

We are IntechOpen, the world's leading publisher of Open Access books Built by scientists, for scientists

6,900

Open access books available

186,000

International authors and editors

200M

Downloads

Our authors are among the

154

Countries delivered to

TOP 1%

most cited scientists

12.2%

Contributors from top 500 universities



WEB OF SCIENCE™

Selection of our books indexed in the Book Citation Index
in Web of Science™ Core Collection (BKCI)

Interested in publishing with us?
Contact book.department@intechopen.com

Numbers displayed above are based on latest data collected.
For more information visit www.intechopen.com



Clinical Engineering

Pietro Derrico, Matteo Ritrovato,
Federico Nocchi, Francesco Faggiano,
Carlo Capussotto, Tiziana Franchin and Liliana De Vivo
*IRCCS Ospedale Pediatrico Bambino Gesù, Rome,
Italy*

1. Introduction

Clinical Engineering (CE) represents the part of *Biomedical Engineering* focused on the applications of theories and methodologies of the broad biomedical engineering field to improve the quality of health services. Its activities especially concern the appropriate management of biomedical technologies (from purchasing to risk controlling) and the development and the adjustment of hospital informative systems and telemedicine networks. *CE* combines with the medicine knowledge for conducting of healthcare activities by providing expertise in a wide spectrum of topics, from human physiology and biomechanics to electronics and computer science.

As biomedical technology developed towards ever more complex systems and spread in every clinical practice, so the field of *CE* grew. Such growth has been accompanied by an analogous expansion of biomedical and clinical engineering studies at the University and development of skills and tasks of *CE* professionals.

The main aim of *CE* is to support the use of biomedical technology by health professionals and hospital organizations with appropriate skills in order to reach the best compromise between clinical efficacy/efficiency, patient and operators safety, care quality and innovation, and management and equipment costs.

CE techniques and methodologies are mainly focused on safe, appropriate and economical management of technologies, as well as on governance and management (limited to specific responsibilities) of healthcare facility. Thus, *CE* covers all those knowledge and methods applied to the management of biomedical technologies, ranging from their early evaluation and assessment, to their technical conduct, to their dismissing. Thus the chapter will highlight different aspects of technology management by exploring technical and/or clinical, and/or economic issues related to the individuation and acquisition of appropriate equipment (i.e., Health Technology Assessment), acceptance testing, management of preventive and corrective maintenance, risk management, planning of quality testing, ICT management, management of maintenance contracts, equipments replacement planning, and so on.

2. Healthcare risk management

Because of the strong pressure on the health structures to optimize the services provided while lowering the associated costs and reducing the likelihood of adverse events, an

organizational approach, in which a Healthcare Risk Management program plays a central role, becomes important.

Mistakes can be minimized, in fact, by creating organizational systems and using technologies to make it easier to do the right thing. It is clear that patient safety can be increased by means of appropriate procedures aimed at avoiding possible mistakes or correcting those that do happen.

In particular, the potential for biomedical equipment related adverse events needs to be analyzed in order to prevent their occurrence: healthcare structures have to use systematic analytical methods and instruments to manage technological risks to both patients and operators.

The aim of the health organizations is to take care of patients, by providing effective, appropriate and, in particular, safe treatments. The healthcare institutions (such as the clinicians themselves) have to ensure the care, as adequate as possible, of patients, avoiding or at least containing damage caused by human and system errors. Healthcare service activities connote, in fact, with the presence of several hazards that have the potential to harm patients and health operators.

Currently the best known approach is the Healthcare Risk Management program, with which it is possible to identify, assess, mitigate and control healthcare facilities risks, and thus realize the concept of "systemic safety".

Originally such approaches focused mainly, if not entirely, on the problem of reducing the "Clinical Risk" (Clinical Risk Management, CRM) with the aim of limiting enterprise liability-costs. In fact, over the course of the last several years healthcare institutions and practitioners have experienced a "malpractice crisis" that has led to the increase in jury verdicts, settlement amounts and insurance premiums, as well as dwindling insurance availability due to carrier withdrawals from the medical malpractice market (McCaffrey & Hagg-Rickert, 2010), and consequent increase of risk retention cost.

Gradually, the focus shifted to clinical problems and thus the term CRM now encompasses strategies to reduce the incidence and magnitude of harm and improve the quality of care (Taylor-Adams, et al., 1999) by focusing on patient safety and patient care related issues, including information gathering systems, loss control efforts, professional liability, risk financing and claims management activities.

2.1 Technological risk management

Dealing with clinical risk and patient safety means also dealing with biomedical technologies. In fact, as medical treatments have greatly progressed along with the analogous technological advances in medical equipment (ME), all medical procedures depend, to some extent, on technology to achieve their goals. Despite the (presupposed) inherent safety of MEs (also guaranteed by a plethora of laws and technical standards), device-related adverse events occur every day in hospitals around the world. Some can be very dangerous and occasionally even deadly.

An adverse event is (as defined by Medicines and Healthcare Products Regulatory Agency, MHRA) "an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons". ME related adverse events can occur for several reasons, ranging from incorrect choice and acquisition of the device, wrong installation, and poor maintenance, to use error and device obsolescence.

As stated before, a systemic approach is needed. Such an approach, identified as Medical Equipments Risk Management (MERM), is part of the global Technology Management

(Wilkins & Holley, 1998) as practised by the Clinical Engineering Department (CED) within the hospital. The specific activities of the MERM process are, as coded by several international standards (AS/NZS 4360:2004; ISO 14971:2007; ISO 31000:2009) regarding risk management applied to general production processes and specifically to the design and production of medical devices (but addressed to manufacturers, not the users, of medical equipment) as follows:

- risk identification
- risk analysis and assessment (including risk prioritization);
- planning of actions to mitigate the risk;
- tracking of information about the implemented actions;
- control and follow up.

All the standards stress that the task of risk assessment, along with risk identification, is the most important element. This is mainly because all the measures the CED (as well as the healthcare organization as a whole) will take to reduce the level of risk will depend on the results of these two phases: an error in assessment would probably lead to several mistakes (and therefore waste of economical and human resources) in the subsequent phases.

Given below is a brief description of the methods available for addressing risk analysis and assessment. However, a thorough analysis of the remaining phases is left to the reader, since they require the active involvement of several lines of professionals, and thus are strongly dependent on the organizational and operational arrangements of the specific healthcare facility.

2.1.1 Methods and techniques

Risk identification and risk analysis are processes aimed at identifying the type of hazard and determining the potential severity associated with an identified risk and the probability that a harmful event will occur. Together, these factors establish the “seriousness of a risk” and guide the clinical engineer’s choice of an appropriate “risk treatment” strategy (including preventive maintenance, user training, definition of a renewal plan, etc.).

Techniques for risk identification and assessment are various and dependent on the specific kind of hazard under assessment. In the healthcare sector, two techniques are widely and commonly used: Failure Mode and Effects Analysis and Root Cause Analysis.

Failure Mode and Effect Analysis (FMEA) is a systematic process for identifying potential process and technical failures, with the intent to eliminate them or minimize their likelihood, before they occur, that is in advance of the occurrence of the adverse event related to the analyzed risk (American Society for Healthcare Risk Management [ASHRM], 2002). Initiated in the 1940s by the U.S. Defense Department, FMEA was further developed by the aerospace and automobile industries, but it was only in the late 1960s that it was first applied to healthcare processes. Since then, in the healthcare sector, Failure Mode and Effects Analysis has been developed as a systematic, proactive method for evaluating clinical processes to identify where and how they might fail, and to assess the relative impact (in terms of damage to patients, workers and facilities) of different failures in order to identify the parts of the process that are most in need of change.

The rationale of FMEA is the acknowledgement that errors are inevitable and predictable, and thus can be anticipated and/or minimized by design.

As suggested by the name, the focus is on the *Failure Mode* (defined as the incorrect behavior of a subsystem or component due to a physical or human reason), on the *Effect* (defined as the consequences of a failure on operation, function or functionality, or status of some item)

and, potentially (in which case the acronym becomes FMECA) on *Criticality* (defined as the combination of the probability that a failure will occur and the severity of its effect on the system or subsystem). In other words FMEA (or FMECA) analysis aims to identify and analyze

- All potential failure modes of a system and components of the system;
- The effects these failures may have on the system and parts of the system;
- How to avoid or reduce the probability of the failures, or mitigate the effects of the failures on the system.

Depicted below is a schematic, step-by-step description of how to conduct the FMEA process:

1. Define the FMEA topic.
 - Write a clear definition of the process to be studied.
 - Narrow the scope of the review so that it is manageable, and the actions are practical and able to be implemented.
2. Assemble the Team.
 - Guarantee the multidisciplinary of the team by including expert representatives of all affected areas.
 - Identify the team leader/coordinator.
3. Prepare a graphic description of the process
 - Create and verify the flow chart.
 - Number each process step.
 - For complex processes, specify the area to focus on.
 - Identify and create a flow chart of the subprocesses.
4. Conduct a Hazard Analysis
 - List all possible/potential failure modes for each process/subprocess.
 - List all the possible causes of the *failure mode* (each failure mode may have multiple failure mode causes).
 - Determine the “severity (S)”, “probability (P)” and “detectability (D).”
 - Determine the Risk Priority Number ($RPN = S \times P \times D$).
 - Determine if the failure mode warrants further action (e.g. $RPN > 32$).
5. Actions and Outcome Measures
 - identify actions or strategies to reduce the *Risk Priority Number* for each failure mode

The other widely adopted methodology is Root Cause Analysis (RCA) that aims to assess risks affecting healthcare activities by investigating the adverse events which have occurred. RCA is an analytic tool for performing a comprehensive, system-based review of critical incidents. It includes the identification of the root cause and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans (Canadian Patient Safety Institute [CPSI], 2006). Unlike FMEA, which is a proactive and preventive process, RCA is carried out retrospectively in response to a specific, harmful event.

