Chapter 9
Assessment of Medical Technologies: Methods and Challenges

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Abstract The present situation of the healthcare systems worldwide strongly calls for a change in the care delivery paradigm and requires to focus more on the long-term outcomes and on what is of real value for patients and the community. This approach can be summarized with the value-based healthcare concept, which can be greatly sustained by the technology innovation. The chapter focuses on the assessment of medical technologies, with special attention to medical devices, and on different methods and problems connected with this evaluation. Special emphasis is given to the different methods (e.g. health technology assessment, cost-utility analyses, and others), and to investment/divestment decisions. The issues of the social return of the investment in healthcare and of the legitimacy of the decisions taken are also considered.

The discussion is then completed with the presentation of the emerging topics about the assessment of medical technologies.

Introduction

For the creation of the best care value for patients and community, the assessment of the medical technologies and innovation, with special attention to medical devices, is needed.

The analysis has to start with the concept of value in healthcare followed by the examination of the different methods for technology evaluation and the definition of investment strategy.

The innovation in hospitals should further not be neglected.

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9.1 The Concept of "Value" in Healthcare

The recent pandemic has made it clear to citizens, hospital professionals, and policymakers that the current paradigms of healthcare delivery must be reloaded. Among the many lessons learnt, one of the most relevant issue is about the role that "innovation" should play in order to rethink and improve healthcare delivery. The focus has shifted from short-term outputs over medium- to long-term outcomes [1]. What matters is the actual capability of healthcare providers (e.g. family doctors, acute and rehabilitation hospitals) to impact positively and significantly the quality of life of citizens and the competitiveness of the served society [2].

This new approach to healthcare delivery is widely known as "Value-Based Healthcare" (VBH). The concept of "value" stems from the original formulation by Porter and Teisberg [3] and is defined as the ratio between the health outcomes that matter to patients and the cost of delivering that outcome. This concept is still under discussion, but there is a growing consensus that the shift from outputs to outcomes obliges healthcare delivery to meet four requirements: participation, personalization, prevention, and prediction [4]. Even if the in-depth discussion of these requirements is beyond the scope of this chapter, a few examples might show their relevance and urgency. First, citizens are claiming for a more active role in the management of their health/disease, because of their progressive empowerment in terms of health literacy, revisiting the traditional scope of the patient–physician alliance. Second, precision medicine has gone far beyond the borders of DNA-based diagnostics to also cover service delivery, acknowledging that socio-demographic factors might affect citizens' experience with the delivery of care and their adherence to therapy/lifestyle. Third, as it happened in other industries, healthcare should deliver care to citizens when they are still healthy to reduce, and possibly avoid—or at least to postpone—the emergence of (chronic) diseases. Fourth, decision-makers are more and more provided with accurate predictions about what might happen and what should be the most effective interventions due to the increased availability of data and the development of machine-learning algorithms. Healthcare providers are needed to explore either new processes or practices to meet these requirements, matching different organizational arrangements and technological configurations [5]. These changes must ground on innovations. Among the different sources of innovation, the seamless development of innovative medical technologies is one of the most relevant ones and the assessment of their potential impact on value generation is the focus of this chapter. Figure 9.1 offers a synthetic view of the linkage between value-based healthcare and innovative medical technologies.

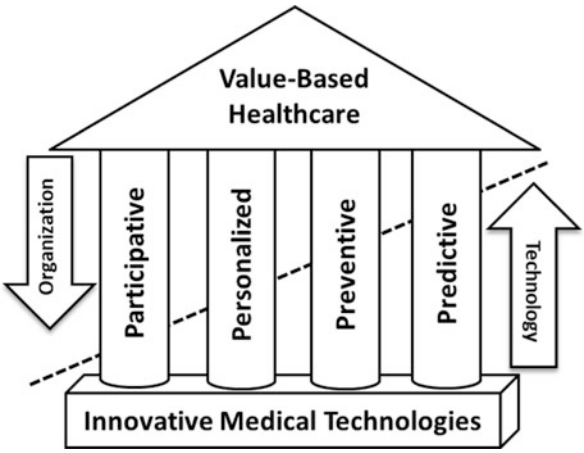

Fig. 9.1 Value-based healthcare and its "pillars"

9.1.1 Value-based Healthcare and Technology Assessment

The increased pace of technological development in healthcare, combined with shrinking financial resources available to adopt them, obliges decision-makers to select, among the most promising innovations, only those that can demonstrate the best value-for-money—i.e. those innovations that prove to generate enough benefits compared to their costs [6]. In this view, how to support decision-making at different levels (national/regional/local/hospital/department/professional) has risen as a priority on the agenda of practitioners and scholars of biomedical engineering, health economics, and medicine. In the last years, the worldwide debate on decision-making concerning the adoption of novel medical technology has grown around the concept of legitimacy. Decision-making must be legitimate. This is particularly relevant for all national healthcare systems whose activities and investments in novel medical technology are based on citizens' taxes.

Legitimacy can be defined as "*a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions*" [7]. This definition clarifies that what is legitimate is socially constructed and might differ in different social groups (e.g. in different healthcare systems). Legitimate decision-making should consider the point-of-view of different groups of stakeholders, such as patients, caregivers, patient advocacy groups, hospital professionals and managers, suppliers, payers, and policymakers. Past research [8] identified four requirements that should ground legitimate decision-making in healthcare. They are (1) rationality, (2) fairness, (3) efficiency, and (4) evidence, as shown in Fig. 9.2.

Figure 9.3 synthesizes the main implications related to the four requirements. Legitimate decision-making should ground on rational methods and processes. In particular, the assessment of novel medical technologies should crystallize the most relevant criteria that can help to gather the most comprehensive understanding of the implications due to their adoption. These criteria should cover different domains,

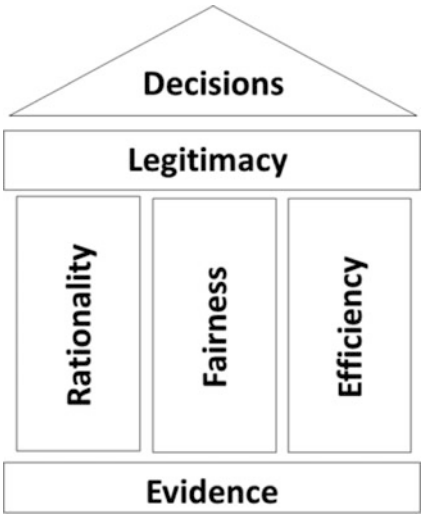

Fig. 9.2 Requirements of legitimate decision-making in healthcare

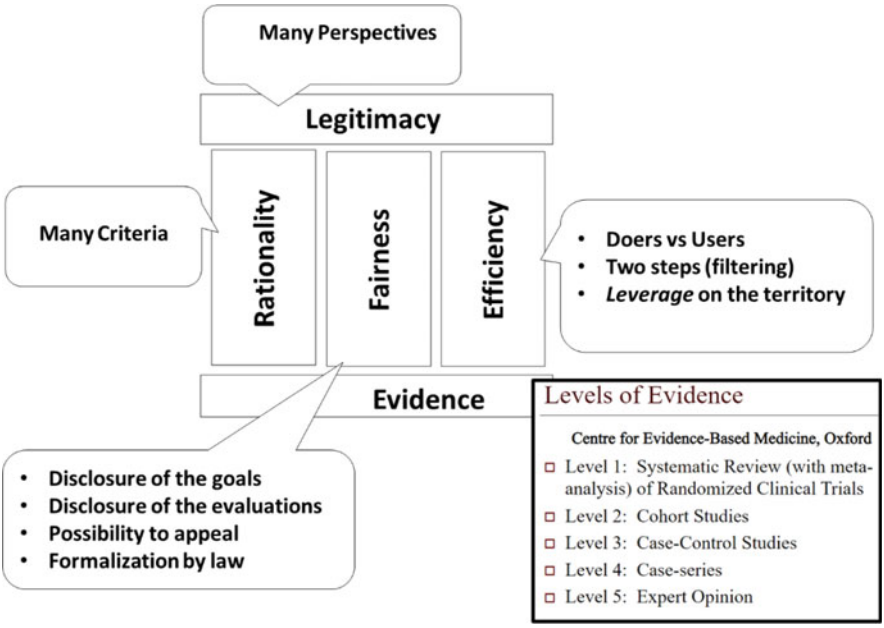

Fig. 9.3 Criteria for legitimate decision-making in healthcare

such as effectiveness, safety, organizational impacts, and efficiency. Legitimate decision-making should be fair, i.e. no group of stakeholders (or beneficiaries) should be privileged or disadvantaged. Past studies identified four conditions for guaranteeing fairness. First, goals of assessment and decision-making should be disclosed. Second, the methods and results of evaluations should be also disclosed.

Third, all groups of stakeholders should be in the condition to appeal to evaluations if they think either that some pieces of evidence have been overlooked or some parts of the evaluation should be revised because being incorrect. Fourth, all these elements should be formalized through laws. Legitimate decision-making should be efficient. The pace of technological development in healthcare is very high and, even if from a theoretical perspective all innovations should be assessed to prove their value-for-money, from a practical perspective this is not feasible. In this view, three arrangements might be implemented. First, users rather than doers should oversee the assessment of novel medical technologies. This means that they should try the best they could to reuse the assessment reports produced by other entities—through collaborative networks—and produce reports only for those innovations that have not been assessed yet by others.

