical equipment

The main target of ME incorporation process is to maximize the benefits—clinical or financial—and minimize the costs—investment or recurrent ones-- especially of the local low resource communities, thus helping them in controlling the health problems effectively. The objectives may vary from one HCC to the other, but they usually include some of the following (Kaur, 2005a; Wang, 2009; WHO, 2011a; Santos & Garcia, 2010):

- Improve clinical results and patient satisfaction.
- Guarantee better access, quality and use of ME.
- Increase patients' life expectancy.
- Decrease the time spent in investigation, treatment and rehabilitation.

- Increase the access of patients to health care in equitable manner.
- Enlarge the coverage of patients' population and geographic areas.
- Reduce risks to patients, clinicians and environment.
- When suitable, keep or improve the ME market.
- Obtain balance between clinical needs, personal desire and available financial resources.
- Introduce pro-active planning to meet long-term needs, and thereby reduce emergency acquisitions.
- Reduce the Total Cost of Ownership (TCO).
- Offer more learning opportunities to clinicians and students when they are academically affiliated.
- Maintain or increase standardization to improve efficiency and reduce risks.
- Increase transparency of the public tender process.
- Encourage the actors involved in the incorporation process to create conditions conducive to establishment of monitoring actions towards the long life cycle of ME, and thus contribute to future planning.
- Observe the valid legal aspects in national and regional contexts.
- Identify the cultural and social barriers and facilitators.

It is important to note that other objectives can be added to the foregoing list depending on the need of each ME or health care. The Clinical Engineer must help in identifying the key factors for achieving the objectives defined. These factors must consider aspects inherent to technology, infrastructure, human resources and costs. They thus have a wide scope for choosing the parameters that meet the challenge of ME incorporation by using Clinical Engineering methodology.

After identifying the parameters, it will be possible to develop a systematized methodology that is based on the decision making domain, health technology assessment (HTA) and health technology incorporation. The Clinical Engineer can, therefore, act as a facilitator and as an actor of a team or interdisciplinary commission that formulates recommendations and supports decision making for ME incorporation, based on the evidence available in literature, in such a way as to minimize or even eliminate subjectivity in decision making.

2.1 Conceptual approach

A conceptual approach is needed to understand health technology, especially ME, its role and life cycle, and the actors involved in its incorporation process.

2.1.1 Medical equipment function

Health care is a human right, according to the Universal Declaration of Human Rights. However, it does not give access to universal health care. The World Health Report commented on this issue, in the context of primary health care, thus: *"Primary care and social protection reforms depend on choosing health-systems policies, such as those related to essential drugs, technology, human resources and financing, which are supportive of the reforms and promote equity and people-centred care"* (WHO, 2008; United Nations, 2011).

In this regard, it can be observed that health systems depend on health technology for the desired health results. It is important to plan ME programs according to the protocols and policies that can result in equitable, safe, appropriate and high technology access. ME requires adjustment, maintenance, repairing, user training and deactivation, which are usually performed by Clinical Engineers. ME is used for diagnostic purposes, treatment of certain diseases and rehabilitation with some kind of accessory input or other equipment. ME does not include implants and disposables (WHO, 2011b).

Technology¹ by itself has low intrinsic value and its value depends on how it is used. It is through the ME that health-predicted needs and benefits are realized, considering its impact on the patients, users, infrastructure, maintenance, costs and valid legislation. If the incorporation is planned and properly guided, then the ME can help policy formulators, decision makers, Clinical Engineers and health professionals in fulfilling their objectives of treating the patients under a better cost-benefit relation. However, if the technology is inappropriately incorporated or used, it can harm people, and cause loss of value and resources (Wang, 2009; National Institute for Health Research [NHS], 2010).

In this context, efforts must be made to manage the ME in a rational way, so that some balance can be found between the desired needs and benefits on the one hand, and the positive or negative impacts on the other. The importance of Clinical Engineering structures is thus evident in offering mechanisms that enable efficient and transparent ME incorporation planning. Nonetheless, the actors involved in the process must be aware that the incorporation is directly linked to the necessity of treating or diagnosing some clinical condition. Consequently, the eligibility of the applicant ME for incorporation must be assessed.

The eligibility refers to justification in realizing the ME assessment in the incorporation. To help this, some issues must be addressed, considering different aspects of demographic density, complexity of the health problem, and the nonexistence of unused ME in the HCC. This could enable the manufacturer and the distributor to guarantee the supply of spare parts during servicing of the equipment.

2.1.2 The medical equipment life cycle

ME is vital to health care service in that it improves the public health system. From the innovation phase to the replacement one, the tools used in the system must have four essential characteristics: availability; accessibility; adjustment; and financial capacity². These would help to enhance the life cycle of the ME in such a way that not all the efforts may not have to be centered on the innovation phase alone, but on the incorporation one too in an adequate and rational manner; this ensures their use in an efficient and equitable way (WHO, 2011b).

¹The majority of dictionaries define technology as the application of knowledge to practical means.

²Relationship between prices of services according to the maintainer, the deposit required for the entry of customers and the ability to pay, or the existence of health insurance by the customer.

In general, ME life cycle presents four phases (WHO, 2011b):

- Research and Development (R & D).
- Regulation.
- Health Technology Assessment (HTA).
- Health Technology Management (HTM).

These phases are efficient as long as they are supported by the health policies which are supervised by trained personnel. While interdependence of these phases is important to achieve the desired results, the operation within each phase must also be planned and executed with protocols that correspond to the administrative level (national, regional and local) (WHO, 2011b).

In the R&D phase, the entry parameters depend on the national policy of health technology R & D and on the health needs of the population. Besides meeting these requirements, the national policy must concentrate on encouraging the industry, so that the industry can generate innovative health products and make them available to whoever needs them (WHO, 2011b).

The regulation phase consists in protecting the society by publishing rules, rehearsing protocols, pre-authorizing purchases, registering, post-sale vigilance and reporting on contra-indications. The focus in this phase is on guaranteeing the safety of patients and technology users (WHO, 2011b).