The main purpose of the RCA is to uncover the factor(s) that led to and caused the serious preventable adverse event. The preventable adverse event is very often the tip of the iceberg. Conducting and writing an RCA is an opportunity to examine how the systems for providing care function. The more areas investigated, the greater the possibility the system(s) will become better functioning and prevent the next event from occurring.

RCA focuses on the “how” and the “why”, not on the “who”. The goals of a root cause analysis are to determine:

- what happened;
- why it happened;
- what can be done to reduce the likelihood of recurrence.

A step by step description of the RCA may be depicted as follows:

1. Plan of action
 - strategies the organization intends to implement in order to reduce the risk of similar events occurring in the future.
 - responsibility for implementation, supervision, pilot testing as appropriate, time lines, and strategies for measuring the effectiveness of the actions.
2. What happened / Facts of the event
 - Information about the patient
 - Details of the event
 - Use of interviews, brain storming, or written description, etc.
3. Why it happened
 - Individuate the contributory factors
4. Identify root causes
 - Identification of the “Root Causes”
5. Minimize recurrence/monitoring
 - Implementation of each specific action that will be measured and communicated

The final goal of both methodologies is to address the commitment of healthcare organizations to reduce the likelihood or severity of adverse events. However, besides their technical, practical and philosophical differences, both present a major fault/drawback when applied to the specific case of medical equipment risk assessment. In fact, the methods themselves require some form of subjective assessment, mainly due to lack of quantitative data on which the assessment could be based. Moreover, to assess the risk related to the entire biomedical technological assets of healthcare facilities would certainly require a more systematic and structured method for collecting and processing data.

A possible solution to this problem could be an adapted implementation of the Risk Map or Risk Matrix (Ruge, 2004; Cox, 2008). A *risk matrix (risk map)* is a table (Cartesian diagram) that presents on its rows (y-axis), the category of *probability (or likelihood or frequency)* and on its columns (x-axis), the category of *severity (or impact or consequences)*. Each cell of the table (or point in the Cartesian plane), which mathematically represents the product of the probability and severity values, is associated to a level of risk that eventually identifies the urgency or priority of the required mitigation actions.

The figure 1 shows an example of risk matrix, where probability and severity have been split into a range of five values, whereas risk level is categorized into three classes.

Thus, the risk assessment problem can be reduced to the estimate of probability and severity values. The estimate of severity does not present any particular concerns: by analyzing equipment design and features (such as, also, the FDA or CE risk classification), device user manual, clinical procedure and medical room in which the ME is used, it should be easy to determine the maximum possible damage the ME could do to the patient (or even to the operator). Moreover, such elements can be easily described by specifically defined numeric variables (for instance, all the considered aspects can be assigned values ranging from 1 to 5, in analogy with the main Risk Matrix axe values) and recorded in the equipment

management system used by the CED. Lastly, by defining a computation method (whose complexity can vary from a very simple linear sum up to more complex fuzzy or neural network systems) the severity value can be associated to each ME owned by the healthcare facility.

However, the achievement of a robust, objective estimate of probability definitely presents more difficulties. In particular, it would be preferable to take into account only measurable characteristics, thus using easily quantifiable numeric variables.

			CONSEQUENCE				
			Minor	Moderate	Serious	Major	Catastrophic
			1	2	3	4	5
LIKLIHOOD	Rare	1					
	Unlikely	2					
	Likely	3					
	Expected	4					
	Certain	5					

Harm occurrence Likelihood levels

- -Certain: will occur on every occasion
- Expected: is expected to occur in most circumstances (e.g. more than 2 times a year)
- Likely: could occur in many circumstances (e.g. probable to happen up to 2 times a year)
- Unlikely: could occur occasionally (e.g. possibility of happening once a year)
- Rare: not expected to happen, but is possible (even if no occurrence registered)

Harm severity levels

- Catastrophic: multiple deaths
- Major: possibility of death or major permanent loss of function (motor, sensory, physiologic, or intellectual)
- Serious: major injury / adverse health outcome (e.g. possibility of permanent lessening of bodily functioning)
- Moderate : moderate injury / adverse health outcome (e.g. increased length of stay)
- Minor: no or minor injury/adverse health outcome;

Estimated risk levels: -Red: unacceptable risk -Yellow: tolerable risk -Green: acceptable risk

Fig. 1. Example of Risk Matrix

The complexity of estimating probability stems from the fact that probability is dependent on three main different but inter-influenced issues: human factor, medical device functional reliability, medical device design and environmental characteristics (Brueley, 1989; Anderson, 1990; Dillon, 2000; FDA, 1997; FDA, 2000; Samore, et al., 2004). So, estimating the probability value must take into account the evaluation of these three elements. In estimating the human factor element, one must take into account not only those characteristics of the ME, of the process and/or of the environment that may facilitate a human error leading to an adverse event, but also the factors that may make the operator take corrective action for a ME or system failure. The ME functional reliability refers to the potential for device (material and/or functional) failure, potentially leading to an adverse event. Aspects to be considered are those related to the device reliability assessment such as the execution of safety checks, assessment of device obsolescence, and respect of a preventive maintenance plan. Medical device design and environmental characteristics are those related respectively to the possibility of the ME having specific features that could lead to an adverse event without the occurrence of material or functional failure or human error, and to the presence of environmental factors that could cause the ME to fail.

When defining the elements to be analyzed on each ME owned by the hospital, two considerations apply:

- Define measurable variables more quantitatively.
- Prefer elements (variables) already monitored by the organization and recorded in an information system (such as the ME management system used by the CED)

Table 1 shows an example of variables for probability estimation.

Human factor	Medical device functional reliability	Medical device design and environmental characteristics
Availability (at point of use) of complete written instructions (e.g., user manual) from the manufacturer	Device obsolescence	Appropriateness of wiring according to clinical activities and devices
Device ergonomics	Existence and respect of a preventive maintenance plan	Environmental conditions (noise, temperature, vibrations, electromagnetic interference, etc.)
Difficult working conditions (staff shortage, staff shifts, etc.)	Results of safety checks (cfr. IEC or ISO or EN safety standards)	The device is appropriate for the clinical needs for which it is intended
Environmental conditions (noise, temperature, lighting, space, etc.)		
Schedule and records of a training and education program on the use of specific ME and its related risks		

Table 1. List of possible variables for estimation of probability.

As is done for estimating severity, the last step consists of defining a computation method to elaborate the identified variables. Also, in this case the complexity of the method may vary from a very simple linear sum up to more complex fuzzy or neural network systems.

3. Health Technology Assessment

Nowadays many factors, ranging from the aging of population to the continuous fast-paced technology innovation, as well as the even more critical scarcity of economic resources, emphasize the importance of correct resource allocation at every level of a national health care system. This background adds to the criticality and complexity of decision-making, rendering essential a thorough evaluation which takes into consideration all the areas (health benefits, risks, costs, etc.) where health technology may have an impact..

A variety of specific methods and tools are available to support health care and medical decision making, for example Health Technology Assessment (HTA), a standardized methodology that can help decision makers select the most appropriate choice for their specific context.

HTA is a multidisciplinary process that systematically examines the technical performance, safety, clinical efficacy, effectiveness, cost, cost-effectiveness ratio, organizational

implications, social consequences and legal and ethical considerations of the application of a health technology (EUNEHTA).

Advances in science and engineering
Intellectual property, especially patent protection
Aging population
“Cascade” effects of unnecessary tests, unexpected results, patient or physician anxiety
Emerging pathogens and other disease threats
Third-party payment
Inability of third-party payers to limit coverage
Financial incentives of technology companies, clinicians, and others
Clinician specialty training at academic medical centers
Malpractice avoidance
Provider competition to offer state-of-the-art technology
Public demand driven by consumer awareness, direct-to-consumer advertising, and mass media reports
Strong economies, high employment

Table 2. Factors that reinforce the market for health technology (Goodman 2004)

The term “health technology” is quite broad and includes the following categories: drugs, biologics, medical devices, equipment and supplies, medical and surgical procedures, support systems, organizational and managerial systems.

HTA may address the direct, intended consequences of technologies as well as their indirect, unintended consequences; its main purpose is to inform technology-related policy-making in health care.

HTA is increasingly used in American and European countries to inform decision- and policy-making in the health care sector and several countries have integrated HTA into policy, governance, reimbursement or regulatory processes.

3.1 Conducting an HTA process

An HTA process is conducted by interdisciplinary groups using explicit analytical frameworks drawing from a variety of methods: given the variety of impacts addressed and the range of methods that may be used in an assessment, several types of experts are needed in HTA.

Depending upon the topic and scope of assessment, these may include a selection of the following (Goodman, 2004):

- Physicians, nurses, dentists, and other clinicians
- Managers of hospitals, clinics, nursing homes, and other health care institutions
- Radiology technicians, laboratory technicians and other health professionals
- Clinical and biomedical engineers
- Pharmacologists
- Patients or patient representatives
- Epidemiologists
- Biostatisticians
- Economists
- Lawyers
- Social scientists
- Ethicists
- Decision scientists
- Computer scientists/programmers
- Librarians/information specialists

According to a recent study there are also significant differences in the practical application of HTA. Whereas in some countries HTA merely studies the clinical effectiveness and perhaps safety and cost-effectiveness of technologies, agencies in other countries apply a broader perspective and also consider other issues, such as ethics, and organizational, social or legal aspects of technology.

It is also known that the HTA activities can be carried out at different levels of health-care systems:

- macro level (international and national - i.e. decision-making within central government institutions)
- meso level (administrative level - i.e. regional or provincial health authorities, agencies, primary health-care units or hospitals);
- micro level (clinical practice)

At each of these levels, however, these activities should be carried out by a multidisciplinary staff, involving clinicians, clinical engineers, economists, epidemiologists, etc.) and, depending on the object of evaluation, also by specifically qualified professionals from the hospital departments.