Second, the available resources for assessment, in terms of time and money, should be focused on a subset of innovations through the crystallization of filtering mechanisms, thus designing a two-stage approach—as done, for example, for the proposals of funding that are submitted to the European Commission. Third, entities that oversee technology assessment should try to leverage the competencies and resources that are available on the territory, involving universities, research centres, scientific associations, hospitals, patient advocacy groups, etc. Finally, these requirements (i.e. rationality, fairness, efficiency) should ground on evidence, as recommended by evidence-based medicine. Dealing with innovations, evaluators will face situations characterized by different levels of evidence, ranging from high levels (e.g. meta-analyses, randomized clinical trials) for more mature medical technologies to low levels (e.g. expert opinions, case series) for emerging ones. This consideration paves the way for discussing the difference between Health Technology Assessment (HTA) and Horizon Scanning (HS). Even if the large audience is more familiar with the concept of HTA when debating about the assessment of novel medical technologies, in the next section the distinction between HTA and HS will be addressed.

9.1.2 Health Technology Assessment

Health Technology Assessment (HTA) has been defined as a form of policy research that examines the short- and long-term consequences (e.g. societal, economic, ethical, legal) of the application of medical technology [9]. It aims at providing decision-makers with the information they need. They may not be able to judge the benefits or consequences of medical technology within a strictly technical context. They must consider the social, economic, and legal implications of any course of action. However, very frequently, the comprehensive information needed by decision-makers is either not available or not in the right form. This supports further the still ongoing debate about what should be the information domains considered by HTA reports, addressing rationality for legitimacy.

Before discussing the proposals that have been developed within the Cost-Utility Analysis (CUA) and the Multi-Criteria Decision Analysis (MCDA) in terms of relevant informative domains, it is worth to clarify the distinction between assessment and decision-making. They are different domains that refer to distinct responsibilities. The separation between those who assess and those who decide upon is connected to legitimacy. Regulators must clarify policy needs and translate them in research questions that researchers from different disciplines can investigate through the design of coherent research projects aimed at gathering robust results. HTA offers the methods to answer the research questions agreed between regulators and researchers. The responsibility of researchers ends once research questions have been answered. Regulators are not involved in the production of results, but their role is to decide upon them—either positively or negatively. Regulators can reject legitimately researchers' results. This might happen either because results overlook relevant pieces of information or because methods that have been applied are not agreed. Therefore, it is necessary a wide agreement—better at the international level—of the language, the methods and reporting that should be employed by those running HTA exercises. In this view, the efforts made in the last years by the INAHTA—the International Network of Agencies for Health Technology Assessment—are worth to mention, with particular attention to the development of (1) an agreed glossary of HTA-related terms with their meaning, (2) a coherent portfolio of methods and tools for the design and carry-out of HTA exercises; (3) a checklist to evaluate the robustness of HTA reports; and (4) a database of past HTA reports facilitating the reuse of the already available assessments.

A similar effort has been made by the EUnetHTA (European network for Health Technology Assessment) European collaboration. This initiative, funded by the European Commission, established a network for HTA across Europe to help the production of reliable, timely, transparent, and transferable information about medical technology. In particular, the network aims at an efficient resource use for HTA (promoting the reuse of previous reports), the sharing of expert knowledge about HTA, and the crystallization of a coherent set of good practices for HTA. In this view, one of the most relevant contributions has been the development of the Core Model reference framework for HTA [10, 11]. Nine domains have been identified as the most relevant for supporting decision-making (Table 9.1). They are:

1. Health problem and current use of technology
2. Description and technical characteristics of the technology
3. Safety
4. Clinical Effectiveness
5. Cost and economic evaluation
6. Ethical analysis
7. Organizational aspects
8. Patient and social aspects
9. Legal aspects

According to EUnetHTA, two different HTA reports can be delivered. On the one hand, decision-makers might be interested in a comprehensive assessment—also

Table 9.1 HTA domains according to the EUnetHTA collaboration

HTA core model domains			
Comprehensive/ Full HTA	*Rapid Relative Effectiveness Assessment (REA)*	Domains whose analysis can be valid for different countries and facilitate the reuse of the HTA report	Health problem and current use of technology
			Description and technical characteristics
			Safety
			Clinical Effectiveness
	Country-specific Appraisal	Domains whose analysis might differ country by country because of the peculiar characteristics	Cost and economic effectiveness
			Ethical analysis
			Organizational aspects
			Patient and social aspects
			Legal Aspects

known as "full HTA report"—that covers all nine criteria. This might be the case for more mature medical technologies, whose evidence is more consistent and broader. On the other hand, decision-makers might be interested in a less comprehensive, more focused assessment. This is the case for a Rapid Relative Effectiveness Assessment (REA) that covers just the first four criteria. This might be the case for emerging medical technologies, whose evidence is more limited and still focused on clinical effectiveness and safety. Interestingly, this distinction is useful also to discuss the potential reuse of HTA reports.

The distinction between "mature" and "novel" medical technologies is salient for their assessment because of different levels of evidence. HTA requires significant bodies of high-quality evidence to support decision-making. Because of that, HTA is usually associated with mature technologies and it is mainly used to manage the diffusion or the disposal of medical technologies that are already in use somewhere. Where the medical technology under assessment is emerging or innovative—meaning that the technology is at the beginning of its diffusion in the healthcare system and that the available evidence is still limited and of lower quality—the assessment refers more to Horizon Scanning (HS) than to HTA [12]. Even if the domains and criteria might be shared among HTA and HS, their difference grounds on the level of evidence that informs assessment reports and the strength of the recommendations that will be submitted to decision-makers.

From a practical perspective, HS reports are of paramount relevance. Where decision-makers are enabled to know in advance that some promising medical technologies will access soon the market and will be available for the clinical practice, they can act to prepare the field to enable and facilitate their fast

diffusion—e.g. developing the required legal framework, providing healthcare professionals with the required competencies.

9.1.3 Economic Assessment of Technology in Healthcare

The economic assessment aims at providing decision-makers with useful, complete, robust evidence about which healthcare strategy—or medical technology—should be preferred among the available alternatives (known as comparators) [6]. The alternatives are benchmarked in terms of consequences and costs (Fig. 9.4). Among the "consequences", the assessment must consider all benefits that derive from the adoption of a specific healthcare strategy/medical technology in terms of any improvement of patients' health or well-being. This refers to the concept of "effectiveness" of a healthcare strategy/medical technology. Among the "costs", the assessment must consider all resources consumed by the adoption of a specific healthcare strategy/medical technology. These resources might be provided by (1) the healthcare system (e.g. from local health agencies, hospitals, nursing homes), (2) the patient or her/his family (e.g. in terms of patient's time, caregivers' time, travel costs); (3) other sectors (e.g. from non-profit organizations, social enterprises). When resources from all sources are included, the economic assessment takes a "societal perspective". Vice versa, when only resources from the healthcare system are considered, the economic assessment takes a "healthcare system perspective". The choice between the two perspectives is related strictly to the specific healthcare strategy/medical technology under assessment. For instance, in the case of mental care services, almost half of the costs come from the patients (and their families) and other sectors. In such a context, a societal perspective should be preferred to provide decision-makers with a more comprehensive understanding of the benefits and costs associated with different alternatives (comparators).

The economic assessment of the different alternatives can be conducted with four main techniques [13] that are pointed out in Fig. 9.5. The distinction among them

