Chapter 6
The Medical Devices in Healthcare Provider Organisations

Carlo Boccato

Abstract Medical devices impact the daily practice of healthcare provider organisations. Elements that contribute to the quality of the healthcare treatment and how they are organised will be discussed in this chapter.

Medical devices in their different declinations and definitions must be considered in respect to their overall life cycle to achieve the best results.

A healthcare provided organisation is a complex system characterised by many multifaceted and non-linear connections among the different components and actors. The adoption of complex medical devices introduces additional factors that increases this complexity. System thinking and a holistic approach are required for the successful management of the activities and to ensure safety and quality of care.

The case of haemodialysis treatment is taken as a paradigm for the application of a complex medical device system for the treatment of a chronic disease, analysing the impacts of the technology on the infrastructure and government of the healthcare provider.

Introduction

Elements that contribute to the quality of the healthcare treatment and their application and organisation need to be considered. In the following a comprehensive picture will be given about the introduction and operation of the medical devices of different complexity in Healthcare Provider Organisations (HPOs). The term HPO identifies every organisations devoted to the diagnosis and treatment of illness or making rehabilitation, considering both in- and outpatients. Most of the following considerations are valid both if the healing actions are conducted inside the organisation itself and when the medical device is used at patient's home under the supervision and responsibility of the HPO.

The starting point is the analysis of the elements that contribute to the quality of the service given to the patients and community and the impact that the application of medical devices has on these elements.

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To ensure the best effectiveness and efficiency, the decision maker should carefully consider all the aspects concerning the requirements and implications for the operation of the medical device along its complete life cycle.

An HPO can be described as a complex system characterised by many multifaceted and non-linear connections among the different components and actors. The healthcare system includes actors ranging from representatives of manufacturers and insurance companies as well as policymakers, to healthcare professionals and patients. The adoption of medical devices, besides the improvement of the patient's outcome, may introduce additional factors escalating this complexity. A holistic approach and a system thinking orientation are required for the successful management of the HPO and to ensure safety, quality of care and risk mitigation.

The case of dialysis treatment will be analysed as a possible paradigm for the application of complex medical devices to the treatment of a chronic disease.

6.1 Setting the Issue

In the following pages we will make reference to the concept of Healthcare Provider Organisation (HPO) as any organisation taking care of patients and aiming at the improvement of their health and quality of life.

This may span from a small single-speciality centre treating a single pathology to a large multi-speciality hospital. The successful operation of the HPO requires to focus on a variety of factors such as the quality of delivered care, the reduction or control of the risks for patients and caregivers and the efficient use of the resources.

An HPO, as most human organisations, can be described as a complex adaptive system (CAS).[1] To successfully manage an HPO many aspects and agents, usually interacting through non-linear relations should be considered. The introduction of a medical device or any complex technology generates different technical and administrative reactions and needs that must be governed [1].

The extensive use of medical devices has an impact on the design and government of the HPO. This is valid both if the device is operated inside the organisation and when it is used at the patient's home under the remote supervision and responsibility of the HPO. In this case, the institution's management should ensure that the patients and caregivers receive the adequate information and training (as applicable) and that the environmental conditions for the successful and safe operation of the device are met, e.g. granting hygiene and compliance to electric safety standards.

To analyse the topic, it is important to clearly define what it is intended with the term *healthcare technology* and what are the target of the HPO in terms of delivered performance and quality.

[1] CAS, a system such as a business or other organization that consists of many connected parts which should change as conditions change in order to succeed (from: Cambridge Business English Dictionary © Cambridge University Press).

6.1.1 Healthcare Technology and Medical Devices

The term *healthcare technology*, as emphasised in the following definition, may refer to a set of very different tools and methods including the medical devices themselves, pharmaceutical products, and vaccines. Although the latter are outside the scope of this book, they might be used in association with a medical device.

Health technology has been defined by WHO [2] as the "*application of* ***organized knowledge and skills*** *in the form of* ***devices****, medicines, vaccines,* ***procedures*** *and* ***systems developed to solve a health problem and improve quality of life****. It is used interchangeably with healthcare technology*" (terms emphasised by the author).

This definition stresses some very important elements. The objective to solve or alleviate health problems or to improve the Quality of Life (QoL) is achieved with:

- Use of devices
- Organised knowledge and skills
- Procedures and systems

It is underlined that the successful application of technologies in healthcare requires the background of a corpus of organised knowledge, skills and procedures.

The given definition of health technology makes reference to the large class of *medical devices*. For these, the most widely recognised definition is:

Medical device is any "*article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means*" [2].[2]

As it can be inferred by this definition, the term medical device identifies a very wide category of products: from a simple wooden tongue depressor, to a Personal Protective Equipment (PPE), to a dialysis filter, up to the most complex magnetic resonance system.

It is also worth to add a further categorisation that can help to underline the difference between "simple" and "complex" medical devices that may involve a very different technical and managerial approach by the HPO.

For this reason, it is useful to add the definition of medical equipment as: "*Medical devices* ***requiring calibration, maintenance, repair, user training, and decommissioning*** *– activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it* ***can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment****.*

[2] This definition is proposed by WHO, but is substantially in line with European Medical Devices Regulation (MDR) and other standards and normative references. Refer to Chap. 4 of this book for a further clarification of the topic.

Medical equipment excludes implantable, disposable or single-use medical devices" (terms emphasised by the author) [2].