In the HTA phase, it is possible to systematically evaluate the proprieties, effects and/or impacts of ME on the deliverance of health care by a well-designed and defined methodology. The main target of this phase is to educate the health policy formulators on related technology. Thus, it is possible to properly plan from incorporation of the ME to the removal of ME. Depending on the issues involved, time frame for decision making and availability of resources, the HTA can be tackled in different ways, such as by more detailed HTA reports, availing of reports produced elsewhere, fast review, and monitoring technological reports (Velasco-Garrido & Busse, 2005; HTA GLOSSARY, 2010).

The HTM phase encompasses a variety of attributions, which include, *inter alia*, the following: identification of needs, collection of reliable data about ME, incorporation process, a complete inventory of ME, maintenance program based on risk reduction and safe operation, aiming for safe tools and high quality health service, allotting sufficient resources to maintain the technology under use, monitoring the clinical effectiveness of ME, updating and deactivation or replacement of unsafe and obsolete equipment (Kaur, 2005b; Santos & Garcia, 2010; WHO, 2011b).

From the foregoing discussion, it follows that each phase has specific attributions. However, it is important to highlight that technology life cycle phases are not independent; that is, action taken in one phase may impact other phases. This underlines the need for adequate planning of ME incorporation, and thus for strengthening technology life cycle, the actors involved and the health system.

The technology life cycle phases can operate at local, regional and national levels. The characteristics, perspectives and impacts of each phase are described in Table 1.

	R&D	Regulations	HTA	HTM
Perspective	Innovative knowledge, application and tools for health services	Safety & efficacy	Population served	Health services provider
Orientation	Personal health services	Population safety	Population health	Community health services
Requirement (Output)	Improved and/or new tools & services	Mandatory compliance	Recommendations on highly complex technologies	Operational rules and guidance for all medical devices
Method	Innovation and improvement	Performance testing, safety assessment & post-market reporting	Systematic analysis, critical review	Operational management of technology life-cycle
Criteria	Market adoption	Safety and quality standards	Epidemiology data, statistics, analysis of efficacy, effectiveness, and appropriateness	Needs analysis, specifications, reliable device availability for clinical use
Outcome	Enhanced health services	Risk mitigation and prevention of harm	Responsiveness and maximization of clinical outcomes and cost-effectiveness	Improved health delivery; sustainable availability of high-quality and safe devices

Table 1. Characteristics of ME life cycle phases (Source: WHO, 2011b).

2.1.3 Actors involved in the incorporation process

Past experience shows that ME incorporation process has not been well coordinated in most countries. In many cases, it led to undesirable results, such as increase in cost, abusive use of the facilities and frustrating managers, users and patients. However, by learning from these experiences, the application of knowledge has been so conditioned as to derive maximum advantage from each of the ME life cycle phases (David & Judd, 1993; Sprague, 1988).

The incorporation process, which involves clinical, technical, financial, infrastructural and human resource impacts, is a challenging task. Therefore, a multidisciplinary team is required to plan and execute the ME incorporation process effectively. The team can prevent recurrence of past errors, and identify the potential factors that may lead to dissatisfactory results. The team must be formed by including representatives from clinical, administrative, financial, clinical engineering, installations, information technology and material management areas. Besides, it needs to be strengthened with specialized knowledge and services of consultants and distributors (Coe & Banta, 1992; Wang, 2009).

The Clinical Engineers can be strong members of the team in that they ensure that the real clinical needs of the user are identified, treated and, when possible, attended to. They can serve as a communication link between professionals of different disciplines involved in the incorporation process, inside or outside the HCC. Besides, their experience and skills can be used to help the HCC in its systematic and safe incorporation of the technology process. It is

fundamental that those Engineers never forget that they are just members of a team and not the only ones responsible for ME incorporation (Harding & Epstein, 2004).

User's integration in the development and assessment of ME is explicitly recommended in literature. This perspective turns out to be beneficial to technology producers, besides highlighting the importance of users inside the incorporation process (Woodside et al, 1998; Kittel et al, 2002; Sarwar & Robinson, 2007). In addition, other approaches directly reflect on the potential impact of the user's integration into the assessment process. (Mcgregor & Brophy, 2005).

Just as Clinical Engineers and users, all other actors in the incorporation process—interns, like patient groups, or externs like manufacturers, distributors or regulators—need to be considered equally important, and treated accordingly (Gibson et al., 2004).

Regarding decision making in ME incorporation, the representation of multiple perspectives of the actors is a key element of justice (Singer et al., 2000). Similar approaches can be found in Drummond et al. (2008), which presents the key principles to guide the HTA.

2.2 Identification of resources for incorporation

It is important to stress that, without necessary resources, adequate planning of ME is not possible, and consequently the incorporation process too. The progress of health technology with assured benefits to the patients and increased efficacy is rather slower within the health systems than in other health service economies. This can be ascribed to several barriers in this process, such as the following (Robert et al., 2009):

- Lack of formal mechanisms to disseminate recommendations and information about ME assessment.
- Availability of adequate data on the cost and price of new health technology.
- Insufficient sharing of information between buyers and sellers that can result in bad purchasing decisions.
- The culture within the health systems is not sufficiently entrepreneurial.
- Lack of financial and technical support to the companies in turning innovative ideas into marketable products.
- Bureaucracy around purchasing procedures.
- Need for training the health system teams in using the new ME.

Fortunately, notwithstanding these barriers, the new ventures introduced by World Health Organization, along with recommendations towards ME, have been well accepted by the country members. These can be turned into better and more efficient health systems. Nowadays, in developing countries like Brazil, some attention is being given to preparation and dissemination of methodology guidelines for assessment and incorporation of ME. This contributes to the development of recommendations to deal with the challenge of ME incorporation process.

Even so, many barriers still remain to be broken down to achieve complete success in ME incorporation and usage. In this context, it is important to identify clearly the needs for adequate planning. One of the most critical necessities is undeniably the human resources. In general, the two common mistakes are excessive centralization of decision-making and

reposing too much confidence in the specialists concerned. Centralizing decisions brings political problems related to favoritism, subjectivity, and lack of transparency. And, too much confidence in specialists needs credibility and general support, which sometimes get worse because of lack of a wider view (Wang, 2009).

Therefore, it is necessary to establish a transparent and efficient process that can identify and plan the actions pertinent to ME incorporation process. As has already been said, the engagement of many actors in this challenge can bring more transparency and a generalized approach, as well as all the relevant factors. So, it is recommended that a multidisciplinary team be formed and supported by representatives of every group of actors involved, where the Clinical Engineer can act as a task facilitator.

