Chapter 11
The Role of Medical Devices in Healthcare Sustainability

Carlo Boccato, Sergio Cerutti, and Joerg Vienken

Abstract The sustainability is an important issue for the human activities and the healthcare system cannot escape this rule. The extensive use of medical devices has an impact in worsening the issue (e.g. due to the large number of disposable items), but also helps to solve the problem if the overall picture is kept in mind.

When discussing about healthcare sustainability, the decision-makers should consider, besides the environmental impact, the social and financial consequences. All those aspects are strongly influenced by the aging of the population and the need to extend the adequate treatment to the whole world community.

After a first definition of what is intended as sustainability in healthcare and an analysis of the main relevant issues, this chapter considers the contribution of medical devices and related technologies to this important topic.

Introduction

The sustainability of our way of life is facing many challenges, involving ecological, financial and social aspects. The healthcare (HC) system is similarly confronted with these challenges, substantially due to the increasing complexity of the medical treatments, the aging of the population and the economic inequality.

Inequality among people is a very important issue. The availability of a good level of healthcare for all the individuals and communities, without limitations due to social and economic conditions or to country and continent of residence, is matter of social justice.

C. Boccato (✉)
Milano, Italy

S. Cerutti
Department of Electronics, Information and Bioengineering, Politecnico di Milano, Milano, Italy
e-mail: sergio.cerutti@polimi.it

J. Vienken
Usingen, Hessen, Germany

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The topic of healthcare sustainability has many correlations with the availability and use of medical devices. They have a strong potential in providing a good and sustainable level of care to individuals and populations, but the impact of their manufacturing and operation on the use of resources and on the environmental pollution should be systematically managed.

In the following pages it will be outlined what it is intended as sustainable healthcare (HC) and what are the challenges that the HC system worldwide is facing now. Then, the contribution of medical devices will be analysed.

11.1 The Healthcare System Sustainability and Its Enemies

The Brundtland Report [1] defines as *sustainable* any activity that "*meets the needs of the present without compromising the ability of future generations to meet their own needs*." [1].

This definition is applicable also to the healthcare systems and embraces several aspects. These aspects should focus not only on the environmental protection and the economic development but also on the very organization of the society. Besides the attention to future generations, the definition of sustainability must include the issue of "social sustainability", intended as the need to ensure the adequate quality of life to people with lower wealth conditions or being located in low resources areas of the world. A discriminatory society cannot be sustainable.

The complexity of our society and the presence of many actors and stakeholders requires to afford all the emerging problems with a systemic view. This is especially true for the HC system sustainability [2, 3]. The key issues undermining the HC system sustainability can be classified into sociopolitical, financial and environmental factors, as summarized in Fig 11.1.

Sociopolitical Issues The inequality of income, and the consequent access to HC services, creates important disparity among people in different geographic areas or belonging to different social classes in the same (even wealthy) country (see Chap. 12). As of year 2017, less than half of the global population is taken care by essential health services [4]. This inequality, besides being morally unacceptable, may undermine the path of the international community to a sustainable development. Ensuring healthy lives and promoting well-being at all ages has been included in the Goal 3 of the UN for a sustainable development [5–7].

Demographic changes, such as the aging of population are other social aspects that strongly influence the sustainability of the system. Besides the cost of the chronic therapies, it also creates a high need for assistance, frequently involving relatives (often not young themselves) as lay caregivers. This gives an additional burden on social organization and economy, e.g. in terms of missed work opportunity.