The concept of medical equipment, even if not considered in these terms within standards like the European Medical Devices Regulation (EU-MDR), is helpful to emphasise the specificity of the more complex medical devices. They require calibration, maintenance, repair, commissioning/decommissioning and can be used in combination with other medical devices, like consumables.[3]

The words highlighted in this definition identify the main competence and responsibilities of managers and operators in the healthcare institution for the operation of complex medical devices over their full life cycle (see also Chap. 5).

The case of the artificial kidney or haemodialysis will be presented in Sect. 6.4 as a possible paradigm of the use of medical devices of different complexity for the treatment of a chronic disease.

The treatment is based on the use of a medical equipment that must be used in combination with consumable medical devices, like dialysis filters, tubing and needles.

6.1.2 The Quality in HPO

In recent years, great attention has been paid to the evaluation and possible improvement of the quality of the services delivered to patients by hospitals and other healthcare provider organisations. This, together with the cost reduction, is presently considered among the most important issues in healthcare management for the improvement of the value of care (see Chap. 10).

The use of medical devices and equipment has a strong impact on the performance and organisation of the HPO and is of course influencing the quality of the delivered treatment. For this reason and for the sake of our discussion, it is useful to make reference to a model describing the quality in healthcare. Many different approaches have been used to assess the quality of care delivered by a HPO, but the most commonly credited ones are the models developed by A. Donabedian and the one proposed by Lohr and Schroeder [3].

Despite already developed in 1966, the Donabedian's paradigm is still a widely accepted model for healthcare quality [3] and will be adopted to support the considerations in the following pages.

This model shows that the quality is obtained by the management of different activities and is constructed by the adequate contextual conditions [3].

This paradigm is based on three components, as summarised in Fig. 6.1.

[3] For the sake of brevity, the terms *device* will be also used when referring to *equipment* or *complex medical device*. The reader should anyway keep in mind the possible implications due to the difference between the two elements.

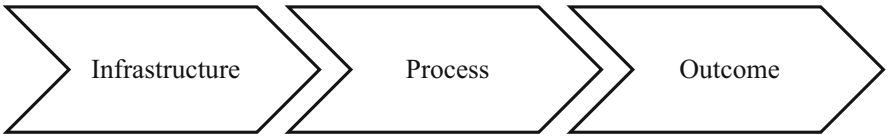

Fig. 6.1 The elements of the Donabedian's model for HPO quality. (Adapted from [4])

By ***structure*** the model refers to the factors related to the internal organisation and management system of the HPO. This includes the human, material and financial resources as well as the managerial actions to take care of these elements. In this text we will refer to this setting as "**infrastructure**" to emphasise the important contribution of the material resources (see also Fig. 6.2).

The second component in Fig. 6.1 concerns the ***process*** put in place to achieve the required results. This includes the technical competences in a broader sense, e.g. including both medical and engineering know-how, and the cooperation among the operators. Another key aspect is the implementation of the procedures aiming at the control and possible reduction of cost and risks connected with the treatment.

Results or ***outcome*** refer to the patient's health status, relief of symptoms, and improved functionality.

The term *outcome* includes the evaluation whether the goals of care have been accomplished, but includes also the evaluation of the final patient's health status, the cost of care and—not least—the patient's satisfaction and the sustainability of the achieved health status.

Even if not always considered in these terms and by the Donabedian's model, the results should include the creation of value for all the involved stakeholders. This includes the benefits for patients and community, the reduction of the cost for the payor for the treatment and the generation of appropriate profit for the HPO owner itself (see also Chap. 1).

It is also useful to split the outcomes into intermediate (like operating site infection rate) and final (i.e. the final effect of the provision of care, like health status, disability level or death) [4].

It is important to note that any healthcare action may have an impact not only on the patients itself, but also on patient's relatives and the whole community.

The contribution of patient's relatives is generally underestimated. Moreover, it can be expected that this involvement will not be available in the near future due to the new reality of the family and community organisation. This would lead to higher need for healthcare professionals and cause higher healthcare financial burden.

The health outcome involves the assessment of a set of specific indicators. These are based on patient's clinical status or on the measurement of the treatment performance (see Chap. 10). Both can, in many cases, directly be assessed by the medical equipment itself through the use of dedicated sensors and computation algorithms (see case report on haemodialysis).

In the following the analysis will be focused on the infrastructure and on the processes as they are influenced by the introduction of medical devices and equipment.

6.2 The Role of the Infrastructure

Many authors underline the importance of the infrastructure for the delivery of good healthcare services. The WHO includes the infrastructure improvement among the elements to overcome the weaknesses of many healthcare systems [1].

We define as *facility infrastructure* the set of all the components which allows an HPO to deliver the required services. Figure 6.2 gives a synthetic overview of the main elements. All these are strongly influenced by the introduction of the medical devices. In addition, due to the complexity of the HPO, any action affecting one of the components may have a strong impact on all other elements.

Making reference to the diagram in Fig. 6.2, it is possible to group the main factors in four main areas.