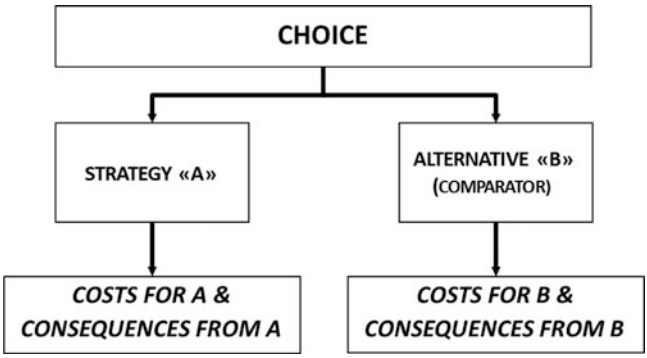

Fig. 9.4 Setting decision-making about technologies in healthcare

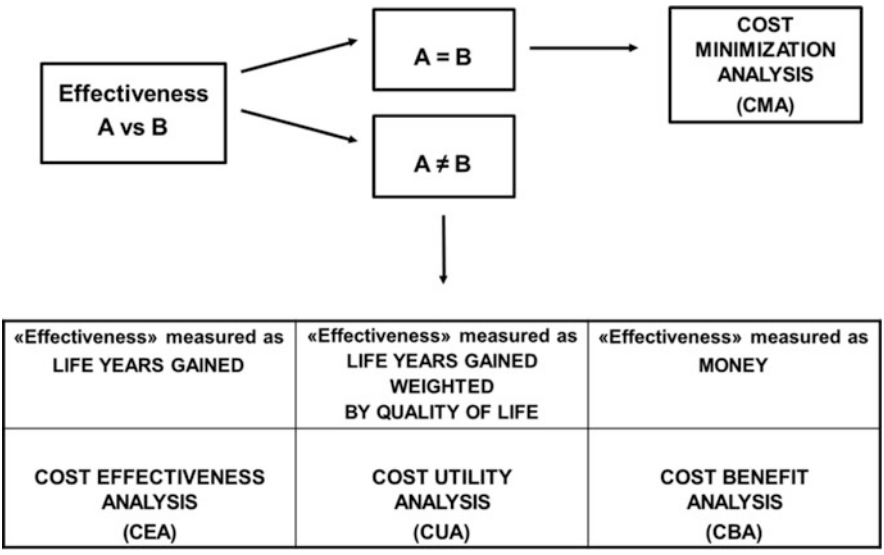

Fig. 9.5 Setting decision-making about technologies in healthcare

relies on how they analyse consequences (effectiveness). If the different alternatives offer similar consequences, the economic assessment compares them against costs, preferring the alternative that minimizes the consumption of resources—namely Cost Minimization Analysis (CMA). This analysis is almost rare because the typical situation is that novel medical technologies claim superior benefits with respect to comparators. An example refers to telemedicine, where economic studies assume that telemedicine offers similar benefits in comparison to face-to-face clinical practice and, in this view, assess potential cost savings (e.g. [14]). Where the alternatives offer different consequences, they can be measured in different ways. The most widely used approach is to measure benefits with primary endpoints—e.g. reduction in mortality or number of life years gained. In this case, the economic assessment is a Cost-Effectiveness Analysis (CEA). Another approach is to measure consequences such as the combination of primary endpoints (life years gained) with an outcome measure such as Quality of Life (QoL), introducing Quality-Adjusted Life Years (QALYs) as a synthetic indicator that captures both variations (quality and quantity). This economic assessment—known as Cost-Utility Analysis (CUA)—should be preferred in the case of diseases or events that, despite they do not affect patients' mortality, reduce, with different levels of severity, their quality of life (e.g. limb amputation, chronic degenerative diseases, kidney failure, coma state). Finally, consequences can be measured in terms of saved costs or value generated, using currency as a unit of measure. This allows a direct comparison—in monetary terms—between benefits and costs (Cost-Benefit Analysis—CBA). The valorization of benefits can be done using different approaches such as the measurement of patients' Willingness-To-Pay (WTP) or revealed preferences.

Table 9.2 Characteristics of the four techniques for economic assessment

Analysis	Costs (measured as . . .)	Consequences (measured as . . .)	Level of use	Strengths	Weaknesses
CMA	Money	There is no measure because they are similar	Low	Consequences re not to be measured	It works only for alternatives with similar consequences
CEA	Money	Disease-related measure	High	Strict relation with the disease	It works only for alternatives in the same clinical domain
CUA	Money	QALYs (Quality-Adjusted Life Years)	Medium	It works for alternatives with different consequences	QALYs receive critics and their measurement is not easy
CBA	Money	Money	Low	It works for alternatives with different consequences	Measuring consequences as "money" is not easy

Table 9.2 offers a synthetic view of the characteristics of the four methods, also in terms of strengths and weaknesses. Among the methods, scholars of health economics recommend CUA as a reference technique for the economic assessment of different healthcare strategies/medical technologies.

In this view, the next section will detail briefly CUA.

9.1.4 Cost-Utility Analysis

Cost-Utility Analysis (CUA) measures the consequences of alternative healthcare strategies/medical technologies by combining quantity and quality of life (QoL) into Quality-Adjusted Life Years (QALYs) [6, 13]. QALYs—that can be computed as the product of life years times the achieved QoL—measure the utility (i.e. the value) generated by a specific healthcare strategy/medical technology. From a theoretical perspective, QoL is a value that goes from 0 to 1, where "1" indicates a situation where the patient has full QoL (this state is typically associated to perfect health) and "0" indicates a situation where the patient has a nil QoL (this state is typically associated to death). Figure 9.6 shows the comparison between two alternatives, A vs B, in terms of the expected length of life before death (horizontal axis) and the expected quality of life (vertical axis).

The incremental benefits generated by the adoption of strategy/technology B (with respect to A) can be measured as the difference between the two areas below the two curves of QoL.

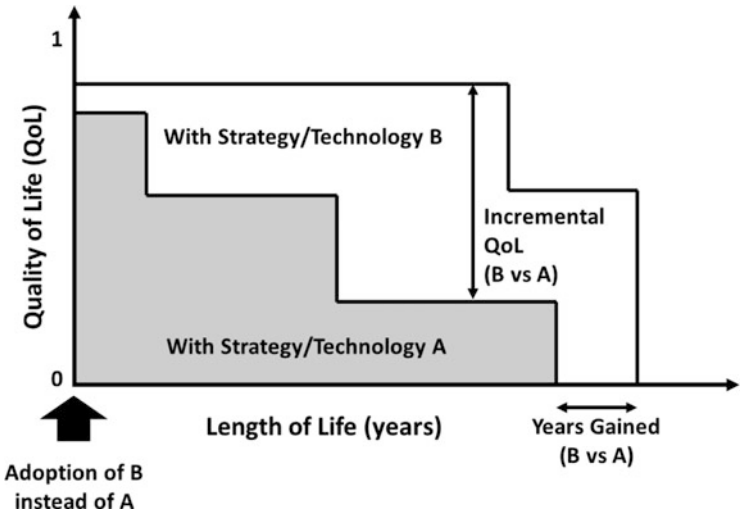

Fig. 9.6 Quality-adjusted life years as a synthetic index

The advantage of CUA compared to CEA is that, while CEA measures consequences just as years gained (i.e. the difference that is shown on the horizontal axis), CUA weights the length of life by the expected QoL, thus providing decision-makers with a more comprehensive understanding of the utility (i.e. the value) generated by different alternatives. This is particularly relevant in those cases where diseases or traumatic events do not affect patients' mortality, such as limb amputation, but they affect QoL [15].

The measurement of QoL is the most critical phase in a CUA. While clinical studies offer evidence about the expected length of life because of alternative healthcare strategies/medical technologies, evidence about the related QoL is less available and must be collected and measured in dedicated economic studies. There are different methods to measure QoL that ground on different theoretical assumptions. On the one hand, there are methods—e.g. the Visual Analogue Scale or Rating Scale, the Standard Gamble, and the Time Trade-Off—that measure individual preferences. These methods share the assumption that QoL is definitively subjective and patients who share the same health situation might perceive a different QoL. On the other hand, there are methods—e.g. the EQ-5D-3L—that measure the health status because they postulate that QoL is determined mainly by the health status of patients and that, in this view, patients who share similar health status perceive similar QoL.

In the followings, the most established methods are described briefly.

The Visual Analogue Scale (VAS) is the simplest and most frequently employed method. It consists of a straight horizontal (or vertical) line of fixed length, usually 100 mm, orientated from the left (worst QoL = 0) to the right (best QoL = 100). The patient indicates her/his perceived QoL on this scale. Collecting the

socio-demographic characteristics of the patient as well as her/his preferences, the researcher, through a regression analysis, can identify those factors that explain QoL.

Concerning the Standard Gamble, the researcher proposes to the patient a hypothetical situation where an intervention is available that might restore her/his perfect health but with a probability $(1 - x)$ to die. The patient is asked to choose between two alternatives (gamble): (a) refuse that intervention and remain in the current condition of imperfect health; (b) accept the intervention (probability of success equal to x). The probability x must be varied until the patient is indifferent between the two alternatives. When the patient cannot decide between them, this means that the utility of the two alternatives is equal (i.e. length of life times QoL). From this equality, it is possible to determine that the QoL of the current health status is equal to x.

Similarly, to the Standard Gamble, the usage of the Time Trade-Off approach requires the researcher to propose to the patient a hypothetical situation where an intervention is available that might restore her/his perfect health but with the side effect to reduce her/his life expectancy from "t" to x. The patient is asked to choose between two alternatives: (a) refuse that intervention and live in a condition of less than perfect health for "t" years; (b) accept the intervention and live x years in perfect health (being x lower than "t"). Time x has to be varied until the patient is indifferent between the two alternatives. When the patient cannot decide between them, this means that the utility (i.e. length of life per QoL) of the two alternatives is equal. From this equality, it is possible to determine that the QoL of the current health status is equal to x/t.

The Euro Quality of Life—5 Dimensions—3 Levels (EQ-5D-3L) approach postulates that QoL is strictly related to the patient's health status and that patients with a similar health status perceive a similar QoL. In this view, QoL is determined by the identification of the current health status of the patient. The health status is evaluated against five dimensions: (1) mobility; (2) self-care; (3) usual activities; (4) pain and discomfort; (5) anxiety and depression. For each dimension, the patient has to report her current status against three levels: (1) no problems; (2) some problems; (3) extreme problems. This allows the researcher to characterize the current health status of the patient with a numerical code. For instance, the sequence 21123 indicates a patient who faces some problems to walk, has no problems with self-care, has no problems with doing usual activities, has a moderate pain/discomfort, and who is extremely anxious/depressed. QoL of the current health status is determined by subtracting to 1 (perfect health) specific coefficients associated with levels 2 or 3 (i.e. situations where the patient is not in perfect health).

Once QALYs have been determined—by calculating QoL with one of the methods described above—they are compared to the consumption of resources—accordingly to the societal or the healthcare system perspective. The comparison between consequences (QALYs) and costs of two alternative healthcare strategies/medical technologies (e.g. A vs B) is carried out through the Incremental Cost-Utility Ratio (ICUR). The ICUR is calculated as the ratio between the incremental costs (costs(B) minus costs(A)) and incremental utility (utility(A) minus utility(B)). In this view, the ICUR means the incremental cost that the healthcare system (or the

society as a whole) must sustain to provide the patient with an additional year in perfect health. This value is compared to a threshold defined by policymakers. The most representative threshold in Europe is the one defined by the National Institute of Clinical Excellence (NICE) equal to 58,600 €/QALY. This implies that only those healthcare strategies/medical technologies whose ICUR against the current practice is lower than 58,600 €/QALY will be considered eligible for reimbursement. The ICUR calculation should be performed for subgroups of patients—e.g. see Cutti et al. [15]—to identify which ones might benefit the most from the adoption of the healthcare strategy/medical technology under assessment and help decision-makers to prioritize the usage of limited financial resources. Similar lines of reasoning can be developed in the case of different healthcare strategies/medical technologies. By comparing them against the additional resources needed to generate one additional year in perfect health, policymakers can rank different healthcare strategies/medical technologies from the most efficient to the most expensive (i.e. accordingly to higher values of ICUR) and develop League Tables [16] to support the prioritization of resource allocation.