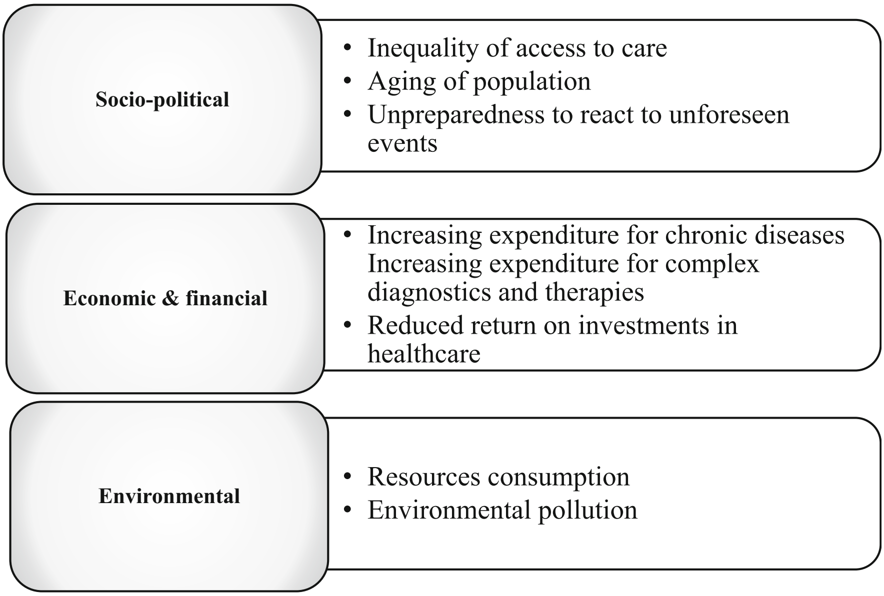

Fig. 11.1 Factors undermining the healthcare system sustainability

An additional issue is the need to rapidly and efficiently react to unforeseen events (or so-called *black swans*)[1] like pandemic or natural calamities. The recent and not yet resolved crisis generated by Corona viruses has shown that the actual pandemic, in addition to the human and economic injuries, has also created disruptions in the HC systems. This, potentially reversing decades of improvement, has also interrupted the campaigns for immunization against other communicable diseases [4]. This made clear the need to revisit the HC policies toward the improvement of system resilience and larger availability of care services.

Economic and Financial Issues As mentioned above, now people live longer, but with an increasing burden of chronic or non-communicable diseases (NCD), usually requiring long-term and often complex and expensive therapies. NCD include Parkinson and Alzheimer disease, diabetes, chronic kidneys disease, strokes, osteoporosis and others.

Living longer, but with the burden of (heavy) disability is one of the main factors undermining he financial sustainability of the HC systems. The decision- and policymakers are struggling with these aspects [9].

[1] Nassim Nicholas Taleb in his book of 2007 [8], introduced the concept of *black swan* referring to the extreme impact of rare and unpredictable events and the human tendency to find a retrospective simplistic explanation for these events.

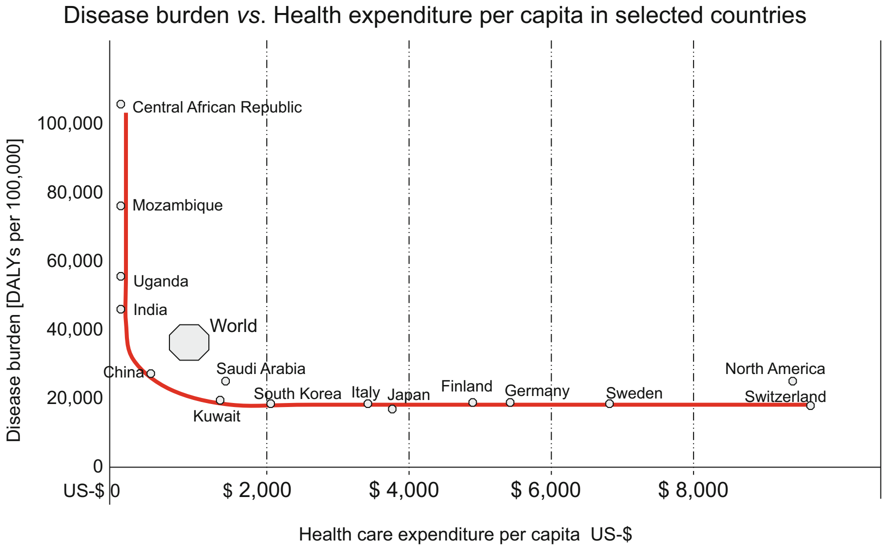

Fig. 11.2 Disease burden vs healthcare expenditure in selected countries. (Adapted from [11])

The DALY[2] parameter can give a synthetic estimation of the overall health quality. The curve in Fig. 11.2 shows the fact that even in front of a healthcare expenditure growth, at least in most wealthy countries, the DALY level does not show a consequent improvement.

The curve in Fig. 11.2 highlights two different topics.

While there still is a considerable space for improvement in many low-income countries, generally characterized by low-resources settings, the most affluent countries are facing a reduction in marginal return on the investment in HC expenditure. This requires a change in HC paradigm favouring a better attention to the delivery of services with real value for the patients (see also Chap. 1).