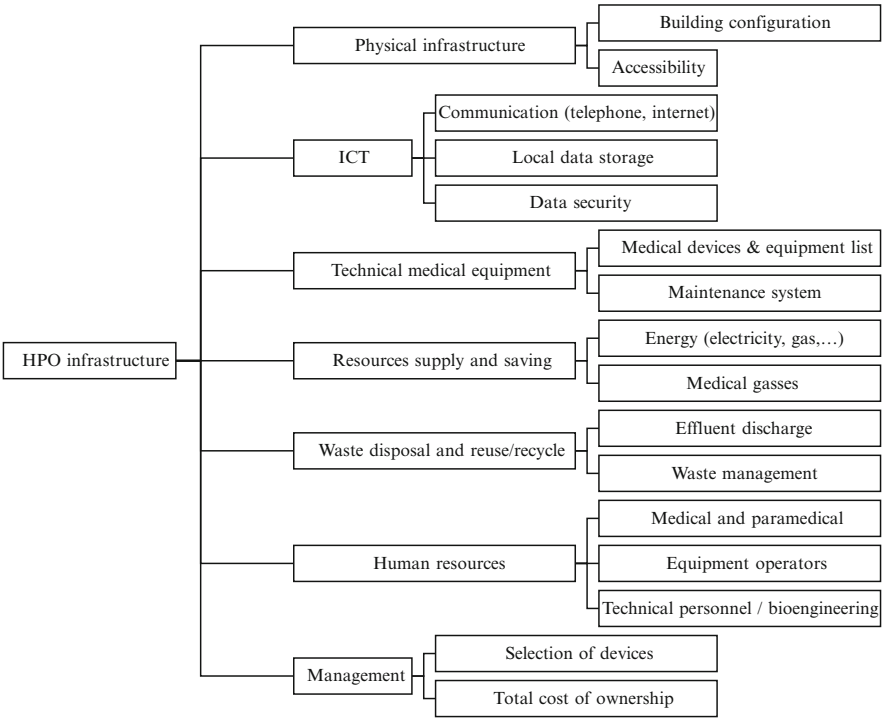

Fig. 6.2 The main components of an HPO infrastructure. *ICT* Information and Communication Technology. (Modified, reduced and adapted from [5])

1. **Physical and technological components**.

   The presence of medical equipment requires to pay attention to specific needs like:

   - Accommodation, that may require a special environment in terms of areas and possible specific local adaptations, e.g. magnetic field shield for the location where a magnetic resonance imaging (MRI) system is installed.
   - Easy access for patients, especially in areas for chronic treatment or diagnostic operations and a smooth workflow for personnel and material delivery, e.g. for consumables.
   - Information and communication technology resources, that are of special importance when data concerning diagnostic imaging must be collected, stored and distributed. Data security is also an important issue, as discussed in Chap. 7.
   - Availability of state-of-the-art and adequately maintained devices and equipment.

2. **Use of resources**.

   The operation of medical devices and equipment may imply a large use of material resources, including e.g. supply of electric energy over dedicated lines, medical gas and purified water. In many cases it must also be paid attention to the effluent fluids that may need specific treatment due to the possible presence of contaminated or toxic substances, like hazardous wastes, disinfecting agents or radioactive isotopes. In most countries, the limit levels of these toxic substances are stated by law.

3. **Human resources**.

   The healthcare institution has been traditionally seen in the past as a *non-technical* environment [7]. The application of (complex) medical devices opens an important set of considerations about the presence of in-house competences as well as the allocation of technical responsibilities. Apart from the obvious need to have well-trained medical operators in larger facilities, where many different pieces of equipment are in operation, the presence of technicians and bioengineers is necessary. These professionals can take care of all devices along their full life cycle: from procurement, operation and maintenance to decommissioning

4. **Management and governance capability**.

   Concerning the medical devices, the HPO management should be also involved in the selection of the devices and in the estimation and management of their total cost of ownership (TCO).

   The estimation and control of TCO is a very important management tool. It is defined as the financial estimation of all direct and indirect costs connected with the ownership and utilisation of a device/equipment or technology. Apart from the pure purchasing cost, it includes all the other costs related to procurement and storage of consumables, equipment maintenance, disposal of obsolete devices and training of personnel. The TCO also gives reason for the hidden costs that, on top of the purchasing price, may arrive up to 85% of the total cost during the overall device's life cycle.

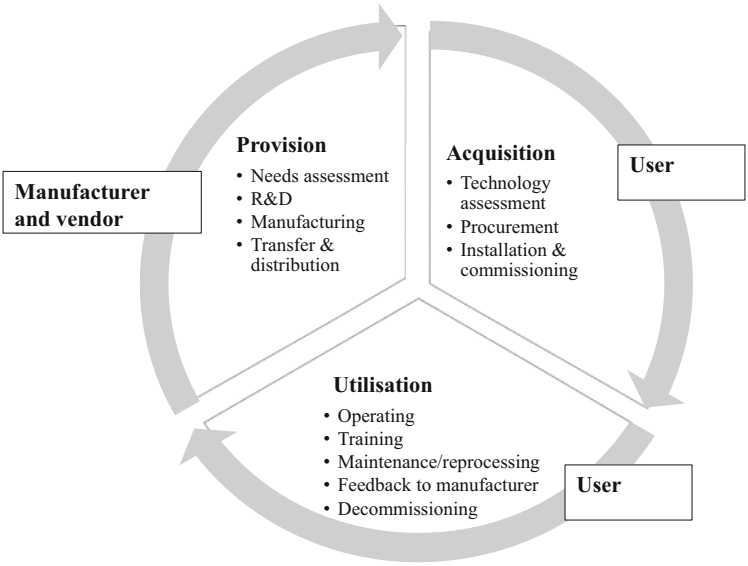

Fig. 6.3 The basic life cycle of a medical device and the actions to be undertaken by the main actors, such as provision, acquisition and utilisation. *R&D* Research and Development. (Adapted from [6])

The diagram in Fig. 6.3 shows the main activities to be undertaken by the responsible persons in HPO during the overall life cycle of the device or equipment. Many of these activities imply their strict relationship with the manufacturer/vendor.