Assessment reason	
New technology	Safety concerns
Changes in old technology	Ethical concerns
New indications for old technology	Economic concerns
New findings	Investment decisions
Structural/organizational changes	

Table 3. Reasons for performing an assessment (Velasco, et al., 2002)

3.2 The technical evaluation

As discussed in the previous paragraph, HTA now represents a multidimensional field of inquiry that increasingly responds to broad social forces such as citizen participation, accelerated technological innovation, and the allocation of scarce resources among competing priorities (Battista, 2006).

However,, this methodology was initially focused and applied on a small scale, concerning (clinical) engineering questions pertaining to a technology's safety and technical performances, and involving the investigation of one or more properties, impacts, or other features of health technologies or applications.

The *technical evaluation* represents, in fact, the core object of Clinical Engineering (CE) activity in HTA and is often conducted at a *meso* level. Many hospitals are increasingly developing HTA processes by means of *HTA Commissions* or structured *HTA Unit*, that include the CED.

In the *Health Technology*, CED are typically involved in the technical evaluation of the *medical electrical equipment* (as defined by the IEC 60601-1-1 normative) and sometimes of *medical devices*.

The main features characterizing these kinds of technologies can be summarized as follows:

- fast-changing technologies: their development is characterized by a constant flow of incremental product improvements;
- device impact on clinical and safety outcome depends on user training and experience that can vary and are hard to evaluate;

- the life cycle of a device is often as short as 18–24 months, which is considerably less than, for example, pharmaceuticals;
- the clinical application of the technology and potential utility for patients (accuracy or effectiveness) in comparison with the reference standard;
- improvement in the operating principle;
- state of development of technology (emerging, new, established);
- impact on organization (implementation phase, change in the treatment, users' qualification, IT requirements, etc.);
- impact on patient and user safety;
- economic aspects (acquisition, maintenance, spare parts, training, etc.);
- devices cannot be evaluated by RCTs – hard to blind and randomize. Early evaluation not possible

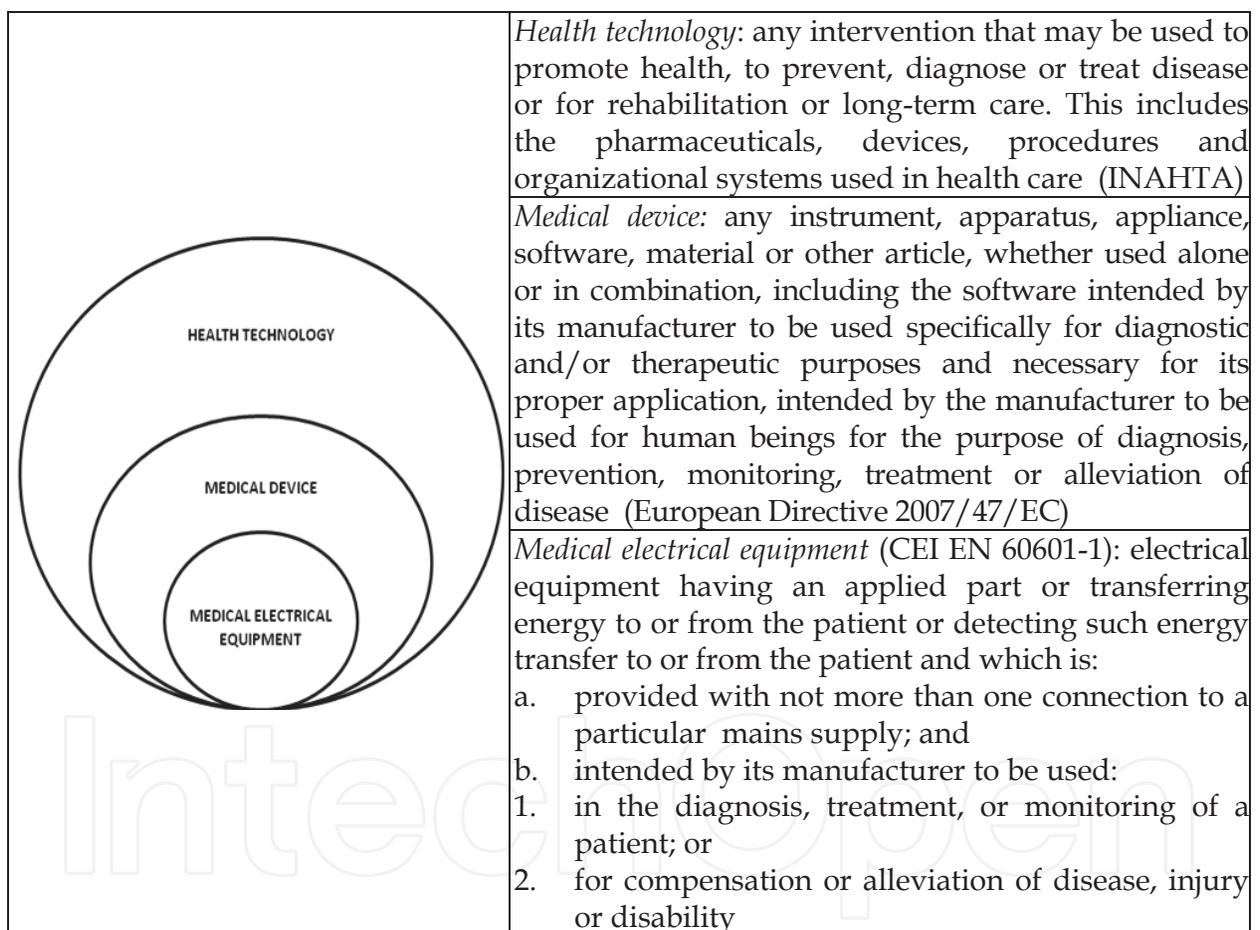


Fig. 2. Representation of Health Technology, Medical Device and Medical Electrical Equipment sets

A further classification of *medical electrical equipment* can be made according to their main characteristics or function. For instance, as can be found in the Italian CIVAB classification, *medical electrical equipment* can be grouped in three technological compartments:

- Functional explorations and therapeutic equipment;
- Medical laboratory or clinical chemistry equipment;
- Bio-imaging equipment.

The HTA process, while maintaining a uniform and systematic approach, may have to primarily focus on different characteristics because of the different weighting or different evaluation methodologies for the following aspects:

- Innovation
- Technology management
- Investment (big ticket technology; high volume purchase; service)
- Safety
- Efficacy
- Organization.

Functional explorations and therapeutic equipment often undergo relevant innovation, such as that involving the change of the physical or biological operating principle, which is difficult to evaluate empirically (“impossibility” of randomized controlled trial (RCT), short Time To Market vs short mean life). As regards safety, *electromedical equipment* are regulated by directives and technical norms that constitute not only a fair guarantee of their safety but also a valid guide to evaluate it for the specific context of its intended utilization. Moreover, patient safety strongly depends on user education and training in equipment use. Equipment’s efficacy is often evaluated only by design data or in vitro or animal model tests. As such devices represent the greater part of an institute’s biomedical equipment assets, organizational, economical and management issues become fairly important: uniformity of equipment can facilitate technological management (including risk issues), rationalize maintenance, take advantage of scale factors (equipment acquisition and renewal, consumables/spare parts).

Assessment of innovation for *Medical Laboratory equipment* has to accommodate the continuous introduction of new reagents and controls as well as the presence of homebrew technology, particularly in the most advanced fields such as Proteomics and Metabolomics. As concerns the management of these technologies, uniformity of equipment is also important for better and easier use by the operators, and ensures the availability of backup equipment. The most common mode of acquisition is by rental or service, where the cost of the equipment is included in the cost of the reagents.

Bio-Imaging equipment have been subject to innovations in virtually all aspects of their functioning, e.g. improvement of technical performances (e.g. spatial resolution), change in physical or biological operating principle (e.g. fMRI), safety for operators and patients (e.g. X-ray dose reduction). Their empirical evaluation is usually more practicable than for other kinds of equipment, particularly when testing no side-effects of technologies. Patient and operator safety relies on operational, technical and organizational issues (e.g. use of minimum dose setting for x-ray exams, implementing X-ray or magnetic shielding walls and ceilings, limiting access to exam room). As their complexity increases, so does the importance of user education and training to ensure a safe use of all the technological facilities. These kinds of technologies may have a very high cost both for their acquisition and for the necessary structural changes.

The aim of the HTA process, developed within a healthcare facility, is to guide decision-makers on the “correct” acquisition or implementation of a health technology, from different viewpoints:

- *clinical* : efficacy, risk/benefit rate, effect on current clinical procedures;
- *technological*: technical and technological efficacy, technical specifications (technological and structural interfaces), management and maintenance activities;
- *enterprise* : efficiency, productivity, impact on human (acceptability) and/or structural (e.g., need for building changes) and/or technological (e.g., need for HIS changes) resources.

3.1.1 Methods for technical evaluation

The evaluation of the technical characteristics of a device can be performed in different ways. A technique based on the European network for Health Technology Assessment (EUnetHTA) model is described below.

The EUnetHTA proposes an assessment scheme based on a basic unit, called assessment *element*. Each *element* defines a piece of information that describes the technology or the consequences or implications of its use, or the patients and the disease for which it is applied. An *assessment element* is composed of an *evaluation area*, a *macro key performance indicator* and a *micro key performance indicator* (see Figure 3a).

The *evaluation area* (*domain*) represents a wide framework within which the technology is considered. It provides an angle of viewing the use, consequences and implications of any technology. The following domains are considered:

The nature of the elements may vary across domains, since the consequences and implications are understood and studied differently in each domain. The following domains are considered:

1. Health problem and current use of technology
2. Technical specifications
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organizational aspects
8. Social aspects
9. Legal aspects.