In addition, this “saturation effect” shows that, having thankfully found therapies for many diseases, we have now to focus on “more difficult” disorders requiring heavier effort in terms of research and more expensive therapies. This is a strong call for policy makers to support research and development of new therapy options (e.g. personalized and precision medicine) aiming at the reduction of diseases burden.

Environmental Issues The production and use of medical devices generate an increasing demand for energy and natural resources (e.g. highly purified water for

[2]Disability Adjusted Life Years—This parameter synthesizes the disease burden on a population due to the years lost for premature mortality and the lower quality of life due to illness or disability (see e.g. [10]). It is computed as: DALY = YLL + YLD. (YLL= years of life lost, YLD = years with disability).

haemodialysis treatment, medical-grade polymers and blends thereof, see also Chap. 2). In addition, the production and disposal of single-use items stress the issue related to the management of possibly contaminated and infectious medical wastes.

The consequences of the environmental impact derived from the extensive application of medical devices of different complexity is becoming more and more relevant due to:

- The extensive use of large number of *resources-demanding* pieces of equipment (e.g. requiring an important amount of energy or water)
- The application of medical-devices-based therapy to a large and increasing part of the population, often affected by chronic diseases requiring long-term and possibly complex treatments
- The extensive use of single-use (disposable) items. This while is decreasing the risks due to cross infection/contamination require high level of resources consumption for their production, and contribute to the creation of potentially contaminated wastes.

Every year an estimated 16 billion injections are administered worldwide, but not all of the needles and syringes are properly disposed of afterwards. Open burning and incineration of healthcare wastes can, under some circumstances, result in the emission of toxic compounds, such as chlorine, dioxins, furans, and most recently particulate matter (e.g. PM 2.5 and PM10).

As a first conclusion, the factors affecting the HC sustainability span from the use of financial resources to the environmental pollutions to some more "socio-political" issues like access to care and decision on investments versus clinical outcome evaluation (see also Chap. 9). All these aspects influence the citizens' expectations and are matter of political as well as technical choices [12].

11.2 Health Care Systems Sustainability and the Impact of Medical Devices

The possible contribution that the application of medical devices can give to sustainability is summarized in Fig. 11.3.

A current model [13] underlines the elements to keep a healthcare system sustainable. Among others, it is useful to consider this index and its vital signs to be evaluated:

- **Access**: Extent to which medicines, treatments, diagnostics or other technology can be accessed by those who need them
- **Health status**: Actual health status and outcomes
- **Innovation**: Developing new and transformative medicines, treatments and technology

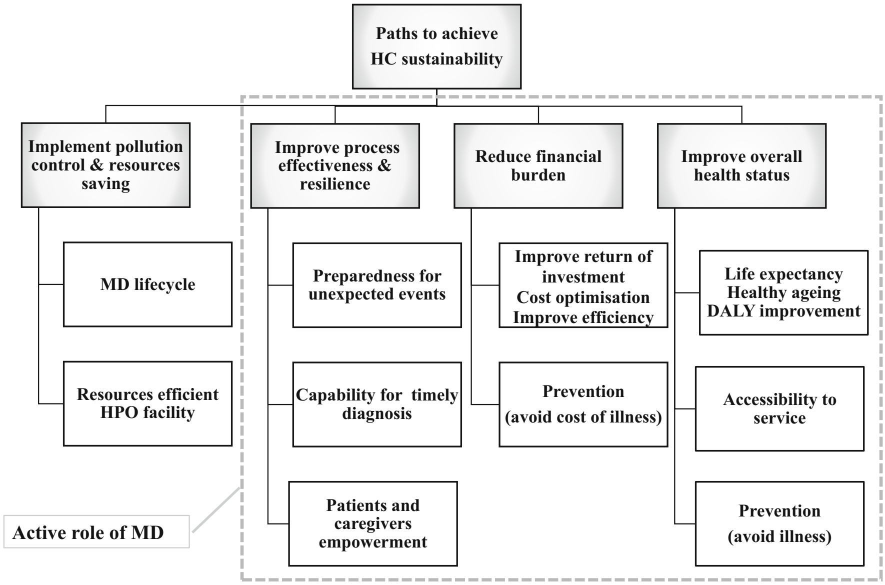

Fig. 11.3 The contribution of medical devices to the healthcare system sustainability. (*HC* Healthcare, *MD* medical device, *HPO* Healthcare Provider Organisation, *DALY* Disability Adjusted Life Years). (Basic concept derived from [13])

- **Quality**: Frontline delivery of healthcare
- **Resilience**: Ability of a healthcare system to continue to meet the populations' needs in the future

According to Fig. 11.3, it is possible to identify the main influences of the medical devices to the sustainability of the HC systems.