As it can be seen from the above chart, the user's role does also include the feedback to the manufacturer/vendor to ensure the timely and continuous evaluation of the efficacy, performance and safety of the devices. This can be achieved by the strict adherence to the *post-market surveillance* program. A more detailed and comprehensive view of the medical device life cycle can be found in Chap. 5.

6.2.1 Acquisition

The acquisition procedure is based on the following steps:

- Assessment of the technology, to ensure it answers to care requirements and whether it is in line with the expectations and culture of the community to be served[4] [7, 8]

[4]This aspect is of special importance to guarantee that the community is willing to accept the medical acts involved with the technology and is available to pay for the delivered service. The acceptance of a medical practice is strongly related to the culture of the community and to the medical literacy of the involved stakeholders.

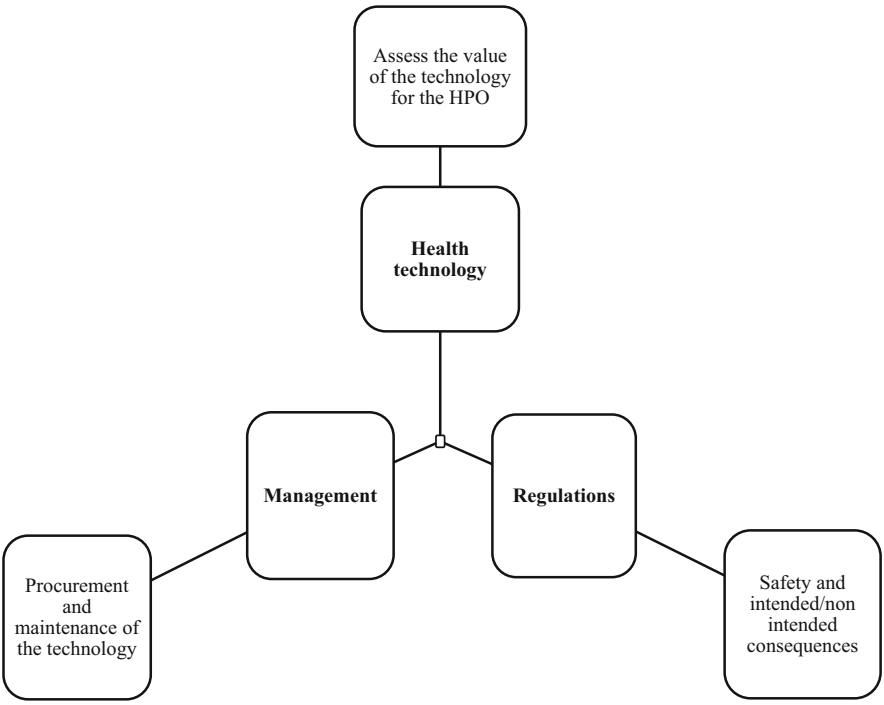

Fig. 6.4 The main aspects to be considered when selecting a medical device (equipment)

- Evaluation and planning of the service to be delivered to the community
- Placement into operation (it includes the availability of the required structural provisions as well as the requirements in terms of personnel and skills)
- Commissioning activity for complex equipment

The procurement activity requires the harmonisation among technical, regulatory and managerial competences as illustrated in Fig. 6.4.

After the assessment of the technology the decision maker should verify that the introduced medical equipment, and its application in the considered environment, is in full compliance with the applicable standards and regulations. This means that it is not only needed to have an equipment according to the required standards and directives, but also to ensure that the needed consumables, the environment and the resources are according to the applicable standards. A possible example is the requirement to have dialysis water in compliance with the best practice, international standards (e.g. ISO 23500-1-19) [9] and legal regulations.

This regulatory aspect also includes the required activities to ensure the safety levels and the risk control.

The safe and effective use of the technology entails the adequate management attention to all the above aspects. Considering the MD life cycle as proposed by the WHO [6] it is important to observe the role the final user has on the safe application

and performance of the medical devices, through the active participation to the post-marketing surveillance activity (i.e. feedback to the supplier/manufacturer as indicated in Fig. 6.3).

6.2.2 *Utilisation*

The user must always consider that each medical device has been designed for a specific **intended use**,[5] to work within well-defined conditions and operated accordingly by trained personnel.

The responsibility of the MD user begins when open the packaging, e.g. related to sterility and absence of pyrogens.

Besides the adequate operational environment and the training of the operators, it is mandatory to ensure the following conditions:

- Clear allocation and documentation of responsibility within the HPO, especially when concerned with complex equipment
- Ensure the maintenance by authorised personnel, that must be regularly trained and certified by the manufacturer or by its representative
- Provide the correct decommissioning of worn-out pieces of equipment and/or disposal of non-reusable items or disinfecting/reconditioning of the parts intended for reuse

For single-use devices, it is important to set up the suitable disposal system. Many of these devices, like needles, syringes or other parts that might have been in contact with body fluids, may be contaminated. Contamination may be due to pathological proteins or microorganisms and their disposal must ensure the safety of patients and operators that may come in contact with them and avoid the pollution of the environment.