9.1.5 Multi-criteria Decision Analysis

In the last years, doubts have arisen about the capability of Cost-Utility Analysis (CUA) to capture the multifaceted consequences generated by alternative healthcare strategies/medical technologies. The progressive establishment of the main principles of Health Technology Assessment (HTA)—rationality, in particular—made clear that decision-makers need evidence about the short- and long-term consequences (e.g. societal, economic, organizational, ethical, legal). All consequences should be considered understanding their impact in terms of costs and QALYs. However, decision-makers have a twofold need of (1) being knowledgeable of the impacts against the various dimensions; and (2) decide about their relative relevance. Because of that, scholars of health economics and decision science argued that Multi-Criteria Decision Analysis (MCDA) should meet these informative needs and provide decision-makers with more actionable knowledge [17].

MCDA assesses alternative healthcare strategies/medical technologies against a set of established criteria that are identified and agreed on by decision-makers based on their informative needs. The relative relevance of these selected criteria is established through weights agreed among decision-makers. In this view, "utility" is not limited to QALYs and it is calculated as the weighted sum of the scores (i.e. the performance) achieved by alternative healthcare strategies/medical technologies against the criteria. Equation (9.1) shows how value must be calculated according to MCDA.

$$\text{Value} = \sum_{n=1}^{N} W_n * S_n \tag{9.1}$$

where:
N = Number of criteria
W = Weight of the criterion "n"
S = Score against the criterion "n"

Equation (9.1): Determination of Value According to MCDA

The list of criteria can be adjusted over time to meet new informative needs of either other decision-makers (e.g. patient advocacy groups) or specific medical technologies. In this view, the literature is rich in examples of criteria. Among the available proposals, the most interesting is the one adopted by the Italian Lombardy Region in their HTA programme [18]. In this proposal, the domains of the Core Model developed by EUnetHTA (that has been described in the section above) have been matched with the criteria developed by EVIDEM to support the appraisal. Table 9.3 shows this match by grouping the EVIDEM criteria (right column) against the domains identified by the EUnetHTA Core Model (left column). While these criteria are relevant and exhaustive for decision-makers at the national/regional level, they are not sufficient for decision-makers at the hospital level. For instance, these criteria do not meet the informative needs about the organizational impacts in terms of new clinical processes, learning curves, resistance to change, etc. All these aspects are better covered in Hospital-Based HTA models (see the next section). Once criteria have been defined and agreed by decision-makers, their relative relevance must be established. Even if there are not reference guidelines about how to define the relative relevance, scholars of decision science agree that the most simple and

Table 9.3 Match between core model domains and EVIDEM appraisal criteria

Current use	• Guidelines & Good practice recommendations • Limitations of alternative technologies in use
Technology	• Completeness and consistency of documentation • Relevance and validity of documentation • Description of technology and benefits areas
Safety	• Improvement of safety and tolerability
Effectiveness	• Improvement of effectiveness and efficacy • Improvement of patient-related outcomes
Organization and economics	• Financial impact on health system • Cost-effectiveness • Impact on other spending
Social, ethical, and legal analysis	• Disease severity • Size of population • General healthcare goals • Coherence with regional planning

valuable method is allocating 100 points among the different criteria (Table 9.4). This allows decision-makers pointing out which criteria are the most relevant. According to the fairness principle (legitimacy theory), weights should be made explicit and known from those that will be evaluated. The authors of this chapter argue that making weights explicit and stable for a medium-long period (e.g. 5 years) can positively contribute to the competitiveness of the MedTech industry with the result that developers and producers of medical technologies will know in advance which criteria (and relative weights) will be used to assess their innovative proposals, allocating their R&D efforts only to those that will have better chances to be positively evaluated.

The last step is the assessment of the alternative healthcare strategies/medical technologies against the agreed criteria. This assessment must be carried out by reviewing all available evidence that has been synthesized in HTA reports. The complexity of this phase relies on the fact that current HTA reports do not cover all assessment criteria and decision-makers might be left without relevant pieces of information. In this view, the agreement of what criteria are the most relevant will contribute positively on the production of relevant evidence, starting from the clinical studies, whose case report form might be enlarged to cover all assessment criteria. The alignment between the informative needs of decision-makers and what researchers collect from the field could significantly benefit the capability of the healthcare system to generate value through the allocation of the limited financial resources only to those healthcare strategies/medical technologies that proved to be the most promising.

From an operative point-of-view, there are no (again) reference guidelines about who and how should give the "scores". About the "who", there are two relevant experiences. On the one hand, the EVIDEM Collaboration suggests that experts of the clinical domain under assessment should score the alternative healthcare strategies/medical technologies. The rationale is that these experts are knowledgeable and could provide expert opinions. On the other hand, the Lombardy Region in Italy creates a group of experts of different disciplines (e.g. medicine, nursing, clinical engineering, economics, law) to maximize the legitimacy of the appraisal exercise. About the "how", the most relevant experience is from Canada [19]. They suggest (see Table 9.4) to score on a Likert scale that goes from "−3" (extremely negative relative performance) to "+3" (extremely positive relative performance).

The "relative value" generated by the medical technology under assessment with respect to its comparators would range from "−3" to "+3"—after normalizing the weights from 0 to 1 (i.e. dividing by 100). As for Cost-Utility Analysis, policymakers must define an acceptance threshold. There are no significant experiences about this; however, the authors of this chapter argue that a threshold around 1.75 might constitute a fair reference.

Table 9.4 Example for parameters and their weights and scores for MCDA

		Scores						
		Extremely negative relative performance	Negative relative performance	Partially negative relative performance	Similar performance	Partially positive relative performance	Positive performance	Extremely positive relative performance
Criteria	Relative weight	−3	−2	−1	0	+1	+2	+3
Guidelines recommendations								
Limitations of alternative technologies								
Completeness of documentation								
Relevance and validity of documentation								
Description of technology								
Improvement of Safety and Tolerability								
Improvement of Effectiveness/ Efficacy								
Improvement of patient-related outcomes								
Financial Impact on Health System								

Cost-effectiveness										
Impact on other expenses										
Disease severity										
Size of population										
General Healthcare Goals										
Coherence with regional planning										
	100 points									

9.1.6 Social Return on Investment (SROI) in Healthcare

The rising doubts about Cost-Utility Analysis (CUA) have incentivized the exploration of alternative approaches to the measurement of the value generated by alternative healthcare strategies/medical technologies. In the previous section, the growing interest in MCDA has been illustrated. Another direction of exploration is offered by the Social Return on Investment (SROI) that has received significant attention in the field of social enterprises and non-profit organizations.

SROI is a method used to account for "social value" when evaluating investments that are oriented to generation of value for the society (like healthcare). This method goes far beyond the traditional economic evaluation tools (like Cost-Benefit Analysis, CBA), by considering the value that is produced for multiple stakeholders in three main domains: economic, social, and environmental [20]. In this view, SROI can be a relevant method in the context of advocacy for investments for health [21]. SROI goes beyond the limitation of the traditional Return on Investment (ROI) that accounts only for shareholder value (i.e. the pecuniary value) and overlooks the positive/negative externalities that might advance the public good [22]. In light of that, evaluators should include a wider range of benefits, complementing the economic domain with the environmental and social ones. SROI is the ratio between the net present value of the whole range of benefits and the net present value of the resources invested [23]. This concept of SROI has been applied at the beginning by philanthropic foundations to demonstrate the impact of the social programmes that have been funded [24]. From this, the concept of SROI has undergone several revisions and it is still at the centre of an intense academic debate about its superiority with respect to CUA and CBA.

So far, to the best knowledge of the authors of this chapter, generally accepted practices to apply the SROI to the assessment of alternative healthcare strategies/medical technologies do not exist and different approaches are in place. However, the five main steps described by Nicholls and Lawlor [25] can be taken as a reference guideline. These steps will be described briefly in the following.

First, it is necessary to establish the scope and identify the most relevant stakeholders. The scope of a SROI analysis is an explicit statement about the boundaries of what will be included. It requires to consider the purpose, the audience, the background, the resources, the range of activities to focus on, the period over which the intervention will be (or has been) delivered, whether the analysis is a forecast or an evaluation. Relevant stakeholders (i.e. people or organizations that are affected or do affect the initiative under evaluation, either positively or negatively) are beneficiaries, caregivers, patient advocacy groups, the healthcare system, the pharmaceutical/MedTech industry, insurance companies, the economic system of the region under analysis, NPOs (Non-Profit Organization) and NGOs (Non-Governmental Organization), municipalities, etc.