A *Macro Key Performance Indicator* (*Macro KPI* or *topic*) represents a more specific area of consideration within any of the *evaluation areas*. One *evaluation area* is divided into several *Macro KPIs*. Similar *Macro KPIs* may be assigned to more than one *evaluation area*. A *Micro Key Performance Indicator* (*Micro KPI* or *issue*) is a specific area of consideration within any of the *Macro KPI*. One *Macro KPI* typically consists of several *Micro KPIs*, but it may also contain only one *Micro KPI*.

The first task to accomplish in order to carry out the HTA process relates to the identification and definition of each KPI. To do this, the following steps are required:

Step 1. Literature search

A thorough literature analysis should be carried out by consulting the most important bibliographical sources such as clinical search engines (Pubmed, Medline, ISI Web of Knowledge, Cochrane Library, etc.), the national and international website of the HTA Agency (INAHTA, HTAi, EUnetHTA, Euroscan) or Institutes (ECRI, FDA, etc.), clinical practice guidelines, grey literature (technical reports from government agencies or scientific research groups, working papers from research groups or committees, white papers, or preprints). Other potential sources of data are manufacturers of the technology, clinicians, nurses, paramedics and patients.

The search can be performed by using main keywords for the technology in question (for example limiting the research in “abstract/title” OR “topic” fields). The most interesting results of these searches are selected and details investigated in order to intensify and develop the assessment.

Step 2. Identify the assessment elements

The analysis of the literature should therefore lead to the definition of the assessment elements, which are the core of the assessment. They are categorized into “evaluation area”,

“macro KPI” and “micro KPI”. In order to make the assessment as objective as possible, the specific characteristics that support the assessment of a single area (and, subsequently, of the whole health technology) must be fully and measurably detailed, therefore objective and “instrumentally” measurable indicators are preferred. Moreover, those KPI that cannot be evaluated a priori should be excluded from the assessment.

Typically, the unit of measurement of KPIs may be:

- metric (e.g. spatial resolution, image uniformity, laser spot size, analytical specificity, etc.)
- expressed as a percentage of coverage of the clinical/production/technical needs (e.g. percentage of coverage of analytical test panel; percentage of coverage of nominal "productivity");
- ON/OFF (presence/absence of a specific feature or functionality)

Numerical Value	Verbal Scale	Explanation
1	Equal importance of both elements	Two elements contribute equally
3	Moderate importance of one element compared to another	Experience and judgment favor one element over another
5	Strong importance of one element compared to another	An element is strongly favored
7	Very strong importance of one element compared to another	An element is very strongly dominant
9	Extreme importance of one element compared to another	An element is favored by at least one order of magnitude
2, 4, 6, 8	Intermediate values	Used to reach a compromise between two judgments

Table 4. Saaty scale

Step 3. Weight of the indicators

After the assessment elements have been identified, it is necessary to define the decision-making framework and in particular to estimate the value of the weight of each element: such activity must involve the whole multidisciplinary evaluation team.

The definition of the weights, in fact, is a constituent part of the mathematical model of data processing, selected among those available in literature, such as the Analytic Hierarchy Process (AHP), expert systems based on Artificial Neural Network (ANN), and methodologies based on decision Fuzzy logic or Support Vector Machine (SVM).

With reference to AHP, for example, a structured questionnaire with a series of "pairwise comparisons" between the assessment elements can be used: each team member will be required, therefore, to compare on a qualitative scale e.g., Saaty scale, see table 4) the relative importance of the two compared elements. Finally, after the comparison of all pairs, the weight of each indicator will be calculated.

Step 4. Value of the indicators

The next step is to assess each technological alternative (the subject of the assessment) on the basis of the mathematical framework so far implemented. For this purpose, we assign values (quantitative or qualitative) to each lowest level KPI (usually a micro KPI, but also macro KPI and, rarely, even an evaluation area), on the basis of available literature data, and technical specifications or expert judgment. These values are then aggregated by the computational model to produce the value and rank of the single health technology.

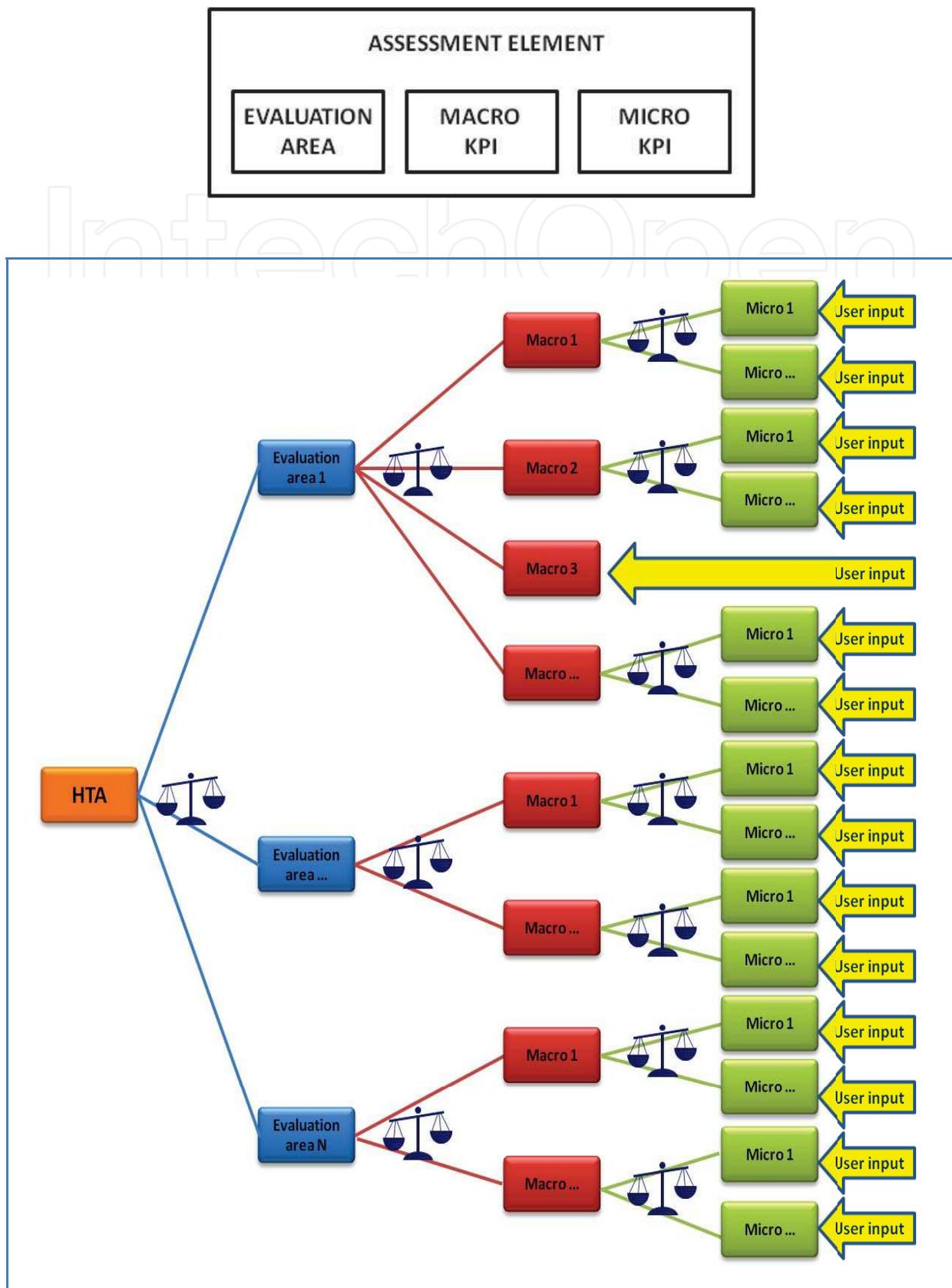


Fig. 3. a) The assessment element ; b) Combination of evaluation areas, macro KPI and micro KPI

Step 4. Results

The results obtained by aggregating the values can be represented graphically or through numerical reports. In particular, results can be processed to allow, for example:

- the comparison between the technological alternatives in order to show the performance on each evaluation area and/or macro KPI and/or Micro KPI;
- the comparison between weights of evaluation areas, macro and micro KPIs
- analysis of the evaluation tree with evidence of weighted values for each technological alternative
- etc.

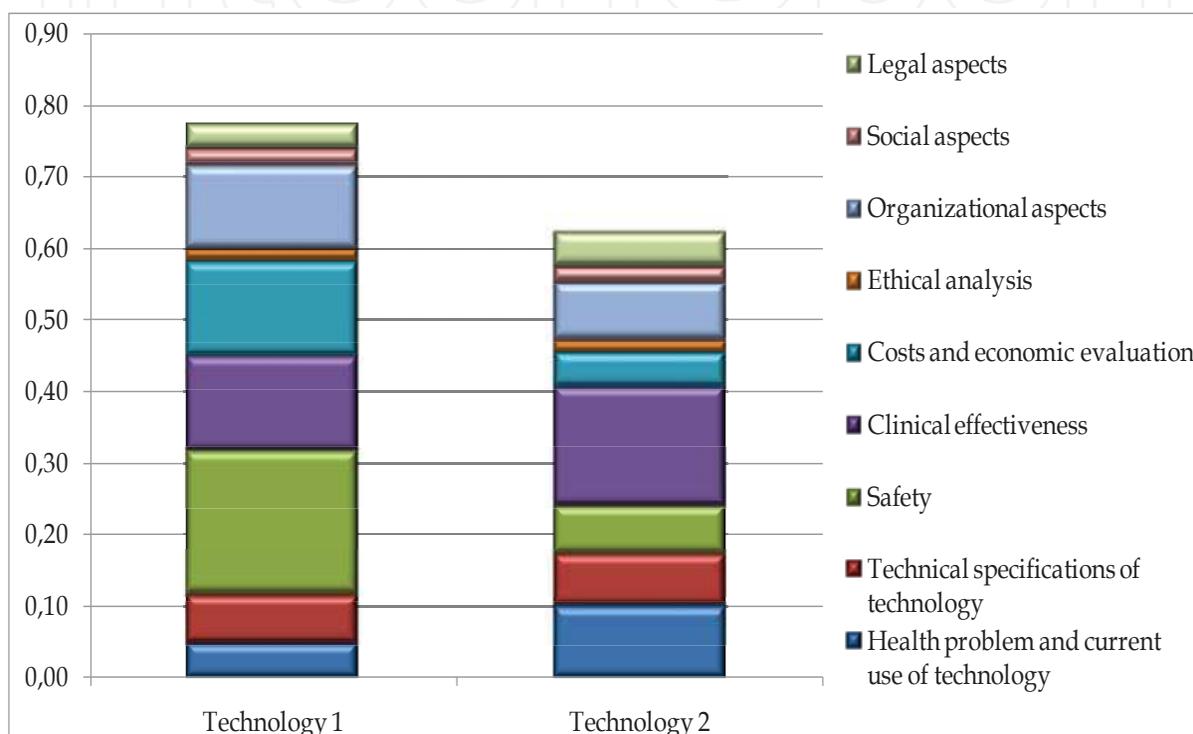


Fig. 4. Example of graphical representation of comparison of two health technologies