In addition, the management should carefully consider the overall cost generated by the ownership and operation of the medical equipment. The *Total Cost of Ownership* (*TCO*) is here a useful concept and is one of the key points in the equipment selection process.

An additional important aspect is relevant to the management of the medical equipment. This is vital to ensure that the device is correctly operated and maintained, but also helps the allocation of the HPO's resources in the optimal way.

A single source database about all the medical equipment available in the HPO should be accessible by key persons and contain the following indications:

- Comprehensive device/equipment information (including technical specification)[6]

[5] A device designed for a defined intended use cannot be applied for alternative (not approved) application.

[6] Reference to the UDI (Unique Device Identifier) as defined by Article 27 of the 2017/745 and Article 24 of Regulation 746/2017 [11].

- Required operator's training and training status
- Location of the MD within the HPO (the location may change according to the operational needs: this must be always updated)
- Indication of the responsible person in charge of the device/equipment
- Utilisation status, including the due date for calibration, preventive maintenance, maintenance history
- Availability and possible expiry dates for consumables (usually up to 5 years and indicated on the MD packaging)
- Total incurred costs for purchasing, maintenance and operation feeding the evaluation of the total cost of ownership
- Warnings about security and risk issues

6.2.3 Reprocessing

For some applications, the HPO might be involved in the reprocessing of devices. It is e.g. the case of cleaning and disinfection/sterilisation of surgical tools or endoscopy equipment.

According to ISO 17664:2017 [10], the reprocessing is the set of activities to be undertaken on a (reusable) medical device to achieve (depending on the operational needs):

- Cleaning, i.e. "removal of contaminants to the extent necessary for further processing or for intended use"
- Disinfection, i.e. "process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose"
- Sterilisation, i.e. "process used to render the product free from viable microorganisms"

Both FDA (Food and Drug Administration in the USA) and EU-MDR (European Union Medical Device Regulation) [11] clearly state the conditions for the reprocessing of the medical devices.

Following the definition given in EU-MDR, reprocessing is intended as:

> *process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.* (Article 2(39) of [10])

In recent years, the generalised tightening of the health budgets has also started the interest for the reuse of devices, even if intended for single use. This practice may in principle not be strictly forbidden, provided that the reprocessing is performed according to specific rules that ensure the device keeps its characteristics in terms of efficacy and safety. In this case, however, the responsible for the reprocessing of the Single-Use Device (SUD) assumes the role a *new manufacturer* of the device and bears all the responsibilities for the performed process. The process should, of course, also include the required quality control steps.

At the basis of this procedure is the evidence that the applied process is scientifically proven and validated to ensure that the reconditioned device can be cleaned, disinfected, functionally tested and reused without any harm for the patients and caregivers.

Patients and healthcare professionals should be granted that the reused device has the same performance and safety margin of a new one.

Whilst the HPO tries to cut cost through the reprocessing of SUDs, the manufacturers are usually not supporting this practice. This may not always be due only to the desire to increase sales, but is also due to purely technical reasons. In most cases, the reprocessing procedure, if not properly performed, may alter the characteristics of the device in an uncontrollable way.

The reuse procedure of many medical device is performed with hazardous chemicals like peracetic acid (CH_3COOOH), sodium hypochlorite (NaOCl) and hydrogen peroxide (H_2O_2). They might damage the components of the device and cause adverse reaction both in patients and operational staff.

The HPO should also be aware of the cost of the overall reconditioning procedure. The cost of quality management for the properly performed reuse procedure may even be higher than the expected cost savings.

Due to economy of scale in production, single-use devices have become cheaper than the overall cost for reconditioning of devices as well as the education of staff for the reuse procedure.

6.3 Impact on the Healthcare Processes

In recent years, the quest for quality and efficiency in healthcare has stimulated the application of process management strategies in many healthcare organisations [12–14].

It is possible to identify five main processes involved in the delivery of healthcare [14] and in the creation of value for patients and the community:

- Keeping people healthy (prevention) and provide a good quality of life
- Detecting health problems
- Diagnosing diseases
- Treating diseases

Chapter 1 gives an overview of the contribution of the medical device technology to the above processes.

The widespread application of medical devices and equipment, besides the impact it has on the infrastructure, requires the adaptation of all processes to the new technology.

This is of particular importance when considering the high rate of innovation characterising the medical device field.

It is important to remark that the pervasive introduction of medical devices and complex pieces of equipment in the HPOs requires a careful management of all the involved risks.

Risk control becomes, then, an even more important aspect of the activities to ensure the success of the healing process.

6.3.1 The Concept of Risk in Medical Devices

It is well known that every medical act is connected with risk. The very term *pharmaceutical* derives from the Greek φάρμακον—*phármakon* that has itself the double valence of remedy (medication) and poison.

Even if it is impossible to eliminate all risks from any human activity, the user of medical devices must consider the need to manage these risks and clearly understand the level of the *risk/benefits* ratio connected to the use of the device. Moreover, the acceptability of the level of risk vs. the benefits might be strongly subjective and strictly linked to the cultural position of the served community.

A Risk Is Not a Disease

It's worth to remind that a risk refers to something at the horizon that may or may not happen. The point is how to manage it.