A first level of contribution is achieved with the environmental-aware design and operation of medical devices during their full lifecycle. This means to consider the environmental impacts of a medical device from its conceptual definition, to the production, to the use and finally to the disposal or decommissioning. The ultimate goal is, without sacrificing the safety and performance, to achieve the most effective use of resources and the lowest production of waste.

A more *active* contribution of the medical devices is in the achievement of a more effective and efficient medical treatments as well as the support that the related technology can give to the extension of care to a larger part of the population, e.g. through self-monitoring devices or telemedicine techniques (see dashed area in Fig. 11.3).

11.2.1 Pollution Control and Resources Saving

In recent years, increasing attention has been paid to the reduction of the resources consumption and waste production in the medical sector, spanning from the careful design of the production process, including the disposal of toxic solvents, to the correct disposal of the expended items. In addition, a careful design of environmentally friendly healthcare buildings is more and more realized.

For instance, the haemodialysis treatment for kidney patients can be considered as a paradigm for the above aspects. The haemodialysis is a long-term chronic treatment (see details in Chap. 6) involving:

- The use of a complex medical equipment (e.g. the dialysis monitor)
- Dialysis fluids and concentrates requiring about 400 L of purified water per treatment. Special (single use) disposable items (like blood lines, dialysis filters, needles, etc.)
- Waste of the spent dialysis fluid during the treatment and disinfecting agents for the cleaning/disinfection of the dialysis monitor
- Energy requirement for the dialysis monitor up to 3.5 kWh per treatment [14].

In addition, a total of 694 kg of waste per patient per year is produced. Most of this waste is potentially infective [13].

Furthermore, due to the high number of disposable items used in haemodialysis, the consumption of energy and the CO_2 production for the delivery of the needed material at the dialysis center should not be neglected.

Many international organizations and private companies dealing with dialysis treatment have initiated, since many years, several initiatives to reduce and control the environmental impact of the haemodialysis related devices.

Among the most relevant recommendations it is possible to list the following:

- Rationalize the use and reuse of the RO discarded water and of the spent dialysis fluid [14–17]
- Optimize electric energy consumption
- Rationalize the waste management
- Reduce the negative externalities, e.g. producing the dialysis concentrate inhouse from highly concentrated media and avoid the transportation of bulky container of dialysis concentrate composed by high percentage of water.

The achievement of a better level of sustainability needs also to consider the overall MD lifecycle.

Attention to sustainability issues should start right from the device's conception and design.

As an example, the IEC 60601-1-9[3] is a collateral standard to the IEC 60601-1 concerning the safety and basic performance of medical electrical equipment.

It aims at improving the environmental impact of an electrical MD through all stages of the device's lifecycle, from the very conception to the end of life. To claim compliance with this standard the manufacturer should consider and document the actions taken to minimize the environmental impact over the full lifecycle of the device.

It is related to other standards, like

- ISO 14971(Medical devices—Application of risk management to medical devices) [18], since the environmental impact must be considered among the element of the risk management process. Among others, it considers the risks connected with possible chemical or biological hazard and emission of toxic substances.
- ISO 14001 (Environmental management systems—Requirements with guidance for use) [19] addresses the implementation of processes for the management of the environmental impacts over the full product's lifecycle.

In addition, the manufacturer should also demonstrate that the expected medical benefits justify the possibly unfavourable environmental impacts generated by the equipment. This evaluation may be influenced by the intended use of a device. The impact accepted for a life-saving equipment may not be tolerated for a device intended for easier conditions or for aesthetic applications.

An additional action to reduce the environmental impact of the medical equipment is relevant to the HPO design. The accommodation and effective operation of complex medical equipment requires also the correct adaptation of the HPO facility where the equipment is installed and operated.

It is important that the facility allows the safe disposal of the exhausted and possibly contaminated parts and fluids, e.g. used personal protective equipment, dialysis filters, drain fluids (see also Chap. 6).