The HTA report

The final HTA report must provide the decision-makers with a clear, understandable summary of the information described above, in order to help them select the most appropriate technology. Moreover, it is essential to follow a standardized scheme, preferably one from a HTA agency or scientific community. However, it cannot be considered acceptable unless it contains the following sections:

- document summary;
- description of the technical characteristics and operating modalities of analyzed technologies;
- summary of findings of literature search;
- description of the criteria, indicators, macro and micro KPI;
- definition of weights;
- assigned values and mathematical processing method;
- results (e.g., ranking, charts, graphs, etc.)
- bibliography

4. Technology management

Hundreds to many thousands of medical devices may need to be managed in a healthcare facility, with several million Euros being invested each year for the acquisition of new health technologies and for planned technology replacement, while thousands of maintenance processes per year are required in order to maintain the efficiency of these devices. As evident from the analysis of adverse events occurring during the last few years, serious incidents can often be related to the malfunctioning of medical devices. In particular, a high degree of obsolescence of the technologies, as well as missed, inadequate or improper maintenance, are among the possible causes of failure not attributable to the manufacturer. Therefore, in every healthcare facility, responsibility for the safe management of medical devices should be identified. The CED can provide a relevant contribution to the prevention of adverse events resulting from medical device failures by the technical and clinical assessment of the technologies to be acquired and proper management of maintenance. Different organizational models can be used to manage the above mentioned activities (Italian Ministry of Health, 2009): an internal service with employees of the healthcare facility; a mixed service, with internal control by clinical engineers as well as by means of maintenance contracts with manufacturers and technicians who may either be employees of the healthcare facility or of specialized companies; finally, an external service, with technical assistance entirely outsourced to a “global service” provider. Each of these three models has advantages and disadvantages. The first approach allows timely intervention and a better control of maintenance activities; however it is only justified when there is a sufficiently large quantity of technological equipment in the healthcare facility, and also requires the continuous training of the technical staff: Furthermore, maintenance contracts with manufacturers are still necessary for high-technology equipment. The second model permits flexibility as regards the organizational structure of the healthcare facility, internal control of processes, and a better integration of skills. The last organizational model is often preferred by healthcare facilities that do not yet have a CED; it allows organizational flexibility, but requires a careful selection of a qualified external company and authoritative supervision by the healthcare facility staff, otherwise control of the processes will be progressively lost and the quality of service will deteriorate.

4.1 Preventive and corrective maintenance, safety and performance tests

Maintenance of medical devices has gradually evolved from the operational repair of out of order equipment to a management function aimed at preventing breakdown and failures, thus reducing risks associated with the use of medical devices, decreasing downtime and contributing to the improvement of diagnostic and therapeutic pathways, where technology is a key determinant. Healthcare facilities should identify responsibilities for maintenance and plan maintenance activities based on a detailed definition of methods, resources (i.e., operators, laboratories, measuring equipment, and maintenance contracts with external suppliers) and tools for supervision of the activities (e.g. dedicated software for the maintenance data management). To ensure adequate quality and safety standards and the rationalization of maintenance activities, a plan for maintenance and safety tests must be implemented, taking into account, for each device, the risks for patients and operators, degree of criticality and function of the device (e.g., therapeutic, diagnostic, or analytical). Within the European Community, preventive maintenance must be planned by the

manufacturer prior to marketing the device. The 2007/47/EC Directive states that “the instructions for use must contain ... details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times”. Preventive maintenance is of critical importance for ensuring the safe use of devices. Therefore, a preventive maintenance plan for each device must be defined, well documented and available at all operational levels to personnel responsible for maintenance tasks, including daily maintenance. Documentation should include informative documents and specific operating instructions which take into account both mandatory technical regulations and the service and user manuals provided by the manufacturer. Preventive maintenance is particularly relevant for life support devices, equipment for diagnosis and treatment, and devices identified as critical in relation to specific aspects such as the intended use of the device, class of risk, clinical features, type of location in which it is installed (e.g. operating room, intensive care unit, ward), and presence of backup units. In carrying out the maintenance, the responsible technician must take into account all the maintenance instructions provided mandatorily by the manufacturer. Without affecting the liability of the manufacturer for any original product defects or faults, the person(s) performing maintenance will assume direct responsibility for all events deriving from this action. It is therefore essential that technicians, whether internal or external (see par. 5), have specific and proven experience. Training programs should be planned and preferably technicians should be trained by the manufacturers of the technologies which they maintain. Software for medical use deserves special consideration. Due to the complexity of systems and interactions, software behaviour may not be completely deterministic even when principles of good design practice are respected. Thus, software maintenance, which is usually performed by the manufacturer, should be supervised by the healthcare facility. Safety and performance tests must be periodically performed in order to ensure compliance with the essential safety requirements set by technical standards. The frequency of tests should be established taking into account criticality of device and according to reference guidelines. Particular attention is required in testing devices that can be used for critical applications (e.g., ventilators, anesthesia machines, infusion pumps, defibrillators, electrosurgical units) and for devices emitting or detecting ionizing radiations. Specific procedures and forms for different types of devices should be adopted to examine, measure, and verify the conformity of the device with the current mandatory technical standards and the instructions contained in the user manuals provided by the manufacturer. Dedicated equipment, for which calibration must be regularly performed and documented, should be used to measure parameters specific to each type of technology. Strategies for improving maintenance will only succeed if supervised effectively by external maintenance technicians in order to ensure their compliance with the agreed conditions (see par. 5). All relevant data relating to the life cycle of each device (from acceptance testing to disposal) must be recorded and made available at different operational levels. In order to ensure full traceability of the maintenance processes, preventive and corrective maintenance activities must be documented by detailed technical reports. In particular, preventive maintenance notice should be used to document the regularity of activities. Forms for maintenance requests to the CED must be defined and corrective maintenance notice should contain data useful for the identification of appropriate indicators (e.g. frequency of failures, time of first intervention, time to resolution, average downtime, distribution of failure types, maintenance costs, cost of spare parts), through which the condition of installed medical equipment can be analyzed.

4.2 Issues in inventory management

Establishing a complete and reliable inventory of medical equipment and ensuring the quality of the data is a complex task. Several different kinds of events, although rare, can lead to discrepancies between the inventory database and the technologies actually being used in a healthcare facility. These mismatches can be significantly reduced by establishing appropriate procedures and ensuring their strict observance. However, the large number of operators, devices and suppliers, the need to give priority to emergency care and the difficulty in directly and continuously monitoring the use of all devices in the healthcare facility, may inevitably produce such discrepancies. Failure to follow correct procedures for new equipment commissioning, for equipment transfer between departments, or for equipment disposal, are among the many possible events that could cause these mismatches. One possible solution is the use of Radio Frequency Identification (RFID) tags and asset tracking systems. However, the use of this approach is limited because of ongoing debate about electromagnetic compatibility issues, and because the considerable cost of installation and management of these systems makes them still out of reach of most healthcare facilities. Until an advanced asset tracking solution is lacking in a healthcare facility, alternative strategies need to be implemented to keep the inventory data up-to-date. One way to monitor and update inventory data is through preventive and corrective maintenance or safety tests performed by CED technicians or by external service providers. Finally, it may be necessary to plan periodic inventory checks, which will be carried out independently or collaboratively by the CED and/or by the assets management office. Such controls may also provide an opportunity to remove devices that are no longer in use but are kept in stock and which may represent a source of risk.

4.3 Acquisitions and replacement plan

During the last decades, planning health technology acquisitions has become of strategic importance for healthcare organizations, both at the national and at facility level. Such planning is also essential task for the reduction of clinical risk associated with the use of medical devices. The importance of acquisition planning is also determined by the considerable increase in technology investments, which is due to the increase in number and rapid technological evolution of medical devices and systems.

Therefore, healthcare organizations should define specific methods for planning the acquisition of health technology. Such methods should take into account the obsolescence of devices, the evolution of technical standards, the possibility of improving safety for patients and healthcare operators, the possible availability of innovative technologies for improving clinical performance, as well as considerations about actual or expected clinical needs, economic or technical feasibility, organizational changes, and investment priorities (e.g., innovative technologies vs device renewal). Moreover, the availability of adequate infrastructure, staff and consumables for the equipment must be foreseen in order to ensure full use of the benefits provided by the new technology. The decision to proceed with the acquisition should be conditional on the presence of a detailed clinical, economic and technical assessment with well defined comparative criteria, carried out by qualified and multidisciplinary staff and inspired by the principles of HTA (see par. 2). An equipment replacement plan is aimed at better identification of investment priorities for device renewal and may be based on the definition of a replacement priority value (RPV). RPV is an index which represents synthetically the level of urgency for the replacement of each device, permitting determination of a replacement priority ranking and planning of a progressive

replacement of technologies (Fennigkoh, 1992). Variables considered by the RPV computational algorithm may come from different sources, principally the CED database and clinical activities records. Variables must be carefully chosen, according to the organization of the healthcare facility and based on data availability. In fact, the effort needed for collecting new data and keeping it up-to-date must be considered in order to limit the amount of new data to be collected and to make the best use of the data already available. A typical model for computing the RPV is based on the use of component indexes, with each index highlighting the impact on a specific aspect of the device replacement. A coefficient must be assigned to each component index in order to weight its contribution to the RPV. Possible aspects that might be taken into account, by defining specific numeric variables, are obsolescence of the device, maintainability (e.g. cost and availability of spare parts), reliability (e.g. downtime or number of failures), criticality, strategic impact, clinical efficacy, efficiency, clinical risk, potential for performance improvement. For example, the cost of replaced spare parts, the number of technical activities performed by the technicians of the CED, the annual cost of contracts and the cost of technical assistance by external suppliers will be taken into account in the computation of the component index for maintenance costs.