With all the above in mind, the stakeholders involved in the production and use of the medical devices must put in force a risk management process to reduce the risks at a technically and ethically acceptable level and agreed by the served community.

The French mathematician and philosopher Blaise Pascal (1623–1662) gave one of the former definitions of risk:

> *Risk should be proportional to the probability of occurrence as well as to the extent of damage.*

This definition can be translated in mathematical terms as:

$$R = p * C$$

where p is the likelihood of an event and C the consequence of this event.

This is the standard definition, also adopted by ISO 14971 [15], that defines the risk as the combination of the *probability* of occurrence of a *harm* and the *severity* of that *harm*.

This means that the risk management must act on the probability of harm and on the possible consequences.

The stakeholders involved in the design, distribution and use of a MD must then take all technical and managerial actions to shape p and C during the overall device life cycle.

This can be achieved setting-up a risk management plan aiming at:

- ***Risk assessment***: Identification and evaluation of the risks connected with the different phases of the device life cycle
- ***Risk control***: Identification and implementation of the measures needed to reduce this risk

As recalled above, it is impossible to eliminate all possible risks from any human activity, and especially from medical acts. This means that every device will be characterised by a *residual risk* (defined in ISO 14971 15 as "*the risk remaining after all the risk control measures have been implemented*").

The *residual risk* is then the key information allowing the physician or the clinical expert to evaluate the benefits and the hazardous situation that may arise in the clinical practice when using the device.

Discussing about risk there are few more considerations to be added.

First is the fact that the evaluation of the *acceptable level of risk* might be strongly subjective and it is highly influenced by cultural standpoints and specific operational situations.[7]

Second, that in the evaluation of risk the possibility of user's errors and the *reasonably foreseeable misuse*,[8] either intentional or unintentional, should be included.[9]

6.3.2 The Risk Management Activity in HPO

The above discussion highlights the risk management among the most important processes that take place in HPO, especially when dealing with medical devices and equipment.

The risk assessment and the risk control should consider the environment and the organisational context in which the device or equipment is used. This should consider, as reminded by [16], all aspects like: "*transport, hospital use, home use, backup systems, interaction with other devices and systems, impact of multiple device environments or multiple device use*".

The risk assessment should include also the possible risk due to the loss of benefit in case of device's malfunctioning or unavailability. This activity requires a deep knowledge of different aspects, including (but not limited to) current clinical

[7] Risk acceptability is strongly influenced by the society's tolerance of risk and by the conditions in which the device is used (routine, emergency or optional therapy).

[8] Defined in ISO 14971 [15] as the use of the device in a way not intended by the manufacturer, but that can result from predictable human behaviour.

[9] One example of intentional misuse is the reuse of a single-use item (without the adequate reconditioning, see Sect. 6.2.3). To possibly prevent this, the manufacturer should give clear indication of the potential harm that this practice may generate.

practice, alternative product and procedures and possible expected changes in clinical practice.

The risks connected to the medical device are usually including physical (e.g. mechanical, electrical, thermal), chemical, radiation or biological harms.

The risk level is very much depending on the user's interaction with the device, and specific provisions must be included in the standard operating procedures (SOPs) to avoid, or minimise, this risk.

The interaction of the user with the device is strongly influenced not only by the design of the device itself, but also on the application environment, that may be a main source of errors [17–19]. The additional risk factors may arise, among others, from user's error or from any device malfunctioning or unavailability, possibly created by wrong or incorrect maintenance or shortage of required consumables. These risks, that are above the *baseline risk profile*[10] of the device itself, shall be considered in the evaluation of the overall risk profile of the HPO operations [16].

J. Reason, making reference to his *Swiss cheese model* [20] recalls the fact that a consistent risk control in a healthcare institution must consider and assess the overall risk involved on top of the baseline risk profile for a given device/equipment. This assessment includes all the possible aspects that may harm the ability of the caregivers to deliver the correct treatment.

It is reported in the literature [20] the case of a fatal outcome due to the wrong calibration of a morphine delivery infusion pump.

The error was generated by the fact that the hospital adopted two kind of infusion pumps with different calibration (mL/day and mL/h, respectively). During the syringe change the nurse applied the calibration in mL/day on a pump that should be calibrated on mL/h. This resulted in a lethal overdose.

The lesson learned by this example is that these kinds of incident can be avoided, or their probability reduced, if the **overall** system is designed to consider the possible errors in the operation of the medical device.

Adequate staffing in order to avoid the hectic generated by personnel overload and careful consideration in the device procurement and personnel training are the key factors to reduce the risks.

[10]The white paper AAMI Risk Principles/2015-08-25 defines the Baseline Risk Profile as the premarket estimation of the actual residual risk from using a properly designed, manufactured and labelled medical device [16].

6.4 A Possible Paradigm: The Case of Blood Purification with Haemodialysis

6.4.1 Short Intro

Haemodialysis (HD) is a life-saving treatment required when a patient has lost, completely or to a major extent, his renal functions. It aims at the purification of the blood from the toxic retention solutes produced by the metabolic processes and in addition at the elimination of excess fluid accumulated in the body.

The treatment is performed with the use of a medical equipment (the artificial kidney) connected to the single patient, equipped with a dedicated set of consumables and supplied with water containing acid and basic concentrates. The treatment consists in taking the blood from the forearm vein of the patient. The blood is guided with a pump through the extracorporeal blood circuit that includes a filter (*dialyser*). The blood flow is usually between 200 and 500 mL/min.