Second, outcomes must be mapped. Outcomes are the positive/negative consequences of the initiative under evaluation. The outcomes perceived by each stakeholder must be recognized. The most recurring outcomes in healthcare are increased

quality of life, social inclusion, increased income, savings for beneficiaries, savings for the healthcare system, savings for the society, increased productivity because of improved health status. In this step, it is required also to recognize the inputs, i.e. what stakeholders are contributing to making the initiative feasible and successful. Typical inputs are the initial costs (fixed and non-fixed assets purchase), personnel training costs and labour costs, maintenance costs, renovation costs, overhead and administration costs, operational costs.

Third, outcomes must be valorized. Outcome indicators represent a preliminary step to monetize the identified outcomes. By multiplying the value of each indicator for its unitary monetary value, the monetary value of each outcome can be obtained. To reach this purpose, financial proxies based on methods such the Willingness-to-Pay (WTP) or the Human Capital are used to estimate the social value of non-traded goods.

Fourth, the impact must be established. The task is estimating how much of the outcomes would have happened anyway without the initiative under evaluation and what proportion of the outcome is generated by the initiative. Therefore, four main elements need to be quantified into percentages: deadweight (amount of outcome that would have happened even if the initiative had not taken place), displacement (how much of the outcome displaced other outcomes—e.g. reducing crime in one area may displace criminal activity to another area), attribution (how much of the outcome was caused by the contribution of other organizations or people), and drop-off (mitigation or decay of the outcomes over time).

Fifth, SROI can be calculated. The Net Present Value (NPV) of outcomes is calculated by adding up all benefits and by subtracting any negative effect in different periods through a discount rate (a reference value is equal to 5%). The net impact of the initiative under analysis can be calculated by deducting the four percentages pointed out previously from the NPV of the outcomes. The SROI ratio is computed by dividing the NPV of the net impact by the Present Value of inputs. Finally, a sensitivity analysis should be carried out to explore how the value generated might vary accordingly to some assumptions.

Many scholars of health economics and health policy claimed that SROI looks like CBA. While both methods translate consequences into monetary terms, SROI, more than CBA, can capture the perspectives of different groups of stakeholders [26].

In this view, SROI has been acknowledged as an extension of the traditional CBA that incorporates the broader socio-economic and environmental outcomes [27]. In the next years, an increasing number of applications of the SROI method to the assessment of alternative healthcare strategies/medical technologies is expected, as well as a discussion about the informative power of SROI assessments with respect to MCDA ones.

9.2 Disinvesting for Investing in Healthcare

The financial sustainability of the national healthcare systems of the most developed countries as we know them nowadays cannot be taken from granted for the next years. The "perfect storm" that has been generated by the combination of population ageing, non-communicable chronic diseases, GDP (Gross Domestic Product) stagnation, medical technology booming, citizen empowerment, etc., pointed out the need for new socio-technical paradigms for healthcare delivery and innovation management. The progressive shrinking of the available financial resources for the adoption of innovative medical technologies—e.g. medical devices, equipment, cancer drugs, digital solutions—enlarges the gap between what healthcare professionals and citizens would need and what they can have available in their daily practice. Innovative medical technologies, that proved to be value-for-money and safe, should be adopted as soon as possible to maximize the generation of societal benefits. Innovation should not be slowed down, or its adoption procrastinated.

In this view, the very question is how to sustain the adoption of novel medical technology in a context of shrinking financial resources. An interesting solution stemmed out from the reasoning about disinvesting for investing. This approach—that has been applied in the USA and Canada, even if done with different methods—grounds on the opportunity to save money from a medical technology already in place to fund the adoption of another medical technology that offers more value.

The example in Fig. 9.7 can clarify the theoretical underpinning of this approach.

Five innovative medical technologies are ready to enter the market. Which one should be prioritized in case of limited financial resources? This problem can be

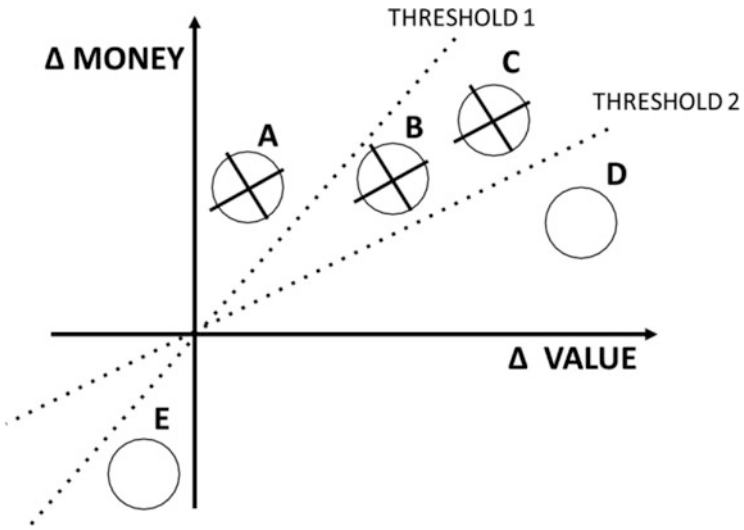

Fig. 9.7 Adopting medical technology E to fund the adoption of medical technology D. For details, see text

approached using a cost-utility analysis. In this view, the five innovations are benchmarked in terms of their incremental cost-utility ratio. The selection is done defining a threshold. In the case of threshold 1, technology A should be rejected because the value—in terms of quality-adjusted life years—is not enough compared to the necessary costs. In the case of a more selective threshold, as threshold 2, technologies B and C would be rejected, too. The choice should go on technology D. But what, if the costs required by technology D do not meet the available financial resources? One opportunity might be to adopt technology E, too. Technology E is very peculiar because it offers the opportunity to save money with respect to the current comparator in daily practice while reducing—on a limited amount—the value for this group of patients. Saving these costs will offer the opportunity to fund the adoption of technology D (looking at Fig. 9.7, costs saved by technology E are pretty much the costs needed to run technology D). In this view, by disinvesting in the comparator of technology would be possible to invest in technology D. Following this line of reasoning—and broadening the discussion about this method—another opportunity is to disinvest from all those medical technologies that allow saving a significant amount of financial resources while limiting the reduction of value for patients. In this way, savings would guarantee the opportunity to invest in a larger number of innovations. *Ça va sans dire*, that this approach might raise ethical concerns. Our opinion is that this approach is rational and ethical because it tries to move the perspective from a group of patients to society. A priority of decision-makers in healthcare should be the maximization of societal benefits against the available resources. In this view, the limited reduction of benefits for a group of patients is more than compensated by the increased benefits for other groups of patients, on the same line of reasoning of the League Tables that compare the ICUR of different technologies/practices [16].

The theoretical arguments found application in real life into two relevant experiences.

On the one hand, the *Choosing Wisely* movement in the USA applied these concepts through a consensus-based approach based on expert judgement elicitation. The scientific associations of the different medical disciplines supported a debate about the members of the association, about the identification every year of five medical technologies/practices to be eliminated to generate enough savings for adopting emerging medical technologies. In this case, the responsibility to identify those technologies/practices to be eliminated is left to the discussion—and agreement—among experts who might evaluate the impacts of such decisions. Moreover, it is interesting the repetitive nature (year after year) of this discussion that confirms the need for healthcare professionals to identify a systematic approach to get access to innovative technologies also in a context of shrinking financial resources.

On the other hand, the Vancouver Coastal Health Authority in Canada designed and implemented an interesting disinvestment programme in 2010 to meet the constraints on the available financial resources and to fund the adoption of new medical technologies. In their well-known study, Mitton et al. [19] described in detail this unique experience thus making possible its application in other healthcare systems. The method grounds again on expert judgement elicitation. However, the

main difference relies on the development of a quantitative approach based on multi-criteria decision analysis (MCDA) to support prioritizat ion and decision-making. In this view, the value of different practices/medical technologies is the result of performance scores against agreed assessment criteria that are weighted according to their relative relevance. Engaging with experts is necessary to legitimize the process, concerning the identification of the assessment criteria and their weight. By applying this MCDA-based approach, the Vancouver Coastal Health Authority in Canada has been able to identify 42 practices/medical technologies to dismiss in order to meet the budgetary constraints while minimizing the lost value for citizens. Moreover, they have been able to identify additional disinvestment opportunities to save money to be reinvested in new practices/medical technologies.

These experiences confirm the applicability in real contexts of the theoretical arguments developed about disinvestment as a strategy for sustaining the adoption of innovations in healthcare. As told, healthcare cannot progress without the systematic adoption of new medical technologies that proved to be value-for-money and safe. In this view, policymakers of the most developed countries should explore the opportunity to design and implement strategies that combine disinvestment from those practices/medical technologies that claim to generate value—but they do not generate enough value actually—to reinvest these savings into practices/medical technologies that can improve equity among citizens, as described in the theoretical example in Fig. 9.7.

9.3 Technology Assessment in Hospitals

9.3.1 The Linkage Between Technology Assessment and Hospital Strategy

Hospitals are at the forefront of technological innovation in healthcare [28]. Hospital professionals scan systematically the horizon in search of novel medical technologies that might contribute to generate additional benefits in terms of effectiveness, efficiency, and safety. In this view, they need clear guidelines and instruments to select only the most promising innovations among the many that go to market and avoid the risk to invest in technologies whose claim of value are not proven.