5. Technical and economic issues in management of service contracts

A quality assurance requirement for clinical assistance is the implementation of related processes based on the principles of best/good practice standards. In the field of management of medical devices, this concept is fundamental for meeting the need of retaining costs and providing effectiveness in patient care.

CEDs are also evaluated as to their ability to implement a policy of Good Management Practice of biomedical technologies (Cheng & Dyro, 2004). Related economic aspects, such as medical equipment maintenance costs, are a critical issue of such management (Table 5).

Element	Financial	Internal processes	Customer satisfaction	Training and continuing education for CE staff
Measure	Staffing Beds per full-time equivalent employee Service/Acquisition ratio	Percent of IPM Complete IPM interval IPM time Repair time	Annual survey	Time spent on these activities Certifications obtained

Table 5. A balanced performance scorecard for Benchmarking CE departments (Gaev, 2010a)

Clinical engineers play a fundamental role in determining the proper strategy for medical equipment maintenance and in recognizing the best available option for supporting these activities. More specifically, the CED is in charge of setting the expected level of performance, monitoring the quality and integrity of the delivered services, dividing activities between internal and external BMETs, and pursuing the goal of an expense reduction policy. For this reason, before maintaining biomedical technologies, CEDs should plan rational acquisitions, allotting part of the organization budget for service contracts.

A service contract is an agreement between a company and a user for the maintenance, in this case, of medical equipment during a specific period of time, usually for a fixed price which may be subject to changes if maintenance activities are performed outside the user's location. The term "maintenance" typically includes inspection, preventive maintenance and repair. The terms and conditions of the contract usually stipulate the days and hours of service, the types of service, the response time, and which parts to be replaced are replaced free of charge" (Gaev, 2010b). This sort of contract can be extended to include the free loan of biomedical technologies. In this case, prices stated in the service contract are for consumables used for the equipment's functions, and are increased to include maintenance costs.

Reasons for having a service contract for a biomedical device are several. The first reason is the impossibility to provide a cost-effective service through in-house CED because of the lack of human and logistical resources. This is particularly common in hospitals where the problem of cost containment is approached with the sole objective of cost cutting and with no other financial or economic performance policy.

The second main cause is that healthcare governance is particularly reluctant to assume responsibility for equipment maintenance, and the belief that original equipment manufacturer (OEM) service contracts represent the "gold standard" is difficult to remove. On the other hand, for certain classes of medical devices (those characterized by high-technological complexity or high consumable costs, such as clinical chemistry analyzers), service contracts seem to be the only realistic solution for accommodating their management costs. The main issues which have to be discussed and negotiated in the drawing up of a service contract are: inspection and preventive maintenance, repair, spare parts, legal and financial aspects.

The term "Inspection and Preventive Maintenance (IPM)" covers all the activities involved in cleaning, lubricating, adjusting, checking for wear, and perhaps replacing components that could cause total breakdown or serious functional impairment of the equipment before the next scheduled inspection (Subhan, 2006).

These activities are well-described in the manufacturer's service manual and are aimed at avoiding the breakdown of a medical device in use, without any apparent warning of failure. Manufacturers are obliged to explicate preventive maintenance actions to healthcare operators or BMETs, and to suggest the minimum inspection frequency. The definition and respect of a timetable for IPM of all medical equipment is fundamental for reducing risk for patients and users, and preventing excessive repair costs by providing timely interventions; and it should be the CED's first priority, and should be decided before carrying out preventive maintenance activities.

Contracts should clearly explain the necessity of making known to all concerned the timetable for the maintenance by external technicians at the beginning of the year, in agreement with the CED and the healthcare personnel. This will allow the organization of clinical activities for healthcare operators and the possibility to enter the whole agenda into the biomedical technology maintenance management system. One other particular observation relates to the availability (at the charge of the contractor) of software update if required for the correct operation of the biomedical instrumentation. The last consideration relates to the possibility for CEDs (according to their competence) to evaluate the IPM requirements of medical equipment (Table 6) and to modify the service intervals recommended by the manufacturer, to obtain a more cost-effective maintenance without adversely affecting patient safety.

Repair (corrective maintenance) is a process to restore the physical integrity, safety and/or performance of a device after a failure. Aspects to be considered pertain to economic, safety and logistic concerns. Contracts should explain who can call for technical support: this aspect is fundamental for organizing the internal maintenance process. One possible solution would be for the healthcare personnel to first of all attempt to resolve the problem by telephone (with proper manufacturer's customer support), and to define an internal procedure for advising the CED of the failure. In this way, the CED can monitor failure resolution time by the manufacturer's technicians by means of its maintenance management system.

Device	Shortest IPM Interval	Longest IPM Interval
Electrosurgical unit	6 months	12 months
Exam light	12 months	No IPM performer
Physiologic monitor	12 months	24 months
Pulse oximeter	12 months	No IPM performer

Table 6. Variations in IPM intervals for selected equipment, proposed by ECRI Inst. (2010)

Another significant aspect related to maintenance contracts is the definition of "bad-management" of biomedical technologies by healthcare personnel which may cause failure of the equipment. Some manufacturers are reluctant (or do not agree) to repair equipment under contract if abuse or improper use by hospital staff caused the failure. It is essential that the internal training of healthcare staff makes them aware of their responsibility for the correct use of biomedical equipment.

Moreover, in the contract, clinical engineers should define a way to evaluate the performance of OEM technicians, and stipulate the right to suspend the service contract in the event of low-quality maintenance work.

A common aspect of IPM and repair contracts is the possibility of a partnership for maintenance activities between the OEM technical support and the BMETs (internal or outsourced). Some manufacturers only permit maintenance activities by qualified (and certified by the OEM itself) technicians. Positive results of partnership contracts were showed just a few years ago. A first Italian joint project between OEMs and in-house service was started in 2002 (De Vivo et al., 2004): in-house personnel received adequate training, both generic (basic principles on which devices work) and specific (how to use, repair and maintain a particular model), for maintaining 90 medical devices (mostly monitoring equipment, ventilators and anesthesia units) in shared OEM/internal BMETs maintenance contracts.

Figure 5 summarizes the success of this program. One important effect was the increased awareness of the OEMs about the need for a rational selection of an effective preventive maintenance program in which service procedures and frequencies are based on real world feedback, efficacy of activities are measured and areas needing improvement are identified.

Clinical Engineers are also in charge of compiling technical reports related to maintenance activities (for instance, by means of an appropriate software system, see par. 6). These data are essential for monitoring the quality of OEM services, and claiming economic and legal penalties. Service contracts should also clearly explain the accuracy level of report writing, to avoid possible future disputes.