However, it is necessary to get information and evidence of internal and external sources of ME, which can enable the planning of ME incorporation. Following are some internal sources of information and evidence and the main factors to be considered for each source (Wang, 2009):

- Current users: efficacy, effectiveness, safety, easy training and usage.
- Clinical Engineering: reliability, safety, maintenance and availability.
- Installation management: requirements of usefulness and environment impact.
- Information Technology: network problems and software support.
- Material management: input, accessories and alternative distributors.

Following are the external sources of information and evidence, and the main factors to be considered (Wang, 2009):

- Health Information Centers: epidemiological data, possible refund, rules and regulations, marketing rivalry, financial problems and HTA reports.
- Manufacturers: product specifications, financial conditions, requisites to installation and functioning, post-purchasing guarantee and support.
- Regulating mediums, Civil Engineers and Architects: infrastructure requisites and impacts, regulations and codes.
- Other distributors: aiding equipment and furniture, alternative supply and service sources.

The multidisciplinary teams at the local level can be considered as determined people to ME incorporation management in the health system as a whole. However, their attributions and actions must be tailored to the needs of the situation. The actions of the multidisciplinary team at local level need administrative and technical support. Systematic research of scientific literature and HTA reports by specialized technicians would be helpful for simultaneous execution of the planning tasks within the timeframe given for ME incorporation process (Kaur, 2005a; WHO, 2011a).

2.3 Evaluation of the necessity for medical equipment incorporation

Prior to ME incorporation, one must clearly understand the difference between desire and need. This is because many acquisitions were made more under the impulse of desire and for subjective reasons, than in the common interest of the majority of the actors, which must be the case. The need for ME incorporation must be assessed rationally by discussions with

the clinical team on the diseases that need to be addressed and the health policies they recommend, and not the technology they want (Wang, 2009).

Besides, a survey must be undertaken to check if the HCC that is going to receive the technology has already some ME that meets the clinical needs under consideration, or if it has any unused equipment. Following are the other questions that must be taken into account in this regard (Kaur, 2005a; WHO, 2011a; Robert et al., 2009; Wang, 2009):

- Does the demographic density of the HCC region that is going to use the ME justify the incorporation?
- Does the ME have an entry in the register of competent regulating establishment?
- Is there any demand in the health service offered by the ME?
- Is there any personal preference from the clinical or administrative team of the HCC?
- Will the ME incorporation and its results impact significantly on the treatment/diagnosis of patients by any other specialist?
- Does the complexity of the identified health problem justify ME incorporation?
- Is there any guarantee that the manufacturer will offer spare parts during the projected life cycle of the ME?

All these issues justify a detailed ME assessment, which needs time, human resources and financial investments. If the majority of the factors justify the need for ME incorporation, one can pass on to the next planning phase, which involves assessment of the impacts upon users, patients, infrastructure and immanent traits of technology. In case the need is not justified, immediate disengagement of the incorporation process must be considered.

Answers to the proposed questions can be found in international and national literature. Yet, the technological park of HCC may have to be covered to check if any unused ME exists. Data in respect of demographic density and demand can be taken from the Health Ministry sites. Interviews with clinical and administrative team, as well as with some manufacturers, are recommended to identify personal preferences and ascertain the capacity to supply the spares, respectively.

When applicable, it might be necessary to assess the amount of ME needed, on the basis of epidemiological data, population to be assisted, geographic distances to be covered, status of the HCC that is recently in need of technology, including its capacity to utilize the equipment or the usage time per case. However, sometimes, it may not be possible to go beyond just the figures, because many variables are subjective or difficult to estimate. Besides, the available data might not be reliable enough to lead to correct indications. Nonetheless, some attempts can be made, assuming potential risks and making adjustments, so that they provide some basis for future assessments (Wang, 2009).

2.4 Impact of medical equipment incorporation

The impact of technology incorporation into health services, particularly of ME, can be viewed in both positive and negative ways. The determining point of the impact will be the way in which the planning is conducted. Therefore, before incorporating ME into the health systems, one must study the likely impact of this equipment on the service, both direct and indirect. One of the main reasons cited for the disuse of ME is sometimes the failure to predict ME's impact (World Health Assembly Health Technologies [WHA], 2007). These

impacts can be portrayed as three pillars: Human Resources, Technology and Infrastructure. Figure 1 shows the impact on health technology from Clinical Engineering view, particularly ME:

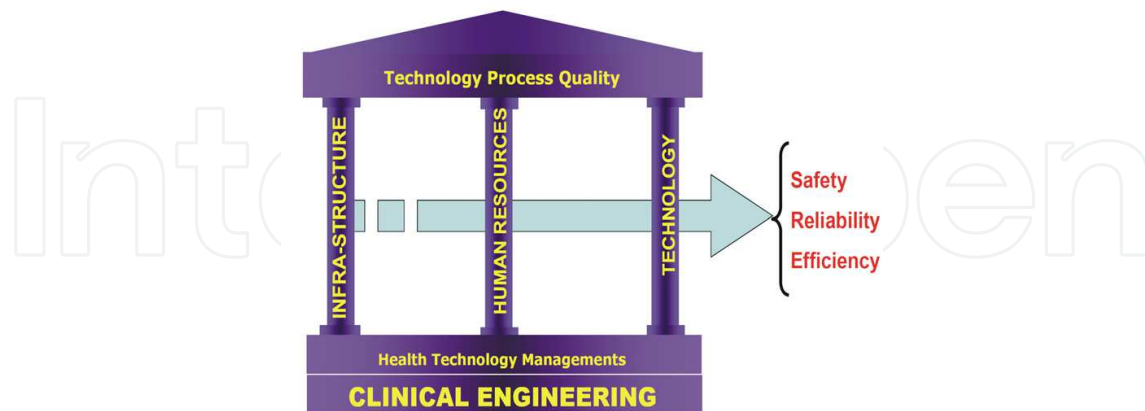


Fig. 1. Impact on health technology, particularly ME, from clinical engineering view must be considered to obtain safety, reliability and efficiency deliverance of health service by ME usage (Source: Santos, Souza & Garcia, 2010).