Therefore, hospitals must own competencies and knowledge to assess medical technologies. In countries—such as Italy—where a reference national HTA Agency is missing, hospitals must be in the possibility to make evidence-based decisions concerning novel medical devices, equipment, digital technologies, etc. Even in those countries—such as England, Denmark, and Canada—where there is a reference national HTA Agency, hospitals must assess medical technologies for several reasons. **First**, not all novel medical technologies that might be of interest for hospitals are evaluated at the national level because of a prioritization strategy. **Second**, HTA reports offer conclusions and recommendations that are often general

and far from the local-sensitive questions of hospitals. **Third**, new and expensive medical technologies arrive mainly at university hospitals which have immediate pressure from manufacturers, professionals, and patients to adopt them. Only later this need reaches the national agenda, where the assessment timeframe is often longer. **Finally**, hospitals have a direct interest (medical, economic, organizational) to push and speed-up both the assessment and the reimbursement of novel technologies at the national level (e.g. medical procedures), sharing their results as well as their HTA reports.

Given that hospitals must own competencies and instruments to assess novel medical technologies, technology assessment should be a relevant phase within a broader responsibility on technology management. Four synergic phases are typically in place. **First**, technology selection, whose aim is to (1) select those technologies that might better support hospital processes, and (2) define what is the most correct timing for the adoption of new medical technologies. **Second**, technology allocation, aimed at defining the best allocation of the available financial resources (1) between old (maintenance) and new (acquisition) medical technologies, and (2) among different departments (homogeneous vs focused distribution of resources). **Third**, technology assessment, that must support hospital decision-makers through an evidence-informed, multidimensional assessment of medical technologies (effectiveness, safety, costs, organizational impact, professional competencies needed, uncertainty etc.) that have been identified in the previous phases. **Finally**, technology management should be aimed at putting in place operative procedures for (1) maintaining and developing the medical technology stock; (2) guaranteeing safety to both hospital professionals and patients; and (3) reducing risks. These four phases are typically under the responsibility of the Clinical Engineering Department because clinical engineers are familiar with medical technologies and managerial instruments.

Technology assessment in hospitals—better known as Hospital-based HTA (HBHTA)—is strictly connected with the hospital strategy. The value of a novel medical technology is the result of how and to what extent this technology might contribute to putting in place the hospital strategy. Hospitals are very different (teaching vs no-teaching, large vs small size, large city vs rural, private vs public, general vs specialized, etc.) and have very different strategies. In this view, the same innovation might be relevant for hospital A and irrelevant for hospital B, because these hospitals are different and are pursuing different strategies. Hospitals that implement HBHTA procedures cannot rely on *one-size-fits-all* organizational solutions but must define a tailored one.

Following this line of reasoning, past research showed that hospitals follow at least three different strategies when they adopt medical technologies [29]. They are (1) Profit Maximization; (2) Technology Leadership; and (3) Clinical Excellence. Each strategy significantly affects the relative relevance of the assessment criteria, prioritizing some criteria—i.e. expected results—with respect to other ones. Therefore, the same medical technology can be adopted by hospital A and rejected by hospital B. In the followings, the most relevant assessment criteria for each strategy are reported.

Hospitals with a profit maximization strategy are expected to adopt novel medical technologies that enable them to generate an economic return and to improve the income statement (revenues against costs). In this view, the most relevant assessment criteria are (1) investment size; (2) savings of operating costs; and (3) additional revenues. Hospitals with a technology leadership strategy are expected to adopt novel medical technologies that allow them to be "technology leaders" and improve their external image to attract doctors and patients. In this view, the most relevant assessment criteria are (1) technology innovativeness; (2) chance of being the "first adopter"; (3) contribution to research and novel knowledge development; (4) contribution to the development of new services; and (5) physicians' pressure. Finally, hospitals with a clinical excellence strategy are expected to adopt novel medical technologies that optimize the satisfaction of clinical needs, regardless of financial considerations, competitive advantages and prestige suggest other choices. Coherently, the most relevant assessment criteria are (1) burden of disease; (2) potential number of beneficiaries; (3) clinical effectiveness; (4) safety; and (5) completion of the current portfolio of health services. As seen, the assessment criteria are expected to be significantly different and linked to the specific strategy that the hospital is putting in place. It is important to clarify that even if the above-cited assessment criteria are the most relevant for each strategy, this does not mean that criteria from other strategies are overlooked completely. For instance, hospitals that aim at profit maximization do not overlook completely criteria, such as clinical effectiveness and safety, but their attention is focused on other dimensions of impact.

9.3.2 The Organizational Arrangements for Technology Assessment in Hospitals

Hospitals implement different, tailored organizational arrangements to support HBHTA [30]. The choice of the most adequate organizational arrangement is related to the maturity of the HBHTA practice. While hospitals that are at the beginning of their experience with HBHTA might prefer a simple and efficient organizational arrangement, hospitals with more legacy might prefer more sophisticated configurations. The variety of organizational arrangements can be synthesized in a two-dimension matrix (Fig. 9.8).

The horizontal dimension deals with the so-called "focus of action" for HBHTA. The focus of action can be either "clinical practice" or "managerial decision-making". The former approach focuses on the assessment of novel medical technologies concerning the expected impacts on mainly effectiveness and safety. Hospitals are at the forefront of technological innovation and many of the technologies that are under assessment do not have a full body and level of evidence. This might be the case for medical devices. The priority for hospital professionals is that novel technologies, with limited evidence, are at least safe and effective for patients, echoing Hippocrates's oath "*first no harm*". The latter approach deals with a more

		Focus of action	
		Clinical Practice	*Managerial decision-making*
Organizational Complexity	*High (team-group-unit)*	"Internal Committee" Model	"HTA Unit" Model
	Low (individual)	"Ambassador" Model	"Mini-HTA" Model

Fig. 9.8 Different organizational arrangements for hospital-based HTA

comprehensive assessment of novel medical technologies, including other criteria such as organizational impacts, investment size and running costs, etc. This might be the case for equipment or digital technologies. Equipment (e.g. surgical robot, diagnostic system) is a capital-intensive technology and hospitals managers must forecast the economic impact—and sustainability over time—of the adoption of such technology (see e.g. Chaps. 5, 6, and 11). Digital technologies reshape processes, practices, and behaviours; in this view, forecasting the expected organizational impacts is a priority for hospital managers and professionals.

In Fig. 9.8, the vertical dimension deals with "organizational complexity", that is measured as the number of professionals involved in HBHTA activities. In hospitals where a single professional is involved, organizational complexity is "Low". On the contrary, in hospitals where a group of professionals is involved, the organizational complexity is "High".

Combining the horizontal and the vertical dimensions, four main different archetype organizational arrangements—labelled as Models—can be identified.

The "Ambassador Model" is a low-complexity approach focused on clinical practice (see also Chap. 3). This approach is the simplest and might be of interest for hospitals that are at the beginning of their journey towards HBHTA. In a nutshell, one (or more) doctor(s) who is recognized as an "opinion leader" on technology assessment is appointed as ambassador of the "HTA message" inside the hospital, with the purpose to persuade other physicians that novel medical technologies should be assessed before deciding to adopt them. Hospital professionals must assess these technologies against safety and effectiveness criteria to inform decision-making.

The "mini-HTA Model" is a low-complexity approach that covers clinical and managerial domains of assessment. This approach, developed in Denmark in 2006, is widely adopted across Europe, even if with variants. Examples are the GANT

method in Spain and MCDA-based methods in Italy. The original version of mini-HTA is a checklist of 26 open questions on four domains (technology, patient, organization, economics) that allow hospital decision-makers to gather a comprehensive understanding of the main impacts concerning the adoption of the novel medical technology. The method is of low complexity because a single hospital professional—typically a clinical engineer—is the main orchestrator of data collection from all professionals who own relevant information and data analysis. The main advantage of this method is that it is efficient and simple, meeting the needs of HBHTA. Vice versa, the main disadvantage concerns the usage of open questions that often do not allow to collect complete and high-quality information.

The "Internal Committee Model" focuses on clinical practice and engages with a large number of hospital professionals. The committee is a permanent organizational structure composed mainly by physicians and clinical engineers who add this task to their daily responsibilities. The focus of their analysis is safety and effectiveness. Committees are very heterogeneous in size and competences and, surprisingly, past research did not provide hospital managers with clear guidelines and advice about how to design high-performing HTA committees. A recent study by Foglia et al. [31] runs a quasi-experiment to gather some insights. They found that (1) quality of HBHTA reports increases where internal committees are composed of professionals from different specialities; (2) size and multi-speciality of the internal committee should not grow too much to avoid inefficiencies due to increased coordination efforts; (3) trust within the members and the attendance of HTA training are key factors to improve performance of HBHTA committees.

Finally, the "HTA Unit Model" is the most complex and expensive organizational arrangement for HBHTA. In this case, a permanent organizational structure composed of hospital professionals from different specialities who are fully dedicated to HTA-related activities is created. With respect to internal committees, the main advantage is that professionals develop specialized competencies in terms of technology assessment, producing HBHTA reports with higher quality in lower time. Methods such as Cochrane Systematic Review, GRADE analysis, and Total Cost of Ownership (TCO) require specialized competencies that are not typically owned by all professionals. In this view, professionals who are part of the HTA Unit can stay-updated concerning HTA methods and tools.

The main disadvantage is that this method is very expensive because professionals are dedicating 100% of their time to technology assessment. This might make sense for those hospitals whose strategy is technological leadership, and the adoption of emerging medical technologies is very frequent.