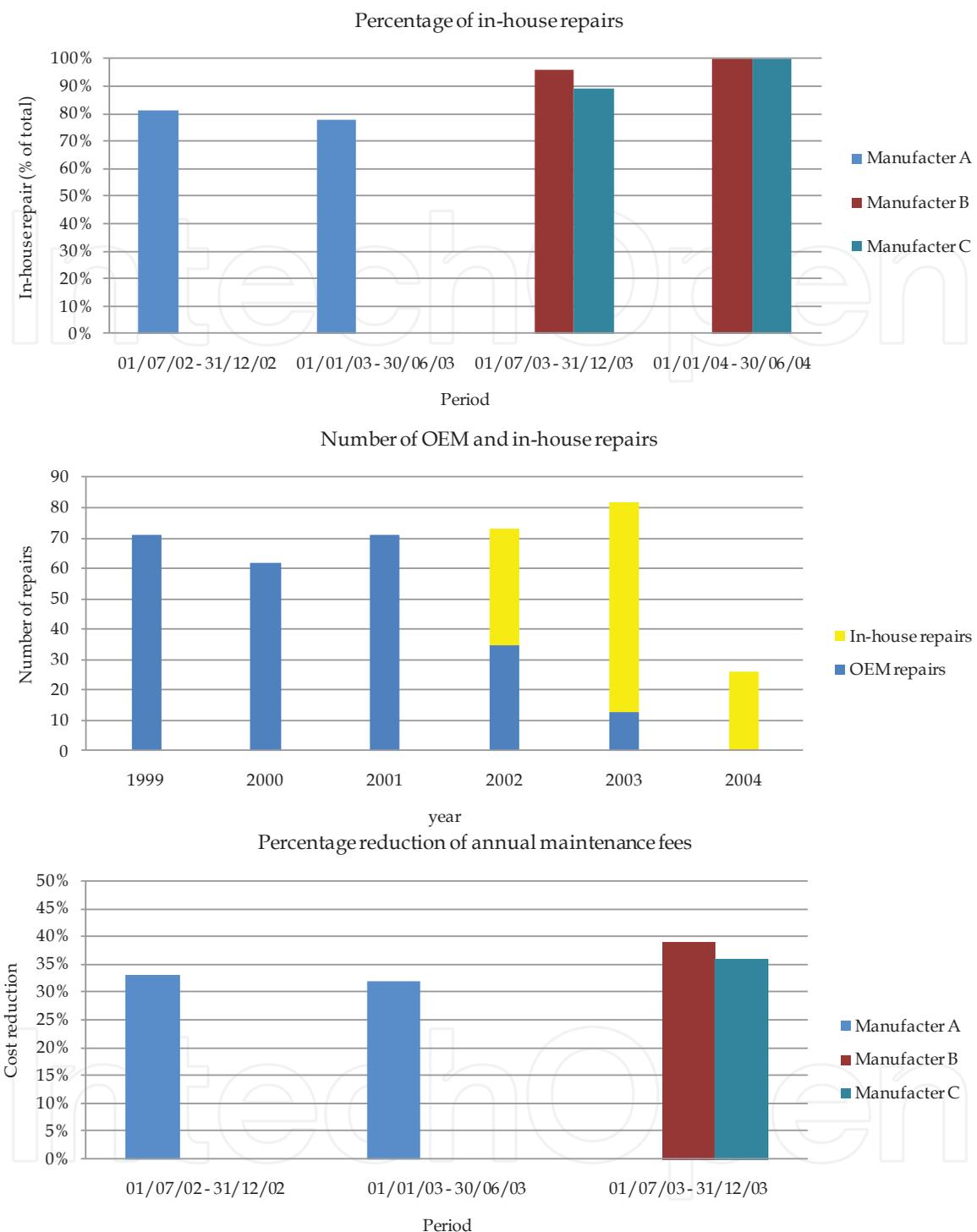


Fig. 5. a) Percentage of in-house repairs (July 2002-March 2004). The number of in-house repairs reached 90% and more after one year and continue to grow as in-house personnel sharpen their required basic skills. b) Number of OEM and in-house repairs (years 1999-2004). The decrease in OEM corrective maintenance was soon significant: as a consequence, OEMs were able to focus their attention on accurate preventive maintenance in order to prevent certain predictable failures. c) Percentage reduction of annual maintenance fees. Significant discounts were obtained based on the percentage of in-house corrective maintenance, justifying the cost related to internal technicians and the energies needed to set up the whole system.

Service contracts should include a specific paragraph on spare parts. OEM contracts usually lack the inclusion of them or any specification of the condition (e.g. new, refurbished) of parts used for maintenance and repair (Gaev, 2010b). It should be the duty of clinical engineers to assess the need for spare parts and include them in the contract, in dedicated annexes.

The economic assessment of service contracts is done using the definition of financial performance indexes. The most common index is the service cost/acquisition cost (S/A) ratio, i.e. the total cost to deliver a service, including parts and labor, divided by the acquisition cost of the equipment. Services delivered by OEMs (or third-party service suppliers) under a full-service contract usually include IPM and repair. The cost of same service delivered by an in-house CED is computed from the amount spent on parts and CED labor (labor hours) multiplied by the "loaded" rate including salary, benefits and other overhead expenses. In-house service is generally less expensive (50 percent less) than full-service OEM contract, even if this estimation varies significantly according to the equipment category. A recent ECRI review shows that imaging and high-tech laboratory equipment has a higher S/A ratio and is thus more costly to maintain than general biomedical equipment, even if this ratio may vary greatly due to institutional (e.g., teaching vs non teaching institution), logistics (e.g., urban vs rural hospital) as well as operational (e.g., low vs high negotiated acquisition price) differences (Gaev, 2010a).

Particular consideration should be given to the drawing-up of penalty clauses for the possibility of non-compliant service, the latter defined in terms of technical response time and equipment uptime/downtime. Moreover, competitive benchmarking for service contracts should also take into account fees for service outside of contract work hours, and any minimum charges required for travel time, service time, and work performed outside of the usual contract provisions. However, to make effective the use of penalty clauses, essential tools have to be set in place such as the computerized management of processes, implementation of a contact center (phone or online) for maintenance requests, systematic review of the quality of maintenance activities, failure analyses, and strict control of performance indicators and maintenance costs.

6. Issues in information technology and Clinical Engineering Department (CED) activities

Any action undertaken to improve the management/control of medical devices in a healthcare facility through an efficient and effective organization of maintenance and technology assessment activities, requires the implementation of operating procedures that enable the standardization of CED processes. However, the rapid evolution of health technologies during the last decades and the spread of heterogeneous technologies, besides bringing undeniable clinical improvements, have resulted in a considerable increase in technology investments, with the subsequent need for tools that can aid decision making in acquiring new technologies and managing the existing ones. To achieve the double goal of correctly applying and automating procedures and of implementing a model for the appropriate management of available resources and the proper definition of priorities, a comprehensive and reliable dataset for health technologies as well as an appropriate software tool to support data management will be required. Electronic archives are thus essential for storing all data and all events in the life of the medical devices managed by the CED, from the technology assessment that should always precede their acquisition until

their disposal. Such a tool will permit safer documentation and reporting of the maintenance and management activities, sharing of information between the CED and other hospital staff, a dramatic improvement in data search, provision of summary statistics, and the definition of indicators that may contribute to the proper management of health technologies. The organization of this database may vary markedly depending on heterogeneous factors such as healthcare facility organization, technical and administrative management policies, number of devices, and resources dedicated to data management. The opportunity to support and significantly improve the management of medical equipment makes it advisable to implement a solution that can be configured and easily updated according to the evolution of specific needs. The configurable features of the system should include database design, user interfaces, queries, reports and statistics. The possibility to configure the database is useful not only for adding tables and fields, but also for the development of new features and adaptation of the software to the organizational structure of the healthcare facility. Configurable user interfaces should include at least the appropriate forms for inventory, acceptance testing, safety and performance tests, maintenance processes, preventive maintenance plan, maintenance contracts, disposal of devices, and administrative data management. Customizable configurations for different users should be guaranteed, in order to adapt the software according to the role and responsibilities of each user, with different data visualization and operating permissions. System users should be allowed to extract and export data in convenient formats (e.g., spreadsheets) for offline processing. Templates for standard documents (e.g. acceptance testing reports, maintenance reports) must be available and it should be easy to obtain automatically filled in and ready-to-print documents. It should be possible to analyze data with a configurable statistics dashboard. Such a system architecture would be suitable for developing methods for health technologies management and for defining indicators for the implementation of a technology replacement plan, the identification of maintenance priorities, and the optimization of resources allocation. Ultimately, being able to customize the software makes it possible to update the structure and configuration of the system according to the organization and evolution of operational requirements specific to a particular healthcare facility, and also makes it a suitable tool to support the development of processes. This feature is also particularly relevant for the purpose of satisfying the requirements for certification and the standards for national and international accreditation. The configuration should be performed or at least supervised by the CED staff, who best know the specific needs of the organizational context in which the software is to be used. Another advisable solution is to adopt systems that are accessible via the facility's intranet. Web-based systems that do not require any client-side software installation are useful for sharing information between the different actors involved and can improve the automation of processes for Health Technology Management (HTM). Moreover, with web-based systems it is possible for health operators to access many support features for the management of technologies. They can submit online requests for corrective maintenance, monitor the real-time evolution of submitted requests, search the database for devices, preventive maintenance plan or safety tests, and receive automatic e-mail notifications when certain events occur (e.g. , maintenance processes closed by biomed technicians, reminders for scheduled maintenance). This approach also has the advantage that only one data entry is needed (e.g., biomed technicians no longer have to re-enter data that have already been entered by the health operators on the maintenance request form). Obviously, all users should be trained in at least the basic principles of the system. The use of such a system for

the management of medical devices can be extended to (or integrated with) the management of other technological facilities, ICT equipment, and other hospital assets.

6.1 Management of the acquisition process

A number of advantages for budget management can be gained by using computerized procedures for online submission of requests from heads of hospital units for the acquisition of new medical devices. Specification of medical device type according to a standard nomenclature system could be required, which would avoid the use of disparate terms for the same equipment. Also, the use of required fields in the electronic request form (e.g., reason for the acquisition, expected benefits, consumables needed) would ensure that all requests contain the essential information for their proper assessment. The medical board, with the support of the CED, would then have the right tools to manage the submitted requests in a uniform manner and make an objective analysis. assign a priority ranking to each request, and finally decide which ones to approve and which to reject. This approach could also be useful for the activation of hospital-based HTA (HB-HTA) processes (see par. 2). Furthermore, the authorization process (i.e., approval by department directors and medical board or medical devices committee) can be automated and differentiated according to the type of acquisition (e.g. property, loan, service, rental, clinical trial). Approval of the request will be automatically notified and immediately available online. The technology renewal plan managed by the CED may be integrated and partially automated in the software by implementing an algorithm for calculating the replacement priority value (see par. 4). Following the approval of requests for new acquisitions and replacement of medical devices, the automation of CED processes would provide valuable support for the management of data and documents relating to the assessment and acquisition of technologies. Information concerning single budget items (e.g., type of acquisition, number of requested devices, allocated budget) and on acquisition progress (i.e., end of the market survey, drafting and issuance of the technical assessment, date of order by the administration, supplier name) can be shared between the CED and the healthcare facility administration, with automatic update of acquisition progress and online availability of documents for each budget item. At all stages, starting from submission of the requests, only a single data entry is needed.

6.2 Acceptance testing and inventory management

In a computerized system for managing CED's processes, each medical device has its own inventory record containing the data relevant to its management (e.g., device model, accessories, system configuration, owner hospital unit, location, administrative data). Each device in the inventory must be uniquely identified, and the CED must place an identifying label on it. As stated above, the adoption of a standard medical device nomenclature for model identification is also strongly recommended. If a web-based system is used, health operators will be able to search for inventory records and obtain lists of devices that can be exported onto spreadsheets. For each device in the inventory, the acceptance testing must be registered in the system. The status of the device can be updated automatically and an e-mail notification sent upon completion of testing.. In order to keep the inventory data up-to-date, in addition to routine administrative tasks, periodic inventory checks must also be made. In this regard, mobile units (e.g., PDA) equipped with a tag (e.g. barcode, RfID) reader, properly configured and synchronized with the CED software system, can be a useful tool. This approach allows easier tracking of devices and verification of equipment

location and condition, as well as updating of system components. Another useful feature is the online availability of documents. These could include pre-acquisition documents (e.g., market survey, technical assessment, order form), user and service manuals, acceptance testing documents and training course forms, as well as pictures of system configurations and accessories.