2.4.1 Impact on human resources

Health professionals are individually responsible for the transparency of their practices in certain aspects of health care offers. Therefore, they have the responsibility, as part of their continuous professional development, to acquire, maintain and disseminate knowledge and abilities in availing of ME. Before inducting health technology into HCC, the managers must ensure that the health professionals are adequately educated to guarantee safe usage of technology (NHS, 2005).

The users' training needs can cover educational services, as well as clinical users' training. Safety training aspects, such as those with laser equipment, must also be considered for inclusion in user training needs (Harding & Epstein, 2004).

Additionally, a training plan is necessary, considering the training material, manuals, trainers and other resources pertinent to the training, as also the need of the establishment of a schedule of personal training activities in order to regard the personal turnover and gradual loss of competence. This plan must take into account some fundamental aspects (NHS, 2005) listed below:

- Degree of ME risk and, therefore, priority level.
- The need for flexible approaches to learning.
- Accessibility to all ME users.
- Constant information about the changes made in the legislation pertinent to ME.

However, for conducting any program one incurs cost, which can be directly related to the learning curve of the user in relation to the ME which will be used.

The learning curve is a tool which can monitor the performance of workers assigned with certain tasks. Through the curves, it is possible to evaluate and plan for more productive tasks, and thereby, to reduce the loss arising out of the inability, which is checked, above all,

in the first periods of implementation (Dar-El, 2000). The tool also allows adequate allocation of tasks to the members of the workgroups so as to enable them complete their performance characteristics, besides the monitoring of costs related to the process (Anzanello & Fogliatto, 2007).

Figure 2 shows the relation of cost versus ME complexity, divided into two categories (A & B). The line 0b represents the cost or time spent to train a technician (beginner) in operating the equipment of category B and the line ba in operating the equipment of category A. From their comparison, it can be seen that the more complex the ME is, the more would be the time (or cost) required to train the professional (Souza et al, 2010; Cheng, 2006).

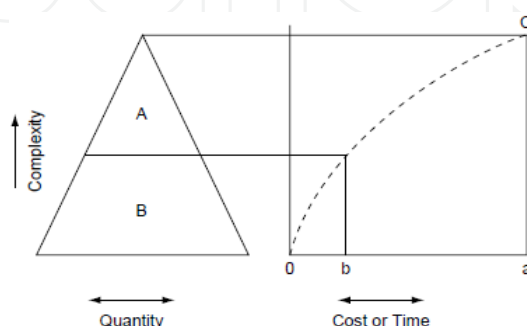


Fig. 2. Training curve based on ME complexity (Source: Cheng, 2004).

In terms of the magnitude of complexity, one can consider classifying the ME based on the following definitions (Calil & Teixeira, 1998):

- Low complexity equipment: The ME of this category has complex electronic or mechanical circuits, but they pose no maintenance problem (e.g., thermal double boiler, sterilizer, sphygmomanometer, mechanical scales, etc.) Those who operate this equipment need not be specialists, and the training they need is quite simple.
- Medical equipment of medium complexity: The ME of this category requires personnel with basic education and training that can meet the repairing needs. Examples of the ME of this category are incubator, centrifuge, cardiac monitor, electrocardiograph, hemodialysis equipment, etc.
- High complexity equipment: The ME of this category demands qualified technicians with specialized training. In many cases, these technicians have higher education and some of them had foreign training. Following are some examples of this equipment: nuclear magnetic resonance, scanner, chemical analyzers (some types), gamma chamber, linear accelerator, ultrasound machine (image diagnosis system), etc.

Therefore, the degree of complexity of ME can help in estimating the costs and the training time required for each ME, because the more complex the ME is, the higher would be the cost and time needed. In other words, from the degree of complexity of the equipment, one can draw a qualitative estimate of the cost and time required to train a person in operating that equipment. For instance, the cost and time required to manage an ultrasound machine, which belongs to the high complexity category, would be much higher than the cost and time required to operate a cardiac monitor that belongs to the medium complexity category.

With that information in mind, it is possible to properly hire specialized training services or even sign maintenance contracts for users' training. However, final cost estimates can be

made only after a market survey and discussions with manufacturers, distributors, and companies specialized in ME training.

2.4.2 Impact on technology

The ME needs to be operated in an efficient and safe way. To achieve this, various factors that may interfere with each other will have to be considered. So, one must prepare a maintenance plan that covers not only preventive or remedial maintenance, but also detects potential and hidden errors that are not usually identified by users, but can cause injury or death to the patients (Kaur, 2005a; Wang, 2009).

For preparing a maintenance plan, one must consider the following actions (Kaur, 2005a):

- Check the guarantee date and enquire if the distributor offers, during the guarantee period, the spares required, and if the guarantee period can be extended for an acceptable cost.
- Check, in case of any breakage of ME, whether the manufacturer will replace or repair the broken part or even offer refund if the equipment has manufacturing or material defects. Will the offer cover all parts of the equipment? Does the manufacturer pay for the shipping expenses?
- Ensure availability of consumables, accessories, spare parts and maintenance materials.
- Check if the maintenance requires the service of a qualified engineer, and if the answer is 'yes', identify the local distributor or representative who can help in case of breakdown or glitch.
- If no distributor or representative is available locally, check if somebody is available at regional or national level.
- To increase the bargaining power for entering into a maintenance contract, check if there are companies, other than the authorized agent, who can offer maintenance service.
- Identify, from the options available, the maintenance contract that has the best cost-benefit ratio for each ME. In most cases, purchasing ME by lending or leasing is advantageous, but it needs to be checked if the input and maintenance costs do not exceed the purchasing costs in a short time.

It is important to note that the ME, which does not have adequate support of maintenance services, consumable goods, and replacement parts, it is probable that the ME may remain unused for long periods and might ultimately be replaced prematurely. Therefore, it is essential to any health establishment, no matter its size, to implement a ME maintenance program. The complexity of this program depends on the size and type of installation, its locale, and necessary resources. The need for a good maintenance program will be the same regardless of whether the ME is in a high income, urban environment or in a low or medium income, rural environment (Kaur, 2005a; WHO, 2011c).

The ME maintenance can be divided into two categories: Inspection and Preventive Maintenance (IPM), and Corrective Maintenance (CM) (see Figure 3). IPM includes all programmed activities that guarantee equipment functionality and prevention of failure³.

³The condition of not meeting intended performance or safety requirements, and/or a breach of physical integrity. A failure is corrected by repair and/or calibration (WHO, 2011b).