11.2.2 Active Contribution of Medical Devices to Sustainability

Making reference to Fig. 11.3, it is possible to see that the medical devices can have an important "active role" in the achievement of the HC system sustainability

This *active* contribution is highlighted in dashed area of Fig. 11.3.

The costs issue is surely the most evident and discussed aspect when talking about healthcare sustainability.

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[3]Medical electrical equipment—Part 1–9: General requirements for basic safety and essential performance—Collateral Standard: Requirements for environmentally conscious design.

As shown in Fig. 11.2, the costs for healthcare are continuously rising even if the overall disease burden (DALY) is not linearly improving with the invested resources.

The way to cope with these issues is to implement a paradigm change [3], based on:

- **Patient's empowerment**. Especially when dealing with a chronic treatment, it can reduce the involvement of professional caregivers and the need for the patient to go to hospital for ambulatorial checks. In this case the availability of medical devices engineered for simple, safe and reliable operation by lay users is a key point.
- **Data collection and sharing**. The sharing among medical staff, possibly located in distant locations, allows for a cooperative diagnosis or for an agreement on the therapy in case of difficult clinical situations. This supports a higher quality of medical care also in remote locations or to small hospital with less resources.

The possibility of remote medical consultation is of special importance in case of natural catastrophes but can also help in building a monitoring and safety network to control a pandemic spread.

The patient's empowerment is considered [20] among the main pillars to ensure the sustainability of the healthcare system. The empowerment of the patients and of the lay caregivers may in fact reduce the cost, but can also improve the quality of the care and the quality of life (QoL) of the patient. The availability of devices that enables the patients to measure the required parameters him/herself can save resources, due to the less need for qualified personnel to take care of "easy" tasks.

This also allows the monitoring of the important parameters at the right time, that may not always be possible with the traditional ambulatory consultation (see case story in Chap. 5).

A basic requirement is that these parameters are reliably collected, stored and made available to the professional caregiver in due time.

Sustainability means also "healthy ageing". Due to the increasing percentage of elder population and the consequent prevalence of chronic diseases, the HC system, to be sustainable, needs to address the way to promote the healthy and autonomous ageing. This means to ensure a better and self-sufficient life in the last part of the existence, but also preventive actions and considerable saving in avoiding acute costly treatments when avoidable [21]. The remote consultation supported by easy operable MDs is a way to grant elder patients with the personalized monitoring and grant the most degree of autonomy.

Conclusion

The pervasive application of medical devices in the modern healthcare has many implications on the sustainability of the HC system.

The most evident one is the need for a sensible design and operation of these devices to ensure that resources, like electric energy and water, are effectively used. Considering the large number of disposable items, it is also important that these are adequately disposed. The reuse of these items can in principle be also considered, but in this case, the reuse process must ensure the safety and efficacy of the reconditioned items. It should also be considered that the reconditioning process is also consuming resources and produce pollution (e.g. spent disinfecting agents). For this reason, a trade-off between disposal and reconditioning should be carefully considered (see also Chap. 6).

Attention should also be paid to the design of the physical environment where the MD is used: the careful design of these areas and locations can contribute to reduce the environmental impact.

The medical devices give an important contribution to the reinforcement of a new paradigm based on the patient's empowerment. The medical equipment can e.g. provide the information about the required physiological parameters in short time directly to the caregivers. In addition to the important cost savings, this last aspect can also contribute to grant a high level of medical therapy to a larger population without restrictions related to geographical location or wealth status.

The patient's empowerment and the easy communication of vital parameters as well as the possibility to obtain quick instrumental data (e.g. from an MRI equipment) evaluated by well-trained experts, possibly remotely located, are important supports for answering to unexpected and critical events as well.

Take Home Message

- The sustainability of the healthcare system is confronted by many challenges, involving environmental, financial and socio-political aspects.
- Medical devices can give a considerable support in improving the HC sustainability, both in terms of better use of resources and supporting a more effective healthcare model.
- The careful use of natural resources and the pollution reduction requires to pay attention to the overall device's lifecycle, from the conception and design to the operation and final disposal.
- Patient's empowerment, prevention of illness, capability for early diagnosis as well as better preparedness to unexpected events are among the most important active contributions that MD can provide to the HC system sustainability.

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