6.3 Maintenance processes

Maintenance processes management could exploit the availability of an appropriate software tool. As stated above, a useful feature is the possibility for health operators, in case of failure of a medical device, to request corrective maintenance online. Maintenance activities should then be recorded in the system by CED biomed technicians. CED can enter and update the maintenance plan (i.e., the preventive maintenance activities for which both internal technicians and external maintenance personnel will be appointed) and share it, as well as related information (e.g. maintenance progress, e-mail notification of upcoming preventive maintenance), with all hospital units involved. Health operators should be allowed to retrieve and export lists of maintenance requests. Thousands of safety and performance tests are performed on medical devices each year by the CED. Thus the availability of test reports to health operators is only possible by implementing an automatic upload system. Radiology equipment deserves a particular mention in that it is usually managed by both CED and the Medical Physics Unit. This requires sharing of information on preventive and corrective maintenance and quality controls. Finally, the software tool can also be used to facilitate the management of spare parts. Online access to maintenance documents (i.e., preventive and corrective maintenance activities, safety and performance test reports, administrative documents) is another desirable feature. The availability of such electronic information enables the CED to analyze the history of maintenance processes for each device, to improve monitoring of maintenance activities performed both by CED technicians and by external maintenance personnel, to verify the compliance of suppliers with maintenance contracts, to gather downtime statistics, and to generate summaries of maintenance costs. Finally, algorithms can be defined and implemented to combine device replacement priority value (see par. 4) and maintenance priority rank for immediate identification of the most urgent corrective actions. Automated information sharing can also be helpful for the disposal of devices. The way this feature can be configured depends on the specific organization. For example, CED could be in charge of notifying the hospital unit of device disposal, while the physical removal of the device would be the responsibility of the facility handling service. An automatic e-mail notification of disposal confirmation to the CED would allow an easier tracking of out of order devices, thus reducing inconvenience and risk for patients and health operators.

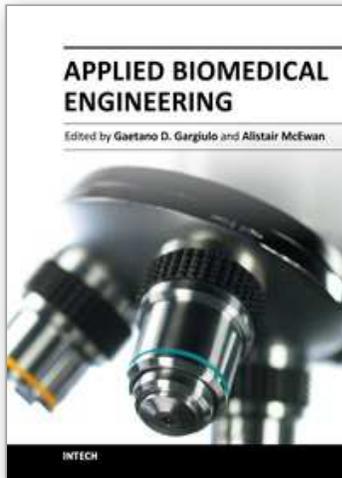
7. References

- American Society for Healthcare Risk Management. (2002). Strategies and tips for maximizing failure mode and effect analysis in an organization. *J Healthc Risk Manag*, 22(3), 9-12.
- Anderson, F. A. (1990). Medical Device Risk Assessment. In *The Medical Device Industry: Science, Technology, and Regulation in a Competitive Environment* (p. 487-493). Marcel Dekker Ltd.

- AS/NZS 4360:2004. *Risk Management Standard*.
- Battista, R. (2006). Expanding the scientific basis of health technology assessment: a research agenda for the next decade. *Int J Technol Assess Health Care* , 22(3), 275-80.
- Brueley, M. (1989). Ergonomics and errors: who is responsible? *Proceedings of the first symposium on Human Factors in medical device*, (p. 6-10).
- Canadian Patient Safety Institute. (2006). *CPSI, Canadian Root Cause Analysis framework: a tool for identifying and addressing the root causes of critical incidents in healthcare*.
- CEI EN 60601-1 (n.d.). Medical electrical equipment, Part 1: General requirements for basic safety and essential performance.
- Cheng, M.; Dyro, J.F. (2004). Good Management Practice for Medical Equipment, In: *Clinical Engineering Handbook*, J. F. Dyro, (Ed.), 108-110, Academic Press Inc., ISBN 978-0-12-226570-9, Burlington, Massachusetts, USA
- Cox, L. J. (2008). What's Wrong with Risk Matrices? *Risk Analysis* , 28 (2), 497-512.
- De Vivo, L.; Derrico, P.; Tomaiuolo, D.; Capussotto, C. ; Reali, A. (2004). Evaluating alternative service contracts for medical equipment, *Proceedings of IEEE EMBS 2004 26th Annual International Conference*, pp. 3485-3488, IBSN 0-7803-8439-3, San Francisco, California, USA, September 1-5, 2004
- Dillon, B. (2000). *Medical Device Reliability and associated areas*. CRC Press.
- Draborg, E., Gyrd-Hansen, D., Poulsen, P. B., & Horder, M. (2005). International comparison of the definition and the practical application of health technology assessment. *Int J Technol Assess Health Care* , 21(1), 89-95.
- EUNEHTA. (n.d.). *Work Package 4: HTA Core Model for Diagnostic Technologies*. Available from www.eunetha.net.
- European Directive 2007/47/EC.
- FDA. (1997). *Design Control Guidance for Medical Device Manufacturers*.
- FDA. (2000). *Guidance for Industry and FDA Premarket and Design Control Reviewers - Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management*.
- Fennigkoh - A Medical Equipment Replacement Model. *Journal of Clinical Engineering*. 17(1):43-47, January/February 1992
- Gaev, J.A. (2010). Benchmarking Service Contracts, In: *TechNation*, June 2010, Available from <https://www.ecri.org/>
- Gaev, J.A. (2010). Successful Measure: benchmarking clinical engineering performance, In: *Health Facilities Management*, February 2010, Available from <https://www.ecri.org/>
- Garrido, V. M., Kristensen, F., Palmhøj Niel, C., & Busse, R. (2008). *Health technology assessment and health policy-making in Europe. Current status, challenges and potential*. Available from www.euro.who.int.
- Goodman, C. (2004). *Introduction to Health Technology Assessment, HTA 101*.
- INAHTA. (n.d.). *Glossary*. Available from www.inahta.org .
- ISO 14971:2007. *Medical devices - Application of risk management to medical devices*.
- ISO 31000:2009. *Risk management - Principles and guidelines*.
- Italian Ministry of Health - Recommendation for the Prevention of Adverse Events Consequent to the Malfunctioning of Medical Devices/Electrical Equipment - Recommendation #9 April 2009
- Mccaffrey, J., & Hagg-Rickert, S. (2010). Development of a Risk Management Program. In A. S. (ASHRM), *Risk Management Handbook for Health Care Organizations*.

- Ruge, B. (2004). Risk Matrix as Tool for Risk Assessment in the Chemical Process Industries. *ESREL 2004*, (p. paper 0192).
- Samore, M. H., Evans, R., Lassen, A., Gould, P., Lloyd, J., Gardner, R., et al. (2004). Journal of the American Medical Association. *Surveillance of medical device-related hazards and adverse events in hospitalized patients*, *JAMA*. 2004;291(3): , 325-334.
- Subhan, A. (2006). Equipment Maintenance, Biomedical. In: *Encyclopedia of Medical Devices and Instrumentation*, J.G.Webster, 289-321, John Wiley & Sons, Inc., NJ USA
- Taylor-Adams, S., Vincent, C., Stanhope, N. (1999). Applying human factors methods to the investigation and analysis of clinical adverse events. *Safety Science* , 31, 143-159.
- Velasco, M., Perleth, M., Drummond, M., Gürtner, F., Jørgensen, T., Jovell, A. (2002). Best practice in undertaking and reporting health technology assessments. *Int J Technol Assess Health Care* , 18(2), 361-422.
- Wilkins, R., & Holley, L. (1998). Risk management in medical equipment management. *Proceedings of the 20th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. 6, p. 3343-3345., Hong Kong Sar, China, October 1998

IntechOpen



Applied Biomedical Engineering

Edited by Dr. Gaetano Gargiulo

ISBN 978-953-307-256-2

Hard cover, 500 pages

Publisher InTech

Published online 23, August, 2011

Published in print edition August, 2011

This book presents a collection of recent and extended academic works in selected topics of biomedical technology, biomedical instrumentations, biomedical signal processing and bio-imaging. This wide range of topics provide a valuable update to researchers in the multidisciplinary area of biomedical engineering and an interesting introduction for engineers new to the area. The techniques covered include modelling, experimentation and discussion with the application areas ranging from bio-sensors development to neurophysiology, telemedicine and biomedical signal classification.

How to reference

In order to correctly reference this scholarly work, feel free to copy and paste the following:

Pietro Derrico, Matteo Ritrovato, Federico Nocchi, Francesco Faggiano, Carlo Capussotto, Tiziana Franchin and Liliana De Vivo (2011). Clinical Engineering, Applied Biomedical Engineering, Dr. Gaetano Gargiulo (Ed.), ISBN: 978-953-307-256-2, InTech, Available from: <http://www.intechopen.com/books/applied-biomedical-engineering/clinical-engineering>

INTECH
open science | open minds

InTech Europe

University Campus STeP Ri
Slavka Krautzeka 83/A
51000 Rijeka, Croatia
Phone: +385 (51) 770 447
Fax: +385 (51) 686 166
www.intechopen.com

InTech China

Unit 405, Office Block, Hotel Equatorial Shanghai
No.65, Yan An Road (West), Shanghai, 200040, China
中国上海市延安西路65号上海国际贵都大饭店办公楼405单元
Phone: +86-21-62489820
Fax: +86-21-62489821

© 2011 The Author(s). Licensee IntechOpen. This chapter is distributed under the terms of the [Creative Commons Attribution-NonCommercial-ShareAlike-3.0 License](#), which permits use, distribution and reproduction for non-commercial purposes, provided the original is properly cited and derivative works building on this content are distributed under the same license.

IntechOpen

IntechOpen