9.3.3 Frameworks for Technology Assessment in Hospitals

While the production of HTA reports at the national/regional level follows established and agreed guidelines, HBHTA reports differ significantly. The reasons are, on the one hand, that HBHTA is a more recent research stream and less research

has been paid so far to this topic by scholars of health economics and health technology assessment, and, on the other hand, the many differences among hospitals—as seen in the previous sections—in terms of strategy, informative needs, and HBHTA practices. Even if widely accepted reference frameworks for HBHTA do not exist, mini-HTA can be assumed as a relevant cornerstone. This method made clear that HBHTA must meet two relevant requirements of any technology assessment exercise. **First**, an assessment must be evidence-based. **Second**, an assessment must consider different domains and not just effectiveness. In this view, the emerging HBHTA frameworks share the same theoretical assumption that both hospital managers and professionals must have been provided with clear guidelines and advice about which criteria refer to for collecting evidence and informing decision-making [32].

Within the variety of HBHTA frameworks that are emerging, two of them are particularly relevant to be discussed. The first one is the IMPAQHTA framework (see Table 9.5) [31]. This approach is interesting because it has been developed to bridge the assessment of medical technologies between national/regional and hospital levels. Grounding on the Core Model developed within the EUnetHTA collaboration, this approach confirms its dimensions for assessment and specify both sub-dimensions and measures in the peculiar context of hospitals (Table 9.5). Sharing the same architecture and technical language, this approach might facilitate information exchanges between the different levels of the healthcare ecosystem and narrow-down the current gap. In particular, the national/regional level is expected to benefit from the assessments run in hospitals that, even if with partial respect to the national/regional level, are timelier and context based.

The second HBHTA approach worth to be discussed grounds on the Innovation Management literature and offers an original point-of-view on how medical technologies should be assessed in hospitals [28]. Based on the legacy of value-risk matrixes, Lettieri and Masella [28] developed an original framework to inform technology assessment in hospitals. Medical technologies should be assessed against two dimensions (Fig. 9.9).

The vertical dimension deals with the concept of "value", i.e. the expected capability of the novel technology to generate benefits in terms of (1) social value creation; (2) economic value creation; and (3) knowledge creation. Table 9.6 crystallizes the criteria to measure expected benefits. Even if with different terminology, these three dimensions of value creation echo the three main strategies hospitals might implement when adopting novel medical technologies. Coherently, many criteria remind to those identified for the different strategies.

The horizontal dimension addresses the concept of "uncertainty", i.e. the possibility that expected benefits might not be achieved. The adoption of a novel medical technology is an investment, i.e. present financial resources are employed to generate additional value in the long term. However, decision-making is taken in the context of bundled information about the future. This means that decision-makers must evaluate and discuss the uncertainty of results. In this framework, the "level of sustainability" means the probability that expected benefits will materialize. The capability of a hospital to achieve expected results is a function of five different

Table 9.5 IMPAQHTA dimensions and sub-dimensions developed within Lombardy Region in Italy

Dimensions	Rational	Sub-dimensions	Quantitative measures
General relevance	Scientific and empirical evidence analysis aimed at providing a comprehensive description of the general relevance for both the technology and the population	Quality of scientific evidence	Considering four dimensions (quality of scientific evidence concerning the comparators, consistency, completeness, and utility of the results), using a four-item evaluation scale derived from "Get Five" approach: the higher the average measure, the preferable the technology
		Description of the pathology and the related technologies	• Prevalence or incidence of the pathology affecting the population related to the catchment area of reference (local, regional, national, etc.) • Number of potential patients treated with the innovative technology, divided by the population affected by the specific analysed disease
Safety	This dimension leads to the evaluation of: • adverse events, mortality, or morbidity • consistency of the innovative technology with health and safety policies • consistency of the innovative technology with its guidelines or protocols	Seriousness of adverse events (mild, moderate, or severe adverse events)	• Incidence of adverse events, divided by the population treated with the technology • Mortality and morbidity rates • Administration of a qualitative questionnaire aimed at rating the consistency of the innovation concerning: (1) health and safety policy and (2) guidelines and protocols, using a 7-item Likert Scale (the higher the average measure, the preferable the technology)
Efficacy	Analysis of the efficacy data retrieved from the scientific literature, referring to how the innovative technology performs in the clinical trials	Efficacy data	i.e. mortality rate related to the use of technology, percentage of success of the treatments compared, sensitivity or specificity of diagnostic images, etc. revealed in randomized controlled trial or literature evidence

(continued)

Table 9.5 (continued)

Dimensions	Rational	Sub-dimensions	Quantitative measures
Effectiveness	Analysis of the effectiveness data of the innovative technology, based on the hospital setting, referring to how innovative technology works in real-world evidence and community settings	Effectiveness data	i.e. mortality rate related to the use of technology, percentage of success of the treatments compared, sensitivity or specificity of diagnostic images, etc. based on the real hospitals setting in which technologies are adopted
Economic financial Impact	Economic and financial impact evaluation, considering: 1. the healthcare process considered, 2. the new technology budget impact implementation, and 3. the number of resources spent about effectiveness and efficiency outcomes	Activity-Based Costing (ABC) Analysis	Process costs comparison considering all the direct costs, and, where possible, the indirect ones (the lower the economic value, the preferable the technology)
		Complete Health Economic Evaluation	Cost-effectiveness, cost-utility, and cost-benefit analysis, calculated as pathway or process costs divided by the outcome indicator (measured with physical, humanistic, or economic units)
		Budget Impact Analysis	Target population multiplied by the pathway or process costs (considering either the ceasing or the incremental costs, comparing at least two different scenarios)
Equity	Evaluation of all aspects related to the introduction of the innovative technology, considering the perspective of the patient, and the following aspects: • access to care on a local level • access to care for the target treated population, including persons of a legally protected status • hospital waiting lists improvement • invasiveness	Equity data	Administration of a qualitative questionnaire aimed at rating the variables related to the equity dimensions, using a 7-item Likert Scale (the higher the average measure, the preferable the technology)
Legal, social, and ethical impact	Analysis of the social and ethical issues that innovative technology could have on the system, considering the	Legal aspects	Administration of qualitative questionnaires aimed at rating the variables related to the legal, social, and

(continued)

Table 9.5 (continued)

Dimensions	Rational	Sub-dimensions	Quantitative measures
	following aspects: • customer satisfaction • productivity loss • market regulation		ethical dimension, using a 7-item Likert Scale (the higher the average measure, the preferable the technology)
		Social and ethical Impact	Reduction in productivity loss (in terms of days, hours, or minutes, evaluated considering the patient's gross monthly income)
Organizational impact	Evaluation of organizational changes occurring after the innovation implementation. The qualitative impact investigates the perception of clinicians, and health professionals, involved in this innovation change management. The quantitative impact aimed at the determination of the investment needed if organizational changes occur. The following aspects are investigated: • additional people • training courses • meetings needed to communicate the technological change • additional equipment, or spaces needed • learning time of the innovative technology	Quantitative impact	Ceasing or incremental costs evaluation and forecast, related to the adoption of the innovative technology in clinical practice, compared with the standard one, considering additional persons, training courses, additional equipment, spaces, or rooms needed
		Qualitative impact	Administration of qualitative questionnaires aimed at rating the variables related to the organizational dimension, using a 7-item Likert Scale (the higher the average measure, the more preferable the technology) both in the short-term (12-month) and in the long-term (36-month) period

IMPAQHTA IMPlementation of A Quick hospital-based HTA

factors. They are (1) economic sustainability; (2) organizational sustainability; (3) technological sustainability; (4) resource sustainability; and (5) context sustainability. Table 9.7 crystallizes the main criteria.

Even a cursory analysis of this framework would make clear why different hospitals might make different decisions concerning the same novel medical technology. While some criteria refer to factors that would receive a similar assessment from different hospitals (e.g. the coherence to the legal framework, the existence of agreed guidelines, the position in the life cycle), other factors are hospital-specific (e.g. technology acceptance among physicians, coherence to the current portfolio of technologies). In this view, hospitals must develop capabilities and competencies for

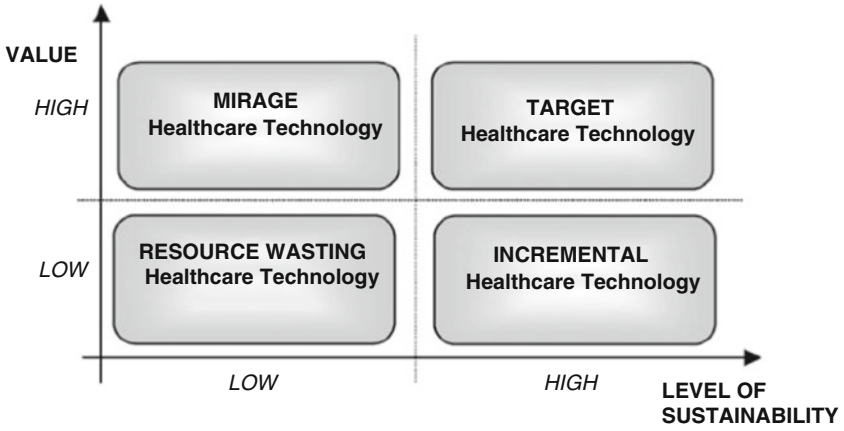

Fig. 9.9 The value/sustainability framework for HBHTA

Table 9.6 Measuring "Value" in hospitals

Perspective	Benefits	Measures
Short-term	Social value creation	Clinical effectiveness
		Patient's or family's satisfaction
	Economic value creation	Revenue generation
		Cost savings
		Gains in either image or reputation
Long-term	Knowledge creation	Development of new health services
		Development of new healthcare technologies
		Building-up of new communities of knowledge

Table 9.7 Measuring "Level of sustainability" in hospitals

Sustainability factor	Measures
Economic	Degree of self-funding
	Ratio "fixed/variable costs"
	Coherence to strategic goals (top managers' commitment)
Organizational	Technology acceptance among physicians
	Uncertainty in clinical practice
Technological	Positioning in the technology life cycle (TRL)
	Coherence to the current portfolio of technologies
Resource	Training intensity
	Coherence of human and physical resources
Context	Coherence to the current legal framework
	Coherence to the generally accepted ethics (legitimacy)

technology assessment also where a national HTA Agency does exist because findings at the national/regional level must be contextualized at the local level.