Inspections of performance and safety verify the functionality and safe usage of a tool. Preventive Maintenance (PM) refers to the programmed activities to ensure that the ME endures its useful life through actions like calibrating, replacing dysfunctional parts, greasing, cleaning, etc. Under PM, the inspection can be done as an individual or group activity to guarantee ME's functionality. CM refers to activities carried out to restore the physical integrity, safety and/or performance of a failure ME (WHO, 2011c).

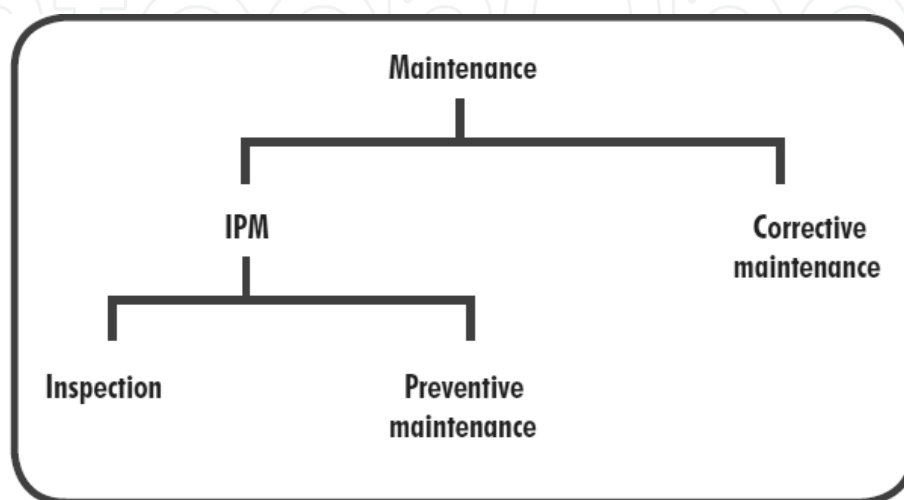


Fig. 3. Categories and types of ME maintenance: Inspection and Preventive Maintenance; and Corrective Maintenance (Source: WHO, 2011c).

2.4.3 Impact on infrastructure

Once the ME is incorporated into HCC, it is important to understand different aspects of the resulting impact on the infrastructure. Following are some of the advance actions to be carried out before acquiring the technology (Calil, 2007; Wang, 2009; WHO, 2011d):

- The space needed to install the ME.
- The type of floor, and equipment weight and disposition in relation with other technology equipment in adjacent rooms.
- Type, size, and position of the place and building.
- Check if the HCC has more than one floor, and if 'yes', identify the floor for installing the ME.
- Ascertain the availability of gas and water supply and their supply conditions, like type, quality and quantity, and pressure.
- Check the availability of power supply for electric connections; also, check if the HCC has an emergency generator.
- Check the need for weatherproofing such as air-conditioning, and quality control (air quality and humidity).
- Other factors that may be specified as installation prerequisites.

These actions are particularly important to HCCs in rural areas and developing countries where stable sources of energy, adequate water supply and controlled environment in terms of temperature and humidity are not always available.

Information about the likely impact on the infrastructure can be obtained from the manufacturers. They usually offer architectonic projects and support structuring layouts for installing robust ME, such as robotic surgery system and magnetic resonance instrument (Wang, 2009).

2.5 Proposed model for medical equipment incorporation

Clinical Engineering plays an important role, through Health Technology Management (HTM), in innovation, incorporation, usage/utilization and ME re-processing. Thus, the proposed model comes from HTM incorporation phase. It is important to highlight here that, in the last few years, the profile has been undergoing some changes in the incorporation process, which are not being released just in the HCC, but also in the entire health system. Therefore, the methodology aimed at helping this process must contemplate taking such actions that can be applied to the benefit of public health (Sônego, 2007; Santos & Garcia, 2010). Figure 4 depicts the conceptualization of the proposed model, with focus on ME incorporation phase.

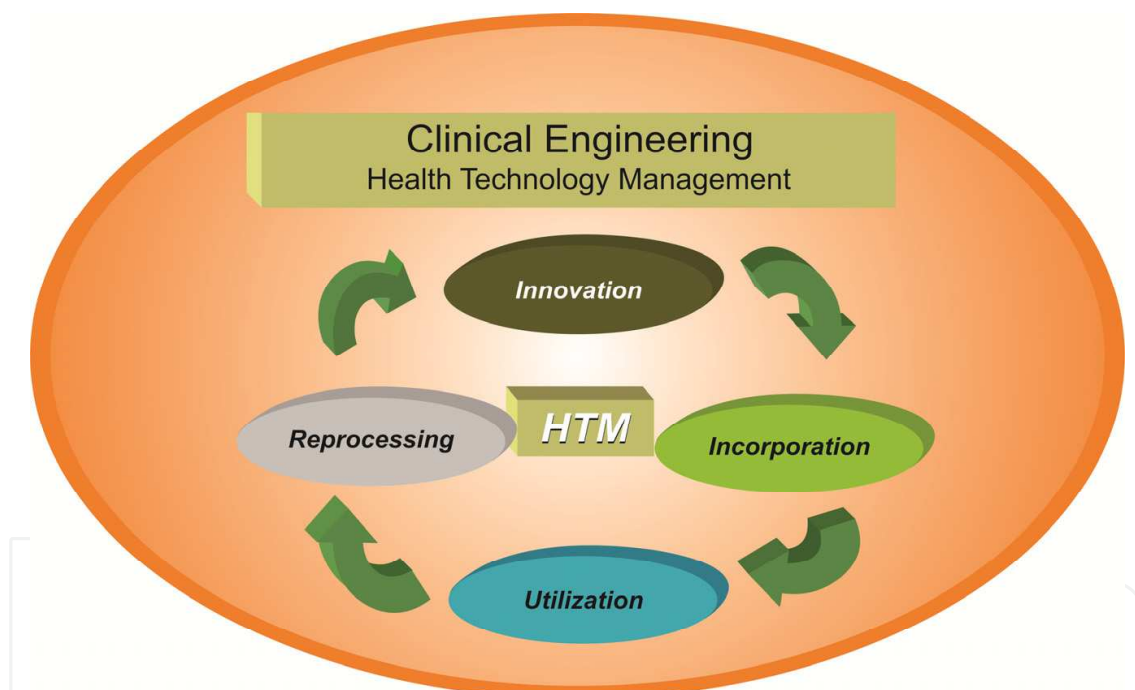


Fig. 4. Conceptualization of the proposed model with focus on ME incorporation phase.