An isotonic fluid (*dialysis fluid*) flows (usually at 500 mL/min or more) in the filter, in the opposite direction of the blood, and provokes the removal of uremic retention products from the blood.

The artificial kidney causes also the removal of excess fluid by the application of a controlled pressure gradient across the dialysis filter with the help of a dedicated pump.

A simplified diagram is shown in Fig. 6.5, where are also indicated the main parts of the artificial kidney and the monitoring and control subsystems.

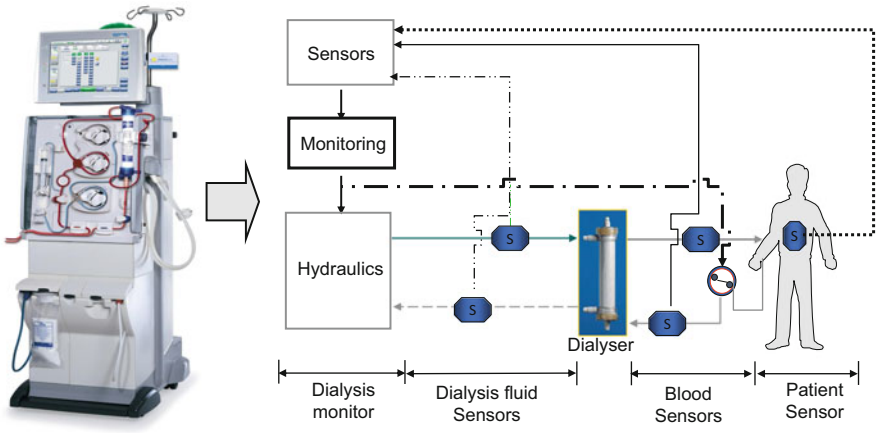

Fig. 6.5 Example of haemodialysis treatment and picture of an artificial kidney system (*5008 Cordiax from Fresenius Medical Care*). The sensors (S) and monitoring system guarantee that all the physiological parameters are kept within the required and safe values and can also give indications about the achievement of the treatment targets. (Adapted from [21]—courtesy of Fresenius Medical Care for the dialysis monitor picture)

The HD treatment requires the careful organisation of the infrastructure and processes supporting it and can be considered as a useful paradigm/model to exemplify the considerations given above.

6.4.2 Operations

The HD treatment is performed (usually) three times a week and lasts about 4 h. During the treatment, the patient should lie on a bed or sit on a special chair.

The treatment is performed in a dedicated area that must be designed and equipped to ensure the safety of patients and personnel, efficiency of the operations and patient's comfort.

As mentioned above, the treatment requires the use of dedicated consumables such as needles, filters, blood lines and chemical products (concentrates) which require to be stocked, taken to the patient's treatment place and discarded with the appropriate procedure after the treatment.

The treatment system requires to be supplied with highly purified water that is prepared onsite. Water usually comes from the municipal water supply network and passes through a water purification system. This system is based on a reverse-osmosis equipment and is implemented onsite according to the need of the centre, e.g. the amount of required water and in relation to the characteristics of the tap water available. The reverse-osmosis device and the parts in contact with the purified water fed to the treatment system are considered medical devices. The water purification system requires a specific design, validation, commissioning, dedicated maintenance and periodic monitoring of the water quality according to the applicable international standards and/or country specific regulations [21].

6.4.3 Infrastructure

The dialysis treatment identifies a specific set of requirements for the infrastructure where the treatment is performed (dialysis centre, dedicated area in a general hospital or in a patient's home).

The presence of the medical equipment and devices dedicated to the dialysis treatment generate some distinctive characteristics[11] for the building where the treatment is performed with respect to other ambulatory facilities [22].

Besides the need to allow for the easiest and most efficient patients- and personnel-flow, a specific set of requirements are:

[11] Here are considered only the features relevant to the application of the dialysis related medical devices/equipment. In addition, all general considerations for the design of a facility for ambulatorial medical practices are applicable.

- A reserved area where the treatment is performed, equipped with:
  - Dedicated electric power supply for the dialysis monitor, separated from other users.
  - Supply of purified water.
  - Drain pipe for waste fluids coming from the dialysis system that are potentially contaminated by biological waste products, chemicals and disinfecting agents. A possible purification system before discarding them in the public sewage network might be required.
  - Provisions for medication preparation and for hygiene procedures for patients and staff, e.g. handwashing stations.
  - Surveillance desk allowing the personnel to watch the patients under treatment and see the possible alarm signal from the dialysis system.
  - Adequate space to accommodate the patient (on bed or chair) and the artificial kidney, with space for access by the caring staff doing treatment, monitoring (e.g. blood pressure measurement) and for emergency operations.
- Large stock areas for consumables (e.g. fistula needles, blood lines, dialysis filters, concentrate containers)
- Separated area for the disposal of the used consumable items (potentially contaminated)
- Dedicated area for the water treatment system

From the above considerations, it appears that the design of the infrastructure of a facility delivering dialysis treatment requires a set of provisions that are strongly related to the presence of the specific medical equipment used: in particular the dialysis- and the water treatment-system.

Table 6.1 (modified and adapted from [22]) shows the specific requirement to the building.

Besides the impacts on the physical infrastructure, the artificial kidney operation requires the organisation of other aspects as summarised in Fig. 6.2.