9.3.4 Acceptance of Innovation in Hospitals

Many medical technologies might disrupt current practice. In this view, physicians' acceptance of these innovations is a salient criterion to measure organizational sustainability, as discussed in the previous section. Past research has gathered a significant body of evidence concerning physicians' resistance—or indifference—to novel medical technologies. A paradigmatic example is offered by telemedicine. The diffusion of ICT-enabled innovations—e.g. electronic medical records, "televisit-solutions"—has fallen far behind expectations, and physicians are still not championing such innovations. These examples make clear that physicians' acceptance is of paramount importance when assessing the adoption of new medical technologies and related changes in their practice and behaviours. Acceptance of innovation—and its antecedents—has been a widely investigated research topic in the last decades. Within an extensive body of literature, two main streams might be crystallized.

On the one hand, scholars of applied psychology and information science developed theoretical explanations grounded on the assumption that "acceptance" is the result of the rational evaluation made by single individuals—in this case, hospital professionals—of pros and cons generated by specific innovations. Coherently to this premise, a variety of user acceptance models, derived from the seminal Technology Acceptance Model (TAM) [33–36], have been generated in the last years (e.g. TAM2, UTAUT). Although there are some differences among the models, they all share a "perceived usefulness" and a "perceived ease of use" as the most relevant predictors of physicians' intention to adopt a novel medical technology [37, 38]. Social pressures are also relevant, but only when exercised by peers (i.e. by other hospital professionals) and not by top managers.

On the other hand, scholars of institutional theory and organization science, especially those dealing with professional organizations such as hospitals, developed theoretical explanations that show how a complex bundle of institutional arrangements (i.e. regulations, social norms, and cultural systems) limit and affect individual behaviours. According to these studies, employees' decision to accept novel medical technologies is not the result of rational evaluations, but of the influence exerted by the overarching structures, rules, social norms, and culture in which they are embedded [37]. Past studies within this research streams crystallized three main institutional factors that might shape hospital professionals' intention to engage in new practices or accept novel medical technologies. **First**, professionals are affected by the expectations of the organization (regulative factor). The more the organization provides coercive or persuasive mechanisms that direct or control practice, the more professionals are likely to comply with these expectations in search of retribution. **Second**, professionals are affected by peer influence (normative factor). The more

the meaning system across professionals is cohesive and aligned towards the adoption or the rejection of novel medical technology, the more professionals are likely to adhere to this social norm without challenging it. **Third**, professionals are affected by initiatives and discussions that are run day-by-day in the organization (cultural factor). The more the organization agrees that the current status quo is not adequate anymore and changes are required, the more professionals are likely to contribute to change by enacting innovative behaviours.

Recent research has started to investigate the potential interplay between individual and institutional factors, arguing that the two theoretical perspectives might be merged into a more comprehensive understanding of what drives hospital professionals' acceptance of new medical technologies. De Benedictis et al. [38] gathered evidence that institutional factors affect individual evaluations and contribute to physicians' acceptance of innovative technologies. These findings reinforce the evidence that the same medical technology might be accepted or rejected by different hospitals, and/or within the same hospital by different groups of professionals. In this view, HBHTA cannot overlook the assessment of the factors that might shape professionals' acceptance of novel medical technologies, also to design and implement strategies that might facilitate its acceptance. The causal connection between the regulative pillar (i.e. the expectations of the organization) and perceived usefulness clarifies that hospital managers are in the position to affect acceptance through initiatives that make more evident the benefits expected by the adoption of specific innovations.

9.3.5 Government of Technology Assessment in Hospitals

As discussed in the previous section, past research has developed a significant body of evidence about the methods and criteria that should be implemented to assess novel medical technologies in hospitals. Surprisingly, fewer efforts have been paid so far about how to assess the "health status" of the HBHTA process itself. This process is of paramount importance for every hospital and its performance in terms of quality, timeliness, and efficiency should be monitored continuously by hospital managers and clinical engineers. From a pragmatic point-of-view, there is no advantage in designing and implementing sophisticated HBHTA processes that are not able to provide decision-makers with relevant—and reliable—information when they need it. In this view, measuring the current performance of the HBHTA process against targets that have been identified and agreed is necessary for implementing corrective actions where needed.

Let us consider this example taken from real cases. Every month about 30 new requests for the adoption of medical technologies are submitted by hospital professionals. They expect to receive a feedback (either positive or negative) in less than 4 weeks. Internal Committees are composed of about ten hospital professionals who add technology assessment of new proposals on top of their daily activities. HTA Units are composed of about five hospital professionals. How should be designed an

Table 9.8 Performance measurement of HBHTA in hospitals

	Volume	Quality	Time	Efficiency (Costs)
Collection of requests	Number of requests per month	Number of complete requests on the total	Number of requests filled in less than 2 days/person	Time spent in consulting proponents
Assessment of requests	Number of requests assessed on the total	Number of appeals from proponents on total proposals	Number of requests assessed within 30 days on the total	Number of requests that have been filtered
Feedback to proponents	Number of rejections discussed with proponents	Number of proponents that accept rejections	The time between rejection and feedback	Time spent in providing proponents with feedback
Support to decision-makers	Number of HBHTA reports	Number of decisions aligned to the recommendations	The time between the delivery of HBHTA reports and decisions	Time spent by decision-makers on HBHTA reports

HBHTA process to meet hospital professionals' expectations in term of high-quality and timely reports, as well as hospital managers' expectations of efficiency and cost containment of the HBHTA process itself?

Foglia et al. [31] shed first light on how to design a hospital Internal Committee for technology assessment to maximize high quality and efficiency. The European project "AdoptHTA" developed practical guidelines for the design of an HBHTA process in hospitals. Iadanza et al. [39] argued the urgency to implement practices of evidence-based management of medical technologies along with their whole lifespan in hospital. Although the undoubted value of these contributions, research on this topic is still at an early stage and further work is necessary to provide hospital managers and clinical engineers with clear and validated guidelines and advice.

Table 9.8 points out an example of key performance indicators (KPIs) that might be used by hospital managers and clinical engineers to monitor the "health status" of the HBHTA process in place.

The design of the most informative KPIs should be complemented with the crystallization of the most adequate targets. By monitoring the capability of the HBHTA process to meet the expected targets (e.g. assessing all received proposals for novel medical technologies with 30 days) over time, hospital managers and clinical engineers might identify improvement areas and implement the necessary corrective actions (e.g. increased the automatization of the HBHTA process through the adoption of a dedicated informative system).

Conclusion and Emerging Topics About the Assessment of Medical Technologies

In the previous sections of this chapter, some avenues of further development of the assessment of medical technologies have been pointed out. At least four "areas" will witness significant improvements within the next years.

First, the traditional approach based on Cost-Utility Analysis (CUA) will be challenged by Multi-Criteria Decision Analysis (MCDA) and Social Return on Investment (SROI). While CUA is a well-established and robust method, its actual informative power is under discussion. The final goal of any assessment exercise is to support decision-making. If decision-makers systematically do not refer to HTA reports to ground their decisions about the adoption of novel medical technologies, this means that evaluators failed to meet their primary goal.

Second, some domains of HTA need an enhanced degree of operationalization. The most evident example is about the "organization" domain. Both at the national/regional and hospital levels, this domain is not fully translated into relevant criteria to be assessed. The extant literature offers different approaches but none of them has been largely adopted and assumed as a generally accepted practice. This issue is particularly relevant and urgent for those innovations, such as telemedicine, that can unfold their potential value only because of significant organizational redesign and changes.

Third, the governance of the HTA process both at the national/regional and hospital levels requires the design of KPIs and targets to monitor its "health status" over time. These KPIs, where agreed by different committees, will allow bench-learning initiatives—as done currently for the performance of different international/regional healthcare systems—and the crystallization of good practices to be shared. This will guarantee the continuous improvement of such processes.

Fourth, the constantly increasing capability to both collect and analyse real-world data (e.g. from electronic medical records, clinical registries, population-health databases, hospital discharge forms, wearables) offers the opportunity to expand the sources of evidence considered within the HTA reports. At national/regional level, the capability to analyse large-volume administrative data might help to complement what is known from the literature with data from the field. This allows to move the discussion about effectiveness from the evidence collected in clinical studies to that collected in daily hospital practice. At the hospital level, the progressive diffusion of data warehouse might help to better forecast the impacts due to the adoption of a novel medical technology.

Take Home Message

- The healthcare system worldwide needs a reload of the present paradigm in the direction of the value-based healthcare approach.
- Innovation and technology are the key factors for the success of this new approach.
- The introduction of technology and innovation must be deeply analysed using the instruments for the evaluation of investment (and divestment) in healthcare (e.g. HTA, CUA, SROI).

(continued)

- The introduction of innovation should also consider the legitimacy of the taken decision and the impact that the new technologies have on care delivery organizations and society.
- A general and mutual understanding among decision-makers in hospitals is needed in order to allow the introduction of novel medical devices.

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