It is important to note that the phases of ME life cycle are not independent, i. e., the actions in any one phase can impact the other phases. Besides, each phase has specific stages, which must be appropriately planned and guided to obtain satisfactory results in respect of the patients. Thus, by monitoring the actions carried out in one phase of technology, and observing the consequent impact on other phases, one can plan in a better way the actions in other phases of the ME life cycle.

Against this background, a model was developed to support the ME incorporation process, as shown in Figure 5.

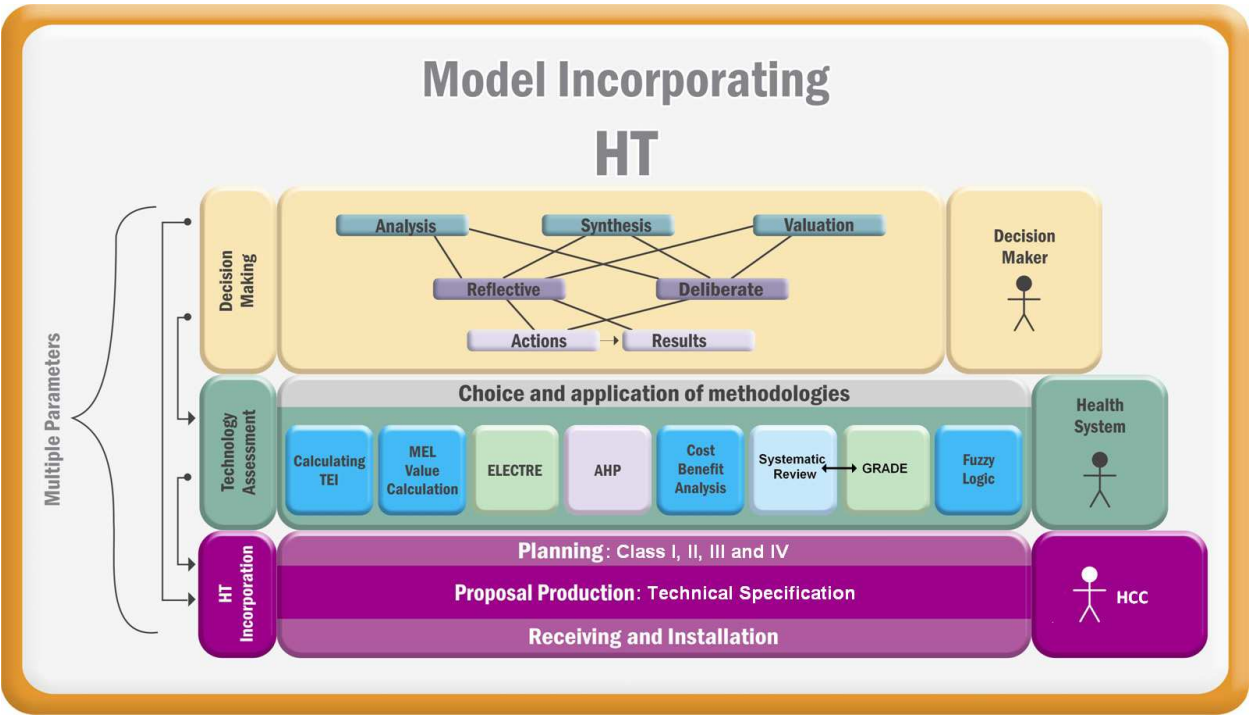


Fig. 5. Model depicting the process of health technology incorporation process, particularly ME. The proposal is based on decision making domains, technology assessment and HT incorporation. The domains establish interconnections, and there are multiple parameters and actors to be considered.

In the decision making domain, interconnections are made among the mind functions, decision making types and actions. The mind functions are made by analysis, synthesis and imagination, and evaluation. The analysis consists in separating a whole into its constituent parts, the synthesis and imagination is the reverse of analysis, that is, it presents or puts the things in groups to make a whole. Evaluation comes into action in mental activities, such as success criteria establishment, performance evaluation and judging people (Adair, 2007).

These functions can relate with those decision making types that can assume a reflective or deliberated form. The reflective one comes from the necessity of reflecting on how people make decisions based on their experiences, where they use the knowledge acquired by experience to identify and evaluate the situations and later make decisions (Fadok, Boyd & Warden, 1995; Zsambock, 1997). The deliberated form is based on reason, which supports the decision process, wherein the decision maker within his/her context will analyze, synthesize and evaluate to achieve the desired result (Klein, 1997; Joseph, 2007). So, from the interconnections between the mind functions and the decision making form, actions and post results can be created with the decision maker as the actor.

The decision analysis, which sets relevant technological alternatives, together with systematic review of studies about the effects of technology on health management, and the economic analysis that relates costs and effects, forms the main methodology used in HTA (Krauss-Silva, 2004).

Within the technology assessment domain, it is possible to choose and apply multi-criteria methodology to support decision making, and assessment methods of clinical evidences and

costs. The methodology that can be employed in the ME assessment includes, *inter alia*, the following approaches: calculation of Maintenance Expended Limits (MEL) value; economic analysis; Elimination and Choice Translation Reality (ELECTRE); Analytic Hierarchy Process (AHP); Multi-Attribute Failure Mode Analysis (MAFMA); Measuring Attractiveness by a Category Based Evaluation Technique (MACBETH); fuzzy logic; systematic review; Grading of Recommendations Assessment, Development and Evaluation (GRADE).

Lastly, the HT incorporation domain includes three stages: planning; proposal production; receiving and installation. These stages show multiple parameters to be evaluated. In the planning stage, four classes of parameters must be considered. These are Class I: Safety; Class II: Efficacy/Effectiveness; Class III: Infrastructure Impacts, Human Resources, Maintenance and Regulatory Aspects; and Class IV: TCO and Economic Analysis. The proposed production stage must enable technical specification of the technology to meet the clinical and technical needs. At the time of receiving the technology, one must check if the technology satisfies the technical specifications, and if it has all the essential accessories. Only after that, the equipment can be installed as planned and commissioned after performance and safety tests.