One important aspect is the availability of an adequate ICT facility. The workflow and the treatment results can be dramatically improved when all dialysis monitors are connected to a central network where all the patients' data are collected, stored and monitored. These data may include the parameters gathered during the treatment by any ancillary medical devices, like blood pressure and temperature monitoring. This information system can also improve the efficiency in the management of the consumables.

The safe and effective operation of the treatment requires the presence of dedicated and trained staff and the clear definition of the responsibility of each operator.

This covers the presence of the medical personnel directly involved in the treatment: mainly physicians for the prescription and supervision of patient's status and trained nurses performing the treatment itself. In addition, trained technicians take care of the continuous maintenance of dialysis equipment and water treatment system [9, 19]. These personnel may also be outsourced, but it should be ready-available for any emergency need.

Table 6.1 The specific characteristics of an HPO infrastructure performing haemodialysis (adapted from 22)

Function	Purposes	Requirements
Dialysis treatment area	Performance of dialysis treatment	Space for the accommodation of dialysis equipment and required supplies
Water treatment room	Allocate the equipment for the preparation and distribution of purified water (dialysis water)	Space to allow the positioning of equipment and the easy maintenance and monitoring
Consumable stock area	Stock of consumable for dialysis treatment (and other medication items)	Temperature and humidity control (as for general pharmaceutical products) Easy access and communication to treatment area
Used consumable disposal area	Allocate the waste products (spent consumables)	Easy access and communication with treatment area and for collection from outside Separation of contaminated waste
Drain fluids treatment	Treatment of discarded fluids (e.g. spent dialysis fluid) before the collection by the public waste fluids system	In some location (depending on the country regulations) the law requires the purification of the discarded fluids from dialysis must be purified from disinfecting agents, pharmaceuticals or excessive biological waste products [23][a]

[a]In some situations, equipment for fluid treatment for water reuse may be foreseen

6.5 Additional Considerations for Low-Income Countries

The use of complex medical devices in low-income countries deserves few additional considerations (see also Chap. 12).

Whilst it is an obvious advantage to allow the populations of poor rural areas to access the most advanced diagnostic and therapeutic solutions, possibly based on complex medical equipment, it is important to ensure preventively that all the technical and logistic prerequisites are in place.

According to [24], between 25 and 35% of the medical devices in the so-called low-income countries are out of order or heavily underused due to lack of maintenance or unavailability of spare parts and consumables.

In addition, the lack of adequate resources reinforces the temptation to reuse disposable items meant for single use and possibly recondition them following cheap but inadequate procedures. This, of course, contribute to worsen the situation and may generate additional risks or bad outcome for patients.

All the above issues may frustrate the efforts done to build a better healthcare system in these countries.

The installation of complex medical equipment, sometimes with the help of donations, should always be completed with the adequate infrastructure, the training

to create the technical competence in loco as well as all the logistic organisation to ensure the timely availability of required consumables with adequate quality.

The organisations developing, producing and selling medical devices and equipment should carefully consider the above aspects. Very performant and expensive products may not be useful in lower-income countries or in remote rural areas without adequate resources. Under these conditions, the required expenditure cannot be afforded and the proper operation and maintenance cannot be ensured. This means that manufacturers should also focus on products that, even if assuring the adequate level of care, quality and safety, are simpler, less expensive and easy to use. This will be one of the most important challenges for the future of the medical device industry.

Conclusion

The introduction of medical devices and equipment of different complexity has an important impact on the structure and on the process of a healthcare provider organisation.

Main impacts on the infrastructure are:

- The physical layout should be designed in order to allow the safe and effective use of the devices. This is to guarantee the smooth workflow allowing for the access of patients and personnel as well as for the delivery and internal distribution of consumables and the disposal of spent single-use devices.
- The facility allows the allocation of specific equipment in dedicated areas (e.g. water treatment system).
- The risk management strategies should be adapted to include the operation of the medical devices and their specific requirements (e.g. the presence of strong magnetic fields in the area where the MRI equipment is installed).

The availability of trained personnel and the clear allocation of responsibilities is mandatory. This may include the presence of a bioengineering/technical department (at least for larger structures) taking care of all the technical issues, e.g. assistance for procurement, commissioning, maintenance, decommissioning.

The use of medical equipment in low-income countries requires a holistic approach focusing on properly designed equipment, its maintenance, the availability of affordable consumable material and the training of personnel *in loco*.

Take Home Message

– In the Healthcare Provider Organisation, the successful application of the medical technologies requires the adoption of a systemic view of the different elements influencing the quality of delivered care. Key factors are infrastructure and processes, training of operators and well-allocated responsibilities.
– The task of the decision makers is to concentrate on the different phases of the medical devices/equipment life cycle, from the acquisition and

(continued)

commissioning to the disposal, to ensure that the quality of the delivered care, the appropriate use of the resources and the best return of the financial investment are achieved.
- The risk management is among the most important topics when considering the healthcare processes related to the extensive use of medical devices and equipment of different complexity.
- The estimation and control of the Total Cost of Ownership (TCO) is a very important management tool. Apart from the pure purchasing cost, the TCO analysis also allows to spot the hidden costs that, on top of the purchasing price, may arrive at up to 85% of the total cost during the overall device's life cycle.
- The application of medical technology in low-income countries deserves the careful consideration of the aspect related to the equipment design and maintenance, the availability of the required infrastructure and consumables as well as the establishment of adequate operators' training.

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