Thus, the architecture of the model depends on the inter-relations the domains, where the HT incorporation domain relates to the decision making one and the technology assessment one has multiple parameters and actors involved in the process (decision maker, health system and HCC).

2.5.1 Surveying parameters to be evaluated

Initially, the researcher must verify whether the foundation available for ME incorporation is strong enough to justify detailed assessment of health technology. This is because a thorough assessment of ME needs time, specialist professionals and consequently investments. If the foundation is found unfavorable, the assessment can be aborted with justifications based on the same questions raised for eligibility assessment, following the issues against item 2.3. However, depending on the context and technology under assessment, the incorporation team might ask additional questions during eligibility assessment for an initial map of the technology and thereby avoid wastage of time and investment over unjustified assessment or even unnecessary ME incorporation.

If the eligibility is found to be favorable to technology, one must identify the phase in which the ME is. This is important, because the ME in the adoption or incorporation phase will possibly have higher variation in clinical effect in comparison with that of the ME in usage phase. The ME in the obsolescence phase must be avoided, because of non-availability of spares and high maintenance costs.

It is important that this survey considers the life cycle phases of technology right from the acquisition phase. The ME identified as belonging to previous phases, such as 'under development' and 'pre-market', which are relevant to the health system, must be evaluated by the *Early awareness and alert systems* of EuroScan (Simpson et al., 2009). This is because the technology under the previous phases of incorporation has specific characteristics, mainly in relation to scientific safety evidence and efficacy/effectiveness, as the ME effect has not been observed in large scale.

After assessing the eligibility and identifying the life cycle phase of the ME under consideration for incorporation, one must undertake a more detailed assessment of the technology. This assessment must satisfy all aspects of Classes I, II, III, IV considered in the planning phase of incorporation, as shown in the model presented in Figure 5.

Classes I and II are essential in the evaluation process, because there must be evidences of safety and efficacy/effectiveness that satisfy at least the minimum conditions for using the technology without causing any harm to the patients and users. These parameters must be evaluated from the clinical data available in literature, systematic reviews or HTA approaches, such as the following: *“Methodological Guidelines: Health Technology Assessment Appraisals”* (BRASIL, 2009a), *“Clinical Evidence for Medical Devices: Regulatory Processes Focusing on Europe and the United States of America”* (WHO, 2010) or *“Health Technology Assessment Handbook”* (Jørgensen, 2007; Stenbæk & Jensen, 2007).

In a rational sense, the ME incorporation team must satisfy itself about the quality of the available evidence and assess whether the criteria of safety and efficacy/effectiveness meet the minimum acceptable conditions required to proceed with the assessment of the ME applicant for incorporation. Failing this, it makes no sense to evaluate other aspects.

However, if the results obtained in Classes I and II are favorable, one must try evaluating Classes III and IV. Class III covers different aspects of infrastructure, human resources, maintenance and regulatory procedures. The investigators are encouraged to consider four essential factors in this regard:

- Learning curve: This criterion refers to the time and effort required to train a user in effective use of the ME. For estimating these, the complexity of the ME must first be assessed, because the more complex the ME is, the more would be the time and effort required to train operators and technical team. For information relevant to this criterion, one must check with the distributors, manufacturers, similar ME inventories, and establishments that publish technical manuals about ME, such as ECRI.
- Installation ease: Installation ease is linked to infrastructure conditions, which may include alteration of physical space, adaptors, accessories, compatibility with other technologies, energy, water and gas supply nets, humidity and temperature controls, and input storage needs. Information relevant to these aspects can be obtained from regulatory establishments and sometimes manufacturer's manuals.
- Maintenance ease: This criterion covers all the conditions necessary for executing the maintenance plan. Foremost among them is the availability of professionals in the region, state or country, who can train the technicians and technology users in operating and maintaining the ME to be installed. Besides, one must also ensure a suitably worded guarantee, availability of spares, facilities for software updating, indigenous availability of authorized distributors, and possibility of finding a third party for maintenance through a contract that is linked to the purchasing of goods or even the renting of ME. The most important thing in meeting these requirements is to identify the best cost-benefit ratio that calls for no compromise in meeting the clinical needs, and the one that ensures optimum utilization of the useful life time of the ME.
- Usability: As far as this criterion is concerned, no single technique can answer all the questions. Therefore, what is needed is a combination of techniques, considering the

medical environment limitations, and the human costs in terms of fatigue, stress, frustration, discomfort and satisfaction, learning talent, ME use tax, adaptability to the task and the user's needs, and user's characteristics. To achieve global usability, one must address the following measures:

- Efficacy: Percentage of aims realized, and of users who completed the task successfully, and the average of completed tasks.
- Efficiency: Time to complete a task, tasks completed per unit of time and monetary cost of task realization.
- Satisfaction: Satisfaction scale and frequency of use and complaints.

The usage measures cited above (or their estimates) can be obtained by interviewing the clinical team or from similar ME inventories, and pre-market study reports submitted to the departments concerned by the registrar of commerce, for example, ANVISA⁴ and FDA⁵.

As regards Class IV costs, the criteria that must be considered are those, which might be covered by the TCO and economic analysis. The TCO corresponds to the sum of the costs of acquisition, operation, maintenance, training and replacement. Calculating these costs is sometimes challenging. Therefore, they might be estimated on the basis of information gathered from the distributors, manufacturers and HTA reports. The idea behind estimating the total property cost is to ensure that one does not go just by the acquisition cost, which can be attractive, but also other costs that might go against technology usage.

Through economic analysis, one can investigate the cost-benefit relation to ascertain if the results obtained from the technology under assessment justify the costs, and whether they compare favorably with other technological options that show good cost-benefit relations. Instructions on economic analysis with focus on health technologies can be obtained from the guide *"Methodological Guidelines: Economic Evaluation of Health Technologies"* (BRASIL, 2009b).

These guidelines would be helpful in undertaking the team activities of ME incorporation. However, with the help of the Clinical Engineer, one can add another criterion. The incorporation process will be a challenging one in the context of variations related to geographical regions, health policies, demand, human and financial resources, and cultural aspects, among other pertinent factors.

3. Conclusions

One of the factors that reaffirms the importance of ME incorporation is the improvement in people's health during the last decade, an achievement that could not reach the poor and other socially marginalized or excluded groups earlier. Increasing inequalities in health status are more evident in rural areas. This situation was created by the uneven distribution of money, power and other resources at global, national and local levels, which were in turn influenced by political equations. The health social determinant is mainly responsible for the inequalities in health. The available evidence points to a two-way relationship between poverty and health. Within this vicious circle, poverty creates poor health, and poor health

⁴ <http://portal.anvisa.gov.br>

⁵ <http://www.fda.gov/>

creates poverty. Within the vicious circle of higher income is good health and good health is related with higher income and welfare (WHO, 2011b).

The Clinical Engineering can contribute, through administration and management of ME, to the preparation, guidance and observation of the impact of methodologies aimed at ME incorporation planning in the HCC in the context of health systems. Additionally, adequate incorporation planning requires multidisciplinary knowledge; so, the Clinical Engineer, who has multidisciplinary education, can act as a facilitator by establishing an interface among the actors involved in ME incorporation and by promoting the culture of constant monitoring of the impact of technology on health, after its incorporation in the health system. The observation of the impacts and the lessons learnt from past and recent needs can contribute to planning future incorporation, (Moraes, 2007; Santos & Garcia, 2010; Signori & Garcia, 2010).

Many times, technology management in health is seen as an independent task, but for a few links with other parts of the health service. In other words, in the past, the technical personnel were hardly ever involved in crucial activities such as investment plans, service quality evaluation or organizational issues. However, this scenario has been undergoing some change in the last few years. So, ME management can now be clearly defined as an integral part of the health system and its activity felt at all levels of the public health service (KAUR, 2005a).

The ME cannot be managed in isolation, but only with other components of the health care, including the aims, procedures, finances, level of personnel and support systems at each health service level. To accomplish this, the creation of a multidisciplinary group of management of technology is recommended for each level (local, estate, and national). This group must have representatives of different disciplines: medical, clinical, clinical engineering, support service, purchasing sector, financial and maintenance team of ME (KAUR, 2005a).

Within this context, the incorporated ME is fundamental to health care service, particularly to diagnosis and disease treatment. The available and accessible ME in health care environment is related to the equity and health service offer that is more relevant to the patients' needs. Any national health plan needs policies, strategies and plans of action to health technologies, especially the ME. A robust health system must guarantee access to safe, efficient and high quality ME, in order to prevent, diagnose and treat diseases and injuries, and help the patients in their rehabilitation, and to promote public health (WHO, 2011b).

ME incorporation is an important element of the HTM. This is a complex and multidisciplinary process for developing the activities to support decision making, though some members of the health team and distributors believe that it is just the action of purchasing. For example, costs outside the budget for additional accessories may become necessary after the supply order for ME has already been placed. Or, some unexpected changes may become necessary in installation plans, because the dimensions and other specifications of the ME have not been properly worked out. This entails considerable costs and delays, besides impairing the quality of the public health system. Yet, the technology may remain completely unused, consequently its use can harm the patient or personnel, thus impacting the public health in a negative way (Harding & Epstein, 2006). It underlines

the need to systematize the ME incorporation process and thereby mitigate or eliminate some negative factors of the process that can affect the technology life cycle.

The model proposed here is based on constructing three domains: Decision Making; Technology Assessment and ME incorporation. It can help the incorporation team in identifying, predicting and guiding the realization of measures to minimize possible unfavorable impacts, as also to maximize the benefits obtained through ME incorporation. This is possible because the model has been built on scientific evidence and reliable information available in literature. Besides, the proposed model would be helpful to future researches in that it represents a consolidated methodology that deals with the multiple parameters involved in the ME incorporation process in a systematic and rational way. The Clinical Engineer, as a multidisciplinary education professional, can be a fundamental actor in methodology development and a facilitator of ME incorporation, which can ensure health service deliverance in a safe, effective, and equitable way, besides rational utilization of the resources in the developing countries.

One can observe that health technology, particularly ME, suffers from lack of clinical evidences in the innovation and incorporation phases of the life cycle. Besides, a higher variation is expected on the clinical effect as compared with the technology under wide usage. This is because the technology that belongs to the initial phases has not been monitored on a large enough scale. Therefore, at the time of incorporation, one must prioritize the ME that is in the usage phase. The Clinical Engineering can be helpful to the incorporation team in the identification phase of the life cycle, as well as in the search, selection and assessment of available evidences in literature so as to ensure that the technology to be incorporated is safe and effective. So, the deliverance of health system with quality and equality contributes to the promotion of public health (Sônego, 2007).

Additionally, it is important to highlight that the phases of technology life cycle are not independent, i. e., actions in any one phase can impact other phases. For example, an inadequate incorporation plan can lead to high costs of maintenance, unavailability of technology, risks to patients and users, and spilling of unsatisfactory clinical results into other phases of the ME life cycle (Moraes, 2007).

Lastly, one must note that, after ME incorporation, the Clinical Engineer retains the management of other phases of technology life cycle with him for future ME updating, improvement and replacement. The services of Clinical Engineering are more necessary at this stage to deal with the responsibility of ME management program within the framework of guidelines that range from the strategic phase to the replacement phase.

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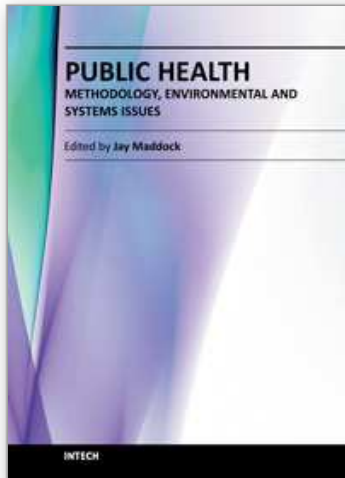
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Public health can be thought of as a series of complex systems. Many things that individual living in high income countries take for granted like the control of infectious disease, clean, potable water, low infant mortality rates require a high functioning systems comprised of numerous actors, locations and interactions to work. Many people only notice public health when that system fails. This book explores several systems in public health including aspects of the food system, health care system and emerging issues including waste minimization in nanosilver. Several chapters address global health concerns including non-communicable disease prevention, poverty and health-longevity medicine. The book also presents several novel methodologies for better modeling and assessment of essential public health issues.

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